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From: Menschik, David
Sent: Tue, 31 Aug 2021 11:48:19 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210827.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 8/27/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20210427	Serious EB05 2021	Fatal EB05 20210	Infant EB05 2021	Child EB05 2021	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 21210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.861	1.737	0.886			0.636	1.381	1.676	1.636	2.365	1.01	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.903	1.693	0.877				1.47	1.846	1.487	2.097	1.344	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.515	0.909	0.883				0.848	0.707	0.63	2.158	1.513	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.063	2.431	0.86			0.597	1.638	2.065	4.095	4.165	1.434	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.414	2.036	0.883			0.469	1.617	2.404	1.865	2.551	1.904	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.287	0.855	0.881			0.597	0.753	1.867	2.985	2.088	1.856	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.095	1.74	0.911	0.512		0.459	1.776	1.864	2.221	2.71	1.417	
COVID19 (COVID19 (JANSSEN))	Arrhythmia	1.958	2.162	0.882				0.881	1.962	1.165	1.528	1.496	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.429	1.174	0.885	0.509		0.309	0.845	2.081	1.056	1.55	1.03	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.551	2.375	0.883			0.54	1.06	1.914	0.655	3.781	0.857	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.364	2.23	0.861				1.544	2.206	1.075	1.838	1.948	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.178	1.948	0.904			0.538	1.618	1.987	1.365	2.995	1.128	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	1.954	1.688	0.883				0.987	0.939	1.58	2.238	0.916	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.27	3.017	0.892			0.838	2.107	2.408	0.783	3.89	1.224	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.582	2.086	0.929	0.512		0.569	1.983	2.44	1.968	3.32	1.671	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.051	1.795	0.891			0.507	1.477	2.022	2.049	2.361	1.569	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.389	1.872	0.904			0.479	2.181	2.136	1.186	3.068	1.915	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.44	1.204	0.886				0.91	2.023	1.174	1.581	0.984	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.419	1.566	0.886			0.415	2.327	2.118	1.971	2.741	1.605	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.032	1.515	0.895	0.511		0.389	1.609	2.205	1.898	2.419	1.337	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.847	0.97	0.881			0.45	1.616	1.74	0.806	2.05	1.078	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.261	0.933	0.882				2.351	1.679	0.809	2.753	1.207	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.108	1.83	0.86				1.263	2.632	1.39	1.674	1.865	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.158	3.512	0.86				3.438	3.786	5.857	6.534	1.673	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6	2.975				0.561	3.632	2.86	0.668	6.628	1.059	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.53	1.982	0.88			0.025	1.836	2.215	1.451	1.991	1.553	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.209	2.213	0.882				1.097	1.176	0.75	3.422	0.709	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.969	1.869					0.956	2.063	1.019	1.382	1.865	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.087	1.853	0.886			0.534	1.788	1.861	2.015	2.322	1.601	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.44	1.08	0.878			0.397	0.995	2.088	0.516	1.894	1.65	
COVID19 (COVID19 (JANSSEN))	Off label use	1.853	0.248	0.88			5.293	0.343	0.572	0.402	1.211	1.672	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.731	0.756					2.505	1.62		2.223		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.478	0.899				0.564	1.71	2.158	1.094	2.351	1.622	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.489	1.8	0.881				0.653	0.974	2.63	2.207	0.909	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.652	2.517	0.903	0.512		0.504	2.204	3.367	1.429	3.339	1.822	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.745	1.51	0.894	0.508		0.333	1.481	2.002	1.337	2.039	1.333	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.766	2.224	0.86			0.429	2.056	3.052	2.238	3.403	1.822	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.853	3.466	0.882				4.367	2.339	0.688	5.901	1.842	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.562					0.58	2.792	2.237	4.884	3.381	2.714	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.628	1.389	0.882	0.744		0.305	1.255	1.957	1.199	2.044	1.116	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.164	1.717	0.906	0.512		0.643	1.612	2.64	2.34	2.428	1.676	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	1.932	1.724	0.886				1.494	1.334	2.129	1.788	1.586	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.98	1.177				0.561	0.96	0.643	0.65	2.006	0.902	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	2.463	1.821	0.893			0.556	1.663	2.074	0.567	2.084	2.426	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	5.709					0.655	3.209	5.961	14.615	6.957	4.918	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	1.898	1.881	0.888			0.42	1.888	2.048	1.271	2.347	1.338	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.346	1.154	0.883			0.556	1.327	1.876	1.289	1.951	1.732	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.561	2.332	1.799	0.512		0.603	2.176	2.431	3.438	2.929	2.042	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.317	1.045	0.881				1.892	1.261	0.65	2.471	0.863	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.264	1.295	0.885			0.588	1.78	2.005	2.072	2.51	1.532	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.765	2.098	0.897	0.512		0.556	2.244	2.163	3.535	3.159	2.127	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.279	1.685				0.475	2.378	1.462	1.523	2.398	1.478	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.038	1.333	0.877			0.474	1.421	1.929	1.908	1.978	1.862	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.831	1.053	0.881				1.18	2.021	1.85	1.966	1.19	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.763	1.864	0.893			0.528	1.132	2.279	4.565	1.725	1.908	
COVID19 (COVID19 (JANSSEN))	Venogram	2.365	2.034					1.71	1.75	0.544	2.4	1.033	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.37	2.845				0.621	2.689	1.821	0.703	4.357	1.039	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.217	2.512	0.882				3.196	3.265	0.757	5.112	1.059	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.265	0.733		3.202	0.715		1.102			1.166	0.765	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.052				0.535	0.33	0.289	0.408	0.542	0.407	1.34	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.309	0.889	0.882		0.81	2.401	0.149	0.221	0.562	2.295	2.351	
COVID19 (COVID19 (PFIZER-	Body height	1.012	0.983	0.884			0.57	0.918	1.102	2.21	1.058	1.475	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.036	1.096	0.879			0.663	1.4	1.572	1.897	2.001	1.502	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.315	1.815	0.913			0.558	1.806	1.901	2.259	2.14	2.06	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.613	0.8	0.882	2.412			0.412			0.435	1.04	
COVID19 (COVID19 (PFIZER-	Investigation	2.169	1.74	0.896			0.514	1.691	1.85	2.355	2.116	1.938	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.898	0.64				1.412	1.922	1.937	2.386	1.887	1.819	
COVID19 (COVID19 (PFIZER-	Weight	2.119	1.34	0.888			0.738	1.542	1.707	2.328	2.114	1.761	

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From: Menschik, David
Sent: Tue, 24 Aug 2021 21:23:42 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
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Drug	Event	VS EB05 20210420	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.768	1.679	0.886			0.43	1.268	1.535	1.601	2.165	0.977	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.845	1.703	0.879				1.431	1.837	1.361	2.078	1.268	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.564	0.892	0.884				0.856	0.799	0.643	2.154	1.515	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.127	2.502	0.892			0.517	1.704	2.059	3.98	4.323	1.426	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.413	2.094	0.884			0.479	1.599	2.404	1.855	2.501	1.931	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.09	0.84				0.519	0.76	1.758	3.171	1.993	1.882	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.067	1.766	0.91	0.512		0.462	1.715	1.903	2.198	2.726	1.392	
COVID19 (COVID19 (JANSSEN))	Areflexia	1.882	2.108	0.881				0.877	1.911	1.054	1.507	1.377	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.719	2.482	0.884			0.539	1.072	1.809	0.657	4.198	0.851	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.319	2.237	0.882				1.544	2.189	0.983	1.811	1.904	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.169	1.946	0.903			0.536	1.62	1.911	1.334	2.857	1.978	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	1.961	1.75	0.884				0.983	0.964	1.519	2.128	0.909	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.128	2.504	0.893			0.544	2.278	2.712	0.747	3.738	1.219	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.49	2.1	0.93	0.512		0.487	1.917	2.372	1.899	3.234	1.868	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.062	1.81	0.891			0.512	1.447	2.021	1.983	2.344	1.532	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.433	1.871	0.906			0.481	2.155	2.101	3.078	3.011	1.869	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.366	1.498	0.888			0.518	2.319	2.042	1.941	2.731	1.516	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.979	1.499	0.892	0.511		0.389	1.576	2.157	1.79	2.361	1.275	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.817	0.978	0.882			0.466	1.613	1.69	0.8	2.044	1.072	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.261	0.939	0.883				2.358	1.693	0.801	2.781	1.184	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	1.979	1.899	0.881				1.234	2.523	1.262	1.835	1.812	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.063	3.431	0.886				2.597	3.914	5.568	6.295	1.502	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.871	2.968				0.561	3.521	2.638	0.669	6.465	1.052	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.834	1.95	0.882			0.027	1.705	2.165	1.353	1.893	1.471	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.163	2.208	0.883				1.574	1.165	0.747	3.148	0.707	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.875	1.899					0.95	2.087	0.932	1.334	1.654	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.009	1.874	0.886			0.47	1.756	1.809	1.956	2.292	1.566	
COVID19 (COVID19 (JANSSEN))	Off label use	1.863	0.25	0.881			5.029	0.351	0.663	0.432	1.178	1.857	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.679	0.755					2.385	1.012		2.121		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.339	0.899				0.543	1.01	2.062	1.084	2.211	1.326	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.874	1.884	0.882				0.652	0.999	2.344	3.378	0.905	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.465	2.469	0.9	0.512		0.503	2.082	3.216	1.414	3.141	1.508	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.603	2.216	0.886			0.274	2.016	3.01	2.173	3.33	1.567	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.709	3.385	0.883				4.225	2.234	0.689	5.671	1.433	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.526					0.576	2.574	2.072	4.767	3.123	2.505	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.062	1.727	0.905	0.512		0.738	1.587	2.014	2.282	2.362	1.653	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	1.873	1.738	0.896				1.446	1.349	2.009	1.721	1.557	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	2.208	1.32	0.889			0.561	1.6	1.83	0.543	1.938	2.046	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	5.159					0.56	3.083	5.618	13.351	6.288	4.475	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	1.861	1.83	0.886			0.418	1.864	1.909	1.239	2.22	1.274	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.3	1.165	0.885			0.555	1.351	1.796	1.263	1.914	1.701	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.439	2.343	1.78	0.512		0.604	2.12	2.369	3.303	2.78	1.943	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.172	1.951	0.892				1.657	1.265	0.651	2.247	0.859	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.172	1.305	0.887			0.585	1.823	1.987	1.944	2.48	1.495	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.728	2.153	0.898	0.512		0.473	2.196	2.18	3.539	3.038	2.142	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.239	1.888					2.35	1.453	1.427	2.413	1.45	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.002	1.292	0.879			0.472	1.453	1.875	1.786	1.938	1.64	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.624	1.676	0.891			0.527	1.098	2.07	4.238	1.586	1.691	
COVID19 (COVID19 (JANSSEN))	Venogram	2.304	1.999					1.796	1.642	0.549	2.351	0.978	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.36	2.85				0.625	2.61	1.828	0.7	4.318	1.039	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.066	2.413	0.883				2.774	3.009	0.754	4.98	0.968	
COVID19 (COVID19 (MODERNA))	No adverse event	1.453	0.801	0.883		0.445	2.134	0.898	0.938	0.807	1.165	1.288	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.209				0.548	0.289	0.269	0.388	0.536	0.374	0.346	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.38	0.868	0.883		0.851	2.471	0.104	0.222	0.59	2.338	2.418	
COVID19 (COVID19 (PFIZER-	Body height	1.838	0.985	0.886			0.567	0.911	1.157	2.09	1.781	1.443	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.121	1.801	0.911			0.94	1.795	1.925	2.166	1.971	1.89	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.704	0.799	0.883	2.264			0.499			0.51	1.038	
COVID19 (COVID19 (PFIZER-	Investigation	2.06	1.735	0.896			0.897	1.673	1.799	2.219	2.012	1.848	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.646	0.636				1.389	1.9	1.663	2.257	1.642	1.776	
COVID19 (COVID19 (PFIZER-	Weight	2.032	1.363	0.889			0.732	1.528	1.892	2.196	2.017	1.718	

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From: Menschik, David
Sent: Wed, 11 Aug 2021 18:57:01 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: FW: [EXTERNAL] FW: Weekly data mining
Attachments: USST_20210806.xls

Hi John,

Intention for this report was to distribute to you/Tom and defer to you/Tom on potential further distribution on CDC end for reasons including its potentially sensitive nature and susceptibility to misinterpretation of raw data taken out of context, as well as facilitating your situational awareness, etc. Accordingly, if you have no objections, moving forward, I'll plan to limit CDC recipients to you and Tom while copying Karen and Theresa. Then you can feel free to share within your group as you deem appropriate.

Best,
David

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, August 10, 2021 7:34 AM
To: Menschik, David <[redacted]>
Cc: Moro, Pedro L (CDC) <psm9@cdc.gov>; Duffy, Jonathan M (CDC) <[redacted]>
Subject: [EXTERNAL] FW: Weekly data mining

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi David,
Please add Pedro Moro and Jonathan Duffy to this email distribution list.

Thanks,

Elaine

From: Menschik, David <[redacted]>
Sent: Tuesday, August 10, 2021 7:23 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

<[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 8/6/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20210408	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 2021	Adult3 EB05 20210	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.766	1.656	0.884				1.396	1.476	1.988	2.044	0.943	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.759	1.736	0.888				1.45	1.792	1.225	2.083	1.189	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.525	6.904	0.892				0.758	0.712	0.689	2.147	1.49	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.043	6.986	0.892				0.949	0.702	0.699	1.48	1.574	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.13	2.588	0.897			0.517	1.612	2.159	3.54	4.292	1.384	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.373	2.145	0.893			0.478	1.536	2.437	1.716	2.378	1.931	
COVID19 (COVID19 (JANSSEN))	Antibody test	1.854	0.82					0.661	1.832	2.373	1.723	1.492	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.034	1.834	0.921	0.512		0.396	1.723	1.948	1.992	2.884	1.359	
COVID19 (COVID19 (JANSSEN))	Areflexia	1.758	2.077	0.88				0.817	1.73	1.026	1.347	1.342	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.665	2.599	0.892			0.536	1.21	1.585	0.659	3.868	0.859	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.119	2.205	0.89				1.427	2.055	0.901	1.658	1.842	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.013	1.979	0.908			0.539	1.7	1.843	1.263	2.555	1.087	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.175	2.582	0.896			0.541	2.33	2.863	0.74	3.823	1.207	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.489	2.141	0.88	0.512		0.487	2.031	2.207	1.811	3.184	1.881	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.98	1.808	0.897			0.51	1.487	1.998	1.655	2.253	1.447	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.348	1.876	0.909			0.477	2.098	2.085	2.8	2.88	1.819	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.333	1.846	0.896			0.514	2.29	2.047	1.824	2.881	1.513	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.932	1.489	0.899	0.61		0.328	1.557	2.131	1.654	2.275	1.26	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.268	6.959	0.891				2.372	1.72	0.792	2.721	1.209	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	1.855	1.846	0.89				1.185	2.351	1.127	1.724	1.69	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.878	3.376	0.896				2.141	4.123	4.096	5.831	1.342	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.599	2.892				0.558	3.379	1.946	0.672	6.124	1.043	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.81	1.981	0.891			0.641	1.694	2.107	1.297	1.798	1.494	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.129	2.219	0.891				1.472	1.264	0.741	2.732	0.712	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.811	1.894					0.907	2.031	0.911	1.278	1.608	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.986	1.881	0.893			0.471	1.736	1.816	1.785	2.265	1.448	
COVID19 (COVID19 (JANSSEN))	Off label use	1.692	6.243	0.89			4.89	0.946	0.61	0.946	1.997	1.556	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.863	6.756					2.263	1.064		1.978		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.017	0.85				0.54	1.468	1.929	0.97	1.96	1.146	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.937	1.998	0.891				0.651	1.02	1.911	2.503	0.921	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.287	2.457	0.905	0.512		0.503	2.052	3.083	1.372	2.795	1.436	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.57	2.257	0.896			0.281	2.01	2.938	2.024	3.232	1.54	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.165	3.161	0.891				3.155	1.809	0.691	6.993	1.251	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.463					0.569	2.428	2.036	4.031	2.41	2.312	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.965	1.763	0.911	0.512		0.652	1.562	1.984	2.131	2.271	1.602	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	4.594						2.628	6.178	11.918	5.371	4.006	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	1.798	1.868	0.894			0.424	1.596	1.932	1.144	2.08	1.253	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.239	1.122	0.892			0.552	1.311	1.777	1.2	1.927	1.59	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.275	2.364	1.765	0.512		0.608	2.08	2.34	3.04	2.588	1.843	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.167	1.902	0.891				1.59	1.19	0.654	2.122	0.877	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.124	1.302	0.894			0.586	1.841	1.969	1.747	2.458	1.413	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.621	2.174	0.901	0.512			2.081	2.174	3.266	2.881	2.12	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.207	1.664					2.462	1.381	1.207	2.352	1.354	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.048	1.34	0.896			0.524	0.966	2.091	3.989	1.4	1.801	
COVID19 (COVID19 (JANSSEN))	Venogram	2.156	2.018					1.663	1.634	0.561	2.23	0.924	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.851	2.998				0.552	2.596	1.733	0.899	4.283	1.647	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.896	2.411	0.891				2.782	2.377	0.747	4.942	0.897	
COVID19 (COVID19 (MODERNA))	Accidental exposure to product	2.128					0.385	0.519	0.471	0.738	0.675	3.77	
COVID19 (COVID19 (MODERNA))	No adverse event	1.588	0.81	0.891		0.47	2.127	0.923	0.969	0.891	1.231	1.343	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.477				0.549	0.387	0.258	0.334	0.565	0.443	0.377	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.379	6.867	0.891		0.763	2.437	0.084	0.236	0.653	2.331	2.392	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.826					1.388	1.873	1.854	2.059	1.803	1.772	

PSI-HHS-000000057472

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From: Menschik, David
Sent: Tue, 20 Jul 2021 11:02:21 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20210716.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/16/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20210716	Serious EB05 2021	Fatal EB05 20210	Infant EB05 2021	Child EB05 20210	Teen EB05 20210	Adult EB05 20210	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 202107	Comment
COVID19	Activated partial	1.602	1.66	0.883				1.496	1.406	1.263	2.051	1.024	
COVID19	Adverse drug	2.457	0.885	0.882				0.775	0.718	0.71	2.094	1.408	
COVID19	Angiogram	3.15	2.603	0.886			0.514	1.58	1.955	4.256	4.278	1.363	
COVID19	Angiogram	2.413	2.188	0.88			0.496	1.596	2.379	1.68	2.377	1.936	
COVID19	Anticoagulant	2.03	1.851	0.906	0.612			1.691	1.952	1.999	2.623	1.349	
COVID19	Blood fibrinogen	2.081	2.272	0.883			0.543	0.999	1.31	0.663	2.575	0.792	
COVID19	CSF protein	1.97	2.019	0.88				1.198	1.809	0.989	1.133	1.9	
COVID19	Cerebral	1.937	1.885	0.901			0.543	1.478	1.763	1.196	2.486	0.958	
COVID19	Cerebral venous	3.255	2.625	0.891			0.538	2.122	3.236	9.756	3.784	1.181	
COVID19	Computerised	2.475	2.17	0.909	0.612		0.492	2.023	2.28	1.801	3.264	1.506	
COVID19	Computerised	2.032	1.852	0.885			0.52	1.493	2.074	1.616	2.264	1.5	
COVID19	Deep vein	2.358	1.9	0.899			0.477	2.067	2.088	2.833	2.845	1.824	
COVID19	Fibrin D dimer	2.345	1.405	0.887			0.431	2.279	2.025	1.87	2.685	1.454	
COVID19	Fibrin D dimer	1.933	1.472	0.886	0.608		0.382	1.567	2.083	1.6	2.295	1.203	
COVID19	Gaze palsy	2.4	0.937	0.88				2.482	1.765	0.805	2.851	1.247	
COVID19	Guillain-Barre	1.628	1.647	0.879				1.137	2.031	0.965	1.382	1.55	
COVID19	Heparin-induced	4.611	3.125	0.885				1.63	3.365	2.144	5.545	1.265	
COVID19	Heparin-induced	5.457	2.83				0.556	3.227	1.622	0.671	5.924	1.045	
COVID19	Immunoglobulin	1.683	1.821	0.88			0.104	1.455	2.026	1.109	1.586	1.426	
COVID19	Jugular vein	2.077	2.225	0.881				1.7	1.127	0.654	2.254	0.739	
COVID19	Magnetic	1.987	1.877	0.882			0.493	1.721	1.78	1.765	2.241	1.438	
COVID19	Off label use	1.597	0.154				4.659	0.362	0.638	9.364	0.988	1.521	
COVID19	On and off	1.591	0.755					2.175	1.004		1.932		
COVID19	Peripheral	4.319	2.102	0.881				0.649	1.044	2.144	4.096	0.924	
COVID19	Platelet count	2.336	2.481	0.902	0.612		0.52	1.983	2.926	1.387	2.707	1.489	
COVID19	Platelet count	2.604	2.272	0.888			0.296	2.006	2.969	2.117	3.216	1.577	
COVID19	Platelet factor 4	5.255	3.136	0.881				2.996	1.792	0.69	5.046	1.236	
COVID19	Poor quality	0.394					0.567	3.009	1.958	4.162	2.531	2.388	
COVID19	Pulmonary	2.015	1.796	0.901	0.612		0.659	1.606	1.949	2.215	2.275	1.625	
COVID19	Therapy non-	4.479						3.253	5.967	11.262	4.811	3.906	
COVID19	Thrombophlebitis	2.127	1.107	0.883			0.55	1.221	1.742	1.112	1.76	1.549	
COVID19	Thrombosis	2.318	2.443	1.838	0.612		0.607	2.047	2.404	3.171	2.617	1.88	
COVID19	Transverse sinus	2.325	1.994	0.881				1.75	1.192	0.654	2.437	0.878	
COVID19	Ultrasound	2.111	1.237	0.885			0.593	1.798	1.992	1.608	2.428	1.394	
COVID19	Ultrasound	2.717	2.222	0.891	0.612			2.071	2.242	3.36	2.879	2.161	
COVID19	Ultrasound	2.401	1.866					2.668	1.426	1.293	2.51	1.474	
COVID19	Venogram	2.114	1.923					1.589	1.535	0.567	2.159	0.826	
COVID19	Venogram	3.719	2.831				0.539	3.083	1.703	0.719	4.023	1.103	
COVID19	Venogram normal	4.153	2.631	0.881				3.455	2.082	0.754	5.307	0.913	
COVID19	Accidental	2.034					0.389	0.528	0.463	0.756	0.674	0.808	
COVID19	No adverse event	1.594	0.819	0.882		0.488	2.08	0.976	1.009	0.9	1.261	1.365	
COVID19	Poor quality	2.417				0.54	0.435	0.332	0.476	0.578	0.544	0.48	
COVID19	Product	2.29	0.875	0.881		0.724	2.339	0.116	0.216	0.741	2.252	2.208	
COVID19	Investigation	1.938	1.734	0.889			0.852	1.709	1.797	2.019	1.896	1.73	
COVID19	Product	1.884					1.405	1.882	1.905	2.086	1.855	1.818	
COVID19	Weight	1.905	1.325	0.886			0.675	1.512	1.672	2	1.879	1.628	

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From: Menschik, David
Sent: Tue, 15 Jun 2021 12:33:18 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Cc: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20210611.xls

Hi Elaine,

Just saw your email (digging out after being on leave) asking to be included for weekly raw data mining output email.
Please see attached.

Best,
David

From: Menschik, David
Sent: Tuesday, June 15, 2021 8:29 AM
To: Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani, Meghna <[redacted]>; Marquez, Paige L (CDC) <[redacted]>; Broder, Karen R (CDC) <[redacted]>; Harrington, Theresa (CDC) <[redacted]>
Subject: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/11/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 202106	Serious EB05 2021	Fatal EB05 202106	Infant EB05 2021	Child EB05 20210	Teen EB05 202106	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 2021	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.386	0.811					0.796	0.858	0.722	1.887	1.414	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.008	2.639	0.885			0.532	1.387	1.668	4.511	3.946	1.23	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.128	2.061	0.879			0.54	1.295	2.097	1.414	2.074	1.655	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.914	1.859	0.897	0.611			1.656	1.569	1.948	2.418	1.204	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	1.796	2.014	0.885			0.547	0.964	1.269	0.574	1.901	0.732	
COVID19 (COVID19 (JANSSEN))	Body temperature	1.918	0.894				1.418	1.874	2.01	1.566	1.873	1.671	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.759	1.874	0.898			0.546	1.329	1.536	1.154	2.109	0.895	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.178	2.689	0.893			0.546	2.052	2.797	0.68	3.561	1.167	
COVID19 (COVID19 (JANSSEN))	Chills	1.436	0.952	0.891			2.099	1.505	1.254	0.938	1.483	1.225	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.326	2.221	0.904	0.611		0.526	1.861	2.028	1.784	3.153	1.331	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.839	1.734	0.884			0.974	1.394	1.721	1.317	2.093	1.293	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.398	1.936	0.894			0.502	2.068	2.145	2.815	2.834	1.86	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.502	1.252	0.889			0.512	2.366	2.093	1.791	2.842	1.461	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.84	1.481	0.891	0.606		0.534	1.479	1.884	1.824	2.378	1.042	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.795	0.941	0.882			0.504	1.596	1.551	0.741	2.023	0.957	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.361	0.926	0.883				2.332	1.691	0.832	2.87	1.107	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.307	3.03	0.887				1.604	3.144	1.551	5.398	1.091	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	4.908	2.66				0.554	1.758	1.446	0.578	4.397	1.079	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.822	1.242	0.886				1.308	1.677	0.876	2	1.011	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.051	2.282	0.883				1.584	1.09	0.68	2.152	0.749	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.018	1.989	0.882			0.556	1.772	1.677	1.831	2.276	1.425	
COVID19 (COVID19 (JANSSEN))	Off label use	1.425	0.188				3.971	0.321	0.544		0.901	1.353	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.72	0.753					1.962	1.031		2.065		
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	4.011	1.716	0.883				0.547	0.926	2.13	2.181	0.851	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.248	2.531	0.898	0.611		0.54	2.022	2.637	1.268	2.893	1.253	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.533	2.142	0.888			0.365	1.921	2.681	2.075	3.199	1.435	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	4.719	2.634	0.863				1.889	1.255	0.688	4.496	0.955	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	6.235					0.495	3.119	1.727	1.173	1.881	2.255	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.877	1.761	0.896	0.611		0.693	1.382	1.825	2.098	2.129	1.473	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	1.676						1.404	1.002	0.64	3.042	0.384	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.161	1.056	0.885			0.547	1.277	1.626	1.228	1.672	1.663	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.33	2.555	1.959	0.611		0.646	2.028	2.457	3.401	2.67	1.806	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.069	1.941	0.883				1.35	1.342	0.651	1.928	0.886	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.148	1.26	0.886			0.533	1.889	1.95	1.688	2.586	1.292	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.601	2.157	0.888				1.968	2.145	3.104	2.818	1.924	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.182	1.712					2.041	1.384	1.134	2.099	1.396	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.883	1.481		0.606			1.362	2.077	1.798	1.898	1.64	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	1.974	1.025	0.881			0.519	1.562	1.599	1.575	2.101	1.283	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.962	0.988					1.433	1.958	1.147	2.122	1.049	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.334	2.717				0.547	2.962	1.516	0.542	3.837	1.091	
COVID19 (COVID19 (JANSSEN))	Venogram normal	1.993	2.787	0.883				3.068	1.81	0.664	5.318	0.845	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.354				0.528	0.502	0.379	0.486	0.681	0.717	0.493	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.155						0.26	0.223	0.331	0.131	0.369	
COVID19 (COVID19 (PFIZER-	Drug ineffective	1.892	1.688	0.899			0.761	1.779	1.96	2.008	1.714	1.702	
COVID19 (COVID19 (PFIZER-	Investigation	2.012	1.704	0.892			0.736	1.721	1.84	2.063	1.973	1.75	
COVID19 (COVID19 (PFIZER-	Product preparation issue	2.068					1.48	1.877	1.847	2.114	1.898	1.812	
COVID19 (COVID19 (PFIZER-	Weight	1.983	1.252	0.885			0.617	1.498	1.724	2.012	1.95	1.628	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 15 Jun 2021 12:28:56 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST_20210611.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/11/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 202106	Serious EB05 2021	Fatal EB05 202106	Infant EB05 2021	Child EB05 2021	Teen EB05 202106	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 202106	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.386	0.811					0.796	0.858	0.722	1.887	1.414	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.008	2.639	0.885			0.532	1.387	1.668	4.511	3.946	1.23	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.128	2.061	0.879			0.54	1.295	2.097	1.414	2.074	1.655	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.914	1.859	0.897	0.611			1.656	1.569	1.948	2.418	1.204	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	1.796	2.014	0.885			0.547	0.964	1.269	0.574	1.901	0.732	
COVID19 (COVID19 (JANSSEN))	Body temperature	1.918	0.894				1.418	1.874	2.01	1.566	1.873	1.671	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.759	1.874	0.898			0.546	1.329	1.536	1.154	2.109	0.895	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.178	2.689	0.893			0.546	2.052	2.797	0.68	3.561	1.167	
COVID19 (COVID19 (JANSSEN))	Chills	1.436	0.952	0.891			2.099	1.505	1.254	0.938	1.483	1.225	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.326	2.221	0.904	0.611		0.526	1.861	2.028	1.784	3.153	1.331	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.830	1.734	0.884			0.974	1.304	1.721	1.317	2.093	1.260	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.398	1.936	0.894			0.502	2.068	2.145	2.815	2.834	1.86	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.502	1.252	0.889			0.512	2.366	2.093	1.791	2.842	1.461	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.84	1.481	0.891	0.606		0.834	1.479	1.884	1.824	2.378	1.042	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.795	0.941	0.882			0.504	1.596	1.551	0.741	2.023	0.957	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.361	0.926	0.883				2.332	1.691	0.832	2.87	1.107	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.307	3.03	0.887				1.604	3.144	1.551	5.398	1.091	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	4.908	2.66				0.554	1.758	1.446	0.578	4.397	1.079	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.822	1.242	0.886				1.308	1.677	0.876	2	1.011	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.051	2.282	0.883				1.584	1.09	0.68	2.152	0.749	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.018	1.989	0.882			0.556	1.772	1.677	1.831	2.276	1.425	
COVID19 (COVID19 (JANSSEN))	Off label use	1.425	0.188				3.971	0.321	0.544		0.901	1.353	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.72	0.753					1.962	1.031		2.065		
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	4.011	1.716	0.883				0.547	0.926	2.13	2.181	0.851	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.248	2.531	0.898	0.611		0.54	2.022	2.637	1.268	2.893	1.253	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.533	2.142	0.888			0.365	1.921	2.681	2.075	3.199	1.435	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	4.719	2.634	0.863				1.889	1.255	0.688	4.496	0.955	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	6.235					0.495	3.119	1.727	1.173	1.881	2.255	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.877	1.761	0.896	0.611		0.693	1.382	1.825	2.098	2.129	1.473	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	1.676						1.404	1.002	0.64	3.042	0.384	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.161	1.056	0.885			0.547	1.277	1.626	1.228	1.672	1.663	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.33	2.555	1.959	0.611		0.646	2.028	2.457	3.401	2.67	1.806	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.069	1.941	0.883				1.35	1.342	0.651	1.928	0.886	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.148	1.26	0.886			0.533	1.889	1.95	1.688	2.586	1.292	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.601	2.157	0.888				1.968	2.145	3.104	2.818	1.924	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.182	1.712					2.041	1.384	1.134	2.099	1.396	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.883	1.481		0.606			1.362	2.077	1.798	1.898	1.64	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	1.974	1.025	0.881			0.519	1.562	1.599	1.575	2.101	1.283	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.962	0.988					1.433	1.958	1.147	2.122	1.049	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.334	2.717				0.547	2.962	1.516	0.542	3.837	1.091	
COVID19 (COVID19 (JANSSEN))	Venogram normal	1.993	2.787	0.883				3.068	1.81	0.664	5.318	0.845	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.354				0.528	0.502	0.379	0.486	0.681	0.717	0.493	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.155						0.26	0.223	0.331	0.131	0.369	
COVID19 (COVID19 (PFIZER-	Drug ineffective	1.892	1.688	0.899			0.761	1.779	1.96	2.008	1.714	1.702	
COVID19 (COVID19 (PFIZER-	Investigation	2.012	1.704	0.892			0.736	1.721	1.84	2.063	1.973	1.75	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.998					1.48	1.877	1.847	2.114	1.898	1.812	
COVID19 (COVID19 (PFIZER-	Weight	1.983	1.252	0.885			0.617	1.498	1.724	2.012	1.95	1.628	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 25 May 2021 10:35:46 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST_20120521.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/21/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210521	Serious EB05 2021(	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.126	0.779					0.769	0.369	0.754	1.761	1.39	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.599	2.613	0.878			0.548	1.188	1.55	4.401	2.79	1.275	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	1.985	2.118					1.185	1.868	1.435	2.122	1.37	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.206	2.372	0.887	0.611			1.687	1.801	2.405	2.772	1.388	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.007	2.853	0.887			0.557	2.252	1.974	0.632	2.977	1.204	
COVID19 (COVID19 (JANSSEN))	Chills	1.377	0.93	0.888			2.314	1.4	1.228	0.94	1.434	1.149	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.256	2.336	0.901	0.611		0.548	1.939	1.868	1.637	2.944	1.314	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.807	1.87	0.881			0.541	1.424	1.451	1.654	2.019	1.226	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.34	1.898	0.887			0.531	1.963	2.116	2.801	2.762	1.782	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.582	1.45	0.886			0.466	2.369	2.019	2.637	2.757	1.553	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.826	1.378	0.886	0.604		0.55	1.362	1.811	1.337	2.163	0.981	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.19	0.882					2.102	1.642	0.686	2.53	1.031	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.14	0.737					2.178	1.654		2.136	0.546	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.296	2.883	0.881				1.298	1.449	2.582	4.578	1.063	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.93	2.321	0.879				1.682	0.63	0.648	1.944	0.62	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.944	2.09	0.876			0.61	1.668	1.523	1.754	2.129	1.401	
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.03	0.679					1.986	1.661		2.001	0.569	
COVID19 (COVID19 (JANSSEN))	Off label use	1.184					3.192	0.29	0.42		0.78	0.993	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	2.812	1.508	0.879				0.531	0.894	2.346	1.75	0.836	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.052	2.346	0.893	0.611		0.54	1.639	2.283	1.317	2.362	1.115	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.507	2.217	0.882			0.467	1.85	2.503	1.908	3.216	1.415	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	2.817	2.587	0.879				1.298	1.158	0.679	2.03	0.905	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.793	1.768	0.887	0.611		0.62	1.305	1.838	2.285	2.094	1.339	
COVID19 (COVID19 (JANSSEN))	Pyrexia	1.418	0.904	0.888			2.325	1.446	1.223	0.942	1.476	1.188	
COVID19 (COVID19 (JANSSEN))	Scan with contrast abnormal	1.834	2.055					1.025	1.606	1.081	1.754	1.151	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	3.049						1.012	2.607	5.96	2.462	2.19	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.249	1.011	0.881			0.557	1.404	1.462	1.34	1.86	1.5	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.308	2.513	1.971	0.611		0.562	2.094	2.359	3.626	2.707	1.697	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.164	2.215	0.879				1.298	1.55	0.668	1.827	0.926	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.028	1.182	0.88			0.549	1.797	1.761	1.585	2.351	1.309	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.607	2.284	0.883				1.883	1.58	3.274	3.026	1.725	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.914	1.233		0.602			1.315	2.072	2.043	1.88	1.685	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.913	1.035					1.379	1.797	1.109	2.147	0.848	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.503	2.646				0.557	1.83	1.41	0.539	2.569	1.003	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.034	2.963	0.879				3.188	1.57	0.665	4.645	0.913	
COVID19 (COVID19 (JANSSEN))	Vital signs measurement	1.893	0.554				0.758	2.017	1.352	1.245	1.86	1.597	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.188				0.528	0.531	0.496	0.548	0.831	0.79	0.678	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.067						0.398	0.312	0.556	0.271	0.484	
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.07	1.622	0.894			0.743	1.936	2.107	2.055	1.884	1.877	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.153	1.689	0.885			0.697	1.841	1.938	2.081	2.061	1.862	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	2.079					1.44	1.625	1.769	2.119	1.979	1.94	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.057	1.212	0.881			0.501	1.465	1.833	1.995	2.023	1.661	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 11 May 2021 11:07:28 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/7/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 4 May 2021 10:50:34 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210430.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/30/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20210430	Serious EB05 2021(	Fatal EB05 202104	Infant EB05 20210(	Child EB05 202104	Teen EB05 202104	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 202104	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.096	0.679					0.623	0.307	0.647	1.606	1.147	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	1.832	2.654	0.873			0.545	0.966	1.215	1.45	1.662	1.045	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.89	2.847	0.878				1.183	1.331	1.746	1.893	1.227	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	1.876	2.697	0.863			0.545	1.489	1.354	0.842	1.719	0.939	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	1.556	2.242	0.906			0.545	1.446	1.319	1.027	1.81	0.879	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	1.877	1.922	0.883				1.534	1.652	1.958	2.07	1.479	
COVID19 (COVID19 (JANSSEN))	Dysmenorrhoea	2.117	0.713					2.323	0.948		2.073		
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.185	1.662	0.88			0.49	2.146	1.621	1.732	2.318	1.328	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	1.964	0.895					1.897	1.465	0.822	2.039	0.999	
COVID19 (COVID19 (JANSSEN))	Head injury	1.592	0.658				0.651	2.034	0.775	0.415	1.412	1.466	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.449	0.781					2.749	1.473		2.427		
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	1.879	2.252	0.877				0.987	0.686	1.329	1.576	0.73	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.382	2.061	0.872			0.574	1.379	1.109	1.039	1.417	1.071	
COVID19 (COVID19 (JANSSEN))	Menstrual disorder	2.016					0.607	1.786	1.725		1.989		
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.224						2.214	1.614		2.167		
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.003	2.182	0.877			0.49	1.652	1.867	1.318	2.327	1.147	
COVID19 (COVID19 (JANSSEN))	Syncope	1.758	0.909	0.88			0.957	2.024	1.518	0.525	1.722	1.885	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.072	2.67	0.873	0.809		0.574	1.836	2.003	2.475	2.322	1.528	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.032	2.369	0.88				1.241	1.602	1.933	2.134	1.347	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	1.427	2.1				0.545	1.266	0.66		1.214	0.821	
COVID19 (COVID19 (JANSSEN))	Venogram normal	1.955	2.238	0.877				1.333	1.197	0.564	1.752	0.716	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.046				0.508	0.504	0.844	0.69	0.924	1.121	1.053	
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.143	1.488	0.869			0.848	1.918	2.331	2.001	1.936	1.832	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.187	1.631	0.88			0.562	1.854	1.909	2.013	2.118	1.83	
COVID19 (COVID19 (PFIZER-BIONTECH))	Off label use	1.79	1.038	0.875				2.028	1.663	1.689	1.841	1.33	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	1.966					0.632	1.107	1.504	2.089	1.814	1.774	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue	2.129	0.947	0.874				1.96	1.739	1.608	2.086	1.399	
COVID19 (COVID19 (PFIZER-BIONTECH))	SARS-CoV-2 test	1.975	1.56	0.893			1.178	1.984	2.04	1.792	1.927	1.862	
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain	1.969	0.749	0.866			0.63	2.126	1.967	1.508	1.868	1.949	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.131	1.142	0.875				1.403	1.707	1.968	2.011	1.849	

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From: Menschik, David
Sent: Tue, 27 Apr 2021 12:41:52 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210423.xls

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/23/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20210423	Serious EB05 2021	Fatal EB05 202104	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.028	0.67					0.806	0.428	0.831	1.353	1.077	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	1.354	2.103	0.878			0.541	0.755	1.05	0.847	1.249	0.767	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.541	2.661	0.88				1.124	1.001	0.918	1.478	0.854	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	1.838	2.971	0.887			0.541	1.466	1.156	0.859	1.694	0.771	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.36	0.798					2.389	1.5		2.344		
COVID19 (COVID19 (JANSSEN))	Interchange of vaccine products	1.636					0.586	1.068	1.29	2.222	1.554	1.128	
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.122						2.041	1.564		2.075		
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.281	2.092	0.887	0.605		0.484	1.047	1.104	1.289	1.349	1.034	
COVID19 (COVID19 (JANSSEN))	Syncope	1.794	0.815	0.88			1.026	2.001	1.557	0.461	1.803	1.647	
COVID19 (COVID19 (JANSSEN))	Thrombosis	3.214	3.039	1.986	0.605		0.597	2.001	1.9	2.112	2.372	1.587	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	1.707	2.129	0.882				1.048	1.419	1.271	1.758	1.05	
COVID19 (COVID19 (MODERNA))	Injection site pruritus	1.985	0.958				0.462	2.026	2.03	1.721	1.975	1.948	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.159	1.668	0.883			0.636	1.758	1.739	1.867	2.031	1.436	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	2.075					1.64	1.247	1.832	2.074	1.962	1.79	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue	2.086	0.942	0.878				1.94	1.698	1.567	2.031	1.377	
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain	2.01	0.778	0.872			0.608	2.165	2.083	1.614	1.905	2.032	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.042	0.963	0.88				1.3	1.527	1.781	1.89	1.455	

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From: Menschik, David
Sent: Tue, 13 Apr 2021 10:12:42 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210408.xls

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our 'US Signals Summary Table' ('as of date' 4/8/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20210408	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20218	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 2021	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Fall	1.053	0.483	0.893			0.506	2.127	0.657	0.276	1.035	0.838	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.968	0.411	0.898				2.141	1.399	1.357	2.013	1.385	
COVID19 (COVID19 (JANSSEN))	Loss of consciousness	1.752	0.907				0.484	2.087	1.343	0.518	1.514	1.731	
COVID19 (COVID19 (JANSSEN))	Syncope	1.914	0.744	0.894			0.559	2.096	1.318	0.549	1.708	1.566	
COVID19 (COVID19 (JANSSEN))	Syringe issue	2.337					0.547	1.651	2.013	0.692	1.614	2.053	
COVID19 (COVID19 (JANSSEN))	Vital signs measurement	2.53	0.706					2.637	1.144	1.292	2.151	1.31	
COVID19 (COVID19 (PFIZER-BIONTECH))	Body temperature	1.839	1.008	0.894		0.030	0.565	1.958	2.095	1.761	1.799	1.653	

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From: Menschik, David
Sent: Tue, 6 Apr 2021 11:58:18 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210401.xls

FYI
(weekly data mining attached per below)

Best,
David

From: Menschik, David
Sent: Tuesday, March 30, 2021 7:02 AM
To: Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani, Meghna <[redacted]>; Marquez, Paige L (CDC) <[redacted]>; Broder, Karen R (CDC) <[redacted]>; Harrington, Theresa (CDC) <[redacted]>
Subject: RE: Weekly data mining

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our 'US Signals Summary Table' ('as of date' 3/26/21) along with 3 slides providing contextual information including caveats and limitations. Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210401	Serious EB05 2021(	Fatal EB05 20210	Infant EB05 2021(	Child EB05 20210	Teen EB05 20210	Adult! EB05 20210	Adult2 EB05 20210	Adult3 EB05 2021(	Female EB05 2021(	Male EB05 202104	Comment
COVID19	Chills	1.775	0.967	0.695			1.031	1.726	1.632	2.143	1.673	1.448	
COVID19	Fall	0.988	0.29				0.504	2.133	0.666	0.186	0.965	0.772	
COVID19	Feeling cold	2.022	0.47	0.895				2.176	1.305	1.555	2.006	1.478	
COVID19	Loss of	1.673	0.85				0.486	2.029	1.31	0.4	1.399	1.686	
COVID19	Syringe issue	2.601					0.545	1.722	2.085	0.747	1.716	2.253	
COVID19	Vital signs	3.023						2.263	1.182	1.995	2.769	1.314	

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From: Menschik, David
Sent: Tue, 30 Mar 2021 11:02:25 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: DE VAERS data mining methods and limitations_2021_03_DRAFT.pptx, USST_20210326.xls

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our 'US Signals Summary Table' ('as of date' 3/26/21) along with 3 slides providing contextual information including caveats and limitations. Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

Data Mining Introduction*

- Statistical method for identifying disproportionality (excess of reported AE for product relative to other products) in large database
- Can be useful for screening and hypothesis generating only
  - Evaluate findings in clinical and epidemiological context (e.g., unexpected?)
  - Compelling hypotheses should be explored (e.g., via case series analyses)
  - Statistical signal of disproportionality ≠ safety signal
- Absence of disproportionality does not confirm absence of safety signal nor negate a signal otherwise detected

*Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff (November 2019; Draft). Available at https://www.fda.gov/media/130216/download

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DE VAERS Data Mining Methods

- Empirica™ Signal software (Oracle)
- Calculates Empiric Bayes Geometric Mean (EBGM) using observed to expected (O/E) vaccine-PT pair ratios
  - EBGM derived from statistical model (Multi-item Gamma Poisson Shrinker; MGPS) that accounts for instability from small numbers*
    - adjusted by age, gender and year received
- Vaccine-PT pairs ranked by lower 5% bound of EBGM CI (EB05)
- Standard alert threshold: EB05 >2
- Weekly US summary table includes subset alerts for age (0-1, 2-8, 9-18, 19-44, 45-64, and ≥65 years), gender, and serious/fatal

*Szarfman A, Tonning JM, Doraiswamy PM. Pharmacovigilance in the 21st century: new systematic tools for an old problem. Pharmacotherapy. 2004 Sep;24(9):1099-104. doi: 10.1592/phco.24.13.1099.38090. PMID: 15460169.

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Limitations of Data Mining Include:

- Impacted by stimulated reporting (e.g., V-safe, media reports)
- False alerts from statistical interaction (e.g., If vaccines X and Y often given concomitantly, statistical signal for vaccine X and AE Z may be driven by vaccine Y)
- MedDRA constraints (e.g., Signal X can be reflected in multiple PTs that individually do not reach alert threshold)
- Confounding (e.g., by indication)
- Other VAERS limitations (e.g., underreporting, variable reporting by source, incomplete reporting, duplicate reporting)

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Drug	Event	US EB05 20210326	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Chills	1.569	0.951	0.693			1.022	1.662	1.626	2.223	2.068	1.548	
COVID19 (COVID19 (JANSSEN))	Fall	1.002	0.287				0.524	2.037	0.71	0.255	1.038	0.642	
COVID19 (COVID19 (JANSSEN))	Feeling cold	2.186						2.282	1.35	1.448	2.246	1.19	
COVID19 (COVID19 (JANSSEN))	Hyperhidrosis	1.875	0.91				0.729	2.003	1.403	0.956	1.741	1.736	
COVID19 (COVID19 (JANSSEN))	Syncope	1.781	0.799					2.194	1.133	0.605	1.67	1.415	
COVID19 (COVID19 (JANSSEN))	Vital signs	2.313						1.739	0.673	0.886	1.497	0.974	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 16 Mar 2021 11:13:10 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST 20210311.xls, DE VAERS data mining methods and limitations_2021_03_DRAFT.pptx

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our 'US Signals Summary Table' ('as of date' 3/11/21) along with 3 slides providing contextual information including caveats and limitations. Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,

David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210311	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021	Male EB05 20210311
COVID19 (COVID19 (JANSSEN))	Chills	2.267					0.571	2.092	1.651	1.672	2.164	1.697

Data Mining Introduction*

- Statistical method for identifying disproportionality (excess of reported AE for product relative to other products) in large database
- Can be useful for screening and hypothesis generating only
  - Evaluate findings in clinical and epidemiological context (e.g., unexpected?)
  - Compelling hypotheses should be explored (e.g., via case series analyses)
  - Statistical signal of disproportionality ≠ safety signal
- Absence of disproportionality does not confirm absence of safety signal nor negate a signal otherwise detected

*Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff (November 2019; Draft). Available at https://www.fda.gov/media/130216/download

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AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

DE VAERS Data Mining Methods

- Empirica™ Signal software (Oracle)
- Calculates Empiric Bayes Geometric Mean (EBGM) using observed to expected (O/E) vaccine-PT pair ratios
  - EBGM derived from statistical model (Multi-item Gamma Poisson Shrinker; MGPS) that accounts for instability from small numbers*
    - adjusted by age, gender and year received
- Vaccine-PT pairs ranked by lower 5% bound of EBGM CI (EB05)
- Standard alert threshold: EB05 >2
- Weekly US summary table includes subset alerts for age (0-1, 2-8, 9-18, 19-44, 45-64, and ≥65 years), gender, and serious/fatal

*Szarfman A, Tonning JM, Doraiswamy PM. Pharmacovigilance in the 21st century: new systematic tools for an old problem. Pharmacotherapy. 2004 Sep;24(9):1099-104. doi: 10.1592/phco.24.13.1099.38090. PMID: 15460169.

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PSI-HHS-000000057498

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Limitations of Data Mining Include:

- Impacted by stimulated reporting (e.g., V-safe, media reports)
- False alerts from statistical interaction (e.g., If vaccines X and Y often given concomitantly, statistical signal for vaccine X and AE Z may be driven by vaccine Y)
- MedDRA constraints (e.g., Signal X can be reflected in multiple PTs that individually do not reach alert threshold)
- Confounding (e.g., by indication)
- Other VAERS limitations (e.g., underreporting, variable reporting by source, incomplete reporting, duplicate reporting)

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AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 12 Jan 2021 22:35:46 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Zinderman, Craig E (FDA/CBER); Baer, Bethany (FDA/CBER)
Subject: RE: Data mining
Attachments: DE VAERS data mining_202001_DRAFT.pptx

Hi John and Tom,

In addition to the overall run (mentioned in earlier email below) which now refreshes weekly, we have our pre-existing (refreshing monthly) subset runs (and I've added a line to the second attached slide to describe them) which have an earlier 'as of date' of 1/6/21. For all of these subset runs for both EUA COVID vaccines, a total of 4 PTs had an EB05 of >2, all of which were in the age 45 - <65 year ("Adult2") subset and that output is as follows:

Drug	Event	Adult2 EB05 20210106	N
COVID19 (COVID19 (PFIZER-BIONTECH))	Dysgeusia	2.118	49
COVID19 (COVID19 (PFIZER-BIONTECH))	Flushing	2.408	118
COVID19 (COVID19 (PFIZER-BIONTECH))	Palpitations	2.004	104
COVID19 (COVID19 (PFIZER-BIONTECH))	Paraesthesia oral	2.184	88

Please feel free to share this hypothesis generating output along with the limitations reflected in the slides with your team/command chain, though these are not intended to be shared more broadly.

Best,
David

PS: I'm planning to be on the 6pm call tonight and available to answer any questions

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From: Menschik, David
Sent: Tuesday, January 12, 2021 1:51 PM
To: Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Marquez, Paige L (CDC) <[redacted]>; Narayan Nair [redacted]
<[redacted]>; Alimchandani, Meghna <[redacted]>;
Zinderman, Craig E <[redacted]>; Baer, Bethany <[redacted]>
Subject: Data mining

Dear John and Tom,

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Our core weekly data mining run (previously refreshing monthly) called "VAERS Signals Weekly US All" was just refreshed this afternoon (as of date 1/10/21) and there are no EB05's >2 for any COVID vaccines. Attached are 3 slides providing contextual information including caveats and limitations that we can discuss at our weekly meeting on Thursday at 2pm.

Best,

David

Data Mining Introduction*

- Statistical method for identifying disproportionality (excess of reported adverse event [AE] for a product relative to other products)
- Hypothesis generating
  - Statistical signal of disproportional reporting (SSDR) ≠ safety signal
- Absence of disproportionality does not confirm absence of safety signal nor negate a signal otherwise detected

*Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff (November 2019; Draft). Available at https://www.fda.gov/media/130216/download

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DE Data Mining Methods

- Empirica™ Signal software (Oracle)
- Calculates Empiric Bayes Geometric Mean (EBGM) using observed to expected (O/E) vaccine-AE pair ratios
  - EBGM derived from statistical model (Multi-item Gamma Poisson Shrinker; MGPS) that accounts for instability from small numbers*
- Results adjusted by gender, year received and age
- Vaccine-PT pairs ranked by lower 5% bound of EBGM confidence interval (EB05)
  - Subsets available monthly for age (0-1, 2-8, 9-18, 19-44, 45-64, ≥65, unknown), gender, and serious/fatal
- Standard threshold for alert: EB05 ≥2

*Szarfman A, Tonning JM, Doraiswamy PM. Pharmacovigilance in the 21st century: new systematic tools for an old problem. Pharmacotherapy. 2004 Sep;24(9):1099-104. doi: 10.1592/phco.24.13.1099.38090. PMID: 15460169.

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Limitations of Data Mining Include:

- Impacted by stimulated reporting (e.g., V-safe program, media reports)
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- MedDRA constraints (e.g., Signal X can be reflected in multiple PTs that individually do not reach alert threshold)
- Confounding by indication and other VAERS limitations (e.g., underreporting, variable reporting by source, incomplete reporting, duplicate reporting)

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From: Menschik, David
Sent: Tue, 12 Jan 2021 18:51:03 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Zinderman, Craig E (FDA/CBER); Baer, Bethany (FDA/CBER)
Subject: Data mining
Attachments: DE VAERS data mining_20200110_DRAFT.pptx

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From: Menschik, David
Sent: Tue, 5 Jul 2022 11:41:43 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: Weekly data mining
Attachments: USST_20220701.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/1/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20220101	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 20220	Adult1 EB05 20220	Adult2 EB05 20220	Adult3 EB05 20220	Female EB05 2022	Male EB05 20220701
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.607	1.468	0.92			0.375	1.177	1.861	1.666	2.665	1.362
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.019	1.484	0.869				1.536	1.967	1.989	2.688	1.366
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.045	1.288	0.983				0.767	1.743	1.738	1.583	1.889
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.126	1.322	1.028			0.45	1.533	2.087	1.986	2.425	1.794
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.385	0.985	0.88			0.522	0.953	0.701	0.739	2.654	1.443
COVID19 (COVID19 (JANSSEN))	Adverse event	2.64	1.091	0.886				0.864	0.906	0.833	1.893	1.714
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.9	1.252	0.903				1.466	1.434	1.672	2.094	1.309
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.509	1.764	0.906			0.485	2.386	1.916	2.044	3.302	1.511
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.051	1.392	0.881				1.781	1.828	1.226	2.144	1.522
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.269	1.605	0.907	0.619		0.408	1.714	2.216	2.205	2.459	1.972
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.789	1.346	0.91			0.351	1.142	2.144	1.024	2.148	1.311
COVID19 (COVID19 (JANSSEN))	Antibody test	2.17	0.824	0.873			0.586	0.863	1.59	2.124	2.071	1.685
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.178	1.45	0.974	0.619		0.41	1.844	2.026	2.25	2.733	1.674
COVID19 (COVID19 (JANSSEN))	Application site pain	2.009						0.891	0.498	0.879	1.037	0.764
COVID19 (COVID19 (JANSSEN))	Areflexia	2.047	1.642	0.896				0.987	2.227	1.307	2.14	1.42
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.757	1.131	0.88				1.203	12	1.397	2.158	0.962
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.823	1.361	0.934	0.617		0.351	1.112	2.196	1.867	2.264	1.32
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.748	1.357	0.941	0.516		0.339	1.091	2.225	1.782	2.135	1.326
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.844	1.279	0.937			0.351	1.517	1.864	1.777	2.18	1.435
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.871	1.343	0.958			0.404	1.383	2.077	1.907	2.188	1.52
COVID19 (COVID19 (JANSSEN))	Blood chloride decreased	1.876	1.252	0.924				1.111	2.032	1.603	1.944	1.598
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.792	1.284	0.961			0.5	1.237	1.948	1.85	2.122	1.339
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	1.985	1.32	0.869			0.576	0.929	2.157	0.855	1.825	1.211
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.755	2.165	0.896			0.498	1.741	2.031	0.958	4.084	1.027
COVID19 (COVID19 (JANSSEN))	Blood lactate dehydrogenase increased	1.767	1.244	0.895	0.619			1.186	2.025	1.309	1.763	1.416
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.777	1.27	0.92			0.175	1.102	1.893	1.763	2.31	1.217
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.7	1.219	0.94			0.551	1.256	1.467	2.036	1.897	1.243
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.841	1.306	0.901	0.616			1.391	2.076	1.744	1.975	1.61
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.657	1.098	0.927				1.707	1.369	1.201	2.019	1.054
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.679	1.337	0.886			0.289	1.389	1.922	1.294	2.024	0.934
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.911	1.259	0.919			0.35	1.097	2.064	1.788	2.111	1.658
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.253	1.407	1.082				1.998	2.264	2.059	2.493	2.018
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.585	1.991	0.873				1.85	3.066	0.98	2.873	2.143
COVID19 (COVID19 (JANSSEN))	Catheter directed thrombolysis	1.774	1.232	0.875			0.532	0.456	1.736	0.806	2.115	0.691
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.23	1.58	0.939			0.521	1.764	1.826	1.5	3.317	1.173
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.755	1.928	0.92			0.529	1.38	1.618	1.254	3.698	1.192
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.71	1.733	0.878				1.466	1.354	1.635	3.611	1.271
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.357	2.172	0.916			0.524	2.579	2.441	0.873	3.924	1.272
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.873	1.27	0.954			0.374	1.369	1.884	1.903	2.077	1.835
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.4	1.614	0.959	0.618		0.597	2.1	2.235	2.017	2.963	1.714
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.988	1.332	0.916			0.436	1.734	1.962	1.8	2.258	1.531
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.008	1.384	0.927			0.524	1.406	2.064	1.974	2.252	1.887
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	1.949	1.241	0.881				0.495	0.609	2.097	1.043	1.707
COVID19 (COVID19 (JANSSEN))	Death	1.877	1.171	0.962				1.223	1.644	1.586	2.084	1.557
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.651	1.805	1.046			0.481	2.27	2.296	3.199	3.308	2.087
COVID19 (COVID19 (JANSSEN))	Endocardial thickening	2.048	1.348	1.106			0.386	1.426	2.084	1.889	2.093	1.85
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.767	1.285	0.932			0.249	1.214	2.04	1.757	2.08	1.368
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.781	1.329	0.937	0.516		0.369	1.218	2.06	1.777	2.072	1.387
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.757	0.84	0.884			0.181	2.023	1.462	0.982	1.848	1.429
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.274	1.281	0.893			0.502	2.179	2.147	1.965	2.533	1.706
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.152	1.46	0.99	0.619		0.293	1.715	2.293	2.257	2.522	1.848
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.945	1.089	0.878			0.435	1.624	2.017	1.104	2.184	1.294
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.329	1.46		0.757			0.875			1.642	1.845
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.214	1.031	0.88			0.402	2.305	1.666	1.215	2.214	1.804
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.897	1.298	0.911			0.391	1.3	1.758	1.684	2.274	1.275
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.746	1.176	0.912				1.225	1.518	1.357	2.23	1.106
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.448	1.818	0.887			0.434	1.617	3.042	1.622	2.392	2.169
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.864	1.271	0.956	0.613		0.527	1.328	2.015	1.789	2.157	1.447
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.76	1.234	0.946	0.613		0.421	1.406	1.942	1.676	2.001	1.429
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.708	3.805	0.894				4.176	5.514	4.346	7.258	3.372
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.145	3.291	0.875			0.55	4.199	5.727	0.74	7.043	2.491
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.669	1.922	0.957			0.416	1.553	2.091	1.946	2.447	1.718
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.09	1.723	0.873			0.611	1.932	2.577	1.376	2.2	1.75
COVID19 (COVID19 (JANSSEN))	Intensive care	1.964	1.389	1.08			0.557	1.478	2.13	2.083	2.351	1.614
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.758	1.198	0.882	0.755		0.377	1.529	1.89	1.429	2.308	1.351
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.931	1.239	0.885				1.366	2.057	1.025	2.102	1.266
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.674	1.778	0.907				0.84	1.422	0.995	1.712	1.824
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.893	1.377	0.879				1.389	1.116	0.712	2.297	0.707
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.869	1.345	0.866				1.267	2.165	1.006	1.661	1.755
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.134	1.668					1.116	2.852	1.018	1.753	1.827
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.985	1.266	0.948				1.449	1.715	1.983	2.357	1.511
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.687	1.229	0.933			0.246	0.997	2.064	1.87	2.074	1.309
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.059	1.486	0.911			0.484	1.758	1.897	2.096	2.297	1.831
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.017	1.354	0.934	0.619		0.488	1.257	2.157	1.838	2.31	1.37
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.724	1.27	0.919			0.357	1.101	1.864	1.59	2.1	0.998
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.826	1.282	0.907			0.376	1.135	2.254	1.556	2.034	1.4
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.262	1.503	1.02			0.474	1.153	2.268	2.046	2.084	2.062
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.914	1.264	0.918	0.616		0.291	0.847	1.863	1.869	2.157	1.705
COVID19 (COVID19 (JANSSEN))	Neonatal dyspnoea	2.377	0.985		0.62						0.874	1.117
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.516	1.205	0.889			0.365	1.107	1.69	1.69	2.117	0.882
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.726	1.258	0.932			0.393	1.104	2.068	1.803	1.973	1.426
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	4.088	0.789					0.744	0.613		3.024	1.076
COVID19 (COVID19 (JANSSEN))	Off label use	2.113	0.661	0.886			0.451	1.235	1.485	1.04	1.528	2.143
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.767	0.751					3.423	0.982		2.244	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.206	0.857				0.512	1.495	2.233	1.039	2.176	1.405
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.062	1.36	0.875				0.657	1.035	1.572	2.268	0.951
COVID19 (COVID19 (JANSSEN))	Platelet count	2.67	2.155	0.914	0.618		0.473	1.863	2.915	2.713	3.04	1.823
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.889	1.306	0.915	0.614		0.331	1.488	2.102	1.664	2.265	1.49
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.553	1.798	0.894			0.448	2.101	2.662	2.219	3.114	1.701
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.76	3.243	0.881				4.263	4.663	0.795	5.61	2.28
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.244	1.652	0.877				0.506	1.669	1.032	2.317	1.335
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.088	1.293	0.956				0.997	2.123	1.706	2.281	1.832
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.76	0.835	0.877		0.693	2.06	0.037	0.002	0.506	1.67	1.812
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.164	1.396					5.055			5.157	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.808	1.237	0.933	0.616		0.319	1.446	1.846	1.744	2.036	1.431
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.917	1.374	0.937	0.754		0.291	1.449	2.27	1.664	2.471	1.439
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.261	1.588	1.05	0.62		0.585	1.819	2.071	2.632	2.528	1.93
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.341	1.514	0.905				1.721	1.727	1.924	2.222	1.925
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.786	1.258	0.936	0.614		0.586	1.349	1.961	1.663	2.084	1.502
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.968	1.319	0.931	0.617		0.379	1.267	2.126	1.828	2.306	1.443
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.329	0.994					2.654	0.508		1.068	0.725
COVID19 (COVID19 (JANSSEN))	Sensory disturbance	2.008	1.306	0.881				1.445	1.86	1.472	1.878	1.748
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.582	1.778	0.885			0.53	1.762	2.039	1.749	2.588	1.822
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.28	2.231	1.096			0.618	3.12	3.176	1.123	2.813	3.343
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.559	0.757	0.876			0.651	3.658	6.592	14.645	7.714	5.681
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.705							0.637	0.568	0.561	1.926
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.942	1.311	0.88			0.505	1.446	1.563	1.464	2.08	1.343
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.274	1.705	0.951			0.36	1.62	2.464	1.885	2.51	1.78
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.924	2.126	1.799	0.62		0.732	2.011	2.487	3.622	2.998	2.401
COVID19 (COVID19 (JANSSEN))	Thrombotic microangiopathy syndrome	5.161	3.818	0.9				3.035	5.716	0.862	5.808	3.996
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.077	1.495	0.876				1.775	1.225	0.623	2.112	0.879
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.345	1.427	0.905			0.711	1.888	2.209	2.139	2.653	1.75
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.655	1.818	0.958	0.619		0.522	2.484	2.295	2.83	3.28	2.108
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.344	1.607	0.91			0.424	2.241	1.969	1.972	2.411	1.843
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.61	3.024	2.476			0.554	1.462	2.46	4.1	2.189	2.366
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.91	0.895					1.25	1.375	0.787	2.084	0.809
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.069	0.907	0.874				0.975	1.573	1.123	1.793	1.113
COVID19 (COVID19 (JANSSEN))	Venogram	2.341	1.747	0.873				2.001	1.601	0.706	2.543	1.064
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.65	1.991				0.608	2.669	1.609	0.659	3.258	1.192
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.84	2.162	0.881				3.587	2	1.055	4.711	1.195
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.474	0.819		9.551	1.374		1.28	0.52		1.472	1.072
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.685	0.994	0.886	0.507	1.393	2.491	0.793	0.607	0.437	0.688	0.646
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.023	1.165				0.504	2.046	1.539	0.607	1.966	1.926
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.523	1.018	0.887	0.362	4.261	2.99	0.159	0.087	0.36	2.538	2.623
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.129	2.004	0.876		0.543	2.724	2.031	1.962	1.571	1.962	2.173
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.045					1.145	1.944	2.002	1.843	1.974	1.923
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.099	1.663	0.889			0.836	1.62	1.782	1.529	1.908	1.887
COVID19 (COVID19 (PFIZER-	Body height	1.967	1.011	0.881		0.484	0.695	0.96	1.465	2.193	1.93	1.553
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.025	1.754	1.664	0.745	0.888	1.147	1.826	1.885	1.887	1.834	1.908
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.853	6.847	0.88	15.347			0.365			0.501	1.215
COVID19 (COVID19 (PFIZER-	Immunisation	2.077	1.652	0.915		1.289	1.245	1.82	2.002	2.282	2.007	1.858
COVID19 (COVID19 (PFIZER-	Investigation	2.043	1.764	0.932		0.76	1.108	1.821	1.942	2.263	1.996	1.896
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.568	0.786		0.394	1.453	1.357	1.859	1.714	2.152	1.573	1.543
COVID19 (COVID19 (PFIZER-	Weight	1.924	1.367	0.891			0.554	1.545	1.736	2.08	1.88	1.743

PSI-HHS-000000057510

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From: Menschik, David
Sent: Tue, 28 Jun 2022 10:49:00 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220624.xls

Sorry – forgot attachment

From: Menschik, David
Sent: Tuesday, June 28, 2022 6:48 AM
To: Shimabukuro, Tom (CDC) <[redacted]>; Su, John (CDC) <[redacted]>; Moro, Pedro L (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani, Meghna <[redacted]>; Broder, Karen R (CDC) <[redacted]>; Mcneil, Michael M (CDC) <[redacted]>; Lale, Allison (CDC) <[redacted]>
Subject: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/24/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022Q4	Serious EB05 2022	Fatal EB05 2022Q	Infant EB05 2022Q	Child EB05 2022Q	Teen EB05 2022Q	Adult EB05 2022Q	Adult2 EB05 2022Q	Adult3 EB05 2022Q	Female EB05 2022Q	Male EB05 2022Q	24
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.998	1.457	0.922			0.376	1.481	1.83	1.846	2.683	1.355	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.019	1.486	0.873				1.539	1.975	1.975	2.664	1.375	
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.023	1.268	0.973				0.779	1.674	1.743	1.588	1.847	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.117	1.318	1.021			0.45	1.522	2.063	1.995	2.437	1.773	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.385	0.966	0.885			0.522	0.953	0.701	0.676	2.628	1.443	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.636	1.89	0.891				0.864	0.967	0.835	1.895	1.714	
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.02	1.751					1.234	1.368		0.887	1.561	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.969	1.26	0.906				1.472	1.441	1.673	2.092	1.319	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.507	1.763	0.909			0.485	2.324	1.924	2.054	3.298	1.515	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.068	1.367	0.884				1.781	1.78	1.23	2.156	1.473	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.29	1.605	0.908			0.406	1.694	2.229	2.181	2.451	1.962	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.783	1.333	0.909			0.355	1.146	2.144	1.468	2.098	1.323	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.162	6.824	0.879			0.566	0.865	1.561	2.126	2.058	1.885	
COVID19 (COVID19 (JANSSEN))	Antiepileptal therapy	2.18	1.587	0.87	0.818		0.412	1.68	2.019	2.068	2.747	1.873	
COVID19 (COVID19 (JANSSEN))	Application site pain	2.008						0.561	0.635	0.678	1.037	0.764	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.049	1.647	0.9				0.967	2.226	1.309	2.138	1.423	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.798	1.132	0.885				1.203	13	1.398	2.156	0.983	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.831	1.342	0.928	0.617		0.351	1.12	2.18	1.862	2.273	1.311	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.75	1.361	0.935	0.516		0.341	1.099	2.224	1.782	2.151	1.318	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.822	1.264	0.928			0.354	1.505	1.842	1.749	2.173	1.41	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.86	1.334	0.948			0.465	1.364	2.068	1.877	2.178	1.508	
COVID19 (COVID19 (JANSSEN))	Blood chloride decreased	1.854	1.239	0.917				1.118	2	1.58	1.908	1.587	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.79	1.283	0.952			0.502	1.242	1.983	1.83	2.125	1.332	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	1.961	1.246	0.878			0.576	0.929	2.157	0.569	1.698	1.211	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.686	2.122	0.896			0.498	1.741	2.031	0.87	3.927	1.026	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.782	1.274	0.923			0.176	1.116	1.904	1.743	2.316	1.223	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.668	1.268	0.936			0.106	1.249	1.463	2.02	1.888	1.223	
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.828	1.301	0.896	0.616			1.372	2.063	1.738	1.951	1.803	
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.632	1.086	0.923				1.707	1.335	1.171	2.021	1.01	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.662	1.326	0.88			0.284	1.398	1.942	1.246	2.021	0.911	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.901	1.252	0.913			0.353	1.088	2.055	1.775	2.089	1.654	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.238	1.401	1.074				1.885	2.245	2.057	2.422	2.001	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.677	1.987	0.875				1.857	3.015	0.884	3.53	2.149	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.235	1.587	0.94			0.521	1.774	1.828	1.499	3.34	1.173	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.759	1.95	0.923			0.529	1.38	1.629	1.259	3.792	1.191	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.716	1.738	0.884				1.468	1.357	1.63	3.624	1.27	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.357	2.172	0.918			0.524	2.579	2.441	0.872	3.924	1.272	
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.866	1.268	0.951			0.378	1.354	1.875	1.9	2.078	1.622	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.411	1.623	0.958	0.518		0.598	2.125	2.261	2.03	2.991	1.714	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.977	1.323	0.912			0.436	1.721	1.945	1.796	2.255	1.511	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.062	1.381	0.925			0.527	1.406	2.044	1.98	2.243	1.683	
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	1.976	1.265	0.886				0.495	0.866	2.111	1.047	1.731	
COVID19 (COVID19 (JANSSEN))	Death	1.673	1.17	0.901				1.226	1.633	1.562	2.065	1.551	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.65	1.804	1.053			0.461	2.273	2.292	3.207	3.307	2.087	
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.034	1.342	1.094			0.558	1.429	2.066	1.859	2.079	1.821	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.778	1.28	0.886			0.25	1.208	2.038	1.734	2.061	1.38	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.76	1.318	0.931	0.616		0.371	1.213	2.031	1.746	2.047	1.371	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.756	6.841	0.889			1.181	2.021	1.454	0.972	1.851	1.421	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.293	1.372	0.897			0.503	2.168	2.138	1.94	2.511	1.899	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.136	1.443	0.878	0.519		0.395	1.705	2.285	2.216	2.511	1.623	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.938	1.06	0.884			0.435	1.624	2.036	1.027	2.197	1.271	
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.33	1.443		0.757			0.675			1.64	1.845	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.214	1.031	0.896			0.402	2.305	1.665	1.213	2.213	1.604	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.864	1.27	0.91			0.394	1.272	1.751	1.619	2.227	1.249	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.778	1.158	0.906				1.225	1.449	1.363	2.175	1.086	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.463	1.823	0.892			0.435	1.617	3.062	1.627	2.398	2.173	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.765	1.265	0.943	0.513		0.527	1.329	2.002	1.774	2.154	1.432	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.751	1.229	0.933	0.513		0.422	1.406	1.93	1.666	2.073	1.419	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.707	3.606	0.896				4.176	3.513	4.344	7.454	3.37	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.149	3.294	0.881			0.55	4.201	5.724	0.739	7.042	2.483	
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.076	1.313	0.958			0.416	1.468	2.085	1.932	2.448	1.69	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.097	1.731	0.881			0.611	1.941	2.577	1.378	2.208	1.756	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.994	1.394	1.062			0.657	1.476	2.117	2.068	2.343	1.805	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.749	1.195	0.883	0.755		0.377	1.525	1.871	1.425	2.287	1.249	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.945	1.249	0.86				1.382	2.056	1.03	2.127	1.27	
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.673	1.778	0.91				0.84	1.421	0.994	1.71	1.623	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.802	1.376	0.884				1.37	1.115	0.712	2.298	0.707	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.863	1.347	0.873				1.269	2.176	1.004	1.648	1.757	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.146	1.681					1.116	2.853	1.02	1.752	1.845	
COVID19 (COVID19 (JANSSEN))	Lung infiltration	1.83	1.154	0.928			0.61	1.284	1.803	1.398	2.002	1.454	
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.964	1.268	0.947				1.446	1.767	1.988	2.35	1.514	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.679	1.225	0.924			0.248	0.997	2.045	1.864	2.08	1.306	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.68	1.487	0.914			0.484	1.798	1.898	2.102	2.312	1.819	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.016	1.358	0.926	0.519		0.503	1.248	2.177	1.815	2.35	1.364	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.719	1.266	0.919			0.359	1.106	1.913	1.523	2.077	1.009	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.818	1.274	0.903			0.378	1.147	2.246	1.521	2.031	1.388	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.268	1.494	1.006			0.475	1.155	2.238	2.041	2.091	2.035	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.813	1.287	0.918	0.516		0.269	0.838	1.998	1.38	2.189	1.105	
COVID19 (COVID19 (JANSSEN))	Neonatal dyspnoea	2.392	6.984		0.62						0.874	1.117	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.564	1.193	0.89			0.368	1.107	1.595	1.618	2.107	0.871	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.725	1.269	0.924			0.395	1.095	2.067	1.807	1.979	1.418	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	4.087	6.789					0.744	0.613		3.027	1.076	
COVID19 (COVID19 (JANSSEN))	Off label use	2.108	0.66	0.893			0.453	1.235	1.47	1.042	1.524	2.142	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.767	6.751					3.427	0.982		2.243		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.265	6.857				0.512	1.495	2.232	1.036	2.175	1.405	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.084	1.358	0.881				0.657	1.034	1.565	2.265	1.95	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.652	2.142	0.916	0.518		0.474	1.863	2.864	2.574	3.014	1.807	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.874	1.301	0.912	0.514		0.333	1.473	2.08	1.664	2.261	1.466	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.54	1.8	0.898			0.448	2.008	2.669	2.141	3.088	1.699	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.759	3.245	0.886				4.284	4.662	0.784	5.648	3.273	
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.249	1.651	0.868				0.586	1.966	1.03	2.316	1.304	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.08	1.292	0.954				1.003	2.179	1.691	2.21	1.842	
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.759	6.834	0.883		0.693	2.059	0.037	0.002	0.507	1.668	1.814	
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.162	1.395					5.058			5.183		
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.779	1.218	0.923	0.516		0.325	1.428	1.617	1.714	2.01	1.405	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.969	1.369	0.933	0.754		0.291	1.453	2.263	1.645	2.41	1.44	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.254	1.583	1.045	0.62		0.586	1.81	2.065	2.623	2.521	1.922	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.34	1.513	0.908				1.721	1.726	1.919	2.221	1.923	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.78	1.254	0.927	0.514		0.59	1.349	1.981	1.653	2.095	1.489	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.962	1.314	0.927	0.517		0.381	1.283	2.12	1.805	2.299	1.437	
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.328	0.994					2.663	0.506		1.068	0.725	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.553	1.798	0.89			0.53	1.763	2.048	1.756	2.611	1.821	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.378	2.228	1.901			0.618	3.095	3.125	1.118	2.773	3.344	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.561	6.757	0.882			0.651	3.774	6.205	14.647	7.697	5.705	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.709							0.638	0.569	0.562	1.026	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.944	1.315	0.896			0.508	1.45	1.562	1.462	2.087	1.342	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.208	1.705	0.954			0.361	1.006	2.39	1.883	2.498	1.776	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.922	2.127	1.753	0.62		0.732	2.017	2.483	3.607	3.003	2.388	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	6.101	3.019	0.903				3.042	5.735	0.563	5.608	3.38	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	3.516	1.495	0.882				1.776	1.225	0.939	3.111	0.879	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.34	1.431	0.909			0.711	1.89	2.202	2.144	2.648	1.744	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.701	1.822	0.966	0.519		0.522	2.502	2.295	2.835	3.278	2.121	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.139	1.61	0.913			0.424	2.231	1.965	1.95	2.465	1.845	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.606	3.027	2.47			0.554	1.44	2.448	4.096	2.178	2.357	
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.913	6.895					1.25	1.374	0.789	2.101	0.809	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.071	6.907	0.881				0.975	1.572	1.125	1.798	1.113	
COVID19 (COVID19 (JANSSEN))	Venogram	2.341	1.746	0.88				2.002	16	0.706	2.543	1.964	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.663	2.002				0.608	2.67	1.618	0.659	3.291	1.792	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.879	2.17	0.886				3.632	2	1.068	4.767	1.199	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.465	6.819		10.497	0.872		1.28	0.521		1.458	1.074	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.685	6.993	0.893	0.511	1.599	2.489	0.794	0.557	0.436	0.688	0.646	
COVID19 (COVID19 (MODERNA))	Mechanical uricaria	2.028	1.186				0.663	2.05	1.541	0.807	1.97	1.93	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.53	1.019	0.892	0.471	5.603	2.99	0.163	0.063	0.36	2.542	2.634	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.129	2.002	0.875			2.721	2.032	1.963	1.571	1.961	2.172	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.648					1.142	1.947	2.004	1.846	1.977	1.926	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.069	1.862	0.893			0.626	1.921	1.793	1.529	1.909	1.868	
COVID19 (COVID19 (PFIZER-	Body height	1.965	1.011	0.886		0.483	0.695	0.959	1.464	2.189	1.928	1.552	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.032	1.751	1.661	0.752	0.884	1.145	1.817	1.878	1.882	1.823	1.903	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.86	6.847	0.886	16.202			0.365			0.513	1.214	
COVID19 (COVID19 (PFIZER-	Immunisation	2.074	1.649	0.917		1.288	1.245	1.818	2	2.279	2.004	1.856	
COVID19 (COVID19 (PFIZER-	Investigation	2.041	1.759	0.928	0.742	1.108	1.818	1.938	2.26	1.695	1.896		
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.591	6.786		1.453	1.363	1.857	1.717	2.153	1.573	1.546		
COVID19 (COVID19 (PFIZER-	Weight	1.925	1.366	0.896			0.654	1.555	1.739	2.077	1.88	1.747	

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From: Menschik, David
Sent: Tue, 21 Jun 2022 11:15:01 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220617.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/17/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EBGS 2022Q1	Serious EBGS 2022	Fatal EBGS 2022Q1	Infant EBGS 2022Q1	Child EBGS 2022Q1	Teen EBGS 2022Q1	Adult EBGS 2022Q1	Adult2 EBGS 2022Q1	Adult3 EBGS 2022Q1	Female EBGS 2022Q1	Male EBGS 2022Q1
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.907	1.483	0.926			0.577	1.486	1.818	1.663	2.634	1.346
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.011	1.477	0.877				1.544	1.985	1.929	2.623	1.382
COVID19 (COVID19 (JANSEN))	Acute respiratory distress syndrome	2.034	1.278	0.974				0.779	1.673	1.761	1.602	1.85
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.111	1.317	1.016			0.452	1.522	2.039	1.994	2.438	1.764
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	3.375	0.988	0.888			0.525	0.954	0.761	0.677	2.628	1.448
COVID19 (COVID19 (JANSEN))	Adverse event	2.626	1.085	0.893				0.864	0.909	0.779	1.892	1.717
COVID19 (COVID19 (JANSEN))	Albumin CSF increased	2.05	1.805					1.235	1.382		0.894	1.561
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.924	1.273	0.908				1.48	1.496	1.676	2.128	1.322
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.502	1.761	0.911			0.487	2.342	1.901	2.067	3.321	1.493
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.063	1.361	0.887				1.782	1.753	1.247	2.162	1.456
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.281	1.599	0.91			0.413	1.972	2.236	2.173	2.448	1.949
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.788	1.336	0.911			0.359	1.15	2.139	1.48	2.117	1.317
COVID19 (COVID19 (JANSEN))	Antibody test	2.164	0.824	0.882			0.568	0.867	1.563	2.113	2.061	1.588
COVID19 (COVID19 (JANSEN))	Antiepileptic therapy	2.179	1.583	0.887	0.62		0.414	1.844	2.018	1.241	2.74	1.661
COVID19 (COVID19 (JANSEN))	Application site pain	2.064						0.561	0.636	0.678	1.037	0.764
COVID19 (COVID19 (JANSEN))	Areflexia	2.055	1.657	0.902				0.97	2.225	1.315	2.13	1.425
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.811	1.139	0.888				1.203	1.367	1.406	2.193	0.966
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.84	1.348	0.93	0.517		0.354	1.127	2.189	1.87	2.288	1.314
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.753	1.368	0.938	0.516		0.251	1.196	2.235	1.801	2.173	1.307
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.81	1.257	0.925			0.299	1.511	1.833	1.734	2.168	1.398
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.864	1.332	0.948			0.389	1.354	2.076	1.869	2.173	1.502
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.798	1.288	0.954			0.459	1.249	1.971	1.84	2.141	1.333
COVID19 (COVID19 (JANSEN))	Blood fibrinogen	1.892	1.197	0.875			0.578	0.929	2.008	0.568	1.698	1.156
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.686	2.12	0.898			3.5	1.744	2.032	0.87	3.932	1.026
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.757	1.257	0.922			0.186	1.091	1.877	1.732	2.288	1.203
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.639	1.307	0.893			0.079	1.353	1.949	1.198	2.016	0.875
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.867	1.244	0.912				1.093	2.026	1.772	2.09	1.031
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.236	1.402	1.071				1.886	2.235	2.06	2.42	1.999
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.561	1.984	0.882				1.866	2.943	0.991	2.531	2.123
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.232	1.596	0.936			0.623	1.776	1.801	1.503	3.332	1.172
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.789	1.95	0.924			0.531	1.381	1.627	1.258	3.794	1.19
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.712	1.737	0.886				1.469	1.396	1.628	3.625	1.269
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.358	2.171	0.915			0.527	2.585	2.403	0.872	3.923	1.271
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.867	1.269	0.953			0.326	1.352	1.882	1.901	2.081	1.821
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.42	1.636	0.961	0.518		3.5	2.124	2.267	2.045	3.004	1.722
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.968	1.314	0.916			0.374	1.71	1.902	1.808	2.249	1.5
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	1.988	1.373	0.926			0.457	1.397	2.033	1.985	2.241	1.861
COVID19 (COVID19 (JANSEN))	Creatinine renal clearance decreased	2.036	1.281	0.889				0.495	0.888	2.089	1.056	1.783
COVID19 (COVID19 (JANSEN))	Death	1.873	1.171	0.961				1.229	1.632	1.584	2.088	1.549
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.643	1.801	1.08			0.463	2.271	2.297	3.159	3.323	2.069
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	2.04	1.347	1.1			0.382	1.429	2.065	1.873	2.093	1.822
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.765	1.273	0.926			0.041	1.217	2.01	1.737	2.073	1.317
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.703	1.316	0.904	0.516		0.265	1.223	2.032	1.746	2.051	1.357
COVID19 (COVID19 (JANSEN))	Feeling cold	1.755	0.843	0.892			1.18	2.018	1.465	0.975	1.85	1.422
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.267	1.275	0.896			0.504	2.171	2.143	1.946	2.522	1.702
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	3.128	1.497	0.877	0.518		0.486	1.758	2.278	2.199	2.813	1.61
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.942	1.062	0.886			0.437	1.63	2.036	1.026	2.198	1.276
COVID19 (COVID19 (JANSEN))	Foetal exposure during pregnancy	2.323	1.418		0.757			0.676			1.637	1.843
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.219	1.033	0.897			0.493	2.31	1.673	1.213	2.224	1.604
COVID19 (COVID19 (JANSEN))	Globulins increased	1.855	1.263	0.913			0.397	1.277	1.738	1.6	2.211	1.239
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.695	1.147	0.912				1.225	1.428	1.337	2.136	1.071
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.458	1.824	0.894			0.436	1.623	3.075	1.632	2.413	2.174
COVID19 (COVID19 (JANSEN))	Haemstocrit decreased	1.753	1.263	0.941	0.513		0.491	1.329	1.999	1.777	2.166	1.422
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.748	1.227	0.931	0.513		0.387	1.404	1.93	1.664	2.073	1.414
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.71	3.894	0.9				4.179	5.576	4.346	7.286	3.37
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.144	3.289	0.883			0.652	4.205	5.722	6.739	7.08	2.481
COVID19 (COVID19 (JANSEN))	Hypoxia	2.073	1.313	0.957				1.488	2.08	1.936	2.45	1.884
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.09	1.722	0.884			0.611	1.943	2.545	1.388	2.213	1.741
COVID19 (COVID19 (JANSEN))	Intensive care	1.94	1.094	1.007			0.621	1.493	2.097	2.063	2.337	1.565
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.73	1.187	0.886	0.755		0.381	1.508	1.862	1.407	2.257	1.237
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	1.929	1.222	0.892				1.382	2.072	0.969	2.082	1.275
COVID19 (COVID19 (JANSEN))	Intracardiac thrombus	2.669	1.776	0.911				0.84	1.42	0.994	1.71	1.622
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.863	1.377	0.887				1.371	1.115	0.712	2.298	0.707
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.866	1.352	0.876				1.271	2.18	1.006	1.852	1.758
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.141	1.685					1.116	2.81	1.034	1.753	1.837
COVID19 (COVID19 (JANSEN))	Lung opacity	1.989	1.273	0.948				1.44	1.709	1.998	2.383	1.514
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.669	1.22	0.924			0.183	1	2.036	1.855	2.01	1.297
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.057	1.466	0.915			0.467	1.769	1.879	2.117	2.323	1.603
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.006	1.35	0.93	0.519		0.435	1.248	2.165	1.818	2.354	1.337
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.7	1.249	0.918			0.233	1.171	1.909	1.493	2.061	0.979
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.811	1.273	0.907			0.31	1.133	2.25	1.537	2.038	1.373
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.279	1.597	1.012			0.477	1.156	2.249	2.093	2.111	2.038
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.598	1.204	0.919	0.516		0.205	0.836	1.881	1.967	2.167	1.095
COVID19 (COVID19 (JANSEN))	Neonatal dyspnoea	2.361	0.981		0.62						0.878	1.116
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.562	1.167	0.894			0.315	1.116	1.569	1.627	2.135	1.65
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.716	1.253	0.926			0.245	1.101	2.049	1.805	1.975	1.404
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	4.081	0.769					0.745	0.613		3.068	1.076
COVID19 (COVID19 (JANSEN))	Orthostatic pain	2.161	0.8	0.889			0.498	1.236	1.48	1.014	1.917	2.156
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.768	0.752					3.437	0.982		2.246	
COVID19 (COVID19 (JANSEN))	Pain assessment	2.204	0.858				0.514	1.495	2.232	1.036	2.133	1.444
COVID19 (COVID19 (JANSEN))	Peripheral embolism	3.688	1.36	0.884				0.657	1.004	1.565	2.266	0.951
COVID19 (COVID19 (JANSEN))	Platelet count	2.653	2.154	0.917	0.518		0.477	1.864	2.883	2.619	3.01	1.809
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.868	1.297	0.916	0.514		0.256	1.453	2.085	1.649	2.24	1.468
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.545	1.806	0.9			0.45	2.092	2.725	2.158	3.098	1.7
COVID19 (COVID19 (JANSEN))	Platelet factor 4	5.802	3.271	0.889				4.258	4.66	6.808	5.732	2.273
COVID19 (COVID19 (JANSEN))	Portal vein thrombosis	2.253	1.571	0.886				0.859	1.883	1.03	2.368	1.334
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	2.064	1.298	0.956				1.003	2.102	1.709	2.243	1.651
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.761	0.834	0.886		0.705	2.06	0.038	0.062	0.511	1.67	1.816
COVID19 (COVID19 (JANSEN))	Prolonged labour	5.184	1.332					5.054			5.157	
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.765	1.208	0.924	0.517		0.326	1.418	1.597	1.7	2.008	1.383
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.9	1.355	0.934	0.754		0.293	1.444	2.26	1.627	2.424	1.44
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.248	1.582	1.048	0.62		0.587	1.806	2.064	2.613	2.528	1.91
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.312	1.482	0.91				1.676	1.69	1.92	2.223	1.871
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.776	1.252	0.928	0.514		0.349	1.345	1.98	1.886	2.011	1.477
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.935	1.294	0.928	0.518		0.277	1.284	2.064	1.785	2.28	1.402
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.328	0.994					2.679	0.506		1.068	0.725
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.61	1.798	0.892			0.532	1.771	2.063	1.752	2.827	1.834
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.371	2.298	1.6			0.619	3.159	3.67	1.129	2.771	3.339
COVID19 (COVID19 (JANSEN))	Therapy non-responder	6.562	6.758	0.885			0.653	3.777	6.56	14.673	7.722	5.704
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.692							0.638	0.568	0.562	1.026
COVID19 (COVID19 (JANSEN))	Thrombectomy	1.947	1.32	0.897			0.511	1.45	1.562	1.47	2.088	1.345
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.281	1.718	0.956			0.367	1.607	2.368	1.905	2.511	1.785
COVID19 (COVID19 (JANSEN))	Thrombosis	2.917	2.12	1.746	0.62		0.733	2.012	2.48	3.629	3	2.376
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	6.084	3.011	0.905				3.052	5.715	6.062	5.606	3.354
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.077	1.497	0.885				1.779	1.225	0.623	2.113	0.879
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.342	1.43	0.91			0.712	1.897	2.197	2.147	2.648	1.743
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.708	1.629	0.908	0.519		0.524	2.506	2.301	2.846	3.3	2.116
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.356	1.625	0.916			0.428	2.251	1.976	1.961	2.431	1.845
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.601	1.016	2.496			0.556	1.453	2.436	4.301	2.194	2.346
COVID19 (COVID19 (JANSEN))	Varicose vein	1.918	0.995					1.23	1.014	0.789	2.191	0.809
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.071	0.907	0.883				0.975	1.573	1.125	1.796	1.113
COVID19 (COVID19 (JANSEN))	Venogram	2.341	1.748	0.882				2.005	16	0.706	2.544	1.064
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.678	2.012				0.81	2.677	1.627	0.659	3.335	1.191
COVID19 (COVID19 (JANSEN))	Venogram normal	3.883	2.17	0.889				3.636	2.002	1.068	4.773	1.199
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.457	0.819		10.502	0.889		1.265	0.521		1.444	1.075
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.684	1.003	0.893	0.511	1.674	2.476	0.794	0.654	0.435	0.687	0.644
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.018	1.165				0.664	2.044	1.523	0.807	1.962	1.921
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.531	1.018	0.894	0.477	6.007	2.987	0.158	0.078	0.338	2.542	2.633
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.129	2.011	0.882			2.796	2.034	1.98	1.571	1.963	2.172
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.039					1.139	1.936	1.989	1.838	1.968	1.912
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.058	1.664	0.896			0.637	1.62	1.781	1.527	1.969	1.886
COVID19 (COVID19 (PFIZER-	Body height	1.965	1.01	0.889		0.483	0.895	0.959	1.466	2.19	1.928	1.553
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.039	1.75	1.059	0.754	0.679	1.141	1.617	1.676	1.676	1.827	1.909
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.86	0.847	0.886	10.298			0.36			0.509	1.243
COVID19 (COVID19 (PFIZER-	Immunisation	2.075	1.658	0.918		1.289	1.243	1.819	2.004	2.282	2.004	1.86
COVID19 (COVID19 (PFIZER-	Investigation	2.049	1.762	0.926		0.74	1.103	1.819	1.946	2.264	1.994	1.903
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.594	0.786			1.451	1.365	1.858	1.717	2.159	1.578	1.549
COVID19 (COVID19 (PFIZER-	Weight	1.928	1.357	0.898			0.854	1.555	1.735	2.078	1.891	1.747

PSI-HHS-000000057514

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From: Menschik, David
Sent: Tue, 14 Jun 2022 10:36:52 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220610.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/10/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20220610	Serious EB05 2022(	Fatal EB05 20220(	Infant EB05 20220(	Child EB05 20220(	Teen EB05 20220(	Adult1 EB05 20220(	Adult2 EB05 20220(	Adult3 EB05 20220(	Female EB05 2022(	US Male EB05 20220610
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.008	1.479	0.903			0.377	1.467	1.848	1.683	2.665	1.336
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.022	1.487	0.882				1.55	1.991	1.945	2.649	1.387
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.066	1.301	0.975				0.78	1.677	1.815	1.603	1.901
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.118	1.32	1.015			0.452	1.472	2.062	1.998	2.451	1.766
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.341	0.969	0.892			0.525	0.954	0.705	0.678	2.628	1.454
COVID19 (COVID19 (JANSSEN))	Adverse event	2.622	1.086	0.897				0.865	0.91	0.781	1.893	1.725
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.149	1.9					1.238	1.412		0.894	1.626
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.933	1.279	0.911				1.483	1.458	1.681	2.143	1.325
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.515	1.768	0.914			0.487	2.349	1.91	2.084	3.345	1.498
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.046	1.358	0.891				1.785	1.743	1.252	2.179	1.412
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.288	1.602	0.911			0.413	1.647	2.255	2.19	2.463	1.948
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.814	1.363	0.915			0.38	1.168	2.171	1.493	2.154	1.332
COVID19 (COVID19 (JANSSEN))	Antibody test	2.148	0.828	0.886			0.568	0.828	1.569	1.97	2.031	1.69
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.181	1.457	0.968	0.619		0.414	1.834	2.032	2.26	2.774	1.657
COVID19 (COVID19 (JANSSEN))	Application site pain	2.004						0.561	0.635	0.679	1.038	0.764
COVID19 (COVID19 (JANSSEN))	Areflexia	2.049	1.646	0.903				0.924	2.247	1.325	2.153	1.468
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.815	1.14	0.892				1.204	1.408	1.41	2.197	0.968
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.863	1.367	0.934	0.617		0.357	1.14	2.225	1.872	2.33	1.317
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.771	1.383	0.943	0.615		0.253	1.114	2.271	1.806	2.201	1.311
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.626	1.266	0.93			0.302	1.011	1.855	1.754	2.166	1.409
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.874	1.346	0.956			0.371	1.364	2.103	1.885	2.198	1.515
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.814	1.3	0.954			0.461	1.244	2.001	1.863	2.159	1.344
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	1.884	1.2	0.883			0.575	0.929	2.012	0.969	1.701	1.197
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.691	2.12	0.899			0.5	1.749	2.035	0.87	3.934	1.027
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.774	1.269	0.926			0.171	1.107	1.9	1.732	2.309	1.21
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.687	1.293	0.939			0.505	1.254	1.992	2.002	1.886	1.227
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.828	1.301	0.905	0.618			1.357	2.017	1.731	1.961	1.597
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.612	1.075	0.92				1.651	1.315	1.162	2.017	0.979
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.646	1.313	0.897			0.086	1.351	1.962	1.205	2.038	0.861
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.896	1.249	0.917				1.061	2.051	1.78	2.109	1.632
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.242	1.404	1.073				1.906	2.264	2.055	2.412	2.012
COVID19 (COVID19 (JANSSEN))	CSF protein increased	3.581	2.001	0.887				1.87	2.96	1.005	2.56	2.139
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.228	1.578	0.938			0.523	1.712	1.842	1.509	3.344	1.153
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.879	1.984	0.927			0.531	1.384	1.682	1.258	3.888	1.2
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.71	1.738	0.89				1.471	1.365	1.64	3.625	1.268
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.363	2.17	0.921			0.525	2.593	2.447	0.872	3.53	1.273
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.871	1.271	0.955			0.328	1.331	1.897	1.904	2.097	1.616
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.433	1.642	0.96	0.618		0.604	2.13	2.25	2.055	3.028	1.729
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.98	1.325	0.919			0.375	1.724	1.942	1.828	2.268	1.503
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.993	1.375	0.926			0.457	1.388	2.043	1.986	2.249	1.663
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	2.064	1.259	0.893				0.495	0.889	2.149	1.961	1.802
COVID19 (COVID19 (JANSSEN))	Death	1.866	1.169	0.962				1.222	1.63	1.575	2.092	1.54
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.646	1.803	1.044			0.463	2.253	2.258	3.192	3.332	2.067
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.047	1.349	1.1			0.363	1.404	2.075	1.887	2.955	1.828
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.789	1.293	0.931			0.042	1.236	2.044	1.75	2.102	1.331
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.775	1.336	0.939	0.619		0.267	1.246	2.055	1.764	2.079	1.374
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.758	0.854	0.898			1.182	2.021	1.459	0.976	1.853	1.424
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.27	1.274	0.903			0.504	2.175	2.153	1.858	2.524	1.707
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.143	1.449	0.977	0.619		0.297	1.708	2.302	2.218	2.529	1.621
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.954	1.07	0.89			0.437	1.641	2.044	1.029	2.221	1.277
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.273	1.597		0.737			0.883			1.941	1.893
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.211	1.02	0.898			0.404	2.274	1.683	1.213	2.235	1.578
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.858	1.265	0.916			0.397	1.278	1.753	1.613	2.248	1.225
COVID19 (COVID19 (JANSSEN))	Glomerular filtration rate decreased	1.766	1.136	0.941				1.052	1.567	1.567	2.001	1.365
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.714	1.157	0.915				1.23	1.44	1.349	2.171	1.081
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.482	1.835	0.897			0.435	1.626	3.113	1.644	2.43	2.203
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.803	1.268	0.943	0.619		0.404	1.328	2.018	1.782	2.185	1.423
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.756	1.231	0.935	0.613		0.389	1.397	1.947	1.67	2.091	1.412
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.716	3.605	0.903				4.183	5.523	4.348	7.27	3.378
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.155	3.398	0.888			0.662	4.206	5.739	0.74	7.055	3.689
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.08	1.316	0.958				1.491	2.099	1.932	2.459	1.689
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.082	1.715	0.885			0.011	1.91	2.553	1.392	2.222	1.72
COVID19 (COVID19 (JANSSEN))	Intensive care	1.946	1.388	1.056			0.022	1.456	2.101	2.08	2.345	1.588
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.739	1.191	0.889	0.755		0.381	1.504	1.865	1.421	2.274	1.241
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.938	1.232	0.896				1.384	2.075	0.978	2.089	1.281
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.677	1.779	0.913				0.84	1.423	0.994	1.714	1.625
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.805	1.374	0.891				1.372	1.119	0.712	2.308	0.707
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.873	1.359	0.881				1.275	2.188	1.011	1.859	1.764
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.136	1.68					1.122	2.779	1.027	1.766	1.814
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.998	1.276	0.948				1.417	1.729	2.005	2.372	1.52
COVID19 (COVID19 (JANSSEN))	Lymphocyte count decreased	1.658	1.168	0.914			0.061	1.065	1.873	1.631	2.009	1.242
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.664	1.23	0.931			0.185	1.005	2.005	1.865	2.071	1.304
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.058	1.465	0.917			0.467	1.777	1.871	2.128	2.333	1.598
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.031	1.367	0.934	0.619		0.438	1.273	2.191	1.824	2.376	1.358
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.71	1.254	0.921			0.243	1.163	1.925	1.501	2.052	0.968
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.832	1.289	0.912			0.314	1.136	2.274	1.554	2.064	1.381
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.278	1.505	1.007			0.477	1.157	2.249	2.055	2.122	2.028
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.528	1.218	0.923	0.619		0.208	0.848	1.928	1.974	2.198	1.108
COVID19 (COVID19 (JANSSEN))	Neonatal dyspnoea	2.399	0.983		0.62						0.879	1.119
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.522	1.2	0.898			0.317	1.136	1.567	1.653	2.178	0.857
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.733	1.265	0.932			0.246	1.108	2.05	1.815	1.966	1.415
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	4.076	0.769					3.745	0.613		3.016	1.076
COVID19 (COVID19 (JANSSEN))	Off label use	2.079	0.593	0.899			0.395	1.239	1.387	0.984	1.458	2.089
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.769	0.751					3.444	0.983		2.253	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.226	0.869				0.611	1.498	2.263	1.111	2.17	1.446
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.098	1.358	0.888				1.657	1.035	1.568	2.284	0.951
COVID19 (COVID19 (JANSSEN))	Platelet count	2.647	2.145	0.919	0.618		0.477	1.828	2.853	2.77	3.018	1.79
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.874	1.302	0.921	0.618		0.259	1.469	2.102	1.662	2.245	1.475
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.55	1.809	0.904			0.45	2.065	2.744	2.167	3.114	1.694
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.812	3.276	0.89				4.293	4.675	0.808	5.74	2.295
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.256	1.67	0.89				0.859	1.887	1.03	2.376	1.334
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.089	1.301	0.959				1.004	2.114	1.725	2.238	1.675
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.766	0.834	0.89		3.719	2.063	0.039	0.002	0.513	1.675	1.819
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.187	1.33					5.053			5.16	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.788	1.222	0.929	0.617		0.333	1.432	1.617	1.721	2.029	1.402
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.911	1.373	0.932	0.756		0.294	1.432	2.282	1.646	2.455	1.44
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.255	1.585	1.062	0.62		0.567	1.809	2.073	2.633	2.534	1.916
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.317	1.484	0.911				1.728	1.672	1.942	2.235	1.87
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.792	1.261	0.932	0.614		0.554	1.352	2	1.667	2.039	1.482
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.948	1.305	0.933	0.617		0.283	1.299	2.095	1.8	2.253	1.411
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.367	1.003					1.699	0.309		1.981	0.73
COVID19 (COVID19 (JANSSEN))	Sensory disturbance	2	1.319	0.893				1.409	1.855	1.492	1.849	1.76
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.561	1.752	0.896			0.535	1.773	1.978	1.77	2.58	1.791
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.401	2.225	1.583			0.523	3.158	3.241	1.152	2.818	3.366
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.539	0.758	0.889			0.652	3.818	6.567	14.559	7.679	5.705
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.682							0.637	0.569	0.561	1.026
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.998	1.323	0.901			0.511	1.468	1.909	1.473	2.099	1.356
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.278	1.714	0.949			0.368	1.611	2.405	1.881	2.497	1.791
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.92	2.125	1.748	0.62		0.728	2.011	2.481	3.638	3.004	2.375
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	9.096	2.96	0.905				2.15	5.765	0.563	6.668	2.602
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.08	1.491	0.889				1.783	1.225	0.623	2.119	0.879
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.351	1.438	0.913			0.712	1.899	2.213	2.156	2.65	1.752
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.704	1.692	0.969	0.619		0.627	2.603	2.282	2.86	3.301	2.11
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.361	1.625	0.918			0.429	2.238	1.993	1.958	2.455	1.837
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.607	3.031	2.48			0.484	1.468	2.528	4.508	2.227	2.382
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.914	0.895					1.251	1.376	0.769	2.106	0.81
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.071	0.907	0.888				0.975	1.517	1.131	1.796	1.113
COVID19 (COVID19 (JANSSEN))	Venogram	2.352	1.745	0.887				2.023	1.903	0.706	2.564	1.065
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.683	2.012				0.61	2.685	1.629	0.659	3.342	1.192
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.885	2.188	0.893				3.637	2.004	1.069	4.776	1.199
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.451	0.819		10.61	3.909		1.265	0.52		1.445	1.055
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.682	1.013	0.9	0.611	1.677	2.483	0.793	0.651	0.435	0.686	0.642
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.015	1.166				0.663	2.04	1.52	0.807	1.96	1.916
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.53	1.019	0.896	0.48	3.972	2.981	0.163	0.074	0.345	2.54	2.633
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.13	2.019	0.887			2.79	2.033	1.98	1.573	1.965	2.173
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.04					1.137	1.932	1.987	1.846	1.972	1.911
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.097	1.671	0.899			0.837	1.619	1.781	1.528	1.91	1.886
COVID19 (COVID19 (PFIZER-BIONTECH))	Body height	1.959	1.001	0.853		3.483	0.695	0.959	1.457	2.187	1.926	1.552
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.036	1.747	1.652	0.758	3.877	1.133	1.803	1.852	1.84	1.821	1.895
COVID19 (COVID19 (PFIZER-BIONTECH))	Exposure via breast milk	0.86	0.846	0.892	16.309			0.38			0.508	1.248
COVID19 (COVID19 (PFIZER-BIONTECH))	Immunisation	2.07	1.655	0.92		1.289	1.243	1.818	1.999	2.278	1.969	1.857
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.041	1.759	0.93		1.736	1.102	1.818	1.943	2.259	1.862	1.9
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	1.595	0.788			1.447	1.366	1.859	1.719	2.156	1.578	1.551
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	1.929	1.37	0.901			0.953	1.552	1.737	2.081	1.892	1.753

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From: Menschik, David
Sent: Tue, 7 Jun 2022 10:00:19 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220603.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/3/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20220403	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	03
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.03	1.485	0.923			0.578	1.473	1.853	1.661	2.698	1.348	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.04	1.499	0.879				1.557	2.004	1.953	2.678	1.396	
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.066	1.303	0.98				0.779	1.675	1.818	1.598	1.903	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.117	1.322	1.017			0.454	1.469	2.064	1.996	2.455	1.761	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.335	0.969	0.888			0.526	0.954	0.713	0.677	2.644	1.454	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.615	1.083	0.893				0.871	0.91	0.782	1.882	1.726	
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.146	1.898					1.239	1.412		0.894	1.623	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.938	1.285	0.91				1.497	1.444	1.702	2.168	1.312	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.536	1.785	0.913			0.488	2.372	1.903	2.077	3.387	1.505	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.053	1.366	0.887				1.785	1.742	1.268	2.184	1.418	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.3	1.613	0.911			0.419	1.602	2.269	2.207	2.471	1.962	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.835	1.384	0.914			0.381	1.18	2.201	1.506	2.174	1.349	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.137	0.83	0.881			0.589	0.825	1.574	1.505	2.005	1.896	
COVID19 (COVID19 (JANSSEN))	Antimyeloid therapy	2.137	1.486	0.872	0.618		0.618	1.846	2.003	2.217	2.783	1.888	
COVID19 (COVID19 (JANSSEN))	Application site pain	2.002						0.561	0.636	0.678	1.037	0.764	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.062	1.66	0.9				0.929	2.271	1.325	2.168	1.415	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.836	1.154	0.888				1.213	1.205	1.416	2.331	0.977	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.872	1.373	0.933	0.516		0.359	1.157	2.205	1.896	2.321	1.328	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.777	1.391	0.944	0.515		0.252	1.125	2.238	1.832	2.198	1.32	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.838	1.275	0.93			0.305	1.519	1.85	1.775	2.201	1.413	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.876	1.348	0.956			0.372	1.372	2.096	1.892	2.196	1.519	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.817	1.302	0.952			0.461	1.244	2.009	1.863	2.15	1.354	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	1.892	1.198	0.878			0.579	0.929	2.01	0.568	1.691	1.157	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.756	2.156	0.896			0.592	1.75	2.103	0.879	4.028	1.03	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.788	1.281	0.927			0.186	1.091	1.935	1.744	2.342	1.211	
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.828	1.301	0.902	0.516			1.361	2.011	1.733	1.959	1.596	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.648	1.314	0.893			0.084	1.306	1.943	1.206	2.032	0.897	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.9	1.251	0.915				1.068	2.051	1.784	2.113	1.634	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.243	1.498	1.08				1.91	2.252	2.057	2.419	2.009	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.551	2.012	0.882				1.878	2.072	1.906	2.582	2.143	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.232	1.582	0.938			0.525	1.713	1.85	1.51	3.341	1.157	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.885	1.89	0.927			0.532	1.385	1.68	1.263	3.912	1.199	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.766	1.734	0.886				1.471	1.365	1.637	3.611	1.297	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.356	2.171	0.919			0.528	2.556	2.444	0.88	3.91	1.276	
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.879	1.279	0.96			0.33	1.336	1.962	1.916	2.108	1.823	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.444	1.653	0.966	0.518		0.605	2.132	2.252	2.067	3.041	1.737	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.992	1.328	0.918			0.376	1.716	1.938	1.847	2.272	1.499	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2	1.383	0.924			0.458	1.388	2.046	2.002	2.246	1.675	
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	2.118	1.316	0.889				0.498	0.868	2.153	1.08	1.792	
COVID19 (COVID19 (JANSSEN))	Death	1.98	1.169	0.962				1.223	1.822	1.572	2.088	1.536	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.637	1.807	1.06			0.464	2.266	2.289	3.172	3.322	2.059	
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.068	1.36	1.122			0.383	1.41	2.088	1.899	2.11	1.836	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.79	1.285	0.93			0.04	1.244	2.016	1.774	2.094	1.337	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.785	1.342	0.94	0.516		0.266	1.257	2.04	1.789	2.077	1.383	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.757	0.857	0.895			0.181	2.024	1.457	0.976	1.852	1.426	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.272	1.874	0.9			0.503	2.179	2.166	1.984	2.884	1.758	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.147	1.454	0.984	0.519		0.296	1.71	2.312	2.218	2.51	1.825	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.937	1.075	0.886			0.438	1.628	2.011	1.035	2.171	1.288	
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.201	1.416		0.756			0.651			1.638	1.756	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.21	1.021	0.896			0.405	2.274	1.662	1.213	2.234	1.578	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.846	1.258	0.909			0.398	1.282	1.739	1.592	2.234	1.214	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.712	1.155	0.911				1.23	1.467	1.373	2.182	1.066	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.468	1.836	0.894			0.437	1.628	3.129	1.646	2.438	2.206	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.868	1.271	0.941	0.513		0.496	1.335	2.02	1.784	2.181	1.43	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.762	1.237	0.936	0.513		0.39	1.404	1.957	1.672	2.084	1.419	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.712	3.607	0.9				4.182	5.521	4.32	7.261	3.373	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.149	3.297	0.883			0.554	4.206	5.734	0.74	7.054	2.479	
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.065	1.322	0.958				1.492	2.103	1.938	2.458	1.696	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.079	1.713	0.901			0.011	1.909	2.046	1.394	2.427	1.711	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.945	1.389	1.06			0.021	1.454	2.055	2.088	2.344	1.59	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.76	1.202	0.889	0.754		0.382	1.526	1.861	1.433	2.292	1.258	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.935	1.231	0.892				1.383	2.074	0.977	2.087	1.28	
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.67	1.774	0.911				0.84	1.422	0.994	1.71	1.822	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.804	1.389	0.887				1.373	1.116	0.712	2.298	1.707	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.875	1.357	0.876				1.277	2.187	1.013	1.662	1.764	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.143	1.69					1.122	2.801	1.031	1.774	1.816	
COVID19 (COVID19 (JANSSEN))	Lung infiltration	1.838	1.16	0.93			0.613	1.25	1.823	1.401	2.002	1.461	
COVID19 (COVID19 (JANSSEN))	Lung opacity	2.064	1.282	0.948				1.425	1.73	2.013	2.38	1.523	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.678	1.225	0.928			0.182	0.996	2.053	1.863	2.061	1.297	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.06	1.465	0.916			0.468	1.77	1.872	2.142	2.338	1.595	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.033	1.372	0.936	0.519		0.439	1.282	2.183	1.83	2.363	1.374	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.702	1.251	0.922			0.242	1.17	1.916	1.475	2.073	0.974	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.846	1.298	0.91			0.314	1.147	2.274	1.579	2.074	1.395	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.252	1.522	1.02			0.478	1.157	2.268	2.066	2.136	2.04	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.933	1.223	0.918	0.516		0.207	0.655	1.901	1.901	2.192	1.116	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.525	1.202	0.894			0.319	1.132	1.602	1.657	2.197	0.849	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.722	1.259	0.926			0.245	1.094	2.066	1.808	1.982	1.405	
COVID19 (COVID19 (JANSSEN))	Neutrophil count	1.698	0.788					0.745	0.813		2.084	1.078	
COVID19 (COVID19 (JANSSEN))	Off label use	2.672	0.596	0.895			8.345	1.219	1.387	0.985	1.488	2.085	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.769	0.751					3.446	0.983		2.248		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.239	0.861				0.515	1.506	2.264	1.11	2.173	1.447	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.089	1.355	0.883				0.657	1.005	1.561	2.268	0.951	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.637	2.148	0.917	0.518		0.478	1.832	2.821	2.758	2.998	1.791	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.87	1.303	0.92	0.514		0.259	1.437	2.1	1.664	2.244	1.469	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.551	1.808	0.901			0.451	2.069	2.74	2.172	3.12	1.893	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.8	3.284	0.885				4.291	4.966		5.733	3.27	
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.254	1.665	0.886				0.859	1.864	1.03	2.367	1.334	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.068	1.304	0.958				1.001	2.105	1.732	2.218	1.884	
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.767	0.833	0.885		0.719	2.082	0.04	0.002	0.512	1.671	1.826	
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.18	1.33					5.046			5.154		
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.794	1.227	0.928	0.516		0.336	1.439	1.629	1.716	2.011	1.421	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.92	1.38	0.935	0.754		0.293	1.434	2.293	1.858	2.451	1.448	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.252	1.588	1.083	0.519		0.589	1.806	2.068	2.633	2.524	1.917	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.326	1.496	0.906				1.766	1.67	1.962	2.231	1.899	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.8	1.267	0.926	0.514		0.556	1.364	2.065	1.672	2.044	1.491	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.946	1.305	0.931	0.517		0.284	1.31	2.092	1.792	2.271	1.423	
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.367	1.003					2.704	0.506		1.081	1.73	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.559	1.723	0.892			0.537	1.774	1.97	1.787	2.563	1.795	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.453	2.211	1.597			0.527	3.258	3.318	1.168	2.883	3.425	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.54	0.757	0.885			0.654	3.618	6.564	14.788	7.668	3.72	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.667							0.637	0.568	0.561	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.961	1.329	0.894			0.512	1.474	1.564	1.476	2.097	1.357	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.28	1.724	0.96			0.368	1.613	2.4	1.891	2.499	1.792	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.919	2.128	1.756	0.519		0.729	2.012	2.461	3.644	2.994	2.389	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	6.07	2.957	0.902				2.15	5.733	0.562	5.595	2.54	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.091	1.514	0.884				1.785	1.231	0.623	2.139	0.879	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.304	1.447	0.912			0.713	1.914	2.226	2.167	2.68	1.756	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.769	1.837	0.976	0.519		0.529	2.505	2.285	2.879	3.302	2.115	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.378	1.84	0.918			0.43	2.235	2.013	1.979	2.485	1.854	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.921	1.545	2.472			0.488	1.514	2.061	1.71	2.275	2.431	
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.912	0.895					1.252	1.375	0.789	2.091	1.81	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.115	0.906	0.883				0.975	1.58	1.136	1.852	1.113	
COVID19 (COVID19 (JANSSEN))	Venogram	2.75	1.741	0.882				2.023	1.602	0.706	2.54	1.964	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.706	2.027				0.611	2.686	1.629	0.665	3.337	1.2	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.914	2.202	0.888				3.659	2.003	1.068	4.832	1.199	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.483	0.824		10.568	0.908		1.266	0.52		1.448	1.057	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.677	0.991	0.891	0.61	1.023	2.472	0.788	0.646	0.432	0.681	0.838	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.015	1.17				0.661	2.041	1.517	0.808	1.961	1.914	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.529	1.018	0.894	0.474	6.06	2.975	0.147	0.07	0.345	2.538	2.633	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.133	2.019	0.882			2.794	2.035	1.982	1.576	1.968	2.176	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.042					1.147	1.936	1.982	1.846	1.978	1.911	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.1	1.869	0.898			0.837	1.621	1.783	1.529	1.913	1.888	
COVID19 (COVID19 (PFIZER-	Body height	1.959	0.992	0.866		0.463	0.696	0.956	1.466	2.166	1.927	1.551	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.043	1.752	1.644	0.754	0.86	1.128	1.779	1.822	1.805	1.811	1.887	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.859	0.856	0.888	16.551			0.36			0.507	1.246	
COVID19 (COVID19 (PFIZER-	Immunisation	2.067	1.666	0.918		1.287	1.244	1.817	1.995	2.277	1.997	1.854	
COVID19 (COVID19 (PFIZER-	Investigation	2.04	1.752	0.929		0.737	1.103	1.814	1.942	2.259	1.98	1.9	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.599	0.785			1.455	1.367	1.857	1.718	2.155	1.581	1.553	
COVID19 (COVID19 (PFIZER-	Weight	1.931	1.356	0.898			0.954	1.558	1.731	2.084	1.894	1.76	

PSI-HHS-000000057518

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From: Menschik, David
Sent: Wed, 1 Jun 2022 10:12:13 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220530.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/30/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20220330	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 20220	Female EB05 2022	Male EB05 20220530
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.581	1.514	0.927			0.378	1.482	1.874	2.01	2.705	1.367
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.054	1.518	0.877				1.573	2.031	1.966	2.683	1.407
COVID19 (COVID19 (JANSEN))	Acute respiratory distress syndrome	2.077	1.317	0.986				0.789	1.672	1.827	1.598	1.921
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.113	1.324	1.02			0.453	1.476	2.064	1.986	2.448	1.757
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	3.326	0.969	0.885			0.527	0.956	0.716	0.677	2.611	1.457
COVID19 (COVID19 (JANSEN))	Adverse event	2.666	1.091	0.891				0.87	0.882	0.781	1.871	1.723
COVID19 (COVID19 (JANSEN))	Albumin CSF increased	2.141	1.898					1.237	1.411		0.893	1.621
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.909	1.278	0.904				1.452	1.443	1.669	2.14	1.286
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.538	1.789	0.911			0.486	2.367	1.507	2.068	3.384	1.507
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.048	1.362	0.886				1.753	1.741	1.28	2.194	1.396
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.319	1.63	0.913			0.414	1.992	2.287	2.213	2.477	1.979
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.822	1.377	0.911			0.383	1.133	2.221	1.489	2.155	1.338
COVID19 (COVID19 (JANSEN))	Antibody test	2.124	0.835	0.878			0.569	0.829	1.575	1.512	1.998	1.677
COVID19 (COVID19 (JANSEN))	Antifungal therapy	2.179	1.589	0.876	0.618		0.418	1.845	2.63	2.241	2.747	1.992
COVID19 (COVID19 (JANSEN))	Application site pain	2						0.56	0.636	0.678	1.038	0.764
COVID19 (COVID19 (JANSEN))	Areflexia	2.058	1.672	0.898				0.941	2.375	1.324	2.28	1.42
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.861	1.158	0.886				1.213	1.231	1.413	2.328	0.881
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.862	1.366	0.929	0.516		0.357	1.166	2.211	1.85	2.285	1.34
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.778	1.393	0.945	0.515		0.252	1.129	2.269	1.813	2.161	1.34
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.827	1.269	0.928			0.305	1.514	1.854	1.747	2.178	1.41
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.873	1.348	0.953			0.371	1.373	2.1	1.878	2.186	1.52
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.819	1.305	0.953			0.461	1.24	2.017	1.863	2.151	1.356
COVID19 (COVID19 (JANSEN))	Blood fibrinogen	1.85	1.197	0.875			0.578	0.929	2.008	0.568	1.697	1.155
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.765	2.165	0.899			0.581	1.747	2.102	0.882	4.052	1.03
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.778	1.276	0.926			0.171	1.071	1.938	1.728	2.32	1.204
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.662	1.208	0.938			0.509	1.261	1.564	2.004	1.883	1.241
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.823	1.301	0.9	0.516			1.355	2.013	1.72	1.944	1.398
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.648	1.313	0.86			0.087	1.361	1.943	1.208	2.024	0.876
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.894	1.249	0.912				1.053	2.069	1.769	2.104	1.629
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.22	1.401	1.071				1.872	2.24	2.033	2.391	1.991
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.581	2.007	0.876				1.845	2.969	1.004	2.507	2.153
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.229	1.582	0.938			0.524	1.711	1.847	1.508	3.338	1.155
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.8	1.96	0.927			0.532	1.383	1.72	1.163	3.993	1.141
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.657	1.734	0.883				1.47	1.363	1.629	3.611	1.265
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.345	2.167	0.917			0.527	2.532	2.442	0.88	3.891	1.275
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.97	1.276	0.958			0.329	1.33	1.962	1.898	2.095	1.615
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.428	1.644	0.954	0.518		0.605	2.115	2.301	2.031	3.028	1.718
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.979	1.325	0.919			0.376	1.713	1.939	1.839	2.253	1.511
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	1.995	1.384	0.925			0.457	1.382	2.042	1.995	2.242	1.668
COVID19 (COVID19 (JANSEN))	Creatinine renal clearance decreased	2.028	1.268	0.886				0.497	0.897	1.986	1.087	1.848
COVID19 (COVID19 (JANSEN))	Death	1.886	1.169	0.962				1.213	1.623	1.566	2.081	1.53
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.635	1.81	1.035			0.484	2.267	2.292	3.166	3.311	2.061
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	2.057	1.363	1.122			0.363	1.415	2.066	1.693	2.094	1.64
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.782	1.292	0.927			0.04	1.254	2.012	1.748	2.06	1.348
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.788	1.344	0.937	0.516		0.267	1.269	2.044	1.77	2.052	1.399
COVID19 (COVID19 (JANSEN))	Fatigue	1.798	0.897	0.899			0.182	2.023	1.403	0.978	1.84	1.488
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.266	1.277	0.898			0.442	2.177	2.164	1.963	2.524	1.897
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.143	1.455	0.986	0.519		0.296	1.717	2.31	2.2	2.507	1.837
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.908	1.075	0.883			0.497	1.63	1.979	1.693	2.152	1.288
COVID19 (COVID19 (JANSEN))	Foetal exposure during pregnancy	2.119	1.396		0.756			0.654			1.598	1.731
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.216	1.025	0.893			0.404	2.272	1.693	1.212	2.233	1.585
COVID19 (COVID19 (JANSEN))	Globulins increased	1.844	1.256	0.906			0.398	1.29	1.747	1.565	2.201	1.226
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.716	1.159	0.911				1.201	1.417	1.385	2.185	1.059
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.478	1.835	0.891			0.438	1.635	3.104	1.642	2.433	2.202
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.892	1.271	0.942	0.512		0.495	1.321	2.031	1.775	2.173	1.427
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.759	1.237	0.936	0.513		0.39	1.39	1.967	1.667	2.088	1.417
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.707	3.607	0.898				4.18	5.516	4.29	7.266	3.367
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.143	3.297	0.88			0.553	4.209	5.724	6.739	7.055	2.468
COVID19 (COVID19 (JANSEN))	Hypoxia	2.062	1.323	0.951				1.496	2.096	1.936	2.407	1.691
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.072	1.719	0.878			0.011	1.924	2.549	1.396	2.228	1.713
COVID19 (COVID19 (JANSEN))	Intensive care	1.941	1.39	1.056			0.022	1.455	2.096	2.078	2.347	1.582
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.766	1.209	0.86	0.754		0.281	1.534	1.909	1.424	2.299	1.259
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	1.903	1.231	0.886				1.383	2.072	0.976	2.084	1.278
COVID19 (COVID19 (JANSEN))	Intracardiac thrombus	2.623	1.751	0.906				0.84	1.403	0.994	1.707	1.597
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.818	1.408	0.884				1.572	1.125	0.712	2.288	0.712
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.876	1.358	0.873				1.277	2.188	1.013	1.666	1.761
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.14	1.691					1.121	2.796	1.03	1.772	1.814
COVID19 (COVID19 (JANSEN))	Lung infiltration	1.824	1.156	0.927			0.612	1.248	1.817	1.381	2	1.443
COVID19 (COVID19 (JANSEN))	Lung opacity	1.988	1.279	0.948				1.426	1.723	1.985	2.354	1.515
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.675	1.224	0.93			0.183	0.997	2.069	1.85	2.041	1.305
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.058	1.483	0.915			0.468	1.769	1.872	2.125	2.338	1.587
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.024	1.366	0.938	0.519		0.439	1.267	2.186	1.872	2.38	1.364
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.687	1.246	0.921			0.245	1.153	1.914	1.484	2.071	0.963
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.86	1.312	0.911			0.314	1.149	2.3	1.586	2.084	1.408
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.267	1.505	1.011			0.476	1.16	2.266	1.999	2.107	2.016
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.532	1.222	0.917	0.516		0.209	0.857	1.904	1.964	2.168	1.126
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.518	1.195	0.892			0.319	1.105	1.611	1.663	2.184	0.842
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.778	1.287	0.93			0.248	1.097	2.073	1.782	1.983	1.415
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	4.062	0.788					0.744	0.612		2.961	1.075
COVID19 (COVID19 (JANSEN))	Off label use	2.052	0.595	0.892			0.228	1.222	1.389	0.959	1.468	2.056
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.769	0.751					3.442	0.983		2.241	
COVID19 (COVID19 (JANSEN))	Pain assessment	2.225	0.861				0.515	1.504	2.201	1.109	2.168	1.444
COVID19 (COVID19 (JANSEN))	Peripheral embolism	3.065	1.355	0.88				0.657	1.035	1.544	2.252	0.951
COVID19 (COVID19 (JANSEN))	Platelet count	2.663	2.18	0.916	0.518		0.478	1.838	2.858	2.745	3.041	1.794
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.866	1.303	0.916	0.514		0.256	1.441	2.094	1.647	2.23	1.474
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.544	1.803	0.896			0.45	2.067	2.739	2.137	3.125	1.677
COVID19 (COVID19 (JANSEN))	Platelet factor 4	5.761	3.28	0.882				4.29	4.866	0.806	5.734	2.256
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.239					1.027	2.108	1.203	0.651	1.668	1.634
COVID19 (COVID19 (JANSEN))	Portal vein thrombosis	2.231	1.64	0.882				0.859	1.854	1.029	2.264	1.334
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	2.067	1.295	0.956				1.006	2.103	1.693	2.221	1.848
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.766	0.639	0.882		0.719	2.062	0.039	0.062	0.512	1.87	1.825
COVID19 (COVID19 (JANSEN))	Prolonged labour	5.167	1.332					5.039			5.138	
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.928	1.39	0.939	0.754		0.293	1.446	2.308	1.653	2.483	1.455
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.252	1.589	1.084	0.519		0.588	1.806	2.069	2.033	2.528	1.916
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.255	1.486	0.907				1.763	1.643	1.908	2.18	1.88
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.801	1.269	0.928	0.514		0.556	1.361	2.021	1.661	2.027	1.504
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.945	1.305	0.932	0.517		0.388	1.307	2.067	1.784	2.273	1.421
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.307	1.003					2.69	0.506		1.08	3.73
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.564	1.723	0.886			0.537	1.773	1.973	1.79	2.567	1.798
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.459	2.294	1.586			0.526	3.208	3.272	1.204	2.81	3.453
COVID19 (COVID19 (JANSEN))	Therapy non-responder	6.543	4.757	0.882			0.653	3.618	6.59	14.803	7.688	5.717
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.66							0.637	0.569	0.561	1.025
COVID19 (COVID19 (JANSEN))	Thrombectomy	1.961	1.333	0.892			0.512	1.481	1.502	1.473	2.093	1.358
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.281	1.73	0.951			0.368	1.616	2.402	1.891	2.498	1.795
COVID19 (COVID19 (JANSEN))	Thrombosis	2.907	2.119	1.749	0.519		0.729	2.004	2.472	3.616	2.978	2.38
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	6.041	2.952	0.899				2.134	5.682	0.562	5.584	2.482
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.069	1.516	0.881				1.782	1.231	0.623	2.132	0.879
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.363	1.442	0.911			0.712	1.906	2.229	2.162	2.682	1.75
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.718	1.844	0.977	0.519		0.528	2.515	2.251	2.888	3.31	2.123
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.309	1.645	0.918			0.429	2.215	2.052	2.019	2.491	1.852
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.625	3.061	2.478			0.488	1.52	2.768	4.889	2.284	2.472
COVID19 (COVID19 (JANSEN))	Varicose vein	1.969	0.895					1.251	1.374	0.789	2.093	0.809
COVID19 (COVID19 (JANSEN))	Vasculitation	2.169	0.907	0.88				0.975	1.579	1.139	1.844	1.112
COVID19 (COVID19 (JANSEN))	Venogram	2.348	1.743	0.879				2.018	16	0.706	2.552	1.064
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.704	2.029				0.61	2.679	1.628	0.665	3.331	1.199
COVID19 (COVID19 (JANSEN))	Venogram normal	3.914	2.205	0.885				3.659	2.064	1.064	4.832	1.199
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.457	0.824		10.463	0.909		1.294	0.52		1.463	1.056
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.674	0.983	0.886	0.509	1.023	2.473	0.758	0.641	0.428	0.877	0.636
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.05	1.143				0.661	2.081	1.528	0.809	1.991	1.954
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.531	1.017	0.892	0.467	6.033	2.578	0.148	0.07	0.345	2.539	2.635
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.137	2.02	0.875			2.79	2.045	1.989	1.578	1.972	2.182
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.104	1.67	0.893			0.636	1.629	1.788	1.529	1.914	1.892
COVID19 (COVID19 (PFIZER-	Body height	1.954	0.992	0.885		0.462	0.696	0.956	1.462	2.187	1.92	1.55
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.04	1.752	1.647	0.753	0.86	1.126	1.736	1.794	1.776	1.809	1.875
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.86	0.856	0.885	16.546			0.363			0.51	1.245
COVID19 (COVID19 (PFIZER-	Immunisation	2.061	1.658	0.916		1.288	1.244	1.605	1.969	2.274	1.588	1.849
COVID19 (COVID19 (PFIZER-	Investigation	2.038	1.752	0.928		0.719	1.1	1.801	1.904	2.255	1.988	1.899
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.661	0.785			1.459	1.368	1.849	1.714	2.154	1.588	1.556
COVID19 (COVID19 (PFIZER-	Weight	1.934	1.355	0.896			0.654	1.553	1.731	2.087	1.898	1.758

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From: Menschik, David
Sent: Tue, 24 May 2022 10:42:56 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220520.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/20/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	2020
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.066	1.532	0.99			0.378	1.486	1.887	2.027	2.733	1.376	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.07	1.538	0.883				1.583	2.044	1.983	2.727	1.411	
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.067	1.33	0.99				0.79	1.679	1.832	1.61	1.925	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.107	1.326	1.017			0.454	1.458	2.046	1.991	2.45	1.747	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.339	0.974	0.886			0.527	0.969	0.735	0.679	0.615	1.478	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.59	1.092	0.894				0.871	0.852	0.786	1.877	1.681	
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.232	1.904					1.305	1.411		0.907	1.625	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.92	1.291	0.908				1.452	1.459	1.669	2.143	1.295	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.558	1.806	0.914			0.488	2.402	1.948	2.082	3.438	1.508	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.066	1.383	0.886				1.779	1.75	1.283	2.211	1.405	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.309	1.631	0.916			0.414	1.631	2.265	2.225	2.471	1.973	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.813	1.37	0.91			0.364	1.117	2.234	1.464	2.128	1.339	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.116	0.823	0.883			0.569	0.79	1.58	1.905	2.003	1.658	
COVID19 (COVID19 (JANSSEN))	Antineoplastic therapy	2.177	1.483	0.873	0.618		0.618	1.84	2.008	2.236	2.762	1.897	
COVID19 (COVID19 (JANSSEN))	Application site pain	2.004						0.56	0.636	0.678	1.038	0.765	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.128	1.709	0.901				0.947	2.418	1.338	2.315	1.433	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.847	1.163	0.89				1.213	1.231	1.419	2.334	0.983	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.884	1.391	0.931	0.516		0.36	1.179	2.251	1.858	2.325	1.348	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.798	1.413	0.947	0.515		0.256	1.126	2.313	1.827	2.183	1.353	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.821	1.268	0.93			0.306	1.485	1.847	1.755	2.168	1.404	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.875	1.352	0.954			0.374	1.361	2.103	1.893	2.15	1.516	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.823	1.309	0.953			0.467	1.232	2.027	1.872	2.151	1.359	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.001	2.186	0.897			0.592	1.75	2.176	0.881	4.064	1.036	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.804	1.3	0.926			0.174	1.077	1.976	1.751	2.357	1.221	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.704	1.217	0.938			0.513	1.254	1.522	2.025	1.891	1.245	
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.824	1.305	0.905	0.516			1.35	2.005	1.736	1.951	1.594	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.648	1.319	0.895			0.085	1.36	1.936	1.216	2.008	0.869	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.898	1.296	0.914				1.041	2.059	1.78	2.127	1.62	
COVID19 (COVID19 (JANSSEN))	Brain oedema	1.576	1.259	0.929				1.196	1.59	0.602	2.006	0.804	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.224	1.411	1.083				1.893	2.202	2.042	2.401	1.985	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.589	2.014	0.883				1.848	2.99	1.003	2.508	2.162	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.215	1.576	0.938			0.524	1.713	1.855	1.507	3.311	1.155	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.819	1.972	0.926			0.532	1.385	1.701	1.165	3.938	1.141	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.696	1.736	0.887				1.471	1.363	1.623	3.601	1.264	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.304	2.149	0.919			0.528	2.504	2.348	0.879	3.871	1.226	
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.873	1.282	0.961			0.331	1.341	1.895	1.905	2.11	1.609	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.444	1.656	0.954	0.518		0.699	2.144	2.313	2.036	3.053	1.727	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.994	1.333	0.918			0.378	1.724	1.967	1.835	2.273	1.519	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.001	1.395	0.927			0.458	1.388	2.047	2	2.244	1.675	
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	2.049	1.289	0.89				0.498	0.897	2.023	1.091	1.856	
COVID19 (COVID19 (JANSSEN))	Death	1.849	1.17	0.963				1.221	1.627	1.546	2.071	1.526	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.618	1.798	1.032			0.484	2.233	2.265	3.14	3.298	2.044	
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.067	1.375	1.139			0.366	1.423	2.097	1.099	2.117	1.843	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.791	1.303	0.93			0.04	1.244	2.042	1.755	2.068	1.353	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.803	1.361	0.94	0.516		0.271	1.27	2.063	1.776	2.071	1.412	
COVID19 (COVID19 (JANSSEN))	Fasting void	1.794	0.899	0.896			1.198	2.023	1.484	0.668	1.847	1.487	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.266	1.278	0.901			0.442	2.186	2.152	1.964	2.538	1.884	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.139	1.453	0.885	0.519		0.295	1.726	2.289	2.21	2.5	1.832	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.939	1.08	0.887			0.437	1.696	1.973	1.03	2.165	1.29	
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.089	1.438		0.756			0.654			1.411	1.727	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.224	1.032	0.897			0.405	2.274	17	1.216	2.24	1.589	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.845	1.259	0.907			0.401	1.293	1.723	1.585	2.237	1.2	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.71	1.155	0.91				1.215	1.425	1.341	2.211	1.038	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.483	1.843	0.894			0.438	1.637	3.135	1.637	2.431	2.209	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.892	1.271	0.942	0.512		0.581	1.314	2.036	1.783	2.175	1.425	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.761	1.239	0.937	0.513		0.393	1.384	1.967	1.674	2.092	1.417	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.709	3.612	0.901				4.186	5.521	4.283	7.268	3.37	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.144	3.303	0.884			0.554	4.212	5.727	6.739	7.055	2.479	
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.062	1.331	0.901				1.004	2.067	1.903	2.403	1.666	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.077	1.725	0.882			0.011	1.927	2.557	1.397	2.241	1.713	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.937	1.393	1.057			0.022	1.434	2.161	2.071	2.342	1.577	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.767	1.209	0.893	0.754		0.284	1.53	1.92	1.437	2.286	1.258	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.916	1.215	0.893				1.384	2.026	0.979	2.093	1.246	
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.624	1.752	0.911				0.84	1.403	0.993	1.708	1.597	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.831	1.448	0.888				1.573	1.125	0.711	2.344	0.712	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.882	1.362	0.878				1.28	2.198	1.011	1.671	1.762	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.149	1.705					1.122	2.841	1.028	1.777	1.822	
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.993	1.287	0.948				1.407	1.733	1.991	2.359	1.521	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.685	1.231	0.931			0.191	0.999	2.074	1.859	2.058	1.308	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.061	1.47	0.917			0.474	1.77	1.877	2.127	2.341	1.592	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.023	1.366	0.938	0.519		0.441	1.229	2.191	1.827	2.338	1.374	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.887	1.255	0.924			0.295	1.135	1.92	1.492	2.054	0.976	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.874	1.326	0.915			0.316	1.154	2.379	1.61	2.099	1.421	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.283	1.523	1.013			0.482	1.191	2.289	2	2.117	2.035	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.933	1.223	0.921	0.516		0.21	0.946	1.932	1.965	2.14	1.126	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.52	1.198	0.896			0.319	1.092	1.626	1.671	2.173	0.849	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.729	1.285	0.932			0.249	1.108	2.08	1.801	1.981	1.411	
COVID19 (COVID19 (JANSSEN))	Neutropenia	1.887	0.788					0.715	0.818		2.397	1.378	
COVID19 (COVID19 (JANSSEN))	Off label use	2.041	0.592	0.896			0.186	1.193	1.353	0.961	1.468	2.024	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.785	0.755					3.449	0.983		2.288		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.229	0.881				0.516	1.506	2.222	1.106	2.11	1.441	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.056	1.359	0.885				0.657	1.034	1.541	2.253	0.951	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.665	2.176	0.918	0.518		0.478	1.841	2.859	2.75	3.047	1.786	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.869	1.31	0.921	0.514		0.281	1.444	2.161	1.655	2.238	1.471	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.554	1.812	0.902			0.45	2.085	2.751	2.13	3.138	1.682	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.789	3.287	0.886				4.298	4.662	0.805	5.733	2.267	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.326					0.879	1.98	1.357	1.452	2.05	2.07	
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.075	1.427	0.887				0.859	1.647	1.027	2.027	1.268	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.08	1.297	0.955				1.013	2.101	1.677	2.253	1.621	
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.767	0.833	0.886		0.719	2.059	0.04	0.002	0.515	1.666	1.828	
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.176	1.306					5.046			5.15		
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.932	1.394	0.94	0.754		0.297	1.443	2.315	1.653	2.486	1.455	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.244	1.586	1.066	0.519		0.589	1.78	2.068	2.627	2.518	1.911	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.205	1.477	0.906				1.766	1.63	1.919	2.16	1.993	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.805	1.274	0.926	0.513		0.562	1.348	2.004	1.669	2.034	1.505	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.949	1.309	0.932	0.517		0.286	1.276	2.113	1.793	2.275	1.418	
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.368	1.003					2.702	0.506		1.08	1.75	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.585	1.737	0.893			0.537	1.774	1.988	1.822	2.574	1.817	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.464	2.229	1.588			0.527	3.219	3.334	1.219	2.913	3.46	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.547	6.757	0.886			0.653	3.621	6.584	14.798	7.71	5.715	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.674							0.637	0.569	0.561	1.026	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.968	1.335	0.896			0.512	1.438	1.515	1.477	2.098	1.343	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.259	1.753	0.952			0.368	1.618	2.433	1.907	2.512	1.811	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.961	2.122	1.743	0.519		0.729	1.992	2.404	3.622	2.973	2.377	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	5.975	2.903	0.902				2.145	5.476	0.562	5.586	1.822	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.051	1.526	0.886				1.784	1.231	0.623	2.133	0.879	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.302	1.444	0.913			0.716	1.915	2.224	2.172	2.695	1.745	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.708	1.838	0.961	0.519		0.528	2.472	2.295	2.872	3.308	2.112	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.378	1.84	0.92			0.43	2.189	2.01	2.021	2.484	1.826	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.998	1.085	0.909			0.491	1.065	2.093	2.202	2.391	2.519	
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.921	0.894					1.252	1.373	0.788	2.092	0.816	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.114	0.906	0.884				0.975	1.579	1.134	1.851	1.112	
COVID19 (COVID19 (JANSSEN))	Venogram	2.349	1.795	0.883				2.021	16	0.705	2.556	1.963	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.709	2.031				0.611	2.685	1.628	0.665	3.334	1.199	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.942	2.226	0.89				3.661	2.061	1.062	4.887	1.198	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.46	0.824		10.43	0.909		1.286	0.52		1.461	1.06	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.671	0.983	0.885	0.909	1.023	2.454	0.786	0.64	0.425	0.674	0.835	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.058	1.142				0.661	2.087	1.544	0.839	2.002	1.953	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.537	1.017	0.895	0.467	5.969	2.577	0.145	0.066	0.354	2.544	2.638	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.145	2.034	0.883			2.793	2.047	1.996	1.584	1.978	2.188	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.111	1.671	0.896			0.637	1.631	1.753	1.533	1.911	1.897	
COVID19 (COVID19 (PFIZER-	Body height	1.948	0.992	0.886		0.482	0.695	0.957	1.442	2.176	1.912	1.546	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.665	1.746	1.044	0.753	0.606	1.119	1.736	1.777	1.772	1.82	1.809	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.857	0.856	0.886	10.519			0.363			0.503	1.241	
COVID19 (COVID19 (PFIZER-	Immunisation	2.052	1.658	0.918		1.287	1.243	1.801	1.98	2.26	1.982	1.842	
COVID19 (COVID19 (PFIZER-	Investigation	2.032	1.75	0.926		0.718	1.086	1.795	1.924	2.239	1.983	1.892	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.601	0.785			1.457	1.389	1.847	1.711	2.139	1.585	1.558	
COVID19 (COVID19 (PFIZER-	Weight	1.942	1.367	0.898			0.943	1.558	1.742	2.097	1.901	1.759	

PSI-HHS-000000057522

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From: Menschik, David
Sent: Tue, 17 May 2022 10:17:58 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: Weekly data mining
Attachments: USST_20220513.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/13/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 202205	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 202209	Adult1 EB05 21220	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 20220513
COVID19 (COVID19 (JANSSEN))	Activated partial	2.062	1.54	0.852			3.382	1.504	1.865	2.049	2.761	1.372
COVID19 (COVID19 (JANSSEN))	Activated partial	2.064	1.534	0.883				1.59	2.027	1.975	2.714	1.406
COVID19 (COVID19 (JANSSEN))	Acute respiratory	2.085	1.333	0.998				0.79	1.676	1.832	1.61	1.922
COVID19 (COVID19 (JANSSEN))	Acute respiratory	2.092	1.322	1.014			3.455	1.42	2.033	1.96	2.421	1.739
COVID19 (COVID19 (JANSSEN))	Adverse drug	3.343	0.975	0.868			3.529	0.973	0.718	0.681	2.622	1.485
COVID19 (COVID19 (JANSSEN))	Adverse event	2.584	1.092	0.894				0.871	0.851	0.731	1.864	1.644
COVID19 (COVID19 (JANSSEN))	Albumin CSF	2.226	1.907					1.304	1.41		0.906	1.624
COVID19 (COVID19 (JANSSEN))	Angiogram	1.907	1.282	0.909				1.453	1.427	1.677	2.099	1.303
COVID19 (COVID19 (JANSSEN))	Angiogram	2.535	1.808	0.914			0.49	2.192	1.955	2.11	3.397	1.494
COVID19 (COVID19 (JANSSEN))	Angiogram	2.081	1.402	0.888				1.801	1.758	1.287	2.254	1.406
COVID19 (COVID19 (JANSSEN))	Angiogram	2.289	1.621	0.912			3.416	1.998	2.281	2.198	2.45	1.953
COVID19 (COVID19 (JANSSEN))	Anion gap	1.808	1.365	0.91			3.367	1.103	2.22	1.478	2.091	1.353
COVID19 (COVID19 (JANSSEN))	Antibody test	2.114	0.822	0.882			0.57	0.792	1.574	1.896	2.002	1.652
COVID19 (COVID19 (JANSSEN))	Anticoagulant	2.172	1.466	0.971	0.619		3.421	1.827	2.029	2.245	2.758	1.649
COVID19 (COVID19 (JANSSEN))	Application site	2.001						0.56	0.635	0.678	1.036	0.764
COVID19 (COVID19 (JANSSEN))	Areflexia	2.147	1.724	0.902				0.957	2.413	1.343	2.312	1.449
COVID19 (COVID19 (JANSSEN))	Arteriogram	1.845	1.164	0.889				1.213	1.231	1.417	2.232	0.883
COVID19 (COVID19 (JANSSEN))	Basophil count	1.873	1.383	0.928	0.616		3.361	1.172	2.28	1.806	2.319	1.328
COVID19 (COVID19 (JANSSEN))	Basophil	1.79	1.408	0.944	0.615		3.256	1.143	2.303	1.794	2.182	1.342
COVID19 (COVID19 (JANSSEN))	Blood albumin	1.81	1.263	0.929			3.307	1.447	1.844	1.751	2.16	1.39
COVID19 (COVID19 (JANSSEN))	Blood calcium	1.856	1.342	0.951			3.375	1.348	2.087	1.875	2.166	1.491
COVID19 (COVID19 (JANSSEN))	Blood chloride	1.812	1.302	0.953			3.469	1.214	2.022	1.86	2.139	1.346
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	2.814	2.199	0.897			3.503	1.748	2.173	0.885	4.053	1.039
COVID19 (COVID19 (JANSSEN))	Blood magnesium	1.806	1.303	0.928			0.17	1.977	1.961	1.766	2.304	1.214
COVID19 (COVID19 (JANSSEN))	Blood potassium	1.899	1.216	0.938			3.516	1.236	1.512	2.04	1.889	1.24
COVID19 (COVID19 (JANSSEN))	Blood sodium	1.823	1.306	0.904	0.616			1.33	2.015	1.736	1.958	1.587
COVID19 (COVID19 (JANSSEN))	Blood urea	1.888	1.251	0.913				1.922	2.048	1.773	2.128	1.602
COVID19 (COVID19 (JANSSEN))	Brain oedema	1.58	1.269	0.931				1.196	1.567	0.603	2.011	0.806
COVID19 (COVID19 (JANSSEN))	COVID-19	2.212	1.41	1.093				1.804	2.238	2.027	2.39	1.978
COVID19 (COVID19 (JANSSEN))	CSF protein	2.589	2.018	0.882				1.847	2.985	1.005	2.517	2.16
COVID19 (COVID19 (JANSSEN))	Cerebral	2.229	1.596	0.939			3.526	1.712	1.878	1.508	3.333	1.151
COVID19 (COVID19 (JANSSEN))	Cerebral mass	2.828	1.982	0.93			3.534	1.384	1.755	1.17	3.923	1.144
COVID19 (COVID19 (JANSSEN))	Cerebral	2.653	1.738	0.886				1.364	1.361	1.629	3.528	1.255
COVID19 (COVID19 (JANSSEN))	Cerebral venous	3.31	2.158	0.919			0.53	2.517	2.344	0.879	3.882	1.225
COVID19 (COVID19 (JANSSEN))	Chest X-ray	1.865	1.28	0.957			3.333	1.318	1.89	1.902	2.104	1.599
COVID19 (COVID19 (JANSSEN))	Computerised	2.436	1.655	0.966	0.618		3.614	2.145	2.295	2.033	3.031	1.729
COVID19 (COVID19 (JANSSEN))	Computerised	1.999	1.338	0.916			3.381	1.711	1.983	1.841	2.275	1.526
COVID19 (COVID19 (JANSSEN))	Computerised	2.001	1.395	0.926			3.483	1.376	2.045	2.009	2.248	1.673
COVID19 (COVID19 (JANSSEN))	Creatinine renal	2.032	1.267	0.89				0.497	0.895	1.995	1.089	1.646
COVID19 (COVID19 (JANSSEN))	Death	1.833	1.164	0.963				1.187	1.621	1.526	2.059	1.558
COVID19 (COVID19 (JANSSEN))	Deep vein	2.61	1.782	1.009			3.466	2.208	2.281	3.137	3.269	2.009
COVID19 (COVID19 (JANSSEN))	Endotracheal	2.056	1.37	1.147			3.367	1.416	2.095	1.874	2.103	1.832
COVID19 (COVID19 (JANSSEN))	Eosinophil count	1.771	1.288	0.927			0.04	1.232	2.054	1.696	2.057	1.325
COVID19 (COVID19 (JANSSEN))	Eosinophil	1.792	1.354	0.938	0.616		3.273	1.268	2.095	1.724	2.062	1.397
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.753	0.857	0.895			1.186	2.023	1.452	0.968	1.844	1.429
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.273	1.295	0.901			3.445	2.188	2.157	1.972	2.539	1.692
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.128	1.441	0.886	0.619		3.298	1.713	2.275	2.201	2.494	1.615
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	1.934	1.081	0.886			0.44	1.636	1.979	1.027	2.167	1.289
COVID19 (COVID19 (JANSSEN))	Foetal exposure	2.085	1.432		0.756			0.654			1.434	1.726
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.23	1.036	0.897			3.406	2.273	1.7	1.228	2.243	1.595
COVID19 (COVID19 (JANSSEN))	Globulins	1.83	1.252	0.908			3.402	1.263	1.699	1.606	2.228	1.184
COVID19 (COVID19 (JANSSEN))	Glucose urine	1.696	1.147	0.907				1.216	1.392	1.343	2.217	1.014
COVID19 (COVID19 (JANSSEN))	Guillain-Barre	2.473	1.842	0.894			0.44	1.637	3.13	1.836	2.432	2.192
COVID19 (COVID19 (JANSSEN))	Haematocrit	1.8	1.272	0.944	0.612		3.502	1.31	2.028	1.778	2.182	1.414
COVID19 (COVID19 (JANSSEN))	Haemoglobin	1.756	1.238	0.937	0.613		3.394	1.373	1.987	1.668	2.096	1.403
COVID19 (COVID19 (JANSSEN))	Heparin-induced	5.706	3.819	0.9				4.186	5.519	4.266	7.267	3.357
COVID19 (COVID19 (JANSSEN))	Heparin-induced	6.457	3.472	0.884			3.556	4.664	5.719	0.739	7.264	3.079
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.076	1.332	0.964				1.511	2.095	1.922	2.448	1.685
COVID19 (COVID19 (JANSSEN))	Immunoglobulin	2.069	1.719	0.877			3.011	1.912	2.545	1.397	2.24	1.704
COVID19 (COVID19 (JANSSEN))	Intensive care	1.937	1.396	1.071			3.022	1.425	2.105	2.071	2.331	1.581
COVID19 (COVID19 (JANSSEN))	International	1.776	1.22	0.894	0.754		3.387	1.523	1.927	1.434	2.318	1.259
COVID19 (COVID19 (JANSSEN))	International	1.897	1.198	0.889				1.384	2.032	0.919	2.051	1.248
COVID19 (COVID19 (JANSSEN))	Intracardiac	2.628	1.759	0.911				0.84	1.402	0.996	1.717	1.595
COVID19 (COVID19 (JANSSEN))	Jugular vein	1.83	1.45	0.869				1.373	1.124	0.711	2.343	0.712
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.875	1.36	0.877				1.264	2.195	1.012	1.674	1.749
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	2.147	1.706					1.125	2.834	1.023	1.781	1.816
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.976	1.281	0.945				1.377	1.72	1.977	2.318	1.52
COVID19 (COVID19 (JANSSEN))	Lymphocyte	1.681	1.23	0.93			3.188	0.998	2.05	1.839	2.058	1.3
COVID19 (COVID19 (JANSSEN))	Lymphocyte	1.414	1.097	0.91	0.614		3.249	1.009	1.421	1.315	2.006	0.851
COVID19 (COVID19 (JANSSEN))	Magnetic	2.056	1.468	0.914			3.475	1.784	1.865	2.132	2.329	1.592
COVID19 (COVID19 (JANSSEN))	Mean cell	2.043	1.383	0.942	0.619		3.446	1.243	2.197	1.851	2.355	1.394
COVID19 (COVID19 (JANSSEN))	Mean cell	1.701	1.258	0.925			3.263	1.117	1.939	1.496	2.04	0.991
COVID19 (COVID19 (JANSSEN))	Mean platelet	1.866	1.318	0.917			3.319	1.16	2.315	1.576	2.107	1.394
COVID19 (COVID19 (JANSSEN))	Mechanical	2.269	1.515	1.019			3.483	1.161	2.278	1.978	2.113	2.015
COVID19 (COVID19 (JANSSEN))	Monocyte	1.521	1.214	0.918	0.616		3.212	0.845	1.915	1.958	2.173	1.105
COVID19 (COVID19 (JANSSEN))	Neutrophil	1.533	1.208	0.898			3.323	1.097	1.645	1.678	2.191	0.856
COVID19 (COVID19 (JANSSEN))	Neutrophil	1.722	1.262	0.929			0.25	1.101	2.088	1.775	1.981	1.4
COVID19 (COVID19 (JANSSEN))	Nonspecific	4.061	0.767					0.744	0.612		2.961	1.076
COVID19 (COVID19 (JANSSEN))	Off label use	2.029	0.599	0.895			3.141	1.195	1.339	0.932	1.473	1.976
COVID19 (COVID19 (JANSSEN))	On and off	1.784	0.755					3.446	0.982		2.288	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.227	0.867				3.518	1.506	2.219	1.104	2.169	1.446
COVID19 (COVID19 (JANSSEN))	Peripheral	3.087	1.362	0.884				0.656	1.034	1.54	2.246	0.951
COVID19 (COVID19 (JANSSEN))	Platelet count	2.66	2.187	0.918	0.618		0.48	1.84	2.864	2.725	3.025	1.802
COVID19 (COVID19 (JANSSEN))	Platelet count	1.872	1.317	0.922	0.614		3.239	1.446	2.105	1.867	2.241	1.472
COVID19 (COVID19 (JANSSEN))	Platelet count	2.562	1.82	0.901			3.451	2.095	2.757	2.134	3.151	1.686
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.782	3.298	0.885				4.298	4.645	0.805	5.733	2.351
COVID19 (COVID19 (JANSSEN))	Poor quality	1.3					0.88	1.957	1.308	1.429	1.993	1.022
COVID19 (COVID19 (JANSSEN))	Portal vein	2.072	1.425	0.886				0.859	1.645	1.026	2.024	1.258
COVID19 (COVID19 (JANSSEN))	Positive airway	2.045	1.292	0.953				1.014	2.083	1.664	2.225	1.613
COVID19 (COVID19 (JANSSEN))	Product	1.772	0.832	0.885		0.72	2.063	0.041	0.002	0.514	1.671	1.832
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.177	1.345					5.05			5.149	
COVID19 (COVID19 (JANSSEN))	Prothrombin time	1.925	1.39	0.941	0.734		3.299	1.447	2.283	1.657	2.448	1.454
COVID19 (COVID19 (JANSSEN))	Pulmonary	2.237	1.584	1.105	0.619		0.59	1.773	2.088	2.618	2.512	1.902
COVID19 (COVID19 (JANSSEN))	Pulmonary	2.286	1.482	0.909				1.726	1.631	1.913	2.161	1.878
COVID19 (COVID19 (JANSSEN))	Red blood cell	1.806	1.276	0.932	0.614		3.564	1.136	2.024	1.67	2.038	1.501
COVID19 (COVID19 (JANSSEN))	Red cell	1.959	1.316	0.935	0.617		3.286	1.303	2.118	1.789	2.285	1.425
COVID19 (COVID19 (JANSSEN))	Russell's viper	1.368	1.004					2.691	0.505		1.08	0.73
COVID19 (COVID19 (JANSSEN))	Superficial vein	2.558	1.646	0.899			3.539	1.774	1.966	1.662	2.577	1.707
COVID19 (COVID19 (JANSSEN))	Suspected COVID-	3.5	2.225	1.59			3.528	3.25	3.31	1.236	2.926	3.457
COVID19 (COVID19 (JANSSEN))	Therapy non-	6.552	0.756	0.885			3.654	3.621	6.582	14.788	7.735	5.71
COVID19 (COVID19 (JANSSEN))	Therapy partial	2.667							0.637	0.569	0.561	1.026
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.966	1.347	0.895			3.514	1.438	1.526	1.478	2.1	1.35
COVID19 (COVID19 (JANSSEN))	Thrombocytopeni	2.301	1.761	0.955			3.369	1.609	2.437	1.919	2.523	1.809
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.892	2.117	1.75	0.619		3.729	1.986	2.45	3.591	2.961	2.374
COVID19 (COVID19 (JANSSEN))	Thrombosis with	6.02	2.943	0.902				2.137	5.422	0.566	5.579	1.94
COVID19 (COVID19 (JANSSEN))	Transverse sinus	2.09	1.527	0.885				1.782	1.23	0.623	2.132	0.879
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.349	1.425	0.914			3.717	1.902	2.211	2.154	2.675	1.736
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.7	1.833	0.963	0.619		0.53	2.449	2.284	2.883	3.303	2.1
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.367	1.629	0.922			3.431	2.159	2.009	2.009	2.474	1.812
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.643	3.079	2.498			3.493	1.574	2.925	5.47	2.356	2.533
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.925	0.894					1.26	1.373	0.787	2.101	0.815
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.113	0.906	0.883				0.975	1.579	1.133	1.851	1.112
COVID19 (COVID19 (JANSSEN))	Venogram	2.331	1.74	0.882				1.99	1.598	0.705	2.491	1.059
COVID19 (COVID19 (JANSSEN))	Venogram	2.706	2.035				3.612	2.68	1.628	0.665	3.331	1.199
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.984	2.258	0.889				3.73	2.049	1.062	4.97	1.198
COVID19 (COVID19 (MODERNA))	Exposure via	1.46	0.823		10.37	0.91		1.286	0.52		1.466	1.051
COVID19 (COVID19 (MODERNA))	Interchange of	0.666	0.956	0.885	0.609	1.023	2.465	0.785	0.635	0.423	0.671	0.633
COVID19 (COVID19 (MODERNA))	Mechanical	2.056	1.138				3.671	2.085	1.533	0.839	2.002	1.566
COVID19 (COVID19 (MODERNA))	Product	2.533	1.016	0.894	0.466	6.063	2.971	0.132	0.061	0.354	2.541	2.633
COVID19 (COVID19 (MODERNA))	Product dose	2.145	2.04	0.882			2.804	2.046	2	1.585	1.98	2.188
COVID19 (COVID19 (MODERNA))	Vaccination	2.106	1.671	0.899			3.837	1.631	1.784	1.532	1.912	1.897
COVID19 (COVID19 (PFIZER-BIONTECH))	Body height	1.946	0.992	0.889		0.482	3.696	0.957	1.437	2.175	1.915	1.546
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.069	1.754	1.685	0.753	0.844	1.117	1.724	1.755	1.779	1.824	1.859
COVID19 (COVID19 (PFIZER-BIONTECH))	Exposure via	0.859	0.859	0.868	16.498			0.963			0.908	1.238
COVID19 (COVID19 (PFIZER-BIONTECH))	Immunisation	2.05	1.657	0.918		1.287	1.243	1.801	1.98	2.259	1.979	1.842
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.031	1.749	0.93		0.716	1.086	1.793	1.928	2.239	1.984	1.892
COVID19 (COVID19 (PFIZER-BIONTECH))	Product	1.604	0.784			1.455	1.371	1.847	1.714	2.148	1.586	1.561
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	1.939	1.351	0.898			3.943	1.558	1.745	2.106	1.906	1.763

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From: Menschik, David
Sent: Tue, 10 May 2022 09:45:59 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220506.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/6/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20220408	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.066	1.546	0.932			0.381	1.506	1.86	2.065	2.755	1.374	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.092	1.562	0.881				1.609	2.096	2	2.763	1.428	Reviewed
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.081	1.34	0.991				0.79	1.662	1.807	1.618	1.906	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.09	1.323	1.017			0.456	1.43	2.023	1.979	2.445	1.72	Reviewed
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.336	0.98	0.884			0.529	1.015	0.717	0.68	2.622	1.515	Other
COVID19 (COVID19 (JANSSEN))	Adverse event	2.557	1.095	0.86				0.871	0.882	0.73	1.878	1.609	Other
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.304	1.965					1.303	1.444		0.907	1.671	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.978	1.293	0.907				1.456	1.44	1.681	2.104	1.313	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.537	1.811	0.912			0.489	2.19	1.965	2.118	3.41	1.493	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.175	1.428	0.885				1.844	1.787	1.291	2.265	1.446	Not an AE
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.304	1.635	0.912			0.415	1.907	2.284	2.216	2.471	1.962	Reviewed
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.809	1.368	0.91			0.366	1.103	2.229	1.469	2.083	1.358	Other
COVID19 (COVID19 (JANSSEN))	Antibody test	2.109	0.823	0.877			0.57	0.795	1.58	1.892	1.987	1.66	Not an AE
COVID19 (COVID19 (JANSSEN))	Antiepileptic therapy	2.37	1.371	0.971		0.618	0.483	1.41	2.041	2.217	2.783	1.881	Other
COVID19 (COVID19 (JANSSEN))	Areflexia	2.137	1.719	0.9				0.905	2.462	1.344	2.258	1.458	Reviewed
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.879	1.166	0.885				1.303	1.231	1.427	2.244	1.024	Reviewed
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.872	1.392	0.923	0.616		0.381	1.175	2.334	1.781	2.383	1.307	Other
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.788	1.41	0.936	0.615		0.258	1.148	2.325	1.756	2.195	1.328	Other
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.812	1.266	0.928			0.309	1.435	1.862	1.746	2.168	1.386	Other
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.864	1.349	0.948			0.375	1.349	2.109	1.868	2.3	1.491	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.823	1.309	0.957			0.469	1.227	2.039	1.865	2.148	1.357	Other
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.809	2.197	0.894			0.503	1.747	2.171	0.885	4.054	1.039	Reviewed
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.81	1.312	0.926			0.173	1.08	1.972	1.171	2.417	1.202	Other
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.663	1.214	0.938			0.517	1.21	1.52	2.027	1.881	1.235	Other
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.827	1.31	0.903	0.616			1.33	2.02	1.74	1.941	1.604	Not an AE
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.891	1.257	0.909				1.029	2.065	1.764	2.134	1.605	Other
COVID19 (COVID19 (JANSSEN))	Brain oedema	1.998	1.246	0.926				1.196	1.955	0.892	2.011	1.77	Other
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.264	1.409	1.092				1.807	2.221	2.082	2.392	1.962	Other
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.571	2.007	0.878				1.782	2.982	1.01	2.459	2.158	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.218	1.583	0.935			0.626	1.711	1.889	1.471	3.348	1.196	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.02	1.98	0.925			0.533	1.384	1.776	1.17	3.922	1.144	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.656	1.741	0.882				1.364	1.365	1.626	3.541	1.265	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.392	2.167	0.917			0.529	2.48	2.352	0.876	3.883	1.225	Reviewed
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.867	1.28	0.956			0.333	1.333	1.897	1.891	2.108	1.597	Confounded-
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.441	1.657	0.908	0.618		0.613	2.144	2.296	2.041	3.038	1.73	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.005	1.344	0.916			0.383	1.714	1.962	1.843	2.274	1.537	Not an AE
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.017	1.407	0.928			0.483	1.386	2.062	2.028	2.268	1.686	Reviewed
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	2.022	1.287	0.886				0.497	0.896	1.968	1.088	1.635	
COVID19 (COVID19 (JANSSEN))	Death	1.832	1.165	0.962				1.189	1.628	1.526	2.053	1.51	Reviewed
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.861	1.784	1.024			0.485	2.194	2.28	3.097	3.287	2.022	Reviewed
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.093	1.38	1.144			0.388	1.415	2.107	1.876	2.118	1.834	Labeled
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.773	1.292	0.92			0.041	1.238	2.086	1.665	2.086	1.305	Other
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.786	1.362	0.933	0.616		0.275	1.276	2.116	1.706	2.073	1.395	Other
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.752	0.856	0.892			0.188	2.017	1.451	0.97	1.845	1.425	Labeled
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.237	1.294	0.897			0.446	2.193	2.161	1.974	2.544	1.895	Other
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.139	1.447	0.881	0.618		0.386	1.716	2.29	2.191	2.493	1.817	Reviewed
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.968	1.082	0.882			0.439	1.656	2.041	1.029	2.193	1.328	Not an AE
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.088	1.412		0.756			0.654			1.431	1.732	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.227	1.043	0.894			0.496	2.252	17	1.238	2.251	1.587	Labeled
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.816	1.242	0.904			0.481	1.231	1.761	1.589	2.181	1.193	Reviewed
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.768	1.154	0.906				1.216	1.362	1.364	2.231	1.019	Other
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.462	1.838	0.89			0.44	1.839	3.167	1.646	2.438	2.167	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemstocrit decreased	1.804	1.276	0.941	0.612		0.503	1.308	2.04	1.778	2.188	1.416	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.789	1.241	0.934	0.613		0.396	1.372	1.977	1.665	2.1	1.404	Reviewed
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.727	3.828	0.896				4.194	5.517	4.497	7.267	3.394	Not an AE
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.456	3.469	0.88			0.555	4.665	5.717	6.739	7.267	3.053	Reviewed
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.056	1.322	0.958				1.511	2.085	1.891	2.434	1.66	Reviewed
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.088	1.72	0.873			0.611	1.885	2.549	1.405	2.248	1.696	Reviewed
COVID19 (COVID19 (JANSSEN))	Intensive care	1.939	1.4	1.07			0.482	1.428	2.11	2.066	2.334	1.501	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.78	1.225	0.89	0.754		0.388	1.549	1.943	1.432	2.317	1.279	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.901	1.209	0.885				1.385	2.032	0.918	2.051	1.251	Not an AE
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.638	1.767	0.906				0.84	1.408	0.906	1.734	1.594	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.831	1.452	0.884				1.387	1.125	0.708	2.353	0.711	Reviewed
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.873	1.36	0.873				1.265	2.188	1.018	1.681	1.738	Not an AE
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.148	1.707					1.128	2.83	1.023	1.785	1.814	Reviewed
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.985	1.29	0.945				1.384	1.741	1.972	2.327	1.529	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.681	1.234	0.924			0.19	1.002	2.094	1.824	2.061	1.294	Other
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.065	1.477	0.912			0.477	1.768	1.877	2.129	2.323	1.812	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.071	1.409	0.946	0.619		0.445	1.26	2.212	1.885	2.381	1.407	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.713	1.268	0.926			0.268	1.123	1.945	1.511	2.053	0.997	Other
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.67	1.325	0.912			0.319	1.164	2.343	1.555	2.118	1.391	Other
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.262	1.529	1.027			0.483	1.164	2.251	1.993	2.124	2.026	Reviewed
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.528	1.22	0.917	0.616		0.213	0.839	1.955	1.98	2.187	1.109	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.519	1.204	0.893			0.324	1.083	1.658	1.659	2.194	0.846	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.725	1.266	0.924			0.232	1.105	2.104	1.763	1.969	1.396	Other
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	4.048	6.786					0.744	0.612		2.953	1.075	Other
COVID19 (COVID19 (JANSSEN))	Off label use	2.021	0.602	0.892			8.105	1.182	1.305	0.932	1.461	1.952	Not an AE
COVID19 (COVID19 (JANSSEN))	Oral administration	1.785	0.794					0.448	0.963		2.289		Other
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.228	0.866				0.517	1.506	2.218	1.107	2.173	1.445	Not an AE
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.17	1.394	0.88				0.656	1.034	1.593	2.382	1.95	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count	2.671	1.166	0.92	0.618		0.479	1.768	2.901	2.696	3.029	1.825	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.867	1.315	0.918	0.614		0.281	1.424	2.11	1.654	2.242	1.462	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.568	1.836	0.898			0.451	2.095	2.761	2.147	3.161	1.889	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.784	3.291	0.881				4.298	4.639	6.804	5.738	2.253	Not an AE
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.065	1.475	0.882				0.859	1.662	1.026	2.021	1.275	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.035	1.29	0.953				1.014	2.074	1.655	2.217	1.804	Other
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.773	0.831	0.881		0.719	2.081	0.041	0.062	0.516	1.672	1.83	Not an AE
COVID19 (COVID19 (JANSSEN))	Prolonged labour	4.623	1.15					4.623			4.483		Other
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.93	1.405	0.94	0.754		0.299	1.431	2.369	1.654	2.443	1.46	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.228	1.579	1.094	0.619		0.59	1.766	2.06	2.615	2.491	1.895	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.28	1.472	0.906				1.734	1.611	1.913	2.162	1.894	Reviewed
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.807	1.28	0.927	0.614		0.566	1.357	2.038	1.665	2.045	1.501	Other
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.957	1.315	0.929	0.617		0.29	1.304	2.137	1.768	2.292	1.411	Other
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.367	1.004					2.681	0.505		1.081	3.73	Reviewed
COVID19 (COVID19 (JANSSEN))	Sensory disturbance	2.007	1.317	0.886				1.43	1.852	1.408	1.838	1.796	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.528	1.595	0.888			0.542	1.781	1.962	1.656	2.4	1.73	Other
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.491	2.221	1.581			0.528	3.213	3.177	1.251	2.911	3.457	Other
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.559	6.758	0.881			0.654	3.618	6.59	15.05	7.734	5.73	Other
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.638							0.636	0.568	0.561	1.025	Other
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.961	1.334	0.892			0.513	1.388	1.525	1.49	2.067	1.351	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.284	1.746	0.947			0.371	1.582	2.467	1.844	2.522	1.779	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.879	2.114	1.747	0.619		0.729	1.981	2.488	3.568	2.945	2.37	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	5.857	3.937	0.899				2.136	3.791	9.565	5.582	1.459	Reviewed
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.148	1.601	0.881				1.912	1.23	0.623	2.157	0.892	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.356	1.427	0.912			0.717	1.905	2.222	2.162	2.674	1.749	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.697	1.826	0.952	0.619		0.532	2.468	2.285	2.83	3.328	2.081	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.37	1.628	0.921			0.431	2.102	2.023	1.906	2.474	1.819	Not an AE
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.64	3.081	2.507			0.493	1.569	2.942		5.633	2.364	Other
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.923	6.893					1.26	1.373	0.787	2.1	0.815	Other
COVID19 (COVID19 (JANSSEN))	Vasodilation	2.112	1.998	0.873				0.979	1.078	1.139	1.881	1.111	Labeled
COVID19 (COVID19 (JANSSEN))	Venogram	2.349	1.769	0.878				1.99	1.61	0.708	2.534	1.069	Not an AE
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.625	2.034				0.612	2.481	1.628	0.665	3.171	1.199	Reviewed
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.065	2.238	0.885				3.73	2.003	1.06	4.914	1.198	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.461	0.822		10.405	0.91		1.286	0.519		1.461	1.861	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.667	0.953	0.88	0.509	1.021	2.461	0.784	0.634	0.421	0.668	0.632	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.093	1.137				0.67	2.079	1.564	0.838	2.091	1.943	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.541	1.02	0.891	0.373	6.15	2.574	0.129	0.057	0.363	2.548	2.644	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.144	2.038	0.878			2.786	2.045	1.998	1.584	1.98	2.186	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.164	1.667	0.892			0.836	1.631	1.792	1.536	1.915	1.889	
COVID19 (COVID19 (PFIZER-	Body height	1.948	6.984	0.886		0.481	0.896	0.957	1.438	2.179	1.913	1.547	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.077	1.758	1.71	0.618	0.845	1.117	1.714	1.747	1.766	1.827	1.862	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.893	0.855	0.864	16.436			0.363			0.507	1.234	
COVID19 (COVID19 (PFIZER-	Immunisation	2.049	1.66	0.916		1.265	1.243	1.502	1.961	2.263	1.978	1.842	
COVID19 (COVID19 (PFIZER-	Investigation	2.031	1.745	0.926		0.716	1.085	1.793	1.931	2.243	1.983	1.892	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.61	6.783			1.462	1.373	1.845	1.722	2.152	1.592	1.565	
COVID19 (COVID19 (PFIZER-	Weight	1.94	1.346	0.896			0.943	1.558	1.745	2.109	1.908	1.764	

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From: Menschik, David
Sent: Tue, 3 May 2022 10:23:36 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220429.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/29/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.066	1.551	0.936			0.581	1.518	1.809	2.059	2.736	1.378	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.108	1.558	0.875				1.597	2.047	2.012	2.791	1.414	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.059	1.322	1.019			0.456	1.44	2.028	1.956	2.433	1.711	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.849	6.958	0.88			0.528	0.968	0.717	0.68	2.583	1.514	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.092	0.887				0.87	0.885	0.729	1.875	1.805	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.899	1.293	0.906				1.457	1.439	1.683	2.102	1.314	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.459	1.812	0.908			0.489	2.119	1.98	2.127	3.479	1.471	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.129	1.411	0.881				1.844	1.753	1.293	2.281	1.405	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.417	1.638	0.907			0.418	1.594	2.296	2.209	2.481	1.964	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.78	1.363	0.906			0.366	1.107	2.157	1.482	2.091	1.339	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.311	6.821	0.873			0.589	0.786	1.076	1.889	1.961	1.001	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.21	1.475	0.983	0.619		0.425	1.812	2.022	2.261	2.748	1.853	Other
COVID19 (COVID19 (JANSEN))	Anefloxia	2.036	1.717	0.894				0.91	2.462	1.279	2.191	1.434	Reviewed
COVID19 (COVID19 (JANSEN))	Aneurysm cerebral abnormal	1.719	1.138	0.879				1.119	1.458	1.469	2.201	0.984	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.854	1.388	0.913	0.516		0.365	1.15	2.338	1.778	2.362	1.3	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.79	1.405	0.933	0.515		0.261	1.129	2.31	1.777	2.198	1.313	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.765	1.263	0.921			0.31	1.408	1.882	1.769	2.157	1.383	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.868	1.349	0.945			0.378	1.342	2.11	1.88	2.218	1.48	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.836	1.246	0.92				1.057	2.067	1.583	1.948	1.541	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.809	1.31	0.956			0.47	1.199	2.051	1.889	2.143	1.364	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.91	2.181	0.892			0.583	1.747	1.935	0.899	3.977	1.943	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.813	1.299	0.925			0.187	1.063	1.948	1.766	2.407	1.178	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.669	1.212	0.933			0.519	1.191	1.512	2.048	1.871	1.227	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.817	1.313	0.908	0.516			1.327	2.026	1.741	1.935	1.607	Not an AE
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.859	1.253	0.909				1.015	2.057	1.762	2.11	1.609	Other
COVID19 (COVID19 (JANSEN))	Brain oedema	1.523	1.249	0.925				1.197	1.563	0.602	2.025	1.77	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.067	1.412	1.096				1.626	2.22	2.014	2.386	1.904	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.607	2.003	0.875				1.733	3.014	1.01	2.404	2.157	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.317	1.581	0.936			0.525	1.711	1.887	1.473	3.341	1.137	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	3.047	1.976	0.928			0.633	1.384	1.713	1.169	3.912	1.143	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.402	1.725	0.879				1.364	1.324	1.622	3.554	1.227	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.219	2.165	0.915			0.529	2.496	2.398	0.879	3.907	1.225	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.769	1.277	0.952			0.336	1.31	1.895	1.888	2.093	1.597	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.52	1.855	0.964	0.518		0.613	2.121	2.362	2.035	3.044	1.722	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.988	1.345	0.913			0.383	1.691	1.996	1.846	2.261	1.534	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.05	1.411	0.926			0.462	1.383	2.045	2.052	2.261	1.687	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.893	1.167	0.963				1.18	1.625	1.522	2.054	1.509	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.581	1.779	1.004			0.465	2.202	2.277	3.066	3.28	2.021	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.913	1.384	1.16			0.368	1.385	2.122	1.879	2.121	1.831	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.763	1.293	0.913			0.042	1.203	2.125	1.663	2.087	1.297	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.78	1.362	0.93	0.516		0.277	1.254	2.123	1.729	2.082	1.385	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.763	6.859	0.889			1.189	2.014	1.463	0.971	1.843	1.426	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.269	1.290	0.896			0.446	2.196	2.172	1.967	2.51	1.712	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.166	1.455	0.957	0.519		1.3	1.716	2.296	2.199	2.488	1.828	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.911	1.083	0.878			0.439	1.656	2.038	1.03	2.186	1.33	Not an AE
COVID19 (COVID19 (JANSEN))	Gastroenteritis	2.262	1.882	0.882			0.488	2.232	1.718	1.241	2.284	1.899	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.834	1.237	0.897			0.402	1.209	1.763	1.585	2.151	1.193	Reviewed
COVID19 (COVID19 (JANSEN))	Glomular filtration rate decreased	1.766	1.139	0.935				1.006	1.968	1.547	2.002	1.356	Other
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.693	1.175	0.907				1.216	1.416	1.393	2.281	1.039	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.336	1.836	0.887			0.44	1.639	3.102	1.649	2.438	2.166	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.81	1.276	0.94	0.512		0.504	1.299	2.045	1.782	2.188	1.416	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.75	1.238	0.93	0.513		0.396	1.363	1.974	1.663	2.091	1.401	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.508	3.636	0.896				4.184	5.513	4.677	7.312	3.389	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.159	3.459	0.876			0.555	4.665	5.709	0.739	7.261	3.05	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.912	1.323	0.964				1.485	2.067	1.889	2.44	1.849	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.08	1.721	0.87			0.011	1.89	2.546	1.405	2.254	1.889	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.832	1.394	1.073			0.022	1.424	2.1	2.057	2.336	1.559	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.823	1.222	0.884	0.754		0.388	1.529	1.926	1.447	2.308	1.276	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.021	1.205	0.901				1.369	2.63	0.913	2.052	1.23	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.948	1.474	0.88				1.402	1.124	0.708	2.401	0.711	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.909	1.358	0.866				1.268	2.183	1.019	1.672	1.743	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.061	1.457					1.095	2.759	1.018	1.751	1.78	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.732	1.261	0.946				1.356	1.736	1.952	2.301	1.518	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.676	1.236	0.921			0.193	0.995	2.093	1.846	2.074	1.291	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.337	1.093	0.900	0.514		0.267	0.986	1.448	1.285	1	0.652	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.065	1.481	0.911			0.477	1.778	1.876	2.147	2.343	1.806	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.063	1.417	0.948	0.519		0.445	1.249	2.241	1.884	2.382	1.422	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.678	1.269	0.924			0.289	1.113	1.962	1.521	2.054	0.992	Other
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.888	1.333	0.912			0.321	1.17	2.342	1.569	2.129	1.392	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.127	1.528	1.031			0.483	1.097	2.299	2.004	2.141	2.005	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.53	1.218	0.914	0.516		0.218	0.845	1.913	1.988	2.205	1.094	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.484	1.203	0.89			0.325	1.085	1.843	1.677	2.205	0.836	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.72	1.267	0.92			0.255	1.094	2.1	1.785	1.999	1.391	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.39	6.786					0.745	0.612		2.945	1.075	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.313	6.622	0.866			0.651	1.106	1.211	0.907	1.472	1.833	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.781	6.754					3.443	0.983		2.288		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.52	6.87				0.517	1.512	2.222	1.12	2.183	1.45	Not an AE
COVID19 (COVID19 (JANSEN))	Paralysis of excitation	3.21	3.389	0.876				2.838	1.639	1.281	3.381	3.88	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.805	2.2	0.918	0.518		0.479	1.764	2.963	2.734	3.048	1.838	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.871	1.314	0.916	0.514		0.262	1.428	2.105	1.647	2.238	1.461	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.74	1.843	0.898			0.45	2.095	2.767	2.186	3.194	1.684	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.015	3.279	0.877				4.299	4.624	0.802	5.723	2.245	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.765	1.283	0.956				1.021	2.022	1.669	2.232	1.568	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.617	6.832	0.877		0.719	2.058	0.043	0.062	0.517	1.671	1.831	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.101	1.048					4.097			2.711		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.926	1.408	0.937	0.754		0.381	1.426	2.311	1.671	2.459	1.46	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.239	1.581	1.115	0.519		0.589	1.762	2.047	2.635	2.498	1.9	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.062	1.467	0.906				1.739	1.574	1.926	2.17	1.842	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.813	1.278	0.924	0.513		0.567	1.343	2.039	1.672	2.04	1.501	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.962	1.322	0.925	0.517		0.291	1.27	2.169	1.776	2.291	1.418	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.307	1.094					2.076	0.565		1.081	3.73	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.37	1.634	0.882			0.542	1.781	1.961	1.649	2.611	1.729	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.228	2.214	1.572			0.528	3.265	3.229	1.265	2.944	3.499	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.618	6.758	0.877			0.854	3.619	6.586	16.036	7.73	5.721	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.627							0.636	0.568	0.861	1.025	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.051	1.357	0.886			0.516	1.403	1.539	1.499	2.096	1.364	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.335	1.743	0.952			0.371	1.583	2.44	1.854	2.503	1.776	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.697	2.107	1.749	0.519		0.729	1.98	2.449	3.561	2.948	2.362	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	5.144	2.926	0.896				2.134	3.666	0.565	5.574	1.453	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.272	1.621	0.876				1.944	1.23	0.622	2.181	0.892	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.362	1.417	0.912			0.717	1.893	2.214	2.175	2.883	1.743	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.659	1.823	0.954	0.519		0.532	2.445	2.271	2.841	3.31	2.078	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.434	1.626	0.922			0.433	2.125	2.028	1.961	2.454	1.813	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.867	1.08	0.876				1.205	2	1.65	1.833	1.324	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.362	3.083	2.483			0.499	1.591	3.016	5.786	2.398	2.561	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.664	6.895					1.26	1.371	0.791	2.098	0.918	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.665	6.906	0.873				0.976	1.576	1.127	1.844	1.111	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.297	1.786	0.874				2.003	1.62	0.708	2.548	1.075	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.655	2.031				0.612	2.479	1.627	0.664	3.168	1.199	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.999	2.294	0.881				3.729	2.062	1.06	4.917	1.196	Not an AE
COVID19 (MODERNA))	Exposure via breast milk	1.37	6.822		10.532	0.911		1.286	0.519		1.487	1.062	
COVID19 (MODERNA))	Interchange of vaccine products	0.589	6.953	0.876	0.509	1.019	2.461	0.783	0.633	0.42	0.669	0.631	
COVID19 (MODERNA))	Mechanical urticaria	0.869	1.138				0.605	2.075	1.544	0.84	1.094	1.936	
COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.367	6.978	0.888	0.135	6.177	2.671	0.112	0.043	0.363	2.548	2.846	
COVID19 (MODERNA))	Product dose omission issue	2.048	2.038	0.874			2.785	2.048	1.999	1.586	1.981	2.188	
COVID19 (MODERNA))	Vaccination complication	2.003	1.668	0.886			0.636	1.515	1.799	1.535	1.911	1.899	
COVID19 (PFIZER-	Body weight	1.945	6.984	0.881		0.481	0.895	0.957	1.402	2.173	1.912	1.546	
COVID19 (PFIZER-	Disease recurrence	2.046	1.101	0.877		0.481	0.744	1.469	1.689	1.878	1.921	1.512	
COVID19 (PFIZER-	Drug ineffective	2.301	1.756	1.707	0.518	0.842	1.115	1.708	1.717	1.745	1.831	1.854	
COVID19 (PFIZER-	Exposure via breast milk	0.753	6.855	0.88	16.407			0.363			0.507	1.234	
COVID19 (PFIZER-	Immunisation	1.747	1.657	0.915		1.285	1.242	1.802	1.979	2.255	1.978	1.84	
COVID19 (PFIZER-	Investigation	2.168	1.746	0.929		0.715	1.085	1.792	1.929	2.233	1.983	1.89	
COVID19 (PFIZER-	Product preparation issue	1.752	6.783			1.46	1.374	1.649	1.723	2.157	1.598	1.566	
COVID19 (PFIZER-	Weight	2.025	1.347	0.892			0.943	1.559	1.743	2.103	1.907	1.762	

PSI-HHS-000000057528

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From: Menschik, David
Sent: Tue, 26 Apr 2022 10:36:35 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220422.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/22/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 2022Q4	Serious EB05 2022	Fatal EB05 2022Q	Infant EB05 2022Q	Child EB05 2022Q	Teen EB05 2022Q	Adult EB05 2022Q	Adult2 EB05 2022Q	Adult3 EB05 2022Q	Female EB05 2022Q	Male EB05 2022Q	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.009	1.561	0.932			0.384	1.534	1.858	2.026	2.701	1.393	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.115	1.586	0.874				1.605	2.055	2.003	2.793	1.421	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.049	1.321	1.018			0.455	1.444	2.005	1.944	2.397	1.708	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.851	6.958	0.878			0.528	0.97	0.776	0.679	2.595	1.514	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.091	0.885				1.875	0.851	0.727	1.874	1.586	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.905	1.297	0.904				1.485	1.437	1.682	2.113	1.313	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.481	1.823	0.907			0.488	2.14	2.067	2.081	3.487	1.485	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.136	1.425	0.88				1.855	1.754	1.299	2.303	1.405	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.43	1.653	0.908			0.421	1.596	2.314	2.215	2.468	1.979	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.789	1.376	0.91			0.388	1.112	2.207	1.499	2.116	1.344	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.315	6.835	0.871			0.589	0.782	1.063	1.887	1.992	1.072	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.216	1.475	0.978	0.519		0.427	1.813	2.025	2.235	2.738	1.853	Other
COVID19 (COVID19 (JANSEN))	Areflexia	2.056	1.707	0.888				0.859	2.512	1.281	2.148	1.441	Reviewed
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.79	1.17	0.877				1.116	1.288	1.366	2.116	0.963	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.864	1.402	0.907	0.516		0.366	1.172	2.341	1.78	2.353	1.323	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.79	1.41	0.929	0.515		0.284	1.146	2.3	1.778	2.185	1.326	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.703	1.268	0.929			0.312	1.394	1.867	1.768	2.158	1.389	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.875	1.354	0.944			0.379	1.343	2.103	1.901	2.224	1.483	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.852	1.26	0.921				1.089	2.022	1.584	1.982	1.554	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.812	1.311	0.953			0.473	1.19	2.038	1.893	2.119	1.37	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.91	2.181	0.89			0.502	1.744	1.935	0.898	3.978	1.942	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.808	1.3	0.922			0.197	1.066	1.945	1.755	2.411	1.172	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.673	1.216	0.935			0.518	1.195	1.505	2.003	1.886	1.221	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.828	1.322	0.906	0.516			1.341	2.027	1.756	1.938	1.621	Not an AE
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.863	1.259	0.911				1.017	2.063	1.77	2.108	1.618	Other
COVID19 (COVID19 (JANSEN))	Brain oedema	1.522	1.247	0.924				1.197	1.561	0.601	2.022	0.769	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.009	1.469	1.089				1.763	2.211	1.99	2.361	1.939	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.618	2.007	0.873				1.732	3.027	1.015	2.424	2.162	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.317	1.582	0.934			0.525	1.71	1.886	1.468	3.343	1.134	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	3.066	1.973	0.926			0.592	1.383	1.765	1.166	3.894	1.141	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.362	1.692	0.877				1.278	1.321	1.613	3.488	1.224	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.218	2.164	0.914			0.528	2.489	2.393	0.878	3.904	1.224	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.769	1.274	0.945			0.337	1.302	1.887	1.872	2.074	1.593	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.528	1.661	0.967	0.518		0.613	2.118	2.309	2.03	3.047	1.725	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.969	1.346	0.91			0.383	1.699	1.982	1.832	2.248	1.538	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.059	1.405	0.924			0.463	1.388	2.05	2.004	2.23	1.689	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.59	1.168	0.963				1.168	1.618	1.516	2.041	1.508	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.555	1.762	0.997			0.464	2.187	2.278	3.02	3.282	1.997	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.904	1.386	1.145			0.387	1.387	2.116	1.863	2.11	1.826	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.78	1.293	0.906			0.043	1.212	2.12	1.644	2.054	1.312	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.775	1.365	0.926	0.516		0.279	1.259	2.113	1.731	2.07	1.391	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.78	6.853	0.887			1.192	2.01	1.449	0.573	1.84	1.423	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.279	1.303	0.896			0.445	2.197	2.161	1.952	2.534	1.71	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.165	1.456	0.978	0.519		0.391	1.712	2.291	2.203	2.473	1.835	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.918	1.087	0.871			0.436	1.662	2.041	1.029	2.188	1.336	Not an AE
COVID19 (COVID19 (JANSEN))	Gastroparesis	2.279	1.087	0.88			0.459	2.288	1.717	1.842	2.288	1.864	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.849	1.254	0.897			0.402	1.225	1.717	1.599	2.18	1.204	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.677	1.195	0.908				1.223	1.427	1.419	2.345	1.048	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.336	1.638	0.885			0.439	1.641	3.101	1.641	2.439	2.165	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.819	1.285	0.943	0.512		0.594	1.299	2.062	1.801	2.3	1.422	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.759	1.244	0.934	0.513		0.396	1.382	1.978	1.678	2.103	1.403	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.567	3.668	0.894				4.184	5.613	4.645	7.402	3.383	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.156	3.456	0.874			0.554	4.668	5.689	6.738	7.257	3.018	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.916	1.328	0.965				1.49	2.077	1.887	2.411	1.855	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.084	1.727	0.898			0.011	1.887	2.553	1.412	2.248	1.897	Other
COVID19 (COVID19 (JANSEN))	Intensive care	1.832	1.395	1.068			0.022	1.402	2.162	2.046	2.323	1.557	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.821	1.226	0.881	0.754		0.389	1.533	1.927	1.442	2.304	1.281	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.021	1.207	0.875				1.385	2.026	0.913	2.048	1.25	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.997	1.471	0.876				1.401	1.103	0.707	2.092	0.711	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.94	1.368	0.866				1.274	2.193	1.021	1.677	1.753	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.084	1.863					1.095	2.748	1.025	1.748	1.786	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.728	1.277	0.944				1.359	1.733	1.932	2.288	1.517	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.663	1.243	0.919			0.197	1.011	2.061	1.858	2.081	1.302	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.069	1.48	0.911			0.476	1.779	1.67	2.127	2.313	1.612	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.071	1.422	0.946	0.519		0.445	1.227	2.262	1.89	2.375	1.436	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.691	1.274	0.922			0.274	1.092	1.971	1.542	2.043	1.008	Other
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.877	1.354	0.915			0.323	1.181	2.361	1.598	2.148	1.41	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.124	1.518	1.024			0.482	1.102	2.26	1.985	2.088	2.002	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.545	1.227	0.914	0.516		0.222	0.863	1.923	1.988	2.212	1.106	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.561	1.209	0.889			0.33	1.102	1.65	1.652	2.198	1.85	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.723	1.272	0.918			0.255	1.109	2.065	1.794	1.998	1.401	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.353	6.785					0.744	0.612		2.951	1.075	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.328	6.82	0.886			8.006	1.205	1.365	0.879	1.485	1.928	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.782	6.753					3.436	0.983		2.288		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.547	6.873				0.516	1.541	2.216	1.116	2.192	1.456	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	3.207	1.388	0.874				0.656	1.034	1.585	2.374	1.95	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.868	2.218	0.917	0.518		0.478	1.786	2.961	2.716	3.05	1.84	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.668	1.286	0.911	0.514		0.286	1.127	2.001	1.621	2.213	1.497	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.739	1.842	0.894			0.45	2.093	2.764	2.156	3.11	1.885	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.016	3.279	0.876				4.3	4.567	0.801	5.725	2.237	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.789	1.291	0.956				1.021	2.049	1.665	2.261	1.582	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.618	6.832	0.875		0.719	2.058	0.073	0.062	0.516	1.67	1.837	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.101	1.048					4.084			2.686		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.936	1.414	0.934	0.753		0.383	1.422	2.328	1.662	2.438	1.476	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.237	1.574	1.071	0.519		0.589	1.755	2.042	2.603	2.495	1.882	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.045	1.438	0.906				1.656	1.541	1.939	2.107	1.834	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.818	1.283	0.923	0.513		0.588	1.344	2.042	1.679	2.043	1.508	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.951	1.324	0.922	0.517		0.295	1.254	2.171	1.781	2.3	1.417	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.357	1.004					2.656	0.505		1.081	1.73	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.378	1.632	0.88			0.541	1.779	1.967	1.651	2.611	1.735	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.228	2.206	1.539			0.527	3.253	3.268	1.27	2.982	3.522	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.022	0.76	0.876			0.653	3.617	6.58	15.204	7.753	5.722	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.639							0.636	0.568	0.561	1.025	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.05	1.36	0.886			0.516	1.407	1.506	1.496	2.094	1.363	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.309	1.748	0.95			0.372	1.587	2.438	1.83	2.51	1.768	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.69	2.097	1.735	0.519		0.729	1.973	2.434	3.538	2.964	2.343	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	5.145	2.923	0.895				2.112	3.362	0.585	5.553	1.443	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.272	1.85	0.875				1.938	1.235	0.622	2.201	0.892	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.381	1.413	0.908			0.716	1.899	2.212	2.179	2.68	1.756	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.763	1.811	0.942	0.519		0.531	2.445	2.251	2.846	3.311	2.06	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.458	1.65	0.922			0.433	2.176	2.64	1.993	2.494	1.832	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.503	1.134	0.898	0.519		0.286	0.824	2.015	1.259	1.664	1.17	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.363	3.076	2.486			0.499	1.598	3.024	5.74	2.402	1.57	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.664	6.898					1.26	1.382	0.769	2.119	0.817	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.02	6.881					0.979	1.577	1.033	1.798	1.11	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.297	1.774	0.872				2.011	1.618	0.707	2.555	1.074	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.685	2.041				0.611	2.471	1.636	0.664	3.208	1.196	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.667	2.233	0.878				3.682	2.001	1.068	4.861	1.197	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.371	6.822		10.463	0.911		1.287	0.519		1.468	1.064	
COVID19 (COVID19 (MODERNA))	Intentional product misuse	0.869	1.931	0.875	0.008	1.017	2.481	0.781	0.604	0.419	0.807	0.892	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.869	1.093				0.605	2.093	1.548	0.843	2.008	1.952	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.368	6.978	0.886	0.133	6.081	2.874	0.1	0.044	0.364	2.552	2.854	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.649	2.039	0.873			2.779	2.054	2.003	1.588	3.068	2.194	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.003	1.667	0.887			0.636	1.632	18	1.537	1.917	1.903	
COVID19 (COVID19 (PFIZER-	Body height	1.945	6.984	0.879		0.48	0.695	0.957	1.431	2.166	1.908	1.545	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.045	1.191	0.873		0.48	0.743	1.468	1.663	1.876	1.921	1.505	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.298	1.763	1.716	0.517	0.834	1.111	1.699	1.708	1.737	1.827	1.849	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.855	0.878	16.327			0.362			0.508	1.23	
COVID19 (COVID19 (PFIZER-	Immunisation	1.747	1.658	0.914		1.285	1.243	1.796	1.974	2.247	1.968	1.835	
COVID19 (COVID19 (PFIZER-	Investgation	2.168	1.751	0.928		0.712	1.085	1.785	1.904	2.226	1.977	1.886	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.753	6.783			1.452	1.373	1.846	1.725	2.159	1.894	1.563	
COVID19 (COVID19 (PFIZER-	Weight	2.025	1.335	0.88			0.596	1.555	1.737	2.102	1.1	1.767	

PSI-HHS-000000057530

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From: Menschik, David
Sent: Tue, 19 Apr 2022 10:42:46 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220415.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/15/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	IVS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.035	1.567	0.934			0.385	1.528	1.839	2.046	2.671	1.397	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.118	1.571	0.881				1.612	2.044	2.016	2.774	1.43	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.053	1.324	1.015			0.457	1.44	2.022	1.925	2.368	1.716	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.852	6.958	0.884			0.528	0.972	0.715	0.679	2.597	1.514	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.091	0.89				0.907	0.85	0.727	1.882	1.566	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.964	1.3	0.906				1.472	1.436	1.68	2.113	1.311	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.487	1.831	0.909			0.493	2.136	2.012	2.085	3.498	1.488	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.148	1.456	0.886				1.91	1.752	1.316	2.324	1.423	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.42	1.653	0.912			0.421	1.581	2.302	2.229	2.48	1.968	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.784	1.369	0.91			0.369	1.112	2.157	1.476	2.105	1.334	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.311	6.623	0.877			0.589	0.791	1.084	1.806	1.984	1.679	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.211	1.474	0.973	0.619		0.428	1.812	2.016	2.22	2.725	1.847	Other
COVID19 (COVID19 (JANSEN))	Anxiety	2.03	1.899	0.892				0.859	2.421	1.285	2.068	1.449	Reviewed
COVID19 (COVID19 (JANSEN))	Aphasia	1.728	1.128	0.886				1.113	1.488	1.377	2.14	0.968	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.871	1.411	0.907	0.516		0.366	1.184	2.361	1.771	2.368	1.323	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.784	1.408	0.927	0.515		0.267	1.144	2.295	1.774	2.18	1.321	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.786	1.267	0.92			0.315	1.415	1.851	1.746	2.133	1.395	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.875	1.358	0.941			0.381	1.336	2.113	1.891	2.211	1.487	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.844	1.249	0.916				1.043	2.004	1.541	1.922	1.539	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.813	1.312	0.948			0.479	1.201	2.033	1.878	2.114	1.373	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.54	2.195	0.896			0.596	1.74	1.903	6.902	4.008	1.947	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.807	1.31	0.925			0.198	1.074	1.929	1.783	2.431	1.178	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.879	1.226	0.938			0.527	1.2	1.51	2.075	1.892	1.232	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.816	1.316	0.903	0.516			1.328	2.006	1.732	1.924	1.51	Not an AE
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.638	1.32	0.887			0.108	1.352	1.988	1.199	2.007	0.913	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.854	1.257	0.911				1.023	2.057	1.76	2.085	1.622	Other
COVID19 (COVID19 (JANSEN))	Brain oedema	1.309	1.293	0.926				1.196	1.081	0.6	2.018	1.78	
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.16	1.402	1.082				1.761	2.2	1.959	2.3	1.942	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.634	2.019	0.878				1.747	3.07	1.018	2.421	2.193	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.335	1.588	0.934			0.525	1.708	1.992	1.466	3.364	1.138	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.953	1.933	0.927			0.533	1.381	1.601	1.164	3.882	1.08	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.322	1.719	0.882				1.278	1.336	1.608	3.51	1.222	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.299	2.191	0.916			0.529	2.499	2.566	6.878	3.954	1.224	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.768	1.27	0.941			0.338	1.315	1.887	1.846	2.061	1.586	Confounded-
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.524	1.653	0.961	0.517		0.617	2.114	2.289	2.001	3.011	1.718	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.985	1.349	0.914			0.385	1.71	1.965	1.848	2.243	1.546	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.057	1.403	0.925			0.483	1.393	2.049	1.986	2.234	1.681	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.589	1.165	0.961				1.169	1.808	1.506	2.025	1.506	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.586	1.761	0.991			0.465	2.185	2.272	3.007	3.27	1.994	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.914	1.395	1.189			0.372	1.388	2.108	1.87	2.118	1.822	Labelled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.755	1.288	0.908			0.643	1.225	2.125	1.612	2.041	1.305	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.763	1.357	0.92	0.516		0.282	1.254	2.114	1.697	2.066	1.372	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.76	6.643	0.889			1.192	2.006	1.451	0.903	1.634	1.416	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.284	1.293	0.898			0.447	2.185	2.162	1.504	2.529	1.892	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.155	1.457	0.968	0.518		0.301	1.709	2.298	2.178	2.466	1.63	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.917	1.091	0.882			0.439	1.96	2.04	1.031	2.11	1.355	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.288	1.06	0.894			0.409	2.299	1.715	1.242	2.274	1.811	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.844	1.254	0.898			0.402	1.243	1.706	1.576	2.155	1.217	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.651	1.211	0.911				1.223	1.44	1.437	2.383	1.057	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.335	1.842	0.86			0.439	1.542	3.075	1.651	2.433	2.158	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.811	1.282	0.941	0.512		0.505	1.296	2.049	1.79	2.188	1.421	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.753	1.245	0.93	0.513		0.353	1.386	1.98	1.668	2.1	1.396	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.527	3.709	0.897				4.18	5.664	4.668	7.395	3.405	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.185	3.466	0.88			0.554	4.668	5.674	6.738	7.258	2.888	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.961	1.32	0.957				1.483	2.054	1.865	2.378	1.646	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.08	1.73	0.875			0.011	1.871	2.564	1.419	2.231	1.706	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.827	1.392	1.063			0.022	1.405	2.09	2.028	2.298	1.556	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.819	1.233	0.887	0.754		0.39	1.531	1.932	1.435	2.295	1.285	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.02	1.21	0.904				1.307	2.069	0.911	2.052	1.247	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.92	1.455	0.883				1.384	1.123	0.707	2.322	0.711	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.937	1.382	0.873				1.275	2.174	1.026	1.681	1.731	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.003	1.835					1.057	2.737	1.029	1.698	1.793	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.733	1.265	0.943				1.383	1.714	1.883	2.245	1.497	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.675	1.239	0.917			0.198	1	2.094	1.85	2.072	1.297	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.345	1.095	0.909	0.513		0.277	0.996	1.468	1.239	2.006	0.659	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.065	1.492	0.913			0.477	1.779	1.881	2.128	2.334	1.808	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.068	1.426	0.94	0.519		0.445	1.234	2.283	1.858	2.383	1.426	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.669	1.257	0.913			0.278	1.093	1.981	1.441	2.014	0.989	Other
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.882	1.373	0.92			0.324	1.174	2.365	1.588	2.161	1.411	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.118	1.516	1.02			0.483	1.106	2.252	1.972	2.07	2.002	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.542	1.225	0.916	0.516		0.224	0.867	1.917	1.975	2.212	1.102	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.479	1.185	0.892			0.25	1.103	1.876	1.62	2.158	0.833	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.778	1.27	0.915			0.256	1.097	2.103	1.782	1.998	1.393	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.353	6.784					0.744	0.612		2.941	1.075	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.03	6.623	0.891			7.871	1.213	1.29	0.883	1.447	1.837	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.781	6.753					3.431	0.983		2.278		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.546	6.872				0.517	1.539	2.209	1.119	2.192	1.458	Not an AE
COVID19 (COVID19 (JANSEN))	Paralysis of excitation	3.264	1.988	0.873				1.888	1.694	1.881	2.348	1.95	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.756	2.204	0.922	0.517		0.481	1.761	2.936	2.594	3.023	1.83	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.864	1.3	0.911	0.513		0.282	1.442	2.08	1.594	2.211	1.443	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.731	1.851	0.898			0.45	2.077	2.762	2.15	3.175	1.673	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.014	3.463	0.881				4.296	4.57	6.801	5.91	2.635	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.781	1.27	0.948				1.02	1.996	1.619	2.111	1.574	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.616	6.831	0.88		0.72	2.053	0.073	0.062	0.515	1.668	1.835	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.1	1.048					4.078			2.837		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.942	1.427	0.936	0.753		0.304	1.431	2.328	1.682	2.448	1.486	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.226	1.567	1.045	0.519		0.589	1.752	2.64	2.561	2.49	1.869	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.048	1.438	0.907				1.668	1.545	1.946	2.091	1.84	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.81	1.277	0.924	0.513		0.521	1.323	2.035	1.673	2.028	1.494	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.949	1.323	0.921	0.517		0.296	1.255	2.182	1.761	2.291	1.414	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.306	1.094					2.642	0.565		1.08	3.75	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.38	1.611	0.885			0.542	1.788	1.964	1.629	2.662	1.698	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.235	2.187	1.504			0.526	3.286	3.285	1.278	3.02	3.539	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.626	6.76	0.881			0.854	3.615	6.571	16.204	7.751	5.722	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.639							0.636	0.568	5.662	1.025	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.069	1.381	0.892			0.516	1.41	1.557	1.503	2.112	1.376	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.302	1.729	0.938			0.372	1.588	2.432	1.758	2.465	1.756	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.69	2.106	1.745	0.519		0.73	1.978	2.417	3.543	2.938	2.341	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	5.144	2.924	0.898				2.099	3.067	6.565	5.548	1.436	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.27	1.765	0.88				1.935	1.234	0.622	2.196	0.892	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.388	1.427	0.914			0.716	1.917	2.216	2.2	2.872	1.765	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.685	1.796	0.936	0.519		0.532	2.435	2.24	2.793	3.272	2.059	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.453	1.642	0.92			0.433	2.171	2.037	1.958	2.484	1.84	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.873	1.373	0.882				1.211	2.01	1.649	1.894	1.308	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.516	1.144	0.899	0.518		0.274	0.834	2.079	1.241	1.68	1.186	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.366	3.965	2.453			3.5	1.615	3.049	5.74	2.418	2.575	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.604	6.896					1.26	1.311	0.789	2.014	0.817	Other
COVID19 (COVID19 (JANSEN))	Vascularitation	2.069	6.884					0.979	1.662	1.032	1.847	1.118	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.295	1.775	0.878				2.007	1.623	0.707	2.568	1.073	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.669	2.092				0.611	2.497	1.805	0.884	3.291	1.196	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.998	3.238	0.884				3.68	1.999	1.056	4.851	1.197	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.371	6.821		10.429	0.912		1.288	0.519		1.47	1.956	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.934	0.877	0.509	1.016	2.495	0.784	0.622	0.417	0.668	0.631	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.889	1.097				0.818	2.102	1.566	0.845	2.017	1.966	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.944	0.891		6.106	2.096	0.095	0.045	0.365	2.561	2.677	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.049	2.04	0.878			2.521	2.056	2.005	1.589	1.981	2.199	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.003	1.667	0.892			0.837	1.833	1.758	1.538	1.919	1.902	
COVID19 (COVID19 (PFIZER-	Body height	1.945	6.984	0.884		0.48	0.671	0.957	1.413	2.162	1.904	1.539	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.045	1.102	0.881		0.48	0.742	1.468	1.682	1.874	1.928	1.501	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.258	1.765	1.717	0.517	0.826	1.099	1.696	1.765	1.725	1.831	1.844	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.855	0.884	16.202			0.362			0.503	1.226	
COVID19 (COVID19 (PFIZER-	Immunisation	1.747	1.86	0.916		1.282	1.234	1.795	1.971	2.243	1.965	1.828	
COVID19 (COVID19 (PFIZER-	Investigation	2.167	1.754	0.93		0.708	1.077	1.762	1.963	2.225	1.975	1.863	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.783			1.445	1.385	1.848	1.725	2.161	1.591	1.557	
COVID19 (COVID19 (PFIZER-	Weight	2.024	1.341	0.894			0.924	1.555	1.729	2.104	1.903	1.757	

PSI-HHS-000000057532

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From: Menschik, David
Sent: Tue, 12 Apr 2022 09:44:43 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220408.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/8/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20220[illegible]	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.039	1.603	0.928			0.376	1.532	1.898	2.056	2.681	1.611	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.125	1.591	0.876				1.624	2.079	2.003	2.765	1.446	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.064	1.337	1.016			0.443	1.457	2.044	1.94	2.389	1.732	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.85	0.965	0.877			0.514	0.979	0.78	0.684	2.617	1.495	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.094	0.883				0.914	0.853	0.732	1.891	1.57	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.966	1.308	0.9				1.467	1.454	1.685	2.123	1.318	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.473	1.834	0.903			0.479	2.086	2.023	2.095	3.481	1.493	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.159	1.496	0.875				1.883	1.785	1.321	2.339	1.432	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.421	1.651	0.896			0.415	1.6	2.298	2.193	2.448	1.971	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.784	1.367	0.906			0.359	1.126	2.182	1.454	2.075	1.34	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.369	0.832	0.87			0.599	0.797	1.099	1.794	1.987	1.684	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.212	1.487	0.964	0.612		0.415	1.815	2.029	2.22	2.712	1.862	Other
COVID19 (COVID19 (JANSEN))	Areflexia	2	1.722	0.887				0.881	2.333	1.298	2.111	1.428	Reviewed
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.738	1.138	0.876				1.199	1.284	1.283	2.14	0.997	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.89	1.444	0.904	0.61		0.359	1.204	2.407	1.772	2.408	1.334	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.752	1.432	0.926	0.609		0.271	1.161	2.321	1.78	2.193	1.335	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.759	1.37	0.917			0.312	1.434	1.848	1.751	2.138	1.401	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.878	1.365	0.939			0.373	1.35	2.121	1.891	2.22	1.492	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.843	1.251	0.914				1.048	2.036	1.527	1.931	1.536	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.836	1.333	0.948			0.42	1.223	2.063	1.905	2.149	1.361	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.902	2.229	0.886			0.482	1.69	1.904	0.912	4.099	1.955	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.807	1.31	0.921			0.251	1.081	1.962	1.805	2.414	1.172	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.669	1.219	0.932			0.516	1.206	1.488	2.071	1.882	1.229	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.815	1.317	0.9	0.609			1.346	2.004	1.71	1.917	1.617	Not an AE
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.648	1.334	0.88			0.201	1.371	1.975	1.209	2.028	0.903	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.855	1.262	0.912				1.044	2.061	1.768	2.087	1.635	Other
COVID19 (COVID19 (JANSEN))	Brain oedema	1.049	1.269	0.92				1.208	1.564	0.603	2.009	0.765	
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.066	1.402	1.082				1.748	2.168	1.954	2.298	1.937	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.703	2.084	0.873				1.819	3.011	1.038	2.531	2.252	Reviewed
COVID19 (COVID19 (JANSEN))	CSF red blood cell count positive	2.004	1.743	0.873				1.398	1.944	0.984	1.982	1.478	
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.328	1.693	0.928			0.511	1.684	1.915	1.468	3.348	1.139	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.834	1.941	0.922			0.519	1.352	1.599	1.168	3.893	1.984	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.361	1.636	0.876				1.115	1.388	1.606	3.194	1.225	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.208	2.182	0.907			0.515	2.431	2.285	0.879	3.941	1.229	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.767	1.271	0.937			0.332	1.323	1.889	1.843	2.058	1.591	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.519	1.655	0.96	0.611		0.606	2.088	2.367	1.992	2.995	1.724	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.991	1.355	0.91			0.376	1.715	1.97	1.857	2.248	1.558	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.058	1.405	0.919			0.449	1.4	2.044	1.992	2.223	1.688	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.551	1.169	0.963				1.154	1.668	1.506	2.028	1.51	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.584	1.774	0.979			0.451	2.178	2.287	3.022	3.289	2.003	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.924	1.39	1.193			0.385	1.368	2.127	1.844	2.101	1.821	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.769	1.297	0.902			0.091	1.243	2.144	1.613	2.046	1.318	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.768	1.37	0.92	0.61		0.287	1.206	2.133	1.701	2.066	1.366	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.777	0.843	0.882			0.199	2.002	1.448	0.965	1.838	1.411	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.292	1.29	0.891			0.436	2.195	2.164	1.902	2.534	1.895	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.119	1.481	0.888	0.612		0.389	1.736	2.288	2.17	2.497	1.883	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.63	1.089	0.875			0.427	1.678	2.056	1.021	2.19	1.358	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.281	1.663	0.888			0.398	2.261	1.738	1.238	2.271	1.514	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.876	1.375	0.892			0.396	1.264	1.743	1.587	2.171	1.243	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.71	1.224	0.907				1.222	1.469	1.446	2.398	1.065	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.338	1.844	0.883			0.428	1.648	2.965	1.646	2.443	2.137	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.814	1.289	0.942	0.606		0.452	1.307	2.05	1.798	2.198	1.419	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.757	1.252	0.925	0.606		0.301	1.381	1.988	1.672	2.108	1.399	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.528	3.694	0.891				4.189	5.619	4.787	7.402	3.363	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.177	3.452	0.873			0.541	4.713	5.838	0.74	7.275	2.866	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.892	1.316	0.944				1.479	2.058	1.85	2.364	1.648	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.088	1.751	0.869			0.018	1.915	2.502	1.424	2.228	1.706	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.826	1.396	1.07			0.027	1.409	2.099	2.016	2.292	1.557	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.636	1.245	0.886	0.746		0.36	1.551	1.952	1.45	2.31	1.29	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.015	1.227	0.878				1.389	2.064	0.914	2.088	1.252	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.857	1.462	0.876				1.359	1.143	0.71	2.26	0.711	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.921	1.355	0.866				1.272	2.16	1.027	1.697	1.692	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.065	1.692					1.075	2.726	1.044	1.75	1.81	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.723	1.257	0.93				1.393	1.703	1.868	2.212	1.506	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.668	1.24	0.914			0.22	1.009	2.089	1.853	2.058	1.506	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.362	1.101	0.896	0.607			1.012	1.493	1.241	2.02	0.844	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.075	1.496	0.908			0.484	1.787	1.884	2.133	2.338	1.616	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.075	1.453	0.936	0.612		0.422	1.254	2.29	1.88	2.413	1.43	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.888	1.385	0.918			0.322	1.209	2.362	1.584	2.179	1.417	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.127	1.537	1.022			0.469	1.074	2.258	1.986	2.102	1.987	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.543	1.23	0.913	0.61		0.236	0.884	1.92	1.983	2.233	1.105	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.467	1.202	0.888			0.086	1.132	1.649	1.641	2.227	0.919	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.713	1.271	0.912			0.265	1.106	2.065	1.782	1.985	1.404	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.274	0.795					0.744	0.612		2.742	1.072	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.33	0.607	0.864			0.199	1.197	1.294	0.883	1.448	1.824	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.752	0.763					3.309	1		2.21		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.529	0.865				0.503	1.528	2.159	1.116	2.194	1.421	Not an AE
COVID19 (COVID19 (JANSEN))	Paralysis of excitation	2.819	1.519	0.873				0.888	1.991	1.873	2.232	0.888	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.784	2.229	0.917	0.611		0.467	1.761	2.909	2.604	3.014	1.864	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.857	1.3	0.908	0.607		0.273	1.447	2.093	1.572	2.192	1.455	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.723	1.853	0.892			0.381	2.083	2.739	3.142	3.178	1.884	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.024	3.426	0.874				4.317	3.698	0.799	5.924	2.34	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.761	1.265	0.941				1.014	2.014	1.601	2.098	1.582	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.621	0.842	0.874		0.72	2.052	0.074	0.062	0.518	1.672	1.834	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.068	1.066					4.266			2.817		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.948	1.451	0.934	0.746		0.383	1.448	2.346	1.697	2.477	1.494	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.229	1.57	1.051	0.613		0.581	1.76	2.033	2.563	2.493	1.862	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.057	1.453	0.901				1.664	1.564	1.549	2.092	1.849	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.818	1.291	0.925	0.607		0.511	1.344	2.048	1.691	2.057	1.502	Other
COVID19 (COVID19 (JANSEN))	Red blood cell transfusion	1.668	1.182	0.888				1.175	1.278	1.184	2.004	0.939	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.944	1.332	0.919	0.611		0.386	1.279	2.179	1.77	2.3	1.431	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.349	1.011					2.338	0.5		1.086	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.398	1.678	0.878			0.528	1.814	1.987	1.613	2.615	1.742	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.926	2.174	1.515			0.614	3.281	3.18	1.272	3.912	3.531	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.024	0.77	0.874			0.644	3.591	6.58	15.094	7.751	5.725	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.377							0.638	0.572	0.568	1.917	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.079	1.399	0.886			0.502	1.406	1.581	1.503	2.107	1.587	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.252	1.739	0.934			0.386	1.588	2.423	1.771	2.44	1.761	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.683	2.096	1.721	0.613		0.724	1.967	2.407	3.574	2.933	2.333	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	5.623	2.905	0.892				1.915	2.668	0.569	5.553	1.448	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.212	1.799	0.873				1.887	1.256	0.626	2.181	0.895	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.402	1.439	0.91			0.709	1.932	2.22	2.208	2.68	1.769	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.682	1.808	0.924	0.612		0.518	2.415	2.24	2.793	3.248	2.064	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.46	1.669	0.916			0.421	2.173	2.095	1.969	2.473	1.852	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.888	1.077	0.876				1.231	2.031	1.669	1.875	1.319	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.515	1.145	0.894	0.612		0.291	0.839	2.082	1.252	1.674	1.199	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.305	3.102	2.511			0.467	1.016	3.015	5.781	2.42	2.571	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.568	0.831					1.263	1.327	0.79	1	0.827	Other
COVID19 (COVID19 (JANSEN))	Vasodilation	2.052	0.894					0.981	1.671	1.031	1.844	1.122	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.228	1.794	0.871				1.993	1.642	0.71	2.594	1.978	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.62	2.085				3.6	2.392	1.722	0.667	3.15	1.264	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.669	2.243	0.878				3.635	1.989	1.055	4.807	1.215	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	0.833		12.892	0.935		1.268	0.515		1.473	1.072	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.581	0.935	0.871	0.503	1.031	2.487	0.782	0.631	0.419	0.667	0.631	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.89	1.123				0.607	2.091	1.564	0.847	2.011	1.955	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.364	0.951	0.884		6.116	2.591	0.096	0.045	0.349	2.561	2.675	
COVID19 (COVID19 (MODERNA))	Product quality issue	2.05	2.04	0.871			2.683	2.052	2.067	1.591	1.988	2.199	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.007	1.679	0.885			0.836	1.643	18	1.536	1.918	1.902	
COVID19 (COVID19 (PFIZER-	Body height	1.946	0.987	0.878		0.489	0.664	0.959	1.423	2.159	1.903	1.543	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.048	1.109	0.874		0.489	0.711	1.461	1.09	1.872	1.927	1.502	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.294	1.764	1.711	0.611	0.82	1.098	1.697	1.769	1.722	1.82	1.842	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	0.865	0.877	19.235			0.364			0.505	1.227	
COVID19 (COVID19 (PFIZER-	Immunisation	1.746	1.664	0.91		1.272	1.235	1.795	1.972	2.24	1.963	1.629	
COVID19 (COVID19 (PFIZER-	Investigation	2.165	1.753	0.924		0.707	1.076	1.778	1.926	2.224	1.974	1.882	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.794			1.443	1.367	1.85	1.727	2.158	1.591	1.56	
COVID19 (COVID19 (PFIZER-	Weight	2.024	1.347	0.886			0.024	1.556	1.732	2.102	1.991	1.758	

PSI-HHS-000000057534

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From: Menschik, David
Sent: Tue, 29 Mar 2022 10:11:18 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220325.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 3/25/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20220(25	Serious EB05 2022(	Fatal EB05 20220	Infant EB05 20220	Child EB05 2022(	Teen EB05 20220	Adult1 EB05 2022(	Adult2 EB05 2022(	Adult3 EB05 2022(	Female EB05 2022(	Male EB05 2022(	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.07	1.882	0.932			0.397	1.56	1.89	2.137	2.1	1.636	Reviewed
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.126	1.603	0.88				1.622	2.097	2.021	2.785	1.455	Reviewed
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.07	1.344	1.016			0.448	1.475	2.059	1.949	2.378	1.76	Reviewed
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.846	0.949	0.885			0.515	0.971	0.784	0.687	2.822	1.463	Other
COVID19 (COVID19 (JANSSEN))	Adverse event	2.016	1.097	0.86				0.917	0.76	0.731	1.874	1.518	Other
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.913	1.33	0.906				1.476	1.457	1.726	2.151	1.326	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.484	1.82	0.907			0.48	2.138	1.981	2.06	3.51	1.452	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.152	1.52	0.888				1.832	1.817	1.338	2.321	1.46	Not an AE
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.449	1.676	0.907			0.42	1.637	2.321	2.249	2.491	2.007	Reviewed
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.758	1.36	0.907			0.384	1.143	2.152	1.434	2.102	1.301	Other
COVID19 (COVID19 (JANSSEN))	Antibody test	2.311	6.837	0.86			0.598	0.804	1.025	1.802	2.911	1.701	Not an AE
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.509	0.966	0.613		0.422	1.829	2.049	2.268	2.761	1.679	Other
COVID19 (COVID19 (JANSSEN))	Areflexia	2.035	1.784	0.894				0.897	2.25	1.315	2.081	1.467	Reviewed
COVID19 (COVID19 (JANSSEN))	Arterial spasm cerebral abnormal	1.784	1.33	0.888				1.111	1.882	1.336	2.173	0.996	Reviewed
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.899	1.466	0.91	0.61		0.368	1.206	2.412	1.825	2.399	1.363	Other
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.81	1.469	0.924	0.608		0.276	1.179	2.321	1.853	2.211	1.361	Other
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.779	1.395	0.926			0.321	1.485	1.836	1.823	2.172	1.427	Other
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.851	1.389	0.94			0.386	1.394	2.11	1.542	2.25	1.519	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride decreased	1.834	1.25	0.913				1.046	2.012	1.543	1.944	1.527	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.858	1.357	0.949			0.431	1.257	2.055	1.961	2.201	1.384	Other
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.089	2.31	0.897			0.499	1.692	1.98	0.941	4.205	1.983	Reviewed
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.84	1.378	0.928			0.26	1.138	1.967	1.855	2.482	1.227	Other
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.68	1.236	0.938			0.521	1.22	1.473	1.15	1.871	1.259	Other
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.822	1.325	0.901	0.609			1.34	2.054	1.736	1.921	1.623	Not an AE
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.58	1.126	0.916				1.415	1.459	1.179	2.062	0.993	Other
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.666	1.358	0.888			0.21	1.405	1.993	1.229	2.059	0.908	Other
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.869	1.275	0.918				1.046	2.05	1.809	2.123	1.043	Other
COVID19 (COVID19 (JANSSEN))	Blood urine present	1.539	1.212	0.912	0.612		0.305	0.955	1.576	1.007	2.007	1.495	Other
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.055	1.409	1.114				1.775	2.264	1.982	2.314	1.958	Other
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.662	2.092	0.882				1.864	2.966	1.946	2.52	2.252	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.332	1.648	0.932			0.512	1.685	1.913	1.483	3.338	1.159	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.863	1.973	0.929			0.52	1.354	1.621	1.182	3.981	1.093	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.302	1.694	0.881				1.116	1.255	1.005	3.311	1.195	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.231	2.142	0.915			0.516	2.224	2.267	0.875	3.84	1.232	Reviewed
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.772	1.272	0.937			0.34	1.346	1.89	1.849	2.08	1.604	Confounded
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.542	1.665	0.962	0.611		0.608	2.108	2.315	2.006	3.03	1.727	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.999	1.361	0.917			0.38	1.703	1.978	1.868	2.264	1.54	Not an AE
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.675	1.423	0.926			0.454	1.428	2.053	2.028	2.266	1.7	Reviewed
COVID19 (COVID19 (JANSSEN))	Death	1.554	1.175	0.963				1.147	1.601	1.522	2.027	1.523	Reviewed
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.58	1.781	0.976			0.453	2.166	2.303	2.996	3.267	2.008	Reviewed
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	1.902	1.391	1.289			0.373	1.373	2.135	1.834	2.082	1.835	Labeled
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.773	1.324	0.91			0.187	1.242	2.178	1.658	2.038	1.367	Other
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.782	1.402	0.922	0.609		0.295	1.26	2.146	1.769	2.064	1.424	Other
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.778	6.838	0.86			1.207	2.006	1.451	0.971	1.844	1.417	Labeled
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.294	1.286	0.898			0.439	2.21	2.181	1.922	2.551	1.719	Other
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.196	1.498	0.886	0.612		0.388	1.791	2.287	2.281	2.472	1.838	Reviewed
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.943	1.092	0.884			0.429	1.667	2.113	1.018	2.214	1.348	Not an AE
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.294	1.875	0.896			0.482	2.274	1.747	1.25	2.301	1.517	Labeled
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.859	1.29	0.896			0.398	1.269	17	1.662	2.171	1.257	Reviewed
COVID19 (COVID19 (JANSSEN))	Glomerular filtration rate decreased	1.771	1.159	0.931				1.019	1.927	1.573	2.025	1.378	Other
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.732	1.238	0.909				1.271	1.436	1.489	2.478	1.061	Other
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.329	1.847	0.887			0.432	1.634	2.944	1.619	2.398	2.162	Reviewed
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.822	1.3	0.943	0.606		0.461	1.337	2.02	1.842	2.218	1.429	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.762	1.259	0.934	0.606		0.311	1.412	1.993	1.708	2.121	1.406	Reviewed
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.521	3.614	0.897				4.144	5.51	4.765	7.308	3.403	Not an AE
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.177	3.445	0.882			0.542	4.716	5.82	6.741	7.271	2.853	Reviewed
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.889	1.302	0.931				1.451	2.045	1.833	2.341	1.634	Reviewed
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.087	1.783	0.88			0.02	1.961	2.571	1.396	2.227	1.745	Reviewed
COVID19 (COVID19 (JANSSEN))	Intensive care	1.606	1.466	1.062			0.629	1.437	2.166	2.004	2.314	1.066	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.833	1.253	0.894	0.746		0.388	1.582	1.927	1.483	2.354	1.297	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.015	1.225	0.886				1.41	2.064	0.923	2.092	1.272	Not an AE
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.915	1.486	0.886				1.36	1.15	0.71	2.312	0.715	Reviewed
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.925	1.356	0.875				1.269	2.184	1.029	1.674	1.734	Not an AE
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.09	1.715					1.081	2.751	1.044	1.74	1.817	Reviewed
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.73	1.269	0.938				1.415	1.749	1.875	2.24	1.526	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.665	1.26	0.92			0.232	1.008	2.093	1.926	2.088	1.326	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.388	1.123	0.905	0.607			1.051	1.501	1.268	2.048	0.868	Other
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.08	1.499	0.912			0.471	1.797	1.869	2.144	2.323	1.825	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.065	1.489	0.939	0.612		0.438	1.262	2.26	1.968	2.438	1.463	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.634	1.244	0.906			0.301	1.128	1.944	1.411	2.013	0.963	Other
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.929	1.448	0.921			0.329	1.257	2.401	1.646	2.237	1.451	Other
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.115	1.525	1.013			0.472	1.005	2.289	1.956	2.01	2	Reviewed
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.559	1.248	0.913	0.609		0.244	0.912	1.919	1.035	2.244	1.137	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.505	1.215	0.899			0.185	1.161	1.648	1.652	2.251	0.833	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.732	1.291	0.916			0.276	1.103	2.089	1.004	2.006	1.434	Other
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.19	6.795					0.744	0.612		2.755	1.052	Other
COVID19 (COVID19 (JANSSEN))	Off label use	1.33	0.53	0.891			7.985	1.163	1.252	0.889	1.424	1.91	Not an AE
COVID19 (COVID19 (JANSSEN))	Oxygen saturation decreased	1.732	6.795					2.326	1		2.212		Other
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.529	6.865				0.505	1.53	2.166	1.116	2.201	1.422	Not an AE
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	2.924	1.413	0.882				0.658	1.061	1.579	2.238	0.953	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count	2.763	1.251	0.916	0.611		0.471	1.785	2.883	1.642	3.023	1.891	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.867	1.314	0.916	0.607		0.286	1.482	2.095	1.577	2.197	1.467	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.735	1.85	0.897			0.383	2.112	2.728	2.14	3.3	1.866	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.024	3.422	0.883				4.322	3.649	0.8	5.928	2.359	Not an AE
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	1.806	1.289	0.942				1.021	2.047	1.63	2.119	1.621	Other
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.623	6.842	0.883		0.72	2.017	0.076	0.002	0.523	1.661	1.792	Not an AE
COVID19 (COVID19 (JANSSEN))	Prolonged labour	1.068	1.065					4.255			2.805		Other
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.763	1.256	0.923	0.61		0.353	1.381	1.575	1.821	2.038	1.417	Other
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.958	1.46	0.935	0.745		0.312	1.47	2.306	1.744	2.512	1.49	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.232	1.581	1.138	0.613		0.582	1.765	2.049	2.564	2.498	1.876	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.697	1.456	0.903				1.066	1.578	1.963	2.692	1.86	Reviewed
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.833	1.306	0.932	0.607		0.517	1.381	2.022	1.745	2.068	1.526	Other
COVID19 (COVID19 (JANSSEN))	Red blood cell transfusion	1.717	1.215	0.896				1.177	1.244	1.24	2.084	0.921	Other
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.984	1.371	0.926	0.611		0.323	1.291	2.219	1.816	2.338	1.47	Other
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.349	1.011					2.328	0.5		1.088	0.731	Reviewed
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.396	1.685	0.887			0.529	1.815	1.988	1.628	2.624	1.743	Other
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.231	2.206	1.556			0.521	3.29	3.277	1.273	3.045	3.564	Other
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.023	6.768	0.883			0.645	3.589	6.577	15.088	7.751	5.758	Other
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.378							0.638	0.572	0.568	1.017	Other
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.676	1.418	0.892			0.584	1.416	1.598	1.51	2.131	1.396	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.294	1.753	0.935			0.372	1.604	2.41	1.815	2.477	1.775	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.661	2.1	1.716	0.613		0.726	1.981	2.41	3.544	2.92	2.336	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.987	2.839	0.898				1.536	2.61	0.573	5.548	1.663	Reviewed
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.213	1.73	0.882				1.886	1.165	0.626	2.018	0.903	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.358	1.447	0.911			0.712	1.937	2.22	2.244	2.693	1.772	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.665	1.815	0.929	0.612		0.519	2.42	2.242	2.824	3.248	2.077	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.46	1.694	0.917			0.425	2.102	2.046	2.007	2.503	1.833	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.894	1.091	0.885				1.222	2.041	1.71	1.871	1.334	Not an AE
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.542	1.176	0.902	0.612		0.303	0.854	2.115	1.31	1.711	1.234	Not an AE
COVID19 (COVID19 (JANSSEN))	Vascular failure	1.395	5.112	2.91			0.499	1.089	3.046	0.628	2.442	2.994	Other
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.566	6.931					1.264	1.344	0.79	2.013	0.828	Other
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.039	6.893					0.921	1.665	1.037	1.801	1.119	Labeled
COVID19 (COVID19 (JANSSEN))	Venogram	2.309	1.796	0.88				1.995	1.648	0.71	2.584	1.079	Not an AE
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.607	2.091				0.801	2.389	1.741	0.663	3.153	1.268	Reviewed
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.959	3.243	0.886				3.635	1.987	1.056	4.808	1.216	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	6.833		12.596	0.935		1.288	0.515		1.451	1.077	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.561	0.92	0.88	0.905	1.024	2.47	0.781	0.621	0.414	0.663	0.624	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.89	1.095				0.815	2.082	1.559	0.847	2.007	1.938	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.364	6.951	0.891		6.108	2.98	0.097	0.046	0.358	2.558	2.673	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.05	2.051	0.882			2.675	2.048	2.011	1.595	1.992	2.199	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.007	1.662	0.892			0.636	1.61	1.801	1.524	1.884	1.865	
COVID19 (COVID19 (PFIZER-	Body height	1.945	6.987	0.886		0.488	0.664	0.959	1.404	2.159	1.3	1.543	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.109	0.883		0.488	0.711	1.462	1.669	1.671	1.928	1.5	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.253	1.761	1.706	0.611	0.802	1.09	1.711	1.72	1.731	1.831	1.844	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.865	0.885	18.911			0.364			0.507	1.218	
COVID19 (COVID19 (PFIZER-	Immunisation	1.748	1.664	0.913		1.272	1.202	1.8	1.973	2.236	1.964	1.625	
COVID19 (COVID19 (PFIZER-	Investigation	2.164	1.756	0.927		0.705	1.091	1.774	1.906	2.224	1.985	1.88	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.755	6.794			1.455	1.368	1.853	1.738	2.165	1.8	1.568	
COVID19 (COVID19 (PFIZER-	Weight	2.023	1.343	0.894			0.922	1.551	1.736	2.107	1.901	1.753	

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From: Menschik, David
Sent: Tue, 15 Mar 2022 10:22:14 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220311.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 3/11/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.08	1.683	0.937			0.592	1.563	1.909	2.08	2.711	1.69	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.15	1.632	0.871				1.646	2.111	2.05	2.807	1.476	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.074	1.338	1.019			0.449	1.473	2.043	1.934	2.342	1.761	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.883	0.953	0.873			0.517	0.974	0.799	0.686	2.607	1.472	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.017	1.083	0.876				0.923	0.77	0.736	1.844	1.51	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.918	1.324	0.5				1.429	1.465	1.743	2.117	1.335	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.529	1.865	0.901			0.484	2.133	2.043	2.087	3.6	1.478	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.175	1.555	0.877				1.855	1.828	1.35	2.358	1.47	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.446	1.674	0.897			0.423	1.661	2.323	2.189	2.486	2.001	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.709	1.486	0.901			0.366	1.163	2.198	1.446	2.136	1.321	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.37	0.823	0.906			0.599	0.819	1.045	1.807	2.033	1.74	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.232	1.51	0.967	0.513		0.425	1.837	2.037	2.28	2.784	1.673	Other
COVID19 (COVID19 (JANSEN))	Anoxia	2.064	1.793	0.884				0.862	2.349	1.336	2.011	1.497	Reviewed
COVID19 (COVID19 (JANSEN))	Antegram carotid abnormal	1.745	1.121	0.87				1.111	1.271	1.242	2.268	0.919	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.919	1.472	0.905	0.61		0.374	1.21	2.464	1.832	2.401	1.361	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.808	1.482	0.923	0.508		0.281	1.18	2.298	1.873	2.214	1.35	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.769	1.316	0.923			0.334	1.469	1.86	1.839	2.178	1.454	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.852	1.396	0.937			0.393	1.394	2.133	1.921	2.25	1.52	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.829	1.242	0.900				1.098	2.001	1.487	1.891	1.528	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.881	1.39	0.964			0.438	1.274	2.085	2.009	2.247	1.405	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.041	2.303	0.888			0.583	1.804	1.923	0.843	4.222	1.941	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.839	1.405	0.932			0.263	1.155	1.957	1.856	2.472	1.222	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.68	1.24	0.936			0.526	1.21	1.5	2.099	1.852	1.273	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.822	1.324	0.891	0.509			1.346	2.03	1.68	1.898	1.616	Not an AE
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.622	1.159	0.916				1.439	1.508	1.211	2.124	1.028	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.662	1.367	0.875			0.221	1.416	1.978	1.189	2.048	1.91	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.669	1.282	0.916				1.076	2.047	1.804	2.112	1.601	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.056	1.407	1.107				1.749	2.213	1.957	2.308	1.943	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.657	2.108	0.869				1.819	2.982	1.061	2.524	2.229	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.339	1.649	0.926			0.513	1.676	1.936	1.499	3.286	1.169	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.969	2.032	0.933			0.521	1.413	1.67	1.182	3.969	1.126	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.297	1.633	0.886				1.121	1.271	1.624	3.22	1.212	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.232	2.174	0.91			0.517	2.255	2.284	0.875	3.884	1.237	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.777	1.269	0.939			0.345	1.361	1.865	1.819	2.047	1.599	Confounded-
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.563	1.693	0.974	0.511		0.612	2.103	2.368	2.04	3.071	1.749	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	2	1.365	0.913			0.382	1.706	1.964	1.847	2.257	1.525	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.078	1.428	0.924			0.454	1.439	2.056	2.013	2.284	1.685	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.594	1.166	0.956				1.139	1.58	1.511	2.005	1.501	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.588	1.777	1.009			0.456	2.178	2.288	2.999	3.274	1.999	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.964	1.42	1.315			0.373	1.393	2.132	1.897	2.08	1.877	Labelled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.763	1.341	0.908			0.12	1.259	2.128	1.703	2.058	1.35	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.787	1.427	0.921	0.509		0.299	1.29	2.136	1.802	2.083	1.433	Other
COVID19 (COVID19 (JANSEN))	Peeling cold	1.778	0.845	0.878			1.206	2.014	1.457	0.977	1.651	1.423	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.301	1.292	0.89			0.439	2.215	2.184	1.525	2.547	1.758	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.117	1.467	0.983	0.512		0.311	1.72	2.262	2.243	2.481	1.62	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.881	1.091	0.871			0.43	1.848	2.068	1.024	2.144	1.378	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.301	1.08	0.883			0.403	2.258	1.756	1.281	2.31	1.807	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.892	1.314	0.891			0.399	1.279	1.689	1.711	2.241	1.237	Reviewed
COVID19 (COVID19 (JANSEN))	Glomerular filtration rate decreased	1.788	1.166	0.934				1.033	1.907	1.547	2.011	1.379	Other
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.787	1.269	0.902				1.312	1.466	1.46	2.447	1.099	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.329	1.656	0.877			0.432	1.614	2.965	1.633	2.388	2.171	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.828	1.306	0.939	0.505		0.463	1.342	2.029	1.819	2.204	1.434	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.772	1.261	0.931	0.506		0.315	1.409	1.963	1.695	2.099	1.418	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.484	3.531	0.888				4.037	5.435	4.733	7.24	3.453	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.179	3.341	0.899			0.543	4.723	5.439	6.741	7.274	1.762	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.887	1.291	0.928				1.465	1.995	1.803	2.301	1.805	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.053	1.796	0.868			0.02	1.934	2.569	1.427	2.244	1.721	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.843	1.421	1.091			0.029	1.464	2.064	2.065	2.328	1.568	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.646	1.274	0.86	0.746		0.393	1.007	1.962	1.46	2.351	1.324	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.015	1.222	0.874				1.42	2.036	0.925	2.107	1.246	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.915	1.494	0.873				1.36	1.158	0.709	2.358	0.715	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.923	1.354	0.861				1.256	2.17	1.645	1.673	1.718	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.092	1.725					1.052	2.684	1.048	1.71	1.769	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.744	1.28	0.941				1.338	1.766	1.885	2.243	1.541	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.651	1.27	0.916			0.258	1.017	2.093	1.937	2.094	1.323	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.382	1.121	0.5	0.507			1.04	1.523	1.223	2.021	0.88	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.061	1.535	0.908			0.473	1.606	1.903	2.166	2.336	1.658	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.126	1.522	0.946	0.512		0.443	1.248	2.307	2.004	2.441	1.499	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.908	1.427	0.912			0.334	1.268	2.363	1.56	2.21	1.427	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.117	1.547	1.023			0.473	0.982	2.296	2.018	2.027	2.017	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.577	1.264	0.908	0.509		0.25	0.921	1.943	2.045	2.29	1.13	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.52	1.228	0.889			0.126	1.155	1.689	1.655	2.21	0.85	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.745	1.312	0.918			0.284	1.114	2.118	1.88	2.021	1.443	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.189	0.794					0.744	0.612		2.693	1.052	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.339	0.536	0.86			0.004	1.195	1.225	0.867	1.414	1.823	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.752	0.762					3.275	1.001		2.207		Other
COVID19 (COVID19 (JANSEN))	Packed red blood cell transfusion	1.771	1.29	0.886				1.214	1.222	1.29	2.145	0.959	Reviewed
COVID19 (COVID19 (JANSEN))	Pain assessment	2.38	0.87				0.512	1.111	2.28	1.114	2.333	1.444	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.922	1.415	0.869				0.657	1.062	1.574	2.227	0.954	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.762	2.257	0.911	0.511		0.471	1.795	2.969	2.477	3.014	1.918	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.872	1.311	0.908	0.508		0.388	1.485	2.089	1.642	2.173	1.485	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.726	1.83	0.886			0.385	2.056	2.709	2.066	3.138	1.645	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.028	3.366	0.87				4.323	2.562	6.813	6.28	1.862	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.756	1.277	0.936				1.029	1.971	1.647	2.04	1.836	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.625	0.84	0.87		0.72	2.005	0.078	0.062	0.459	1.648	1.783	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.068	1.085					4.248			2.75		Other
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.779	1.265	0.919	0.61		0.355	1.406	1.823	1.765	2.023	1.425	Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.966	1.482	0.934	0.745		0.317	1.493	2.333	1.703	2.53	1.495	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.234	1.586	1.465	0.513		0.582	1.767	2.063	2.569	2.497	1.885	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.044	1.47	0.898				1.695	1.561	2.009	2.117	1.864	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.644	1.311	0.931	0.506		0.525	1.365	2.042	1.734	2.04	1.531	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	2.012	1.385	0.924	0.511		0.328	1.324	2.249	1.798	2.362	1.466	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.363	1.02					2.3	0.499		1.096	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.397	1.486	0.876			0.53	1.814	1.064	1.518	2.575	1.702	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.229	2.162	1.494			0.522	3.201	3.237	1.277	2.993	3.502	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.021	6.767	0.87			0.645	3.584	6.632	15.085	7.776	5.79	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.373							0.637	0.571	0.568	1.017	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.088	1.4	0.882			0.507	1.371	1.58	1.527	2.171	1.342	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.259	1.753	0.94			0.374	1.613	2.402	1.785	2.457	1.768	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.68	2.082	1.701	0.513		0.728	1.982	2.261	3.526	2.898	2.307	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.968	2.643	0.886				1.654	1.361	0.572	5.768	1.498	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.213	1.733	0.87				1.88	1.192	0.625	2.04	0.904	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.408	1.468	0.907			0.726	1.938	2.244	2.273	2.734	1.779	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.766	1.822	0.925	0.512		0.52	2.445	2.242	2.839	3.281	2.073	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.485	1.673	0.917			0.437	2.135	2.029	2.067	2.488	1.862	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.865	1.09	0.873				1.232	2.037	1.722	1.881	1.34	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.571	1.202	0.896	0.512		0.393	0.661	2.131	1.32	1.722	1.209	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.387	3.096	2.491			0.484	1.611	3.057	6.204	2.433	2.571	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.575	0.913					1.288	1.285	0.794	2.073	0.768	Other
COVID19 (COVID19 (JANSEN))	Vasodilation	2.555	1.894					0.936	1.667	1.899	2.801	1.15	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.284	1.759	0.867				1.944	1.603	0.71	2.614	1.008	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.62	2.069				0.601	2.376	1.662	0.666	3.191	1.208	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.634	2.25	0.874				3.767	2.009	0.93	4.827	1.235	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	0.832		12.029	0.935		1.266	0.514		1.438	1.005	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.915	0.871	0.505	1.015	2.47	0.778	0.618	0.409	0.658	0.621	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.901	1.07				0.696	2.017	1.524	0.814	1.938	1.902	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.364	0.985	0.88		5.92	2.569	0.1	0.047	0.374	2.548	2.654	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.05	2.039	0.869			2.656	2.021	2.001	1.592	1.98	2.182	
COVID19 (COVID19 (PFIZER-	Body height	1.947	0.988	0.874			0.641	0.944	1.398	2.177	1.921	1.537	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.048	1.113	0.87		0.487	0.711	1.464	1.691	1.884	1.942	1.51	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.252	1.785	1.733	0.512	0.789	1.09	1.723	1.736	1.76	1.874	1.877	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	0.864	0.873	17.047			0.375			0.47	1.266	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.69	0.913		1.271	1.236	1.622	1.991	2.256	1.982	1.846	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.773	0.921		0.689	1.08	1.78	1.908	2.26	2.031	1.897	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	0.793			1.457	1.378	1.861	1.745	2.178	1.614	1.579	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.358	0.884			0.661	1.541	1.782	2.129	1.934	1.767	

PSI-HHS-000000057538

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From: Menschik, David
Sent: Tue, 22 Feb 2022 10:29:29 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220218.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 2/18/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022(1	Serious EB05 2022	Fatal EB05 2022(	Infant EB05 2022(	Child EB05 2022(	Teen EB05 2022(	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022(	Female EB05 2022(	Male EB05 2022(	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.697	1.87	0.909			0.597	1.577	1.963	1.847	2.665	1.671	Reviewed
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.186	1.687	0.873				1.683	2.12	2.144	2.918	1.504	Reviewed
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.062	1.342	1.02			0.452	1.431	2.024	1.866	2.321	1.7	Reviewed
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.871	6.961	0.867			0.518	0.972	0.867	0.688	2.561	1.468	Other
COVID19 (COVID19 (JANSSEN))	Adverse event	2.018	1.055	0.874				0.9	0.769	0.751	1.788	1.509	Other
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.924	1.383	0.903				1.444	1.457	1.789	2.18	1.308	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.571	1.885	0.903			0.485	2.18	2.013	2.176	3.703	1.444	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.157	1.505	0.871				1.878	1.777	1.249	2.383	1.378	Not an AE
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.456	1.702	0.901			0.425	1.666	2.331	2.174	2.565	1.962	Reviewed
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.865	1.407	0.886			0.368	1.171	2.216	1.35	2.174	1.283	Other
COVID19 (COVID19 (JANSSEN))	Antibody test	2.309	6.818	0.859			0.553	0.815	1.077	1.92	2.044	1.765	Not an AE
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.227	1.519	0.962	0.612		0.427	1.845	2.014	2.238	2.761	1.829	Other
COVID19 (COVID19 (JANSSEN))	Areflexia	2.131	1.831	0.875				0.859	2.257	1.413	1.899	1.527	Reviewed
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.788	1.288	0.883				1.138	1.178	1.361	2.324	0.898	Reviewed
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.892	1.44	0.886	0.61		0.326	1.214	2.353	1.771	2.381	1.309	Other
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.786	1.479	0.902	0.608		0.286	1.21	2.26	1.801	2.207	1.318	Other
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.792	1.309	0.896			0.397	1.467	1.865	1.767	2.13	1.609	Other
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.88	1.381	0.906			0.396	1.389	2.112	1.847	2.233	1.473	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.968	1.41	0.948			0.462	1.295	2.13	1.964	2.282	1.394	Other
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.123	2.345	0.884			0.504	1.798	1.928	0.856	4.249	1.048	Reviewed
COVID19 (COVID19 (JANSSEN))	Blood lactate dehydrogenase increased	1.664	1.253	0.878	0.612			1.095	2.063	1.153	1.597	1.369	Not an AE
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.818	1.384	0.925			0.263	1.14	1.935	1.818	2.433	1.187	Other
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.672	1.224	0.914			0.527	1.19	1.483	2.036	1.852	1.201	Other
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.821	1.329	0.878	0.609			1.342	2.017	1.665	1.964	1.596	Not an AE
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.634	1.157	0.912				1.491	1.509	1.112	2.208	0.945	Other
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.673	1.359	0.863			0.224	1.403	1.939	1.214	2.06	0.871	Other
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.842	1.297	0.861				1.063	2.052	1.882	2.068	1.09	Other
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.031	1.405	1.106				1.698	2.166	1.886	2.28	1.882	Other
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.731	2.123	0.862				1.774	2.93	1.084	2.484	2.215	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	3.92	1.602	0.921			0.514	1.678	1.849	1.45	3.164	1.112	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.803	1.943	0.913			0.522	1.445	1.381	1.197	3.789	1.004	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.279	1.614	0.859				1.12	1.288	1.621	3.123	1.205	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.203	2.174	0.906			0.518	2.268	2.223	0.877	3.883	1.167	Reviewed
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.771	1.27	0.93			0.349	1.321	1.859	1.79	2.011	1.557	Confounded-
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.577	1.704	0.968	0.611		0.617	2.124	2.321	2.047	3.068	1.743	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.998	1.362	0.901			0.385	1.693	1.96	1.804	2.234	1.509	Not an AE
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.078	1.43	0.92			0.458	1.412	2.03	1.987	2.28	1.646	Reviewed
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.586	1.78	1.043			0.457	2.162	2.267	3.028	3.253	1.978	Reviewed
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	1.935	1.375	1.213			0.378	1.295	2.082	1.741	1.934	1.807	Labeled
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.755	1.318	0.892				1.261	2.105	1.618	2.045	1.285	Other
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.771	1.486	0.897	0.609		0.301	1.309	2.164	1.698	2.078	1.373	Other
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	6.837	0.87			1.206	2.013	1.467	0.96	1.85	1.418	Labeled
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.305	1.246	0.863			0.44	2.164	2.143	1.806	2.494	1.966	Other
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.168	1.443	0.955	0.612		0.314	1.664	2.25	2.175	2.42	1.591	Reviewed
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.958	1.107	0.866			0.434	1.63	2.109	1.03	2.139	1.382	Not an AE
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.305	1.09	0.875			0.459	2.237	1.79	1.203	2.281	1.618	Labeled
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.871	1.315	0.882			0.4	1.329	1.65	1.656	2.253	1.213	Reviewed
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.784	1.242	0.89				1.33	1.382	1.428	2.315	1.081	Other
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.337	1.648	0.871				1.551	2.977	1.634	2.315	2.169	Reviewed
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.825	1.295	0.906	0.606		0.425	1.339	2.038	1.746	2.191	1.398	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.768	1.258	0.904	0.607		0.319	1.409	1.97	1.625	2.088	1.389	Reviewed
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.57	3.623	0.884				4.086	5.267	5.341	7.208	3.908	Not an AE
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.469	3.503	0.863			0.564	4.723	5.631	6.753	7.723	3.825	Reviewed
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.883	1.311	0.934				1.472	1.978	1.784	2.283	1.593	Reviewed
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.108	1.604	0.863			0.021	1.927	2.57	1.447	2.252	1.674	Reviewed
COVID19 (COVID19 (JANSSEN))	Intensive care	1.837	1.42	1.057			0.029	1.468	2.064	2.022	2.303	1.533	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.86	1.285	0.884	0.747		0.395	1.605	1.98	1.452	2.35	1.321	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.016	1.243	0.868				1.429	2.042	0.927	2.12	1.25	Not an AE
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.901	1.627	0.897				1.374	1.171	0.714	2.404	0.727	Reviewed
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.912	1.344	0.858				1.219	2.149	1.009	1.688	1.662	Not an AE
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.068	1.728					1.012	2.606	1.059	1.703	1.743	Reviewed
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.717	1.274	0.936				1.407	1.726	1.815	2.184	1.499	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.702	1.289	0.91			0.173	1.028	2.111	1.958	2.128	1.306	Other
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.067	1.532	0.899			0.476	1.794	1.873	2.12	2.327	1.618	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.068	1.474	0.915	0.612		0.449	1.227	2.332	1.804	2.371	1.427	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.866	1.392	0.897			0.337	1.261	2.35	1.403	2.186	1.332	Other
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.104	1.55	1.06			0.477	0.995	2.285	1.868	1.974	1.981	Reviewed
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.881	1.259	0.888	0.609		0.257	0.905	1.945	2.013	2.284	1.105	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.498	1.204	0.87			0.128	1.174	1.657	1.51	2.221	0.834	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.75	1.327	0.911			0.233	1.125	2.128	1.878	2.054	1.413	Other
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.152	6.792					0.748	0.612		2.278	1.05	Other
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	6.569	0.874			8.015	1.208	1.176	0.85	1.41	1.922	Not an AE
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.753	6.762					3.286	1		2.221		Other
COVID19 (COVID19 (JANSSEN))	Packed red blood cell transfusion	1.741	1.238	0.883				1.214	1.183	1.157	2.049	0.871	Reviewed
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.332	6.876				0.513	1.509	2.224	1.051	2.241	1.429	Not an AE
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	2.53	1.487	0.863				0.657	1.099	1.582	2.469	0.953	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count	2.773	2.243	0.908	0.611		0.472	1.805	3.05	2.519	3.122	1.781	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.988	1.286	0.896	0.606		0.289	1.484	2.078	1.488	2.193	1.418	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.726	1.841	0.882			0.388	2.046	2.716	1.984	3.111	1.841	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.027	3.397	0.864				4.294	26	0.814	6.281	1.855	Not an AE
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.308					0.985	9.807	2.948	4.607	4.238	3.729	Not an AE
COVID19 (COVID19 (JANSSEN))	Prolonged labour	1.098	1.064					4.181			2.651		Other
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.965	1.511	0.927	0.748		0.324	1.518	2.352	1.674	2.531	1.516	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.232	1.572	1.482	0.613		0.584	1.738	2.016	2.567	2.472	1.836	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.045	1.503	0.892				1.69	1.579	2.029	2.081	1.883	Reviewed
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.839	1.303	0.901	0.607		0.329	1.373	2.053	1.659	2.05	1.501	Other
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.004	1.381	0.914	0.611		0.333	1.329	2.265	1.735	2.384	1.426	Other
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.364	1.021					2.312	0.499		1.096	0.731	Reviewed
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.407	1.517	0.87			0.531	1.764	1.965	1.537	2.614	1.869	Other
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.236	2.186	1.438			0.522	3.105	3.105	1.225	2.868	3.273	Other
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.023	6.775	0.884			0.646	3.507	6.672	15.044	7.798	5.605	Other
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.362							0.638	0.573	0.568	1.018	Other
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.111	1.421	0.878			0.509	1.387	1.59	1.486	2.2	1.326	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.303	1.767	0.937			0.374	1.612	2.384	1.73	2.49	1.71	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.68	2.079	1.666	0.613		0.733	1.959	2.378	3.523	2.883	2.266	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.59	2.533	0.884				1.641	0.898	0.573	5.11	3.68	Reviewed
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.254	1.771	0.863				1.883	1.189	0.634	2.059	0.908	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.412	1.465	0.897			0.728	1.909	2.254	2.281	2.741	1.774	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.707	1.839	0.925	0.612		0.521	2.453	2.241	2.801	3.298	2.062	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.487	1.678	0.906			0.438	2.085	2.049	2.033	2.473	1.841	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.867	1.101	0.868				1.227	2.063	1.724	1.902	1.328	Not an AE
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.555	1.172	0.881	0.612		0.308	0.902	2.64	1.226	1.743	1.158	Not an AE
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.059	2.43			0.497	1.602	3.015	6.18	2.388	2.477	Other
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.036	6.891					0.89	1.657	1.039	1.821	1.095	Labeled
COVID19 (COVID19 (JANSSEN))	Venogram	2.308	1.804	0.86				1.949	1.634	0.709	2.648	1.022	Not an AE
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.678	2.115				0.602	2.372	1.696	0.669	3.222	1.224	Reviewed
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.667	2.278	0.866				3.755	2.052	0.926	4.677	1.233	Not an AE
COVID19 (MODERNA))	Exposure via breast milk	1.314	6.835		7.598	0.936		1.236	0.514		1.36	0.905	
COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.934	0.86	0.605	0.775	2.44	0.776	0.609	0.398	0.646	0.808	
COVID19 (MODERNA))	Mechanical urticaria	0.961	1.035				0.699	2.075	1.561	0.792	1.961	2.004	
COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.984	0.874		5.793	2.931	0.105	0.048	0.383	2.533	2.632	
COVID19 (MODERNA))	Product dose omission issue	2.051	2.04	0.952			2.394	1.994	1.95	1.57	1.902	2.111	
COVID19 (PFIZER-	Body height	1.648	6.988	0.868			0.639	0.943	1.377	2.157	1.993	1.52	
COVID19 (PFIZER-	Disease recurrence	2.047	1.09	0.864		0.484	0.71	1.446	1.673	1.871	1.938	1.497	
COVID19 (PFIZER-	Drug ineffective	2.291	1.776	1.721	0.612	0.772	1.077	1.711	1.722	1.753	1.877	1.871	
COVID19 (PFIZER-	Exposure via breast milk	0.752	6.848	0.867	11.89			0.391			0.454	1.344	
COVID19 (PFIZER-	Immunisation	1.743	1.685	0.911		1.271	1.223	1.808	1.976	2.222	1.958	1.821	
COVID19 (PFIZER-	Investigation	2.102	1.778	0.907		0.666	1.072	1.767	1.908	2.246	2.037	1.897	
COVID19 (PFIZER-	Product preparation issue	1.754	6.791			1.467	1.378	1.856	1.743	2.179	1.622	1.586	
COVID19 (PFIZER-	Weight	2.022	1.345	0.875			0.898	1.54	1.746	2.143	1.91	1.769	

PSI-HHS-000000057540

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From: Menschik, David
Sent: Tue, 15 Feb 2022 12:01:11 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220211_.xls

Hi All,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 2/11/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022[1]	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.091	1.683	0.91			0.597	1.595	1.964	1.98	2.08[illegible]		1.672 Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.194	1.686	0.872				1.692	2.068	2.162	2.915	1.499	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.058	1.334	1.012			0.454	1.4	1.963	1.845	2.262	1.894	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.871	6.961	0.865			0.518	0.977	0.867	0.688	2.557	1.474	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.018	1.055	0.872				0.905	0.738	0.753	1.783	1.507	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.924	1.386	0.902				1.443	1.463	1.786	2.192	1.326	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.574	1.891	0.903			0.485	2.18	2.011	2.2	3.711	1.444	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.173	1.542	0.869				1.884	1.802	1.273	2.392	1.407	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.45	1.703	0.897			0.425	1.85	2.328	2.166	2.548	1.96	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.818	1.427	0.86			0.388	1.184	2.231	1.358	2.194	1.293	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.309	6.606	0.856			0.563	0.823	1.005	1.807	2.011	1.701	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.228	1.518	0.957	0.613		0.428	1.833	1.99	2.24	2.763	1.807	Other
COVID19 (COVID19 (JANSEN))	Anoxia	2.121	1.833	0.874				0.862	2.279	1.428	1.908	1.518	Reviewed
COVID19 (COVID19 (JANSEN))	Antinuclear cerebral abnormal	1.798	1.188	0.862				1.138	1.178	1.366	2.311	0.891	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.898	1.436	0.88	0.61		0.326	1.222	2.32	1.773	2.344	1.321	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.789	1.468	0.892	0.609		0.286	1.215	2.239	1.774	2.166	1.327	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.785	1.397	0.888			0.33	1.469	1.812	1.767	2.138	1.403	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.882	1.381	0.905			0.397	1.4	2.085	1.862	2.23	1.472	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.907	1.41	0.944			0.444	1.306	2.096	1.988	2.278	1.391	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.22	2.384	0.883			0.504	1.797	2.004	0.86	4.281	1.859	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.826	1.383	0.923			0.284	1.157	1.863	1.836	2.412	1.186	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.662	1.231	0.911			0.529	1.197	1.489	2.044	1.853	1.213	Other
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.619	1.138	0.906				1.506	1.421	1.115	2.148	0.919	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.665	1.354	0.858			0.227	1.389	1.947	1.223	2.047	0.874	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.832	1.246	0.878				1.075	2.062	1.681	2.028	1.584	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.028	1.4	1.1				1.67	2.126	1.876	2.191	1.886	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.752	2.116	0.861				1.773	2.804	1.083	2.488	2.21	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.307	1.612	0.918			0.514	1.702	1.826	1.454	3.2	1.089	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.882	1.97	0.912			0.522	1.446	1.39	1.204	3.902	1.004	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.378	1.635	0.857				1.12	1.365	1.522	2.91	1.211	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.242	2.18	0.904			0.518	2.267	2.238	0.877	3.861	1.185	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.567	1.704	0.956	0.612		0.616	2.149	2.317	2.013	3.078	1.723	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.662	1.371	0.896			0.385	1.685	1.965	1.823	2.232	1.53	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.065	1.443	0.925			0.458	1.408	2.043	2.006	2.287	1.854	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.586	1.767	1.014			0.457	2.141	2.246	3.02	3.221	1.964	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.927	1.37	1.174			0.379	1.297	2.062	1.723	1.888	1.811	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.763	1.308	0.882				1.268	2.078	1.594	3	1.298	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.772	1.395	0.885	0.609		0.382	1.303	2.081	1.683	2.025	1.39	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.779	6.843	0.869			1.106	2.01	1.465	0.964	1.844	1.414	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.304	1.241	0.875			0.441	2.179	2.132	1.811	2.48	1.879	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.17	1.453	0.966	0.612		0.316	1.669	2.248	2.162	2.434	1.59	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.998	1.092	0.863			0.435	1.831	2.038	1.03	2.118	1.361	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.306	1.094	0.877			0.466	2.257	1.754	1.304	2.362	1.615	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.873	1.303	0.877			3.4	1.345	1.627	1.627	2.188	1.231	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.771	1.21	0.886				1.349	1.299	1.429	2.177	1.087	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.331	1.898	0.87				1.597	2.882	1.999	2.283	2.143	Reviewed
COVID19 (COVID19 (JANSEN))	Haemstocrit decreased	1.823	1.291	0.906	0.606		0.425	1.347	2.066	1.751	2.177	1.395	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.767	1.257	0.9	0.607		0.319	1.418	1.941	1.634	2.077	1.386	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.57	3.82	0.882				4.083	5.307	5.305	7.304	2.999	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.408	3.498	0.861			0.544	4.722	5.62	6.752	7.733	1.821	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.88	1.3	0.924				1.469	1.95	1.749	2.248	1.573	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.095	1.797	0.861			0.022	1.91	2.515	1.457	2.251	1.865	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.845	1.425	1.043			0.029	1.479	2.055	2.023	2.288	1.54	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.862	1.287	0.885	0.747		0.396	1.617	1.947	1.471	2.34	1.322	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.078	1.246	0.866				1.432	2.045	0.923	2.129	1.247	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.951	1.627	0.865				1.374	1.17	0.714	2.393	0.727	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.911	1.358	0.853				1.223	2.15	1.024	1.697	1.866	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.069	1.722					1.012	2.599	1.056	1.701	1.74	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.712	1.273	0.904				1.405	1.706	1.696	2.173	1.406	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.704	1.286	0.902			0.173	1.034	2.091	1.964	2.105	1.313	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.09	1.536	0.894			0.476	1.792	1.878	2.108	2.328	1.615	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.066	1.476	0.911	0.612		0.451	1.211	2.208	1.852	2.357	1.435	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.863	1.372	0.895			0.337	1.266	2.272	1.426	2.137	1.332	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.088	1.529	1.023			0.478	0.999	2.254	1.842	1.993	1.976	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.588	1.265	0.889	0.609		0.257	0.91	1.941	2.03	2.286	1.112	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.506	1.202	0.869			0.13	1.179	1.642	1.519	2.195	0.841	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.752	1.32	0.902			0.235	1.132	2.092	1.879	2.018	1.423	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.191	6.791					0.748	0.612		2.247	1.049	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.34	6.496	0.873			7.951	1.219	1.143	0.85	1.388	1.914	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.753	6.761					3.285	1		2.214		Other
COVID19 (COVID19 (JANSEN))	Packed red blood cell transfusion	1.746	1.283	0.882				1.214	1.193	1.175	2.1	0.879	Reviewed
COVID19 (COVID19 (JANSEN))	Pain assessment	2.559	6.878				0.513	1.586	2.23	1.06	2.261	1.442	Not an AE
COVID19 (COVID19 (JANSEN))	Pericardial effusion	2.927	1.486	0.861				0.657	1.059	1.58	2.451	0.953	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count	2.772	2.246	0.906	0.611		0.472	1.769	3.062	2.572	3.108	1.779	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.671	1.301	0.891	0.609		0.29	1.492	2.067	1.496	2.174	1.428	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.726	1.829	0.881			0.388	2.011	2.716	1.979	3.101	1.627	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.027	3.391	0.862				4.285	2.563	0.614	6.284	1.945	Not an AE
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.398					0.087	0.151	0.402	0.738	0.884	0.038	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.068	1.065					3.233			1.785		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.964	1.518	0.926	0.746		0.325	1.523	2.327	1.697	2.534	1.519	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.239	1.588	1.471	0.613		0.584	1.725	2.61	2.563	2.467	1.817	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.044	1.5	0.891				1.66	1.564	1.571	2.066	1.826	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.84	1.302	0.897	0.608		0.529	1.38	2.028	1.672	2.04	1.505	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.956	1.377	0.906	0.611		0.335	1.309	2.232	1.754	2.338	1.437	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.363	1.021					2.313	0.5		1.098	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.466	1.516	0.868			0.531	1.703	1.962	1.543	2.541	1.868	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.236	2.185	1.298			0.523	3.078	3.063	1.246	2.814	3.211	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.023	6.773	0.862			0.646	3.586	5.667	15.026	7.795	5.828	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.379							0.638	6.572	0.568	1.018	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.311	1.44	0.877			0.508	1.391	1.587	1.505	2.225	1.326	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.361	1.763	0.904			0.374	1.02	2.37	1.737	2.461	1.705	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.679	2.075	1.672	0.613		0.732	1.954	2.381	3.503	2.873	2.244	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.59	3.529	0.882				1.639	0.897	0.573	5.131	1.68	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.239	1.796	0.861				1.884	1.196	0.833	2.084	0.908	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.414	1.485	0.896			0.639	1.899	2.244	2.309	2.309	1.757	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.71	1.838	0.924	0.613		0.521	2.415	2.233	2.805	3.267	2.059	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.504	1.681	0.91			0.438	2.068	2.044	2.032	2.485	1.824	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.887	1.102	0.868				1.236	2.066	1.734	1.912	1.333	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.367	3.071	2.462			0.501	1.574	2.969	6.15	2.34	2.446	Other
COVID19 (COVID19 (JANSEN))	Vasculitis	2.035	6.893					0.89	1.655	1.045	1.821	1.089	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.365	1.804	0.858				1.949	1.633	0.708	2.638	1.022	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.69	2.122				0.802	2.37	1.694	0.671	3.241	1.224	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.087	3.279	0.866				3.765	2.05	0.927	4.91	1.233	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.378	6.835		7.707	0.936		1.236	0.575		1.398	0.912	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	6.59	6.923	0.858	0.605	0.782	2.444	0.777	0.606	0.395	0.648	0.804	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.901	1.917				0.84	2.061	1.454	0.79	1.931	2.907	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.904	0.872		5.644	2.517	0.101	0.049	0.383	2.528	2.618	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.051	2.051	0.86			2.385	2.005	1.902	1.671	1.901	2.115	
COVID19 (COVID19 (PFIZER-	Body height	1.948	6.988	0.866			0.614	0.943	1.377	2.17	1.915	1.52	
COVID19 (COVID19 (PFIZER-	Bladder [illegible]	2.547	1.883	0.862		0.469	0.71	1.442	1.888	1.874	1.994	1.906	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.765	1.722	0.612	0.751	1.076	1.713	1.722	1.761	1.907	1.898	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.848	0.866	17.906			0.391			0.451	1.349	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.68	0.909		1.272	1.221	1.869	1.982	2.234	1.978	1.836	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.77	0.9		0.665	1.07	1.767	1.93	2.26	2.057	1.902	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.791			1.48	1.38	1.858	1.745	2.184	1.632	1.591	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.34	0.878			0.897	1.537	1.738	2.154	1.957	1.766	

PSI-HHS-000000057542

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From: Menschik, David
Sent: Tue, 8 Feb 2022 11:51:51 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: Weekly data mining
Attachments: USST_20220204.xls

Hi All,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 2/4/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022(0	Serious EB05 2022(	Fatal EB05 2022(	Infant EB05 2022(	Child EB05 2022(	Teen EB05 2022(	Adult1 EB05 2022(	Adult2 EB05 2022(	Adult3 EB05 2022(	Female EB05 2022(	Male EB05 2022(	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.086	1.681	0.906			0.597	1.58	3.9	2.043	2.681	1.651	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.208	1.706	0.874				1.686	2.125	2.197	2.98	1.497	Reviewed
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.04	1.341	1.005			0.455	1.435	2.009	1.827	2.298	1.678	Reviewed
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.882	6.961	0.867			0.519	0.977	0.865	0.687	2.554	1.442	Other
COVID19 (COVID19 (JANSSEN))	Adverse event	2.018	1.059	0.875				0.908	0.739	0.759	1.755	1.493	Other
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.941	1.386	0.903				1.454	1.444	1.785	2.252	1.298	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.557	1.89	0.904			0.487	2.178	1.963	2.225	3.771	1.416	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.196	1.586	0.871				1.895	1.817	1.299	2.43	1.421	Not an AE
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.426	1.687	0.898			0.426	1.593	2.309	2.169	2.501	1.942	Reviewed
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.812	1.429	0.888			0.372	1.184	2.226	1.351	2.192	1.283	Other
COVID19 (COVID19 (JANSSEN))	Antibody test	2.309	6.807	0.86			0.063	0.634	1.001	1.889	2.024	1.737	Not an AE
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.234	1.514	0.955	0.612		0.43	1.799	1.99	2.256	2.75	1.809	Other
COVID19 (COVID19 (JANSSEN))	Areflexia	2.123	1.835	0.876				0.819	2.234	1.434	1.855	1.572	Reviewed
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.41	1.141	0.881				1.138	1.166	1.491	2.421	0.958	Reviewed
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.905	1.437	0.876	0.61		0.329	1.228	2.348	1.713	2.364	1.292	Other
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.789	1.466	0.883	0.609		0.287	1.237	2.238	1.713	2.162	1.313	Other
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.799	1.3	0.883			0.333	1.459	1.828	1.761	2.165	1.381	Other
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.873	1.374	0.896			0.399	1.41	2.074	1.835	2.241	1.449	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.923	1.423	0.936			0.449	1.323	2.121	1.971	2.296	1.396	Other
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.273	2.429	0.885			0.504	1.844	2.168	0.86	4.355	1.967	Reviewed
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.825	1.386	0.915			0.287	1.173	1.932	1.752	2.482	1.158	Other
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.675	1.221	0.906			0.533	1.192	1.478	2.01	1.857	1.171	Other
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.594	1.12	0.902				1.428	1.45	1.056	2.144	1.07	Other
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.654	1.36	0.881			0.231	1.377	1.906	1.251	2.043	0.872	Other
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.828	1.233	0.874				1.066	2.013	1.634	2.032	1.548	Other
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.003	1.413	1.157				1.85	2.111	1.903	2.211	1.886	Other
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.779	2.149	0.953				1.815	2.897	1.093	2.43	2.267	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.307	1.616	0.917			0.514	1.711	1.823	1.459	3.214	1.088	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.883	1.966	0.912			0.522	1.445	1.987	1.203	3.881	1.002	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.289	1.663	0.86				1.129	1.364	1.526	2.845	1.23	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.243	2.176	0.905			0.518	2.265	2.236	0.877	3.857	1.183	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.586	1.728	0.961	0.611		0.616	2.149	2.327	2.071	3.132	1.736	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.997	1.381	0.898			0.386	1.707	1.969	1.814	2.31	1.517	Not an AE
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.078	1.432	0.921			0.458	1.376	2.045	1.979	2.288	1.818	Reviewed
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.593	1.77	1.016			0.458	2.141	2.248	3.049	3.224	1.977	Reviewed
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	1.925	1.396	1.216			0.379	1.324	2.075	1.761	1.92	1.828	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.761	1.309	0.881				1.257	2.142	1.505	2.043	1.244	Other
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.755	1.377	0.876	0.609		0.304	1.205	2.081	1.61	2.024	1.351	Other
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	6.836	0.871			1.109	2.012	1.452	0.968	1.848	1.413	Labeled
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.304	1.234	0.881			0.442	2.157	2.124	1.841	2.473	1.677	Other
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.166	1.445	0.96	0.612		0.319	1.656	2.258	2.184	2.429	1.585	Reviewed
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.961	1.078	0.866			0.438	1.642	2.049	0.966	2.121	1.356	Not an AE
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.321	1.109	0.878			0.408	2.27	1.772	1.317	2.366	1.025	Labeled
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.882	1.328	0.88			0.401	1.351	1.647	1.663	2.228	1.242	Reviewed
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.811	1.227	0.896				1.369	1.326	1.403	2.184	1.108	Other
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.338	1.838	0.87				1.831	2.862	1.613	2.84	2.166	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemstocrit decreased	1.822	1.295	0.901	0.606		0.426	1.333	2.023	1.753	2.196	1.384	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.77	1.263	0.899	0.607		0.321	1.413	1.966	1.625	2.094	1.381	Reviewed
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.585	3.55	0.883				3.871	5.208	5.262	7.103	1.85	Not an AE
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.469	3.492	0.884			0.544	4.733	5.581	6.753	7.738	1.803	Reviewed
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.862	1.296	0.922				1.498	1.941	1.731	2.264	1.544	Reviewed
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.08	1.812	0.864			0.023	1.918	2.529	1.457	2.238	1.885	Reviewed
COVID19 (COVID19 (JANSSEN))	Intensive care	1.849	1.43	1.049			0.03	1.433	2.67	2.048	2.288	1.536	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.866	1.281	0.883	0.747		0.387	1.595	1.984	1.454	2.381	1.283	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.078	1.267	0.898				1.435	2.047	0.935	2.153	1.253	Not an AE
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.951	1.626	0.868				1.375	1.178	0.713	2.461	0.726	Reviewed
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.908	1.359	0.857				1.208	2.127	1.036	1.698	1.639	Not an AE
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.049	1.691					0.977	2.556	1.054	1.665	1.718	Reviewed
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.694	1.249	0.926				1.311	1.672	1.776	2.112	1.404	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.691	1.273	0.891			0.179	1.041	2.08	1.514	2.105	1.286	Other
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.103	1.554	0.895			0.476	1.81	1.876	2.145	2.35	1.62	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.108	1.469	0.902	0.612		0.462	1.184	2.21	1.823	2.398	1.377	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.866	1.375	0.896			0.338	1.279	2.264	1.421	2.144	1.331	Other
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.079	1.531	1.016			0.478	0.957	2.248	1.868	1.881	1.894	Reviewed
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.581	1.264	0.887	0.609		0.259	0.916	1.936	1.017	2.325	1.091	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.526	1.217	0.868			0.136	1.191	1.64	1.543	2.231	0.833	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.733	1.302	0.894			0.239	1.128	2.069	1.833	1.998	1.399	Other
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.191	6.792					0.761	0.612		2.231	1.068	Other
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	6.491	0.875			7.877	1.229	1.13	0.827	1.392	1.899	Not an AE
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.753	6.762					3.286	1		2.212		Other
COVID19 (COVID19 (JANSSEN))	Packed red blood cell transfusion	1.724	1.307	0.886				1.134	1.226	1.195	2.037	0.898	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.518	6.858				0.514	1.582	2.202	1.082	2.321	1.41	Not an AE
COVID19 (COVID19 (JANSSEN))	Pericardial effusion	2.928	1.488	0.863				0.657	1.06	1.587	2.448	0.953	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count	2.773	2.249	0.908	0.611		0.473	1.776	3.095	2.593	3.145	1.786	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.669	1.295	0.867	0.609		0.282	1.477	2.009	1.499	2.14	1.429	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.722	1.843	0.883			0.388	2.007	2.746	1.991	3.124	1.627	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.028	3.382	0.866				4.274	2.562	6.815	6.288	1.842	Not an AE
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.388					0.666	0.191	3.371	0.811	4.888	0.88	Not an AE
COVID19 (COVID19 (JANSSEN))	Prolonged labour	1.068	1.066					3.193			1.774		
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.955	1.517	0.921	0.746		0.328	1.525	2.366	1.657	2.601	1.48	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.225	1.572	1.48	0.613		0.587	1.698	2.036	2.577	2.468	1.815	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.043	1.476	0.892				1.658	1.568	1.515	1.996	1.81	Reviewed
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.844	1.31	0.891	0.608		0.531	1.378	2.044	1.675	2.066	1.495	Other
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.968	1.35	0.896	0.611		0.336	1.273	2.202	1.729	2.338	1.369	Other
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.363	1.021					2.314	0.499		1.097	0.731	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.466	1.536	0.87			0.531	1.709	1.966	1.536	2.555	1.866	Other
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.236	2.191	1.398			0.524	3.105	2.969	1.273	2.767	3.174	Other
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.023	6.773	0.865			0.646	3.587	5.663	14.992	7.792	5.82	Other
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.38							0.638	6.571	0.568	1.019	Other
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.128	1.452	0.88			0.509	1.399	1.57	1.517	2.257	1.308	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.303	1.776	0.937			0.375	1.616	2.376	1.769	2.481	1.717	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.662	2.088	1.569	0.613		0.73	1.959	2.364	3.492	2.864	2.242	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.991	3.395	0.884				1.18	0.896	0.572	4.103	1.68	Reviewed
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.234	1.796	0.864				1.885	1.196	0.833	2.084	0.908	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.417	1.475	0.893			0.638	1.879	2.266	2.285	2.753	1.743	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.719	1.833	0.924	0.612		0.521	2.357	2.235	2.824	3.271	2.042	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.52	1.727	0.916			0.438	2.095	2.065	2.144	2.544	1.843	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.88	1.099	0.865				1.242	2.069	1.737	1.921	1.325	Not an AE
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.081	2.466			0.502	1.56	2.968	6.199	2.313	2.436	Other
COVID19 (COVID19 (JANSSEN))	Vasculitis	2.036	6.893					0.89	1.654	1.044	1.848	1.886	Labeled
COVID19 (COVID19 (JANSSEN))	Venogram	2.327	1.829	0.881				1.945	1.666	0.707	2.626	1.04	Not an AE
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.725	2.141				0.802	2.367	1.723	0.671	3.23	1.237	Reviewed
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.088	3.279	0.868				3.764	2.051	0.927	4.908	1.235	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.378	6.835		7.725	0.936		1.237	0.575		1.393	0.911	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	6.59	0.93	0.86	0.605	0.781	2.44	0.78	0.603	0.394	0.648	0.803	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.902	6.977				0.618	2.038	1.464	0.789	1.911	1.974	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.305	6.963	0.873		5.553	2.9	0.105	0.049	0.366	2.512	2.807	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.051	2.05	0.863			2.382	2.004	1.902	1.671	1.901	2.114	
COVID19 (COVID19 (PFIZER-	Body height	1.948	6.989	0.868			0.587	0.944	1.362	2.185	1.915	1.523	
COVID19 (COVID19 (PFIZER-	Bladder recurrence	2.547	1.894	0.884		0.469	0.71	1.448	1.49	1.903	1.971	1.906	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.77	1.597	0.612	0.726	1.065	1.721	1.731	1.759	1.935	1.912	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.848	0.867	17.941			0.391			0.451	1.351	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.695	0.91		1.273	1.223	1.818	1.989	2.231	1.996	1.852	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.763	0.893		0.649	1.07	1.773	1.929	2.248	2.071	1.913	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.753	6.755			1.512	1.388	1.854	1.743	2.197	1.65	1.808	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.338	0.875			0.891	1.537	1.748	2.166	1.972	1.773	

PSI-HHS-000000057544

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From: Menschik, David
Sent: Tue, 1 Feb 2022 11:00:24 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220128.xls

Hi All,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 1/28/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20220128	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 20220	Female EB05 2022	Male EB05 202201	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.72	1.695	0.909			0.597	1.563	1.905	2.017	2.734	1.44	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.23	1.73	0.876				1.732	2.117	2.233	3.024	1.515	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.04	1.331	0.996			0.457	1.448	1.976	1.831	2.301	1.662	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.885	6.967	0.87			0.518	0.98	0.812	0.694	2.567	1.453	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.019	1.861	0.877				0.912	0.748	0.762	1.734	1.505	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.948	1.379	0.898				1.483	1.428	1.813	2.24	1.302	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.669	1.894	0.901			0.487	2.204	1.943	2.332	3.783	1.428	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.229	1.653	0.874				1.937	1.881	1.322	2.478	1.457	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.464	1.706	0.894			0.425	1.615	2.301	2.182	2.539	1.949	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.828	1.457	0.86			0.373	1.211	2.223	1.382	2.15	1.316	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.309	6.824	0.906			0.584	0.636	1.009	1.923	2.074	1.709	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.244	1.539	0.967	0.612		0.432	1.807	2.015	2.329	2.805	1.822	Other
COVID19 (COVID19 (JANSEN))	Areflexia	2.134	1.869	0.876				0.85	2.17	1.451	1.937	1.554	Reviewed
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.831	1.197	0.887				1.136	1.184	1.427	2.499	0.868	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.929	1.477	0.878	0.61		0.329	1.233	2.415	1.736	2.397	1.315	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.789	1.485	0.882	0.609		0.289	1.251	2.257	1.717	2.171	1.316	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.796	1.306	0.88			0.335	1.467	1.842	1.758	2.188	1.374	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.889	1.392	0.894			0.402	1.425	2.118	1.836	2.27	1.461	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.965	1.466	0.931			0.451	1.363	2.192	1.98	2.334	1.439	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.273	2.459	0.886			0.504	1.844	2.168	0.875	4.407	1.074	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.757	1.36	0.914			0.288	1.156	1.915	1.713	2.403	1.139	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.668	1.243	0.911			0.535	1.209	1.514	2.033	1.882	1.197	Other
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.592	1.123	0.902				1.38	1.481	1.044	2.131	1.87	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.668	1.397	0.864			0.234	1.401	1.94	1.273	2.068	0.889	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.837	1.234	0.872				1.086	2.03	1.619	2.027	1.557	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.013	1.417	1.286				1.89	2.124	1.906	2.218	1.903	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.715	2.139	0.996				1.775	2.995	1.1	2.018	2.253	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.311	1.643	0.918			0.518	1.712	1.85	1.474	3.275	1.1	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.976	1.956	0.906			0.522	1.473	1.328	1.205	3.951	0.949	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.269	1.619	0.862				1.13	1.365	1.466	2.842	1.196	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.243	2.186	0.908			0.519	2.263	2.236	0.877	3.918	1.184	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.615	1.751	0.946	0.611		0.615	2.204	2.31	2.128	3.214	1.733	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	2.003	1.401	0.897			0.386	1.711	1.909	1.834	2.264	1.53	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.088	1.46	0.921			0.458	1.396	2.063	2.036	2.321	1.844	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.601	1.77	0.991			0.457	2.148	2.255	3.027	3.211	1.981	Reviewed
COVID19 (COVID19 (JANSEN))	Embolic stroke	1.497	1.083	0.87				0.456	0.962	2.031	1.724	0.861	Reviewed
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.769	1.323	0.885				1.257	2.165	1.539	2.079	1.24	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.741	1.364	0.877	0.609		0.304	1.203	2.079	1.561	2.028	1.311	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.78	6.838	0.874			1.111	2.007	1.458	0.973	1.852	1.407	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.304	1.242	0.883			0.376	2.171	2.139	1.841	2.502	1.674	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.176	1.483	0.946	0.612		0.321	1.684	2.272	2.192	2.431	1.808	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.561	1.063	0.864			0.409	1.646	2.066	0.898	2.136	1.337	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.265	1.675	0.877			0.409	2.276	1.747	1.26	2.414	1.566	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.88	1.329	0.882			0.401	1.368	1.615	1.657	2.206	1.235	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.835	1.258	0.888				1.414	1.32	1.437	2.216	1.121	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.339	1.644	0.872				1.336	2.369	1.62	2.281	2.169	Reviewed
COVID19 (COVID19 (JANSEN))	Haemstocrit decreased	1.838	1.314	0.904	0.606		0.428	1.353	2.055	1.769	2.212	1.409	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.788	1.28	0.905	0.607		0.321	1.419	2.069	1.634	2.194	1.404	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.589	5.592	0.885				3.951	5.16	5.868	7.391	3.742	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.469	5.562	0.866			0.544	4.723	5.918	0.753	7.737	1.975	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.868	1.291	0.924				1.489	1.934	1.733	2.278	1.529	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.095	1.837	0.867			0.024	1.969	2.528	1.468	2.24	1.708	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.851	1.425	1.05			0.03	1.441	2.05	2.061	2.274	1.534	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.85	1.273	0.883	0.747		0.388	1.616	1.963	1.415	2.402	1.256	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.076	1.295	0.871				1.436	2.022	0.858	2.171	1.27	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.951	1.628	0.87				1.376	1.179	0.714	2.468	0.726	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.91	1.368	0.859				1.202	2.148	1.046	1.691	1.851	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.049	1.723					0.984	2.586	1.072	1.688	1.731	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.707	1.226	0.916				1.006	1.606	1.704	2.117	1.429	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte count decreased	1.588	1.149	0.864			0.197	1.076	1.838	1.5	2.008	1.1	
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.669	1.274	0.892			0.181	1.04	2.082	1.923	2.117	1.277	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.417	1.678	0.893			0.475	1.823	1.887	2.182	2.372	1.833	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.126	1.491	0.9	0.612		0.454	1.212	2.33	1.817	2.423	1.378	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.89	1.413	0.896			0.338	1.3	2.307	1.457	2.17	1.364	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.092	1.498	0.998			0.478	0.964	2.214	1.82	1.849	1.952	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.58	1.271	0.891	0.609		0.259	0.919	1.962	2.025	2.348	1.087	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.527	1.229	0.871			0.141	1.208	1.65	1.536	2.234	0.849	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.721	1.383	0.895			0.24	1.119	2.08	1.843	2.013	1.386	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.102	6.726					0.761	0.612		1.961	1.068	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.34	6.493	0.876			7.876	1.236	1.116	0.829	1.391	1.914	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.753	6.761					3.279	1.001		2.214		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.514	6.859				0.513	1.584	2.11	1.077	2.28	1.372	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.931	1.482	0.866				0.657	1.06	1.594	2.455	0.954	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.762	2.236	0.911	0.611		0.472	1.781	3.085	2.481	3.178	1.772	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.675	1.306	0.892	0.609		0.282	1.463	2.057	1.516	2.159	1.44	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.722	1.878	0.885			0.391	2.015	2.803	2.023	3.174	1.638	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.027	3.374	0.867				4.274	2.592	0.816	6.288	1.945	Not an AE
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.398					0.666	0.156	3.261	0.875	4.89	0.89	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.068	1.066					3.192			1.778		
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.776	1.255	0.885	0.611		0.384	1.39	1.634	1.646	2.024	1.344	Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	2.069	1.531	0.919	0.746		0.329	1.548	2.399	1.621	2.629	1.479	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.224	1.576	1.506	0.613		0.586	1.701	2.033	2.576	2.48	1.815	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.048	1.477	0.896				1.674	1.581	1.901	1.998	1.811	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.879	1.341	0.894	0.608		0.536	1.42	2.09	1.7	2.108	1.532	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	2.002	1.377	0.894	0.611		0.338	1.32	2.237	1.739	2.389	1.351	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.363	1.022					2.309	0.499		1.097	0.731	
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.408	1.441	0.872			0.531	1.717	1.925	1.441	2.451	1.866	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.234	2.326	1.502			0.524	2.745	2.87	1.212	2.698	3.144	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.022	6.781	0.867			0.646	3.584	6.704	15.368	7.823	5.846	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.378							0.638	0.572	0.568	1.019	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.13	1.485	0.858			0.555	1.409	1.561	1.539	2.282	1.32	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.304	1.784	0.934			0.374	1.628	2.42	1.732	2.511	1.721	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.663	2.097	1.578	0.613		0.729	1.959	2.41	3.498	2.878	2.246	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.961	2.411	0.888				1.181	0.765	0.573	4.676	3.68	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.234	1.799	0.866				1.884	1.197	0.633	2.088	0.908	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.42	1.489	0.894			0.638	1.887	2.262	2.343	2.767	1.753	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.73	1.851	0.926	0.612		0.521	2.372	2.261	2.865	3.291	2.067	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.538	1.754	0.927			0.442	2.112	2.054	2.243	2.581	1.86	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.883	1.186	0.867				1.254	2.077	1.765	1.934	1.336	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.367	3.159	2.504			0.501	1.486	2.945	6.191	2.288	2.418	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.036	6.897					0.89	1.663	1.045	1.859	1.088	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.343	1.875	0.866				1.961	1.68	6.708	2.791	1.04	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.8	2.182				0.603	2.433	1.745	0.676	3.472	1.237	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.211	2.337	0.87				3.901	2.056	0.927	5.02	1.253	Not an AE
COVID19 (COVID19 (JANSEN))	White blood cell count decreased	1.72	1.24	0.861			0.187	1.57	1.529	1.642	2.007	1.189	Other
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.375	6.836		7.735	0.937		1.238	0.515		1.342	0.912	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.946	0.861	0.505	0.782	2.435	0.751	0.662	0.393	0.644	0.603	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.962	6.833				0.458	2.029	1.426	0.719	1.895	1.845	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.949	0.873		5.346	2.888	0.106	0.65	0.387	2.581	2.591	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.951	2.05	0.898			2.982	2.004	1.861	1.071	1.901	2.115	
COVID19 (COVID19 (PFIZER-	Body height	1.948	1.001	0.871			0.587	0.944	1.385	2.18	1.924	1.523	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.083	0.867		0.482	0.709	1.444	1.689	1.9	1.979	1.505	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.261	1.767	1.7	0.612	0.709	1.664	1.737	1.728	1.764	1.931	1.906	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.848	0.87	17.964			0.391			0.461	1.349	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.688	0.909		1.272	1.221	1.819	1.979	2.216	1.98	1.839	
COVID19 (COVID19 (PFIZER-	Investigation	2.102	1.765	0.894		0.647	1.07	1.772	1.931	2.248	2.074	1.908	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.753	6.754			1.532	1.394	1.851	1.732	2.2	1.655	1.815	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.349	0.881			0.891	1.538	1.755	2.163	1.979	1.77	

PSI-HHS-000000057546

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From: Menschik, David
Sent: Tue, 25 Jan 2022 11:40:47 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20220121.xls

Hi All,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 1/21/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.108	1.717	0.906			0.602	1.558	1.966	2.092	2.71	1.654	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.23	1.736	0.88				1.698	2.128	2.286	3.094	1.491	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.04	1.327	0.996			0.457	1.423	1.986	1.809	2.312	1.841	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.892	6.934	0.874			0.518	0.98	0.817	0.633	2.581	1.471	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.022	1.07	0.88				0.926	0.763	0.765	1.753	1.516	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.932	1.331	0.9				1.476	1.413	1.704	2.235	1.257	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.634	1.932	0.902			0.486	2.248	1.967	2.465	3.876	1.446	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.235	1.617	0.87				1.936	1.875	1.201	2.388	1.468	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.461	1.725	0.897			0.425	1.604	2.368	2.189	2.588	1.944	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.826	1.46	0.86			0.375	1.227	2.241	1.324	2.184	1.318	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.39	6.817	0.869			0.593	0.843	1.047	1.866	2.094	1.791	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.241	1.55	0.974	0.612		0.432	1.809	1.968	2.398	2.838	1.816	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.134	1.883	0.882				0.85	2.171	1.477	1.91	1.56	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.849	1.18	0.871				1.148	1.184	1.47	2.08	0.918	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.923	1.481	0.881	0.61		0.332	1.226	2.408	1.762	2.393	1.311	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.783	1.487	0.885	0.609		0.295	1.252	2.25	1.725	2.166	1.318	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.778	1.303	0.883			0.337	1.432	1.84	1.758	2.171	1.365	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.855	1.402	0.896			0.406	1.431	2.127	1.852	2.274	1.476	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.993	1.464	0.924			0.451	1.356	2.203	1.987	2.323	1.441	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.236	2.454	0.885			0.503	1.843	2.266	0.784	4.29	1.887	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.818	1.391	0.913			0.268	1.178	1.948	1.722	2.398	1.171	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.665	1.241	0.906			0.538	1.211	1.468	2.043	1.864	1.205	
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.526	1.09	0.904				1.331	1.465	0.95	2.024	0.827	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.668	1.401	0.868			0.235	1.41	1.935	1.292	2.092	0.877	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.825	1.239	0.874				1.105	2.018	1.624	2.062	1.536	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.005	1.44	1.395				1.684	2.117	1.963	2.293	1.898	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.717	2.101	0.87				1.805	2.989	1.061	2.398	2.305	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.374	1.618	0.917			0.517	1.711	1.855	1.433	3.23	1.1	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	3.079	2.042	0.912			0.522	1.473	1.369	1.228	4.088	0.969	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.29	1.635	0.87				1.073	1.305	1.47	2.731	1.224	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.246	2.193	0.907			0.519	2.293	2.299	0.878	3.924	1.191	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.507	1.76	0.946	0.611		0.622	2.195	2.32	2.123	3.251	1.721	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.611	1.398	0.896			0.387	1.707	2.009	1.735	3.234	1.514	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.088	1.473	0.923			0.461	1.41	2.084	2.031	2.328	1.655	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.601	1.775	0.993			0.46	2.143	2.258	3.042	3.214	1.986	
COVID19 (COVID19 (JANSSEN))	Embolic stroke	1.498	1.089	0.874				0.455	0.962	2.159	1.722	0.867	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.742	1.306	0.887				1.253	2.12	1.528	2.043	1.227	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.719	1.352	0.881	0.61		0.306	1.202	2.037	1.561	2.008	1.295	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.84	0.877			1.117	2.007	1.463	0.974	1.852	1.405	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.254	1.244	0.886			0.378	2.172	2.135	1.903	2.527	1.673	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.146	1.448	0.937	0.612		0.325	1.647	2.259	2.175	2.462	1.59	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.566	1.065	0.869			0.438	1.657	2.093	0.853	2.13	1.359	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.269	1.977	0.86			0.409	2.276	1.746	1.26	2.411	1.566	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.877	1.33	0.887			3.4	1.385	1.57	1.7	2.188	1.237	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.821	1.247	0.888				1.429	1.309	1.397	2.221	1.102	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.319	1.939	0.872				1.888	2.342	1.628	2.883	2.198	
COVID19 (COVID19 (JANSSEN))	Haemostatic decreased	1.824	1.315	0.904	0.607		0.432	1.336	2.044	1.793	2.213	1.402	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.776	1.28	0.91	0.608		0.325	1.4	2.063	1.648	2.107	1.395	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.59	5.587	0.886				4.037	5.161	5.862	7.294	2.856	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.486	5.607	0.87			0.543	4.727	5.899	0.761	7.741	2.065	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.872	1.313	0.928				1.505	1.931	1.784	2.308	1.555	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.062	1.837	0.871			0.025	1.993	2.514	1.479	2.237	1.713	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.851	1.417	1.056			0.031	1.415	2.045	2.048	2.258	1.52	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.868	1.304	0.896	0.747		0.402	1.599	2.005	1.453	2.443	1.28	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.078	1.396	0.875				1.441	2.078	0.983	2.186	1.273	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.952	1.685	0.874				1.376	1.195	0.714	2.466	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.908	1.366	0.864				1.212	2.14	1.054	1.698	1.843	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.049	1.736					0.998	2.583	1.087	1.693	1.744	
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.666	1.209	0.923				1.239	1.603	1.734	2.07	1.404	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.668	1.27	0.895			0.184	1.022	2.074	1.923	2.105	1.263	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.388	1.126	0.89	0.608			1.008	1.508	1.193	2.028	0.869	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.514	1.581	0.886			0.476	1.82	1.867	2.171	2.384	1.823	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.124	1.495	0.9	0.612		0.459	1.213	2.318	1.836	2.441	1.362	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.963	1.435	0.903			0.342	1.311	2.34	1.459	2.198	1.373	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.082	1.479	0.993			0.478	0.972	2.186	1.794	1.893	1.889	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.569	1.272	0.886	0.61		0.264	0.917	1.945	2.034	2.363	1.07	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.512	1.223	0.872			0.152	1.2	1.672	1.472	2.223	0.843	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.729	1.313	0.9			0.243	1.112	2.088	1.865	2.017	1.387	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.194	6.725					0.761	0.612		1.958	1.068	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	6.414	0.875			7.887	1.246	1.105	0.801	1.381	1.918	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.754	0.76					3.273	1.061		2.213		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.515	6.857				0.513	1.61	2.139	1.095	2.284	1.403	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.063	1.553	0.87				0.657	1.061	1.69	2.715	0.954	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.763	2.259	0.91	0.611		0.472	1.804	3.062	2.386	3.159	1.786	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.674	1.317	0.896	0.609		0.297	1.463	2.077	1.513	2.171	1.442	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.723	1.935	0.888			0.39	2.023	2.834	2.175	3.231	1.667	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.028	5.384	0.871				4.266	2.603	0.817	6.291	1.838	
COVID19 (COVID19 (JANSSEN))	Pure red cell aplasia	1.388					0.666	0.153	3.378	3.888	4.888	4.887	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	1.761	1.334	0.936				0.973	1.873	1.713	2.004	1.629	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.747	1.247	0.883	0.611		0.364	1.382	1.633	1.611	2.004	1.328	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.051	1.558	0.919	0.746		0.334	1.54	2.459	1.642	2.683	1.496	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.215	1.577	1.513	0.613		0.588	1.704	2.031	2.582	2.483	1.812	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.048	1.46	0.896				1.673	1.563	1.912	1.998	1.796	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.87	1.345	0.894	0.608		0.539	1.412	2.086	1.711	2.114	1.525	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.003	1.38	0.896	0.611		0.34	1.261	2.273	1.734	2.368	1.402	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.354	1.354	0.876			0.531	1.717	1.865	1.443	2.405	1.638	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.235	2.33	1.092			0.526	2.679	2.72	1.176	2.845	3.11	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.024	6.779	0.871			0.645	3.584	5.663	15.36	7.795	5.841	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.387							0.638	6.572	0.568	1.02	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.141	1.516	0.886			0.508	1.429	1.588	1.564	2.31	1.337	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.313	1.836	0.936			0.374	1.66	2.451	1.765	2.582	1.749	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.68	2.097	1.666	0.613		0.653	1.96	2.368	3.481	2.878	2.227	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.962	3.393	0.889				1.181	0.765	0.573	4.065	1.68	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.236	1.62	0.87				1.883	1.205	0.633	2.121	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.41	1.466	0.897			0.639	1.892	2.25	2.375	2.785	1.74	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.721	1.862	0.932	0.612		0.524	2.373	2.255	2.972	3.291	2.081	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.515	1.741	0.912			0.444	2.135	2.064	2.028	2.491	1.885	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.884	1.115	0.871				1.26	2.085	1.791	1.948	1.341	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.17	2.42			0.515	1.487	2.948	6.268	2.294	2.376	
COVID19 (COVID19 (JANSSEN))	Vasculitis	2.036	6.896					0.891	1.663	1.052	1.868	1.887	
COVID19 (COVID19 (JANSSEN))	Venogram	2.361	1.878	0.87				2.002	1.681	0.708	2.848	1.04	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.778	2.195				0.803	2.429	1.763	0.676	3.604	1.191	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.188	3.315	0.874				3.856	2.099	0.946	5.02	1.201	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.712	1.243	0.866			0.196	1.556	1.504	1.671	2.007	1.168	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.375	6.834		7.743	0.937		1.217	0.514		1.332	0.911	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.953	0.866	0.605	0.644	2.425	0.783	0.599	0.391	0.642	0.601	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.921	0.877		5.307	2.663	0.107	0.65	0.387	2.473	2.565	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.051	2.05	0.868			2.388	2.003	1.951	1.671	1.904	2.114	
COVID19 (COVID19 (PFIZER-	Body height	1.948	1.018	0.874			0.587	0.944	1.386	2.213	1.937	1.524	
COVID19 (COVID19 (PFIZER-	Device failure	2.547	1.984	0.871		0.48	0.799	1.448	1.868	1.827	1.981	1.58	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.762	1.588		0.682	1.056	1.735	1.736	1.778	1.974	1.927	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	6.847	0.873	17.976			0.402			0.459	1.353	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.651	0.896		1.273	1.229	1.808	1.998	2.246	2.021	1.869	
COVID19 (COVID19 (PFIZER-	Investigation	2.161	1.762	0.896		0.648	1.07	1.779	1.933	2.273	2.092	1.918	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.753	6.753			1.561	1.402	1.881	1.764	2.253	1.687	1.64	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.36	0.884			0.892	1.536	1.752	2.187	1.998	1.781	

PSI-HHS-000000057548

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 18 Jan 2022 11:16:29 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20220114.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 1/14/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.108	1.733	0.907			0.032	1.558	1.984	2.091	2.755	1.675	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.255	1.782	0.884				1.732	2.18	2.259	3.093	1.531	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.036	1.325	0.988			0.46	1.419	1.979	1.797	2.317	1.629	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.908	0.939	0.873			0.518	0.95	0.831	0.638	2.602	1.489	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.021	1.049	0.876				0.925	0.694	0.772	1.713	1.487	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.935	1.318	0.5				1.475	1.414	1.667	2.237	1.233	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.654	1.97	0.908			0.49	2.266	1.968	2.501	3.927	1.451	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.237	1.628	0.869				1.914	1.893	1.21	2.421	1.453	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.474	1.745	0.896			0.426	1.613	2.366	2.241	2.637	1.945	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.62	1.454	0.86			0.377	1.221	2.24	1.3	2.17	1.318	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.39	0.804	0.866			0.553	0.846	1.048	1.897	2.098	1.778	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.236	1.541	0.963	0.612		0.433	1.821	1.977	2.341	2.778	1.626	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.154	1.876	0.882				0.856	2.105	1.496	1.984	1.522	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.447	1.169	0.87				1.146	1.134	1.052	2.446	0.888	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.928	1.493	0.88	0.61		0.337	1.225	2.449	1.746	2.388	1.321	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.758	1.5	0.883	0.509		0.301	1.263	2.265	1.738	2.187	1.328	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.707	1.317	0.882			0.361	1.462	1.868	1.782	2.171	1.394	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.916	1.427	0.896			0.412	1.444	2.166	1.875	2.295	1.503	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.969	1.485	0.924			0.456	1.349	2.218	2.022	2.362	1.444	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.236	2.456	0.884			0.504	1.844	2.266	0.785	4.292	1.888	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.86	1.444	0.917			0.281	1.209	1.976	1.759	2.448	1.208	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.685	1.246	0.903			0.545	1.225	1.483	2.052	1.866	1.205	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.698	1.45	0.867			0.24	1.427	1.996	1.206	2.111	0.901	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.835	1.255	0.868				1.138	2.035	1.647	2.088	1.557	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2	1.441	1.298				1.709	2.107	1.958	2.292	1.897	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.787	2.16	0.866				1.803	2.967	1.073	2.442	2.27	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.335	1.693	0.921			0.518	1.819	1.872	1.453	3.331	1.124	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.953	2.027	0.906			0.522	1.474	1.306	1.231	4.103	0.913	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.29	1.682	0.869				1.074	1.333	1.489	2.772	1.246	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.267	2.271	0.916			0.519	2.415	2.267	0.883	3.964	1.206	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.621	1.801	0.948	0.611		0.626	2.274	2.338	2.154	3.328	1.743	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.068	1.39	0.896			0.392	1.665	2.013	1.742	2.241	1.487	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.666	1.89	0.923			0.484	1.423	2.09	2.062	3.353	1.663	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.609	1.774	1.009			0.461	2.155	2.282	2.96	3.193	1.992	
COVID19 (COVID19 (JANSSEN))	Embolic stroke	1.509	1.097	0.873				0.454	0.97	2.159	1.771	0.866	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.744	1.308	0.884				1.261	2.121	1.515	2.044	1.221	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.725	1.351	0.876	0.61		0.311	1.306	2.046	1.536	2.012	1.3	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.846	0.876			1.122	2.007	1.459	0.968	1.855	1.404	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.287	1.264	0.882			0.378	2.176	2.156	1.907	2.534	1.855	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.742	1.436	0.925	0.612		0.33	1.638	2.276	2.166	2.408	1.585	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.959	1.043	0.867			0.409	1.661	2.043	0.858	2.123	1.341	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.313	1.108	0.881			0.409	2.304	1.755	1.294	2.475	1.574	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.669	1.342	0.906			0.404	1.387	1.55	1.664	2.202	1.222	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.818	1.243	0.888				1.455	1.278	1.403	2.242	1.083	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.317	1.837	0.868				1.524	2.919	1.623	2.204	2.164	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.848	1.341	0.896	0.607		0.497	1.335	2.078	1.484	2.244	1.458	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.79	1.301	0.903	0.608		0.328	1.419	2.017	1.679	2.116	1.421	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.615	3.62	0.886				4.037	52	5.868	7.241	2.966	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.458	3.604	0.869			0.544	4.726	5.881	6.761	7.743	3.944	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.871	1.32	0.922				1.53	1.973	1.752	2.311	1.554	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.103	1.849	0.872			0.026	1.982	2.527	1.477	2.257	1.715	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.857	1.422	1.043			0.032	1.431	2.062	2.036	2.253	1.527	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.873	1.323	0.883	0.747		0.468	1.629	2	1.475	2.468	1.296	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.016	1.339	0.874				1.439	2.105	0.984	2.291	1.292	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.046	1.837	0.873				1.51	1.196	0.719	2.911	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.91	1.398	0.864				1.209	2.164	1.056	1.717	1.853	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.047	1.737					0.955	2.576	1.096	1.692	1.749	
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.68	1.202	0.92				1.235	1.592	1.74	2.008	1.425	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.679	1.205	0.896			0.192	1.031	2.078	1.846	2.124	1.205	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.405	1.137	0.89	0.608			1.029	1.541	1.132	2.034	0.688	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.122	1.586	0.886			0.479	1.854	1.864	2.149	2.411	1.807	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.149	1.518	0.906	0.612		0.469	1.236	2.349	1.83	2.457	1.388	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.861	1.435	0.901			0.346	1.289	2.332	1.456	2.208	1.339	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.671	1.478	0.972			0.485	0.991	2.279	1.698	1.892	1.875	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.589	1.285	0.89	0.61		0.27	0.925	1.983	1.026	2.361	1.085	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.536	1.241	0.871			0.172	1.225	1.718	1.427	2.242	0.864	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.738	1.324	0.898			0.248	1.117	2.104	1.882	2.034	1.391	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.195	0.724					0.762	0.612		1.962	1.069	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	0.365	0.873			7.745	1.23	1.109	0.807	1.361	1.922	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.755	0.759					3.269	1.062		2.218		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.516	0.857				0.514	1.607	2.138	1.097	2.302	1.403	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.063	1.553	0.899				0.657	1.062	1.683	2.725	0.954	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	2.773	2.315	0.918	0.611		0.474	1.823	3.05	2.558	3.157	1.785	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.89	1.353	0.899	0.609		0.298	1.531	2.093	1.538	2.196	1.469	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.727	1.966	0.867			0.392	2.03	2.653	2.243	3.24	1.693	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.093	3.423	0.87				4.226	3.867	0.817	6.292	2.171	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.368					0.986	4.121	3.31	5.945	4.543	3.991	
COVID19 (COVID19 (JANSSEN))	Product dose decreased	1.798	1.382	0.886	0.611		0.384	1.391	1.67	1.409	2.61	1.381	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.025	1.567	0.914	0.746		0.338	1.551	2.429	1.66	2.638	1.505	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.225	1.585	1.528	0.613		0.588	1.713	2.034	2.59	2.484	1.814	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.647	1.488	0.898				1.697	1.58	1.842	3.084	1.807	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.882	1.368	0.896	0.608		0.543	1.434	2.108	1.741	2.138	1.552	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.039	1.426	0.9	0.611		0.345	1.303	2.306	1.782	2.418	1.432	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.4	1.467	0.875			0.531	1.731	1.935	1.477	2.443	1.706	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.23	1.366	1.106			0.528	2.646	2.657	1.167	2.697	3.112	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.034	6.781	0.87			0.646	3.583	6.652	15.654	7.795	5.87	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.367							0.637	0.572	0.568	1.019	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.148	1.544	0.886			0.508	1.45	1.619	1.512	2.268	1.369	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.335	1.884	0.949			0.374	1.67	2.503	1.808	2.577	1.786	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.88	2.082	1.675	0.613		0.654	1.961	2.394	3.485	2.869	2.226	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.993	2.367	0.867				1.192	0.765	0.373	4.081	0.801	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.253	1.837	0.869				1.884	1.267	0.637	2.148	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.393	1.449	0.896			0.64	1.896	2.219	2.377	2.782	1.717	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.76	1.975	0.928	0.612		0.524	2.369	2.282	2.964	3.309	2.102	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.526	1.736	0.906			0.444	2.156	2.057	1.679	2.507	1.862	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.878	1.111	0.87				1.271	2.078	1.808	1.962	1.331	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.368	1.109	2.461			0.521	1.422	2.885	6.302	2.268	2.358	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.038	0.869					0.895	1.677	0.564	1.813	1.096	
COVID19 (COVID19 (JANSSEN))	Venogram	2.413	1.916	0.866				2.107	1.681	0.709	2.864	1.04	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.865	2.236				0.604	2.645	1.765	0.676	3.738	1.192	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.268	2.327	0.873				3.857	2.1	0.96	5.021	1.205	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.723	1.268	0.865			0.283	1.585	1.517	1.708	2.005	1.218	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	0.834		7.552	0.938		1.218	0.514		1.333	0.911	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.934	0.866	0.605	0.844	2.384	0.774	0.595	0.391	0.638	0.597	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	0.928	0.876		5.334	2.847	0.092	0.051	0.386	2.468	2.548	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.052	2.047	0.868			2.326	2.003	1.95	1.57	1.903	2.111	
COVID19 (COVID19 (PFIZER-	Body height	1.946	1.016	0.873			0.587	0.944	1.366	2.216	1.937	1.524	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.084	0.87		0.479	0.709	1.445	1.627	1.927	1.98	1.515	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.76	1.692		0.623	1.048	1.745	1.741	1.801	1.981	1.938	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	0.847	0.872	17.971			0.402			0.401	1.35	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.629	0.898		1.28	1.23	1.786	1.99	2.251	2.013	1.857	
COVID19 (COVID19 (PFIZER-	Investigation	2.161	1.756	0.896		0.645	1.068	1.775	1.938	2.268	2.093	1.919	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	0.752			1.588	1.407	1.872	1.761	2.259	1.691	1.648	
COVID19 (COVID19 (PFIZER-	Weight	2.021	1.351	0.883			0.882	1.532	1.749	2.187	1.998	1.779	

PSI-HHS-000000057550

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From: Menschik, David
Sent: Wed, 12 Jan 2022 14:03:51 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST_20220107.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 1/7/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022[0]	Serious EB05 2022	Fatal EB05 2022[1]	Infant EB05 2022[2]	Child EB05 2022[3]	Teen EB05 2022[4]	Adult1 EB05 2022[5]	Adult2 EB05 2022[6]	Adult3 EB05 2022[7]	Female EB05 2022[8]	Male EB05 2022[9]	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.586	1.763	0.905			0.484	1.605	1.938	2.063	2.771	1.886	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.254	1.774	0.884				1.735	2.222	2.202	3.081	1.545	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.032	1.332	0.977			0.461	1.417	1.949	1.843	2.328	1.639	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.91	0.941	0.875			0.523	0.942	0.843	0.648	2.608	1.505	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.02	1.054	0.881				0.954	0.772	0.772	1.688	1.486	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.954	1.34	0.901				1.502	1.423	1.684	2.25	1.253	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.742	2.011	0.907			0.491	2.296	2.012	2.581	3.966	1.482	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.257	1.641	0.872				1.953	1.879	1.21	2.413	1.469	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.484	1.78	0.896			0.43	1.626	2.38	2.354	2.713	1.966	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.769	1.422	0.886			0.378	1.212	2.235	1.202	2.132	1.297	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.309	0.823	0.966			0.595	0.804	1.068	1.925	2.068	1.8	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.243	1.544	0.953	0.612		0.435	1.84	1.985	2.33	2.778	1.628	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.145	1.923	0.881				0.875	2.192	1.425	2.015	1.528	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.478	1.168	0.872				1.146	1.146	1.046	2.49	0.938	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.921	1.518	0.881	0.61		0.34	1.221	2.485	1.76	2.398	1.327	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.777	1.5	0.883	0.609		0.384	1.265	2.253	1.726	2.173	1.319	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.78	1.316	0.883			0.364	1.485	1.858	1.734	2.184	1.372	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.921	1.448	0.898			0.415	1.459	2.186	1.898	2.311	1.522	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.976	1.503	0.918			0.461	1.368	2.252	1.972	2.364	1.461	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.371	2.505	0.886			0.505	1.897	2.477	0.785	4.371	1.101	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.84	1.44	0.918			0.284	1.231	1.972	1.703	2.443	1.193	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.676	1.25	0.899			0.548	1.237	1.481	2.031	1.874	1.193	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.725	1.595	0.87			0.243	1.471	2.011	1.316	2.151	0.923	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.828	1.251	0.871				1.138	2.027	1.642	2.102	1.536	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2	1.433	1.28				1.659	2.063	1.988	2.297	1.878	
COVID19 (COVID19 (JANSSEN))	CSF immunoglobulin increased	2.037	1.701					0.953	1.401	0.545	0.89	1.585	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.788	2.199	0.966				1.627	3.007	1.976	2.487	2.319	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.344	1.707	0.916			0.519	1.841	1.875	1.47	3.388	1.073	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	3.011	2.042	0.906			0.527	1.474	1.308	1.242	4.161	0.919	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.29	1.656	0.878				1.075	1.304	1.426	2.867	1.2	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.31	2.267	0.917			0.524	2.414	2.295	0.883	3.94	1.216	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.613	1.803	0.946	0.611		0.631	2.291	2.324	2.141	3.342	1.72	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.013	1.394	0.898			0.384	1.674	2.064	1.762	2.261	1.486	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.074	1.467	0.916			0.465	1.431	2.072	1.986	2.344	1.62	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.607	1.789	0.909			0.462	2.181	2.288	2.995	3.205	2.01	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.737	1.319	0.884				1.281	2.145	1.496	2.052	1.223	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.768	1.35	0.877	0.61		0.314	1.326	2.022	1.526	1.982	1.316	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.838	0.879			1.13	2.002	1.466	0.976	1.854	1.415	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.286	1.253	0.878			0.379	2.192	2.148	1.903	2.531	1.673	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.14	1.444	0.926	0.612		0.333	1.657	2.27	2.193	2.438	1.573	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.969	1.037	0.87			0.441	1.673	2.052	0.8	2.139	1.329	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.313	1.101	0.883			0.411	2.293	1.763	1.294	2.488	1.57	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.676	1.366	0.866			0.405	1.415	1.506	1.693	2.246	1.215	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.847	1.279	0.89				1.482	1.297	1.423	2.293	1.103	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.313	1.845	0.87				1.534	2.894	1.661	2.173	2.178	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.88	1.388	0.896	0.607		0.441	1.377	2.078	1.844	2.287	1.444	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.783	1.306	0.901	0.608		0.331	1.431	2.028	1.68	2.121	1.43	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.616	3.655	0.89				4.039	5.261	5.872	7.242	2.97	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.469	5.593	0.872			0.565	4.729	5.913	6.761	7.748	3.989	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.869	1.333	0.922				1.577	1.987	1.767	2.317	1.582	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.111	1.852	0.874			0.027	1.986	2.574	1.428	2.292	1.703	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.858	1.424	1.044			0.033	1.437	2.038	2.058	2.241	1.529	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.867	1.346	0.888	0.747		0.409	1.651	2.019	1.492	2.494	1.319	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.017	1.395	0.876				1.472	2.129	0.99	2.237	1.315	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.046	1.843	0.875				1.511	1.197	0.719	2.903	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.905	1.425	0.867				1.213	2.176	1.07	1.72	1.671	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.047	1.769					0.962	2.635	1.096	1.704	1.768	
COVID19 (COVID19 (JANSSEN))	Lymphocyte count decreased	1.561	1.142	0.872			0.209	1.092	1.767	1.524	2.003	1.067	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.667	1.282	0.894			0.195	1.057	2.066	1.92	2.134	1.254	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.405	1.146	0.894	0.608			1.034	1.546	1.141	2.03	0.7	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.14	1.615	0.887			0.484	1.862	1.908	2.175	2.448	1.808	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.135	1.52	0.906	0.612		0.462	1.221	2.243	1.917	2.444	1.379	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.616	1.215	0.879			0.334	1.026	2.004	1.292	1.951	0.905	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.882	1.451	0.902			0.349	1.29	2.302	1.506	2.202	1.354	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.076	1.508	0.974			0.486	1	2.218	1.752	1.905	1.889	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.59	1.297	0.893	0.61		0.275	0.941	2.062	2.041	2.407	1.087	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.551	1.264	0.875			0.183	1.239	1.748	1.446	2.262	0.885	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.724	1.319	0.896			0.251	1.143	2.083	1.861	2.037	1.382	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.194	0.724					0.782	0.611		1.958	1.068	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	0.324	0.875			7.692	1.229	1.133	0.821	1.372	1.933	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.755	0.759					3.265	1.063		2.213		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.525	0.86				0.514	1.675	2.155	1.114	2.448	1.431	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.068	1.567	0.872				0.657	1.063	1.688	2.714	0.955	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.773	2.351	0.92	0.611		0.475	1.84	3.063	2.592	3.173	1.793	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.669	1.366	0.896	0.609		0.3	1.551	2.113	1.546	2.198	1.491	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.723	2.031	0.888			0.393	2.065	2.944	2.295	3.325	1.72	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.063	3.504	0.872				4.529	3.85	0.818	6.295	2.64	
COVID19 (COVID19 (JANSSEN))	Post cardiac procedure complication	1.388					0.286	2.13	3.218	3.917	4.861	4.828	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.755	1.268	0.885	0.611		0.365	1.416	1.676	1.59	2.006	1.356	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.025	1.587	0.918	0.746		0.339	1.575	2.439	1.647	2.64	1.514	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.224	1.604	1.537	0.613		0.59	1.716	2.065	2.65	2.504	1.827	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.047	1.524	0.896				1.711	1.593	1.851	1.964	1.817	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.883	1.374	0.896	0.608		0.566	1.451	2.114	1.732	2.127	1.563	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.027	1.426	0.904	0.611		0.348	1.286	2.289	1.806	2.373	1.453	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.4	1.396	0.877			0.532	1.731	1.962	1.379	2.348	1.707	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.229	2.389	1.145			0.531	2.35	2.478	1.216	2.682	3.094	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.031	6.781	0.872			0.646	3.583	6.659	15.657	7.795	5.822	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.388							0.637	0.572	0.568	1.019	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.148	1.558	0.887			0.511	1.451	1.632	1.485	2.308	1.349	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.333	1.892	0.937			0.38	1.675	2.485	1.815	2.588	1.781	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.673	2.104	1.734	0.612		0.656	1.956	2.399	3.506	2.651	2.214	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.41	2.188	0.885				1.182	0.766		1.874	0.681	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.254	1.844	0.872				1.883	1.208	0.637	2.147	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.402	1.441	0.894			0.447	1.886	2.223	2.379	2.797	1.719	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.748	1.882	0.916	0.612		0.525	2.417	2.268	2.94	3.288	2.105	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.527	1.752	0.909			0.447	2.175	2.017	2.035	2.48	1.879	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.884	1.124	0.873				1.261	2.083	1.763	1.966	1.298	
COVID19 (COVID19 (JANSSEN))	Urine ketone body present	1.638	1.197	0.883	0.611		0.278	1.096	1.718	1.577	2.024	0.933	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.206	2.512			0.527	1.356	2.821	6.255	2.211	2.309	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.722	1.241	0.936			0.464	0.943	1.213	2.05	1.613	1.469	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.036	0.87					0.895	1.633	0.965	1.828	1.04	
COVID19 (COVID19 (JANSSEN))	Venogram	2.414	1.938	0.869				2.145	1.701	0.714	2.938	1.05	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.942	2.269				0.604	2.82	1.766	0.677	3.872	1.192	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.173	2.309	0.875				3.944	2.101	0.836	5.041	1.208	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.734	1.304	0.87			0.204	1.61	1.554	1.729	2.015	1.251	
COVID19 (MODERNA))	Exposure via breast milk	1.378	0.836		7.538	0.937		1.218	0.513		1.333	0.923	
COVID19 (MODERNA))	Interchange of vaccine products	0.39	0.945	0.866	0.505	0.53	2.381	0.771	0.589	0.39	0.631	0.597	
COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.368	0.931	0.875		3.012	2.533	0.09	0.061	0.394	2.457	2.525	
COVID19 (MODERNA))	Product dose omission issue	2.052	2.044	0.871			2.328	2	1.948	1.569	1.3	2.11	
COVID19 (COVID19 (PFIZER-	Body height	1.946	1.016	0.875			0.088	0.944	1.398	2.219	1.997	1.923	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.071	0.872			0.691	1.469	1.685	1.926	1.997	1.529	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.761	1.682		0.562	1.033	1.734	1.745	1.816	2.027	1.968	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.761	0.847	0.875	17.944			0.402			0.458	1.346	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.591	0.892		1.28	1.237	1.74	1.58	2.293	2.058	1.845	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.743	0.897		0.608	1.068	1.777	1.94	2.289	2.105	1.937	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	0.752			1.628	1.398	1.891	1.768	2.285	1.711	1.649	
COVID19 (COVID19 (PFIZER-	Weight	2.021	1.349	0.885			0.882	1.528	1.739	2.202	2.003	1.773	

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From: Menschik, David
Sent: Tue, 4 Jan 2022 11:39:01 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211231.xls

Good morning,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 12/31/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.12	1.74	0.907			0.655	1.55	1.966	2.016	2.714	1.675	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.284	1.797	0.887				1.747	2.236	2.268	3.117	1.572	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.019	1.333	0.982			0.461	1.42	1.949	1.835	2.3	1.851	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.911	0.943	0.878			0.523	0.957	0.843	0.651	2.611	1.525	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.022	1.068	0.884				0.961	0.718	0.78	1.684	1.495	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.948	1.334	0.903				1.473	1.431	1.69	2.208	1.288	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.749	2.018	0.906			0.491	2.222	2.064	2.702	3.968	1.477	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.249	1.671	0.876				1.96	1.868	1.224	2.413	1.479	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.485	1.806	0.903			0.43	1.634	2.421	2.369	2.748	1.987	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.787	1.431	0.893			0.38	1.179	2.268	1.187	2.128	1.298	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.309	0.822	0.872			0.066	0.806	1.092	1.923	2.082	1.8	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.245	1.553	0.995	0.612		0.437	1.856	1.962	2.359	2.77	1.636	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.113	1.893	0.883				0.875	2.113	1.434	1.931	1.532	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.449	1.178	0.872				1.147	1.161	1.024	2.482	0.903	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.908	1.492	0.884	0.61		0.34	1.199	2.514	1.677	2.321	1.33	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.773	1.487	0.884	0.609		0.305	1.246	2.264	1.661	2.151	1.311	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.775	1.294	0.886			0.344	1.473	1.85	1.683	2.113	1.373	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.918	1.434	0.898			0.416	1.446	2.206	1.841	2.291	1.511	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.976	1.488	0.915			0.464	1.352	2.301	1.896	2.363	1.438	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.368	2.525	0.888			0.505	1.928	2.47	0.785	4.425	1.101	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.851	1.427	0.916			0.283	1.248	1.997	1.612	2.398	1.194	
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.507	1.08	0.902				1.359	1.376	0.926	2.008	0.795	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.737	1.516	0.874			0.247	1.44	2.078	1.333	2.11	0.919	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.833	1.244	0.879				1.141	2.037	1.61	2.061	1.543	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.995	1.441	1.358				1.603	2.084	1.987	2.324	1.962	
COVID19 (COVID19 (JANSSEN))	CSF immunoglobulin increased	2.034	1.77					0.953	1.463	0.545	0.898	1.583	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.701	2.202	0.873				1.823	3.03	1.086	2.515	2.312	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.004	1.724	0.873				1.305	1.751	1.081	1.742	1.46	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.357	1.729	0.92			0.518	1.876	1.891	1.49	3.438	1.087	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	3.039	2.068	0.907			0.627	1.473	1.909	1.263	4.262	0.919	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.289	1.679	0.875				1.086	1.334	1.45	2.912	1.2	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.309	2.277	0.918			0.524	2.407	2.295	0.893	3.967	1.216	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.651	1.832	0.943	0.611		0.631	2.333	2.345	2.19	3.391	1.742	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.017	1.394	0.9			0.395	1.645	2.034	1.758	2.235	1.502	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.675	1.483	0.918			0.467	1.435	2.067	2.032	2.353	1.636	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.807	1.796	0.978			0.465	2.171	2.297	3.016	3.213	2.015	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.769	1.328	0.888				1.277	2.205	1.463	2.058	1.291	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.685	1.309	0.879	0.61		0.314	1.284	2.054	1.392	1.908	1.299	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.833	0.881			1.133	2.018	1.471	0.98	1.861	1.421	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.286	1.278	0.881			0.379	2.196	2.177	1.917	2.542	1.89	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.145	1.451	0.928	0.612		0.336	1.656	2.285	2.211	2.447	1.577	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.953	1.022	0.874			0.442	1.689	2.026	0.729	2.131	1.314	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.337	1.114	0.866			0.41	2.372	1.763	1.304	2.492	1.802	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.865	1.328	0.889			0.407	1.428	1.599	1.585	2.208	1.205	
COVID19 (COVID19 (JANSSEN))	Glomerular filtration rate decreased	1.775	1.161	0.898				1.014	2.63	1.4	1.965	1.36	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.849	1.28	0.886				1.017	1.909	1.379	2.393	1.105	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.301	1.85	0.873				1.516	2.927	1.889	2.3	2.17	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.848	1.343	0.909	0.607		0.442	1.368	2.106	1.797	2.227	1.446	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.792	1.3	0.902	0.608		0.392	1.402	2.065	1.644	2.105	1.429	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.676	3.858	0.892				4.036	5.157	5.876	7.238	3.96	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.499	3.567	0.875			0.565	4.728	5.768	0.761	7.744	1.713	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.872	1.327	0.92				1.535	1.972	1.759	2.317	1.559	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.114	1.887	0.877			0.027	1.969	2.563	1.517	2.31	1.725	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.861	1.434	1.097			0.033	1.438	2.047	2.08	2.27	1.523	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.911	1.366	0.891	0.747		0.412	1.646	2.048	1.522	2.544	1.326	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.016	1.39	0.878				1.472	2.163	0.99	2.238	1.329	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.045	1.84	0.878				1.509	1.198	0.72	2.887	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.854	1.433	0.87				1.219	2.186	1.083	1.708	1.702	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.02	1.795					0.979	2.006	1.096	1.673	1.796	
COVID19 (COVID19 (JANSSEN))	Lymphocyte count decreased	1.574	1.148	0.874			0.216	1.096	1.796	1.509	2.018	1.067	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.668	1.275	0.896			0.196	1.055	2.099	1.847	2.128	1.234	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.153	1.629	0.888			0.483	1.884	1.868	2.209	2.468	1.61	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.143	1.516	0.91	0.612		0.464	1.234	2.405	1.744	2.438	1.368	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.645	1.224	0.882			0.335	1.035	2.006	1.318	1.94	0.922	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.67	1.391	0.902			0.35	1.247	2.28	1.45	2.155	1.323	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.088	1.518	0.977			0.486	1	2.219	1.768	1.951	1.865	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.588	1.292	0.89	0.61		0.275	0.939	2.048	1.972	2.388	1.084	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.549	1.252	0.878			0.185	1.182	1.789	1.454	2.223	0.896	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.732	1.315	0.897			0.251	1.145	2.164	1.827	2.034	1.376	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.151	0.725					0.762	0.611		1.953	1.869	
COVID19 (COVID19 (JANSSEN))	Off label use	1.339	0.266	0.878			7.656	1.234	1.134	0.821	1.374	1.936	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.754	0.759					0.246	1.063		2.295		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.523	0.86				0.514	1.674	2.192	1.114	2.445	1.431	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.214	1.631	0.875				0.657	1.063	1.82	2.685	0.962	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.772	2.352	0.921	0.611		0.474	1.646	3.063	2.01	3.162	1.793	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.887	1.362	0.896	0.609		0.301	1.556	2.116	1.502	2.191	1.481	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.725	1.978	0.891			0.394	2.046	2.95	2.203	3.298	1.708	
COVID19 (COVID19 (JANSSEN))	Platelet count v	6.669	3.917	0.875				4.027	3.863	6.837	6.381	2.814	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.305					0.968	4.127	3.304	5.945	4.498	4.026	
COVID19 (COVID19 (JANSSEN))	Prothombin time prolonged	2.038	1.598	0.92	0.746		0.342	1.584	2.469	1.652	2.688	1.517	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.222	1.696	1.508	0.612		0.596	1.705	2.069	2.677	2.901	1.804	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.047	1.541	0.896				1.687	1.601	1.878	1.984	1.798	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.881	1.367	0.897	0.608		0.548	1.432	2.143	1.696	2.12	1.556	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.033	1.409	0.905	0.611		0.349	1.273	2.338	1.726	2.363	1.427	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.403	1.362	0.88			0.532	1.691	1.915	1.415	2.398	1.678	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.228	2.434	1.038			0.531	2.308	2.316	1.207	2.647	3.084	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.03	6.786	0.876			0.646	3.575	6.662	15.662	7.823	5.822	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.377							0.637	0.572	0.568	1.919	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.171	1.594	0.889			0.511	1.467	1.632	1.528	2.345	1.364	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.338	1.904	0.941			0.382	1.691	2.488	1.836	2.638	1.778	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.675	2.124	1.758	0.612		0.655	1.953	2.464	3.51	2.86	2.21	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.408	2.205	0.887				1.182	0.766		1.87	0.881	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.289	1.868	0.875				1.944	1.209	0.837	2.2	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.402	1.429	0.896			0.555	1.879	2.202	2.43	2.78	1.714	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.748	1.888	0.915	0.612		0.528	2.438	2.275	2.927	3.312	2.106	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.454	1.72	0.9			0.446	2.215	2.016	1.875	2.48	1.842	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.88	1.098	0.876				1.254	2.049	1.715	1.928	1.369	
COVID19 (COVID19 (JANSSEN))	Urine ketone body present	1.639	1.201	0.886	0.611		0.277	1.07	1.729	1.607	2.028	0.936	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.217	2.511			0.526	1.339	2.777	6.25	2.174	2.302	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.727	1.265	0.938			0.486	0.901	1.202	2.087	1.612	1.467	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.027	0.872					0.899	1.639	0.973	1.823	1.956	
COVID19 (COVID19 (JANSSEN))	Venogram	2.413	1.97	0.873				2.182	1.701	0.719	3.013	1.05	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.939	2.279				0.604	2.808	1.767	0.681	3.903	1.192	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.242	2.331	0.878				3.995	2.148	0.836	5.161	1.208	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	0.833		7.828	0.938		1.218	0.512		1.333	0.923	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.551	0.948	0.873	0.505	0.644	2.299	0.77	0.582	0.387	0.627	0.589	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.304	0.926	0.861		4.619	2.624	0.096	0.051	0.387	2.448	2.526	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.052	2.046	0.874			2.32	2.001	1.948	1.569	1.8	2.11	
COVID19 (COVID19 (PFIZER-	Body height	1.945	1.018	0.878			0.588	0.944	1.386	2.218	1.937	1.523	
COVID19 (COVID19 (PFIZER-	Product counterfeit	3.048	1.971	0.875			0.691	1.491	1.965	1.926	3.005	1.929	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.758	1.578		0.562	1.035	1.732	1.747	1.821	2.027	1.966	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	0.846	0.878	17.903			0.402			0.458	1.347	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.587	0.894		1.279	1.237	1.733	1.969	2.294	2.067	1.837	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.741	0.898		0.608	1.089	1.776	1.94	2.29	2.104	1.935	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	0.752			1.664	1.419	1.884	1.767	2.285	1.721	1.677	
COVID19 (COVID19 (PFIZER-	Weight	2.021	1.347	0.887			0.883	1.529	1.74	2.202	2.092	1.773	

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From: Menschik, David
Sent: Tue, 14 Dec 2021 12:20:02 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: 20211210_USST.xls

Good morning,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 12/10/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211/1	Serious EB05 2021	Fatal EB05 2021	Infant EB05 20211	Child EB05 2021	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.197	1.759	0.903			0.598	1.565	2.061	1.908	2.882	1.382	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.239	1.764	0.886				1.678	2.199	2.135	2.966	1.515	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.963	1.314	0.985			0.459	1.368	1.883	1.818	2.251	1.518	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.932	6.896	0.88			0.521	0.952	0.865	0.664	2.494	1.522	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.025	1.019	0.885				0.939	0.678	0.789	1.611	1.425	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.923	1.315	0.908				1.455	1.371	1.659	2.314	1.141	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.833	2.097	0.905			0.494	2.214	2.079	2.922	4.176	1.469	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.179	1.645	0.879				1.947	1.86	1.126	2.372	1.442	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.482	1.828	0.904			0.429	1.672	2.396	2.349	2.686	2.02	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.765	1.471	0.897			0.373	1.205	2.281	1.126	2.174	1.279	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.308	0.847	0.877			0.588	0.675	1.708	2.031	2.137	1.887	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.57	0.966	0.512		0.437	1.874	1.968	2.352	2.767	1.842	
COVID19 (COVID19 (JANSSEN))	Anefloxia	2.117	1.931	0.887				0.885	2.062	1.455	2.011	1.506	
COVID19 (COVID19 (JANSSEN))	Aspartate aminotransferase abnormal	1.948	1.248	0.876				1.171	1.124	1.892	2.484	1.58	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.911	1.547	0.89	0.509		0.333	1.173	2.522	1.713	2.327	1.314	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.808	1.557	0.89	0.509		3.3	1.276	2.367	1.675	2.151	1.341	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.765	1.28	0.885			0.339	1.49	1.835	1.607	2.073	1.35	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.941	1.464	0.901			0.409	1.463	2.21	1.881	2.297	1.526	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.012	1.539	0.913			0.462	1.385	2.349	1.892	2.467	1.457	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.509	2.566	0.892			0.506	1.871	2.629	0.796	4.493	1.129	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen increased	1.786	1.504	0.885			0.335	1.022	2.021	0.944	1.668	1.28	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.864	1.469	0.916			0.278	1.228	2.059	1.585	2.411	1.188	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.764	1.605	0.875			0.237	1.424	2.137	1.417	2.182	1.95	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.968	1.404	1.328				1.557	1.989	1.93	2.256	1.797	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.737	2.205	0.877				1.838	2.921	1.111	2.383	2.319	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.034	1.765	0.877				1.355	1.669	1.105	1.684	1.508	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.319	1.894	0.926			0.92	1.916	1.902	1.003	3.48	1.129	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.685	1.967	0.911			0.529	1.184	1.332	1.197	3.723	0.943	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.185	1.584	0.878				1.13	1.229	1.327	2.734	1.014	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.267	2.323	0.926			0.622	2.367	2.377	0.813	3.977	1.214	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.642	1.869	0.958	0.511		0.636	2.342	2.395	2.195	3.471	1.755	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.064	1.41	0.902			0.394	1.651	2.003	1.754	2.196	1.513	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.662	1.545	0.921			0.484	1.44	2.103	2.083	2.4	1.851	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.611	1.827	1.013			0.48	2.153	2.282	3.127	3.224	2.021	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.769	1.386	0.894				1.246	2.226	1.569	2.082	1.244	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.688	1.326	0.886	0.61		0.307	1.243	2.035	1.459	1.885	1.304	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.255	1.303	0.853			0.376	2.207	2.126	2.021	2.545	1.666	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.154	1.469	0.93	0.511		0.332	1.686	2.306	2.157	2.473	1.554	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.963	1.922	0.878			0.433	1.707	2.051	0.741	2.182	1.301	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.274	1.927	0.886			0.405	2.34	1.731	1.102	2.462	1.492	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.874	1.36	0.891			3.4	1.435	1.55	1.537	2.124	1.236	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.815	1.271	0.89				1.301	1.34	1.341	2.202	1.071	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.311	1.662	0.976				1.462	2.913	1.695	2.177	2.144	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.846	1.355	0.911	0.506		0.434	1.388	2.089	1.79	2.218	1.442	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.773	1.308	0.906	0.507		0.327	1.45	2.018	1.645	2.097	1.426	
COVID19 (COVID19 (JANSSEN))	Heparin induced thrombocytopenia test	3.664	2.714	0.886				3.884	3.126	6.732	7.144	3.167	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.584	3.57	0.879			0.544	4.684	5.734	0.771	7.693	1.778	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.838	1.309	0.917				1.489	1.54	1.736	2.277	1.524	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.105	1.921	0.882			0.634	1.936	2.837	1.565	2.293	1.733	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.854	1.43	1.097			0.531	1.443	1.998	2.065	2.288	1.462	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.878	1.332	0.896	0.748		0.409	1.644	2	1.45	2.468	1.291	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.014	1.329	0.883				1.404	2.076	1.007	2.192	1.255	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.058	1.676	0.882				1.497	1.197	0.729	2.979	0.733	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.859	1.453	0.875				1.226	2.164	1.098	1.88	1.716	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.046	1.761					0.951	2.545	1.119	1.542	1.88	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.654	1.267	0.899			0.189	1.042	2.063	1.848	2.073	1.226	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.137	1.643	0.884			0.485	1.845	1.896	2.217	2.494	1.57	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.117	1.622	0.911	0.511		0.461	1.226	2.422	1.694	2.389	1.388	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.632	1.224	0.868			0.309	1.014	2.046	1.233	1.868	0.969	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.898	1.439	0.903			0.344	1.29	2.329	1.417	2.2	1.313	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.075	1.48	0.96			0.485	1.008	2.128	1.672	1.95	1.753	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.674	1.309	0.88	0.61		0.268	0.947	2.034	1.966	2.359	1.081	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.565	1.288	0.883			0.186	1.229	1.733	1.44	2.228	0.896	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.727	1.311	0.898			0.247	1.149	2.07	1.815	1.993	1.372	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.188	6.724					0.761	0.61		1.767	0.896	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	6.232	0.88			7.058	0.757	0.629	0.421	1.051	1.544	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.752	0.76					3.134	1.003		2.17		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.522	0.865				0.512	1.689	2.381	1.14	2.578	1.494	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.206	1.642	0.879				0.656	1.063	1.849	2.614	0.962	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.779	2.439	0.921	0.61		0.47	1.869	3.144	2.139	3.165	1.813	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.901	1.414	0.904	0.508		0.292	1.591	2.138	1.518	2.208	1.503	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.735	2.015	0.894			0.393	2.05	3.029	2.244	3.376	1.708	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.062	3.496	0.879				4.482	3.633	6.682	6.265	1.838	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.305					0.97	4.053	3.445	6.104	4.524	4.055	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.024	1.586	0.923	0.745		0.334	1.569	2.419	1.612	2.604	1.492	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.236	1.646	1.603	0.512		0.589	1.716	2.124	2.676	2.523	1.86	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.067	1.521	0.891				1.559	1.562	1.886	1.938	1.725	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.875	1.373	0.894	0.507		0.336	1.417	2.134	1.664	2.083	1.337	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.03	1.421	0.905	0.61		0.353	1.28	2.281	1.759	2.42	1.375	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.388	1.342	0.884			0.53	1.648	1.928	1.457	2.497	1.868	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.236	2.597	1.736			0.529	1.947	2.265	1.177	2.654	3.048	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.026	0.79	0.879			0.645	3.266	6.704	15.851	7.891	6.015	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.372							0.635	0.571	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.13	1.575	0.892			0.515	1.431	1.645	1.389	2.178	1.386	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.35	1.953	0.936			0.376	1.717	2.479	1.779	2.638	1.776	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.677	2.114	1.784	0.512		0.651	1.955	2.378	3.471	2.865	2.183	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	2.913	1.556	0.886				0.954	0.766		1.236	3.66	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.18	1.786	0.878				1.727	1.268	0.641	2.033	0.908	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.425	1.443	0.898			0.65	1.935	2.183	2.408	2.787	1.708	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.738	1.899	0.907	0.512		0.525	2.37	2.258	2.988	3.228	2.134	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.47	1.714	0.901			0.444	2.261	1.969	1.836	2.453	1.852	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.769	1.327	0.881	0.61			1.257	1.939	2.002	1.732	1.645	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.886	1.092	0.88				1.256	2.024	1.716	1.957	1.223	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.357	3.227	2.731			0.834	1.261	2.674	6.769	2.094	2.215	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.723	1.3	0.928			0.464	0.911	1.25	2.038	1.562	1.408	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.046	0.878					0.909	1.598	0.983	1.811	1.053	
COVID19 (COVID19 (JANSSEN))	Venogram	2.447	1.969	0.877				2.202	1.632	0.72	2.87	1.06	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.015	2.324				0.606	2.737	1.786	0.693	3.99	1.199	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.135	2.36	0.882				3.925	1.972	0.846	5.048	1.226	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	6.835		7.798	0.905		1.219	0.572		1.332	0.942	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.885	0.877		0.651	2.182	0.759	0.577	0.381	0.61	3.58	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.366	6.934	0.884		3.996	2.782	0.103	0.065	0.397	2.431	2.517	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.053	2.011	0.878			2.288	2.003	1.946	1.568	1.901	2.108	
COVID19 (COVID19 (PFIZER-	Body height	1.949	1.019	0.882			0.99	0.944	1.302	2.21	1.924	1.906	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.045	1.054	0.879			0.663	1.508	1.688	1.926	2.013	1.526	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.736	1.534		0.507	1.018	1.72	1.788	1.875	2.031	1.98	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.791	6.846	0.861	17.752			0.402			0.458	1.326	
COVID19 (COVID19 (PFIZER-	Immunisation	1.742	1.393	0.88		1.367	1.204	1.577	1.849	2.163	1.963	1.895	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.731	0.901		0.505	1.05	1.767	1.967	2.351	2.124	1.971	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.702	1.755			1.883	1.075	1.875	1.745	2.278	1.741	1.899	
COVID19 (COVID19 (PFIZER-	Weight	2.02	1.316	0.889			0.691	1.531	1.742	2.195	1.991	1.762	

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From: Menschik, David
Sent: Tue, 7 Dec 2021 11:22:50 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211203.xls

Good morning,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 12/3/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.22	1.812	0.905			0.598	1.601	2.067	1.97	2.924	1.634	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.227	1.758	0.86				1.681	2.217	2.081	2.98	1.497	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.001	1.333	0.978			0.457	1.361	1.901	1.84	2.292	1.846	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.965	0.901	0.88			0.52	0.998	0.865	0.677	2.508	1.555	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.047	1.007	0.896				0.954	0.715	0.812	1.631	1.448	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.946	1.325	0.906				1.478	1.393	1.628	2.384	1.126	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.972	2.158	0.902			0.493	2.377	2.1	3.242	4.282	1.494	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.212	1.67	0.881				1.924	1.89	1.14	2.415	1.446	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.501	1.859	0.906			0.427	1.713	2.412	2.418	2.748	2.047	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.816	1.498	0.898			0.371	1.192	2.322	1.155	2.17	1.305	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.307	0.949	0.878			0.599	0.884	1.773	2.095	2.191	1.898	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.585	0.954	0.612		0.433	1.864	1.987	2.407	2.787	1.846	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.117	1.94	0.887				0.897	2.063	1.461	2.013	1.52	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.978	1.27	0.879				1.398	1.112	1.849	2.944	0.918	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.919	1.551	0.891	0.61		0.332	1.206	2.547	1.672	2.371	1.298	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.811	1.564	0.893	0.609		0.298	1.208	2.336	1.634	2.18	1.332	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.806	1.307	0.889			0.336	1.533	1.873	1.831	2.111	1.376	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.98	1.482	0.904			0.403	1.487	2.263	1.873	2.31	1.554	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.093	1.574	0.915			0.456	1.416	2.371	1.942	2.443	1.464	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.51	2.567	0.892			0.505	1.869	2.604	0.797	4.477	1.129	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen increased	1.818	1.583	0.886			0.333	1.051	2.102	0.954	1.668	1.323	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.917	1.536	0.916			0.279	1.222	2.138	1.646	2.533	1.207	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.803	1.661	0.877			0.231	1.421	2.222	1.454	2.198	1.98	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.815	1.232	0.889				1.109	2.027	1.564	1.993	1.544	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.977	1.393	1.367				1.438	2.026	1.9	2.186	1.819	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.737	2.191	0.877				1.806	2.928	1.113	2.379	2.304	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.04	1.766	0.878				1.304	1.67	1.113	1.691	1.907	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.333	1.829	0.922			0.52	1.94	1.902	1.532	3.557	1.114	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.608	1.916	0.911			0.534	1.228	1.333	1.09	3.261	0.964	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.164	1.446	0.878				1.13	1.23	1.331	2.674	1.014	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.255	2.289	0.916			0.521	2.252	2.341	0.814	3.916	1.173	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.676	1.889	0.947	0.611		0.636	2.426	2.412	2.206	3.511	1.768	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.668	1.421	0.902			0.384	1.687	2.067	1.777	3.211	1.515	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.109	1.577	0.917			0.461	1.454	2.133	2.149	2.446	1.674	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.613	1.834	1.007			0.458	2.143	2.253	3.139	3.247	2.014	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.839	1.454	0.896				1.273	2.34	1.607	2.15	1.272	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.717	1.356	0.888	0.61		0.384	1.259	2.09	1.48	1.938	1.31	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.778	0.834	0.886			1.142	2.009	1.474	1.01	1.868	1.425	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.255	1.323	0.885			0.373	2.23	2.131	2.1	2.558	1.719	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.162	1.488	0.925	0.611		0.329	1.718	2.333	2.165	2.531	1.544	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.965	1.024	0.876			0.429	1.704	1.964	0.742	2.155	1.259	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.287	1.037	0.887			0.402	2.333	1.749	1.119	2.488	1.495	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.903	1.307	0.882			0.4	1.436	1.583	1.564	2.111	1.202	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.862	1.318	0.891				1.323	1.378	1.376	2.27	1.106	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.312	1.859	0.878				1.42	2.901	1.714	2.158	2.156	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.807	1.349	0.811	0.607		0.429	1.407	2.113	1.788	2.82	1.498	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.775	1.315	0.91	0.607		0.321	1.457	2.04	1.647	2.104	1.43	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.663	3.712	0.896				3.981	5.112	6.755	7.134	3.152	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.896	5.654	0.88			0.544	5.224	5.739	6.772	7.673	3.102	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.842	1.305	0.915				1.427	1.964	1.722	2.263	1.522	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.099	1.916	0.883			0.022	1.933	2.634	1.583	2.248	1.743	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.844	1.422	1.063			0.03	1.432	2.012	2.066	2.272	1.452	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.898	1.36	0.898	0.746		0.468	1.659	2.079	1.446	2.524	1.304	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.013	1.329	0.884				1.402	2.067	1.017	2.208	1.256	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.113	1.906	0.882				1.564	1.198	0.729	2.974	0.744	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.899	1.469	0.876				1.232	2.18	1.101	1.707	1.718	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.046	1.776					0.955	2.544	1.138	1.557	1.89	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.666	1.28	0.904			0.187	1.044	2.096	1.87	2.095	1.238	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.107	1.693	0.905			0.469	1.629	1.902	2.279	2.514	1.506	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.173	1.577	0.91	0.611		0.458	1.269	2.505	1.72	2.444	1.432	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.651	1.241	0.886			0.337	1.034	2.068	1.214	1.912	0.988	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.866	1.427	0.901			0.34	1.212	2.328	1.406	2.218	1.297	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.048	1.473	0.949			0.484	1.012	2.116	1.698	1.951	1.74	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.586	1.322	0.899	0.61		0.285	0.971	2.09	1.933	2.377	1.087	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.598	1.327	0.884			0.15	1.248	1.792	1.475	2.286	1.91	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.736	1.322	0.902			0.244	1.151	2.099	1.827	2.002	1.384	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.159	0.725					0.761	0.61		1.605	0.896	
COVID19 (COVID19 (JANSSEN))	Off label use	1.339	0.239	0.88			5.71	0.275	0.394	0.324	0.842	1.265	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.783	0.758					3.122	1.003		2.17		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.535	0.868				0.511	1.687	2.362	1.142	2.558	1.424	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.211	1.633	0.878				0.656	1.064	1.883	2.637	0.962	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.779	2.485	0.922	0.61		0.469	1.841	3.139	2.199	3.138	1.896	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.868	1.407	0.906	0.609		0.291	1.591	2.125	1.511	2.209	1.49	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.734	2.006	0.894			0.388	2.038	3.081	2.23	3.387	1.704	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.06	3.906	0.66				4.466	3.609	0.662	6.243	1.624	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.304					0.664	4.059	3.449	6.226	4.576	4.014	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.098	1.624	0.923	0.745		0.331	1.587	2.485	1.629	2.696	1.497	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.234	1.849	1.391	0.612		0.586	1.796	3.137	2.712	2.88	1.886	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.067	1.549	0.894				1.574	1.563	1.919	1.947	1.732	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.902	1.398	0.901	0.608		0.53	1.479	2.18	1.69	2.111	1.595	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.057	1.448	0.908	0.61		0.562	1.515	2.323	1.759	2.468	1.384	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.407	1.405	0.884			0.535	1.612	1.963	1.482	2.383	1.707	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.228	2.569	1.694			0.529	1.899	2.279	1.19	2.68	3.049	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.025	6.788	0.88			0.645	3.256	6.698	15.886	7.887	6.915	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.378							0.635	0.572	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.164	1.587	0.899			0.515	1.446	1.664	1.338	2.137	1.411	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.36	1.865	0.934			0.375	1.719	2.462	1.795	2.662	1.776	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.677	2.121	1.779	0.612		0.655	1.963	2.387	3.449	2.808	2.181	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	2.264	1.286	0.884				0.955	0.766		1.237	1.68	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.216	1.806	0.875				1.779	1.208	0.641	2.084	0.908	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.407	1.464	0.899			0.645	1.912	2.193	2.464	2.781	1.726	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	1.914	0.908	0.612		0.527	2.328	2.291	2.971	3.226	2.135	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.515	1.733	0.898			0.446	2.318	2.023	1.826	2.484	1.894	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.888	1.097	0.881				1.27	2.001	1.73	1.984	1.237	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.843	1.207	0.882	0.611		0.315	0.868	2.079	1.301	1.837	1.054	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.337	1.169	2.604			0.531	1.249	2.605	5.621	2.058	2.199	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.714	1.329	0.943			0.466	0.92	1.242	2.094	1.544	1.53	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.054	0.876					0.915	1.599	0.984	1.823	1.053	
COVID19 (COVID19 (JANSSEN))	Venogram	2.447	1.945	0.878				2.105	1.662	0.72	2.861	1.914	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.086	2.341				0.605	2.884	1.786	0.694	3.974	1.216	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.171	2.376	0.883				3.971	1.972	0.848	5.104	1.226	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	0.833		7.911	0.896		1.219	0.511		1.33	0.941	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.884	0.878		0.655	2.123	0.754	0.569	0.377	0.602	0.572	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.263	0.932	0.886		3.714	2.753	0.106	0.095	0.498	2.414	2.485	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.055	2.011	0.879			2.295	2.008	1.948	1.567	1.891	2.11	
COVID19 (COVID19 (PFIZER-	Body height	1.944	1.019	0.883			0.593	0.944	1.362	2.211	1.924	1.508	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.045	1.059	0.86			0.665	1.306	1.677	1.951	2.012	1.536	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.28	1.732	1.513		0.51	1.011	1.712	1.781	1.866	2.036	1.983	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.791	0.846	0.882	17.898			0.401			0.458	1.327	
COVID19 (COVID19 (PFIZER-	Immunisation	1.742	1.394	0.889		0.897	1.193	1.491	1.704	2.079	1.995	1.019	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.728	0.902			1.06	1.762	1.96	2.347	2.123	1.969	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	0.752			1.723	1.34	1.867	1.746	2.282	1.757	1.721	
COVID19 (COVID19 (PFIZER-	Weight	2.02	1.312	0.86			0.897	1.537	1.736	2.196	1.998	1.763	

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From: Menschik, David
Sent: Tue, 30 Nov 2021 11:30:14 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211126.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 11/26/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.208	1.822	0.903			0.584	1.591	2.067	2.001	2.831	1.654	
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.222	1.759	0.891				1.642	2.258	2.032	2.932	1.492	
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.001	1.361	0.979			0.455	1.323	1.944	1.88	2.358	1.842	
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.977	6.902	0.88			0.52	0.996	0.809	0.68	2.466	1.554	
COVID19 (COVID19 (JANSEN))	Adverse event	2.062	6.992	0.885				0.965	0.727	0.767	1.623	1.471	
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.932	1.347	0.906				1.502	1.403	1.601	2.386	1.135	
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.989	2.168	0.896			0.497	2.297	2.068	3.385	4.295	1.484	
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.212	1.674	0.88				1.869	1.906	1.147	2.428	1.423	
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.519	1.89	0.898			0.427	1.706	2.448	2.429	2.768	2.059	
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.867	1.591	0.896			0.386	1.231	2.411	1.181	2.238	1.336	
COVID19 (COVID19 (JANSEN))	Antibody test	2.303	6.836	0.877			0.569	0.887	1.702	1.906	2.154	1.875	
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.228	1.599	0.965	0.512		0.435	1.853	1.99	2.45	2.801	1.64	
COVID19 (COVID19 (JANSEN))	Anoxia	2.131	1.966	0.89				0.895	2.088	1.485	2.031	1.529	
COVID19 (COVID19 (JANSEN))	Antigram cerebil abnormal	1.978	1.278	0.879				1.284	1.77	1.89	2.84	0.918	
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.947	1.605	0.891	0.61		0.329	1.204	2.627	1.716	2.423	1.301	
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.817	1.59	0.89	0.509		0.293	1.282	2.352	1.679	2.224	1.304	
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.785	1.295	0.884			0.332	1.509	1.798	1.661	2.086	1.35	
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.964	1.499	0.904			0.399	1.459	2.27	1.907	2.317	1.544	
COVID19 (COVID19 (JANSEN))	Blood chloride increased	2.078	1.606	0.913			0.455	1.412	2.362	2.004	2.482	1.478	
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.564	2.618	0.892			0.568	1.865	2.615	6.813	4.599	1.133	
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.882	1.539	0.908			0.273	1.215	2.077	1.636	2.551	1.142	
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.811	1.684	0.875			0.225	1.428	2.235	1.471	2.185	0.995	
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.817	1.233	0.884				1.059	2.012	1.56	2.022	1.497	
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	1.978	1.381	1.368				1.372	1.966	1.906	2.151	1.786	
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.722	2.204	0.877				1.739	2.906	1.134	2.42	2.29	
COVID19 (COVID19 (JANSEN))	CSF red blood cell count positive	2.062	1.81	0.877				1.292	1.666	1.13	1.624	1.522	
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.308	1.643	0.925			0.519	1.936	1.901	1.54	3.006	1.958	
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.666	1.92	0.911			0.534	1.227	1.331	1.092	3.235	0.964	
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.154	1.484	0.879				1.129	1.239	1.342	2.561	1.024	
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.306	2.299	0.916			0.621	2.245	2.305	0.82	3.804	1.175	
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.702	1.918	0.947	0.511		0.633	2.403	2.436	2.257	3.581	1.763	
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	2.065	1.441	0.901			0.391	1.662	2.02	1.788	2.223	1.523	
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.121	1.581	0.901			0.484	1.481	2.13	2.147	2.48	1.676	
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.61	1.851	1.049			0.456	2.144	2.254	3.241	3.261	2.017	
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.861	1.488	0.896				1.284	2.326	1.65	2.171	1.268	
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.707	1.358	0.886	0.61		0.391	1.265	2.08	1.487	1.957	1.274	
COVID19 (COVID19 (JANSEN))	Feeling cold	1.778	6.828	0.885			1.134	2.012	1.477	1.018	1.873	1.426	
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.29	1.308	0.884			0.375	2.186	2.134	2.021	2.56	1.851	
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.155	1.49	0.916	0.511		0.328	1.693	2.329	2.178	2.504	1.546	
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.97	1.013	0.878			0.426	1.698	1.962	0.746	2.161	1.225	
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.276	1.019	0.884			0.408	2.281	1.723	1.121	2.521	1.434	
COVID19 (COVID19 (JANSEN))	Globulins increased	1.928	1.442	0.892			0.4	1.432	1.554	1.64	2.098	1.293	
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.708	1.24	0.892				1.256	1.29	1.346	2.144	1.04	
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.317	1.844	0.876				1.402	2.864	1.758	2.151	2.125	
COVID19 (COVID19 (JANSEN))	Haemstocrit decreased	1.849	1.368	0.91	0.507		0.425	1.386	2.117	1.79	2.224	1.434	
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.779	1.318	0.896	0.507		0.381	1.481	2.037	1.693	2.118	1.406	
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.558	3.884	0.896				3.986	4.968	6.279	7.058	2.873	
COVID19 (COVID19 (JANSEN))	Hepain-induced thrombocytopenia test positive	6.887	3.547	0.879			0.544	5.201	5.71	6.662	7.648	1.816	
COVID19 (COVID19 (JANSEN))	Hypnosis	1.845	1.3	0.914				1.373	1.902	1.732	2.231	1.511	
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.69	1.912	0.88			0.021	1.939	2.567	1.61	2.23	1.726	
COVID19 (COVID19 (JANSEN))	Intensive care	1.839	1.421	1.024			0.029	1.4	2.008	2.057	2.24	1.443	
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.877	1.347	0.892	0.745		0.402	1.836	2.016	1.472	2.501	1.277	
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.013	1.336	0.883				1.399	2.092	1.018	2.212	1.253	
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	2.131	1.926	0.882				1.562	1.196	0.735	2.947	0.747	
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.992	1.489	0.875				1.235	2.166	1.12	1.703	1.732	
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.015	1.727					0.871	2.441	1.147	1.487	1.818	
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.674	1.29	0.901			0.184	1.042	2.093	1.89	2.105	1.23	
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.172	1.69	0.885			0.488	1.817	1.943	2.328	2.528	1.605	
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.147	1.571	0.907	0.511		0.459	1.252	2.446	1.712	2.492	1.415	
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.669	1.26	0.884			0.335	1.049	2.065	1.239	1.945	0.975	
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.887	1.439	0.897			0.339	1.317	2.336	1.356	2.191	1.282	
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.002	1.471	0.946			0.482	1.024	2.106	1.659	1.953	1.716	
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.669	1.354	0.892	0.61		0.261	0.96	2.136	1.984	2.434	1.08	
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.589	1.318	0.886			0.163	1.196	1.812	1.493	2.271	0.894	
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.733	1.325	0.897			0.24	1.151	2.08	1.827	1.993	1.374	
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.189	6.724					0.761	0.61		1.602	0.896	
COVID19 (COVID19 (JANSEN))	Off label use	1.339	6.301	0.882			6.614	0.276	0.4	0.328	0.85	1.24	
COVID19 (COVID19 (JANSEN))	On and off phenomenan	1.763	6.759					3.108	1.062		2.18		
COVID19 (COVID19 (JANSEN))	Pain assessment	2.535	6.889				0.51	1.746	2.297	1.144	2.58	1.433	
COVID19 (COVID19 (JANSEN))	Peripheral embolism	3.372	1.709	0.875				0.656	1.063	2.144	2.621	0.969	
COVID19 (COVID19 (JANSEN))	Platelet count	2.779	2.494	0.921	0.61		0.482	1.845	3.129	2.269	3.152	1.867	
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.886	1.414	0.901	0.509		0.292	1.574	2.101	1.543	2.202	1.483	
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.737	2.03	0.894			0.39	2.004	3.142	2.24	3.43	1.669	
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.05	3.505	0.88				4.447	3.576	6.882	6.228	1.944	
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.393					0.656	4.016	3.414	5.92	4.57	3.94	
COVID19 (COVID19 (JANSEN))	Prothombin time prolonged	2.037	1.617	0.914	0.745		0.326	1.562	2.466	1.614	2.681	1.481	
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.237	1.666	1.57	0.512		0.583	1.703	2.15	2.73	2.567	1.855	
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.668	1.883	0.884				1.288	1.33	1.338	1.942	1.724	
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.902	1.402	0.895	0.508		0.524	1.48	2.181	1.684	2.12	1.578	
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	2.061	1.456	0.904	0.61		0.352	1.319	2.276	1.787	2.478	1.362	
COVID19 (COVID19 (JANSEN))	Subarachnoid haemorrhage	1.79	1.132	1.456			0.544	1.52	1.65	0.972	2.048	0.782	
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.42	1.35	0.884			0.535	1.585	1.978	1.522	2.324	1.753	
COVID19 (COVID19 (JANSEN))	Superior sagittal sinus thrombosis	1.585	1.206	0.877			0.544	1.134	0.828	0.645	2.098	0.67	
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.221	2.55	1.617			0.529	1.898	2.365	1.196	2.684	3.083	
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.028	6.796	0.88			0.665	3.244	6.762	15.691	7.794	6.058	
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.375							0.635	0.572	0.568	1.026	
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.104	1.616	0.88			0.514	1.413	1.667	1.352	2.165	1.398	
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.347	1.966	0.926			0.38	1.734	2.443	1.783	2.643	1.771	
COVID19 (COVID19 (JANSEN))	Thrombosis	2.677	2.131	1.807	0.512		0.651	1.965	2.362	3.479	2.822	2.166	
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.216	1.812	0.876				1.776	1.219	0.642	2.131	0.907	
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.424	1.47	0.898			0.646	1.905	2.165	2.5	2.771	1.72	
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.75	1.935	0.905	0.512		0.527	2.307	2.307	3.091	3.304	2.118	
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.65	1.767	0.901			0.447	2.331	2.009	1.897	2.524	1.883	
COVID19 (COVID19 (JANSEN))	Ultrasound scan	1.769	1.345	0.882	0.61			1.266	1.967	2.006	1.747	1.883	
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.866	1.113	0.88				1.283	2.059	1.764	1.982	1.23	
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.644	1.211	0.881	0.511		0.31	0.882	2.028	1.265	1.811	1.051	
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.334	1.154	2.632			0.529	1.232	2.602	5.662	2.028	2.217	
COVID19 (COVID19 (JANSEN))	Vaccine breakthrough infection	1.719	1.417	0.938			0.464	0.906	1.298	2.18	1.611	1.584	
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.054	6.877					0.913	1.565	0.985	1.824	1.051	
COVID19 (COVID19 (JANSEN))	Venogram	2.447	1.962	0.877				2.019	1.662	0.721	2.823	1.012	
COVID19 (COVID19 (JANSEN))	Venogram abnormal	3.088	2.342				0.604	2.648	1.782	0.694	3.845	1.213	
COVID19 (COVID19 (JANSEN))	Venogram normal	4.19	2.374	0.882				3.833	2.012	6.849	5.088	1.223	
COVID19 (COVID19 (JANSEN))	White blood cell count decreased	1.736	1.317	0.882			0.175	1.65	1.538	1.645	2.004	1.217	
COVID19 (MODERNA))	Exposure via breast milk	1.376	6.833		7.937	0.895		1.206	0.512		1.322	0.941	
COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.86	0.878		0.661	2.091	0.747	0.566	0.375	0.595	0.568	
COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.36	6.928	0.884		3.677	2.722	0.109	0.044	0.42	2.391	2.463	
COVID19 (MODERNA))	Product dose omission issue	2.057	2.011	0.876			2.245	2.006	1.951	1.566	1.3	2.113	
COVID19 (PFIZER-	Body height	1.944	1.019	0.882			0.584	0.927	1.352	2.213	1.923	1.507	
COVID19 (PFIZER-	Disease recurrence	2.051	1.072	0.88			0.667	1.509	1.695	1.946	2.01	1.573	
COVID19 (PFIZER-	Drug ineffective	2.89	1.795	1.019			1.617	1.715	1.782	1.979	2.04	1.995	
COVID19 (PFIZER-	Exposure via breast milk	0.791	6.847	0.881	17.415			0.407			0.461	1.325	
COVID19 (PFIZER-	Immunisation	1.741	1.221	0.884		0.915	1.153	1.446	1.717	2.053	1.851	1.586	
COVID19 (PFIZER-	Investigation	2.169	1.727	0.901			1.658	1.756	1.966	2.346	2.124	1.964	
COVID19 (PFIZER-	Product preparation issue	1.752	6.752			1.933	1.35	1.867	1.73	2.275	1.761	1.728	
COVID19 (PFIZER-	Weight	2.02	1.313	0.89			0.866	1.539	1.729	2.202	1.998	1.77	

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From: Menschik, David
Sent: Tue, 2 Nov 2021 16:09:28 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211029.xls

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/29/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021(2)	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.193	1.805	0.884			0.586	1.611	1.918	1.781	2.71	1.295	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.203	1.784	0.884				1.639	2.225	1.925	2.897	1.453	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.961	1.312	0.94			0.467	1.25	1.753	1.763	2.201	1.536	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.059	0.89	0.883				0.841	0.73	0.731	2.382	1.564	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.054	1.005	0.884				0.997	0.684	0.72	1.588	1.436	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.933	1.327	0.901				1.536	1.353	1.533	2.377	1.092	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.004	2.206	0.894			0.499	2.273	2.061	3.279	4.386	1.354	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.188	1.656	0.881				1.731	1.803	1.216	2.342	1.366	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.546	1.949	0.893			0.435	1.713	2.5	2.36	2.781	2.056	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.911	1.663	0.896			0.388	1.313	2.417	1.022	2.314	1.301	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.348	0.875	0.86			0.578	0.899	1.74	1.906	2.094	1.934	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.243	1.669	1.064	0.612		0.434	1.853	1.996	2.599	2.886	1.613	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.063	1.919	0.882				0.864	1.913	1.423	1.772	1.527	
COVID19 (COVID19 (JANSSEN))	Aspartate aminotransferase abnormal	1.819	1.221	0.881				1.16	1.178	1.356	2.493	0.938	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.886	1.591	0.882	0.909		0.336	1.239	2.441	1.579	2.298	1.223	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.719	1.542	0.88	0.908		0.295	1.292	2.276	1.363	2.08	1.189	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.765	1.293	0.885			0.339	1.508	1.812	1.531	2.075	1.25	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.919	1.486	0.893			0.407	1.43	2.254	1.728	2.244	1.466	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.953	1.539	0.901			0.459	1.439	2.252	1.768	2.38	1.351	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.517	2.66	0.89			0.511	1.852	2.44	0.738	4.604	1.073	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.889	1.633	0.894			0.286	1.166	2.144	1.545	2.602	1.994	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.745	1.607	0.88			0.214	1.401	2.065	1.241	2.051	1.92	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.915	1.326	1.002				1.338	1.762	1.81	2.002	1.676	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.655	2.194	0.88				1.687	2.6	1.159	2.37	2.15	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.306	1.863	0.913			0.523	2.049	1.915	1.443	3.458	1.998	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.55	1.961	0.899			0.538	1.291	1.268	0.995	3.353	0.971	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.113	1.337	0.861				1.123	1.139	1.306	2.497	1.04	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.489	2.496	0.902			0.525	2.672	2.562	0.825	4.162	1.222	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.748	1.987	0.932	0.611		0.636	2.375	2.48	2.271	3.611	1.773	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.69	1.592	0.897			0.496	1.708	2.016	1.752	3.334	1.523	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.146	1.636	0.907			0.467	1.494	2.172	2.063	2.473	1.64	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.665	1.872	0.923			0.486	2.176	2.273	3.254	3.227	2.027	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.797	1.486	0.877				1.296	2.301	1.45	2.121	1.182	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.765	0.784	0.88			1.137	2.001	1.564	1.004	1.894	1.404	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.295	1.293	0.888			0.377	2.208	2.089	1.924	2.542	1.633	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.16	1.522	0.912	0.611		0.333	1.692	2.371	2.148	2.583	1.483	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.953	0.994	0.881			0.427	1.707	1.901	0.756	2.224	1.182	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.358	1.038	0.888			0.419	2.208	1.79	1.136	2.621	1.448	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.659	1.229	0.887				1.192	1.21	1.243	2.131	0.913	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.297	1.894	0.88				1.399	2.84	1.742	2.162	2.101	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.831	1.372	0.896	0.606		0.433	1.372	2.118	1.689	2.224	1.339	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.767	1.316	0.898	0.607		0.393	1.447	2.023	1.554	2.08	1.347	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.69	2.695	0.89				4.027	4.856	6.152	7.14	2.473	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.814	3.509	0.882			0.569	5.092	5.536	0.666	7.528	1.388	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.79	1.24	0.893				1.254	1.788	1.61	2.038	1.412	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.079	1.841	0.881			0.618	1.874	3.478	1.494	2.217	1.887	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.787	1.422	0.984			0.029	1.404	1.978	1.906	2.188	1.382	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.831	1.319	0.882	0.746		0.401	1.626	1.926	1.382	2.362	1.219	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.905	1.225	0.886				1.367	1.945	0.904	2.038	1.205	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.149	2.006	0.882				1.599	1.139	0.744	2.78	0.765	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.9	1.537	0.88				1.251	2.161	1.098	1.698	1.73	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.039	1.797					0.9	2.342	1.173	1.497	1.795	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.568	1.243	0.885			0.184	1.037	2.042	1.66	2.002	1.137	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.186	1.736	0.887			0.505	1.811	1.937	2.319	2.539	1.805	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.052	1.483	0.886	0.611		0.465	1.331	2.314	1.409	2.27	1.273	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.78	1.279	0.885			0.351	1.275	2.226	1.031	2.127	1.064	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.055	1.533	0.937			0.496	0.996	2.061	1.654	1.988	1.845	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.585	1.346	0.89	0.61		0.224	0.964	2.111	1.893	2.408	1.02	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.616	1.349	0.906			0.15	1.222	1.609	1.342	2.492	0.918	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.645	1.267	0.896			0.24	1.138	2.011	1.594	1.899	1.256	
COVID19 (COVID19 (JANSSEN))	Off label use	1.449	0.216	0.881			5.946	0.324	0.471	0.383	0.911	1.253	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.746	0.757					3.03	0.998		2.15		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.592	0.876				0.524	1.782	2.289	1.165	2.634	1.473	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.51	1.765	0.882				0.656	1.068	2.571	2.482	0.974	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.755	1.489	0.927	0.611		0.485	1.886	3.113	1.789	3.11	1.816	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.848	1.405	0.897	0.609		0.295	1.563	2.037	1.463	2.161	1.415	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.762	2.085	0.894			0.404	2.095	3.1	2.302	3.484	1.7	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.998	3.519	0.882				4.353	3.241	0.685	6.13	1.931	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.265					0.885	4.019	3.183	6.153	4.622	3.771	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.945	1.577	0.902	0.744		0.265	1.521	2.337	1.508	2.523	1.375	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.246	1.679	1.041	0.612		0.584	1.667	2.164	2.68	2.537	1.83	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.064	1.552	0.888				1.53	1.473	2.101	1.91	1.964	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.69	1.402	0.886	0.607		0.537	1.515	2.147	1.571	2.102	1.508	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.021	1.434	0.89	0.609		0.358	1.35	2.183	1.646	2.41	1.249	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.79	1.171	0.905			0.549	1.015	1.074	0.899	2.062	0.909	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.227	1.169	0.884			0.539	1.374	1.776	1.416	1.878	1.735	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.68	1.351	0.883			0.549	1.132	0.826	0.648	2.785	1.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.248	2.722	1.007			0.553	1.86	3.329	1.198	2.73	3.184	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.038	6.797	0.883			0.648	3.617	6.722	15.126	7.93	5.992	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.267							0.634	0.577	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.134	1.701	0.899			0.518	1.432	1.665	1.385	2.264	1.365	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.343	2.013	0.91			0.397	1.788	2.361	1.672	2.837	1.834	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.682	2.18	1.872	0.612		0.572	2.019	2.396	3.547	2.866	2.159	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.302	1.947	0.882				1.966	1.242	0.645	2.375	0.915	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.39	1.432	0.896			0.648	1.923	2.196	2.365	2.752	1.676	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	1.964	0.899	0.612		0.54	2.309	2.285	3.146	3.208	2.146	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.603	1.868	0.895			0.456	2.588	2.02	1.841	2.736	1.848	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.945	1.14	0.883				1.356	2.119	1.725	2.053	1.288	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.651	1.255	0.879	0.611		0.31	0.885	2.008	1.222	1.88	1.005	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.239	1.003	2.537			0.539	1.184	2.391	4.976	1.861	2.082	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.661	0.881					0.929	1.569	0.976	1.822	1.071	
COVID19 (COVID19 (JANSSEN))	Venogram	2.684	2.005					2.15	1.758	0.721	3.098	0.996	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.385	3.522				0.606	2.964	1.884	0.703	4.205	1.193	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.266	2.611	0.882				3.874	2.212	0.845	5.213	1.19	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.371	0.832		7.378	0.884		1.207	0.513		1.329	1.004	
COVID19 (COVID19 (MODERNA))	Headache	0.968	0.959	0.888	6		0.301	0.943	0.984	1.013	0.954	1.019	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.357	0.947	0.887		1.156	2.623	0.115	0.04	0.493	2.36	2.417	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.042	1.997	0.881			2.204	2.002	1.945	1.574	1.884	2.12	
COVID19 (COVID19 (PFIZER-	Body height	1.931	1.021	0.885			1.6	0.927	1.307	2.186	1.908	1.496	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.05	1.049	0.882			0.637	1.527	1.69	1.944	2.007	1.596	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.284	1.717	1.305			1.024	1.728	1.792	1.941	2.04	1.98	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.726	0.846	0.884	13.852			0.393			0.422	1.14	
COVID19 (COVID19 (PFIZER-	Investigation	2.141	1.707	0.901			1.048	1.729	1.928	2.309	2.11	1.929	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.317	0.329	0.875		3.945	0.321	0.16	0.049	0.301	0.294	1.34	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.768	0.751				1.343	1.853	1.799	2.276	1.784	1.728	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.336	0.891			0.854	1.536	1.728	2.152	2.001	1.78	

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From: Menschik, David
Sent: Tue, 19 Oct 2021 10:13:43 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211015.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/15/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.106	1.812	0.88			0.605	1.606	1.858	1.679	2.834	1.178	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.992	1.613	0.866				1.452	2.119	1.594	2.373	1.38	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.837	1.253	0.923			0.486	1.227	1.684	1.605	2.146	1.362	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.102	6.887	0.871				0.86	0.729	0.742	2.444	1.595	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.788	1.202	0.886				1.324	1.344	1.279	2.011	1.034	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.997	2.232	0.879			0.597	1.875	2.074	3.606	4.256	1.378	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.088	1.585	0.868				1.737	1.662	1.104	2.142	1.353	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.57	2.006	0.883			0.453	1.72	2.596	2.197	2.98	1.997	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.784	1.529	0.873			0.379	1.193	2.464	0.771	2.078	1.248	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.249	6.812	0.867			0.584	0.82	1.668	2.002	2.017	1.83	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.224	1.681	1.000	0.612		0.445	1.875	2.61	2.42	2.861	1.593	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.823	1.172	0.868				0.911	1.172	1.401	2.217	0.937	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.731	1.375	0.87	0.61		0.342	1.144	2.408	1.211	1.968	1.209	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.887	1.491	0.889	0.609		0.368	1.217	2.165	1.199	1.824	1.366	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.779	1.366	0.869			0.413	1.324	2.154	1.444	2.008	1.37	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.829	1.381	0.878			0.471	1.283	2.179	1.495	2.134	1.259	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.376	5.847	0.879			0.519	1.524	2.464	0.733	3.453	1.819	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.717	1.443	0.879			0.264	1.114	1.998	1.285	2.275	0.992	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.672	1.549	0.866			0.194	1.296	2.068	1.211	1.973	0.876	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.628	2.203	0.867				1.571	2.662	1.176	2.255	2.128	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.671	1.176	0.874				1.266	0.942		2.165	0.613	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.248	1.849	0.908			0.531	1.794	1.927	1.45	3.271	1.107	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.564	2.01	0.892			0.598	1.147	13	1.009	3.342	0.978	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.021	1.444	0.868				1.005	1.096	1.366	2.273	1.015	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.415	2.509	0.886			0.532	2.626	2.504	0.823	4.048	1.231	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.719	2.002	0.944	0.611		0.649	2.242	2.479	2.213	3.526	1.764	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.932	1.429	0.876			0.419	1.039	1.989	1.013	2.091	1.472	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.064	1.627	0.896			0.485	1.465	2.14	1.905	2.387	1.592	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.553	1.841	0.905			0.477	2.193	2.192	3.194	3.138	1.99	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.649	1.321	0.868				1.161	2.264	1.241	1.844	1.153	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.281	1.309	0.877			0.385	2.159	2.082	1.949	2.539	1.585	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.122	1.479	0.9	0.611		0.342	1.653	2.353	1.959	2.568	1.42	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.975	1.093	0.868			0.436	1.666	1.968	0.777	2.179	1.14	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.301	6.978	0.874			0.43	2.346	1.757	0.933	2.618	1.355	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.277	1.872	0.866				1.322	2.837	1.659	2.121	2.051	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.718	1.304	0.88	0.606		0.442	1.266	2.033	1.549	2.085	1.25	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.42	3.584	0.875				3.943	4.472	5.482	6.847	2.105	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.722	3.447	0.869			0.557	5.027	5.136	0.668	7.434	1.066	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.047	1.954	0.869			0.018	1.847	2.482	1.52	2.171	1.847	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.728	1.402	0.949			0.027	1.356	1.929	1.809	2.13	1.318	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.748	1.255	0.861	0.746		0.413	1.598	1.867	1.223	2.104	1.228	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.991	1.283	0.874				1.387	1.963	0.913	2.059	1.22	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.128	2.026	0.909				1.564	1.142	0.745	2.464	0.774	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.823	1.419	0.866				1.205	2.072	1.053	1.662	1.618	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.971	1.764					0.906	2.265	1.083	1.468	1.712	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.199	1.749	0.871			0.518	1.8	1.806	2.289	2.881	1.998	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	1.9	1.35	0.861	0.611		0.47	1.333	2.108	1.214	2.107	1.15	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.662	1.212	0.863			0.359	1.218	2.28	0.796	2.008	1.012	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.515	1.296	0.882	0.61		0.223	0.95	2.048	1.731	2.281	0.973	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.561	1.236	0.871			0.121	1.249	1.674	1.093	2.174	0.768	
COVID19 (COVID19 (JANSSEN))	Off label use	1.577	6.267	0.867			5.617	0.37	0.545	0.438	0.982	1.4	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.809	0.757					2.927	1.019		2.346		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.502	6.856				0.536	1.736	2.213	1.084	2.455	1.43	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.768	1.895	0.888				0.656	1.078	2.616	2.32	0.995	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.697	2.454	0.924	0.611		0.496	1.91	3.065	1.736	3.128	1.753	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.841	1.436	0.891	0.61		0.303	1.572	2.05	1.44	2.184	1.406	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.766	2.13	0.882			0.413	2.106	3.052	2.406	3.472	1.704	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.039	3.56	0.869				4.305	2.935	0.688	6.038	2.07	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.101					0.604	3.999	2.96	3.913	4.077	3.99	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.829	1.48	0.877	0.744		0.274	1.473	2.261	1.272	2.328	1.291	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.204	1.672	0.968	0.612		0.596	1.666	2.115	2.561	2.533	1.787	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.005	1.55	0.877				1.549	1.361	2.105	1.913	1.56	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.789	1.333	0.871	0.608		0.551	1.415	2.094	1.412	1.983	1.425	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.877	1.325	0.869	0.609		0.388	1.301	2.068	1.432	2.208	1.169	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.222	1.145	0.872			0.547	1.398	1.764	1.277	1.844	1.755	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.143	2.642	1.836			0.541	2.018	2.364	0.89	2.666	3.068	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.068	6.603				0.653	3.897	6.602	15.3	8.267	5.807	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.075							0.634	0.582	0.57	1.019	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.037	1.602	0.877			0.531	1.337	1.515	1.416	2.108	1.28	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.217	1.957	0.889			0.407	1.797	2.218	1.539	2.602	1.595	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.658	2.186	1.862	0.612		0.591	2.02	2.385	3.517	2.839	2.156	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.26	1.923	0.899				1.935	1.237	0.647	2.291	0.913	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.277	1.298	0.878			0.656	1.812	2.065	2.223	2.571	1.633	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	2.002	0.884	0.612		0.55	2.273	2.278	3.265	3.222	2.129	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.469	1.761	0.877			0.47	2.092	1.665	1.465	2.47	1.941	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.744	1.283	0.865	0.61			1.18	1.961	2.005	1.702	1.838	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.98	1.171	0.871				1.373	2.174	1.771	2.104	1.298	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.128	2.788	2.281			0.379	1.083	2.312	4.888	1.771	1.997	
COVID19 (COVID19 (JANSSEN))	Venogram	2.791	2.076					2.114	1.801	0.722	3.193	1.015	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.365	2.534				0.617	2.907	1.862	0.704	4.132	1.195	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.31	3.527	0.869				3.636	2.489	0.883	5.358	1.077	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.303	6.769		6.795	0.832		1.193	0.513		1.295	0.945	
COVID19 (COVID19 (MODERNA))	Headache	0.968	6.961	0.867	5.591		0.308	0.945	0.985	1.014	0.954	1.027	
COVID19 (COVID19 (MODERNA))	No adverse event	1.212	6.842	0.875		0.271	2.015	0.915	0.897	0.752	1.084	1.202	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.367	6.928	0.872		1.348	2.583	0.144	0.065	0.578	2.398	2.43	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.985	1.87	0.868			2.087	1.954	1.912	1.549	1.856	2.071	
COVID19 (COVID19 (PFIZER-	Body height	1.933	1.002	0.872			0.604	0.878	1.282	2.213	1.911	1.484	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.069	1.051	0.867			0.641	1.514	1.672	1.549	2.018	1.59	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.258	1.72	0.955			1.006	1.74	1.817	1.988	2.064	1.993	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.685	6.845	0.871	10.376			0.353			0.402	1.115	
COVID19 (COVID19 (PFIZER-	Investigation	2.158	1.696	0.891			1.02	1.726	1.927	2.316	2.123	1.806	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.31	6.347	0.863		4.284	0.311	0.22	0.052	0.286	0.287	0.332	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.835	6.752				1.376	1.883	1.886	2.327	1.838	1.78	
COVID19 (COVID19 (PFIZER-	Weight	2.036	1.296	0.878			0.85	1.516	1.71	2.211	2.011	1.764	

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From: Menschik, David
Sent: Tue, 12 Oct 2021 10:30:11 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST_20211008.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/8/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211108	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 202116	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.603	1.751	0.891			0.486	1.568	1.727	1.585	2.611	1.137	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.017	1.661	0.88				1.516	2.046	1.649	2.348	1.42	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.862	1.241	0.92			0.488	1.272	1.61	1.571	2.06	1.345	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.072	0.894	0.885				0.871	0.741	0.749	2.455	1.587	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.017	2.254	0.891			0.51	1.937	2.013	3.715	4.338	1.396	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.065	1.601	0.882				1.729	1.616	1.127	2.042	1.384	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.589	2	0.892			0.455	1.691	2.565	2.223	2.94	1.986	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.703	1.428	0.887			0.381	1.115	2.253	0.796	1.938	1.217	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.207	0.811	0.882			0.59	0.825	1.653	1.894	1.965	1.831	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.22	1.684	1	0.512		0.446	1.86	2.009	2.406	2.871	1.576	
COVID19 (COVID19 (JANSSEN))	Anxiety	2.089	2.009	0.883				0.894	1.929	1.317	1.998	1.336	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.689	1.347	0.886	0.61		0.344	1.122	2.362	1.181	1.884	1.201	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.531	1.354	0.886	0.61		0.308	1.178	2.097	1.076	1.778	1.101	
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.715	1.339	0.883			0.418	1.316	2.049	1.169	1.942	1.339	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.73	1.29	0.887			0.472	1.279	2.03	1.347	2.048	1.171	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.6	2.726	0.891			0.522	1.677	2.202	0.756	4.662	0.976	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.698	1.448	0.888			0.357	1.13	1.977	1.217	2.301	0.997	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.602	2.198	0.882				1.586	2.538	1.189	2.175	2.123	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.784	1.22	0.887				1.339	0.941		2.698	0.618	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.274	1.881	0.914			0.539	1.863	1.904	1.469	3.321	1.121	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.564	1.966	0.901			0.549	1.046	1.299	1.024	3.429	0.916	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.052	1.528	0.883				1.006	1.094	1.478	2.351	1.014	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.388	2.5	0.896			0.535	2.66	2.501	0.743	3.992	1.244	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.739	2.04	0.938	0.511		0.649	2.291	2.454	2.255	3.571	1.761	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.91	1.403	0.888			0.416	1.605	2.002	1.453	2.061	1.453	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.113	1.656	0.905			0.489	1.485	2.122	1.99	2.432	1.602	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.567	1.892	0.917			0.479	2.183	2.209	0.249	3.138	2.013	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.668	1.285	0.886				1.152	2.208	1.264	1.778	1.129	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.753	0.797	0.882			1.163	2.004	1.521	1.018	1.907	1.411	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.307	1.329	0.89			0.391	2.168	2.119	1.914	2.561	1.596	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.098	1.452	0.905	0.511		0.344	1.619	2.314	1.934	2.532	1.395	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.976	0.993	0.882			0.439	1.676	1.883	0.785	2.174	1.146	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.36	0.934	0.886			0.532	2.334	1.665	0.549	2.852	1.331	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.354	1.902	0.881				1.339	2.847	1.691	2.128	2.101	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.671	1.269	0.89	0.507		0.446	1.236	1.943	1.531	2.018	1.219	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.33	3.47	0.891				3.71	4.374	5.465	6.881	1.84	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.627	3.345	0.883			0.56	4.748	5.142	6.669	7.331	1.069	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.046	1.957	0.883			0.619	1.816	2.462	1.548	2.123	1.864	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.702	1.395	0.936			0.604	1.337	1.864	1.826	2.073	1.314	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.709	1.234	0.878	0.746		0.419	1.565	1.768	1.211	2.053	1.196	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.947	1.283	0.887				1.353	1.977	0.92	2.068	1.207	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.112	2.005	0.883				1.499	1.153	0.745	2.761	0.704	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.627	1.45	0.881				1.209	2.093	1.067	1.661	1.605	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.958	1.746					0.916	2.21	1.083	1.417	1.734	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.168	1.77	0.886			0.52	1.825	1.899	2.261	2.542	1.564	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	1.879	1.397	0.88	0.511		0.477	1.349	1.907	1.283	2.7	1.108	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.587	1.128	0.88			0.36	1.17	2.161	0.641	1.873	0.946	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.473	1.268	0.896	0.61		0.22	0.957	1.943	1.731	2.236	0.932	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.408	1.17	0.884			0.199	1.19	1.581	1.066	2.104	0.711	
COVID19 (COVID19 (JANSSEN))	Off label use	1.565	0.288	0.883			0.37	0.37	0.549	0.441	0.885	1.399	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.799	0.758					2.899	1.017		2.311		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.501	0.86				0.539	1.735	2.253	1.084	2.468	1.427	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.758	1.895	0.883				0.656	1.077	2.545	2.278	0.996	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.681	2.449	0.925	0.512		0.488	1.919	3.134	1.734	3.199	1.74	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.82	1.439	0.896	0.61		0.397	1.543	2.042	1.45	2.141	1.384	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.767	2.138	0.892			0.413	2.125	3.062	2.451	3.53	1.894	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.023	3.54	0.883				4.296	3.171	0.688	6.007	2.09	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.041					0.86	3.913	2.978	5.887	4.478	3.67	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.765	1.436	0.908	0.740		0.274	1.436	2.159	1.269	2.264	1.249	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.21	1.676	0.952	0.512		0.681	1.662	2.132	2.521	2.528	1.797	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	1.998	1.559	0.889				1.521	1.367	2.149	1.918	1.548	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.742	1.298	0.886	0.609		0.561	1.347	2.013	1.419	1.982	1.409	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.765	1.263	0.879	0.61		0.371	1.233	1.943	1.396	2.103	1.115	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.264	1.105	0.885			0.55	1.397	1.76	1.287	1.853	1.711	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.674	1.663	1.788			0.544	2.012	2.392	0.833	2.654	3.019	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.927	0.61				0.855	3.498	6.583	15.574	8.083	5.763	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.2	1.962	0.896			0.408	1.822	2.197	1.511	2.614	1.56	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.638	2.205	1.825	0.512		0.6	2.028	2.377	3.557	2.832	2.152	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.267	1.934	0.883				1.768	1.268	0.652	2.4	0.857	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.295	1.292	0.888			0.656	1.842	2.084	2.197	2.582	1.853	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.762	2	0.896	0.512		0.551	2.257	2.275	3.335	3.242	2.137	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.448	1.752	0.88			0.473	2.686	1.769	1.472	2.411	1.799	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.744	1.3	0.88	0.509			1.195	1.504	2.044	1.698	1.648	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.976	1.159	0.885				1.364	2.178	1.787	2.101	1.294	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.409	2.696	2.173			0.377	1.001	2.343	4.743	1.962	2.16	
COVID19 (COVID19 (JANSSEN))	Venogram	2.765	2.105					2.207	1.751	0.723	3.157	1.015	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.268	2.473				0.619	2.71	1.792	0.765	4.233	1.023	
COVID19 (COVID19 (JANSSEN))	Venous pressure normal	4.281	2.479	0.883				3.36	2.439	0.883	8.23	0.854	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.274	0.767		5.851	0.797		1.187	0.515		1.293	0.935	
COVID19 (COVID19 (MODERNA))	Headache	0.967	0.958	0.88	4.09		0.304	0.944	0.986	1.014	0.953	1.026	
COVID19 (COVID19 (MODERNA))	No adverse event	1.227	0.842	0.888		0.294	2.026	0.9	0.906	0.766	1.103	1.211	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.384	0.928	0.885		1.316	2.56	0.172	0.167	0.581	2.408	2.437	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.947	1.953	0.882			2.119	1.963	1.894	1.529	1.832	2.045	
COVID19 (COVID19 (PFIZER-	Body height	1.53	1.002	0.886			0.604	0.879	1.268	2.218	1.903	1.476	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.058	1.051	0.882			0.641	1.509	1.671	1.961	2.023	1.587	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.252	1.708	0.954			0.599	1.755	1.876	2	2.068	1.987	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.655	0.847	0.885	9.271			0.384			0.406	1.108	
COVID19 (COVID19 (PFIZER-	Investigation	2.158	1.701	0.9			1.012	1.725	1.918	2.335	2.127	1.936	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.307	0.346	0.878		4.258	0.307	0.233	0.099	0.319	0.284	0.329	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.84	0.753				1.381	1.881	1.898	2.312	1.831	1.773	
COVID19 (COVID19 (PFIZER-	Weight	2.609	1.285	0.88			0.946	1.513	1.704	2.219	2.02	1.702	

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From: Menschik, David
Sent: Tue, 28 Sep 2021 09:57:14 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210924.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 9/24/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20210624	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.987	1.734	0.88			0.414	1.368	1.776	1.557	2.368	1.171	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.987	1.677	0.863				1.479	2.029	1.582	2.177	1.451	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.717	1.212	0.915			0.489	1.175	1.519	1.499	2.011	1.223	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.036	6.911	0.87				0.848	0.758	0.762	2.488	1.511	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.726	1.188	0.881				1.373	1.245	1.222	1	0.974	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.56	2.267	0.88			0.511	2.02	1.92	3.635	4.224	1.399	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.071	1.662	0.866				1.739	1.657	1.02	1.971	1.419	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.502	1.999	0.879			0.463	1.688	2.471	2.128	2.899	1.904	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.711	1.482	0.87			0.385	1.147	2.277	0.783	1.851	1.199	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.217	6.843	0.866			0.591	0.834	1.732	1.801	1.974	1.847	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.199	1.691	1.347	0.612		0.46	1.534	1.961	2.340	2.873	1.323	
COVID19 (COVID19 (JANSSEN))	Anelleria	2.164	2.128	0.867				0.883	2.068	1.337	1.679	1.593	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.617	1.297	0.872	0.61		0.354	1.038	2.427	1.049	1.792	1.148	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.487	1.388	0.874	0.61		0.283	1.197	2.08	1.021	1.724	1.08	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.204	2.585	0.876			0.527	1.323	2.013	0.756	4.558	0.905	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.557	2.255	0.866				1.568	2.538	1.214	2.235	2.07	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.612	1.39	0.875				1.342	0.972		3.823	0.828	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.231	1.892	0.909			0.54	1.783	1.967	1.39	3.188	1.107	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.395	1.944	0.894			0.551	1.047	1.203	1.043	3.338	0.853	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.003	1.486	0.867				1.023	1.032	1.51	2.254	0.984	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.178	2.413	0.882			0.536	2.374	2.641	6.747	3.807	1.195	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.658	2.057	0.937	0.611		0.567	2.26	2.423	2.196	3.479	1.744	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.145	1.722	0.9			0.498	1.512	2.065	2.105	2.48	1.809	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.53	1.835	0.896			0.484	2.179	2.165	3.135	3.133	1.95	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.666	1.305	0.871				1.1	2.291	1.158	1.791	1.08	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.755	6.788	0.867			1.169	2.004	1.518	1.005	1.906	1.411	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.329	1.397	0.876			0.397	2.239	2.092	1.849	2.98	1.973	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.121	1.51	0.894	0.612		0.357	1.619	2.345	2.064	2.511	1.444	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.888	6.991	0.867			0.447	1.636	1.85	0.788	2.103	1.14	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.28	0.92	0.868			0.499	2.427	1.626	0.886	2.64	1.269	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.272	1.932	0.864				1.275	2.88	1.557	2.073	2.053	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.407	3.516	0.876				3.391	4.39	6.46	6.695	2.214	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.264	3.121	0.868			0.561	6.379	3.833	6.668	6.973	1.869	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.047	1.995	0.868			0.021	1.905	2.432	1.538	2.155	1.837	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.97	1.333	0.874				1.388	1.937	0.95	2.01	1.217	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.224	2.116	0.868				1.547	1.17	0.751	3.033	0.714	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.817	1.448	0.865				1.117	2.131	1.08	1.648	1.808	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.945	1.781					0.936	2.249	1.006	1.398	1.722	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.432	1.162	0.869			0.191	0.918	2.062	1.361	1.744	1.038	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.169	1.808	0.872			0.524	1.886	1.892	2.171	2.51	1.593	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.54	1.099	0.862			0.372	1.113	2.1	0.587	1.834	0.883	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.368	1.196	0.88	0.61		0.143	0.889	1.836	1.573	2.038	0.883	
COVID19 (COVID19 (JANSSEN))	Off label use	1.661	0.25	0.866			0.494	0.375	0.589	0.343	1.062	1.535	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.785	6.757					2.883	1.014		2.283		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.554	6.877				0.54	1.838	2.15	1.118	2.498	1.443	
COVID19 (COVID19 (JANSSEN))	Peripheral ischaemia	3.894	1.024	0.887				0.896	1.978	2.318	2.834	1.011	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.721	2.453	0.914	0.612		0.504	2.023	3.18	1.886	3.24	1.887	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.809	1.449	0.883	0.61		0.323	1.558	2.035	1.343	2.133	1.361	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.774	2.167	0.879			0.42	2.134	3.072	2.394	3.498	1.678	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.958	3.523	0.868				4.273	2.585	6.688	5.961	1.716	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1					0.789	3.855	3.069	6.042	4.481	3.803	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.743	1.428	0.873	0.745		0.284	1.361	2.179	1.229	2.157	1.235	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.174	1.675	0.936	0.512		0.617	1.619	2.087	2.512	2.482	1.764	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.064	1.603	0.873				1.573	1.372	2.002	1.878	1.598	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.465	1.165				0.581	0.967	0.847	0.65	2.148	0.808	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	2.917	2.425	0.93			0.545	1.864	2.365	0.653	2.431	2.882	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.843					0.656	3.473	6.559	15.105	8.004	5.857	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.104	1.889	0.878			0.418	1.726	2.184	1.384	2.535	1.466	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.201	1.135	0.87			0.552	1.407	1.776	1.365	1.972	1.672	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.641	2.227	1.748	0.612		0.599	2.034	2.388	3.502	2.84	2.144	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.188	1.886	0.867				1.637	1.177	0.65	2.244	0.856	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.266	1.29	0.871			0.572	1.814	2.063	2.14	2.544	1.836	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.756	2.015	0.896	0.612		0.564	2.286	2.296	3.477	3.31	2.121	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.431	1.756	0.868			0.477	2.559	1.745	1.497	2.481	1.76	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.007	1.385	0.861			0.471	1.368	1.921	1.9	1.898	1.705	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.928	1.157	0.87				1.319	2.1	1.783	2.041	1.262	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.471	2.416	1.72			0.586	0.995	2.262	4.7	1.956	2.124	
COVID19 (COVID19 (JANSSEN))	Venogram	2.669	2.108					1.924	1.969	0.633	3.01	1.027	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.246	2.504				0.619	2.703	1.729	6.704	4.11	1.035	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.45	2.611	0.868				3.643	3.68	6.875	5.472	1.108	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.265	6.767		4.152	0.764		1.178	0.517		1.278	0.882	
COVID19 (COVID19 (MODERNA))	No adverse event	1.249	6.848	0.875		0.298	2.007	0.914	0.929	0.779	1.124	1.22	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.375	6.908	0.87		0.979	2.505	0.151	0.216	0.617	2.395	2.625	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.885	1.922	0.866			2.002	1.915	1.845	1.484	1.784	1.983	
COVID19 (COVID19 (PFIZER-	Body height	1.94	6.965	0.871			0.603	0.604	1.201	2.204	1.912	1.404	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.072	1.036	0.866			0.64	1.459	1.664	2.001	2.04	1.567	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.316	1.737	0.932			1.008	1.771	1.895	2.117	2.101	2.025	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	5.894	6.817	0.87	0.304			0.398			6.393	1.06	
COVID19 (COVID19 (PFIZER-	Investigation	2.177	1.707	0.89			0.996	1.721	1.912	2.393	2.142	1.957	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.308	6.368	0.862		3.373	0.396	0.249	0.108	0.35	0.282	0.329	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.883	6.659				1.39	1.893	1.904	3.568	1.845	1.766	
COVID19 (COVID19 (PFIZER-	Weight	2.065	1.287	0.877			0.823	1.518	1.662	2.299	2.052	1.772	

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From: Menschik, David
Sent: Tue, 21 Sep 2021 10:41:52 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210917.xls

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 9/17/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 2021Q1	Serious EB05 2021	Fatal EB05 2021Q	Infant EB05 2021Q	Child EB05 2021Q	Teen EB05 2021Q	Adult1 EB05 2021Q	Adult2 EB05 2021Q	Adult3 EB05 2021Q	Female EB05 2021	Male EB05 2021Q	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.993	1.739	0.876			0.611	1.408	1.739	1.576	2.393	1.149	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.952	1.659	0.857				1.486	1.912	1.598	2.151	1.409	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.958	0.92	0.866				0.881	0.758	0.608	2.398	1.53	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.063	2.337	0.876			0.51	2.014	1.962	3.741	4.298	1.432	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.662	1.663	0.881				1.682	1.642	1.031	1.92	1.431	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.512	2.021	0.872			0.462	1.706	2.491	2.071	2.83	1.942	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.844	1.486	0.866			0.484	1.12	2.125	0.797	1.911	1.127	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.223	6.854	0.86			0.59	0.795	1.796	1.885	1.942	1.911	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.186	1.713	1.722	0.613		0.46	1.814	1.964	2.368	2.868	1.504	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.136	2.109	0.861				0.883	2.161	1.239	1.611	1.603	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.549	1.278	0.867	0.61		0.286	0.995	2.264	1.074	1.711	1.095	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.339	2.82	0.871			0.526	1.376	2.016	0.757	4.523	0.921	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.505	2.218	0.86				1.568	2.401	1.139	2.072	2.018	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.808	1.382	0.888				1.34	0.973		2.087	0.809	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.268	1.941	0.91			0.54	1.506	2.002	1.409	3.248	1.126	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.223	1.852	0.881			0.551	1.048	1.203	0.95	2.673	0.854	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.039	1.572	0.863				1.035	1.009	1.545	3.299	0.991	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.285	2.485	0.878			0.536	2.443	2.834	0.751	3.923	1.209	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.684	1.969	0.931	0.613		0.585	2.286	2.452	2.073	3.564	1.674	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.166	1.76	0.898			0.496	1.544	2.057	2.134	2.463	1.633	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.56	1.857	0.894			0.482	2.213	2.196	3.18	3.182	1.972	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.576	1.324	0.866				1.051	2.294	1.177	1.785	1.06	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.803	6.786	0.861			1.166	2.009	1.525	1.023	1.91	1.42	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.353	1.364	0.872			0.394	2.281	2.113	1.851	2.654	1.562	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.121	1.529	0.892	0.611		0.356	1.644	2.323	2.057	2.528	1.419	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.91	6.998	0.861			0.447	1.636	1.887	0.802	2.107	1.171	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.262	6.931	0.862				2.416	1.638	0.886	2.69	1.239	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.254	1.92	0.858				1.247	2.841	1.515	2.05	2.028	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.432	3.537	0.874				3.378	4.391	6.735	6.748	2.211	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.286	3.102	0.862			0.681	4.366	3.589	6.668	6.96	1.969	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.964	1.967	0.862			0.022	1.871	2.341	1.503	2.117	1.578	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.958	1.311	0.869				1.405	1.894	0.952	2.092	1.182	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.393	3.217	0.862				1.689	1.185	0.763	3.768	0.714	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.824	1.455	0.859				1.134	2.145	1.028	1.648	1.816	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.927	1.809					0.953	2.157	1.009	1.368	1.713	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.17	1.829	0.867			0.532	1.806	1.908	2.097	2.591	1.597	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.486	1.094	0.856			0.28	1.067	2.065	0.598	1.792	0.861	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.368	1.201	0.875	0.61		0.049	0.908	1.757	1.621	2.063	0.873	
COVID19 (COVID19 (JANSSEN))	Off label use	1.702	6.277	0.86			5.317	0.288	0.619	0.32	1.114	1.517	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.777	6.757					2.831	1.013		2.267		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.44	6.879				0.545	1.568	2.111	1.136	2.38	1.334	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.984	1.969	0.861				0.556	1.075	3.182	2.398	1.012	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.662	2.397	0.913	0.613		0.503	1.965	3.267	1.633	3.234	1.961	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.812	1.473	0.881	0.508		0.323	1.578	2.021	1.353	2.162	1.347	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.757	2.159	0.874			0.418	2.119	3.066	2.333	3.495	1.633	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	3.839	3.884	0.882				4.283	2.401	6.668	6.668	1.715	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.958					0.785	3.86	2.918	6.069	4.438	3.519	
COVID19 (COVID19 (JANSSEN))	Prothombin time prolonged	1.723	1.416	0.868	0.744		0.283	1.351	2.148	1.235	2.154	1.207	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.184	1.689	0.926	0.613		0.619	1.647	2.063	2.496	2.504	1.76	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.029	1.86	0.868				1.585	1.363	2.1	1.885	1.628	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.483	1.197				0.561	0.968	0.863	0.65	2.134	0.616	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	2.889	2.298	0.918			0.551	1.839	2.217	0.653	2.378	2.873	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.677					0.656	3.446	6.544	14.741	7.838	5.502	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.041	1.864	0.874			0.416	1.711	2.109	1.367	2.47	1.403	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.398	1.202	0.866			0.551	1.417	1.846	1.433	2.024	1.726	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.66	2.254	1.738	0.613		0.609	2.075	2.409	3.546	2.908	2.115	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.268	1.958	0.862				1.907	1.19	0.65	2.42	0.857	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.295	1.278	0.867			0.67	1.776	2.067	2.133	2.538	1.625	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.781	2.015	0.893	0.613		0.563	2.281	2.247	3.435	3.275	2.13	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.38	1.781	0.859			0.475	2.443	1.677	1.52	2.414	1.653	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.767	1.37	0.857	0.509			1.194	2.063	1.979	1.738	1.635	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.027	1.338	0.856			0.469	1.283	1.925	1.846	1.981	1.732	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.917	1.113	0.861				1.29	2.067	1.924	2.024	1.261	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.455	2.285	1.008			0.599	1.054	2.265	4.699	1.941	2.121	
COVID19 (COVID19 (JANSSEN))	Venogram	2.645	1.145					1.917	1.836	0.836	2.928	1.028	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.382	2.577				0.818	2.795	1.811	0.705	4.38	1.036	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.389	2.532	0.862				3.584	2.708	0.876	5.477	1.038	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.259	6.775		4.564	0.733		1.17	0.517		1.261	0.878	
COVID19 (COVID19 (MODERNA))	No adverse event	1.263	6.834	0.868		0.309	2.016	0.92	0.938	0.785	1.13	1.233	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.355	6.908	0.865		0.905	2.475	0.163	0.232	0.627	2.372	2.405	
COVID19 (COVID19 (PFIZER-	Body height	1.967	6.976	0.866			0.568	0.889	1.25	2.287	1.922	1.497	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.062	1.039	0.86			0.641	1.449	1.607	2.014	2.043	1.571	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.349	1.746	0.926			0.666	1.767	1.865	2.13	2.13	2.045	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.598	6.794	0.862	4.766			0.4			0.402	0.976	
COVID19 (COVID19 (PFIZER-	Investigation	2.169	1.714	0.896			0.861	1.715	1.967	2.401	2.147	1.966	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.302	6.368	0.856		2.611	0.303	0.224	0.118	0.36	0.278	0.324	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.665	6.653				1.401	1.899	1.907	2.391	1.86	1.801	
COVID19 (COVID19 (PFIZER-	Weight	2.068	1.286	0.872			0.793	1.911	1.664	2.282	2.091	1.793	

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From: Menschik, David
Sent: Tue, 14 Sep 2021 10:16:54 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210910.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 9/10/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20210110	Serious EB05 2021	Fatal EB05 20210	Infant EB05 2021Q	Child EB05 2021Q	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 20210	Female EB05 2021	Male EB05 21210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.971	1.778	0.875			0.225	1.437	1.603	1.819	2.444	1.131	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.56	1.67	0.86				1.55	1.894	1.526	2.101	1.433	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.905	6.923	0.867				0.832	0.799	0.609	2.397	1.492	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.712	1.174	0.874				1.333	1.262	1.176	2.031	0.923	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.248	2.446	0.877			0.511	1.997	2.085	4.007	4.351	1.489	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.574	2.071	0.872			0.47	1.737	2.549	2.121	2.857	2.006	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.674	1.539	0.868			0.41	1.157	2.068	0.827	1.928	1.159	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.261	6.829	0.862			0.595	0.762	1.828	2.027	1.973	1.946	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.153	1.743	1.478	0.512		0.461	1.847	1.953	2.36	2.87	1.509	
COVID19 (COVID19 (JANSSEN))	Anxiety	2.174	3.093	0.864				0.884	2.003	1.241	1.571	1.808	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.009	1.284	0.871	0.509		0.297	1.015	2.22	1.101	1.701	1.111	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.136	2.499	0.869			0.543	1.252	2.032	0.656	4.18	0.937	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.642	1.463	0.872			0.274	1.096	1.962	1.122	2.01	1.007	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.448	2.371	0.862				1.897	2.868	1.078	2.83	2.071	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.258	1.945	0.911			0.541	1.715	2.028	1.409	3.184	1.127	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.358	1.941	0.882			0.552	1.049	1.233	0.958	2.784	0.872	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.866	1.824	0.864				1.037	0.988	1.553	3.344	0.993	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.298	2.5	0.879			0.537	2.442	2.866	0.752	3.932	1.212	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.726	2.193	0.933	0.512		0.574	2.261	2.522	2.066	3.58	1.733	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.888	1.443	0.875			0.343	1.618	2	1.329	1.935	1.535	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.226	1.815	0.897			0.514	1.551	2.14	2.255	2.548	1.864	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.573	1.877	0.896			0.484	2.228	2.193	3.26	3.13	1.982	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.559	1.358	0.871				1.06	2.258	1.223	1.771	1.091	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.815	6.801	0.863			1.177	2.021	1.532	1.033	1.91	1.431	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.379	1.388	0.874			0.415	2.305	2.104	1.845	2.701	1.566	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.132	1.564	0.892	0.511		0.387	1.653	2.314	2.086	2.53	1.425	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.922	1.099	0.860			0.492	1.036	1.863	0.803	2.123	1.177	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.203	6.938	0.864				2.42	1.657	0.889	2.732	1.254	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.264	1.921	0.861				1.283	2.806	1.425	2.022	2.039	
COVID19 (COVID19 (JANSSEN))	Heparin induced thrombocytopenia test	5.265	3.518	0.876				3.381	4.091	6.29	6.694	1.83	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.303	3.111	0.864			0.553	4.371	3.667	6.669	6.962	1.971	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.005	1.976	0.868			0.024	1.904	2.32	1.461	2.116	1.585	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.668	1.411	0.943			0.684	1.262	1.899	1.783	3.008	1.283	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.956	1.291	0.871				1.382	1.9	0.954	2.064	1.195	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.405	2.229	0.864				1.66	1.187	0.752	3.781	0.715	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.752	1.441	0.881				1.125	2.107	0.981	1.648	1.554	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.989	1.883					0.967	2.23	1.02	1.398	1.766	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.179	1.854	0.869			0.539	1.874	1.93	2.088	2.483	1.614	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.501	1.191	0.858			0.298	1.059	2.099	0.559	1.767	0.888	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.378	1.215	0.878	0.509		0.055	0.935	1.744	1.654	2.051	0.882	
COVID19 (COVID19 (JANSSEN))	Off label use	1.723	6.309	0.862			0.316	0.295	0.55	0.346	1.13	1.556	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.781	6.757					2.819	1.014		2.273		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.332	6.886				0.546	1.571	2.053	1.05	2.214	1.326	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	4.01	1.982	0.864				0.655	1.076	3.418	2.43	1.014	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.728	2.407	0.914	0.512		0.504	2.066	3.318	1.649	3.288	1.684	
COVID19 (COVID19 (JANSSEN))	Platelet count abnormal	1.469	1.488	0.88	0.509		0.358	1.338	2.039	1.041	2.134	1.362	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.75	2.155	0.876			0.424	2.122	3.057	2.261	3.487	1.83	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.947	3.52	0.864				4.27	2.651	6.689	5.923	1.719	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.835					0.647	3.208	2.349	6.288	3.934	3.004	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.73	1.421	0.868	0.744		3.3	1.37	2.082	1.258	2.167	1.201	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.207	1.716	0.924	0.512		0.639	1.644	2.113	2.563	2.533	1.773	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.065	1.714	0.868				1.613	1.408	2.22	1.931	1.835	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.498	1.204				0.563	0.969	0.863	0.651	2.145	0.817	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	2.822	2.267	0.896			0.557	1.763	2.162	0.666	2.334	2.823	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.667					0.657	3.448	6.5	14.814	7.813	5.53	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.041	1.862	0.877			0.42	1.743	2.089	1.35	2.461	1.396	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.39	1.211	0.867			0.553	1.374	1.865	1.442	2.021	1.735	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.668	2.276	1.791	0.512		0.61	2.108	2.405	3.538	2.922	2.122	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.368	2.01	0.904				2.001	1.192	0.651	2.097	0.809	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.234	1.275	0.866			0.588	1.771	2.046	2.129	2.52	1.589	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.79	2.026	0.885	0.512		0.568	2.298	2.215	3.474	3.246	2.137	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.374	1.775				0.48	2.473	1.623	1.489	2.477	1.569	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.788	1.427	0.86	0.508			1.196	2.048	1.951	1.71	1.67	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.061	1.387	0.858			0.471	1.371	1.973	2.014	1.944	1.74	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.911	1.125	0.864				1.271	2.056	1.988	2.024	1.245	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.401	2.246	0.913			3.6	0.98	2.221	4.517	1.906	2.055	
COVID19 (COVID19 (JANSSEN))	Venogram	2.58	2.068					1.802	1.908	0.542	2.733	1.03	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.395	2.593				0.619	2.793	1.819	0.705	4.388	1.038	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.307	2.476	0.864				3.589	2.747	0.759	5.354	1.04	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.26	6.775		3.748	0.724		1.183	0.517		1.271	0.837	
COVID19 (COVID19 (MODERNA))	No adverse event	1.266	6.834	0.87		0.298	2.002	0.919	0.936	0.783	1.128	1.231	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.342	6.911	0.867		0.82	2.459	0.169	0.232	0.626	2.354	2.391	
COVID19 (COVID19 (PFIZER-	Body height	1.955	6.979	0.867			0.569	0.891	1.25	2.288	1.82	1.497	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.09	1.031	0.862			0.642	1.442	1.669	2.008	2.051	1.569	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.39	1.751	0.926			0.966	1.766	1.865	2.169	2.134	2.056	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.59	6.795	0.864	4.067			0.379			0.387	1.004	
COVID19 (COVID19 (PFIZER-	Investigation	2.156	1.726	0.887			0.96	1.719	1.901	2.406	2.148	1.979	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.239	6.317	0.897		2.173	1.3	0.208	0.178	0.361	0.273	0.328	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.886	6.651				1.398	1.898	1.901	2.39	1.858	1.806	
COVID19 (COVID19 (PFIZER-	Weight	2.062	1.302	0.874			0.784	1.527	1.693	2.31	2.073	1.766	

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From: Menschik, David
Sent: Tue, 7 Sep 2021 10:51:35 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210903.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 9/3/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20210103	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021	Male EB05 202106	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.927	1.775	0.882			0.421	1.396	1.648	1.575	2.474	1.058	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.933	1.687	0.871				1.455	1.909	1.55	2.094	1.403	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.803	6.929	0.878				0.835	0.755	0.606	2.296	1.496	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.158	2.465	0.886			0.509	1.942	2.08	4.057	4.278	1.484	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.526	2.089	0.88			0.47	1.698	2.523	2.029	2.71	1.98	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.669	1.472	0.875			0.424	1.107	2.012	0.774	1.787	1.167	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.259	6.836	0.874			0.598	0.775	1.962	2.134	2.017	1.96	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.157	1.755	0.946	0.512		0.455	1.804	1.936	2.311	2.823	1.474	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.047	2.155	0.876				0.877	1.965	1.258	1.578	1.515	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.46	1.201	0.875	0.509		3.3	0.918	2.108	1.038	1.566	1.072	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.618	2.409	0.878			0.541	1.103	1.962	0.605	3.974	0.933	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.41	2.22	0.875				1.561	2.286	1.085	1.848	2.002	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.185	1.918	0.905			0.539	1.618	2.065	1.361	2.972	1.119	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.039	1.884	0.881			0.48	0.881	1.827	0.998	2.214	0.796	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.059	1.725	0.876				1.086	0.987	1.559	2.308	1.013	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.244	2.509	0.888			0.535	2.353	2.857	0.751	3.843	1.218	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.668	2.096	0.926	0.512		0.571	2.117	2.511	2.004	3.448	1.711	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.189	1.823	0.898			0.51	1.546	2.078	2.241	2.462	1.862	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.56	1.895	0.902			0.48	2.243	2.181	3.219	3.162	1.975	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.484	1.232	0.875				0.983	2.077	1.153	1.618	1.037	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.807	6.817	0.876			1.211	2.008	1.514	1.052	1.91	1.427	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.404	1.5	0.884			0.415	2.317	2.117	1.9	2.722	1.589	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.103	1.58	0.892	0.511		0.383	1.625	2.264	2.107	2.48	1.411	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.889	0.969	0.875			0.45	1.667	1.753	0.806	2.117	1.115	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.296	6.949	0.876				2.365	1.688	0.892	2.751	1.252	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.203	1.932	0.873				1.262	2.74	1.44	1.987	1.991	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	0.225	0.043	0.886				3.266	3.961	6.041	6.602	1.79	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.101	2.994				0.561	3.729	3.369	0.668	6.737	1.965	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.967	1.98	0.874			0.026	1.847	2.277	1.468	2.048	1.572	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.67	1.199	0.881				1.203	1.808	0.903	2.011	1.11	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.328	2.229	0.876				1.621	1.182	0.752	3.61	0.712	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.607	1.384	0.874				1.001	2.036	0.986	1.521	1.515	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.977	1.958					0.963	2.197	1.027	1.38	1.757	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.135	1.85	0.881			0.533	1.78	1.93	2.048	2.411	1.597	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.464	1.087	0.873			3.3	1.025	2.083	0.512	1.691	0.892	
COVID19 (COVID19 (JANSSEN))	Off label use	1.8	6.332	0.874			5.195	0.315	0.572	0.36	1.178	1.564	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.769	6.757					2.621	1.004		2.315		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.437	6.888				0.545	1.64	2.063	1.083	2.311	1.371	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.651	1.798	0.875				0.653	0.977	2.896	2.311	0.913	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.615	2.433	0.917	0.512		0.505	2.084	3.32	1.434	3.259	1.86	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.772	1.486	0.887	0.509		0.33	1.502	2.068	1.325	2.068	1.362	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.748	2.207	0.888			0.427	2.104	3.077	2.26	3.478	1.825	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.627	3.499	0.876				4.174	2.512	0.666	5.782	1.675	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.782					0.579	2.981	2.241	5.017	3.72	2.817	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.652	1.365	0.876	0.744		0.302	1.263	2.014	1.22	2.068	1.147	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.172	1.738	0.816	0.512		0.449	1.936	2.068	2.471	2.468	1.748	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.01	1.723	0.879			1.498	1.378	2.241	1.85	1.821		
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.448	1.184				0.561	0.943	0.861	0.65	2.064	0.803	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	2.731	1.215	0.9			0.556	1.722	2.122	0.673	2.315	2.661	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.415					0.656	2.586	6.408	14.711	7.484	5.344	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.006	1.862	0.883			0.42	1.685	2.089	1.324	2.382	1.394	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.354	1.164	0.878			0.551	1.357	1.868	1.282	1.971	1.749	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.645	2.279	1.753	0.512		0.606	2.132	2.437	3.537	2.914	2.096	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.379	2.057	0.873				1.933	1.208	0.65	2.558	0.868	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.227	1.292	0.88			0.585	1.772	2.039	2.122	2.528	1.574	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.837	2.106	0.893	0.512		0.56	2.332	2.249	3.575	3.281	2.173	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.352	1.756				0.477	2.473	1.539	1.526	2.485	1.534	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.773	1.452	0.872	0.508			1.191	2.041	1.924	1.753	1.623	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.651	1.309	0.871			0.467	1.421	1.955	1.666	1.994	1.702	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.871	1.083	0.876				1.198	2.024	2.007	1.98	1.225	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.351	2.145	0.908			0.598	0.995	2.134	4.463	1.831	2.002	
COVID19 (COVID19 (JANSSEN))	Venogram	2.346	2.02					1.662	1.777	0.539	2.407	1.824	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.368	2.631				0.617	2.662	1.863	0.704	4.298	1.946	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.143	2.443	0.876				3.269	2.629	0.758	5.197	1.035	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.264	6.755		3.215	0.715		1.181	0.516		1.261	0.824	
COVID19 (COVID19 (MODERNA))	No adverse event	1.263	6.835	0.88		0.336	2.003	0.909	0.91	0.772	1.113	1.222	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.306	6.862	0.876		0.81	2.422	0.141	0.214	0.619	2.313	2.36	
COVID19 (COVID19 (PFIZER-	Body height	1.998	6.981	0.878			0.57	0.903	1.235	2.282	1.912	1.501	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.115	1.022	0.874			0.643	1.446	1.606	1.988	2.071	1.565	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.459	1.759	0.926			0.571	1.835	1.938	2.236	2.238	2.143	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.575	6.819	0.878	2.72			0.363			0.382	1.021	
COVID19 (COVID19 (PFIZER-	Investigation	2.238	1.736	0.894			0.528	1.736	1.911	2.419	2.181	2.012	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.52	6.643				1.412	1.939	1.976	2.435	1.899	1.837	
COVID19 (COVID19 (PFIZER-	Weight	2.108	1.31	0.884			0.782	1.511	1.683	2.336	2.102	1.77	

PSI-HHS-000000057574

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From: Menschik, David
Sent: Tue, 17 Aug 2021 11:00:32 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210813.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 8/13/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	VS EB05 20210413	Serious EB05 2021	Fatal EB05 20210	Infant EB05 2021	Child EB05 2021	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 20210	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.78	1.77	0.886			0.035	1.346	1.484	1.353	2.164	0.997	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.804	1.7	0.878				1.455	1.753	1.287	2.024	1.235	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.613	6.901	0.884				0.885	0.776	0.68	2.18	1.581	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.97	2.48	0.89			0.514	1.609	2.64	3.596	4.181	1.366	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.367	2.108	0.886			0.479	1.553	2.404	1.721	2.458	1.883	
COVID19 (COVID19 (JANSSEN))	Antibody test	1.956	0.84					0.706	1.84	3.29	1.807	1.567	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.001	1.792	0.912	0.512		0.472	1.725	1.901	2.013	2.667	1.361	
COVID19 (COVID19 (JANSSEN))	Areflexia	1.804	2.091	0.881				0.888	1.786	1.02	1.403	1.367	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.744	2.505	0.886			0.536	1.213	1.606	0.658	4.004	0.861	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.267	2.194	0.882				1.431	2.104	0.957	1.663	1.857	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.049	1.974	0.902			0.535	1.736	1.862	1.269	2.691	1.904	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.071	2.51	0.893			0.541	2.353	2.52	0.738	3.718	1.193	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.447	2.109	0.914	0.512		0.488	1.966	2.292	1.849	3.123	1.565	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.618	1.818	0.891			0.508	1.471	2.068	1.792	2.873	1.908	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.382	1.887	0.908			0.478	2.172	2.079	2.841	2.932	1.834	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.325	1.52	0.888			0.414	2.287	2.025	1.849	2.677	1.493	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.978	1.547	0.899	0.511		0.374	1.618	2.133	1.713	2.348	1.271	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.253	0.94	0.883				2.39	1.685	0.793	2.74	1.168	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	1.842	1.845	0.881				1.203	2.403	1.104	1.698	1.7	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.928	3.464	0.886				2.549	3.752	5.132	6.015	1.484	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.755	2.965				0.558	3.458	2.476	0.671	6.328	1.945	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.81	1.967	0.882			0.035	1.72	2.109	1.298	1.88	1.46	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.071	2.167	0.882				1.561	1.142	0.743	2.664	0.705	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.817	1.881					0.952	2.061	0.908	1.318	1.588	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.01	1.878	0.888			0.473	1.78	1.812	1.841	2.267	1.508	
COVID19 (COVID19 (JANSSEN))	Off label use	1.757	0.25	0.881			5.022	0.351	0.614	0.441	1.142	1.62	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.928	6.734					2.327	1.905		2.028		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.16	0.9				0.54	1.622	1.958	0.979	2.013	1.302	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	4.022	1.992	0.882				0.651	1.02	2.004	2.696	0.922	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.361	2.489	0.9	0.512		1.5	2.06	3.18	1.36	2.927	1.457	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.581	2.244	0.886			0.277	2.005	2.969	2.029	3.261	1.535	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.422	3.298	0.883				3.824	2.145	0.691	5.255	1.422	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.898					0.571	2.591	2.069	4.169	3.624	2.312	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.022	1.755	0.907	0.512		0.735	1.565	2.008	2.161	2.307	1.626	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	4.733						3.463	5.566	12.191	5.638	4.987	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	1.806	1.858	0.886			0.422	1.666	1.895	1.156	2.137	1.242	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.267	1.122	0.885			0.552	1.305	1.812	1.218	1.937	1.627	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.325	2.357	1.808	0.512		0.605	2.077	2.341	3.088	2.645	1.877	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.123	1.868	0.882				1.64	1.195	0.653	2.181	0.855	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.107	1.289	0.887			0.582	1.811	1.927	1.827	2.43	1.421	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.662	2.181	0.898	0.512		0.489	2.177	2.167	3.362	2.934	2.127	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.224	1.687					2.387	1.468	1.31	2.37	1.385	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	0.922	1.476	0.906			0.524	1.059	2.001	3.844	1.398	1.521	
COVID19 (COVID19 (JANSSEN))	Venogram	2.251	2.025					1.783	1.663	0.659	2.343	0.977	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.308	2.821				0.623	2.436	1.843	0.7	4.328	1.032	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.61	2.497	0.883				2.819	2.819	0.749	5.084	0.898	
COVID19 (COVID19 (MODERNA))	Accidental exposure to product	2.066					0.388	0.519	0.47	0.73	0.65	0.759	
COVID19 (COVID19 (MODERNA))	No adverse event	1.531	6.801	0.883		0.459	2.141	0.914	0.96	0.859	1.214	1.326	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.439				0.547	0.29	0.249	0.385	0.555	0.418	0.376	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.356	6.869	0.883		0.847	2.47	0.108	0.23	0.857	2.348	2.426	
COVID19 (COVID19 (PFIZER-	Drug ineffective	1.901	1.795	0.911			0.638	1.778	1.903	2.016	1.741	1.719	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.791	0.799	0.883	2.73			0.587			0.571	1.005	
COVID19 (COVID19 (PFIZER-	Investigation	1.946	1.735	0.896			0.695	1.685	1.772	2.04	1.901	1.754	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.814	6.636				1.367	1.88	1.852	2.084	1.803	1.751	
COVID19 (COVID19 (PFIZER-	Weight	1.976	1.366	0.886			0.73	1.516	1.66	2.039	1.88	1.852	

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From: Menschik, David
Sent: Tue, 10 Aug 2021 11:22:47 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20210806.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 8/6/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	VS EB05 20210408	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.766	1.656	0.884				1.396	1.476	1.288	2.064	0.943	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.759	1.736	0.888				1.45	1.792	1.225	2.083	1.189	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.525	6.904	0.892				0.758	0.712	0.689	2.147	1.49	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.043	6.986	0.892				0.949	0.702	0.699	1.48	1.574	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.13	2.588	0.897			0.517	1.612	2.159	3.54	4.292	1.384	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.373	2.145	0.893			0.478	1.536	2.437	1.716	2.378	1.931	
COVID19 (COVID19 (JANSSEN))	Antibody test	1.854	0.82					0.661	1.832	2.373	1.723	1.492	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.034	1.834	0.921	0.512		0.396	1.723	1.948	1.992	2.884	1.359	
COVID19 (COVID19 (JANSSEN))	Areflexia	1.758	2.077	0.88				0.817	1.73	1.026	1.347	1.342	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.665	2.599	0.892			0.536	1.21	1.585	0.659	3.868	0.859	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.119	2.205	0.89				1.427	2.055	0.901	1.658	1.842	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.013	1.979	0.908			0.539	1.7	1.843	1.263	2.555	1.087	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.175	2.582	0.896			0.541	2.33	2.863	0.74	3.823	1.207	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.489	2.141	0.88	0.512		0.487	2.031	2.207	1.811	3.184	1.881	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.98	1.808	0.897			0.51	1.487	1.998	1.655	2.253	1.447	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.348	1.876	0.909			0.477	2.098	2.085	2.8	2.88	1.819	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.333	1.846	0.896			0.514	2.29	2.047	1.824	2.881	1.513	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.932	1.489	0.899	0.61		0.328	1.557	2.131	1.654	2.275	1.26	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.268	6.959	0.891				2.372	1.72	0.792	2.721	1.209	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	1.855	1.846	0.89				1.185	2.351	1.127	1.724	1.69	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.878	3.376	0.896				2.141	4.123	4.096	5.831	1.342	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.599	2.892				0.558	3.379	1.946	0.672	6.124	1.043	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.81	1.981	0.891			0.641	1.694	2.107	1.297	1.798	1.494	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.129	2.219	0.891				1.472	1.264	0.741	2.732	0.712	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.811	1.894					0.907	2.031	0.911	1.278	1.608	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.986	1.881	0.893			0.471	1.736	1.816	1.785	2.265	1.448	
COVID19 (COVID19 (JANSSEN))	Off label use	1.692	6.243	0.89			4.89	0.946	0.61	0.946	1.097	1.556	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.863	6.756					2.263	1.064		1.978		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.017	0.85				0.54	1.468	1.929	0.97	1.96	1.146	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.937	1.998	0.891				0.651	1.02	1.911	2.503	0.921	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.287	2.457	0.905	0.512		0.503	2.052	3.083	1.372	2.795	1.436	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.57	2.257	0.896			0.281	2.01	2.938	2.024	3.232	1.54	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.165	3.161	0.891				3.155	1.809	0.691	6.993	1.251	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.463					0.569	2.428	2.036	4.031	2.41	2.312	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.965	1.763	0.911	0.512		0.652	1.562	1.984	2.131	2.271	1.602	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	4.594						2.628	6.178	11.918	5.371	4.006	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	1.798	1.868	0.894			0.424	1.596	1.932	1.144	2.08	1.253	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.239	1.122	0.892			0.552	1.311	1.777	1.2	1.927	1.59	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.275	2.364	1.765	0.512		0.608	2.08	2.34	3.04	2.588	1.843	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.167	1.902	0.891				1.59	1.19	0.654	2.122	0.877	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.124	1.302	0.894			0.586	1.841	1.969	1.747	2.458	1.413	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.621	2.174	0.901	0.512			2.081	2.174	3.266	2.801	2.12	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.207	1.664					2.462	1.381	1.207	2.352	1.354	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.048	1.34	0.896			0.524	0.966	2.091	3.989	1.4	1.801	
COVID19 (COVID19 (JANSSEN))	Venogram	2.156	2.018					1.663	1.634	0.561	2.23	0.924	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.851	2.998				0.552	2.586	1.733	0.889	4.283	1.647	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.866	2.411	0.891				2.782	2.377	0.747	4.942	0.897	
COVID19 (COVID19 (MODERNA))	Accidental exposure to product	2.128					0.385	0.519	0.471	0.738	0.675	3.77	
COVID19 (COVID19 (MODERNA))	No adverse event	1.588	0.81	0.891		0.47	2.127	0.923	0.969	0.891	1.231	1.343	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.477				0.549	0.287	0.258	0.334	0.565	0.443	0.377	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.379	6.867	0.891		0.763	2.437	0.084	0.236	0.653	2.331	2.392	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.826					1.388	1.873	1.854	2.059	1.803	1.772	

PSI-HHS-000000057578

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From: Menschik, David
Sent: Tue, 27 Jul 2021 11:09:11 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: Weekly data mining
Attachments: USST_20210723.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/23/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	VS EB05 20210723	Serious EB05 20211	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021	Male EB05 21210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.508	6.959	0.876				0.776	0.718	6.703	2.164	1.666	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.957	2.527	0.883			0.514	1.556	1.934	3.789	4.091	1.356	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.377	2.156	0.873			0.482	1.557	2.385	1.675	2.393	1.899	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.008	1.825	0.911	0.612		0.405	1.725	1.916	1.916	2.634	1.329	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.38	2.416	0.877			0.564	1.098	1.426	6.663	3.264	0.863	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.677	2.102	0.873				1.249	1.953	6.979	1.295	1.932	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.937	1.893	0.898			0.543	1.582	1.763	1.214	2.512	0.961	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.188	2.577	0.886			0.538	2.238	2.922	6.741	3.873	1.117	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.408	2.106	0.908	0.612		0.482	2.023	2.217	1.746	3.122	1.494	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.992	1.809	0.878			0.521	1.473	2.014	1.591	2.222	1.461	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.313	1.893	0.902			0.477	2.081	2.115	2.893	2.866	1.843	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.354	1.518	0.881			0.419	2.304	2.06	1.88	2.683	1.491	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.919	1.447	0.886	0.609		0.349	1.56	2.065	1.622	2.271	1.212	
COVID19 (COVID19 (JANSSEN))	Guarantee	2.379	6.992	0.873				2.846	1.736	6.756	2.434	1.297	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	1.776	1.764	0.872				1.136	2.274	1.025	1.543	1.678	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.74	3.251	0.881				2.096	3.763	1.84	5.717	1.34	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.569	3.923				0.556	3.263	1.936	6.671	6.673	1.043	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.73	1.88	0.874			0.074	1.509	2.063	1.149	1.647	1.483	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.056	2.171	0.874				1.592	1.123	6.654	2.271	0.724	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.654	1.614					0.812	2.014	6.696	1.044	1.564	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.947	1.823	0.875			0.486	1.741	1.735	1.71	2.14	1.452	
COVID19 (COVID19 (JANSSEN))	Off label use	1.62	6.148				4.741	0.356	0.635	0.36	1.014	1.545	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.592	6.758					2.192	1.002		1.943		
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	4.047	2.022	0.874				0.649	1.018	2.148	2.828	0.922	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.332	2.462	0.894	0.612		0.516	2.107	2.984	1.356	2.77	1.461	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.577	2.271	0.882			0.296	1.98	2.955	2.051	3.195	1.564	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.269	3.133	0.874				3.034	1.753	6.69	6.667	1.237	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.411					0.82	2.315	1.908	4.224	2.348	2.138	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.002	1.782	0.906	0.612		0.647	1.592	1.979	2.148	2.27	1.813	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	4.46						2.498	6.661	11.289	4.969	3.873	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	1.733	1.815	0.881			0.434	1.52	1.933	1.033	2.054	1.166	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.073	1.992	0.876			0.55	1.203	1.702	1.101	1.711	1.526	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.314	2.436	1.875	0.612		0.607	2.068	2.389	5.189	2.82	1.877	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.333	1.987	0.874				1.756	1.187	6.654	2.458	0.877	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.105	1.229	0.88			0.588	1.833	1.942	1.682	2.443	1.372	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.656	2.166	0.89	0.612			2.05	2.182	3.31	2.81	2.125	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.276	1.743					2.508	1.395	1.268	2.408	1.394	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.013	1.29	0.87			0.471	1.476	1.873	1.741	2.014	1.558	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.825	1.945					1.238	1.969	1.589	2.007	1.126	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	0.83	1.039	0.877			0.526	0.846	1.825	2.066	1.148	1.302	
COVID19 (COVID19 (JANSSEN))	Venogram	2.151	2.034					1.699	1.531	6.568	2.281	0.826	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.516	2.723				0.539	3.066	1.641	0.7	4.527	1.876	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.19	2.623	0.874				3.472	2.066	6.753	5.321	0.912	
COVID19 (COVID19 (MODERNA))	Accidental exposure to product	2.085					0.392	0.531	0.468	6.758	0.675	0.812	
COVID19 (COVID19 (MODERNA))	No adverse event	1.602	6.808	0.875		0.494	2.106	0.968	1.015	0.904	1.272	1.366	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.428				0.618	0.377	0.308	0.458	6.883	0.474	0.456	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.325	6.878	0.874		0.741	2.379	0.111	0.214	0.718	2.288	2.337	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.867					1.388	1.875	1.882	2.056	1.831	1.81	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 6 Jul 2021 17:52:16 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210702.xls

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/2/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	VS EB05 20210102	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.885	1.893	0.883				1.721	1.475	1.103	2.101	1.033	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.385	0.86	0.881				0.709	0.638	0.711	1.992	1.411	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.341	2.659	0.887			0.519	1.663	1.997	4.302	4.321	1.396	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.409	2.181	0.875			0.522	1.566	2.411	1.522	2.38	1.895	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.068	1.868	0.915	0.612			1.742	1.908	2.04	2.691	1.322	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.126	2.297	0.883			0.544	1.003	1.319	0.666	2.761	0.793	
COVID19 (COVID19 (JANSSEN))	Body temperature	1.961	6.907				1.397	2.008	2.013	1.506	1.922	1.73	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	1.977	2.037	0.88				1.227	1.775	0.936	1.218	1.794	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.92	1.865	0.901			0.544	1.425	1.8	1.137	2.456	1.97	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	1.948	1.609	0.883			0.55	0.822	1.171	0.849	2.214	0.742	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.469	2.722	0.891			0.544	2.266	3.027	0.706	4.021	1.211	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.561	2.234	0.905	0.612		0.501	2.118	2.324	1.841	3.397	1.531	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.031	1.837	0.884			0.543	1.396	2.021	1.705	2.333	1.421	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.484	1.829	0.887			0.468	2.163	2.149	2.643	2.82	1.819	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.455	1.476	0.887			0.443	2.392	2.094	1.901	2.839	1.48	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.009	1.462	0.889	0.608		0.412	1.611	2.188	1.494	2.38	1.204	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.486	0.95	0.88				2.406	1.861	0.813	3.924	1.195	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.651	3.112	0.886				1.641	3.063	3.508	5.657	1.189	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.621	2.865				0.557	3.245	1.645	0.676	5.948	1.968	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.84	1.272	0.884				1.345	1.692	0.928	2.047	1.019	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.315	2.27	0.881				1.867	1.15	0.653	2.561	0.754	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.071	1.946	0.883			0.512	1.76	1.842	1.841	2.328	1.499	
COVID19 (COVID19 (JANSSEN))	Off label use	1.542	6.156				4.381	0.368	0.649	0.368	0.961	1.461	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.598	0.755					2.19	1.006		1.948		
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	4.711	2.021	0.881				0.669	0.54	2.279	4.218	1.86	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.434	2.567	0.903	0.612		0.526	2.166	3.082	1.448	2.899	1.515	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.611	2.23	0.897			0.393	2.003	2.943	2.134	3.271	1.99	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.169	3.046	0.881				3.016	1.522	0.689	4.815	1.245	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.367					0.562	2.802	1.812	2.507	2.309	2.269	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.047	1.798	0.9	0.612		0.675	1.569	1.983	2.245	2.3	1.644	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	4.419						3.236	6.033	10.958	4.8	3.887	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.117	1.112	0.883			0.551	1.227	17	1.133	1.725	1.567	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.399	1.529	1.908	0.612		0.62	2.185	2.496	3.245	2.723	1.909	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.271	1.934	0.881				1.579	1.217	0.653	2.327	0.881	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.159	1.25	0.884			0.516	1.863	1.998	1.669	2.514	1.371	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.705	2.226	0.886	0.612			2.102	2.365	3.139	2.943	2.211	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.484	1.963					2.713	1.477	1.274	2.608	1.469	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.81	1.449	0.879	0.601			1.329	2.006	1.654	1.838	1.564	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	1.954	1.157	0.878			0.493	1.517	1.771	1.627	2.108	1.388	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.838	1.021					1.284	1.908	1.442	2.06	1.021	
COVID19 (COVID19 (JANSSEN))	Venogram	2.233	1.987					1.722	1.5	0.565	2.247	0.851	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.788	2.844				0.54	3.156	1.794	0.634	4.603	1.063	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.976	2.569	0.881				3.257	2.002	0.663	5.291	0.636	
COVID19 (COVID19 (MODERNA))	Accidental exposure to product	2.023					0.386	0.545	0.46	0.753	0.683	0.804	
COVID19 (COVID19 (MODERNA))	No adverse event	1.597	6.833	0.883		0.501	2.022	0.982	1.005	0.904	1.24	1.353	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.418				0.608	0.468	0.348	0.448	0.618	0.877	0.48	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.247	6.875	0.88		0.716	2.294	0.123	0.215	0.738	2.295	2.271	
COVID19 (COVID19 (PFIZER-	Investigation	1.55	1.727	0.89			0.661	1.701	1.814	2.031	1.912	1.727	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.59					1.375	1.871	1.895	2.069	1.884	1.84	
COVID19 (COVID19 (PFIZER-	Weight	1.924	1.31	0.885			0.644	1.512	1.682	2.015	1.561	1.629	

PSI-HHS-000000057582

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 29 Jun 2021 12:39:12 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210625.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/25/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	VS EB05 20210625	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.383	6.861	0.879				0.707	0.658	0.711	1.98	1.369	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.414	2.713	0.886			0.524	1.657	1.984	4.51	4.284	1.443	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.442	2.166	0.873			0.533	1.609	2.411	1.495	2.368	1.945	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.065	1.905	0.903	0.612			1.827	1.885	2.051	2.698	1.355	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.285	2.286	0.882			0.551	1.031	1.318	0.67	2.91	0.816	
COVID19 (COVID19 (JANSSEN))	Body temperature	1.998	6.904				1.379	2.025	2.069	1.555	1.948	1.736	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.957	1.923	0.896			0.543	1.483	1.779	1.175	2.584	0.981	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	1.978	1.836	0.882			0.55	0.821	1.172	0.856	2.205	0.746	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.632	2.758	0.88			0.55	2.363	3.739	0.763	4.075	1.261	
COVID19 (COVID19 (JANSSEN))	Chills	1.466	6.956	0.888			2.03	1.544	1.279	0.943	1.589	1.259	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.566	2.253	0.900	0.612		0.51	2.146	2.303	1.839	3.481	1.483	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.038	1.834	0.879			0.551	1.391	2.031	1.661	2.243	1.475	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.406	1.834	0.893			0.489	2.192	2.176	2.897	2.871	1.933	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.479	1.91	0.886			0.48	2.109	2.136	1.783	2.871	1.97	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.057	1.488	0.889	0.508		0.45	1.603	2.219	1.501	2.451	1.209	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.809	6.958	0.879			0.483	1.528	1.719	0.806	2	0.999	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.438	6.961	0.879				2.433	1.822	0.814	2.936	1.215	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.61	3.157	0.884				1.633	3.004	3.55	5.8	1.165	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.49	2.749				0.557	2.141	1.64	0.675	5.774	1.968	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.853	1.315	0.883				1.395	1.765	0.934	2.082	1.058	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.382	2.301	0.88				1.853	1.172	0.653	2.771	0.754	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.088	1.959	0.882			0.532	1.77	1.825	1.845	2.295	1.536	
COVID19 (COVID19 (JANSSEN))	Off label use	1.568	6.167				4.221	0.377	0.555	0.368	0.823	1.479	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.647	6.754					2.544	1.021		2.118		
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	4.712	2.015	0.879				0.668	0.54	2.296	4.212	1.86	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.375	2.536	0.896	0.612		0.531	2.131	3.04	1.228	2.94	1.37	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.662	2.258	0.896			0.276	2.011	3.008	2.194	3.38	1.966	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.634	2.989	0.88				2.42	1.325	0.688	5.061	1.057	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.331					0.565	2.488	1.867	2.024	2.132	2.213	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.068	1.897	0.897	0.612		0.68	1.908	1.965	2.247	2.302	1.667	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	4.356						2.136	5.687	9.642	4.581	3.928	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.109	1.08	0.882			0.551	1.256	1.587	1.197	1.671	1.575	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.391	2.544	1.879	0.612		0.64	2.103	2.482	3.35	2.688	1.906	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.354	1.975	0.88				1.572	1.248	0.652	2.308	0.894	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.181	1.267	0.880			0.52	1.884	2.029	1.681	2.584	1.349	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.809	2.197	0.886	0.612			2.126	2.332	3.228	2.902	1.24	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.489	1.924					2.645	1.463	1.238	2.542	1.514	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	1.969	1.102	0.877			0.497	1.533	1.663	1.612	2.093	1.308	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.841	6.966					1.297	1.964	1.343	2.046	1.99	
COVID19 (COVID19 (JANSSEN))	Venogram	2.229	1.988					1.619	1.5	0.568	2.274	0.846	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	4.03	2.91				0.545	3.621	1.789	0.633	4.674	1.107	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.195	2.626	0.88				3.475	1.962	0.662	5.371	0.861	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.417				0.528	0.434	0.356	0.5	0.637	0.398	0.486	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.193	6.877	0.879		0.725	2.237	0.126	0.214	0.736	2.15	2.221	
COVID19 (COVID19 (PFIZER-	Investigation	1.969	1.736	0.886			0.776	1.694	1.822	2.053	1.933	1.73	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.844					1.379	1.88	1.907	2.084	1.907	1.883	
COVID19 (COVID19 (PFIZER-	Weight	1.929	1.299	0.884			0.666	1.495	1.668	2.016	1.908	1.626	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 22 Jun 2021 10:51:27 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210618.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/18/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210618	Serious EB05 20210	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 20210	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.329	6.836	0.883				0.701	0.569	0.719	1.661	1.355	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.403	2.766	0.887			0.521	1.668	1.971	4.523	4.278	1.441	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.355	2.121	0.88			0.536	1.55	2.304	1.438	2.227	1.891	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.949	1.846	0.897	0.612			1.72	1.719	1.884	2.373	1.338	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.154	2.259	0.886			0.549	1.017	1.287	0.669	2.609	0.808	
COVID19 (COVID19 (JANSSEN))	Body temperature	1.963	0.887				1.367	1.958	2.026	1.535	1.927	1.704	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.866	1.882	0.9			0.541	1.389	1.734	1.129	2.461	0.898	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	1.908	1.61	0.886			0.548	0.815	1.159	0.855	2.098	0.741	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.586	2.787	0.893			0.548	2.335	3.5	0.766	3.948	1.257	
COVID19 (COVID19 (JANSSEN))	Chills	1.453	0.948	0.86			2.042	1.525	1.266	0.945	1.499	1.243	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.48	2.25	0.908	0.612		0.596	2.032	2.226	1.802	3.387	1.442	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.965	1.798	0.884			0.557	1.351	1.899	1.64	2.203	1.388	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.439	1.936	0.894			0.485	2.121	2.177	2.881	2.882	1.903	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.171	1.249	0.884			0.488	2.35	2.126	1.791	2.893	1.468	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.011	1.453	0.891	0.508		0.483	1.657	2.031	1.466	2.392	1.164	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.819	0.982	0.883			0.493	1.521	1.716	0.813	2.068	1.96	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.369	0.945	0.883				2.443	1.722	0.828	2.868	1.162	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.635	3.119	0.887				1.615	2.704	3.288	5.931	1.991	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.662	2.816				0.555	1.954	1.81	0.674	5.588	1.106	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.229	2.274	0.883				1.984	1.057	0.652	2.808	0.747	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.069	1.979	0.882			0.542	1.773	1.827	1.838	2.33	1.528	
COVID19 (COVID19 (JANSSEN))	Off label use	1.467	0.305				3.778	0.372	0.561	0.369	0.911	1.438	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.61	6.753					2.254	1.072		2.014		
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	4.255	1.704	0.883				0.551	0.934	2.215	2.433	0.856	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.459	2.701	0.896	0.612		0.542	2.206	3.049	1.245	2.951	1.446	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.567	2.189	0.888			0.335	1.928	2.843	2.207	3.247	1.561	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.166	2.949	0.884				2.946	1.285	0.687	5.088	0.972	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.301					0.583	2.53	1.71	2.807	1.965	2.429	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.004	1.777	0.896	0.612		0.69	1.508	1.943	2.196	2.228	1.62	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	4.249						1.894	5.579	9.692	4.374	3.616	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.142	1.034	0.885			0.549	1.296	1.584	1.194	1.667	1.637	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.365	2.529	1.837	0.612		0.641	2.139	2.488	3.331	2.723	1.882	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.168	1.892	0.883				1.415	1.251	0.655	2.109	0.885	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.17	1.253	0.886			0.53	1.867	2.03	1.634	2.611	1.317	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.767	2.184	0.886				2.143	2.285	3.227	2.88	2.183	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.385	1.854					2.497	1.417	1.171	2.358	1.481	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.892	1.448	0.882	0.505			1.385	2.062	1.73	1.897	1.634	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	1.963	1.054	0.881			0.505	1.552	1.58	1.628	2.068	1.303	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.943	6.969					1.379	1.988	1.236	2.147	1.026	
COVID19 (COVID19 (JANSSEN))	Venogram	2.352	2.036					1.769	1.505	0.569	2.298	1.82	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.975	2.913				0.543	3.641	1.736	0.632	4.511	1.117	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.149	2.736	0.884				3.208	2.053	0.665	5.261	0.953	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.369				0.528	0.449	0.264	0.367	0.632	0.393	0.396	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.088	6.904	0.883		0.713	2.125	0.132	0.222	0.732	2.058	2.116	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.204						0.157	0.185	0.328	0.087	0.327	
COVID19 (COVID19 (PFIZER-	Investigation	1.98	1.725	0.882			0.724	1.69	1.803	2.089	1.842	1.736	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.969					1.403	1.887	1.924	2.095	1.927	1.885	
COVID19 (COVID19 (PFIZER-	Weight	1.939	1.261	0.886			0.651	1.47	1.712	2.009	1.921	1.6	

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From: Menschik, David
Sent: Tue, 8 Jun 2021 10:55:18 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST_20210604.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/4/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210804	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20216	Child EB05 20210	Teen EB05 202104	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 2021	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.158	0.751					0.732	0.389	0.714	1.777	1.371	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.84	2.638	0.882			0.538	1.299	1.684	4.285	3.818	1.163	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.064	2.094	0.88			0.546	1.257	2.038	1.368	2.113	1.54	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.866	1.859	0.894	0.611			1.521	1.48	1.861	2.285	1.175	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.678	1.834	0.895			0.554	1.214	1.468	1.171	2.067	0.844	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	2.872	2.65	0.891			0.538	2.129	2.148	0.681	3.24	1.082	
COVID19 (COVID19 (JANSSEN))	Chills	1.409	0.925	0.889			2.278	1.462	1.239	0.937	1.459	1.194	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.324	2.311	0.909	0.611		0.531	1.779	2.032	1.815	3.168	1.314	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.789	1.794	0.883			0.592	1.269	1.656	1.538	2.08	1.206	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.357	1.917	0.893			0.518	2.023	2.105	2.883	2.796	1.796	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.023	1.32	0.866			0.922	2.361	2.106	1.937	2.840	1.496	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.854	1.384	0.89	0.606		0.572	1.388	1.857	1.428	2.278	0.972	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.809	0.926	0.881			0.602	1.548	1.542	0.737	2.084	0.929	
COVID19 (COVID19 (JANSSEN))	Gait delay	2.248	0.824	0.881				2.239	1.666	0.634	2.78	1.099	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	1.957	2.842	0.885				1.231	1.881	1.508	5.262	0.933	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	1.365	2.161				0.554	1.355	1.047	0.574	1.955	0.918	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.06	2.343	0.881				1.59	1.033	0.651	3.087	0.891	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.986	2.054	0.88			0.571	1.962	1.625	1.66	2.228	1.419	
COVID19 (COVID19 (JANSSEN))	Off label use	1.3					3.741	0.31	9.428		0.824	1.145	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	1.777	1.684	0.881				0.542	9.916	2.381	2.101	0.845	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.13	2.425	0.898	0.611		0.539	1.832	2.472	1.276	2.487	1.186	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.42	2.028	0.886			0.403	1.833	2.493	1.879	3.105	1.339	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	4.306	2.809	0.882				1.998	1.217	0.686	3.771	0.938	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.179					0.498	2.211	1.505	0.577	1.599	1.746	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.807	1.757	0.895	0.611		0.669	1.289	1.747	2.099	2.093	1.38	
COVID19 (COVID19 (JANSSEN))	Pyrexia	1.438	0.897	0.889			2.157	1.499	1.228	0.928	1.483	1.232	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	3.491						1.348	4.309	8.572	3.471	2.791	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.247	1.087	0.883			0.554	1.262	1.685	1.258	1.736	1.881	
COVID19 (COVID19 (JANSSEN))	Thrombosis	1.288	2.548	1.975	0.611		0.659	2.002	2.41	3.378	2.875	1.714	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.077	1.214	0.884			0.539	1.766	1.899	1.628	2.481	1.278	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.599	2.207	0.889				1.985	2.127	2.858	2.955	1.836	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.894	1.319		0.603			1.338	2.106	1.892	1.915	1.833	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	1.982	1.043	0.879				1.488	1.683	1.586	3.095	1.3	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.962	0.985					1.382	1.979	1.138	2.247	0.898	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.993	2.686				0.547	2.467	1.474	0.54	3.364	1.917	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.172	2.843	0.882				3.761	1.691	0.661	5.117	0.884	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.266				0.528	0.516	0.431	9.517	0.792	0.787	0.57	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.133						0.358	9.258	0.511	0.232	0.456	
COVID19 (COVID19 (PFIZER-	Drug ineffective	1.964	1.682	0.897			0.746	1.823	1.998	2.034	1.779	1.773	
COVID19 (COVID19 (PFIZER-	Investigation	2.053	1.705	0.889			0.712	1.751	1.843	2.071	2.001	1.751	
COVID19 (COVID19 (PFIZER-	Product preparation issue	2.021					1.513	1.777	1.863	2.124	1.947	1.924	
COVID19 (COVID19 (PFIZER-	Weight	2.02	1.254	0.884			0.576	1.431	1.744	2.028	1.98	1.624	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 1 Jun 2021 13:02:19 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST_20210528.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/28/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20210528	Serious EB05 2021	Fatal EB05 21210	Infant EB05 2021	Child EB05 20210	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.674	0.747					0.755	0.386	0.737	0.726	1.297	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.783	2.706	0.881			0.539	1.252	1.655	4.4	3.47	1.202	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.004	2.114	0.877			0.547	1.245	1.889	1.423	2.04	1.489	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.006	2.125	0.894	0.611			1.552	1.61	1.961	2.462	1.281	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	2.885	2.762	0.868			0.547	2.202	2.056	0.607	2.962	1.151	
COVID19 (COVID19 (JANSSEN))	Chills	1.383	0.919	0.891			2.366	1.479	1.228	0.925	1.437	1.162	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.306	2.372	0.907	0.611		0.539	1.71	1.976	1.843	3.055	1.328	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.852	1.912	0.883			0.521	1.39	1.605	1.647	2.121	1.247	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.335	1.894	0.888			0.519	2.031	2.103	2.671	2.737	1.797	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	1.527	1.424	0.887			0.453	2.363	2.1	2.081	2.812	1.52	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.85	1.396	0.889	0.602		0.606	1.464	1.85	1.38	2.213	0.998	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.823	0.941	0.88			0.542	1.522	1.612	0.741	2.003	0.976	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	1.258	0.877					2.18	1.667	0.764	2.741	1.017	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	1.437	0.94	0.888				1.389	1.673	1.484	1.58	1.082	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	2.665	2.041				0.556	1.273	0.96	0.568	1.526	0.932	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.011	2.381	0.881				1.828	0.914	0.647	1.922	0.7	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.983	2.095	0.88			0.606	1.566	1.589	1.973	2.161	1.416	
COVID19 (COVID19 (JANSSEN))	Off label use	1.245					3.639	0.267	0.429		0.803	1.075	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.031	1.594	0.88				0.535	0.905	2.123	1.889	0.837	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.055	2.32	0.894	0.611		0.54	1.867	2.328	1.285	2.363	1.172	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.383	2.082	0.886			0.43	1.797	2.421	1.791	2.997	1.356	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	1.498	2.676	0.881				1.359	1.183	0.681	2.251	0.919	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.797	1.798	0.893	0.611		0.803	1.26	1.729	2.171	2.094	1.362	
COVID19 (COVID19 (JANSSEN))	Pyrexia	1.421	0.881	0.889			2.3	1.465	1.221	0.928	1.472	1.203	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	3.219						1.285	3.279	7.901	2.831	2.433	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.228	1.043	0.882			0.556	1.43	1.432	1.342	1.733	1.599	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.292	2.512	1.897	0.611		0.674	2.67	2.392	3.484	2.889	1.696	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.195	2.21	0.88				1.426	1.189	0.656	1.914	0.914	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.03	1.11	0.882			0.549	1.717	1.909	1.511	2.357	1.304	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.689	2.317	0.897				2.075	2.034	3.64	3.112	1.811	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.941	1.247		0.6			1.302	2.167	1.964	1.938	1.689	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	2.03	1.022					1.418	2.015	1.181	2.317	0.901	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.894	2.778				0.556	2.071	1.456	0.64	2.98	1.099	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.155	2.971	0.881				3.414	1.673	0.668	4.845	0.911	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.225				0.128	0.536	0.47	0.546	0.808	0.794	0.617	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.142						0.345	0.331	0.531	0.235	0.486	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.058	1.64	0.896			0.723	1.881	2.055	2.088	1.864	1.853	
COVID19 (COVID19 (PFIZER-	Investigation	2.133	1.672	0.888			0.678	1.827	1.899	2.101	2.079	1.843	
COVID19 (COVID19 (PFIZER-	Product preparation issue	2.063					1.513	1.75	1.835	2.16	1.978	1.953	
COVID19 (COVID19 (PFIZER-	Weight	2.05	1.187	0.881			0.581	1.446	1.773	2.024	2.015	1.62	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 18 May 2021 11:08:29 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20120514.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/14/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210514	Serious EB05 2021(	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.064	0.628					0.639	0.378	0.742	1.606	1.296	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.55	2.605	0.884			0.55	1.118	1.466	4.639	2.474	1.301	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	1.963	2.164					1.175	1.735	1.46	2.023	1.36	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.314	2.546	0.893	0.611			1.78	1.534	3.24	3.005	1.42	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	2.742	2.846	0.892			0.55	1.975	1.933	0.633	2.553	1.2	
COVID19 (COVID19 (JANSSEN))	Cerebral venous thrombosis	1.84	2.138	0.885				1.128	0.937	0.86	1.529	0.811	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.142	2.261	0.909	0.611		0.55	1.813	1.705	1.651	2.81	1.171	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.267	1.878	0.893			0.527	1.915	2.031	2.689	2.662	1.702	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.502	1.532	0.891			0.509	2.238	1.97	3.319	2.711	1.511	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.82	1.413	0.892			0.563	1.383	1.747	1.39	2.083	0.98	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.239	0.9					2.145	1.642	0.896	2.449	1.063	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.251	0.714					2.376	1.554		2.249	0.54	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	1.732	2.839	0.887				1.128	1.357	2.058	3.867	0.963	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.669	2.279	0.886				1.373	0.82	0.844	1.632	0.812	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.877	2.085	0.883			0.563	1.669	1.502	1.608	2.05	1.339	
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.102						2.05	1.619		2.072	0.565	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	2.168	1.387	0.885				0.525	0.879	1.965	1.59	0.825	
COVID19 (COVID19 (JANSSEN))	Platelet count	1.928	2.12	0.893	0.611		0.509	1.402	2.146	1.226	2.229	1.043	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.477	2.178	0.889			0.474	1.885	2.464	1.539	3.028	1.431	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	2.391	2.133	0.886				1.103	1.042	0.676	1.52	0.735	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.831	1.868	0.891	0.611		0.603	1.315	1.67	2.299	2.076	1.399	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	2.689						0.875	1.605	5.402	1.928	1.831	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.105	0.973	0.887			0.55	1.301	1.404	1.44	1.898	1.482	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.293	2.535	1.881	0.611		0.575	2.017	2.301	3.465	2.653	1.709	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.253	2.287	0.885				1.286	1.32	0.682	1.967	0.931	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.052	1.285	0.887			0.55	1.67	1.604	1.689	2.302	1.362	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.569	2.38	0.889				1.742	1.981	2.865	3.199	1.811	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.909	1.15		0.5			1.344	2.019	2.012	1.899	1.841	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.872	1.022					1.258	1.764	1.163	2.067	0.88	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.027	2.455				0.55	1.501	1.275	0.548	1.841	0.991	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.137	3.081	0.887				2.96	1.662	0.676	4.439	0.956	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.152				0.528	0.562	0.606	0.564	0.874	0.61	0.75	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.097						0.555	0.419	0.611	0.457	0.705	
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.108	1.634	0.895			0.779	1.973	2.162	2.065	1.921	1.914	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.202	1.735	0.891			0.631	1.844	1.967	2.107	2.129	1.895	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	2.115					0.626	1.559	1.778	2.148	1.986	1.968	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue	2.085	0.962	0.885			0.5	1.923	1.7	1.619	2.038	1.446	
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain	1.871	0.718	0.879			0.628	2.007	1.854	1.582	1.798	1.855	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.16	1.199	0.888			0.631	1.478	1.822	2.017	2.066	1.718	

PSI-HHS-000000057592

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From: Menschik, David
Sent: Tue, 11 May 2021 12:40:32 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20210507.xls

Apologies all for forgetting the attachment – please see attached.

Thanks,
David

From: Menschik, David
Sent: Tuesday, May 11, 2021 7:07 AM
To: Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani, Meghna <[redacted]>; Marquez, Paige L (CDC) <[redacted]>; Broder, Karen R (CDC) <[redacted]>; Harrington, Theresa (CDC) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/7/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210507	Serious EB05 2021(	Fatal EB05 20210[	Infant EB05 20210[	Child EB05 20210[	Teen EB05 20210[	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 20210[	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.113	0.661					0.607	0.384	0.734	1.706	1.293	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.338	2.721	0.88			0.548	1.06	1.415	3.837	2.055	1.245	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	1.818	2.268					1.071	1.588	1.406	1.873	1.259	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.168	2.678	0.888	0.61			1.542	1.516	2.175	2.408	1.391	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	2.315	2.771	0.889			0.548	1.642	1.785	0.632	2.058	1.193	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	1.982	2.344	0.916	0.61		0.548	1.631	1.627	1.446	2.408	1.046	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.118	1.923	0.891				1.768	1.898	2.349	2.373	1.866	
COVID19 (COVID19 (JANSSEN))	Dysmenorrhoea	1.96	0.707					2.074	0.941		1.929		
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.389	1.541	0.888			0.501	2.274	1.81	2.264	2.595	1.4	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.152	0.887					2.075	1.585	0.702	2.295	1.025	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.365	0.769					2.498	1.552		2.353		
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	2.813	2.707	0.884				1.019	1.237	1.411	2.391	0.884	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.519	2.201	0.882				1.233	0.791	0.644	1.463	0.897	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.692	2.063	0.879			0.547	1.613	1.362	1.327	1.769	1.243	
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.174						2.182	1.528		2.143		
COVID19 (COVID19 (JANSSEN))	Platelet count	1.786	2.108	0.89	0.61		0.521	1.235	1.939	1.19	2.068	0.941	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.313	2.259	0.885			0.462	1.788	2.243	1.575	2.703	1.362	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.662	1.913	0.888	0.61		0.503	1.176	1.524	2.05	1.885	1.265	
COVID19 (COVID19 (JANSSEN))	Syncope	1.797	0.903	0.885	0.61		0.899	2.038	1.566	0.646	1.787	1.71	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	2.156						0.753	1.12	0.942	1.513	1.419	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.255	2.649	0.999	0.61		0.561	2.034	2.128	3.398	2.564	1.676	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	1.702	2.049	0.881				1.168	1.257	0.563	1.463	0.922	
COVID19 (COVID19 (JANSSEN))	Ultrasound doppler	2.021	1.344	0.853			0.548	1.717	1.741	1.613	2.116	1.461	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.306	2.333	0.896				1.507	1.809	2.256	2.612	1.501	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	1.715	2.299				0.548	1.358	1.211		1.547	0.902	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.314	2.832	0.883				2.046	1.409	0.673	3.449	0.869	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.113				0.521	0.562	0.768	0.834	0.878	1.099	0.917	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.038						0.586	0.469	0.57	0.501	0.896	
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.134	1.626	0.891			0.703	2	2.211	2.087	1.946	1.925	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.212	1.712	0.888			0.638	1.862	1.953	2.076	2.138	1.876	
COVID19 (COVID19 (PFIZER-BIONTECH))	Off label use	1.76	1.064	0.882			0.28	2.011	1.67	1.687	1.751	1.378	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	2.035					0.668	1.29	1.569	2.145	1.89	1.855	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue	2.117	0.969	0.881			0.512	1.954	1.713	1.619	2.065	1.458	
COVID19 (COVID19 (PFIZER-BIONTECH))	SARS-CoV-2 test	1.958	1.612	0.898			1.313	1.953	2.02	1.828	1.91	1.856	
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain	1.942	0.751	0.875			0.601	2.067	1.953	1.645	1.868	1.92	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.179	1.242	0.884				1.459	1.845	2.022	2.072	1.71	

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Tue, 20 Apr 2021 10:16:33 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST_20210416.xls

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/16/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 202104	Serious EB05 2021	Fatal EB05 202104	Infant EB05 202104	Child EB05 202104	Teen EB05 202104	Adult1 EB05 202104	Adult2 EB05 202104	Adult3 EB05 2021	Female EB05 2021	Male EB05 202104	Comment
COVID19 (COVID19 (JANSSEN))	Fall	1.498	0.751	0.887			0.652	2.409	1.007	0.447	1.446	1.318	
COVID19 (COVID19 (JANSSEN))	Loss of consciousness	1.975	0.958	0.86			0.751	2.29	1.599	0.582	1.862	1.857	
COVID19 (COVID19 (JANSSEN))	Syncope	1.979	0.783	0.884			0.843	2.224	1.588	0.58	1.88	1.846	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	2.368						0.539		0.658	0.992	0.692	
COVID19 (COVID19 (JANSSEN))	Thrombosis	1.282	2.317	0.904				0.671	1.094	1.005	1.268	0.983	
COVID19 (COVID19 (JANSSEN))	Vital signs measurement	2.308	0.662				0.525	2.247	1.491	1.497	2.245	1.883	
COVID19 (COVID19 (PFIZER-BIONTECH))	Body temperature	1.786	1.629	0.89		0.038	0.545	1.994	2.004	1.758	1.763	1.636	

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From: Menschik, David
Sent: Sun, 7 Nov 2021 18:05:41 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER)
Subject: RE: [EXTERNAL] data mining for dose 3 mRNA, dose 2 Janssen

Hi John,

Understand we don't currently have the capability to do our Empirical Bayesian data mining analyses by dose number in series.
(Will circle back if feasible after discussing with our contractor)

Best,
David

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, November 06, 2021 9:51 AM
To: Nair, Narayan <[redacted]>; Menschik, David <[redacted]>
Cc: Zinderman, Craig E <[redacted]>
Subject: RE: [EXTERNAL] data mining for dose 3 mRNA, dose 2 Janssen

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Hi Narayan,

Thanks! Please don't go to any extra effort – I just thought to ask. A convenience sample, if you will. ☺ If no specific data mining's been done yet, I can just say so (if that's okay).

- John

From: Nair, Narayan <[redacted]>
Sent: Saturday, November 6, 2021 9:08 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Menschik, David (FDA/CBER) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] data mining for dose 3 mRNA, dose 2 Janssen

Hi John,
We will try and get this info back to you before your VaST meeting.

Narayan

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, November 6, 2021 8:37 AM

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To: Menschik, David <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>
Subject: [EXTERNAL] data mining for dose 3 mRNA, dose 2 Janssen

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi folks,

I learned that I'm to present updated data to VaST on Monday. Are data mining results available for dose 3 of mRNA vaccines (and dose 2 for Janssen)? (b)(5)

(b)(5)

If no such analyses have been run (or if no signals have yet to be detected), may I share that information at VaST?

Thanks! I hope you're off to a good start to the weekend.

- John

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From: Menschik, David
Sent: Tue, 2 Nov 2021 16:09:28 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211029.xls

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/29/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021(20	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.193	1.805	0.884			0.586	1.611	1.918	1.781	2.71	1.295	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.203	1.784	0.884				1.639	2.225	1.925	2.897	1.453	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.961	1.312	0.94			0.467	1.25	1.753	1.763	2.201	1.536	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.059	0.89	0.883				0.841	0.73	0.731	2.382	1.564	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.054	1.005	0.884				0.997	0.684	0.72	1.588	1.436	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.933	1.327	0.901				1.536	1.353	1.533	2.377	1.092	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.004	2.206	0.894			0.499	2.273	2.061	3.279	4.386	1.354	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.188	1.656	0.881				1.731	1.803	1.216	2.342	1.366	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.546	1.949	0.893			0.435	1.713	2.5	2.36	2.781	2.056	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.911	1.663	0.896			0.388	1.313	2.417	1.022	2.314	1.301	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.348	0.875	0.86			0.578	0.899	1.74	1.906	2.094	1.934	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.243	1.869	1.064	0.612		0.434	1.853	1.996	2.599	2.886	1.613	
COVID19 (COVID19 (JANSSEN))	Anorexia	2.063	1.919	0.882				0.864	1.913	1.423	1.772	1.527	
COVID19 (COVID19 (JANSSEN))	Aspartate aminotransferase abnormal	1.819	1.221	0.881				1.16	1.178	1.396	2.493	0.938	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.886	1.591	0.882	0.509		0.336	1.239	2.441	1.579	2.298	1.223	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.719	1.542	0.88	0.508		0.295	1.292	2.276	1.363	2.08	1.189	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.765	1.293	0.885			0.339	1.508	1.812	1.531	2.075	1.25	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.919	1.486	0.893			0.407	1.43	2.254	1.728	2.244	1.466	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.953	1.539	0.901			0.459	1.439	2.252	1.768	2.38	1.351	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.517	2.66	0.89			0.511	1.852	2.44	0.738	4.604	1.073	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.889	1.633	0.894			0.286	1.166	2.144	1.545	2.602	1.994	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.745	1.607	0.88			0.214	1.401	2.065	1.241	2.053	1.92	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.915	1.326	1.002				1.338	1.762	1.81	2.002	1.676	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.655	2.194	0.88				1.687	2.6	1.159	2.37	2.15	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.306	1.863	0.913			0.523	2.049	1.915	1.443	3.458	1.998	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.55	1.961	0.899			0.538	1.291	1.268	0.995	3.353	0.971	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.113	1.337	0.861				1.123	1.139	1.306	2.497	1.04	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.489	2.496	0.902			0.525	2.672	2.562	0.825	4.162	1.222	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.748	1.987	0.932	0.611		0.636	2.375	2.48	2.271	3.611	1.773	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.69	1.592	0.897			0.496	1.708	2.016	1.752	3.334	1.523	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.146	1.636	0.907			0.467	1.494	2.172	2.063	2.473	1.64	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.665	1.872	0.923			0.486	2.176	2.273	3.254	3.227	2.027	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.797	1.486	0.877				1.296	2.301	1.45	2.121	1.182	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.765	0.784	0.88			1.137	2.001	1.564	1.004	1.894	1.404	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.295	1.293	0.888			0.377	2.208	2.089	1.924	2.542	1.633	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.16	1.522	0.912	0.611		0.333	1.692	2.371	2.148	2.583	1.483	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.993	0.994	0.881			0.427	1.707	1.901	0.756	2.224	1.182	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.358	1.038	0.888			0.419	2.208	1.79	1.136	2.621	1.448	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.659	1.229	0.887				1.192	1.21	1.243	2.131	0.913	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.297	1.894	0.88				1.399	2.84	1.742	2.162	2.101	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.831	1.372	0.896	0.506		0.433	1.372	2.118	1.689	2.224	1.339	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.767	1.316	0.898	0.507		0.393	1.447	2.023	1.554	2.08	1.347	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.69	2.695	0.89				4.027	4.856	6.152	7.14	2.473	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.814	3.509	0.882			0.549	5.092	5.536	0.666	7.528	1.388	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.79	1.24	0.893				1.254	1.788	1.61	2.038	1.412	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.079	1.841	0.881			0.618	1.874	2.478	1.494	2.217	1.887	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.787	1.422	0.984			0.029	1.404	1.978	1.906	2.188	1.382	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.831	1.319	0.882	0.746		0.401	1.626	1.926	1.382	2.362	1.219	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.905	1.225	0.886				1.367	1.945	0.904	2.038	1.205	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.149	2.006	0.882				1.599	1.139	0.744	2.78	0.765	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.9	1.537	0.88				1.251	2.161	1.098	1.698	1.73	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.039	1.797					0.9	2.342	1.173	1.497	1.795	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.568	1.243	0.885			0.184	1.037	2.042	1.66	2.002	1.137	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.186	1.736	0.887			0.505	1.811	1.937	2.319	2.539	1.805	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.052	1.483	0.886	0.611		0.465	1.331	2.314	1.409	2.27	1.273	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.78	1.279	0.885			0.351	1.275	2.226	1.031	2.127	1.064	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.055	1.533	0.937			0.496	0.996	2.061	1.654	1.988	1.845	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.585	1.346	0.89	0.61		0.224	0.964	2.111	1.893	2.408	1.02	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.616	1.349	0.906			0.15	1.222	1.609	1.342	2.492	0.918	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.645	1.267	0.896			0.24	1.138	2.011	1.594	1.899	1.256	
COVID19 (COVID19 (JANSSEN))	Off label use	1.449	0.216	0.881			5.946	0.324	0.471	0.383	0.911	1.253	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.746	0.757					3.03	0.998		2.15		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.592	0.876				0.524	1.782	2.289	1.165	2.634	1.473	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.51	1.765	0.882				0.696	1.068	2.571	2.482	0.974	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.755	1.489	0.927	0.611		0.485	1.886	3.113	1.789	3.11	1.816	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.848	1.405	0.897	0.509		0.295	1.563	2.037	1.463	2.161	1.415	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.762	2.085	0.894			0.404	2.095	3.1	2.302	3.484	1.7	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.998	3.519	0.882				4.353	3.241	0.685	6.13	1.931	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.205					0.885	4.019	3.183	6.153	4.622	3.771	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.945	1.577	0.902	0.744		0.265	1.521	2.337	1.508	2.523	1.375	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.246	1.679	1.041	0.612		0.584	1.667	2.164	2.68	2.537	1.83	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.064	1.552	0.888				1.53	1.473	2.101	1.91	1.964	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.69	1.402	0.886	0.507		0.537	1.515	2.147	1.571	2.102	1.508	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.021	1.434	0.89	0.509		0.358	1.35	2.183	1.646	2.41	1.249	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.79	1.171	0.905			0.549	1.015	1.074	0.899	2.062	0.909	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.227	1.169	0.884			0.539	1.374	1.776	1.416	1.878	1.735	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.68	1.351	0.883			0.549	1.132	0.826	0.648	2.785	1.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.248	2.722	1.007			0.553	1.86	3.329	1.198	2.73	3.184	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.038	6.797	0.883			0.648	3.617	6.722	15.126	7.93	5.992	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.267							0.634	0.577	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.134	1.701	0.899			0.518	1.432	1.665	1.385	2.264	1.365	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.343	2.013	0.91			0.397	1.788	2.361	1.672	2.837	1.834	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.682	2.18	1.872	0.612		0.572	2.019	2.396	3.547	2.866	2.159	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.302	1.947	0.882				1.966	1.242	0.645	2.375	0.915	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.39	1.432	0.896			0.648	1.923	2.196	2.365	2.752	1.676	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	1.964	0.899	0.612		0.54	2.369	2.285	3.146	3.208	2.146	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.603	1.868	0.895			0.456	2.588	2.02	1.841	2.736	1.848	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.945	1.14	0.883				1.356	2.119	1.725	2.053	1.288	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.651	1.255	0.879	0.611		0.31	0.885	2.008	1.222	1.85	1.005	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.239	3.003	2.537			0.539	1.184	2.391	4.976	1.861	2.982	
COVID19 (COVID19 (JANSSEN))	Vasodilation	2.661	0.881					0.929	1.569	0.976	1.822	1.071	
COVID19 (COVID19 (JANSSEN))	Venogram	2.684	2.005					2.15	1.758	0.721	3.098	0.996	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.385	3.522				0.606	2.964	1.884	0.703	4.205	1.193	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.266	2.611	0.882				3.874	2.212	0.845	5.211	1.19	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.371	0.832		7.378	0.884		1.207	0.513		1.329	1.004	
COVID19 (COVID19 (MODERNA))	Headache	0.968	0.959	0.888	6		0.301	0.943	0.984	1.013	0.954	1.019	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.357	0.947	0.887		1.156	2.623	0.115	0.04	0.493	2.36	2.417	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.042	1.997	0.881			2.204	2.002	1.945	1.574	1.884	2.12	
COVID19 (COVID19 (PFIZER-	Body height	1.931	1.021	0.885			1.6	0.927	1.307	2.186	1.908	1.496	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.05	1.049	0.882			0.637	1.527	1.69	1.944	2.007	1.596	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.284	1.717	1.305			1.024	1.728	1.792	1.941	2.04	1.98	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.726	0.846	0.884	13.852			0.393			0.422	1.14	
COVID19 (COVID19 (PFIZER-	Investigation	2.141	1.707	0.901			1.048	1.729	1.928	2.309	2.11	1.929	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.317	0.329	0.875		3.945	0.321	0.16	0.049	0.301	0.294	1.34	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.768	0.751				1.343	1.853	1.799	2.276	1.784	1.728	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.336	0.891			0.854	1.536	1.728	2.152	2.001	1.78	

PSI-HHS-000000057600

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From: Menschik, David
Sent: Tue, 26 Oct 2021 16:15:43 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Niu, Manette (FDA/CBER); Baumblatt, Jane (FDA/CBER)
Subject: RE: [EXTERNAL] RE: Weekly data mining

FYI: regarding the alert for headache (n=6), the VAERS IDs are:
1737643-1
1621625-1
1238626-1
1272428-1
0953219-1
0937279-1

Vaccine Name	Symptom: PT	N	EB05	SUBSET
COVID19 (COVID19 (MODERNA))	Headache	6	5.803	00_23.9mo

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 26, 2021 10:43 AM
To: Menschik, David <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani, Meghna <[redacted]>; Broder, Karen R (CDC) <[redacted]>; Harrington, Theresa (CDC) <[redacted]>
Subject: [EXTERNAL] RE: Weekly data mining

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Hi David,

Thanks for sharing. Looks to me like the biggest signals (i.e., EB05 >=2) pertain to TTS and thromboembolic events, primarily DVT.

(b)(5)

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, October 26, 2021 7:14 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER)

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<[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>;
Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/22/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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From: Menschik, David
Sent: Tue, 26 Oct 2021 11:13:30 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211022.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/22/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021(22	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.512	1.79	0.886			0.402	1.642	1.856	1.661	2.774	1.214	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.088	1.699	0.873				1.576	2.15	1.71	2.634	1.388	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.86	1.257	0.93			0.478	1.209	1.763	1.62	2.131	1.418	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.157	6.902	0.874				0.861	0.753	0.737	2.475	1.821	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.643	1.015	0.877				1.019	0.693	0.723	1.611	1.455	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.821	1.247	0.896				1.373	1.362	1.369	2.051	1.098	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.957	2.191	0.886			0.503	1.859	2.102	3.387	4.211	1.383	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.113	1.805	0.872				1.726	1.75	1.09	2.215	1.341	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.546	1.969	0.896			0.446	1.686	2.549	2.272	2.818	2.035	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.974	1.695	0.885			0.373	1.298	2.453	0.996	2.266	1.319	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.337	0.803	0.871			0.081	0.898	1.732	1.939	2.096	1.921	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.672	0.956	0.512		0.443	1.863	2.064	2.47	2.874	1.589	
COVID19 (COVID19 (JANSSEN))	Anoxia	2.011	1.886	0.873				0.862	1.867	1.331	1.681	1.492	
COVID19 (COVID19 (JANSSEN))	Antiphospholipid syndrome	1.81	1.188	0.872				0.899	1.178	1.368	2.134	0.939	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.811	1.507	0.875	0.508		0.338	1.186	2.424	1.418	2.149	1.201	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.665	1.478	0.873	0.508		3.3	1.26	2.211	1.247	1.978	1.153	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.833	1.421	0.88			0.413	1.352	2.211	1.583	2.103	1.424	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.938	1.491	0.891			0.467	1.33	2.292	1.653	2.316	1.292	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.237	2.584	0.882			0.515	1.67	2.113	0.737	4.428	1.903	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.762	1.479	0.882			0.263	1.134	2.018	1.36	2.4	0.997	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.691	1.564	0.871			0.203	1.339	2.039	1.198	2.01	0.863	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.647	2.206	0.871				1.617	2.612	1.173	2.345	2.13	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.233	1.828	0.907			0.527	1.723	1.914	1.452	3.284	1.095	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.513	1.969	0.894			0.542	1.148	1.362	0.997	3.271	0.974	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.027	1.436	0.872				0.973	1.194	1.354	2.291	1.035	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.398	2.491	0.886			0.528	2.574	2.522	0.823	4.072	1.217	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.717	1.984	0.904	0.511		0.647	2.259	2.46	2.206	3.928	1.772	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.969	1.451	0.886			0.413	1.648	2.079	1.589	2.15	1.486	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.076	1.599	0.894			0.477	1.452	2.15	1.893	2.371	1.594	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.576	1.663	0.922			0.473	2.199	2.246	3.24	3.174	2.009	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.765	1.462	0.87				1.298	2.286	1.373	2.051	1.169	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.278	1.336	0.881			0.382	2.194	2.069	1.89	2.55	1.583	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.127	1.487	0.908	0.511		0.338	1.632	2.392	2.076	2.852	1.449	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.964	1.007	0.872			0.433	1.712	1.968	0.769	2.206	1.207	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.321	1.009	0.88			0.423	2.341	1.79	0.989	2.591	1.413	
COVID19 (COVID19 (JANSSEN))	Guillain-Barré syndrome	2.265	1.907	0.874				1.333	2.877	1.765	2.15	2.109	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.758	1.326	0.89	0.506		0.439	1.281	2.072	1.62	2.132	1.286	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.707	1.28	0.887	0.507		0.34	1.375	1.971	1.497	2.041	1.277	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.627	3.707	0.853				4.089	4.85	5.522	7.11	2.291	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.755	3.489	0.873			0.553	5.044	5.353	6.667	7.467	1.208	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.054	1.943	0.872			0.02	1.856	2.475	1.554	2.182	1.858	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.749	1.4	0.955			0.029	1.352	1.964	1.823	2.128	1.347	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.783	1.286	0.872	0.746		0.409	1.586	1.943	1.27	2.211	1.231	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.901	1.238	0.878				1.359	1.944	0.907	2.038	1.202	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.124	2.016	0.873				1.589	1.137	0.744	2.681	0.764	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.861	1.484	0.87				1.199	2.153	2.076	1.883	1.665	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.047	1.825					0.902	2.361	1.175	1.515	1.788	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.535	1.201	0.877			0.184	1.012	2.016	1.514	1.91	1.09	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.171	1.745	0.876			0.515	1.778	1.907	2.315	2.511	1.595	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	1.966	1.403	0.873	0.511		0.488	1.344	2.226	1.251	2.171	1.207	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.717	1.227	0.872			0.357	1.23	2.275	0.863	2.053	1.017	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.018	1.515	0.936			3.5	0.955	2.023	1.626	1.915	1.832	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.531	1.302	0.881	0.61		0.225	0.987	2.003	1.734	2.337	0.972	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.561	1.32	0.875			0.13	1.225	1.896	1.243	2.351	0.791	
COVID19 (COVID19 (JANSSEN))	Off label use	1.469	0.23	0.872			5.899	0.347	0.502	0.41	0.925	1.339	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.764	0.758					2.979	1.068		2.203		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.541	6.855				0.532	1.827	2.172	1.171	2.541	1.459	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.441	1.789	0.873				0.656	1.067	2.551	2.379	0.972	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.719	2.497	0.922	0.511		0.466	1.003	3.104	1.796	3.124	1.791	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.842	1.419	0.894	0.508		0.299	1.549	2.033	1.469	2.147	1.413	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.754	2.1	0.887			0.41	2.104	3.036	2.353	3.445	1.71	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.067	3.544	0.874				4.321	3.004	9.686	6.083	2.004	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.151					0.883	3.986	2.903	6.155	4.56	3.718	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.878	1.519	0.893	0.744		0.269	1.495	2.33	1.333	2.38	1.338	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.309	1.872	1.006	0.512		0.591	1.654	2.139	1.557	2.535	1.796	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.027	1.549	0.881				1.514	1.481	2.077	1.902	1.807	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.847	1.377	0.877	0.507		0.566	1.435	2.121	1.543	2.054	1.468	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.971	1.493	0.88	0.509		0.383	1.308	2.186	1.546	2.347	1.211	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.247	1.182	0.876			0.543	1.4	1.776	1.406	1.893	1.744	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.56	1.237	0.872			0.553	1.033	0.825	0.65	2.148	0.668	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.219	2.742	1.941			0.537	2.045	2.341	1.163	2.685	3.191	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.998	6.737				0.651	3.574	6.684	15.215	7.897	5.883	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.158							0.604	0.58	0.569	1.021	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.067	1.676	0.888			0.527	1.413	1.582	1.405	2.083	1.405	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.259	2.009	0.9			0.491	1.782	2.316	1.642	2.742	1.621	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.665	2.178	1.814	0.512		0.582	2.002	2.39	3.528	2.861	2.147	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.274	1.957	0.873				1.949	1.209	0.646	2.322	0.913	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.332	1.809	0.884			0.48	1.691	2.14	2.218	2.884	1.66	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.74	1.985	0.887	0.512		0.547	2.306	2.283	3.137	3.193	2.141	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.551	1.814	0.886			0.483	2.656	1.973	1.642	2.617	1.844	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.948	1.156	0.878				1.361	2.138	1.747	2.054	1.289	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.182	2.797	2.377			0.583	1.15	2.337	4.791	1.834	2.013	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.063	6.881					0.868	1.585	0.972	1.773	1.012	
COVID19 (COVID19 (JANSSEN))	Venogram	2.674	2.031					2.176	1.749	0.721	3.085	0.993	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.356	2.532				0.608	2.931	1.87	0.703	4.161	1.169	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.164	2.444	0.873				3.685	2.181	0.851	5.132	1.122	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.334	0.831		7.31	0.871		1.197	0.513		1.314	0.953	
COVID19 (COVID19 (MODERNA))	Headache	0.969	0.963	0.876	5.803		0.305	0.945	0.985	1.014	0.955	1.025	
COVID19 (COVID19 (MODERNA))	No adverse event	1.157	0.844	0.878		0.273	2.025	0.917	0.903	0.762	1.091	1.205	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.373	6.944	0.878		1.223	2.6	0.12	0.051	0.534	2.378	2.422	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.42	1.966	0.872			2.16	1.966	1.903	1.07	1.84	2.102	
COVID19 (COVID19 (PFIZER-	Body height	1.931	1.011	0.876			0.602	0.875	1.32	2.197	1.908	1.489	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.058	1.049	0.872			0.639	1.515	1.68	1.943	2.014	1.801	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.268	1.711	0.965			1.013	1.736	1.799	1.952	2.058	1.991	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.708	0.818	0.875	11.894			0.396			0.407	1.177	
COVID19 (COVID19 (PFIZER-	Investigation	2.151	1.702	0.896			1.035	1.734	1.935	2.31	2.122	1.934	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.314	6.328	0.886		4.084	0.317	0.188	0.052	0.29	0.291	0.337	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.757	6.752				1.35	1.865	1.85	2.301	1.808	1.752	
COVID19 (COVID19 (PFIZER-	Weight	2.038	1.324	0.882			0.853	1.521	1.726	2.202	2.011	1.777	

PSI-HHS-000000057604

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From: Menschik, David
Sent: Thu, 21 Oct 2021 17:34:59 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER)
Subject: RE: [EXTERNAL] Re: Moderna booster dose

Wondering if perhaps the VAERS "Dose number in series" box could be moved next to "Vaccine" box to presumably increase reporting rate?

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, October 21, 2021 12:26 PM
To: Su, John (CDC) <[redacted]>; Nair, Narayan <[redacted]>; Menschik, David <[redacted]>; Alimchandani, Meghna <[redacted]>; Marquez, Paige L (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>
Subject: RE: [EXTERNAL] Re: Moderna booster dose

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That's fine. I think (b)(5) (b)(5)

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, October 21, 2021 12:22 PM
To: Nair, Narayan (FDA/CBER) <[redacted]>; Menschik, David (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] Re: Moderna booster dose

I'd be happy to defer discussion on this topic until Tuesday. Given a full 2 days of ACIP, I'd also be happy deferring our 5 p.m. meeting until Tuesday as well…But I wasn't sure if we had other topics to discuss (which might very well be the case, depending upon ACIP…)

- John

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From: Nair, Narayan <[redacted]>
Sent: Thursday, October 21, 2021 12:08 PM
To: Menschik, David (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] Re: Moderna booster dose

Hi Tom/Paige/John

David and Craig are not available tonight and I think it would be helpful to have them part of this discussion. If a meeting is needed I was wondering if we could set something up for early next week when they will be able to attend.

Narayan

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, October 20, 2021 1:45 PM
To: Menschik, David <[redacted]>; Zinderman, Craig E <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Su, John (CDC) <[redacted]>
Subject: RE: [EXTERNAL] Re: Moderna booster dose

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Hey Tom,
John and I just spoke. Let's bring up this topic on the 5-6pm CDC/FDA call tomorrow night.

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Wednesday, October 20, 2021 1:26 PM
To: Menschik, David <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: [EXTERNAL] Re: Moderna booster dose

Tom- I will hold off on discussing this topic with GDIT until further notice. Please let me know if I should set up a call to talk about this issue in more detail.

Paige

From: Menschik, David <[redacted]>
Sent: Wednesday, October 20, 2021 11:44 AM
To: Zinderman, Craig E (FDA/CBER) <[redacted]>; Shimabukuro, Tom

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(CDC/DDID/NCEZID/DHQP) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: [EXTERNAL] Re: Moderna booster dose

This indeed seems complicated. Agree with concerns below, plus If we label Moderna lower dose as a booster, and then the lower dose becomes the initial dose for pediatrics, it will add to the confusion. There's also the issue of data mining – if these are captured as separate vaccines, data mining output interpretation will become confusing and may not be meaningfully interpretable. Seems cleanest to keep same vaccine name as is regardless of dose and then build assumed dose in to downstream analyses/reporting (e.g., for 5-11 year-olds, assume they are getting a pediatric dose for Pfizer; for 3+ dose of Moderna [good reporting rate for dose number in series], assume the lower dose, etc.)

From: Zinderman, Craig E <[redacted]>
Sent: Wednesday, October 20, 2021 11:28 AM
To: Shimabukuro, Tom (CDC) <[redacted]>; Marquez, Paige L (CDC) <[redacted]>
Cc: Su, John (CDC) <[redacted]>; Menschik, David <[redacted]>
Subject: RE: [EXTERNAL] Re: Moderna booster dose

++ David

Thanks Tom. I can understand the interest in isolating Booster-related reports. However, I seem some challenges with doing this: First, it seems unlikely that programming changes could happen that quickly. Also, do we have separate drop down listings for other vaccines with multiple dosages/pediatric dosages? If not, this booster category would be inconsistent with other VAERS reporting. Last, the absence of a listing for a Pfizer booster would leave reporters wondering how to report their Pfizer booster.

Is there elsewhere in the form where dose could be captured?

Thanks,
Craig.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 19, 2021 8:57 PM
To: Marquez, Paige L (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Su, John (CDC) <[redacted]>
Subject: [EXTERNAL] Re: Moderna booster dose

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It could happen as early as Friday and just go with whatever nomenclature is easiest. Thanks.

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From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 19, 2021 8:50:40 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Moderna booster dose

Hey Tom,
How soon would you guys need to [(b)(5)]? I will need to work with GDIT to add this additional entry to the website and writable pdf. I would assume they will request at least a week notification. CDC will need to update their surveillance programs as well.

Note: If this is the only variation of the vaccine, I would recommend [(b)(5)]
[(b)(5)]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 19, 2021 11:02 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
Cc: Licata, Charles (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Moderna booster dose

I think [(b)(5)]
[(b)(5)]
[(b)(5)] I'm including Craig to see if he has any ideas.

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 19, 2021 10:58 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Licata, Charles (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Moderna booster dose

Hey Tom,
When you say [(b)(5)]
[(b)(5)]
I'm thinking [(b)(5)]
[(b)(5)]?
Should this [(b)(5)] or should it [(b)(5)]
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Maybe we can have a quick call.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 19, 2021 10:41 AM

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To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Licata, Charles (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Moderna booster dose

(b)(5)

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David
Sent: Wed, 20 Oct 2021 15:44:26 +0000
To: Zinderman, Craig E (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
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Cc: Licata, Charles (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Moderna booster dose

(b)(5)

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From: Menschik, David
Sent: Tue, 19 Oct 2021 10:13:43 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211015.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/15/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.106	1.812	0.88			0.605	1.606	1.858	1.679	2.834	1.178	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.992	1.613	0.896				1.452	2.119	1.594	2.373	1.38	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.837	1.253	0.923			0.486	1.227	1.684	1.605	2.146	1.362	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.102	6.887	0.871				0.86	0.729	0.742	2.444	1.595	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.788	1.202	0.886				1.324	1.344	1.279	2.011	1.034	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.997	2.232	0.879			0.597	1.875	2.074	3.606	4.256	1.378	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.088	1.585	0.868				1.737	1.662	1.104	2.142	1.353	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.57	2.006	0.883			0.453	1.72	2.596	2.197	2.98	1.997	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.784	1.529	0.873			0.379	1.193	2.464	0.771	2.078	1.248	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.249	6.812	0.867			0.584	0.82	1.668	2.002	2.017	1.83	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.224	1.681	1.000	0.612		0.445	1.875	2.61	2.42	2.861	1.593	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.823	1.172	0.868				0.911	1.172	1.401	2.217	0.937	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.731	1.375	0.87	0.61		0.342	1.144	2.408	1.211	1.968	1.209	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.887	1.491	0.889	0.606		0.368	1.217	2.165	1.199	1.824	1.366	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.779	1.366	0.869			0.413	1.324	2.154	1.444	2.008	1.37	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.829	1.381	0.878			0.471	1.283	2.179	1.495	2.134	1.259	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.376	5.847	0.879			0.519	1.524	2.464	0.733	3.453	1.819	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.717	1.443	0.879			0.264	1.114	1.998	1.285	2.275	0.992	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.672	1.549	0.866			0.194	1.296	2.068	1.211	1.973	0.876	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.628	2.203	0.867				1.571	2.662	1.176	2.255	2.128	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.671	1.176	0.874				1.266	0.942		2.165	0.613	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.248	1.849	0.908			0.531	1.794	1.927	1.45	3.271	1.107	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.564	2.01	0.892			0.566	1.147	13	1.009	3.342	0.978	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.021	1.444	0.868				1.005	1.096	1.366	2.273	1.015	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.415	2.509	0.886			0.532	2.626	2.504	0.823	4.048	1.231	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.719	2.002	0.944	0.611		0.649	2.242	2.479	2.213	3.524	1.764	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.932	1.429	0.876			0.419	1.039	1.989	1.013	2.091	1.472	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.064	1.627	0.896			0.485	1.465	2.14	1.905	2.387	1.592	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.553	1.841	0.905			0.477	2.193	2.192	3.194	3.138	1.99	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.649	1.321	0.868				1.161	2.264	1.241	1.844	1.153	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.281	1.309	0.877			0.385	2.159	2.082	1.949	2.539	1.585	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.122	1.479	0.9	0.611		0.342	1.653	2.353	1.959	2.568	1.42	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.975	1.093	0.868			0.436	1.666	1.968	0.777	2.179	1.14	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.301	6.978	0.874			0.43	2.346	1.757	0.933	2.618	1.355	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.277	1.872	0.866				1.322	2.837	1.659	2.121	2.051	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.718	1.304	0.88	0.606		0.442	1.266	2.033	1.549	2.085	1.25	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.42	3.584	0.875				3.943	4.472	5.482	6.847	2.105	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.722	3.447	0.869			0.557	5.027	5.136	0.668	7.434	1.066	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.047	1.954	0.869			0.018	1.847	2.482	1.52	2.171	1.847	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.728	1.402	0.949			0.027	1.356	1.929	1.809	2.13	1.318	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.748	1.255	0.861	0.746		0.413	1.598	1.867	1.223	2.104	1.228	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.991	1.283	0.874				1.387	1.963	0.913	2.059	1.22	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.128	2.026	0.909				1.564	1.142	0.745	2.464	0.774	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.823	1.419	0.866				1.205	2.072	1.053	1.662	1.618	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.971	1.764					0.906	2.265	1.083	1.468	1.712	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.199	1.749	0.871			0.518	1.8	1.806	2.289	2.881	1.998	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	1.9	1.35	0.861	0.611		0.47	1.333	2.108	1.214	2.107	1.15	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.662	1.212	0.863			0.359	1.218	2.28	0.796	2.008	1.012	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.515	1.296	0.882	0.61		0.223	0.95	2.048	1.731	2.381	0.973	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.561	1.236	0.871			0.121	1.249	1.674	1.093	2.174	0.768	
COVID19 (COVID19 (JANSSEN))	Off label use	1.577	6.267	0.867			5.617	0.37	0.545	0.438	0.982	1.4	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.809	0.757					2.927	1.019		2.346		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.502	6.856				0.536	1.736	2.213	1.084	2.455	1.43	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.768	1.895	0.888				0.656	1.078	2.616	2.33	0.995	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.697	2.454	0.924	0.611		0.496	1.91	3.065	1.736	3.128	1.753	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.841	1.436	0.891	0.61		0.303	1.572	2.05	1.44	2.184	1.406	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.766	2.13	0.882			0.413	2.106	3.052	2.406	3.472	1.704	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.039	3.56	0.869				4.305	2.975	0.688	6.038	2.07	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.101					0.604	3.999	2.96	3.913	4.077	3.99	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.829	1.48	0.877	0.744		0.274	1.473	2.261	1.272	2.328	1.291	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.204	1.672	0.968	0.612		0.596	1.666	2.115	2.561	2.533	1.787	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.005	1.55	0.877				1.549	1.361	2.105	1.913	1.56	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.789	1.333	0.871	0.608		0.551	1.415	2.094	1.412	1.983	1.425	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.877	1.325	0.869	0.609		0.388	1.301	2.068	1.432	2.208	1.169	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.222	1.145	0.872			0.547	1.398	1.764	1.277	1.844	1.755	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.143	2.642	1.836			0.541	2.018	2.364	0.89	2.666	3.068	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.068	6.603				0.653	3.897	6.602	15.3	8.267	5.807	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.075							0.634	0.582	0.57	1.019	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.037	1.602	0.877			0.531	1.337	1.515	1.416	2.108	1.28	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.217	1.957	0.889			0.407	1.797	2.218	1.539	2.602	1.595	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.658	2.186	1.862	0.612		0.591	2.02	2.385	3.517	2.839	2.156	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.26	1.923	0.899				1.935	1.237	0.647	2.291	0.913	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.277	1.298	0.878			0.656	1.812	2.065	2.223	2.571	1.633	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	2.002	0.884	0.612		0.55	2.273	2.278	3.265	3.222	2.129	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.469	1.761	0.877			0.47	2.092	1.665	1.465	2.47	1.641	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.744	1.283	0.865	0.61			1.18	1.961	2.005	1.702	1.838	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.98	1.171	0.871				1.373	2.174	1.771	2.104	1.298	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.128	2.788	2.281			0.379	0.983	2.312	4.888	1.771	1.897	
COVID19 (COVID19 (JANSSEN))	Venogram	2.791	2.076					2.114	1.801	0.722	3.193	1.015	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.365	2.534				0.617	2.907	1.862	0.704	4.132	1.195	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.31	3.527	0.869				3.636	2.489	0.883	5.358	1.077	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.303	6.769		6.795	0.832		1.193	0.513		1.295	0.945	
COVID19 (COVID19 (MODERNA))	Headache	0.968	6.961	0.867	5.591		0.308	0.945	0.985	1.014	0.954	1.027	
COVID19 (COVID19 (MODERNA))	No adverse event	1.212	6.842	0.875		0.271	2.015	0.915	0.897	0.752	1.084	1.202	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.387	6.928	0.872		1.348	2.583	0.144	0.065	0.578	2.398	2.43	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.985	1.87	0.868			2.087	1.954	1.912	1.549	1.856	2.071	
COVID19 (COVID19 (PFIZER-	Body height	1.933	1.002	0.872			0.604	0.878	1.282	2.213	1.911	1.484	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.069	1.051	0.867			0.641	1.514	1.672	1.549	2.018	1.59	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.258	1.72	0.955			1.006	1.74	1.817	1.988	2.064	1.993	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.685	6.845	0.871	10.376			0.353			0.402	1.115	
COVID19 (COVID19 (PFIZER-	Investigation	2.158	1.696	0.891			1.02	1.726	1.927	2.316	2.123	1.836	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.31	6.347	0.863		4.284	0.311	0.22	0.052	0.286	0.287	0.332	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.835	6.752				1.376	1.883	1.886	2.327	1.838	1.78	
COVID19 (COVID19 (PFIZER-	Weight	2.036	1.296	0.878			0.85	1.516	1.71	2.211	2.011	1.764	

PSI-HHS-000000057614

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From: Menschik, David
Sent: Tue, 12 Oct 2021 10:30:11 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: Weekly data mining
Attachments: USST_20211008.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/8/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211108	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 202116	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.603	1.751	0.891			0.496	1.568	1.727	1.585	2.611	1.137	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.017	1.661	0.88				1.516	2.046	1.649	2.348	1.42	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.862	1.241	0.92			0.488	1.272	1.61	1.571	2.06	1.345	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.072	0.894	0.885				0.871	0.741	0.749	2.455	1.587	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.017	2.254	0.891			0.51	1.937	2.013	3.715	4.336	1.396	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.065	1.601	0.882				1.729	1.616	1.127	2.042	1.384	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.588	2	0.892			0.455	1.691	2.565	2.223	2.94	1.986	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.703	1.428	0.887			0.381	1.115	2.253	0.796	1.938	1.217	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.207	0.811	0.882			0.59	0.825	1.653	1.894	1.965	1.831	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.22	1.684	1	0.512		0.446	1.86	2.009	2.406	2.871	1.576	
COVID19 (COVID19 (JANSSEN))	Anxiety	2.089	2.009	0.883				0.894	1.929	1.317	1.998	1.336	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.689	1.347	0.886	0.61		0.344	1.122	2.362	1.181	1.884	1.201	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.531	1.354	0.886	0.61		0.308	1.178	2.097	1.076	1.778	1.101	
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.715	1.339	0.883			0.418	1.215	2.049	1.169	1.942	1.339	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.73	1.29	0.887			0.472	1.279	2.03	1.347	2.048	1.171	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.8	2.726	0.891			0.522	1.677	2.202	0.756	4.662	0.976	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.698	1.448	0.888			0.357	1.13	1.977	1.217	2.301	0.997	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.602	2.198	0.882				1.586	2.538	1.189	2.175	2.123	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.784	1.22	0.887				1.339	0.941		2.698	0.618	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.274	1.881	0.914			0.539	1.863	1.904	1.469	3.321	1.121	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.564	1.966	0.901			0.549	1.046	1.299	1.024	3.429	0.916	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.052	1.528	0.883				1.006	1.094	1.478	2.351	1.014	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.388	2.5	0.896			0.535	2.66	2.521	0.743	3.992	1.244	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.739	2.04	0.938	0.511		0.649	2.291	2.454	2.255	3.571	1.761	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.91	1.403	0.888			0.416	1.605	2.002	1.453	2.061	1.453	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.113	1.656	0.905			0.489	1.485	2.122	1.99	2.432	1.602	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.597	1.992	0.917			0.479	2.183	2.209	0.249	3.138	2.013	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.668	1.285	0.886				1.152	2.208	1.264	1.778	1.129	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.753	0.797	0.882			1.163	2.004	1.521	1.018	1.907	1.411	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.307	1.329	0.89			0.391	2.168	2.119	1.914	2.563	1.596	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.098	1.452	0.905	0.511		0.344	1.619	2.314	1.934	2.532	1.395	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.976	0.993	0.882			0.439	1.676	1.883	0.785	2.174	1.146	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.36	0.934	0.886			0.532	2.334	1.665	0.549	2.852	1.331	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.354	1.902	0.881				1.339	2.847	1.691	2.128	2.101	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.671	1.269	0.89	0.507		0.446	1.236	1.943	1.531	2.018	1.219	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.33	3.47	0.891				3.71	4.374	5.465	6.881	1.84	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.627	3.345	0.883			0.56	4.748	5.142	6.669	7.331	1.069	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.046	1.957	0.883			0.619	1.816	2.492	1.548	2.123	1.864	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.702	1.395	0.939			0.604	1.337	1.894	1.826	2.073	1.314	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.709	1.234	0.878	0.746		0.419	1.565	1.768	1.211	2.053	1.196	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.947	1.283	0.887				1.353	1.977	0.92	2.068	1.207	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.112	2.005	0.883				1.499	1.153	0.745	2.761	0.704	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.627	1.45	0.881				1.209	2.093	1.007	1.661	1.605	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.958	1.746					0.916	2.21	1.083	1.417	1.734	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.168	1.77	0.885			0.52	1.825	1.899	2.261	2.542	1.564	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	1.879	1.397	0.88	0.511		0.477	1.349	1.907	1.283	2.7	1.108	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.587	1.128	0.88			0.36	1.17	2.161	0.641	1.873	0.946	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.473	1.268	0.895	0.61		0.22	0.957	1.943	1.731	2.236	0.932	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.408	1.17	0.884			0.199	1.19	1.581	1.066	2.104	0.711	
COVID19 (COVID19 (JANSSEN))	Off label use	1.565	0.288	0.883			5.691	0.37	0.549	0.441	0.885	1.399	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.799	0.758					2.899	1.017		2.311		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.501	0.86				0.539	1.735	2.253	1.084	2.468	1.427	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.758	1.895	0.883				0.656	1.077	2.545	2.278	0.996	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.661	2.449	0.925	0.512		0.498	1.919	3.134	1.734	3.199	1.74	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.82	1.439	0.896	0.61		0.397	1.543	2.042	1.45	2.141	1.384	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.767	2.138	0.892			0.413	2.125	3.062	2.451	3.53	1.894	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.023	3.54	0.883				4.296	3.171	0.888	6.007	2.09	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.041					0.86	3.913	2.978	5.887	4.478	3.67	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.765	1.436	0.898	0.746		0.274	1.436	2.159	1.269	2.264	1.249	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.21	1.676	0.952	0.512		0.681	1.662	2.132	2.521	2.528	1.797	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	1.998	1.559	0.889				1.521	1.367	2.149	1.918	1.548	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.742	1.298	0.886	0.609		0.561	1.347	2.013	1.419	1.982	1.409	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.765	1.263	0.879	0.61		0.371	1.233	1.943	1.396	2.103	1.115	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.264	1.105	0.885			0.55	1.397	1.76	1.287	1.853	1.711	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.674	1.663	1.788			0.544	2.012	2.392	0.833	2.654	3.019	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.927	0.61				0.855	3.498	6.583	15.574	8.083	5.763	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.2	1.962	0.896			0.408	1.822	2.197	1.511	2.614	1.56	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.638	2.205	1.825	0.512		3.6	2.028	2.377	3.557	2.832	2.152	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.267	1.934	0.883				1.768	1.268	0.652	2.4	0.857	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.295	1.292	0.888			0.666	1.842	2.084	2.197	2.582	1.853	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.762	2	0.896	0.512		0.551	2.257	2.275	3.335	3.242	2.137	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.448	1.752	0.88			0.473	2.686	1.769	1.472	2.411	1.799	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.744	1.3	0.88	0.509			1.195	1.504	2.044	1.698	1.648	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.976	1.159	0.885				1.364	2.178	1.787	2.101	1.294	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.409	2.696	2.173			0.377	1.001	2.343	4.743	1.962	2.16	
COVID19 (COVID19 (JANSSEN))	Venogram	2.765	2.105					2.207	1.751	0.723	3.157	1.015	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.268	2.473				0.619	2.71	1.792	0.765	4.233	1.023	
COVID19 (COVID19 (JANSSEN))	Venous stenosis	4.281	2.479	0.883				3.36	2.439	0.883	8.23	0.854	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.274	0.767		5.851	0.797		1.187	0.515		1.293	0.935	
COVID19 (COVID19 (MODERNA))	Headache	0.967	0.958	0.88	4.09		0.394	0.944	0.986	1.014	0.953	1.026	
COVID19 (COVID19 (MODERNA))	No adverse event	1.227	0.842	0.888		0.294	2.026	0.9	0.906	0.766	1.103	1.211	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.394	0.928	0.885		1.316	2.56	0.172	0.167	0.581	2.408	2.437	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.947	1.953	0.882			2.119	1.963	1.894	1.529	1.832	2.045	
COVID19 (COVID19 (PFIZER-	Body height	1.53	1.002	0.886			0.604	0.879	1.268	2.218	1.903	1.476	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.058	1.051	0.882			0.641	1.509	1.671	1.961	2.023	1.587	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.252	1.708	0.954			0.599	1.755	1.876	2	2.068	1.987	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.655	0.847	0.885	9.271			0.384			0.404	1.108	
COVID19 (COVID19 (PFIZER-	Investigation	2.158	1.701	0.9			1.012	1.725	1.918	2.335	2.127	1.936	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.307	0.346	0.878		4.258	0.307	0.233	0.089	0.319	0.284	0.329	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.84	0.753				1.381	1.881	1.898	2.312	1.831	1.773	
COVID19 (COVID19 (PFIZER-	Weight	2.609	1.285	0.88			0.946	1.513	1.704	2.219	2.02	1.702	

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From: Menschik, David
Sent: Tue, 5 Oct 2021 10:01:55 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211001.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/1/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211100	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 202110	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.936	1.684	0.886			0.497	1.33	1.736	1.597	2.374	1.144	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.04	1.717	0.878				1.515	2.043	1.71	2.297	1.459	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.81	1.261	0.923			0.489	1.221	1.553	1.642	2.057	1.344	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.059	6.903	0.882				0.894	0.746	0.752	2.48	1.584	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.744	1.195	0.86				1.373	1.318	1.199	2.027	0.992	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.074	2.278	0.886			0.511	1.937	1.948	3.949	4.31	1.414	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.084	1.651	0.878				1.797	1.614	1.082	2.038	1.392	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.511	1.987	0.888			0.456	1.691	2.497	2.152	2.881	1.932	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.69	1.439	0.882			0.386	1.137	2.251	0.776	1.94	1.189	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.171	6.819	0.878			0.591	0.829	1.676	1.778	1.947	1.797	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.203	1.689	1.347	0.612		0.446	1.539	1.998	2.376	2.868	1.944	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.142	2.09	0.879				0.883	2.046	1.339	1.668	1.58	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.623	1.298	0.882	0.509		0.396	1.022	2.422	1.118	1.821	1.132	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.808	1.366	0.882	0.509		0.396	1.141	2.663	1.214	1.797	1.286	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.66	1.303	0.879			0.416	1.262	2.001	1.381	1.851	1.311	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.059	2.535	0.886			0.523	1.296	1.999	0.756	4.324	0.906	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.602	1.39	0.885			0.36	1.094	1.894	1.191	2.088	0.977	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.581	2.226	0.878				1.542	2.54	1.208	2.221	2.058	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.776	1.223	0.894				1.341	0.941		2.655	0.818	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.26	1.888	0.911			0.54	1.784	1.928	1.479	3.348	1.09	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.411	1.932	0.893			0.551	1.047	1.203	1.042	3.365	0.854	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.049	1.549	0.879				1.005	1.09	1.499	2.341	1.016	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.217	2.421	0.891			0.537	2.495	2.567	0.748	3.837	1.196	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.76	2.075	0.932	0.611		0.649	2.281	2.446	2.329	3.566	1.781	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.174	1.729	0.906			0.492	1.51	2.172	2.091	2.488	1.648	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.542	1.84	0.904			0.481	2.167	2.195	3.16	3.107	1.987	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.937	1.275	0.882				1.073	2.245	1.218	1.795	1.953	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.864	0.79	0.875			1.161	2.013	1.536	1.008	1.915	1.421	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.32	1.327	0.886			0.392	2.206	2.089	1.965	2.572	1.801	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.108	1.471	0.896	0.611		0.347	1.635	2.305	1.997	2.627	1.403	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.871	6.985	0.876			0.442	1.613	1.862	0.785	2.104	1.12	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.253	0.93	0.88			0.439	2.324	1.663	0.882	2.671	1.244	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.339	1.962	0.877				1.342	2.879	1.687	2.112	1.12	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.36	3.473	0.889				3.398	4.462	6	6.68	1.982	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.307	3.114	0.88			0.561	4.385	3.443	6.669	6.978	1.969	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.028	1.959	0.88			0.619	1.851	2.461	1.516	2.099	1.647	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.68	1.396	0.956			0.593	1.317	1.809	1.828	2.044	1.298	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.74	1.284	0.874	0.745		0.421	1.58	1.777	1.249	2.063	1.222	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.54	1.276	0.885				1.373	1.923	0.934	2.062	1.192	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.161	2.058	0.88				1.5	1.17	0.746	2.727	0.714	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.83	1.446	0.877				1.194	2.09	1.081	1.674	1.61	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.963	1.784					0.926	2.23	1.091	1.445	1.711	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.162	1.866	0.882			0.522	1.677	1.887	2.299	2.544	1.6	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.553	1.108	0.875			0.364	1.098	2.143	0.629	1.854	0.892	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.4	1.221	0.888	0.509		0.22	0.877	1.872	1.677	2.125	0.881	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.378	1.183	0.879			0.112	1.128	1.941	1.028	2.093	0.863	
COVID19 (COVID19 (JANSSEN))	Off label use	1.608	6.237	0.878			5.549	0.383	0.573	0.376	1.022	1.434	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.789	6.757					2.892	1.014		2.295		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.515	6.875				0.54	1.839	2.139	1.095	2.539	1.395	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.723	1.906	0.879				0.656	1.075	2.447	2.21	0.996	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.729	2.466	0.928	0.612		0.504	1.97	3.141	1.683	3.232	1.714	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.862	1.432	0.892	0.509		0.31	1.558	2.041	1.339	2.133	1.352	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.772	2.16	0.86			0.416	2.112	3.064	2.553	3.484	1.892	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6	3.558	0.88				4.279	3.638	6.689	5.968	2.984	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.008					0.856	3.865	2.946	5.888	4.388	3.636	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.761	1.432	0.884	0.744		0.273	1.368	2.192	1.271	2.211	1.235	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.204	1.683	0.945	0.612		0.804	1.642	2.129	2.54	2.504	1.802	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.01	1.99	0.884				1.561	1.402	2.007	1.88	1.595	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.772	1.245	0.876	0.509		0.374	1.123	1.998	1.465	2.012	1.143	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.213	1.089	0.882			0.552	1.377	1.735	1.354	1.894	1.66	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.017	2.584	1.572			0.546	1.985	2.309	0.773	2.561	2.979	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.976	6.813				6.682	3.471	6.68	15.272	8.03	5.677	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.169	1.938	0.891			0.412	1.756	2.233	1.413	2.623	1.5	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.634	2.217	1.751	0.612		0.599	2.028	2.393	3.522	2.827	2.159	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.153	1.847	0.88				1.768	1.178	0.663	2.171	0.857	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.264	1.275	0.883			0.667	1.796	2.065	2.13	2.542	1.635	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.827	2.056	0.894	0.612		0.551	2.353	2.299	3.511	3.31	2.185	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.46	1.765	0.884			0.473	2.7	1.735	1.466	2.411	1.78	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.927	1.137	0.882				1.345	2.081	1.731	2.033	1.274	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.527	2.641	2.128			0.577	1.052	2.281	4.826	2.008	2.183	
COVID19 (COVID19 (JANSSEN))	Venogram	2.61	2.059					2.059	1.77	0.631	2.878	1.016	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.21	2.469				0.619	2.71	1.992	0.705	4.101	1.936	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.265	2.502	0.88				3.57	2.517	0.875	5.282	1.993	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.268	6.786		3.524	0.778		1.179	0.517		1.281	0.886	
COVID19 (COVID19 (MODERNA))	Headache	0.964	6.955	0.876	2.343		0.303	0.941	0.965	1.011	0.954	1.022	
COVID19 (COVID19 (MODERNA))	No adverse event	1.246	0.84	0.884		0.252	2.014	0.915	0.926	0.781	1.124	1.218	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.353	6.909	0.882		1.203	2.528	0.173	0.295	0.598	2.401	2.438	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.319	1.339	0.873			0.284	1.341	1.187	1.307	1.808	1.05	
COVID19 (COVID19 (PFIZER-	Body height	1.935	6.994	0.882			0.603	0.88	1.266	2.236	1.915	1.473	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.053	1.052	0.878			0.64	1.47	1.663	1.967	2.022	1.566	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.269	1.704	0.936			1.098	1.751	1.92	3.038	2.075	1.886	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.66	6.846	0.882	7.751			0.384			0.407	1.131	
COVID19 (COVID19 (PFIZER-	Investigation	2.155	1.7	0.897			1.005	1.723	1.907	2.354	2.13	1.93	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.305	6.357	0.875		3.331	0.305	0.259	0.102	0.329	0.282	0.329	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.852	6.658				1.361	1.68	1.915	2.336	1.847	1.775	
COVID19 (COVID19 (PFIZER-	Weight	2.045	1.287	0.887			0.623	1.51	1.704	2.241	2.034	1.756	

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From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 2 Dec 2021 12:55:05 +0000
To: Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: DE VAERS data mining methods and limitations_2021_03_DRAFT.pptx
Attachments: DE VAERS data mining methods and limitations_2021_03_DRAFT.pptx

Hi Allison,

These slides shared by FDA may be helpful in answering some of your questions and explaining data mining

Pedro

Data Mining Introduction*

- Statistical method for identifying disproportionality (excess of reported AE for product relative to other products) in large database
- Can be useful for screening and hypothesis generating only
  - Evaluate findings in clinical and epidemiological context (e.g., unexpected?)
  - Compelling hypotheses should be explored (e.g., via case series analyses)
  - Statistical signal of disproportionality ≠ safety signal
- Absence of disproportionality does not confirm absence of safety signal nor negate a signal otherwise detected

*Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff (November 2019; Draft). Available at https://www.fda.gov/media/130216/download

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DE VAERS Data Mining Methods

- Empirica™ Signal software (Oracle)
- Calculates Empiric Bayes Geometric Mean (EBGM) using observed to expected (O/E) vaccine-PT pair ratios
  - EBGM derived from statistical model (Multi-item Gamma Poisson Shrinker; MGPS) that accounts for instability from small numbers*
    - adjusted by age, gender and year received
- Vaccine-PT pairs ranked by lower 5% bound of EBGM CI (EB05)
- Standard alert threshold: EB05 >2
- Weekly US summary table includes subset alerts for age (0-1, 2-8, 9-18, 19-44, 45-64, and ≥65 years), gender, and serious/fatal

*Szarfman A, Tonning JM, Doraiswamy PM. Pharmacovigilance in the 21st century: new systematic tools for an old problem. Pharmacotherapy. 2004 Sep;24(9):1099-104. doi: 10.1592/phco.24.13.1099.38090. PMID: 15460169.

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Limitations of Data Mining Include:

- Impacted by stimulated reporting (e.g., V-safe, media reports)
- False alerts from statistical interaction (e.g., If vaccines X and Y often given concomitantly, statistical signal for vaccine X and AE Z may be driven by vaccine Y)
- MedDRA constraints (e.g., Signal X can be reflected in multiple PTs that individually do not reach alert threshold)
- Confounding (e.g., by indication)
- Other VAERS limitations (e.g., underreporting, variable reporting by source, incomplete reporting, duplicate reporting)

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From: Broder, Karen (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 12 Nov 2021 22:55:35 +0000
To: See, Isaac (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: Fwd: Weekly data mining
Attachments: USST_20211105.xls

Do not forward
Karen

Get Outlook for iOS
From: Menschik, David <[redacted]>
Sent: Tuesday, November 9, 2021 8:33:46 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 11/5/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211105	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.79	1.827	0.892			0.585	1.595	1.936	1.873	2.91	1.321	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.277	1.841	0.883				1.673	2.295	2.074	3.12	1.478	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.972	1.32	0.961			0.462	1.283	1.78	1.819	2.271	1.534	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.977	6.878	0.875				0.86	0.721	0.722	2.352	1.532	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.662	6.992	0.876				0.945	0.745	0.718	1.633	1.368	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.896	1.312	0.909				1.495	1.346	1.512	2.345	1.385	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.05	2.202	0.89			0.498	2.245	2.062	3.44	4.433	1.362	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.203	1.672	0.872				1.79	1.822	1.198	2.443	1.336	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.534	1.931	0.888			0.433	1.714	2.492	2.36	2.784	2.059	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.914	1.657	0.887			0.364	1.289	2.463	1.041	2.35	1.295	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.29	6.872	0.872			0.572	0.898	1.736	1.883	2.708	1.924	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.238	1.656	1.106	0.512		0.433	1.869	2.011	2.522	2.855	1.628	
COVID19 (COVID19 (JANSSEN))	Anoxia	2.12	1.948	0.878				0.899	1.917	1.527	1.84	1.546	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.998	1.291	0.876				1.181	1.18	1.116	2.792	1.93	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.955	1.651	0.877	0.509		0.335	1.202	2.585	1.711	2.37	1.29	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.751	1.559	0.874	0.508		0.292	1.271	2.34	1.438	2.148	1.202	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.755	1.28	0.875			0.333	1.473	1.785	1.563	2.114	1.22	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.948	1.502	0.886			0.402	1.421	2.273	1.819	2.304	1.475	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.02	1.565	0.897			0.452	1.439	2.271	1.863	2.438	1.36	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.412	2.595	0.885			0.51	1.857	2.118	0.738	4.418	1.075	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.839	1.559	0.888			0.26	1.179	2.087	1.507	2.575	1.046	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.712	1.544	0.87			0.217	1.359	2.02	1.296	2.064	0.877	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.762	1.209	0.872				1.042	1.964	1.527	2.014	1.394	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.938	1.334	1.067				1.322	1.818	1.812	2.028	1.892	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.708	2.215	0.872				1.673	2.707	1.162	2.403	2.212	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.328	1.887	0.918			0.521	2.143	1.868	1.492	3.52	1.108	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.364	1.86	0.893			0.537	1.236	1.23	0.997	2.882	0.909	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.168	1.527	0.873				1.124	1.201	1.362	2.471	1.041	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.402	2.432	0.896			0.523	2.534	2.465	0.822	4.118	1.193	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.732	1.969	0.930	0.511		0.605	2.398	2.462	2.266	3.634	1.744	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.026	1.492	0.896			0.484	1.692	2.018	1.768	2.248	1.516	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.116	1.605	0.907			0.462	1.502	2.125	2.056	2.437	1.63	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.614	1.894	1.001			0.66	2.176	2.298	3.235	3.343	2.035	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.817	1.505	0.871				1.268	2.363	1.516	2.133	1.212	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.779	6.802	0.872			1.131	2.003	1.495	0.992	1.883	1.414	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.278	1.271	0.881			0.376	2.207	2.077	1.847	2.505	1.644	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.166	1.512	0.912	0.511		0.33	1.705	2.327	2.212	2.588	1.485	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.53	0.997	0.873			0.423	1.696	1.931	0.75	2.194	1.182	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.329	1.82	0.88			0.418	2.278	1.761	1.134	2.601	1.429	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.857	1.382	0.882			0.403	1.373	1.514	1.499	2.014	1.219	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.788	1.261	0.882				1.171	1.244	1.39	2.044	1.047	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.303	1.886	0.872				1.394	2.825	1.783	2.181	2.091	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.833	1.366	0.896	0.506		0.426	1.37	2.106	1.72	2.238	1.345	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.755	1.303	0.897	0.507		0.327	1.423	1.98	1.586	2.088	1.336	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.665	3.88	0.884				4.009	4.841	6.183	6.914	2.874	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.838	3.818	0.874			0.847	5.116	5.897	6.992	7.893	3.868	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.803	1.234	0.89				1.312	1.768	1.612	2.08	1.405	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.074	1.931	0.875			0.619	1.872	2.564	1.651	2.205	1.883	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.751	1.414	1.01			0.629	1.408	1.948	1.969	2.207	1.58	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.834	1.315	0.882	0.746		0.395	1.639	1.886	1.425	2.378	1.23	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.922	1.215	0.879				1.416	1.935	0.899	2.088	1.197	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.164	1.961	0.874				1.602	1.122	0.744	2.831	0.755	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.857	1.531	0.871				1.231	2.162	1.155	1.705	1.723	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.022	1.764					0.896	2.323	1.163	1.488	1.78	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.628	1.267	0.888			0.182	1.001	2.077	1.779	2.073	1.141	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.174	1.718	0.882			0.502	1.773	1.996	2.307	2.536	1.587	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.08	1.524	0.886	0.511		0.46	1.295	2.348	1.507	2.37	1.283	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.841	1.227	0.874			0.339	1.034	2.093	1.024	1.912	0.895	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.773	1.209	0.877			0.347	1.26	2.207	1.077	2.072	1.123	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.04	1.495	0.935			0.494	0.993	2.025	1.671	1.927	1.863	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.617	1.376	0.887	0.61		0.283	0.965	2.13	1.974	2.512	1.027	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.598	1.317	0.876			0.131	1.221	1.823	1.313	2.337	0.899	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.682	1.295	0.883			0.241	1.106	2.044	1.752	1.982	1.276	
COVID19 (COVID19 (JANSSEN))	Off label use	1.387	0.21	0.872			5.809	0.298	0.429	0.361	0.865	1.236	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.752	6.758					3.059	0.968		3.173		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.575	6.874				0.517	1.767	2.297	1.169	2.631	1.469	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.393	1.716	0.874				0.656	1.069	2.083	2.544	0.966	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.752	2.503	0.922	0.61		0.483	1.86	3.156	1.786	3.138	1.837	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.855	1.406	0.893	0.509		0.291	1.595	2.019	1.486	2.183	1.411	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.73	2.987	0.888			3.4	2.067	3.09	2.201	3.461	1.883	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.016	3.523	0.875				4.382	3.335	0.685	6.151	1.933	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.227					0.886	4.034	3.298	6.151	4.92	3.842	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.85	1.586	0.900	0.744		0.326	1.514	2.321	1.53	2.548	1.379	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.246	1.679	1.511	0.512		0.583	1.697	2.15	2.68	2.581	1.829	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.046	1.532	0.960				1.546	1.403	2.066	1.867	1.661	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.885	1.392	0.88	0.507		0.528	1.496	2.137	1.602	2.113	1.496	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.043	1.44	0.884	0.509		0.356	1.307	2.251	1.639	2.458	1.264	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.738	1.178	0.888			0.547	1.098	1.699	0.881	2.284	0.757	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.282	1.2	0.876			0.538	1.498	1.78	1.377	1.957	1.749	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.665	1.349	0.876			0.547	1.132	0.827	0.647	2.857	1.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.215	2.643	1.727			0.531	1.882	2.354	1.296	2.673	3.109	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.077	6.797	0.875			0.647	3.642	6.746	15.322	8.003	5.996	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.289							0.635	0.576	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.116	1.675	0.886			0.516	1.416	1.686	1.384	2.27	1.346	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.378	2.044	0.916			0.39	1.846	2.378	1.688	2.811	1.701	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.68	2.17	1.564	0.512		0.571	2.007	2.389	3.532	2.868	2.166	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.255	1.907	0.874				1.974	1.224	0.644	2.402	0.904	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.357	1.445	0.893			0.648	1.928	2.165	2.371	2.786	1.66	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.752	1.971	0.892	0.512		0.534	2.388	2.299	3.024	3.228	2.153	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.53	1.811	0.892			0.454	2.494	1.983	1.777	2.651	1.805	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.803	1.152	0.875				1.336	2.076	1.782	2.054	1.265	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.673	1.267	0.876	0.511		0.309	0.86	2.082	1.291	1.858	1.045	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.257	2.99	2.501			0.537	1.179	2.423	5.159	1.904	2.087	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.685	1.419	0.92			0.49	0.975	1.262	2.048	1.648	1.554	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.055	6.881					0.93	1.804	0.979	1.87	1.055	
COVID19 (COVID19 (JANSSEN))	Venogram	2.68	2.009					2.174	1.738	0.721	3.011	1.045	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.411	2.523				0.605	2.98	1.889	0.703	4.221	1.195	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.282	2.509	0.874				3.954	2.152	0.846	5.231	1.192	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.353	6.833		7.466	0.885		1.192	0.513		1.318	0.982	
COVID19 (COVID19 (MODERNA))	Headache	0.966	6.962	0.884	6.091		0.304	0.941	0.961	1.012	0.953	1.014	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.344	6.933	0.88		1.158	2.624	0.12	0.036	0.491	2.348	2.404	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.045	2.006	0.873			2.214	2.003	1.947	1.572	1.895	2.117	
COVID19 (COVID19 (PFIZER-	Body height	1.932	1.02	0.877			0.599	0.927	1.336	2.191	1.903	1.499	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.957	0.874			0.606	1.502	1.955	1.849	2.007	1.576	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.274	1.723	1.46			1.025	1.723	1.784	1.924	2.034	1.968	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.74	6.846	0.876	14.049			0.413			0.431	1.162	
COVID19 (COVID19 (PFIZER-	Investigation	2.142	1.712	0.897			1.057	1.739	1.932	2.319	2.112	1.933	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.32	6.289	0.866		3.489	0.323	0.174	0.052	0.301	0.296	0.344	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.774	6.752				1.345	1.86	1.807	2.29	1.793	1.735	
COVID19 (COVID19 (PFIZER-	Weight	3.658	1.913	0.886			0.672	1.035	1.732	2.2	3.091	1.779	

PSI-HHS-000000057624

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From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 2 Feb 2023 21:30:06 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: Fwd: [EXTERNAL] Data mining for bivalent COVID-19 vaccines

Get Outlook for iOS
From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 2, 2023 4:29 PM
To: Nair, Narayan (FDA/CBER) <[redacted]>
Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[redacted]>
Subject: Re: [EXTERNAL] Data mining for bivalent COVID-19 vaccines

Thanks Narayan

Pedro

Get Outlook for iOS
From: Nair, Narayan <[redacted]>
Sent: Thursday, February 2, 2023 4:11:21 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] Data mining for bivalent COVID-19 vaccines

Dear Pedro,
We have not had any disproportionality alerts from Data Mining to suggest an increase risk for hypertension for the COVID-19 vaccines.

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, February 2, 2023 12:28 PM
To: Nair, Narayan <[redacted]>
Cc: Alimchandani, Meghna <[redacted]>; Mba-Jonas, Adamma (CBER) <[redacted]>
Subject: [EXTERNAL] Data mining for bivalent COVID-19 vaccines

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Narayan,

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(b)(5)

Thanks

Pedro

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From: Menschik, David (FDA/CBER)
Sent: Tue, 9 Mar 2021 11:50:08 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: Weekly data mining

Good morning John and Tom,

This "US Signals Summary Table" had no alerts (EB05>2) for any PT for any EUA COVID vaccine (as of 3/5/21).

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David (FDA/CBER)
Sent: Tue, 2 Mar 2021 13:01:56 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: Weekly data mining

Hi John and Tom,

As you may be aware we recently shifted from monthly to weekly data mining which includes the subset runs (age, gender, serious/fatal) that were previously available monthly. Alert (EB05>2) output from these weekly runs is captured in our "US Signals Summary Table" and we plan to regularly share this output with you.
This "US Signals Summary Table" had no alerts (EB05>2) for any PT for any EUA COVID vaccine (as of 2/26/21).

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David (FDA/CBER)
Sent: Tue, 23 Feb 2021 11:47:58 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: Data mining

Hi John and Tom,

Our "VAERS Signals Weekly US All" run had no alerts (EB05>2) for any PT for any EUA COVID vaccine (as of 2/18/21).

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David (FDA/CBER)
Sent: Tue, 16 Feb 2021 11:33:02 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: RE: Data mining

Hi John and Tom,

Our "VAERS Signals Weekly US All" run had no alerts (EB05>2) for any PT for any EUA COVID vaccine (as of 2/11/21).

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David (FDA/CBER)
Sent: Tue, 9 Feb 2021 11:59:02 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER)
Subject: Data mining

Dear John and Tom,

Our "VAERS Signals Weekly US All" run had no alerts (EB05>2) for any PT for any EUA COVID vaccine (as of 2/4/21).
Our monthly data mining (including stratified) runs had no alerts (EB05>2) for any EUA COVID vaccine (as of 2/4/21).

Best,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David (FDA/CBER)
Sent: Tue, 2 Feb 2021 22:01:15 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER)
Subject: RE: Weekly data mining

Will plan to include you on such future emails – sorry for excluding you Tom!

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, February 02, 2021 5:00 PM
To: Su, John (CDC) <[redacted]>; Menschik, David <[redacted]>
Cc: Marquez, Paige L (CDC) <[redacted]>; Nair, Narayan <[redacted]>; Zinderman, Craig E <[redacted]>; Alimchandani, Meghna <[redacted]>
Subject: RE: Weekly data mining

Thanks. Please include me on these data mining email.
Tom

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, February 2, 2021 9:26 AM
To: Menschik, David (FDA/CBER) <[redacted]>
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Hi David,

Thanks for sharing! Good to know. CCing Tom for his awareness. Thanks again!

- Joh

From: Menschik, David <[redacted]>
Sent: Tuesday, February 2, 2021 7:57 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>
Subject: Weekly data mining

Good morning John,

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Our "VAERS Signals Weekly US All" run had no alerts (EB05>2) for any PT for either EUA COVID vaccine (as of 1/29/21).

Best,

David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David (FDA/CBER)
Sent: Tue, 2 Feb 2021 12:57:04 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER)
Subject: Weekly data mining

Good morning John,

Our "VAERS Signals Weekly US All" run had no alerts (EB05>2) for any PT for either EUA COVID vaccine (as of 1/29/21).

Best,

David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

From: Menschik, David (FDA/CBER)
Sent: Mon, 25 Jan 2021 11:38:57 +0000
To: Nair, Narayan (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Zinderman, Craig E (FDA/CBER)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Gee, Julianne (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Addendum: the data mining was refreshed as of 1/22/21 (updated in red font below) and still no EB05>2 alert for any PT for either COVID vaccine for the overall domestic run.
Would also clarify, that the absence of EB05>2 below refers to our weekly overall domestic run ("VAERS Signals Weekly US All"; i.e., does not include foreign, stratified runs, etc.) – suggested additional edit below in red font to reflect this…

From: Menschik, David
Sent: Monday, January 25, 2021 6:20 AM
To: Nair, Narayan <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>; Zinderman, Craig E <[redacted]>
Cc: Su, John (CDC) <[redacted]>; Gee, Julianne M (CDC) <[redacted]>
Subject: RE: Weekly data mining

The statement "Identifies adverse event-vaccine pairs reported at least twice as frequently as expected for a COVID-19 vaccine compared to the VAERS database" refers to the EBGM. Since we're using EB05 (lower 5% bound of EBGM 90% CI), may be more accurate to say that the EB05>2 provides a high degree of confidence that a vaccine-adverse event pair was reported at least twice as frequently as expected…

Suggested edits in red font:

- FDA uses data mining to identify disproportional adverse event reporting for vaccines, including COVID-19 vaccines
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- Most recent (1/22/21) weekly results: No empirical Bayesian data mining alerts (EB05>2) detected for any adverse event-COVID-19 vaccine pair among domestic VAERS reports

Best,
David

From: Nair, Narayan <[redacted]>
Sent: Sunday, January 24, 2021 3:37 PM
To: Shimabukuro, Tom (CDC) <[redacted]>; Zinderman, Craig E <[redacted]>; Menschik, David <[redacted]>

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Cc: Su, John (CDC) <[redacted]>; Gee, Julianne M (CDC) <[redacted]>
Subject: RE: Weekly data mining

This looks good to me Tom, I had no further edits.

Narayan

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, January 23, 2021 11:58 AM
To: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Menschik, David <[redacted]>
Cc: Su, John (CDC) <[redacted]>; Gee, Julianne M (CDC) <[redacted]>
Subject: RE: Weekly data mining

Thanks.

From: Zinderman, Craig E <[redacted]>
Sent: Saturday, January 23, 2021 10:51 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Menschik, David (FDA/CBER) <[redacted]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Tom:
I made a few edits. Narayan and David may have further thoughts. Wanted to portray the idea that this is something we have always done for vaccines (and all drugs and biologics actually), so have experience with it. Also, as you know, there were a few findings for other, previous subset runs (although none that were worrisome), so re-framed the results bullet to specify the 1/15 run.

Thanks,
Craig

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, January 22, 2021 11:13 PM
To: Nair, Narayan <[redacted]>; Zinderman, Craig E <[redacted]>;

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Menschik, David <[redacted]>
Cc: Su, John (CDC) <[redacted]>; Gee, Julianne M (CDC) <[redacted]>
Subject: RE: Weekly data mining

Are you okay with this language for the Jan 27 ACIP presentation? Feel free to edit. Thanks.

(b)(5)

From: Menschik, David <[redacted]>
Sent: Thursday, January 21, 2021 9:53 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: Weekly data mining

Good morning John,

Our "VAERS Signals Weekly US All" run had no alerts (EB05>2) for any PT for either EUA COVID vaccine (as of 1/15/21).

Best,

David

David Menschik, MD, MPH
Associate Director for Surveillance Informatics
Division of Epidemiology/Office of Biostatistics and Epidemiology
Center for Biologics Evaluation and Research/FDA
[redacted]

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From: Menschik, David (FDA/CBER)
Sent: Mon, 25 Jan 2021 11:38:57 +0000
To: Nair, Narayan (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Zinderman, Craig E (FDA/CBER)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Gee, Julianne (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Addendum: the data mining was refreshed as of 1/22/21 (updated in red font below) and still no EB05>2 alert for any PT for either COVID vaccine for the overall domestic run.
Would also clarify, that the absence of EB05>2 below refers to our weekly overall domestic run ("VAERS Signals Weekly US All"; i.e., does not include foreign, stratified runs, etc.) – suggested additional edit below in red font to reflect this…

From: Menschik, David
Sent: Monday, January 25, 2021 6:20 AM
To: Nair, Narayan <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>; Zinderman, Craig E <[redacted]>
Cc: Su, John (CDC) <[redacted]>; Gee, Julianne M (CDC) <[redacted]>
Subject: RE: Weekly data mining

The statement "Identifies adverse event-vaccine pairs reported at least twice as frequently as expected for a COVID-19 vaccine compared to the VAERS database" refers to the EBGM. Since we're using EB05 (lower 5% bound of EBGM 90% CI), may be more accurate to say that the EB05>2 provides a high degree of confidence that a vaccine-adverse event pair was reported at least twice as frequently as expected…

Suggested edits in red font:

- FDA uses data mining to identify disproportional adverse event reporting for vaccines, including COVID-19 vaccines
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Subject: RE: Weekly data mining

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David Menschik, MD, MPH
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From: Menschik, David (FDA/CBER)
Sent: Mon, 25 Jan 2021 11:19:55 +0000
To: Nair, Narayan (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Zinderman, Craig E (FDA/CBER)
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AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

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To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
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David Menschik, MD, MPH
Associate Director for Surveillance Informatics
Division of Epidemiology/Office of Biostatistics and Epidemiology
Center for Biologics Evaluation and Research/FDA
[redacted]

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From: Menschik, David (FDA/CBER)
Sent: Thu, 21 Jan 2021 14:53:15 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER)
Subject: Weekly data mining

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From: Menschik, David (FDA/CBER)
Sent: Tue, 12 Jan 2021 22:35:46 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Zinderman, Craig E (FDA/CBER); Baer, Bethany (FDA/CBER)
Subject: RE: Data mining
Attachments: DE VAERS data mining_202001_DRAFT.pptx

Hi John and Tom,

In addition to the overall run (mentioned in earlier email below) which now refreshes weekly, we have our pre-existing (refreshing monthly) subset runs (and I've added a line to the second attached slide to describe them) which have an earlier 'as of date' of 1/6/21. For all of these subset runs for both EUA COVID vaccines, a total of 4 PTs had an EB05 of >2, all of which were in the age 45 - <65 year ("Adult2") subset and that output is as follows:

Drug	Event	Adult2 EB05 20210106	N
COVID19 (COVID19 (PFIZER-BIONTECH))	Dysgeusia	2.118	49
COVID19 (COVID19 (PFIZER-BIONTECH))	Flushing	2.408	118
COVID19 (COVID19 (PFIZER-BIONTECH))	Palpitations	2.004	104
COVID19 (COVID19 (PFIZER-BIONTECH))	Paraesthesia oral	2.184	88

Please feel free to share this hypothesis generating output along with the limitations reflected in the slides with your team/command chain, though these are not intended to be shared more broadly.

Best,
David

PS: I'm planning to be on the 6pm call tonight and available to answer any questions

---

From: Menschik, David
Sent: Tuesday, January 12, 2021 1:51 PM
To: Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Marquez, Paige L (CDC) <[redacted]>; Narayan Nair <[redacted]>; Alimchandani, Meghna <[redacted]>; Zinderman, Craig E <[redacted]>; Baer, Bethany <[redacted]>
Subject: Data mining

Dear John and Tom,

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Our core weekly data mining run (previously refreshing monthly) called "VAERS Signals Weekly US All" was just refreshed this afternoon (as of date 1/10/21) and there are no EB05's >2 for any COVID vaccines. Attached are 3 slides providing contextual information including caveats and limitations that we can discuss at our weekly meeting on Thursday at 2pm.

Best,

David

Data Mining Introduction*

- Statistical method for identifying disproportionality (excess of reported adverse event [AE] for a product relative to other products)
- Hypothesis generating
  - Statistical signal of disproportional reporting (SSDR) ≠ safety signal
- Absence of disproportionality does not confirm absence of safety signal nor negate a signal otherwise detected

*Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff (November 2019; Draft). Available at https://www.fda.gov/media/130216/download

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DE Data Mining Methods

- Empirica™ Signal software (Oracle)
- Calculates Empiric Bayes Geometric Mean (EBGM) using observed to expected (O/E) vaccine-AE pair ratios
  - EBGM derived from statistical model (Multi-item Gamma Poisson Shrinker; MGPS) that accounts for instability from small numbers*
- Results adjusted by gender, year received and age
- Vaccine-PT pairs ranked by lower 5% bound of EBGM confidence interval (EB05)
  - Subsets available monthly for age (0-1, 2-8, 9-18, 19-44, 45-64, ≥65, unknown), gender, and serious/fatal
- Standard threshold for alert: EB05 ≥2

*Szarfman A, Tonning JM, Doraiswamy PM. Pharmacovigilance in the 21st century: new systematic tools for an old problem. Pharmacotherapy. 2004 Sep;24(9):1099-104. doi: 10.1592/phco.24.13.1099.38090. PMID: 15460169.

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Limitations of Data Mining Include:

- Impacted by stimulated reporting (e.g., V-safe program, media reports)
- Potential statistical interaction (e.g., If vaccines X and Y often given concomitantly, statistical signal for vaccine X and AE Z may be driven by vaccine Y)
- MedDRA constraints (e.g., Signal X can be reflected in multiple PTs that individually do not reach alert threshold)
- Confounding by indication and other VAERS limitations (e.g., underreporting, variable reporting by source, incomplete reporting, duplicate reporting)

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From: Menschik, David (FDA/CBER)
Sent: Tue, 12 Jan 2021 21:57:43 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Data mining

I'll include him on the email...

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, January 12, 2021 4:57 PM
To: Menschik, David <[redacted]>
Subject: RE: Data mining

Awesome! Thanks. If I may, I'll share with Tom, too.

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, January 12, 2021 4:42 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Data mining

Great and stay tuned – I will be sharing a little more info on data mining later today when I finish up a different task...

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, January 12, 2021 4:29 PM
To: Menschik, David <[redacted]>
Subject: RE: Data mining

Please feel free – I think we'd all be enthusiastic to see what data mining data there is.

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, January 12, 2021 4:23 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Data mining

For Thursday meeting, would be great if we could do data mining early since Bethany will only be available for the first 30 minutes and she has more experience than me...

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, January 12, 2021 1:56 PM
To: Menschik, David <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Marquez, Paige L (CDC) <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani,

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Meghna <[redacted]>; Zinderman, Craig E <[redacted]>;
Baer, Bethany <[redacted]>
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Hi David,

Awesome! Thanks for sharing.

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From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 7 Apr 2021 19:24:46 +0000
To: Haber, Penina (CDC/DDID/NCEZID/DHQP)
Subject: FW: Data mining results for Prevnar 13 and Pneumovax 23
Attachments: Pneumovax 23 data mining - US signals from age groups - 4.5.21.xls, Pneumovax 23 data mining - US signals summary table - 4.5.21.xls, Pneumovax 23 data mining - World-US signals - 4.5.21.xls, Prevnar 13 data mining - World-US signals - 4.5.21.xls

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From: Day, Brendan <[redacted]>
Sent: Tuesday, April 6, 2021 8:40 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Data mining results for Prevnar 13 and Pneumovax 23

Hi Pedro,

I am the reviewer assigned Prevnar 13 and Pneumovax 23 for postmarketing surveillance in CBER. Please see the data mining explanation below and results attached. Note that our standard data mining runs stratify results for adults into three age groups (19-44.9, 45-64.9, and 65+). At this time, we are not able to stratify results into two age groups (18-64.9, 65+). -

The following data mining results were obtained for each product from Empirica Signal on April 5, 2021, with a data lock point of April 1, 2021. Data mining results were obtained using the following "Main Views" in Empirica Signal:

1. US signals summary table
    a. This table provides a summary view for the following data mining runs:
        i. Age group (Note: Adult 1 = 19-44.9 years, Adult 2 = 45-64.9 years, and Adult 3 = 65 and above)
        ii. Gender
        iii. Serious/fatal
2. US signals from age groups
    a. In addition to EB05 by age group provided in the above US signals summary table, this table also provides the number of reports for each event within a subgroup.
3. World/US signals
    a. This table compares data mining signals for the World vs. the US only (all age groups combined).

Note: There were no terms with EB05 > 2 for Prevnar 13 in the US signals summary table (including the US signals from age groups). Therefore, only the World/US signals table is included for Prevnar 13.

Empirica Signal is an application for generating statistical scores for combinations of drugs and events in a drug safety database. It applies a statistical algorithm called a Multi-item Gamma Poisson Shrinker (MPGS) to generate an Empirical Bayes Geometric Mean (EBGM), which is an improved estimate of the

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Relative Reporting Ratio. EB05 is the lower bound of the 90% confidence interval (EB05-EB95) for an EBGM. EB05 is a value such that there is about a 5% probability that the true value of the Relative Reporting Ratio lies below it. EB05 values greater than 2 are considered signals of disproportionate reporting (highlighted in the attached spreadsheets). An EB05 of 2 means that there is a 95% chance that the true Relative Reporting Ratio is at least 2.

Data mining covers the entire postmarketing period for this product, from initial licensure through the data lock date listed. The background database contains VAERS reports since 1990. Data mining findings are subject to a number of potential limitations and are to be regarded as "hypothesis generating." Data mining findings do not imply causality.

Please feel free to reach out with any questions.

Regards,
Brendan

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Drug	SOC	Event	US Infant N 20210401	US Infant EB05 20210401	US Child N 20210401	US Child EB05 20210401	US Teen N 20210401	US Teen EB05 20210401	US Adult1 N 20210401	US Adult1 EB05 20210401	US Adult2 N 20210401	US Adult2 EB05 20210401	US Adult3 N 20210401	US Adult3 EB05 20210401	Comment
PNEUMO	Infec	Abscess			8	3.183	7	1.258	13	1.022	18	1.186	17	0.812	
PNEUMO	Inv	Antibody test abnormal			5	5.289	4	0.913	1	0.347	2	0.39	2	0.493	
PNEUMO	Inv	Antibody test negative	1	0.566	19	9.026	3	0.538	8	0.315	14	0.908	7	0.359	
PNEUMO	Inv	Band neutrophil count increased			3	6.863	1	0.558	10	2.068	6	0.92	4	0.444	
PNEUMO	Inv	Band neutrophil percentage increased			6	1.528	7	1.166	23	2.984	9	0.738	18	0.696	
PNEUMO	Inv	Blood bilirubin increased	1	0.528	7	0.78	10	1.11	33	1.439	21	0.561	45	0.619	
PNEUMO	Inv	Blood culture	1	0.372	14	7.015	12	7.986	43	4.665	20	1.18	38	1.216	
PNEUMO	Inv	Blood culture negative	3	0.258	44	8.35	30	6.451	142	4.671	118	2.079	146	1.263	
PNEUMO	Inv	Blood immunoglobulin G decreased	1	0.584	5	4.497	2	0.646	3	0.631	4	0.533	5	0.534	
PNEUMO	Inv	Blood sodium decreased	1	0.361	11	2.374	16	4.311	89	2.281	92	1.047	146	0.671	
PNEUMO	Inv	Body temperature increased	15	0.639	34	1.716	33	1.62	206	2.386	267	1.665	331	1.185	
PNEUMO	Infec	Cellulitis	3	0.832	98	2.996	134	7.72	711	8.73	991	3.186	1633	2.69	
PNEUMO	Inv	Chest X-ray abnormal	3	0.428	21	4.664	10	1.101	48	1.346	76	0.898	180	0.652	
PNEUMO	Genrl	Chills	1	0.428	23	2.748	72	1.98	825	1.851	1310	1.141	1843	0.843	
PNEUMO	Inv	Clostridium test negative			5	4.293	1	0.558	6	0.988	3	0.449	3	0.351	
PNEUMO	Inv	Computerised tomogram abnormal			3	0.858	8	0.874	78	2.051	70	0.905	84	0.488	
PNEUMO	Genrl	Condition aggravated	1	0.324	20	2.047	13	0.817	70	0.864	115	0.679	135	0.41	
PNEUMO	Inv	C-reactive protein increased	6	0.563	56	13.091	47	6.793	89	2.071	61	0.925	111	0.852	
PNEUMO	Skin	Erythema	18	0.533	121	1.033	191	2.121	1306	2.44	2575	2.06	5807	1.75	
PNEUMO	Inv	Full blood count	7	0.534	26	2.022	24	1.418	111	1.665	113	1.233	139	1.145	
PNEUMO	Inv	Full blood count abnormal	1	0.513	2	0.609	2	0.611	24	2.075	12	0.838	12	0.718	
PNEUMO	Genrl	Gait disturbance	4	0.541	56	3.445	10	0.556	38	0.435	70	0.352	132	0.364	
PNEUMO	Genrl	Gait inability	1	0.444	23	3.574	1	0.345	12	0.455	35	0.505	63	0.411	
PNEUMO	Inv	Haematocrit decreased	3	0.37	26	8.924	25	3.97	171	2.196	134	1.109	250	0.789	
PNEUMO	Inv	Haemoglobin decreased	2	0.335	18	6.197	26	4.14	173	2.348	139	1.187	250	0.798	
PNEUMO	Nerv	Hypokinesia	3	0.642	29	5.001	18	1.351	105	1.868	149	1.1	226	0.96	
PNEUMO	Genrl	Injected limb mobility decreased	3	0.64	15	5.681	35	5.738	324	2.253	494	1.849	949	1.697	
PNEUMO	Infec	Injection site cellulitis	1	0.456	31	2.448	34	6.097	163	5.224	207	2.739	344	2.186	
PNEUMO	Genrl	Injection site erythema	33	0.578	223	0.999	294	2.321	1996	2.662	3307	1.729	6658	1.496	
PNEUMO	Genrl	Injection site induration	8	0.468	57	0.979	76	2.276	339	2.101	458	1.352	680	1.305	
PNEUMO	Genrl	Injection site movement impairment	2	0.701	9	3.598	2	0.671	4	0.685	7	0.839	8	0.685	
PNEUMO	Genrl	Injection site oedema	8	0.736	74	1.137	80	2.754	380	2.983	647	2.169	1201	1.641	
PNEUMO	Genrl	Injection site pain	24	1.515	267	2.889	263	3.334	1826	2.183	2967	1.544	5303	1.442	
PNEUMO	Genrl	Injection site reaction	8	0.647	46	1.147	52	2.393	294	1.961	471	1.499	764	1.167	
PNEUMO	Genrl	Injection site streaking			2	0.619	4	0.8	46	4.196	54	2.503	64	1.483	
PNEUMO	Genrl	Injection site swelling	15	0.443	181	1.287	201	2.281	1525	2.744	2531	1.863	5332	1.728	
PNEUMO	Genrl	Injection site warmth	5	0.548	83	0.812	110	1.943	820	2.42	1428	1.701	2829	1.551	
PNEUMO	Musc	Joint range of motion decreased			12	6.266	11	1.171	119	1.444	168	0.966	240	1.082	
PNEUMO	Inv	Laboratory test abnormal	6	0.715	16	2.304	14	0.896	54	0.486	57	0.549	71	0.475	
PNEUMO	Blood	Leukocytosis	3	0.696	13	6.092	24	9.462	117	5.667	72	1.867	87	0.969	
PNEUMO	Genrl	Local reaction	1	0.386	26	1.235	33	1.918	133	2.184	192	1.641	305	1.5	
PNEUMO	Inv	Lymphocyte percentage decreased	1	0.337	36	8.647	45	5.424	201	2.801	163	1.353	236	0.814	
PNEUMO	Inv	Magnetic resonance imaging abnormal	1	0.466	17	6.858	10	1.001	56	0.704	59	0.6	67	0.542	
PNEUMO	Inj&P	Medication error	23	3.499	4	0.533	6	0.526	20	0.62	29	0.508	38	0.384	
PNEUMO	Musc	Mobility decreased	1	0.523	9	3.268	4	0.572	214	1.853	343	1.324	836	1.357	
PNEUMO	Inv	Monocyte count increased	1	0.372	11	4.501	16	5.342	77	3.351	43	1.183	77	0.895	
PNEUMO	Inv	Monocyte percentage increased			14	3.577	14	1.281	77	1.808	63	0.932	117	0.802	
PNEUMO	Musc	Myalgia	1	0.578	20	2.845	58	1.52	485	1.248	686	0.783	923	0.715	
PNEUMO	Musc	Myositis	2	0.711	12	9.841	8	2.15	15	1.084	8	0.406	18	0.801	
PNEUMO	Inv	Neutrophil count increased	4	0.674	19	6.745	22	5.345	123	3.121	94	1.568	122	0.87	
PNEUMO	Inv	Neutrophil percentage increased			39	9.121	40	4.887	196	2.911	166	1.434	235	0.857	
PNEUMO	Genrl	Oedema	1	0.42	18	0.724	41	2.852	146	2.057	255	1.649	463	1.488	
PNEUMO	Genrl	Oedema peripheral	4	0.817	22	1.242	21	1.506	123	2.148	206	1.768	458	1.581	
PNEUMO	Genrl	Pain	13	0.978	85	2.089	179	2.106	1371	1.515	2256	1.086	3642	1.033	
PNEUMO	Musc	Pain in extremity	4	0.811	75	4.544	110	2.361	1084	1.981	1809	1.414	3888	1.392	
PNEUMO	Genrl	Peripheral swelling	5	0.617	60	1.881	107	2.844	782	3.282	1637	2.645	3978	2.248	
PNEUMO	Inv	Platelet count decreased	1	0.331	12	2.22	9	0.907	52	1.443	41	0.67	118	0.694	
PNEUMO	Inv	Platelet count normal			5	3.882	6	0.907	13	0.677	11	0.57	22	0.611	
PNEUMO	Infec	Pneumonia	7	0.883	17	3.1	13	1.403	51	1.745	110	1.544	197	0.871	
PNEUMO	Inv	Procalcitonin increased			1	0.548	2	0.668	9	2.195	4	0.61	21	0.909	
PNEUMO	Inj&P	Product administered to patient of inappropri	108	3.017	3	0.109	5	0.338	22	0.378	24	0.173	15	0.185	
PNEUMO	Genrl	Pyrexia	99	0.66	361	2.584	416	2.867	2216	2.334	2911	1.522	3449	1.111	
PNEUMO	Inv	Red blood cell count decreased			16	6.538	15	1.592	119	2.07	103	1.076	183	0.741	
PNEUMO	Inv	Red blood cell sedimentation rate increased	1	0.42	37	7.637	26	3.094	71	1.531	55	0.852	99	0.658	
PNEUMO	Inv	Reticulocyte count increased	1	0.506	2	0.682	6	0.883			3	0.908	1	0.483	
PNEUMO	Infec	Sepsis	4	0.753	5	0.988	14	7.697	64	5.585	54	1.979	85	0.825	
PNEUMO	Skin	Skin striae					4	0.811	21	4.115	21	1.639	20	1.115	
PNEUMO	Skin	Skin warm	2	0.387	30	0.866	51	1.474	463	2.494	911	2.07	2159	1.899	
PNEUMO	Surg	Surgery			6	4.828	2	0.616	7	0.687	11	0.628	18	0.653	
PNEUMO	Genrl	Swelling	10	0.79	57	1.063	81	1.991	535	2.018	1031	1.725	1949	1.568	
PNEUMO	Genrl	Systemic inflammatory response syndrome			3	0.679	4	1.15	50	5.036	24	1.904	20	0.918	
PNEUMO	Card	Tachycardia			22	4.581	24	1.713	130	1.52	80	0.78	99	0.753	
PNEUMO	Genrl	Tenderness	2	0.527	30	1.212	51	1.894	333	2.243	496	1.768	877	1.623	
PNEUMO	Inv	Ultrasound scan abnormal	3	0.856	10	7.232	14	4.647	46	1.685	36	1.086	48	0.883	
PNEUMO	Inv	Ultrasound scan normal	1	0.531	7	4.275	7	0.952	46	1.698	36	1.306	43	1.01	
PNEUMO	Inj&P	Vaccination complication	3	0.454	26	3.868	35	3.801	132	1.469	148	1.269	253	1.131	
PNEUMO	Musc	Weight bearing difficulty	2	0.603	40	11.591	3	0.693	4	0.384	5	0.308	14	0.458	
PNEUMO	Inv	White blood cell count increased	7	0.485	85	10.366	93	7.182	454	3.764	365	1.967	391	1.019	
PNEUMO	Inj&P	Wrong product administered	233	9.662	18	0.908	21	1.005	33	0.491	28	0.267	46	0.317	
PNEUMO	Inv	X-ray limb abnormal			10	7.396	1	0.548	5	0.548	20	0.676	53	0.775	
PNEUMO	Inv	X-ray limb normal			7	3.496	6	1.038	20	1.03	9	0.358	27	0.679	

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Drug	Event	US EB05 20210401	US Serious EB05 20210401	US Fatal EB05 20210401	US Infant EB05 20210401	US Child EB05 20210401	US Teen EB05 20210401	US Adult1 EB05 20210401	US Adult2 EB05 20210401	US Adult3 EB05 20210401	US Female EB05 20210401	US Male EB05 20210401	Comment
PNEUMO	Abscess	1.551	1.735	0.895		3.185	1.256	1.022	1.115	0.812	1.4	1.256	
PNEUMO	Antibody test abnormal	0.862	0.749	0.894		5.289	0.913	0.347	0.39	0.493	0.806	0.752	
PNEUMO	Antibody test negative	0.723	0.557	0.894	0.865	9.038	0.639	0.315	0.606	0.356	0.66	0.843	
PNEUMO	Band neutrophil count increased	1.328	1.111			0.863	0.558	2.068	0.92	0.444	1.283	0.822	
PNEUMO	Band neutrophil percentage increased	1.473	1.13	0.892		1.528	1.166	2.994	0.738	0.696	1.459	1.123	
PNEUMO	Blood bilirubin increased	0.931	0.945	0.894	0.528	5.78	1.17	1.439	0.557	0.616	0.754	0.962	
PNEUMO	Blood culture	2.349	2.203	0.895	0.372	7.015	7.989	4.685	1.18	1.216	2.078	2.358	
PNEUMO	Blood culture negative	2.322	2.063	0.896	0.258	8.35	6.457	4.671	2.079	1.263	2.469	1.959	
PNEUMO	Blood immunoglobulin G decreased	1.253	0.807	0.896	0.584	4.407	0.646	0.631	0.513	0.534	1.348	0.721	
PNEUMO	Blood sodium decreased	1.078	1.068	0.895	0.361	2.374	4.111	2.281	1.047	0.671	1.093	0.981	
PNEUMO	Body temperature increased	1.667	2.099	0.896	0.639	1.716	1.63	3.396	1.665	1.186	1.691	1.693	
PNEUMO	Cellulitis	2.939	3.774	0.898	0.522	2.968	7.73	5.79	3.184	2.03	2.774	3.21	
PNEUMO	Chest X-ray abnormal	0.873	0.878	0.897	0.428	4.664	1.101	1.346	0.838	0.652	0.817	0.858	
PNEUMO	Chills	1.101	1.757	0.898	0.428	2.748	1.99	1.851	1.141	0.843	1.065	1.14	
PNEUMO	Clostridium test negative	0.859	0.834	0.895		4.292	0.558	0.988	0.449	0.354	0.731	0.8	
PNEUMO	Computerised tomogram abnormal	0.862	0.898	0.894		0.651	0.879	2.051	0.995	0.488	0.872	0.832	
PNEUMO	Condition aggravated	0.62	0.805	0.9	0.324	2.047	0.617	0.666	0.679	0.41	0.579	0.639	
PNEUMO	C-reactive protein increased	1.566	1.514	0.896	0.563	13.091	8.792	2.071	0.923	0.852	1.635	1.393	
PNEUMO	Erythema	1.83	2.467	0.896	0.533	1.033	2.121	2.44	2.96	1.76	1.836	2.231	
PNEUMO	Fasciitis	1.85	2.317			0.885	1.213	0.749	0.696	0.697	1.022	1.376	
PNEUMO	Full blood count	1.468	1.14	0.896	0.534	2.022	1.418	1.665	1.233	1.145	1.421	1.384	
PNEUMO	Full blood count abnormal	1.476	0.949	0.894	0.513	0.609	0.611	2.075	0.838	0.718	1.179	1.281	
PNEUMO	Gait disturbance	0.484	0.38	0.894	0.541	3.445	0.556	0.435	0.352	0.364	0.485	0.457	
PNEUMO	Gait inability	0.566	0.427		0.444	3.574	0.345	0.455	0.535	0.411	0.452	0.664	
PNEUMO	Haematocrit decreased	1.212	1.205	0.895	0.37	8.924	3.97	2.195	1.139	0.789	1.283	1.369	
PNEUMO	Haemoglobin decreased	1.251	1.254	0.898	0.335	6.197	4.16	2.348	1.187	0.798	1.314	1.115	
PNEUMO	Human rhinovirus test positive	2.08	1.012	0.898	0.578	1.065	0.667	0.522	0.594		1.822	0.738	
PNEUMO	Hypokinesia	1.328	0.919	0.893	0.642	5.001	1.353	1.869	1.1	0.96	1.278	1.204	
PNEUMO	Induration	1.627	2.753			0.613	1.238	1.805	1.38	1.559	1.551	1.896	
PNEUMO	Injected limb mobility decreased	1.905	2.232		0.84	5.681	5.739	2.253	1.649	1.697	1.885	1.812	
PNEUMO	Injection site abscess	1.366	2.199			0.756	0.784	0.888	1.238	0.935	1.305	1.164	
PNEUMO	Injection site cellulitis	3.085	4.037	0.894	0.456	2.441	6.097	5.228	2.719	2.186	2.737	3.852	
PNEUMO	Injection site erythema	1.729	3.779	0.9	0.578	0.999	2.321	2.662	1.729	1.496	1.568	2.272	
PNEUMO	Injection site hypersensitivity	1.17	2.6		0.605	1.1	1.903	1.904	1.538	1.306	1.462	1.856	
PNEUMO	Injection site induration	1.517	3.735	0.898	0.465	0.979	2.278	2.107	1.352	1.305	1.358	2.07	
PNEUMO	Injection site infection	1.712	2.552		0.579	0.479	0.965	1.955	1.648	1.181	1.455	1.765	
PNEUMO	Injection site inflammation	1.554	2.383		0.607	0.773	0.777	1.912	1.481	1.319	1.442	1.82	
PNEUMO	Injection site movement impairment	1.581	0.916		0.701	3.598	0.671	0.685	0.839	0.685	1.349	1.145	
PNEUMO	Injection site oedema	1.984	3.273		0.739	1.137	2.754	2.933	2.119	1.641	1.874	2.343	
PNEUMO	Injection site pain	1.669	3.018	0.902	1.515	2.689	3.334	2.183	1.944	1.442	1.936	1.927	
PNEUMO	Injection site rash	1.1	2.375		0.129	1.021	1.601	1.947	1.112	0.871	1.041	1.273	
PNEUMO	Injection site reaction	1.563	2.575	0.895	0.647	1.147	2.353	1.901	1.484	1.167	1.425	1.905	
PNEUMO	Injection site streaking	2.948	2.005			0.619	0.9	4.195	2.593	1.483	2.168	2.938	
PNEUMO	Injection site swelling	1.85	3.577	0.899	0.443	1.267	2.281	2.744	1.863	1.728	1.791	2.411	
PNEUMO	Injection site warmth	1.749	3.853	0.895	0.349	0.813	1.943	2.42	1.791	1.551	1.583	2.387	
PNEUMO	Joint range of motion decreased	1.218	1.169			6.268	1.171	1.444	0.995	1.082	1.164	1.261	
PNEUMO	Laboratory test abnormal	0.577	0.768	0.897	0.715	2.304	0.898	0.489	0.549	0.478	0.693	0.958	
PNEUMO	Leukocytosis	2.257	2.958	0.894	0.698	6.031	9.462	5.557	1.857	0.989	2.165	2.365	
PNEUMO	Local reaction	1.871	2.871		0.386	1.233	1.918	2.184	1.641	1.5	1.672	2.197	
PNEUMO	Lymphocyte percentage decreased	1.452	1.367	0.891	0.337	8.647	5.424	2.807	1.353	0.818	1.493	1.311	
PNEUMO	Magnetic resonance imaging abnormal	0.783	0.888	0.893	0.492	6.853	1.831	0.738	0.6	0.542	0.843	0.828	
PNEUMO	Medication error	0.574	1.036		3.499	0.533	0.526	0.82	0.586	0.384	0.483	0.992	
PNEUMO	Mobility decreased	1.463	0.964	0.893	0.523	3.268	0.572	1.853	1.324	1.357	1.508	1.324	
PNEUMO	Monocyte count increased	1.611	1.482	0.891	0.372	4.601	5.342	3.351	1.183	0.896	1.701	1.332	
PNEUMO	Monocyte percentage increased	1.147	1.073	0.893		3.577	1.263	1.808	0.912	0.802	1.152	1.052	
PNEUMO	Myalgia	0.862	0.974	0.894	0.578	2.845	1.52	1.248	0.783	0.715	0.855	0.847	
PNEUMO	Myositis	1.306	1.262		0.711	9.543	2.15	1.064	0.496	0.801	1.243	1.353	
PNEUMO	Neutrophil count increased	1.667	1.553	0.896	0.674	6.745	5.345	3.127	1.588	0.87	1.653	1.552	
PNEUMO	Neutrophil percentage increased	1.511	1.405	0.892		9.121	4.897	2.917	1.434	0.857	1.555	1.355	
PNEUMO	Oedema	1.777	1.142	0.893	0.42	0.724	2.852	2.057	1.049	1.486	1.64	1.367	
PNEUMO	Oedema peripheral	1.925	1.174	0.894	0.817	1.242	1.508	2.149	1.788	1.581	1.88	1.576	
PNEUMO	Pain	1.172	1.141	0.889	0.578	2.089	2.106	1.519	1.095	1.033	1.148	1.198	
PNEUMO	Pain in extremity	1.529	1.403	0.896	0.611	4.544	2.363	1.981	1.414	1.392	1.509	1.537	
PNEUMO	Peripheral swelling	2.515	2.408	0.894	0.617	1.861	2.846	3.282	2.645	2.246	2.419	2.755	
PNEUMO	Platelet count decreased	0.901	0.927	0.893	0.331	2.22	0.907	1.443	0.57	0.694	0.844	0.886	
PNEUMO	Platelet count normal	0.869	0.881	0.893		3.882	0.907	0.677	0.57	0.611	0.75	0.881	
PNEUMO	Pneumococcal infection	4.007	1.745	0.897		0.68	0.894	0.831	0.611		1.212	3.416	
PNEUMO	Pneumonia	1.411	1.215	0.908	0.863	3.1	1.403	1.745	1.544	0.871	1.297	1.128	
PNEUMO	Procalcitonin increased	1.301	1.211	0.893		0.543	0.668	2.195	0.81	0.909	1.151	1.334	
PNEUMO	Product administered to patient of inappropriate age	0.459	0.674		3.017	0.109	0.339	0.378	0.173	0.185	0.373	0.425	
PNEUMO	Pyrexia	1.516	1.846	0.899	0.66	2.544	2.961	2.334	1.522	1.111	1.486	1.538	
PNEUMO	Red blood cell count decreased	1.121	1.156	0.894		6.538	1.592	2.07	1.076	0.741	1.186	0.999	
PNEUMO	Red blood cell sedimentation rate increased	1.065	1.064	0.896	0.42	7.637	3.094	1.531	0.652	0.658	1.065	0.972	
PNEUMO	Reticulocyte count increased	1.812	1.173	0.894	0.896	0.662	6.695		0.698	0.483	0.908	1.641	
PNEUMO	Sepsis	1.824	1.892	0.9	0.753	0.988	7.697	5.595	1.979	0.825	1.91	1.5	
PNEUMO	Skin striae	2.261	0.882				0.819	4.115	1.639	1.115	1.881	1.739	
PNEUMO	Skin warm	2.064	2.746	0.894	0.387	0.869	1.474	2.496	2.37	1.896	1.934	2.499	
PNEUMO	Surgery	0.873	0.89	0.894		4.823	0.616	0.687	0.678	0.653	0.894	0.726	
PNEUMO	Swelling	1.741	1.842	0.893	0.79	1.063	1.991	2.018	1.725	1.568	1.633	2.011	
PNEUMO	Systemic inflammatory response syndrome	2.487	2.502			0.873	1.19	5.036	1.394	0.916	2.129	1.972	
PNEUMO	Tachycardia	1.121	1.255	0.897		4.581	1.713	1.52	0.78	0.753	1.008	1.224	
PNEUMO	Tenderness	1.857	1.98		0.527	1.212	1.894	2.242	1.788	1.623	1.758	2.313	
PNEUMO	Ultrasound scan abnormal	1.597	1.695	0.896	0.656	7.232	5.047	1.669	1.086	0.969	1.573	1.336	
PNEUMO	Ultrasound scan normal	1.601	1.642	0.894	0.531	4.279	0.952	1.699	1.395	1.01	1.447	1.5	
PNEUMO	Vaccination complication	1.477	1.687		0.454	3.663	3.801	1.489	1.219	1.131	1.43	1.401	
PNEUMO	Vaccination site erythema	1.667	2.226	0.895			0.693	1.463	1.13	1.101	1.407	1.345	
PNEUMO	Vaccination site pain	1.372	2.09	0.895	0.587	0.666	1.076	1.416	1.179	1.12	1.247	1.391	
PNEUMO	Vaccination site swelling	1.45	2.32			0.561	1.058	1.584	1.158	1.213	1.289	1.552	
PNEUMO	Vasodilatation	1.691	1.882		0.874	0.802	1.038	1.813	1.765	1.333	1.484	2.348	
PNEUMO	Weight bearing difficulty	1.123	0.996		0.603	11.595	0.693	0.384	0.308	0.458	0.746	1.441	
PNEUMO	White blood cell count increased	2.022	1.67	0.89	0.485	10.366	7.183	3.768	1.967	1.019	2.162	1.756	
PNEUMO	Wrong product administered	1.037	0.927		9.662	0.908	1.005	0.497	0.257	0.317	0.97	1.028	
PNEUMO	X-ray limb abnormal	0.901	0.961	0.897		7.399	0.546	0.549	0.676	0.775	0.809	0.892	
PNEUMO	X-ray limb normal	0.902	1.007			3.498	1.038	1.03	0.358	0.679	0.813	0.989	

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Drug	SOC	Event	World N 20210401	World EB05 20210401	US N 20210401	US EB05 20210401	Comment
PNEUMO	Inv	Blood culture	146	2.437	128	2.349	
PNEUMO	Inv	Blood culture negative	549	2.306	488	2.322	
PNEUMO	Inv	Blood culture positive	150	2.12	50	1.098	
PNEUMO	Infec	Cellulitis	4202	2.897	3946	2.939	
PNEUMO	Inv	C-reactive protein increased	839	2.068	370	1.586	
PNEUMO	Infec	Dermo-hypodermitis	12	2.033			
PNEUMO	Infec	Erysipelas	122	3.318	13	1.434	
PNEUMO	Inv	Human rhinovirus test positive	13	1.722	10	2.08	
PNEUMO	Genrl	Hyperthermia	56	2	2	0.576	
PNEUMO	Infec	Injection site cellulitis	974	3.003	886	3.085	
PNEUMO	Infec	Injection site infection	203	2.027	158	1.712	
PNEUMO	Genrl	Injection site necrosis	45	2.064	23	1.548	
PNEUMO	Genrl	Injection site streaking	216	2.921	216	2.948	
PNEUMO	Blood	Leukocytosis	390	2.22	319	2.257	
PNEUMO	Infec	Lymphangitis	56	2.155	31	1.548	
PNEUMO	Infec	Necrotising fasciitis	20	2.33	13	1.523	
PNEUMO	Genrl	Peripheral swelling	7323	2.513	6900	2.515	
PNEUMO	Infec	Pneumococcal infection	91	4.324	23	4.007	
PNEUMO	Infec	Pneumonia	1102	2.083	491	1.411	
PNEUMO	Infec	Pneumonia pneumococcal	72	2.775	7	0.702	
PNEUMO	Infec	Pneumonia streptococcal	45	3.66	5	0.738	
PNEUMO	Infec	Sepsis	434	2.255	214	1.824	
PNEUMO	Skin	Skin striae	70	2.183	70	2.261	
PNEUMO	Skin	Skin warm	3829	2.027	3733	2.054	
PNEUMO	Infec	Soft tissue infection	39	3.793	11	1.132	
PNEUMO	Surg	Splenectomy	20	2.044	13	1.462	
PNEUMO	Genrl	Systemic inflammatory response syndrome	117	3.218	83	2.497	
PNEUMO	Resp	Tonsillar hypertrophy	47	2.558	2	0.273	
PNEUMO	Infec	Tonsillitis	58	2.372	2	0.321	
PNEUMO	Inv	White blood cell count increased	1814	2.204	1420	2.022	

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Drug	SOC	Event	World N 20210401	World EB05 20210401	US N 20210401	US EB05 20210401	Comment
PNEUMO	Immun	Allergy to metals	193	2.098	1	0.437	
PNEUMO	Inj&P	Heat oedema	7	2.064			
PNEUMO	Genrl	Injection site abscess sterile	50	6.379	6	0.707	
PNEUMO	Infec	Meningitis pneumococcal	248	2.475	25	1.593	
PNEUMO	Infec	Pneumococcal bacteraemia	280	2.583	6	0.789	
PNEUMO	Infec	Pneumococcal infection	167	2.54	15	1.493	
PNEUMO	Immun	Reaction to excipient	103	2.409	1	0.489	
PNEUMO	Inj&P	Scratch	126	2.341	30	1.009	
PNEUMO	Inv	Serology positive	57	3.304	1	0.56	
PNEUMO	Inj&P	Skin wound	45	3.201	3	0.713	
PNEUMO	Inv	Streptococcus test positive	606	2.43	96	1.461	
PNEUMO	Genrl	Vaccination site granuloma	115	2.179	1	0.5	
PNEUMO	Genrl	Vaccination site pruritus	49	2.057	4	0.702	
PNEUMO	Inj&P	Wound	68	2.258	17	1.054	

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From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 2 Nov 2021 19:49:01 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211029.xls

Hi John,

Would it be possible to add Anni Khatri-Dua and Allison Lale to these reports? I would like to train them on these reports before I leave.

Thank you.

Theresa

From: Menschik, David <[redacted]>
Sent: Tuesday, November 2, 2021 12:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/29/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.193	1.805	0.884			0.586	1.611	1.918	1.781	2.71	1.295	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.203	1.784	0.884				1.639	2.225	1.925	2.897	1.453	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.961	1.312	0.94			0.467	1.25	1.753	1.763	2.201	1.536	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.059	0.89	0.883				0.841	0.73	0.731	2.382	1.564	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.054	1.005	0.884				0.997	0.684	0.72	1.589	1.436	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.933	1.327	0.901				1.536	1.353	1.533	2.377	1.092	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.004	2.206	0.894			0.499	2.273	2.061	3.279	4.386	1.354	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.188	1.656	0.881				1.731	1.803	1.216	2.342	1.366	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.546	1.949	0.893			0.435	1.713	2.5	2.36	2.781	2.056	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.911	1.663	0.896			0.388	1.313	2.417	1.022	2.314	1.301	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.348	0.875	0.86			0.578	0.899	1.74	1.906	2.094	1.934	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.243	1.669	1.064	0.512		0.434	1.853	1.996	2.599	2.886	1.613	
COVID19 (COVID19 (JANSSEN))	Anorexia	2.063	1.919	0.882				0.864	1.913	1.423	1.772	1.527	
COVID19 (COVID19 (JANSSEN))	Aspiration cerebral abnormal	1.819	1.221	0.881				1.16	1.178	1.356	2.493	0.938	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.886	1.591	0.882	0.509		0.336	1.239	2.441	1.579	2.298	1.223	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.719	1.542	0.88	0.508		0.295	1.292	2.276	1.363	2.08	1.189	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.765	1.293	0.885			0.339	1.508	1.812	1.531	2.075	1.25	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.919	1.486	0.893			0.407	1.43	2.254	1.728	2.244	1.466	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.953	1.539	0.901			0.459	1.439	2.252	1.768	2.38	1.351	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.517	2.66	0.89			0.511	1.852	2.44	0.738	4.604	1.073	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.889	1.633	0.894			0.286	1.166	2.144	1.545	2.602	1.994	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.745	1.607	0.88			0.214	1.401	2.065	1.241	2.051	1.92	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.915	1.326	1.002				1.338	1.762	1.81	2.002	1.676	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.655	2.194	0.88				1.687	2.6	1.159	2.37	2.15	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.306	1.863	0.913			0.523	2.049	1.915	1.443	3.458	1.998	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.55	1.961	0.899			0.538	1.291	1.268	0.995	3.353	0.971	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.113	1.337	0.861				1.123	1.139	1.306	2.497	1.04	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.489	2.496	0.902			0.525	2.672	2.562	0.825	4.162	1.222	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.748	1.987	0.932	0.511		0.636	2.375	2.48	2.271	3.611	1.773	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.69	1.592	0.897			0.496	1.708	2.016	1.752	3.334	1.523	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.146	1.636	0.907			0.467	1.494	2.172	2.063	2.473	1.64	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.665	1.872	0.923			0.486	2.176	2.273	3.254	3.227	2.027	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.797	1.486	0.877				1.296	2.301	1.45	2.121	1.182	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.765	0.784	0.88			1.137	2.001	1.564	1.004	1.894	1.404	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.295	1.293	0.888			0.377	2.208	2.089	1.924	2.542	1.633	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.16	1.522	0.912	0.511		0.333	1.692	2.371	2.148	2.583	1.483	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.953	0.994	0.881			0.427	1.707	1.901	0.756	2.224	1.182	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.358	1.038	0.888			0.419	2.208	1.79	1.136	2.621	1.448	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.659	1.229	0.887				1.192	1.21	1.243	2.131	0.913	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.297	1.894	0.88				1.399	2.84	1.742	2.162	2.101	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.831	1.372	0.896	0.506		0.433	1.372	2.118	1.689	2.224	1.339	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.767	1.316	0.898	0.507		0.393	1.447	2.023	1.554	2.08	1.347	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.69	2.695	0.89				4.027	4.856	6.152	7.14	2.473	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.814	3.509	0.882			0.549	5.092	5.536	0.666	7.528	1.388	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.79	1.24	0.893				1.254	1.788	1.61	2.038	1.412	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.079	1.841	0.881			0.618	1.874	3.478	1.494	2.217	1.887	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.787	1.422	0.984			0.029	1.404	1.978	1.906	2.188	1.382	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.831	1.319	0.882	0.746		0.401	1.626	1.926	1.382	2.362	1.219	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.905	1.225	0.886				1.567	1.945	0.904	2.038	1.205	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.149	2.006	0.882				1.599	1.139	0.744	2.78	0.785	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.9	1.537	0.88				1.251	2.161	1.098	1.698	1.73	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.039	1.797					0.9	2.342	1.173	1.497	1.795	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.568	1.243	0.885			0.184	1.037	2.042	1.66	2.002	1.137	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.186	1.736	0.887			0.505	1.811	1.937	2.319	2.539	1.805	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.052	1.483	0.886	0.511		0.465	1.331	2.314	1.409	2.27	1.273	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.78	1.279	0.885			0.351	1.275	2.226	1.031	2.127	1.064	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.055	1.533	0.937			0.496	0.996	2.061	1.654	1.988	1.845	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.585	1.346	0.89	0.61		0.224	0.964	2.111	1.893	2.408	1.02	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.616	1.349	0.906			0.15	1.222	1.609	1.342	2.492	0.918	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.645	1.267	0.896			0.24	1.138	2.011	1.594	1.899	1.256	
COVID19 (COVID19 (JANSSEN))	Off label use	1.449	0.216	0.881			5.946	0.324	0.471	0.383	0.911	1.253	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.746	0.757					3.03	0.998		2.15		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.592	0.876				0.524	1.782	2.289	1.165	2.634	1.473	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.51	1.765	0.882				0.656	1.068	2.571	2.482	0.974	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.755	1.489	0.927	0.511		0.485	1.886	3.113	1.789	3.11	1.816	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.848	1.405	0.897	0.509		0.295	1.563	2.037	1.463	2.161	1.415	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.762	2.085	0.894			0.404	2.095	3.1	2.302	3.484	1.7	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.998	3.519	0.882				4.353	3.241	0.685	6.13	1.931	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.265					0.885	4.019	3.183	6.153	4.622	3.771	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.945	1.577	0.902	0.744		0.265	1.521	2.337	1.508	2.523	1.375	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.246	1.679	1.041	0.512		0.584	1.667	2.164	2.68	2.537	1.83	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.064	1.552	0.888				1.53	1.473	2.101	1.91	1.964	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.89	1.402	0.886	0.507		0.537	1.515	2.147	1.571	2.102	1.508	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.021	1.434	0.89	0.509		0.358	1.35	2.183	1.646	2.41	1.249	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.79	1.171	0.905			0.549	1.015	1.074	0.899	2.062	0.909	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.227	1.169	0.884			0.539	1.374	1.776	1.416	1.878	1.735	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.68	1.351	0.883			0.549	1.132	0.826	0.648	2.785	1.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.248	2.722	1.007			0.553	1.86	3.328	1.198	2.73	3.184	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.038	6.797	0.883			0.648	3.617	6.722	15.126	7.93	5.992	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.267							0.634	0.577	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.134	1.701	0.899			0.518	1.432	1.665	1.385	2.264	1.365	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.343	2.013	0.91			0.397	1.788	2.361	1.672	2.837	1.834	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.682	2.18	1.872	0.512		0.572	2.019	2.396	3.547	2.866	2.159	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.302	1.947	0.882				1.966	1.242	0.645	2.375	0.915	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.39	1.432	0.896			0.648	1.923	2.196	2.365	2.752	1.676	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	1.964	0.899	0.512		0.54	2.309	2.285	3.146	3.208	2.146	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.603	1.868	0.895			0.456	2.588	2.02	1.841	2.736	1.848	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.945	1.14	0.883				1.356	2.119	1.725	2.053	1.288	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.651	1.255	0.879	0.511		0.31	0.885	2.008	1.222	1.88	1.005	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.239	1.003	2.537			0.539	1.184	2.391	4.976	1.861	2.082	
COVID19 (COVID19 (JANSSEN))	Vasodilation	2.661	0.881					0.929	1.569	0.976	1.822	1.071	
COVID19 (COVID19 (JANSSEN))	Venogram	2.684	2.005					2.15	1.758	0.721	3.098	0.996	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.385	3.522				0.606	2.964	1.884	0.703	4.205	1.193	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.266	2.611	0.882				3.874	2.212	0.845	5.211	1.19	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.371	0.832		7.378	0.884		1.207	0.513		1.329	1.004	
COVID19 (COVID19 (MODERNA))	Headache	0.968	0.959	0.858	6		0.301	0.943	0.984	1.013	0.954	1.019	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.357	0.947	0.887		1.156	2.623	0.115	0.04	0.493	2.36	2.417	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.042	1.997	0.881			2.204	2.002	1.945	1.574	1.884	2.12	
COVID19 (COVID19 (PFIZER-	Body height	1.931	1.021	0.885			1.6	0.927	1.307	2.186	1.908	1.496	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.05	1.049	0.882			0.637	1.527	1.69	1.944	2.007	1.596	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.284	1.717	1.305			1.024	1.728	1.792	1.941	2.04	1.98	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.726	0.846	0.884	13.852			0.393			0.422	1.14	
COVID19 (COVID19 (PFIZER-	Investigation	2.141	1.707	0.901			1.048	1.729	1.928	2.309	2.11	1.929	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.317	0.326	0.875		3.945	0.321	0.16	0.049	0.301	0.294	1.34	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.768	0.751				1.343	1.853	1.799	2.276	1.784	1.728	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.336	0.891			0.854	1.536	1.728	2.152	2.001	1.78	

PSI-HHS-000000057660

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 17 May 2022 11:55:30 +0000
To: Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP); Shay, David (CDC/DDID/NCIRD/ID); Gee, Julianne (CDC/DDID/NCEZID/DHQP)
Cc: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220513.xls

I'm not sure if you are aware or not, but (b)(5) a while back, actually.

From: Menschik, David <[redacted]>
Sent: Tuesday, May 17, 2022 6:18 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/13/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 202205	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 202209	Adult1 EB05 21220	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 20220513
COVID19 (COVID19 (JANSSEN))	Activated partial	2.062	1.54	0.852			3.382	1.504	1.865	2.049	2.761	1.372
COVID19 (COVID19 (JANSSEN))	Activated partial	2.064	1.534	0.883				1.59	2.027	1.975	2.714	1.406
COVID19 (COVID19 (JANSSEN))	Acute respiratory	2.085	1.333	0.998				0.79	1.676	1.832	1.61	1.922
COVID19 (COVID19 (JANSSEN))	Acute respiratory	2.092	1.322	1.014			3.455	1.42	2.033	1.96	2.421	1.739
COVID19 (COVID19 (JANSSEN))	Adverse drug	3.343	0.975	0.868			3.529	0.973	0.718	0.681	2.622	1.485
COVID19 (COVID19 (JANSSEN))	Adverse event	2.584	1.092	0.894				0.871	0.851	0.731	1.864	1.644
COVID19 (COVID19 (JANSSEN))	Albumin CSF	2.226	1.907					1.304	1.41		0.906	1.624
COVID19 (COVID19 (JANSSEN))	Angiogram	1.907	1.282	0.909				1.453	1.427	1.677	2.099	1.303
COVID19 (COVID19 (JANSSEN))	Angiogram	2.535	1.808	0.914			0.49	2.192	1.955	2.11	3.397	1.494
COVID19 (COVID19 (JANSSEN))	Angiogram	2.081	1.402	0.888				1.801	1.758	1.287	2.254	1.406
COVID19 (COVID19 (JANSSEN))	Angiogram	2.289	1.621	0.912			3.416	1.998	2.281	2.198	2.45	1.953
COVID19 (COVID19 (JANSSEN))	Anion gap	1.808	1.365	0.91			3.367	1.103	2.22	1.478	2.091	1.353
COVID19 (COVID19 (JANSSEN))	Antibody test	2.114	0.822	0.882			0.57	0.792	1.574	1.896	2.002	1.652
COVID19 (COVID19 (JANSSEN))	Anticoagulant	2.172	1.466	0.971	0.619		3.421	1.827	2.029	2.245	2.758	1.649
COVID19 (COVID19 (JANSSEN))	Application site	2.001						0.56	0.635	0.678	1.036	0.764
COVID19 (COVID19 (JANSSEN))	Areflexia	2.147	1.724	0.902				0.957	2.413	1.343	2.312	1.449
COVID19 (COVID19 (JANSSEN))	Arteriogram	1.845	1.164	0.889				1.213	1.231	1.417	2.232	0.883
COVID19 (COVID19 (JANSSEN))	Basophil count	1.873	1.383	0.928	0.616		3.361	1.172	2.28	1.806	2.319	1.328
COVID19 (COVID19 (JANSSEN))	Basophil	1.79	1.408	0.944	0.615		3.256	1.143	2.303	1.794	2.182	1.342
COVID19 (COVID19 (JANSSEN))	Blood albumin	1.81	1.263	0.929			3.307	1.447	1.844	1.751	2.16	1.39
COVID19 (COVID19 (JANSSEN))	Blood calcium	1.856	1.342	0.951			3.375	1.348	2.087	1.875	2.166	1.491
COVID19 (COVID19 (JANSSEN))	Blood chloride	1.812	1.302	0.953			3.469	1.214	2.022	1.86	2.139	1.346
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	2.814	2.199	0.897			3.503	1.748	2.173	0.885	4.053	1.039
COVID19 (COVID19 (JANSSEN))	Blood magnesium	1.806	1.303	0.928			0.17	1.977	1.961	1.766	2.304	1.214
COVID19 (COVID19 (JANSSEN))	Blood potassium	1.699	1.216	0.938			3.516	1.236	1.512	2.04	1.869	1.24
COVID19 (COVID19 (JANSSEN))	Blood sodium	1.823	1.306	0.904	0.616			1.33	2.015	1.736	1.958	1.537
COVID19 (COVID19 (JANSSEN))	Blood urea	1.888	1.251	0.913				1.922	2.048	1.773	2.128	1.602
COVID19 (COVID19 (JANSSEN))	Brain oedema	1.58	1.269	0.931				1.196	1.567	0.603	2.011	0.806
COVID19 (COVID19 (JANSSEN))	COVID-19	2.212	1.41	1.093				1.804	2.238	2.027	2.39	1.978
COVID19 (COVID19 (JANSSEN))	CSF protein	2.589	2.018	0.882				1.847	2.985	1.005	2.517	2.16
COVID19 (COVID19 (JANSSEN))	Cerebral	2.229	1.596	0.939			3.526	1.712	1.878	1.508	3.333	1.151
COVID19 (COVID19 (JANSSEN))	Cerebral mass	2.828	1.982	0.93			3.534	1.384	1.755	1.17	3.923	1.144
COVID19 (COVID19 (JANSSEN))	Cerebral	2.653	1.738	0.886				1.364	1.361	1.629	3.528	1.265
COVID19 (COVID19 (JANSSEN))	Cerebral venous	3.31	2.158	0.919			0.53	2.517	2.344	0.879	3.882	1.225
COVID19 (COVID19 (JANSSEN))	Chest X-ray	1.865	1.28	0.957			3.333	1.318	1.89	1.902	2.104	1.599
COVID19 (COVID19 (JANSSEN))	Computerised	2.436	1.655	0.966	0.618		3.614	2.145	2.295	2.033	3.031	1.729
COVID19 (COVID19 (JANSSEN))	Computerised	1.999	1.338	0.916			3.381	1.711	1.983	1.841	2.275	1.526
COVID19 (COVID19 (JANSSEN))	Computerised	2.001	1.395	0.926			3.483	1.376	2.045	2.009	2.248	1.673
COVID19 (COVID19 (JANSSEN))	Creatinine renal	2.032	1.267	0.89				0.497	0.895	1.995	1.089	1.646
COVID19 (COVID19 (JANSSEN))	Death	1.833	1.164	0.963				1.187	1.621	1.526	2.059	1.558
COVID19 (COVID19 (JANSSEN))	Deep vein	2.61	1.782	1.009			3.466	2.208	2.281	3.137	3.269	2.009
COVID19 (COVID19 (JANSSEN))	Endotracheal	2.056	1.37	1.147			3.367	1.416	2.095	1.874	2.103	1.832
COVID19 (COVID19 (JANSSEN))	Eosinophil count	1.771	1.288	0.927			0.04	1.232	2.054	1.696	2.057	1.325
COVID19 (COVID19 (JANSSEN))	Eosinophil	1.792	1.354	0.938	0.616		3.273	1.268	2.095	1.724	2.062	1.397
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.753	0.857	0.895			1.186	2.023	1.452	0.968	1.844	1.429
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.273	1.295	0.901			3.445	2.188	2.157	1.972	2.539	1.692
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.128	1.441	0.886	0.619		3.298	1.713	2.275	2.201	2.494	1.615
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	1.934	1.081	0.886			0.44	1.636	1.979	1.027	2.167	1.289
COVID19 (COVID19 (JANSSEN))	Foetal exposure	2.085	1.432		0.756			0.654			1.434	1.726
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.23	1.036	0.897			3.406	2.273	1.7	1.228	2.243	1.595
COVID19 (COVID19 (JANSSEN))	Globulins	1.83	1.252	0.908			3.402	1.263	1.699	1.606	2.228	1.184
COVID19 (COVID19 (JANSSEN))	Glucose urine	1.696	1.147	0.907				1.216	1.392	1.343	2.217	1.014
COVID19 (COVID19 (JANSSEN))	Guillain-Barre	2.473	1.842	0.894			0.44	1.637	3.13	1.836	2.432	2.192
COVID19 (COVID19 (JANSSEN))	Haematocrit	1.8	1.272	0.944	0.612		3.502	1.31	2.028	1.778	2.182	1.414
COVID19 (COVID19 (JANSSEN))	Haemoglobin	1.756	1.238	0.937	0.613		3.394	1.373	1.987	1.668	2.096	1.403
COVID19 (COVID19 (JANSSEN))	Heparin-induced	5.706	3.819	0.9				4.186	5.519	4.266	7.267	3.357
COVID19 (COVID19 (JANSSEN))	Heparin-induced	6.457	3.472	0.884			3.556	4.664	5.719	0.739	7.264	3.079
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.076	1.332	0.964				1.511	2.095	1.922	2.448	1.685
COVID19 (COVID19 (JANSSEN))	Immunoglobulin	2.069	1.719	0.877			3.011	1.912	2.545	1.397	2.24	1.704
COVID19 (COVID19 (JANSSEN))	Intensive care	1.937	1.396	1.071			3.022	1.425	2.105	2.071	2.331	1.581
COVID19 (COVID19 (JANSSEN))	International	1.776	1.22	0.894	0.754		3.387	1.523	1.927	1.434	2.318	1.259
COVID19 (COVID19 (JANSSEN))	International	1.897	1.198	0.889				1.384	2.032	0.919	2.051	1.248
COVID19 (COVID19 (JANSSEN))	Intracardiac	2.628	1.759	0.911				0.84	1.402	0.996	1.717	1.595
COVID19 (COVID19 (JANSSEN))	Jugular vein	1.83	1.45	0.869				1.373	1.124	0.711	2.343	0.712
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.875	1.36	0.877				1.264	2.195	1.012	1.674	1.749
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	2.147	1.706					1.125	2.834	1.023	1.781	1.816
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.976	1.281	0.945				1.377	1.72	1.977	2.318	1.52
COVID19 (COVID19 (JANSSEN))	Lymphocyte	1.681	1.23	0.93			3.188	0.998	2.05	1.839	2.058	1.3
COVID19 (COVID19 (JANSSEN))	Lymphocyte	1.414	1.097	0.91	0.614		3.249	1.009	1.421	1.315	2.006	0.851
COVID19 (COVID19 (JANSSEN))	Magnetic	2.056	1.468	0.914			3.475	1.784	1.865	2.132	2.329	1.592
COVID19 (COVID19 (JANSSEN))	Mean cell	2.043	1.383	0.942	0.619		3.446	1.243	2.197	1.851	2.355	1.394
COVID19 (COVID19 (JANSSEN))	Mean cell	1.701	1.258	0.925			3.263	1.117	1.939	1.496	2.04	0.991
COVID19 (COVID19 (JANSSEN))	Mean platelet	1.866	1.318	0.917			3.319	1.16	2.315	1.576	2.107	1.394
COVID19 (COVID19 (JANSSEN))	Mechanical	2.269	1.515	1.019			3.483	1.161	2.278	1.978	2.113	2.015
COVID19 (COVID19 (JANSSEN))	Monocyte	1.521	1.214	0.918	0.616		3.212	0.845	1.915	1.958	2.173	1.105
COVID19 (COVID19 (JANSSEN))	Neutrophil	1.533	1.208	0.898			3.323	1.097	1.645	1.678	2.191	0.856
COVID19 (COVID19 (JANSSEN))	Neutrophil	1.722	1.262	0.929			0.25	1.101	2.088	1.775	1.981	1.4
COVID19 (COVID19 (JANSSEN))	Nonspecific	4.061	0.767					0.744	0.612		2.961	1.076
COVID19 (COVID19 (JANSSEN))	Off label use	2.029	0.599	0.895			3.141	1.195	1.339	0.932	1.473	1.976
COVID19 (COVID19 (JANSSEN))	On and off	1.784	0.755					3.446	0.982		2.288	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.227	0.867				3.518	1.506	2.219	1.104	2.169	1.446
COVID19 (COVID19 (JANSSEN))	Peripheral	3.087	1.362	0.884				0.656	1.034	1.54	2.246	0.951
COVID19 (COVID19 (JANSSEN))	Platelet count	2.66	2.187	0.918	0.618		0.48	1.84	2.864	2.725	3.025	1.802
COVID19 (COVID19 (JANSSEN))	Platelet count	1.872	1.317	0.922	0.614		3.239	1.448	2.105	1.867	2.241	1.472
COVID19 (COVID19 (JANSSEN))	Platelet count	2.562	1.82	0.901			3.451	2.095	2.757	2.134	3.151	1.686
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.782	3.298	0.885				4.298	4.645	0.805	5.733	2.351
COVID19 (COVID19 (JANSSEN))	Poor quality	1.3					0.88	1.957	1.308	1.429	1.993	2.022
COVID19 (COVID19 (JANSSEN))	Portal vein	2.072	1.425	0.886				0.859	1.645	1.026	2.024	1.258
COVID19 (COVID19 (JANSSEN))	Positive airway	2.045	1.292	0.953				1.014	2.083	1.664	2.225	1.613
COVID19 (COVID19 (JANSSEN))	Product	1.772	0.832	0.885		0.72	2.063	0.041	0.002	0.514	1.671	1.832
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.177	1.345					5.05			5.149	
COVID19 (COVID19 (JANSSEN))	Prothrombin time	1.925	1.39	0.941	0.734		3.299	1.447	2.283	1.657	2.448	1.454
COVID19 (COVID19 (JANSSEN))	Pulmonary	2.237	1.584	1.105	0.619		0.59	1.773	2.088	2.618	2.512	1.902
COVID19 (COVID19 (JANSSEN))	Pulmonary	2.286	1.482	0.909				1.726	1.631	1.913	2.161	1.878
COVID19 (COVID19 (JANSSEN))	Red blood cell	1.806	1.276	0.932	0.614		3.564	1.136	2.024	1.67	2.038	1.501
COVID19 (COVID19 (JANSSEN))	Red cell	1.959	1.316	0.935	0.617		3.286	1.303	2.118	1.789	2.285	1.425
COVID19 (COVID19 (JANSSEN))	Russell's viper	1.368	1.004					2.691	0.505		1.08	0.73
COVID19 (COVID19 (JANSSEN))	Superficial vein	2.558	1.646	0.899			3.539	1.774	1.966	1.662	2.577	1.707
COVID19 (COVID19 (JANSSEN))	Suspected COVID-	3.5	2.225	1.59			3.528	3.25	3.31	1.236	2.926	3.457
COVID19 (COVID19 (JANSSEN))	Therapy non-	6.552	0.756	0.885			3.654	3.621	6.582	14.788	7.735	5.71
COVID19 (COVID19 (JANSSEN))	Therapy partial	2.667							0.637	0.569	0.561	1.026
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.966	1.347	0.895			3.514	1.438	1.526	1.478	2.1	1.35
COVID19 (COVID19 (JANSSEN))	Thrombocytopeni	2.301	1.761	0.955			3.369	1.609	2.437	1.919	2.523	1.809
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.892	2.117	1.75	0.619		3.729	1.986	2.45	3.591	2.961	2.374
COVID19 (COVID19 (JANSSEN))	Thrombosis with	6.02	2.943	0.902				2.137	5.422	0.566	5.579	1.94
COVID19 (COVID19 (JANSSEN))	Transverse sinus	2.09	1.527	0.885				1.782	1.23	0.623	2.132	0.879
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.349	1.425	0.914			3.717	1.902	2.211	2.154	2.675	1.736
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.7	1.833	0.963	0.619		0.53	2.449	2.284	2.883	3.303	2.1
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.367	1.629	0.922			3.431	2.159	2.009	2.009	2.474	1.812
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.643	3.079	2.498			3.493	1.574	2.925	5.47	2.356	2.533
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.925	0.894					1.26	1.373	0.787	2.101	0.815
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.113	0.906	0.883				0.975	1.579	1.133	1.851	1.112
COVID19 (COVID19 (JANSSEN))	Venogram	2.331	1.74	0.882				1.99	1.598	0.705	2.491	1.059
COVID19 (COVID19 (JANSSEN))	Venogram	2.706	2.035				3.612	2.68	1.628	0.665	3.331	1.199
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.984	2.258	0.889				3.73	2.049	1.062	4.97	1.198
COVID19 (COVID19 (MODERNA))	Exposure via	1.46	0.823		10.37	0.91		1.286	0.52		1.466	1.051
COVID19 (COVID19 (MODERNA))	Interchange of	0.666	0.956	0.885	0.609	1.023	2.465	0.785	0.635	0.423	0.671	0.633
COVID19 (COVID19 (MODERNA))	Mechanical	2.056	1.138				3.671	2.085	1.533	0.839	2.002	1.646
COVID19 (COVID19 (MODERNA))	Product	2.533	1.016	0.894	0.466	6.063	2.971	0.132	0.061	0.354	2.541	2.633
COVID19 (COVID19 (MODERNA))	Product dose	2.145	2.04	0.882			2.804	2.046	2	1.585	1.98	2.188
COVID19 (COVID19 (MODERNA))	Vaccination	2.106	1.671	0.899			3.837	1.631	1.784	1.532	1.912	1.897
COVID19 (COVID19 (PFIZER-BIONTECH))	Body height	1.946	0.992	0.889		0.482	3.696	0.957	1.437	2.175	1.915	1.546
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.069	1.754	1.685	0.753	0.844	1.117	1.724	1.755	1.779	1.824	1.859
COVID19 (COVID19 (PFIZER-BIONTECH))	Exposure via	0.859	0.859	0.868	16.498			0.363			0.908	1.238
COVID19 (COVID19 (PFIZER-BIONTECH))	Immunisation	2.05	1.657	0.918		1.287	1.243	1.801	1.98	2.259	1.979	1.842
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.031	1.749	0.93		0.716	1.086	1.793	1.928	2.239	1.984	1.892
COVID19 (COVID19 (PFIZER-BIONTECH))	Product	1.604	0.784			1.455	1.371	1.847	1.714	2.148	1.586	1.561
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	1.939	1.351	0.898			3.943	1.558	1.745	2.106	1.906	1.763

PSI-HHS-000000057662

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 1 Mar 2022 16:06:58 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220225.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, March 1, 2022 5:57 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 2/25/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022(25	Serious EB05 2022	Fatal EB05 2022(3	Infant EB05 2022(0	Child EB05 2022(	Teen EB05 2022(0	Adult1 EB05 2022(	Adult2 EB05 2022(	Adult3 EB05 2022(	Female EB05 2022(	Male EB05 2022(	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.666	1.686	0.913			0.597	1.576	1.965	1.668	2.665	1.48	Reviewed
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.174	1.672	0.873				1.676	2.11	2.12	2.877	1.5	Reviewed
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.068	1.34	1.02			0.452	1.419	2.034	1.888	2.318	1.722	Reviewed
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.871	6.961	0.87			0.518	0.973	0.865	0.689	2.573	1.469	Other
COVID19 (COVID19 (JANSSEN))	Adverse event	2.018	1.064	0.877				0.925	0.765	0.75	1.824	1.51	Other
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.913	1.35	0.901				1.437	1.462	1.777	2.157	1.326	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.555	1.881	0.902			0.485	2.134	2.015	2.138	3.674	1.437	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.154	1.522	0.873				1.874	1.811	1.242	2.373	1.407	Not an AE
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.443	1.686	0.898			0.425	1.651	2.327	2.163	2.538	1.963	Reviewed
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.812	1.421	0.893			0.388	1.198	2.216	1.407	2.171	1.308	Other
COVID19 (COVID19 (JANSSEN))	Antibody test	2.309	0.817	0.863			0.563	0.811	1.075	1.909	2.092	1.744	Not an AE
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.229	1.516	0.96	0.512		0.427	1.834	2.026	2.246	2.77	1.832	Other
COVID19 (COVID19 (JANSSEN))	Areflexia	2.118	1.809	0.876				0.86	2.258	1.385	1.884	1.519	Reviewed
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.78	1.118	0.868				1.106	1.178	1.366	2.284	0.868	Reviewed
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.89	1.431	0.886	0.61		0.325	1.21	2.339	1.771	2.38	1.314	Other
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.787	1.477	0.906	0.508		0.286	1.206	2.251	1.83	2.203	1.328	Other
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.791	1.306	0.9			0.397	1.456	1.873	1.767	2.162	1.419	Other
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.878	1.38	0.912			0.394	1.378	2.113	1.88	2.224	1.482	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.897	1.397	0.944			0.442	1.292	2.176	1.944	2.281	1.391	Other
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.124	2.342	0.886			0.504	1.803	1.908	0.857	4.253	1.048	Reviewed
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.836	1.391	0.926			0.263	1.14	1.961	1.812	2.462	1.193	Other
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.681	1.236	0.92			0.527	1.192	1.5	2.071	1.855	1.235	Other
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.819	1.324	0.881	0.509			1.331	2.019	1.665	1.897	1.597	Not an AE
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.652	1.162	0.912				1.476	1.532	1.135	2.148	0.998	Other
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.675	1.36	0.866			0.225	1.398	1.953	1.213	2.045	0.891	Other
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.854	1.257	0.89				1.068	2.044	1.711	2.087	1.59	Other
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.04	1.419	1.122				1.731	2.186	1.923	2.281	1.912	Other
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.715	2.108	0.896				1.762	2.907	1.077	2.482	2.2	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.32	1.623	0.922			0.514	1.681	1.883	1.448	3.168	1.145	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.867	1.885	0.912			0.622	1.409	1.383	1.174	3.703	0.993	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.279	1.699	0.962				1.12	1.281	1.617	3.124	1.295	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.243	2.168	0.907			0.517	2.257	2.226	0.877	3.847	1.189	Reviewed
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.776	1.27	0.926			0.368	1.329	1.836	1.791	2.033	1.564	Confounded
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.566	1.695	0.956	0.511		0.614	2.102	2.327	2.028	3.045	1.741	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.991	1.363	0.902			0.384	1.698	1.967	1.804	2.238	1.516	Not an AE
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.073	1.428	0.914			0.456	1.435	2.031	1.979	2.283	1.648	Reviewed
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.585	1.77	0.998			0.457	2.155	2.263	3.018	3.248	1.974	Reviewed
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	1.94	1.376	1.153			0.375	1.348	2.094	1.734	1.952	1.816	Labeled
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.752	1.307	0.88				1.256	2.095	1.612	2.021	1.29	Other
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.773	1.408	0.902	0.509		0.301	1.301	2.098	1.734	2.077	1.384	Other
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.779	0.836	0.872			1.206	2.013	1.455	0.967	1.81	1.416	Labeled
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.305	1.241	0.886			0.44	2.184	2.15	1.816	2.484	1.693	Other
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.161	1.443	0.904	0.512		0.314	1.663	2.241	2.102	2.42	1.602	Reviewed
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.963	1.1	0.868			0.432	1.646	2.062	1.033	2.163	1.372	Not an AE
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.305	1.09	0.881			0.405	2.26	1.752	1.302	2.352	1.608	Labeled
COVID19 (COVID19 (JANSSEN))	Glabellar tap test	1.877	1.305	0.886			0.4	1.329	1.836	1.697	2.204	1.564	Reviewed
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.799	1.236	0.896				1.31	1.37	1.465	2.344	1.068	Other
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.338	1.846	0.871				1.579	2.978	1.633	2.34	2.172	Reviewed
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.839	1.299	0.919	0.508		0.424	1.33	2.007	1.775	2.19	1.411	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.771	1.257	0.906	0.507		0.317	1.4	1.966	1.641	2.078	1.397	Reviewed
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.57	3.618	0.886				4.091	5.267	5.38	7.214	3.016	Not an AE
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.408	3.449	0.866			0.543	4.721	5.662	6.746	7.557	1.837	Reviewed
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.885	1.299	0.931				1.468	1.977	1.776	2.23	1.561	Reviewed
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.104	1.806	0.885			0.02	1.924	2.54	1.44	2.247	1.882	Reviewed
COVID19 (COVID19 (JANSSEN))	Intensive care	1.843	1.418	1.056			0.029	1.48	2.063	2.013	2.312	1.537	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.883	1.276	0.884	0.747		0.394	1.589	1.971	1.453	2.338	1.316	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.016	1.237	0.871				1.43	2.045	0.922	2.114	1.252	Not an AE
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.917	1.522	0.866				1.374	1.165	0.709	2.414	0.714	Reviewed
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.999	1.341	0.956				1.215	2.163	1	1.678	1.674	Not an AE
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.066	1.733					1.054	2.615	1.059	1.694	1.782	Reviewed
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.72	1.269	0.932				1.396	1.726	1.824	2.188	1.501	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.669	1.283	0.91			0.173	1.02	2.1	1.864	2.118	1.31	Other
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.09	1.534	0.898			0.478	1.802	1.88	2.127	2.311	1.832	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.1	1.479	0.921	0.512		0.449	1.248	2.317	1.842	2.386	1.444	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.867	1.391	0.9			0.398	1.265	2.345	1.445	2.231	1.396	Other
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.057	1.524	1.018			0.476	0.991	2.264	1.862	1.954	1.975	Reviewed
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.58	1.255	0.892	0.509		0.257	0.911	1.936	2.008	2.293	1.104	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.489	1.202	0.872			0.129	1.186	1.648	1.501	2.209	0.844	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.746	1.32	0.911			0.233	1.115	2.117	1.884	2.043	1.417	Other
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.153	6.793					0.749	0.612		2.393	1.05	Other
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	0.56	0.877			0.028	1.193	1.175	0.851	1.405	1.931	Not an AE
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.754	6.762					3.297	1		2.218		Other
COVID19 (COVID19 (JANSSEN))	Packed red blood cell transfusion	1.73	1.217	0.884				1.213	1.178	1.148	2.028	0.865	Reviewed
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.552	0.875				0.513	1.55	2.206	1.044	2.22	1.428	Not an AE
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	2.932	1.467	0.906				0.956	1.059	1.562	2.461	0.953	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count	2.76	2.241	0.906	0.511		0.472	1.799	2.996	2.444	3.064	1.779	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.866	1.294	0.892	0.509		0.289	1.476	2.078	1.472	2.168	1.418	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.727	1.884	0.884			0.387	2.091	2.709	1.971	3.113	1.836	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.027	3.381	0.867				4.302	2.565	0.813	6.276	1.862	Not an AE
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.306					0.565	2.951	2.386	3.114	3.581	3.106	Not an AE
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	1.854	1.299	0.938				1.054	1.968	1.831	2.029	1.626	Other
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.628	6.839	0.866		0.72	2.008	0.08	0.062	0.462	1.644	1.789	
COVID19 (COVID19 (JANSSEN))	Prolonged labour	1.098	1.064					4.216			2.718		Other
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.976	1.497	0.928	0.746		0.323	1.513	2.326	1.692	2.527	1.508	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.23	1.581	1.444	0.513		0.584	1.752	2.027	2.568	2.475	1.883	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.045	1.477	0.894				1.679	1.572	2.02	2.088	1.872	Reviewed
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.842	1.303	0.906	0.507		0.529	1.364	2.063	1.673	2.046	1.51	Other
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.012	1.387	0.92	0.511		0.333	1.324	2.277	1.747	2.358	1.452	Other
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.364	1.02					2.324	0.499		1.098	0.731	Reviewed
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.398	1.5	0.872			0.531	1.811	1.968	1.543	2.608	1.711	Other
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.236	2.157	1.443			0.522	3.076	3.131	1.229	2.931	3.356	Other
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.023	6.775	0.867			0.646	3.59	6.68	15.047	7.802	1.84	Other
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.384							0.638	0.573	0.568	1.018	Other
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.108	1.432	0.88			0.508	1.381	1.582	1.543	2.199	1.36	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.301	1.76	0.941			0.372	1.604	2.38	1.773	2.476	1.741	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.681	2.08	1.066	0.513		0.734	1.977	2.365	3.516	2.902	2.287	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.09	2.524	0.886				1.651	0.899	0.574	5.186	1.68	Reviewed
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.225	1.753	0.868				1.886	1.19	0.63	2.038	0.908	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.417	1.476	0.908			0.728	1.925	2.25	2.369	2.754	1.779	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.714	1.836	0.924	0.512		0.521	2.448	2.242	2.853	3.311	2.061	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.509	1.704	0.92			0.438	2.121	2.053	2.101	2.522	1.855	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.887	1.097	0.871				1.226	2.04	1.727	1.885	1.327	Not an AE
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.546	1.176	0.886	0.512		0.306	0.902	2.026	1.256	1.743	1.172	Not an AE
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.069	2.444			0.494	1.589	3.076	6.184	2.41	2.502	Other
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.036	6.892					0.884	1.658	1.033	1.811	1.086	Labeled
COVID19 (COVID19 (JANSSEN))	Venogram	2.308	1.795	0.863				1.942	1.622	0.709	2.634	1.915	Not an AE
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.608	2.092				0.602	2.361	1.67	0.67	3.232	1.211	Reviewed
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.067	2.275	0.871				3.767	2.051	0.928	4.678	1.233	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	6.836		9.058	0.936		1.238	0.515		1.375	0.894	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.09	1.893	0.862	0.000	1.015	2.441	0.782	0.621	0.4	0.693	0.915	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.901	1.028				0.64	2.111	1.575	0.825	2.002	2.03	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.986	0.877		5.962	2.567	0.105	0.048	0.38	2.544	2.846	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.051	2.04	0.866			2.395	1.995	1.961	1.566	1.993	2.106	
COVID19 (COVID19 (PFIZER-	Body height	1.948	6.988	0.871			0.639	0.943	1.374	2.148	1.898	1.519	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.096	0.867		0.485	0.71	1.453	1.676	1.868	1.923	1.491	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.783	1.724	0.512	0.778	1.077	1.707	1.718	1.751	1.846	1.842	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.792	6.849	0.87	17.744			0.391			0.473	1.325	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.688	0.911		1.271	1.224	1.792	1.983	2.209	1.933	1.796	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.777	0.908		0.668	1.075	1.767	1.92	2.23	2.015	1.879	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.792			1.458	1.375	1.849	1.732	2.165	1.612	1.576	
COVID19 (COVID19 (PFIZER-	Weight	2.023	1.358	0.881			0.698	1.544	1.74	2.133	1.938	1.763	

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 21 Dec 2021 16:25:19 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211217.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, December 21, 2021 10:44 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 12/17/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.139	1.747	0.902			0.681	1.535	1.961	1.84	2.861	1.378	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.284	1.812	0.887				1.704	2.267	2.202	3.074	1.563	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.967	1.319	0.984			0.461	1.35	1.853	1.821	2.228	1.639	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.52	0.912	0.88			0.522	0.953	0.867	0.662	2.508	1.572	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.028	1.029	0.883				0.961	0.672	0.785	1.597	1.515	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.967	1.373	0.906				1.432	1.441	1.757	2.334	1.229	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.823	2.104	0.909			0.496	2.224	2.096	3.072	4.148	1.513	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.177	1.623	0.877				1.925	1.853	1.111	2.357	1.427	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.467	1.808	0.903			0.429	1.619	2.36	2.397	2.654	2	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.773	1.435	0.896			0.376	1.191	2.276	1.098	2.11	1.269	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.308	0.838	0.873			0.589	0.911	1.745	1.987	2.122	1.865	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.231	1.558	0.965	0.512		0.441	1.842	1.958	2.347	2.74	1.835	
COVID19 (COVID19 (JANSSEN))	Anoxia	2.103	1.899	0.885				0.873	2.044	1.442	1.931	1.506	
COVID19 (COVID19 (JANSSEN))	Aortogram cerebral abnormal	1.939	1.231	0.879				1.189	1.134	1.082	2.731	0.914	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.905	1.527	0.888	0.509		0.338	1.179	2.519	1.705	2.296	1.34	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.778	1.521	0.888	0.509		0.385	1.238	2.285	1.67	2.125	1.324	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.756	1.285	0.882			0.363	1.446	1.888	1.601	2.054	1.379	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.923	1.449	0.898			0.413	1.438	2.214	1.853	2.261	1.536	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.986	1.508	0.912			0.467	1.353	2.322	1.869	2.364	1.445	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.41	2.516	0.89			0.507	1.783	2.65	0.786	4.465	1.106	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.836	1.431	0.914			0.28	1.187	2.046	1.587	2.348	1.194	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.745	1.552	0.873			0.238	1.43	2.1	1.363	2.156	0.936	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.763	1.223	0.881				1.053	2.006	1.567	1.97	1.529	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.978	1.443	1.384				1.596	2.036	1.973	2.311	1.83	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.71	2.213	0.878				1.81	3.007	1.1	2.466	2.301	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.335	1.786	0.925			0.521	1.882	1.92	1.486	3.472	1.109	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.76	2.003	0.91			0.53	1.31	1.307	1.194	3.968	0.931	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.215	1.572	0.876				1.101	1.222	1.394	2.764	1.001	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.303	2.313	0.924			0.523	2.337	2.364	0.809	3.978	1.214	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.638	1.866	0.851	0.511		0.636	2.3	2.366	2.16	3.432	1.74	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.969	1.401	0.9			0.392	1.057	1.966	1.783	2.384	1.516	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.094	1.525	0.919			0.468	1.413	2.087	2.082	2.371	1.643	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.668	1.895	0.98			0.482	2.118	2.277	3.027	3.171	2.008	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.781	1.359	0.892				1.264	2.241	1.498	2.052	1.254	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.681	1.313	0.884	0.61		0.311	1.262	2.037	1.407	1.873	1.302	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.781	0.834	0.883			0.129	2.002	1.471	0.997	1.858	1.423	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.288	1.302	0.884			0.375	2.204	2.134	1.968	2.547	1.867	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.149	1.456	0.929	0.511		0.338	1.659	2.298	2.138	2.448	1.555	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.96	1.011	0.876			0.437	1.693	2.019	0.734	2.148	1.302	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.269	1.089	0.887			0.406	2.35	1.771	1.164	2.451	1.561	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.852	1.316	0.886			0.403	1.435	1.536	1.518	2.111	1.212	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.752	1.251	0.888				1.302	1.33	1.313	2.183	1.058	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.287	1.656	0.876				1.516	2.666	1.077	2.157	2.163	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.837	1.344	0.909	0.506		0.44	1.368	2.111	1.759	2.191	1.452	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.771	1.301	0.903	0.507		0.332	1.426	2.042	1.618	2.073	1.436	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.44	3.89	0.881				4.009	4.882	6.187	7.191	2.99	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.498	3.555	0.877			0.544	4.694	5.745	0.762	7.708	1.712	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.882	1.321	0.915				1.507	1.946	1.735	2.266	1.548	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.115	1.927	0.88			0.535	1.958	2.65	1.531	3.319	1.748	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.856	1.44	1.113			0.532	1.433	2.029	2.074	2.268	1.502	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.879	1.325	0.894	0.747		0.413	1.613	2.008	1.444	2.458	1.291	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.029	1.342	0.881				1.39	2.089	0.995	2.148	1.279	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.056	1.883	0.88				1.499	1.197	0.724	2.925	0.733	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.895	1.441	0.873				1.234	2.15	1.089	1.709	1.889	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.023	1.812					0.99	2.656	1.112	1.685	1.829	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.663	1.279	0.897			0.192	1.043	2.113	1.836	2.091	1.244	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.141	1.64	0.885			0.489	1.843	1.891	2.208	2.495	1.567	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.12	1.526	0.906	0.511		0.464	1.193	2.43	1.721	2.4	1.378	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.661	1.232	0.883			0.309	1.004	2.046	1.319	1.91	0.944	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.874	1.417	0.901			0.349	1.251	2.321	1.418	2.144	1.335	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.094	1.511	0.964			0.487	1.009	2.173	1.695	1.982	1.785	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.647	1.296	0.886	0.61		0.27	0.951	2.023	1.948	2.353	1.075	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.553	1.265	0.881			0.172	1.212	1.757	1.396	2.204	0.891	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.732	1.321	0.895			0.249	1.15	2.179	1.782	2.001	1.387	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.188	0.725					0.761	0.611		1.958	0.895	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	0.228	0.878			7.528	1.25	1.161	0.813	1.392	1.952	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.752	0.76					3.17	1.002		2.183		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.522	0.864				0.513	1.677	2.364	1.131	2.511	1.479	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.205	1.648	0.877				0.656	1.063	1.834	2.65	0.962	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.762	2.458	0.916	0.61		0.472	1.886	3.167	2.578	3.194	1.838	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.899	1.397	0.901	0.508		0.298	1.564	2.145	1.498	2.208	1.495	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.13	1.978	0.892			0.394	2.027	2.978	2.176	3.288	1.709	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.063	3.513	0.878				4.493	3.726	0.681	6.271	1.847	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.305					0.577	4.068	3.443	6.177	4.557	4.085	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.029	1.566	0.922	0.745		0.339	1.566	2.436	1.602	2.597	1.51	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.23	1.634	1.542	0.512		0.592	1.691	2.094	2.698	2.511	1.842	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.068	1.557	0.894				1.603	1.645	1.923	1.957	1.781	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.828	1.398	0.893	0.507		0.342	1.128	2.104	1.629	2.082	1.565	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.017	1.407	0.903	0.61		0.357	1.241	2.32	1.726	2.369	1.402	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.378	1.278	0.882			0.531	1.639	1.891	1.452	2.377	1.845	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.227	2.533	1.676			0.53	2.026	2.207	1.166	2.644	3.024	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.028	6.789	0.878			0.646	3.52	6.721	15.803	7.878	5.992	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.373							0.636	0.572	0.568	1.024	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.152	1.551	0.891			0.516	1.407	1.664	1.362	2.214	1.353	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.34	1.947	0.94			0.379	1.695	2.49	1.809	2.866	1.767	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.678	2.131	1.786	0.512		0.65	1.95	2.383	3.463	2.805	2.195	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	2.911	2.073	0.887				0.954	0.766		1.731	1.68	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.18	1.772	0.877				1.732	1.267	0.638	2.022	0.908	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.42	1.447	0.897			0.652	1.894	2.193	2.431	2.774	1.718	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.743	1.897	0.906	0.512		0.528	2.314	2.26	2.983	3.247	2.104	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.469	1.692	0.904			0.446	2.267	1.961	1.636	2.482	1.824	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.859	1.106	0.878				1.245	2.043	1.757	1.956	1.239	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.363	1.219	2.674			0.533	1.302	2.684	5.882	2.121	2.224	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.734	1.273	0.934			0.464	0.881	1.227	2.022	1.553	1.481	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.026	0.877					0.909	1.576	0.981	1.797	1.054	
COVID19 (COVID19 (JANSSEN))	Venogram	2.429	1.977	0.875				2.219	1.698	0.719	2.975	1.06	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.964	2.312				0.607	2.759	1.797	0.686	3.971	1.195	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.189	2.315	0.88				3.966	1.935	0.837	4.999	1.221	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.378	0.834		7.579	0.94		1.219	0.513		1.332	0.943	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.939	0.875		0.65	2.231	0.767	0.585	0.384	0.611	0.585	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.366	0.934	0.883		4.537	2.812	0.1	0.054	0.416	2.438	2.522	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.003	2.021	0.876			2.359	2.002	1.948	1.571	1.903	2.111	
COVID19 (COVID19 (PFIZER-	Body height	1.945	1.018	0.88			0.589	0.944	1.374	2.211	1.928	1.514	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.97	0.877			0.661	1.508	1.665	1.828	2.012	1.94	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.726	1.57		0.505	1.016	1.725	1.781	1.855	2.034	1.975	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	0.847	0.878	17.588			0.402			0.451	1.326	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.466	0.894		1.317	1.22	1.026	1.663	2.194	1.901	1.739	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.736	0.901		0.565	1.048	1.769	1.972	2.352	2.128	1.965	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.751	0.752			1.729	1.425	1.875	1.752	2.278	1.733	1.886	
COVID19 (COVID19 (PFIZER-	Weight	2.651	1.922	0.886			0.888	1.917	1.741	2.196	2.691	1.782	

PSI-HHS-000000057666

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 8 Mar 2022 13:42:20 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220304.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, March 8, 2022 5:24 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 3/4/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2022(0	Serious EB05 2022	Fatal EB05 2022(	Infant EB05 2022(	Child EB05 2022(	Teen EB05 2022(	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022(	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.086	1.705	0.933			0.597	1.606	1.961	2.083	2.764	1.508	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.163	1.652	0.872				1.673	2.105	2.082	2.851	1.489	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.07	1.341	1.024			0.449	1.444	2.043	1.93	2.378	1.734	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.859	6.956	0.871			0.518	0.974	0.804	0.686	2.588	1.471	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.018	1.08	0.878				0.924	0.769	0.737	1.844	1.508	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.969	1.321	0.5				1.436	1.437	1.755	2.151	1.307	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.535	1.872	0.901			0.485	2.134	2.063	2.082	3.627	1.476	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.166	1.548	0.875				1.854	1.865	1.36	2.347	1.47	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.454	1.686	0.898			0.423	1.683	2.325	2.199	2.511	2.002	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.788	1.4	0.892			0.367	1.171	2.209	1.385	2.143	1.308	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.331	6.824	0.864			0.581	0.616	1.066	1.87	2.032	1.755	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.237	1.517	0.972	0.613		0.427	1.839	2.034	2.293	2.783	1.866	Other
COVID19 (COVID19 (JANSEN))	Anuria	2.109	1.82	0.883				0.861	2.388	1.351	2.022	1.513	Reviewed
COVID19 (COVID19 (JANSEN))	Arterogram carotid abnormal	1.727	1.13	0.868				1.111	1.242	1.311	2.314	0.918	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.916	1.45	0.894	0.61		0.325	1.226	2.404	1.763	2.391	1.334	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.865	1.489	0.915	0.509		0.285	1.204	2.305	1.833	2.215	1.353	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.803	1.339	0.919			0.336	1.476	1.896	1.833	2.178	1.474	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.853	1.4	0.932			0.392	1.406	2.14	1.9	2.244	1.52	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.834	1.251	0.902				1.083	2.032	1.453	1.938	1.506	
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.887	1.402	0.961			0.439	1.292	2.058	2.007	2.267	1.41	Other
COVID19 (COVID19 (JANSEN))	Blood creatinine decreased	1.706	1.35	0.861	0.507		0.371	1.216	1.822	1.572	2.008	0.948	
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.064	2.332	0.887			0.503	1.804	1.926	0.853	4.257	1.045	Reviewed
COVID19 (COVID19 (JANSEN))	Blood lactate dehydrogenase increased	1.601	1.257	0.86	0.513			1.097	2.02	1.19	1.608	1.391	Not an AE
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.849	1.407	0.93			0.263	1.134	1.988	1.844	2.545	1.189	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.667	1.25	0.936			0.527	1.225	1.516	2.083	1.872	1.268	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.832	1.334	0.885	0.509			1.367	2.05	1.661	1.914	1.817	Not an AE
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.69	1.178	0.916				1.476	1.937	1.229	2.197	1.04	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.668	1.387	0.873			0.225	1.429	1.969	1.205	2.063	0.926	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.871	1.282	0.908				1.088	2.068	1.775	2.112	1.644	Other
COVID19 (COVID19 (JANSEN))	Breath sounds abnormal	1.747	1.287	0.904				1.157	2	1.458	1.651	1.846	
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.048	1.417	1.148				1.736	2.207	1.976	2.315	1.95	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.662	2.121	0.867				1.765	3.013	1.075	2.594	2.216	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.339	1.639	0.928			0.513	1.684	1.947	1.455	3.282	1.171	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.971	2.031	0.932			0.521	1.412	1.667	1.18	3.958	1.124	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.257	1.634	0.866				1.121	1.277	1.618	3.218	1.216	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.242	2.197	0.909			0.517	2.256	2.33	0.879	3.911	1.244	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.775	1.273	0.936			0.396	1.36	1.899	1.813	2.054	1.591	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.564	1.696	0.978	0.612		0.612	2.109	2.396	2.033	3.064	1.757	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.985	1.358	0.901			0.382	1.698	1.969	1.819	2.24	1.525	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.074	1.425	0.921			0.455	1.448	2.044	2.001	2.298	1.866	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.554	1.17	0.957				1.115	1.566	1.516	2.011	1.499	
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.586	1.774	0.998			0.456	2.167	2.261	3.008	3.267	1.996	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.941	1.466	1.261			0.373	1.375	2.129	1.601	2.021	1.671	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.771	1.318	0.894				1.273	2.142	1.605	2.044	1.312	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.767	1.425	0.911	0.61		0.301	1.306	2.146	1.747	2.088	1.42	Other
COVID19 (COVID19 (JANSEN))	Fasting coma	1.779	6.844	0.877			1.266	2.015	1.06	0.877	1.881	1.488	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.304	1.3	0.89			0.438	2.212	2.194	1.928	2.551	1.752	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.169	1.463	0.972	0.512		0.31	1.713	2.262	2.211	2.462	1.813	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.959	1.096	0.869			0.43	1.645	2.065	1.028	3.157	1.373	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.304	1.884	0.881			0.494	2.258	1.756	1.289	2.342	1.806	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.898	1.33	0.892			0.399	1.31	1.689	1.718	2.267	1.241	Reviewed
COVID19 (COVID19 (JANSEN))	Glomerular filtration rate decreased	1.772	1.171	0.932				1.043	1.962	1.531	2.007	1.396	
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.808	1.275	0.898				1.312	1.484	1.439	2.408	1.116	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.327	1.839	0.875				1.584	2.983	1.628	2.368	2.16	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.836	1.369	0.938	0.506		0.42	1.347	2.045	1.812	2.215	1.426	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.779	1.269	0.934	0.506		0.315	1.415	1.977	1.692	2.102	1.425	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.527	3.546	0.886				4.034	5.463	4.702	7.268	3.348	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.325	3.419	0.867			0.543	4.723	5.688	6.741	7.571	1.778	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.692	1.393	0.931				1.474	2.006	1.61	2.31	1.605	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.056	1.792	0.896			0.02	1.91	2.546	1.431	2.232	1.71	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.844	1.42	1.076			0.028	1.461	2.099	2.04	2.335	1.549	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.864	1.281	0.892	0.747		0.282	1.615	1.996	1.487	2.358	1.328	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.016	1.224	0.872				1.429	2.041	0.923	2.116	1.247	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.916	1.485	0.871				1.36	1.157	0.709	2.364	0.715	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.914	1.36	0.859				1.218	2.175	1.05	1.678	1.709	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.086	1.726					1.051	2.662	1.052	1.723	1.77	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.739	1.28	0.942				1.399	1.765	1.884	2.21	1.527	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.702	1.287	0.92			0.172	1.03	2.112	1.965	2.114	1.39	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.362	1.117	0.895	0.507			1.023	1.535	1.18	2.009	0.884	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.052	1.548	0.909			0.473	1.805	1.913	2.174	2.351	1.857	Reviewed
Mean cell haemoglobin concentration decreased		2.112	1.513	0.937	0.512		0.446	1.263	2.321	1.944	2.403	1.516	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.963	1.425	0.91			0.396	1.283	2.379	1.536	2.231	1.401	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.098	1.533	1.014			0.473	0.989	2.272	1.935	2.002	1.996	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.584	1.271	0.901	0.509		0.255	0.927	1.968	2.027	2.301	1.132	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.525	1.234	0.861			0.129	1.19	1.704	1.56	2.278	0.905	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.752	1.328	0.922			0.233	1.128	2.136	1.893	2.046	1.442	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.19	6.782					0.744	0.612		2.712	1.052	Other
COVID19 (COVID19 (JANSEN))	Orthostatic vital signs	1.338	6.356	0.873			0.033	1.255	1.191	0.878	1.418	1.228	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.753	6.782					3.281	1.001		2.215		Other
COVID19 (COVID19 (JANSEN))	Packed red blood cell transfusion	1.771	1.281	0.885				1.214	1.18	1.289	2.138	0.922	Reviewed
COVID19 (COVID19 (JANSEN))	Pain assessment	2.561	6.868				0.513	1.539	2.216	1.038	2.231	1.401	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.925	1.414	0.867				0.657	1.062	1.578	2.238	0.953	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.767	2.259	0.91	0.511		0.471	1.609	3.014	2.395	3.086	1.873	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.868	1.304	0.906	0.508		0.288	1.488	2.074	1.523	2.177	1.444	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.727	1.82	0.887			0.386	2.063	2.711	2.023	3.134	1.643	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.027	3.384	0.868				4.319	5.978	6.814	6.273	1.862	Not an AE
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.308					0.942	2.133	1.756	1.596	2.527	2.266	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.81	1.294	0.937				1.037	1.981	1.669	2.082	1.629	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.628	6.837	0.868		0.72	2.006	0.081	0.002	0.461	1.648	1.789	
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.668	1.066					4.243			2.774		Other
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.76	1.281	0.906	0.61		0.355	1.411	1.604	1.703	2.01	1.415	Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.975	1.495	0.933	0.746		0.316	1.523	2.307	1.894	2.538	1.503	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.233	1.585	1.469	0.613		0.582	1.761	2.058	2.562	2.467	1.889	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.644	1.468	0.897				1.686	1.562	2.017	2.111	1.867	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.844	1.313	0.925	0.507		0.527	1.37	2.06	1.712	2.055	1.534	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	2.019	1.398	0.926	0.511		0.33	1.33	2.276	1.797	2.358	1.491	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.363	1.02					2.306	0.499		1.094	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.357	1.495	0.873			0.53	1.814	1.969	1.525	2.598	1.701	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.23	2.148	1.486			0.522	3.076	3.213	1.27	2.967	3.466	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.022	6.767	0.869			0.645	3.586	6.631	15.064	7.771	5.826	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.378							0.637	0.571	0.568	1.017	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.108	1.421	0.882			0.508	1.384	1.588	1.539	2.2	1.352	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.303	1.752	0.936			0.372	1.612	2.387	1.764	2.472	1.745	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.663	2.089	1.701	0.513		0.729	1.977	2.394	3.535	2.997	2.302	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.989	2.663	0.887				1.654	1.355	0.572	5.757	1.238	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.233	1.75	0.868				1.882	1.162	0.629	2.042	0.908	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.411	1.477	0.907			0.725	1.946	2.233	2.265	2.754	1.764	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.709	1.831	0.928	0.512		0.52	2.449	2.243	2.851	3.312	2.066	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.509	1.696	0.918			0.437	2.152	2.042	2.107	2.511	1.88	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.969	1.09	0.871				1.242	2.008	1.72	1.991	1.501	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.543	1.176	0.887	0.512		0.305	0.895	2.095	1.225	1.713	1.205	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.367	3.097	2.494			0.485	1.613	3.05	6.265	2.438	2.567	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.576	6.912					1.296	1.264	0.802	2.097	0.772	
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.035	6.896					0.882	1.663	1.037	1.811	1.088	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.284	1.77	0.866				1.944	1.609	0.71	2.64	1.908	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.621	2.083				0.602	2.377	1.673	0.666	3.231	1.208	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.067	3.275	0.872				3.758	2.051	0.929	4.88	1.234	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	0.83		11.346	0.935		1.267	0.514		1.422	1.016	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.906	0.864	0.605	1.018	2.439	0.78	0.615	0.406	0.653	0.619	
COVID19 (COVID19 (MODERNA))	Mechanical unicana	0.901	1.072				0.621	2.036	1.528	0.816	1.662	1.922	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.987	0.878		5.943	2.555	0.103	0.047	0.378	2.548	2.654	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.15	2.04	0.867			2.662	2.034	2.068	1.593	1.982	2.19	
COVID19 (COVID19 (PFIZER-	Body height	1.947	6.966	0.872			0.641	0.944	1.365	2.169	1.914	1.535	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.048	1.114	0.868		0.488	0.711	1.462	1.687	1.88	1.937	1.506	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.292	1.783	1.737	0.512	0.781	1.086	1.721	1.733	1.758	1.872	1.872	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.792	6.863	0.871	17.407			0.376			0.41	1.258	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.679	0.912		1.271	1.232	1.813	1.98	2.244	1.971	1.834	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.779	0.92		0.669	1.078	1.781	1.906	2.252	2.031	1.892	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.792			1.454	1.379	1.857	1.742	2.181	1.617	1.58	
COVID19 (COVID19 (PFIZER-	Weight	2.023	1.357	0.883			3.9	1.537	1.75	2.139	1.94	1.773	

PSI-HHS-000000057668

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 15 Mar 2022 13:52:36 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220311.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, March 15, 2022 6:22 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 3/11/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20220	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 20220	Adult1 EB05 20220	Adult2 EB05 20220	Adult3 EB05 20220	Female EB05 2022	Male EB05 20220	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.08	1.683	0.937			0.592	1.563	1.909	2.08	2.711	1.69	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.15	1.632	0.871				1.646	2.111	2.05	2.807	1.476	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.074	1.338	1.019			0.449	1.473	2.043	1.934	2.342	1.761	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.883	0.953	0.873			0.517	0.974	0.799	0.686	2.607	1.472	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.017	1.083	0.876				0.923	0.77	0.736	1.844	1.51	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.918	1.324	0.5				1.429	1.465	1.743	2.117	1.335	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.529	1.865	0.901			0.484	2.133	2.043	2.087	3.6	1.478	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.175	1.555	0.877				1.855	1.828	1.35	2.358	1.47	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.446	1.674	0.897			0.423	1.661	2.323	2.189	2.486	2.001	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.709	1.486	0.901			0.366	1.163	2.198	1.446	2.136	1.321	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.37	0.823	0.906			0.599	0.819	1.048	1.807	2.033	1.74	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.232	1.51	0.967	0.613		0.425	1.837	2.037	2.28	2.784	1.673	Other
COVID19 (COVID19 (JANSEN))	Anoxia	2.064	1.793	0.884				0.862	2.349	1.336	2.011	1.497	Reviewed
COVID19 (COVID19 (JANSEN))	Antiphospholipid antibody	1.747	1.121	0.87				1.111	1.274	1.042	2.248	0.919	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.919	1.472	0.905	0.61		0.374	1.21	2.464	1.832	2.401	1.361	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.808	1.482	0.923	0.508		0.281	1.18	2.298	1.873	2.214	1.35	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.769	1.316	0.923			0.334	1.469	1.86	1.839	2.178	1.454	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.852	1.396	0.937			0.393	1.394	2.133	1.921	2.25	1.52	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.829	1.242	0.900				1.098	2.001	1.487	1.891	1.528	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.881	1.39	0.964			0.438	1.274	2.085	2.009	2.247	1.405	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.041	2.303	0.888			0.583	1.804	1.923	0.843	4.222	1.941	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.839	1.405	0.932			0.263	1.155	1.957	1.856	2.472	1.222	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.68	1.24	0.936			0.526	1.21	1.5	2.099	1.852	1.273	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.822	1.324	0.891	0.609			1.346	2.03	1.68	1.898	1.616	Not an AE
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.622	1.159	0.916				1.439	1.568	1.211	2.124	1.028	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.662	1.367	0.875			0.221	1.416	1.978	1.189	2.048	1.91	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.669	1.282	0.916				1.076	2.047	1.804	2.112	1.601	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.056	1.407	1.107				1.749	2.213	1.957	2.308	1.943	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.657	2.108	0.869				1.819	2.982	1.061	2.524	2.229	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.339	1.649	0.926			0.513	1.676	1.936	1.499	3.286	1.169	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.969	2.032	0.933			0.521	1.413	1.67	1.182	3.969	1.126	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.297	1.633	0.886				1.121	1.271	1.624	3.22	1.212	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.232	2.174	0.91			0.517	2.255	2.284	0.875	3.884	1.237	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.777	1.269	0.939			0.345	1.361	1.865	1.819	2.047	1.599	Confounded-
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.563	1.693	0.974	0.511		0.612	2.103	2.368	2.04	3.071	1.749	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	2	1.365	0.913			0.382	1.706	1.964	1.847	2.257	1.525	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.078	1.428	0.924			0.454	1.439	2.056	2.013	2.284	1.685	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.594	1.166	0.956				1.139	1.58	1.511	2.005	1.501	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.588	1.777	1.009			0.456	2.178	2.288	2.999	3.274	1.999	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.964	1.42	1.315			0.373	1.393	2.132	1.897	2.08	1.877	Labelled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.763	1.341	0.908			0.12	1.259	2.128	1.703	2.058	1.35	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.787	1.427	0.921	0.509		0.299	1.29	2.136	1.802	2.083	1.433	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.778	0.845	0.878			1.206	2.014	1.457	0.977	1.651	1.423	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.301	1.292	0.89			0.439	2.215	2.184	1.525	2.547	1.758	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.117	1.467	0.983	0.512		0.311	1.72	2.262	2.243	2.481	1.62	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.881	1.091	0.871			0.43	1.446	2.068	1.024	2.144	1.378	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.301	1.08	0.883			0.403	2.258	1.756	1.281	2.31	1.807	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.892	1.314	0.891			0.399	1.279	1.689	1.711	2.241	1.237	Reviewed
COVID19 (COVID19 (JANSEN))	Glomerular filtration rate decreased	1.788	1.166	0.934				1.033	1.907	1.547	2.011	1.379	Other
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.787	1.269	0.902				1.312	1.466	1.46	2.447	1.099	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.329	1.656	0.877			0.432	1.614	2.965	1.633	2.388	2.171	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.828	1.306	0.939	0.505		0.463	1.342	2.029	1.819	2.294	1.434	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.772	1.261	0.931	0.506		0.315	1.409	1.963	1.695	2.099	1.418	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.484	3.531	0.888				4.037	5.435	4.733	7.24	3.453	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.179	3.341	0.899			0.543	4.723	5.439	6.741	7.274	3.762	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.887	1.291	0.928				1.465	1.995	1.803	2.301	1.805	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.053	1.796	0.868			0.02	1.934	2.569	1.427	2.244	1.721	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.843	1.421	1.091			0.029	1.464	2.094	2.065	2.328	1.568	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.646	1.274	0.86	0.746		0.393	1.007	1.962	1.46	2.351	1.324	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.015	1.222	0.874				1.42	2.036	0.925	2.107	1.246	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.915	1.494	0.873				1.36	1.158	0.709	2.358	0.715	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.923	1.354	0.861				1.256	2.17	1.645	1.673	1.718	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.092	1.725					1.052	2.684	1.048	1.71	1.769	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.744	1.28	0.941				1.338	1.766	1.885	2.243	1.541	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.651	1.27	0.916			0.258	1.017	2.093	1.937	2.094	1.323	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.382	1.121	0.5	0.507			1.04	1.523	1.223	2.021	0.88	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.061	1.535	0.908			0.473	1.606	1.903	2.166	2.336	1.658	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.126	1.522	0.946	0.512		0.443	1.248	2.307	2.004	2.441	1.499	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.908	1.427	0.912			0.334	1.268	2.363	1.56	2.21	1.427	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.117	1.547	1.023			0.473	0.982	2.296	2.018	2.027	2.017	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.577	1.264	0.906	0.509		0.25	0.921	1.943	2.045	2.29	1.13	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.52	1.228	0.889			0.126	1.155	1.689	1.655	2.21	0.85	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.745	1.312	0.918			0.284	1.114	2.118	1.88	2.021	1.443	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.189	0.794					0.744	0.612		2.693	1.052	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.339	0.536	0.86			0.004	1.195	1.225	0.667	1.414	1.823	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.752	0.762					3.275	1.001		2.207		Other
COVID19 (COVID19 (JANSEN))	Packed red blood cell transfusion	1.771	1.29	0.886				1.214	1.222	1.29	2.145	0.959	Reviewed
COVID19 (COVID19 (JANSEN))	Pancytopenia	2.28	1.57	0.87			0.512	1.514	2.28	1.114	2.233	1.444	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.922	1.415	0.869				0.657	1.062	1.574	2.227	0.954	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.762	2.257	0.911	0.511		0.471	1.795	2.969	2.477	3.014	1.918	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.872	1.311	0.908	0.508		0.388	1.485	2.089	1.642	2.173	1.485	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.726	1.83	0.886			0.385	2.056	2.709	2.066	3.138	1.645	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.028	3.366	0.87				4.323	5.562	6.813	6.28	1.862	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.756	1.277	0.936				1.029	1.971	1.647	2.04	1.836	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.625	0.84	0.87		0.72	2.005	0.078	0.062	0.459	1.648	1.783	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.068	1.085					4.248			2.75		Other
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.779	1.265	0.919	0.61		0.355	1.406	1.823	1.765	2.023	1.425	Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.966	1.482	0.934	0.745		0.317	1.493	2.333	1.703	2.53	1.495	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.234	1.586	1.465	0.513		0.582	1.767	2.063	2.569	2.497	1.885	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.044	1.47	0.898				1.695	1.561	2.009	2.117	1.864	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.644	1.311	0.931	0.506		0.525	1.365	2.042	1.734	2.04	1.531	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	2.012	1.385	0.924	0.511		0.328	1.324	2.249	1.798	2.362	1.466	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.363	1.02					2.3	0.499		1.096	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.397	1.486	0.876			0.53	1.814	1.064	1.518	2.575	1.702	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.229	2.162	1.494			0.522	3.201	3.237	1.277	2.993	3.502	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.021	6.767	0.87			0.645	3.584	6.632	15.085	7.776	5.79	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.373							0.637	0.571	0.568	1.017	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.088	1.4	0.882			0.507	1.371	1.58	1.527	2.171	1.342	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.259	1.753	0.94			0.374	1.613	2.402	1.785	2.457	1.769	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.68	2.082	1.701	0.513		0.728	1.982	2.261	3.526	2.898	2.307	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.968	2.643	0.886				1.654	1.361	0.572	5.768	1.498	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.213	1.733	0.87				1.88	1.192	0.625	2.04	0.904	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.408	1.468	0.907			0.726	1.938	2.244	2.273	2.734	1.779	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.764	1.822	0.925	0.512		0.52	2.445	2.242	2.839	3.281	2.073	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.485	1.673	0.917			0.437	2.135	2.029	2.067	2.488	1.862	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.865	1.09	0.873				1.232	2.037	1.722	1.881	1.34	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.571	1.202	0.896	0.512		0.393	0.661	2.131	1.32	1.722	1.209	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.987	3.096	2.491			0.484	1.611	3.057	6.204	2.433	2.571	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.575	0.913					1.288	1.285	0.794	2.073	0.768	Other
COVID19 (COVID19 (JANSEN))	Vasodilation	2.555	1.894					0.936	1.667	1.936	2.801	1.15	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.284	1.759	0.867				1.944	1.603	0.71	2.614	1.008	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.62	2.069				0.601	2.376	1.662	0.666	3.191	1.208	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.634	2.25	0.874				3.767	2.009	0.93	4.827	1.235	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	0.832		12.029	0.935		1.266	0.514		1.438	1.005	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.915	0.871	0.505	1.015	2.47	0.778	0.618	0.409	0.658	0.621	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.901	1.07				0.696	2.017	1.524	0.814	1.938	1.902	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.364	0.985	0.88		5.92	2.169	0.1	0.047	0.374	2.548	2.654	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.05	2.039	0.869			2.656	2.021	2.001	1.592	1.98	2.182	
COVID19 (COVID19 (PFIZER-	Body height	1.947	0.988	0.874			0.641	0.944	1.398	2.177	1.921	1.537	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.048	1.113	0.87		0.487	0.711	1.464	1.691	1.884	1.942	1.51	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.252	1.785	1.733	0.512	0.789	1.09	1.723	1.736	1.76	1.874	1.877	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	0.864	0.873	17.047			0.375			0.47	1.266	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.69	0.913		1.271	1.236	1.622	1.991	2.256	1.982	1.846	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.773	0.921		0.689	1.08	1.78	1.908	2.26	2.031	1.897	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	0.793			1.457	1.378	1.861	1.745	2.178	1.614	1.579	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.358	0.884			0.661	1.541	1.782	2.129	1.934	1.767	

PSI-HHS-000000057670

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 29 Mar 2022 13:35:27 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220325.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, March 29, 2022 6:11 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 3/25/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20220	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 2022	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.07	1.882	0.932			0.387	1.56	1.89	2.137	2.1	1.836	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.126	1.603	0.88				1.622	2.097	2.021	2.785	1.455	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.07	1.344	1.016			0.448	1.475	2.059	1.949	2.378	1.76	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.846	0.949	0.885			0.515	0.971	0.784	0.687	2.822	1.463	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.097	0.86				0.917	0.76	0.731	1.874	1.518	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.913	1.33	0.906				1.476	1.457	1.726	2.151	1.326	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.484	1.82	0.907			0.48	2.138	1.981	2.06	3.51	1.452	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.152	1.52	0.888				1.832	1.817	1.338	2.321	1.46	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.449	1.676	0.907			0.42	1.637	2.321	2.249	2.491	2.007	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.758	1.36	0.907			0.384	1.143	2.152	1.434	2.102	1.301	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.311	6.837	0.86			0.556	0.804	1.025	1.802	2.011	1.701	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.228	1.509	0.966	0.613		0.422	1.829	2.049	2.268	2.761	1.679	Other
COVID19 (COVID19 (JANSEN))	Anoxia	2.035	1.784	0.894				0.897	2.35	1.315	2.081	1.467	Reviewed
COVID19 (COVID19 (JANSEN))	Arterial occlusive disease	1.784	1.33	0.888				1.111	1.882	1.338	2.173	0.996	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.899	1.466	0.91	0.61		0.368	1.206	2.412	1.825	2.399	1.363	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.81	1.469	0.924	0.608		0.276	1.179	2.321	1.853	2.211	1.361	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.779	1.395	0.926			0.321	1.485	1.836	1.823	2.172	1.427	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.851	1.389	0.94			0.386	1.394	2.11	1.542	2.25	1.519	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.834	1.25	0.913				1.046	2.012	1.543	1.944	1.527	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.858	1.357	0.949			0.431	1.257	2.055	1.961	2.201	1.384	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.089	2.31	0.897			0.499	1.692	1.98	0.941	4.205	1.983	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.84	1.378	0.928			0.26	1.138	1.967	1.855	2.482	1.227	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.68	1.236	0.938			0.521	1.22	1.473	1.22	2.15	1.871	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.822	1.325	0.901	0.609			1.34	2.054	1.736	1.921	1.623	Not an AE
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.58	1.126	0.916				1.415	1.459	1.179	2.062	0.993	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.666	1.358	0.888			0.21	1.405	1.993	1.229	2.059	0.908	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.869	1.275	0.918				1.046	2.05	1.809	2.123	1.043	Other
COVID19 (COVID19 (JANSEN))	Blood urine present	1.539	1.212	0.912	0.612		0.305	0.955	1.576	1.276	2.007	1.495	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.055	1.409	1.114				1.775	2.264	1.982	2.314	1.958	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.662	2.092	0.882				1.864	2.966	1.946	2.52	2.252	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.332	1.648	0.932			0.512	1.685	1.913	1.483	3.338	1.159	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.863	1.973	0.929			0.52	1.354	1.621	1.182	3.981	1.093	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.302	1.694	0.881				1.116	1.255	1.005	3.211	1.195	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.231	2.142	0.915			0.516	2.224	2.267	0.875	3.84	1.232	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.772	1.272	0.937			0.34	1.346	1.89	1.849	2.08	1.604	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.542	1.665	0.962	0.611		0.608	2.108	2.315	2.006	3.03	1.727	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.999	1.361	0.917			0.38	1.703	1.978	1.868	2.264	1.54	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.675	1.423	0.926			0.454	1.428	2.053	2.028	2.266	1.7	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.554	1.175	0.963				1.147	1.601	1.522	2.027	1.523	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.58	1.781	0.976			0.453	2.166	2.303	2.996	3.267	2.008	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.902	1.391	1.289			0.373	1.373	2.135	1.834	2.082	1.835	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.773	1.324	0.91			0.187	1.242	2.178	1.658	2.038	1.367	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.782	1.402	0.922	0.609		0.295	1.26	2.146	1.769	2.064	1.424	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.778	6.838	0.86			1.207	2.006	1.451	0.971	1.844	1.417	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.294	1.286	0.898			0.439	2.21	2.181	1.922	2.551	1.719	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.196	1.498	0.886	0.612		0.388	1.791	2.287	2.281	2.472	1.838	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.943	1.092	0.884			0.429	1.667	2.113	1.018	2.214	1.348	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.294	1.875	0.896			0.482	2.274	1.747	1.25	2.301	1.517	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.859	1.29	0.896			0.398	1.269	17	1.662	2.171	1.257	Reviewed
COVID19 (COVID19 (JANSEN))	Glomerular filtration rate decreased	1.771	1.159	0.931				1.019	1.927	1.573	2.025	1.378	Other
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.732	1.238	0.909				1.271	1.436	1.489	2.478	1.061	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.329	1.847	0.887			0.432	1.634	2.944	1.619	2.398	2.162	Reviewed
COVID19 (COVID19 (JANSEN))	Haemstocrit decreased	1.822	1.3	0.943	0.606		0.461	1.337	2.02	1.842	2.218	1.429	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.762	1.259	0.934	0.606		0.311	1.412	1.993	1.708	2.121	1.406	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.521	3.614	0.897				4.144	5.51	4.765	7.308	3.403	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.177	3.445	0.882			0.542	4.716	5.82	6.741	7.271	2.853	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.889	1.302	0.931				1.451	2.045	1.833	2.341	1.634	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.087	1.783	0.88			0.02	1.961	2.571	1.396	2.227	1.745	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.606	1.466	1.062			0.629	1.437	2.166	2.004	2.314	1.906	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.833	1.253	0.894	0.746		0.388	1.582	1.927	1.483	2.354	1.297	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.015	1.225	0.886				1.41	2.064	0.923	2.092	1.272	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.915	1.486	0.886				1.36	1.15	0.71	2.312	0.715	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.925	1.356	0.875				1.269	2.184	1.029	1.674	1.734	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.09	1.715					1.081	2.751	1.044	1.74	1.817	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.79	1.269	0.938				1.415	1.749	1.875	2.24	1.526	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.665	1.26	0.92			0.232	1.008	2.093	1.926	2.088	1.326	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.388	1.123	0.905	0.607			1.051	1.501	1.268	2.048	0.868	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.08	1.499	0.912			0.471	1.797	1.869	2.144	2.323	1.825	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.065	1.489	0.939	0.612		0.438	1.262	2.26	1.968	2.438	1.463	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.634	1.244	0.906			0.301	1.128	1.944	1.411	2.013	0.963	Other
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.929	1.448	0.921			0.329	1.257	2.401	1.646	2.237	1.451	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.115	1.525	1.013			0.472	1.005	2.289	1.956	2.01	2	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.559	1.248	0.913	0.609		0.244	0.912	1.919	1.035	2.244	1.137	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.505	1.215	0.899			0.185	1.161	1.648	1.652	2.251	0.833	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.732	1.291	0.916			0.276	1.103	2.089	1.604	2.006	1.434	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.19	6.795					0.744	0.612		2.755	1.052	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.33	0.53	0.891			7.985	1.163	1.252	0.889	1.424	1.91	Not an AE
COVID19 (COVID19 (JANSEN))	Oxygen saturation decreased	1.732	6.795					2.326	1		2.212		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.529	6.865				0.505	1.53	2.166	1.116	2.201	1.422	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.924	1.413	0.882				0.658	1.061	1.579	2.238	0.953	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.763	2.251	0.916	0.611		0.471	1.785	2.883	2.642	3.023	1.893	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.867	1.314	0.916	0.607		0.286	1.482	2.095	1.577	2.197	1.467	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.735	1.85	0.897			0.383	2.112	2.728	2.14	3.3	1.866	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.024	3.422	0.883				4.322	3.649	0.8	5.928	2.359	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.806	1.289	0.942				1.021	2.047	1.63	2.119	1.621	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.623	6.842	0.883		0.72	2.017	0.076	0.002	0.523	1.661	1.792	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.068	1.065					4.255			2.805		Other
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.763	1.256	0.923	0.61		0.353	1.381	1.575	1.821	2.038	1.417	Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.958	1.46	0.935	0.745		0.312	1.47	2.306	1.744	2.512	1.49	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.232	1.581	1.138	0.613		0.582	1.765	2.049	2.564	2.498	1.876	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.697	1.456	0.903				1.066	1.575	1.963	2.692	1.86	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.833	1.306	0.932	0.607		0.517	1.381	2.022	1.745	2.068	1.526	Other
COVID19 (COVID19 (JANSEN))	Red blood cell transfusion	1.717	1.215	0.896				1.177	1.244	1.24	2.084	0.921	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.984	1.371	0.926	0.611		0.323	1.291	2.219	1.816	2.338	1.47	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.349	1.011					2.328	0.5		1.088	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.396	1.685	0.887			0.529	1.815	1.988	1.628	2.624	1.743	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.231	3.206	1.556			0.521	3.29	3.277	1.273	3.045	3.564	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.023	6.768	0.883			0.645	3.589	6.577	15.088	7.751	5.758	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.378							0.638	0.572	0.568	1.017	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.676	1.418	0.892			0.584	1.416	1.598	1.51	2.131	1.396	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.294	1.753	0.935			0.372	1.604	2.41	1.815	2.477	1.775	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.661	2.1	1.716	0.613		0.726	1.981	2.41	3.544	2.92	2.336	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.987	2.839	0.898				1.536	2.61	0.573	5.548	1.663	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.213	1.73	0.882				1.886	1.165	0.626	2.018	0.903	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.358	1.447	0.911			0.712	1.937	2.22	2.244	2.693	1.772	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.665	1.815	0.929	0.612		0.519	2.42	2.242	2.824	3.248	2.077	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.46	1.694	0.917			0.425	2.102	2.046	2.007	2.503	1.833	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.894	1.091	0.885				1.222	2.041	1.71	1.871	1.334	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.542	1.176	0.902	0.612		0.303	0.854	2.115	1.31	1.711	1.234	Not an AE
COVID19 (COVID19 (JANSEN))	Vascular failure	1.365	5.112	2.91			0.499	1.089	3.048	0.628	2.442	2.994	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.566	6.931					1.264	1.344	0.79	2.013	0.828	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.039	6.893					0.921	1.665	1.037	1.801	1.119	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.309	1.796	0.88				1.995	1.648	0.71	2.584	1.079	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.607	2.091				0.601	2.389	1.741	0.663	3.153	1.268	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.959	3.243	0.886				3.635	1.987	1.056	4.808	1.216	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	6.833		12.596	0.935		1.288	0.515		1.451	1.077	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.561	0.92	0.88	0.905	1.024	2.47	0.781	0.621	0.414	0.663	0.624	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.89	1.095				0.615	2.082	1.559	0.847	2.007	1.938	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.364	6.951	0.891		6.108	2.98	0.097	0.046	0.358	2.558	2.673	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.05	2.051	0.882			2.675	2.048	2.011	1.595	1.992	2.199	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.007	1.662	0.892			0.636	1.61	1.801	1.524	1.884	1.865	
COVID19 (COVID19 (PFIZER-	Body height	1.945	6.987	0.886		0.488	0.664	0.959	1.404	2.159	1.3	1.543	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.109	0.883		0.488	0.711	1.462	1.669	1.671	1.928	1.5	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.253	1.761	1.706	0.611	0.802	1.09	1.711	1.72	1.731	1.831	1.844	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.865	0.885	18.911			0.364			0.507	1.218	
COVID19 (COVID19 (PFIZER-	Immunisation	1.748	1.664	0.913		1.272	1.202	1.8	1.973	2.236	1.964	1.825	
COVID19 (COVID19 (PFIZER-	Investigation	2.164	1.756	0.927		0.705	1.091	1.774	1.906	2.224	1.985	1.88	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.755	6.794			1.455	1.368	1.853	1.738	2.165	1.8	1.568	
COVID19 (COVID19 (PFIZER-	Weight	2.023	1.343	0.894			0.922	1.551	1.736	2.107	1.901	1.753	

PSI-HHS-000000057672

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From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 1 Feb 2022 18:30:29 +0000
To: Broder, Karen (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220121.xls

Hi All,

I've been forwarding the weekly email to Mike and Allison, but I think that my name should be removed from this listserv and have Mike or Allison's name added instead.
Do you want me to email David Menschik or Narayan Nair, or do you want to let them know?

Thank you.

Theresa

From: Menschik, David <[redacted]>
Sent: Tuesday, January 25, 2022 6:41 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Hi All,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 1/21/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20220	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 20220	Adult1 EB05 20220	Adult2 EB05 20220	Adult3 EB05 20220	Female EB05 2022	Male EB05 20220	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.108	1.717	0.906			0.602	1.558	1.966	2.092	2.71	1.654	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.23	1.736	0.88				1.698	2.128	2.286	3.094	1.491	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.04	1.327	0.996			0.457	1.423	1.986	1.809	2.312	1.841	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.892	6.934	0.874			0.518	0.98	0.817	0.633	2.581	1.471	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.022	1.07	0.88				0.926	0.763	0.765	1.753	1.516	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.932	1.331	0.9				1.476	1.413	1.704	2.235	1.257	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.634	1.932	0.902			0.486	2.248	1.967	2.465	3.876	1.446	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.235	1.617	0.87				1.936	1.875	1.201	2.388	1.468	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.461	1.725	0.897			0.425	1.604	2.368	2.189	2.588	1.944	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.826	1.46	0.86			0.375	1.227	2.241	1.324	2.184	1.318	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.39	6.817	0.869			0.593	0.843	1.047	1.866	2.094	1.791	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.241	1.55	0.974	0.612		0.432	1.809	1.968	2.398	2.838	1.816	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.134	1.883	0.882				0.85	2.171	1.477	1.91	1.56	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.449	1.18	0.871				1.148	1.184	1.47	2.08	0.918	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.923	1.481	0.881	0.61		0.332	1.226	2.408	1.762	2.393	1.311	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.783	1.487	0.885	0.609		0.295	1.252	2.25	1.725	2.166	1.318	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.778	1.303	0.883			0.337	1.432	1.84	1.758	2.171	1.365	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.855	1.402	0.896			0.406	1.431	2.127	1.852	2.274	1.476	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.993	1.464	0.924			0.451	1.356	2.203	1.987	2.323	1.441	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.236	2.454	0.885			0.503	1.843	2.266	0.784	4.29	1.887	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.818	1.391	0.913			0.268	1.178	1.948	1.722	2.398	1.171	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.665	1.241	0.906			0.538	1.211	1.468	2.043	1.864	1.205	
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.526	1.09	0.904				1.331	1.465	0.95	2.024	0.827	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.668	1.401	0.868			0.235	1.41	1.935	1.292	2.092	0.877	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.825	1.239	0.874				1.105	2.018	1.624	2.062	1.536	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.005	1.44	1.395				1.684	2.117	1.963	2.293	1.898	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.717	2.101	0.87				1.805	2.989	1.061	2.398	2.305	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.374	1.618	0.917			0.517	1.711	1.855	1.433	3.23	1.1	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	3.079	2.042	0.912			0.522	1.473	1.369	1.228	4.088	0.969	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.29	1.635	0.87				1.073	1.305	1.47	2.731	1.224	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.246	2.193	0.907			0.519	2.293	2.299	0.878	3.924	1.191	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.507	1.76	0.946	0.611		0.622	2.195	2.32	2.123	3.251	1.721	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.651	1.398	0.896			0.387	1.707	2.009	1.735	3.234	1.514	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.088	1.473	0.923			0.461	1.41	2.084	2.031	2.328	1.855	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.601	1.775	0.993			0.46	2.143	2.258	3.042	3.214	1.986	
COVID19 (COVID19 (JANSSEN))	Embolic stroke	1.498	1.089	0.874				0.455	0.962	2.159	1.722	0.867	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.742	1.306	0.887				1.253	2.12	1.528	2.043	1.227	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.719	1.352	0.881	0.61		0.306	1.202	2.037	1.561	2.008	1.295	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.84	0.877			1.117	2.007	1.463	0.974	1.852	1.405	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.254	1.244	0.886			0.378	2.172	2.135	1.903	2.527	1.673	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.146	1.448	0.937	0.612		0.325	1.647	2.259	2.175	2.462	1.59	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.566	1.065	0.868			0.438	1.657	2.093	0.853	2.13	1.359	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.269	1.977	0.86			0.409	2.276	1.746	1.26	2.411	1.566	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.877	1.33	0.887			3.4	1.385	1.57	1.7	2.188	1.237	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.821	1.247	0.888				1.429	1.309	1.397	2.221	1.102	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.319	1.939	0.872				1.888	2.342	1.628	2.883	2.198	
COVID19 (COVID19 (JANSSEN))	Haemostatic decreased	1.824	1.315	0.904	0.607		0.432	1.336	2.044	1.793	2.213	1.402	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.776	1.28	0.91	0.608		0.325	1.4	2.063	1.648	2.107	1.395	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.59	5.587	0.886				4.037	5.161	5.862	7.294	2.856	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.486	5.607	0.87			0.543	4.727	5.899	6.761	7.741	2.955	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.872	1.313	0.928				1.505	1.931	1.784	2.308	1.555	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.062	1.837	0.871			0.025	1.993	2.514	1.479	2.237	1.713	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.851	1.417	1.056			0.031	1.415	2.045	2.048	2.258	1.52	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.868	1.304	0.896	0.747		0.402	1.599	2.005	1.453	2.443	1.28	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.078	1.396	0.875				1.441	2.078	0.983	2.186	1.273	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.952	1.685	0.874				1.376	1.195	0.714	2.466	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.908	1.366	0.864				1.212	2.14	1.054	1.698	1.843	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.049	1.736					0.998	2.583	1.087	1.693	1.744	
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.666	1.209	0.923				1.233	1.603	1.734	2.07	1.404	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.668	1.27	0.895			0.184	1.022	2.074	1.923	2.105	1.263	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.388	1.126	0.89	0.608			1.008	1.508	1.193	2.028	0.869	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.514	1.581	0.886			0.476	1.82	1.867	2.171	2.384	1.823	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.124	1.495	0.9	0.612		0.459	1.213	2.318	1.836	2.441	1.362	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.963	1.435	0.903			0.342	1.311	2.34	1.459	2.198	1.373	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.082	1.479	0.993			0.478	0.972	2.186	1.794	1.893	1.889	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.569	1.272	0.886	0.61		0.264	0.917	1.945	2.034	2.363	1.07	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.512	1.223	0.872			0.152	1.2	1.872	1.472	2.223	0.843	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.729	1.313	0.9			0.243	1.112	2.088	1.865	2.017	1.387	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.194	6.725					0.761	0.612		1.958	1.068	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	6.414	0.875			7.887	1.246	1.105	0.801	1.381	1.918	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.754	0.76					3.273	1.061		2.213		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.515	6.857				0.513	1.61	2.139	1.095	2.284	1.403	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.063	1.553	0.87				0.657	1.061	1.69	2.715	0.954	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.763	2.259	0.91	0.611		0.472	1.804	3.062	2.386	3.159	1.786	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.674	1.317	0.896	0.609		0.297	1.463	2.077	1.513	2.171	1.442	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.723	1.935	0.888			0.39	2.023	2.834	2.175	3.231	1.667	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.028	5.384	0.871				4.266	2.603	0.817	6.291	1.838	
COVID19 (COVID19 (JANSSEN))	Pure red cell aplasia	1.388					0.666	0.153	3.378	3.888	4.888	4.827	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	1.761	1.334	0.936				0.973	1.873	1.713	2.004	1.629	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.747	1.247	0.883	0.611		0.364	1.382	1.933	1.611	2.004	1.328	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.651	1.558	0.919	0.746		0.334	1.54	2.469	1.642	2.683	1.496	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.215	1.577	1.513	0.613		0.588	1.704	2.031	2.582	2.483	1.812	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.048	1.46	0.896				1.673	1.563	1.912	1.998	1.796	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.87	1.345	0.894	0.608		0.539	1.412	2.086	1.711	2.114	1.525	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.003	1.38	0.896	0.611		0.34	1.261	2.273	1.734	2.368	1.402	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.354	1.354	0.876			0.531	1.717	1.865	1.443	2.405	1.638	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.235	2.33	1.092			0.526	2.679	2.72	1.176	2.845	3.11	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.024	6.779	0.871			0.645	3.584	5.663	15.36	7.795	5.841	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.387							0.638	6.572	0.568	1.02	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.141	1.516	0.886			0.508	1.429	1.588	1.564	2.31	1.337	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.313	1.836	0.936			0.374	1.66	2.451	1.765	2.582	1.749	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.68	2.097	1.666	0.613		0.653	1.96	2.398	3.481	2.878	2.227	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.962	3.393	0.889				1.181	0.765	0.573	4.065	1.68	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.236	1.62	0.87				1.883	1.206	0.633	2.121	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.41	1.466	0.897			0.639	1.892	2.25	2.375	2.785	1.74	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.721	1.862	0.932	0.612		0.524	2.373	2.255	2.972	3.291	2.081	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.515	1.741	0.912			0.444	2.135	2.064	2.028	2.491	1.885	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.884	1.115	0.871				1.26	2.085	1.791	1.948	1.341	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.17	2.42			0.515	1.487	2.948	6.268	2.294	2.376	
COVID19 (COVID19 (JANSSEN))	Vasculitis	2.036	6.896					0.891	1.663	1.052	1.868	1.887	
COVID19 (COVID19 (JANSSEN))	Venogram	2.361	1.878	0.87				2.002	1.681	0.708	2.848	1.04	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.778	2.195				0.803	2.429	1.763	0.676	3.604	1.191	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.188	2.315	0.874				3.856	2.099	0.946	5.02	1.201	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.712	1.243	0.866			0.196	1.556	1.534	1.671	2.007	1.168	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.375	6.834		7.743	0.937		1.217	0.514		1.332	0.911	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.953	0.866	0.605	0.644	2.425	0.783	0.599	0.391	0.642	0.601	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.921	0.877		5.307	2.663	0.107	0.65	0.387	2.473	2.565	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.051	2.05	0.868			2.388	2.003	1.951	1.671	1.904	2.114	
COVID19 (COVID19 (PFIZER-	Body height	1.948	1.018	0.874			0.587	0.944	1.386	2.213	1.937	1.524	
COVID19 (COVID19 (PFIZER-	Product counterfeit	3.647	1.984	9.871		0.48	0.769	1.448	1.868	1.827	1.981	1.58	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.762	1.588		0.682	1.056	1.735	1.736	1.778	1.974	1.927	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	6.847	0.873	17.976			0.402			0.459	1.353	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.651	0.896		1.273	1.229	1.808	1.998	2.246	2.021	1.869	
COVID19 (COVID19 (PFIZER-	Investigation	2.161	1.762	0.896		0.648	1.07	1.779	1.933	2.273	2.092	1.918	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.753	6.753			1.561	1.402	1.881	1.764	2.253	1.687	1.64	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.36	0.884			0.892	1.536	1.752	2.187	1.998	1.781	

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 19 Apr 2022 13:54:46 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220415.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, April 19, 2022 6:43 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/15/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.035	1.567	0.934			0.385	1.528	1.839	2.046	2.671	1.397	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.118	1.571	0.881				1.612	2.044	2.016	2.774	1.43	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.053	1.324	1.015			0.457	1.44	2.022	1.925	2.369	1.716	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.852	6.958	0.884			0.528	0.972	0.715	0.679	2.597	1.514	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.091	0.89				0.907	0.85	0.727	1.882	1.566	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.964	1.3	0.906				1.472	1.436	1.68	2.113	1.311	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.487	1.831	0.909			0.493	2.136	2.012	2.085	3.498	1.488	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.148	1.456	0.886				1.91	1.752	1.316	2.324	1.423	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.42	1.653	0.912			0.421	1.581	2.302	2.229	2.48	1.968	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.784	1.369	0.91			0.369	1.112	2.157	1.476	2.105	1.334	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.311	6.623	0.877			0.589	0.791	1.064	1.806	1.984	1.679	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.211	1.474	0.973	0.619		0.428	1.812	2.016	2.22	2.725	1.847	Other
COVID19 (COVID19 (JANSEN))	Anxiety	2.03	1.899	0.892				0.859	2.421	1.285	2.068	1.449	Reviewed
COVID19 (COVID19 (JANSEN))	Aphasia	1.728	1.128	0.886				1.113	1.488	1.377	2.14	0.968	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.871	1.411	0.907	0.516		0.366	1.184	2.361	1.771	2.361	1.323	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.784	1.408	0.927	0.515		0.267	1.144	2.295	1.774	2.18	1.321	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.786	1.267	0.92			0.315	1.415	1.851	1.746	2.133	1.395	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.875	1.358	0.941			0.381	1.336	2.113	1.891	2.211	1.487	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.844	1.249	0.916				1.043	2.004	1.541	1.922	1.539	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.813	1.312	0.948			0.479	1.201	2.033	1.878	2.114	1.373	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.54	2.195	0.896			0.596	1.74	1.903	6.902	4.008	1.947	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.807	1.31	0.925			0.198	1.074	1.929	1.783	2.431	1.178	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.879	1.226	0.938			0.527	1.2	1.51	2.075	1.892	1.232	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.816	1.316	0.903	0.516			1.328	2.006	1.732	1.924	1.51	Not an AE
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.638	1.32	0.887			0.108	1.352	1.988	1.199	2.007	0.913	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.854	1.257	0.911				1.023	2.057	1.76	2.085	1.622	Other
COVID19 (COVID19 (JANSEN))	Brain oedema	1.309	1.293	0.926				1.196	1.081	0.6	2.018	1.78	
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.16	1.402	1.082				1.761	2.2	1.959	2.3	1.942	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.634	2.019	0.878				1.747	3.07	1.018	2.421	2.193	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.335	1.588	0.934			0.525	1.708	1.992	1.466	3.364	1.138	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.953	1.933	0.927			0.533	1.381	1.601	1.164	3.882	1.08	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.322	1.719	0.882				1.278	1.336	1.608	3.51	1.222	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.299	2.191	0.916			0.529	2.499	2.568	6.878	3.954	1.224	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.768	1.27	0.941			0.338	1.315	1.887	1.846	2.061	1.586	Confounded-
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.524	1.653	0.961	0.517		0.617	2.114	2.289	2.001	3.011	1.718	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.985	1.349	0.914			0.385	1.71	1.965	1.848	2.243	1.546	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.057	1.403	0.925			0.483	1.393	2.049	1.986	2.234	1.681	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.589	1.165	0.961				1.169	1.808	1.506	2.025	1.506	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.586	1.761	0.991			0.465	2.185	2.272	3.007	3.27	1.994	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.914	1.395	1.189			0.372	1.388	2.108	1.87	2.118	1.822	Labelled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.755	1.288	0.908			0.643	1.225	2.125	1.612	2.041	1.305	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.763	1.357	0.92	0.516		0.282	1.254	2.114	1.697	2.066	1.372	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.76	6.643	0.889			1.192	2.006	1.451	0.903	1.634	1.416	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.284	1.293	0.898			0.447	2.185	2.162	1.504	2.529	1.892	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.155	1.457	0.968	0.518		0.301	1.709	2.298	2.178	2.466	1.63	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.817	1.091	0.882			0.439	1.96	2.64	1.031	2.13	1.355	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.288	1.06	0.894			0.409	2.299	1.715	1.242	2.274	1.811	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.844	1.254	0.898			0.402	1.243	1.706	1.576	2.155	1.217	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.651	1.211	0.911				1.223	1.44	1.437	2.383	1.057	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.335	1.842	0.86			0.439	1.542	3.075	1.651	2.433	2.158	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.811	1.282	0.941	0.512		0.505	1.296	2.049	1.79	2.188	1.421	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.753	1.245	0.93	0.513		0.353	1.386	1.98	1.668	2.1	1.396	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.527	3.709	0.897				4.18	5.664	4.668	7.395	3.405	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.185	3.466	0.86			0.554	4.668	5.674	6.738	7.258	2.888	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.961	1.32	0.957				1.483	2.054	1.865	2.378	1.646	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.08	1.73	0.875			0.011	1.871	2.564	1.419	2.231	1.706	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.827	1.392	1.063			0.022	1.405	2.09	2.028	2.298	1.556	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.819	1.233	0.887	0.754		0.39	1.531	1.932	1.435	2.295	1.285	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.02	1.21	0.904				1.307	2.069	0.911	2.055	1.247	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.92	1.455	0.883				1.384	1.123	0.707	2.322	0.711	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.937	1.382	0.873				1.275	2.174	1.026	1.681	1.731	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.003	1.835					1.057	2.737	1.029	1.698	1.793	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.733	1.265	0.943				1.383	1.714	1.883	2.245	1.497	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.675	1.239	0.917			0.198	1	2.094	1.85	2.072	1.297	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.345	1.095	0.909	0.513		0.277	0.996	1.468	1.239	2.006	0.659	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.065	1.492	0.913			0.477	1.779	1.881	2.128	2.334	1.808	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.068	1.426	0.94	0.519		0.445	1.234	2.283	1.858	2.383	1.426	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.669	1.257	0.913			0.278	1.093	1.981	1.441	2.014	0.989	Other
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.882	1.373	0.92			0.324	1.174	2.365	1.588	2.161	1.411	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.118	1.516	1.02			0.483	1.106	2.252	1.972	2.07	2.002	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.542	1.225	0.916	0.516		0.224	0.867	1.917	1.975	2.212	1.102	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.479	1.185	0.892			0.25	1.103	1.876	1.62	2.158	0.833	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.778	1.27	0.915			0.256	1.097	2.103	1.782	1.998	1.393	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.353	6.784					0.744	0.612		2.941	1.075	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.03	6.623	0.891			7.871	1.213	1.29	0.883	1.447	1.837	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.781	6.753					3.431	0.983		2.278		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.546	6.872				0.517	1.539	2.209	1.119	2.192	1.458	Not an AE
COVID19 (COVID19 (JANSEN))	Paralysis of excitation	3.264	1.988	0.873				1.888	1.694	1.881	2.348	1.95	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.756	2.204	0.922	0.517		0.481	1.761	2.936	2.594	3.023	1.83	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.864	1.3	0.911	0.513		0.282	1.442	2.08	1.594	2.211	1.443	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.731	1.851	0.898			0.45	2.077	2.762	2.15	3.175	1.673	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.014	3.463	0.881				4.296	4.57	6.801	5.91	2.635	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.781	1.27	0.948				1.02	1.996	1.619	2.111	1.574	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.616	6.831	0.88		0.72	2.053	0.073	0.062	0.515	1.668	1.835	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.1	1.048					4.078			2.837		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.942	1.427	0.936	0.753		0.304	1.431	2.328	1.682	2.448	1.486	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.226	1.567	1.045	0.519		0.589	1.752	2.64	2.561	2.49	1.869	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.048	1.438	0.907				1.668	1.545	1.946	2.091	1.84	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.81	1.277	0.924	0.513		0.521	1.323	2.035	1.673	2.028	1.494	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.949	1.323	0.921	0.517		0.296	1.255	2.182	1.761	2.291	1.414	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.306	1.094					2.642	0.565		1.08	3.75	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.38	1.611	0.885			0.542	1.788	1.964	1.629	2.662	1.698	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.235	2.187	1.504			0.526	3.286	3.285	1.278	3.02	3.539	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.626	6.76	0.881			0.854	3.615	6.571	16.204	7.751	5.722	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.639							0.636	0.568	0.562	1.025	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.069	1.381	0.892			0.516	1.41	1.557	1.503	2.112	1.376	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.302	1.729	0.938			0.372	1.588	2.432	1.758	2.465	1.756	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.69	2.106	1.745	0.519		0.73	1.978	2.417	3.543	2.939	2.341	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	5.144	2.924	0.898				2.099	3.067	6.565	5.548	1.436	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.27	1.765	0.88				1.935	1.234	0.622	2.198	0.892	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.388	1.427	0.914			0.716	1.917	2.216	2.2	2.872	1.765	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.685	1.796	0.936	0.519		0.532	2.435	2.24	2.793	3.272	2.059	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.453	1.642	0.92			0.433	2.171	2.037	1.958	2.484	1.84	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.873	1.373	0.882				1.211	2.01	1.649	1.894	1.308	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.516	1.144	0.899	0.518		0.274	0.834	2.079	1.241	1.68	1.186	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.366	3.965	2.453			3.5	1.615	3.049	5.74	2.418	2.575	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.604	6.896					1.26	1.311	0.789	2.014	0.817	Other
COVID19 (COVID19 (JANSEN))	Vascularitation	2.069	6.884					0.979	1.662	1.032	1.847	1.116	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.295	1.775	0.878				2.007	1.623	0.707	2.568	1.073	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.669	2.092				0.611	2.497	1.805	0.884	3.091	1.196	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.998	3.238	0.884				3.68	1.999	1.056	4.859	1.197	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.371	6.821			10.429	0.912	1.288	0.519		1.47	1.956	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.934	0.877	0.509	1.016	2.495	0.784	0.622	0.417	0.668	0.631	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.889	1.097				0.818	2.102	1.566	0.845	2.017	1.966	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.944	0.891		6.106	2.096	0.095	0.045	0.365	2.561	2.677	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.049	2.94	0.878			2.621	2.056	2.005	1.589	1.981	2.199	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.053	1.667	0.892			0.837	1.833	1.758	1.538	1.919	1.902	
COVID19 (COVID19 (PFIZER-	Body height	1.945	6.984	0.884		0.48	0.671	0.957	1.413	2.162	1.904	1.539	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.045	1.102	0.881		0.48	0.742	1.468	1.682	1.874	1.928	1.501	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.258	1.765	1.717	0.517	0.826	1.099	1.696	1.765	1.725	1.831	1.844	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.855	0.884	16.202			0.362			0.503	1.226	
COVID19 (COVID19 (PFIZER-	Immunisation	1.747	1.86	0.916		1.282	1.234	1.795	1.971	2.243	1.965	1.828	
COVID19 (COVID19 (PFIZER-	Investigation	2.167	1.754	0.93		0.708	1.077	1.762	1.963	2.225	1.975	1.863	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.783			1.445	1.385	1.848	1.725	2.161	1.591	1.557	
COVID19 (COVID19 (PFIZER-	Weight	2.024	1.341	0.894			0.924	1.555	1.729	2.104	1.903	1.757	

PSI-HHS-000000057676

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 26 Apr 2022 12:00:24 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220422.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, April 26, 2022 6:37 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/22/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022Q4	Serious EB05 2022	Fatal EB05 2022Q	Infant EB05 2022Q	Child EB05 2022Q	Teen EB05 2022Q	Adult1 EB05 2022Q	Adult2 EB05 2022Q	Adult3 EB05 2022Q	Female EB05 2022Q	Male EB05 2022Q	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.009	1.561	0.932			0.384	1.534	1.858	2.026	2.701	1.393	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.115	1.586	0.874				1.605	2.065	2.003	2.793	1.421	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.049	1.321	1.018			0.455	1.444	2.005	1.944	2.397	1.708	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.851	6.958	0.878			0.528	0.97	0.776	0.679	2.595	1.514	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.091	0.885				1.485	0.851	0.727	1.874	1.586	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.905	1.297	0.904				1.465	1.437	1.682	2.113	1.313	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.481	1.823	0.907			0.488	2.14	2.067	2.081	3.487	1.485	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.136	1.425	0.88				1.855	1.754	1.299	2.303	1.405	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.43	1.653	0.908			0.421	1.596	2.314	2.215	2.468	1.979	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.789	1.376	0.91			0.388	1.112	2.207	1.499	2.116	1.344	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.315	6.835	0.871			0.589	0.782	1.063	1.887	1.992	1.072	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.216	1.475	0.978	0.519		0.427	1.813	2.025	2.235	2.738	1.853	Other
COVID19 (COVID19 (JANSEN))	Anoxia	2.056	1.707	0.888				0.859	2.512	1.281	2.148	1.441	Reviewed
COVID19 (COVID19 (JANSEN))	Antigram sputum abnormal	1.79	1.17	0.877				1.116	1.288	1.366	2.118	0.963	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.864	1.402	0.907	0.516		0.366	1.172	2.341	1.78	2.353	1.323	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.79	1.41	0.929	0.515		0.284	1.146	2.3	1.778	2.185	1.326	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.703	1.268	0.929			0.312	1.394	1.867	1.768	2.155	1.389	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.875	1.354	0.944			0.379	1.343	2.103	1.901	2.224	1.483	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.852	1.26	0.921				1.089	2.022	1.584	1.962	1.554	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.812	1.311	0.953			0.473	1.19	2.038	1.893	2.119	1.37	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.91	2.181	0.89			0.502	1.744	1.935	0.898	3.978	1.042	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.808	1.3	0.922			0.197	1.066	1.945	1.755	2.411	1.172	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.673	1.216	0.935			0.518	1.195	1.505	2.003	1.886	1.221	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.828	1.322	0.906	0.516			1.341	2.027	1.756	1.938	1.621	Not an AE
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.863	1.259	0.911				1.017	2.063	1.77	2.108	1.618	Other
COVID19 (COVID19 (JANSEN))	Brain oedema	1.522	1.247	0.924				1.197	1.561	0.601	2.022	0.769	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.009	1.469	1.089				1.763	2.211	1.99	2.361	1.939	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.618	2.007	0.873				1.732	3.027	1.015	2.424	2.162	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.317	1.582	0.934			0.525	1.71	1.886	1.468	3.343	1.134	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	3.066	1.973	0.926			0.592	1.383	1.765	1.166	3.894	1.141	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.362	1.692	0.877				1.278	1.321	1.613	3.488	1.224	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.218	2.164	0.914			0.528	2.489	2.393	0.878	3.904	1.224	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.769	1.274	0.945			0.337	1.302	1.887	1.872	2.074	1.593	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.528	1.661	0.967	0.518		0.613	2.118	2.309	2.03	3.047	1.725	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.969	1.346	0.91			0.383	1.699	1.982	1.832	2.248	1.538	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.059	1.405	0.924			0.463	1.388	2.05	2.004	2.23	1.689	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.59	1.168	0.963				1.168	1.618	1.516	2.041	1.508	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.555	1.762	0.997			0.464	2.187	2.278	3.02	3.282	1.997	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.904	1.386	1.145			0.387	1.387	2.116	1.863	2.11	1.826	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.78	1.293	0.906			0.043	1.212	2.12	1.644	2.054	1.312	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.775	1.365	0.926	0.516		0.279	1.259	2.113	1.731	2.07	1.391	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.78	6.853	0.887			1.192	2.01	1.449	0.573	1.84	1.423	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.279	1.303	0.896			0.445	2.197	2.161	1.952	2.534	1.71	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.165	1.456	0.978	0.519		0.391	1.712	2.291	2.203	2.473	1.835	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.918	1.087	0.871			0.436	1.662	2.041	1.029	2.188	1.336	Not an AE
COVID19 (COVID19 (JANSEN))	Gastroplegy	2.279	1.087	0.88			0.436	2.288	1.717	1.242	2.288	1.804	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.849	1.254	0.897			0.402	1.225	1.717	1.599	2.18	1.204	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.677	1.195	0.908				1.223	1.427	1.419	2.345	1.048	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.336	1.638	0.885			0.439	1.641	3.161	1.641	2.439	2.165	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.819	1.285	0.943	0.512		0.594	1.299	2.062	1.801	2.3	1.422	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.759	1.244	0.934	0.513		0.396	1.382	1.978	1.678	2.103	1.403	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.567	3.668	0.894				4.184	5.613	4.645	7.402	3.383	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.156	3.456	0.874			0.554	4.668	5.689	6.738	7.257	3.018	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.916	1.328	0.965				1.49	2.077	1.887	2.411	1.855	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.084	1.727	0.898			0.011	1.887	2.553	1.412	2.248	1.897	Other
COVID19 (COVID19 (JANSEN))	Intensive care	1.832	1.395	1.068			0.022	1.402	2.162	2.046	2.323	1.557	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.821	1.226	0.881	0.754		0.389	1.533	1.927	1.442	2.304	1.281	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.021	1.207	0.875				1.385	2.026	0.913	2.048	1.25	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.997	1.471	0.876				1.401	1.103	0.707	2.092	0.711	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.94	1.368	0.866				1.274	2.193	1.021	1.677	1.753	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.084	1.863					1.095	2.748	1.025	1.748	1.786	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.728	1.277	0.944				1.359	1.733	1.932	2.288	1.517	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.663	1.243	0.919			0.197	1.011	2.061	1.858	2.081	1.302	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.069	1.48	0.911			0.476	1.779	1.67	2.127	2.313	1.612	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.071	1.422	0.946	0.519		0.445	1.227	2.262	1.89	2.375	1.436	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.691	1.274	0.922			0.274	1.092	1.971	1.542	2.043	1.008	Other
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.877	1.354	0.915			0.323	1.181	2.361	1.598	2.148	1.41	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.124	1.518	1.024			0.482	1.102	2.26	1.985	2.088	2.002	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.545	1.227	0.914	0.516		0.222	0.863	1.923	1.988	2.212	1.106	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.561	1.209	0.889			0.33	1.102	1.65	1.652	2.198	1.85	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.723	1.272	0.918			0.255	1.109	2.065	1.794	1.998	1.401	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.353	6.785					0.744	0.612		2.951	1.075	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.328	0.82	0.886			0.006	1.205	1.365	0.879	1.485	1.925	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.782	6.753					3.436	0.983		2.288		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.547	6.873				0.516	1.541	2.216	1.116	2.192	1.456	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	3.207	1.388	0.874				0.656	1.034	1.585	2.374	1.95	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.868	2.218	0.917	0.518		0.478	1.786	2.961	2.716	3.05	1.84	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.668	1.286	0.911	0.514		0.286	1.127	2.001	1.621	2.213	1.497	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.739	1.842	0.894			0.45	2.093	2.764	2.156	3.11	1.885	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.016	3.279	0.876				4.3	4.567	0.801	5.725	2.237	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.789	1.291	0.956				1.021	2.049	1.655	2.261	1.582	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.618	6.832	0.875		0.719	2.058	0.073	0.062	0.516	1.67	1.837	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.101	1.048					4.084			2.686		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.936	1.414	0.934	0.753		0.393	1.422	2.328	1.662	2.438	1.476	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.237	1.574	1.071	0.519		0.589	1.755	2.042	2.603	2.495	1.882	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.045	1.438	0.906				1.656	1.541	1.939	2.107	1.834	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.818	1.283	0.923	0.513		0.588	1.344	2.042	1.679	2.043	1.508	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.951	1.324	0.922	0.517		0.295	1.254	2.171	1.781	2.3	1.417	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.357	1.004					2.656	0.505		1.081	1.73	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.378	1.632	0.88			0.541	1.779	1.967	1.651	2.611	1.735	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.228	2.206	1.539			0.527	3.253	3.268	1.27	2.982	3.522	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.022	0.76	0.876			0.653	3.617	6.58	15.204	7.753	5.722	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.639							0.636	0.568	0.561	1.025	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.05	1.36	0.886			0.516	1.407	1.506	1.496	2.094	1.363	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.309	1.748	0.95			0.372	1.587	2.438	1.83	2.51	1.768	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.69	2.097	1.735	0.519		0.729	1.973	2.434	3.538	2.964	2.343	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	5.145	2.923	0.895				2.112	3.362	0.585	5.553	1.443	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.272	1.85	0.875				1.938	1.235	0.622	2.201	0.892	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.381	1.413	0.908			0.716	1.899	2.212	2.179	2.68	1.756	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.763	1.811	0.942	0.519		0.531	2.445	2.251	2.846	3.311	2.06	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.458	1.65	0.922			0.433	2.176	2.64	1.993	2.494	1.832	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.503	1.134	0.898	0.519		0.286	0.824	2.015	1.259	1.664	1.17	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.363	3.076	2.486			0.499	1.598	3.024	5.74	2.402	1.57	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.664	6.898					1.26	1.382	0.769	2.119	0.817	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.02	6.881					0.979	1.577	1.033	1.798	1.11	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.297	1.774	0.872				2.011	1.618	0.707	2.555	1.074	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.665	2.041				0.611	2.471	1.636	0.664	3.208	1.196	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.997	2.233	0.878				3.682	2.001	1.068	4.861	1.197	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.371	6.822		10.463	0.911		1.287	0.519		1.468	1.064	
COVID19 (COVID19 (MODERNA))	Intentional product use issue	0.869	1.951	0.875	0.008	1.017	2.481	0.781	0.804	0.419	0.887	0.892	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.869	1.093				0.605	2.093	1.548	0.843	2.008	1.952	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.368	6.978	0.886	0.133	6.081	2.874	0.1	0.044	0.364	2.552	2.854	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.649	2.039	0.873			2.779	2.054	2.003	1.588	1.985	3.194	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.003	1.667	0.887			0.636	1.632	18	1.537	1.917	1.903	
COVID19 (COVID19 (PFIZER-	Body height	1.945	6.984	0.879		0.48	0.695	0.957	1.431	2.166	1.908	1.545	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.045	1.191	0.873		0.48	0.743	1.468	1.663	1.876	1.921	1.505	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.298	1.763	1.716	0.517	0.834	1.111	1.699	1.708	1.737	1.827	1.849	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.855	0.878	16.327			0.362			0.508	1.23	
COVID19 (COVID19 (PFIZER-	Immunisation	1.747	1.658	0.914		1.285	1.243	1.796	1.974	2.247	1.968	1.835	
COVID19 (COVID19 (PFIZER-	Investgation	2.168	1.751	0.928		0.712	1.085	1.785	1.904	2.226	1.977	1.886	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.753	6.783			1.452	1.373	1.846	1.725	2.159	1.894	1.563	
COVID19 (COVID19 (PFIZER-	Weight	2.025	1.335	0.88			0.596	1.555	1.737	2.102	1.1	1.767	

PSI-HHS-000000057678

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 5 Apr 2022 17:38:36 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220401.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, April 5, 2022 6:42 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/1/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2022Q4	Serious EB05 2022	Fatal EB05 2022Q	Infant EB05 2022Q	Child EB05 2022Q	Teen EB05 2022Q	Adult EB05 2022Q	Adult2 EB05 2022Q	Adult3 EB05 2022Q	Female EB05 2022Q	Male EB05 2022Q	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.661	1.636	0.927			0.378	1.533	1.839	2.084	2.711	1.072	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.113	1.58	0.873				1.609	2.079	1.993	2.746	1.445	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.068	1.338	1.018			0.444	1.469	2.009	1.953	2.38	1.741	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.841	0.949	0.877			0.514	0.971	0.78	0.687	2.621	1.492	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.093	0.883				0.917	0.853	0.732	1.893	1.571	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.91	1.314	0.9				1.475	1.464	1.696	2.127	1.324	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.476	1.818	0.903			0.479	2.126	2.063	2.037	3.502	1.451	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.164	1.527	0.88				1.883	1.804	1.334	2.352	1.451	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.431	1.661	0.902			0.416	1.606	2.303	2.222	2.472	1.977	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.751	1.34	0.900			0.361	1.133	2.144		1.404	2.079	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.368	0.833	0.871			0.597	0.804	1.061	1.796	1.998	1.092	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.219	1.492	0.961	0.513		0.419	1.816	2.043	2.232	2.725	1.872	Other
COVID19 (COVID19 (JANSEN))	Anoxia	2.035	1.764	0.888				0.897	2.295	1.315	2.08	1.452	Reviewed
COVID19 (COVID19 (JANSEN))	Asparagin carotid abnormal	1.748	1.116	0.877				1.11	1.284	1.33	2.11	0.983	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.963	1.485	0.907	0.61		0.365	1.202	2.421	1.81	2.412	1.359	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.809	1.454	0.929	0.509		0.275	1.164	2.342	1.824	2.294	1.361	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.782	1.278	0.923			0.316	1.445	1.818	1.79	2.141	1.608	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.878	1.372	0.942			0.38	1.371	2.11	1.911	2.228	1.505	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.846	1.255	0.916				1.031	2.027	1.557	1.941	1.542	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.844	1.343	0.953			0.423	1.241	2.069	1.922	2.172	1.387	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.966	2.255	0.86			0.484	1.69	1.98	0.913	4.095	1.969	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.81	1.332	0.924			0.252	1.119	1.919	1.812	2.437	1.192	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.67	1.228	0.934			0.518	1.221	1.479	2.101	1.879	1.251	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.817	1.323	0.902	0.509			1.339	2.038	1.73	1.934	1.818	Not an AE
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.663	1.354	0.881			0.294	1.386	1.996	1.218	2.058	0.909	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.861	1.27	0.917				1.051	2.063	1.785	2.111	1.639	Other
COVID19 (COVID19 (JANSEN))	Brain oedema	1.009	1.28	0.92				1.22	1.065	0.606	2.009	0.795	
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.057	1.389	1.001				1.731	2.185	1.971	2.285	1.947	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.668	2.079	0.873				1.834	2.996	1.039	2.58	2.232	Reviewed
COVID19 (COVID19 (JANSEN))	CSF red blood cell count positive	1.964	1.763	0.873				1.409	1.978	0.99	2.014	1.498	
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.326	1.616	0.928			0.511	1.684	1.935	1.476	3.358	1.15	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.836	1.965	0.925			0.519	1.353	1.621	1.175	3.934	1.093	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.361	1.635	0.876				1.115	1.293	1.605	3.311	1.236	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.156	2.124	0.907			0.515	2.223	2.267	0.874	3.804	1.231	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.772	1.273	0.944			0.336	1.344	1.853	1.846	2.061	1.602	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.536	1.664	0.964	0.511		0.607	2.117	2.325	1.996	3.023	1.733	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.991	1.362	0.912			0.379	1.721	1.965	1.864	2.264	1.547	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.063	1.409	0.922			0.45	1.411	2.048	2.006	2.242	1.892	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.551	1.169	0.954				1.136	1.661	1.512	2.028	1.51	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.579	1.782	0.972			0.452	2.178	2.361	2.965	3.258	2.008	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.928	1.384	1.248			0.386	1.359	2.136	1.831	2.1	1.816	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.759	1.304	0.906			0.102	1.23	2.142	1.647	2.033	1.34	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.763	1.307	0.923	0.61		0.293	1.202	2.149	1.747	2.074	1.413	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.776	0.846	0.882			1.207	2.003	1.449	0.969	1.841	1.414	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.3	1.285	0.892			0.436	2.212	2.181	1.909	2.544	1.716	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.152	1.48	0.87	0.512		0.384	1.797	2.233	2.188	2.493	1.853	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.942	1.093	0.875			0.428	1.663	2.165	1.021	2.214	1.343	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.286	1.669	0.888			0.399	2.259	1.747	1.245	2.281	1.617	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.853	1.271	0.898			0.396	1.239	1.72	1.821	2.133	1.258	Reviewed
COVID19 (COVID19 (JANSEN))	Glomerular filtration rate decreased	1.767	1.152	0.931				0.999	1.928	1.556	2.051	1.369	Other
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.732	1.233	0.907				1.255	1.461	1.456	2.421	1.077	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.345	1.853	0.882			0.43	1.64	2.947	1.655	2.418	2.166	Reviewed
COVID19 (COVID19 (JANSEN))	Haemstocrit decreased	1.815	1.294	0.946	0.506		0.458	1.329	2.025	1.823	2.202	1.427	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.787	1.255	0.936	0.506		0.388	1.405	1.963	1.693	2.112	1.408	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.527	3.691	0.891				4.19	5.618	4.762	7.4	3.362	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.177	3.451	0.873			0.541	4.714	5.822	6.741	7.271	2.853	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.891	1.307	0.94				1.462	2.066	1.833	2.354	1.638	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.057	1.774	0.871			0.619	1.959	2.54	1.431	2.253	1.735	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.609	1.493	1.006			0.629	1.426	2.116	2.016	2.314	1.993	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.831	1.244	0.887	0.746		0.382	1.559	1.926	1.466	2.337	1.287	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.015	1.224	0.878				1.39	2.064	0.914	2.087	1.253	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.997	1.49	0.877				1.399	1.15	0.71	2.31	0.711	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.901	1.365	0.866				1.288	2.179	1.027	1.688	1.731	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.69	1.695					1.08	2.751	1.04	1.756	1.817	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.728	1.262	0.933				1.41	1.715	1.866	2.318	1.517	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.68	1.252	0.921			0.228	1.004	2.102	1.892	2.073	1.324	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.378	1.111	0.9	0.507			1.035	1.493	1.25	2.03	0.657	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.071	1.493	0.908			0.485	1.779	1.871	2.132	2.311	1.814	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.063	1.466	0.944	0.512		0.435	1.261	2.271	1.935	2.422	1.454	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.651	1.245	0.908			3.3	1.119	1.998	1.419	2.011	0.985	Other
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.924	1.41	0.921			0.325	1.236	2.407	1.605	2.195	1.45	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.121	1.513	1.018			0.47	0.996	2.275	1.958	2.058	1.981	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.592	1.25	0.916	0.61		0.242	0.912	1.955	2.016	2.254	1.132	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.5	1.201	0.886			0.099	1.14	1.63	1.66	2.237	0.818	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.721	1.28	0.916			0.272	1.094	2.104	1.832	1.983	1.424	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.275	0.794					0.744	0.612		2.744	1.073	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.33	0.607	0.884			0.023	1.199	1.263	0.887	1.444	1.918	Not an AE
COVID19 (COVID19 (JANSEN))	Oxygen saturation decreased	1.732	0.782					0.356	1		2.21		
COVID19 (COVID19 (JANSEN))	Pain assessment	2.529	0.864				0.503	1.529	2.199	1.117	2.194	1.422	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.924	1.41	0.873				0.658	1.061	1.572	2.234	0.953	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.708	2.294	0.917	0.511		0.468	1.8	2.911	2.582	3.05	1.886	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.858	1.307	0.906	0.507		0.281	1.451	2.102	1.569	2.194	1.461	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.735	1.847	0.892			0.382	2.105	2.728	2.138	3.195	1.865	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.023	3.429	0.875				4.318	3.641	0.799	5.922	2.351	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.861	1.276	0.944				1.014	2.003	1.62	2.122	1.596	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.623	0.841	0.874		0.72	2.027	0.075	0.002	0.519	1.661	1.802	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.068	1.066					4.262			2.814		Other
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.751	1.232	0.916	0.61		0.345	1.362	1.572	1.766	2.011	1.393	Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.948	1.447	0.936	0.746		0.307	1.455	2.31	1.72	2.49	1.484	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.233	1.577	1.06	0.513		0.581	1.762	2.049	2.56	2.498	1.872	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.697	1.482	0.901				1.999	1.55	1.939	2.108	1.656	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.822	1.296	0.93	0.507		0.516	1.371	2.012	1.723	2.063	1.509	Other
COVID19 (COVID19 (JANSEN))	Red blood cell transfusion	1.712	1.203	0.886				1.176	1.287	1.21	2.022	0.956	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.957	1.342	0.923	0.511		0.311	1.296	2.18	1.786	2.311	1.436	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.349	1.011					2.328	0.5		1.088	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.396	1.67	0.878			0.528	1.814	1.987	1.612	2.614	1.743	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.224	2.187	1.542			0.517	3.314	3.224	1.271	3.021	3.562	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.023	6.768	0.875			0.644	3.588	6.579	15.105	7.71	5.725	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.38							0.638	0.572	0.564	1.017	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.076	1.406	0.886			0.503	1.407	1.598	1.502	2.118	1.394	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.257	1.751	0.937			0.388	1.595	2.437	1.798	2.478	1.777	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.682	2.095	1.717	0.513		0.726	1.976	2.409	3.559	2.936	2.33	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	5.022	3.937	0.892				1.911	2.596	0.573	5.552	1.53	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.213	1.628	0.874				1.885	1.268	0.626	2.181	0.903	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.401	1.447	0.911			0.711	1.932	2.225	2.236	2.685	1.779	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.682	1.811	0.925	0.512		0.519	2.414	2.249	2.787	3.25	2.071	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.47	1.681	0.917			0.424	2.19	2.075	1.974	2.501	1.892	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.889	1.085	0.876				1.235	2.033	1.679	1.882	1.325	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.532	1.159	0.896	0.512		3.3	0.844	2.101	1.276	1.688	1.225	Not an AE
COVID19 (COVID19 (JANSEN))	Vascular failure	1.365	1.101	0.916			0.495	1.031	3.026	0.994	2.491	2.982	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.566	0.931					1.264	1.344	0.79	2.012	0.828	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.039	0.893					0.921	1.665	1.032	1.798	1.119	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.263	1.796	0.871				1.995	1.648	0.71	2.585	1.079	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.607	2.092				3.6	2.388	1.74	0.663	3.151	1.268	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.959	2.244	0.878				3.634	1.987	1.055	4.807	1.216	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	0.833		12.758	0.935		1.289	0.515		1.474	1.075	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.561	0.923	0.871	0.904	1.031	2.472	0.781	0.625	0.418	0.667	0.627	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.89	1.094				0.608	2.087	1.563	0.847	2.008	1.95	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	0.951	0.884		6.187	2.591	0.096	0.046	0.351	2.568	2.677	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.05	2.041	0.871			2.885	2.051	2.009	1.595	1.994	2.197	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.007	1.695	0.888			0.636	1.61	1.801	1.523	1.887	1.864	
COVID19 (COVID19 (PFIZER-	Body height	1.948	0.987	0.878		0.488	0.863	0.959	1.423	2.16	1.3	1.543	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.11	0.874		0.488	0.71	1.462	1.69	1.671	1.923	1.501	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.259	1.762	1.71	0.511	0.801	1.092	1.709	1.711	1.724	1.828	1.845	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	0.864	0.877	19.089			0.364			0.504	1.222	
COVID19 (COVID19 (PFIZER-	Immunisation	1.746	1.686	0.91		1.272	1.231	1.706	1.971	2.238	1.954	1.827	
COVID19 (COVID19 (PFIZER-	Investigation	2.164	1.751	0.924		0.705	1.073	1.776	1.931	2.226	1.974	1.881	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.758	0.793			1.444	1.364	1.852	1.736	2.166	1.594	1.561	
COVID19 (COVID19 (PFIZER-	Weight	2.024	1.396	0.888			0.922	1.55	1.731	2.107	1.901	1.757	

PSI-HHS-000000057680

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 3 May 2022 12:01:56 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220429.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, May 3, 2022 6:24 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/29/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2022[0-2]	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.048	1.551	0.936			0.581	1.518	1.807	2.059	2.736	1.378	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.108	1.558	0.875				1.597	2.047	2.012	2.791	1.414	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.059	1.322	1.019			0.456	1.44	2.028	1.956	2.433	1.711	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.849	6.958	0.88			0.528	0.968	0.717	0.68	2.583	1.514	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.016	1.092	0.887				0.87	0.885	0.729	1.875	1.805	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.899	1.293	0.906				1.457	1.439	1.683	2.102	1.314	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.459	1.812	0.908			0.489	2.119	1.98	2.127	3.479	1.471	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.129	1.411	0.881				1.844	1.753	1.293	2.281	1.405	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.417	1.638	0.907			0.418	1.594	2.296	2.209	2.481	1.964	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.78	1.363	0.906			0.386	1.107	2.157	1.482	2.093	1.339	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.311	6.821	0.873			0.589	0.786	1.076	1.889	1.961	1.001	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.21	1.475	0.983	0.619		0.425	1.812	2.022	2.261	2.748	1.853	Other
COVID19 (COVID19 (JANSEN))	Areflexia	2.036	1.717	0.894				0.91	2.462	1.279	2.191	1.434	Reviewed
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.719	1.138	0.879				1.119	1.458	1.489	2.201	0.984	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.854	1.388	0.913	0.516		0.365	1.15	2.338	1.778	2.362	1.3	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.79	1.405	0.933	0.515		0.261	1.129	2.31	1.777	2.198	1.313	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.765	1.263	0.921			0.31	1.403	1.882	1.769	2.157	1.383	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.868	1.349	0.945			0.378	1.342	2.11	1.88	2.218	1.48	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.836	1.246	0.92				1.057	2.067	1.583	1.948	1.541	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.809	1.31	0.956			0.47	1.199	2.051	1.889	2.143	1.364	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.91	2.181	0.892			0.583	1.747	1.935	0.899	3.977	1.943	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.813	1.299	0.925			0.187	1.063	1.948	1.766	2.407	1.178	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.669	1.212	0.933			0.519	1.191	1.512	2.048	1.871	1.227	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.817	1.313	0.908	0.516			1.327	2.026	1.741	1.935	1.607	Not an AE
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.859	1.253	0.909				1.015	2.057	1.762	2.11	1.609	Other
COVID19 (COVID19 (JANSEN))	Brain oedema	1.523	1.249	0.925				1.197	1.563	0.602	2.025	1.27	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.067	1.412	1.096				1.626	2.22	2.014	2.386	1.904	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.607	2.003	0.875				1.733	3.014	1.01	2.464	2.157	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.317	1.581	0.936			0.525	1.711	1.887	1.473	3.343	1.137	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	3.047	1.976	0.928			0.633	1.384	1.713	1.169	3.812	1.143	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.402	1.725	0.879				1.364	1.324	1.622	3.554	1.227	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.219	2.165	0.915			0.529	2.496	2.398	0.879	3.907	1.225	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.769	1.277	0.952			0.336	1.31	1.895	1.888	2.093	1.597	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.52	1.855	0.964	0.518		0.613	2.121	2.362	2.035	3.044	1.722	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.988	1.345	0.913			0.383	1.691	1.996	1.846	2.261	1.534	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.05	1.411	0.926			0.462	1.383	2.045	2.052	2.261	1.687	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.893	1.167	0.963				1.18	1.625	1.522	2.054	1.509	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.581	1.779	1.004			0.465	2.202	2.277	3.066	3.28	2.021	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.913	1.384	1.16			0.388	1.385	2.122	1.879	2.121	1.831	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.763	1.293	0.913			0.042	1.203	2.125	1.663	2.087	1.297	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.78	1.362	0.90	0.516		0.277	1.254	2.123	1.729	2.082	1.385	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.763	6.859	0.889			1.189	2.014	1.463	0.971	1.843	1.426	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.269	1.290	0.896			0.446	2.196	2.172	1.967	2.51	1.712	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.166	1.455	0.957	0.519		1.3	1.716	2.296	2.199	2.488	1.828	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.911	1.083	0.878			0.439	1.656	2.038	1.03	2.186	1.33	Not an AE
COVID19 (COVID19 (JANSEN))	Gastroenteritis	2.262	1.882	0.882			0.488	2.232	1.718	1.241	2.284	1.899	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.834	1.237	0.897			0.402	1.209	1.763	1.585	2.151	1.193	Reviewed
COVID19 (COVID19 (JANSEN))	Glomular filtration rate decreased	1.766	1.139	0.935				1.006	1.968	1.547	2.002	1.356	Other
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.693	1.175	0.907				1.216	1.416	1.393	2.281	1.039	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.336	1.836	0.887			0.44	1.639	3.102	1.649	2.438	2.166	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.81	1.276	0.94	0.512		0.504	1.299	2.045	1.782	2.188	1.416	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.75	1.238	0.93	0.513		0.396	1.363	1.974	1.663	2.091	1.401	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.508	3.636	0.896				4.184	5.513	4.677	7.312	3.389	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.159	3.459	0.876			0.555	4.665	5.709	0.739	7.261	3.05	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.912	1.323	0.964				1.485	2.067	1.889	2.44	1.849	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.08	1.721	0.87			0.011	1.89	2.546	1.405	2.254	1.889	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.832	1.394	1.073			0.022	1.424	2.1	2.057	2.336	1.559	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.823	1.222	0.884	0.754		0.388	1.529	1.926	1.447	2.308	1.276	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.021	1.205	0.901				1.369	2.63	0.913	2.092	1.23	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.948	1.474	0.88				1.402	1.124	0.708	2.401	0.711	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.909	1.358	0.866				1.268	2.183	1.019	1.672	1.743	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.061	1.457					1.095	2.759	1.018	1.751	1.78	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.732	1.261	0.946				1.356	1.736	1.952	2.301	1.518	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.676	1.236	0.921			0.193	0.995	2.093	1.846	2.074	1.291	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.337	1.093	0.900	0.514		0.267	0.986	1.448	1.285	1	0.652	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.065	1.481	0.911			0.477	1.778	1.876	2.147	2.343	1.806	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.063	1.417	0.948	0.519		0.445	1.249	2.241	1.884	2.382	1.422	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.678	1.269	0.924			0.289	1.113	1.962	1.521	2.054	0.992	Other
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.888	1.333	0.912			0.321	1.17	2.342	1.569	2.129	1.392	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.127	1.528	1.031			0.483	1.097	2.299	2.004	2.141	2.005	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.53	1.218	0.914	0.516		0.218	0.845	1.913	1.988	2.205	1.094	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.484	1.203	0.89			0.325	1.085	1.843	1.677	2.205	0.836	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.72	1.267	0.92			0.255	1.094	2.1	1.785	1.999	1.391	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.39	6.786					0.745	0.612		2.945	1.075	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.313	6.622	0.866			0.651	1.106	1.211	0.907	1.472	1.833	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.781	6.754					3.443	0.983		2.288		Other
COVID19 (COVID19 (JANSEN))	Pain assessment	2.52	6.87				0.517	1.512	2.222	1.12	2.183	1.45	Not an AE
COVID19 (COVID19 (JANSEN))	Paralysis of excitation	3.21	1.389	0.876				2.036	1.033	1.281	3.381	1.88	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.805	2.2	0.918	0.518		0.479	1.764	2.963	2.734	3.048	1.838	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.871	1.314	0.916	0.514		0.262	1.428	2.105	1.647	2.238	1.461	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.74	1.843	0.898			0.45	2.095	2.767	3.186	3.194	1.683	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.015	3.279	0.877				4.299	4.624	0.802	5.723	2.245	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.765	1.283	0.956				1.021	2.022	1.669	2.232	1.568	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.617	6.832	0.877		0.719	2.058	0.043	0.062	0.517	1.671	1.831	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.101	1.048					4.097			2.711		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.926	1.408	0.937	0.754		0.381	1.426	2.311	1.671	2.459	1.46	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.239	1.581	1.115	0.519		0.589	1.762	2.047	2.635	2.498	1.9	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.062	1.467	0.906				1.739	1.574	1.926	2.17	1.842	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.813	1.278	0.924	0.513		0.567	1.343	2.039	1.672	2.04	1.501	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.992	1.322	0.925	0.517		0.291	1.27	2.169	1.776	2.291	1.418	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.307	1.094					2.076	0.565		1.081	3.73	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.37	1.634	0.882			0.542	1.781	1.961	1.649	2.611	1.729	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.228	2.214	1.572			0.528	3.265	3.229	1.265	2.944	3.499	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.618	6.758	0.877			0.854	3.619	6.586	16.036	7.73	5.721	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.627							0.636	0.568	0.861	1.025	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.051	1.357	0.886			0.516	1.403	1.539	1.499	2.096	1.364	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.335	1.743	0.952			0.371	1.583	2.44	1.854	2.503	1.776	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.697	2.107	1.749	0.519		0.729	1.98	2.449	3.561	2.948	2.362	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	5.144	2.926	0.896				2.134	3.666	0.565	5.574	1.453	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.272	1.621	0.876				1.944	1.23	0.622	2.181	0.892	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.362	1.417	0.912			0.717	1.893	2.214	2.175	2.883	1.743	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.659	1.823	0.954	0.519		0.532	2.445	2.271	2.841	3.31	2.078	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.434	1.626	0.922			0.433	2.125	2.028	1.961	2.454	1.813	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.867	1.08	0.876				1.205	2	1.65	1.833	1.324	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.362	3.083	2.483			0.499	1.591	3.016	5.786	2.398	2.561	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.664	6.895					1.26	1.371	0.791	2.098	0.918	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.665	6.906	0.873				0.976	1.576	1.127	1.844	1.111	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.297	1.786	0.874				2.003	1.62	0.708	2.548	1.075	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.655	2.031				0.612	2.479	1.627	0.664	3.168	1.199	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	3.599	2.294	0.881				3.729	2.062	1.06	4.917	1.196	Not an AE
COVID19 (MODERNA))	Exposure via breast milk	1.37	6.822		10.532	0.911		1.286	0.519		1.487	1.062	
COVID19 (MODERNA))	Interchange of vaccine products	0.589	6.953	0.876	0.509	1.019	2.461	0.783	0.633	0.42	0.669	0.631	
COVID19 (MODERNA))	Mechanical urticaria	0.869	1.138				0.605	2.075	1.544	0.84	1.094	1.936	
COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.367	6.978	0.888	0.135	6.177	2.671	0.112	0.043	0.363	2.548	2.846	
COVID19 (MODERNA))	Product dose omission issue	2.048	2.038	0.874			2.785	2.048	1.999	1.586	1.981	2.188	
COVID19 (MODERNA))	Vaccination complication	2.003	1.668	0.886			0.636	1.515	1.799	1.535	1.911	1.899	
COVID19 (COVID19 (PFIZER-	Body height	1.945	6.984	0.881		0.481	0.895	0.957	1.402	2.173	1.912	1.546	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.101	0.877		0.481	0.744	1.469	1.689	1.878	1.921	1.512	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.301	1.756	1.707	0.518	0.842	1.115	1.708	1.717	1.745	1.831	1.854	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.753	6.855	0.88	16.407			0.363			0.507	1.234	
COVID19 (COVID19 (PFIZER-	Immunisation	1.747	1.657	0.915		1.285	1.242	1.802	1.979	2.255	1.978	1.84	
COVID19 (COVID19 (PFIZER-	Investigation	2.168	1.746	0.929		0.715	1.085	1.792	1.929	2.233	1.983	1.89	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	6.783			1.46	1.374	1.649	1.723	2.157	1.598	1.566	
COVID19 (COVID19 (PFIZER-	Weight	2.025	1.347	0.892			0.943	1.559	1.743	2.103	1.907	1.762	

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 10 May 2022 13:29:07 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220506.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, May 10, 2022 5:46 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/6/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20220408	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.066	1.546	0.932			0.381	1.506	1.86	2.065	2.755	1.374	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.092	1.562	0.881				1.609	2.096	2	2.763	1.428	Reviewed
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.081	1.34	0.991				0.79	1.662	1.807	1.618	1.906	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.09	1.323	1.017			0.456	1.43	2.023	1.979	2.445	1.72	Reviewed
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.336	0.98	0.884			0.529	1.015	0.717	0.68	2.622	1.515	Other
COVID19 (COVID19 (JANSSEN))	Adverse event	2.557	1.085	0.86				0.871	0.882	0.73	1.878	1.609	Other
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.304	1.965					1.303	1.444		0.907	1.671	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.978	1.293	0.907				1.456	1.44	1.681	2.104	1.313	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.537	1.811	0.912			0.489	2.19	1.965	2.118	3.41	1.493	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.175	1.428	0.885				1.844	1.787	1.291	2.265	1.446	Not an AE
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.304	1.635	0.912			0.415	1.907	2.284	2.216	2.471	1.962	Reviewed
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.809	1.368	0.91			0.366	1.103	2.229	1.469	2.083	1.358	Other
COVID19 (COVID19 (JANSSEN))	Antibody test	2.109	0.823	0.877			0.57	0.795	1.58	1.892	1.987	1.66	Not an AE
COVID19 (COVID19 (JANSSEN))	Antiepileptic therapy	2.37	1.371	0.971		0.618	0.483	1.41	2.041	2.217	2.783	1.881	Other
COVID19 (COVID19 (JANSSEN))	Areflexia	2.137	1.719	0.9				0.905	2.462	1.344	2.258	1.458	Reviewed
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.879	1.166	0.885				1.303	1.231	1.427	2.244	1.024	Reviewed
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.872	1.392	0.929	0.616		0.381	1.175	2.304	1.781	2.383	1.307	Other
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.788	1.41	0.936	0.615		0.258	1.148	2.325	1.756	2.195	1.328	Other
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.812	1.266	0.928			0.309	1.435	1.862	1.746	2.168	1.386	Other
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.864	1.349	0.948			0.375	1.349	2.109	1.868	2.3	1.491	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.823	1.309	0.957			0.469	1.227	2.039	1.865	2.148	1.357	Other
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.809	2.197	0.894			0.503	1.747	2.171	0.885	4.054	1.039	Reviewed
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.81	1.312	0.926			0.173	1.08	1.972	1.771	2.417	1.202	Other
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.663	1.214	0.938			0.517	1.21	1.52	2.027	1.881	1.235	Other
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.827	1.31	0.903	0.616			1.33	2.02	1.74	1.941	1.604	Not an AE
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.891	1.257	0.909				1.029	2.065	1.764	2.134	1.605	Other
COVID19 (COVID19 (JANSSEN))	Brain oedema	1.008	1.246	0.926				1.196	1.665	0.892	2.011	1.77	Other
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.264	1.409	1.092				1.807	2.221	2.082	2.393	1.962	Other
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.571	2.007	0.878				1.782	2.982	1.01	2.459	2.158	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.218	1.583	0.935			0.626	1.711	1.889	1.471	3.348	1.196	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.02	1.98	0.925			0.533	1.384	1.776	1.17	3.922	1.144	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.668	1.741	0.882				1.364	1.365	1.626	3.541	1.265	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.392	2.167	0.917			0.529	2.48	2.352	0.876	3.883	1.225	Reviewed
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.867	1.28	0.956			0.333	1.333	1.897	1.891	2.108	1.597	Confounded-
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.441	1.657	0.908	0.618		0.613	2.144	2.296	2.041	3.038	1.73	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.005	1.344	0.916			0.383	1.714	1.962	1.843	2.274	1.537	Not an AE
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.017	1.407	0.928			0.483	1.386	2.062	2.028	2.268	1.686	Reviewed
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	2.022	1.287	0.886				0.497	0.896	1.968	1.088	1.635	
COVID19 (COVID19 (JANSSEN))	Death	1.832	1.165	0.962				1.189	1.628	1.526	2.053	1.51	Reviewed
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.861	1.784	1.024			0.485	2.194	2.28	3.097	3.287	2.022	Reviewed
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.093	1.38	1.144			0.388	1.415	2.107	1.876	2.118	1.834	Labeled
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.773	1.292	0.92			0.041	1.238	2.086	1.665	2.086	1.305	Other
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.786	1.362	0.933	0.616		0.275	1.276	2.116	1.706	2.073	1.395	Other
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.752	0.856	0.892			0.188	2.017	1.451	0.97	1.845	1.425	Labeled
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.237	1.294	0.897			0.446	2.193	2.161	1.974	2.544	1.895	Other
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.139	1.447	0.881	0.618		0.386	1.716	2.29	2.191	2.493	1.617	Reviewed
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.968	1.082	0.882			0.439	1.656	2.041	1.029	2.193	1.328	Not an AE
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.088	1.412		0.756			0.654			1.431	1.732	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.227	1.043	0.894			0.496	2.252	17	1.238	2.251	1.587	Labeled
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.816	1.242	0.904			0.481	1.231	1.761	1.589	2.181	1.193	Reviewed
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.768	1.154	0.906				1.216	1.362	1.364	2.231	1.019	Other
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.462	1.838	0.89			0.44	1.839	3.167	1.646	2.438	2.167	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemstocrit decreased	1.804	1.276	0.941	0.612		0.503	1.308	2.04	1.778	2.188	1.416	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.789	1.241	0.934	0.613		0.396	1.372	1.977	1.665	2.1	1.404	Reviewed
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.727	3.828	0.896				4.194	5.517	4.497	7.267	3.394	Not an AE
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.456	3.469	0.88			0.555	4.665	5.717	6.739	7.267	3.053	Reviewed
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.056	1.322	0.958				1.511	2.085	1.891	2.439	1.66	Reviewed
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.088	1.72	0.873			0.611	1.885	2.549	1.405	2.248	1.696	Reviewed
COVID19 (COVID19 (JANSSEN))	Intensive care	1.939	1.4	1.07			0.482	1.428	2.11	2.066	2.334	1.501	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.78	1.225	0.89	0.754		0.388	1.549	1.943	1.432	2.317	1.279	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.901	1.209	0.885				1.385	2.032	0.918	2.051	1.251	Not an AE
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.638	1.767	0.906				0.84	1.408	0.996	1.734	1.594	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.831	1.452	0.884				1.387	1.125	0.708	2.353	0.711	Reviewed
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.873	1.36	0.873				1.265	2.188	1.018	1.681	1.738	Not an AE
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.148	1.707					1.128	2.83	1.023	1.785	1.814	Reviewed
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.985	1.29	0.945				1.384	1.741	1.972	2.327	1.529	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.681	1.234	0.924			0.19	1.002	2.094	1.824	2.061	1.294	Other
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.065	1.477	0.912			0.477	1.768	1.877	2.129	2.323	1.812	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.071	1.409	0.946	0.619		0.445	1.26	2.212	1.885	2.381	1.407	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.713	1.268	0.926			0.268	1.123	1.945	1.511	2.053	0.997	Other
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.67	1.325	0.912			0.319	1.164	2.343	1.555	2.118	1.391	Other
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.262	1.529	1.027			0.483	1.164	2.251	1.993	2.124	2.026	Reviewed
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.528	1.22	0.917	0.616		0.213	0.839	1.955	1.98	2.187	1.109	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.519	1.204	0.893			0.324	1.083	1.658	1.659	2.194	0.846	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.725	1.266	0.924			0.232	1.105	2.104	1.763	1.969	1.396	Other
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	4.048	6.786					0.744	0.612		2.953	1.075	Other
COVID19 (COVID19 (JANSSEN))	Off label use	2.021	0.602	0.892			8.105	1.182	1.305	0.932	1.461	1.952	Not an AE
COVID19 (COVID19 (JANSSEN))	Oral off presentation	1.785	6.784					3.448	0.963		3.288		Other
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.228	6.866				0.517	1.506	2.218	1.107	2.173	1.445	Not an AE
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.17	1.394	0.88				0.656	1.034	1.593	2.382	1.95	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count	2.671	1.166	0.92	0.618		0.479	1.788	2.901	2.696	3.029	1.825	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.867	1.315	0.918	0.614		0.261	1.424	2.11	1.654	2.242	1.462	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.568	1.836	0.898			0.451	2.095	2.761	2.147	3.161	1.889	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.784	3.291	0.881				4.298	4.639	6.804	5.738	2.253	Not an AE
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.065	1.475	0.882				0.859	1.662	1.026	2.021	1.275	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.035	1.29	0.953				1.014	2.074	1.655	2.217	1.804	Other
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.773	0.831	0.881		0.719	2.061	0.041	0.062	0.516	1.672	1.83	Not an AE
COVID19 (COVID19 (JANSSEN))	Prolonged labour	4.623	1.15					4.623			4.483		Other
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.93	1.405	0.94	0.754		0.299	1.431	2.369	1.654	2.443	1.46	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.228	1.579	1.094	0.619		0.59	1.766	2.06	2.615	2.491	1.895	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.28	1.472	0.906				1.734	1.611	1.913	2.162	1.894	Reviewed
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.867	1.28	0.927	0.614		0.566	1.357	2.038	1.665	2.045	1.501	Other
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.957	1.315	0.929	0.617		0.29	1.304	2.137	1.768	2.292	1.411	Other
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.367	1.004					2.681	0.505		1.081	3.73	Reviewed
COVID19 (COVID19 (JANSSEN))	Sensory disturbance	2.007	1.317	0.886				1.43	1.852	1.408	1.838	1.796	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.528	1.595	0.888			0.542	1.781	1.962	1.656	2.4	1.73	Other
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.491	2.221	1.581			0.528	3.213	3.177	1.251	2.911	3.457	Other
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.559	6.758	0.881			0.654	3.618	6.99	15.05	7.734	5.73	Other
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.638							0.636	0.568	0.561	1.025	Other
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.961	1.334	0.892			0.513	1.388	1.525	1.49	2.067	1.351	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.284	1.746	0.947			0.371	1.582	2.467	1.844	2.522	1.779	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.879	2.114	1.747	0.619		0.729	1.981	2.488	3.568	2.945	2.37	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	5.857	3.937	0.899				2.136	3.791	9.565	5.582	1.459	Reviewed
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.148	1.601	0.881				1.912	1.23	0.623	2.157	0.892	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.356	1.427	0.912			0.717	1.905	2.222	2.162	2.674	1.749	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.697	1.826	0.952	0.619		0.532	2.468	2.285	2.83	3.328	2.081	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.37	1.628	0.921			0.431	2.102	2.023	1.906	2.474	1.819	Not an AE
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.64	3.081	2.507			0.493	1.569	2.942	5.633	2.364	2.946	Other
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.923	6.893					1.26	1.373	0.787	2.1	0.815	Other
COVID19 (COVID19 (JANSSEN))	Vasodilation	2.112	6.966	0.873				0.978	1.078	1.139	1.891	1.111	Labeled
COVID19 (COVID19 (JANSSEN))	Venogram	2.349	1.769	0.878				1.99	1.61	0.708	2.534	1.069	Not an AE
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.625	2.034				0.612	2.481	1.628	0.665	3.171	1.199	Reviewed
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.065	2.238	0.885				3.73	2.003	1.06	4.911	1.198	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.461	0.822		10.405	0.91		1.286	0.519		1.461	1.861	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.667	6.953	0.88	0.609	1.021	2.461	0.784	0.634	0.421	0.668	0.632	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.093	1.137				0.67	2.079	1.564	0.838	2.091	1.943	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.541	1.02	0.891	0.373	6.15	2.574	0.129	0.057	0.363	2.548	2.644	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.144	2.038	0.878			2.786	2.045	1.998	1.584	1.98	2.186	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.164	1.667	0.892			0.836	1.631	1.792	1.536	1.915	1.889	
COVID19 (COVID19 (PFIZER-	Body height	1.948	6.984	0.886		0.481	0.896	0.957	1.438	2.179	1.913	1.547	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.077	1.758	1.71	0.618	0.845	1.117	1.714	1.747	1.766	1.827	1.862	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.893	0.855	0.864	16.436			0.363			0.507	1.234	
COVID19 (COVID19 (PFIZER-	Immunisation	2.049	1.66	0.916		1.265	1.243	1.502	1.961	2.263	1.978	1.842	
COVID19 (COVID19 (PFIZER-	Investigation	2.031	1.745	0.926		0.716	1.085	1.793	1.931	2.243	1.983	1.892	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.61	6.783			1.462	1.373	1.845	1.722	2.152	1.592	1.565	
COVID19 (COVID19 (PFIZER-	Weight	1.94	1.346	0.896			0.443	1.558	1.745	2.109	1.908	1.764	

PSI-HHS-000000057684

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 18 May 2022 04:23:13 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220513.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, May 17, 2022 6:18 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/13/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 202205	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 202209	Adult1 EB05 21220	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 20220513
COVID19 (COVID19 (JANSSEN))	Activated partial	2.062	1.54	0.852			3.382	1.504	1.865	2.049	2.761	1.372
COVID19 (COVID19 (JANSSEN))	Activated partial	2.064	1.534	0.883				1.59	2.027	1.975	2.714	1.406
COVID19 (COVID19 (JANSSEN))	Acute respiratory	2.085	1.333	0.998				0.79	1.676	1.832	1.61	1.922
COVID19 (COVID19 (JANSSEN))	Acute respiratory	2.092	1.322	1.014			3.455	1.42	2.033	1.96	2.421	1.739
COVID19 (COVID19 (JANSSEN))	Adverse drug	3.343	0.975	0.868			3.529	0.973	0.718	0.681	2.622	1.485
COVID19 (COVID19 (JANSSEN))	Adverse event	2.584	1.092	0.894				0.871	0.851	0.731	1.864	1.644
COVID19 (COVID19 (JANSSEN))	Albumin CSF	2.226	1.907					1.304	1.41		0.906	1.624
COVID19 (COVID19 (JANSSEN))	Angiogram	1.907	1.282	0.909				1.453	1.427	1.677	2.099	1.303
COVID19 (COVID19 (JANSSEN))	Angiogram	2.535	1.808	0.914			0.49	2.192	1.955	2.11	3.397	1.494
COVID19 (COVID19 (JANSSEN))	Angiogram	2.081	1.402	0.888				1.801	1.758	1.287	2.254	1.406
COVID19 (COVID19 (JANSSEN))	Angiogram	2.289	1.621	0.912			3.416	1.598	2.281	2.198	2.45	1.953
COVID19 (COVID19 (JANSSEN))	Anion gap	1.808	1.365	0.91			3.367	1.103	2.22	1.478	2.091	1.353
COVID19 (COVID19 (JANSSEN))	Antibody test	2.114	0.822	0.882			0.57	0.792	1.574	1.896	2.002	1.852
COVID19 (COVID19 (JANSSEN))	Anticoagulant	2.172	1.466	0.971	0.619		3.421	1.827	2.029	2.245	2.758	1.649
COVID19 (COVID19 (JANSSEN))	Application site	2.001						0.56	0.635	0.678	1.036	0.764
COVID19 (COVID19 (JANSSEN))	Areflexia	2.147	1.724	0.902				0.957	2.413	1.343	2.312	1.449
COVID19 (COVID19 (JANSSEN))	Arteriogram	1.845	1.164	0.889				1.213	1.231	1.417	2.232	0.883
COVID19 (COVID19 (JANSSEN))	Basophil count	1.873	1.383	0.928	0.616		3.361	1.172	2.28	1.806	2.319	1.328
COVID19 (COVID19 (JANSSEN))	Basophil	1.79	1.408	0.944	0.615		3.256	1.143	2.303	1.794	2.182	1.342
COVID19 (COVID19 (JANSSEN))	Blood albumin	1.81	1.263	0.929			3.307	1.447	1.844	1.751	2.16	1.39
COVID19 (COVID19 (JANSSEN))	Blood calcium	1.856	1.342	0.951			3.375	1.348	2.087	1.875	2.166	1.491
COVID19 (COVID19 (JANSSEN))	Blood chloride	1.812	1.302	0.953			3.469	1.214	2.022	1.86	2.139	1.346
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	2.814	2.199	0.897			3.503	1.748	2.173	0.885	4.053	1.039
COVID19 (COVID19 (JANSSEN))	Blood magnesium	1.806	1.303	0.928			0.17	1.977	1.961	1.766	2.304	1.214
COVID19 (COVID19 (JANSSEN))	Blood potassium	1.899	1.216	0.938			3.516	1.236	1.512	2.04	1.889	1.24
COVID19 (COVID19 (JANSSEN))	Blood sodium	1.823	1.306	0.904	0.616			1.33	2.015	1.736	1.958	1.587
COVID19 (COVID19 (JANSSEN))	Blood urea	1.888	1.251	0.913				1.922	2.048	1.773	2.128	1.602
COVID19 (COVID19 (JANSSEN))	Brain oedema	1.58	1.269	0.931				1.196	1.567	0.603	2.011	0.806
COVID19 (COVID19 (JANSSEN))	COVID-19	2.212	1.41	1.093				1.804	2.238	2.027	2.39	1.978
COVID19 (COVID19 (JANSSEN))	CSF protein	2.589	2.018	0.882				1.847	2.985	1.005	2.517	2.16
COVID19 (COVID19 (JANSSEN))	Cerebral	2.229	1.596	0.939			3.526	1.712	1.878	1.508	3.333	1.151
COVID19 (COVID19 (JANSSEN))	Cerebral mass	2.828	1.982	0.93			3.534	1.384	1.755	1.17	3.923	1.144
COVID19 (COVID19 (JANSSEN))	Cerebral	2.653	1.738	0.886				1.364	1.361	1.629	3.528	1.255
COVID19 (COVID19 (JANSSEN))	Cerebral venous	3.31	2.158	0.919			0.53	2.517	2.344	0.879	3.882	1.225
COVID19 (COVID19 (JANSSEN))	Chest X-ray	1.865	1.28	0.957			3.333	1.318	1.89	1.902	2.104	1.599
COVID19 (COVID19 (JANSSEN))	Computerised	2.436	1.655	0.966	0.618		3.614	2.145	2.295	2.033	3.031	1.729
COVID19 (COVID19 (JANSSEN))	Computerised	1.999	1.338	0.916			3.381	1.711	1.983	1.841	2.275	1.526
COVID19 (COVID19 (JANSSEN))	Computerised	2.001	1.395	0.926			3.483	1.376	2.045	2.009	2.248	1.673
COVID19 (COVID19 (JANSSEN))	Creatinine renal	2.032	1.267	0.89				0.497	0.895	1.995	1.089	1.646
COVID19 (COVID19 (JANSSEN))	Death	1.833	1.164	0.963				1.187	1.621	1.526	2.059	1.558
COVID19 (COVID19 (JANSSEN))	Deep vein	2.61	1.782	1.009			3.466	2.208	2.281	3.137	3.269	2.009
COVID19 (COVID19 (JANSSEN))	Endotracheal	2.056	1.37	1.147			3.367	1.416	2.095	1.874	2.103	1.832
COVID19 (COVID19 (JANSSEN))	Eosinophil count	1.771	1.288	0.927			0.04	1.232	2.054	1.696	2.057	1.325
COVID19 (COVID19 (JANSSEN))	Eosinophil	1.792	1.354	0.938	0.616		3.273	1.268	2.095	1.724	2.062	1.397
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.753	0.857	0.895			1.186	2.023	1.452	0.968	1.844	1.429
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.273	1.295	0.901			3.445	2.188	2.157	1.972	2.539	1.692
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.128	1.441	0.886	0.619		3.298	1.713	2.275	2.201	2.494	1.615
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	1.934	1.081	0.886			0.44	1.636	1.979	1.027	2.167	1.289
COVID19 (COVID19 (JANSSEN))	Foetal exposure	2.085	1.432		0.756			0.654			1.434	1.726
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.23	1.036	0.897			3.406	2.273	1.7	1.228	2.243	1.595
COVID19 (COVID19 (JANSSEN))	Globulins	1.83	1.252	0.908			3.402	1.263	1.699	1.606	2.228	1.184
COVID19 (COVID19 (JANSSEN))	Glucose urine	1.696	1.147	0.907				1.216	1.392	1.343	2.217	1.014
COVID19 (COVID19 (JANSSEN))	Guillain-Barre	2.473	1.842	0.894			0.44	1.637	3.13	1.836	2.432	2.192
COVID19 (COVID19 (JANSSEN))	Haematocrit	1.8	1.272	0.944	0.612		3.502	1.31	2.028	1.778	2.182	1.414
COVID19 (COVID19 (JANSSEN))	Haemoglobin	1.756	1.238	0.937	0.613		3.394	1.373	1.987	1.668	2.096	1.403
COVID19 (COVID19 (JANSSEN))	Heparin-induced	5.706	3.819	0.9				4.186	5.519	4.266	7.267	3.357
COVID19 (COVID19 (JANSSEN))	Heparin-induced	6.457	3.472	0.884			3.556	4.664	5.719	0.739	7.264	3.079
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.076	1.332	0.964				1.511	2.095	1.922	2.448	1.685
COVID19 (COVID19 (JANSSEN))	Immunoglobulin	2.069	1.719	0.877			3.011	1.912	2.545	1.397	2.24	1.704
COVID19 (COVID19 (JANSSEN))	Intensive care	1.937	1.396	1.071			3.022	1.425	2.105	2.071	2.331	1.581
COVID19 (COVID19 (JANSSEN))	International	1.776	1.22	0.894	0.754		3.387	1.523	1.927	1.434	2.318	1.259
COVID19 (COVID19 (JANSSEN))	International	1.897	1.198	0.889				1.384	2.032	0.919	2.051	1.248
COVID19 (COVID19 (JANSSEN))	Intracardiac	2.628	1.759	0.911				0.84	1.402	0.996	1.717	1.595
COVID19 (COVID19 (JANSSEN))	Jugular vein	1.83	1.45	0.869				1.373	1.124	0.711	2.343	0.712
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.875	1.36	0.877				1.264	2.195	1.012	1.674	1.749
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	2.147	1.706					1.125	2.834	1.023	1.781	1.816
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.976	1.281	0.945				1.377	1.72	1.977	2.318	1.52
COVID19 (COVID19 (JANSSEN))	Lymphocyte	1.681	1.23	0.93			3.188	0.998	2.05	1.839	2.058	1.3
COVID19 (COVID19 (JANSSEN))	Lymphocyte	1.414	1.097	0.91	0.614		3.249	1.009	1.421	1.315	2.006	0.851
COVID19 (COVID19 (JANSSEN))	Magnetic	2.056	1.468	0.914			3.475	1.784	1.865	2.132	2.329	1.592
COVID19 (COVID19 (JANSSEN))	Mean cell	2.043	1.383	0.942	0.619		3.446	1.243	2.197	1.851	2.355	1.394
COVID19 (COVID19 (JANSSEN))	Mean cell	1.701	1.258	0.925			3.263	1.117	1.939	1.496	2.04	0.991
COVID19 (COVID19 (JANSSEN))	Mean platelet	1.866	1.318	0.917			3.319	1.16	2.315	1.576	2.107	1.394
COVID19 (COVID19 (JANSSEN))	Mechanical	2.269	1.515	1.019			3.483	1.161	2.278	1.978	2.113	2.015
COVID19 (COVID19 (JANSSEN))	Monocyte	1.521	1.214	0.918	0.616		3.212	0.845	1.915	1.958	2.173	1.105
COVID19 (COVID19 (JANSSEN))	Neutrophil	1.533	1.208	0.898			3.323	1.097	1.645	1.678	2.191	0.856
COVID19 (COVID19 (JANSSEN))	Neutrophil	1.722	1.262	0.929			0.25	1.101	2.088	1.775	1.981	1.4
COVID19 (COVID19 (JANSSEN))	Nonspecific	4.061	0.767					0.744	0.612		2.961	1.076
COVID19 (COVID19 (JANSSEN))	Off label use	2.029	0.599	0.895			3.141	1.195	1.339	0.932	1.473	1.976
COVID19 (COVID19 (JANSSEN))	On and off	1.784	0.755					3.446	0.982		2.288	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.227	0.867				3.518	1.506	2.219	1.104	2.169	1.446
COVID19 (COVID19 (JANSSEN))	Peripheral	3.087	1.362	0.884				0.656	1.034	1.54	2.246	0.951
COVID19 (COVID19 (JANSSEN))	Platelet count	2.66	2.187	0.918	0.618		0.48	1.84	2.864	2.725	3.025	1.802
COVID19 (COVID19 (JANSSEN))	Platelet count	1.872	1.317	0.922	0.614		3.239	1.446	2.105	1.867	2.241	1.472
COVID19 (COVID19 (JANSSEN))	Platelet count	2.562	1.82	0.901			3.451	2.095	2.757	2.134	3.151	1.686
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.782	3.298	0.885				4.298	4.645	0.805	5.733	2.351
COVID19 (COVID19 (JANSSEN))	Poor quality	1.3					0.88	1.957	1.308	1.429	1.993	2.022
COVID19 (COVID19 (JANSSEN))	Portal vein	2.072	1.425	0.886				0.859	1.645	1.026	2.024	1.258
COVID19 (COVID19 (JANSSEN))	Positive airway	2.045	1.292	0.953				1.014	2.083	1.664	2.225	1.613
COVID19 (COVID19 (JANSSEN))	Product	1.772	0.832	0.885		0.72	2.063	0.041	0.002	0.514	1.671	1.832
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.177	1.345					5.05			5.149	
COVID19 (COVID19 (JANSSEN))	Prothrombin time	1.925	1.39	0.941	0.734		3.299	1.447	2.283	1.657	2.448	1.454
COVID19 (COVID19 (JANSSEN))	Pulmonary	2.237	1.584	1.105	0.619		0.59	1.773	2.088	2.618	2.512	1.902
COVID19 (COVID19 (JANSSEN))	Pulmonary	2.286	1.482	0.909				1.726	1.631	1.913	2.161	1.878
COVID19 (COVID19 (JANSSEN))	Red blood cell	1.806	1.276	0.932	0.614		3.564	1.136	2.024	1.67	2.038	1.501
COVID19 (COVID19 (JANSSEN))	Red cell	1.959	1.316	0.935	0.617		3.286	1.303	2.118	1.789	2.285	1.425
COVID19 (COVID19 (JANSSEN))	Russell's viper	1.368	1.004					2.691	0.505		1.08	0.73
COVID19 (COVID19 (JANSSEN))	Superficial vein	2.558	1.646	0.899			3.539	1.774	1.966	1.662	2.577	1.707
COVID19 (COVID19 (JANSSEN))	Suspected COVID-	3.5	2.225	1.59			3.528	3.25	3.31	1.236	2.926	3.457
COVID19 (COVID19 (JANSSEN))	Therapy non-	6.552	0.756	0.885			3.654	3.621	6.582	14.788	7.735	5.71
COVID19 (COVID19 (JANSSEN))	Therapy partial	2.667							0.637	0.569	0.561	1.026
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.966	1.347	0.895			3.514	1.438	1.528	1.478	2.1	1.35
COVID19 (COVID19 (JANSSEN))	Thrombocytopeni	2.301	1.761	0.955			3.369	1.609	2.437	1.919	2.523	1.809
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.892	2.117	1.75	0.619		3.729	1.986	2.45	3.591	2.961	2.374
COVID19 (COVID19 (JANSSEN))	Thrombosis with	6.02	2.943	0.902				2.137	5.422	0.566	5.579	1.94
COVID19 (COVID19 (JANSSEN))	Transverse sinus	2.09	1.527	0.885				1.782	1.23	0.623	2.132	0.879
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.349	1.425	0.914			3.717	1.902	2.211	2.154	2.675	1.736
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.7	1.833	0.963	0.619		0.53	2.449	2.284	2.883	3.303	2.1
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.367	1.629	0.922			3.431	2.159	2.009	2.009	2.474	1.812
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.643	3.079	2.498			3.493	1.574	2.925	5.47	2.356	2.533
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.925	0.894					1.26	1.373	0.787	2.101	0.815
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.113	0.906	0.883				0.975	1.579	1.133	1.851	1.112
COVID19 (COVID19 (JANSSEN))	Venogram	2.331	1.74	0.882				1.99	1.598	0.705	2.491	1.059
COVID19 (COVID19 (JANSSEN))	Venogram	2.706	2.035				3.612	2.68	1.628	0.665	3.331	1.199
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.984	2.258	0.889				3.73	2.049	1.062	4.97	1.198
COVID19 (COVID19 (MODERNA))	Exposure via	1.46	0.823		10.37	0.91		1.286	0.52		1.466	1.051
COVID19 (COVID19 (MODERNA))	Interchange of	0.666	0.956	0.885	0.609	1.023	2.465	0.785	0.635	0.423	0.671	0.633
COVID19 (COVID19 (MODERNA))	Mechanical	2.056	1.138				3.671	2.085	1.533	0.839	2.002	1.566
COVID19 (COVID19 (MODERNA))	Product	2.533	1.016	0.894	0.466	6.063	2.971	0.132	0.061	0.354	2.541	2.633
COVID19 (COVID19 (MODERNA))	Product dose	2.145	2.04	0.882			2.804	2.046	2	1.585	1.98	2.188
COVID19 (COVID19 (MODERNA))	Vaccination	2.106	1.671	0.899			3.837	1.631	1.784	1.532	1.912	1.897
COVID19 (COVID19 (PFIZER-BIONTECH))	Body height	1.946	0.992	0.889		0.482	3.696	0.957	1.437	2.175	1.915	1.546
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.069	1.754	1.685	0.753	0.844	1.117	1.724	1.755	1.779	1.824	1.859
COVID19 (COVID19 (PFIZER-BIONTECH))	Exposure via	0.859	0.859	0.868	16.498			0.363			0.908	1.238
COVID19 (COVID19 (PFIZER-BIONTECH))	Immunisation	2.05	1.657	0.918		1.287	1.243	1.801	1.98	2.259	1.979	1.842
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.031	1.749	0.93		0.716	1.086	1.793	1.928	2.239	1.984	1.892
COVID19 (COVID19 (PFIZER-BIONTECH))	Product	1.604	0.784			1.455	1.371	1.847	1.714	2.148	1.586	1.561
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	1.939	1.351	0.898			3.943	1.558	1.745	2.106	1.906	1.763

PSI-HHS-000000057686

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 12 Jan 2022 14:26:20 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220107.xls

FYI.

From: Menschik, David <[redacted]>
Sent: Wednesday, January 12, 2022 9:04 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 1/7/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022(0)	Serious EB05 2022	Fatal EB05 2022(0)	Infant EB05 2022(0)	Child EB05 2022(0)	Teen EB05 2022(0)	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022(0)	Female EB05 2022	Male EB05 2022(0)	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.586	1.763	0.908			0.484	1.605	1.978	2.063	2.771	1.886	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.254	1.774	0.884				1.735	2.222	2.202	3.081	1.545	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.032	1.332	0.977			0.461	1.417	1.949	1.843	2.328	1.639	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.91	0.941	0.875			0.523	0.942	0.843	0.648	2.608	1.505	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.02	1.054	0.881				0.954	0.772	0.772	1.688	1.486	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.954	1.34	0.901				1.502	1.423	1.684	2.25	1.253	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.742	2.011	0.907			0.491	2.296	2.012	2.581	3.966	1.482	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.257	1.641	0.872				1.953	1.879	1.21	2.413	1.469	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.484	1.78	0.896			0.43	1.626	2.38	2.354	2.713	1.966	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.769	1.422	0.886			0.378	1.212	2.235	1.202	2.132	1.297	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.309	0.823	0.999			0.595	0.804	1.068	1.925	2.088	1.8	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.243	1.544	0.953	0.612		0.435	1.84	1.985	2.33	2.778	1.628	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.145	1.923	0.881				0.875	2.192	1.425	2.015	1.528	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.478	1.168	0.872				1.146	1.146	1.046	2.49	0.938	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.921	1.518	0.881	0.61		0.34	1.221	2.485	1.76	2.398	1.327	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.777	1.5	0.883	0.609		0.384	1.265	2.253	1.726	2.173	1.319	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.78	1.316	0.883			0.364	1.485	1.858	1.734	2.184	1.372	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.921	1.448	0.898			0.415	1.459	2.186	1.898	2.311	1.522	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.976	1.503	0.918			0.461	1.368	2.252	1.972	2.364	1.461	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.371	2.505	0.886			0.505	1.897	2.477	0.785	4.371	1.101	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.84	1.44	0.918			0.284	1.231	1.972	1.703	2.443	1.193	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.676	1.25	0.899			0.548	1.237	1.481	2.031	1.874	1.193	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.725	1.595	0.87			0.243	1.471	2.011	1.316	2.151	0.923	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.828	1.251	0.871				1.138	2.027	1.642	2.102	1.536	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2	1.433	1.28				1.659	2.063	1.988	2.297	1.878	
COVID19 (COVID19 (JANSSEN))	CSF immunoglobulin increased	2.037	1.701					0.953	1.431	0.545	0.89	1.585	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.788	2.199	0.966				1.627	3.007	1.976	2.487	2.319	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.344	1.707	0.916			0.519	1.841	1.875	1.47	3.388	1.073	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	3.011	2.042	0.906			0.527	1.474	1.308	1.242	4.161	0.919	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.29	1.656	0.873				1.075	1.304	1.426	2.867	1.2	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.31	2.267	0.917			0.524	2.414	2.295	0.883	3.94	1.216	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.613	1.803	0.946	0.611		0.631	2.291	2.324	2.141	3.342	1.72	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.013	1.394	0.898			0.384	1.674	2.064	1.762	2.261	1.486	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.074	1.467	0.916			0.465	1.431	2.072	1.986	2.344	1.62	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.607	1.789	0.909			0.462	2.181	2.288	2.995	3.205	2.01	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.737	1.319	0.884				1.281	2.145	1.496	2.052	1.223	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.768	1.35	0.877	0.61		0.314	1.326	2.022	1.526	1.982	1.316	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.838	0.879			1.13	2.002	1.466	0.976	1.854	1.415	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.286	1.253	0.878			0.379	2.192	2.148	1.903	2.531	1.673	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.14	1.444	0.926	0.612		0.333	1.657	2.27	2.193	2.438	1.573	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.969	1.037	0.87			0.441	1.673	2.062	0.8	2.139	1.329	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.313	1.101	0.883			0.411	2.293	1.763	1.294	2.488	1.57	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.676	1.366	0.866			0.405	1.415	1.506	1.693	2.246	1.215	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.847	1.279	0.89				1.482	1.297	1.423	2.293	1.103	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.313	1.845	0.87				1.534	2.894	1.661	2.173	2.178	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.88	1.388	0.896	0.607		0.441	1.377	2.078	1.844	2.287	1.444	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.783	1.306	0.901	0.608		0.331	1.431	2.028	1.68	2.121	1.43	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.616	3.655	0.89				4.039	5.261	5.872	7.242	2.97	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.469	5.593	0.872			0.565	4.729	5.913	6.761	7.748	2.989	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.869	1.333	0.922				1.577	1.987	1.767	2.317	1.582	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.111	1.852	0.874			0.027	1.986	2.574	1.428	2.292	1.703	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.858	1.424	1.044			0.033	1.437	2.038	2.058	2.241	1.529	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.867	1.346	0.888	0.747		0.409	1.651	2.019	1.492	2.494	1.319	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.017	1.395	0.878				1.472	2.129	0.99	2.237	1.315	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.046	1.843	0.875				1.511	1.197	0.719	2.903	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.905	1.425	0.867				1.213	2.176	1.07	1.72	1.671	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.047	1.769					0.962	2.635	1.096	1.704	1.768	
COVID19 (COVID19 (JANSSEN))	Lymphocyte count decreased	1.561	1.142	0.872			0.209	1.092	1.767	1.524	2.003	1.067	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.667	1.282	0.894			0.195	1.057	2.066	1.92	2.134	1.254	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.405	1.146	0.894	0.608			1.034	1.546	1.141	2.03	0.7	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.14	1.615	0.887			0.484	1.862	1.908	2.175	2.448	1.808	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.135	1.52	0.906	0.612		0.462	1.221	2.243	1.917	2.444	1.379	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.616	1.215	0.879			0.334	1.026	2.004	1.292	1.951	0.905	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.882	1.451	0.902			0.349	1.29	2.302	1.506	2.202	1.354	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.076	1.508	0.974			0.486	1	2.218	1.752	1.905	1.889	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.59	1.297	0.893	0.61		0.275	0.941	2.062	2.041	2.407	1.087	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.551	1.264	0.875			0.183	1.239	1.748	1.446	2.262	0.885	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.724	1.319	0.896			0.251	1.143	2.083	1.861	2.037	1.382	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.194	0.724					0.782	0.611		1.958	1.068	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	0.324	0.875			7.692	1.229	1.133	0.821	1.372	1.933	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.755	0.759					3.265	1.063		2.213		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.525	0.86				0.514	1.675	2.155	1.114	2.448	1.431	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.068	1.567	0.872				0.657	1.063	1.688	2.714	0.955	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.773	2.351	0.92	0.611		0.475	1.84	3.063	2.592	3.173	1.793	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.669	1.366	0.896	0.609		0.3	1.551	2.113	1.546	2.198	1.491	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.723	2.031	0.888			0.393	2.065	2.944	2.295	3.325	1.72	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.063	3.504	0.872				4.529	3.85	0.818	6.295	2.64	
COVID19 (COVID19 (JANSSEN))	Post-vitamin K administration	1.388					0.888	2.13	3.218	3.917	4.881	4.888	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.755	1.288	0.885	0.611		0.365	1.416	1.676	1.59	2.008	1.356	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.025	1.587	0.918	0.746		0.339	1.575	2.439	1.647	2.64	1.514	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.224	1.604	1.537	0.613		0.59	1.716	2.065	2.85	2.504	1.827	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.047	1.524	0.896				1.711	1.593	1.851	1.964	1.817	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.883	1.374	0.896	0.608		0.566	1.451	2.114	1.732	2.127	1.563	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.027	1.426	0.904	0.611		0.348	1.286	2.289	1.806	2.373	1.453	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.4	1.396	0.877			0.532	1.731	1.962	1.379	2.348	1.707	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.229	2.389	1.145			0.531	2.35	2.478	1.216	2.682	3.094	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.031	6.781	0.872			0.646	3.583	6.659	15.657	7.795	5.822	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.388							0.637	0.572	0.568	1.919	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.148	1.558	0.887			0.511	1.451	1.832	1.485	2.308	1.349	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.333	1.892	0.937			0.38	1.675	2.485	1.815	2.588	1.781	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.673	2.104	1.734	0.612		0.656	1.956	2.399	3.506	2.651	2.214	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.41	2.188	0.885				1.182	0.766		1.874	0.681	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.254	1.844	0.872				1.883	1.208	0.637	2.147	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.402	1.441	0.894			0.447	1.886	2.223	2.379	2.797	1.719	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.748	1.882	0.918	0.612		0.525	2.417	2.268	2.94	3.288	2.105	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.527	1.752	0.900			0.447	2.175	2.017	2.035	2.48	1.879	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.884	1.124	0.873				1.261	2.083	1.763	1.966	1.298	
COVID19 (COVID19 (JANSSEN))	Urine ketone body present	1.638	1.197	0.883	0.611		0.278	1.096	1.718	1.577	2.024	0.933	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.206	2.512			0.527	1.356	2.821	6.205	2.211	2.309	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.722	1.241	0.936			0.464	0.943	1.213	2.05	1.613	1.469	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.036	0.87					0.895	1.633	0.965	1.828	1.04	
COVID19 (COVID19 (JANSSEN))	Venogram	2.414	1.938	0.869				2.145	1.701	0.714	2.938	1.05	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.942	2.269				0.604	2.82	1.766	0.677	3.872	1.192	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.113	2.309	0.875				3.944	2.101	0.836	5.041	1.208	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.734	1.304	0.87			0.204	1.61	1.554	1.729	2.015	1.251	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.378	0.836		7.538	0.937		1.218	0.513		1.333	0.923	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.39	0.945	0.866	0.505	0.53	2.381	0.771	0.589	0.39	0.631	0.597	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.368	0.931	0.875	3.012	2.533	0.09	0.061	0.394	2.457	2.525		
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.052	2.044	0.871			2.328	2	1.948	1.569	1.3	2.11	
COVID19 (COVID19 (PFIZER-	Body height	1.946	1.016	0.875			0.888	0.944	1.398	2.219	1.997	1.923	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.071	0.872			0.691	1.469	1.885	1.926	1.997	1.529	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.761	1.682		0.562	1.033	1.734	1.745	1.816	2.027	1.968	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.761	0.847	0.875	17.944			0.402			0.458	1.346	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.591	0.892		1.28	1.237	1.74	1.58	2.293	2.058	1.845	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.743	0.897		0.608	1.068	1.777	1.94	2.289	2.105	1.937	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	0.752			1.628	1.398	1.891	1.768	2.285	1.711	1.649	
COVID19 (COVID19 (PFIZER-	Weight	2.021	1.349	0.885			0.882	1.528	1.739	2.202	2.003	1.773	

PSI-HHS-000000057688

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 7 Dec 2021 13:12:47 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211203.xls

Hi Elaine,

FYI.

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, December 7, 2021 6:23 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 12/3/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.22	1.812	0.905			0.598	1.601	2.067	1.97	2.924	1.634	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.227	1.758	0.86				1.681	2.217	2.081	2.98	1.497	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.001	1.333	0.978			0.457	1.361	1.931	1.84	2.292	1.846	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.965	0.901	0.88			0.52	0.998	0.865	0.677	2.508	1.555	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.047	1.007	0.896				0.954	0.715	0.812	1.631	1.448	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.946	1.325	0.906				1.478	1.393	1.628	2.384	1.126	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.972	2.158	0.902			0.493	2.377	2.1	3.242	4.282	1.494	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.212	1.67	0.881				1.924	1.89	1.14	2.415	1.446	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.501	1.859	0.906			0.427	1.713	2.412	2.418	2.748	2.047	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.816	1.498	0.898			0.371	1.192	2.322	1.155	2.17	1.305	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.307	0.949	0.878			0.599	0.884	1.773	2.095	2.191	1.898	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.585	0.954	0.612		0.433	1.864	1.987	2.407	2.787	1.846	
COVID19 (COVID19 (JANSSEN))	Anoxia	2.117	1.94	0.887				0.897	2.063	1.461	2.013	1.52	
COVID19 (COVID19 (JANSSEN))	Antiphospholipid antibody abnormal	1.978	1.27	0.879				1.398	1.172	1.849	2.944	0.918	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.919	1.551	0.891	0.61		0.332	1.206	2.547	1.672	2.371	1.298	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.811	1.564	0.893	0.609		0.298	1.208	2.336	1.634	2.18	1.332	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.806	1.307	0.889			0.336	1.533	1.873	1.831	2.111	1.376	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.98	1.482	0.904			0.403	1.487	2.263	1.873	2.31	1.554	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.093	1.574	0.915			0.456	1.416	2.371	1.942	2.443	1.464	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.51	2.567	0.892			0.505	1.869	2.604	0.797	4.477	1.129	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen increased	1.818	1.583	0.886			0.333	1.051	2.102	0.954	1.668	1.323	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.917	1.536	0.916			0.279	1.222	2.138	1.646	2.533	1.207	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.803	1.661	0.877			0.231	1.421	2.222	1.454	2.198	1.98	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.815	1.232	0.889				1.109	2.027	1.564	1.993	1.544	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.977	1.393	1.367				1.438	2.026	1.9	2.186	1.819	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.737	2.191	0.877				1.806	2.928	1.113	2.379	2.304	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.04	1.766	0.878				1.304	1.67	1.113	1.691	1.907	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.333	1.829	0.922			0.52	1.94	1.902	1.532	3.557	1.114	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.606	1.916	0.911			0.534	1.228	1.333	1.09	3.261	0.964	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.164	1.446	0.878				1.13	1.23	1.331	2.674	1.014	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.255	2.289	0.916			0.521	2.252	2.341	0.814	3.916	1.173	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.676	1.889	0.947	0.611		0.636	2.426	2.412	2.206	3.511	1.768	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.068	1.421	0.902			0.384	1.687	2.067	1.777	2.311	1.515	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.109	1.577	0.917			0.461	1.454	2.133	2.149	2.446	1.674	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.613	1.834	1.007			0.458	2.143	2.253	3.139	3.247	2.014	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.839	1.454	0.896				1.273	2.34	1.607	2.15	1.272	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.717	1.356	0.888	0.61		0.384	1.259	2.09	1.48	1.938	1.31	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.778	0.834	0.886			1.142	2.009	1.474	1.01	1.868	1.425	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.255	1.323	0.885			0.373	2.23	2.131	2.1	2.558	1.719	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.762	1.488	0.925	0.611		0.329	1.718	2.333	2.765	2.531	1.544	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.965	1.024	0.876			0.429	1.704	1.964	0.742	2.155	1.259	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.287	1.037	0.887			0.402	2.333	1.749	1.119	2.488	1.495	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.903	1.307	0.882			0.4	1.436	1.583	1.564	2.111	1.202	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.862	1.318	0.891				1.323	1.378	1.376	2.27	1.106	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.312	1.859	0.878				1.42	2.901	1.714	2.158	2.156	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.807	1.349	0.811	0.607		0.429	1.407	2.113	1.788	2.22	1.498	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.775	1.315	0.91	0.607		0.321	1.457	2.04	1.647	2.104	1.43	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.663	3.712	0.896				3.981	5.112	6.755	7.134	3.152	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.896	5.654	0.88			0.544	5.224	5.739	6.772	7.673	3.102	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.842	1.305	0.915				1.427	1.964	1.722	2.263	1.522	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.099	1.916	0.883			0.022	1.933	2.634	1.583	2.248	1.743	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.844	1.422	1.063			0.03	1.432	2.012	2.066	2.272	1.452	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.898	1.36	0.898	0.746		0.468	1.659	2.079	1.446	2.524	1.304	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.013	1.329	0.884				1.402	2.067	1.017	2.208	1.256	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.113	1.906	0.882				1.564	1.198	0.729	2.974	0.744	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.899	1.469	0.876				1.232	2.18	1.101	1.707	1.718	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.046	1.776					0.955	2.544	1.138	1.557	1.89	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.666	1.28	0.904			0.187	1.044	2.096	1.87	2.095	1.238	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.107	1.693	0.905			0.469	1.629	1.902	2.279	2.514	1.506	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.173	1.577	0.91	0.611		0.458	1.269	2.505	1.72	2.444	1.432	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.651	1.241	0.886			0.337	1.034	2.068	1.214	1.912	0.988	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.886	1.427	0.901			0.34	1.212	2.328	1.406	2.218	1.297	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.048	1.473	0.949			0.484	1.012	2.116	1.698	1.951	1.74	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.586	1.322	0.899	0.61		0.285	0.971	2.09	1.933	2.377	1.087	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.598	1.327	0.884			0.15	1.248	1.792	1.475	2.286	1.91	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.736	1.322	0.902			0.244	1.151	2.099	1.827	2.002	1.384	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.159	0.725					0.761	0.61		1.605	0.896	
COVID19 (COVID19 (JANSSEN))	Off label use	1.339	0.239	0.88			5.71	0.275	0.394	0.324	0.842	1.265	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.783	0.758					3.122	1.003		2.17		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.535	0.868				0.511	1.687	2.362	1.142	2.558	1.424	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.211	1.633	0.878				0.656	1.064	1.883	2.637	0.962	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.779	2.485	0.922	0.61		0.469	1.841	3.139	2.199	3.138	1.896	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.868	1.407	0.906	0.609		0.291	1.591	2.125	1.511	2.209	1.49	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.734	2.006	0.894			0.388	2.038	3.081	2.23	3.387	1.704	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.06	3.906	0.86				4.466	3.609	0.662	6.243	1.624	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.304					0.864	4.059	3.449	6.226	4.576	4.014	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.098	1.624	0.923	0.745		0.331	1.587	2.485	1.629	2.696	1.497	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.234	1.648	1.391	0.612		0.386	1.796	3.137	2.712	2.88	1.886	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.067	1.549	0.894				1.574	1.563	1.919	1.947	1.732	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.902	1.398	0.901	0.608		0.53	1.479	2.18	1.69	2.111	1.595	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.057	1.448	0.908	0.61		0.562	1.515	2.323	1.759	2.468	1.384	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.407	1.405	0.884			0.535	1.612	1.963	1.482	2.383	1.707	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.228	2.569	1.694			0.529	1.899	2.279	1.19	2.68	3.049	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.025	6.788	0.88			0.645	3.256	6.698	15.886	7.887	6.915	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.378							0.635	0.572	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.164	1.587	0.899			0.515	1.446	1.664	1.338	2.137	1.411	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.36	1.865	0.934			0.375	1.719	2.462	1.795	2.662	1.776	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.677	2.121	1.779	0.612		0.655	1.963	2.387	3.449	2.808	2.181	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	2.264	1.286	0.884				0.955	0.766		1.237	1.68	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.216	1.806	0.875				1.779	1.208	0.641	2.084	0.908	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.407	1.464	0.899			0.645	1.912	2.193	2.464	2.781	1.726	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	1.914	0.908	0.612		0.527	2.328	2.291	2.971	3.226	2.135	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.515	1.733	0.898			0.446	2.318	2.023	1.826	2.484	1.894	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.888	1.097	0.881				1.27	2.001	1.73	1.984	1.237	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.843	1.207	0.882	0.611		0.315	0.868	2.079	1.301	1.837	1.054	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.337	1.169	2.604			0.531	1.249	2.605	5.621	2.058	2.199	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.714	1.329	0.943			0.466	0.92	1.242	2.094	1.544	1.53	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.054	0.876					0.915	1.599	0.984	1.823	1.053	
COVID19 (COVID19 (JANSSEN))	Venogram	2.447	1.945	0.878				2.105	1.662	0.72	2.861	1.914	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.086	2.341				0.605	2.884	1.786	0.694	3.974	1.216	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.171	2.376	0.883				3.971	1.972	0.848	5.104	1.226	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	0.833		7.911	0.896		1.219	0.511		1.33	0.941	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.884	0.878		0.655	2.123	0.754	0.569	0.377	0.602	0.572	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.263	0.932	0.886		3.714	2.753	0.106	0.095	0.498	2.414	2.485	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.055	2.011	0.879			2.295	2.008	1.948	1.567	1.891	2.11	
COVID19 (COVID19 (PFIZER-	Body height	1.944	1.019	0.883			0.593	0.944	1.362	2.211	1.924	1.508	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.045	1.059	0.86			0.665	1.306	1.677	1.951	2.012	1.536	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.28	1.732	1.513		0.51	1.011	1.712	1.781	1.866	2.036	1.983	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.791	0.846	0.882	17.898			0.401			0.458	1.327	
COVID19 (COVID19 (PFIZER-	Immunisation	1.742	1.394	0.889		0.897	1.193	1.491	1.704	2.079	1.995	1.019	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.728	0.902			1.06	1.762	1.96	2.347	2.123	1.969	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	0.752			1.723	1.34	1.867	1.746	2.282	1.757	1.721	
COVID19 (COVID19 (PFIZER-	Weight	2.02	1.312	0.86			0.897	1.537	1.736	2.196	1.998	1.763	

PSI-HHS-000000057690

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 24 May 2022 12:57:21 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220520.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, May 24, 2022 6:43 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/20/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20220201	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	05 20
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.066	1.532	0.99			0.378	1.486	1.887	2.027	2.733	1.376	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.07	1.538	0.883				1.583	2.044	1.983	2.727	1.411	
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.067	1.33	0.99				0.79	1.679	1.832	1.61	1.925	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.107	1.326	1.017			0.454	1.458	2.046	1.991	2.45	1.747	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.339	0.974	0.886			0.527	0.969	0.735	0.679	2.615	1.478	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.59	1.092	0.894				0.871	0.852	0.786	1.877	1.681	
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.232	1.904					1.305	1.411		0.907	1.625	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.92	1.291	0.908				1.452	1.459	1.669	2.143	1.295	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.558	1.806	0.914			0.488	2.402	1.948	2.082	3.438	1.508	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.066	1.383	0.886				1.779	1.75	1.283	2.211	1.405	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.309	1.631	0.916			0.414	1.631	2.265	2.225	2.471	1.973	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.813	1.37	0.91			0.364	1.117	2.234	1.464	2.128	1.339	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.116	0.823	0.883			0.569	0.79	1.58	1.905	2.003	1.658	
COVID19 (COVID19 (JANSSEN))	Antineoplastic therapy	2.177	1.483	0.873	0.618		0.618	1.84	2.008	2.236	2.762	1.897	
COVID19 (COVID19 (JANSSEN))	Application site pain	2.004						0.56	0.636	0.678	1.038	0.765	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.128	1.709	0.901				0.947	2.418	1.338	2.315	1.433	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.847	1.163	0.89				1.213	1.231	1.419	2.334	0.983	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.884	1.391	0.931	0.516		0.36	1.179	2.251	1.858	2.325	1.348	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.798	1.413	0.947	0.515		0.256	1.126	2.313	1.827	2.183	1.353	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.821	1.268	0.93			0.306	1.485	1.847	1.755	2.168	1.404	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.875	1.352	0.954			0.374	1.361	2.103	1.893	2.15	1.516	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.823	1.309	0.953			0.467	1.232	2.027	1.872	2.151	1.359	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.861	2.186	0.897			0.592	1.75	2.176	0.881	4.064	1.036	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.804	1.3	0.926			0.174	1.077	1.976	1.751	2.357	1.221	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.704	1.217	0.938			0.513	1.254	1.522	2.025	1.891	1.245	
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.824	1.305	0.905	0.516			1.35	2.005	1.736	1.951	1.594	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.648	1.319	0.895			0.085	1.36	1.936	1.216	2.008	0.869	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.898	1.296	0.914				1.041	2.059	1.78	2.127	1.62	
COVID19 (COVID19 (JANSSEN))	Brain oedema	1.576	1.259	0.929				1.196	1.59	0.602	2.006	0.804	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.224	1.411	1.083				1.893	2.202	2.042	2.401	1.985	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.589	2.014	0.883				1.848	2.99	1.003	2.508	2.162	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.215	1.576	0.938			0.524	1.713	1.865	1.507	3.311	1.155	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.819	1.972	0.926			0.532	1.385	1.701	1.165	3.938	1.141	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.666	1.736	0.887				1.471	1.363	1.623	3.601	1.264	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.304	2.149	0.919			0.528	2.504	2.348	0.879	3.871	1.226	
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.873	1.282	0.961			0.331	1.341	1.895	1.905	2.11	1.609	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.444	1.656	0.954	0.518		0.699	2.144	2.313	2.036	3.053	1.727	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.994	1.333	0.918			0.378	1.724	1.967	1.835	2.273	1.519	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.001	1.395	0.927			0.458	1.388	2.047	2	2.244	1.675	
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	2.049	1.289	0.89				0.498	0.897	2.023	1.091	1.856	
COVID19 (COVID19 (JANSSEN))	Death	1.849	1.17	0.963				1.221	1.627	1.546	2.071	1.526	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.618	1.798	1.032			0.484	2.233	2.265	3.14	3.298	2.044	
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.067	1.375	1.139			0.366	1.423	2.097	1.099	2.117	1.843	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.791	1.303	0.93			0.04	1.244	2.042	1.755	2.068	1.353	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.803	1.361	0.94	0.516		0.271	1.27	2.063	1.776	2.071	1.412	
COVID19 (COVID19 (JANSSEN))	Fasting void	1.794	0.899	0.896			1.198	2.023	1.484	0.668	1.847	1.487	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.266	1.278	0.901			0.442	2.186	2.152	1.964	2.538	1.884	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.139	1.453	0.886	0.519		0.295	1.726	2.289	2.21	2.5	1.832	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.939	1.08	0.887			0.437	1.696	1.973	1.03	2.165	1.29	
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.089	1.438		0.756			0.654			1.411	1.727	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.224	1.032	0.897			0.405	2.274	17	1.216	2.24	1.589	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.845	1.259	0.907			0.401	1.293	1.723	1.585	2.237	1.2	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.71	1.155	0.91				1.215	1.425	1.341	2.211	1.038	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.483	1.843	0.894			0.438	1.637	3.135	1.637	2.431	2.209	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.892	1.271	0.942	0.512		0.581	1.314	2.036	1.783	2.175	1.425	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.761	1.239	0.937	0.513		0.393	1.384	1.967	1.674	2.092	1.417	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.709	3.612	0.901				4.186	5.521	4.283	7.268	3.37	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.144	3.303	0.884			0.554	4.212	5.727	6.739	7.055	2.479	
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.062	1.331	0.901				1.004	2.067	1.903	2.403	1.666	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.077	1.725	0.882			0.011	1.927	2.557	1.397	2.241	1.713	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.937	1.393	1.057			0.022	1.434	2.161	2.071	2.342	1.577	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.767	1.209	0.893	0.754		0.284	1.53	1.92	1.437	2.286	1.258	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.916	1.215	0.893				1.384	2.026	0.979	2.093	1.246	
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.624	1.752	0.911				0.84	1.403	0.993	3.709	1.597	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.831	1.448	0.888				1.573	1.125	0.711	2.344	0.712	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.882	1.362	0.878				1.28	2.198	1.011	1.671	1.762	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.149	1.705					1.122	2.841	1.028	1.777	1.822	
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.993	1.287	0.948				1.407	1.733	1.991	2.359	1.521	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.685	1.231	0.931			0.191	0.999	2.074	1.859	2.058	1.308	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.061	1.47	0.917			0.474	1.77	1.877	2.127	2.341	1.592	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.023	1.366	0.938	0.519		0.441	1.229	2.191	1.827	2.338	1.374	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.887	1.255	0.924			0.295	1.135	1.92	1.492	2.054	0.976	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.874	1.326	0.915			0.316	1.154	2.379	1.61	2.099	1.421	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.283	1.523	1.013			0.482	1.191	2.289	2	2.117	2.035	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.933	1.223	0.921	0.516		0.21	0.946	1.932	1.965	2.14	1.126	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.52	1.198	0.896			0.319	1.092	1.626	1.671	2.173	0.849	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.729	1.285	0.932			0.249	1.108	2.08	1.801	1.981	1.411	
COVID19 (COVID19 (JANSSEN))	Neutrophil count	1.697	0.795					0.715	0.815		2.397	1.378	
COVID19 (COVID19 (JANSSEN))	Off label use	2.041	0.592	0.896			0.186	1.193	1.353	0.961	1.468	2.024	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.785	0.755					3.449	0.983		2.288		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.229	0.881				0.516	1.506	2.222	1.106	2.11	1.441	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.056	1.359	0.885				0.657	1.034	1.541	2.253	0.951	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.665	2.176	0.918	0.518		0.478	1.841	2.859	2.75	3.047	1.786	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.869	1.31	0.921	0.514		0.281	1.444	2.161	1.655	2.238	1.471	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.554	1.812	0.902			0.45	2.085	2.751	2.13	3.139	1.682	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.789	3.287	0.886				4.298	4.662	0.805	5.733	2.267	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.326					0.879	1.98	1.357	1.452	2.05	2.07	
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.075	1.427	0.887				0.859	1.647	1.027	2.027	1.268	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.08	1.297	0.955				1.013	2.101	1.677	2.253	1.821	
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.767	0.833	0.886		0.719	2.059	0.04	0.002	0.515	1.666	1.828	
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.176	1.306					5.046			5.15		
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.932	1.394	0.94	0.754		0.297	1.443	2.315	1.653	2.486	1.455	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.244	1.586	1.066	0.519		0.589	1.78	2.068	2.627	2.518	1.911	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.205	1.477	0.906				1.766	1.63	1.919	2.16	1.993	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.805	1.274	0.926	0.513		0.562	1.348	2.004	1.669	2.034	1.505	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.949	1.309	0.932	0.517		0.286	1.276	2.113	1.793	2.275	1.418	
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.368	1.003					2.702	0.506		1.08	1.75	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.585	1.737	0.893			0.537	1.774	1.988	1.822	2.574	1.817	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.464	2.229	1.588			0.527	3.219	3.334	1.219	2.913	3.46	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.547	6.757	0.886			0.653	3.621	6.584	14.798	7.71	5.715	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.674							0.637	0.569	0.561	1.026	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.968	1.335	0.896			0.512	1.438	1.515	1.477	2.098	1.343	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.259	1.753	0.952			0.368	1.618	2.433	1.907	2.512	1.811	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.961	2.122	1.743	0.519		0.729	1.992	2.404	3.622	2.973	2.377	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	5.975	2.903	0.902				2.145	5.476	0.562	5.586	1.822	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.051	1.526	0.886				1.784	1.231	0.623	2.133	0.879	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.302	1.444	0.913			0.716	1.915	2.224	2.172	2.695	1.745	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.708	1.838	0.961	0.519		0.528	2.472	2.295	2.872	3.308	2.112	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.378	1.84	0.92			0.43	2.189	2.01	2.021	2.484	1.826	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.998	1.085	0.909			0.491	1.065	2.093	2.202	2.391	2.519	
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.921	0.894					1.252	1.373	0.788	2.092	0.816	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.114	0.906	0.884				0.975	1.579	1.134	1.851	1.112	
COVID19 (COVID19 (JANSSEN))	Venogram	2.349	1.795	0.883				2.021	16	0.705	2.556	1.963	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.709	2.031				0.611	2.685	1.628	0.665	3.334	1.199	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.942	2.226	0.89				3.661	2.061	1.062	4.887	1.198	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.46	0.824		10.43	0.909		1.286	0.52		1.461	1.06	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.671	0.983	0.885	0.909	1.023	2.454	1.786	0.64	0.425	0.674	0.835	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.058	1.142				0.661	2.087	1.544	0.839	2.002	1.953	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.537	1.017	0.895	0.467	5.969	2.977	0.145	0.066	0.354	2.544	2.638	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.145	2.034	0.883			2.793	2.047	1.996	1.584	1.978	2.188	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.111	1.671	0.896			0.637	1.631	1.753	1.533	1.911	1.897	
COVID19 (COVID19 (PFIZER-	Body height	1.948	0.992	0.886		0.482	0.695	0.957	1.442	2.176	1.912	1.546	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.005	1.745	1.044	0.753	0.606	1.119	1.736	1.777	1.772	1.82	1.809	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.857	0.856	0.886	10.519			0.363			0.503	1.241	
COVID19 (COVID19 (PFIZER-	Immunisation	2.052	1.658	0.918		1.287	1.243	1.801	1.98	2.26	1.982	1.842	
COVID19 (COVID19 (PFIZER-	Investigation	2.032	1.75	0.926		0.718	1.086	1.795	1.924	2.239	1.983	1.892	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.601	0.785			1.457	1.389	1.847	1.711	2.139	1.585	1.558	
COVID19 (COVID19 (PFIZER-	Weight	1.942	1.367	0.898			0.943	1.558	1.742	2.097	1.901	1.759	

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 28 Jun 2022 14:40:29 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220624.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, June 28, 2022 6:49 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Sorry – forgot attachment

From: Menschik, David
Sent: Tuesday, June 28, 2022 6:48 AM
To: Shimabukuro, Tom (CDC) <[redacted]>; Su, John (CDC) <[redacted]>; Moro, Pedro L (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani, Meghna <[redacted]>; Broder, Karen R (CDC) <[redacted]>; Mcneil, Michael M (CDC) <mmm2@cdc.gov>; Lale, Allison (CDC) <[redacted]>
Subject: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/24/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20220624	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 20220	Adult1 EB05 20220	Adult2 EB05 20220	Adult3 EB05 20220	Female EB05 2022	Male EB05 20220624
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.998	1.457	0.922			0.378	1.481	1.83	1.846	2.683	1.355
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.019	1.486	0.873				1.539	1.975	1.975	2.664	1.375
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.023	1.268	0.973				0.779	1.674	1.743	1.588	1.847
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.117	1.318	1.021			0.45	1.522	2.063	1.995	2.437	1.773
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.385	0.966	0.885			0.522	0.953	0.701	0.676	2.628	1.443
COVID19 (COVID19 (JANSSEN))	Adverse event	2.636	1.09	0.891				0.864	0.967	0.835	1.895	1.714
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.02	1.751					1.234	1.368		0.887	1.561
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.969	1.26	0.906				1.472	1.441	1.673	2.092	1.319
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.507	1.763	0.909			0.485	2.324	1.924	2.054	3.298	1.515
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.068	1.367	0.884				1.781	1.78	1.23	2.156	1.473
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.29	1.605	0.908			0.406	1.694	2.229	2.181	2.451	1.962
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.783	1.333	0.909			0.355	1.146	2.144	1.468	2.098	1.323
COVID19 (COVID19 (JANSSEN))	Antibody test	2.162	6.824	0.879			0.566	0.865	1.561	2.126	2.058	1.885
COVID19 (COVID19 (JANSSEN))	Antiepileptic therapy	2.18	1.587	0.87	0.618		0.512	1.68	2.019	2.063	2.747	1.873
COVID19 (COVID19 (JANSSEN))	Application site pain	2.008						0.561	0.635	0.678	1.037	0.764
COVID19 (COVID19 (JANSSEN))	Areflexia	2.049	1.647	0.9				0.967	2.226	1.309	2.138	1.423
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.798	1.132	0.885				1.203	13	1.398	2.156	0.983
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.831	1.342	0.928	0.617		0.351	1.12	2.18	1.862	2.273	1.311
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.75	1.361	0.935	0.516		0.341	1.099	2.224	1.782	2.151	1.318
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.822	1.264	0.928			0.354	1.505	1.842	1.749	2.173	1.41
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.86	1.334	0.948			0.405	1.364	2.068	1.877	2.178	1.508
COVID19 (COVID19 (JANSSEN))	Blood chloride decreased	1.854	1.239	0.917				1.118	2	1.58	1.908	1.587
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.79	1.283	0.952			0.502	1.242	1.983	1.83	2.125	1.332
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	1.961	1.246	0.878			0.576	0.929	2.157	0.569	1.698	1.211
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.686	2.122	0.896			0.498	1.741	2.031	0.87	3.927	1.026
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.782	1.274	0.923			0.176	1.116	1.904	1.743	2.316	1.223
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.668	1.265	0.936			0.106	1.249	1.463	2.02	1.888	1.223
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.828	1.301	0.896	0.616			1.372	2.063	1.738	1.951	1.603
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.632	1.086	0.923				1.707	1.335	1.171	2.021	1.01
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.662	1.326	0.88			0.284	1.398	1.942	1.246	2.021	0.911
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.901	1.252	0.913			0.353	1.088	2.055	1.775	2.089	1.654
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.238	1.401	1.074				1.885	2.245	2.057	2.422	2.001
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.677	1.987	0.875				1.857	3.015	0.884	3.53	2.149
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.235	1.587	0.94			0.521	1.774	1.828	1.499	3.34	1.173
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.759	1.95	0.923			0.529	1.38	1.629	1.259	3.792	1.191
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.716	1.738	0.884				1.468	1.357	1.63	3.624	1.27
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.357	2.172	0.918			0.524	2.579	2.441	0.872	3.924	1.272
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.866	1.268	0.951			0.378	1.354	1.875	1.9	2.078	1.622
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.411	1.623	0.958	0.618		0.598	2.125	2.261	2.03	2.991	1.714
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.977	1.323	0.912			0.436	1.721	1.945	1.796	2.255	1.511
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.062	1.381	0.925			0.527	1.406	2.044	1.98	2.243	1.683
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	1.976	1.265	0.886				0.495	0.866	2.111	1.047	1.731
COVID19 (COVID19 (JANSSEN))	Death	1.673	1.17	0.901				1.226	1.633	1.562	2.065	1.551
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.65	1.804	1.053			0.481	2.273	2.292	3.207	3.307	2.087
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.034	1.342	1.094			0.558	1.429	2.066	1.859	2.079	1.821
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.778	1.28	0.886			0.25	1.208	2.038	1.734	2.061	1.38
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.76	1.318	0.931	0.616		0.371	1.213	2.031	1.746	2.047	1.371
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.756	6.841	0.889			1.181	2.021	1.454	0.972	1.851	1.421
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.093	1.372	0.897			0.503	2.168	2.138	1.94	2.517	1.699
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.136	1.443	0.878	0.619		0.395	1.705	2.285	2.216	2.511	1.623
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.938	1.06	0.884			0.435	1.624	2.036	1.027	2.197	1.271
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.33	1.443		0.757			0.675			1.64	1.845
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.214	1.031	0.896			0.402	2.305	1.665	1.213	2.213	1.604
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.864	1.27	0.91			0.394	1.272	1.751	1.619	2.227	1.249
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.778	1.158	0.906				1.225	1.449	1.363	2.175	1.086
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.463	1.823	0.892			0.435	1.617	3.062	1.627	2.398	2.173
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.765	1.265	0.943	0.613		0.527	1.329	2.002	1.774	2.154	1.432
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.751	1.229	0.933	0.613		0.422	1.406	1.93	1.666	2.073	1.419
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.707	3.606	0.896				4.176	3.513	4.344	7.456	3.37
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.143	3.294	0.881			0.55	4.201	5.724	0.739	7.042	2.483
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.076	1.313	0.958			0.416	1.468	2.085	1.932	2.448	1.69
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.097	1.731	0.881			0.611	1.941	2.577	1.378	2.208	1.756
COVID19 (COVID19 (JANSSEN))	Intensive care	1.994	1.394	1.062			0.657	1.476	2.117	2.068	2.343	1.805
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.749	1.195	0.883	0.755		0.377	1.525	1.871	1.425	2.287	1.249
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.945	1.249	0.86				1.382	2.056	1.03	2.127	1.27
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.673	1.778	0.91				0.84	1.421	0.994	1.71	1.623
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.802	1.376	0.884				1.37	1.115	0.712	2.298	0.707
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.863	1.347	0.873				1.269	2.176	1.004	1.648	1.757
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.146	1.681					1.116	2.853	1.02	1.752	1.845
COVID19 (COVID19 (JANSSEN))	Lung infiltration	1.83	1.154	0.928			0.61	1.284	1.803	1.398	2.002	1.454
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.964	1.268	0.947				1.446	1.767	1.988	2.35	1.514
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.679	1.225	0.924			0.248	0.997	2.045	1.864	2.08	1.306
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.68	1.487	0.914			0.484	1.798	1.898	2.102	2.312	1.819
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.016	1.358	0.926	0.619		0.503	1.248	2.177	1.815	2.35	1.364
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.719	1.266	0.919			0.359	1.106	1.913	1.523	2.077	1.009
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.818	1.274	0.903			0.378	1.147	2.246	1.521	2.031	1.388
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.268	1.494	1.006			0.475	1.155	2.238	2.041	2.091	2.035
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.813	1.287	0.918	0.616		0.359	0.938	1.998	1.98	2.189	1.105
COVID19 (COVID19 (JANSSEN))	Neonatal dyspnoea	2.392	6.984		0.62						0.874	1.117
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.564	1.193	0.89			0.368	1.107	1.595	1.618	2.107	0.871
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.725	1.269	0.924			0.395	1.095	2.067	1.807	1.979	1.418
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	4.087	6.789					0.744	0.613		3.027	1.076
COVID19 (COVID19 (JANSSEN))	Off label use	2.108	0.66	0.893			0.453	1.235	1.47	1.042	1.524	2.142
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.767	6.751					3.427	0.982		2.243	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.265	6.857				0.512	1.495	2.232	1.036	2.175	1.405
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.084	1.358	0.881				0.657	1.034	1.565	2.265	1.95
COVID19 (COVID19 (JANSSEN))	Platelet count	2.652	2.142	0.916	0.618		0.474	1.863	2.864	2.574	3.014	1.807
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.874	1.301	0.912	0.614		0.333	1.473	2.08	1.664	2.261	1.466
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.54	1.8	0.898			0.448	2.008	2.669	2.141	3.088	1.699
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.759	3.245	0.886				4.284	4.662	0.784	5.648	3.273
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.249	1.651	0.868				0.595	1.966	1.03	2.316	1.304
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.08	1.292	0.954				1.003	2.179	1.691	2.21	1.842
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.759	6.834	0.883		0.693	2.059	0.037	0.002	0.507	1.668	1.814
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.162	1.395					5.058			5.183	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.779	1.218	0.923	0.616		0.325	1.428	1.617	1.714	2.01	1.405
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.969	1.369	0.933	0.754		0.291	1.453	2.263	1.645	2.41	1.44
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.254	1.583	1.045	0.62		0.588	1.81	2.065	2.623	2.521	1.922
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.34	1.513	0.908				1.721	1.726	1.919	2.221	1.923
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.78	1.254	0.927	0.614		0.59	1.349	1.981	1.653	2.095	1.489
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.962	1.314	0.927	0.617		0.381	1.283	2.12	1.805	2.299	1.437
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.328	6.994					2.663	0.506		1.068	0.725
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.553	1.798	0.89			0.53	1.763	2.048	1.756	2.611	1.821
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.378	2.228	1.901			0.618	3.095	3.125	1.118	2.773	3.344
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.561	6.757	0.882			0.651	3.774	6.205	14.647	7.697	5.705
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.709							0.638	0.569	0.562	1.026
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.944	1.315	0.896			0.508	1.45	1.562	1.462	2.087	1.342
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.208	1.705	0.954			0.561	1.006	2.39	1.883	2.498	1.776
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.922	2.127	1.753	0.62		0.732	2.017	2.483	3.607	3.003	2.388
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	6.101	3.019	0.903				3.042	5.735	0.563	5.608	3.38
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	3.516	1.495	0.882				1.776	1.225	0.939	3.111	0.879
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.34	1.431	0.909			0.711	1.89	2.202	2.144	2.648	1.744
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.701	1.822	0.966	0.619		0.522	2.502	2.295	2.835	3.278	2.121
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.139	1.61	0.913			0.424	2.231	1.965	1.95	2.465	1.845
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.606	3.027	2.47			0.554	1.44	2.448	4.096	2.178	2.357
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.913	6.895					1.25	1.374	0.789	2.101	0.809
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.071	6.907	0.881				0.975	1.572	1.125	1.798	1.113
COVID19 (COVID19 (JANSSEN))	Venogram	2.341	1.746	0.88				2.002	16	0.706	2.543	1.964
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.663	2.002				0.608	2.67	1.618	0.659	3.291	1.192
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.879	2.17	0.886				3.632	2	1.068	4.767	1.199
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.465	6.819		10.497	0.872		1.28	0.521		1.458	1.074
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.685	6.993	0.893	0.511	1.599	2.489	0.794	0.557	0.436	0.688	0.646
COVID19 (COVID19 (MODERNA))	Mechanical uricaria	2.028	1.186				0.663	2.05	1.541	0.807	1.97	1.93
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.53	1.019	0.892	0.471	5.603	2.99	0.163	0.063	0.36	2.542	2.634
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.129	2.002	0.875			2.721	2.032	1.963	1.571	1.961	2.172
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.048					1.142	1.947	2.004	1.846	1.977	1.926
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.069	1.862	0.893			0.626	1.921	1.793	1.529	1.909	1.868
COVID19 (COVID19 (PFIZER-	Body height	1.965	1.011	0.886		0.483	0.695	0.959	1.464	2.189	1.928	1.552
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.032	1.751	1.661	0.752	0.884	1.145	1.817	1.878	1.882	1.823	1.903
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.86	6.847	0.886	16.202			0.365			0.513	1.214
COVID19 (COVID19 (PFIZER-	Immunisation	2.074	1.649	0.917		1.288	1.245	1.818	2	2.279	2.004	1.856
COVID19 (COVID19 (PFIZER-	Investigation	2.041	1.759	0.928	0.742	1.108	1.818	1.938	2.26	1.695	1.896	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.591	6.786			1.453	1.363	1.857	1.717	2.153	1.573	1.546
COVID19 (COVID19 (PFIZER-	Weight	1.925	1.366	0.896			0.654	1.555	1.739	2.077	1.88	1.747

PSI-HHS-000000057695

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 12 Jul 2022 20:20:37 +0000
To: Menschik, David (FDA/CBER)
Cc: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220708.xls

Hi David,
Normally you include the brand name for the COVID-19 vaccine data mining tables.
Were they left off this version by accident?

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, July 12, 2022 4:11 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

FYI

From: Zinderman, Craig E <[redacted]>
Sent: Tuesday, July 12, 2022 2:26 PM
To: Menschik, David (FDA/CBER) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good Afternoon :

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/8/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
Craig

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Drug	Event	US EB05 20220708	Serious EB05 2022	Fatal EB05 20220	Infant EB05 2022	Child EB05 20220	Teen EB05 20220	Adult EB05 20220	Adult2 EB05 20220	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022070
COVID19	Activated partial	2.025	1.408	0.92			0.375	1.449	1.891	1.958	2.656	1.372
COVID19	Activated partial	2.013	1.479	0.868				1.53	1.965	1.982	2.671	1.364
COVID19	Acute respiratory	2.048	1.288	0.984				0.768	1.745	1.741	1.586	1.892
COVID19	Acute respiratory	2.144	1.327	1.033			0.45	1.529	2.093	2.011	2.434	1.817
COVID19	Adverse drug	3.392	0.986	0.879			0.522	0.949	0.701	0.736	2.65	1.439
COVID19	Adverse event	2.647	1.106	0.885				0.864	0.907	0.832	1.895	1.732
COVID19	Angiogram	1.898	1.25	0.902				1.462	1.435	1.67	2.092	1.309
COVID19	Angiogram	2.505	1.76	0.905			0.484	2.359	1.92	2.041	3.282	1.512
COVID19	Angiogram	2.089	1.389	0.88				1.781	1.829	1.221	2.143	1.521
COVID19	Angiogram	2.299	1.602	0.907	0.62		0.408	1.707	2.211	2.224	2.451	1.978
COVID19	Anion gap	1.79	1.34	0.906			0.351	1.138	2.14	1.517	2.143	1.306
COVID19	Antibody test	2.173	0.829	0.875			0.566	0.864	1.592	2.129	2.079	1.683
COVID19	Anticoagulant	2.186	1.451	0.974	0.62		0.408	1.842	2.043	2.263	2.741	1.684
COVID19	Application site	2.009						0.561	0.636	0.678	1.037	0.764
COVID19	Areflexia	2.042	1.639	0.895				0.964	2.23	1.302	2.133	1.418
COVID19	Arteriogram	1.792	1.128	0.878				1.186	1.2	1.398	2.136	0.962
COVID19	Basophil count	1.824	1.332	0.932	0.617		0.348	1.104	2.187	1.857	2.242	1.319
COVID19	Basophil	1.74	1.349	0.94	0.616		0.337	1.084	2.226	1.77	2.121	1.322
COVID19	Blood albumin	1.835	1.271	0.934			0.348	1.506	1.861	1.767	2.176	1.429
COVID19	Blood calcium	1.869	1.339	0.956			0.401	1.36	2.072	1.907	2.178	1.521
COVID19	Blood chloride	1.868	1.247	0.923				1.108	2.028	1.595	1.935	1.593
COVID19	Blood chloride	1.707	1.284	0.964			0.498	1.233	1.962	1.655	2.123	1.348
COVID19	Blood fibrinogen	1.951	1.288	0.868			0.576	0.928	2.161	0.655	1.827	1.203
COVID19	Blood fibrinogen	2.787	2.158	0.895			0.498	1.741	2.034	0.955	4.045	1.027
COVID19	Blood lactate	1.711	1.245	0.895	0.619			1.184	2.05	1.307	1.758	1.426
COVID19	Blood magnesium	1.769	1.263	0.919			0.163	1.102	1.885	1.754	2.291	1.214
COVID19	Blood potassium	1.705	1.22	0.943			0.549	1.254	1.485	2.089	1.901	1.253
COVID19	Blood sodium	1.835	1.302	0.899	0.616			1.386	2.016	1.739	1.97	1.607
COVID19	Blood sodium	1.648	1.092	0.926				1.707	1.359	1.189	2.015	1.047
COVID19	Blood urea	1.669	1.325	0.888			0.284	1.371	1.944	1.291	2.023	0.926
COVID19	Blood urea	1.911	1.258	0.921			0.349	1.09	2.061	1.795	2.109	1.659
COVID19	COVID-19	2.275	1.416	1.09				1.971	2.286	2.079	2.447	2.046
COVID19	CSF protein	2.577	1.987	0.872				1.844	3.053	0.978	2.563	2.136
COVID19	Catheter directed	1.775	1.233	0.874			0.532	0.456	1.738	0.806	2.116	0.691
COVID19	Cerebral	2.235	1.586	0.939			0.52	1.764	1.828	1.504	3.33	1.174
COVID19	Cerebral mass	2.765	1.929	0.92			0.528	1.379	1.62	1.256	3.709	1.193
COVID19	Cerebral	2.709	1.732	0.877				1.468	1.348	1.646	3.626	1.267
COVID19	Cerebral venous	3.328	2.174	0.916			0.524	2.066	2.446	0.874	3.567	1.474
COVID19	Chest X-ray	1.876	1.269	0.954			0.371	1.364	1.891	1.907	2.076	1.64
COVID19	Computerised	2.403	1.617	0.963	0.618		0.596	2.088	2.252	2.035	2.954	1.726
COVID19	Computerised	1.994	1.335	0.915			0.435	1.73	1.962	1.821	2.271	1.528
COVID19	Computerised	2.005	1.38	0.925			0.523	1.397	2.062	1.982	2.243	1.689
COVID19	Creatinine renal	1.95	1.241	0.88				0.496	0.869	2.126	1.044	1.719
COVID19	Death	1.878	1.17	0.961				1.222	1.647	1.59	2.087	1.559
COVID19	Deep vein	2.654	1.802	1.046			0.46	2.269	2.297	3.204	3.305	2.092
COVID19	Endotracheal	2.049	1.346	1.108			0.358	1.424	2.063	1.881	2.093	1.837
COVID19	Eosinophil count	1.778	1.277	0.93			0.247	1.204	2.041	1.745	2.042	1.365
COVID19	Eosinophil	1.773	1.321	0.935	0.616		0.368	1.21	2.061	1.763	2.061	1.381
COVID19	Feeling cold	1.756	0.837	0.883			1.182	2.023	1.45	0.982	1.847	1.428
COVID19	Fibrin D dimer	2.271	1.273	0.893			0.502	2.18	2.149	1.958	2.534	1.701
COVID19	Fibrin D dimer	2.155	1.463	0.993	0.619		0.292	1.708	2.297	2.272	2.511	1.662
COVID19	Fibrin D dimer	1.945	1.067	0.877			0.434	1.621	2.019	1.106	2.186	1.293
COVID19	Foetal exposure	2.335	1.511		0.758			0.676			1.645	1.847
COVID19	Gaze palsy	2.213	1.031	0.89			0.401	2.3	1.666	1.216	2.211	1.605
COVID19	Globulins	1.893	1.289	0.91			0.391	1.286	1.784	1.674	2.285	1.269
COVID19	Glucose urine	1.747	1.178	0.912				1.225	1.518	1.358	2.232	1.106
COVID19	Guillain-Barre	2.467	1.824	0.884			0.434	1.614	3.066	1.623	2.428	2.178
COVID19	Haematocrit	1.801	1.267	0.954	0.613		0.526	1.321	2.021	1.781	2.154	1.443
COVID19	Haemoglobin	1.755	1.23	0.942	0.613		0.42	1.402	1.94	1.672	2.075	1.425
COVID19	Heparin-induced	5.652	3.536	0.894				4.143	5.516	4.361	7.211	3.318
COVID19	Heparin-induced	6.149	3.296	0.874			0.55	4.198	5.731	0.74	7.048	2.497
COVID19	Hypoxia	2.109	1.328	0.966			0.415	1.554	2.098	1.974	2.449	1.744
COVID19	Immunoglobulin	2.095	1.727	0.872			0.01	1.925	2.605	1.373	2.22	1.747
COVID19	Intensive care	1.964	1.398	1.078			0.056	1.471	2.129	2.094	2.35	1.615
COVID19	International	1.76	1.199	0.88	0.755		0.377	1.524	1.891	1.44	2.319	1.248
COVID19	International	1.933	1.24	0.884				1.366	2.058	1.027	2.103	1.268
COVID19	Intracardiac	2.679	1.765	0.907				0.84	1.423	0.995	1.713	1.625
COVID19	Jugular vein	1.789	1.379	0.878				1.369	1.107	0.712	2.299	0.702
COVID19	Lumbar puncture	1.883	1.361	0.865				1.285	2.191	1.005	1.687	1.755
COVID19	Lumbar puncture	2.159	1.69					1.116	2.955	1.012	1.801	1.822
COVID19	Lung opacity	1.994	1.268	0.948				1.449	1.738	1.984	2.358	1.526
COVID19	Lymphocyte	1.681	1.224	0.93			0.244	0.993	2.061	1.862	2.066	1.305
COVID19	Magnetic	2.054	1.463	0.911			0.463	1.752	1.893	2.095	2.286	1.63
COVID19	Mean cell	2.006	1.345	0.933	0.619		0.495	1.251	2.149	1.826	2.339	1.362
COVID19	Mean cell	1.722	1.208	0.919			0.357	1.156	1.865	1.586	2.097	0.996
COVID19	Mean platelet	1.814	1.273	0.906			0.374	1.122	2.251	1.551	2.015	1.396
COVID19	Mechanical	2.296	1.51	1.022			0.474	1.148	2.268	2.084	2.103	2.073
COVID19	Monocyte	1.509	1.199	0.917	0.616		0.198	0.845	1.889	1.955	2.161	1.099
COVID19	Neonatal	2.395	0.988		0.62						0.876	1.118
COVID19	Neutrophil	1.619	1.199	0.888			0.364	1.099	1.612	1.688	2.114	0.883
COVID19	Neutrophil	1.72	1.253	0.93			0.291	1.097	2.068	1.795	1.963	1.422
COVID19	Nonspecific	4.09	0.789					0.744	0.613		3.031	1.076
COVID19	Off label use	2.124	0.663	0.866			8.494	1.249	1.502	1.041	1.035	2.153
COVID19	On and off	1.768	0.752					3.425	0.982		2.243	
COVID19	Pain assessment	2.209	0.858				0.511	1.495	2.236	1.039	2.179	1.407
COVID19	Peripheral	3.089	1.361	0.874				0.657	1.035	1.573	2.27	0.951
COVID19	Platelet count	2.681	2.157	0.917	0.618		0.473	1.863	2.922	2.713	3.069	1.818
COVID19	Platelet count	1.885	1.302	0.913	0.616		0.331	1.486	2.102	1.656	2.261	1.487
COVID19	Platelet count	2.555	1.798	0.894			0.448	2.099	2.701	2.22	3.11	1.705
COVID19	Platelet factor 4	5.769	3.247	0.88				4.283	4.675	0.795	5.658	2.286
COVID19	Portal vein	2.246	1.654	0.876				0.656	1.872	1.033	2.321	1.335
COVID19	Positive airway	2.089	1.293	0.955				0.997	2.105	1.725	2.274	1.643
COVID19	Product	1.758	0.834	0.876		0.693	2.06	0.036	0.002	0.504	1.668	1.813
COVID19	Prolonged labour	5.189	1.34					5.058			5.161	
COVID19	Protein total	1.798	1.231	0.931	0.617		0.316	1.44	1.64	1.736	2.032	1.423
COVID19	Prothrombin time	1.913	1.37	0.937	0.755		0.291	1.446	2.271	1.658	2.465	1.437
COVID19	Pulmonary	2.262	1.587	1.049	0.62		0.585	1.817	2.071	2.644	2.527	1.934
COVID19	Pulmonary	2.341	1.514	0.905				1.717	1.729	1.921	2.223	1.923
COVID19	Red cell	1.961	1.313	0.929	0.618		0.379	1.26	2.127	1.817	2.297	1.437
COVID19	Respiratory failure	1.932	1.203	0.967				0.987	1.825	1.88	2.036	1.629
COVID19	Russell's viper	1.315	0.988					2.395	0.506		1.059	0.725
COVID19	Sensory	2.013	1.328	0.88				1.443	1.872	1.474	1.878	1.763
COVID19	Superficial vein	2.586	1.78	0.884			0.53	1.762	2.041	1.756	2.593	1.823
COVID19	Suspected COVID-	3.403	2.259	1.603			0.618	3.222	3.227	1.144	2.643	3.353
COVID19	Therapy non-	6.555	0.754	0.875			0.651	3.659	5.568	14.656	7.7	5.683
COVID19	Therapy partial	2.709							0.637	0.568	0.561	1.026
COVID19	Thrombectomy	1.944	1.312	0.88			0.508	1.446	1.504	1.466	2.083	1.345
COVID19	Thrombocytopenia	2.271	1.701	0.951			0.36	1.62	2.407	1.874	2.512	1.776
COVID19	Thrombosis	2.929	2.134	1.772	0.62		0.732	2.024	2.484	3.625	2.994	2.409
COVID19	Thrombosis with	6.119	3.023	0.899				3.045	5.768	0.562	5.614	3.423
COVID19	Transverse sinus	2.058	1.499	0.875				1.776	1.216	0.623	2.115	0.873
COVID19	Ultrasound	2.341	1.422	0.905			0.711	1.86	2.208	2.134	2.644	1.75
COVID19	Ultrasound	2.705	1.823	0.958	0.619		0.522	2.497	2.298	2.869	3.285	2.122
COVID19	Ultrasound	2.336	1.599	0.91			0.421	2.23	1.957	1.963	2.398	1.842
COVID19	Vaccination failure	1.609	3.025	2.479			0.554	1.453	2.418	3.846	2.163	2.344
COVID19	Varicose vein	1.912	0.896					1.249	1.375	0.787	2.098	0.81
COVID19	Vasodilatation	2.071	0.907	0.873				0.874	1.574	1.123	1.794	1.113
COVID19	Venogram	2.324	1.74	0.872				2.003	1.59	0.703	2.514	1.061
COVID19	Venogram	2.653	1.992				0.608	2.673	1.61	0.659	3.261	1.192
COVID19	Venogram normal	3.841	2.163	0.88				3.587	2.002	1.055	4.716	1.195
COVID19	Accidental	2					0.788	1.513	1.521	1.299	1.745	1.775
COVID19	Exposure via	1.484	0.819		8.173	3.722		1.28	0.52		1.485	1.072
COVID19	Interchange of	0.688	0.999	0.886	0.602	1.255	2.482	0.794	0.661	0.438	0.689	0.649
COVID19	Mechanical	2.029	1.193				0.665	2.052	1.543	0.834	1.975	1.928
COVID19	Product	2.514	0.990	0.887	0.381	3.34	2.993	0.162	0.086	0.353	2.53	2.616
COVID19	Product dose	2.131	2.004	0.875		0.542	2.727	2.027	1.984	1.571	1.963	2.172
COVID19	Product	2.053					1.148	1.95	2.012	1.85	1.982	1.93
COVID19	Vaccination	2.103	1.673	0.89			0.836	1.621	1.783	1.53	1.909	1.888
COVID19	Body height	1.986	1.019	0.88		0.485	0.695	0.959	1.47	2.19	1.929	1.553
COVID19	Drug ineffective	2.028	1.756	1.683	0.742	0.897	1.143	1.838	1.895	1.915	1.835	1.91

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COVID19	Exposure via	0.849	0.847	0.879	14.425	0.156		0.365			0.508	1.216
COVID19	Immunisation	2.075	1.645	0.915		1.269	1.247	1.616	2	2.279	2.006	1.658
COVID19	Investigation	2.038	1.762	0.932		0.765	1.109	1.822	1.936	2.25	1.986	1.9
COVID19	Product	1.588	0.786		0.348	1.463	1.358	1.658	1.711	2.146	1.573	1.546
COVID19	Weight	1.91	1.37	0.891			0.955	1.544	1.717	2.078	1.673	1.739

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 5 Jul 2022 14:16:56 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220701.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, July 5, 2022 7:42 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/1/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20220101	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 20220	Female EB05 2022	Male EB05 20220701
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.007	1.468	0.92			0.375	1.177	1.861	1.966	2.661	1.362
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.019	1.484	0.869				1.536	1.967	1.989	2.688	1.366
COVID19 (COVID19 (JANSEN))	Acute respiratory distress syndrome	2.045	1.288	0.983				0.767	1.743	1.738	1.583	1.889
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.126	1.322	1.028			0.45	1.533	2.087	1.986	2.425	1.794
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	3.385	0.985	0.88			0.522	0.953	0.701	0.739	2.654	1.443
COVID19 (COVID19 (JANSEN))	Adverse event	2.64	1.091	0.886				0.864	0.906	0.833	1.893	1.714
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.9	1.252	0.903				1.466	1.434	1.672	2.094	1.309
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.509	1.764	0.906			0.485	2.386	1.916	2.044	3.302	1.511
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.051	1.392	0.881				1.781	1.828	1.226	2.141	1.522
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.269	1.605	0.907	0.619		0.408	1.714	2.216	2.205	2.459	1.972
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.789	1.346	0.91			0.351	1.142	2.144	1.024	2.148	1.311
COVID19 (COVID19 (JANSEN))	Antibody test	2.17	0.824	0.873			0.586	0.863	1.59	2.124	2.071	1.685
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.178	1.45	0.974	0.619		0.41	1.844	2.026	2.25	2.733	1.674
COVID19 (COVID19 (JANSEN))	Application site pain	2.009						0.891	0.498	0.879	1.037	0.791
COVID19 (COVID19 (JANSEN))	Areflexia	2.047	1.642	0.896				0.987	2.227	1.307	2.14	1.42
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.757	1.131	0.88				1.203	12	1.397	2.158	0.962
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.833	1.361	0.934	0.617		0.351	1.112	2.196	1.867	2.264	1.32
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.748	1.357	0.941	0.516		0.339	1.091	2.225	1.782	2.135	1.326
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.844	1.279	0.937			0.351	1.517	1.864	1.777	2.18	1.435
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.871	1.343	0.958			0.404	1.383	2.077	1.907	2.188	1.52
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.876	1.252	0.924				1.111	2.032	1.603	1.944	1.598
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.792	1.284	0.961			0.5	1.237	1.948	1.85	2.122	1.339
COVID19 (COVID19 (JANSEN))	Blood fibrinogen	1.985	1.32	0.869			0.576	0.929	2.157	0.855	1.825	1.211
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	2.755	2.165	0.896			0.498	1.741	2.031	0.958	4.084	1.027
COVID19 (COVID19 (JANSEN))	Blood lactate dehydrogenase increased	1.767	1.244	0.895	0.619			1.186	2.025	1.309	1.763	1.416
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.777	1.27	0.92			0.175	1.102	1.893	1.763	2.31	1.217
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.7	1.219	0.94			0.551	1.256	1.467	2.036	1.897	1.243
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.841	1.306	0.901	0.616			1.391	2.076	1.744	1.975	1.61
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.657	1.098	0.927				1.707	1.369	1.201	2.019	1.054
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.679	1.337	0.886			0.289	1.389	1.922	1.294	2.024	0.934
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.911	1.259	0.919			0.35	1.097	2.064	1.788	2.111	1.658
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.253	1.407	1.082				1.998	2.264	2.059	2.493	2.018
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.585	1.991	0.873				1.85	3.066	0.98	2.873	2.143
COVID19 (COVID19 (JANSEN))	Catheter directed thrombolysis	1.774	1.232	0.875			0.532	0.456	1.736	0.806	2.115	0.691
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.23	1.58	0.939			0.521	1.764	1.826	1.5	3.317	1.173
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.755	1.928	0.92			0.529	1.38	1.618	1.254	3.698	1.192
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.71	1.733	0.878				1.466	1.354	1.635	3.611	1.271
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.357	2.172	0.916			0.524	2.579	2.441	0.873	3.924	1.272
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.873	1.27	0.954			0.374	1.369	1.884	1.903	2.077	1.835
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.4	1.614	0.959	0.618		0.597	2.1	2.235	2.017	2.963	1.714
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.988	1.332	0.916			0.436	1.734	1.962	1.8	2.258	1.531
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.008	1.384	0.927			0.524	1.406	2.064	1.974	2.252	1.887
COVID19 (COVID19 (JANSEN))	Creatinine renal clearance decreased	1.949	1.241	0.881				0.495	0.609	2.097	1.043	1.707
COVID19 (COVID19 (JANSEN))	Death	1.877	1.171	0.962				1.223	1.644	1.586	2.084	1.557
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.651	1.805	1.046			0.481	2.27	2.296	3.199	3.304	2.087
COVID19 (COVID19 (JANSEN))	Endovascular intervention	2.008	1.348	1.106			0.386	1.426	2.064	1.889	2.093	1.83
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.767	1.285	0.932			0.249	1.214	2.04	1.757	2.08	1.368
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.781	1.329	0.937	0.516		0.369	1.218	2.06	1.777	2.072	1.387
COVID19 (COVID19 (JANSEN))	Feeling cold	1.757	0.84	0.884			0.181	2.023	1.462	0.982	1.848	1.429
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.274	1.281	0.893			0.502	2.179	2.147	1.965	2.533	1.706
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.152	1.46	0.99	0.619		0.293	1.715	2.293	2.257	2.522	1.848
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.945	1.089	0.878			0.435	1.624	2.017	1.104	2.184	1.294
COVID19 (COVID19 (JANSEN))	Foetal exposure during pregnancy	2.329	1.46		0.757			0.875			1.642	1.845
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.214	1.031	0.88			0.402	2.305	1.666	1.215	2.214	1.804
COVID19 (COVID19 (JANSEN))	Globulins increased	1.897	1.298	0.911			0.391	1.3	1.758	1.684	2.274	1.275
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.746	1.176	0.912				1.225	1.518	1.357	2.23	1.106
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.448	1.818	0.887			0.434	1.617	3.042	1.622	2.392	2.169
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.864	1.271	0.956	0.613		0.527	1.328	2.015	1.789	2.157	1.447
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.76	1.234	0.946	0.613		0.421	1.400	1.942	1.670	2.001	1.429
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.708	3.805	0.894				4.176	5.514	4.346	7.258	3.372
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.145	3.291	0.875			0.55	4.199	5.727	0.74	7.043	2.491
COVID19 (COVID19 (JANSEN))	Hypoxia	2.069	1.322	0.957			0.416	1.553	2.091	1.946	2.447	1.718
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.09	1.723	0.873			0.611	1.932	2.577	1.376	2.2	1.75
COVID19 (COVID19 (JANSEN))	Intensive care	1.964	1.389	1.08			0.557	1.478	2.13	2.083	2.351	1.614
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.758	1.198	0.882	0.755		0.377	1.529	1.89	1.429	2.308	1.351
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	1.931	1.239	0.885				1.366	2.057	1.025	2.102	1.266
COVID19 (COVID19 (JANSEN))	Intracardiac thrombus	2.674	1.778	0.907				0.84	1.422	0.995	1.712	1.824
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.893	1.377	0.879				1.389	1.116	0.712	2.297	0.707
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.869	1.345	0.866				1.267	2.185	1.006	1.661	1.755
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.134	1.668					1.116	2.852	1.018	1.753	1.827
COVID19 (COVID19 (JANSEN))	Lung opacity	1.985	1.266	0.948				1.449	1.715	1.983	2.357	1.511
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.687	1.229	0.933			0.246	0.997	2.064	1.87	2.074	1.309
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.059	1.486	0.911			0.484	1.758	1.897	2.096	2.297	1.831
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.017	1.354	0.934	0.619		0.488	1.257	2.157	1.838	2.31	1.37
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin decreased	1.724	1.27	0.919			0.357	1.101	1.864	1.59	2.1	0.996
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.826	1.282	0.907			0.376	1.135	2.254	1.556	2.034	1.4
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.262	1.503	1.02			0.474	1.153	2.268	2.046	2.084	2.062
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.914	1.264	0.918	0.616		0.291	0.847	1.863	2.157	1.705	1.705
COVID19 (COVID19 (JANSEN))	Neonatal dyspnoea	2.377	0.985		0.62						0.874	1.117
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.516	1.205	0.889			0.365	1.107	1.69	1.69	2.117	0.882
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.726	1.258	0.932			0.393	1.104	2.068	1.803	1.973	1.426
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	4.088	0.789					0.744	0.613		3.024	1.076
COVID19 (COVID19 (JANSEN))	Off label use	2.113	0.661	0.886			0.451	1.235	1.485	1.04	1.528	2.143
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.767	0.751					3.423	0.982		2.244	
COVID19 (COVID19 (JANSEN))	Pain assessment	2.206	0.857				0.512	1.495	2.233	1.039	2.176	1.405
COVID19 (COVID19 (JANSEN))	Peripheral embolism	3.062	1.36	0.875				0.657	1.035	1.572	2.268	0.951
COVID19 (COVID19 (JANSEN))	Platelet count	2.67	2.155	0.914	0.618		0.473	1.863	2.915	2.713	3.04	1.823
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.889	1.306	0.915	0.614		0.331	1.488	2.102	1.664	2.265	1.49
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.553	1.798	0.894			0.448	2.101	2.662	2.219	3.114	1.701
COVID19 (COVID19 (JANSEN))	Platelet factor 4	5.76	3.243	0.881				4.263	4.663	0.795	5.61	3.28
COVID19 (COVID19 (JANSEN))	Portal vein thrombosis	2.244	1.652	0.877				0.506	1.669	1.032	2.317	1.335
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	2.088	1.293	0.956				0.997	2.123	1.706	2.281	1.832
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.76	0.835	0.877		0.693	2.06	0.037	0.002	0.506	1.67	1.812
COVID19 (COVID19 (JANSEN))	Prolonged labour	5.164	1.396					5.068			5.157	
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.808	1.237	0.933	0.616		0.319	1.446	1.646	1.744	2.036	1.431
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.917	1.374	0.937	0.754		0.291	1.449	2.27	1.664	2.471	1.439
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.261	1.588	1.05	0.62		0.585	1.819	2.071	2.632	2.528	1.93
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.341	1.514	0.905				1.721	1.727	1.924	2.222	1.925
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.786	1.258	0.936	0.614		0.586	1.349	1.961	1.663	2.084	1.502
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.968	1.319	0.931	0.617		0.379	1.267	2.126	1.828	2.306	1.443
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.329	0.994					2.654	0.508		1.068	0.725
COVID19 (COVID19 (JANSEN))	Sensory disturbance	2.008	1.306	0.881				1.445	1.86	1.472	1.878	1.748
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.582	1.778	0.885			0.53	1.762	2.039	1.749	2.588	1.822
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.28	2.231	1.096			0.618	3.12	3.176	1.123	2.813	3.343
COVID19 (COVID19 (JANSEN))	Therapy non-responder	6.559	0.757	0.876			0.651	3.658	6.592	14.645	7.714	5.681
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.705							0.637	0.568	0.561	1.926
COVID19 (COVID19 (JANSEN))	Thrombectomy	1.942	1.311	0.88			0.505	1.446	1.563	1.464	2.08	1.343
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.274	1.705	0.951			0.36	1.62	2.464	1.885	2.51	1.78
COVID19 (COVID19 (JANSEN))	Thrombosis	2.924	2.126	1.799	0.62		0.732	2.011	2.487	3.622	2.998	2.401
COVID19 (COVID19 (JANSEN))	Thrombotic microangiopathy syndrome	5.161	5.018	0.9				3.035	5.716	0.862	5.808	3.996
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.077	1.495	0.876				1.775	1.225	0.623	2.112	0.879
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.345	1.427	0.905			0.711	1.888	2.209	2.139	2.653	1.75
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.655	1.818	0.958	0.619		0.522	2.484	2.295	2.83	3.28	2.108
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.344	1.607	0.91			0.424	2.241	1.969	1.972	2.411	1.843
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.61	3.024	2.476			0.554	1.462	2.46	4.1	2.169	2.366
COVID19 (COVID19 (JANSEN))	Varicose vein	1.91	0.895					1.25	1.375	0.787	2.084	0.809
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.069	0.907	0.874				0.975	1.573	1.123	1.793	1.113
COVID19 (COVID19 (JANSEN))	Venogram	2.341	1.747	0.873				2.001	1.601	0.706	2.543	1.064
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.65	1.991				0.608	2.669	1.609	0.659	3.258	1.192
COVID19 (COVID19 (JANSEN))	Venogram normal	3.84	2.162	0.881				3.587	2	1.055	4.711	1.195
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.474	0.819		0.551	1.374		1.28	0.52		1.472	1.072
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.685	0.994	0.886	0.507	1.393	2.491	0.793	0.607	0.437	0.688	0.646
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.023	1.165				0.604	2.046	1.539	0.607	1.966	1.926
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.523	1.018	0.887	0.362	4.261	2.99	0.159	0.087	0.36	2.538	2.623
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.129	2.004	0.876		0.543	2.724	2.031	1.962	1.571	1.962	2.173
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.045					1.145	1.944	2.002	1.843	1.974	1.923
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.099	1.663	0.889			0.836	1.62	1.782	1.529	1.908	1.887
COVID19 (COVID19 (PFIZER-	Body height	1.967	1.011	0.881		0.484	0.695	0.96	1.465	2.193	1.93	1.553
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.025	1.754	1.664	0.745	0.888	1.147	1.826	1.885	1.887	1.834	1.908
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.853	0.847	0.88	15.347			0.365			0.501	1.215
COVID19 (COVID19 (PFIZER-	Immunisation	2.077	1.652	0.915		1.289	1.245	1.82	2.002	2.282	2.007	1.858
COVID19 (COVID19 (PFIZER-	Investigation	2.043	1.764	0.932		0.76	1.108	1.821	1.942	2.263	1.996	1.896
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.568	0.786		0.394	1.453	1.357	1.859	1.714	2.152	1.573	1.543
COVID19 (COVID19 (PFIZER-	Weight	1.924	1.367	0.891			0.554	1.545	1.736	2.08	1.88	1.743

PSI-HHS-000000057701

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 7 Jun 2022 12:28:37 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220603.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, June 7, 2022 6:00 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/3/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20220403	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 20220	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	03
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.03	1.685	0.923			0.378	1.473	1.853	1.981	2.698	1.348	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.04	1.499	0.879				1.557	2.004	1.953	2.678	1.396	
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.066	1.303	0.98				0.779	1.675	1.818	1.598	1.903	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.117	1.322	1.017			0.454	1.469	2.064	1.996	2.455	1.761	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.335	0.969	0.886			0.526	0.954	0.713	0.677	2.644	1.454	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.615	1.083	0.893				0.871	0.91	0.782	1.882	1.726	
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.146	1.898					1.239	1.412		0.894	1.623	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.938	1.285	0.91				1.497	1.444	1.702	2.168	1.312	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.536	1.785	0.913			0.488	2.372	1.903	2.077	3.387	1.505	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.053	1.366	0.887				1.785	1.742	1.268	2.184	1.418	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.3	1.613	0.911			0.415	1.602	2.269	2.207	2.471	1.962	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.835	1.384	0.914			0.381	1.18	2.201	1.506	2.174	1.349	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.137	0.83	0.881			0.589	0.825	1.574	1.505	2.005	1.896	
COVID19 (COVID19 (JANSSEN))	Antimyeloid therapy	2.137	1.486	0.872	0.618		0.618	1.846	2.003	2.217	2.783	1.888	
COVID19 (COVID19 (JANSSEN))	Application site pain	2.002						0.561	0.636	0.678	1.037	0.764	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.062	1.66	0.9				0.929	2.271	1.325	2.168	1.415	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.836	1.154	0.888				1.213	1.205	1.416	2.331	0.977	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.872	1.373	0.933	0.516		0.359	1.157	2.205	1.896	2.321	1.328	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.777	1.391	0.944	0.515		0.252	1.125	2.238	1.832	2.198	1.32	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.838	1.275	0.93			0.305	1.519	1.85	1.775	2.201	1.413	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.876	1.348	0.956			0.372	1.372	2.096	1.892	2.196	1.519	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.817	1.302	0.952			0.461	1.244	2.009	1.863	2.15	1.354	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	1.892	1.198	0.878			0.579	0.929	2.01	0.568	1.695	1.157	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.756	2.156	0.896			0.592	1.75	2.103	0.879	4.028	1.03	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.788	1.281	0.927			0.186	1.091	1.935	1.744	2.342	1.211	
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.828	1.301	0.902	0.516			1.361	2.011	1.733	1.959	1.596	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.648	1.314	0.893			0.084	1.306	1.943	1.206	2.032	0.897	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.9	1.251	0.915				1.068	2.051	1.784	2.113	1.634	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.243	1.498	1.08				1.91	2.252	2.057	2.419	2.009	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.551	2.012	0.882				1.878	2.072	1.005	2.582	2.143	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.232	1.582	0.938			0.525	1.713	1.85	1.51	3.341	1.157	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.885	1.99	0.927			0.532	1.385	1.68	1.263	3.912	1.199	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.766	1.734	0.886				1.471	1.365	1.837	3.611	1.297	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.356	2.171	0.919			0.528	2.556	2.444	0.88	3.91	1.276	
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.879	1.279	0.96			0.33	1.336	1.962	1.916	2.108	1.823	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.444	1.653	0.966	0.518		0.605	2.132	2.252	2.067	3.041	1.737	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.992	1.328	0.918			0.376	1.716	1.938	1.847	2.272	1.499	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2	1.383	0.924			0.458	1.388	2.046	2.002	2.246	1.675	
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	2.118	1.316	0.889				0.498	0.868	2.153	1.08	1.792	
COVID19 (COVID19 (JANSSEN))	Death	1.98	1.169	0.962				1.223	1.822	1.572	2.088	1.536	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.637	1.807	1.06			0.464	2.266	2.289	3.172	3.322	2.059	
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.068	1.36	1.122			0.383	1.41	2.088	1.899	2.11	1.836	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.79	1.285	0.93			0.04	1.244	2.015	1.774	2.094	1.337	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.785	1.342	0.94	0.516		0.266	1.257	2.04	1.789	2.077	1.383	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.757	0.857	0.895			0.181	2.024	1.457	0.976	1.852	1.426	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.272	1.274	0.9			0.403	2.179	2.166	1.884	2.884	1.756	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.147	1.454	0.984	0.519		0.296	1.71	2.312	2.218	2.51	1.825	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.937	1.075	0.886			0.438	1.628	2.011	1.035	2.171	1.288	
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.201	1.416		0.756			0.651			1.638	1.756	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.21	1.021	0.896			0.405	2.274	1.662	1.213	2.234	1.578	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.846	1.258	0.909			0.398	1.282	1.739	1.592	2.234	1.214	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.712	1.155	0.911				1.23	1.467	1.373	2.182	1.066	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.468	1.836	0.894			0.437	1.628	3.129	1.646	2.438	2.206	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.868	1.271	0.941	0.513		0.496	1.335	2.02	1.784	2.181	1.43	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.762	1.237	0.936	0.513		0.39	1.404	1.957	1.672	2.084	1.419	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.712	3.607	0.9				4.182	5.521	4.32	7.261	3.373	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.149	3.297	0.883			0.554	4.206	5.734	0.74	7.054	2.479	
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.065	1.322	0.958				1.492	2.103	1.938	2.458	1.696	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.079	1.713	0.901			0.011	1.909	2.046	1.394	2.427	1.711	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.945	1.389	1.06			0.021	1.454	2.055	2.088	2.344	1.59	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.76	1.202	0.889	0.754		0.382	1.526	1.861	1.433	2.292	1.258	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.935	1.231	0.892				1.383	2.074	0.977	2.097	1.28	
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.67	1.774	0.911				0.84	1.422	0.994	1.71	1.822	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.804	1.389	0.887				1.373	1.116	0.712	2.298	1.707	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.875	1.357	0.876				1.277	2.187	1.013	1.662	1.764	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.143	1.69					1.122	2.801	1.031	1.774	1.816	
COVID19 (COVID19 (JANSSEN))	Lung infiltration	1.838	1.16	0.93			0.613	1.25	1.823	1.401	2.002	1.461	
COVID19 (COVID19 (JANSSEN))	Lung opacity	2.064	1.282	0.948				1.425	1.73	2.013	2.38	1.523	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.678	1.225	0.928			0.182	0.996	2.053	1.863	2.061	1.297	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.06	1.465	0.916			0.468	1.77	1.872	2.142	2.338	1.595	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.033	1.372	0.936	0.519		0.439	1.282	2.183	1.83	2.363	1.374	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.702	1.251	0.922			0.242	1.17	1.916	1.475	2.073	0.974	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.846	1.298	0.91			0.314	1.147	2.274	1.579	2.074	1.395	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.252	1.522	1.02			0.478	1.157	2.268	2.066	2.136	2.04	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.933	1.223	0.918	0.516		0.207	0.655	1.901	1.901	2.192	1.116	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.525	1.202	0.894			0.319	1.132	1.602	1.657	2.197	0.849	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.722	1.259	0.926			0.245	1.099	2.066	1.808	1.982	1.405	
COVID19 (COVID19 (JANSSEN))	Neutrophil count	1.698	1.288					0.748	0.813		2.384	1.278	
COVID19 (COVID19 (JANSSEN))	Off label use	2.072	0.596	0.895			8.345	1.219	1.387	0.985	1.488	2.085	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.769	0.751					3.446	0.983		2.248		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.239	0.881				0.515	1.506	2.264	1.11	2.173	1.447	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.089	1.355	0.883				0.657	1.005	1.561	2.268	0.951	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.637	2.148	0.917	0.518		0.478	1.832	2.821	2.758	2.998	1.791	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.87	1.303	0.92	0.514		0.259	1.437	2.1	1.664	2.244	1.469	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.551	1.808	0.901			0.451	2.069	2.74	2.172	3.12	1.893	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.8	3.284	0.885				4.291	4.966		6.807	5.733	2.27
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.254	1.665	0.886				0.859	1.864	1.03	2.367	1.334	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.068	1.304	0.958				1.001	2.105	1.732	2.218	1.884	
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.767	0.833	0.885		0.719	2.082	0.04	0.002	0.512	1.671	1.826	
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.18	1.33					5.046			5.154		
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.794	1.227	0.928	0.516		0.336	1.439	1.629	1.716	2.011	1.421	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.92	1.38	0.935	0.754		0.293	1.434	2.293	1.858	2.451	1.448	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.252	1.588	1.083	0.519		0.589	1.806	2.068	2.633	2.524	1.917	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.326	1.496	0.906				1.766	1.67	1.962	2.231	1.899	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.8	1.267	0.926	0.514		0.556	1.364	2.065	1.672	2.044	1.491	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.946	1.305	0.931	0.517		0.284	1.31	2.092	1.792	2.271	1.423	
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.367	1.003					2.704	0.506		1.081	1.73	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.559	1.723	0.892			0.537	1.774	1.97	1.787	2.561	1.795	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.453	2.211	1.597			0.527	3.258	3.318	1.168	2.883	3.425	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.54	0.757	0.885			0.654	3.618	6.564	14.788	7.668	3.72	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.667							0.637	0.568	0.561	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.961	1.329	0.894			0.512	1.474	1.564	1.476	2.097	1.357	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.28	1.724	0.96			0.368	1.613	2.4	1.891	2.499	1.792	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.919	2.128	1.756	0.519		0.729	2.012	2.461	3.644	2.994	2.389	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	6.07	2.957	0.902				2.15	5.733	0.562	5.595	2.54	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.091	1.514	0.884				1.785	1.231	0.623	2.139	0.879	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.304	1.447	0.912			0.713	1.914	2.226	2.167	2.68	1.756	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.769	1.837	0.976	0.519		0.529	2.505	2.285	2.879	3.302	2.115	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.378	1.84	0.918			0.43	2.235	2.013	1.979	2.485	1.854	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.921	1.545	2.472			0.488	1.514	2.061	1.471	2.275	2.431	
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.912	0.895					1.252	1.375	0.789	2.091	1.81	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.115	0.906	0.883				0.975	1.58	1.136	1.852	1.113	
COVID19 (COVID19 (JANSSEN))	Venogram	2.35	1.741	0.882				2.023	1.602	0.706	2.54	1.964	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.706	2.027				0.611	2.686	1.629	0.665	3.337	1.2	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.914	2.202	0.888				3.659	2.003	1.068	4.832	1.199	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.483	0.824		10.568	0.908		1.266	0.52		1.448	1.057	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.677	0.991	0.891	0.61	1.023	2.472	0.788	0.646	0.432	0.661	0.838	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.015	1.17				0.661	2.041	1.517	0.808	1.961	1.914	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.529	1.018	0.894	0.474	6.06	2.975	0.147	0.07	0.345	2.538	2.633	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.133	2.019	0.882			2.794	2.035	1.982	1.576	1.968	2.176	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.042					1.147	1.936	1.982	1.846	1.978	1.911	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.1	1.869	0.898			0.837	1.621	1.783	1.529	1.913	1.888	
COVID19 (COVID19 (PFIZER-	Body height	1.959	0.992	0.856		0.463	0.696	0.956	1.466	2.166	1.927	1.551	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.043	1.752	1.644	0.754	0.86	1.128	1.779	1.822	1.805	1.811	1.887	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.859	0.856	0.888	16.551			0.36			0.507	1.246	
COVID19 (COVID19 (PFIZER-	Immunisation	2.067	1.656	0.918		1.287	1.244	1.817	1.995	2.277	1.997	1.854	
COVID19 (COVID19 (PFIZER-	Investigation	2.04	1.752	0.929		0.737	1.103	1.814	1.942	2.259	1.98	1.9	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.599	0.785			1.455	1.367	1.857	1.718	2.155	1.581	1.553	
COVID19 (COVID19 (PFIZER-	Weight	1.931	1.356	0.898			0.954	1.558	1.731	2.084	1.894	1.76	

PSI-HHS-000000057703

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 14 Jun 2022 12:48:56 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220610.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, June 14, 2022 6:37 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/10/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	US EB05 20220610	Serious EB05 2022(	Fatal EB05 20220(	Infant EB05 20220(	Child EB05 20220(	Teen EB05 20220(	Adult1 EB05 20220(	Adult2 EB05 20220(	Adult3 EB05 20220(	Female EB05 2022(	US Male EB05 20220610
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.008	1.479	9.903			0.377	1.467	1.848	1.683	2.665	1.336
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.022	1.487	9.882				1.55	1.991	1.945	2.649	1.387
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.066	1.301	9.975				0.78	1.677	1.815	1.603	1.901
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.118	1.32	1.015			0.452	1.472	2.062	1.956	2.451	1.766
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.341	0.969	9.892			0.525	0.954	0.705	0.678	2.628	1.454
COVID19 (COVID19 (JANSSEN))	Adverse event	2.622	1.086	9.897				0.865	0.91	0.781	1.893	1.725
COVID19 (COVID19 (JANSSEN))	Albumin CSF increased	2.149	1.9					1.238	1.412		0.894	1.626
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.933	1.279	9.911				1.483	1.458	1.681	2.143	1.325
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.515	1.768	9.914			0.487	2.349	1.91	2.084	3.345	1.498
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.046	1.358	9.891				1.785	1.743	1.252	2.179	1.412
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.288	1.602	9.911			0.413	1.647	2.285	2.19	2.463	1.948
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.814	1.363	9.915			0.36	1.168	2.171	1.493	2.154	1.332
COVID19 (COVID19 (JANSSEN))	Antibody test	2.148	0.828	9.886			0.568	0.828	1.569	1.97	2.031	1.69
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.181	1.457	9.968	0.619		0.414	1.834	2.032	2.26	2.774	1.657
COVID19 (COVID19 (JANSSEN))	Application site pain	2.004						0.561	0.635	0.679	1.038	0.764
COVID19 (COVID19 (JANSSEN))	Areflexia	2.049	1.646	9.903				0.924	2.247	1.325	2.153	1.468
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.815	1.14	9.892				1.204	1.408	1.41	2.197	0.968
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.863	1.367	9.934	0.617		0.357	1.14	2.225	1.872	2.33	1.317
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.771	1.383	9.943	0.615		0.253	1.114	2.271	1.806	2.201	1.311
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.626	1.266	0.93			0.302	1.011	1.855	1.754	2.166	1.409
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.874	1.346	9.956			0.371	1.364	2.103	1.885	2.198	1.515
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.814	1.3	9.954			0.461	1.244	2.001	1.863	2.159	1.344
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	1.884	1.2	9.883			0.575	0.929	2.012	0.969	1.701	1.197
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.691	2.12	9.899			0.5	1.749	2.035	0.87	3.934	1.027
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.774	1.269	9.926			0.171	1.107	1.9	1.732	2.309	1.21
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.687	1.293	9.939			0.505	1.254	1.592	2.002	1.886	1.227
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.828	1.301	9.905	0.619			1.357	2.017	1.731	1.961	1.597
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.612	1.075	0.92				1.651	1.319	1.162	2.017	0.979
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.646	1.313	9.897			0.086	1.351	1.962	1.205	2.038	0.861
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.896	1.249	9.917				1.061	2.051	1.78	2.109	1.632
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.242	1.404	1.073				1.906	2.264	2.055	2.412	2.012
COVID19 (COVID19 (JANSSEN))	CSF protein increased	3.581	2.001	9.887				1.87	2.96	1.005	2.56	2.139
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.228	1.578	9.938			0.523	1.712	1.842	1.509	3.344	1.153
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.879	1.984	9.927			0.531	1.384	1.682	1.258	3.888	1.2
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.71	1.738	0.89				1.471	1.365	1.64	3.625	1.268
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.363	2.17	9.921			0.526	2.593	2.447	0.872	3.53	1.273
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.871	1.271	9.955			0.328	1.331	1.897	1.904	2.097	1.616
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.433	1.642	0.96	0.618		0.604	2.13	2.25	2.055	3.028	1.729
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.98	1.325	9.919			0.375	1.724	1.942	1.828	2.268	1.503
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.993	1.375	9.926			0.457	1.388	2.043	1.986	2.249	1.663
COVID19 (COVID19 (JANSSEN))	Creatinine renal clearance decreased	2.064	1.259	9.893				0.495	0.889	2.149	1.061	1.802
COVID19 (COVID19 (JANSSEN))	Death	1.866	1.169	9.962				1.222	1.63	1.575	2.092	1.54
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.646	1.803	1.044			0.463	2.253	2.258	3.192	3.332	2.067
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	2.047	1.349	1.1			0.363	1.404	2.075	1.887	2.955	1.828
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.789	1.293	9.931			0.042	1.236	2.044	1.75	2.102	1.331
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.775	1.336	9.939	0.619		0.267	1.246	2.055	1.764	2.079	1.374
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.758	0.854	9.898			1.182	2.021	1.459	0.976	1.853	1.424
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.27	1.274	9.903			0.504	2.175	2.153	1.958	2.524	1.707
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.143	1.449	9.977	0.619		0.297	1.708	2.302	2.218	2.529	1.621
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.954	1.07	0.89			0.437	1.641	2.044	1.029	2.221	1.277
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.273	1.597		0.737			0.883			1.941	1.893
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.211	1.02	9.898			0.404	2.274	1.683	1.213	2.235	1.578
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.858	1.265	9.916			0.397	1.278	1.753	1.613	2.248	1.225
COVID19 (COVID19 (JANSSEN))	Glomerular filtration rate decreased	1.766	1.136	9.941				1.052	1.567	1.567	2.001	1.365
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.714	1.157	9.915				1.23	1.44	1.349	2.171	1.081
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.482	1.835	9.897			0.435	1.626	3.113	1.644	2.43	2.203
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.803	1.268	9.943	0.619		0.404	1.328	2.018	1.782	2.185	1.423
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.756	1.231	9.935	0.619		0.389	1.397	1.947	1.67	2.091	1.412
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.716	3.605	9.903				4.183	5.523	4.348	7.27	3.378
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.155	3.398	9.888			0.662	4.206	5.739	0.74	7.055	3.689
COVID19 (COVID19 (JANSSEN))	Hypoxia	2.08	1.316	9.958				1.491	2.099	1.932	2.459	1.689
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.082	1.715	9.885			0.011	1.91	2.553	1.392	2.222	1.72
COVID19 (COVID19 (JANSSEN))	Intensive care	1.946	1.388	1.056			0.022	1.456	2.101	2.08	2.345	1.588
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.739	1.191	9.889	0.755		0.381	1.504	1.865	1.421	2.274	1.241
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.938	1.232	9.896				1.384	2.075	0.978	2.089	1.281
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.677	1.779	9.913				0.84	1.423	0.994	1.714	1.625
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.805	1.374	9.891				1.372	1.119	0.712	2.308	0.707
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.873	1.359	9.881				1.275	2.188	1.011	1.859	1.764
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.136	1.68					1.122	2.779	1.027	1.766	1.814
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.998	1.276	9.948				1.417	1.729	2.005	2.372	1.52
COVID19 (COVID19 (JANSSEN))	Lymphocyte count decreased	1.658	1.168	9.914			0.061	1.065	1.873	1.631	2.009	1.242
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.664	1.23	9.931			0.185	1.005	2.005	1.865	2.071	1.304
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.058	1.465	9.917			0.467	1.777	1.871	2.128	2.333	1.598
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.031	1.367	9.934	0.619		0.438	1.273	2.191	1.824	2.376	1.358
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.71	1.254	9.921			0.243	1.163	1.925	1.501	2.052	0.968
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.832	1.289	9.912			0.314	1.136	2.274	1.554	2.064	1.381
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.278	1.505	1.007			0.477	1.157	2.249	2.055	2.122	2.028
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.528	1.218	9.923	0.619		0.208	0.848	1.928	1.974	2.198	1.108
COVID19 (COVID19 (JANSSEN))	Neonatal dyspnoea	2.399	0.983		0.62						0.879	1.119
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.522	1.2	9.898			0.317	1.136	1.567	1.653	2.178	0.857
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.733	1.265	9.932			0.246	1.108	2.05	1.815	1.966	1.415
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	4.076	0.769					3.745	0.613		3.016	1.076
COVID19 (COVID19 (JANSSEN))	Off label use	2.079	0.593	9.899			8.396	1.239	1.387	0.984	1.458	2.089
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.769	0.751					3.444	0.983		2.253	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.226	0.869				0.611	1.498	2.263	1.111	2.17	1.446
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.098	1.358	9.888				1.657	1.035	1.568	2.284	0.951
COVID19 (COVID19 (JANSSEN))	Platelet count	2.647	2.145	9.919	0.618		0.477	1.828	2.853	2.77	3.018	1.79
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.874	1.302	9.921	0.618		0.259	1.469	2.102	1.662	2.245	1.475
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.55	1.809	9.904			0.45	2.065	2.744	2.167	3.114	1.694
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.812	3.276	0.89				4.293	4.675	0.808	5.74	2.295
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.256	1.67	0.89				0.859	1.887	1.03	2.376	1.334
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.089	1.301	9.959				1.004	2.114	1.725	2.238	1.675
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.766	0.834	0.89		9.719	2.063	0.039	0.002	0.513	1.675	1.819
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.187	1.33					5.053			5.16	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.788	1.222	9.929	0.617		0.333	1.432	1.617	1.721	2.029	1.402
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.911	1.373	9.932	0.756		0.294	1.432	2.282	1.646	2.455	1.44
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.255	1.585	1.062	0.62		0.567	1.809	2.073	2.633	2.534	1.916
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.317	1.484	9.911				1.728	1.672	1.942	2.235	1.87
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.792	1.261	9.932	0.614		0.554	1.352	2	1.667	2.039	1.482
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.948	1.305	9.933	0.617		0.283	1.299	2.095	1.8	2.253	1.411
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.367	1.003					0.699	0.309		1.081	0.73
COVID19 (COVID19 (JANSSEN))	Sensory disturbance	2	1.319	9.893				1.409	1.855	1.492	1.849	1.76
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.561	1.752	9.896			0.535	1.773	1.978	1.77	2.58	1.791
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.401	2.225	1.583			0.523	3.158	3.241	1.152	2.818	3.366
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.539	0.759	9.889			0.652	3.818	6.567	14.559	7.679	5.705
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.682							0.637	0.569	0.561	1.026
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.998	1.323	9.901			0.511	1.468	1.909	1.473	2.099	1.356
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.278	1.714	9.949			0.368	1.611	2.405	1.881	2.497	1.791
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.92	2.125	1.748	0.62		0.728	2.011	2.481	3.638	3.004	2.375
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	9.096	2.96	9.905				2.15	5.765	0.563	6.668	2.602
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.08	1.491	9.889				1.783	1.225	0.623	2.119	0.879
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.351	1.438	9.913			0.712	1.899	2.213	2.156	2.65	1.752
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.704	1.692	9.969	0.619		0.627	2.603	2.282	2.86	3.301	2.11
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.361	1.625	9.918			0.429	2.238	1.993	1.958	2.455	1.837
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.607	3.031	2.48			0.484	1.468	2.528	4.508	2.227	2.382
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.914	0.895					1.251	1.376	0.769	2.106	0.81
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.071	0.907	9.888				0.975	1.517	1.131	1.796	1.113
COVID19 (COVID19 (JANSSEN))	Venogram	2.352	1.745	9.887				2.023	1.903	0.706	2.564	1.065
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.683	2.012				0.61	2.685	1.629	0.659	3.342	1.192
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.885	2.188	9.893				3.637	2.004	1.069	4.776	1.199
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.451	0.819		10.61	9.909		1.265	0.52		1.445	1.055
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	9.682	1.013	0.9	0.611	1.677	2.483	9.793	0.651	0.435	0.686	0.642
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.015	1.165				0.663	2.04	1.52	0.807	1.96	1.916
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.53	1.019	9.896	0.48	3.972	2.981	3.163	0.074	0.345	2.54	2.633
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.13	2.019	9.887			2.79	2.033	1.98	1.573	1.965	2.173
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.04					1.137	1.932	1.987	1.846	1.972	1.911
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.097	1.671	9.899			0.837	1.619	1.781	1.528	1.91	1.886
COVID19 (COVID19 (PFIZER-BIONTECH))	Body height	1.959	1.001	9.853		9.483	0.695	0.959	1.457	2.187	1.926	1.552
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.036	1.747	1.652	0.758	9.877	1.133	1.803	1.852	1.84	1.821	1.895
COVID19 (COVID19 (PFIZER-BIONTECH))	Exposure via breast milk	0.86	0.846	9.892	16.309			0.38			0.508	1.248
COVID19 (COVID19 (PFIZER-BIONTECH))	Immunisation	2.07	1.655	0.92		1.289	1.243	1.818	1.999	2.278	1.969	1.857
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.041	1.759	0.93		9.736	1.102	1.818	1.943	2.259	1.862	1.9
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	1.595	0.788			1.447	1.366	1.859	1.719	2.156	1.578	1.551
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	1.929	1.37	9.901			0.953	1.552	1.737	2.081	1.892	1.753

PSI-HHS-000000057705

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 18 Jan 2022 15:13:06 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220114.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, January 18, 2022 6:16 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 1/14/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022Q1	Serious EB05 2022Q	Fatal EB05 2022Q1	Infant EB05 2022Q1	Child EB05 2022Q1	Teen EB05 2022Q1	Adult EB05 2022Q1	Adult2 EB05 2022Q1	Adult3 EB05 2022Q1	Female EB05 2022Q1	Male EB05 2022Q1	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.108	1.733	0.907			0.032	1.558	1.984	2.091	2.755	1.675	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.255	1.782	0.884				1.732	2.18	2.259	3.093	1.531	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.036	1.325	0.988			0.46	1.419	1.979	1.797	2.317	1.629	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.908	0.939	0.873			0.518	0.95	0.831	0.638	2.602	1.489	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.021	1.049	0.876				0.925	0.694	0.772	1.713	1.487	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.935	1.318	0.5				1.475	1.414	1.667	2.237	1.233	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.654	1.97	0.908			0.49	2.266	1.968	2.501	3.927	1.451	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.237	1.628	0.869				1.914	1.893	1.21	2.421	1.453	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.474	1.745	0.896			0.426	1.613	2.366	2.241	2.637	1.945	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.62	1.454	0.86			0.377	1.221	2.24	1.3	2.17	1.318	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.39	0.804	0.866			0.053	0.846	1.048	1.897	2.098	1.778	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.236	1.541	0.963	0.612		0.433	1.821	1.977	2.341	2.778	1.626	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.154	1.876	0.882				0.856	2.105	1.496	1.984	1.522	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.647	1.169	0.87				1.146	1.134	1.052	2.446	0.868	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.928	1.493	0.88	0.61		0.337	1.225	2.449	1.746	2.388	1.321	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.758	1.5	0.883	0.509		0.301	1.263	2.265	1.738	2.187	1.328	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.707	1.317	0.882			0.361	1.462	1.868	1.762	2.171	1.394	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.916	1.427	0.896			0.412	1.444	2.166	1.875	2.295	1.503	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.969	1.485	0.924			0.456	1.349	2.218	2.022	2.362	1.444	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.236	2.456	0.884			0.504	1.844	2.266	0.785	4.292	1.888	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.86	1.444	0.917			0.281	1.209	1.976	1.759	2.448	1.208	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.685	1.246	0.903			0.545	1.225	1.483	2.052	1.866	1.205	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.698	1.45	0.867			0.24	1.427	1.996	1.206	2.111	0.901	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.835	1.255	0.868				1.138	2.035	1.647	2.088	1.557	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2	1.441	1.298				1.709	2.107	1.958	2.292	1.897	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.787	2.16	0.866				1.803	2.967	1.073	2.442	2.27	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.335	1.693	0.921			0.518	1.819	1.872	1.403	3.331	1.124	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.953	2.027	0.906			0.522	1.474	1.306	1.231	4.103	0.913	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.29	1.682	0.869				1.074	1.333	1.489	2.772	1.246	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.267	2.271	0.916			0.519	2.415	2.267	0.883	3.964	1.206	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.621	1.801	0.948	0.611		0.626	2.274	2.338	2.154	3.328	1.743	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.068	1.39	0.896			0.392	1.665	2.013	1.742	2.241	1.487	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.666	1.89	0.923			0.484	1.423	2.09	2.062	3.353	1.663	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.609	1.774	1.009			0.461	2.155	2.282	2.96	3.193	1.992	
COVID19 (COVID19 (JANSSEN))	Embolic stroke	1.509	1.097	0.873				0.454	0.97	2.159	1.771	0.866	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.744	1.308	0.884				1.261	2.121	1.515	2.044	1.221	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.725	1.351	0.876	0.61		0.311	1.306	2.046	1.536	2.012	1.3	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.846	0.876			1.122	2.007	1.459	0.968	1.855	1.404	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.287	1.264	0.882			0.378	2.176	2.156	1.907	2.534	1.855	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.742	1.436	0.925	0.612		0.33	1.638	2.276	2.166	2.408	1.585	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.959	1.043	0.867			0.409	1.661	2.043	0.858	2.123	1.341	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.313	1.108	0.881			0.409	2.304	1.755	1.294	2.475	1.574	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.669	1.342	0.906			0.404	1.387	1.55	1.664	2.202	1.222	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.818	1.243	0.888				1.455	1.278	1.403	2.242	1.083	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.317	1.837	0.868				1.524	2.919	1.823	2.204	2.164	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.848	1.341	0.896	0.607		0.497	1.335	2.078	1.884	2.284	1.439	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.79	1.301	0.903	0.608		0.328	1.419	2.017	1.679	2.116	1.421	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.615	3.62	0.886				4.037	52	5.868	7.241	2.966	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.458	3.604	0.869			0.544	4.726	5.881	6.761	7.743	3.944	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.871	1.32	0.922				1.53	1.973	1.752	2.311	1.554	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.103	1.849	0.872			0.026	1.982	2.527	1.477	2.257	1.715	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.857	1.422	1.043			0.032	1.431	2.062	2.036	2.253	1.527	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.873	1.323	0.883	0.747		0.468	1.629	2	1.475	2.468	1.296	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.016	1.339	0.874				1.439	2.105	0.984	2.291	1.292	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.046	1.837	0.873				1.51	1.196	0.719	2.911	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.91	1.398	0.864				1.209	2.164	1.056	1.717	1.853	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.047	1.737					0.955	2.576	1.096	1.692	1.749	
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.68	1.202	0.92				1.235	1.592	1.74	2.008	1.425	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.679	1.205	0.896			0.192	1.031	2.078	1.846	2.124	1.205	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.405	1.137	0.89	0.608			1.029	1.541	1.132	2.034	0.688	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.122	1.586	0.886			0.479	1.854	1.864	2.149	2.411	1.807	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.149	1.518	0.906	0.612		0.469	1.236	2.349	1.83	2.457	1.388	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.861	1.435	0.901			0.346	1.289	2.332	1.456	2.291	1.339	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.671	1.478	0.972			0.485	0.991	2.279	1.698	1.892	1.875	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.589	1.285	0.89	0.61		0.27	0.925	1.983	1.026	2.361	1.085	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.536	1.241	0.871			0.172	1.225	1.718	1.427	2.242	0.864	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.738	1.324	0.898			0.248	1.117	2.104	1.882	2.034	1.391	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.195	0.724					0.762	0.612		1.962	1.069	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	0.365	0.873			7.745	1.23	1.109	0.807	1.361	1.922	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.755	0.759					3.269	1.062		2.218		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.516	0.857				0.514	1.607	2.138	1.097	2.302	1.403	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.063	1.553	0.899				0.657	1.062	1.683	2.725	0.954	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	2.773	2.315	0.918	0.611		0.474	1.823	3.05	2.558	3.157	1.785	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.89	1.353	0.899	0.609		0.298	1.531	2.093	1.538	2.196	1.469	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.727	1.966	0.867			0.392	2.03	2.653	2.243	3.24	1.693	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.003	3.423	0.87				4.226	3.867	0.817	6.292	2.171	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.368					0.986	4.121	3.31	5.945	4.543	3.991	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.798	1.382	0.886	0.611		0.284	1.391	1.67	1.809	2.61	1.381	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.025	1.567	0.914	0.746		0.338	1.551	2.429	1.66	2.638	1.505	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.225	1.585	1.528	0.613		0.588	1.713	2.034	2.59	2.484	1.814	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.647	1.488	0.898				1.697	1.58	1.842	3.064	1.807	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.882	1.368	0.896	0.608		0.543	1.434	2.108	1.741	2.138	1.552	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.039	1.426	0.9	0.611		0.345	1.303	2.306	1.782	2.418	1.432	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.4	1.467	0.875			0.531	1.731	1.935	1.477	2.447	1.706	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.23	1.366	1.106			0.528	2.646	2.657	1.167	2.697	3.112	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.034	6.781	0.87			0.646	3.583	6.652	15.654	7.795	5.87	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.367							0.637	0.572	0.568	1.019	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.148	1.544	0.886			0.508	1.45	1.619	1.512	2.268	1.369	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.335	1.884	0.949			0.374	1.67	2.503	1.808	2.577	1.786	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.88	2.082	1.675	0.613		0.654	1.961	2.394	3.485	2.869	2.226	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.993	2.367	0.867				1.182	0.765	0.373	4.081	0.801	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.253	1.837	0.869				1.884	1.267	0.637	2.148	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.393	1.449	0.896			0.64	1.896	2.219	2.377	2.782	1.717	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.76	1.975	0.928	0.612		0.524	2.369	2.282	2.964	3.309	2.102	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.526	1.736	0.906			0.444	2.156	2.057	1.679	2.507	1.862	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.878	1.111	0.87				1.271	2.078	1.808	1.962	1.331	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.368	1.109	2.461			0.521	1.422	2.885	6.302	2.268	2.358	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.038	0.869					0.895	1.677	0.564	1.813	1.096	
COVID19 (COVID19 (JANSSEN))	Venogram	2.413	1.916	0.866				2.107	1.681	0.709	2.864	1.04	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.865	2.236				0.604	2.645	1.765	0.676	3.738	1.192	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.218	2.327	0.873				3.857	2.1	0.96	5.021	1.205	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.723	1.268	0.865			0.283	1.585	1.517	1.708	2.005	1.218	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	0.834		7.852	0.938		1.218	0.514		1.333	0.911	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.934	0.866	0.605	0.844	2.384	0.774	0.595	0.391	0.638	0.597	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	0.928	0.876		5.334	2.847	0.092	0.051	0.386	2.468	2.548	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.052	2.047	0.868			2.326	2.003	1.95	1.57	1.903	2.111	
COVID19 (COVID19 (PFIZER-	Body height	1.946	1.016	0.873			0.587	0.944	1.366	2.216	1.937	1.524	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.084	0.87		0.479	0.709	1.445	1.627	1.927	1.98	1.515	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.76	1.692		0.623	1.048	1.745	1.741	1.801	1.981	1.938	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	0.847	0.872	17.971			0.402			0.405	1.35	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.629	0.898		1.28	1.23	1.786	1.99	2.251	2.013	1.857	
COVID19 (COVID19 (PFIZER-	Investigation	2.161	1.756	0.896		0.645	1.068	1.775	1.938	2.268	2.093	1.919	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	0.752			1.588	1.407	1.872	1.761	2.259	1.691	1.648	
COVID19 (COVID19 (PFIZER-	Weight	2.021	1.351	0.883			0.882	1.532	1.749	2.187	1.998	1.779	

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 25 Jan 2022 14:50:29 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220121.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, January 25, 2022 6:41 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Hi All,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 1/21/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.108	1.717	0.906			0.602	1.558	1.966	2.092	2.71	1.654	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.23	1.736	0.88				1.698	2.128	2.286	3.094	1.491	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.04	1.327	0.996			0.457	1.423	1.986	1.809	2.312	1.841	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.892	6.934	0.874			0.518	0.98	0.817	0.633	2.581	1.471	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.022	1.07	0.88				0.926	0.763	0.765	1.753	1.516	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.932	1.331	0.9				1.476	1.413	1.704	2.238	1.257	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.634	1.932	0.902			0.486	2.248	1.967	2.465	3.876	1.446	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.235	1.617	0.87				1.936	1.875	1.201	2.388	1.468	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.461	1.725	0.897			0.425	1.604	2.368	2.189	2.588	1.944	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.826	1.46	0.86			0.375	1.227	2.241	1.324	2.184	1.318	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.39	6.817	0.869			0.593	0.843	1.047	1.866	2.094	1.791	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.241	1.55	0.974	0.612		0.432	1.809	1.968	2.398	2.838	1.816	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.134	1.883	0.882				0.85	2.171	1.477	1.91	1.56	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.449	1.18	0.871				1.148	1.184	1.47	2.08	0.918	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.923	1.481	0.881	0.61		0.332	1.226	2.408	1.762	2.393	1.311	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.783	1.487	0.885	0.609		0.295	1.252	2.25	1.725	2.166	1.318	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.778	1.303	0.883			0.337	1.432	1.84	1.758	2.171	1.365	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.855	1.402	0.896			0.406	1.431	2.127	1.852	2.274	1.476	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.993	1.464	0.924			0.451	1.356	2.203	1.987	2.323	1.441	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.236	2.454	0.885			0.503	1.843	2.266	0.784	4.29	1.087	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.818	1.391	0.913			0.268	1.178	1.948	1.722	2.398	1.171	
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.665	1.241	0.906			0.538	1.211	1.468	2.043	1.864	1.205	
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.526	1.09	0.904				1.331	1.465	0.95	2.024	0.827	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.668	1.401	0.868			0.235	1.41	1.935	1.292	2.092	0.877	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.825	1.239	0.874				1.105	2.018	1.624	2.062	1.536	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.005	1.44	1.395				1.684	2.117	1.963	2.293	1.898	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.717	2.101	0.87				1.805	2.989	1.061	2.398	2.305	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.374	1.618	0.917			0.517	1.711	1.855	1.433	3.23	1.1	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	3.079	2.042	0.912			0.522	1.473	1.369	1.228	4.088	0.969	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.29	1.635	0.87				1.073	1.305	1.47	2.731	1.224	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.246	2.193	0.907			0.519	2.293	2.299	0.878	3.924	1.191	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.507	1.76	0.946	0.611		0.622	2.195	2.32	2.123	3.251	1.721	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.651	1.398	0.896			0.387	1.707	2.009	1.735	3.234	1.514	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.088	1.473	0.923			0.461	1.41	2.084	2.031	2.328	1.655	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.601	1.775	0.993			0.46	2.143	2.258	3.042	3.214	1.986	
COVID19 (COVID19 (JANSSEN))	Embolic stroke	1.498	1.089	0.874				0.455	0.962	2.159	1.722	0.867	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.742	1.306	0.887				1.253	2.12	1.528	2.043	1.227	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.719	1.352	0.881	0.61		0.306	1.202	2.037	1.561	2.008	1.295	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.84	0.877			1.117	2.007	1.463	0.974	1.852	1.405	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.254	1.244	0.886			0.378	2.172	2.135	1.903	2.527	1.673	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.146	1.448	0.937	0.612		0.325	1.647	2.259	2.175	2.462	1.59	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.566	1.065	0.869			0.438	1.657	2.093	0.853	2.13	1.359	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.269	1.977	0.86			0.409	2.276	1.746	1.26	2.411	1.566	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.877	1.33	0.887			3.4	1.385	1.57	1.7	2.188	1.237	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.821	1.247	0.888				1.429	1.309	1.397	2.221	1.102	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.319	1.939	0.872				1.888	2.842	1.628	2.883	2.198	
COVID19 (COVID19 (JANSSEN))	Haemostatic decreased	1.824	1.315	0.904	0.607		0.432	1.336	2.044	1.793	2.213	1.402	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.776	1.28	0.91	0.608		0.325	1.4	2.063	1.648	2.107	1.395	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.59	5.587	0.886				4.037	5.161	5.862	7.294	2.856	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.486	5.607	0.87			0.543	4.727	5.899	0.761	7.741	2.065	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.872	1.313	0.928				1.505	1.931	1.784	2.308	1.555	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.062	1.837	0.871			0.025	1.993	2.514	1.479	2.237	1.713	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.851	1.417	1.056			0.031	1.415	2.045	2.048	2.258	1.52	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.868	1.304	0.896	0.747		0.402	1.599	2.005	1.453	2.443	1.28	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.078	1.396	0.875				1.441	2.078	0.983	2.186	1.273	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.952	1.685	0.874				1.376	1.195	0.714	2.466	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.908	1.366	0.864				1.212	2.14	1.054	1.698	1.843	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.049	1.736					0.998	2.583	1.087	1.693	1.744	
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.666	1.209	0.923				1.239	1.603	1.734	2.07	1.404	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.668	1.27	0.895			0.184	1.022	2.074	1.923	2.105	1.263	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.388	1.126	0.89	0.608			1.008	1.508	1.193	2.028	0.869	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.514	1.881	0.886			0.476	1.82	1.867	2.171	2.384	1.823	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.124	1.495	0.9	0.612		0.459	1.213	2.318	1.836	2.441	1.362	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.963	1.435	0.903			0.342	1.311	2.34	1.459	2.198	1.373	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.082	1.479	0.993			0.478	0.972	2.186	1.794	1.893	1.889	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.569	1.272	0.886	0.61		0.264	0.917	1.945	2.034	2.363	1.07	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.512	1.223	0.872			0.152	1.2	1.872	1.472	2.223	0.843	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.729	1.313	0.9			0.243	1.112	2.088	1.865	2.017	1.387	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.194	6.725					0.761	0.612		1.958	1.068	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	6.414	0.875			7.887	1.246	1.105	0.801	1.381	1.918	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.754	0.76					3.273	1.061		2.213		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.515	6.857				0.513	1.61	2.139	1.095	2.284	1.403	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.063	1.553	0.87				0.657	1.061	1.69	2.715	0.954	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.763	2.259	0.91	0.611		0.472	1.804	3.062	2.386	3.159	1.786	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.674	1.317	0.896	0.609		0.297	1.463	2.077	1.513	2.171	1.442	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.723	1.935	0.888			0.39	2.023	2.834	2.175	3.231	1.667	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.028	3.384	0.871				4.266	2.603	0.817	6.291	1.838	
COVID19 (COVID19 (JANSSEN))	Post cardiac arrest syndrome	1.388					0.666	0.153	3.378	3.888	4.888	4.827	
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	1.761	1.334	0.936				0.973	1.873	1.713	2.004	1.629	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.747	1.247	0.883	0.611		0.364	1.382	1.933	1.611	2.004	1.328	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.651	1.558	0.919	0.746		0.334	1.54	2.459	1.642	2.683	1.496	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.215	1.577	1.513	0.613		0.588	1.704	2.031	2.582	2.483	1.812	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.048	1.46	0.896				1.673	1.563	1.912	1.998	1.796	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.87	1.345	0.894	0.608		0.539	1.412	2.086	1.711	2.114	1.525	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.003	1.38	0.896	0.611		0.34	1.261	2.273	1.734	2.368	1.402	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.354	1.354	0.876			0.531	1.717	1.865	1.443	2.405	1.638	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.235	2.33	1.092			0.526	2.679	2.72	1.176	2.845	3.11	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.024	6.779	0.871			0.645	3.584	5.663	15.36	7.795	5.841	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.387							0.638	6.572	0.568	1.02	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.141	1.516	0.886			0.508	1.429	1.588	1.564	2.31	1.337	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.313	1.836	0.936			0.374	1.66	2.451	1.765	2.582	1.749	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.68	2.097	1.666	0.613		0.653	1.96	2.368	3.481	2.878	2.227	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.962	3.393	0.889				1.181	0.765	0.573	4.065	1.68	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.236	1.62	0.87				1.883	1.206	0.633	2.121	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.41	1.466	0.897			0.639	1.892	2.25	2.375	2.785	1.74	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.721	1.862	0.932	0.612		0.524	2.373	2.255	2.972	3.291	2.081	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.515	1.741	0.912			0.444	2.135	2.064	2.028	2.491	1.885	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.884	1.115	0.871				1.26	2.085	1.791	1.948	1.341	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.17	2.42			0.515	1.487	2.948	6.268	2.294	2.376	
COVID19 (COVID19 (JANSSEN))	Vasculitis	2.036	6.896					0.891	1.663	1.052	1.868	1.887	
COVID19 (COVID19 (JANSSEN))	Venogram	2.361	1.878	0.87				2.002	1.681	0.708	2.848	1.04	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.778	2.195				0.803	2.429	1.763	0.676	3.604	1.191	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.188	3.315	0.874				3.856	2.099	0.946	5.02	1.201	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.712	1.243	0.866			0.196	1.556	2.104	1.671	2.007	1.168	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.375	6.834		7.743	0.937		1.217	0.514		1.332	0.911	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.953	0.866	0.605	0.644	2.425	0.783	0.599	0.391	0.642	0.601	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.921	0.877		5.307	2.663	0.107	0.65	0.387	2.473	2.565	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.051	2.05	0.868			2.388	2.003	1.951	1.671	1.904	2.114	
COVID19 (COVID19 (PFIZER-	Body height	1.948	1.018	0.874			0.587	0.944	1.386	2.213	1.937	1.524	
COVID19 (COVID19 (PFIZER-	Device failure	2.547	1.984	0.871		0.48	0.799	1.448	1.988	1.827	1.981	1.58	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.762	1.588		0.682	1.056	1.735	1.736	1.778	1.974	1.927	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	6.847	0.873	17.976			0.402			0.459	1.353	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.651	0.896		1.273	1.229	1.808	1.998	2.246	2.021	1.869	
COVID19 (COVID19 (PFIZER-	Investigation	2.161	1.762	0.896		0.648	1.07	1.779	1.933	2.273	2.092	1.918	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.753	6.753			1.561	1.402	1.881	1.764	2.253	1.687	1.64	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.36	0.884			0.892	1.536	1.752	2.187	1.998	1.781	

PSI-HHS-000000057709

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 8 Feb 2022 13:05:35 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220204.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, February 8, 2022 6:52 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Hi All,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 2/4/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2022(0	Serious EB05 2022(	Fatal EB05 2022(	Infant EB05 2022(	Child EB05 2022(	Teen EB05 2022(	Adult1 EB05 2022(	Adult2 EB05 2022(	Adult3 EB05 2022(	Female EB05 2022(	Male EB05 2022(	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.086	1.681	0.906			0.597	1.58	1.9	2.043	2.681	1.651	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.208	1.706	0.874				1.686	2.125	2.197	2.98	1.497	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.04	1.341	1.005			0.455	1.435	2.009	1.827	2.298	1.678	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.882	6.961	0.867			0.519	0.977	0.865	0.687	2.554	1.442	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.018	1.059	0.875				0.908	0.739	0.759	1.755	1.493	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.941	1.386	0.903				1.454	1.444	1.785	2.252	1.298	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.557	1.89	0.904			0.487	2.178	1.963	2.225	3.771	1.416	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.196	1.586	0.871				1.895	1.817	1.299	2.43	1.421	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.426	1.687	0.898			0.426	1.593	2.309	2.169	2.501	1.942	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.812	1.429	0.888			0.372	1.184	2.226	1.351	2.192	1.283	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.309	6.807	0.86			0.063	0.634	1.031	1.889	2.024	1.757	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.234	1.514	0.955	0.612		0.43	1.799	1.99	2.256	2.75	1.809	Other
COVID19 (COVID19 (JANSEN))	Areflexia	2.123	1.835	0.876				0.819	2.234	1.434	1.855	1.572	Reviewed
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.41	1.141	0.881				1.138	1.166	1.491	2.421	0.958	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.905	1.437	0.876	0.61		0.329	1.228	2.348	1.713	2.364	1.292	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.789	1.466	0.883	0.609		0.287	1.237	2.238	1.713	2.162	1.313	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.799	1.3	0.883			0.333	1.459	1.828	1.761	2.165	1.381	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.873	1.374	0.896			0.399	1.41	2.074	1.835	2.241	1.449	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.923	1.423	0.936			0.449	1.323	2.121	1.971	2.296	1.396	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.273	2.429	0.885			0.504	1.844	2.168	0.86	4.355	1.967	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.825	1.386	0.915			0.287	1.173	1.932	1.752	2.482	1.158	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.675	1.221	0.906			0.533	1.192	1.478	2.01	1.857	1.171	Other
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.594	1.12	0.902				1.428	1.45	1.056	2.144	1.07	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.654	1.36	0.881			0.231	1.377	1.906	1.251	2.043	0.872	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.828	1.233	0.874				1.066	2.013	1.634	2.032	1.548	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.003	1.413	1.157				1.85	2.111	1.903	2.211	1.886	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.779	2.149	0.953				1.815	2.897	1.093	2.43	2.267	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.307	1.616	0.917			0.514	1.711	1.823	1.459	3.214	1.088	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.883	1.966	0.912			0.522	1.445	1.987	1.203	3.881	1.002	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.289	1.663	0.86				1.129	1.364	1.526	2.845	1.23	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.243	2.176	0.905			0.518	2.265	2.236	0.877	3.857	1.183	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.586	1.728	0.961	0.611		0.616	2.149	2.327	2.071	3.132	1.736	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.997	1.381	0.898			0.386	1.707	1.969	1.814	2.31	1.517	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.078	1.432	0.921			0.458	1.376	2.045	1.979	2.288	1.818	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.593	1.77	1.016			0.458	2.141	2.248	3.049	3.224	1.977	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.925	1.396	1.216			0.379	1.324	2.075	1.761	1.92	1.828	
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.761	1.306	0.881				1.257	2.142	1.505	2.043	1.244	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.755	1.377	0.876	0.609		0.304	1.205	2.081	1.61	2.024	1.351	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.78	6.836	0.871			1.109	2.012	1.452	0.968	1.848	1.413	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.304	1.234	0.881			0.442	2.157	2.124	1.841	2.473	1.677	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.166	1.445	0.96	0.612		0.319	1.656	2.258	2.184	2.429	1.585	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.961	1.078	0.866			0.438	1.642	2.049	0.966	2.121	1.356	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.321	1.109	0.878			0.408	2.27	1.772	1.317	2.366	1.025	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.882	1.328	0.88			0.401	1.351	1.647	1.663	2.228	1.242	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.811	1.227	0.896				1.369	1.326	1.403	2.184	1.108	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.338	1.838	0.87				1.831	2.862	1.613	2.84	2.166	Reviewed
COVID19 (COVID19 (JANSEN))	Haemstocrit decreased	1.822	1.295	0.901	0.606		0.426	1.333	2.023	1.753	2.196	1.384	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.77	1.263	0.899	0.607		0.321	1.413	1.966	1.625	2.094	1.381	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.585	3.55	0.883				3.871	5.208	5.262	7.103	1.85	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.469	3.492	0.884			0.544	4.733	5.581	6.753	7.738	1.803	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.862	1.296	0.922				1.498	1.941	1.731	2.264	1.544	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.08	1.812	0.864			0.023	1.918	2.529	1.457	2.238	1.885	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.849	1.43	1.049			0.03	1.433	2.67	2.048	2.288	1.536	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.866	1.281	0.883	0.747		0.387	1.595	1.984	1.454	2.381	1.283	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.078	1.267	0.898				1.435	2.047	0.935	2.152	1.253	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.951	1.626	0.868				1.375	1.178	0.713	2.462	0.726	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.908	1.359	0.857				1.208	2.127	1.036	1.698	1.639	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.049	1.691					0.977	2.556	1.054	1.665	1.718	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.694	1.249	0.926				1.311	1.672	1.776	2.112	1.404	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.691	1.273	0.891			0.179	1.041	2.08	1.514	2.108	1.286	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.103	1.554	0.896			0.476	1.81	1.876	2.145	2.33	1.62	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.108	1.469	0.902	0.612		0.462	1.184	2.21	1.823	2.398	1.377	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.866	1.375	0.896			0.338	1.279	2.264	1.421	2.144	1.331	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.079	1.531	1.016			0.478	0.957	2.248	1.868	1.881	1.894	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.581	1.264	0.887	0.609		0.259	0.916	1.936	1.017	2.325	1.091	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.526	1.217	0.868			0.136	1.191	1.64	1.543	2.231	0.833	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.733	1.302	0.894			0.239	1.128	2.069	1.833	1.998	1.399	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.191	6.792					0.761	0.612		2.231	1.068	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.34	6.491	0.875			7.877	1.229	1.13	0.827	1.392	1.899	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.753	6.762					3.286	1		2.212		Other
COVID19 (COVID19 (JANSEN))	Packed red blood cell transfusion	1.724	1.307	0.886				1.134	1.226	1.195	2.037	0.898	
COVID19 (COVID19 (JANSEN))	Pain assessment	2.518	6.858				0.514	1.582	2.202	1.082	2.321	1.41	Not an AE
COVID19 (COVID19 (JANSEN))	Pericoronal embolism	2.928	1.488	0.863				0.657	1.06	1.587	2.448	0.953	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.773	2.249	0.908	0.611		0.473	1.776	3.095	2.593	3.145	1.786	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.669	1.295	0.867	0.609		0.282	1.477	2.009	1.499	2.14	1.429	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.722	1.843	0.883			0.388	2.007	2.746	1.991	3.124	1.627	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.028	3.382	0.866				4.274	2.562	6.815	6.288	1.842	Not an AE
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.398					0.086	0.151	3.371	0.811	4.088		Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.068	1.066					3.193			1.774		
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.955	1.517	0.921	0.746		0.328	1.525	2.366	1.657	2.601	1.48	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.225	1.572	1.48	0.613		0.587	1.698	2.036	2.577	2.468	1.815	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.043	1.476	0.892				1.658	1.568	1.515	1.998	1.81	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.844	1.31	0.891	0.608		0.531	1.378	2.044	1.675	2.066	1.495	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	1.968	1.35	0.896	0.611		0.336	1.273	2.202	1.729	2.338	1.369	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.363	1.021					2.314	0.499		1.097	0.731	
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.466	1.536	0.87			0.531	1.709	1.966	1.536	2.555	1.866	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.236	2.191	1.398			0.524	3.105	2.969	1.273	2.767	3.174	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.023	6.773	0.865			0.646	3.587	5.663	14.992	7.792	5.82	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.38							0.638	6.571	0.568	1.019	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.128	1.452	0.88			0.509	1.399	1.57	1.517	2.257	1.308	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.303	1.776	0.937			0.375	1.616	2.376	1.769	2.491	1.717	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.662	2.088	1.569	0.613		0.73	1.959	2.364	3.492	2.864	2.242	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.991	3.395	0.884				1.18	0.896	0.572	4.103	1.68	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.234	1.796	0.864				1.885	1.196	0.833	2.084	0.908	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.417	1.475	0.893			0.638	1.879	2.266	2.285	2.753	1.743	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.719	1.833	0.924	0.612		0.521	2.357	2.235	2.824	3.271	2.042	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.52	1.727	0.916			0.438	2.095	2.065	2.144	2.544	1.843	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.88	1.099	0.865				1.242	2.069	1.737	1.921	1.325	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.367	3.081	2.466			0.502	1.56	2.968	6.199	2.313	2.436	Other
COVID19 (COVID19 (JANSEN))	Vasculitis	2.036	6.893					0.89	1.654	1.044	1.848	1.886	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.327	1.829	0.881				1.945	1.666	0.707	2.626	1.04	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.725	2.141				0.802	2.367	1.723	0.671	3.23	1.237	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.088	3.279	0.868				3.764	2.051	0.927	4.908	1.235	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.378	6.835		7.725	0.936		1.237	0.575		1.393	0.911	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	6.59	0.93	0.86	0.605	0.781	2.44	0.78	0.603	0.394	0.648	0.803	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.902	6.977				0.618	2.038	1.464	0.789	1.911	1.974	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.963	0.873		5.553	2.9	0.105	0.049	0.366	2.512	2.807	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.051	2.05	0.863			2.382	2.004	1.902	1.671	1.901	2.114	
COVID19 (COVID19 (PFIZER-	Body height	1.948	6.989	0.868			0.587	0.944	1.362	2.185	1.915	1.523	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.547	1.894	0.884		0.469	0.71	1.448	1.49	1.909	1.971	1.906	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.77	1.697	0.612	0.726	1.665	1.721	1.731	1.759	1.935	1.912	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.848	0.867	17.941			0.391			0.451	1.351	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.695	0.91		1.273	1.223	1.818	1.989	2.231	1.998	1.852	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.763	0.893		0.648	1.07	1.773	1.929	2.248	2.071	1.913	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.753	6.755			1.512	1.388	1.854	1.743	2.197	1.65	1.808	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.338	0.875			0.891	1.537	1.748	2.166	1.972	1.773	

PSI-HHS-000000057711

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 11 Jun 2021 19:52:47 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20210604.xls

From: Menschik, David <[redacted]>
Sent: Tuesday, June 8, 2021 6:55 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 6/4/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20210804	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20216	Child EB05 20210	Teen EB05 202104	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 2021	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.158	0.751					0.732	0.389	0.714	1.777	1.371	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.84	2.638	0.882			0.538	1.299	1.684	4.285	3.818	1.163	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.064	2.094	0.88			0.546	1.257	2.038	1.368	2.113	1.54	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.866	1.859	0.894	0.611			1.521	1.48	1.861	2.285	1.175	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	1.678	1.834	0.895			0.554	1.214	1.468	1.171	2.067	0.844	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	2.872	2.65	0.891			0.538	2.129	2.148	0.681	3.24	1.082	
COVID19 (COVID19 (JANSSEN))	Chills	1.409	0.925	0.889			2.278	1.462	1.239	0.937	1.459	1.194	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.324	2.311	0.909	0.611		0.531	1.779	2.032	1.815	3.168	1.314	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.789	1.794	0.883			0.592	1.269	1.656	1.538	2.08	1.206	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.357	1.917	0.893			0.518	2.023	2.105	2.883	2.796	1.796	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	1.923	1.32	0.866			0.922	2.361	2.106	1.937	2.840	1.496	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.854	1.384	0.89	0.606		0.572	1.388	1.857	1.428	2.278	0.972	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.809	0.926	0.881			0.602	1.548	1.542	0.737	2.084	0.929	
COVID19 (COVID19 (JANSSEN))	Gout attack	2.248	0.824	0.881				2.239	1.666	0.634	2.78	1.099	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	1.957	2.842	0.885				1.231	1.881	1.508	5.262	0.933	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	1.365	2.161				0.554	1.355	1.047	0.574	1.955	0.918	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.06	2.343	0.881				1.59	1.033	0.651	3.087	0.691	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.986	2.054	0.88			0.571	1.962	1.625	1.66	2.228	1.419	
COVID19 (COVID19 (JANSSEN))	Off label use	1.3					3.741	0.31	9.428		0.824	1.145	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	1.777	1.684	0.881				0.542	9.916	2.381	2.101	0.845	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.13	2.425	0.898	0.611		0.539	1.832	2.472	1.276	2.487	1.186	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.42	2.028	0.886			0.403	1.833	2.493	1.879	3.105	1.339	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	4.306	2.809	0.882				1.998	1.217	0.686	3.771	0.938	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.179					0.498	2.211	1.505	0.577	1.599	1.746	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.807	1.757	0.895	0.611		0.689	1.289	1.747	2.099	2.093	1.38	
COVID19 (COVID19 (JANSSEN))	Pyrexia	1.438	0.897	0.889			2.157	1.499	1.228	0.928	1.483	1.232	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	3.491						1.348	4.309	8.572	3.471	2.791	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.247	1.087	0.883			0.554	1.262	1.685	1.258	1.736	1.881	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.288	2.548	1.975	0.611		0.659	2.002	2.41	3.378	2.875	1.714	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.077	1.214	0.884			0.599	1.766	1.999	1.628	2.481	1.278	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.599	2.207	0.889				1.985	2.127	2.858	2.955	1.836	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.894	1.319		0.603			1.338	2.106	1.892	1.915	1.833	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	1.982	1.043	0.879				1.488	1.683	1.586	3.095	1.3	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.962	0.985					1.382	1.979	1.138	2.247	0.898	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.993	2.686				0.547	2.467	1.474	0.54	3.364	1.917	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.172	2.843	0.882				3.761	1.691	0.661	5.117	0.884	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.266				0.528	0.516	0.431	9.517	0.792	0.787	0.57	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.133						0.358	9.258	0.511	0.232	0.456	
COVID19 (COVID19 (PFIZER-	Drug ineffective	1.964	1.682	0.897			0.746	1.823	1.998	2.034	1.779	1.773	
COVID19 (COVID19 (PFIZER-	Investigation	2.053	1.705	0.889			0.712	1.751	1.843	2.071	2.001	1.751	
COVID19 (COVID19 (PFIZER-	Product preparation issue	2.021					1.513	1.777	1.863	2.124	1.947	1.924	
COVID19 (COVID19 (PFIZER-	Weight	2.02	1.254	0.884			0.576	1.431	1.744	2.028	1.98	1.624	

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 4 Jan 2022 13:24:22 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211231.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, January 4, 2022 6:39 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 12/31/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20211	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.12	1.74	0.907			0.655	1.55	1.966	2.016	2.714	1.675	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.284	1.797	0.887				1.747	2.236	2.268	3.117	1.572	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.019	1.333	0.982			0.461	1.42	1.949	1.835	2.3	1.851	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.911	0.943	0.878			0.523	0.957	0.843	0.651	2.611	1.525	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.022	1.068	0.884				0.961	0.718	0.78	1.684	1.495	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.948	1.334	0.903				1.473	1.431	1.69	2.208	1.288	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.749	2.018	0.906			0.491	2.222	2.064	2.702	3.968	1.477	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.249	1.671	0.876				1.96	1.868	1.224	2.413	1.479	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.485	1.806	0.903			0.43	1.634	2.421	2.369	2.748	1.987	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.787	1.431	0.893			0.38	1.179	2.268	1.187	2.128	1.298	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.309	0.822	0.872			0.066	0.806	1.092	1.923	2.082	1.8	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.245	1.553	0.995	0.612		0.437	1.856	1.962	2.359	2.77	1.636	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.113	1.893	0.883				0.875	2.113	1.434	1.931	1.532	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.449	1.178	0.872				1.147	1.161	1.024	2.482	0.903	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.908	1.492	0.884	0.61		0.34	1.199	2.514	1.677	2.321	1.33	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.773	1.487	0.884	0.609		0.305	1.246	2.264	1.661	2.151	1.311	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.775	1.294	0.886			0.344	1.473	1.85	1.683	2.313	1.373	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.918	1.434	0.898			0.476	1.446	2.206	1.841	2.291	1.511	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.976	1.488	0.915			0.464	1.352	2.301	1.896	2.363	1.438	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.368	2.525	0.888			0.505	1.928	2.47	0.785	4.425	1.101	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.851	1.427	0.916			0.283	1.248	1.997	1.612	2.398	1.194	
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.507	1.08	0.902				1.359	1.376	0.926	2.008	0.795	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.737	1.516	0.874			0.247	1.44	2.076	1.333	2.17	0.919	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.833	1.244	0.879				1.141	2.037	1.61	2.061	1.543	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.995	1.441	1.358				1.603	2.084	1.987	2.324	1.962	
COVID19 (COVID19 (JANSSEN))	CSF immunoglobulin increased	2.034	1.77					0.953	1.463	0.545	0.898	1.583	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.701	2.202	0.873				1.823	3.03	1.086	2.515	2.312	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.004	1.724	0.873				1.305	1.751	1.081	1.742	1.46	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.357	1.729	0.92			0.518	1.876	1.891	1.49	3.438	1.087	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	3.039	2.068	0.907			0.627	1.473	1.909	1.263	4.262	0.919	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.289	1.679	0.875				1.086	1.334	1.45	2.912	1.2	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.309	2.277	0.918			0.524	2.407	2.295	0.893	3.967	1.216	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.651	1.832	0.943	0.611		0.631	2.333	2.345	2.19	3.391	1.742	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.017	1.394	0.9			0.395	1.645	2.034	1.758	2.235	1.502	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.675	1.483	0.918			0.467	1.435	2.067	2.032	2.353	1.636	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.807	1.796	0.978			0.465	2.171	2.297	3.016	3.213	2.015	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.769	1.328	0.888				1.277	2.205	1.463	2.058	1.291	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.685	1.309	0.879	0.61		0.314	1.284	2.054	1.392	1.908	1.299	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	0.833	0.881			0.133	2.018	1.471	0.98	1.861	1.421	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.286	1.278	0.881			0.379	2.196	2.177	1.917	2.542	1.89	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.145	1.451	0.928	0.612		0.336	1.656	2.285	2.211	2.447	1.577	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.953	1.022	0.874			0.442	1.689	2.026	0.729	2.131	1.314	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.337	1.114	0.866			0.41	2.372	1.763	1.304	2.492	1.802	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.865	1.328	0.889			0.407	1.428	1.599	1.585	2.208	1.205	
COVID19 (COVID19 (JANSSEN))	Glomerular filtration rate decreased	1.775	1.161	0.898				1.014	2.63	1.4	1.965	1.36	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.849	1.28	0.886				1.017	1.909	1.379	2.393	1.105	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.301	1.85	0.873				1.516	2.927	1.889	2.3	2.17	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.848	1.343	0.909	0.607		0.442	1.368	2.106	1.797	2.227	1.446	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.792	1.3	0.902	0.608		0.392	1.402	2.062	1.644	2.108	1.429	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.676	3.858	0.892				4.036	5.157	5.876	7.238	3.96	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.499	3.567	0.875			0.565	4.728	5.768	6.761	7.744	1.713	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.872	1.327	0.92				1.535	1.972	1.759	2.317	1.559	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.114	1.887	0.877			0.027	1.969	2.563	1.517	2.31	1.725	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.861	1.434	1.097			0.033	1.438	2.047	2.08	2.27	1.523	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.911	1.366	0.891	0.747		0.412	1.646	2.048	1.522	2.544	1.326	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.016	1.39	0.878				1.472	2.163	0.99	2.238	1.329	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.045	1.84	0.878				1.509	1.198	0.72	2.887	0.734	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.854	1.433	0.87				1.219	2.186	1.083	1.708	1.702	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.02	1.795					0.979	2.006	1.096	1.673	1.796	
COVID19 (COVID19 (JANSSEN))	Lymphocyte count decreased	1.574	1.148	0.874			0.216	1.096	1.796	1.509	2.018	1.067	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.668	1.275	0.896			0.196	1.055	2.099	1.847	2.128	1.234	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.153	1.629	0.888			0.483	1.884	1.868	2.209	2.468	1.61	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.143	1.516	0.91	0.612		0.464	1.234	2.405	1.744	2.438	1.368	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.645	1.224	0.882			0.335	1.035	2.006	1.318	1.94	0.922	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.67	1.391	0.902			0.35	1.247	2.28	1.45	2.155	1.323	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.088	1.518	0.977			0.486	1	2.219	1.768	1.951	1.865	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.588	1.292	0.89	0.61		0.275	0.939	2.048	1.972	2.388	1.084	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.549	1.252	0.878			0.185	1.182	1.789	1.454	2.223	0.896	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.732	1.315	0.897			0.251	1.145	2.164	1.827	2.034	1.376	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.151	0.725					0.762	0.611		1.955	1.069	
COVID19 (COVID19 (JANSSEN))	Off label use	1.339	0.266	0.878			7.656	1.234	1.134	0.821	1.374	1.936	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.754	0.759					0.246	1.063		2.295		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.523	0.86				0.514	1.674	2.192	1.114	2.445	1.431	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.214	1.631	0.875				0.657	1.063	1.82	2.685	0.962	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.772	2.352	0.921	0.611		0.474	1.646	3.063	2.01	3.162	1.793	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.887	1.362	0.896	0.609		0.301	1.556	2.116	1.502	2.191	1.481	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.725	1.978	0.891			0.394	2.046	2.95	2.203	3.298	1.708	
COVID19 (COVID19 (JANSSEN))	Platelet count v	6.669	3.917	0.875				4.027	3.863	6.837	6.284	2.814	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.305					0.968	4.127	3.304	5.945	4.498	4.026	
COVID19 (COVID19 (JANSSEN))	Prothombin time prolonged	2.038	1.598	0.92	0.746		0.342	1.584	2.469	1.652	2.688	1.517	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.222	1.606	1.508	0.612		0.596	1.705	2.069	2.677	2.901	1.804	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.047	1.541	0.896				1.687	1.601	1.878	1.984	1.798	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.881	1.367	0.897	0.608		0.548	1.432	2.143	1.696	2.12	1.556	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.033	1.409	0.905	0.611		0.349	1.273	2.338	1.726	2.363	1.427	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.403	1.362	0.88			0.532	1.691	1.915	1.415	2.398	1.678	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.228	2.434	1.038			0.531	2.308	2.316	1.207	2.647	3.084	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.03	6.786	0.876			0.646	3.575	6.662	15.662	7.823	5.822	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.377							0.637	0.572	0.568	1.919	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.171	1.594	0.889			0.511	1.467	1.632	1.528	2.345	1.364	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.338	1.904	0.941			0.382	1.691	2.448	1.836	2.638	1.776	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.675	2.124	1.758	0.612		0.655	1.953	2.464	3.51	2.86	2.21	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.408	2.205	0.887				1.182	0.766		1.87	0.881	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.289	1.868	0.875				1.944	1.209	0.837	2.2	0.909	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.402	1.429	0.896			0.555	1.879	2.202	2.43	2.79	1.714	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.748	1.888	0.915	0.612		0.528	2.438	2.275	2.927	3.312	2.106	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.454	1.72	0.9			0.446	2.215	2.016	1.875	2.48	1.842	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.88	1.098	0.876				1.254	2.049	1.715	1.929	1.369	
COVID19 (COVID19 (JANSSEN))	Urine ketone body present	1.639	1.201	0.886	0.611		0.277	1.07	1.729	1.607	2.028	0.936	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.217	2.511			0.526	1.339	2.777	6.25	2.174	2.302	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.727	1.265	0.938			0.486	0.901	1.202	2.087	1.612	1.467	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.027	0.872					0.899	1.639	0.973	1.823	1.956	
COVID19 (COVID19 (JANSSEN))	Venogram	2.413	1.97	0.873				2.182	1.701	0.719	3.013	1.05	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.939	2.279				0.604	2.808	1.767	0.681	3.903	1.192	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.242	2.331	0.878				3.995	2.148	0.836	5.161	1.208	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	0.833		7.828	0.938		1.218	0.512		1.333	0.923	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.551	0.948	0.873	0.505	0.644	2.299	0.77	0.582	0.387	0.627	0.589	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.304	0.926	0.861		4.819	2.624	0.096	0.051	0.387	2.448	2.526	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.052	2.046	0.874			2.32	2.001	1.948	1.569	1.8	2.11	
COVID19 (COVID19 (PFIZER-	Body height	1.945	1.018	0.878			0.588	0.944	1.386	2.218	1.937	1.523	
COVID19 (COVID19 (PFIZER-	Product counterfeit	3.048	1.971	0.875			0.691	1.491	1.965	1.926	2.501	1.929	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.758	1.578		0.562	1.035	1.732	1.747	1.821	2.027	1.966	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	0.846	0.878	17.903			0.402			0.458	1.347	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.587	0.894		1.279	1.237	1.733	1.969	2.294	2.067	1.837	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.741	0.898		0.608	1.089	1.776	1.94	2.29	2.104	1.935	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.752	0.752			1.664	1.419	1.884	1.767	2.285	1.721	1.677	
COVID19 (COVID19 (PFIZER-	Weight	2.021	1.347	0.887			0.883	1.529	1.74	2.202	2.092	1.773	

PSI-HHS-000000057715

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 23 Nov 2021 21:45:39 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Freeborn, Emma (CDC/DDID/NCEZID/DHQP) (CTR); Roberts, Amy (CDC/DDID/NCEZID/DHQP) (CTR)
Subject: FW: Weekly data mining
Attachments: USST_20211119.xls

Hi all,
FYI-attached are the latest data mining results. Please do not share this.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, November 23, 2021 4:06 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

FYI.

- John

From: Zinderman, Craig E <[redacted]>
Sent: Tuesday, November 23, 2021 3:14 PM
To: Menschik, David (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 11/19/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 202111Q	US Serious EB05 202111Q	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time	2.264	1.938	0.893			0.384	1.63	3.068	1.953	2.866	1.446	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time	2.229	1.769	0.893				1.638	2.22	2.087	2.929	1.483	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.988	1.337	0.981			0.455	1.325	1.899	1.616	2.309	1.595	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.959	0.885	0.881				0.993	1.758	0.662	2.359	1.559	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.052	0.997	0.886				0.932	1.734	0.708	1.892	1.446	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.94	1.374	0.911				1.519	1.397	1.621	2.432	1.135	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.008	2.164	0.998			0.497	2.254	2.087	3.142	4.289	1.453	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.23	1.715	0.882				1.968	1.931	1.154	2.449	1.45	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.538	1.912	0.901			0.427	1.72	2.466	2.438	2.814	2.045	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.883	1.597	0.897			0.367	1.233	2.406	1.153	2.234	1.325	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.392	0.861	0.879			0.373	0.881	1.704	1.832	2.129	1.901	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.224	1.614	0.888	0.612		0.434	1.853	1.992	2.431	2.823	1.623	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.134	1.943	0.891				0.864	2.003	1.492	1.932	1.527	
COVID19 (COVID19 (JANSSEN))	Arthrogram carotid abnormal	2.021	1.298	0.981				1.288	1.188	1.862	2.762	0.978	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.959	1.619	6.89	0.61		0.331	1.235	2.571	1.72	2.449	1.273	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.817	1.583	6.89	0.609		0.293	1.262	2.311	1.66	2.23	1.273	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.793	1.292	0.886			0.331	1.48	1.788	1.649	2.078	1.32	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.965	1.498	0.901			0.4	1.442	2.262	1.883	2.306	1.52	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.079	1.608	0.913			0.454	1.428	2.342	2.025	2.469	1.466	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.59	2.633	0.893			0.509	1.865	2.583	0.819	4.579	1.135	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.907	1.577	0.911			0.269	1.225	2.091	1.629	2.593	1.132	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.825	1.677	0.881			0.222	1.432	2.161	1.501	2.155	1.006	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.813	1.227	0.884				1.041	2.005	1.536	2.008	1.477	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.983	1.371	1.384				1.403	1.936	1.862	2.079	1.788	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.697	2.19	0.879				1.664	2.88	1.137	2.305	2.282	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.022	1.76	0.879				1.219	1.658	1.129	1.54	1.524	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.333	1.856	0.929			0.52	1.961	1.823	1.001	3.026	1.097	
COVID19 (COVID19 (JANSSEN))	Cerebral ischaemia	2.603	1.976	0.916			0.535	1.227	1.327	1.097	3.913	0.962	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.156	1.526	0.881				1.127	1.251	1.339	2.626	1.02	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.302	2.316	0.917			0.521	2.272	2.32	0.916	3.966	1.171	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.702	1.928	0.956	0.611		0.537	2.382	2.416	2.273	3.584	1.769	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.022	1.468	0.903			0.395	1.665	2.03	1.804	2.231	1.534	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.139	1.615	0.923			0.463	1.486	2.147	2.146	2.447	1.685	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.605	1.853	1.045			0.456	2.17	2.278	3.218	3.269	2.009	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.846	1.492	0.891				1.266	2.308	1.611	2.198	1.226	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.71	1.355	0.884	0.61		0.301	1.27	2.043	1.451	1.971	1.243	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.778	0.83	0.886			1.132	2.013	1.481	0.969	1.875	1.422	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.283	1.317	0.886			0.375	2.17	2.136	2.009	2.542	1.66	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.162	1.502	0.916	0.611		0.328	1.707	2.332	2.2	2.544	1.522	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.975	1.016	6.88			0.427	1.737	1.965	0.745	2.21	1.241	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.278	1	0.885			0.41	2.25	1.724	1.119	2.552	1.398	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.943	1.478	0.894			0.398	1.368	1.582	1.661	2.082	1.309	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.769	1.247	0.893				1.153	1.305	1.36	2.097	1.051	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.303	1.851	0.878				1.402	2.875	1.693	2.133	2.118	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.852	1.364	6.91	0.606		0.428	1.377	2.095	1.782	2.203	1.417	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.778	1.368	0.897	0.607		0.382	1.441	1.993	1.643	2.088	1.39	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.563	3.685	0.896				3.948	4.971	6.266	7.035	2.857	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	6.877	3.8	0.881			0.545	5.167	5.591	0.663	7.822	1.39	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.833	1.263	0.908				1.375	1.879	1.833	2.172	1.445	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.077	1.506	0.881			0.019	1.916	2.542	1.611	2.235	1.699	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.824	1.408	1.032			0.029	1.385	1.975	2.019	2.24	1.407	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.877	1.355	0.894	0.746		0.4	1.64	1.977	1.493	2.478	1.275	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.011	1.306	0.885				1.415	2.027	1.025	2.176	1.259	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.129	1.927	0.883				1.561	1.193	0.736	2.912	0.746	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.902	1.51	0.877				1.236	2.168	1.133	1.711	1.736	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.018	1.73					0.869	2.424	1.146	1.483	1.816	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.677	1.288	0.9			0.182	1.05	2.075	1.869	2.096	1.215	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head	2.176	1.706	0.888			0.482	1.759	1.957	2.327	2.522	1.616	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration	2.144	1.566	0.907	0.611		0.455	1.226	2.454	1.005	2.407	1.393	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.667	1.246	0.886			0.336	1.028	2.041	1.211	1.907	0.962	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.842	1.354	0.894			0.338	1.25	2.259	1.291	2.161	1.183	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.048	1.501	0.953			0.482	1.016	2.128	1.692	1.968	1.723	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.62	1.363	0.894	0.61		0.259	0.963	2.106	1.969	2.473	1.059	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.591	1.294	0.887			0.13	1.194	1.797	1.447	2.277	0.863	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.732	1.317	0.898			0.239	1.157	2.055	1.8	1.981	1.353	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.181	0.723					0.761	0.61		1.337	0.895	
COVID19 (COVID19 (JANSSEN))	Off label use	1.335	0.315	0.883			6.209	0.261	1.411	0.33	0.905	1.226	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.751	0.756					3.105	1		2.191		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.531	0.869				0.511	1.742	2.285	1.148	2.588	1.428	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.368	1.715	6.88				0.656	1.06	2.114	2.582	0.968	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.775	2.516	6.92	0.61		0.482	1.65	3.11	2.149	3.115	1.877	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.874	1.407	0.9	0.609		0.291	1.578	1.947	1.547	2.198	1.451	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.731	2.037	0.895			0.393	2	2.123	2.275	3.437	1.671	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.054	3.501	0.881				4.422	3.442	0.683	6.21	1.937	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.294					0.993	3.976	2.357	5.674	4.597	3.072	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.028	1.619	0.916	0.744		0.324	1.546	2.416	1.642	2.535	1.455	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.233	1.661	1.571	0.612		0.586	1.707	2.153	2.655	2.572	1.833	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.071	1.371	0.988				1.389	1.397	1.667	1.82	1.71	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.92	1.409	0.898	0.607		0.529	1.471	2.182	1.685	2.121	1.57	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.076	1.454	0.903	0.609		0.353	1.27	2.271	1.783	2.449	1.345	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.729	1.15	1.76			0.545	1.519	1.953	0.974	2.125	0.788	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.418	1.354	0.885			0.536	1.539	1.985	1.516	2.274	1.76	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.584	1.243	6.88			0.545	1.133	6.827	0.645	2.377	0.869	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.22	2.571	1.099			0.53	1.921	2.306	1.198	2.68	3.069	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.084	0.796	0.881			0.646	3.232	8.726	15.527	7.878	6.03	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.351							1.635	0.572	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.091	1.638	0.891			0.515	1.362	1.696	1.36	2.206	1.381	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.351	1.973	0.922			0.382	1.735	2.423	1.783	2.702	1.72	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.674	2.137	1.823	0.612		0.649	1.961	2.372	3.478	2.812	2.162	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.214	1.812	6.88				1.836	1.215	0.642	2.181	0.906	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.425	1.466	0.9			0.649	1.913	2.157	2.523	2.564	1.692	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.734	1.934	0.906	0.612		0.527	2.358	2.283	3.068	3.322	2.096	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.518	1.78	0.9			0.447	2.308	2	1.875	2.502	1.871	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.896	1.126	0.881				1.208	2.051	1.8	2.01	1.235	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.659	1.232	0.883	0.611		0.31	0.885	2.033	1.283	1.838	1.064	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.314	3.121	2.568			0.528	1.211	2.56	5.622	2.006	2.16	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.695	1.373	0.927			0.464	0.958	1.255	2.105	1.58	1.528	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.051	0.877					0.912	1.59	0.988	1.821	1.048	
COVID19 (COVID19 (JANSSEN))	Venogram	2.445	1.962	0.879				2.017	1.656	0.721	2.802	1.009	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.082	2.368				0.604	2.646	1.774	0.694	3.928	1.209	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.289	2.448	0.883				3.922	2.108	0.848	5.21	1.24	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.746	1.315	0.884			0.173	1.645	1.525	1.64	2.001	1.201	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.37	0.834		7.297	0.904		1.208	0.512		1.32	0.939	
COVID19 (COVID19 (MODERNA))	Headache	0.966	0.962	0.889	6.085		0.306	0.941	1.978	1.013	0.955	1.008	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.589	0.851	0.879		0.668	2.065	0.741	1.561	0.372	0.588	0.565	
COVID19 (COVID19 (MODERNA))	Product administered to patient of	2.358	0.928	0.895		2.419	2.693	0.115	0.833	0.438	2.378	2.436	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.053	2.006	6.88			2.238	2.004	1.949	1.597	1.597	2.116	
COVID19 (COVID19 (PFIZER-	Body height	1.942	1.016	0.883			0.565	0.927	1.339	2.213	1.923	1.506	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.049	1.066	0.881			0.634	1.502	1.689	1.946	2.067	1.574	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.385	1.726	1.291			1.619	1.718	1.765	1.886	2.594	1.979	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.789	0.847	0.882	18.917			0.407			0.462	1.319	
COVID19 (COVID19 (PFIZER-	Investigation	2.157	1.726	0.902			1.052	1.753	1.954	2.344	2.121	1.958	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.759	0.752			2.134	1.359	1.862	1.738	2.286	1.781	1.736	
COVID19 (COVID19 (PFIZER-	Weight	2.018	1.292	6.89			0.868	1.525	1.713	2.2	1.998	1.762	

PSI-HHS-000000057718

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 9 Sep 2021 15:59:37 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20210903.xls

FYI-attached is FDA data mining. Please do not share this with anyone.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, September 7, 2021 9:50 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

Hi Elaine,

FYI.

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, September 7, 2021 6:52 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 $\geq$2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 9/3/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 20210103	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021	Male EB05 202106	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.927	1.775	0.882			0.421	1.596	1.648	1.575	2.474	1.058	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.933	1.687	0.871				1.455	1.909	1.55	2.094	1.403	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.803	6.929	0.878				0.835	0.755	0.606	2.296	1.496	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.158	2.465	0.886			0.509	1.942	2.08	4.057	4.278	1.484	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.526	2.089	0.88			0.47	1.698	2.523	2.029	2.71	1.98	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.669	1.472	0.875			0.424	1.107	2.012	0.774	1.787	1.167	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.259	6.836	0.874			0.598	0.775	1.962	2.134	2.017	1.96	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.157	1.755	0.946	0.512		0.455	1.804	1.936	2.311	2.823	1.474	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.047	2.155	0.876				0.877	1.965	1.258	1.578	1.515	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.46	1.201	0.876	0.509		3.3	0.918	2.108	1.038	1.566	1.072	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.618	2.409	0.878			0.541	1.103	1.962	0.605	3.974	0.933	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.41	2.22	0.875				1.561	2.286	1.085	1.848	2.002	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.185	1.918	0.905			0.539	1.618	2.065	1.361	2.972	1.119	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.039	1.884	0.881			0.48	0.881	1.827	0.998	2.214	0.796	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.059	1.725	0.876				1.086	0.987	1.559	2.308	1.013	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.244	2.509	0.888			0.535	2.353	2.857	0.751	3.843	1.218	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.668	2.096	0.926	0.512		0.571	2.117	2.511	2.004	3.448	1.711	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.189	1.823	0.898			0.51	1.546	2.078	2.241	2.462	1.862	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.56	1.895	0.902			0.48	2.243	2.181	3.219	3.162	1.975	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.484	1.232	0.875				0.983	2.077	1.153	1.618	1.037	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.807	6.817	0.876			1.211	2.008	1.514	1.052	1.91	1.427	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.404	1.5	0.884			0.415	2.317	2.117	1.9	2.722	1.589	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.103	1.58	0.892	0.511		0.363	1.625	2.264	2.107	2.48	1.411	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.889	0.969	0.875			0.45	1.667	1.753	0.806	2.117	1.115	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.296	6.949	0.876				2.365	1.688	0.892	2.751	1.252	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.203	1.932	0.873				1.262	2.74	1.44	1.987	1.991	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	0.225	0.043	0.886				3.266	3.961	6.041	6.602	1.79	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.101	2.994				0.561	3.729	3.369	0.668	6.737	1.965	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.967	1.98	0.874			0.026	1.847	2.277	1.468	2.048	1.572	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.67	1.199	0.881				1.203	1.808	0.903	2.011	1.11	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.328	2.229	0.876				1.621	1.182	0.752	3.61	0.712	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.607	1.384	0.874				1.001	2.036	0.986	1.521	1.515	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.977	1.958					0.963	2.197	1.027	1.38	1.757	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.135	1.85	0.881			0.533	1.78	1.93	2.048	2.411	1.597	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.464	1.087	0.873			3.3	1.025	2.083	0.512	1.691	0.892	
COVID19 (COVID19 (JANSSEN))	Off label use	1.8	6.332	0.874			5.195	0.315	0.572	0.36	1.178	1.564	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.769	6.757					2.621	1.004		2.315		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.437	6.888				0.545	1.64	2.063	1.083	2.311	1.371	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.651	1.798	0.875				0.653	0.977	2.896	2.311	0.913	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.615	2.433	0.917	0.512		0.505	2.084	3.32	1.434	3.259	1.86	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.772	1.486	0.887	0.509		0.33	1.502	2.068	1.325	2.068	1.362	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.748	2.207	0.888			0.427	2.104	3.077	2.26	3.478	1.825	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.627	3.499	0.876				4.174	2.512	0.666	5.782	1.675	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.782					0.579	2.981	2.241	5.017	3.72	2.817	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.652	1.365	0.876	0.744		0.302	1.263	2.014	1.22	2.068	1.147	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.172	1.738	0.816	0.512		0.449	1.936	2.068	2.471	2.468	1.748	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.01	1.723	0.879			1.498	1.378	2.241	1.85	1.821		
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.448	1.184				0.561	0.943	0.861	0.65	2.064	0.803	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	2.731	1.215	0.9			0.556	1.722	2.122	0.673	2.315	2.661	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.415					0.656	2.586	6.408	14.711	7.484	5.344	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.006	1.862	0.883			0.42	1.685	2.089	1.324	2.382	1.394	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.354	1.164	0.878			0.551	1.357	1.868	1.282	1.971	1.749	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.645	2.279	1.753	0.512		0.606	2.132	2.437	3.537	2.914	2.096	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.379	2.057	0.873				1.933	1.208	0.65	2.558	0.868	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.227	1.292	0.88			0.585	1.772	2.039	2.122	2.528	1.574	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.837	2.106	0.893	0.512		0.56	2.332	2.249	3.575	3.281	2.173	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.352	1.756				0.477	2.473	1.539	1.526	2.485	1.534	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.773	1.452	0.872	0.508			1.191	2.041	1.924	1.753	1.623	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.651	1.309	0.871			0.467	1.421	1.955	1.666	1.994	1.702	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.871	1.083	0.876				1.198	2.024	2.007	1.98	1.225	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.351	2.145	0.908			0.598	0.995	2.134	4.463	1.831	2.002	
COVID19 (COVID19 (JANSSEN))	Venogram	2.346	2.02					1.662	1.777	0.539	2.407	1.824	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.368	2.631				0.617	2.662	1.863	0.704	4.298	1.946	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.143	2.443	0.876				3.269	2.629	0.758	5.197	1.035	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.264	6.755		3.215	0.715		1.181	0.516		1.261	0.824	
COVID19 (COVID19 (MODERNA))	No adverse event	1.263	6.835	0.88		0.336	2.003	0.909	0.91	0.772	1.113	1.222	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.306	6.862	0.876		0.81	2.422	0.141	0.214	0.619	2.313	2.36	
COVID19 (COVID19 (PFIZER-	Body height	1.998	6.981	0.878			0.57	0.903	1.235	2.282	1.912	1.501	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.115	1.022	0.874			0.643	1.446	1.606	1.988	2.071	1.565	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.459	1.759	0.926			0.571	1.835	1.938	2.236	2.238	2.143	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.575	6.819	0.878	2.72			0.363			0.382	1.021	
COVID19 (COVID19 (PFIZER-	Investigation	2.238	1.736	0.894			0.528	1.736	1.911	2.419	2.181	2.012	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.52	6.643				1.412	1.939	1.976	2.435	1.899	1.837	
COVID19 (COVID19 (PFIZER-	Weight	2.108	1.31	0.884			0.782	1.511	1.683	2.336	2.102	1.77	

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 6 Oct 2021 14:14:07 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211001.xls

Pedro, Jonathan:
FYI see attached-please do not distribute.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 5, 2021 9:08 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

FYSA.

From: Menschik, David <[redacted]>
Sent: Tuesday, October 5, 2021 6:02 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/1/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2021[10	Serious EB05 2021	Fatal EB05 2021[0	Infant EB05 2021[	Child EB05 2021[	Teen EB05 2021[	Adult1 EB05 2021[	Adult2 EB05 2021[	Adult3 EB05 2021[	Female EB05 2021	Male EB05 2021[	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.936	1.684	0.886			0.497	1.33	1.736	1.597	2.374	1.144	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.04	1.717	0.878				1.515	2.043	1.71	2.297	1.459	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.81	1.261	0.923			0.489	1.221	1.553	1.642	2.057	1.344	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.059	6.903	0.882				0.894	0.746	0.752	2.48	1.584	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.744	1.195	0.86				1.373	1.318	1.199	2.027	0.992	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.074	2.278	0.886			0.511	1.937	1.948	3.949	4.31	1.414	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.084	1.651	0.878				1.797	1.614	1.082	2.038	1.392	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.511	1.987	0.888			0.456	1.691	2.497	2.152	2.881	1.932	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.69	1.439	0.882			0.386	1.137	2.251	0.776	1.94	1.189	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.171	6.819	0.878			0.591	0.829	1.676	1.778	1.947	1.797	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.203	1.689	1.347	0.612		0.446	1.539	1.998	2.376	2.868	1.944	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.142	2.09	0.879				0.883	2.046	1.339	1.668	1.58	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.623	1.298	0.882	0.509		0.396	1.022	2.422	1.118	1.821	1.132	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.808	1.366	0.882	0.509		0.396	1.141	2.663	1.214	1.797	1.286	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.66	1.303	0.879			0.416	1.262	2.001	1.381	1.851	1.311	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.059	2.535	0.886			0.523	1.296	1.999	0.756	4.324	0.906	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.602	1.39	0.885			0.36	1.094	1.894	1.191	2.088	0.977	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.581	2.226	0.878				1.542	2.54	1.208	2.221	2.058	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.776	1.223	0.894				1.341	0.941		2.655	0.818	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.26	1.888	0.911			0.54	1.784	1.928	1.479	3.348	1.09	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.411	1.932	0.893			0.551	1.047	1.203	1.042	3.365	0.854	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.049	1.549	0.879				1.005	1.09	1.499	2.341	1.016	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.217	2.421	0.891			0.537	2.495	2.567	0.748	3.837	1.196	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.76	2.075	0.932	0.611		0.649	2.281	2.446	2.329	3.566	1.781	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.174	1.729	0.906			0.492	1.51	2.172	2.091	2.488	1.648	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.542	1.84	0.904			0.481	2.167	2.195	3.16	3.107	1.987	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.937	1.275	0.882				1.073	2.245	1.218	1.795	1.953	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.864	0.79	0.875			1.161	2.013	1.536	1.008	1.915	1.421	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.32	1.327	0.886			0.392	2.206	2.089	1.965	2.572	1.801	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.108	1.471	0.896	0.611		0.347	1.935	2.305	1.997	2.527	1.493	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.871	0.985	0.876			0.442	1.613	1.862	0.785	2.104	1.12	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.253	0.93	0.88			0.439	2.324	1.663	0.882	2.671	1.244	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.339	1.962	0.877				1.342	2.879	1.687	2.112	1.12	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.36	3.473	0.889				3.398	4.462	6	6.68	1.982	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.307	3.114	0.88			0.561	4.385	3.443	6.669	6.978	1.969	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.028	1.959	0.88			0.619	1.851	2.461	1.516	2.099	1.647	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.68	1.396	0.956			0.593	1.317	1.809	1.828	2.044	1.298	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.74	1.284	0.874	0.745		0.421	1.58	1.777	1.249	2.063	1.222	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.54	1.276	0.885				1.373	1.923	0.934	2.062	1.192	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.161	2.056	0.88				1.5	1.17	0.746	2.727	0.714	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.83	1.446	0.877				1.194	2.09	1.081	1.674	1.61	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.963	1.784					0.926	2.23	1.091	1.445	1.711	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.162	1.866	0.882			0.522	1.677	1.887	2.299	2.548	1.6	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.553	1.108	0.875			0.364	1.098	2.143	0.629	1.854	0.892	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.4	1.221	0.888	0.509		0.22	0.877	1.872	1.677	2.125	0.881	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.378	1.183	0.879			0.112	1.128	1.941	1.028	2.093	0.863	
COVID19 (COVID19 (JANSSEN))	Off label use	1.608	6.237	0.878			5.549	0.383	0.573	0.376	1.022	1.434	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.789	6.757					2.892	1.014		2.295		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.515	6.875				0.54	1.839	2.139	1.095	2.539	1.395	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.723	1.906	0.879				0.656	1.075	2.447	2.21	0.996	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.729	2.466	0.928	0.612		0.504	1.97	3.141	1.683	3.232	1.714	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.862	1.432	0.892	0.509		0.31	1.558	2.041	1.339	2.133	1.352	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.772	2.16	0.89			0.416	2.112	3.064	2.553	3.484	1.892	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6	3.558	0.88				4.279	3.638	6.685	5.968	2.884	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.008					0.856	3.865	2.946	5.888	4.388	3.636	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.761	1.432	0.884	0.744		0.273	1.368	2.192	1.271	2.211	1.235	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.204	1.683	0.945	0.612		0.804	1.642	2.129	2.54	2.504	1.802	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.01	1.99	0.884				1.561	1.462	2.007	1.88	1.595	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.772	1.245	0.876	0.509		0.374	1.123	1.998	1.495	2.012	1.143	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.213	1.089	0.882			0.552	1.377	1.735	1.354	1.894	1.66	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.017	2.584	1.572			0.546	1.985	2.309	0.773	2.561	2.979	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.976	6.813				6.682	3.471	6.68	15.272	8.03	5.677	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.169	1.938	0.891			0.412	1.756	2.233	1.413	2.623	1.5	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.634	2.217	1.751	0.612		0.599	2.028	2.393	3.522	2.827	2.159	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.153	1.847	0.88				1.768	1.178	0.663	2.171	0.857	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.264	1.275	0.883			0.667	1.796	2.065	2.13	2.542	1.635	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.827	2.056	0.894	0.612		0.551	2.353	2.299	3.511	3.31	2.185	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.46	1.765	0.884			0.473	2.7	1.735	1.466	2.411	1.78	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.927	1.137	0.882				1.345	2.081	1.731	2.033	1.274	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.527	2.641	2.128			0.577	1.052	2.281	4.826	2.008	2.183	
COVID19 (COVID19 (JANSSEN))	Venogram	2.61	2.059					2.059	1.77	0.631	2.878	1.016	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.21	2.469				0.619	2.71	1.992	0.705	4.101	1.936	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.265	2.502	0.88				3.57	2.517	0.875	5.292	1.993	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.268	6.786		3.524	0.778		1.179	0.517		1.281	0.886	
COVID19 (COVID19 (MODERNA))	Headache	0.964	6.955	0.876	2.343		0.303	0.941	0.965	1.011	0.954	1.022	
COVID19 (COVID19 (MODERNA))	No adverse event	1.246	0.84	0.884		0.292	2.014	0.915	0.926	0.781	1.124	1.218	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.353	6.909	0.882		1.203	2.528	0.173	0.295	0.598	2.401	2.438	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.818	1.838	0.873			0.484	1.841	1.187	1.007	1.888	1.68	
COVID19 (COVID19 (PFIZER-	Body height	1.935	6.994	0.882			0.603	0.88	1.266	2.236	1.915	1.473	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.053	1.052	0.878			0.64	1.47	1.663	1.967	2.022	1.566	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.269	1.704	0.936			1.098	1.751	1.92	3.038	2.075	1.886	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.66	6.846	0.882	7.751			0.384			0.407	1.131	
COVID19 (COVID19 (PFIZER-	Investigation	2.155	1.7	0.897			1.005	1.723	1.907	2.354	2.13	1.93	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.305	6.357	0.875		3.331	0.305	0.259	0.102	0.329	0.282	0.329	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.852	6.658				1.361	1.68	1.915	2.336	1.847	1.775	
COVID19 (COVID19 (PFIZER-	Weight	2.045	1.287	0.887			0.623	1.51	1.704	2.241	2.034	1.756	

PSI-HHS-000000057723

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 19 Oct 2021 12:49:36 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211015.xls

Pedro, Jonathan:
FYI-please see attached and do not distribute further.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 19, 2021 8:47 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

Hi Elaine,

The latest data mining from FDA.

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, October 19, 2021 6:14 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/15/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2021	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.106	1.812	0.88			0.605	1.606	1.858	1.679	2.834	1.178	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.992	1.613	0.866				1.452	2.119	1.594	2.373	1.38	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.837	1.253	0.923			0.486	1.227	1.684	1.605	2.146	1.362	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.102	6.887	0.871				0.86	0.729	0.742	2.444	1.595	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.788	1.202	0.886				1.324	1.344	1.279	2.011	1.034	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.997	2.232	0.875			0.597	1.875	2.074	3.606	4.256	1.378	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.088	1.585	0.868				1.737	1.662	1.104	2.142	1.353	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.57	2.006	0.883			0.453	1.72	2.596	2.197	2.98	1.997	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.784	1.529	0.873			0.379	1.193	2.464	0.771	2.078	1.248	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.249	6.812	0.867			0.584	0.82	1.668	2.002	2.017	1.83	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.224	1.681	1.000	0.612		0.445	1.875	2.61	2.42	2.861	1.593	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.823	1.172	0.868				0.911	1.172	1.401	2.217	0.937	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.731	1.375	0.87	0.61		0.342	1.144	2.408	1.211	1.968	1.209	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.887	1.491	0.889	0.606		0.368	1.217	2.165	1.199	1.824	1.366	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.779	1.366	0.869			0.413	1.324	2.154	1.444	2.008	1.37	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.829	1.381	0.878			0.471	1.283	2.179	1.495	2.134	1.259	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.376	5.847	0.879			0.519	1.524	2.464	0.733	3.453	1.819	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.717	1.443	0.879			0.264	1.114	1.998	1.285	2.275	0.992	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.672	1.549	0.866			0.194	1.296	2.068	1.211	1.973	0.876	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.628	2.203	0.867				1.571	2.662	1.176	2.255	2.128	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.671	1.176	0.874				1.266	0.942		2.165	0.613	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.248	1.849	0.908			0.531	1.794	1.927	1.45	3.271	1.107	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.564	2.01	0.892			0.598	1.147	13	1.009	3.342	0.978	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.021	1.444	0.868				1.005	1.096	1.366	2.273	1.015	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.415	2.509	0.886			0.532	2.626	2.504	0.823	4.048	1.231	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.719	2.002	0.944	0.611		0.649	2.242	2.479	2.213	3.526	1.764	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.932	1.429	0.876			0.419	1.039	1.989	1.013	2.091	1.472	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.064	1.627	0.896			0.485	1.465	2.14	1.905	2.387	1.592	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.553	1.841	0.905			0.477	2.193	2.192	3.194	3.138	1.99	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.649	1.321	0.868				1.161	2.264	1.241	1.844	1.153	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.281	1.309	0.877			0.385	2.159	2.082	1.949	2.539	1.585	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.122	1.479	0.9	0.611		0.342	1.653	2.353	1.959	2.568	1.42	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.975	1.093	0.868			0.436	1.666	1.968	0.777	2.179	1.14	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.301	6.978	0.874			0.43	2.346	1.757	0.933	2.618	1.355	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.277	1.872	0.866				1.322	2.837	1.659	2.121	2.051	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.718	1.304	0.88	0.606		0.442	1.266	2.033	1.549	2.085	1.25	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.42	3.584	0.875				3.943	4.472	5.482	6.847	2.105	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.722	3.447	0.869			0.557	5.027	5.136	0.668	7.434	1.066	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.047	1.954	0.869			0.018	1.847	2.482	1.52	2.171	1.847	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.728	1.402	0.949			0.027	1.356	1.929	1.809	2.13	1.318	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.748	1.255	0.861	0.746		0.413	1.598	1.867	1.223	2.104	1.228	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.991	1.283	0.874				1.387	1.963	0.913	2.059	1.22	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.128	2.026	0.909				1.564	1.142	0.745	2.464	0.774	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.823	1.419	0.866				1.205	2.072	1.053	1.662	1.618	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.971	1.764					0.906	2.265	1.083	1.468	1.712	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.199	1.749	0.871			0.518	1.8	1.806	2.289	2.881	1.998	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	1.9	1.35	0.861	0.611		0.47	1.333	2.108	1.214	2.107	1.15	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.662	1.212	0.863			0.359	1.218	2.28	0.796	2.008	1.012	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.515	1.296	0.882	0.61		0.223	0.95	2.048	1.731	2.281	0.973	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.561	1.236	0.871			0.121	1.249	1.674	1.093	2.174	0.768	
COVID19 (COVID19 (JANSSEN))	Off label use	1.577	6.267	0.867			5.617	0.37	0.545	0.438	0.982	1.4	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.809	0.757					2.927	1.019		2.346		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.502	6.856				0.536	1.736	2.213	1.084	2.455	1.43	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.768	1.895	0.888				0.656	1.078	2.616	2.32	0.995	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.697	2.454	0.924	0.611		0.496	1.91	3.065	1.736	3.129	1.753	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.841	1.436	0.891	0.61		0.303	1.572	2.05	1.44	2.184	1.406	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.766	2.13	0.882			0.413	2.106	3.052	2.406	3.472	1.704	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.039	3.56	0.869				4.305	2.935	0.688	6.038	2.07	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.101					0.604	3.999	2.96	3.913	4.077	3.99	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.829	1.48	0.877	0.744		0.274	1.473	2.261	1.272	2.328	1.291	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.204	1.672	0.968	0.612		0.596	1.666	2.115	2.561	2.533	1.787	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.005	1.55	0.877				1.549	1.361	2.105	1.913	1.56	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.789	1.333	0.871	0.608		0.551	1.415	2.094	1.412	1.983	1.425	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.877	1.325	0.869	0.609		0.388	1.301	2.068	1.432	2.208	1.169	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.222	1.145	0.872			0.567	1.398	1.764	1.277	1.844	1.755	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.143	2.642	1.836			0.541	2.018	2.364	0.89	2.666	3.068	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.068	6.603				0.653	3.897	6.602	15.3	8.267	5.807	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.075							0.634	0.582	0.57	1.019	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.037	1.602	0.877			0.531	1.337	1.515	1.416	2.108	1.28	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.217	1.957	0.889			0.407	1.797	2.218	1.539	2.602	1.595	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.658	2.186	1.862	0.612		0.591	2.02	2.385	3.517	2.839	2.156	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.26	1.923	0.899				1.935	1.237	0.647	2.291	0.913	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.277	1.298	0.878			0.656	1.812	2.065	2.223	2.571	1.633	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	2.002	0.884	0.612		0.55	2.273	2.278	3.265	3.222	2.129	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.469	1.761	0.877			0.47	2.092	1.665	1.465	2.47	1.641	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.744	1.283	0.865	0.61			1.18	1.961	2.005	1.702	1.838	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.98	1.171	0.871				1.373	2.174	1.771	2.104	1.298	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.128	2.788	2.281			0.379	0.983	2.312	4.888	1.771	1.997	
COVID19 (COVID19 (JANSSEN))	Venogram	2.791	2.076					2.114	1.801	0.722	3.193	1.015	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.365	2.534				0.617	2.907	1.862	0.704	4.132	1.195	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.31	3.527	0.869				3.636	2.489	0.883	5.358	1.077	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.303	6.769		6.795	0.832		1.193	0.513		1.295	0.945	
COVID19 (COVID19 (MODERNA))	Headache	0.968	6.961	0.867	5.591		0.308	0.945	0.985	1.014	0.954	1.027	
COVID19 (COVID19 (MODERNA))	No adverse event	1.212	6.842	0.875		0.271	2.015	0.915	0.897	0.752	1.084	1.202	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.367	6.928	0.872		1.348	2.583	0.144	0.065	0.578	2.398	2.43	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.985	1.87	0.868			2.087	1.954	1.912	1.549	1.856	2.071	
COVID19 (COVID19 (PFIZER-	Body height	1.933	1.002	0.872			0.604	0.878	1.282	2.213	1.911	1.484	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.069	1.051	0.867			0.641	1.514	1.672	1.549	2.018	1.59	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.258	1.72	0.955			1.006	1.74	1.817	1.988	2.064	1.993	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.685	6.845	0.871	10.376			0.353			0.402	1.115	
COVID19 (COVID19 (PFIZER-	Investigation	2.158	1.696	0.891			1.02	1.726	1.927	2.316	2.123	1.806	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.31	6.347	0.863		4.284	0.311	0.22	0.052	0.286	0.287	0.332	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.835	6.752				1.376	1.883	1.886	2.327	1.838	1.78	
COVID19 (COVID19 (PFIZER-	Weight	2.036	1.296	0.878			0.85	1.516	1.71	2.211	2.011	1.764	

PSI-HHS-000000057726

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 26 Oct 2021 14:40:15 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211022.xls

Pedro, Jonathan:
FYI-please do NOT share.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, October 26, 2021 10:23 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, October 26, 2021 7:14 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 $\geq$2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/22/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021(22	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.512	1.79	0.886			0.602	1.642	1.856	1.661	2.774	1.214	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.088	1.699	0.873				1.576	2.15	1.71	2.634	1.388	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.86	1.257	0.93			0.478	1.209	1.763	1.62	2.131	1.418	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.157	6.902	0.874				0.861	0.753	0.737	2.475	1.821	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.043	1.015	0.877				1.019	0.693	0.723	1.611	1.455	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.821	1.247	0.896				1.373	1.362	1.369	2.051	1.098	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.957	2.191	0.886			0.503	1.859	2.102	3.387	4.211	1.383	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.113	1.805	0.872				1.726	1.75	1.09	2.215	1.341	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.546	1.969	0.886			0.446	1.686	2.549	2.272	2.818	2.035	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.914	1.695	0.885			0.373	1.298	2.453	0.996	2.266	1.319	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.337	0.863	0.871			0.081	0.898	1.732	1.939	2.094	1.921	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.672	0.956	0.512		0.443	1.863	2.064	2.47	2.874	1.589	
COVID19 (COVID19 (JANSSEN))	Anorexia	2.011	1.886	0.873				0.862	1.867	1.331	1.681	1.492	
COVID19 (COVID19 (JANSSEN))	Antiphospholipid antibody abnormal	1.81	1.188	0.872				0.899	1.178	1.368	2.134	0.939	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.811	1.507	0.875	0.509		0.338	1.186	2.424	1.418	2.149	1.201	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.665	1.478	0.873	0.508		1.3	1.26	2.211	1.247	1.978	1.153	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.833	1.421	0.88			0.413	1.352	2.211	1.583	2.103	1.424	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.938	1.491	0.891			0.467	1.33	2.292	1.653	2.316	1.292	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.237	2.584	0.882			0.515	1.67	2.113	0.737	4.428	1.903	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.762	1.479	0.882			0.263	1.134	2.018	1.36	2.4	0.997	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.691	1.564	0.871			0.203	1.339	2.039	1.198	2.01	0.863	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.647	2.206	0.871				1.617	2.612	1.173	2.345	2.13	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.233	1.828	0.907			0.527	1.723	1.914	1.452	3.284	1.095	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.513	1.969	0.894			0.542	1.148	1.362	0.997	3.271	0.974	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.027	1.436	0.872				0.973	1.194	1.354	2.291	1.035	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.398	2.491	0.886			0.528	2.574	2.522	0.823	4.072	1.217	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.717	1.984	0.904	0.511		0.647	2.259	2.46	2.206	3.928	1.772	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.969	1.451	0.886			0.413	1.648	2.079	1.589	2.15	1.486	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.076	1.599	0.894			0.477	1.452	2.15	1.893	2.371	1.594	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.576	1.663	0.922			0.473	2.199	2.246	3.24	3.174	2.009	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.765	1.462	0.87				1.298	2.286	1.373	2.051	1.169	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.278	1.336	0.881			0.382	2.194	2.069	1.89	2.55	1.583	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.127	1.487	0.908	0.511		0.338	1.632	2.392	2.076	2.852	1.449	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.964	1.007	0.872			0.433	1.712	1.968	0.769	2.206	1.207	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.321	1.009	0.88			0.423	2.341	1.79	0.989	2.591	1.413	
COVID19 (COVID19 (JANSSEN))	Guillain-Barré syndrome	2.265	1.907	0.874				1.333	2.877	1.765	2.15	2.109	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.758	1.326	0.89	0.506		0.439	1.281	2.072	1.62	2.132	1.286	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.707	1.28	0.887	0.507		0.34	1.375	1.971	1.497	2.041	1.277	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.627	3.707	0.853				4.089	4.85	5.522	7.11	2.291	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.755	3.489	0.873			0.553	5.044	5.353	6.667	7.467	1.208	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.054	1.943	0.872			0.02	1.856	2.475	1.554	2.182	1.858	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.749	1.4	0.955			0.029	1.352	1.964	1.823	2.128	1.347	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.783	1.286	0.872	0.746		0.409	1.586	1.943	1.27	2.213	1.231	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.901	1.238	0.878				1.359	1.944	0.907	2.038	1.202	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.124	2.016	0.873				1.589	1.137	0.744	2.681	0.764	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.861	1.484	0.87				1.199	2.153	2.082	1.988	1.665	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.047	1.825					0.902	2.361	1.175	1.515	1.788	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.535	1.201	0.877			0.184	1.012	2.016	1.514	1.91	1.09	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.171	1.745	0.876			0.515	1.778	1.907	2.315	2.511	1.595	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	1.966	1.403	0.873	0.511		0.488	1.344	2.226	1.251	2.171	1.207	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.717	1.227	0.872			0.357	1.23	2.275	0.863	2.053	1.017	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.018	1.515	0.936			3.5	0.955	2.023	1.626	1.915	1.832	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.531	1.302	0.881	0.61		0.225	0.987	2.003	1.734	2.337	0.972	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.561	1.32	0.875			0.13	1.225	1.896	1.243	2.351	0.791	
COVID19 (COVID19 (JANSSEN))	Off label use	1.469	0.23	0.872			5.899	0.347	0.502	0.41	0.925	1.339	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.764	6.758					2.979	1.068		2.203		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.541	6.855				0.532	1.827	2.172	1.171	2.541	1.459	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.441	1.789	0.873				0.656	1.067	2.551	2.379	0.972	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.719	2.497	0.922	0.511		0.466	1.003	3.104	1.796	3.124	1.791	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.842	1.419	0.894	0.508		0.299	1.549	2.033	1.469	2.147	1.413	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.754	2.1	0.887			0.41	2.104	3.036	2.353	3.445	1.71	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.067	3.544	0.874				4.321	3.004	9.686	6.083	2.004	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.151					0.883	3.986	2.963	6.155	4.56	3.718	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.878	1.519	0.893	0.744		0.269	1.495	2.33	1.333	2.38	1.338	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.309	1.872	1.006	0.512		0.591	1.654	2.139	1.557	2.535	1.796	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.027	1.549	0.881				1.514	1.481	2.077	1.902	1.807	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.847	1.377	0.877	0.507		0.566	1.435	2.121	1.543	2.056	1.468	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.971	1.493	0.88	0.509		0.383	1.308	2.186	1.546	2.347	1.211	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.247	1.182	0.876			0.543	1.4	1.776	1.406	1.893	1.744	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.56	1.237	0.872			0.553	1.033	0.825	0.65	2.148	0.668	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.219	2.742	1.941			0.537	2.045	2.341	1.163	2.685	3.191	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.998	6.737				0.651	3.574	6.684	15.215	7.897	5.883	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.158							0.604	0.58	0.569	1.021	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.067	1.676	0.888			0.527	1.413	1.582	1.405	2.083	1.405	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.259	2.009	0.9			0.491	1.782	2.316	1.642	2.742	1.621	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.665	2.178	1.814	0.512		0.582	2.002	2.09	3.528	2.861	2.147	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.274	1.957	0.873				1.949	1.209	0.646	2.322	0.913	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.332	1.809	0.884			0.48	1.691	2.14	2.218	2.884	1.66	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.74	1.985	0.887	0.512		0.547	2.306	2.283	3.137	3.193	2.141	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.551	1.814	0.886			0.463	2.656	1.973	1.642	2.617	1.844	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.948	1.156	0.878				1.361	2.138	1.747	2.054	1.289	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.182	2.797	2.377			0.583	1.15	2.337	4.791	1.834	2.013	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.063	6.881					0.868	1.585	0.972	1.773	1.012	
COVID19 (COVID19 (JANSSEN))	Venogram	2.674	2.031					2.176	1.749	0.721	3.085	0.993	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.356	2.532				0.608	2.931	1.87	0.703	4.161	1.169	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.164	2.444	0.873				3.685	2.181	0.851	5.132	1.122	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.334	6.831		7.31	0.871		1.197	0.513		1.314	0.953	
COVID19 (COVID19 (MODERNA))	Headache	0.969	6.963	0.876	5.803		0.305	0.945	0.985	1.014	0.955	1.025	
COVID19 (COVID19 (MODERNA))	No adverse event	1.157	6.844	0.878		0.273	2.025	0.917	0.903	0.762	1.091	1.205	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.373	6.944	0.878		1.223	2.6	0.12	0.051	0.534	2.378	2.422	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.42	1.966	0.872			2.16	1.966	1.903	1.07	1.84	2.102	
COVID19 (COVID19 (PFIZER-	Body height	1.931	1.011	0.876			0.602	0.875	1.32	2.197	1.908	1.489	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.058	1.049	0.872			0.639	1.515	1.68	1.943	2.014	1.801	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.268	1.711	0.965			1.013	1.736	1.799	1.952	2.058	1.991	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.708	6.818	0.875	11.694			0.396			0.407	1.177	
COVID19 (COVID19 (PFIZER-	Investigation	2.151	1.702	0.896			1.035	1.734	1.935	2.31	2.122	1.934	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.314	6.328	0.866		4.084	0.317	0.188	0.052	0.29	0.291	0.337	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.757	6.752				1.35	1.865	1.85	2.301	1.808	1.752	
COVID19 (COVID19 (PFIZER-	Weight	2.038	1.324	0.882			0.853	1.521	1.726	2.202	2.011	1.777	

PSI-HHS-000000057729

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 2 Nov 2021 16:23:39 +0000
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211029.xls

Pedro, John:
FYI-please see attached and do not share.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, November 2, 2021 12:21 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

FYI.

From: Menschik, David <[redacted]>
Sent: Tuesday, November 2, 2021 12:09 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/29/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	VS EB05 2021[20	Serious EB05 2021	Fatal EB05 2021[	Infant EB05 2021[	Child EB05 2021[	Teen EB05 2021[	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021[	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.193	1.805	0.884			0.586	1.611	1.918	1.781	2.71	1.295	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.203	1.784	0.884				1.639	2.225	1.925	2.897	1.453	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.961	1.312	0.94			0.467	1.25	1.753	1.763	2.201	1.536	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.059	0.89	0.883				0.841	0.73	0.731	2.382	1.564	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.054	1.005	0.884				0.997	0.684	0.72	1.588	1.436	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.933	1.327	0.901				1.536	1.353	1.533	2.377	1.092	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.004	2.206	0.894			0.499	2.273	2.061	3.279	4.386	1.354	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.188	1.656	0.881				1.731	1.803	1.216	2.342	1.366	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.546	1.949	0.893			0.435	1.713	2.5	2.36	2.781	2.056	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.911	1.663	0.896			0.388	1.313	2.417	1.022	2.314	1.301	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.348	0.875	0.86			0.578	0.899	1.74	1.906	2.094	1.934	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.243	1.869	1.064	0.612		0.434	1.853	1.996	2.599	2.886	1.613	
COVID19 (COVID19 (JANSSEN))	Anorexia	2.063	1.919	0.882				0.864	1.913	1.423	1.772	1.527	
COVID19 (COVID19 (JANSSEN))	Aspiration cerebral abnormal	1.819	1.221	0.881				1.16	1.178	1.396	2.493	0.938	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.886	1.591	0.882	0.509		0.336	1.239	2.441	1.579	2.298	1.223	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.719	1.542	0.88	0.508		0.295	1.292	2.276	1.363	2.08	1.189	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.765	1.293	0.885			0.339	1.508	1.812	1.531	2.075	1.25	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.919	1.486	0.893			0.407	1.43	2.254	1.728	2.244	1.466	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.953	1.539	0.901			0.459	1.439	2.252	1.768	2.38	1.351	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.517	2.66	0.89			0.511	1.852	2.44	0.738	4.604	1.073	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.889	1.633	0.894			0.286	1.166	2.144	1.545	2.602	1.994	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.745	1.607	0.88			0.214	1.401	2.065	1.241	2.051	1.92	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.915	1.326	1.002				1.336	1.762	1.81	2.002	1.676	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.655	2.194	0.88				1.687	2.6	1.159	2.37	2.15	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.306	1.863	0.913			0.523	2.049	1.915	1.443	3.458	1.998	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.55	1.961	0.899			0.538	1.291	1.268	0.995	3.353	0.971	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.113	1.337	0.861				1.123	1.139	1.306	2.497	1.04	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.489	2.496	0.902			0.525	2.672	2.562	0.825	4.162	1.222	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.748	1.987	0.932	0.511		0.636	2.375	2.48	2.271	3.611	1.773	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.69	1.592	0.897			0.496	1.708	2.016	1.752	3.334	1.523	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.146	1.636	0.907			0.467	1.494	2.172	2.063	2.473	1.64	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.665	1.872	0.923			0.486	2.176	2.273	3.254	3.227	2.027	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.797	1.486	0.877				1.296	2.301	1.45	2.121	1.182	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.765	0.784	0.88			1.137	2.001	1.564	1.004	1.894	1.404	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.295	1.293	0.888			0.377	2.208	2.089	1.924	2.542	1.633	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.16	1.522	0.912	0.611		0.333	1.692	2.371	2.148	2.583	1.483	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.993	0.994	0.881			0.427	1.707	1.901	0.756	2.224	1.182	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.358	1.038	0.888			0.419	2.208	1.79	1.136	2.621	1.448	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.659	1.229	0.887				1.192	1.21	1.243	2.131	0.913	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.297	1.894	0.88				1.399	2.84	1.742	2.162	2.101	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.831	1.372	0.896	0.506		0.433	1.372	2.118	1.689	2.224	1.339	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.767	1.316	0.898	0.507		0.333	1.447	2.023	1.554	2.08	1.347	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.69	2.695	0.89				4.027	4.856	6.152	7.14	2.473	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.814	3.509	0.882			0.549	5.092	5.536	0.666	7.528	1.388	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.79	1.24	0.893				1.254	1.788	1.61	2.038	1.412	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.079	1.841	0.881			0.618	1.874	3.478	1.494	2.217	1.887	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.787	1.422	0.984			0.029	1.404	1.978	1.906	2.188	1.382	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.831	1.319	0.882	0.746		0.401	1.626	1.926	1.382	2.362	1.219	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.905	1.225	0.886				1.367	1.945	0.904	2.038	1.205	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.149	2.006	0.882				1.599	1.139	0.744	2.78	0.765	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.9	1.537	0.88				1.251	2.161	1.098	1.698	1.73	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.039	1.797					0.9	2.342	1.173	1.497	1.795	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.568	1.243	0.885			0.184	1.037	2.042	1.66	2.002	1.137	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.186	1.736	0.887			0.505	1.811	1.937	2.319	2.539	1.805	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.052	1.483	0.886	0.511		0.465	1.331	2.314	1.409	2.27	1.273	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.78	1.279	0.885			0.351	1.275	2.226	1.031	2.127	1.064	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.055	1.533	0.937			0.496	0.996	2.061	1.654	1.988	1.845	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.585	1.346	0.89	0.61		0.224	0.964	2.111	1.893	2.408	1.02	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.616	1.349	0.906			0.15	1.222	1.609	1.342	2.492	0.918	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.645	1.267	0.896			0.24	1.138	2.011	1.594	1.899	1.256	
COVID19 (COVID19 (JANSSEN))	Off label use	1.449	0.216	0.881			5.946	0.324	0.471	0.383	0.911	1.253	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.746	0.757					3.03	0.998		2.15		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.592	0.876				0.524	1.782	2.289	1.165	2.634	1.473	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.51	1.765	0.882				0.696	1.068	2.571	2.482	0.974	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.755	1.489	0.927	0.511		0.485	1.886	3.113	1.789	3.11	1.816	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.848	1.405	0.897	0.509		0.295	1.563	2.037	1.463	2.161	1.415	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.762	2.085	0.894			0.404	2.095	3.1	2.302	3.484	1.7	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.998	3.519	0.882				4.353	3.241	0.685	6.13	1.931	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.205					0.885	4.019	3.183	6.153	4.622	3.771	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.945	1.577	0.902	0.744		0.265	1.521	2.337	1.508	2.523	1.375	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.246	1.679	1.041	0.512		0.584	1.667	2.164	2.68	2.537	1.83	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.064	1.552	0.888				1.53	1.473	2.101	1.91	1.964	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.69	1.402	0.886	0.507		0.537	1.515	2.147	1.571	2.102	1.508	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.021	1.434	0.89	0.509		0.358	1.35	2.183	1.646	2.41	1.249	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.79	1.171	0.905			0.549	1.015	1.074	0.899	2.062	0.909	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.227	1.169	0.884			0.539	1.374	1.776	1.416	1.878	1.735	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.68	1.351	0.883			0.549	1.132	0.826	0.648	2.785	1.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.248	2.722	1.007			0.553	1.86	3.328	1.198	2.73	3.184	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.038	6.797	0.883			0.648	3.617	6.722	15.126	7.93	5.992	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.267							0.634	0.577	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.134	1.701	0.899			0.518	1.432	1.665	1.385	2.264	1.365	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.343	2.013	0.91			0.397	1.788	2.361	1.672	2.837	1.834	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.682	2.18	1.872	0.512		0.572	2.019	2.396	3.547	2.866	2.159	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.302	1.947	0.882				1.966	1.242	0.645	2.375	0.915	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.39	1.432	0.896			0.648	1.923	2.196	2.365	2.752	1.676	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.746	1.964	0.899	0.512		0.54	2.369	2.285	3.146	3.208	2.146	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.603	1.868	0.895			0.456	2.588	2.02	1.841	2.736	1.848	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.945	1.14	0.883				1.356	2.119	1.725	2.053	1.288	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.651	1.255	0.879	0.511		0.31	0.885	2.008	1.222	1.85	1.005	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.239	1.003	2.537			0.539	1.184	2.391	4.976	1.861	2.982	
COVID19 (COVID19 (JANSSEN))	Vasodilation	2.661	0.881					0.929	1.569	0.976	1.822	1.071	
COVID19 (COVID19 (JANSSEN))	Venogram	2.684	2.005					2.15	1.758	0.721	3.098	0.996	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.385	3.522				0.606	2.964	1.884	0.703	4.205	1.193	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.266	2.611	0.882				3.874	2.212	0.845	5.211	1.19	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.371	0.832		7.378	0.884		1.207	0.513		1.329	1.004	
COVID19 (COVID19 (MODERNA))	Headache	0.988	0.959	0.888	6		0.301	0.943	0.984	1.013	0.954	1.019	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.357	0.947	0.887		1.156	2.623	0.115	0.04	0.493	2.36	2.417	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.042	1.997	0.881			2.204	2.002	1.945	1.574	1.884	2.12	
COVID19 (COVID19 (PFIZER-	Body height	1.931	1.021	0.885			1.6	0.927	1.307	2.186	1.908	1.496	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.05	1.049	0.882			0.637	1.527	1.69	1.944	2.007	1.596	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.284	1.717	1.305			1.024	1.728	1.792	1.941	2.04	1.98	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.726	0.846	0.884	13.852			0.393			0.422	1.14	
COVID19 (COVID19 (PFIZER-	Investigation	2.141	1.707	0.901			1.048	1.729	1.928	2.309	2.11	1.929	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.317	0.326	0.875		3.945	0.321	0.16	0.049	0.201	0.294	1.34	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.768	0.751				1.343	1.853	1.799	2.276	1.784	1.728	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.336	0.891			0.854	1.536	1.728	2.152	2.001	1.78	

PSI-HHS-000000057732

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 9 Nov 2021 13:57:53 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211105.xls

FYI-please do not share.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, November 9, 2021 8:37 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

Hi all,

FYI: please see enclosed. Allison, I think someone else in CISA was asking for a copy – please remind me who?

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, November 9, 2021 8:34 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 11/5/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,

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David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 20211105	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	3.79	1.827	0.892			0.585	1.595	1.906	1.873	2.91	1.321	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.277	1.841	0.883				1.673	2.295	2.074	3.12	1.478	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.972	1.32	0.961			0.462	1.283	1.78	1.819	2.271	1.534	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.977	6.878	0.875				0.86	0.721	0.722	2.352	1.532	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.662	6.992	0.876				0.945	0.745	0.718	1.633	1.368	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.896	1.312	0.909				1.495	1.346	1.512	2.345	1.385	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.05	2.202	0.89			0.498	2.245	2.062	3.44	4.433	1.362	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.203	1.672	0.872				1.79	1.822	1.198	2.443	1.336	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.534	1.931	0.888			0.433	1.714	2.492	2.36	2.784	2.059	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.914	1.657	0.887			0.364	1.289	2.463	1.041	2.35	1.295	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.29	6.872	0.872			0.572	0.898	1.736	1.883	2.708	1.924	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.238	1.656	1.106	0.512		0.433	1.869	2.011	2.522	2.855	1.628	
COVID19 (COVID19 (JANSSEN))	Anoxia	2.12	1.948	0.878				0.899	1.917	1.527	1.84	1.546	
COVID19 (COVID19 (JANSSEN))	Aortogram cerebral abnormal	1.898	1.291	0.876				1.181	1.48	1.116	2.792	0.93	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.955	1.651	0.877	0.509		0.335	1.202	2.585	1.711	2.37	1.29	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.751	1.559	0.874	0.508		0.292	1.271	2.34	1.438	2.148	1.202	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.755	1.28	0.875			0.333	1.473	1.785	1.563	2.114	1.22	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.948	1.502	0.886			0.402	1.421	2.273	1.819	2.304	1.475	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.02	1.565	0.897			0.452	1.439	2.271	1.863	2.438	1.36	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.412	2.595	0.885			0.51	1.857	2.118	0.738	4.418	1.075	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.839	1.559	0.888			0.26	1.179	2.087	1.507	2.575	1.046	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.712	1.544	0.87			0.217	1.359	2.02	1.296	2.064	0.877	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.762	1.289	0.872				1.042	1.964	1.527	2.014	1.394	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.938	1.334	1.067				1.322	1.818	1.812	2.028	1.892	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.708	2.215	0.872				1.673	2.707	1.162	2.401	2.212	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.328	1.887	0.918			0.521	2.143	1.868	1.492	3.52	1.108	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.364	1.86	0.893			0.537	1.236	1.23	0.997	2.882	0.909	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.168	1.527	0.873				1.124	1.201	1.362	2.471	1.041	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.402	2.432	0.896			0.523	2.534	2.465	0.822	4.118	1.193	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.732	1.969	0.930	0.511		0.605	2.398	2.462	2.266	3.634	1.744	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.026	1.492	0.896			0.484	1.692	2.018	1.768	2.245	1.516	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.116	1.605	0.907			0.462	1.502	2.125	2.056	2.437	1.63	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.614	1.894	1.001			0.66	2.176	2.298	3.235	3.343	2.035	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.817	1.505	0.871				1.268	2.363	1.516	2.133	1.212	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.779	6.802	0.872			1.131	2.003	1.495	0.992	1.883	1.414	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.278	1.271	0.881			0.376	2.207	2.077	1.847	2.505	1.644	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.166	1.512	0.912	0.511		0.33	1.705	2.327	2.212	2.588	1.485	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.53	0.997	0.873			0.423	1.696	1.931	0.75	2.194	1.182	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.329	1.82	0.88			0.418	2.278	1.761	1.134	2.601	1.429	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.857	1.382	0.882			0.403	1.373	1.514	1.499	2.014	1.219	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.788	1.261	0.882				1.171	1.244	1.39	2.044	1.047	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.303	1.886	0.872				1.394	2.825	1.783	2.181	2.091	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.833	1.366	0.896	0.506		0.426	1.37	2.106	1.72	2.238	1.345	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.755	1.303	0.897	0.507		0.327	1.423	1.98	1.586	2.088	1.336	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.665	3.88	0.884				4.009	4.841	6.183	6.914	2.874	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.838	3.818	0.874			0.847	5.116	5.897	6.992	7.893	3.868	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.803	1.234	0.89				1.312	1.768	1.612	2.08	1.405	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.074	1.931	0.875			0.619	1.872	2.564	1.651	2.205	1.883	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.751	1.414	1.01			0.629	1.408	1.948	1.969	2.207	1.38	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.834	1.315	0.882	0.746		0.395	1.639	1.886	1.425	2.378	1.23	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.922	1.215	0.879				1.416	1.935	0.899	2.088	1.197	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.164	1.961	0.874				1.602	1.122	0.744	2.831	0.755	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.857	1.531	0.871				1.231	2.162	1.155	1.705	1.723	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.022	1.764					0.896	2.323	1.163	1.488	1.78	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.628	1.267	0.888			0.182	1.001	2.077	1.779	2.077	1.141	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.174	1.718	0.882			0.502	1.773	1.996	2.307	2.536	1.587	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.08	1.524	0.886	0.511		0.46	1.295	2.348	1.507	2.37	1.283	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.841	1.227	0.874			0.339	1.034	2.093	1.024	1.912	0.895	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.773	1.209	0.877			0.347	1.26	2.207	1.077	2.072	1.123	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.04	1.495	0.935			0.494	0.993	2.025	1.671	1.927	1.863	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.617	1.376	0.887	0.61		0.283	0.965	2.13	1.974	2.512	1.027	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.598	1.317	0.876			0.131	1.221	1.823	1.313	2.337	0.899	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.682	1.295	0.883			0.241	1.106	2.044	1.752	1.982	1.276	
COVID19 (COVID19 (JANSSEN))	Off label use	1.387	0.21	0.872			5.809	0.298	0.429	0.361	0.865	1.236	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.752	6.758					3.059	0.968		3.173		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.575	6.874				0.517	1.767	2.297	1.169	2.631	1.469	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.393	1.716	0.874				0.656	1.069	2.083	2.544	0.966	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.752	2.503	0.922	0.61		0.483	1.86	3.156	1.786	3.138	1.837	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.855	1.406	0.893	0.509		0.291	1.595	2.019	1.486	2.181	1.411	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.73	2.987	0.888			3.4	2.067	3.09	2.201	3.461	1.883	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.016	3.523	0.875				4.382	3.335	0.685	6.151	1.933	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.227					0.886	4.034	3.298	6.151	4.92	3.842	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.85	1.586	0.900	0.744		0.326	1.514	2.321	1.53	2.548	1.379	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.246	1.679	1.511	0.512		0.583	1.697	2.15	2.68	2.581	1.829	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.046	1.532	0.960				1.546	1.403	2.066	1.867	1.901	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.885	1.392	0.88	0.507		0.528	1.496	2.137	1.602	2.113	1.496	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.043	1.44	0.884	0.509		0.356	1.307	2.251	1.639	2.458	1.264	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.738	1.178	0.888			0.547	1.098	1.699	0.881	2.284	0.757	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.282	1.2	0.876			0.538	1.498	1.78	1.377	1.957	1.749	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.665	1.349	0.876			0.547	1.132	0.827	0.647	2.857	1.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.215	2.643	1.727			0.531	1.882	2.354	1.296	2.673	3.109	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.077	6.797	0.875			0.647	3.642	6.746	15.322	8.003	5.996	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.289							0.635	0.576	0.568	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.116	1.675	0.886			0.516	1.416	1.686	1.384	2.27	1.346	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.378	2.044	0.916			0.39	1.846	2.378	1.688	2.811	1.701	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.68	2.17	1.864	0.512		0.571	2.007	2.389	3.532	2.868	2.166	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.255	1.907	0.874				1.974	1.224	0.644	2.402	0.904	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.357	1.445	0.893			0.648	1.928	2.165	2.371	2.786	1.66	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.752	1.971	0.892	0.512		0.534	2.388	2.299	3.024	3.228	2.153	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.53	1.811	0.892			0.454	2.494	1.983	1.777	2.651	1.805	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.803	1.152	0.875				1.336	2.076	1.782	2.054	1.265	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.673	1.267	0.876	0.511		0.309	0.86	2.082	1.291	1.858	1.045	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.257	2.99	2.501			0.537	1.179	2.423	5.159	1.904	2.087	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.685	1.419	0.92			0.49	0.975	1.262	2.048	1.648	1.554	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.055	6.881					0.93	1.804	0.979	1.87	1.055	
COVID19 (COVID19 (JANSSEN))	Venogram	2.68	2.009					2.174	1.738	0.721	3.011	1.045	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.411	2.523				0.605	2.98	1.889	0.703	4.221	1.195	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.282	2.509	0.874				3.954	2.152	0.846	5.231	1.192	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.353	6.833		7.466	0.885		1.192	0.513		1.318	0.982	
COVID19 (COVID19 (MODERNA))	Headache	0.966	6.962	0.884	6.091		0.304	0.941	0.961	1.012	0.953	1.014	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.344	6.933	0.88		1.158	2.624	0.12	0.036	0.491	2.348	2.404	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.045	2.006	0.873			2.214	2.003	1.947	1.572	1.895	2.117	
COVID19 (COVID19 (PFIZER-	Body height	1.932	1.02	0.877			0.599	0.927	1.336	2.191	1.908	1.499	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.957	0.874			0.606	1.502	1.955	1.849	2.007	1.576	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.274	1.723	1.46			1.025	1.723	1.784	1.924	2.034	1.968	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.74	6.846	0.876	14.049			0.413			0.431	1.162	
COVID19 (COVID19 (PFIZER-	Investigation	2.142	1.712	0.897			1.057	1.739	1.932	2.319	2.112	1.933	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.32	6.289	0.866		3.489	0.323	0.174	0.052	0.301	0.296	0.344	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.774	6.752				1.345	1.86	1.807	2.29	1.793	1.735	
COVID19 (COVID19 (PFIZER-	Weight	3.658	1.913	0.886			0.672	1.035	1.732	2.2	3.091	1.779	

PSI-HHS-000000057735

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From: Lale, Allison (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 1 Dec 2021 16:38:57 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20211126.xls

Hi Pedro,
Thank you again for speaking with me and providing information on the interpretation of this excel. If you/FDA happen to have a couple slides explaining this output, (b)(5) that would be great. If not, no worries!

Allison

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, November 30, 2021 8:08 AM
To: Dua, Anamika (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, November 30, 2021 6:30 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 11/26/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2021|20	Serious EB05 2021	Fatal EB05 2021|1	Infant EB05 2021|1	Child EB05 2021|	Teen EB05 2021|1	Adult1 EB05 2021|	Adult2 EB05 2021|	Adult3 EB05 2021|	Female EB05 2021	Male EB05 2021|1	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.208	1.822	0.903			0.584	1.591	2.067	2.001	2.831	1.654	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.222	1.759	0.891				1.642	2.258	2.032	2.932	1.492	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.001	1.361	0.979			0.455	1.323	1.944	1.88	2.358	1.842	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.977	6.902	0.88			0.52	0.996	0.809	0.68	2.466	1.554	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.062	6.992	0.885				0.965	0.727	0.767	1.628	1.471	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.932	1.347	0.906				1.502	1.403	1.601	2.388	1.135	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.989	2.168	0.896			0.497	2.297	2.068	3.385	4.295	1.484	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.212	1.674	0.88				1.869	1.906	1.147	2.428	1.423	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.519	1.89	0.898			0.427	1.706	2.448	2.429	2.768	2.059	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.867	1.591	0.896			0.386	1.231	2.411	1.181	2.238	1.336	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.303	6.836	0.877			0.569	0.887	1.702	1.906	2.104	1.875	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.599	0.965	0.512		0.435	1.853	1.99	2.45	2.801	1.64	
COVID19 (COVID19 (JANSSEN))	Anoxia	2.131	1.966	0.89				0.895	2.088	1.485	2.031	1.529	
COVID19 (COVID19 (JANSSEN))	Antiphospholipid antibody abnormal	1.978	1.278	0.879				1.284	1.17	1.89	2.84	0.918	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.947	1.605	0.891	0.61		0.329	1.204	2.627	1.716	2.422	1.301	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.817	1.59	0.89	0.509		0.293	1.282	2.352	1.679	2.224	1.304	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.785	1.295	0.884			0.332	1.509	1.798	1.661	2.086	1.35	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.964	1.499	0.904			0.399	1.459	2.27	1.907	2.317	1.544	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.078	1.606	0.913			0.455	1.412	2.362	2.004	2.482	1.478	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.564	2.618	0.892			0.568	1.865	2.615	6.813	4.599	1.133	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.882	1.539	0.908			0.273	1.215	2.077	1.636	2.551	1.142	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.811	1.684	0.875			0.225	1.428	2.235	1.471	2.185	0.995	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.817	1.233	0.884				1.059	2.012	1.56	2.022	1.497	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.978	1.381	1.368				1.372	1.966	1.906	2.151	1.786	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.722	2.204	0.877				1.739	2.906	1.134	2.42	2.29	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.062	1.81	0.877				1.292	1.666	1.13	1.624	1.522	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.308	1.643	0.925			0.519	1.936	1.901	1.54	3.009	1.958	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.666	1.92	0.911			0.534	1.227	1.331	1.092	3.235	0.964	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.154	1.484	0.879				1.129	1.239	1.342	2.568	1.024	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.306	2.299	0.916			0.621	2.245	2.305	0.82	3.804	1.175	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.702	1.918	0.947	0.511		0.633	2.403	2.436	2.257	3.581	1.763	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.065	1.441	0.901			0.391	1.662	2.02	1.788	2.223	1.523	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.121	1.581	0.901			0.484	1.481	2.13	2.147	2.48	1.676	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.61	1.851	1.049			0.456	2.144	2.254	3.241	3.261	2.017	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.861	1.488	0.896				1.284	2.326	1.65	2.172	1.268	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.707	1.358	0.886	0.61		0.391	1.265	2.08	1.487	1.957	1.274	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.778	6.828	0.885			1.134	2.012	1.477	1.018	1.873	1.426	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.29	1.308	0.884			0.375	2.186	2.134	2.021	2.58	1.851	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.155	1.49	0.916	0.511		0.328	1.693	2.329	2.178	2.504	1.546	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.97	1.013	0.878			0.426	1.698	1.962	0.746	2.161	1.225	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.276	1.019	0.884			0.488	2.281	1.723	1.121	2.521	1.434	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.928	1.442	0.892			3.4	1.432	1.554	1.64	2.098	1.293	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.708	1.24	0.892				1.256	1.29	1.346	2.144	1.04	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.317	1.844	0.876				1.402	2.864	1.758	2.151	2.125	
COVID19 (COVID19 (JANSSEN))	Haemstocrit decreased	1.849	1.368	0.91	0.507		0.425	1.386	2.117	1.79	2.224	1.434	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.775	1.318	0.896	0.507		0.381	1.481	2.057	1.693	2.118	1.406	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.558	3.884	0.896				3.986	4.968	6.279	7.058	2.873	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.887	3.547	0.879			0.544	5.201	5.71	6.662	7.648	1.816	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.845	1.3	0.914				1.575	1.902	1.722	2.221	1.511	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.69	1.912	0.88			0.021	1.939	2.567	1.61	2.23	1.726	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.839	1.421	1.024			0.029	1.4	2.008	2.057	2.24	1.443	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.877	1.347	0.892	0.745		0.402	1.836	2.016	1.472	2.501	1.277	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.013	1.336	0.883				1.399	2.092	1.018	2.212	1.253	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.131	1.926	0.882				1.562	1.196	0.735	2.947	0.747	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.992	1.489	0.875				1.235	2.166	1.12	1.703	1.732	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.015	1.727					0.871	2.441	1.147	1.487	1.818	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.674	1.29	0.901			0.184	1.042	2.093	1.89	2.105	1.23	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.172	1.69	0.885			0.488	1.817	1.943	2.328	2.528	1.605	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.147	1.571	0.907	0.511		0.456	1.252	2.446	1.712	2.492	1.415	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.669	1.26	0.884			0.335	1.049	2.065	1.239	1.945	0.975	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.887	1.439	0.897			0.339	1.317	2.336	1.356	2.191	1.282	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.002	1.471	0.946			0.482	1.024	2.106	1.659	1.953	1.716	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.669	1.354	0.892	0.61		0.261	0.96	2.136	1.984	2.434	1.08	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.589	1.318	0.886			0.163	1.196	1.812	1.493	2.271	0.894	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.733	1.325	0.897			0.24	1.151	2.08	1.827	1.993	1.374	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.189	6.724					0.761	0.61		1.602	0.896	
COVID19 (COVID19 (JANSSEN))	Off label use	1.339	6.301	0.882			6.614	0.276	0.4	0.328	0.85	1.24	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.763	6.759					3.108	1.062		2.18		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.535	6.889				0.51	1.746	2.297	1.144	2.58	1.433	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.372	1.709	0.875				0.656	1.063	2.144	2.621	0.969	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.779	2.494	0.921	0.61		0.482	1.845	3.129	2.269	3.152	1.867	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.886	1.414	0.901	0.509		0.292	1.574	2.101	1.543	2.202	1.483	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.737	2.03	0.894			0.39	2.004	3.142	2.24	3.43	1.669	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.05	3.505	0.88				4.447	3.576	6.682	6.228	1.944	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.393					0.656	4.016	3.414	5.92	4.57	3.94	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.037	1.617	0.914	0.745		0.326	1.562	2.466	1.614	2.681	1.481	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.237	1.686	1.57	0.512		0.583	1.703	2.15	2.73	2.567	1.855	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.668	1.883	0.884				1.288	1.33	1.338	1.842	1.724	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.902	1.402	0.895	0.508		0.524	1.48	2.181	1.684	2.12	1.578	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.061	1.456	0.904	0.61		0.352	1.319	2.276	1.787	2.478	1.362	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.79	1.132	1.456			0.544	1.52	1.65	0.972	2.048	0.782	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.42	1.35	0.884			0.535	1.585	1.978	1.522	2.324	1.753	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.585	1.206	0.877			0.544	1.134	0.828	0.645	2.098	0.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.221	2.55	1.617			0.529	1.898	2.365	1.196	2.684	3.083	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.028	6.796	0.88			0.665	3.244	6.762	15.691	7.784	6.058	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.375							0.635	0.572	0.568	1.026	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.104	1.616	0.88			0.514	1.413	1.667	1.352	2.165	1.398	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.347	1.966	0.926			0.38	1.734	2.443	1.783	2.642	1.771	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.677	2.131	1.807	0.512		0.651	1.965	2.362	3.479	2.822	2.166	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.216	1.812	0.876				1.776	1.219	0.642	2.131	0.907	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.404	1.47	0.898			0.646	1.905	2.165	2.5	2.771	1.72	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.75	1.935	0.905	0.512		0.527	2.307	2.307	3.091	3.304	2.118	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.65	1.767	0.901			0.447	2.331	2.009	1.897	2.524	1.883	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.769	1.345	0.882	0.61			1.266	1.967	2.006	1.747	1.683	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.866	1.113	0.88				1.283	2.059	1.764	1.982	1.23	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.644	1.211	0.881	0.511		0.31	0.882	2.028	1.265	1.811	1.051	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.334	1.154	2.632			0.529	1.232	2.602	5.662	2.028	2.217	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.719	1.417	0.938			0.464	0.906	1.298	2.18	1.611	1.584	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.054	6.877					0.913	1.565	0.985	1.824	1.051	
COVID19 (COVID19 (JANSSEN))	Venogram	2.447	1.962	0.877				2.019	1.662	0.721	2.823	1.012	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.088	2.342				0.604	2.648	1.782	0.694	3.845	1.213	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.19	2.374	0.882				3.833	2.012	6.849	5.088	1.223	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.736	1.317	0.882			0.175	1.65	1.538	1.645	2.004	1.217	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	6.833		7.937	0.895		1.206	0.512		1.322	0.941	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.86	0.878		0.661	2.091	0.747	0.566	0.375	0.595	0.568	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.36	6.928	0.884		3.677	2.722	0.109	0.044	0.42	2.391	2.463	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.057	2.011	0.876			2.245	2.006	1.951	1.566	1.3	2.115	
COVID19 (PFIZER-	Body height	1.944	1.019	0.882			0.584	0.927	1.382	2.213	1.923	1.507	
COVID19 (PFIZER-	Disease recurrence	2.051	1.072	0.88			0.667	1.509	1.695	1.946	2.01	1.573	
COVID19 (PFIZER-	Drug ineffective	2.89	1.795	1.019			1.017	1.715	1.782	1.979	2.04	1.995	
COVID19 (PFIZER-	Exposure via breast milk	0.791	6.847	0.881	17.415			0.407			0.461	1.325	
COVID19 (PFIZER-	Immunisation	1.741	1.221	0.884		0.915	1.153	1.446	1.717	2.053	1.851	1.586	
COVID19 (PFIZER-	Investigation	2.169	1.727	0.901			1.658	1.756	1.966	2.346	2.124	1.964	
COVID19 (PFIZER-	Product preparation issue	1.752	6.752			1.933	1.35	1.867	1.73	2.275	1.761	1.728	
COVID19 (PFIZER-	Weight	2.02	1.313	0.89			0.886	1.539	1.729	2.202	1.998	1.77	

PSI-HHS-000000057738

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From: Lale, Allison (CDC/DDID/NCEZID/DHQP)
Sent: Sat, 26 Nov 2022 23:28:15 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220701.xls

Hi Pedro,

I was just wondering (b)(5)
(b)(5)

For example, we have an upcoming (b)(5)
(b)(5)

Thanks,
Allison

p.s. Hope you had a good holiday!

From: Menschik, David <[redacted]>
Sent: Tuesday, July 5, 2022 7:42 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/1/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20220101	Serious EB05 2022	Fatal EB05 20220	Infant EB05 20220	Child EB05 20220	Teen EB05 20220	Adult1 EB05 20220	Adult2 EB05 20220	Adult3 EB05 20220	Female EB05 20220	Male EB05 20220701
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.607	1.468	0.92			0.375	1.477	1.861	1.666	2.661	1.362
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.019	1.484	0.869				1.536	1.967	1.989	2.688	1.366
COVID19 (COVID19 (JANSSEN))	Acute respiratory distress syndrome	2.045	1.288	0.983				0.767	1.743	1.738	1.583	1.889
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.126	1.322	1.028			0.45	1.533	2.087	1.986	2.425	1.794
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.385	0.985	0.88			0.522	0.953	0.701	0.739	2.654	1.443
COVID19 (COVID19 (JANSSEN))	Adverse event	2.64	1.091	0.886				0.864	0.906	0.833	1.893	1.714
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.9	1.252	0.903				1.466	1.434	1.672	2.094	1.309
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.509	1.764	0.906			0.485	2.386	1.916	2.044	3.302	1.511
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.051	1.392	0.881				1.781	1.828	1.226	2.144	1.522
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.269	1.605	0.907	0.619		0.408	1.714	2.216	2.205	2.459	1.972
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.789	1.346	0.91			0.351	1.142	2.144	1.024	2.148	1.311
COVID19 (COVID19 (JANSSEN))	Antibody test	2.17	0.824	0.873			0.586	0.863	1.59	2.124	2.071	1.685
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.178	1.45	0.974	0.619		0.41	1.844	2.026	2.25	2.733	1.674
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COVID19 (COVID19 (JANSSEN))	Areflexia	2.047	1.642	0.896				0.987	2.227	1.307	2.14	1.42
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.757	1.131	0.88				1.203	12	1.397	2.158	0.962
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.833	1.361	0.934	0.617		0.351	1.112	2.196	1.867	2.364	1.32
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.748	1.357	0.941	0.516		0.339	1.091	2.225	1.782	2.135	1.326
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.844	1.279	0.937			0.351	1.517	1.864	1.777	2.18	1.435
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.871	1.343	0.958			0.404	1.383	2.077	1.907	2.188	1.52
COVID19 (COVID19 (JANSSEN))	Blood chloride decreased	1.876	1.252	0.924				1.111	2.032	1.603	1.944	1.598
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.792	1.284	0.961			0.5	1.237	1.948	1.85	2.122	1.339
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	1.985	1.32	0.869			0.576	0.929	2.157	0.855	1.825	1.211
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.755	2.165	0.896			0.498	1.741	2.031	0.958	4.084	1.027
COVID19 (COVID19 (JANSSEN))	Blood lactate dehydrogenase increased	1.767	1.244	0.895	0.619			1.186	2.025	1.309	1.763	1.416
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.777	1.27	0.92			0.175	1.102	1.893	1.763	2.31	1.217
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.7	1.219	0.94			0.551	1.256	1.467	2.036	1.897	1.243
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.841	1.306	0.901	0.616			1.391	2.076	1.744	1.975	1.61
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.657	1.098	0.927				1.707	1.369	1.201	2.019	1.054
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COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.679	1.337	0.886			0.289	1.389	1.922	1.294	2.024	0.934
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.911	1.259	0.919			0.35	1.097	2.064	1.788	2.111	1.658
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.253	1.407	1.082				1.998	2.264	2.059	2.493	2.018
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.585	1.991	0.873				1.85	3.066	0.98	2.873	2.143
COVID19 (COVID19 (JANSSEN))	Catheter directed thrombolysis	1.774	1.232	0.875			0.532	0.456	1.736	0.806	2.115	0.691
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.23	1.58	0.939			0.521	1.764	1.826	1.5	3.317	1.173
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.755	1.928	0.92			0.529	1.38	1.618	1.254	3.698	1.192
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.71	1.733	0.878				1.466	1.354	1.635	3.611	1.271
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.357	2.172	0.916			0.524	2.579	2.441	0.873	3.924	1.272
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.873	1.27	0.954			0.374	1.369	1.884	1.903	2.077	1.835
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.4	1.614	0.956	0.618		0.597	2.1	2.235	2.017	2.963	1.714
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.988	1.332	0.916			0.436	1.734	1.962	1.8	2.258	1.531
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.008	1.384	0.927			0.524	1.406	2.064	1.974	2.252	1.887
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COVID19 (COVID19 (JANSSEN))	Death	1.877	1.171	0.962				1.223	1.644	1.586	2.084	1.557
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.651	1.805	1.046			0.481	2.27	2.296	3.199	3.304	2.087
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COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.767	1.285	0.932			0.249	1.214	2.04	1.757	2.08	1.368
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.781	1.329	0.937	0.516		0.369	1.218	2.06	1.777	2.072	1.387
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.757	0.84	0.884			0.181	2.023	1.462	0.982	1.848	1.429
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.274	1.281	0.893			0.502	2.179	2.147	1.965	2.532	1.706
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.152	1.46	0.99	0.619		0.293	1.715	2.293	2.257	2.522	1.848
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.945	1.089	0.878			0.435	1.624	2.017	1.104	2.184	1.294
COVID19 (COVID19 (JANSSEN))	Foetal exposure during pregnancy	2.329	1.46		0.757			0.875			1.642	1.845
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.214	1.031	0.88			0.402	2.305	1.666	1.215	2.214	1.804
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.897	1.298	0.911			0.391	1.3	1.758	1.684	2.274	1.275
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.746	1.176	0.912				1.225	1.518	1.357	2.23	1.106
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.448	1.818	0.887			0.434	1.617	3.042	1.622	2.392	2.169
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.864	1.271	0.956	0.613		0.527	1.328	2.015	1.789	2.157	1.447
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.76	1.234	0.946	0.613		0.421	1.406	1.942	1.676	2.001	1.429
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.708	3.805	0.894				4.176	5.514	4.346	7.258	3.372
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.145	3.291	0.875			0.55	4.199	5.727	0.74	7.043	2.491
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COVID19 (COVID19 (JANSSEN))	Hypoxia	2.069	1.322	0.857			0.416	1.553	2.091	1.946	2.447	1.718
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.09	1.723	0.873			0.611	1.932	2.577	1.376	2.2	1.75
COVID19 (COVID19 (JANSSEN))	Intensive care	1.964	1.389	1.08			0.557	1.478	2.13	2.083	2.351	1.614
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COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.758	1.198	0.882	0.755		0.377	1.529	1.89	1.429	2.308	1.251
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.931	1.239	0.885				1.366	2.057	1.025	2.102	1.266
COVID19 (COVID19 (JANSSEN))	Intracardiac thrombus	2.674	1.778	0.907				0.84	1.422	0.995	1.712	1.824
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.893	1.377	0.878				1.389	1.116	0.712	2.297	0.707
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.869	1.345	0.866				1.267	2.185	1.006	1.661	1.755
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.134	1.668					1.116	2.852	1.018	1.753	1.827
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.985	1.266	0.948				1.449	1.715	1.983	2.357	1.511
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.687	1.229	0.933			0.246	0.997	2.064	1.87	2.074	1.309
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.059	1.486	0.911			0.484	1.756	1.897	2.096	2.297	1.831
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.017	1.354	0.934	0.619		0.488	1.257	2.157	1.838	2.31	1.37
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.724	1.27	0.919			0.357	1.101	1.864	1.59	2.1	0.998
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.826	1.282	0.907			0.376	1.135	2.254	1.556	2.034	1.4
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.262	1.503	1.02			0.474	1.153	2.268	2.046	2.084	2.062
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COVID19 (COVID19 (JANSSEN))	Neonatal dyspnoea	2.377	0.985		0.62						0.874	1.117
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.516	1.205	0.889			0.365	1.107	1.69	1.69	2.117	0.882
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.726	1.258	0.932			0.393	1.104	2.068	1.803	1.973	1.426
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	4.088	0.789					0.744	0.613		3.024	1.076
COVID19 (COVID19 (JANSSEN))	Off label use	2.113	0.661	0.886			0.451	1.235	1.485	1.04	1.528	2.143
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.767	0.751					3.423	0.982		2.244	
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.206	0.857				0.512	1.495	2.233	1.039	2.176	1.405
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.062	1.36	0.875				0.657	1.035	1.572	2.268	0.951
COVID19 (COVID19 (JANSSEN))	Platelet count	2.67	2.155	0.914	0.618		0.473	1.863	2.915	2.713	3.04	1.823
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.889	1.306	0.915	0.614		0.331	1.488	2.102	1.664	2.265	1.49
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.553	1.798	0.894			0.448	2.101	2.662	2.219	3.114	1.701
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.76	3.243	0.881				4.263	4.663	0.795	5.61	2.28
COVID19 (COVID19 (JANSSEN))	Portal vein thrombosis	2.244	1.652	0.877				0.506	1.869	1.032	2.317	1.335
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	2.088	1.293	0.956				0.997	2.123	1.706	2.281	1.832
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.76	6.835	0.877		0.693	2.06	0.037	0.002	0.506	1.67	1.812
COVID19 (COVID19 (JANSSEN))	Prolonged labour	5.164	1.396					5.065			5.157	
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.808	1.237	0.933	0.616		0.319	1.446	1.846	1.744	2.036	1.431
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.917	1.374	0.937	0.754		0.291	1.449	2.27	1.664	2.471	1.439
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.261	1.588	1.05	0.62		0.585	1.819	2.071	2.632	2.528	1.93
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.341	1.514	0.905				1.721	1.727	1.924	2.222	1.925
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.786	1.258	0.936	0.614		0.586	1.349	1.961	1.663	2.084	1.502
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.968	1.319	0.931	0.617		0.379	1.257	2.126	1.828	2.306	1.443
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.329	0.994					2.654	0.508		1.068	0.725
COVID19 (COVID19 (JANSSEN))	Sensory disturbance	2.008	1.306	0.881				1.445	1.86	1.472	1.878	1.748
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.582	1.778	0.885			0.53	1.762	2.039	1.749	2.588	1.822
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.28	2.231	1.096			0.618	3.12	3.176	1.123	2.813	3.343
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.559	0.757	0.876			0.651	3.658	6.592	14.645	7.714	5.681
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.705							0.637	0.568	0.561	1.926
COVID19 (COVID19 (JANSSEN))	Thrombectomy	1.942	1.311	0.88			0.505	1.446	1.563	1.464	2.08	1.343
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.274	1.705	0.951			0.36	1.62	2.464	1.885	2.51	1.78
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.924	2.126	1.799	0.62		0.732	2.011	2.487	3.622	2.998	2.401
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COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.077	1.495	0.876				1.775	1.225	0.623	2.112	0.879
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.345	1.427	0.905			0.711	1.888	2.209	2.139	2.653	1.75
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.655	1.818	0.958	0.619		0.522	2.484	2.295	2.83	3.28	2.108
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.344	1.607	0.91			0.424	2.241	1.969	1.972	2.411	1.843
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.61	3.024	2.476			0.554	1.462	2.46	4.1	2.189	2.366
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.91	0.895					1.25	1.375	0.787	2.084	0.809
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.069	0.907	0.874				0.975	1.573	1.123	1.793	1.113
COVID19 (COVID19 (JANSSEN))	Venogram	2.341	1.747	0.873				2.001	1.601	0.706	2.543	1.064
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.65	1.991				0.608	2.669	1.609	0.659	3.258	1.192
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.84	2.162	0.881				3.587	2	1.055	4.711	1.195
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.474	0.819		0.551	1.374		1.28	0.52		1.472	1.072
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.685	6.994	0.886	0.507	1.393	2.491	0.793	0.607	0.437	0.688	0.646
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COVID19 (COVID19 (MODERNA))	Mechanical urticaria	2.023	1.165				0.604	2.046	1.539	0.607	1.966	1.926
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.523	1.018	0.887	0.362	4.261	2.99	0.159	0.087	0.36	2.538	2.623
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.129	2.004	0.876		0.543	2.724	2.031	1.962	1.571	1.962	2.173
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.045					1.145	1.944	2.002	1.843	1.974	1.923
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.099	1.663	0.889			0.636	1.62	1.782	1.529	1.908	1.887
COVID19 (COVID19 (PFIZER-	Body height	1.967	1.011	0.881		0.484	0.695	0.96	1.465	2.193	1.93	1.553
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.025	1.754	1.664	0.745	0.888	1.147	1.826	1.885	1.887	1.834	1.908
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.853	6.847	0.88	15.347			0.365			0.501	1.215
COVID19 (COVID19 (PFIZER-	Immunisation	2.077	1.652	0.915		1.289	1.245	1.82	2.002	2.282	2.007	1.858
COVID19 (COVID19 (PFIZER-	Investigation	2.043	1.764	0.932		0.76	1.108	1.821	1.942	2.263	1.996	1.896
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.568	6.786		0.394	1.453	1.357	1.859	1.714	2.152	1.573	1.543
COVID19 (COVID19 (PFIZER-	Weight	1.924	1.367	0.891			0.554	1.545	1.736	2.08	1.88	1.743

PSI-HHS-000000057741

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 11 Jun 2021 19:51:53 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20120521.xls

From: Menschik, David <[redacted]>
Sent: Tuesday, May 25, 2021 6:36 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/21/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210521	Serious EB05 2021(	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.126	0.779					0.769	0.369	0.754	1.761	1.39	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.599	2.613	0.878			0.548	1.188	1.55	4.401	2.79	1.275	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	1.985	2.118					1.185	1.868	1.435	2.122	1.37	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.206	2.372	0.887	0.611			1.687	1.801	2.405	2.772	1.388	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.007	2.853	0.887			0.557	2.252	1.974	0.632	2.977	1.204	
COVID19 (COVID19 (JANSSEN))	Chills	1.377	0.93	0.888			2.314	1.4	1.228	0.94	1.434	1.149	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.256	2.336	0.901	0.611		0.548	1.939	1.868	1.637	2.944	1.314	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.807	1.87	0.881			0.541	1.424	1.451	1.654	2.019	1.226	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.34	1.898	0.887			0.531	1.963	2.116	2.801	2.762	1.782	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.582	1.45	0.886			0.466	2.369	2.019	2.637	2.757	1.553	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.826	1.378	0.886	0.604		0.55	1.362	1.811	1.337	2.163	0.981	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.19	0.882					2.102	1.642	0.686	2.53	1.031	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.14	0.737					2.178	1.654		2.136	0.546	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.296	2.883	0.881				1.298	1.449	2.582	4.578	1.063	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.93	2.321	0.879				1.682	0.63	0.648	1.944	0.62	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.944	2.09	0.876			0.61	1.668	1.523	1.754	2.129	1.401	
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.03	0.679					1.986	1.661		2.001	0.569	
COVID19 (COVID19 (JANSSEN))	Off label use	1.184					3.192	0.29	0.42		0.78	0.993	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	2.812	1.508	0.879				0.531	0.894	2.346	1.75	0.836	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.052	2.346	0.893	0.611		0.54	1.639	2.283	1.317	2.362	1.115	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.507	2.217	0.882			0.467	1.85	2.503	1.908	3.216	1.415	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	2.817	2.587	0.879				1.298	1.158	0.679	2.03	0.905	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.793	1.768	0.887	0.611		0.62	1.305	1.838	2.285	2.094	1.339	
COVID19 (COVID19 (JANSSEN))	Pyrexia	1.418	0.904	0.888			2.325	1.446	1.223	0.942	1.476	1.188	
COVID19 (COVID19 (JANSSEN))	Scan with contrast abnormal	1.834	2.055					1.025	1.606	1.081	1.754	1.151	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	3.049						1.012	2.607	5.96	2.462	2.19	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.249	1.011	0.881			0.557	1.404	1.462	1.34	1.86	1.5	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.305	2.513	1.971	0.611		0.552	2.094	2.359	3.626	2.707	1.697	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.164	2.215	0.879				1.298	1.55	0.668	1.827	0.926	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.028	1.182	0.88			0.549	1.797	1.761	1.585	2.351	1.309	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.607	2.284	0.883				1.883	1.58	3.274	3.026	1.725	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.914	1.233		0.602			1.315	2.072	2.043	1.88	1.685	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.913	1.035					1.379	1.797	1.109	2.147	0.848	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.503	2.646				0.557	1.83	1.41	0.539	2.569	1.003	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.034	2.963	0.879				3.188	1.87	0.665	4.645	0.913	
COVID19 (COVID19 (JANSSEN))	Vital signs measurement	1.893	0.554				0.758	2.017	1.352	1.245	1.86	1.597	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.188				0.528	0.531	0.496	0.548	0.831	0.79	0.678	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.067						0.398	0.312	0.556	0.271	0.484	
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.07	1.622	0.894			0.743	1.936	2.107	2.055	1.884	1.877	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.153	1.689	0.885			0.697	1.841	1.938	2.081	2.081	1.862	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	2.079					1.44	1.625	1.769	2.119	1.979	1.94	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.057	1.212	0.881			0.501	1.465	1.833	1.995	2.023	1.661	

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 29 Apr 2021 17:59:19 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20210423.xls

Hi folks,

Elaine raised the point about (b)(5) (b)(5) Please see the enclosed weekly data mining results shared by FDA. (b)(5) (b)(5) (b)(5)

Please let me know if you have any questions. I'll try to remember to forward these data when I get them in future weeks. Thanks!

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, April 27, 2021 8:42 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Hi John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/23/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20210423	Serious EB05 2021	Fatal EB05 202104	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.028	0.67					0.806	0.428	0.831	1.353	1.077	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	1.354	2.103	0.878			0.541	0.755	1.05	0.847	1.249	0.767	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.541	2.661	0.88				1.124	1.001	0.918	1.478	0.854	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	1.838	2.971	0.887			0.541	1.466	1.156	0.859	1.694	0.771	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.36	0.798					2.389	1.5		2.344		
COVID19 (COVID19 (JANSSEN))	Interchange of vaccine products	1.636					0.586	1.068	1.29	2.222	1.554	1.128	
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.122						2.041	1.564		2.075		
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.281	2.092	0.887	0.605		0.484	1.047	1.104	1.289	1.349	1.034	
COVID19 (COVID19 (JANSSEN))	Syncope	1.794	0.815	0.88			1.026	2.001	1.557	0.461	1.803	1.647	
COVID19 (COVID19 (JANSSEN))	Thrombosis	3.214	3.039	1.986	0.605		0.597	2.001	1.9	2.112	2.372	1.587	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	1.707	2.129	0.882				1.048	1.419	1.271	1.758	1.05	
COVID19 (COVID19 (MODERNA))	Injection site pruritus	1.985	0.958				0.462	2.026	2.03	1.721	1.975	1.948	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.159	1.668	0.883			0.636	1.758	1.739	1.867	2.031	1.436	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	2.075					1.64	1.247	1.832	2.074	1.962	1.79	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue	2.086	0.942	0.878				1.94	1.698	1.567	2.031	1.377	
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain	2.01	0.778	0.872			0.608	2.165	2.083	1.614	1.905	2.032	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.042	0.963	0.88				1.3	1.527	1.781	1.89	1.455	

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 7 May 2021 18:25:39 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20210430.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, May 4, 2021 6:51 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/30/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210430	Serious EB05 2021(	Fatal EB05 202104	Infant EB05 20210(	Child EB05 202104	Teen EB05 202104	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 202104	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.096	0.679					0.623	0.307	0.647	1.606	1.147	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	1.832	2.654	0.873			0.545	0.966	1.215	1.45	1.662	1.045	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	1.89	2.847	0.878				1.183	1.331	1.746	1.893	1.227	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	1.876	2.697	0.863			0.545	1.489	1.354	0.842	1.719	0.939	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	1.556	2.242	0.906			0.545	1.446	1.319	1.027	1.81	0.879	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	1.877	1.922	0.883				1.534	1.652	1.958	2.07	1.479	
COVID19 (COVID19 (JANSSEN))	Dysmenorrhoea	2.117	0.713					2.323	0.948		2.073		
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.185	1.662	0.88			0.49	2.146	1.621	1.732	2.318	1.328	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	1.964	0.895					1.897	1.465	0.822	2.039	0.999	
COVID19 (COVID19 (JANSSEN))	Head injury	1.592	0.658				0.651	2.034	0.775	0.415	1.412	1.466	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.449	0.781					2.749	1.473		2.427		
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	1.879	2.252	0.877				0.987	0.686	1.329	1.576	0.73	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.382	2.061	0.872			0.574	1.379	1.109	1.039	1.417	1.071	
COVID19 (COVID19 (JANSSEN))	Menstrual disorder	2.016					0.607	1.786	1.725		1.989		
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.224						2.214	1.614		2.167		
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.003	2.182	0.877			0.49	1.652	1.867	1.318	2.327	1.147	
COVID19 (COVID19 (JANSSEN))	Syncope	1.758	0.909	0.88			0.957	2.024	1.518	0.525	1.722	1.885	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.072	2.67	0.873	0.809		0.574	1.836	2.003	2.475	2.322	1.528	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.032	2.369	0.88				1.241	1.602	1.933	2.134	1.347	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	1.427	2.1				0.545	1.266	0.66		1.214	0.821	
COVID19 (COVID19 (JANSSEN))	Venogram normal	1.955	2.238	0.877				1.333	1.197	0.564	1.752	0.716	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.046				0.508	0.504	0.844	0.69	0.924	1.121	1.053	
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.143	1.488	0.869			0.848	1.918	2.331	2.001	1.936	1.832	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.187	1.631	0.88			0.562	1.854	1.909	2.013	2.118	1.83	
COVID19 (COVID19 (PFIZER-BIONTECH))	Off label use	1.79	1.038	0.875				2.028	1.663	1.689	1.841	1.33	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	1.966					0.632	1.107	1.504	2.089	1.814	1.774	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue	2.129	0.947	0.874				1.96	1.739	1.608	2.086	1.399	
COVID19 (COVID19 (PFIZER-BIONTECH))	SARS-CoV-2 test	1.975	1.56	0.893			1.178	1.984	2.04	1.792	1.927	1.862	
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain	1.969	0.749	0.866			0.63	2.126	1.967	1.508	1.868	1.949	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.131	1.142	0.875				1.403	1.707	1.968	2.011	1.849	

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 13 May 2021 20:24:40 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20210507.xls

Pedro,
Sharing this FYI

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, May 13, 2021 4:10 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

From: Menschik, David <[redacted]>
Sent: Tuesday, May 11, 2021 8:41 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Apologies all for forgetting the attachment – please see attached.

Thanks,
David

From: Menschik, David
Sent: Tuesday, May 11, 2021 7:07 AM
To: Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani, Meghna <[redacted]>; Marquez, Paige L (CDC) <[redacted]>; Broder, Karen R (CDC) <[redacted]>; Harrington, Theresa (CDC) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/7/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	US EB05 20210507	Serious EB05 2021(	Fatal EB05 20210[	Infant EB05 20210[	Child EB05 20210[	Teen EB05 20210[	Adult1 EB05 20210	Adult2 EB05 20210	Adult3 EB05 20210	Female EB05 2021(	Male EB05 20210[	Comment
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.113	0.661					0.607	0.384	0.734	1.706	1.293	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.338	2.721	0.88			0.548	1.06	1.415	3.837	2.055	1.245	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	1.818	2.268					1.071	1.588	1.406	1.873	1.259	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.168	2.678	0.888	0.61			1.542	1.516	2.175	2.408	1.391	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	2.315	2.771	0.889			0.548	1.642	1.785	0.632	2.058	1.193	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	1.982	2.344	0.916	0.61		0.548	1.631	1.627	1.446	2.408	1.046	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.118	1.923	0.891				1.768	1.898	2.349	2.373	1.866	
COVID19 (COVID19 (JANSSEN))	Dysmenorrhoea	1.96	0.707					2.074	0.941		1.929		
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.389	1.541	0.888			0.501	2.274	1.81	2.264	2.595	1.4	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.152	0.887					2.075	1.585	0.702	2.295	1.025	
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding	2.365	0.769					2.498	1.552		2.353		
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	2.813	2.707	0.884				1.019	1.237	1.411	2.391	0.884	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.519	2.201	0.882				1.233	0.791	0.644	1.463	0.897	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.692	2.063	0.879			0.547	1.613	1.362	1.327	1.769	1.243	
COVID19 (COVID19 (JANSSEN))	Menstruation irregular	2.174						2.182	1.528		2.143		
COVID19 (COVID19 (JANSSEN))	Platelet count	1.786	2.108	0.89	0.61		0.521	1.235	1.939	1.19	2.068	0.941	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.313	2.259	0.885			0.462	1.788	2.243	1.575	2.703	1.362	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.662	1.913	0.888	0.61		0.503	1.176	1.524	2.05	1.885	1.265	
COVID19 (COVID19 (JANSSEN))	Syncope	1.797	0.903	0.885	0.61		0.899	2.038	1.566	0.646	1.787	1.71	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	2.156						0.753	1.12	0.942	1.513	1.419	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.255	2.649	0.999	0.61		0.561	2.034	2.128	3.398	2.564	1.676	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	1.702	2.049	0.881				1.168	1.257	0.563	1.463	0.922	
COVID19 (COVID19 (JANSSEN))	Ultrasound doppler	2.021	1.344	0.853			0.548	1.717	1.741	1.613	2.116	1.461	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.306	2.333	0.896				1.507	1.809	2.256	2.612	1.501	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	1.715	2.299				0.548	1.358	1.211		1.547	0.902	
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.314	2.832	0.883				2.046	1.409	0.673	3.449	0.869	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.113				0.521	0.562	0.768	0.834	0.878	1.099	0.917	
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue	2.038						0.586	0.469	0.57	0.501	0.896	
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective	2.134	1.626	0.891			0.703	2	2.211	2.087	1.946	1.925	
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation	2.212	1.712	0.888			0.638	1.862	1.953	2.076	2.138	1.876	
COVID19 (COVID19 (PFIZER-BIONTECH))	Off label use	1.76	1.064	0.882			0.28	2.011	1.67	1.687	1.751	1.378	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue	2.035					0.668	1.29	1.569	2.145	1.89	1.855	
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue	2.117	0.969	0.881			0.512	1.954	1.713	1.619	2.065	1.458	
COVID19 (COVID19 (PFIZER-BIONTECH))	SARS-CoV-2 test	1.958	1.612	0.898			1.313	1.953	2.02	1.828	1.91	1.856	
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain	1.942	0.751	0.875			0.601	2.067	1.953	1.645	1.868	1.92	
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight	2.179	1.242	0.884				1.459	1.845	2.022	2.072	1.71	

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 4 Aug 2021 21:28:56 +0000
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_2021_0730.xls

Attached is the latest FDA data mining summary for COVID vaccine.

Thanks,

Elaine

From: Zinderman, Craig E <[redacted]>
Sent: Wednesday, August 4, 2021 4:26 PM
To: Menschik, David (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/30/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

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Drug	Event	US EB05 20210713	Serious EB05 2021	Fatal EB05 20210	Infant EB05 20210	Child EB05 20210	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial	1.778	1.727	0.882				1.463	1.755	1.124	2.032	1.161	
COVID19 (COVID19 (JANSSEN))	Adverse drug	2.522	0.907	0.887				0.763	0.72	0.696	2.146	1.474	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.014	0.992	0.886				0.963	0.702	0.646	1.483	1.511	
COVID19 (COVID19 (JANSSEN))	Angiogram	3.068	2.068	0.892			0.515	1.529	2.021	3.046	4.206	1.37	
COVID19 (COVID19 (JANSSEN))	Angiogram	2.363	2.142	0.886			0.488	1.525	2.394	1.703	2.44	1.564	
COVID19 (COVID19 (JANSSEN))	Anticoagulant	2.015	1.826	0.914	0.612		0.397	1.716	1.89	2.017	2.641	1.342	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen	2.557	2.462	0.887			0.539	1.21	1.431	0.664	3.046	0.565	
COVID19 (COVID19 (JANSSEN))	CSF protein	2.11	2.135	0.884				1.283	2.013	0.976	1.384	1.917	
COVID19 (COVID19 (JANSSEN))	Cerebral	1.969	1.952	0.905			0.537	1.696	1.763	1.241	2.527	1.026	
COVID19 (COVID19 (JANSSEN))	Cerebral venous	3.298	2.607	0.895			0.539	2.381	2.851	0.741	3.812	1.225	
COVID19 (COVID19 (JANSSEN))	Computerised	2.435	2.137	0.914	0.612		0.49	2.082	2.251	1.756	3.143	1.531	
COVID19 (COVID19 (JANSSEN))	Computerised	1.979	1.802	0.889			0.511	1.505	2.022	1.568	2.255	1.439	
COVID19 (COVID19 (JANSSEN))	Deep vein	2.369	1.884	0.906			0.474	2.114	2.112	2.812	2.861	1.839	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.352	1.565	0.89			0.42	2.335	2.038	1.787	2.678	1.51	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	1.92	1.468	0.893	0.61		0.34	1.561	2.076	1.653	2.256	1.247	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.346	0.944	0.884				2.508	1.704	0.797	2.848	1.246	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre	1.891	1.81	0.894				1.111	2.346	1.056	1.575	1.696	
COVID19 (COVID19 (JANSSEN))	Heparin-induced	4.811	3.363	0.891				2.126	3.813	4.121	5.748	1.343	
COVID19 (COVID19 (JANSSEN))	Heparin-induced	5.589	2.91				0.557	3.332	1.942	0.672	8.107	1.044	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin	1.783	1.956	0.885			0.06	1.597	2.152	1.222	1.732	1.494	
COVID19 (COVID19 (JANSSEN))	Jugular vein	2.024	2.168	0.885				1.003	1.125	0.651	2.308	0.725	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.749	1.817					0.814	2.05	0.839	1.133	1.534	
COVID19 (COVID19 (JANSSEN))	Magnetic	1.963	1.862	0.886			0.478	1.745	1.774	1.742	2.202	1.455	
COVID19 (COVID19 (JANSSEN))	Off label use	1.627	0.147				4.801	0.352	0.621	0.353	1.02	1.526	
COVID19 (COVID19 (JANSSEN))	On and off	1.6	0.757					2.232	1.033		1.962		
COVID19 (COVID19 (JANSSEN))	Peripheral	3.999	2.016	0.885				0.65	1.019	1.914	2.488	0.922	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.313	2.533	0.902	0.612		0.511	2.064	2.991	1.368	2.782	1.446	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.551	2.259	0.891			0.286	1.969	2.921	2.033	3.172	1.552	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	4.987	3.252	0.885				3.108	1.805	0.692	4.867	1.315	
COVID19 (COVID19 (JANSSEN))	Poor quality	0.425					0.593	2.24	1.957	4.132	2.297	2.123	
COVID19 (COVID19 (JANSSEN))	Pulmonary	1.994	1.771	0.907	0.612		0.649	1.576	1.974	2.131	2.282	1.59	
COVID19 (COVID19 (JANSSEN))	Therapy non-	4.549						2.566	6.305	11.62	5.216	3.937	
COVID19 (COVID19 (JANSSEN))	Thrombocytopeni	1.811	1.891	0.889			0.432	1.574	1.949	1.123	2.108	1.253	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis	2.135	1.143	0.887			0.551	1.26	1.688	1.201	1.817	1.529	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.298	2.408	1.824	0.612		0.605	2.079	2.359	3.114	2.6	1.879	
COVID19 (COVID19 (JANSSEN))	Transverse sinus	2.255	1.951	0.885				1.638	1.189	0.854	2.208	0.877	
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.129	1.263	0.889			0.59	1.889	1.939	1.69	2.484	1.383	
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.647	2.17	0.897	0.612			2.055	2.19	3.318	2.77	2.145	
COVID19 (COVID19 (JANSSEN))	Ultrasound	2.273	1.708					2.592	1.344	1.305	2.398	1.406	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	2.014	1.374	0.882			0.473	1.521	1.852	1.72	1.994	1.588	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.808	1.03					1.236	1.848	1.867	2	1.287	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	0.966	1.24	0.889			0.527	0.956	1.978	3.041	1.299	1.501	
COVID19 (COVID19 (JANSSEN))	Venogram	2.282	2.059					1.675	1.685	0.565	2.326	0.891	
COVID19 (COVID19 (JANSSEN))	Venogram	3.295	2.635				0.53	2.967	1.953	0.7	4.286	1.062	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.072	2.512	0.885				3.105	2.373	0.754	5.081	0.914	
COVID19 (COVID19 (MODERNA))	No adverse event	1.572	0.81	0.886		0.488	2.098	0.925	0.977	0.893	1.24	1.34	
COVID19 (COVID19 (MODERNA))	Accidental	2.114					0.381	0.533	0.47	0.737	0.675	0.787	
COVID19 (COVID19 (MODERNA))	Poor quality	2.466				0.544	0.329	0.278	0.383	0.547	0.444	0.405	
COVID19 (COVID19 (MODERNA))	Product	2.36	0.867	0.885		0.754	2.422	0.089	0.24	0.671	2.318	2.381	
COVID19 (COVID19 (PFIZER-	Product	1.849					1.397	1.877	1.857	2.066	1.828	1.786	

PSI-HHS-000000057752

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 6 Sep 2021 14:57:02 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20210827.xls

FYI-see attached data mining results but do not share with anyone.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, September 3, 2021 6:12 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

From: Menschik, David <[redacted]>
Sent: Tuesday, August 31, 2021 7:48 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 8/27/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Drug	Event	VS EB05 20210427	Serious EB05 2021	Fatal EB05 20210	Infant EB05 2021	Child EB05 2021	Teen EB05 20210	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 21210	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.861	1.737	0.886			0.636	1.381	1.679	1.636	2.365	1.01	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.903	1.693	0.877				1.47	1.846	1.487	2.097	1.344	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.515	0.909	0.883				0.848	0.707	0.63	2.158	1.513	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.063	2.431	0.86			0.597	1.638	2.065	4.095	4.165	1.434	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.414	2.036	0.883			0.469	1.617	2.404	1.865	2.551	1.904	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.287	0.855	0.881			0.597	0.753	1.867	2.985	2.088	1.856	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.095	1.74	0.911	0.512		0.459	1.776	1.864	2.221	2.71	1.417	
COVID19 (COVID19 (JANSSEN))	Anelleria	1.958	2.162	0.882				0.881	1.962	1.165	1.528	1.496	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.429	1.174	0.885	0.509		0.309	0.845	2.081	1.056	1.55	1.03	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.551	2.375	0.883			0.54	1.06	1.914	0.655	3.781	0.857	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.364	2.23	0.861				1.544	2.206	1.075	1.838	1.948	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.178	1.948	0.904			0.538	1.618	1.987	1.365	2.995	1.128	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	1.954	1.688	0.883				0.987	0.939	1.58	2.238	0.916	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.27	3.017	0.892			0.838	2.107	2.408	0.783	3.89	1.224	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.582	2.086	0.929	0.512		0.569	1.983	2.44	1.968	3.32	1.671	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.051	1.795	0.891			0.507	1.477	2.022	2.049	2.361	1.569	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.389	1.872	0.904			0.479	2.181	2.136	1.186	3.068	1.915	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.44	1.204	0.886				0.91	2.023	1.174	1.581	0.984	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.419	1.566	0.886			0.415	2.327	2.118	1.971	2.741	1.605	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.032	1.515	0.895	0.511		0.389	1.609	2.205	1.898	2.419	1.337	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.847	0.97	0.881			0.45	1.616	1.74	0.806	2.05	1.078	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.261	0.933	0.882				2.351	1.679	0.809	2.753	1.207	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.108	1.83	0.86				1.263	2.632	1.39	1.674	1.865	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.158	3.512	0.86				3.438	3.786	5.857	6.534	1.673	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6	2.975				0.561	3.632	2.86	0.668	6.628	1.059	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.53	1.982	0.88			0.025	1.836	2.215	1.451	1.991	1.553	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.209	2.213	0.882				1.097	1.176	0.75	3.422	0.709	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.909	1.869					0.956	2.063	1.019	1.382	1.865	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.087	1.853	0.886			0.534	1.788	1.861	2.015	2.322	1.601	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.44	1.08	0.878			0.397	0.995	2.088	0.516	1.894	1.65	
COVID19 (COVID19 (JANSSEN))	Off label use	1.853	0.248	0.88			5.293	0.343	0.572	0.402	1.211	1.672	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.731	0.756					2.505	1.62		2.223		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.478	0.899				0.564	1.71	2.158	1.094	2.351	1.622	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.489	1.8	0.881				0.653	0.974	2.63	2.207	0.909	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.652	2.517	0.903	0.512		0.504	2.204	3.367	1.429	3.339	1.822	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.745	1.51	0.894	0.508		0.333	1.481	2.002	1.337	2.039	1.333	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.766	2.224	0.86			0.429	2.056	3.052	2.238	3.403	1.822	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	5.853	3.466	0.882				4.367	2.339	0.688	5.901	1.842	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.562					0.58	2.792	2.237	4.884	3.381	2.714	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.628	1.389	0.882	0.744		0.305	1.255	1.957	1.199	2.044	1.116	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.164	1.717	0.906	0.512		0.643	1.612	2.64	2.34	2.428	1.676	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	1.932	1.724	0.886				1.494	1.334	2.129	1.788	1.586	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.98	1.177				0.561	0.96	0.643	0.65	2.006	0.902	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	2.463	1.821	0.893			0.556	1.663	2.074	0.567	2.084	2.426	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	5.709					0.655	3.209	5.961	14.615	6.957	4.918	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	1.898	1.881	0.888			0.42	1.888	2.048	1.271	2.347	1.338	
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.346	1.154	0.883			0.556	1.327	1.876	1.289	1.951	1.732	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.561	2.332	1.799	0.512		0.603	2.176	2.431	3.438	2.929	2.042	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.317	1.045	0.881				1.892	1.261	0.65	2.471	0.863	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.264	1.295	0.885			0.588	1.78	2.005	2.072	2.51	1.532	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.765	2.098	0.897	0.512		0.556	2.244	2.163	3.535	3.159	2.127	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.279	1.685				0.475	2.378	1.462	1.523	2.398	1.478	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal	2.038	1.333	0.877			0.474	1.421	1.929	1.908	1.978	1.862	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.831	1.053	0.881				1.18	2.021	1.85	1.966	1.19	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.763	1.864	0.893			0.528	1.132	2.279	4.565	1.725	1.908	
COVID19 (COVID19 (JANSSEN))	Venogram	2.365	2.034					1.71	1.75	0.544	2.4	1.033	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.37	2.845				0.621	2.689	1.821	0.703	4.357	1.039	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.217	2.512	0.882				3.196	3.265	0.757	5.112	1.059	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.265	0.733		3.202	0.715		1.102			1.166	0.765	
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.052				0.535	0.33	0.289	0.408	0.542	0.407	1.34	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.309	0.889	0.882		0.81	2.401	0.149	0.221	0.562	2.295	2.351	
COVID19 (COVID19 (PFIZER-	Body height	1.012	0.983	0.884			0.57	0.918	1.102	2.21	1.058	1.475	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.036	1.096	0.879			0.663	1.4	1.572	1.897	2.001	1.502	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.315	1.815	0.913			0.558	1.806	1.901	2.259	2.14	2.06	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.613	0.8	0.882	2.412			0.412			0.435	1.04	
COVID19 (COVID19 (PFIZER-	Investigation	2.169	1.74	0.896			0.514	1.691	1.85	2.355	2.116	1.938	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.898	0.64				1.412	1.922	1.937	2.386	1.887	1.819	
COVID19 (COVID19 (PFIZER-	Weight	2.119	1.34	0.888			0.738	1.542	1.707	2.328	2.114	1.761	

PSI-HHS-000000057754

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 16 Nov 2021 14:40:36 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Freeborn, Emma (CDC/DDID/NCEZID/DHQP) (CTR); Roberts, Amy (CDC/DDID/NCEZID/DHQP) (CTR)
Subject: FW: Weekly data mining
Attachments: USST_20211112.xls

Attached are the most recent data mining results from FDA.
Please do not share this data.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, November 16, 2021 8:45 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

Hi Elaine,

FYI.

Karen, I know folks on CISA (Allison, I think?) have been requesting these data. Would you please share with them? Thanks!

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, November 16, 2021 6:48 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 11/12/21). Please feel free to share this hypothesis

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generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2021(1)	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021(1)	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.169	1.816	0.896			0.592	1.622	1.67	1.896	2.893	1.359	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.254	1.804	0.892				1.646	2.268	2.087	3.071	1.465	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.976	1.314	0.962			0.458	1.303	1.8	1.81	2.273	1.549	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.952	6.893	0.883				0.897	0.717	0.69	2.265	1.557	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.048	6.984	0.896				0.908	0.718	0.714	1.602	1.416	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.89	1.3	0.904				1.468	1.328	1.495	2.326	1.078	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.01	2.172	0.901			0.497	2.266	2.068	3.255	4.338	1.407	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.19	1.644	0.88				1.753	1.853	1.179	2.373	1.362	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.546	1.931	0.896			0.426	1.748	2.455	2.437	2.852	2.037	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.965	1.647	0.896			0.386	1.241	2.451	1.121	2.274	1.327	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.348	6.865	0.86			0.572	0.899	1.75	1.831	2.131	1.895	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.218	1.633	1.075	0.512		0.432	1.858	1.998	2.466	2.824	1.819	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.102	1.975	0.892				0.892	2.027	1.509	1.94	1.544	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.978	1.262	0.882				1.256	1.161	1.123	2.881	1.06	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.946	1.623	0.886	0.509		0.329	1.216	2.597	1.67	2.438	1.243	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.819	1.608	0.887	0.508		0.291	1.291	2.356	1.618	2.234	1.257	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.755	1.271	0.884			0.33	1.478	1.773	1.576	2.048	1.237	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.949	1.496	0.896			1.4	1.423	2.262	1.843	2.301	1.485	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.043	1.579	0.908			0.451	1.417	2.288	1.956	2.444	1.399	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.69	2.691	0.894			0.509	1.863	2.817	0.83	4.688	1.138	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.841	1.529	0.901			0.263	1.204	2.05	1.514	2.555	1.05	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.79	1.641	0.88			0.215	1.389	2.101	1.508	2.139	0.942	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.784	1.215	0.878				1.073	1.967	1.508	2.021	1.43	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.971	1.349	1.337				1.404	1.846	1.846	2.033	1.747	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.698	2.192	0.88				1.676	2.772	1.147	2.343	2.234	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.019	1.783	0.88				1.227	1.627	1.131	1.578	1.483	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.324	1.849	0.924			0.521	2.06	1.867	1.486	3.038	1.099	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.636	1.988	0.916			0.536	1.226	1.325	1.1	3.674	1.96	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.155	1.582	0.882				1.125	1.25	1.353	2.647	1.031	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.435	2.42	0.916			0.622	2.547	2.464	0.818	4.138	1.179	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.737	1.956	0.961	0.511		0.636	2.382	2.434	2.316	3.637	1.754	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.02	1.469	0.901			0.397	1.674	2.007	1.863	2.227	1.526	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.114	1.598	0.916			0.484	1.482	2.119	2.096	2.68	1.623	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.604	1.873	0.97			0.456	2.159	2.283	3.231	3.232	2.034	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.838	1.504	0.886				1.302	2.348	1.552	2.171	1.219	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.688	1.345	0.88	0.61		0.391	1.274	2.041	1.369	1.984	1.205	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.78	6.836	0.887			1.117	2.013	1.49	1	1.881	1.425	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.251	1.323	0.885			0.372	2.17	2.127	2.019	2.523	1.867	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.144	1.593	0.912	0.511		0.325	1.687	2.335	2.217	2.578	1.474	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.964	1.021	0.881			0.425	1.731	1.961	0.751	2.13	1.253	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.257	1.015	0.887			0.416	2.256	1.752	1.13	2.594	1.414	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.946	1.507	0.889			0.398	1.406	1.616	1.601	2.104	1.294	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.764	1.255	0.889				1.16	1.266	1.371	2.096	1.037	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.289	1.872	0.879				1.378	2.869	1.75	2.123	2.095	
COVID19 (COVID19 (JANSSEN))	Haemstocrit decreased	1.847	1.365	0.904	0.507		0.426	1.357	2.113	1.766	2.227	1.384	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.798	1.398	0.894	0.507		0.388	1.428	1.992	1.632	2.088	1.366	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.579	3.662	0.893				3.989	4.855	6.228	6.998	2.888	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.863	3.49	0.882			0.546	5.13	5.575	8.664	7.582	1.389	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.836	1.348	0.9				1.357	1.817	1.833	2.172	1.396	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.074	1.918	0.883			0.019	1.917	2.492	1.631	2.214	1.885	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.828	1.433	1.053			0.028	1.401	1.99	2.038	2.246	1.417	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.855	1.322	0.894	0.746		0.397	1.625	1.941	1.433	2.458	1.22	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.966	1.294	0.886				1.381	1.979	1.026	2.103	1.257	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.131	1.954	0.885				1.606	1.162	0.735	3.111	0.748	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.898	1.532	0.878				1.237	2.158	1.135	1.704	1.727	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.005	1.731					0.887	2.317	1.16	1.515	1.753	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.657	1.278	0.896			0.179	1.03	2.089	1.807	2.102	1.17	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.157	1.691	0.886			0.493	1.771	1.943	2.279	2.497	1.593	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.128	1.599	0.901	0.511		0.459	1.275	2.466	1.039	2.397	1.319	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.663	1.24	0.888			0.339	1.02	2.098	1.113	1.911	0.922	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.822	1.339	0.891			0.34	1.269	2.263	1.191	2.156	1.15	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.035	1.457	0.936			0.49	0.988	2.061	1.63	1.918	1.657	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.619	1.371	0.892	0.61		0.256	0.985	2.109	1.982	2.507	1.037	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.555	1.298	0.887			0.12	1.212	1.8	1.4	2.318	0.828	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.711	1.307	0.891			0.24	1.133	2.057	1.749	1.981	1.311	
COVID19 (COVID19 (JANSSEN))	Off label use	1.341	6.203	0.88			6.031	0.282	0.409	0.339	0.834	1.209	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.751	6.758					3.089	0.969		2.186		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.537	6.875				0.512	1.771	2.279	1.168	2.637	1.44	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.38	1.71	0.882				0.656	1.08	2.091	2.581	0.967	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.768	2.504	0.912	0.61		0.483	1.864	3.159	1.941	3.158	1.841	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.869	1.409	0.9	0.509		0.289	1.605	2.03	1.515	2.202	1.429	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.726	2.067	0.896			0.394	2.019	3.128	2.319	3.468	1.683	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.641	3.492	0.882				4.394	3.399	6.683	6.175	1.935	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.259					0.669	4.014	3.383	5.896	4.534	3.831	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.965	1.597	0.913	0.744		0.325	1.519	2.374	1.602	2.66	1.39	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.239	1.689	1.517	0.512		0.884	1.69	2.154	2.65	2.565	1.833	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.064	1.543	0.894				1.557	1.462	2.009	1.874	1.884	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.917	1.413	0.881	0.508		0.507	1.478	2.19	1.665	2.157	1.848	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.092	1.489	0.899	0.509		0.355	1.321	2.321	1.701	2.485	1.319	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.761	1.196	1.786			0.546	1.657	1.068	0.984	2.321	0.779	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.311	1.217	0.886			0.537	1.5	1.85	1.384	2.048	1.796	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.583	1.242	0.881			0.546	1.132	0.827	0.646	2.368	1.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.178	2.572	1.699			0.531	1.897	2.281	1.2	2.842	3.055	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.086	6.797	0.882			0.647	3.45	6.766	15.432	7.994	6.001	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.251							0.635	0.574	0.568	1.024	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.093	1.623	0.892			0.516	1.398	1.64	1.372	2.211	1.333	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.351	2.037	0.92			0.386	1.516	2.47	1.719	2.823	1.724	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.666	2.156	1.832	0.512		0.646	1.978	2.379	3.516	2.84	2.164	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.252	1.901	0.882				1.982	1.226	0.643	2.413	0.904	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.401	1.442	0.898			0.648	1.945	2.135	2.444	2.788	1.869	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.720	1.946	0.897	0.512		0.526	2.357	2.272	3.016	3.246	2.114	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.495	1.777	0.898			0.446	2.402	1.987	1.811	2.604	1.794	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.805	1.148	0.883				1.313	2.066	1.777	2.015	1.25	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.642	1.241	0.883	0.511		0.396	0.867	2.091	1.266	1.884	1.092	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.294	3.097	2.518			0.534	1.22	2.565	5.521	1.971	2.128	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.68	1.368	0.925			0.468	0.989	1.225	2.086	1.548	1.56	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.068	6.882					0.923	1.568	0.982	1.851	1.945	
COVID19 (COVID19 (JANSSEN))	Venogram	2.573	1.978					2.14	1.72	0.721	2.901	1.934	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.2	2.44				0.605	2.731	1.848	0.695	4.145	1.16	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.259	2.472	0.886				3.964	2.099	0.847	5.184	1.193	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.353	6.834		7.532	0.894		1.194	0.513		1.321	0.959	
COVID19 (COVID19 (MODERNA))	Headache	0.965	6.962	0.891	6.267		0.304	0.941	0.979	1.012	0.954	1.01	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.358	6.935	0.887		1.256	2.656	0.125	0.035	0.467	2.364	2.415	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.045	2.007	0.881			2.262	2.006	1.945	1.967	1.899	2.115	
COVID19 (COVID19 (PFIZER-	Body height	1.94	1.019	0.885			0.597	0.926	1.338	2.204	1.917	1.503	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.053	1.966	0.882			0.635	1.501	1.696	1.965	2.012	1.58	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.275	1.719	1.451			1.022	1.714	1.76	1.91	2.02	1.97	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.763	6.848	0.884	14.99			0.412			0.434	1.239	
COVID19 (COVID19 (PFIZER-	Incorrect dose administered	0.936	6.824	0.879		2.243	1.038	0.975	0.913	0.912	0.944	0.964	
COVID19 (COVID19 (PFIZER-	Investigation	2.152	1.724	0.908			1.095	1.751	1.941	2.337	2.15	1.955	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.79	6.752			2.497	1.363	1.88	1.814	2.281	1.808	1.752	
COVID19 (COVID19 (PFIZER-	Weight	2.016	1.303	0.891			0.87	1.519	1.708	2.213	1.998	1.766	

PSI-HHS-000000057757

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 15 Feb 2022 13:23:00 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220211_.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, February 15, 2022 7:01 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Hi All,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 2/11/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2022[1]	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.691	1.683	0.91			0.597	1.595	1.964	1.58	2.686	1.672	Reviewed
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.194	1.686	0.872				1.692	2.068	2.162	2.915	1.499	Reviewed
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.058	1.334	1.012			0.454	1.4	1.963	1.845	2.262	1.894	Reviewed
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.871	6.961	0.865			0.518	0.977	0.867	0.688	2.557	1.474	Other
COVID19 (COVID19 (JANSSEN))	Adverse event	2.018	1.055	0.872				0.905	0.738	0.753	1.783	1.507	Other
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.924	1.386	0.902				1.443	1.463	1.786	2.192	1.326	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.574	1.891	0.903			0.485	2.18	2.011	2.2	3.711	1.444	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.173	1.542	0.869				1.884	1.802	1.273	2.392	1.407	Not an AE
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.45	1.703	0.897			0.425	1.85	2.328	2.166	2.548	1.96	Reviewed
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.818	1.427	0.86			0.388	1.184	2.231	1.358	2.194	1.293	Other
COVID19 (COVID19 (JANSSEN))	Antibody test	2.309	6.806	0.856			0.563	0.823	1.005	1.807	2.011	1.701	Not an AE
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.518	0.957	0.613		0.428	1.833	1.99	2.24	2.763	1.807	Other
COVID19 (COVID19 (JANSSEN))	Areflexia	2.121	1.833	0.874				0.862	2.219	1.428	1.908	1.518	Reviewed
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	1.758	1.128	0.862				1.139	1.178	1.366	2.311	0.891	Reviewed
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.898	1.436	0.88	0.61		0.326	1.222	2.32	1.773	2.344	1.321	Other
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.789	1.468	0.892	0.609		0.286	1.215	2.239	1.774	2.166	1.327	Other
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.785	1.397	0.888			0.33	1.469	1.812	1.767	2.138	1.403	Other
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.882	1.381	0.905			0.397	1.4	2.085	1.862	2.23	1.472	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.907	1.41	0.944			0.444	1.306	2.096	1.988	2.278	1.391	Other
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.22	2.384	0.883			0.504	1.797	2.004	0.86	4.281	1.859	Reviewed
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.826	1.383	0.923			0.284	1.157	1.863	1.836	2.412	1.186	Other
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.662	1.231	0.911			0.529	1.197	1.469	2.044	1.853	1.213	Other
COVID19 (COVID19 (JANSSEN))	Blood sodium increased	1.619	1.138	0.906				1.506	1.421	1.115	2.148	0.919	Other
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.665	1.354	0.858			0.227	1.389	1.937	1.223	2.047	0.874	Other
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.832	1.246	0.878				1.075	2.062	1.681	2.028	1.584	Other
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.028	1.4	1.1				1.67	2.126	1.876	2.191	1.886	Other
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.752	2.116	0.861				1.773	2.804	1.083	2.488	2.21	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.307	1.612	0.918			0.514	1.702	1.826	1.454	3.2	1.089	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.882	1.97	0.912			0.522	1.446	1.39	1.204	3.902	1.004	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.878	1.935	0.857				1.12	1.365	1.928	2.91	1.211	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.242	2.18	0.904			0.518	2.267	2.238	0.877	3.861	1.185	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.567	1.704	0.956	0.612		0.616	2.149	2.317	2.013	3.078	1.723	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.642	1.371	0.896			0.385	1.685	1.965	1.823	2.232	1.53	Not an AE
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.065	1.443	0.925			0.458	1.408	2.043	2.006	2.287	1.854	Reviewed
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.586	1.767	1.014			0.457	2.141	2.246	3.02	3.221	1.964	Reviewed
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	1.927	1.37	1.174			0.379	1.297	2.062	1.723	1.888	1.811	Labeled
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.763	1.308	0.882				1.268	2.078	1.594	3	1.298	Other
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.772	1.395	0.885	0.609		0.382	1.303	2.081	1.683	2.025	1.39	Other
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.779	6.843	0.869			1.106	2.01	1.465	0.964	1.844	1.414	Labeled
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.304	1.241	0.875			0.441	2.179	2.132	1.811	2.48	1.679	Other
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.17	1.453	0.966	0.612		0.316	1.669	2.248	2.162	2.434	1.59	Reviewed
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.568	1.092	0.863			0.435	1.631	2.038	1.03	2.118	1.361	Not an AE
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.306	1.094	0.877			0.466	2.257	1.754	1.304	2.362	1.615	Labeled
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.873	1.303	0.877			3.4	1.345	1.627	1.627	2.188	1.231	Reviewed
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.771	1.21	0.886				1.349	1.299	1.429	2.177	1.087	Other
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.331	1.898	0.87				1.597	2.882	1.668	2.283	2.143	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemstocrit decreased	1.823	1.291	0.906	0.606		0.425	1.347	2.066	1.751	2.177	1.395	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.767	1.257	0.9	0.607		0.319	1.418	1.941	1.634	2.077	1.386	Reviewed
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.57	3.82	0.882				4.083	5.307	5.305	7.304	2.999	Not an AE
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.408	3.498	0.861			0.544	4.722	5.62	6.752	7.733	1.821	Reviewed
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.88	1.3	0.924				1.469	1.95	1.749	2.248	1.573	Reviewed
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.095	1.797	0.861			0.022	1.91	2.515	1.457	2.251	1.865	Reviewed
COVID19 (COVID19 (JANSSEN))	Intensive care	1.845	1.425	1.043			0.029	1.479	2.055	2.023	2.288	1.54	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.862	1.287	0.885	0.747		0.396	1.617	1.947	1.471	2.34	1.322	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.078	1.246	0.866				1.432	2.045	0.923	2.129	1.247	Not an AE
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.951	1.627	0.865				1.374	1.17	0.714	2.393	0.727	Reviewed
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.911	1.358	0.853				1.223	2.15	1.024	1.697	1.866	Not an AE
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.069	1.722					1.012	2.599	1.056	1.701	1.74	Reviewed
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.712	1.273	0.904				1.405	1.706	1.696	2.178	1.406	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.704	1.286	0.902			0.173	1.034	2.091	1.964	2.105	1.313	Other
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.09	1.536	0.894			0.476	1.792	1.878	2.108	2.328	1.615	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.066	1.476	0.911	0.612		0.451	1.211	2.208	1.852	2.357	1.426	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.863	1.372	0.895			0.337	1.266	2.272	1.426	2.137	1.332	Other
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.088	1.529	1.023			0.478	0.999	2.254	1.842	1.993	1.976	Reviewed
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.588	1.265	0.889	0.609		0.257	0.91	1.941	2.03	2.286	1.112	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.506	1.202	0.869			0.13	1.179	1.642	1.519	2.195	0.841	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.752	1.32	0.902			0.235	1.132	2.092	1.879	2.018	1.423	Other
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.191	6.791					0.748	0.612		2.247	1.949	Other
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	6.496	0.873			7.951	1.219	1.143	0.85	1.388	1.914	Not an AE
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.753	6.761					3.285	1		2.214		Other
COVID19 (COVID19 (JANSSEN))	Packed red blood cell transfusion	1.746	1.283	0.882				1.214	1.193	1.175	2.1	0.879	Reviewed
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.559	6.878				0.513	1.586	2.23	1.06	2.261	1.442	Not an AE
COVID19 (COVID19 (JANSSEN))	Pericardial effusion	2.927	1.486	0.861				0.657	1.059	1.58	2.451	0.953	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet count	2.772	2.246	0.906	0.611		0.472	1.769	3.092	2.572	3.108	1.779	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.671	1.301	0.891	0.609		0.29	1.492	2.067	1.496	2.174	1.428	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.726	1.829	0.881			0.388	2.011	2.716	1.979	3.101	1.627	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.027	3.391	0.862				4.285	2.563	0.614	6.284	1.945	Not an AE
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.398					0.087	0.151	3.402	2.738	4.088	4.038	Not an AE
COVID19 (COVID19 (JANSSEN))	Prolonged labour	1.068	1.065					3.233			1.785		Other
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.964	1.518	0.926	0.746		0.325	1.523	2.337	1.697	2.534	1.519	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.239	1.588	1.471	0.613		0.584	1.725	2.61	2.567	2.468	1.817	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.044	1.5	0.891				1.66	1.564	1.971	2.066	1.826	Reviewed
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.84	1.302	0.897	0.608		0.529	1.38	2.028	1.672	2.04	1.505	Other
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.956	1.377	0.906	0.611		0.335	1.309	2.232	1.754	2.338	1.437	Other
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.363	1.021					2.313	0.5		1.098	0.731	Reviewed
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.466	1.516	0.868			0.531	1.703	1.962	1.543	2.541	1.868	Other
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.236	2.185	1.298			0.523	3.078	3.063	1.246	2.814	3.211	Other
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.023	6.773	0.862			0.646	3.586	5.667	15.026	7.795	5.828	Other
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.379							0.636	6.572	0.568	1.018	Other
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.311	1.44	0.877			0.508	1.391	1.587	1.505	2.225	1.326	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.361	1.763	0.904			0.374	1.02	2.37	1.737	2.461	1.705	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.679	2.075	1.672	0.613		0.732	1.954	2.381	3.503	2.873	2.244	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	4.59	3.529	0.882				1.639	0.897	0.573	5.131	1.68	Reviewed
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.239	1.796	0.861				1.884	1.196	0.833	2.684	0.908	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.414	1.485	0.896			0.639	1.899	2.244	2.309	2.309	1.757	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.71	1.838	0.924	0.613		0.521	2.415	2.233	2.805	3.267	2.059	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.504	1.681	0.91			0.438	2.068	2.044	2.032	2.485	1.824	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.887	1.102	0.868				1.236	2.066	1.734	1.912	1.333	Not an AE
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.367	3.071	2.462			0.501	1.574	2.969	6.15	2.34	2.446	Other
COVID19 (COVID19 (JANSSEN))	Vasculitis	2.035	6.893					0.89	1.655	1.045	1.821	1.089	Labeled
COVID19 (COVID19 (JANSSEN))	Venogram	2.365	1.804	0.858				1.949	1.633	0.708	2.638	1.022	Not an AE
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.69	2.122				0.802	2.37	1.694	0.671	3.241	1.224	Reviewed
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.087	3.279	0.866				3.765	2.05	0.927	4.91	1.233	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.378	6.835		7.707	0.936		1.236	0.575		1.398	0.912	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	6.59	6.923	0.858	0.605	0.782	2.444	0.777	0.606	0.395	0.648	0.804	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.901	1.917				0.84	2.061	1.454	0.79	1.931	2.007	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.904	0.872		5.644	2.517	0.101	0.049	0.383	2.528	2.618	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.051	2.051	0.86			2.385	2.005	1.902	1.671	1.901	2.113	
COVID19 (COVID19 (PFIZER-	Body height	1.948	6.988	0.866			0.614	0.943	1.377	2.17	1.915	1.52	
COVID19 (COVID19 (PFIZER-	Bladder recurrence	2.547	1.983	0.902		0.469	0.71	1.442	1.988	1.974	1.994	1.906	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.765	1.722	0.612	0.751	1.076	1.713	1.722	1.761	1.907	1.898	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.848	0.866	17.906			0.391			0.451	1.349	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.68	0.909		1.272	1.221	1.869	1.982	2.234	1.978	1.836	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.77	0.9		0.665	1.07	1.767	1.93	2.26	2.057	1.902	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.791			1.48	1.38	1.858	1.745	2.184	1.632	1.591	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.34	0.878			0.897	1.537	1.738	2.154	1.957	1.766	

PSI-HHS-000000057759

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 22 Feb 2022 16:29:15 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: FW: Weekly data mining
Attachments: USST_20220218.xls

FYI

From: Menschik, David <[redacted]>
Sent: Tuesday, February 22, 2022 5:29 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 2/18/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

THIS MESSAGE, INCLUDING ANY ATTACHMENTS, IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

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Drug	Event	VS EB05 2022(1	Serious EB05 2022	Fatal EB05 2022(	Infant EB05 2022(	Child EB05 2022(	Teen EB05 2022(	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022(	Female EB05 2022(	Male EB05 2022(	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.697	1.87	0.909			0.597	1.577	1.963	1.847	2.665	1.671	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.188	1.687	0.873				1.683	2.12	2.144	2.918	1.504	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.062	1.342	1.02			0.452	1.431	2.024	1.866	2.321	1.7	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.871	6.961	0.867			0.518	0.972	0.867	0.688	2.581	1.468	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.018	1.055	0.874				0.9	0.769	0.751	1.788	1.509	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.924	1.383	0.903				1.444	1.457	1.789	2.18	1.328	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.571	1.885	0.903			0.485	2.18	2.013	2.176	3.703	1.444	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.157	1.505	0.871				1.878	1.777	1.249	2.383	1.378	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.456	1.702	0.901			0.425	1.666	2.331	2.174	2.565	1.962	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.865	1.407	0.886			0.388	1.171	2.216	1.35	2.174	1.283	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.309	6.818	0.859			0.593	0.815	1.077	1.92	2.044	1.765	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.227	1.519	0.962	0.612		0.427	1.845	2.014	2.238	2.761	1.829	Other
COVID19 (COVID19 (JANSEN))	Areflexia	2.131	1.831	0.875				0.859	2.257	1.413	1.899	1.527	Reviewed
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.746	1.128	0.883				1.138	1.178	1.361	2.324	0.896	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.892	1.44	0.886	0.61		0.326	1.214	2.353	1.771	2.381	1.309	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.786	1.479	0.902	0.608		0.286	1.21	2.26	1.801	2.207	1.318	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.762	1.309	0.896			0.337	1.467	1.865	1.767	2.13	1.609	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.88	1.381	0.909			0.396	1.389	2.112	1.847	2.233	1.473	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.968	1.41	0.948			0.462	1.295	2.13	1.964	2.282	1.394	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.123	2.345	0.884			0.504	1.798	1.928	0.856	4.249	1.048	Reviewed
COVID19 (COVID19 (JANSEN))	Blood lactate dehydrogenase increased	1.664	1.253	0.878	0.612			1.095	2.063	1.153	1.597	1.369	Not an AE
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.818	1.384	0.925			0.263	1.14	1.935	1.818	2.433	1.187	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.672	1.224	0.914			0.527	1.19	1.483	2.036	1.853	1.201	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.821	1.329	0.878	0.609			1.342	2.017	1.665	1.964	1.596	Not an AE
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.634	1.157	0.912				1.491	1.509	1.112	2.208	0.945	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.673	1.359	0.863			0.224	1.403	1.939	1.214	2.06	0.871	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.842	1.297	0.861				1.063	2.052	1.882	2.068	1.09	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.031	1.405	1.106				1.698	2.166	1.886	2.28	1.882	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.731	2.123	0.862				1.774	2.93	1.084	2.484	2.215	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	3.92	1.602	0.921			0.514	1.678	1.849	1.45	3.164	1.112	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.803	1.943	0.913			0.522	1.445	1.381	1.197	3.789	1.004	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.279	1.614	0.859				1.12	1.288	1.621	3.123	1.205	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.203	2.174	0.906			0.518	2.268	2.223	0.877	3.883	1.167	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.771	1.27	0.93			0.349	1.321	1.859	1.79	2.018	1.557	Confounded-
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.577	1.704	0.968	0.611		0.617	2.124	2.321	2.047	3.068	1.743	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.998	1.362	0.901			0.385	1.693	1.96	1.804	2.234	1.509	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.078	1.43	0.92			0.458	1.412	2.03	1.997	2.28	1.646	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.586	1.78	1.043			0.457	2.162	2.267	3.028	3.253	1.978	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.935	1.375	1.213			0.378	1.295	2.082	1.741	1.934	1.807	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.755	1.318	0.892				1.261	2.105	1.618	2.045	1.285	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.771	1.406	0.897	0.609		0.301	1.309	2.164	1.698	2.078	1.373	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.78	6.837	0.87			1.206	2.013	1.467	0.96	1.85	1.418	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.305	1.246	0.863			0.44	2.164	2.143	1.806	2.494	1.666	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.168	1.443	0.965	0.612		0.314	1.664	2.25	2.175	2.42	1.591	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.958	1.107	0.866			0.434	1.63	2.109	1.03	2.139	1.382	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.305	1.09	0.875			0.459	2.237	1.79	1.203	2.281	1.618	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.871	1.315	0.882			9.4	1.329	1.65	1.656	2.253	1.213	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.784	1.242	0.89				1.33	1.382	1.428	2.315	1.081	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.337	1.648	0.871				1.551	2.977	1.834	3.315	2.169	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.825	1.295	0.906	0.606		0.425	1.339	2.038	1.746	2.191	1.398	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.768	1.258	0.904	0.607		0.319	1.409	1.97	1.625	2.088	1.389	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.57	3.623	0.884				4.086	5.267	5.341	7.208	3.008	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.469	3.503	0.863			0.564	4.723	5.631	6.753	7.723	1.825	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.883	1.311	0.934				1.472	1.978	1.784	2.283	1.593	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.108	1.804	0.863			0.621	1.927	2.57	1.447	2.252	1.674	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.837	1.42	1.057			0.629	1.468	2.064	2.022	2.303	1.533	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.86	1.285	0.884	0.747		0.395	1.605	1.98	1.452	2.35	1.321	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.016	1.243	0.868				1.429	2.042	0.927	2.12	1.25	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.901	1.627	0.897				1.374	1.171	0.714	2.404	0.727	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.912	1.344	0.856				1.219	2.149	1.009	1.686	1.662	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.068	1.728					1.012	2.606	1.059	1.703	1.743	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.717	1.274	0.936				1.407	1.726	1.815	2.184	1.499	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.702	1.289	0.91			0.173	1.028	2.111	1.958	2.128	1.306	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.067	1.532	0.899			0.476	1.794	1.873	2.12	2.327	1.618	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.068	1.474	0.915	0.612		0.449	1.227	2.332	1.804	2.371	1.427	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.866	1.392	0.897			0.337	1.261	2.35	1.403	2.188	1.332	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.104	1.55	1.06			0.477	0.995	2.285	1.868	1.974	1.981	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.681	1.259	0.888	0.609		0.257	0.905	1.945	2.013	2.284	1.105	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.498	1.204	0.87			0.128	1.174	1.657	1.51	2.221	0.834	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.75	1.327	0.911			0.233	1.125	2.128	1.878	2.054	1.413	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.152	6.792					0.748	0.612		2.278	1.05	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.34	6.569	0.874			8.015	1.208	1.176	0.85	1.41	1.922	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.753	6.762					3.286	1		2.221		Other
COVID19 (COVID19 (JANSEN))	Packed red blood cell transfusion	1.741	1.238	0.883				1.214	1.183	1.157	2.049	0.871	Reviewed
COVID19 (COVID19 (JANSEN))	Pain assessment	2.332	6.876				0.513	1.509	2.224	1.051	2.241	1.429	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.53	1.487	0.863				0.657	1.099	1.582	2.469	0.953	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.773	2.243	0.908	0.611		0.472	1.805	3.05	2.519	3.122	1.781	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.988	1.396	0.896	0.606		0.289	1.484	2.078	1.488	2.193	1.418	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.726	1.841	0.882			0.388	2.046	2.716	1.984	3.111	1.841	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.027	3.397	0.864				4.294	26	0.814	6.281	1.855	Not an AE
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.398					0.985	9.807	2.948	4.607	4.238	3.729	Not an AE
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.098	1.064					4.181			2.651		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.965	1.511	0.927	0.748		0.324	1.518	2.352	1.674	2.531	1.516	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.232	1.572	1.482	0.613		0.584	1.738	2.016	2.567	2.472	1.836	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.045	1.503	0.892				1.69	1.579	2.029	2.081	1.883	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.839	1.303	0.901	0.607		0.329	1.373	2.053	1.659	2.05	1.501	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	2.004	1.381	0.914	0.611		0.333	1.329	2.265	1.735	2.384	1.426	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.364	1.021					2.312	0.499		1.098	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.407	1.517	0.87			0.531	1.764	1.965	1.537	2.614	1.869	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.236	2.186	1.438			0.522	3.105	3.105	1.225	2.868	3.273	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.023	6.775	0.884			0.646	3.507	6.672	15.044	7.798	5.605	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.362							0.638	0.573	0.568	1.018	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.111	1.421	0.878			0.509	1.387	1.59	1.486	2.2	1.326	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.303	1.757	0.937			0.374	1.612	2.384	1.73	2.49	1.71	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.68	2.079	1.666	0.613		0.733	1.959	2.378	3.523	2.883	2.266	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.59	2.533	0.884				1.641	0.898	0.573	5.11	3.68	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.254	1.771	0.863				1.883	1.189	0.634	2.059	0.908	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.412	1.465	0.897			0.728	1.909	2.254	2.281	2.741	1.774	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.707	1.839	0.925	0.612		0.521	2.453	2.241	2.801	3.298	2.062	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.487	1.678	0.906			0.438	2.085	2.049	2.033	2.473	1.841	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.867	1.101	0.868				1.227	2.063	1.724	1.902	1.328	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.555	1.172	0.881	0.612		0.308	0.902	2.64	1.226	1.743	1.158	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.367	3.059	2.43			0.497	1.602	3.015	6.18	2.388	2.477	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.036	6.891					0.89	1.657	1.039	1.821	1.095	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.308	1.804	0.86				1.949	1.634	0.709	2.648	1.022	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.678	2.115				0.602	2.372	1.696	0.669	3.222	1.224	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.667	2.278	0.866				3.755	2.052	0.926	4.677	1.233	Not an AE
COVID19 (MODERNA))	Exposure via breast milk	1.314	6.835		7.598	0.936		1.236	0.514		1.36	0.905	
COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.934	0.86	0.605	0.775	2.44	0.776	0.609	0.398	0.646	0.808	
COVID19 (MODERNA))	Mechanical urticaria	0.961	1.035				0.699	2.075	1.561	0.792	1.961	2.004	
COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.984	0.874		5.793	2.931	0.105	0.048	0.383	2.533	2.632	
COVID19 (MODERNA))	Product dose omission issue	2.051	2.04	0.952			2.394	1.994	1.95	1.57	1.902	2.111	
COVID19 (PFIZER-	Body height	1.648	6.986	0.868			0.639	0.943	1.377	2.157	1.993	1.52	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.09	0.864		0.484	0.71	1.446	1.673	1.871	1.938	1.497	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.291	1.776	1.721	0.612	0.772	1.077	1.711	1.722	1.753	1.877	1.871	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	6.848	0.867	11.89			0.391			0.454	1.344	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.685	0.911		1.271	1.223	1.808	1.976	2.222	1.958	1.821	
COVID19 (COVID19 (PFIZER-	Investigation	2.102	1.778	0.907		0.666	1.072	1.767	1.908	2.246	2.037	1.897	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.791			1.467	1.378	1.856	1.743	2.179	1.622	1.586	
COVID19 (COVID19 (PFIZER-	Weight	2.022	1.345	0.875			0.898	1.54	1.746	2.143	1.91	1.769	

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