

From: Gee, Julianne (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 26 Apr 2021 02:41:56 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: FW: [EXTERNAL] data mining for 4 month review

Hi John -
David didn't respond to the email I sent from Wednesday. Did he follow-up with you regarding data mining for mRNA vaccines?
Please let us know!

Thanks,
Julianne

From: Gee, Julianne (CDC/DDID/NCEZID/DHQP)
Sent: Wednesday, April 21, 2021 11:17 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Menschik, David (FDA/CBER) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining for 4 month review

Thanks!

We are hoping to have a draft completed by May 3rd.
Please let us know if you would like to have a short call to discuss this week or early next week.

-Julianne

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, April 21, 2021 10:07 AM
To: Menschik, David (FDA/CBER) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining for 4 month review

Awesome! Thanks.

- John

From: Menschik, David <[REDACTED]>
Sent: Wednesday, April 21, 2021 10:03 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining for 4 month review

I'll plan to discuss here regarding what can be shared, how, etc...

From: Menschik, David
Sent: Wednesday, April 21, 2021 10:02 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining for 4 month review

Thanks John for the heads up!

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, April 20, 2021 3:47 PM
To: Menschik, David <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]>; Shimabukuro, Tom (CDC) <[REDACTED]>
Subject: [EXTERNAL] data mining for 4 month review

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Hi David,

[REDACTED] (b)(5)
[REDACTED] (b)(5) If we may, we'd like to include FDA data mining results. In addition to the data itself, I expect [REDACTED] (b)(5)
[REDACTED] (b)(5)

Just wanted to give you a heads up. I'm not totally clear on by when we would need these data, and other details will be pending, but I wanted to let you know what I know.

Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 3 Oct 2022 12:55:52 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR); Goodman, Jeremy A. (CDC/DDID/NCEZID/DHQP); DHQP_Policy (CDC)
Subject: FW: [EXTERNAL] Empirical Bayesian (EB) Data Mining

FYI: Moving forward, all EB Data Mining for COVID-19 FOIA Requests seeking reports after July 5, will be referred to FDA for processing.

From: Sly, Elizabeth <[REDACTED]>
Sent: Friday, September 30, 2022 3:14 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>
Cc: Burk, Suzann (FDA/CBER) <[REDACTED]>; Viana, Bruno A. (CDC/OCOO/OD) <[REDACTED]>
Subject: RE: [EXTERNAL] Empirical Bayesian (EB) Data Mining

Hi PerStephanie,

I do not know the exact date but, yes, the weekly reports from FDA to CDC were discontinued. If you need more detailed information, it's best to speak to have the CDC VAERS SMEs speak with the FDA VAERS SMEs directly.

Thanks,

Liz

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, September 30, 2022 3:04 PM
To: Sly, Elizabeth <[REDACTED]>; Mitchell, Elnetta (CDC) <[REDACTED]>
Cc: Burk, Suzann <[REDACTED]>; Viana, Bruno A (CDC) <[REDACTED]>
Subject: RE: [EXTERNAL] Empirical Bayesian (EB) Data Mining

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Thank you so much for looking into this matter. Just for clarification, [REDACTED] (b)(5)

[REDACTED] (b)(5)

Thanks again and have a super duper weekend!

PerStephanie

From: Sly, Elizabeth <[REDACTED]>
Sent: Friday, September 30, 2022 2:53 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>
Cc: Burk, Suzann (FDA/CBER) <[REDACTED]>; Viana, Bruno A. (CDC/OCOO/OD) <[REDACTED]>
Subject: RE: [EXTERNAL] Empirical Bayesian (EB) Data Mining

Hi PerStephanie and Elnetta,

I reached out to our VAERS SMEs in CBER's Office of Biostatistics and Pharmacovigilance (OPBV). They let me know that the information you provided is not accurate and that FDA is still regularly conducting data mining for all approved/authorized vaccines.

For some additional information, here is an FDA website link that describes FDA datamining efforts.
<https://www.fda.gov/science-research/data-mining>

I would encourage your SMEs to follow up directly with OBPV for further information, if needed.

Thanks,

Liz

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, September 26, 2022 4:30 PM
To: Sly, Elizabeth <[REDACTED]>; Mitchell, Elnetta (CDC) <[REDACTED]>
Cc: Burk, Suzann <[REDACTED]>
Subject: RE: [EXTERNAL] Empirical Bayesian (EB) 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.

At this time, we are seeking clarification. We will not use this as a response since this is really discussing FDA efforts not CDC. We will reserve the right to let you share with requestors your rationale.

Thanks so much!

-p

From: Sly, Elizabeth <[REDACTED]>
Sent: Monday, September 26, 2022 4:13 PM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Burk, Suzann (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Empirical Bayesian (EB) Data Mining

Hi Elnetta,

I will need to reach out to our SMEs about this. Is this information that will be used/quoted in a FOIA request response letter or just needed as background information?

Thanks,

Liz

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>
Sent: Monday, September 26, 2022 3:58 PM
To: Sly, Elizabeth <[REDACTED]>
Cc: Thompson, Perstephanie (CDC) <[REDACTED]>
Subject: [EXTERNAL] Empirical Bayesian (EB) 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.

Good Afternoon Elizabeth,

One of our SMEs stated that it is their understanding that

[REDACTED] (b)(5)

[REDACTED] (b)(5)

[REDACTED] (b)(5)

Is this accurate? Please advise. Thanks.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: [REDACTED]
Phone: [REDACTED]

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 22 Sep 2021 16:43:32 +0000
To: Menschik, David
Subject: RE: data mining limitations

Hi David,

Signal detection with VAERS data has always been tricky business. I think (b)(5)

(b)(5)

Appreciate the below language. Thanks!

- John

From: Menschik, David <[REDACTED]>
Sent: Wednesday, September 22, 2021 12:33 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: data mining limitations

Hi John,

In the mRNA vaccine review article that we're co-authors on, we recently expanded data mining limitations section as per attached work-in-progress draft (Hannah indicated acceptance of the language) and excerpt below for convenience:

EB data mining has multiple limitations²² including that an absence of a disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event.

Thought it might be helpful to share this manuscript update with you, especially if folks on your end may be placing excess value on data mining alerts (EB05>2) or the absence of specific data mining alerts.

Best,
David

PS: If you'd like to discuss more, happy to do so by phone (better suited than email...)

From: Haber, Penina (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 7 Apr 2021 20:51:12 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: Data mining results for Prevnar 13 and Pneumovax 23

Hi

let me know what I can help?

I think it will move once we get data from Paige

I looked at Mikado e mail she said they are scheduled for a call may 11 she is trying to get a later date in May

good evening

p

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, April 7, 2021 4:47 PM
To: Haber, Penina (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Data mining results for Prevnar 13 and Pneumovax 23

I am using Tom's slides as a template. I just changed the dates and of course the data will be a little different. I already have something but still needs work

Pedro

From: Haber, Penina (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, April 7, 2021 4:45 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Data mining results for Prevnar 13 and Pneumovax 23

ok

agree no need table just few bullets of the results by vaccine name
good evening

p

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, April 7, 2021 4:41 PM
To: Haber, Penina (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Data mining results for Prevnar 13 and Pneumovax 23

I'm not sure if I'll use a table, maybe just a slide. Will let you know later

Maybe you can review some of the

[REDACTED] (b)(5)

[REDACTED] (b)(5)

Pedro

From: Haber, Penina (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, April 7, 2021 4:39 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Data mining results for Prevnar 13 and Pneumovax 23

great
do you want me to summarize it into a table?
talk to you soon

p

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, April 7, 2021 3:25 PM
To: Haber, Penina (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Data mining results for Prevnar 13 and Pneumovax 23

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 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

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 29 Jul 2021 12:17:01 +0000
To: Kim, Yeowon
Cc: Wei, Shaokui (FDA/CBER)
Subject: Re: Data mining results for Varivax and ProQuad, 2006-2020 (U.S. reports only)

Hello Yeowon and Shaokui,

I'll review once I'm in Atlanta and I'll let you know if I have any questions

Thanks so much!

Pedro

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From: Kim, Yeowon <[REDACTED]>
Sent: Wednesday, July 28, 2021 1:58:32 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Wei, Shaokui (FDA/CBER) <[REDACTED]>
Subject: Data mining results for Varivax and ProQuad, 2006-2020 (U.S. reports only)

Dear Pedro,

Please see the attached documents for the data mining results for Varivax and ProQuad for the requested time period 01 January 2006 to 31 December 2020 (U.S. reports only). We wrote a brief summary of the methods and results (Word file) and created a summary table of PTs with an EB05 ≥ 2.0 (Excel file). Also attached are the comprehensive data mining results (Excel files) for each vaccine. Shaokui also looked at the cumulative data mining results for Varivax since U.S. approval (1995 to present) for comparison; per Shaokui, the results were similar to that for the requested time interval. Since ProQuad was approved in 2005 (close to the start of the requested time interval), I don't think the results would differ.

We would like to kindly request that Kosal Nguon (FDA contractor) be mentioned in the acknowledgments section of the paper, as he helped us with the data mining run.

Please let us know if you have any questions. I am out on leave next week, but Shaokui will be available to answer any questions.

Cheers,
Yeowon

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, July 16, 2021 4:52 PM
To: Kim, Yeowon <[REDACTED]>

Cc: Wei, Shaokui <[REDACTED]>

Subject: RE: [EXTERNAL] VAERS safety review of Varicella Vaccines

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Hi Yeowon,

I think [REDACTED] (b)(5)

Thanks

Pedro

From: Kim, Yeowon <[REDACTED]>

Sent: Friday, July 16, 2021 4:50 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Cc: Wei, Shaokui (FDA/CBER) <[REDACTED]>

Subject: RE: [EXTERNAL] VAERS safety review of Varicella Vaccines

Hi Pedro,

Shaokui and I are working on the requested data mining runs. We are planning to provide separate results for each vaccine (Proquad, Varivax) for U.S. reports received 01 Jan 2006 to 31 Dec 2020. Please let us know if it's sufficient to provide the overall results or whether you also wanted results stratified by specific age groups and/or by gender. Looking at the overall results for Proquad, there are only two PTs with a EB05>2, so it may not add much to stratify by age groups and/or by gender.

Cheers,
Yeowon

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Sent: Friday, July 9, 2021 1:14 PM

To: Wei, Shaokui <[REDACTED]>; Kim, Yeowon <[REDACTED]>

Cc: Nair, Narayan <[REDACTED]>; Su, John (CDC) <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>; Niu, Manette <[REDACTED]>

Subject: RE: [EXTERNAL] VAERS safety review of Varicella Vaccines

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That's great Shaokui!

Just let me know if you have any questions

Thank you!

Pedro

From: Wei, Shaokui <[REDACTED]>
Sent: Friday, July 9, 2021 1:13 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Kim, Yeowon <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>; Niu, Manette (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] VAERS safety review of Varicella Vaccines

Hi Pedro,

Thank you for including us. I also will provide you the data mining results for Varivax with a brief summary by the end of this month.

Thank you,
Shaokui

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, July 09, 2021 12:44 PM
To: Kim, Yeowon <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]>; Su, John (CDC) <[REDACTED]>; Wei, Shaokui <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] VAERS safety review of Varicella Vaccines

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Yeowon,

That's great! The end of July works fine.

If any questions come up just let me know

Thanks!

Pedro

From: Kim, Yeowon <[REDACTED]>
Sent: Friday, July 9, 2021 12:41 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Wei, Shaokui (FDA/CBER) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] VAERS safety review of Varicella Vaccines

Hi Pedro,

Thanks for reaching out. I'm happy to help out with the project and can provide the data mining results for MMRV (ProQuad) for the period specified, along with a brief paragraph summarizing the results. I will aim to get this to you by the end of the month; please let me know if this works for you. Appreciate you including us as co-authors. I will reach out with any questions.

Cheers,
Yeowon

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, July 9, 2021 12:04 PM
To: Kim, Yeowon <[REDACTED]>; Wei, Shaokui <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]>; Su, John (CDC) <[REDACTED]>
Subject: FW: [EXTERNAL] VAERS safety review of Varicella Vaccines

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Hello Yeowon and Shaokui,

As I explained to Narayan we are doing an assessment of the post-licensure safety of Varivax and MMRV vaccines in VAERS for the period going from January 1, 2006 to December 31, 2020. This is a project we are doing with Mona Marin and Jessica Leung at NCIRD (National Center for Immunization and Respiratory Diseases) at CDC. They are both SMEs on varicella and other viral vaccines at CDC. There have been a few studies on the safety of Varivax in the past. The last one was the Chavez et al paper which I include and there is also a safety assessment of the second dose of Varivax done by John Su, the team lead (my supervisor) of VAERS in our office. Data mining analysis will be an important part of the safety evaluation of these vaccines and I wanted to ask for your help with this. You would, of course be co-authors in this project. The period of this review is indicated above. I don't have any specifications other than the dates indicated above and that this is for US reports only. The plan is to have a manuscript ready for clearance by early September. I believe Mona intends to publish this in JID.

Let me know if you have any questions.

Thank you

Pedro

From: Nair, Narayan <[REDACTED]>
Sent: Wednesday, June 30, 2021 3:05 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Kim, Yeowon <[REDACTED]>;
Wei, Shaokui (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] VAERS safety review of Varicella Vaccines

Hi Pedro,

Here are the reviewers:

Varivax- Shaokui Wei

MMRV- Yeowon Kim

I cc'ed both of them on this email.

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Sent: Tuesday, June 29, 2021 4:50 PM

To: Nair, Narayan <[REDACTED]>

Cc: Su, John (CDC) <[REDACTED]>

Subject: [EXTERNAL] VAERS safety review of Varicella Vaccines

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Hi Narayan,

I hope you are doing well. We are working with our colleagues from the Division of Viral Diseases at NCIRD at CDC (Mona Marin and Jessica Leung) on a post-licensure review of the safety of varicella vaccines in VAERS. There have been some publications on this from VAERS but this review would go from 1/1/2006 through 12/31/2020 for both Varivax and MMRV. We wanted to ask your help with the data mining analysis for these two brands of varicella vaccines for the specified periods. Could you put me in touch with the person responsible for the data mining of varicella vaccines at FDA?

Thank you

Pedro

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 23 Feb 2021 13:05:45 +0000
To: Menschik, David (FDA/CBER); 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); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: RE: Data mining

Thanks for the update.

From: Menschik, David <[REDACTED]>
Sent: Tuesday, February 23, 2021 6:48 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (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: 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

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 9 Feb 2021 15:08:25 +0000
To: Menschik, David (FDA/CBER); 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)
Subject: RE: Data mining

Thank you for the update!

From: Menschik, David <[REDACTED]>
Sent: Tuesday, February 9, 2021 6:59 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (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: 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 16 Feb 2021 14:53:47 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Menschik, David (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: RE: Data mining

Thanks, David – that’s good to know.

- John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, February 16, 2021 8:22 AM
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]>; Zinderman, Craig E (FDA/CBER) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Data mining

Thanks David.

From: Menschik, David <[REDACTED]>
Sent: Tuesday, February 16, 2021 6:33 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (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: 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 23 Feb 2021 13:00:50 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Menschik, David (FDA/CBER)
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 David,

No news is good news. 😊 Thanks!

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd [REDACTED]
Atlanta, GA 30329
[REDACTED] (office)
[REDACTED] (fax)

From: Menschik, David <David.Menschik@fda.hhs.gov>
Sent: Tuesday, February 23, 2021 6:47:58 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (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: 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 9 Feb 2021 19:51:48 +0000
To: Menschik, David; 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: RE: Data mining

Hi David,

Thanks for sharing! That's good to know.

- John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, February 9, 2021 6:59 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (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: 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

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 11 Aug 2021 20:46:08 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Distributing weekly data mining raw output

Thanks-Can I share with Jonathan and Pedro since they are responding to inquiries?

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, August 11, 2021 4:42 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Distributing weekly data mining raw output

Hi Elaine,

Please see enclosed, and (per FDA's request to keep these data closer hold) don't share.

Thanks!

- John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, August 11, 2021 4:33 PM
To: Menschik, David (FDA/CBER) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Distributing weekly data mining raw output

Thanks David.

John-please share this data with me.

From: Menschik, David <[REDACTED]>
Sent: Wednesday, August 11, 2021 4:26 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: Distributing weekly data mining raw output

Hi Elaine,

I saw your email about expanding the data mining raw output distribution list. Our plan is actually to limit its distribution, largely for data security reasons.

Moving forward I'll be forwarding this output to John Su as your group's POC and he has discretion to share with other team members (e.g., upon request by you/others in the group) as needed. Sorry for any inconvenience.

Best,
David

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 11 Aug 2021 20:41:44 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Distributing weekly data mining raw output
Attachments: USST_20210806.xls

Hi Elaine,

Please see enclosed, and (per FDA's request to keep these data closer hold) don't share.

Thanks!

• John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, August 11, 2021 4:33 PM
To: Menschik, David (FDA/CBER) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Distributing weekly data mining raw output

Thanks David.

John-please share this data with me.

From: Menschik, David <[REDACTED]>
Sent: Wednesday, August 11, 2021 4:26 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: Distributing weekly data mining raw output

Hi Elaine,

I saw your email about expanding the data mining raw output distribution list. Our plan is actually to limit its distribution, largely for data security reasons.

Moving forward I'll be forwarding this output to John Su as your group's POC and he has discretion to share with other team members (e.g., upon request by you/others in the group) as needed. Sorry for any inconvenience.

Best,
David

Drug	Event	JS EB05 2021	JS EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Ten EB05 2021	Adult EB05 2021	Adult EB05 2021	Adult EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.716	1.555	0.888				1.364	1.1	1.28	1.04	1.04	1843
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	1.739	1.736	0.888				1.45	1.72	1.225	2.061	1.189	1.49
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.525	1.934	0.852				0.758	0.772	0.689	2.141	1.49	1574
COVID19 (COVID19 (JANSSEN))	Adverse event	2.043	1.988	0.902				0.949	0.702	0.656	1.44	1.54	1374
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.3	2.585	0.857				1.612	2.139	3.54	4.282	1.384	1384
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.373	2.145	0.80				0.478	1.536	2.47	1.718	2.378	1331
COVID19 (COVID19 (JANSSEN))	Antibody test	1.894	1.82					0.661	1.822	2.373	1.723	1.492	1492
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.634	1.834					0.467	1.723	1.962	2.884	1.339	1339
COVID19 (COVID19 (JANSSEN))	Anaemia	1.758	2.077	0.86		0512		0.817	1.73	1.026	1.347	1.342	1342
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.655	2.509	0.83				0.536	1.21	1.555	0.659	3.868	0.659
COVID19 (COVID19 (JANSSEN))	CRP protein increased	2.759	2.025	0.86				1.427	2.095	0.963	1.058	1.842	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	2.893	0.74	3.821	1.207
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.409	2.141	0.86		0412		0.467	2.681	2.847	1.815	2.185	1.881
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	1.58	1.808	0.857				0.51	1.487	1.568	1.656	2.252	1.447
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.348	1.876	0.906				0.477	2.098	2.085	2.8	2.85	1819
COVID19 (COVID19 (JANSSEN))	Ethrin D dimer	2.323	1.846	0.886				0.414	2.29	2.067	1.824	2.661	1.913
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	1.932	1.489	0.899		081		0.328	1.557	2.131	1.654	2.275	1.26
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.268	1.959	0.891					2.372	1.72	0.792	2.721	1.209
COVID19 (COVID19 (JANSSEN))	Gullain-Barre syndrome	1.855	1.846	0.86				1.185	2.351	1.127	1.724	1.69	1.69
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	4.878	2.376	0.996				2.141	4.123	4.096	5.831	1.342	1.342
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	5.599	2.852					0.558	3.379	1.946	0.672	8.128	1.043
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	1.11	1.991	0.891				0.641	1.694	2.107	1.297	1.788	1.694
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.129	2.219	0.891				1.472	1.204	0.741	2.732	0.712	1.712
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.811	1.894	0.83				0.907	2.031	0.911	1.271	1.608	1.608
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	1.988	1.881	0.83				0.471	1.736	1.836	1.785	2.265	1.448
COVID19 (COVID19 (JANSSEN))	Off-rater use	1.652	1.643	0.86				4.89	0.346	0.61	0.346	1.051	1.050
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.603	0.756						2.283	1.004		1.074	1.146
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.017	1.85					1.465	1.929	0.87	1.98	1.98	1.146
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	5.027	1.998	0.891				0.94	0.651	1.62	1.991	2.603	0.821
COVID19 (COVID19 (JANSSEN))	Platelet count	2.287	2.457	0.906		0512		0.503	2.082	3.083	1.372	2.798	1.436
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.57	2.257	0.906				0.281	2.01	2.038	2.024	3.232	1.54
COVID19 (COVID19 (JANSSEN))	Platelet factor 2	5.185	3.161	0.891					3.155	1.809	6.681	4.803	1.241
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	0.463						0.589	2.428	2.036	4.031	2.41	2.312
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	1.995	1.763	0.911		0512		0.652	1.562	1.884	2.131	2.271	1.602
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	4.594						2.608	6.135	11.958	5.371	4.036	4.036
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	1.758	1.888	0.884				0.424	1.598	1.932	1.144	2.08	1.253
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial	2.239	1.122	0.83				0.552	1.311	1.777	1.2	1.927	1.56
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.275	2.364	1.765		0512		0.608	2.08	2.24	3.04	2.989	1.843
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.187	1.922	0.891				1.59	1.39	0.854	2.122	0.877	0.877
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.124	1.302	0.894				0.386	1.841	1.959	1.747	2.451	1.413
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.621	2.174	0.901		0512		2.081	2.174	3.266	2.801	2.12	2.12
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.207	1.694						2.492	1.381	1.257	2.352	1.054
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	2.154	1.915					0.882	1.663	1.634	0.561	2.22	0.824
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.221	2.998						1.739	3.499	4.233	1.947	1.947
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.886	2.411	0.891					2.762	2.377	0.747	4.842	0.897
COVID19 (COVID19 (MODERNA))	Accidental exposure to product	2.128						0.385	0.519	0.471	0.738	0.874	0.77
COVID19 (COVID19 (MODERNA))	No adverse event	1.548	0.81	0.801		0.47		2.127	0.923	0.969	0.891	1.231	1.345
COVID19 (COVID19 (MODERNA))	Poor quality product administered	2.477				0.545		0.287	0.258	0.374	0.565	0.443	0.377
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.373				0.783		2.437	0.684	0.236	0.653	2.331	2.362
COVID19 (COVID19 (PFIZER))	Product preparation issue	1.828	0.867	0.891				1.388	1.873	1.854	2.059	1.803	1.772

From: Coffin, Nicole (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 20 Jan 2023 19:47:30 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Capers, Catherine (Katy) (CDC/DDID/NCEZID/DHQP); Kroop, Seth (CDC/DDID/NCEZID/DHQP); Griffis, Kevin (CDC/OD/OADC)
Subject: RE: Update on Safety Signal
Attachments: Updated Posting Draft 01202023.docx, Updated Posting Draft 01202023_1-20-2023.docx

Thanks Tom.

Kevin – will give you a call to discuss how best to proceed

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, January 20, 2023 2:31 PM
To: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Capers, Catherine (Katy) (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Update on Safety Signal

They accepted some of my suggestions (my draft is the 1-20-2023 document with my comments). I think we need to [REDACTED] (b)(5)

[REDACTED] (b)(5)

From: Marks, Peter <[REDACTED]>
Sent: Friday, January 20, 2023 2:22 PM
To: Walensky, Rochelle (CDC/OD) <[REDACTED]>; Califf, Robert <[REDACTED]>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/OD) <[REDACTED]>; Helfand, Rita (CDC/DDID/NCEZID/OD) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Hussain, Sana (FDA/CBER) <[REDACTED]>; Kaslow, David (FDA/CBER) <[REDACTED]>; Anderson, Steven (FDA/CBER) <[REDACTED]>; Forshee, Richard (FDA/CBER) <[REDACTED]>; Tierney, Julia (FDA/OC) <[REDACTED]>; Berger, Sherri (CDC/OD/OCS) <[REDACTED]>
Subject: Update on Safety Signal

Dear Rochelle and Rob,

Several of the career staff from CDC and FDA met today to discuss the recent VSD findings and how to proceed further. We had an excellent discussion, reached good alignment, and wanted to provide you with a paper briefing on how we propose to proceed moving forward.

1. There was agreement that the VSD presentation to the ACIP Working Group on 1/19/2023 was reassuring that the signal previously observed was likely the result of confounding factors, and did not represent a true safety risk. However, to have reassurance for future vaccination campaigns that will combine COVID-19 and influenza vaccines, we will immediately initiate a formal epidemiologic study of stroke risk with the bivalent boosters.

2. There was agreement that we would proceed with a brief presentation of the VSD findings at the upcoming VRBPAC meeting, with the preface that they are an example of how the vaccine safety surveillance system in the US is working to detect and then resolve potential signals in real time. We will aim to have this be an informational presentation and not have it become a significant topic of discussion at the meeting.
3. The group suggests that on Monday morning we update the current CDC-FDA webpage posting with a box at the top of the current posting that notes the reassuring findings. We think that this will take down the temperature moving into the VRBPAC meeting. The language below might be tweaked further, but we would not intend to say anything much longer:

Updated Jan. 23, 2023

Update from CDC & FDA Indicates that the Bivalent COVID-19 Booster Vaccine Remains Safe for Use in Persons Aged 65 Years and Older

Additional evidence has now been evaluated regarding the safety of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Multiple international databases that were queried are not showing a safety signal for ischemic stroke. Further analysis of data from the CMS database continues to show no evidence of a signal for ischemic stroke. And additional analyses of data from CDC's Vaccine Safety Datalink indicate there may be other factors that are contributing to the signal that was observed and that it does not represent a true safety risk. Both CDC & FDA will continue to closely monitor the safety of the COVID-19 vaccines and will keep the public informed of their findings.

[CDC & FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older | CDC](#)

Best Regards,
Peter

Peter Marks, MD, PhD (he/him/his)
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
[REDACTED]
Silver Spring, MD 20993

[REDACTED] voice
[REDACTED] fax
[REDACTED]



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Updated Jan. 23, 2023

Update from CDC & FDA Indicates that the Bivalent COVID-19 Booster Vaccine Remains Safe for Use in Persons Aged 65 Years and Older

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[CDC & FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older | CDC](#)

(b)(5)

From: Shay, David (CDC/DDID/NCIRD/ID)
Sent: Tue, 17 May 2022 12:53:31 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP); Gee, Julianne (CDC/DDID/NCEZID/DHQP)
Cc: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining -- GBS signal for J&J

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, May 17, 2022 7:56 AM
To: Abara, Winston E. (CDC/DDID/NCHHSTP/DSTDP) <[REDACTED]>; Shay, David (CDC/DDID/NCIRD/ID) <[REDACTED]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

I'm not sure if you are aware or not, [REDACTED] 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 \geq 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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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.

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 1 Feb 2022 18:44:41 +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: RE: Weekly data mining

OK

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, February 1, 2022 1:44 PM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Both if possible, otherwise Mike.

Karen

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, February 1, 2022 1:44 PM
To: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Ok. Do you want Mike or Allison to be the new POC?

Theresa

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, February 1, 2022 1:31 PM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

I suggest you send the email.

Thanks,
Karen

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, February 1, 2022 1:30 PM
To: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 29 Apr 2021 18:07:53 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thank you!

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Thursday, April 29, 2021 1:59 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

Hi folks,

Elaine raised the point about signal detection and being aware of such in responding to inquiries. Please see the enclosed weekly data mining results shared by FDA. [REDACTED] (b)(5)

[REDACTED] (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 \geq 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

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 2 Feb 2021 22:23:51 +0000
To: Menschik, David (FDA/CBER); 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

No problem.

From: Menschik, David <[REDACTED]>
Sent: Tuesday, February 2, 2021 5:01 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; 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: 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,

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

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 1 Mar 2022 16:36:21 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, March 1, 2022 11:07 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: FW: Weekly data mining

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 2 Nov 2021 16:23:01 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John!

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 \geq 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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From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 2 Nov 2021 20:27:50 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

OK. Yes I understand.
I can be removed after December 23.

Theresa

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, November 2, 2021 3:53 PM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Hi Theresa,

FDA is trying to be judicious re: sharing of data mining results. I've been sharing them with Elaine; I'll add Anni and Allison to my list.

- John

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, November 2, 2021 3:49 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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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From: Dua, Anamika (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 9 Nov 2021 18:43:42 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thank you!

Anni

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, November 9, 2021 11:36 AM
To: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Dua, Anamika (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Hi Allison,

Thanks! Anni, please see enclosed data mining from FDA.

• John

From: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, November 9, 2021 11:09 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Hi John,

I think Anni Dua was the other person we were adding to this weekly email.

Thank you!
Allison

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 25 Jan 2022 14:55:21 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, January 25, 2022 9:50 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 7 Jun 2022 14:04:06 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, June 7, 2022 8:29 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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]>; Allmchandani, 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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 7 Dec 2021 13:19:39 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, December 7, 2021 8:13 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, 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 \geq 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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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.

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 20 Jul 2021 15:02:29 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thank you!

t

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, July 20, 2021 11:02 AM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Yeah, the flexibility of telework is very helpful for times like these. Stay safe, safe travels, and I hope y'all find some peace.

- John

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, July 20, 2021 10:58 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Appreciate the kind words.

I will probably have to return to (b) and work from there during August. (b)(6)

(b)(6)

We are working on getting someone to help with light housecleaning and meals, but there is high demand for those types of assistants. As I was leaving for the airport to return to ATL, (b)(6) asked when I could return to (b)(6)

Karen is supportive of me working from (b)(6)

Theresa

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, July 20, 2021 10:54 AM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Maybe we should clarify (b)(5)

Thanks for the info! I hope getting settled back into work is going okay.

- John

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, July 20, 2021 10:52 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Hi John,

[REDACTED] (b)(5) has been on the list for weeks.

FYI. When I worked on a review of reports of cranial nerve palsies many years ago with Jane Woo, [REDACTED] (b)(5) [REDACTED] (b)(5) was one of the codes we reviewed. When we read the reports, a number of the [REDACTED] (b)(5) reports were reports of [REDACTED] (b)(5) [REDACTED] (b)(5)

Theresa

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, July 20, 2021 10:36 AM
To: Menschik, David (FDA/CBER) <[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) <[REDACTED]>
Subject: RE: Weekly data mining

Hi David,

Thanks for sharing! Seems most of the flags deal [REDACTED] (b)(6) [REDACTED] (b)(6) which might reflect the increased attention the condition is getting in the media. My two cents.

What's your take?

- John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, July 20, 2021 7:02 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]>; 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]>

<[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' 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

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 19 Oct 2021 12:48:52 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

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 \geq 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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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.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 12 Jan 2022 14:31:01 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, January 12, 2022 9:26 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 29 Mar 2022 13:41:45 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, March 29, 2022 9:35 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 15 Mar 2022 14:02:18 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, March 15, 2022 9:53 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 5 Apr 2022 18:00:53 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, April 5, 2022 1:39 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 28 Jun 2022 14:55:32 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, June 28, 2022 10:40 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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) <[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 \geq 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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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 2 Mar 2021 14:57:43 +0000
To: Menschik, David; 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: Weekly data mining

Hi David,

Thanks for sharing – good to know!

- John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, March 2, 2021 8:02 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (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

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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 15 Jun 2021 16:08:52 +0000
To: Menschik, David; 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Hi David,

Thanks for sharing. If I'm reading these data right, (b)(5)

(b)(5)

• John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, June 15, 2021 8:29 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' 6/11/21). 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 22 Jun 2021 13:25:35 +0000
To: Menschik, David; 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Hi David,

Thanks for sharing!

• John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, June 22, 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 \geq 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 23 Nov 2021 21:06:34 +0000
To: Zinderman, Craig E; Menschik, David (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks for sharing. Have a terrific Thanksgiving holiday!

- 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 \geq 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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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 14 Jul 2021 22:12:00 +0000
To: Alimchandani, Meghna; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Cc: Nair, Narayan (FDA/CBER); Menschik, David (FDA/CBER); Zinderman, Craig E (FDA/CBER)
Subject: RE: Weekly data mining

Thanks for sharing!

- John

From: Alimchandani, Meghna <[REDACTED]>
Sent: Wednesday, July 14, 2021 2:51 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Menschik, David (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (FDA/CBER) <[REDACTED]>
Subject: 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 EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date 7/9/21'). 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,
Meghna

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 24 Aug 2021 21:47:00 +0000
To: Menschik, David; 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks for sharing!

- John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, August 24, 2021 5:24 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 \geq 2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 8/20/21). 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

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 8 Feb 2022 13:33:40 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, February 8, 2022 8:06 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 9 Nov 2021 13:50:26 +0000
To: Menschik, David; 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Hi David,

Thanks for sharing! I see a few blips here and there about emerging concerns (b)(5). For the most part, I think (b)(5)

(b)(5)

My two cents. What impressions did other folks have?

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 \geq 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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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.

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 9 Mar 2021 13:12:50 +0000
To: Menschik, David; 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: Weekly data mining

Hi David,

Glad to hear it. Thanks!

• John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, March 9, 2021 6:50 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (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,

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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 9 Nov 2021 16:36:29 +0000
To: Lale, Allison (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Cc: Dua, Anamika (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20211105.xls

Hi Allison,

Thanks! Anni, please see enclosed data mining from FDA.

- John

From: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, November 9, 2021 11:09 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Hi John,
I think Anni Dua was the other person we were adding to this weekly email.

Thank you!
Allison

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 \geq 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	IS EB05 2021	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Tenr EB05 2021	Adult EB05 2021	Adult EB05 2021	Adult EB05 2021	Adult EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.19	0.27	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.21
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.27	1.84	0.88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.478
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.972	1.32	0.901	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.934
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.877	1.878	0.907	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.533
COVID19 (COVID19 (JANSSEN))	Adverse event	2.052	0.952	0.676	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.386
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.886	1.312	0.900	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.085
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.05	2.202	0.98	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.302
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.253	1.271	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.336
COVID19 (COVID19 (JANSSEN))	Angiogram coronary abnormal	2.534	1.931	0.888	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.059
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.974	1.857	0.887	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.295
COVID19 (COVID19 (JANSSEN))	Anticoag test	2.29	0.972	0.676	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.824
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.238	1.658	1.106	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.828
COVID19 (COVID19 (JANSSEN))	Antifla	2.12	1.948	0.878	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.545
COVID19 (COVID19 (JANSSEN))	Antigenemia result abnormal	1.888	0.876	0.676	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.793
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.955	0.851	0.877	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.29
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.751	1.559	0.874	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.202
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.795	1.28	0.876	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.272
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.948	1.502	0.886	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.475
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.02	1.565	0.897	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.36
COVID19 (COVID19 (JANSSEN))	Blood ferritin decreased	3.472	2.585	0.885	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.075
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.839	1.559	0.888	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.046
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.772	1.544	0.87	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.877
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.762	1.209	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.294
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.938	1.334	1.067	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.892
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.708	2.215	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.212
COVID19 (COVID19 (JANSSEN))	Cardiac haemorrhage	2.528	1.807	0.918	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.108
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.304	1.89	0.890	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.999
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.108	1.527	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.041
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.462	2.422	0.898	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.931
COVID19 (COVID19 (JANSSEN))	Computed tomogram head abnormal	2.732	1.950	0.920	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.744
COVID19 (COVID19 (JANSSEN))	Computed tomogram head normal	2.026	1.492	0.896	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.918
COVID19 (COVID19 (JANSSEN))	Computed tomogram thorax abnormal	2.176	1.608	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.633
COVID19 (COVID19 (JANSSEN))	Computed tomogram thorax normal	2.454	1.884	0.901	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.035
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	1.817	1.505	0.877	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.212
COVID19 (COVID19 (JANSSEN))	Fevering cold	1.778	0.802	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.615
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.285	1.821	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.844
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.158	1.512	0.912	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.884
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.53	0.997	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.182
COVID19 (COVID19 (JANSSEN))	Gate	2.229	1.821	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.778
COVID19 (COVID19 (JANSSEN))	Goutans increased	1.857	1.382	0.882	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.219
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.726	1.261	0.882	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.047
COVID19 (COVID19 (JANSSEN))	Gullain-Barre syndrome	2.303	1.888	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.091
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.823	1.060	0.906	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.040
COVID19 (COVID19 (JANSSEN))	Haemoglobin increased	1.795	1.303	0.897	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.336
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	0.805	0.805	0.886	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.074
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	0.805	0.805	0.886	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.989
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.803	1.234	0.88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.883
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.75	1.821	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.291
COVID19 (COVID19 (JANSSEN))	Intensive care	1.761	1.414	1.01	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.58
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.834	1.315	0.882	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.737
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.162	1.415	0.876	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.127
COVID19 (COVID19 (JANSSEN))	Joufar vein thrombosis	2.104	1.961	0.874	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.755
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.867	1.531	0.871	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.723
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.022	1.768	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.488
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.628	1.267	0.888	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.141
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.174	1.718	0.882	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.587
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head normal	1.886	1.208	0.886	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.749
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration increased	1.841	1.227	0.874	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.895
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.770	1.209	0.877	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.895
COVID19 (COVID19 (JANSSEN))	Metabolic acidosis	2.04	1.292	0.88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.163
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.617	1.376	0.887	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.027
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.586	1.217	0.876	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.909
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.682	1.292	0.880	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.123
COVID19 (COVID19 (JANSSEN))	Off taste	1.387	0.921	0.872	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.885
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.752	0.758	0.88	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.175
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.575	0.874	0.874	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.969
COVID19 (COVID19 (JANSSEN))	Peripneumonia	3.363	1.746	0.874	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.866
COVID19 (COVID19 (JANSSEN))	Platelet count	2.752	2.503	0.922	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.829
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.855	1.406	0.890	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.411
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.73	2.067	0.886	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.833
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.019	2.523	0.875	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.833
COVID19 (COVID19 (JANSSEN))	Plaz quantity product administered	1.227												

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 12 Jul 2022 20:18:25 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

It's for COVID-19 vaccines. (b)(5) I suspect (b)(5)
(b)(5) You can ask David for clarification.

I think (b)(5)
(b)(5)

- John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <(b)(5)>
Sent: Tuesday, July 12, 2022 4:17 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: Weekly data mining

John,
The brand name of the vaccine was left of this list.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <(b)(5)>
Sent: Tuesday, July 12, 2022 4:11 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <(b)(5)>
Subject: FW: Weekly data mining

FYI

From: Zinderman, Craig E <(b)(5)>
Sent: Tuesday, July 12, 2022 2:26 PM
To: Menschik, David (FDA/CBER) <(b)(5)>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <(b)(5)>; Su, John (CDC/DDID/NCEZID/DHQP) <(b)(5)>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <(b)(5)>
Cc: Nair, Narayan (FDA/CBER) <(b)(5)>; Alimchandani, Meghna (FDA/CBER) <(b)(5)>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <(b)(5)>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <(b)(5)>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <(b)(5)>
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 \geq 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

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.

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 23 Mar 2021 18:39:52 +0000
To: Zinderman, Craig E; Menschik, David (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Hi Craig,

Thanks for sharing!

- John

From: Zinderman, Craig E <[REDACTED]>
Sent: Tuesday, March 23, 2021 2:00 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]>
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 \geq 2) for all EUA SARS-CoV-2 vaccine VAERS reports from our 'US Signals Summary Table' ('as of date' 3/19/21) 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,
Craig

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 16 Mar 2021 12:51:04 +0000
To: Menschik, David; 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: Weekly data mining

Hi David,

Thanks for sharing!

- John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, March 16, 2021 7:13 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (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

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 \geq 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 6 Apr 2021 13:55:05 +0000
To: Menschik, David; 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Good to know. Thanks for sharing!

- John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, April 6, 2021 7:58 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

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 \geq 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 13 Apr 2021 11:56:38 +0000
To: Menschik, David; 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks for sharing, David!

- John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, April 13, 2021 6:13 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 \geq 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 30 Mar 2021 11:46:33 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Menschik, David (FDA/CBER)
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/NCEZID/DHQP)
Subject: Re: Weekly data mining

Hi David,

Thanks for sharing! I get the impression [redacted] (b)(5)
[redacted] (b)(5)

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd [redacted]
Atlanta, GA 30329



From: Menschik, David <[redacted]>
Sent: Tuesday, March 30, 2021 7:02:25 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 '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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 4 May 2021 12:56:48 +0000
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP)
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP)
Subject: Re: Weekly data mining

Just me pretending to know what I'm talking about... 😏

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd [REDACTED]
Atlanta, GA 30329
[REDACTED]

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, May 4, 2021 8:50:13 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Thank you. 😊

Theresa

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, May 4, 2021 8:28 AM
To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: Re: Weekly data mining

Hi Theresa,

I'll have to look at the data more closely. Offhand, I think [REDACTED] (b)(5)

[REDACTED] (b)(5)

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention

1600 Clifton Rd [REDACTED]
Atlanta, GA 30329

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, May 4, 2021 8:19:24 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Weekly data mining

Hi John,

What about the [REDACTED] (b)(5)?

We had received inquiries asking about this before [REDACTED] (b)(5)

[REDACTED] (b)(5)

Theresa

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, May 4, 2021 8:00 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Menschik, David (FDA/CBER) <[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 David,

Thanks for sharing! Looks like [REDACTED] (b)(5)

[REDACTED] (b)(5)

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd [REDACTED]
Atlanta, GA 30329

From: Menschik, David <[REDACTED]>
Sent: Tuesday, May 4, 2021 6:50:34 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]>; 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 \geq 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

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 11 Jun 2021 19:59:19 +0000
To: Menschik, David (FDA/CBER)
Cc: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Hi David,
Please add my email ([REDACTED]) to your list to receive the emails regarding the weekly data mining.

Thanks,

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, June 11, 2021 3:52 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 27 Apr 2021 16:20:04 +0000
To: Menschik, David (FDA/CBER); 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks for sharing, David! Interesting stuff.

- 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 \geq 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

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 25 May 2021 23:12:31 +0000
To: Menschik, David (FDA/CBER); 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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks for sharing, David!

- John

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 \geq 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

From: Lale, Allison (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 28 Nov 2022 23:09:10 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Oh interesting. Thank you Pedro.

Like I said, we used to just verbally mention on CISA calls that X, Y, Z preferred term had not signaled in VAERS - [redacted] (b)(5)

Thanks!
Allison

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, November 26, 2022 7:49 PM
To: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Hi Allison,

I think that because of the [redacted] (b)(5)
[redacted] (b)(5) I'll reach out to David Menschik and ask for the latest weekly report

Thanks

Pedro

From: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, November 26, 2022 6:28 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

Hi Pedro,

I was just wondering [redacted] (b)(5)
[redacted] (b)(5)

For example, we have an upcoming case of [redacted] (b)(5)
[redacted] (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 \geq 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.

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 7 Dec 2021 13:20:23 +0000
To: Menschik, David (FDA/CBER); Shimabukuro, Tom (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/NCEZID/DHQP)
Subject: RE: Weekly data mining

Hi David,

Thanks for sharing! I'm noting [REDACTED] (b)(5)

[REDACTED] (b)(5)

Also noting [REDACTED] (b)(5)

[REDACTED] (b)(5)

[REDACTED] (b)(5)

Offhand musings as I wait for the coffee to kick in... Thanks!

--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 \geq 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

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.

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 13 May 2021 20:28:37 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Thursday, May 13, 2021 4:25 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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,

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' 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

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 23 Nov 2021 21:44:53 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 22 Feb 2022 16:45:38 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, February 22, 2022 11:29 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Weekly data mining

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 \geq 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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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 9 Sep 2021 15:59:02 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John!

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

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 6 Sep 2021 14:57:13 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John!

Elaine

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, September 3, 2021 6:12 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
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 \geq 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

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 26 Oct 2021 14:39:36 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining

Thanks John!

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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From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 21 May 2021 17:45:07 +0000
To: Alimchandani, Meghna; Mba-Jonas, Adamma (CBER) (FDA/CBER)
Subject: RE: [EXTERNAL] Data mining (pregnancy)

Thanks Meghna

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Friday, May 21, 2021 1:44 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining (pregnancy)

Pedro,
Adamma will get back to you on this later this afternoon (thanks, Adamma).
Thanks!

Best regards,
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, May 21, 2021 11:49 AM
To: Alimchandani, Meghna <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining (pregnancy)

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 Meghna,

I was wondering if you were able to run this analysis?

Thanks

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Monday, May 17, 2021 11:31 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining (pregnancy)

We will get back to you on this, Pedro.

Thanks
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Saturday, May 15, 2021 8:00 PM
To: Alimchandani, Meghna <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: [EXTERNAL] Data mining (pregnancy)

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.

Hello Adamma and Meghna,

I hope you are enjoying your weekend. On May 24 I have to do the monthly presentation to the VAST group here at CDC on an update of the pregnancy monitoring in VAERS.

Do you think you could ask the contractor to do a data mining run as has been done before stratified by sex female and age 15-54 years? The locked point could be last Friday 5/14 if possible

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 21 May 2021 19:27:12 +0000
To: Mba-Jonas, Adamma (CBER); Alimchandani, Meghna (FDA/CBER)
Subject: RE: [EXTERNAL] Data mining (pregnancy)

Thanks so much Adamma!

Pedro

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Friday, May 21, 2021 3:05 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining (pregnancy)

Hi, Pedro – just ran the analysis. Still (as of 5/14) no pregnancy-related signals for any Covid vaccine!

Adamma

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, May 21, 2021 11:49 AM
To: Alimchandani, Meghna <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining (pregnancy)

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 Meghna,

I was wondering if you were able to run this analysis?

Thanks

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Monday, May 17, 2021 11:31 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining (pregnancy)

We will get back to you on this, Pedro.

Thanks

Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Saturday, May 15, 2021 8:00 PM
To: Alimchandani, Meghna <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: [EXTERNAL] Data mining (pregnancy)

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.

Hello Adamma and Meghna,

I hope you are enjoying your weekend. On May 24 I have to do the monthly presentation to the VAST group here at CDC on an update of the pregnancy monitoring in VAERS.

Do you think you could ask the contractor to do a data mining run as has been done before stratified by sex female and age 15-54 years? The locked point could be last Friday 5/14 if possible

Thanks

Pedro

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 15 Mar 2021 13:41:58 +0000
To: Nair, Narayan
Cc: Goud, Ravi (FDA/CBER); Niu, Manette (FDA/CBER)
Subject: RE: [EXTERNAL] data mining for cholera vaccine (Vaxchora)

Hi folks,

Thanks for the quick turnaround of this request! Should I simply share with the workgroup Ravi's interpretations, or is sharing the below table okay?

- John

From: Nair, Narayan <[REDACTED]>
Sent: Monday, March 15, 2021 7:44 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Goud, Ravi (FDA/CBER) <[REDACTED]>; Niu, Manette (FDA/CBER) <[REDACTED]>
Subject: FW: [EXTERNAL] data mining for cholera vaccine (Vaxchora)

Hi John

Here are the data mining results for Vaxchora. Ravi ran this and as he states below his interpretation is these results are related to giving to younger population than it is indicated or eating around the time of administration. Please feel free to reach out to Ravi for questions.

Here are the results, only ones >2 are in general US analysis :

Drug	Event	US EB05 202102
CHOLERA (VAXCHORA)	Labelled drug-food interaction medication error	7.859
CHOLERA (VAXCHORA)	Product administered to patient of inappropriate age	5.55
CHOLERA (VAXCHORA)	Product preparation issue	2.203
CHOLERA (VAXCHORA)	Wrong technique in product usage process	4.932

Inappropriate age findings is for <18 as was not initially approved for this, other findings are related to medication error/product preparation for this oral vaccine that requires people not eat around ingestion.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, March 8, 2021 1:24 PM

To: Nair, Narayan <[REDACTED]>

Subject: [EXTERNAL] data mining for cholera vaccine (Vaxchora)

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,

Something **not** COVID for once! :)

The Cholera ACIP workgroup would appreciate a data mining run for cholera vaccine, through the end of Feb 2021. They plan to report data at the June ACIP meeting, and so are hoping for data around the end of April. Please let me know if that request would be doable. Thanks!

- John

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 8 Mar 2021 19:32:03 +0000
To: Nair, Narayan
Cc: Niu, Manette (FDA/CBER)
Subject: RE: [EXTERNAL] data mining for cholera vaccine (Vaxchora)

Sounds great, thanks!

- John

From: Nair, Narayan <[REDACTED]>
Sent: Monday, March 8, 2021 2:31 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Niu, Manette (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining for cholera vaccine (Vaxchora)

Hi John,
My memory proved right (for once!). Ravi is the reviewer. He is on leave but should be back on Wed. Manette is the Acting Branch Chief and I cc'ed her. She and Ravi will be in touch.

Narayan

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, March 8, 2021 1:27 PM
To: Nair, Narayan <[REDACTED]>
Subject: RE: [EXTERNAL] data mining for cholera vaccine (Vaxchora)

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.

Much appreciated – thanks!

- John

From: Nair, Narayan <[REDACTED]>
Sent: Monday, March 8, 2021 1:27 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining for cholera vaccine (Vaxchora)

Shouldn't be an issue. I will forward to the reviewer that handles this vaccine – I think it is Ravi but not positive.

Narayan

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, March 8, 2021 1:24 PM
To: Nair, Narayan <[REDACTED]>
Subject: [EXTERNAL] data mining for cholera vaccine (Vaxchora)

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,

Something **not** COVID for once! :)

The Cholera ACIP workgroup would appreciate a data mining run for cholera vaccine, through the end of Feb 2021. They plan to report data at the June ACIP meeting, and so are hoping for data around the end of April. Please let me know if that request would be doable. Thanks!

- John

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 4 Jan 2023 15:06:12 +0000
To: Nair, Narayan
Cc: Goodman, Jeremy A. (CDC/DDID/NCEZID/DHQP)
Subject: RE: [EXTERNAL] data mining for COVID-19 vaccine

Hi Narayan,

No worries, and thanks for the update! For future reference, (b)(5)
(b)(5) Thanks again! And welcome to the new year.



• John

From: Nair, Narayan <[REDACTED]>
Sent: Wednesday, January 4, 2023 7:21 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Goodman, Jeremy A. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining for COVID-19 vaccine

Hi John,
Hope you and your family had a great holiday and Happy New Year. We had EB data mining in place from the beginning of the rollout as we do for all vaccines.

FYI - we have shifted some of our responsibilities in our Division so David will no longer be responsible for fielding questions about data mining. Feel free to contact me if questions come up. I sent a message out earlier but I think I forgot to include you. Sorry about that.

Narayan

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, January 03, 2023 9:39 AM
To: Menschik, David <[REDACTED]>
Cc: Goodman, Jeremy A (CDC) <[REDACTED]>
Subject: [EXTERNAL] data mining for COVID-19 vaccine

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,

I hope the holidays treated you well, and that the new year is off to a good start!

We're responding to a FOIA, so we want to confirm dates and make sure we're all on the same page. When did FDA begin EB data mining analysis on COVID-19 vaccine data? Thanks!

- John

John R. Su, M.D., Ph.D., M.P.H.

CAPT, U.S. Public Health Service

Acting Deputy Director

Immunization Safety Office

Centers for Disease Control and Prevention

1600 Clifton Road, [REDACTED]

Atlanta, GA 30333



From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Sun, 7 Nov 2021 22:09:44 +0000
To: Menschik, David
Cc: Nair, Narayan (FDA/CBER); Zinderman, Craig E (FDA/CBER)
Subject: RE: [EXTERNAL] data mining for dose 3 mRNA, dose 2 Janssen

Hi David,

Good to know. Thanks for the info!

- John

From: Menschik, David <[REDACTED]>
Sent: Sunday, November 7, 2021 1:06 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (FDA/CBER) <[REDACTED]>
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
To: Menschik, David <[REDACTED]>
Cc: Zinderman, Craig E <[REDACTED]>; Nair, Narayan <[REDACTED]>
Subject: [EXTERNAL] data mining for dose 3 mRNA, dose 2 Janssen

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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)? [REDACTED] (b)(5)

[REDACTED] (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

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 19 Oct 2022 15:08:18 +0000
To: Nair, Narayan
Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); Rouse, Douglas (FDA/CBER); Jason, Christopher (FDA/CBER)
Subject: RE: [EXTERNAL] Data mining for (b)(5)

Thanks Narayan

Pedro

From: Nair, Narayan <[REDACTED]>
Sent: Wednesday, October 19, 2022 9:51 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Rouse, Douglas (FDA/CBER) <[REDACTED]>; Jason, Christopher (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining for (b)(5)

Hi Pedro,

I am putting you in touch with Doug Rouse and Chris Jason who are monitoring (b)(5) for DPV.

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, October 19, 2022 9:43 AM
To: Nair, Narayan <[REDACTED]>
Cc: Duffy, Jonathan M (CDC) <[REDACTED]>
Subject: [EXTERNAL] Data mining for (b)(5)

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,

I hope you are doing well. I was wondering if FDA is doing data mining for (b)(5) and if so if you could let me know who I should reach out for any recent findings

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 19 Oct 2022 15:30:06 +0000
To: Rouse, Douglas; Nair, Narayan (FDA/CBER)
Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); Jason, Christopher (FDA/CBER)
Subject: RE: [EXTERNAL] Data mining for (b)(5)

Hi Doug,

Thanks so much for sending these data so promptly. Have any adjustment been done in this data mining analysis to take into account the Covid-19 vaccines? Have you done any analysis where you excluded the Covid-19 vaccines?

We've contacted the (b)(5)

(b)(5)

If we have question about the data mining findings I'll let you know

Thanks again

Pedro

From: Rouse, Douglas <>
Sent: Wednesday, October 19, 2022 10:51 AM
To: Nair, Narayan (FDA/CBER) <>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <>; Jason, Christopher (FDA/CBER) <>
Subject: RE: [EXTERNAL] Data mining for (b)(5)

Hello Pedro,

Attached are data mining results run this morning using Empirica Signals for the US and US/World view with a DLP of 14 Oct 2022, sorted from highest EB05 to lowest. The data mining results are viewed as hypothesis generating. The majority of the AEs are injection site reactions and highlighted in yellow. Most of the remainder are issues with vaccination (didn't get a wheal, gave ID to someone under 18, vaccine leaked out of syringe or out of injection site, product kept thawed too long before administering, etc.) The few others listed are not really AEs.

Hope that is of value.

Have you received any additional information on the two autopsy results?

Thx

Doug

Douglas Rouse, MD, MPH

Medical Officer

Pharmacovigilance Branch 2

Division of Pharmacovigilance

Office of Biostatistics and Pharmacovigilance

Center for Biologics Evaluation and Research

U.S. Food and Drug Administration



From: Nair, Narayan <[REDACTED]>

Sent: Wednesday, October 19, 2022 9:51 AM

To: Moro, Pedro L (CDC) <[REDACTED]>

Cc: Duffy, Jonathan M (CDC) <[REDACTED]>; Rouse, Douglas <[REDACTED]>; Jason, Christopher <[REDACTED]>

Subject: RE: [EXTERNAL] Data mining for (b)(5)

Hi Pedro,

I am putting you in touch with Doug Rouse and Chris Jason who are monitoring (b)(5) for DPV.

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Sent: Wednesday, October 19, 2022 9:43 AM

To: Nair, Narayan <[REDACTED]>

Cc: Duffy, Jonathan M (CDC) <[REDACTED]>

Subject: [EXTERNAL] Data mining for (b)(5)

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,

I hope you are doing well. I was wondering if FDA is doing data mining for (b)(5) and if so if you could let me know who I should reach out for any recent findings

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 19 Oct 2022 18:53:39 +0000
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP)
Subject: RE: [EXTERNAL] Data mining for Jynneos

Ok

Pedro

From: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>
Sent: Wednesday, October 19, 2022 2:53 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: [EXTERNAL] Data mining for Jynneos

(b)(5)

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, October 19, 2022 2:31 PM
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining for Jynneos

We could. We would have to invite someone from FDA in the co-authorship. One drawback (b)(5)

(b)(5)

Pedro

From: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, October 19, 2022 2:22 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining for Jynneos

I was not planning [REDACTED] (b)(5) ?

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, October 19, 2022 1:48 PM
To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: [EXTERNAL] Data mining for Jynneos

Hi Jonathan,

(b)(5)

Thanks

Pedro

From: Nair, Narayan <[REDACTED]>
Sent: Wednesday, October 19, 2022 1:32 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Rouse, Douglas (FDA/CBER) <[REDACTED]>
Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Jason, Christopher (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining for (b)(5)

Pedro, I think the conclusions as you phrase it is accurate but Doug please chime in. Is this statement intended for some type of public document for internal use?

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, October 19, 2022 12:27 PM
To: Rouse, Douglas <[REDACTED]>; Nair, Narayan <[REDACTED]>
Cc: Duffy, Jonathan M (CDC) <[REDACTED]>; Jason, Christopher <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining for (b)(5)

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Doug,

In looking at these results can we conclude that (b)(5)

Thanks

Pedro

From: Rouse, Douglas <[REDACTED]>
Sent: Wednesday, October 19, 2022 10:51 AM
To: Nair, Narayan (FDA/CBER) <[REDACTED]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Jason, Christopher (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining for (b)(5)

Hello Pedro,

Attached are data mining results run this morning using Empirica Signals for the US and US/World view with a DLP of 14 Oct 2022, sorted from highest EB05 to lowest. The data mining results are viewed as

hypothesis generating. The majority of the AEs are injection site reactions and highlighted in yellow. Most of the remainder are issues with vaccination (didn't get a wheal, gave ID to someone under 18, vaccine leaked out of syringe or out of injection site, product kept thawed too long before administering, etc.) The few others listed are not really AEs.

Hope that is of value.

Have you received any additional information on the two autopsy results?

Thx

Doug

Douglas Rouse, MD, MPH

Medical Officer

**Pharmacovigilance Branch 2
Division of Pharmacovigilance
Office of Biostatistics and Pharmacovigilance
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration**

[REDACTED]

From: Nair, Narayan <[REDACTED]>
Sent: Wednesday, October 19, 2022 9:51 AM
To: Moro, Pedro L (CDC) <[REDACTED]>
Cc: Duffy, Jonathan M (CDC) <[REDACTED]>; Rouse, Douglas <[REDACTED]>; Jason, Christopher <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining for (b)(5)

Hi Pedro,
I am putting you in touch with Doug Rouse and Chris Jason who are monitoring (b)(5) for DPV.

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, October 19, 2022 9:43 AM
To: Nair, Narayan <[REDACTED]>
Cc: Duffy, Jonathan M (CDC) <[REDACTED]>
Subject: [EXTERNAL] Data mining for (b)(5)

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,

I hope you are doing well. I was wondering if FDA is doing data mining for (b)(5) and if so if you could let me know who I should reach out for any recent findings

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 24 Aug 2022 16:08:07 +0000
To: Alimchandani, Meghna (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER)
Subject: Re: [EXTERNAL] Data mining pregnancy reports- August 29

Thanks Adamma!

Pedro

Get [Outlook for iOS](#)

From: Alimchandani, Meghna <[REDACTED]>
Sent: Wednesday, August 24, 2022 10:34:21 AM
To: Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports- August 29

Thanks, Adamma!

Meghna

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Wednesday, August 24, 2022 10:34 AM
To: Moro, Pedro L (CDC) <[REDACTED]>; Alimchandani, Meghna <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports- August 29

Hi, Pedro – as of 8/19, ‘prolonged labour’ and Janssen vaccine remains the only pregnancy-related datamining alert for COVID vaccines.

Adamma

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, August 23, 2022 11:03 AM
To: Mba-Jonas, Adamma (CBER) <[REDACTED]>; Alimchandani, Meghna <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports- August 29

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Thanks Adamma

Pedro

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Tuesday, August 23, 2022 10:59 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports- August 29

Hi, Pedro – I'll do the datamining today!

Adamma

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, August 19, 2022 9:48 AM
To: Mba-Jonas, Adamma (CBER) <[REDACTED]>; Alimchandani, Meghna <[REDACTED]>
Subject: [EXTERNAL] Data mining pregnancy reports- August 29

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.

Hello Adamma and Meghna,

I hope you've had a nice week. On August 29 there is a maternal session at VAST where presentations from each of the teams here will be given. I'll be giving the VAERS update. Do you think we could show some recent data mining findings?

Thanks and have a nice weekend

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 18 Nov 2021 19:38:17 +0000
To: Mba-Jonas, Adamma (CBER); Alimchandani, Meghna (FDA/CBER)
Subject: RE: [EXTERNAL] data mining pregnancy reports

Thanks

Pedro

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Thursday, November 18, 2021 2:37 PM
To: Alimchandani, Meghna (FDA/CBER) <[REDACTED]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: Re: [EXTERNAL] data mining pregnancy reports

No problem, it's already with Narayan!

Adamma

From: Alimchandani, Meghna <[REDACTED]>
Sent: Thursday, November 18, 2021 2:36:45 PM
To: Moro, Pedro L (CDC) <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining pregnancy reports

No...it was pretty minor...nothing substantive that would hold back clearance.
Adamma – I would proceed with next level clearance with the version in which Deb added her comments. Since I am a coauthor, you can send to Narayan for Division level clearance.

Thanks
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Thursday, November 18, 2021 2:34 PM
To: Alimchandani, Meghna <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining pregnancy reports

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Meghna,

Do they need me to respond to the comments for the manuscript to continue with the clearance process there?

Thanks

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Thursday, November 18, 2021 1:44 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining pregnancy reports

Pedro – attached manuscript with a couple minor comments from one of the SMEs doing clearance for this; I wasn't sure if Adamma had already sent this to you so please disregard if you already received this version.

Adamma – thanks for running the data mining.

Best,
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, November 17, 2021 4:01 PM
To: Mba-Jonas, Adamma (CBER) <[REDACTED]>; Alimchandani, Meghna <[REDACTED]>
Subject: RE: [EXTERNAL] data mining pregnancy reports

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Thanks Adamma!

Pedro

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Wednesday, November 17, 2021 3:09 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] data mining pregnancy reports

Still no pregnancy data mining alerts; DLP 11/12.

Adamma

From: Mba-Jonas, Adamma (CBER)
Sent: Wednesday, November 17, 2021 2:36 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alimchandani, Meghna

< [REDACTED] >

Subject: RE: [EXTERNAL] data mining pregnancy reports

Hi, Pedro – yes, manuscript is in clearance. I can check datamining, will get that to you shortly.

Adamma

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < [REDACTED] >

Sent: Wednesday, November 17, 2021 2:13 PM

To: Mba-Jonas, Adamma (CBER) < [REDACTED] >; Alimchandani, Meghna

< [REDACTED] >

Subject: [EXTERNAL] data mining pregnancy reports

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 Adamma and Meghna,

I suppose the pregnancy manuscript is still in clearance. I wanted to ask you if you could do a datamining analysis for pregnancy reports similar to what has been done before. I need to provide an update to the VAST maternal session next Monday November 22

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 25 Feb 2022 22:20:55 +0000
To: Mba-Jonas, Adamma (CBER); Alimchandani, Meghna (FDA/CBER)
Subject: RE: [EXTERNAL] Data mining pregnancy reports

Hi Adamma,

Thanks for sending this update!

Have a great weekend

Pedro

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Friday, February 25, 2022 3:27 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports

Hi, Pedro – the data run for 2/18 yielded one new alert, ‘prolonged labour,’ for Janssen. The run assesses US females aged 15-54, and the EB05 was 2.84.

The alert is comprised of 10 cases, with the following VAERS IDs:

1763919
1770376
1776840
1832535
1850057
1853124
1879192
2023966
2061590
2115602

Review of the cases reveals that several of them have obvious confounding factors (maternal obesity, gestational diabetes, cervical abnormalities) that could be causal, so not much to go on for now. Jane Woo continues to follow this alert.

Adamma

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Friday, February 25, 2022 9:19 AM
To: Alimchandani, Meghna <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports

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Ok

Thanks Meghna.

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Friday, February 25, 2022 8:53 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports

Pedro,

We are actually working with our contractor to sort out some issues with the data mining run. Sorry for the delay. We will get results to you as soon as they are available...if not by Monday, then soon after we hope.

Best,
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Thursday, February 24, 2022 5:15 PM
To: Alimchandani, Meghna <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports

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.

Hello Meghna and Adamma,

I hope you are fine. Just wanted to remind you about this request. I hope it can be done before next Monday

Thanks

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Monday, February 14, 2022 10:08 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER)

<[REDACTED]>

Subject: RE: [EXTERNAL] Data mining pregnancy reports

Thanks, Pedro. Sounds good; we will get back to you on data mining.
And good luck with the submission to Vaccine; thanks for the update.

Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Sent: Friday, February 11, 2022 4:11 PM

To: Mba-Jonas, Adamma (CBER) <[REDACTED]>

Cc: Alimchandani, Meghna <[REDACTED]>

Subject: [EXTERNAL] Data mining pregnancy reports

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.

Hello Adamma and Meghna,

I hope you are doing well. There is going to be a maternal safety session at the VAST meeting on February 28 and I will be presenting an update on maternal Covid-19 vaccine safety from VAERS. Would you be able to look at the data mining as has been done in the past with a recent lock point?

[REDACTED]

(b)(5)

I hope you have a nice weekend

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 15 Sep 2021 14:05:41 +0000
To: Mba-Jonas, Adamma (CBER)
Cc: Alimchandani, Meghna (FDA/CBER)
Subject: RE: [EXTERNAL] Data mining pregnancy reports

Thanks Adamma!

Pedro

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Wednesday, September 15, 2021 10:02 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Alimchandani, Meghna (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports

Hi, Pedro – I'll run this and get back to you.

Adamma

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, September 15, 2021 10:00 AM
To: Mba-Jonas, Adamma (CBER) <[REDACTED]>; Alimchandani, Meghna <[REDACTED]>
Subject: [EXTERNAL] Data mining pregnancy reports

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.

Good morning Adamma and Meghna,

There is going to be a safety session at the upcoming ACIP meeting at the end of September which will include updates from the v-safe pregnancy registry, VAERS and the VSD. I am preparing the slides for VAERS and I will include some of the slides I used for VAST including perhaps one for datamining If time permits. We need to present the slides next Monday to the VAST group to get some feedback. Could you do a data mining run as has been done in the past with a more recent lock point?

Sorry for the short notice

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 15 Sep 2021 16:56:58 +0000
To: Alimchandani, Meghna (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER)
Subject: Re: [EXTERNAL] Data mining pregnancy reports

Great!

Thanks so much Adams!

Pedro

Get [Outlook for iOS](#)

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Wednesday, September 15, 2021 12:38:01 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining pregnancy reports

Hi, Pedro – no datamining alerts. DLP 9/10.

Adamma

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Sent: Wednesday, September 15, 2021 10:00 AM
To: Mba-Jonas, Adamma (CBER) <[REDACTED]>; Alimchandani, Meghna <[REDACTED]>
Subject: [EXTERNAL] Data mining pregnancy reports

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Good morning Adamma and Meghna,

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Sorry for the short notice

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 23 Jun 2021 16:44:41 +0000
To: Alimchandani, Meghna (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER)
Subject: Re: [EXTERNAL] Data mining

Thank you Adamma and Meghna!

Pedro

Get [Outlook for iOS](#)

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Wednesday, June 23, 2021 12:16:31 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining

Hi, just checked the datamining, still no pregnancy-related signals as of 6/18.

Adamma

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, June 23, 2021 10:05 AM
To: Alimchandani, Meghna <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] 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.

Thanks!

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Wednesday, June 23, 2021 7:39 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] Data mining

Thanks, Pedro.
Adamma will get back to you on this. (Thanks, Adamma!)

Best regards
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, June 21, 2021 6:54 PM
To: Mba-Ignas Adamma (CBER) <[REDACTED]>; Alimchandani, Meghna
<[REDACTED]>
Subject: [EXTERNAL] 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.

Hello Adamma and Meghna,

I hope you had a nice weekend. I have to give an update to the VAST group here at CDC on pregnancy reports in VAERS next Monday June 28. Do you think you could ask the contractor to do a data mining run similar to what has been done before?.

[REDACTED] (b)(5)

[REDACTED] (b)(5)

Thanks

Pedro

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 11 Aug 2021 19:11:31 +0000
To: Menschik, David
Subject: RE: [EXTERNAL] FW: Weekly data mining

Hi David,

To be clear: you're limiting receipt of this report to Tom and me, and allowing us to decide who on CDC's end should receive a copy – (b)(5) Correct?

- John

From: Menschik, David <[REDACTED]>
Sent: Wednesday, August 11, 2021 2:57 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: [EXTERNAL] FW: Weekly data mining

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) <[REDACTED]>; 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) <[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' 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

From: McNeil, Michael (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 21 Nov 2022 18:33:17 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Zinderman, Craig E (FDA/CBER)
Subject: RE: [EXTERNAL] inquiry re: data mining and "masking"
Attachments: RE: This week

Yes, the joint responses are fine with me also.
Thanks all,
Mike

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, November 21, 2022 1:31 PM
To: Nair, Narayan (FDA/CBER) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (FDA/CBER) <[REDACTED]>
Cc: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] inquiry re: data mining and "masking"

Absolutely fine by me, thanks. Mike?

- John

From: Nair, Narayan <[REDACTED]>
Sent: Monday, November 21, 2022 12:52 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (FDA/CBER) <[REDACTED]>
Cc: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] inquiry re: data mining and "masking"

Thanks John, if OK with you we will respond to MHRA and cc you and Mike.

Narayan

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, November 21, 2022 10:26 AM
To: Alimchandani, Meghna <[REDACTED]>; Zinderman, Craig E <[REDACTED]>; Nair, Narayan <[REDACTED]>
Cc: McNeil, Michael M (CDC) <[REDACTED]>
Subject: [EXTERNAL] inquiry re: data mining and "masking"

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,

As discussed; please see enclosed. Just a heads-up that you might be contacted about this paper in relation to how FDA performs data mining.

- John

John R. Su, M.D., Ph.D., M.P.H.

CAPT, U.S. Public Health Service

Acting Deputy Director

Immunization Safety Office

Centers for Disease Control and Prevention

1600 Clifton Road, [REDACTED]

Atlanta, GA 30329-4027



From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 27 Apr 2021 16:11:58 +0000
To: Menschik, David; Nair, Narayan (FDA/CBER)
Cc: Welsh, Kerry (FDA/CBER); Baumblatt, Jane (FDA/CBER)
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Hi David,

Thanks for the update. Will do!

• John

From: Menschik, David <[REDACTED]>
Sent: Tuesday, April 27, 2021 12:11 PM
To: Nair, Narayan (FDA/CBER) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Welsh, Kerry (FDA/CBER) <[REDACTED]>; Baumblatt, Jane (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Hi John,
Please include me and Bethany for the data mining aspects.
Best,
David

From: Nair, Narayan <[REDACTED]>
Sent: Tuesday, April 27, 2021 11:32 AM
To: Su, John (CDC) <[REDACTED]>; Menschik, David <[REDACTED]>
Cc: Welsh, Kerry <[REDACTED]>; Baumblatt, Jane <[REDACTED]>
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Sorry hit send before I cc'ed them.

Narayan

From: Nair, Narayan
Sent: Tuesday, April 27, 2021 11:31 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Menschik, David <[REDACTED]>
Cc: Shimabukuro, Tom (CDC) <[REDACTED]>; Gee, Julianne M (CDC) <[REDACTED]>
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Hi John,
Please include Kerry and Jane B. who are cc'ed on this email.

Narayan

From: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, April 27, 2021 9:28 AM
To: Nair, Narayan <[REDACTED]>; Menschik, David <[REDACTED]>
Cc: Shimabukuro, Tom (CDC) <[REDACTED]>; Gee, Julianne M (CDC) <[REDACTED]>
Subject: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

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.

Good morning,

[REDACTED]
(b)(5)

(b)(5) We'd like to include data mining results, and would like to touch base on the topic. Would there be a good time this week to discuss, and who should be included? I think Kerry Walsh and Jane Baumblatt are reviewing Moderna and Pfizer?

Thanks!

- John

From: "Broder, Karen (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
To: "Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Olson, Christine (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Gallego, Ruth (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
Cc: "Shay, David (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "McNeil, Michael (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Starrett, Tracie (CDC/DDID/NCEZID/DHQP) (CTR)" <[REDACTED]>, "Kroop, Seth (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
Subject: RE: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Date: Mon, 17 Apr 2023 22:25:00 +0000

Importance: Normal

PerStephanie,

Good evening. The only portion of the request the involves CISA is "all deliverables in section C4." The CISA team would defer to the COR for the deliverables.

I would recommend that for the entire response, please ensure if there are an PII in responsive documents that could identify individuals that they are redacted per processes that have been under discussion. The physical security justification may also be warranted.

Sincerely,

Karen R. Broder, MD
Captain, United States Public Health Service
Chief Medical Officer
Immunization Safety Office
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Phone: [REDACTED] Fax: [REDACTED]

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, April 17, 2023 11:14 AM
To: Olson, Christine (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Shay, David (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Starrett, Tracie (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>; Kroop,

Seth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: FW: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Importance: High

Good morning,

Please see the attached FOIA Request. I would like to close this out by recommending that the FOIA Office work with the requester to narrow the scope. Along with our request to narrow the scope, I want to provide them with a volume cost estimate since the requester is only willing to pay \$25.00. At this time, we only need one person from each team that will have a complete set up documents to respond to the volume cost estimate. Please identify that one person in your group, review the attached request, and provide me with the following:

- The amount of time it will take to conduct the search and review the documents
- The number of pages (best guess)
- Sample of your responsive documents... 3 - 5 pages from each SME

I look forward to receiving your estimate by Wednesday, 19th close of business. If you have any questions, please call me.

Thank you so much,

-p

From: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Sent: Wednesday, April 12, 2023 3:30 PM

To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alldredge, Berta (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: RE: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Hi Elnetta and PerStephanie,

Thank you for today's discussion regarding FOIA for the Lukos Clinical contract. This contract provides vaccine safety clinical services for the Pregnancy Registry, VAERS and CISA teams.

If you need more detailed info other than hiring updates and monthly reports, please get with the following SMEs/Technical Monitors:

1. Pregnancy Registry: Christine Olson ([REDACTED]), Andrea Sharma ([REDACTED])
2. CISA: Sehwa Kim ([REDACTED]), Mike McNeil ([REDACTED]), Karen Broder ([REDACTED])
3. VAERS: Pedro Moro ([REDACTED]), Ruth Gallego ([REDACTED])

Thanks,

Bonita Johnson

Principal Management Official

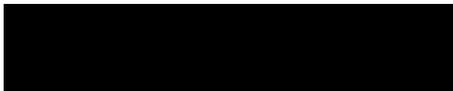
Immunization Safety Office/DHQP/NCEZID

[REDACTED]

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>
Sent: Wednesday, April 12, 2023 3:00 PM
To: Alldredge, Berta (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Attached is an additional item to discussion during Teams Meeting regarding FOIA 23-00947

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention



From: "Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
To: "Broder, Karen (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Olson, Christine (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Gallego, Ruth (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
Cc: "Shay, David (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "McNeil, Michael (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Starrett, Tracie (CDC/DDID/NCEZID/DHQP) (CTR)" <[REDACTED]>, "Kroop, Seth (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
Subject: RE: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135
Date: Mon, 17 Apr 2023 22:43:29 +0000
Importance: Normal

Karen, thanks for following up! After you got off the call, Dr. McNeil, me and some of the other CISA Team members stayed on to confirm that CISA would not have any additional documents. We also discussed submitting the justification to protect the names, commercial and proprietary information, and having the FOIA Office to follow-up with the contractor using Executive Order 12600. Lastly, I plan to request an opaque copy of the documents before they are released to the requester. I will keep you posted. Thanks!

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, April 17, 2023 6:25 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Olson, Christine (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Shay, David (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Starrett, Tracie (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

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Sincerely,

Karen R. Broder, MD
Captain, United States Public Health Service
Chief Medical Officer
Immunization Safety Office
Division of Healthcare Quality Promotion

Centers for Disease Control and Prevention
[REDACTED]

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, April 17, 2023 11:14 AM
To: Olson, Christine (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Shay, David (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Starrett, Tracie (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135
Importance: High

Good morning,

Please see the attached FOIA Request. I would like to close this out by recommending that the FOIA Office work with the requester to narrow the scope. Along with our request to narrow the scope, I want to provide them with a volume cost estimate since the requester is only willing to pay \$25.00. At this time, we only need one person from each team that will have a complete set up documents to respond to the volume cost estimate. Please identify that one person in your group, review the attached request, and provide me with the following:

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- The number of pages (best guess)
- Sample of your responsive documents... 3 - 5 pages from each SME

I look forward to receiving your estimate by Wednesday, 19th close of business. If you have any questions, please call me.

Thank you so much,

-p

From: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Wednesday, April 12, 2023 3:30 PM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alldredge, Berta (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Hi Elnetta and PerStephanie,

Thank you for today's discussion regarding FOIA for the Lukos Clinical contract. This contract provides vaccine safety clinical services for the Pregnancy Registry, VAERS and CISA teams.

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

If you need more detailed info other than hiring updates and monthly reports, please get with the following SMEs/Technical Monitors:

1. Pregnancy Registry: Christine Olson ([REDACTED]), Andrea Sharma ([REDACTED])
2. CISA: Sehwa Kim ([REDACTED]), Mike McNeil ([REDACTED]), Karen Broder ([REDACTED])
3. VAERS: Pedro Moro ([REDACTED]), Ruth Gallego ([REDACTED])

Thanks,

Bonita Johnson
Principal Management Official
Immunization Safety Office/DHQP/NCEZID

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) [REDACTED]
Sent: Wednesday, April 12, 2023 3:00 PM
To: Alldredge, Berta (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Attached is an additional item to discussion during Teams Meeting regarding FOIA 23-00947

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention

From: "Olson, Christine (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
To: "Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Gallego, Ruth (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
Cc: "Shay, David (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "McNeil, Michael (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Broder, Karen (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Starrett, Tracie (CDC/DDID/NCEZID/DHQP) (CTR)" <[REDACTED]>, "Kroop, Seth (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Su, John (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>

Subject: RE: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Date: Wed, 19 Apr 2023 17:39:31 +0000

Importance: Normal

Good afternoon, PerStephanie and Tracie,

Thank you for discussing this. I'll defer the time-estimate as we discussed and address the ask as it relates to the Pregnancy Registry. I've conducted searches of our files and my responses are below.

1a. The weekly updates listed in Task 6 did not actually occur within the scope of this contract or otherwise. The tasks listed in this contract language were, as is very typical, written many months ahead of when the contract was executed and program had contract staff available for work through this mechanism. The tasks were written to include any potential foreseeable needs at the time and written in a fairly broad way so that we could ensure we had resources to meet the program needs at the future time additional staff would be available. As we discussed, over the course of the pandemic response, these needs changed and fluctuated greatly, given the situation. Therefore, this listed task was not ever performed under this contract.

1b. The contract staff also did not participate in responses to inquiries. We actually received very few inquiries at all, and any that we did receive were not assigned to anyone employed through this contract.

2. As we discussed, there are not discreet deliverables listed in C4. The only deliverables listed in the SOW are those in C5 and would have been provided by the contracting company directly to the COR as is indicated in the SOW specifications.

I'm happy to discuss further if there is any additional clarification around this request and determine if any materials we have are relevant.

Thank you,
Christine

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, April 17, 2023 11:14 AM
To: Olson, Christine (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Shay, David (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Starrett, Tracie (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>; Kroop,

Seth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: FW: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Importance: High

Good morning,

Please see the attached FOIA Request. I would like to close this out by recommending that the FOIA Office work with the requester to narrow the scope. Along with our request to narrow the scope, I want to provide them with a volume cost estimate since the requester is only willing to pay \$25.00. At this time, we only need one person from each team that will have a complete set up documents to respond to the volume cost estimate. Please identify that one person in your group, review the attached request, and provide me with the following:

- The amount of time it will take to conduct the search and review the documents
- The number of pages (best guess)
- Sample of your responsive documents... 3 - 5 pages from each SME

I look forward to receiving your estimate by Wednesday, 19th close of business. If you have any questions, please call me.

Thank you so much,

-p

From: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Sent: Wednesday, April 12, 2023 3:30 PM

To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alldredge, Berta (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: RE: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Hi Elnetta and PerStephanie,

Thank you for today's discussion regarding FOIA for the Lukos Clinical contract. This contract provides vaccine safety clinical services for the Pregnancy Registry, VAERS and CISA teams.

If you need more detailed info other than hiring updates and monthly reports, please get with the following SMEs/Technical Monitors:

1. Pregnancy Registry: Christine Olson ([REDACTED]), Andrea Sharma ([REDACTED])
2. CISA: Sehwa Kim ([REDACTED]), Mike McNeil ([REDACTED]), Karen Broder ([REDACTED])
3. VAERS: Pedro Moro ([REDACTED]), Ruth Gallego ([REDACTED])

Thanks,

Bonita Johnson

Principal Management Official

Immunization Safety Office/DHQP/NCEZID



From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) [REDACTED]
Sent: Wednesday, April 12, 2023 3:00 PM
To: Alldredge, Berta (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Attached is an additional item to discussion during Teams Meeting regarding FOIA 23-00947

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention

[REDACTED]

From: "Gallego, Ruth (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
To: "Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Olson, Christine (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>, "Moro, Pedro (CDC/DDID/NCEZID/DHQP)" <[REDACTED]>
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Subject: RE: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135
Date: Wed, 19 Apr 2023 18:37:06 +0000
Importance: Normal
Embedded: Monthly_Status_Report_-_Lukos_15135; Lukos_Feb_Monthly_Report; Monthly_Report_-_Lukos_15135

Good afternoon,

This request is specific to task 6: v-safe Pregnancy Registry and pregnancy related issues, while VAERS program is under task 2 and task 4

For deliverables under C4, attached are 3 monthly reports I have received for Jan, Feb, and Mar 2023. Outlook search strategy "lukos report"

Tasks 2-6	Provide status report for all tasks that identifies, accomplishments, status of on-going projects challenges/barriers and proposed solutions	1 Word Document by Email	15th day of each month	COR
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Thank you,
Ruth

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, April 17, 2023 11:14 AM
To: Olson, Christine (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Kim, Sehwa (Susan) (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Shay, David (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Starrett, Tracie (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: FW: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135
Importance: High

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Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Alldredge, Berta (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
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3. VAERS: Pedro Moro ([REDACTED]), Ruth Gallego ([REDACTED])

Thanks,

Bonita Johnson
Principal Management Official
Immunization Safety Office/DHQP/NCEZID

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[REDACTED]>
Sent: Wednesday, April 12, 2023 3:00 PM
To: Alldredge, Berta (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Subject: Additional Item to Discuss during Teams Meeting regarding FOIA 23-00947 - Lukos Clinical Contract 15135

Attached is an additional item to discussion during Teams Meeting regarding FOIA 23-00947

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
[REDACTED]

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