

Sent: Tue, 16 Aug 2022 19:21:56 +0000
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP); Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

I would simply say, (b)(5)

(b)(5)

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Tuesday, August 16, 2022 3:14 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

In an effort to ensure that we are responding to the requester appropriately, please confirm that the following response is accurate.

(b)(5)

Thanks so much!!!

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 22, 2022 12:00 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

The only reports or publications that might derive from FDA data mining results would be publications for myocarditis and TTS, which we've already provided.

I think there's a misconception that some formal report or presentation is generated after the data mining results are released. Those data are taken into consideration of evaluating potential safety signals, but no such reports or presentations were created specifically due to results from data mining.

With regard to safety signal evaluation, we've already provided ACIP presentations, daily and weekly VAERS data tables, PRR data tables, and EB data mining results from FDA. I don't think we have anything else we can offer.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 22, 2022 11:44 AM
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Subject: RE: 22-01789-FOIA: Request for Documents

Or if the concerns from the data mining produced a scientific article that would also be responsive.

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Friday, July 22, 2022 10:50 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good Morning Dr. Su,

After reviewing the request again, the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC. With that said, is/was there anything that drew concerns with the data mining reports that may have motivated you or anyone else to produce a report expressing concerns? If yes, please provide documentation. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, July 20, 2022 12:08 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Please see enclosed emails, which contain the data mining results from FDA during Feb 1 through Sept 30, 2021, inclusive, as specified in the FOIA request. I received no reports during this

period until Mar 16. The reports are included as enclosures in these emails; if time permits, we can copy and paste those reports so the names of people in the email are not disclosed.

Please let me know if you have any questions, or need more information from me. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, July 20, 2022 11:25 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Hi John,

We need those data mining report that ISO received from David Menschik to close out this request. Thanks!

-p

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: Friday, July 8, 2022 8:55 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

LoL, please don't hate me...The request is asking us to provide possible data mining results that FDA sent ISO. Therefore, we have to search and provide the responsive documents. What will happen next is that CDC FOIA Office will redact the reports since they are from FDA (another federal agency) and direct the requester to FDA. This will show that we conducted the search and it addresses the original concern of FDA

(b)(5) Keep in mind, that the FOIA process does not share other federal agencies records. However, we still have to conducted the search and surrender the documents but the actual data is redacted.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 8, 2022 8:37 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Okay, that ask makes more sense. Yes, we did receive data mining reports. David Menschik at FDA sends them to us. So yes, please refer to FDA for those reports. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 8, 2022 8:31 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good morning,

For clarification, are you saying FDA did not send us any reports regarding data mining? This request is asking for possible data mining results that we would have received from FDA. Please advise.

Best,
-p

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, July 7, 2022 8:01 PM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi Elnetta,

To my knowledge, no reports of possible concern based on data mining results were created. Please let me know if you have any questions. Thanks!

- John

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Thursday, July 7, 2022 7:50 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: FW: 22-01789-FOIA: Request for Documents

Good Morning Dr. Moro and Dr. Su,

We received the attached FOIA requesting all "reports of possible concern based on the data mining results" the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating

Procedures for COVID-19. This FOIA request appears to be similar to a previous FOIA 22-01479 specifically portion #2. See attached CDC adverse event FOIA document.

Any assistance, comments, and input you can provide is greatly appreciated. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
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Phone: 404.498.0360

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, August 17, 2022 1:12 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

John and all...

I think your TTS & myocarditis papers are responsive being that EB data mining contributed to signal detection.

My main concerns are

- ensuring we are providing the responsive documents that addresses the request
- how do we address follow-up questions regarding data mining and initial response

(b)(5)

In the spirit of FOIA we are providing those documents that are responsive.

(b)(5)

(b)(5)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, August 17, 2022 10:40 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

To be clear: no documents, other than the results themselves provided by FDA, contain Empirical Bayesian (EB) data mining results.

EB data mining contributed to signal detection of specific adverse events later determined to be causally associated with COVID-19 vaccines: thrombosis with thrombocytopenia syndrome (TTS) and Janssen's Ad26.COVID.S vaccine, and myocarditis and the mRNA COVID-19 vaccines. Because of that contribution, I suggested links to those papers.

If the intent is to identify documents that contain the actual results of EB data mining itself, the only such documents are the EB data mining results provided by FDA – and we’ve already provided those results.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, August 17, 2022 10:30 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Good morning,

After a good night’s sleep, I have some follow-up questions.

Are we saying that all the links found on the [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) page in the section titled COVID-19 Vaccine Safety Articles and Studies by Topic include FDA data mining? If yes, then we can refer them to the link as proposed by Tom and have them to scroll down to the specific area on the page. If not, I recommend that we include the listing of specific articles that Dr. Su provided to us on TTS and myocarditis. If we provide a general link, we must provide the specific direction to the actual responsive materials.

Regarding the link to ACIP, are we saying that all ACIP meetings after January 27, 2021, include FDA data mining results/review of possible concerns following the COVID-19 vaccination? If that is not the case, then we need specific meetings which Elnetta already has a listing of ACIP meetings with presentations on TTS & myocarditis from Oct. 2021 – May 2022.

Please advise on both points.

Thanks,
-p

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 4:34 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Per Stephanie,

ISO response:

- CDC reports that incorporate FDA data mining results are publicly available at: [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) scroll down to COVID-19 Vaccine Safety Articles and Studies by Topic and [ACIP Meetings Information | CDC](#) beginning January 27, 2021 to present.

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

Teleworking Mondays and Fridays

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Sent: Tuesday, August 16, 2022 4:19 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Well, the data mining for mRNA vaccines didn't really contribute to much of anything. You might want to just say something like, reports that incorporate FDA data provided to CDC are available at

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Tuesday, August 16, 2022 4:00 PM

To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)

<pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: Re: 22-01789-FOIA: Request for Documents

That looks okay to me.

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
(404) 498-0698 (office)
(404) 498-0666 (fax)

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 3:59:13 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Tom and John,

Given your responses, confirming you are OK with DHQP FOIA providing the following response in the FOIA response sheet:

Results provided from FDA's Empirical Bayesian data mining have contributed to CDC reports on vaccine safety concerns. This information is publicly available on the following CDC websites:

[Vaccine Safety Publications](#) | [Research](#) | [Vaccine Safety](#) | [CDC and ACIP Meetings Information](#) | [CDC](#)

Thanks.

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

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Atlanta, GA 30329

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(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

Teleworking Mondays and Fridays

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Sent: Tuesday, August 16, 2022 3:48 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

I would prefer the minimalist approach if that possible and just refer to [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) and [ACIP Meetings Information | CDC](#) for CDC's reports on vaccine safety concerns.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Tuesday, August 16, 2022 3:33 PM

To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Maybe I can offer an abridged version of my response to PerStephanie:

“ The only reports of concern based on Empirical Bayesian data mining results would be publications for myocarditis and thrombosis with thrombocytopenia syndrome, links to which have already been provided.”

In truth, we really didn't base any reports on EB data mining results – but they contributed to analyses that were published on myocarditis and TTS.

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>

Sent: Tuesday, August 16, 2022 3:25 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie

(CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
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Tom,
Reattaching the original request from ICAN (see PDF).

PerStephanie- can you share the draft FOIA response sheet so Tom and John can see how this may be submitted back to the FOIA office?

Thanks.
-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

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Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
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Could I see the original FOIA request. Did it come in a letter?

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Tuesday, August 16, 2022 3:14 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Importance: High

In an effort to ensure that we are responding to the requester appropriately, please confirm that the following response is accurate.

(b)(5)

Thanks so much!!!

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Friday, July 22, 2022 12:00 PM

To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

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The only reports or publications that might derive from FDA data mining results would be publications for myocarditis and TTS, which we've already provided.

I think there's a misconception that some formal report or presentation is generated after the data mining results are released. Those data are taken into consideration of evaluating potential safety signals, but no such reports or presentations were created specifically due to results from data mining.

With regard to safety signal evaluation, we've already provided ACIP presentations, daily and weekly VAERS data tables, PRR data tables, and EB data mining results from FDA. I don't think we have anything else we can offer.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Friday, July 22, 2022 11:44 AM

To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Or if the concerns from the data mining produced a scientific article that would also be responsive.

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>

Sent: Friday, July 22, 2022 10:50 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good Morning Dr. Su,

After reviewing the request again, the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC. With that said, is/was there anything that drew concerns with the data mining reports that may have motivated you or anyone else to produce a report expressing concerns? If yes, please provide documentation. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
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Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, July 20, 2022 12:08 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Please see enclosed emails, which contain the data mining results from FDA during Feb 1 through Sept 30, 2021, inclusive, as specified in the FOIA request. I received no reports during this period until Mar 16. The reports are included as enclosures in these emails; if time permits, we can copy and paste those reports so the names of people in the email are not disclosed.

Please let me know if you have any questions, or need more information from me. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, July 20, 2022 11:25 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Hi John,

We need those data mining report that ISO received from David Menschik to close out this request. Thanks!

-p

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: Friday, July 8, 2022 8:55 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

LoL, please don't hate me...The request is asking us to provide possible data mining results that FDA sent ISO. Therefore, we have to search and provide the responsive documents. What will happen next is that CDC FOIA Office will redact the reports since they are from FDA (another federal agency) and direct the requester to FDA. This will show that we conducted the search and it addresses the original concern of FDA sharing data mining results. Keep in mind, that the FOIA process does not share other federal agencies records. However, we still have to conducted the search and surrender the documents but the actual data is redacted.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 8, 2022 8:37 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Okay, that ask makes more sense. Yes, we did receive data mining reports. David Menschik at FDA sends them to us. So yes, please refer to FDA for those reports. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 8, 2022 8:31 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good morning,

For clarification, are you saying FDA did not send us any reports regarding data mining? This request is asking for possible data mining results that we would have received from FDA. Please advise.

Best,
-p

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, July 7, 2022 8:01 PM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi Elnetta,

To my knowledge, no reports of possible concern based on data mining results were created. Please let me know if you have any questions. Thanks!

- John

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Thursday, July 7, 2022 7:50 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: FW: 22-01789-FOIA: Request for Documents

Good Morning Dr. Moro and Dr. Su,

We received the attached FOIA requesting all "reports of possible concern based on the data mining results" the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating Procedures for COVID-19. This FOIA request appears to be similar to a previous FOIA 22-01479 specifically portion #2. See attached CDC adverse event FOIA document.

Any assistance, comments, and input you can provide is greatly appreciated. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 24 Aug 2022 15:17:02 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: DHQP_Policy (CDC); Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Subject: RE: 22-01789-FOIA: Request for Documents

Thanks, Elnetta and PerStephanie for all your work on this one! No additional comments/concerns on Jeremy and I.

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

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1600 Clifton Road, MS H16- 2

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(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Wednesday, August 24, 2022 11:09 AM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

This looks good to me. In fact, we can probably use this as a starting template for future FOIAs (i.e., simply add websites for publications and presentations as necessary to address the request). Thanks.

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Tuesday, August 23, 2022 4:30 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good afternoon all,

Whew! I hope the response to this FOIA request is finally at the point of being closed out/resolved.

PerStephanie and I met with the FOIA office on several occasions to review, re-review and interpret this FOIA request. Based on our conversation threads below, conversations with the FOIA office, and responses that have been provided for similar FOIA requests, attached for your review is "Detailed_Response_for_22-01789_Document_1" - our approach to respond. We are providing links to CDC reports that incorporate FDA data mining results that are publicly available, a listing of TTS and Myocarditis publications, and links to ACIP Meeting Presentations (October 2021 – May 2022) on Thrombosis with Thrombocytopenia Syndrome and Myocarditis following COVID-19 vaccinations that should appropriately address this FOIA request. Please review, provide comments/thoughts on our approach, and advise. Thank you.

Also attached are the initial FOIA requests for your reference. Keep in mind that the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Wednesday, August 17, 2022 1:15 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

PerStephanie,

Given where we are and the background of the FOIA request, it may be easier to have another call to chat about this one with our SMEs.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

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(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

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From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Wednesday, August 17, 2022 1:12 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Importance: High

John and all...

I think your TTS & myocarditis papers are responsive being that EB data mining contributed to signal detection.

My main concerns are

- ensuring we are providing the responsive documents that addresses the request
- how do we address follow-up questions regarding data mining and initial response

(b)(5)

In the spirit of FOIA we are providing those documents that are responsive.

(b)(5)

(b)(5)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Wednesday, August 17, 2022 10:40 AM

To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Nguyen, Lyn

(CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

To be clear: no documents, other than the results themselves provided by FDA, contain Empirical Bayesian (EB) data mining results.

EB data mining contributed to signal detection of specific adverse events later determined to be causally associated with COVID-19 vaccines: thrombosis with thrombocytopenia syndrome (TTS) and Janssen's Ad26.COV2.S vaccine, and myocarditis and the mRNA COVID-19 vaccines. Because of that contribution, I suggested links to those papers.

If the intent is to identify documents that contain the actual results of EB data mining itself, the only such documents are the EB data mining results provided by FDA – and we've already provided those results.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, August 17, 2022 10:30 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Good morning,

After a good night's sleep, I have some follow-up questions.

Are we saying that all the links found on the [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) page in the section titled COVID-19 Vaccine Safety Articles and Studies by Topic include FDA data mining? If yes, then we can refer them to the link as proposed by Tom and have them to scroll down to the specific area on the page. If not, I recommend that we include the listing of specific articles that Dr. Su provided to us on TTS and myocarditis. If we provide a general link, we must provide the specific direction to the actual responsive materials.

Regarding the link to ACIP, are we saying that all ACIP meetings after January 27, 2021, include FDA data mining results/review of possible concerns following the COVID-19 vaccination? If that is not the case, then we need specific meetings which

Elnetta already has a listing of ACIP meetings with presentations on TTS & myocarditis from Oct. 2021 – May 2022.

Please advise on both points.

Thanks,

-p

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>

Sent: Tuesday, August 16, 2022 4:34 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Per Stephanie,

ISO response:

- CDC reports that incorporate FDA data mining results are publicly available at: [Vaccine Safety Publications | Research | Vaccine Safety | CDC scroll down to COVID-19 Vaccine Safety Articles and Studies by Topic and ACIP Meetings Information | CDC beginning January 27, 2021 to present.](#)

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

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(E-mail) ivx1@cdc.gov

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Tuesday, August 16, 2022 4:19 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Well, the data mining for mRNA vaccines didn't really contribute to much of anything. You might want to just say something like, reports that incorporate FDA data provided to CDC are available at

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, August 16, 2022 4:00 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: Re: 22-01789-FOIA: Request for Documents

That looks okay to me.

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
(404) 498-0698 (office)
(404) 498-0666 (fax)

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 3:59:13 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Tom and John,

Given your responses, confirming you are OK with DHQP FOIA providing the following response in the FOIA response sheet:

Results provided from FDA's Empirical Bayesian data mining have contributed to CDC reports on vaccine safety concerns. This information is publicly available on the following CDC websites:

[Vaccine Safety Publications | Research | Vaccine Safety | CDC and ACIP Meetings Information | CDC](#)

Thanks.

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

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Atlanta, GA 30329

(Tel) 404.639.7391

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(E-mail) ivx1@cdc.gov

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Sent: Tuesday, August 16, 2022 3:48 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

I would prefer the minimalist approach if that possible and just refer to [Vaccine Safety Publications | Research | Vaccine Safety | CDC and ACIP Meetings Information | CDC](#) for CDC's reports on vaccine safety concerns.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Tuesday, August 16, 2022 3:33 PM

To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Maybe I can offer an abridged version of my response to PerStephanie:

“ The only reports of concern based on Empirical Bayesian data mining results would be publications for myocarditis and thrombosis with thrombocytopenia syndrome, links to which have already been provided.”

In truth, we really didn't base any reports on EB data mining results – but they contributed to analyses that were published on myocarditis and TTS.

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>

Sent: Tuesday, August 16, 2022 3:25 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Tom,

Reattaching the original request from ICAN (see PDF).

PerStephanie- can you share the draft FOIA response sheet so Tom and John can see how this may be submitted back to the FOIA office?

Thanks.

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

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(E-mail) ivx1@cdc.gov

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Tuesday, August 16, 2022 3:22 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Could I see the original FOIA request. Did it come in a letter?

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Tuesday, August 16, 2022 3:14 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

In an effort to ensure that we are responding to the requester appropriately, please confirm that the following response is accurate.

(b)(5)

Thanks so much!!!

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 22, 2022 12:00 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

The only reports or publications that might derive from FDA data mining results would be publications for myocarditis and TTS, which we've already provided.

I think there's a misconception that some formal report or presentation is generated after the data mining results are released. Those data are taken into consideration of evaluating potential safety signals, but no such reports or presentations were created specifically due to results from data mining.

With regard to safety signal evaluation, we've already provided ACIP presentations, daily and weekly VAERS data tables, PRR data tables, and EB data mining results from FDA. I don't think we have anything else we can offer.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 22, 2022 11:44 AM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Or if the concerns from the data mining produced a scientific article that would also be responsive.

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Friday, July 22, 2022 10:50 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good Morning Dr. Su,

After reviewing the request again, the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC. With that said, is/was there anything that drew concerns with the data mining reports that may have motivated you or anyone else to produce a report expressing concerns? If yes, please provide documentation. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell13@cdc.gov
Phone: 404.498.0360

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, July 20, 2022 12:08 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Please see enclosed emails, which contain the data mining results from FDA during Feb 1 through Sept 30, 2021, inclusive, as specified in the FOIA request. I received no reports during this

period until Mar 16. The reports are included as enclosures in these emails; if time permits, we can copy and paste those reports so the names of people in the email are not disclosed.

Please let me know if you have any questions, or need more information from me. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, July 20, 2022 11:25 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Hi John,

We need those data mining report that ISO received from David Menschik to close out this request. Thanks!

-p

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: Friday, July 8, 2022 8:55 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

LoL, please don't hate me...The request is asking us to provide possible data mining results that FDA sent ISO. Therefore, we have to search and provide the responsive documents. What will happen next is that CDC FOIA Office will redact the reports since they are from FDA (another federal agency) and direct the requester to FDA. This will show that we conducted the search and it addresses the original concern of FDA sharing data mining results. Keep in mind, that the FOIA process does not share other federal agencies records. However, we still have to conducted the search and surrender the documents but the actual data is redacted.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 8, 2022 8:37 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Okay, that ask makes more sense. Yes, we did receive data mining reports. David Menschik at FDA sends them to us. So yes, please refer to FDA for those reports. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 8, 2022 8:31 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good morning,

For clarification, are you saying FDA did not send us any reports regarding data mining? This request is asking for possible data mining results that we would have received from FDA. Please advise.

Best,
-p

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, July 7, 2022 8:01 PM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi Elnetta,

To my knowledge, no reports of possible concern based on data mining results were created. Please let me know if you have any questions. Thanks!

- John

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Thursday, July 7, 2022 7:50 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: FW: 22-01789-FOIA: Request for Documents

Good Morning Dr. Moro and Dr. Su,

We received the attached FOIA requesting all "reports of possible concern based on the data mining results" the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating

Procedures for COVID-19. This FOIA request appears to be similar to a previous FOIA 22-01479 specifically portion #2. See attached CDC adverse event FOIA document.

Any assistance, comments, and input you can provide is greatly appreciated. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR)
Sent: Tue, 23 Aug 2022 20:29:43 +0000
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: DHQP_Policy (CDC); Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Subject: RE: 22-01789-FOIA: Request for Documents
Attachments: IR#0802F - CDC - Reports of Possible Concern – VAERS SOP for COVID-19.pdf, PAL Request Form.pdf, Detailed_Response_for_22-01789_Document_1.docx

Good afternoon all,

Whew! I hope the response to this FOIA request is finally at the point of being closed out/resolved.

PerStephanie and I met with the FOIA office on several occasions to review, re-review and interpret this FOIA request. Based on our conversation threads below, conversations with the FOIA office, and responses that have been provided for similar FOIA requests, attached for your review is "Detailed_Response_for_22-01789_Document_1" - our approach to respond. We are providing links to CDC reports that incorporate FDA data mining results that are publicly available, a listing of TTS and Myocarditis publications, and links to ACIP Meeting Presentations (October 2021 – May 2022) on Thrombosis with Thrombocytopenia Syndrome and Myocarditis following COVID-19 vaccinations that should appropriately address this FOIA request. Please review, provide comments/thoughts on our approach, and advise. Thank you.

Also attached are the initial FOIA requests for your reference. Keep in mind that the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Wednesday, August 17, 2022 1:15 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

PerStephanie,

Given where we are and the background of the FOIA request, it may be easier to have another call to chat about this one with our SMEs.

Thanks.

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

Teleworking Mondays and Fridays

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Wednesday, August 17, 2022 1:12 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Importance: High

John and all...

I think your TTS & myocarditis papers are responsive being that EB data mining contributed to signal detection.

My main concerns are

- ensuring we are providing the responsive documents that addresses the request
- how do we address follow-up questions regarding data mining and initial response

(b)(5)

In the spirit of FOIA we are providing those documents that are responsive

(b)(5)

(b)(5)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, August 17, 2022 10:40 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

To be clear: no documents, other than the results themselves provided by FDA, contain Empirical Bayesian (EB) data mining results.

EB data mining contributed to signal detection of specific adverse events later determined to be causally associated with COVID-19 vaccines: thrombosis with thrombocytopenia syndrome (TTS) and Janssen's Ad26.COVID.S vaccine, and myocarditis and the mRNA COVID-19 vaccines. Because of that contribution, I suggested links to those papers.

If the intent is to identify documents that contain the actual results of EB data mining itself, the only such documents are the EB data mining results provided by FDA – and we've already provided those results.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, August 17, 2022 10:30 AM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Good morning,

After a good night's sleep, I have some follow-up questions.

Are we saying that all the links found on the [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) page in the section titled COVID-19 Vaccine Safety Articles and Studies by Topic include FDA data mining? If yes, then we can refer them to the link as proposed by Tom and have them to scroll down to the specific area on the page. If not, I recommend that we include the listing of specific articles that Dr. Su provided to us on

TTS and myocarditis. If we provide a general link, we must provide the specific direction to the actual responsive materials.

Regarding the link to ACIP, are we saying that all ACIP meetings after January 27, 2021, include FDA data mining results/review of possible concerns following the COVID-19 vaccination? If that is not the case, then we need specific meetings which Elnetta already has a listing of ACIP meetings with presentations on TTS & myocarditis from Oct. 2021 – May 2022.

Please advise on both points.

Thanks,

-p

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 4:34 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Per Stephanie,

ISO response:

- CDC reports that incorporate FDA data mining results are publicly available at: [Vaccine Safety Publications | Research | Vaccine Safety | CDC scroll down to COVID-19 Vaccine Safety Articles and Studies by Topic and ACIP Meetings Information | CDC beginning January 27, 2021 to present.](#)

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

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1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

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(E-mail) ivx1@cdc.gov

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Tuesday, August 16, 2022 4:19 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Well, the data mining for mRNA vaccines didn't really contribute to much of anything. You might want to just say something like, reports that incorporate FDA data provided to CDC are available at

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, August 16, 2022 4:00 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: Re: 22-01789-FOIA: Request for Documents

That looks okay to me.

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
(404) 498-0698 (office)
(404) 498-0666 (fax)

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 3:59:13 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Tom and John,

Given your responses, confirming you are OK with DHQP FOIA providing the following response in the FOIA response sheet:

Results provided from FDA's Empirical Bayesian data mining have contributed to CDC reports on vaccine safety concerns. This information is publicly available on the following CDC websites:
[Vaccine Safety Publications | Research | Vaccine Safety | CDC and ACIP Meetings Information | CDC](#)

Thanks.
-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

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Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Sent: Tuesday, August 16, 2022 3:48 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

I would prefer the minimalist approach if that possible and just refer to [Vaccine Safety Publications | Research | Vaccine Safety | CDC and ACIP Meetings Information | CDC](#) for CDC's reports on vaccine safety concerns.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, August 16, 2022 3:33 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Maybe I can offer an abridged version of my response to PerStephanie:

“ The only reports of concern based on Empirical Bayesian data mining results would be publications for myocarditis and thrombosis with thrombocytopenia syndrome, links to which have already been provided.”

In truth, we really didn't base any reports on EB data mining results – but they contributed to analyses that were published on myocarditis and TTS.

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 3:25 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Tom,
Reattaching the original request from ICAN (see PDF).

PerStephanie- can you share the draft FOIA response sheet so Tom and John can see how this may be submitted back to the FOIA office?

Thanks.
-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

Teleworking Mondays and Fridays

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Tuesday, August 16, 2022 3:22 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Could I see the original FOIA request. Did it come in a letter?

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Tuesday, August 16, 2022 3:14 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

In an effort to ensure that we are responding to the requester appropriately, please confirm that the following response is accurate.

(b)(5)

Thanks so much!!!

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 22, 2022 12:00 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

The only reports or publications that might derive from FDA data mining results would be publications for myocarditis and TTS, which we've already provided.

I think there's a misconception that some formal report or presentation is generated after the data mining results are released. Those data are taken into consideration of evaluating potential safety signals, but no such reports or presentations were created specifically due to results from data mining.

With regard to safety signal evaluation, we've already provided ACIP presentations, daily and weekly VAERS data tables, PRR data tables, and EB data mining results from FDA. I don't think we have anything else we can offer.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 22, 2022 11:44 AM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Or if the concerns from the data mining produced a scientific article that would also be responsive.

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Friday, July 22, 2022 10:50 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good Morning Dr. Su,

After reviewing the request again, the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC. With that said, is/was there anything that drew concerns with the data mining reports that may have motivated you or anyone else to produce a report expressing concerns? If yes, please provide documentation. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, July 20, 2022 12:08 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Please see enclosed emails, which contain the data mining results from FDA during Feb 1 through Sept 30, 2021, inclusive, as specified in the FOIA request. I received no reports during this period until Mar 16. The reports are included as enclosures in these emails; if time permits, we can copy and paste those reports so the names of people in the email are not disclosed.

Please let me know if you have any questions, or need more information from me. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, July 20, 2022 11:25 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Hi John,

We need those data mining report that ISO received from David Menschik to close out this request. Thanks!

-p

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: Friday, July 8, 2022 8:55 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

LoL, please don't hate me...The request is asking us to provide possible data mining results that FDA sent ISO. Therefore, we have to search and provide the responsive documents. What will happen next is that CDC FOIA Office will redact the reports since they are from FDA (another federal agency) and direct the requester to FDA. This will show that we conducted the search and it addresses the original concern of FDA sharing data mining results. Keep in mind, that the FOIA process does not share other federal agencies records. However, we still have to conducted the search and surrender the documents but the actual data is redacted.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 8, 2022 8:37 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP)

<psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Okay, that ask makes more sense. Yes, we did receive data mining reports. David Menschik at FDA sends them to us. So yes, please refer to FDA for those reports. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Friday, July 8, 2022 8:31 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Good morning,

For clarification, are you saying FDA did not send us any reports regarding data mining? This request is asking for possible data mining results that we would have received from FDA. Please advise.

Best,

-p

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Thursday, July 7, 2022 8:01 PM

To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Hi Elnetta,

To my knowledge, no reports of possible concern based on data mining results were created. Please let me know if you have any questions. Thanks!

- John

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>

Sent: Thursday, July 7, 2022 7:50 AM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Subject: FW: 22-01789-FOIA: Request for Documents

Good Morning Dr. Moro and Dr. Su,

We received the attached FOIA requesting all “reports of possible concern based on the data mining results” the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating Procedures for COVID-19. This FOIA request appears to be similar to a previous FOIA 22-01479 specifically portion #2. See attached CDC adverse event FOIA document.

Any assistance, comments, and input you can provide is greatly appreciated. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

CDC FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL

June 30, 2022

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

Re: "Reports of Possible Concern" – VAERS Standard Operating Procedures for COVID-19 (IR#0802F)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

All "reports of possible concern based on the data mining results" the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating Procedures for COVID-19.¹

Information helpful to fulfilling the request: The CDC's Immunization Safety Office is the likely custodian of responsive records.

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. (**Exhibit A.**) As part of its mission, ICAN actively investigates and disseminates information regarding vaccine safety issues for free, including through its website,² a weekly health news and talk show,³ and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a

¹ See <https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf>.

² <https://www.icandecide.org/>.

³ <https://thehighwire.com/>.

media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately take further administrative or legal action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.

Colin M. Farnsworth Esq.

Exhibit A

DECLARATION OF CATHARINE LAYTON

STATE OF TEXAS

COUNTY OF HAYS

I, Catharine Layton, being duly sworn on oath do say:

1. I am the Chief Operating Officer of the Informed Consent Action Network (ICAN), a not-for-profit 501(c)(3) organization whose mission is to disseminate scientific health information to the public.

2. I have been an officer of ICAN since its founding in 2016. I oversee all day-to-day operations of the organization and all ICAN's programs. Together with our CEO and Board, I ensure that all efforts are focused on our mission statement and ensure that ICAN stays in compliance with all required rules and regulations.

3. In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website hosts the organization's largest education program, The HighWire with Del Bigtree. Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

4. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

5. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts.

6. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act (FOIA).

7. ICAN uses records it obtains from its FOIA requests to carry out its public mission and support its role as a non-profit news-media organization in the field of health and medical safety, but as a non-profit, ICAN does not have a commercial interest in the records it seeks through FOIA.

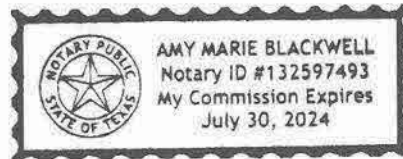
8. Based on what I know as the Chief Operating Officer, as well what has been demonstrated by ICAN's past and current investigative reporting, for purposes of FOIA's Fee Waiver provisions, ICAN certainly qualifies as a "representative of the news media."

Signed 3 day of May 2022


Signature of Catharine Layton

I, Amy Blackwell Notary public for the state of Texas witnessed
said Catharine Layton sign the above statement this 3 day of May, 2022
(month)

Notary Public for 



Submit New Request

Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

Aaron Siri

Attorney
Siri & Glimstad LLP
200 Park Ave
17th Floor
New York, 10166
Phone 212-532-1091
foia@sirillp.com

Requester Default Category: All Others

General Information

Action Office	HQ
Action Office Instructions	CDC/ATSDR FOIA Office 1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
Request Type	FOIA
Requester Category	News Media
Delivery Mode	

Shipping Address

Street1	200 Park Ave
Street2	17th Floor
City	New York
State	NY
State (Other)	
Country	United States
Zip Code	10166

Request Information

Description	[IR#0802F] All "reports of possible concern based on the data mining results" the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating Procedures for COVID-19. Information helpful to fulfilling the request: The CDC's Immunization Safety Office is the likely custodian of responsive records.
Date Range for Record Search:From	
Date Range for Record Search:To	
Description Document	IR#0802F - CDC - Reports of Possible Concern – VAERS SOP for COVID-19.pdf

Fee Information

Willing Amount	\$25
Fee Waiver Requested	Yes
Fee Waiver Request Reason	ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. See attached request for further details.
Willing to Pay All Fees	No

Billing Address

Street1	200 Park Ave
Street2	17th Floor
City	New York
State	NY
State (Other)	
Country	United States
Zip Code	10166

Other Information

Name	
Company	
Phone	
Fax	
Email Address	
Street1	200 Park Ave
Street2	17th Floor
City	New York
State	NY
State (Other)	
Country	United States
Zip Code	10166

Expedite Information

Expedite Reason

Detailed_Response_for_22-01789_Document_1

Request:

All “reports of possible concern based on the data mining results” the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating Procedures for COVID-19.1

ISO Response:

CDC reports that incorporate FDA data mining results are publicly available at: <https://www.cdc.gov/vaccinesafety/research/publications/index.html> and <https://www.cdc.gov/vaccines/acip/meetings/index.html>

Additionally, below is a listing of TTS and Myocarditis publications as well as links to ACIP Meeting Presentations (October 2021 – May 2022) on Thrombosis with Thrombocytopenia Syndrome and Myocarditis following COVID-19 vaccinations.

Below is a listing of TTS and Myocarditis publications that may serve as a resource.

TTS publications:

See I, Su JR, Lale A, Woo EJ, Guh AY, Shimabukuro TT, Streiff MB, Rao AK, Wheeler AP, Beavers SF, Durbin AP, Edwards K, Miller E, Harrington TA, Mba-Jonas A, Nair N, Nguyen DT, Talaat KR, Urrutia VC, Walker SC, Creech CB, Clark TA, DeStefano F, Broder KR. **US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021.** JAMA. 2021 Jun 22;325(24):2448-2456. doi: 10.1001/jama.2021.7517. PMID: 33929487; PMCID: PMC8087975. <https://pubmed.ncbi.nlm.nih.gov/33929487/>

See I, Lale A, Marquez P, Streiff MB, Wheeler AP, Tepper NK, Woo EJ, Broder KR, Edwards KM, Gallego R, Geller AI, Jackson KA, Sharma S, Talaat KR, Walter EB, Akpan IJ, Ortel TL, Urrutia VC, Walker SC, Yui JC, Shimabukuro TT, Mba-Jonas A, Su JR, Shay DK. **Case Series of Thrombosis With Thrombocytopenia Syndrome After COVID-19 Vaccination-United States, December 2020 to August 2021.** Ann Intern Med. 2022 Apr;175(4):513-522. doi: 10.7326/M21-4502. Epub 2022 Jan 18. PMID: 35038274; PMCID: PMC8787833. <https://pubmed.ncbi.nlm.nih.gov/35038274/>

Oliver SE, Wallace M, See I, Mbaeyi S, Godfrey M, Hadler SC, Jatlaoui TC, Twentyman E, Hughes MM, Rao AK, Fiore A, Su JR, Broder KR, Shimabukuro T, Lale A, Shay DK, Markowitz LE, Wharton M, Bell BP, Brooks O, McNally V, Lee GM, Talbot HK, Daley MF. Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices - United States, December 2021. MMWR Morb Mortal Wkly Rep. 2022 Jan 21;71(3):90-95. doi: 10.15585/mmwr.mm7103a4. PMID: 35051137; PMCID: PMC8774160. https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm?s_cid=mm7103a4_w

Detailed_Response_for_22-01789_Document_1

Myocarditis publications:

Paddock CD, Reagan-Steiner S, Su JR, Oster ME, Martines RB, Bhatnagar J, Shimabukuro TT. Autopsy Histopathologic Cardiac Findings in Two Adolescents Following the Second COVID-19 Vaccine Dose. *Arch Pathol Lab Med* 2022 Apr 11. Doi: 10.5858/arpa.2022-0084-LE. Online ahead of print.

Block JP, Boehmer TK, Forrest CB, Carton TW, Lee GM, Ajani UA, Christakis DA, Cowell LG, Draper C, Ghildayal N, Harris AM, Kappelman MD, Ko JY, Mayer KH, Nagavedu K, Oster ME, Paranjape A, Puro J, Ritchey MD, Shay DK, Thacker D, Gundlapalli AV. Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination – PCORnet, United States, January 2021-January 2022. *MMWR Morb Mortal Wkly Rep*. 2022 Apr 1;71.

Oster ME, Shay DK, Su JR, Gee J, Creech B, Broder KR, Edwards K, Soslow JH, Dendy JM, Schlaudecker E, Lang SM, Barnett ED, Ruberg FL, Smith MJ, Campbell MJ, Lopes RD, Sperling LS, Baumblatt JA, Thompson DL, Marquez PL, Strid P, Woo J, Puglsey R, Reagan-Steiner S, DeStefano F, Shimabukuro TT. Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US from December 2020 to August 2021 *JAMA*. 2022 Jan 18;327(4):331-340. Online ahead of print.

Gargano JW, Wallace M, Hadler SC, Langley G, Su JR, Oster ME, Broder KR, Gee J, Weintraub E, Shimabukuro T, Scobie HM, Moulia D, Markowitz LE, Wharton M, McNally VV, Romero JR, Keipp Talbot H, Lee GM, Daley MF, Oliver SE. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021 *MMWR Morb Mortal Wkly Rep*. 2021 Jul 9;70:977-982.

Shay DK, Shimabukuro, TT, DeStefano F. Myocarditis After Immunization with mRNA-Based COVID-19 Vaccines: Editorial. *JAMA Cardiol*. Published online June 29, 2021. doi:10.1001/jamacardio.2021.2821.

ACIP Presentations (October 2021 – May 2022) Thrombosis With Thrombocytopenia and Myocarditis following COVID-19 vaccinations

October 2021

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/03-COVID-Heaton-Douguih-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/06-COVID-Shimabukuro-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf>

Detailed_Response_for_22-01789_Document_1

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/09-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/08-COVID-Klein-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/09-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/10-COVID-jones-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/11-COVID-Dooling-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/12-COVID-Reddy-508.pdf>

November 2021

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/02-COVID-Gurtman-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/04-COVID-Oster-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/05-COVID-Shimabukuro-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/08-COVID-Oliver-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/02-COVID-Perez-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/04-COVID-Shimabukuro-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/05-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-19/06-COVID-Oliver-508.pdf>

Detailed_Response_for_22-01789_Document_1

December 2021

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/03-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/04-COVID-Oliver-2021-12-16.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/05-COVID-Su-508.pdf>

January 2022

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/02-COVID-Su-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/03-COVID-Hause-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/04-COVID-Klein-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/05-COVID-Twentyman-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/06-COVID-Oliver-2022-01-05.pdf>

February 2022

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/02-COVID-Das-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/03-COVID-Shimabukuro-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04-COVID-Kracalic-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/05-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/05-COVID-Talbot-508.pdf>

Detailed_Response_for_22-01789_Document_1

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/06-COVID-Wallace-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/07-COVID-Oliver-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/09-COVID-Tunis-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/10-COVID-Klein-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/11-COVID-Moulia-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/12-COVID-Oliver-508.pdf>

April 2022

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/03-COVID-Klein-Shimabukuro-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/04-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/05-COVID-Oliver-508.pdf>

May 2022

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/03-COVID-Shimabukuro-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/04-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/05-COVID-Sabharwal-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/06-COVID-Oliver-508.pdf>

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 16 Aug 2022 20:28:01 +0000
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Nguyen, Lyn (CDC/DDID/NCEZID/DHQP); Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: DHQP_Policy (CDC)
Subject: RE: 22-01789-FOIA: Request for Documents

I would use these two links: [Vaccine Safety Publications | Research | Vaccine Safety | CDC and ACIP Meetings Information | CDC](#)

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Tuesday, August 16, 2022 4:26 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

ISO Response: Reports that incorporate FDA data provided to CDC can be found at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>. As of July 22, 2022, no new unexpected safety signals in VAERS have been identified from FDA data mining results.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Tuesday, August 16, 2022 4:19 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Well, the data mining for mRNA vaccines didn't really contribute to much of anything. You might want to just say something like, reports that incorporate FDA data provided to CDC are available at

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, August 16, 2022 4:00 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: Re: 22-01789-FOIA: Request for Documents

That looks okay to me.

— John

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
(404) 498-0698 (office)
(404) 498-0666 (fax)

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 3:59:13 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Tom and John,

Given your responses, confirming you are OK with DHQP FOIA providing the following response in the FOIA response sheet:

Results provided from FDA's Empirical Bayesian data mining have contributed to CDC reports on vaccine safety concerns. This information is publicly available on the following CDC websites:
[Vaccine Safety Publications | Research | Vaccine Safety | CDC and ACIP Meetings Information | CDC](#)

Thanks.
-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

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I would prefer the minimalist approach if that possible and just refer to [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) and [ACIP Meetings Information | CDC](#) for CDC's reports on vaccine safety concerns.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
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Maybe I can offer an abridged version of my response to PerStephanie:

“ The only reports of concern based on Empirical Bayesian data mining results would be publications for myocarditis and thrombosis with thrombocytopenia syndrome, links to which have already been provided.”

In truth, we really didn't base any reports on EB data mining results – but they contributed to analyses that were published on myocarditis and TTS.

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Tom,
Reattaching the original request from ICAN (see PDF).

PerStephanie- can you share the draft FOIA response sheet so Tom and John can see how this may be submitted back to the FOIA office?

Thanks.
-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

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Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
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Could I see the original FOIA request. Did it come in a letter?

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Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

In an effort to ensure that we are responding to the requester appropriately, please confirm that the following response is accurate.

(b)(5)

Thanks so much!!!

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Friday, July 22, 2022 12:00 PM

To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

The only reports or publications that might derive from FDA data mining results would be publications for myocarditis and TTS, which we've already provided.

I think there's a misconception that some formal report or presentation is generated after the data mining results are released. Those data are taken into consideration of evaluating potential safety signals, but no such reports or presentations were created specifically due to results from data mining.

With regard to safety signal evaluation, we've already provided ACIP presentations, daily and weekly VAERS data tables, PRR data tables, and EB data mining results from FDA. I don't think we have anything else we can offer.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Friday, July 22, 2022 11:44 AM

To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Or if the concerns from the data mining produced a scientific article that would also be responsive.

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>

Sent: Friday, July 22, 2022 10:50 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Good Morning Dr. Su,

After reviewing the request again, the requester is seeking all “reports of possible concern based on the data mining results” the FDA shared with the CDC. With that said, is/was there anything that drew concerns with the data mining reports that may have motivated you or anyone else to produce a report expressing concerns? If yes, please provide documentation. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, July 20, 2022 12:08 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Please see enclosed emails, which contain the data mining results from FDA during Feb 1 through Sept 30, 2021, inclusive, as specified in the FOIA request. I received no reports during this period until Mar 16. The reports are included as enclosures in these emails; if time permits, we can copy and paste those reports so the names of people in the email are not disclosed.

Please let me know if you have any questions, or need more information from me. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, July 20, 2022 11:25 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Hi John,

We need those data mining report that ISO received from David Menschik to close out this request. Thanks!

-p

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: Friday, July 8, 2022 8:55 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

LoL, please don't hate me... The request is asking us to provide possible data mining results that FDA sent ISO. Therefore, we have to search and provide the responsive documents. What will happen next is that CDC FOIA Office will redact the reports since they are from FDA (another federal agency) and direct the requester to FDA. This will show that we conducted the search and it addresses the original concern of FDA sharing data mining results. Keep in mind, that the FOIA process does not share other federal agencies records. However, we still have to conducted the search and surrender the documents but the actual data is redacted.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 8, 2022 8:37 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Okay, that ask makes more sense. Yes, we did receive data mining reports. David Menschik at FDA sends them to us. So yes, please refer to FDA for those reports. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 8, 2022 8:31 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good morning,

For clarification, are you saying FDA did not send us any reports regarding data mining? This request is asking for possible data mining results that we would have received from FDA. Please advise.

Best,
-p

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, July 7, 2022 8:01 PM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi Elnetta,

To my knowledge, no reports of possible concern based on data mining results were created. Please let me know if you have any questions. Thanks!

- John

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Thursday, July 7, 2022 7:50 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: FW: 22-01789-FOIA: Request for Documents

Good Morning Dr. Moro and Dr. Su,

We received the attached FOIA requesting all "reports of possible concern based on the data mining results" the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating Procedures for COVID-19. This FOIA request appears to be similar to a previous FOIA 22-01479 specifically portion #2. See attached CDC adverse event FOIA document.

Any assistance, comments, and input you can provide is greatly appreciated. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 16 Aug 2022 20:35:27 +0000
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: DHQP_Policy (CDC)
Subject: RE: 22-01789-FOIA: Request for Documents

Thanks Lyn. We will close it out with your response below.

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 4:34 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Per Stephanie,

ISO response:

- CDC reports that incorporate FDA data mining results are publicly available at: [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) and [ACIP Meetings Information | CDC](#)

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

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To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Well, the data mining for mRNA vaccines didn't really contribute to much of anything. You might want to just say something like, reports that incorporate FDA data provided to CDC are available at

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
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Tom and John,

Given your responses, confirming you are OK with DHQP FOIA providing the following response in the FOIA response sheet:

Results provided from FDA's Empirical Bayesian data mining have contributed to CDC reports on vaccine safety concerns. This information is publicly available on the following CDC websites:

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Thanks.

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Tom,

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PerStephanie- can you share the draft FOIA response sheet so Tom and John can see how this may be submitted back to the FOIA office?

Thanks.

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

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Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

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(b)(5)

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To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

The only reports or publications that might derive from FDA data mining results would be publications for myocarditis and TTS, which we've already provided.

I think there's a misconception that some formal report or presentation is generated after the data mining results are released. Those data are taken into consideration of evaluating potential safety signals, but no such reports or presentations were created specifically due to results from data mining.

With regard to safety signal evaluation, we've already provided ACIP presentations, daily and weekly VAERS data tables, PRR data tables, and EB data mining results from FDA. I don't think we have anything else we can offer.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 22, 2022 11:44 AM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Or if the concerns from the data mining produced a scientific article that would also be responsive.

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Friday, July 22, 2022 10:50 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good Morning Dr. Su,

After reviewing the request again, the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC. With that said, is/was there anything that drew concerns with the data mining reports that may have motivated you or anyone else to produce a report expressing concerns? If yes, please provide documentation. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell13@cdc.gov
Phone: 404.498.0360

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, July 20, 2022 12:08 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Please see enclosed emails, which contain the data mining results from FDA during Feb 1 through Sept 30, 2021, inclusive, as specified in the FOIA request. I received no reports during this

period until Mar 16. The reports are included as enclosures in these emails; if time permits, we can copy and paste those reports so the names of people in the email are not disclosed.

Please let me know if you have any questions, or need more information from me. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, July 20, 2022 11:25 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Hi John,

We need those data mining report that ISO received from David Menschik to close out this request. Thanks!

-p

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Sent: Friday, July 8, 2022 8:55 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

LoL, please don't hate me...The request is asking us to provide possible data mining results that FDA sent ISO. Therefore, we have to search and provide the responsive documents. What will happen next is that CDC FOIA Office will redact the reports since they are from FDA (another federal agency) and direct the requester to FDA. This will show that we conducted the search and it addresses the original concern of FDA sharing data mining results. Keep in mind, that the FOIA process does not share other federal agencies records. However, we still have to conducted the search and surrender the documents but the actual data is redacted.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, July 8, 2022 8:37 AM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Okay, that ask makes more sense. Yes, we did receive data mining reports. David Menschik at FDA sends them to us. So yes, please refer to FDA for those reports. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Friday, July 8, 2022 8:31 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good morning,

For clarification, are you saying FDA did not send us any reports regarding data mining? This request is asking for possible data mining results that we would have received from FDA. Please advise.

Best,
-p

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, July 7, 2022 8:01 PM
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Hi Elnetta,

To my knowledge, no reports of possible concern based on data mining results were created. Please let me know if you have any questions. Thanks!

- John

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Thursday, July 7, 2022 7:50 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: FW: 22-01789-FOIA: Request for Documents

Good Morning Dr. Moro and Dr. Su,

We received the attached FOIA requesting all "reports of possible concern based on the data mining results" the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating

Procedures for COVID-19. This FOIA request appears to be similar to a previous FOIA 22-01479 specifically portion #2. See attached CDC adverse event FOIA document.

Any assistance, comments, and input you can provide is greatly appreciated. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 24 Aug 2022 01:55:51 +0000
To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR); Nguyen, Lyn (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: DHQP_Policy (CDC); Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Subject: RE: 22-01789-FOIA: Request for Documents

Hi folks,

I think the materials provided are sufficient to respond to the FOIA. Thanks!

- John

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Tuesday, August 23, 2022 4:30 PM
To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Good afternoon all,

Whew! I hope the response to this FOIA request is finally at the point of being closed out/resolved.

PerStephanie and I met with the FOIA office on several occasions to review, re-review and interpret this FOIA request. Based on our conversation threads below, conversations with the FOIA office, and responses that have been provided for similar FOIA requests, attached for your review is "Detailed_Response_for_22-01789_Document_1" - our approach to respond. We are providing links to CDC reports that incorporate FDA data mining results that are publicly available, a listing of TTS and Myocarditis publications, and links to ACIP Meeting Presentations (October 2021 – May 2022) on Thrombosis with Thrombocytopenia Syndrome and Myocarditis following COVID-19 vaccinations that should appropriately address this FOIA request. Please review, provide comments/thoughts on our approach, and advise. Thank you.

Also attached are the initial FOIA requests for your reference. Keep in mind that the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Wednesday, August 17, 2022 1:15 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

PerStephanie,

Given where we are and the background of the FOIA request, it may be easier to have another call to chat about this one with our SMEs.

Thanks.
-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

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From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Sent: Wednesday, August 17, 2022 1:12 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

John and all...

I think your TTS & myocarditis papers are responsive being that EB data mining contributed to signal detection.

My main concerns are

- ensuring we are providing the responsive documents that addresses the request
- how do we address follow-up questions regarding data mining and initial response

(b)(5)

In the spirit of FOIA we are providing those documents that are responsive.

(b)(5)

(b)(5)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Wednesday, August 17, 2022 10:40 AM

To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

To be clear: no documents, other than the results themselves provided by FDA, contain Empirical Bayesian (EB) data mining results.

EB data mining contributed to signal detection of specific adverse events later determined to be causally associated with COVID-19 vaccines: thrombosis with thrombocytopenia syndrome (TTS) and Janssen's Ad26.COVID.S vaccine, and myocarditis and the mRNA COVID-19 vaccines. Because of that contribution, I suggested links to those papers.

If the intent is to identify documents that contain the actual results of EB data mining itself, the only such documents are the EB data mining results provided by FDA – and we've already provided those results.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Wednesday, August 17, 2022 10:30 AM

To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents
Importance: High

Good morning,

After a good night's sleep, I have some follow-up questions.

Are we saying that all the links found on the [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) page in the section titled COVID-19 Vaccine Safety Articles and Studies by Topic include FDA data mining? If yes, then we can refer them to the link as proposed by Tom and have them to scroll down to the specific area on the page. If not, I recommend that we include the listing of specific articles that Dr. Su provided to us on TTS and myocarditis. If we provide a general link, we must provide the specific direction to the actual responsive materials.

Regarding the link to ACIP, are we saying that all ACIP meetings after January 27, 2021, include FDA data mining results/review of possible concerns following the COVID-19 vaccination? If that is not the case, then we need specific meetings which Elnetta already has a listing of ACIP meetings with presentations on TTS & myocarditis from Oct. 2021 – May 2022.

Please advise on both points.

Thanks,
-p

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 4:34 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Per Stephanie,

ISO response:

- CDC reports that incorporate FDA data mining results are publicly available at: [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) scroll down to COVID-19 Vaccine Safety Articles and Studies by Topic and [ACIP Meetings Information | CDC](#) beginning January 27, 2021 to present.

-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Sent: Tuesday, August 16, 2022 4:19 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Well, the data mining for mRNA vaccines didn't really contribute to much of anything. You might want to just say something like, reports that incorporate FDA data provided to CDC are available at

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Tuesday, August 16, 2022 4:00 PM

To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: Re: 22-01789-FOIA: Request for Documents

That looks okay to me.

— John

John R. Su, MD, PhD, MPH

CAPT, USPHS

Immunization Safety Office

Centers for Disease Control and Prevention

1600 Clifton Rd MS V18-4

Atlanta, GA 30329
(404) 498-0698 (office)
(404) 498-0666 (fax)

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>
Sent: Tuesday, August 16, 2022 3:59:13 PM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>
Subject: RE: 22-01789-FOIA: Request for Documents

Tom and John,

Given your responses, confirming you are OK with DHQP FOIA providing the following response in the FOIA response sheet:

Results provided from FDA's Empirical Bayesian data mining have contributed to CDC reports on vaccine safety concerns. This information is publicly available on the following CDC websites:
[Vaccine Safety Publications](#) | [Research](#) | [Vaccine Safety](#) | [CDC and ACIP Meetings Information](#) | [CDC](#)

Thanks.
-Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

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From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Sent: Tuesday, August 16, 2022 3:48 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nguyen, Lyn (CDC/DDID/NCEZID/DHQP)

<ivx1@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

I would prefer the minimalist approach if that possible and just refer to [Vaccine Safety Publications | Research | Vaccine Safety | CDC](#) and [ACIP Meetings Information | CDC](#) for CDC's reports on vaccine safety concerns.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Tuesday, August 16, 2022 3:33 PM

To: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Maybe I can offer an abridged version of my response to PerStephanie:

“ The only reports of concern based on Empirical Bayesian data mining results would be publications for myocarditis and thrombosis with thrombocytopenia syndrome, links to which have already been provided.”

In truth, we really didn't base any reports on EB data mining results – but they contributed to analyses that were published on myocarditis and TTS.

- John

From: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>

Sent: Tuesday, August 16, 2022 3:25 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: DHQP_Policy (CDC) <DHQP_Policy@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Tom,

Reattaching the original request from ICAN (see PDF).

PerStephanie- can you share the draft FOIA response sheet so Tom and John can see how this may be submitted back to the FOIA office?

Thanks.

Lyn

Lyn Thi Nguyen, MPH (*she/her*)

Public Health Analyst - Division of Healthcare Quality Promotion – NCEZID

U.S. Centers for Disease Control and Prevention

1600 Clifton Road, MS H16- 2

Atlanta, GA 30329

(Tel) 404.639.7391

(Cell) 404.386.3994

(E-mail) ivx1@cdc.gov

Teleworking Mondays and Fridays

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Sent: Tuesday, August 16, 2022 3:22 PM

To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Could I see the original FOIA request. Did it come in a letter?

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Tuesday, August 16, 2022 3:14 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: Nguyen, Lyn (CDC/DDID/NCEZID/DHQP) <ivx1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Importance: High

In an effort to ensure that we are responding to the requester appropriately, please confirm that the following response is accurate.

(b)(5)

Thanks so much!!!

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Friday, July 22, 2022 12:00 PM

To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

The only reports or publications that might derive from FDA data mining results would be publications for myocarditis and TTS, which we've already provided.

I think there's a misconception that some formal report or presentation is generated after the data mining results are released. Those data are taken into consideration of evaluating potential safety signals, but no such reports or presentations were created specifically due to results from data mining.

With regard to safety signal evaluation, we've already provided ACIP presentations, daily and weekly VAERS data tables, PRR data tables, and EB data mining results from FDA. I don't think we have anything else we can offer.

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Friday, July 22, 2022 11:44 AM

To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Or if the concerns from the data mining produced a scientific article that would also be responsive.

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>

Sent: Friday, July 22, 2022 10:50 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Good Morning Dr. Su,

After reviewing the request again, the requester is seeking all "reports of possible concern based on the data mining results" the FDA shared with the CDC. With that said, is/was there anything that drew concerns with the data mining reports that may have motivated you or anyone else to produce a report expressing concerns? If yes, please provide documentation. Thank you.

Elnetta Mitchell, MBA

Goldbelt C6, LLC

DHQP/NCEZID/CDC

Centers for Disease Control and Prevention

Email: EMitchell3@cdc.gov

Phone: 404.498.0360

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Wednesday, July 20, 2022 12:08 PM

To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Please see enclosed emails, which contain the data mining results from FDA during Feb 1 through Sept 30, 2021, inclusive, as specified in the FOIA request. I received no reports during this period until Mar 16. The reports are included as enclosures in these emails; if time permits, we can copy and paste those reports so the names of people in the email are not disclosed.

Please let me know if you have any questions, or need more information from me. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Wednesday, July 20, 2022 11:25 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Importance: High

Hi John,

We need those data mining report that ISO received from David Menschik to close out this request. Thanks!

-p

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)

Sent: Friday, July 8, 2022 8:55 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

LoL, please don't hate me...The request is asking us to provide possible data mining results that FDA sent ISO. Therefore, we have to search and provide the responsive documents. What will happen next is that CDC FOIA Office will redact the reports since

they are from FDA (another federal agency) and direct the requester to FDA. This will show that we conducted the search and it addresses the original concern of FDA sharing data mining results. Keep in mind, that the FOIA process does not share other federal agencies records. However, we still have to conducted the search and surrender the documents but the actual data is redacted.

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Friday, July 8, 2022 8:37 AM

To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Hi PerStephanie,

Okay, that ask makes more sense. Yes, we did receive data mining reports. David Menschik at FDA sends them to us. So yes, please refer to FDA for those reports. Thanks!

- John

From: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Sent: Friday, July 8, 2022 8:31 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Good morning,

For clarification, are you saying FDA did not send us any reports regarding data mining? This request is asking for possible data mining results that we would have received from FDA. Please advise.

Best,

-p

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Thursday, July 7, 2022 8:01 PM

To: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>

Subject: RE: 22-01789-FOIA: Request for Documents

Hi Elnetta,

To my knowledge, no reports of possible concern based on data mining results were created. Please let me know if you have any questions. Thanks!

- John

From: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <ssx5@cdc.gov>
Sent: Thursday, July 7, 2022 7:50 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <pxt2@cdc.gov>
Subject: FW: 22-01789-FOIA: Request for Documents

Good Morning Dr. Moro and Dr. Su,

We received the attached FOIA requesting all “reports of possible concern based on the data mining results” the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating Procedures for COVID-19. This FOIA request appears to be similar to a previous FOIA 22-01479 specifically portion #2. See attached CDC adverse event FOIA document.

Any assistance, comments, and input you can provide is greatly appreciated. Thank you.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: EMitchell3@cdc.gov
Phone: 404.498.0360