From: Kristin X. Goddard

**Sent:** Fri, 30 Apr 2021 22:26:00 +0000

To: NICOLA P KLEIN; Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Hanson, Kayla E;

Ned Lewis

Subject: RE: updated VaST slideset - with chart review updates

Attachments: VSD RCA Covid-19 vax - update VaST - 05-03-2021.V2\_KH\_kg.pptx

(b)(5)

## Kristin

From: NICOLA P KLEIN < Nicola. Klein@kp.org> Sent: Thursday, April 29, 2021 5:56 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Hanson, Kayla E

<hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard <Kristin.X.Goddard@kp.org>; Ned Lewis

<Ned.Lewis@kp.org>

Subject: RE: updated VaST slideset

Eric and I revised the slides. Please use this version when updating. Nicky

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

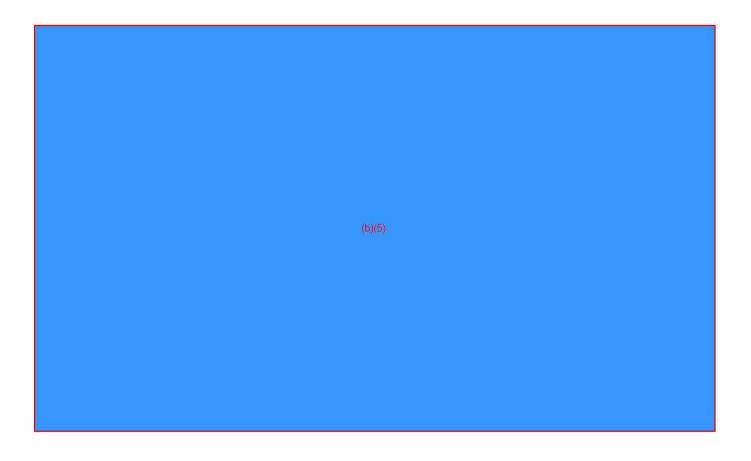
Sent: Thursday, April 29, 2021 6:58 AM

To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard

< Kristin.X.Goddard@kp.org>; NICOLA P KLEIN < Nicola.Klein@kp.org>; Ned Lewis < Ned.Lewis@kp.org>

Subject: updated VaST slideset

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From: NICOLA P KLEIN

**Sent:** Fri, 30 Apr 2021 00:56:19 +0000

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Hanson, Kayla E; Kristin X. Goddard;

Ned Lewis

Subject: RE: updated VaST slideset

Attachments: VSD RCA Covid-19 vax - update VaST - 05-03-2021.V2.pptx

Eric and I revised the slides. Please use this version when updating. Nicky

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

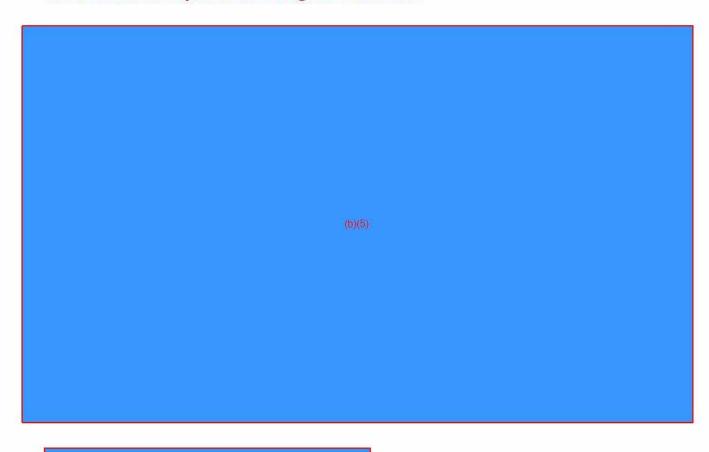
Sent: Thursday, April 29, 2021 6:58 AM

To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard

<Kristin.X.Goddard@kp.org>; NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>

Subject: updated VaST slideset

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Subject: updated VaST slideset Attachments: VSD RCA Covid-19 vax - update VaST - 05-03-2021.pptx

Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

Hanson, Kayla E; Kristin X. Goddard; NICOLA P KLEIN; Ned Lewis

Thu, 29 Apr 2021 13:58:08 +0000

From:

Sent:

To:

























































































































































































Walke, Henry (CDC/DDID/NCEZID/DPEI) From:

Sent: Thu, 4 Mar 2021 01:12:37 +0000 To: Walensky, Rochelle (CDC/OD)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD); Romanik, Nikki

Jo (CDC/OD/OCS)

Subject: Director's Brief: Thursday March 4, 2021

Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE - DIRECTORS BRIEF 20210304.pdf

# Will send prelim counts in AM

## Thursday March 3, 2021

	Cumulative Total	Daily	7-Day Daily Average	Change from Prior 7-Day Period
Cases <sup>2,3</sup>	28,514,774	54,276	63,938	-2.4%
Hospital Admissions (Confirmed) <sup>4</sup>	1,809,100	4,533	5,650	-13.0%
Hospital Admissions (All) <sup>4</sup>	3,354,035	9,251	11,372	-7.4%
Hospital In-Patient Beds ≥30% COVID-195	N/A	N/A	0.9%	-36.7%
Deaths <sup>2</sup>	515,277	2,103	1,990	-4.3%
Test Volume <sup>6</sup>	335,876,223	N/A	1,177,275	7.0%
Test Positivity <sup>6</sup>	8.9%	N/A	4.6%	-13.5%

	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Receiving 2 Doses (% Population)
Overall US	163,759,745	107,028,890	80,540,474	52,855,579 (15.9)	26,957,804 (8.1)
Federal Pharmacy Partnership					Commence of the Commence of th
for Long-Term Care Program	N/A	N/A	7,218,655	4,669,986	2,510,471
(Subset of Overall Numbers)					

Data as of Mar 3, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID Data Tracker

Progress towards 100M dose target (doses reported since 1/20/2021; Day 41): 64,015,193 (overall); 5,310,399 (LTCF)

- Cases: The current 7-day average of new cases decreased by 2.4% compared to the previous week. There has been a 7-week downward trend resulting in an overall 74.4% decline since the highest peak of the 7-day moving average of new cases on January 11, 2021 (249,360 to 63,938).
  - 28,514,774 COVID-19 cases reported as of Mar 2, 2021 with 54,276 new cases reported.
  - The 7-day average number of new cases decreased by 2.4% to 63,938 new cases per day compared to the previous 7-day period.\*
  - During the 7 days ending March 1, 2021, regarding cases:

<sup>1</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 05:00 ET today.

<sup>&</sup>lt;sup>2</sup> Time period: Jan 22, 2020 – Mar 2, 2021; confirmed and probable cases.

<sup>3</sup> California reported 806 historical deaths on Feb 25, and Texas reported 2,990 historical cases on Feb 27, 2021 and 1,840 historical cases on Mar 1, 2021. This will temporarily impact rates and averages. Beginning Feb 24, 2021, South Carolina reconciles their historical data every Wednesday.

<sup>\*</sup>Time period: Aug 1, 2020 - Mar 1, 2021; (All) includes both confirmed and suspect cases.

<sup>&</sup>lt;sup>1</sup> Time period: Feb 16, 2021 - Mar 1, 2021.

Time period: Mar 1, 2020 - Feb 28, 2021; Time period for test volume 7-day average and percent change: Feb 11, 2021 - Feb 24, 2021.

includes data for US States, DC, US Territories, and Federal entities, and pharmacies (see table on last page for details). Total doses allocated are through Mar 28,

- 26 (46.4%) jurisdictions are decreasing
- 30 (53.6%) jurisdictions are increasing

\*The current 7-day average of new cases is impacted by a historical correction of 2,990 and 1,840 cases reported by Texas on February 27, 2021 and March 1, 2021, respectively. The 7-day average number of new cases (excluding historical cases reported in the past two weeks) decreased by 3.4% to 63,248 new cases per day compared to the previous 7-day average of 65,485.

- Testing: RT-PCR test volume appears to be increasing. RT-PCR test positivity continues to decline (7-day average now 4.6%); 1 jurisdiction remains >=10% positivity (TX).
  - The national 7-day average test volume for Feb 18 Feb 24, 2021, was 1,177,275 up 7.0% from 1,099,850 the previous 7-days
  - The national 7-day average percent positivity for Feb 22 Feb 28, 2021, is 4.6%, down 0.7 percentage points from 5.3% the previous week
  - o 7-day average positivity is high (>=10%) in 1 jurisdiction (2% of all jurisdictions): TX
  - 7-day average positivity is low (<5%) in 28 jurisdictions (55% of all jurisdictions)</li>
  - Positivity is decreasing in 46 jurisdictions (90% of all jurisdictions)
- Hospitalizations: The new confirmed COVID-19 admissions 7-day average (5,650) has decreased 65.8% since the peak on January 9, 2021 (16,540)
  - The 7-day average number of new admissions of patients with confirmed COVID-19 decreased by 13.0% to 5,650 during the most recent week, Feb 23–Mar 1, 2021
  - The 7-day average number of hospitalized patients with confirmed COVID-19 decreased by 17.3% to 45,607 during the most recent week, Feb 23–Mar 1, 2021
  - The peak above refers to the date of the highest 7-day moving average
    - The single-day peaks are:
      - Admissions: Jan 05, 2021–18,009
      - Hospitalizations: Jan 05, 2021 125,422
- Deaths: The current 7-day average of new deaths decreased by 4.3% compared to the previous week. There has been a 7-week downward trend resulting in an overall 41.1% decline since the highest peak of the 7-day moving average of new deaths on January 13, 2021 (3,378 to 1,990).
  - 515,277 COVID-19 deaths reported as of Mar 2, 2021 with 2,103 new deaths reported.
  - The 7-day average number of new deaths decreased by 4.3% to 1,990 new deaths per day compared to the previous 7-day period.\*

\*The current 7-day average of new deaths is impacted by a historical correction of 806 deaths reported by California on February 25, 2021. The 7-day average number of new deaths (excluding historical deaths reported in the past two weeks) decreased by 9.8% to 1,875 new deaths per day compared to the previous 7-day average of 2,079.

 Emerging Variants: At least 48 jurisdictions with reported variant cases. CDC genomic surveillance activities continue to ramp up. There are more than 145,000 sequences in GISAID from U.S. submitters.

#### B.1.1.7 Variant

- Cumulative in US (AL, AK, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OR, PA, PR, RI, SC, TN, TX, UT, VA, WA, WI, WV, and WY)
  - 2,580\* cases in 48 jurisdictions
  - As of March 3, 2021, there are two cases attributed to the B.1.1.7 variant that also contains the E484K substitution in GISAID in Oregon and New York City.

#### P.1 Variant

- Cumulative in U.S. (AK, FL, MD, MN, OK, and OR)
  - 11\* cases in 6 jurisdictions
  - (SBU) There are two cases in New Jersey attributed to the P.1 variant that CDC is not authorized to report publicly. This case is not reflected in the total variant case numbers shown above.

#### B.1.351 Variant

- o Cumulative in US (CA, CT, DC, FL, GA, ID, IL, MA, MD, NC, NV, NY, SC, TN, TX, VA, WA)
  - 66\* cases in 17 jurisdictions
  - (SBU) There are two additional cases in New York, one additional case in Wyoming, and four additional cases in Washington attributed to the B.1.351 variant that CDC is not authorized to report publicly. These cases are not reflected in the total variant case numbers shown above.

### Other Variants

- CDC is monitoring other variants in addition to the variants of concern highlighted above, including B.1.427/9, B.1.526, and P.2 variants of interest. Currently, through NS3 enhanced surveillance, state public health laboratories are asked to submit specimens that contain the E484K or N501Y substitutions or deletions in the S protein for sequencing, isolation, and further characterization at CDC.
- Vaccine: More than 52 million people or 15.9% of the population have received at least 1 dose. Just reached an average of over 2 million doses administered per day
  - Overall, 80,540,474 vaccine doses have been administered.
    - In total, 15.9% (N= 52,855,579) of the population has received 1 or more doses.
    - 8.1% of the population (N= 26,957,804) has received two doses.
    - Progress towards 100M dose target (doses reported since 1/20/2021; Day 41):
       64,015,193 doses
      - Overall, 7,218,655 doses have been administered in LTCFs
      - 4,669,986 people in LTCFs have received 1 or more doses
  - Doses in LTCF reported since 01/20/2021 (Day 41): 5,310,399 doses
  - Daily vaccine doses administered and reported to CDC increased to an average of 2,010,790 doses reported per day over the past week (previous week: 1,454,731 doses reported per day, on average).
  - Retail Pharmacy Program: The Federal Retail Pharmacy Program is adapting to prioritize vaccinating all school staff and childcare workers during the month of March. CDC is also working with jurisdictions to prioritize this population in other delivery sites.

 Each year CDC helps distribute and administer about 80 million vaccines through its Vaccines for Children Program – we've now accomplished that same yearly total in 11.5 weeks.
 Additionally, we're now averaging 2 million doses administered per day.

#### Other Publications

Lancet Child and Adolescent Health: Factors associated with severe outcomes in patients with multisystem inflammatory syndrome in children (MIS-C), March-October 2020.

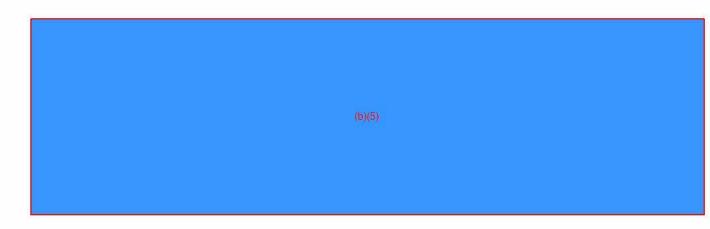
- Describes factors associated with severe outcomes for patients with COVID-19-associated multisystem inflammatory syndrome in children (MIS-C).
  - Paper describes 1,080 hospitalized patients <21 years with dates of MIS-C onset from March 11-October 10, 2020.
  - Outcomes of interest were ICU admission, decreased cardiac function, shock, myocarditis, and coronary artery abnormalities.
  - Demographic characteristics, signs and symptoms, and laboratory findings were assessed for associations with the outcomes, controlling for all pre-existing factors.
  - Primary results include:
    - Patients 6-12 years old were more likely to have severe outcomes compared to those under the age of 5 years, and these risks were even higher for patients 13-20 years old.
    - Male sex was associated with coronary artery abnormalities and myocarditis.
    - Non-Hispanic Black patients were more likely to be admitted to the ICU and experience decreased heart function.
    - Patients with shortness of breath and abdominal pain were more likely to be admitted to the ICU.
    - Elevated levels of certain lab markers (troponin, BNP, and proBNP, as well as d-dimer, CRP, and ferritin) and lower levels of lymphocytes and platelets were linked to ICU admission, shock and decreased cardiac function.
  - Manuscript being published 3/4

## MMWR Releases

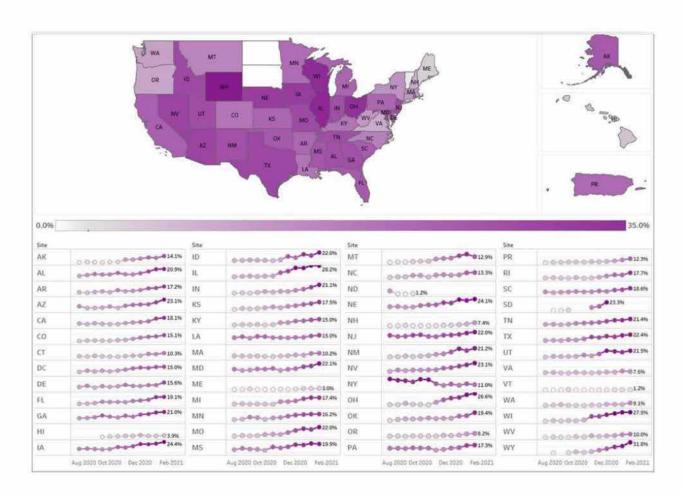
 Two MMWR reports related to COVID-19 are scheduled as part of the <u>regular issue</u> of the Weekly, with the embargo lifting on <u>Thursday</u>, <u>March 4</u>, at 1 pm. Please note that the titles, content, and timing might change.

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Page 289			
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**FYI**Updated the website today on national seroprevalence from two rounds in January. See below. <a href="https://covid.cdc.gov/covid-data-tracker/#national-lab">https://covid.cdc.gov/covid-data-tracker/#national-lab</a>



CDC COVID-19 Response Update Report

**DIRECTOR'S BRIEF** 

# Thursday, March 4, 2021



**US Department of Health and Human Services** 

Centers for Disease Control and Prevention

### Preliminary COVID-19 Case and Death Data<sup>1</sup>

	E	N. C.		
Data Through	Total Cases	New Cases	Total Deaths	New Deaths
Mar 3, 2021				

Source: State-level Aggregated Case and Death Counts (ACDC)

COVID-19 Summary							
	Cumulative Total	Daily	7-Day Daily Average	Change from Prior 7-Day Period			
Cases <sup>2,3</sup>	28,514,774	54,276	63,938	-2.4%			
Hospital Admissions (Confirmed) <sup>4</sup>	1,809,100	4,533	5,650	-13.0%			
Hospital Admissions (All) <sup>4</sup>	3,354,035	9,251	11,372	-7.4%			
Hospital In-Patient Beds ≥30% COVID-195	N/A	N/A	0.9%	-36.7%			
Deaths <sup>2</sup>	515,277	2,103	1,990	-4.3%			
Test Volume <sup>6</sup>	335,876,223	N/A	1,177,275	7.0%			
Test Positivity <sup>6</sup>	8.9%	N/A	4.6%	-13.5%			

Source: HHS Protect; DSEW

COVID-19 Vaccinations in the U	United States'
--------------------------------	----------------

	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Receiving 2 Doses (% Population)
Overall US	163,759,745	107,028,890	80,540,474	52,855,579 (15.9)	26,957,804 (8.1)
Federal Pharmacy Partnership					
for Long-Term Care Program	N/A	N/A	7,218,655	4,669,986	2,510,471
(Subset of Overall Numbers)	870		×8 35		

Data as of Mar 3, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID Data Tracker

Progress towards 100M dose target (doses reported since 1/20/2021; Day 41): 64,015,193 (overall); 5,310,399 (LTCF)

<sup>&</sup>lt;sup>1</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

<sup>&</sup>lt;sup>2</sup> Time period: Jan 22, 2020 – Mar 2, 2021; confirmed and probable cases.

<sup>&</sup>lt;sup>3</sup> California reported 806 historical deaths on Feb 25, and Texas reported 2,990 historical cases on Feb 27, 2021 and 1,840 historical cases on Mar 1, 2021. This will temporarily impact rates and averages. Beginning Feb 24, 2021, South Carolina reconciles their historical data every Wednesday.

<sup>&</sup>lt;sup>4</sup> Time period: Aug 1, 2020 – Mar 1, 2021; (All) includes both confirmed and suspect cases.

<sup>&</sup>lt;sup>5</sup> Time period: Feb 16, 2021 – Mar 1, 2021.

<sup>&</sup>lt;sup>6</sup> Time period: Mar 1, 2020 – Feb 28, 2021; Time period for test volume 7-day average and percent change: Feb 11, 2021 – Feb 24, 2021.

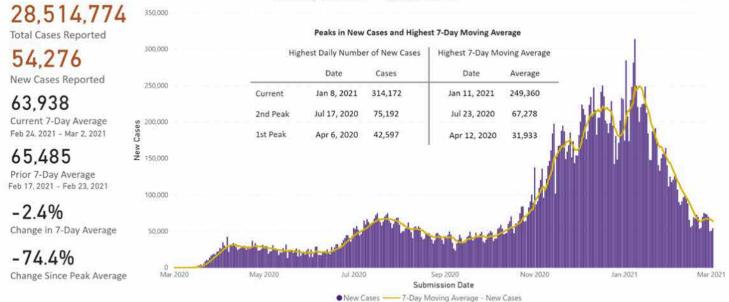
<sup>7</sup> Includes data for US States, DC, US Territories, and Federal entities, and pharmacies (see table on last page for details). Total doses allocated are through Mar 28, 2021



# Daily Change in COVID-19 Cases, United States

January 22, 2020\* - March 2, 2021





\*Graph displays data for Mar 1, 2020, to date. Totals include cases reported since Jan 22, 2020. As of Apr 12, 2020, data include confirmed and probable cases reported from jurisdictions. On Nov 7, 2020, 33,864 probable cases were reclassi and removed. Texas reported 2,990 historical cases on Feb 27, 2021 and 1,840 historical cases on Mar 1, 2021. These historical cases are excluded during identification of the highest peaks in new cases, but are included in the number of cumulative cases Beginning Feb 24, 2021, counts will reflect updates to South Carolina's historical data each Wednesday

Last Updated: Mar 3, 2021, 15:52

# New Admissions of Patients with Confirmed COVID-19, United States August 1, 2020 - March 1, 2021





1,809,100

Total New Admissions Aug 1, 2020 - Mar 1, 2021

4,533 New Admissions Mar 1, 2021

5,650

Feb 23, 2021 - Mar 1, 2021

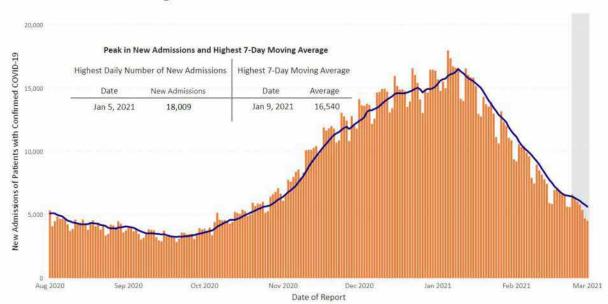
6,495

Prior 7-Day Average Feb 16, 2021 - Feb 22, 2021

-13.0% Change in 7-Day Average

-65.8%

Change Since Peak 7-Day Average



Daily Admissions of Patients with Confirmed COVID-19 — 7-Day Moving Average

Based on reporting from all hospitals (N=5,262)

Due to potential reporting delays, data reported in the most recent 7 days (as represented by the shaded bar) should be interpreted with caution. Data reported prior to Aug 1, 2020 are unavailable.

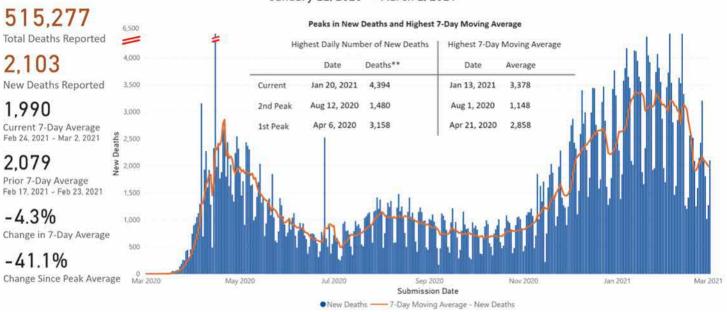
Last Updated: Mar 5, 2021



# Daily Change in COVID-19 Deaths, United States

January 22, 2020\* - March 2, 2021





<sup>\*</sup> Graph displays data starting on Mar 1, 2020. Totals include deaths reported since Jan 22, 2020. As of Apr 12, 2020, confirmed and probable cases reported from jurisdiction

Daily SARS-CoV-2 RT-PCR Percent Test Positivity and Test Volume, United States

Last Updated: Mar 3, 2021, 15:52

Data Source: CDC Case Surveillance, state-level aggregated COVID-19 Cases, HHS Protect; Visualization; CDC CPR DEO Situational Awareness Public Health Science Team

#### March 1, 2020 - February 28, 2021 335,876,223 Peaks in Single Day and 7-Day Average Percent Positivity Total Test Volume Highest Single Day Highest 7-Day Average Date Percent Positiv Percent Positivity 1,177,275 Jan 3, 2021 Jan 4, 2021 Current 7-Day Avg. Daily Test Volume 25% Feb 18, 2021 - Feb 24, 2021 2.0M Jul 5, 2020 11.3% Jul B, 2020 1,099,850 Peaks in Single Day and 7-Day Average Test Volume Highest Single Day Highest 7-Day Average Prior 7-Day Avg. Daily Test Volume Feb 11, 2021 – Feb 17, 2021 Date Date Test Volume Test Volume 1.5M Current Daily Test Volume Percent Positivity 7.0% Jul 22, 2020 1.093.874 Percent Change in 7-Day Avg. 4.6% 1.0M Current 7-Day Avg. % Positivity 7-Day Avg. Feb 22, 2021 - Feb 28, 2021 5.3% Prior 7-Day Avg. % Positivity 0.5M 5% Feb 15, 2021 - Feb 21, 2021 -13.5% Percent Change in 7-Day Avg. -0.7Sep 2020

Data (shaded) for the most recent four days may be incomplete. 7-Day average test volume line ends before the gray shaded area to reduce the influence of incomplete data in the most recent four days.

Last Updated: Mar 3, 2021, 10:39.

HHS Protect Unified Laboratory Testing Dataset: Data, Analytics, & Visualization Task Force: Visualization: CDC CPR DEG Situational Awareness Public Health Scientist To

Date Reported

Daily Test Volume — 7-Day Avg. Daily Test Volume — 7-Day Avg. Percent Positivity

Percentage Point Difference in 7-Day Averages

<sup>\*\*</sup>Various states reported historical deaths on Apr 15, 2020 (4,059 probable deaths), Jun 25, 2020 (1,824 probable deaths), Feb 4, 2021 (1,507 confirmed deaths), Feb 12, 2021 (2,559 deaths), Feb 13, 2021 (1,204 deaths), and Feb 25, 2021 (806 deaths). These historical deaths are excluded during identification of the highest peaks of new deaths, but are included in the number of cumulative cases. Beginning Feb 24, 2021, counts will reflect updates to South Carolina's historical data each Wednesday.



COVID-19 Vac		on and Admin	istration rep	orted to CDC	by State/Ter				
State/Territory, Federal	Doses Allocated	Doses Do	elivered	Doses Adı	ministered	People R ≥1 [	eceiving Dose	People R 2 De	leceiving oses
Entity, or Pharmacy <sup>9</sup>	Total <sup>10</sup>	Total	Rate/100K Population	Total	Rate/100K Population	Total	% of Population	Total	% of Population
Alabama	2,045,725	1,461,320	29,803	972,161	19,827	658,906	13.4%	338,967	6.9
Alaska	570,085	372,725	50,950	269,941	36,900	170,243	23.3%	102,472	14.0
Arizona	2,893,000	2,244,885	30,842	1,889,742	25,963	1,308,334	18.0%	613,681	8.4
Arkansas	1,243,350	963,040	31,912	670,815	22,229	441,126	14.6%	242,346	8.0
California	16,184,500	12,528,070	31,707	9,497,125	24,036	6,672,891	16.9%	2,997,721	7.6
Colorado	2,313,490	1,747,350	30,343	1,428,854	24,812	954,209	16.6%	499,066	8.
Connecticut	1,641,060	1,281,935	35,956	1,040,154	29,174	740,054	20.8%	310,667	8.
Delaware	419,630	323,935	33,266	225,417	23,149	152,876	15.7%	83,782	8.
Florida	8,882,685	6,744,275	31,401	5,077,891	23,643	3,297,947	15.4%	1,833,883	8
Georgia	4,210,250	3,067,745	28,893	2,085,047	19,638	1,309,558	12.3%	780,276	7.
Hawaii	617,520	536,520	37,893	392,771	27,741	251,867	17.8%	147,043	10.
Idaho	687,665	517,115	28,937	409,641	22,923	267,570	15.0%	138,642	7.
Illinois	5,360,065	3,722,705	29,378	2,958,947	23,351	2,092,244	16.5%	884,810	7.
Indiana	2,744,140	2,053,030	30,496	1,624,577	24,131	1,035,893	15.4%	604,449	9.
lowa	1,303,650	940,045	29,795	740,713	23,477	553,471	17.5%	193,643	6.
Kansas	1,199,620	868,885	29,825	629,548	21,609	429,853	14.8%	210,351	7.
Kentucky	1,869,415	1,418,685	31,754	1,061,236	23,754	715,889	16.0%	362,062	8.
Louisiana	1,937,770	1,479,200	31,819	1,084,499	23,329	709,457	15.3%	395,300	8.
Maine	590,150	451,450	33,585	334,325	24,871	225,674	16.8%	106,463	7.
Maryland	2,520,270	1,946,505	32,197	1,390,370	22,998	934,749	15.5%	516,955	8.
Massachusetts	2,944,770	2.115,560	30,694	1,837,816	26,664	1,316,940	19.1%	562,289	8.
Michigan	4,196,665	3,103,600	31,077	2,389,534	23,927	1,534,341	15.4%	866,351	8.
Minnesota	2,300,545	1,653,440	29,318	1,443,875	25,602	985,742	17.5%	486,432	8.
Mississippi	1,231,935	898,945	30,205	646,440	21,721	435,977	14.6%	228,512	7.
Missouri	2,557,725	1,709,605	27,855	1,384,067	22,551	921,875	15.0%	477,486	7.
Montana	457,475	342,145	32,013	286,163	26,775	193,790	18.1%	96,839	9.
Nebraska	790,855	604,380	31,244	484,888	25,066	323,898	16.7%	170,153	8.
Nevada	1,226,335	883,370	28,679	723,182	23,479	473,373	15.4%	249,472	8.
New Hampshire	590,450	437,345	32,165	330,538	24,309	239,451	17.6%	99,785	7.
New Jersey	3,739,750	2,618,060	29,475	2,187,330	24,626	1,497,304	16.9%	745,182	8.
New Mexico	883,385	800,425	38,173	721,489	34,409	472,126	22.5%	255,621	12.
New York	8,366,660	5,987,175	30,777	4,495,821	23,111	2,965,267	15.2%	1,556,522	8.
North Carolina	4,256,845	3,028,055	28,871	2,545,103	24,267	1,686,160	16.1%	916,706	8.
North Dakota	327,560	266,470	34,967	238,848	31,342	155,338	20.4%	83,505	11.
Ohio	4,869,455	3,573,485	30,571	2,723,208	23,297	1,801,523	15.4%	978,945	8.
Oklahoma	1,608,740	1,408,880	35,605	1,124,662	28,422	726,784	18.4%	413,355	10.
Oregon	1,751,475	1,293,095	30,659	1,038,342	24,618	667,785	15.8%	377,528	9.
Pennsylvania	5,493,340	4,025,115	31,441	2,886,451	22,547	2,027,556	15.8%	911,602	7.
Rhode Island	466,075	350,915	33,125	275,799	26,034	200,683	18.9%	81,944	7.
South Carolina	2,088,690	1,482,565	28,795	1,123,049	21,812	757,128	14.7%	368,642	7.
South Dakota	370,025	341,900	38,648	282,575	31,942	189,817	21.5%	97,606	11.
Tennessee	2,793,780	1,974,990	28,920	1,405,604	20,582	953,568	14.0%	495,032	7.
Texas	11,153,515	8,234,755	28,400	5,956,629	20,543	4,001,348	13.8%	2,182,085	7.
Utah	1,161,410	879,350	27,429	722,301	22,530	423,021	13.2%	196,395	6.
Vermont	292,000	227,350	36,435	171,557	27,494	112,844	18.1%	60,078	9.
Virginia	3,546,975	2,735,305	32,046	2,171,427	25,440	1,418,234	16.6%	769,180	9.
Washington	3,145,280	2,443,300	32,086	1,841,160	24,178	1,206,474	15.8%	662,168	8.
West Virginia	794,620	644,595	35,968	536,534	29,938	327,437	18.3%	213,929	11.
Wisconsin	2,450,795	1,814,215	31,159	1,521,200	26,127	1,000,207	17.2%	536,537	9.
	2,450,795		36,529	TATAL CONTRACTOR STREET	27,088	Lucian Division Law Law	100000000000000000000000000000000000000		10.
Wyoming American Samoa		211,415		156,776		104,459	18.0%	57,895	
	43,610	29,450	52,883	21,079	37,851	12,949	23.3%	8,099	14.
CNMI	44,010	43,610	76,667	18,894	33,216	11,260	19.8%	7,954	14.

<sup>8</sup> Green shading indicates higher rates of distribution or vaccine administration relative to other states/territories. Rates calculated based on 2019 Census data for US States, DC, and PR, and 2018 Census data for all other US Territories. Population data not available for Federal Entities or pharmacies.

<sup>9</sup> CNMI = Commonwealth of the Northern Mariana Islands, FEMA = Federal Emergency Management Agency, FSM = Federated States of Micronesia, HRSA = Heath Resources and Services Administration, RMI = Republic of the Marshall Islands, and USVI = US Virgin Islands.

10 Total doses allocated are through Mar 28, 2021. Total doses allocated includes second dose allocations that are not yet available to order.



### COVID-19 Director's Brief - Thursday, Mar 4, 2021 INTERNAL - NOT FOR FURTHER DISTRIBUTION

COVID-19 Vac	cine Distributi	on and Admin	istration Rep	orted to CDC	by State/Teri	the same of the sa		A STATE OF THE PARTY OF T	
State/Territory, Federal	Doses Allocated	Doses De	elivered	Doses Adr	ministered	2/	leceiving Dose		teceiving oses
Entity, or Pharmacy <sup>9</sup>	Total <sup>10</sup>	Total	Rate/100K Population	Total	Rate/100K Population	Total	% of Population	Total	% of Population
FSM	47,400	30,000	28,946	15,705	15,153	10,767	10.4%	5,317	5.1%
Guam	87,860	65,500	39,513	55,402	33,421	34,560	20.8%	20,385	12.3%
Marshall Islands	35,600	21,000	35,951	11,351	19,432	8,835	15.1%	2,459	4.2%
Palau	14,800	14,600	81,532	8,185	45,708	5,085	28.4%	3,099	17.3%
Puerto Rico	1,470,700	1,056,070	33,067	554,694	17,368	363,587	11.4%	202,776	6.39
US Virgin Islands	56,280	37,680	35,995	19,736	18,854	13,286	12.7%	6,849	6.5%
Unspecified <sup>11</sup>	N/A	4,674,950	N/A	2,200,074	N/A	220,523	N/A	70,420	N/A
USA 12	163,759,745	107,028,890	32,238	80,540,474	24,259	52,855,579	15.9%	26,957,804	8.1%
Bureau of Prisons	106,670	65,335	N/A	62,745	N/A	38,000	N/A	24,513	N/A
Dept of Defense	2,323,995	1,556,605	N/A	1,017,839	N/A	694,151	N/A	312,894	N/A
Dept of State	110,870	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
FEMA	2,168,855	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
HRSA	932,280	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Indian Health Service	1,378,015	948,600	N/A	588,253	N/A	398,016	N/A	184,195	N/A
Veterans Health	4,023,750	2,779,685	N/A	2,420,189	N/A	1,565,132	N/A	853,672	N/A
Federal Agencies	11,044,435	5,350,225		4,089,026		2,695,299		1,375,274	
Ahold Delhaize	58,920	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Albertsons	571,560	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Costco	37,700	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CPESN	244,940	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
cvs	4,303,270	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
GeriMed	12,300	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Good Neighbor	110,960	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Health Mart	55,600	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
H-E-B	205,060	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Hy-Vee	281,660	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N//
Kroger	926,995	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Med Shoppe/ LeaderNet	210,040	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Meijer	310,415	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MHA	157,105	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Publix	329,000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Rite Aid	1,463,240	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Southeastern Groc	73,040	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Торсо	187,660	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Walgreens	3,607,270	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Walmart	2,105,680	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pharmacies	15,252,415								

N/A = Not available (no data)

Data as of Mar 3, 2021, 06:00 ET; Sources: Data Monitoring and Reporting Section, Vaccine Task force; COVID Tracker; US Census

<sup>&</sup>lt;sup>11</sup> Includes doses delivered or administered by federal agencies outside the US or in unspecified states or territories.

<sup>&</sup>lt;sup>12</sup> Totals for states and territories include doses delivered to or administered by federal agencies. The overall total also includes doses delivered to or administered by federal agencies where the state or territory was not specified. The overall total of doses allocated includes data from federal agencies and pharmacies.

From: Broder, Karen (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 10 Mar 2021 13:08:56 +0000

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John

(CDC/DDID/NCEZID/DHQP); Destefano, Frank (CDC/DDID/NCEZID/DHQP)

Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to

the Israeli National Focal Point to discuss Pfizer vaccine **Attachments:** 05-covid-Shimabukuro.pdf

#### Tom,

Please see two considerations below.

Do you want to (b)(6)	(b)(6)	
. Do vou want to	(b)(6)	
	(b)(6)	
	(1980)	
cs,		
KS,		

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

Sent: Wednesday, March 10, 2021 7:38 AM

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

<krb2@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>

(b)(5)

Subject: FW: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli

National Focal Point to discuss (b)(5)

This is for that joint FDA-CDC to the Israeli MOH. Please let me know if you have any thoughts. Thanks. Tom

From: Nair, Narayan < Narayan.Nair@fda.hhs.gov>

Sent: Tuesday, March 9, 2021 9:10 AM

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

Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli

National Focal Point to discuss

Hi Tom,

Here are some draft responses to the Israeli Ministry of Health's inquiry.

(b)(5)

(b)(5)

Narayan

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

Sent: Sunday, February 28, 2021 3:06 PM

To: Anderson, Steven < Steven.Anderson@fda.hhs.gov>; Forshee, Richard < Richard.Forshee@fda.hhs.gov>; Nair, Narayan < Narayan.Nair@fda.hhs.gov> Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (b)(5)
CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.
FYI.
From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov> Sent: Sunday, February 28, 2021 2:28 PM  To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < zmt0@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov> Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < dpl9@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < kaf6@cdc.gov>; Beauvais, Denise (CDC/DDID/NCIRD/OD) < cry2@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy < eocevent417@cdc.gov>; McClure, Susan (CDC/DDPHSIS/CGH/OD) < zur1@cdc.gov> Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (D)(5)  Seeing that Denise is out. + Susan  Susan - can you please help coordinate?  Thanks, -d
From: Fitter, David L. (CDC/DDPHSIS/CGH/GID)
Sent: Sunday, February 28, 2021 2:26 PM  To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < \( \text{zmt0@cdc.gov} \); Shimabukuro, Tom  (CDC/DDID/NCEZID/DHQP) < \( \text{ayv6@cdc.gov} \)  Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < \( \text{dpl9@cdc.gov} \); Fox, Kimberley (CDC/DDID/NCIRD/DBD)  <\( \text{kaf6@cdc.gov} \); Beauvais, Denise (CDC/DDID/NCIRD/OD) < \( \text{cry2@cdc.gov} \); CDC IMS 2019 NCOV  Response VTF Policy < \( \text{eocevent417@cdc.gov} \)  Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (b)(5)
Thanks, Stacey.
Denise – can you help set this up via policy?
Best, David

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < <a href="mailto:zmt0@cdc.gov">zmt0@cdc.gov</a>>

Sent: Sunday, February 28, 2021 1:35 PM

To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov >; Shimabukuro, Tom						
(CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov"&gt;ayv6@cdc.gov</a>						
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < <a href="mailto:dpl9@cdc.gov">dpl9@cdc.gov"&gt;dpl9@cdc.gov</a> ; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < kaf6@cdc.gov>						
Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point						
to discuss (b)(5)						
Thanks David. Do you want Tom and I to coordinate a	call? This was sent to multiple units.					
From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@	Ocdc.gov>					
Sent: Sunday, February 28, 2021 11:15 AM						
To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < xmt0@	cdc.gov>; Shimabukuro, Tom					
(CDC/DDID/NCEZID/DHQP) <a 6="" @="" cdc.gov="" v="" y=""></a>	IOVA: Fox Kimberley (CDC/DDID/NCIRD/DRD)					
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < <a href="mailto:dpl9@cdc.gov">dpl9@cdc.gov"&gt;dpl9@cdc.gov</a> ; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < <a href="mailto:kaf6@cdc.gov">kaf6@cdc.gov</a>						
Subject: FW: Task ID: 42633 - HHS SOC RFI: Provide a P	oint of Contact to the Israeli National Focal Point					
to discuss (b)(5)						
Importance: ніgn						
Stacey and Tom,						
Please see below re discussing with Israeli Vaccine FP	(b)(5)					
Thanks,						
David						
The second secon	And the second					
From: CDC IMS Task Tracker (CDC) < eoctasktracker@c	dc.gov>					
<b>Sent:</b> Sunday, February 28, 2021 1:13 PM <b>To:</b> CDC IMS 2019 NCOV Response VTF Vaccine Safety	Sencevent/16@cdc gov>: CDC IMS 2019 NCOV					
Response VTF Policy < <u>eocevent417@cdc.gov</u> >; CDC IM						
<eocevent516@cdc.gov>; CDC IMS 2019 NCOV Respor</eocevent516@cdc.gov>						
Cc: CDC IMS Task Tracker (CDC) < eoctasktracker@cdc.	gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD)					
< kaf6@cdc.gov >; Fitter, David L. (CDC/DDPHSIS/CGH/C	GID) < <u>vid3@cdc.gov</u> >; Lubar, Debra					
(CDC/DDID/NCEZID/OD) < dpl9@cdc.gov>						
Subject: Task ID: 42633 - HHS SOC RFI: Provide a Point	of Contact to the Israeli National Focal Point to					
discuss (b)(5) Importance: High						
importance. (ngii						

**Task ID:** 42633

Suspense: 3/2/2021 17:00:00

**Assigned To:** CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roee Singer MD, MPH	(b)(6)	
Phone #: (b)(6)		
Subject: HHS SOC RFI: Provide a Point of Cont	act to the Israeli National F	ocal Point to discuss
(b)(5)		
Description:	(b)(5)	
	(b)(5)	
· · · · · · · · · · · · · · · · · · ·		

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".

















































































Subject: Attachments: COVID(b)(6)past	Sent: Fri, 9 Apr 2021 21:09:35 +0000  To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Lagarde, Melanie (CDC/OCOO/OSSAM/OHC); Su, John (CDC/DDID/NCEZID/DHQP)  Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine  Attachments: COVID (b)(6) history.rtf, COVID (b)(6) past history-safety profile.rtf,		
	(b)(5)		
Sincerely, Pedro			
	(b)(5)		

(b)(5)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Sent: Friday, April 9, 2021 4:13 PM

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

(CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,

Melanie and Ldiscussed that if

b)(5)

(b)(5)

I will get back to you with a revised response soon.

Thanks, Elaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>

Sent: Friday, April 9, 2021 4:09 PM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

(b)(5)

Elaine or John, do you have any edits?

Thanks for sending this

Pedro

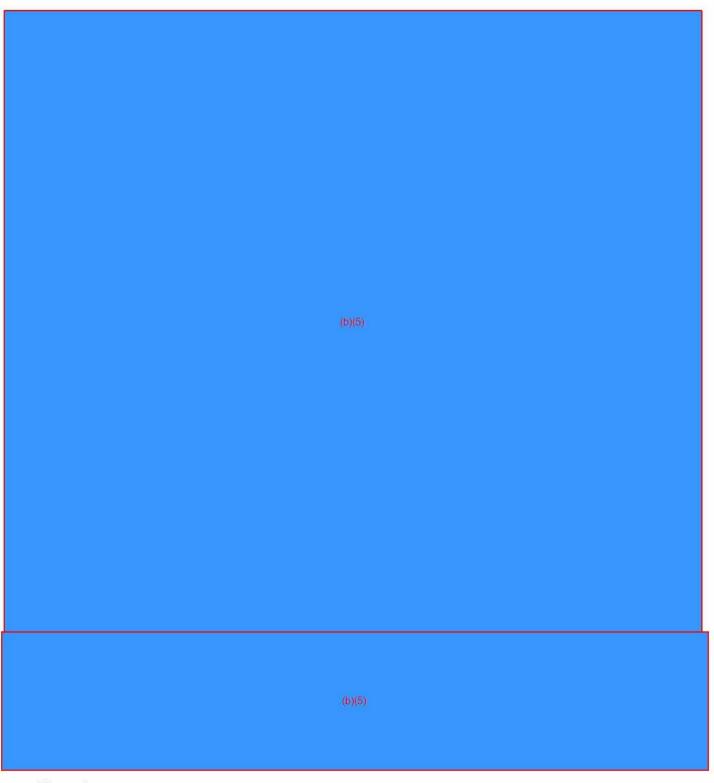
From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < <a href="mvl3@cdc.gov">mvl3@cdc.gov">mvl3@cdc.gov</a>

Sent: Friday, April 9, 2021 3:48 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>; Su, John (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ezu2@cdc.gov">ezu2@cdc.gov</a>> Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

(b)(5)	
Sincerely, Pedro	
(b)(5)	
	_
(b)(5)	



Sincerely, CDC Immunization Safety Office Staff Atlanta, GA

## Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC)

Sent: Thursday, April 8, 2021 1:13 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro.

Thank you. Got it. Makes sense. Happy to work on this. I'll send another draft.

Thanks again.

Melanie

## Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>

Sent: Thursday, April 8, 2021 1:09 PM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

Thanks for sending this. I have a few questions and suggestions.

(b)(5)

(b)(5)

Thanks again

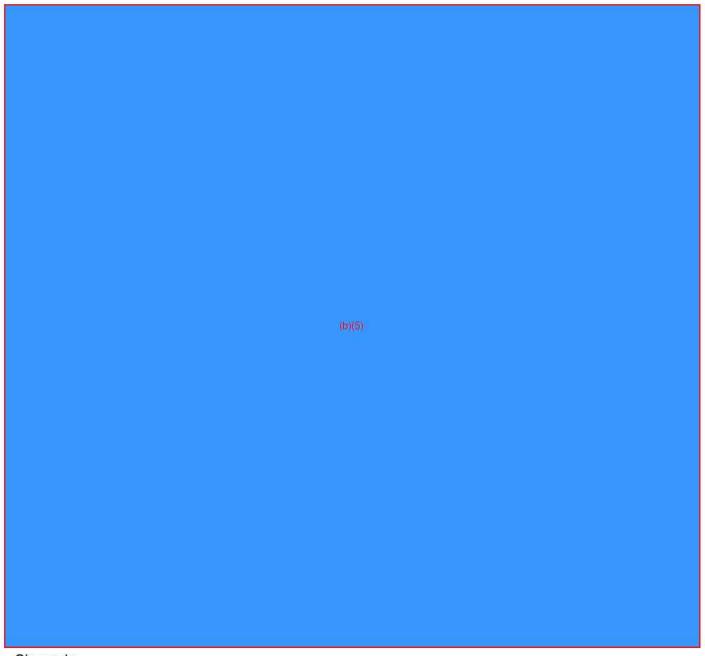
Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov>

Sent: Thursday, April 8, 2021 12:56 PM

Subject: DRAFT RE: Autoimmune dx post vaccine

(b)(5)



Sincerely, CDC Immunization Safety Office Staff Atlanta, GA

Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> > Sent: Thursday, April 8, 2021 9:15 AM				
To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < <a href="mvl3@cdc.gov">mvl3@cdc.gov</a> Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < <a href="mailto:psm9@cdc.gov">psm9@cdc.gov</a> Subject: RE: Autoimmune dx post vaccine				
Hi Melanie, Please let me know if you can draft a response for this inquiry. Thanks, ELaine				
From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov> Sent: Wednesday, April 7, 2021 6:19 PM To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov> Subject: FW: Autoimmune dx post vaccine				
Elaine,				
(b)(5)				
Pedro				
From: dale nordenberg (b)(6)  Sent: Wednesday, April 7, 2021 5:16 PM  To: Robert Chen (b)(6)  Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>; Miller, Elaine R.  (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>  Subject: Re: Autoimmune dx post vaccine				
Hi				
(b)(5), (b)(6)				
Thanks!				
Sent from my iPhone				
On Apr 7, 2021, at 5:08 PM, Robert Chen (b)(6) wrote:				
Dale?				

Robert (Bob) Chen MD MA

Scientific Director, Brighton Collaboration Land: 1-404-248-0536 Cell: 1-678-662-0516

email: (b)(6)

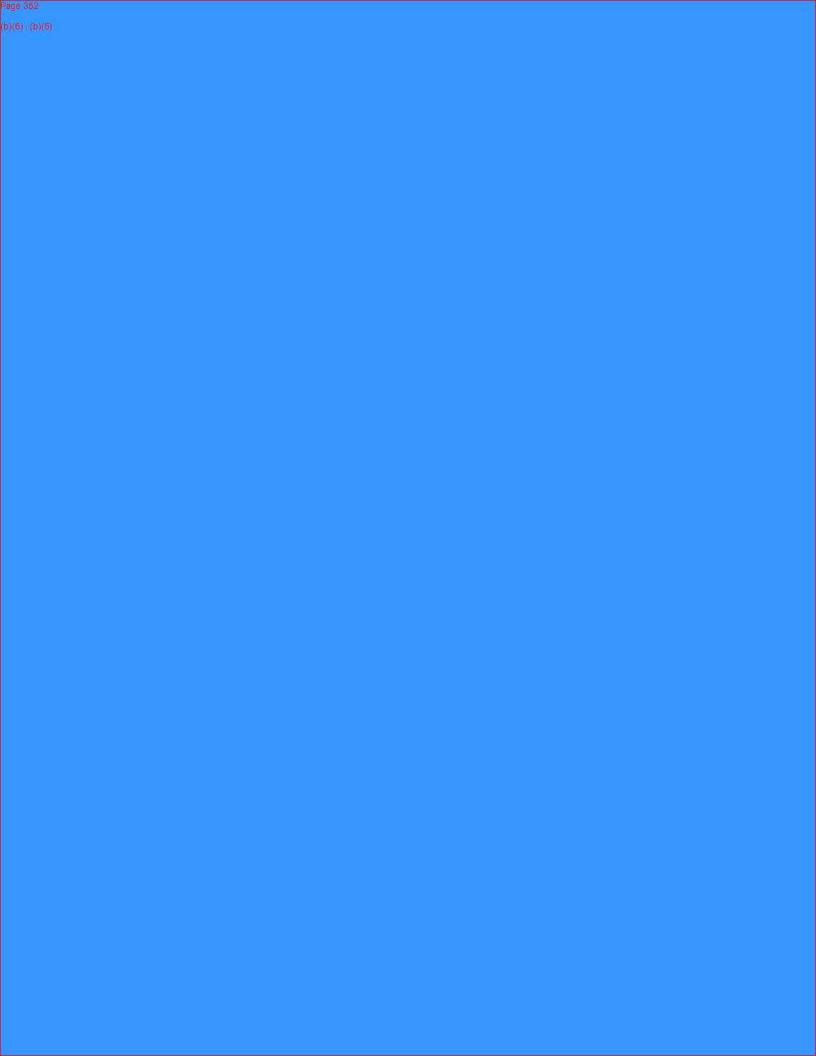
On Wed, Apr 7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov > wrote: Hi Bob,

(b)(5)					
(b)(5) ?	- A				
Pedro					
From: Robert Chen (b)(6)  Sent: Wednesday, April 7, 2021 3:33 PM  To: Nordenberg, Dale (CDC gmail.com) (b)(6)					
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc	gov>				
Subject: Re: Autoimmune dx post vaccine					
(b)(5) . E	Sob				
On Wed, Apr 7, 2021 at 1:07 AM dale nordenberg (b)(6) wrote:					
(b)(d)	n				
(b)(6)					
Dale					
Sent from my iPhone					
Robert (Bob) Chen MD MA Scientific Director, Brighton Collaboration					
Land: 1-404-248-0536 Cell: 1-678-662-0516 email: (b)(6)					













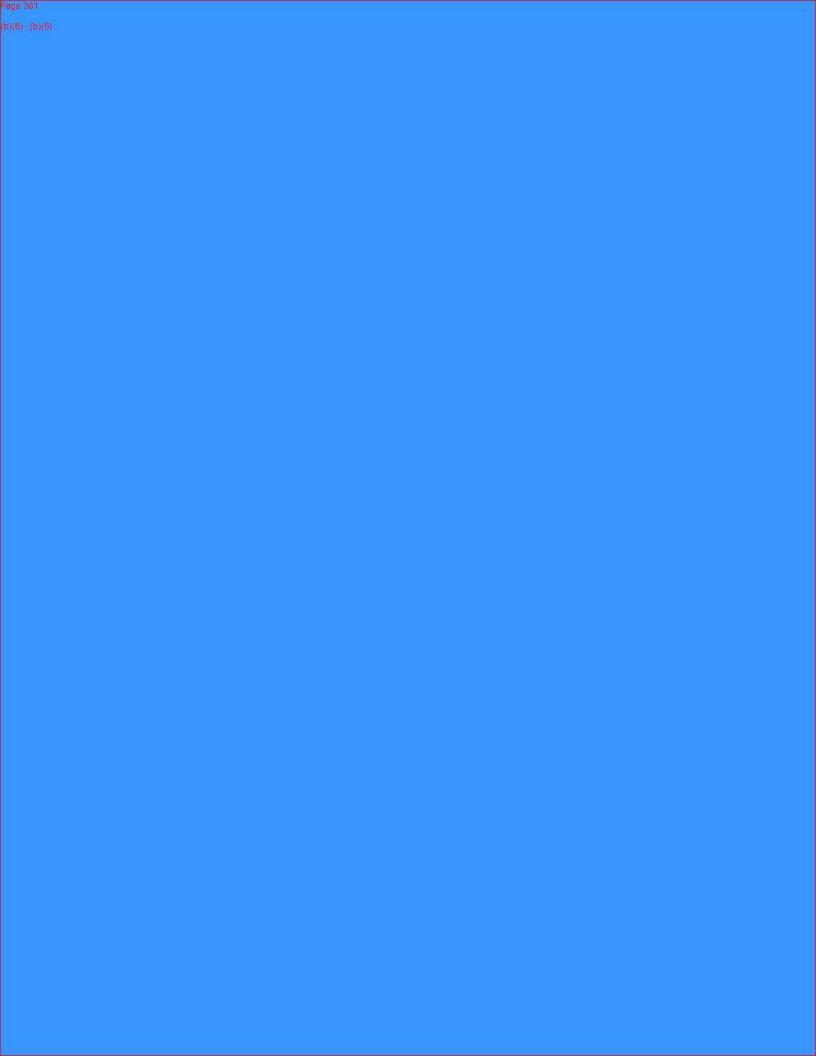












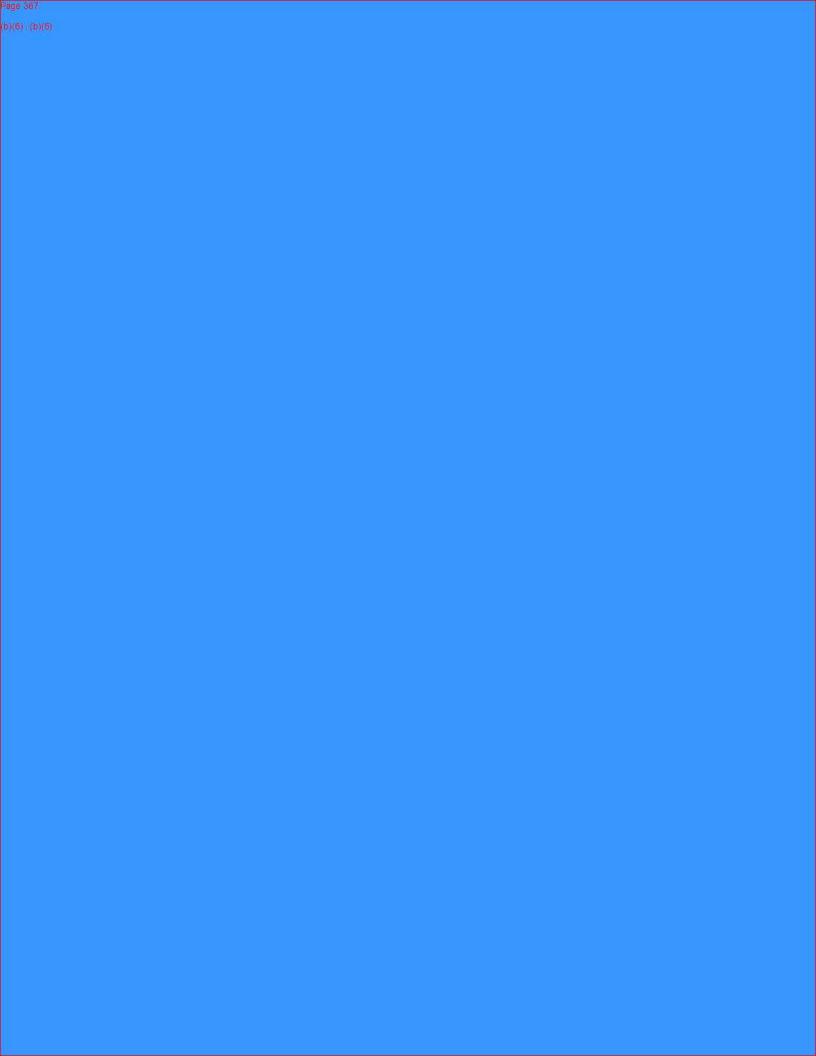


























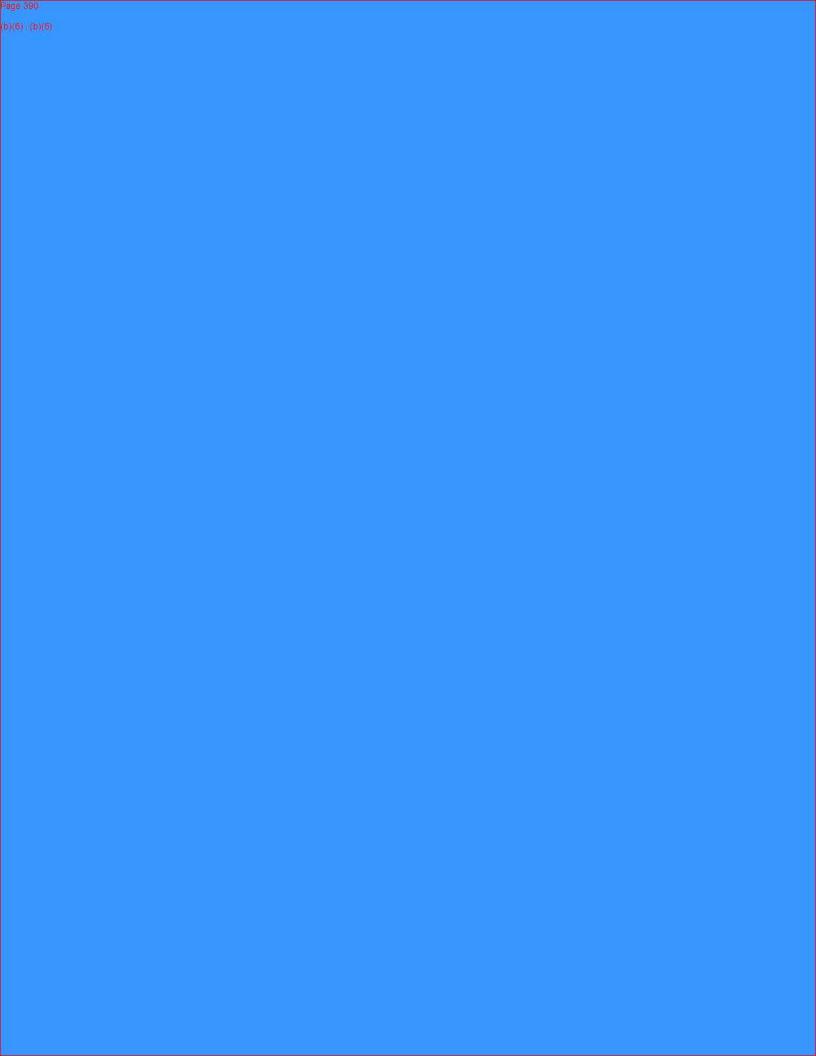




















































































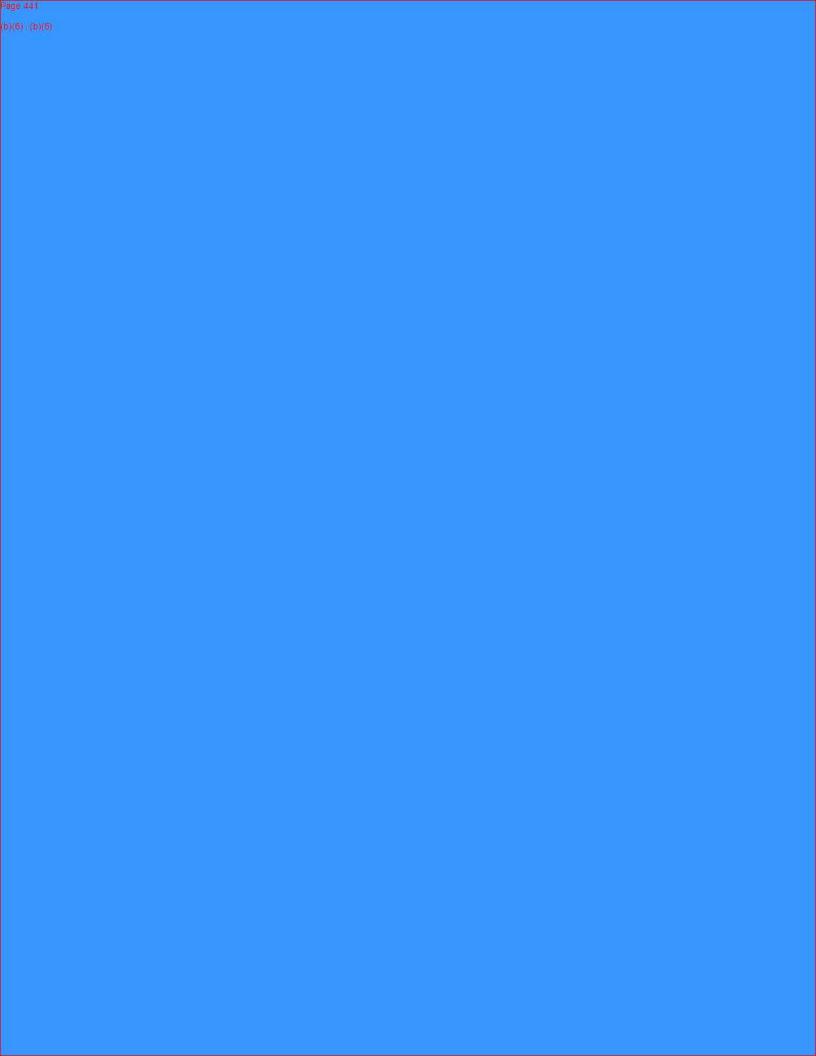






































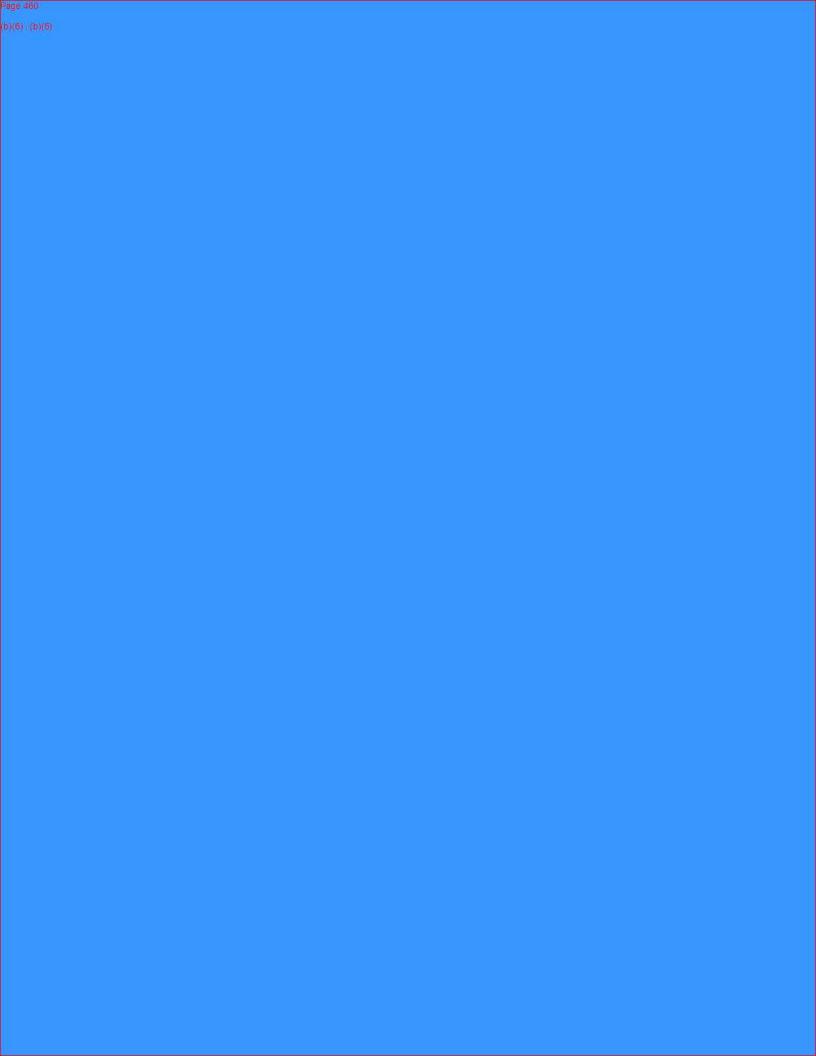




















From: (b)(6)

 Sent:
 Fri, 4 Dec 2020 19:21:28 +0000 (UTC)

 To:
 Su, John (CDC/DDID/NCEZID/DHQP)

**Subject:** Fwd: Your Submission

Attachments: Myopericarditis paper - 11-24-2020.docx, Tables.docx, Response to

Reviewers.docx

I didn't have any comments. Great job with the manuscript.

I hope all is well with you and you had a wonderful Thanksgiving with your family.

Regards,

Maria

----Original Message-----

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

To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Welsh, Kerry (FDA/CBER)

<Kerry.Welsh@fda.hhs.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Carmen Ng (b)(6) M Cano (b)(6)

Sent: Tue, Nov 24, 2020 6:48 pm Subject: FW: Your Submission

Hi folks,

I hope you're staying healthy and safe during these strange times!

Please find enclosed the revised myopericarditis paper, with responses to the below reviewers comments. Please take a look, and let me know if you have any questions, concerns, or other feedback by COB next Thursday (3 Dec); if I don't hear from you, I'll assume you're good with these responses. I will then resubmit our paper to *Vaccine*.

Thanks for your hard work!

-- John

----Original Message-----

From: eesserver@eesmail.elsevier.com <eesserver@eesmail.elsevier.com>

Sent: Thursday, October 15, 2020 11:03 PM

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

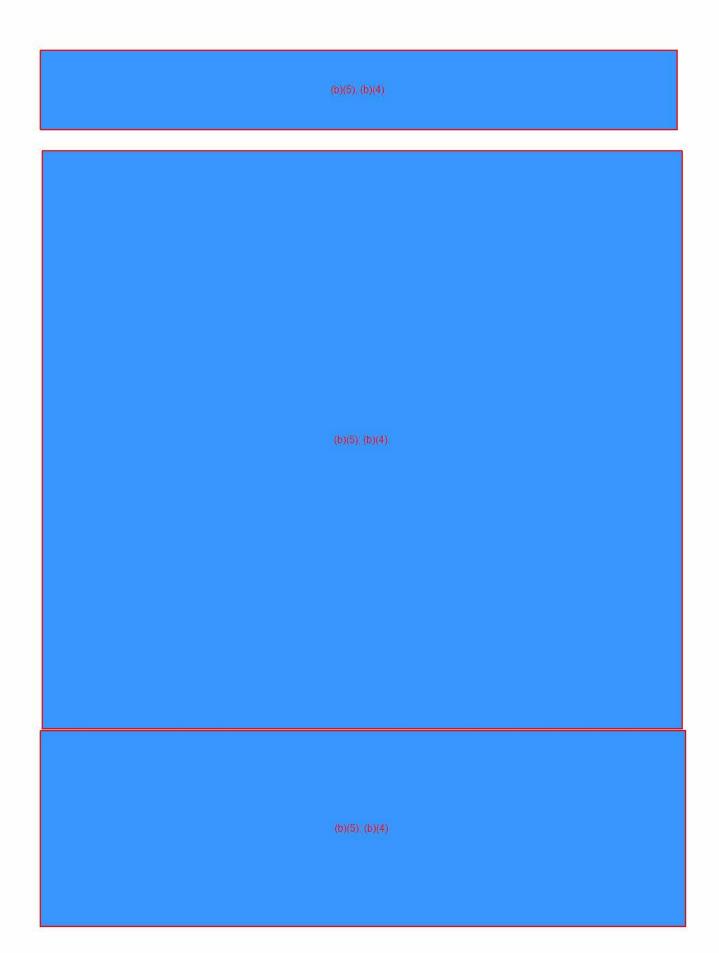
Subject: Your Submission

Ms. Ref. No.: JVAC-D-20-01671

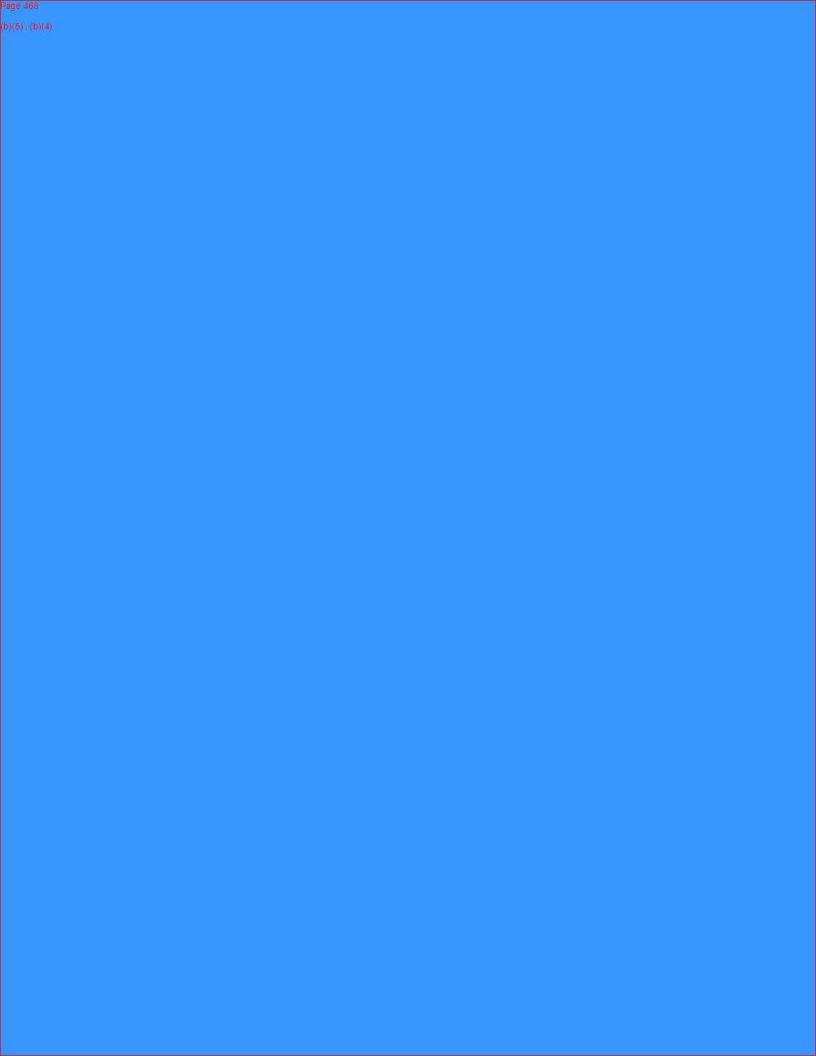
Title: (b)(5), (b)(4)

(b)(5) (b)(4)

Dear John,



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Yours sincerely,	
Robert T Chen, MD MA Associate Editor Vaccine or its open access mirror	
view the files	
Reviewers' comments:	
(b)( <del>-</del>	5), (b)(4)



































 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Tue, 24 Nov 2020 23:48:53 +0000

To: McNeil, Michael (CDC/DDID/NCEZID/DHQP); Welsh, Kerry (FDA/CBER);

Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Carmen Ng; ming yan; M Cano

Subject: FW: Your Submission

Attachments: Myopericarditis paper - 11-24-2020.docx, Tables.docx, Response to

Reviewers.docx

Hi folks,

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Thanks for your hard work!

-- John

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From: eesserver@eesmail.elsevier.com <eesserver@eesmail.elsevier.com>

Sent: Thursday, October 15, 2020 11:03 PM

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

Subject: Your Submission

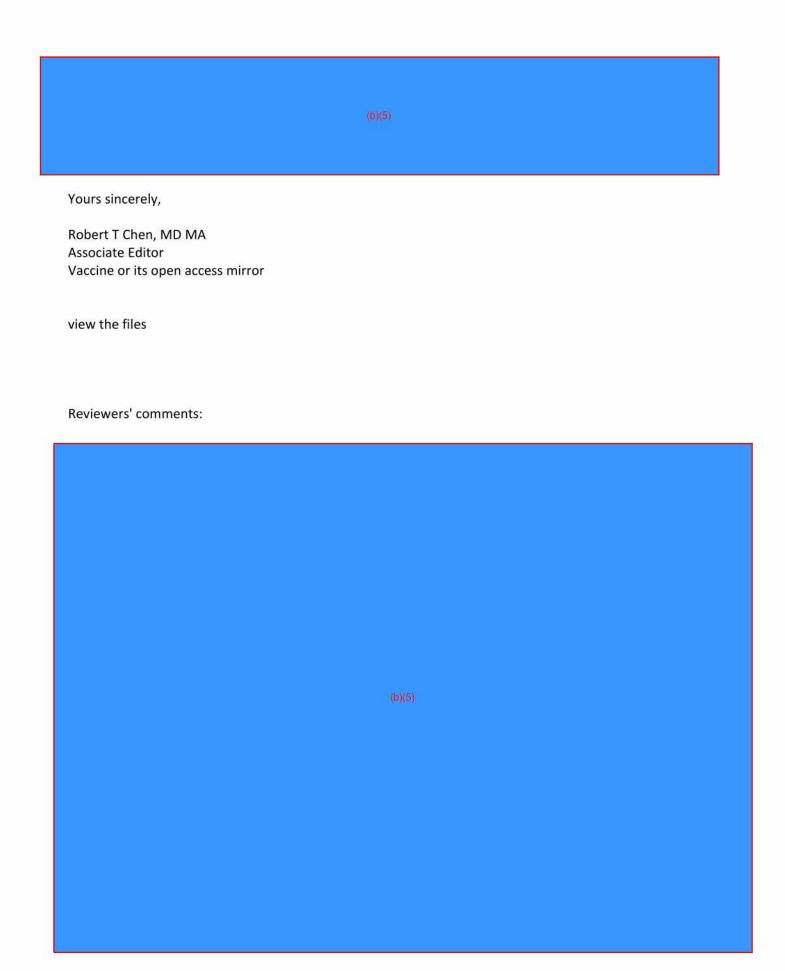
Ms. Ref. No.: JVAC-D-20-01671

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and

Title.

Page 497			
(b)(5)			

































 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Thu, 1 Apr 2021 18:51:49 +0000

To: McCormick, David (CDC/DDID/NCEZID/DVBD); Destefano, Frank

(CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa

(CDC/DDID/NCEZID/DHQP); Rao, Agam K. (CDC/DDID/NCEZID/DHCPP)

Subject: RE: VAERS Review of Myocarditis/Myopericarditis for DoD Discussion Tomorrow

Attachments: VAERS myopericarditis Vaccine 2021.pdf

Hi David,

(b)(5)

John

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From: McCormick, David (CDC/DDID/NCEZID/DVBD) <yup1@cdc.gov>

Sent: Thursday, April 1, 2021 1:59 PM

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

<fxd1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa

(CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>

Subject: VAERS Review of Myocarditis/Myopericarditis for DoD Discussion Tomorrow

Hi all,

(b)(5)

Any comments or suggestions for improvement are welcome.

Please send any comments by 10AM 4/2 so that I

have a chance to incorporate them into the presentation.

(

Best, David

# David McCormick, MD, MPH

LCDR, US Public Health Service
EIS Officer
Centers for Disease Control and Prevention
Bacterial Diseases Branch | Division of Vector-Borne Diseases
Fort Collins, CO
yup1@cdc.gov | Office 970-225-4272 | Cell 970-787-5036

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# Myopericarditis after vaccination, Vaccine Adverse Event Reporting System (VAERS), 1990–2018



John R. Su<sup>a,\*</sup>, Michael M. McNeil<sup>a</sup>, Kerry J. Welsh<sup>b</sup>, Paige L. Marquez<sup>a</sup>, Carmen Ng<sup>a,1</sup>, Ming Yan<sup>a</sup>, Maria V. Cano<sup>a</sup>

#### ARTICLE INFO

# Article history: Received 10 September 2020 Received in revised form 11 December 2020 Accepted 12 December 2020 Available online 6 January 2021

Keywords; Myopericarditis Vaccine Adverse event Surveillance VAERS

#### ABSTRACT

Background: Myopericarditis after vaccination has been sporadically reported in the medical literature. Here, we present a thorough descriptive analysis of reports to a national passive vaccine safety surveillance system (VAERS) of myopericarditis after vaccines licensed for use in the United States.

Methods: We identified U.S. reports of myopericarditis received by VAERS during 1990–2018 that met a published case definition for myopericarditis or were physician-diagnosed. We stratified analysis by age group (<19, 19–49, ≥50 years), describing reports by serious/non-serious status, sex, time to symptom onset after vaccination, vaccine(s) administered, and exposure to other known causes of myopericarditis. We used Empirical Bayesian data mining to detect disproportionate reporting of myopericarditis after vaccination.

Results: VAERS received 620,195 reports during 1990–2018: 708 (0.1%) met the case definition or were physician-diagnosed as myopericarditis. Most (79%) myopericarditis reports described males; 69% were serious; 72% had symptom onset  $\leq$  2 weeks postvaccination. Overall, smallpox (59%) and anthrax (23%) vaccines were most commonly reported. By age, among persons aged < 19 years, Haemophilus influenzae type b (22, 22%) and hepatitis B (18, 18%); among persons aged 19–49 years smallpox (387, 79%); among persons aged  $\geq$  50 years inactivated influenza (31, 36%) and live attenuated zoster (19, 22%) vaccines were most commonly reported. The vaccines most commonly reported remained unchanged when excluding 138 reports describing other known causes of myopericarditis. Data mining revealed disproportionate reporting of myopericarditis only after smallpox vaccine.

Conclusions: Despite the introduction of new vaccines over the years, myopericarditis remains rarely reported after vaccines licensed for use in the United States. In this analysis, myopericarditis was most commonly reported after smallpox vaccine, and less commonly after other vaccines.

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#### 1. Introduction

Myocarditis (inflammation of the myocardium, or heart muscle) and pericarditis (inflammation of the pericardium, or tissue overlying the heart muscle) often occur together (termed myopericarditis), and can range in severity from mild and without symptoms, to severe [1]. Myopericarditis has many causes, including viral infections [1].

Although not establishing causality, myopericarditis has been reported after vaccinations. Myopericarditis is known to occur after administration of smallpox vaccine [2]. Amsel et al., described myocarditis in a male aged 3 months after receiving both combined diphtheria, tetanus, and pertussis (DTP) vaccine, and oral

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<sup>&</sup>lt;sup>b</sup> Center for Biologicals Evaluation and Research, Food and Drug Administration (FDA), United States

Abbreviations: AE, adverse event; CDC, Centers for Disease Control and Prevention; DTP, combined diphtheria, tetanus, and whole cell pertussis vaccine; EBGM, Empirical Bayes Geometric Mean; FDA, Food and Drug Administration; HPV, human papillomavirus; IIV, trivalent inactivated influenza vaccine; MedDRA, Medical Dictionary for Regulatory Activities; MGPS, Multi-Item Gamma Poisson Shrinker; MMR, combined measles, mumps, and rubella vaccine; PT, Preferred Term; VAERS, Vaccine Adverse Event Reporting System.

<sup>\*</sup> Corresponding author at: Immunization Safety Office, Centers for Disease Control and Prevention, 1600 Clifton Rd, MS V18-4, Atlanta, GA 30329, United States

E-mail address: ezu2@cdc.gov (J.R. Su).

<sup>&</sup>lt;sup>1</sup> Currently at Division of Health Economics, Policy and Management, University of Hong Kong, School of Public Health.

polio vaccine [3]. de Meester et al. described pericarditis after vaccination with influenza vaccine [4], Peyriere et al. described pericarditis after hepatitis B vaccine [5], and Mei et al. have described recurrent pericarditis after inactivated influenza (IIV) [6]. Except for smallpox vaccine, none of these reports described vaccines licensed for use in the United States.

Myopericarditis after live virus vaccines other than smallpox vaccine has been explored to some degree [7,8]. Reports of myopericarditis after inactivated vaccines have been scant, mostly after IIV [4,9], including a recently published case report attributing myocarditis to adjuvanted inactivated influenza vaccine (Fluad®, Sequirus) [9]. Further, several vaccines that are not IIV – including both live attenuated and inactivated vaccines – have been licensed for use in the United States over the past several years. To better characterize myopericarditis after vaccination, we reviewed and described reports of myopericarditis received by the Vaccine Adverse Event Reporting System (VAERS).

#### 2. Methods

#### 2.1. Data source

VAERS is a national spontaneous reporting system for monitoring AEs after vaccination [10]. Reports of AEs following vaccines licensed for use in the United States are accepted from healthcare providers, vaccine manufacturers, vaccine recipients and other persons and entities, including the military. Reported signs and symptoms are coded using Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs) [11]. MedDRA PTs are not necessarily medically confirmed diagnoses, and a VAERS report can be assigned multiple MedDRA PTs. The Code of Federal Regulations defines a report as serious if at least one of the following conditions is reported: death, life-threatening illness, hospitalization or prolongation of existing hospitalization, permanent disability, or a congenital anomaly or birth defect [12]. An AE might therefore present as an acutely severe condition, but not be classified as a serious report. For non-manufacturer serious reports, medical records are routinely requested and made available to VAERS personnel. Due to regulatory processes [13], vaccine manufacturers will request and review medical records before reporting a serious report to VAERS: as a result, serious reports from vaccine manufacturers typically do not contain medical records that VAERS personnel can review.

#### 2.2. Descriptive analysis

We searched the VAERS database for reports of myocarditis, pericarditis, myopericarditis, and perimyocarditis following vaccination received by VAERS during January 1, 1990 through December 31, 2018 (among U.S. reports processed by CDC through May 31, 2019). We searched for reports containing PTs that included the words "myocarditis", "coxsackie carditis", "pericarditis", and "pericardial effusion"; a complete list of PTs searched is available in the Supplemental Materials. Our search included PTs from past versions of the MedDRA browser, to capture reports using these older PTs. All identified reports were reviewed for signs and symptoms that met case definitions previously used for surveillance of myopericarditis after smallpox vaccine [14]; we also included for review reports where there was a diagnosis by a physician, regardless of if the reported case met the published case definition. Reports of cases that either met the definition for myocarditis or pericarditis, or were diagnosed by a physician, were stratified by age group (<19 years, 19-49 years, ≥50 years), in part because of age differences in recommended vaccination schedules [15,16], and the known association between smallpox vaccine, administered routinely to selected populations, and myopericarditis [2,14]. For each age group, we analyzed cases by seriousness of report (death, serious, or non-serious), sex, and time from vaccination to onset of symptoms. In addition, we analyzed by whether vaccines were given alone or concomitantly with other vaccines. Because myopericarditis is commonly viral in origin in the community [1], we conducted a secondary analysis that excluded reports in which patients exhibited signs or symptoms of influenza-like illness (including fever, malaise, upper or lower respiratory symptoms, gastrointestinal symptoms like nausea or vomiting) or had a history of such symptoms within 42 days of symptom onset for myopericarditis [14].

#### 2.3. Estimated reporting rates

Data on doses of vaccine that were distributed or administered are difficult to obtain. Estimating reporting rates of AEs after vaccination using data from VAERS is therefore challenging. For smallpox vaccine, doses administered data were unavailable, but doses distributed data were available. We were able to estimate crude reporting rates of myopericarditis after smallpox vaccine using reports received during 2014 through 2018 as the numerator, divided by doses distributed during the corresponding time period (which included disbursements to the U.S. military) (Centers for Disease Control and Prevention, Division of State and Local Readiness, personal communication) as the denominator; rates were estimated as reports per 1,000 doses distributed. For influenza vaccine, vaccine coverage data were available, and could be used to estimate doses administered. We therefore estimated annual crude reporting rates for influenza vaccine (all types), with reports received during 2014 through 2018 as the numerator, with population estimates and vaccine coverage for the corresponding year multiplied as the denominator [18,19]; rates for 2 age groups (1-17 years, >18 years) were estimated. From these annual crude reporting rates, median rates of reports per million doses administered were estimated for 2014 through 2018.

#### 2.4. Disproportionality analysis

Empirical Bayesian data mining techniques [17] were used to identify MedDRA PTs related to myopericarditis that occurred among U.S. reports more often than expected following each individual U.S. licensed vaccine: AEs after a given vaccine were compared to AEs reported for all vaccines, with adjustment for age, sex, and year of report receipt. The statistic calculated for this data mining analysis was the Empirical Bayes Geometric Mean (EBGM) and its associated 90% confidence interval (EB05, EB95). An EB05  $\geq$  2.0 indicates a vaccine-event pair occurs at least twice as often as expected, assuming that vaccine-event pairs are random, and is the commonly used threshold for considering an AE as a potential signal [18]; we thus used an EB05  $\geq$  2.0. Disproportionality analyses are intended to assess potential associations between a vaccine and an AE, but do not imply causality between the vaccine-event pair.

The data in this analysis resulted from routine public health surveillance activities. U.S. federal law specifies that these activities do not constitute research. This analysis was therefore exempt from institutional review.

#### 3. Results

#### 3.1. Descriptive analysis

During the analytic period, VAERS received a total of 620,195 reports. Of these reports, 708 (0.1%) either met the published case

definition for myopericarditis [14] or were diagnosed by a physician as myopericarditis (Table 1). Most reports described males (79%), and most reports were classified as serious (69%), with a reported time to symptom onset of 14 days or less (72%). Median reported age was 24 years (range: 0 to 90 years): among people ≤ 18 years of age, median age was 8 years (range: 0 to 18 years); among people 19 to 49 years of age, median age was 25 years (range: 19 to 49 years), with 75% of reports among people 19 to 31 years of age; among people ≥ 50 years, median age was 64 years (range: 50 to 90 years). We observed notable differences by age group: most reports (69%) were among persons 19 to 49 years of age, most of whom (90%) were males, and most of whom reported a time to symptom onset of 8 to 14 days after vaccination (whereas for other age groups, the greatest proportion of

reported persons had symptom onset within 7 days of vaccination). Also, in over half of reports among persons 18 years of age and younger, the patient died. When excluding reports after small-pox vaccine, most reports still described males, were classified as serious, reported time to symptom onset of 14 days or less, with similar median ages and distribution of sex by age (data not shown).

Considering all vaccines (regardless if administered with other vaccines, or alone), the most frequently reported vaccines were smallpox (59%), anthrax (23%), and typhoid (13%) vaccines; IIV was also frequently reported (11%) (Table 2). Among persons 18 years of age and younger, the most frequently reported vaccines were *Haemophilus influenzae* type b (22%) and hepatitis B (18%) vaccines; among persons 19 to 49 years of age, smallpox vaccine

**Table 1**Reported cases of myopericarditis, general characteristics by age group, 1990–2018.

	0 to 18 years n = 99 (%)	19 to 49 years n = 490 (%)	50 + years n = 85 (%)	Unreported n = 34 (%)	Total N = 708 (%)
Sex					
Male	55 (56)	439 (90)	42 (49)	23 (68)	559 (79)
Female	44 (44)	51 (10)	43 (51)	7 (21)	145 (20)
Unreported	0 (0)	0 (0)	0 (0)	4 (12)	4(1)
Seriousness*					
Non-serious	5 (5)	184 (38)	13 (15)	19 (56)	221 (31)
Serious, non-death	40 (40)	294 (60)	63 (74)	15 (44)	412 (58)
Serious, death	54 (55)	12 (2)	9 (11)	0(0)	75 (11)
Diagnosis	7.50-25-25-25-45	10 A 20 E	CHANGE CONT.	2625734634	(40 A.B. 17 11 B.)
Both MMWR definition and MD	54 (55)	293 (60)	39 (46)	8 (24)	394 (56)
MMWR only	20 (20)	45 (9)	21 (25)	4 (12)	90 (13)
MD only	25 (25)	152 (31)	25 (29)	22 (65)	224 (32)
Time to onset, days	Overes Made Co.	1510(B10V 7030A)75	00-00 \$400-50	Organia Maranto	100000000000000000000000000000000000000
≤7	46 (46)	111 (23)	49 (58)	3 (9)	209 (30)
8 to 14	15 (15)	263 (54)	8 (9)	14 (41)	300 (42)
15 to 29	8 (8)	62 (13)	13 (15)	1 (3)	84 (12)
≥30	14 (14)	20 (4)	4 (5)	1 (3)	39 (6)
unreported	16 (16)	34 (7)	11 (13)	15 (44)	76 (11)

<sup>\*</sup> Serious defined as death, life-threatening illness, hospitalization or prolongation of existing hospitalization, permanent disability, or a congenital anomaly or birth defect.

 Table 2

 Most frequently reported vaccines among myopericarditis reports, by age.

	Age group, years (%)						
Vaccine*	0-18 n = 99	19-49 n = 490	≥50 n = 85	Not reported n = 34	Total N = 708		
Smallpox	6 (6)	387 (79)	4 (5)	19 (56)	416 (59		
Anthrax	5 (5)	151 (31)	1(1)	6 (18)	163 (23		
Typhoid	3 (3)	83 (17)	2(2)	2 (6)	90 (13)		
Influenza, inactivated	11 (11)	33 (7)	31 (36)	2 (6)	77 (11)		
Hepatitis B	18 (18)	17 (3)	3 (4)	3 (9)	41 (6)		
Influenza, not specified	3 (3)	22 (4)	13 (15)	2 (6)	40 (6)		
Tdap	9 (9)	17 (3)	3 (4)	1 (3)	30 (4)		
Influenza, live attenuated	3 (3)	22 (4)	0(0)	3 (9)	28 (4)		
Hepatitis A	12 (12)	9 (2)	1(1)	3 (9)	25 (4)		
Varicella	16 (16)	6(1)	0(0)	2 (6)	24(3)		
Haemophilus influenzae type b	22 (22)	0 (0)	0 (0)	0 (0)	22 (3)		
Zoster, live attenuated	0(0)	0 (0)	19 (22)	2 (6)	21(3)		
MMR	13 (13)	7 (1)	0(0)	0 (0)	20(3)		
4-valent HPV	16 (16)	3 (1)	0 (0)	0 (0)	19 (3)		
DTaP**	14 (14)	2 (0)	1(1)	1 (3)	18 (3)		
Meningococcal conjugate	14 (14)	2(0)	0(0)	2 (6)	18 (3)		
Polio, inactivated	11 (11)	4(1)	0 (0)	1 (3)	16(2)		
Pneumococcal polysaccharide	1(1)	8 (2)	4 (5)	0 (0)	13 (2)		
Pneumococcal conjugate, 7-valent	12 (12)	0 (0)	0 (0)	0 (0)	12(2)		
Pneumococcal conjugate, 13-valent	7 (7)	1 (0)	3 (4)	1 (3)	12(2)		

<sup>\*</sup> Counts not mutually exclusive; in descending order of overall reports.

<sup>&</sup>quot;Case definition from published analysis [ref]; MD = clinical diagnosis by a physician.

<sup>&</sup>quot;Tdap = combined tetanus and diphtheria toxoid, acellular pertussis vaccine MMR = combined measles, mumps, and rubella vaccine; HPV = human papillomavirus vaccine; DTaP = combined diphtheria and tetanus toxoid, acellular pertussis vaccine.

(79%) was most frequently reported; and among persons 50 years of age and older IIV (36%) and live attenuated zoster (22%) vaccines were most frequently reported.

Of vaccines administered alone, the most frequently reported vaccines were smallpox (53%) and IIV (12%) vaccines (Table 3). By age, among persons 18 years of age and younger, the most frequently reported vaccines were 4-valent human papillomavirus (HPV) (25%) and hepatitis B (13%) vaccines; among persons 19 to 49 years of age, smallpox vaccine (71%) was most frequently reported; and among persons 50 years of age and older IIV (38%) and live attenuated zoster (23%) vaccines were most frequently reported.

Of the 708 identified reports of myopericarditis, 138 (19%) described signs or symptoms of influenza-like illness up to 42 days prior to symptom onset for myopericarditis. Reported median age was 24 years (range: 0 to 90 years); 101 (73%) reported persons were male, and 37 (27%) were female. Of these 138 reports, 129 reports were serious, including 31 (24%) reports where the patient died; 21 (68%) of these reported deaths had histologic evidence of

myopericarditis on autopsy. Reported median time to symptom onset was 8 days after vaccination (range: 0 to 1,025 days). When excluding these 138 reports from consideration, the most frequently reported vaccines – both administered with other vaccines and administered alone – the order of vaccines most commonly reported did not change appreciably (Tables 4 and 5).

We identified 75 reports of myopericarditis in which the patient died. Median reported age was 7 years (range: 0 to 80 years); 40 reported patients were male, and 35 were female. Median time to onset of myopericarditis was 6 days after vaccination (range: 0 to 571 days). In 60 (80%) reports, myopericarditis could be attributed to other known causes (e.g., viral infection, disseminated bacterial infection, systemic lupus erythematosus), including 45 of 54 (83%) reported deaths among patients aged 0 to 18 years (Table 1). Of the remaining 15 reports, the reported vaccines reflected recommended vaccines for the patient's age: among 5 reports describing patients < 1 year of age, 4 received vaccines containing diphtheria and tetanus toxoids, and acellular pertussis antigen, and 3 received pneumococcal conjugate vaccines (2 received the

Table 3
Most frequently reported vaccines administered alone among myopericarditis reports, by age.

	Age group, year	ıp, years (%)					
Vaccine*	0-18 n = 40	19-49 n = 307	≥50 n = 77	Not reported n = 25	Total n = 449		
Smallpox	2 (5)	219 (71)	4 (5)	13 (52)	238 (53		
Influenza, inactivated	4 (10)	19 (6)	29 (38)	0 (0)	52 (12)		
Zoster, live attenuated	0 (0)	0 (0)	18 (23)	2 (8)	20 (4)		
Anthrax	1 (3)	16 (5)	1(1)	0 (0)	18 (4)		
Influenza, not specified	1 (3)	4(1)	10 (13)	2 (8)	17 (4)		
Tdap Tdap	1 (3)	12 (4)	2(3)	1 (4)	16 (4)		
Hepatitis B	5 (13)	6(2)	2(3)	0 (0)	13 (3)		
4-valent HPV	10 (25)	1 (0)	0(0)	0 (0)	11(2)		
Influenza, live attenuated	1(3)	7 (2)	0(0)	1 (4)	9(2)		
Hepatitis A	1(3)	3(1)	1(1)	1 (4)	6(1)		
Meningococcal conjugate	4 (10)	1 (0)	0(0)	1 (4)	6(1)		
Varicella, live attenuated	3 (8)	2(1)	0(0)	1 (4)	6(1)		
MMR**	3 (8)	2(1)	0(0)	0 (0)	5(1)		
Pneumococcal conjugate, 13-valent	0 (0)	1 (0)	3 (4)	1 (4)	5(1)		

<sup>\*</sup> Counts in descending order of overall reports.

Table 4
Most frequently reported vaccines among myopericarditis reports, excluding recent illness, by age.

Vaccine*	Age group, year	Age group, years (%)						
	0-18 n = 63	19-49 n = 409	≥50 n = 63	Not reported n = 35	Total n = 570			
Smallpox	5 (8)	345 (84)	4 (6)	18 (51)	372 (65)			
Anthrax	3 (5)	117 (29)	1(2)	6 (17)	127 (22)			
Typhoid	2 (3)	71 (17)	1(2)	2 (6)	76 (13)			
Influenza, inactivated	7 (11)	23 (6)	26 (41)	1 (3)	57 (10)			
Influenza, not specified	0(0)	18 (4)	7 (11)	6 (17)	31 (5)			
Hepatitis B	11 (18)	12 (3)	2(3)	2 (6)	27 (5)			
Tdap	8 (13)	6(2)	3 (5)	4 (11)	21 (4)			
Influenza, live attenuated	1(2)	15 (4)	0(0)	2 (6)	18 (3)			
Hepatitis A	8 (13)	6(2)	1(2)	2 (6)	17 (3)			
Zoster, live attenuated	0(0)	0 (0)	14 (22)	2 (6)	16 (3)			
4-valent HPV	12 (19)	3 (1)	0(0)	0 (0)	15 (3)			
MMR	8 (13)	6 (2)	0(0)	0 (0)	14 (3)			
Haemophilus influenzae type b	13 (21)	0 (0)	0(0)	0 (0)	13 (2)			
Meningococcal conjugate	10 (16)	2(1)	0(0)	1 (3)	13 (2)			
DTaP**	9 (14)	0 (0)	0 (0)	3 (9)	12(2)			

<sup>\*</sup> Counts not mutually exclusive; in descending order of overall reports; excludes reports describing people with documented flu-like symptoms (including gastrointestinal symptoms) prior to vaccination, and within 30 days of symptom onset.

<sup>&</sup>quot;Tdap = combined tetanus and diphtheria toxoid, acellular pertussis vaccine; HPV = human papillomavirus vaccine; MMR = combined measles, mumps, and rubella vaccine.

Tdap = combined tetanus and diphtheria toxoid, acellular pertussis vaccine HPV = human papillomavirus vaccine; MMR = combined measles, mumps, and rubella vaccine; DTaP = combined diphtheria and tetanus toxoid, acellular pertussis vaccine.

Table 5
Most frequently reported vaccines administered alone among myopericarditis reports, excluding recent illness, by age.

Vaccine*	Age group, years (%)						
	0-18 n = 25	19-49 n = 262	≥50 n = 58	Not reported n = 26	Total, n = 371		
Smallpox	2 (8)	208 (79)	4 (7)	12 (46)	226 (61		
Influenza, inactivated	2 (8)	12 (6)	23 (40)	0 (0)	37 (10)		
Zoster, live attenuated	0 (0)	0 (0)	13 (22)	2(8)	15 (4)		
Anthrax	0 (0)	11 (4)	1 (2)	0 (0)	12(3)		
Influenza, not specified	0 (0)	1 (0)	6 (10)	5 (19)	12(3)		
4-valent HPV	9 (36)	1 (0)	0 (0)	0 (0)	10(3)		
Tdap	1 (4)	4(2)	2(3)	3 (12)	10(3)		
Hepatitis B	2 (8)	5 (2)	2(3)	0 (0)	9(2)		
Influenza, live attenuated	0 (0)	4(2)	0(0)	1 (4)	5(1)		
Hepatitis A	1 (4)	2(1)	1(2)	0 (0)	4(1)		
Meningococcal conjugate	2 (8)	1 (0)	0(0)	1 (4)	4(1)		

<sup>\*</sup> Counts in descending order of overall reports.

13-valent vaccine, 1 received the 7-valent vaccine); among 4 reports describing patients 12 to 18 years of age, 2 received meningococcal conjugate vaccines, 1 received 4-valent HPV vaccine, and another received monovalent mumps vaccine; among 6 reports describing patients 19 years of age and older, 2 received smallpox vaccine, 2 received influenza vaccine (not specified), 1 received IIV, and 1 received live attenuated zoster vaccine.

#### 3.2. Estimated reporting rates

During 2014 through 2018, myopericarditis after smallpox vaccine was reported to VAERS at an estimated rate of 4.0 per 1,000 doses distributed. Regardless of age group, estimated median reporting rates of myopericarditis during 2014 through 2018 after influenza vaccine (all types) was < 0.1 per 1,000,000 doses administered.

#### 3.3. Disproportionality analysis

Disproportionality analysis identified an elevated EB05 ( $\geq$ 2.0) for smallpox vaccine and the myopericarditis-related PTs of "Myocarditis", "Pericardial disease", "Pericardial effusion", and "Pericarditis". An EB05  $\geq$  2.0 was found for anthrax vaccine and the PTs "Myocarditis", "Pericardial disease", and "Pericarditis"; most patients (95%) received a concomitant smallpox vaccine. An EB05  $\geq$  2.0 was also identified for typhoid vaccine and the PT "Pericardial disease"; review of these typhoid vaccine reports revealed that all patients received smallpox vaccine concomitantly with typhoid vaccine. No other product-specific vaccine had an EB05  $\geq$  2.0 for any myopericarditis-related PT.

#### 4. Discussion

We performed a comprehensive review of post-licensure vaccine surveillance data on myopericarditis, using both a published case definition [14] and review of medical records to identify such reports. Smallpox vaccine remained the most commonly reported vaccine, while other reported vaccines were consistent with vaccine types recommended for the given age group of the patient and therefore might reflect relative frequencies of vaccine exposures per recommended schedules for vaccination [17,18]. Myopericarditis remained a rarely reported AE after vaccines (0.1% of reported AEs during the analytic period), and this analysis revealed no new or unexpected safety concerns.

Distribution of reports by sex was similar to previous case series among hospitalized pediatric and adult patients (Table 1). A case series describing myocarditis among children and adolescents

18 years of age and younger found a comparable proportion (57%) of cases among males [19], but a case series among adults hospitalized in a group of Finnish hospitals found a preponderance of cases among males<55 years of age [20]. A potential explanation for these differences by sex and age remains elusive, although findings in studies with BALB/c mouse models of acute coxsackievirus-induced myocarditis suggest possible biologic mechanisms [21,22]. The patients in both case series would be considered serious by definition (due to hospitalization); likewise, a large proportion of serious reports were observed in the VAERS data.

Reported case fatality after acute myocarditis among pediatric patients has been reported around 8% to 12% [23,24]. The high proportion of deaths reported among persons 18 years of age and younger in this analysis (Table 1) would seem unusual. However, biased reporting to VAERS can occur, and deaths after vaccination among otherwise healthy young people might be more prone to report compared to deaths among older or less healthy populations [10]. Conversely, younger persons (such as children) who experience mild myopericarditis might not be reported to VAERS; such lack of reporting would skew the proportion of reported deaths among this population. These and other limitations of VAERS will be discussed shortly.

The high proportion of reported myopericarditis after smallpox vaccine (Tables 2 and 3) likely reflects the known association between myopericarditis and smallpox vaccine [2,14], which is also reflected in the disproportionality analysis results. The preponderance of myopericarditis after smallpox vaccine reported among people 19 to 31 years of age (predominately male) in this analysis is consistent with smallpox vaccination among selected military personnel [25]. Indeed, during the analytic period, the military conducted active surveillance (and subsequent reporting to VAERS) of myopericarditis after smallpox vaccine [26]. Despite this potential simulated reporting, the most frequently reported vaccines, by age range, would not vary after discounting smallpox vaccine (Tables 3 and 4) (except among people 19-49 years of age). Disproportionate reporting of anthrax and typhoid vaccines and myopericarditis-related PTs likely reflect coadministration with smallpox vaccine, as was common practice in the military during the analytic period [26].

During 2008–2018, ACAM2000® was the smallpox vaccine in use (prior to 2008, Dryvax® was the smallpox vaccine used). Myopericarditis after ACAM2000 has been reported at rate of 5.7 per 1,000 doses administered [27]. A rate of 6.9 per 1,000 doses administered has been reported among people receiving their first dose of ACAM2000 [28]. The estimated reporting rate of myopericarditis we observed after smallpox vaccine during 2014–2018 (4.0 per 1,000 doses distributed) is comparable to these rates.

<sup>&</sup>quot; HPV = human papillomavirus vaccine.

Other vaccines after which myopericarditis was reported largely reflect recommended vaccination schedules for people in the corresponding age groups [15,16]. Myopericarditis has not been described previously after hepatitis B, Haemophilus influenzae type b, 9-valent HPV, or live attenuated zoster vaccines that were licensed for use in the United States, and only sparse case reports describe myocarditis after inactivated influenza and diphtheria, tetanus, and inactivated polio vaccines [9,29,30]. Myopericarditis has been reported after 4-valent HPV vaccine [31]. Of interest, myopericarditis is commonly caused by viral infections, [1] including varicella zoster virus [32]. Discounting smallpox vaccine, myopericarditis after live attenuated viral vaccines was reported infrequently (Tables 2 and 3), a result consistent with a past report describing no increased risk of myopericarditis after live attenuated virus vaccines (except smallpox vaccine) [7]. Together, these observations suggest that - aside from smallpox vaccine myopericarditis after vaccines licensed for use in the United States is rare. As noted in the below paragraph, these reports do not establish a causal relationship between vaccines myopericarditis.

VAERS is a passive surveillance system that gathers reports from across the United States, and can detect rare events [10], like myopericarditis, after vaccination. VAERS also shares the limitations of passive surveillance systems: under-reporting, reporting biases, inconsistent data quality and completeness, changes in reporting over time, and lack of an unvaccinated comparison group [10,13]. These limitations generally do not allow VAERS data to determine if a vaccine caused a particular adverse event, including myopericarditis or death. Also, because doses administered data were not available, we used doses distributed as the denominator in estimating reporting rates after smallpox vaccine. That our estimates (4.0 per 1,000 doses distributed) are comparable to known rates of myopericarditis after smallpox vaccine (5.7 per 1,000 doses administered) is reassuring. Also reassuring is the confirmation of the known association between smallpox vaccine and cardiacrelated PTs on disproportionality analysis (EB05 > 2).

Given that smallpox vaccine continues to be administered to selected military and civilian personnel [25,33] and that new vaccines continue to be approved for use, continuing surveillance for myopericarditis after vaccination is warranted. However, this analysis revealed no unexpected safety concerns, and reports of myopericarditis after vaccines remain rare.

#### 5. Note

This article reflects the views of the authors and should not be construed to represent FDA's views or policies.

#### 6. Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC), or the US Food and Drug Administration (FDA). Mention of a product or company name does not constitute endorsement by the CDC or FDA.

#### **Declaration of Competing Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

#### Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2020.12.046.

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- infection. Pediatr Cardiol 2010;31:703–6.
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- Vaccine in Laboratory and Health Care Personnel at Risk for Occupational Exposure to Orthopoxviruses Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2015. MMWR Morb Mortal Wkly Rep 2016:65:257-62.

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) Thu, 25 Mar 2021 18:17:00 +0000 Sent: To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) Cc: Subject: RE: WHO GACVS sub-committee - request for information Attachments: Table 3a Daily VAW COVID19 Reports Overall Summary.pdf, Table 2 Weekly Prespecified Conditions of VAERS COVID19 Reports.pdf, Table 3a Daily VAW COVID19 Reports Overall Summary.pdf

(b)(5)

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

Sent: Wednesday, March 17, 2021 3:56 PM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>; Licata, Charles

 $(CDC/DDID/NCEZID/DHQP) < \underline{kui5@cdc.gov}; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) \\$ 

<qsq2@cdc.gov>

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Subject: FW: WHO GACVS sub-committee - request for information

Hi folks,

Please see below email chain. (b)(5)

Tom, (b)(5)

(b)(5)

Thanks!

• John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

Sent: Wednesday, March 17, 2021 1:24 PM

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

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

Subject: RE: WHO GACVS sub-committee - request for information

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, March 17, 2021 12:26 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

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

Subject: RE: WHO GACVS sub-committee - request for information

(b)(5) (b)(5) . Thanks.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Wednesday, March 17, 2021 12:24 PM

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

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

Subject: RE: WHO GACVS sub-committee - request for information

Tom,
John is out today (b)(5)
Elaine

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, March 17, 2021 12:09 PM

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

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** FW: WHO GACVS sub-committee - request for information

(b)(5) Thanks.

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Sent: Wednesday, March 17, 2021 3:47 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov">dvj3@cdc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">iyk3@cdc.gov</a>; PAL, Shanthi Narayan <a href="mailto:pals@who.int">pals@who.int</a>;

JANIN, Annick < janina@who.int>

Subject: Re: WHO GACVS sub-committee - request for information

#### Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopaenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

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

Sent: Wednesday, 17 March 2021 6:43 AM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<a href="mailto:</a>, conklin, Laura (CDC/DDPHSIS/CGH/GID") <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov</a>; conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov</a>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < <u>iyk3@cdc.gov</u>> **Subject:** RE: WHO GACVS sub-committee - request for information

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I'm happy to talk when convenient. I'm Cc'ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

### Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Monday, March 8, 2021 10:05 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>

Subject: WHO GACVS sub-committee - request for information

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM

Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia

Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)

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Page 540		
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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Mon, 26 Oct 2020 17:50:32 +0000

To: Hanson, Kayla E; Kristin Goddard, MPH (kristin.x.goddard@kp.org)

Cc: Donahue, James G DVM/PhD

Subject: RE: RCA Outcome Questions/Recommendations

Attachments: nihms-1019376.pdf

(b)(5)

From: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>

Sent: Monday, October 26, 2020 1:40 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Kristin Goddard, MPH

(kristin.x.goddard@kp.org) < kristin.x.goddard@kp.org>

Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>

Subject: RE: RCA Outcome Questions/Recommendations

(b)(5) -Kayla

From: Hanson, Kayla E

Sent: Thursday, October 22, 2020 1:59 PM

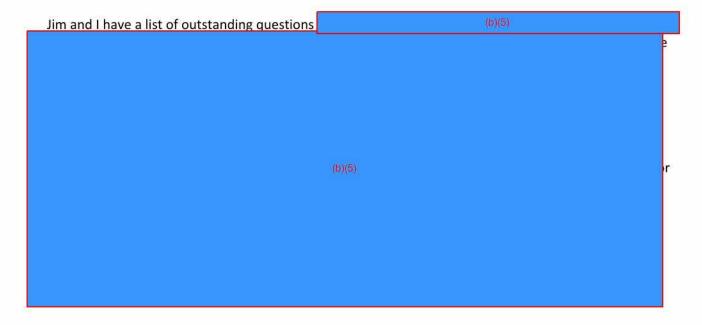
To: Weintraub, Eric (CDC/OID/NCEZID) < eiw8@cdc.gov >; Kristin Goddard, MPH

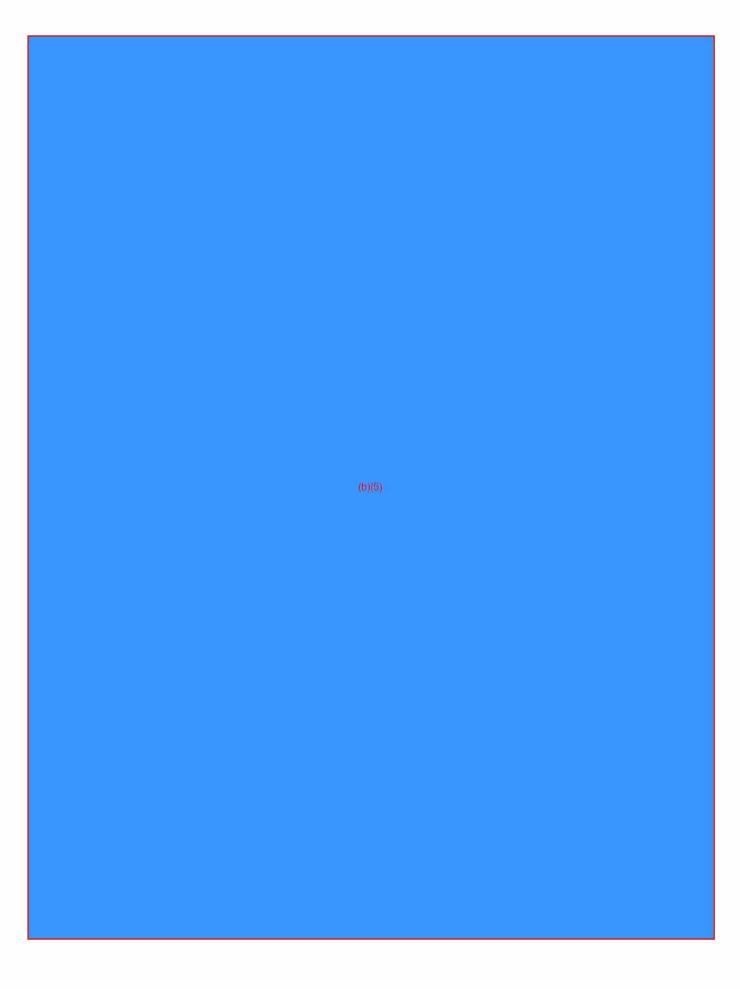
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**Subject:** RCA Outcome Questions/Recommendations

Hi Kristin and Eric,





Best, Kayla

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# Myocarditis and pericarditis are rare following live viral vaccinations in adults

Jennifer Kuntz, Bradley Crane, Sheila Weinmann, Allison L. Naleway\*, and Vaccine Safety Datalink Investigator Team<sup>1</sup>

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# **Abstract**

Reports of myocarditis and pericarditis following smallpox vaccination in adults suggested a need to assess inflammatory cardiac disease risk among adults who receive live viral vaccinations. From 1996 through 2007, among 416,629 vaccinated adults in the Vaccine Safety Datalink, we identified one probable pericarditis case and no cases of myocarditis in the 42 days following a live viral vaccination. Our self-controlled risk interval analysis found that, based on one case identified during the risk interval and 10 cases during the control interval, there is no increased risk of myopericarditis in the 42 days following vaccination (IRR, 0.57; 95% CI, 0.07, 4.51). Our study suggests that the occurrence of myopericarditis following live viral vaccination is rare with an estimated incidence of 0.24 per 100,000 vaccinated, which is not higher than the background rate and is much lower than the incidence rates reported following smallpox vaccination.

# Keywords

Myocarditis; Pericarditis; Vaccination adverse effects

# 1. Introduction

Reports of cardiac complications – including myocarditis, pericarditis, and arrhythmias – following smallpox vaccination, have dated back to the 1950s in the United States, although a total of only six such cases were reported prior to 2003 [1–4]. This changed when, from December 2002 through December 2003, a campaign was held to vaccinate 540,824 U.S. military personnel against smallpox using DryVax vaccine. During this campaign, 67 cases of myocarditis or pericarditis were reported with an average period of 10 days between vaccination and symptom onset [5].

Although cardiovascular complications due to vaccination are rare, these reports of myocarditis and pericarditis following smallpox vaccination in adults have raised the issue

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of assessing inflammatory cardiac disease risk following other live viral vaccinations in adults. We sought to determine the risk of myocarditis and pericarditis following the administration of non-smallpox, live viral vaccinations among adults.

# 2. Methods

We identified a retrospective cohort of adults 18 years and older who received a measles-mumps-rubella vaccine (MMR), varicella vaccine (VZV), oral polio vaccine (OPV), or yellow fever vaccine (YFV) between January 1, 1996 and December 31, 2007 at four integrated healthcare delivery organizations: Kaiser Permanente Northwest, Kaiser Permanente Washington (formerly Group Health), Northern California Kaiser Permanente, and Southern California Kaiser Permanente. These organizations collaborate with the Centers for Disease Control and Prevention (CDC) as the Vaccine Safety Datalink (VSD) to conduct population-based research on vaccine safety [6,7]. The cohort was restricted to patients with at least 6 months of health plan enrollment prior to their first live viral vaccination. We then identified cohort members who had a diagnosis of myocarditis or pericarditis within the study period at any point following vaccination.

Acute myocarditis was identified with the following ICD-9 codes: 422.0 (acute myocarditis in diseases classified elsewhere); 422.90 (acute myocarditis NOS); 422.91 (idiopathic myocarditis); 422.99 (other and unspecified acute myocarditis); and, 429.0 (myocarditis unspecified). Acute pericarditis was identified with ICD-9 code 420.x. We identified the earliest diagnosis during the study period and cases diagnosed prior to 1996 were excluded. We also collected information about comorbid conditions diagnosed prior to the myocarditis or pericarditis diagnosis date, including diabetes, hyperlipidemia, hypertension, coronary insufficiency, prior myocardial infarction, chronic ischemic heart disease, coronary artery disease, and connective tissue disorder.

During medical record abstraction, we confirmed that the cardiac event diagnosis was recorded in the medical record and the earliest diagnosis occurred during the study period. We excluded diagnoses that were miscoded or considered to be a 'rule-out' diagnosis, could not be confirmed because of a lack of information in the medical record, or occurred prior to 1996. We also collected information about cardiac symptoms, co-morbidities, and diagnostic tests (e.g., echocardiograms, chest x-rays, cardiac enzymes). A cardiology nurse and physician then further classified cases with validated diagnoses as definite, probable or possible according to surveillance case definitions for myocarditis and pericarditis developed by the U.S. Department of Defense and CDC for their smallpox vaccine program [8–10]. We defined definite pericarditis cases as those with at least two of the following criteria: presence of chest pain made worse by lying down and relieved by sitting up or leaning forward; pericardial rub or auscultatory sign with 1-3 components per beat; electrocardiogram with ST elevations, or PR depressions without reciprocal ST depressions; presence of abnormal collection of pericardial fluid on echocardiogram; or, histopathologic evidence of pericardial inflammation. Persons with elevated cardiac enzymes or evidence of myocardial inflammation plus at least two of the following criteria were considered definite myocarditis cases: presence of dyspnea, palpitations, or chest pain; electrocardiogram

(ECG) abnormalities; or evidence of focal or diffuse depressed left ventricular function identified by an imaging study.

We conducted a self-controlled risk interval analysis using conditional Poisson regression. Our analysis included possible, probable, and definite cases who were vaccinated during the study period, and we used a composite outcome of myopericarditis consistent with many of the previously published smallpox vaccine studies. We defined the risk interval as the 42-day window following YFV, VZV, OPV, or MMR vaccination; the control interval was defined as the time period 85 to 365 days following vaccination. We censored a 'wash out' period of 43 to 84 days after vaccination. We selected the 42-day exposure window based on prior smallpox vaccination investigations that suggested these cardiac events developed soon after vaccination at a mean onset time of 10 days [11]. We calculated an incidence rate ratio (IRR) and 95% confidence interval (CI), which compared the incidence of myopericarditis in the risk interval to incidence in the control interval.

This study was approved by the Institutional Review Boards at all participating sites.

# 3. Results

We identified 416,629 adults who received at least one live viral vaccine between 1996 and 2007 and met eligibility criteria (Fig. 1). Two hundred ninety-seven thousand doses of measles, mumps, or rubella-containing vaccine, 87,295 doses of VZV, 76,606 doses of YFV, and 35,291 doses of OPV were administered to this cohort during the study period. Of the 416,629 eligible vaccinated adults, 120 had a coded pericarditis diagnosis and 32 had a coded myocarditis diagnosis at any time following vaccination. After review of these potential cases, 54 (45%) had a validated pericarditis diagnosis and 18 (56%) had a validated myocarditis diagnosis. The remaining 80 potential cases were excluded because they had miscoded or rule-out diagnoses, lacked sufficient information in the medical record to confirm the diagnosis, or were diagnosed prior to 1996. Twelve (67%) of the myocarditis diagnoses occurred among 18–29-year-olds, whereas pericarditis was more evenly distributed across the age strata. Both diagnoses were more common in males than females (myocarditis: 79% male; pericarditis: 69% male). Hypertension (n = 16, 30%) and hyperlipidemia (n = 11, 20%) were common comorbid diagnoses in pericarditis cases. After adjudication, only 5 patients were classified as definite pericarditis and only 3 were classified as definite myocarditis cases according to the DoD/CDC definitions.

One probable pericarditis case occurred in the 42 days following vaccination; no myocarditis cases and no definite or possible pericarditis cases occurred in the 42-day period. The one probable pericarditis case occurred 36 days after YFV. This patient also received tetanus-diphtheria (Td) and meningococcal vaccines on the same day as YFV and inactivated polio, hepatitis A, and influenza vaccines in the four days after YFV. Thus, the incidence rate of diagnosed myopericarditis in the 42 days following vaccination with VZV, YFV, OPV, or MMR was 0.24 per 100,000 vaccinated. The remaining 71 definite, probable, and possible cases occurred at least 43 days after vaccination and were relatively evenly distributed over the course of the maximum of 10 years of follow-up after vaccination (Fig. 2). Only 10 of these cases occurred in the 85 to 365 days following vaccination control window. Based on

the one case identified during the risk interval and 10 cases that occurred during the control interval, we found no increased risk of myopericarditis in the 42 days following vaccination (IRR, 0.57; 95% CI, 0.07, 4.51).

# 4. Discussion

There are limited published data about cardiac events after non-smallpox vaccinations. This study evaluated myopericarditis risk after non-smallpox, live viral vaccination in a population-based cohort. Seven cases of pericarditis after hepatitis B and influenza vaccine were reported in 1980–90s [12,13]. In 2000, a case of myopericarditis in a 31-year old man was reported 2 days after diphtheria, tetanus and polio vaccination [14]. Additional research reported no detectable increase in the risk of myocardial infarction or stroke following influenza, tetanus, or pneumococcal vaccinations [15,16].

In the absence of additional incidence studies of non-smallpox vaccinations, we can only compare our rates to those from published smallpox vaccination studies [5,17]. Among U.S. military personnel, the observed incidence of myopericarditis that came to medical attention over a 30-day observation window following smallpox vaccination was 12.3 cases per 100,000 [5]. In turn, Engler et al. prospectively followed a cohort of 1081 healthy military personnel to identify cardiac symptoms, biomarkers (specifically troponin T), and ECG changes, and identified four cases of probable myocarditis and one case of suspected pericarditis in the 30 days after smallpox vaccination, resulting in a higher incidence of 463 cases per 100,000 [17]. While our study does not speak to risk related to smallpox vaccination, our results provide evidence for the lack of an association between other commonly-administered live viral vaccines and these cardiac outcomes.

Myocarditis and pericarditis are inflammatory processes with variable and unpredictable clinical presentations and course. Thus, diagnosis of these conditions is often difficult. Considering this, we acknowledge the potential for underestimation of the true occurrence of myocarditis and pericarditis, as patients may not present in the healthcare setting for these conditions or the diagnosis may not be accurately reflected in coded data. For example, the Engler et al. study reported a higher incidence of myopericarditis after vaccination through active follow up of vaccinated participants; the authors note that 3 of the 5 cases they observed would not have sought medical care for their symptoms outside of the study protocol [15]. Reducing the underestimation and misclassification of cases would require further enhancement of VSD active surveillance, an effort that would not be feasible, especially given the population size that would be needed to detect rare outcomes such as these.

Our study focused on non-smallpox, live viral vaccines recommended for previously unvaccinated adults, those without documented immunity, or those at increased risk for exposure or transmission, such as healthcare personnel or international travelers. Although a live attenuated influenza vaccine was licensed in 2003 for use in adults, we did not include it in our analysis since use of the vaccine in adults during most of the study period was limited in the VSD. A herpes zoster vaccine was licensed and recommended for adults 60 years of age and older in 2006, but also was not included in this analysis; a separate VSD study

reported no increased risk of myocarditis or pericarditis in the 1–42 days following zoster vaccination [18].

We found that the rate of myocarditis and pericarditis in the 42 days following VZV, YFV, OPV, or MMR vaccination was very low and was not statistically different than the rate of these events during unexposed, control intervals. These findings confirm that cardiovascular complications related to commonly-administered, live viral vaccination are rare in adults.

# **Acknowledgements**

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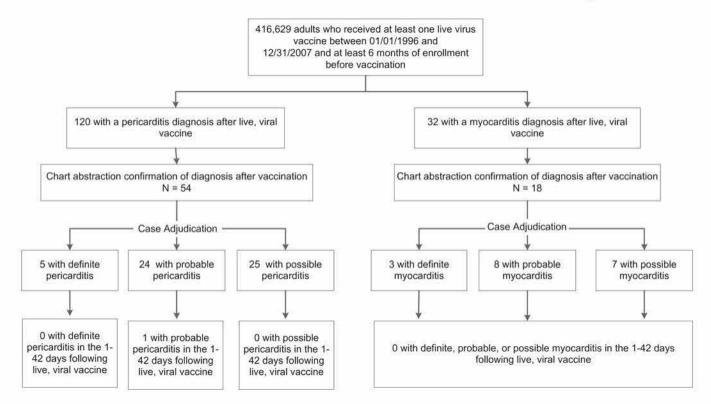


Fig. 1.

Identification and validation of myocarditis and pericarditis cases following live viral vaccination.

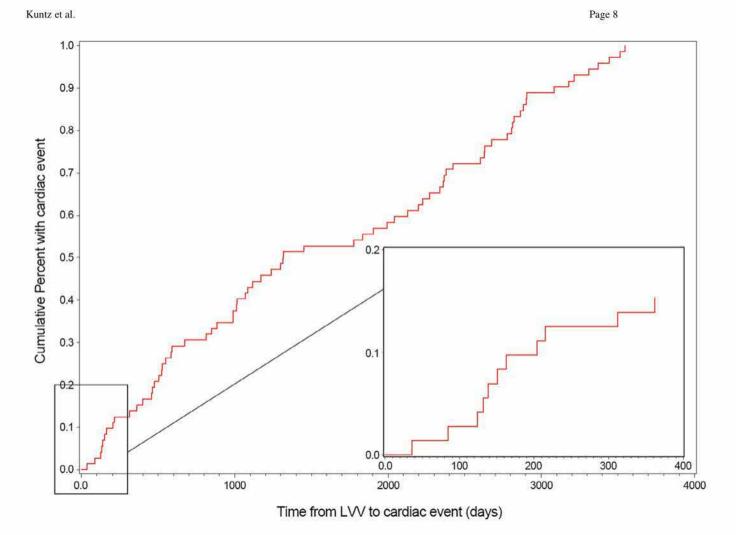


Fig. 2. Distribution of myocarditis (n = 18) and pericarditis (n = 54) cases over time since live viral vaccination.

Sent: Thu, 4 Mar 2021 12:24:13 +0000

Subject: FW: Director's Brief: Thursday March 4, 2021

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Thursday, March 4, 2021 7:12 AM

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Romanik, Nikki Jo (CDC/OD/OCS) <kon6@cdc.gov> Subject: Director's Brief: Thursday March 4, 2021

# Thursday March 4, 2021

	Cumulative	Daily	7-Day	Change from Prior
	Total		Daily Average	7-Day Period
Cases <sup>2,3</sup>	28,514,774	54,276	63,938	-2.4%
Hospital Admissions (Confirmed) <sup>4</sup>	1,809,100	4,533	5,650	-13.0%
Hospital Admissions (All)4	3,354,035	9,251	11,372	-7.4%
Hospital In-Patient Beds ≥30% COVID-195	N/A	N/A	0.9%	-36.7%
Deaths <sup>2</sup>	515,277	2,103	1,990	-4.3%
Test Volume <sup>6</sup>	335,876,223	N/A	1,177,275	7.0%
Test Positivity <sup>6</sup>	8.9%	N/A	4.6%	-13.5%

COVID-19 Vaccinations in the United States <sup>7</sup>						
	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Receiving 2 Doses (% Population)	
Overall US	163,759,745	107,028,890	80,540,474	52,855,579 (15.9)	26,957,804 (8.1)	
Federal Pharmacy Partnership for Long-Term Care Program (Subset of Overall Numbers)	N/A	N/A	7,218,655	4,669,986	2,510,471	

Data as of Mar 3, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID Data Tracker

Progress towards 100M dose target (doses reported since 1/20/2021; Day 41): 64,015,193 (overall); 5,310,399 (LTCF)

. Cases: The current 7-day average of new cases decreased by 2.4% compared to the previous week. There has been a 7-week downward trend resulting in an overall 74.4% decline since the highest peak of the 7-day moving average of new cases on January 11, 2021 (249,360 to 63,938).

28,514,774 COVID-19 cases reported as of Mar 2, 2021 with 54,276 new cases reported.

<sup>&</sup>lt;sup>3</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change.

Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

Time period: Jan 22, 2020 – Mar 2, 2021; confirmed and probable cases.

California reported 806 historical deaths on Feb 25, and Texas reported 2,990 historical cases on Feb 27, 2021 and 1,840 historical cases on Mar 1, 2021. This will temporarily impact rates and averages. Beginning Feb 24, 2021, South Carolina reconciles their historical data every Wednesday.

Time period: Aug 1, 2020 – Mar 1, 2021; (All) includes both confirmed and suspect cases.

<sup>&</sup>lt;sup>5</sup> Time period: Feb 16, 2021 - Mar 1, 2021.

Time period: Mar 1, 2020 - Feb 28, 2021; Time period for test volume 7-day average and percent change: Feb 11, 2021 - Feb 24, 2021.

<sup>7</sup> Includes data for US States, DC, US Territories, and Federal entities, and pharmacies (see table on last page for details). Total doses allocated are through Mar 28, 2021

- The 7-day average number of new cases decreased by 2.4% to 63,938 new cases per day compared to the previous 7-day period.\*
- During the 7 days ending March 1, 2021, regarding cases:
  - 26 (46.4%) jurisdictions are decreasing
  - 30 (53.6%) jurisdictions are increasing

\*The current 7-day average of new cases is impacted by a historical correction of 2,990 and 1,840 cases reported by Texas on February 27, 2021 and March 1, 2021, respectively. The 7-day average number of new cases (excluding historical cases reported in the past two weeks) decreased by 3.4% to 63,248 new cases per day compared to the previous 7-day average of 65,485.

- Testing: RT-PCR test volume appears to be increasing. RT-PCR test positivity continues to decline (7-day average now 4.6%); 1 jurisdiction remains >=10% positivity (TX).
  - The national 7-day average test volume for Feb 18 Feb 24, 2021, was 1,177,275 up 7.0% from 1,099,850 the previous 7-days
  - The national 7-day average percent positivity for Feb 22 Feb 28, 2021, is 4.6%, down 0.7
     percentage points from 5.3% the previous week
  - o 7-day average positivity is high (>=10%) in 1 jurisdiction (2% of all jurisdictions): TX
  - 7-day average positivity is low (<5%) in 28 jurisdictions (55% of all jurisdictions)</li>
  - Positivity is decreasing in 46 jurisdictions (90% of all jurisdictions)
- Hospitalizations: The new confirmed COVID-19 admissions 7-day average (5,650) has decreased 65.8% since the peak on January 9, 2021 (16,540)
  - The 7-day average number of new admissions of patients with confirmed COVID-19 decreased by 13.0% to 5,650 during the most recent week, Feb 23–Mar 1, 2021
  - The 7-day average number of hospitalized patients with confirmed COVID-19 decreased by 17.3% to 45,607 during the most recent week, Feb 23–Mar 1, 2021
  - The peak above refers to the date of the highest 7-day moving average
    - The single-day peaks are:
      - Admissions: Jan 05, 2021– 18,009
      - Hospitalizations: Jan 05, 2021 125,422
- Deaths: The current 7-day average of new deaths decreased by 4.3% compared to the
  previous week. There has been a 7-week downward trend resulting in an overall 41.1% decline since
  the highest peak of the 7-day moving average of new deaths on January 13, 2021 (3,378 to 1,990).
  - 515,277 COVID-19 deaths reported as of Mar 2, 2021 with 2,103 new deaths reported.
  - The 7-day average number of new deaths decreased by 4.3% to 1,990 new deaths per day compared to the previous 7-day period.\*

\*The current 7-day average of new deaths is impacted by a historical correction of 806 deaths reported by California on February 25, 2021. The 7-day average number of new deaths (excluding historical deaths reported in the past two weeks) decreased by 9.8% to 1,875 new deaths per day compared to the previous 7-day average of 2,079.

• Emerging Variants: At least 48 jurisdictions with reported variant cases. CDC genomic surveillance activities continue to ramp up. There are more than 145,000 sequences in GISAID from U.S. submitters.

# B.1.1.7 Variant

- Cumulative in US (AL, AK, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OR, PA, PR, RI, SC, TN, TX, UT, VA, WA, WI, WV, and WY)
  - 2,580\* cases in 48 jurisdictions
  - As of March 3, 2021, there are two cases attributed to the B.1.1.7 variant that also contains the E484K substitution in GISAID in Oregon and New York City.

#### P.1 Variant

- Cumulative in U.S. (AK, FL, MD, MN, OK, and OR)
  - 11\* cases in 6 jurisdictions
  - (SBU) There are two cases in New Jersey attributed to the P.1 variant that CDC is not authorized to report publicly. This case is not reflected in the total variant case numbers shown above.

#### B.1.351 Variant

- Cumulative in US (CA, CT, DC, FL, GA, ID, IL, MA, MD, NC, NV, NY, SC, TN, TX, VA, WA)
  - 66\* cases in 17 jurisdictions
  - (SBU) There are two additional cases in New York, one additional case in Wyoming, and four additional cases in Washington attributed to the B.1.351 variant that CDC is not authorized to report publicly. These cases are not reflected in the total variant case numbers shown above.

#### **Other Variants**

- CDC is monitoring other variants in addition to the variants of concern highlighted above, including B.1.427/9, B.1.526, and P.2 variants of interest. Currently, through NS3 enhanced surveillance, state public health laboratories are asked to submit specimens that contain the E484K or N501Y substitutions or deletions in the S protein for sequencing, isolation, and further characterization at CDC.
- Vaccine: More than 52 million people or 15.9% of the population have received at least 1 dose. Just reached an average of over 2 million doses administered per day
  - Overall, 80,540,474 vaccine doses have been administered.
    - In total, 15.9% (N= 52,855,579) of the population has received 1 or more doses.
    - 8.1% of the population (N= 26,957,804) has received two doses.
    - Progress towards 100M dose target (doses reported since 1/20/2021; Day 41): 64,015,193 doses
      - Overall, 7,218,655 doses have been administered in LTCFs
      - 4,669,986 people in LTCFs have received 1 or more doses
  - o Doses in LTCF reported since 01/20/2021 (Day 41): 5,310,399 doses
  - Daily vaccine doses administered and reported to CDC increased to an average of 2,010,790 doses reported per day over the past week (previous week: 1,454,731 doses reported per day, on average).
  - Retail Pharmacy Program: The Federal Retail Pharmacy Program is adapting to prioritize vaccinating all school staff and childcare workers during the month of March. CDC is also working with jurisdictions to prioritize this population in other delivery sites.

 Each year CDC helps distribute and administer about 80 million vaccines through its Vaccines for Children Program – we've now accomplished that same yearly total in 11.5 weeks. Additionally, we're now averaging 2 million doses administered per day.

#### Other Publications

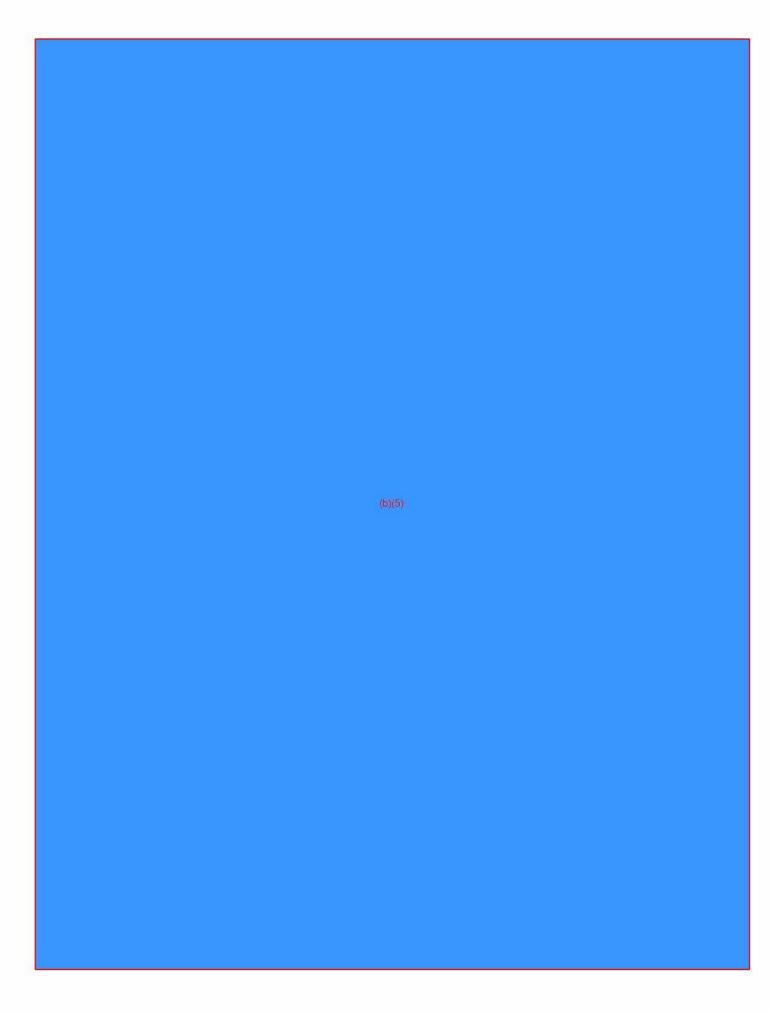
Lancet Child and Adolescent Health: Factors associated with severe outcomes in patients with multisystem inflammatory syndrome in children (MIS-C), March-October 2020.

- Describes factors associated with severe outcomes for patients with COVID-19-associated multisystem inflammatory syndrome in children (MIS-C).
  - Paper describes 1,080 hospitalized patients <21 years with dates of MIS-C onset from March 11-October 10, 2020.
  - Outcomes of interest were ICU admission, decreased cardiac function, shock, myocarditis, and coronary artery abnormalities.
  - Demographic characteristics, signs and symptoms, and laboratory findings were assessed for associations with the outcomes, controlling for all pre-existing factors.
  - Primary results include:
    - Patients 6-12 years old were more likely to have severe outcomes compared to those under the age of 5 years, and these risks were even higher for patients 13-20 years old.
    - Male sex was associated with coronary artery abnormalities and myocarditis.
    - Non-Hispanic Black patients were more likely to be admitted to the ICU and experience decreased heart function.
    - Patients with shortness of breath and abdominal pain were more likely to be admitted to the ICU.
    - Elevated levels of certain lab markers (troponin, BNP, and proBNP, as well as ddimer, CRP, and ferritin) and lower levels of lymphocytes and platelets were linked to ICU admission, shock and decreased cardiac function.
  - Manuscript being published 3/4

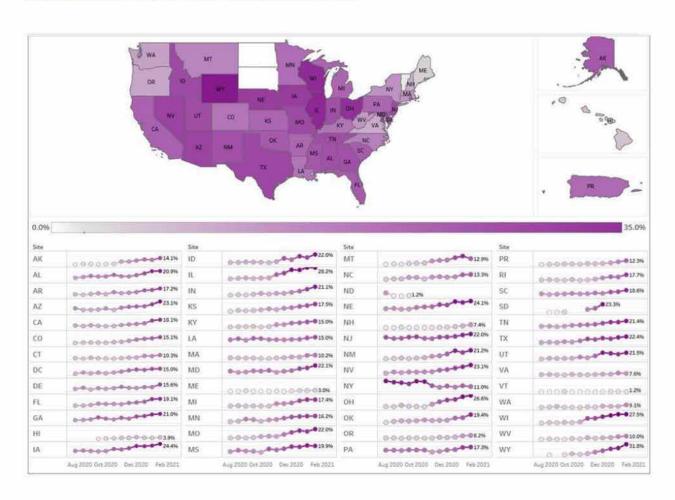
#### MMWR Releases

	(b)(5)		

• Two MMWR reports related to COVID-19 are scheduled as part of the regular issue of the Weekly, with



**FYI**Updated the website today on national seroprevalence from two rounds in January. See below. <a href="https://covid.cdc.gov/covid-data-tracker/#national-lab">https://covid.cdc.gov/covid-data-tracker/#national-lab</a>



From: Hanson, Kayla E

**Sent:** Thu, 22 Oct 2020 18:58:49 +0000

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Kristin Goddard, MPH

(kristin.x.goddard@kp.org)

Cc: Donahue, James G DVM/PhD

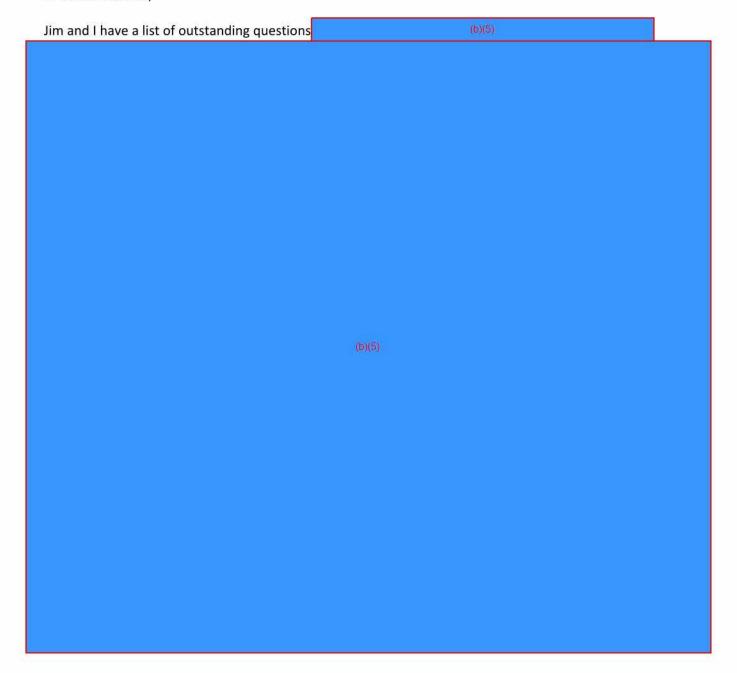
Subject: RCA Outcome Questions/Recommendations

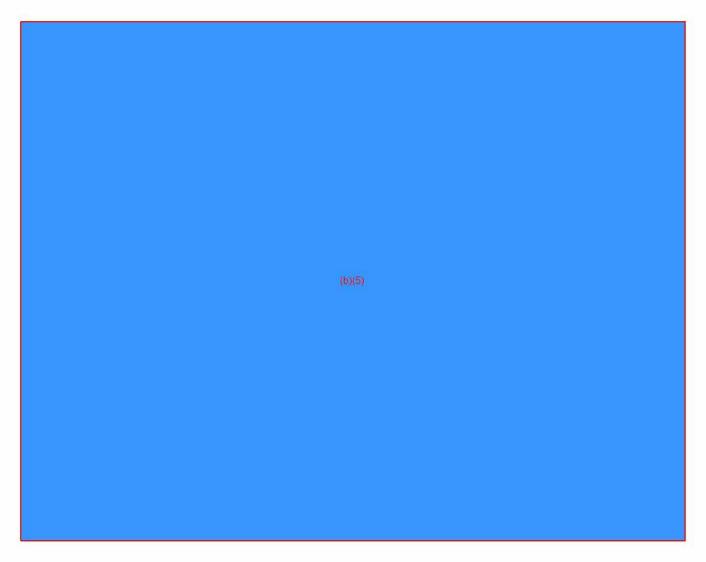
Attachments: COVID-19 RCA Outcomes Draft Table 2020-10-22.docx, COVID-19 RCA

Outcomes Draft ICD Code List\_2020-10-22.xlsx, Summary\_COVID-19 RCA AEs

incident\_definition\_exclusions10-21-2020.docx

Hi Kristin and Eric,





Best, Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health

Marshfield Clinic Research Institute | → 1000 North Oak Avenue (ML2), Marshfield, WI 54449

1-715-221-6482 | 1-715-389-3880 | hanson.kayla@marshfieldresearch.org

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Walke, Henry (CDC/DDID/NCEZID/DPEI) From:

Sent: Thu, 4 Mar 2021 12:11:49 +0000 To: Walensky, Rochelle (CDC/OD)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD); Romanik, Nikki

Jo (CDC/OD/OCS)

Subject: Director's Brief: Thursday March 4, 2021

# Thursday March 4, 2021

	Cumulative Total	Daily	7-Day Daily Average	Change from Prior 7-Day Period
Cases <sup>2,3</sup>	28,514,774	54,276	63,938	-2.4%
Hospital Admissions (Confirmed)4	1,809,100	4,533	5,650	-13.0%
Hospital Admissions (All)4	3,354,035	9,251	11,372	-7.4%
Hospital In-Patient Beds ≥30% COVID-195	N/A	N/A	0.9%	-36.7%
Deaths <sup>2</sup>	515,277	2,103	1,990	-4.3%
Test Volume <sup>6</sup>	335,876,223	N/A	1,177,275	7.0%
Test Positivity <sup>6</sup>	8.9%	N/A	4.6%	-13.5%

	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Receiving 2 Doses (% Population)
Overall US	163,759,745	107,028,890	80,540,474	52,855,579 (15.9)	26,957,804 (8.1)
Federal Pharmacy Partnership for Long-Term Care Program (Subset of Overall Numbers)	N/A	N/A	7,218,655	4,669,986	2,510,471

Data as of Mar 3, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID Data Tracker

Progress towards 100M dose target (doses reported since 1/20/2021; Day 41): 64,015,193 (overall); 5,310,399 (LTCF)

- Cases: The current 7-day average of new cases decreased by 2.4% compared to the previous week. There has been a 7-week downward trend resulting in an overall 74.4% decline since the highest peak of the 7-day moving average of new cases on January 11, 2021 (249,360 to 63,938).
  - o 28,514,774 COVID-19 cases reported as of Mar 2, 2021 with 54,276 new cases reported.
  - The 7-day average number of new cases decreased by 2.4% to 63,938 new cases per day compared to the previous 7-day period.\*
  - During the 7 days ending March 1, 2021, regarding cases:
    - 26 (46.4%) jurisdictions are decreasing
    - 30 (53.6%) jurisdictions are increasing

<sup>&</sup>lt;sup>1</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

Time period: Jan 22, 2020 - Mar 2, 2021; confirmed and probable cases

California reported 806 historical deaths on Feb 25, and Texas reported 2,990 historical cases on Feb 27, 2021 and 1,840 historical cases on Mar 1, 2021. This will temporarily impact rates and averages. Beginning Feb 24, 2021, South Carolina reconciles their historical data every Wednesday.

<sup>\*</sup> Time period: Aug 1, 2020 - Mar 1, 2021; (All) includes both confirmed and suspect cases. <sup>3</sup> Time period: Feb 16: 2021 - Mar 1: 2021

Time period: Mar 1, 2020 - Feb 28, 2021; Time period for test volume 7-day average and percent change: Feb 11, 2021 - Feb 24, 2021.

Includes data for US States, DC, US Territories, and Federal entities, and pharmacies (see table on last page for details). Total doses allocated are through Mar 28, 2021

\*The current 7-day average of new cases is impacted by a historical correction of 2,990 and 1,840 cases reported by Texas on February 27, 2021 and March 1, 2021, respectively. The 7-day average number of new cases (excluding historical cases reported in the past two weeks) decreased by 3.4% to 63,248 new cases per day compared to the previous 7-day average of 65,485.

- Testing: RT-PCR test volume appears to be increasing. RT-PCR test positivity continues to decline (7-day average now 4.6%); 1 jurisdiction remains >=10% positivity (TX).
  - The national 7-day average test volume for Feb 18 Feb 24, 2021, was 1,177,275 up 7.0% from 1,099,850 the previous 7-days
  - The national 7-day average percent positivity for Feb 22 Feb 28, 2021, is 4.6%, down 0.7 percentage points from 5.3% the previous week
  - 7-day average positivity is high (>=10%) in 1 jurisdiction (2% of all jurisdictions): TX
  - o 7-day average positivity is low (<5%) in 28 jurisdictions (55% of all jurisdictions)
  - Positivity is decreasing in 46 jurisdictions (90% of all jurisdictions)
- Hospitalizations: The new confirmed COVID-19 admissions 7-day average (5,650) has decreased 65.8% since the peak on January 9, 2021 (16,540)
  - The 7-day average number of new admissions of patients with confirmed COVID-19 decreased by 13.0% to 5,650 during the most recent week, Feb 23–Mar 1, 2021
  - The 7-day average number of hospitalized patients with confirmed COVID-19 decreased by 17.3% to 45,607 during the most recent week, Feb 23–Mar 1, 2021
  - o The peak above refers to the date of the highest 7-day moving average
    - The single-day peaks are:
      - Admissions: Jan 05, 2021–18,009
      - Hospitalizations: Jan 05, 2021 125,422
- Deaths: The current 7-day average of new deaths decreased by 4.3% compared to the previous week. There has been a 7-week downward trend resulting in an overall 41.1% decline since the highest peak of the 7-day moving average of new deaths on January 13, 2021 (3,378 to 1,990).
  - o 515,277 COVID-19 deaths reported as of Mar 2, 2021 with 2,103 new deaths reported.
  - The 7-day average number of new deaths decreased by 4.3% to 1,990 new deaths per day compared to the previous 7-day period.\*

\*The current 7-day average of new deaths is impacted by a historical correction of 806 deaths reported by California on February 25, 2021. The 7-day average number of new deaths (excluding historical deaths reported in the past two weeks) decreased by 9.8% to 1,875 new deaths per day compared to the previous 7-day average of 2,079.

 Emerging Variants: At least 48 jurisdictions with reported variant cases. CDC genomic surveillance activities continue to ramp up. There are more than 145,000 sequences in GISAID from U.S. submitters.

B.1.1.7 Variant

- Cumulative in US (AL, AK, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OR, PA, PR, RI, SC, TN, TX, UT, VA, WA, WI, WV, and WY)
  - 2,580\* cases in 48 jurisdictions
  - As of March 3, 2021, there are two cases attributed to the B.1.1.7 variant that also contains the E484K substitution in GISAID in Oregon and New York City.

#### P.1 Variant

- Cumulative in U.S. (AK, FL, MD, MN, OK, and OR)
  - 11\* cases in 6 jurisdictions
  - (SBU) There are two cases in New Jersey attributed to the P.1 variant that CDC is not
    authorized to report publicly. This case is not reflected in the total variant case numbers
    shown above.

# B.1.351 Variant

- o Cumulative in US (CA, CT, DC, FL, GA, ID, IL, MA, MD, NC, NV, NY, SC, TN, TX, VA, WA)
  - 66\* cases in 17 jurisdictions
  - (SBU) There are two additional cases in New York, one additional case in Wyoming, and four additional cases in Washington attributed to the B.1.351 variant that CDC is not authorized to report publicly. These cases are not reflected in the total variant case numbers shown above.

# **Other Variants**

- CDC is monitoring other variants in addition to the variants of concern highlighted above, including B.1.427/9, B.1.526, and P.2 variants of interest. Currently, through NS3 enhanced surveillance, state public health laboratories are asked to submit specimens that contain the E484K or N501Y substitutions or deletions in the S protein for sequencing, isolation, and further characterization at CDC.
- Vaccine: More than 52 million people or 15.9% of the population have received at least 1 dose. Just reached an average of over 2 million doses administered per day
  - Overall, 80,540,474 vaccine doses have been administered.
    - In total, 15.9% (N= 52,855,579) of the population has received 1 or more doses.
    - 8.1% of the population (N= 26,957,804) has received two doses.
    - Progress towards 100M dose target (doses reported since 1/20/2021; Day 41):
       64,015,193 doses
      - Overall, 7,218,655 doses have been administered in LTCFs
      - 4,669,986 people in LTCFs have received 1 or more doses
  - o Doses in LTCF reported since 01/20/2021 (Day 41): 5,310,399 doses
  - Daily vaccine doses administered and reported to CDC increased to an average of 2,010,790 doses reported per day over the past week (previous week: 1,454,731 doses reported per day, on average).
  - Retail Pharmacy Program: The Federal Retail Pharmacy Program is adapting to prioritize vaccinating all school staff and childcare workers during the month of March. CDC is also working with jurisdictions to prioritize this population in other delivery sites.

 Each year CDC helps distribute and administer about 80 million vaccines through its Vaccines for Children Program – we've now accomplished that same yearly total in 11.5 weeks.
 Additionally, we're now averaging 2 million doses administered per day.

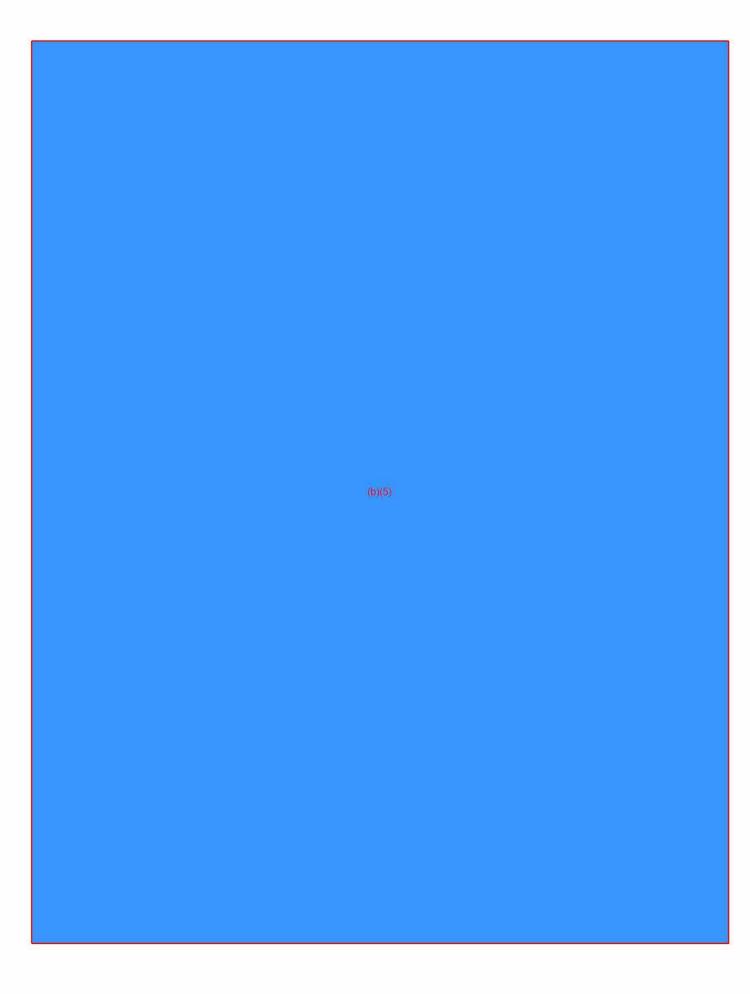
# Other Publications

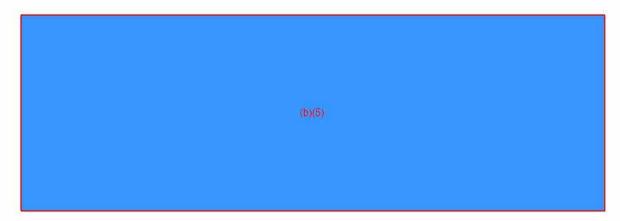
Lancet Child and Adolescent Health: Factors associated with severe outcomes in patients with multisystem inflammatory syndrome in children (MIS-C), March-October 2020.

- Describes factors associated with severe outcomes for patients with COVID-19-associated multisystem inflammatory syndrome in children (MIS-C).
  - Paper describes 1,080 hospitalized patients <21 years with dates of MIS-C onset from March 11-October 10, 2020.
  - Outcomes of interest were ICU admission, decreased cardiac function, shock, myocarditis, and coronary artery abnormalities.
  - Demographic characteristics, signs and symptoms, and laboratory findings were assessed for associations with the outcomes, controlling for all pre-existing factors.
  - Primary results include:
    - Patients 6-12 years old were more likely to have severe outcomes compared to those under the age of 5 years, and these risks were even higher for patients 13-20 years old.
    - Male sex was associated with coronary artery abnormalities and myocarditis.
    - Non-Hispanic Black patients were more likely to be admitted to the ICU and experience decreased heart function.
    - Patients with shortness of breath and abdominal pain were more likely to be admitted to the ICU.
    - Elevated levels of certain lab markers (troponin, BNP, and proBNP, as well as d-dimer, CRP, and ferritin) and lower levels of lymphocytes and platelets were linked to ICU admission, shock and decreased cardiac function.
  - Manuscript being published 3/4

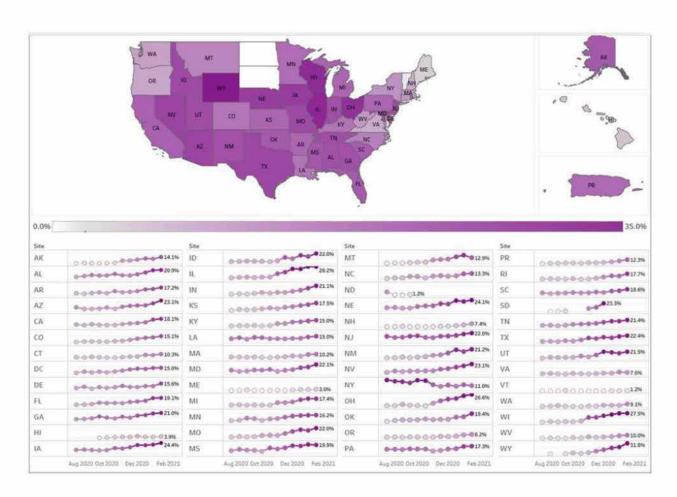
# **MMWR** Releases

 Two MMWR reports related to COVID-19 are scheduled as part of the <u>regular issue</u> of the Weekly, with the embargo lifting on <u>Thursday</u>, <u>March 4</u>, at 1 pm. Please note that the titles, content, and timing might change.





**FYI**Updated the website today on national seroprevalence from two rounds in January. See below. <a href="https://covid.cdc.gov/covid-data-tracker/#national-lab">https://covid.cdc.gov/covid-data-tracker/#national-lab</a>



From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Fri, 23 Oct 2020 14:22:05 +0000

To: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); Panagiotakopoulos, Lakshmi

(CDC/DDID/NCEZID/DHQP); Myers, Tanya R. (CDC/DDID/NCEZID/DHQP); McNeil, Michael

(CDC/DDID/NCEZID/DHQP); Kamidani, Satoshi (CDC/DDID/NCEZID/DHQP) **Subject:** FW: RCA Outcome Questions/Recommendations

Attachments: COVID-19 RCA Outcomes Draft Table 2020-10-22.docx, COVID-19 RCA

Outcomes Draft ICD Code List 2020-10-22.xlsx, Summary COVID-19 RCA AEs

incident\_definition\_exclusions10-21-2020.docx

Fyi – see questions and comments below

From: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Sent: Thursday, October 22, 2020 2:59 PM

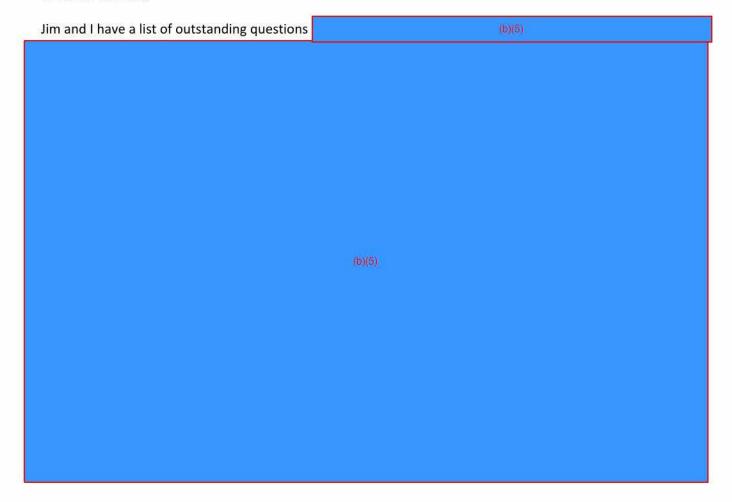
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Kristin Goddard, MPH

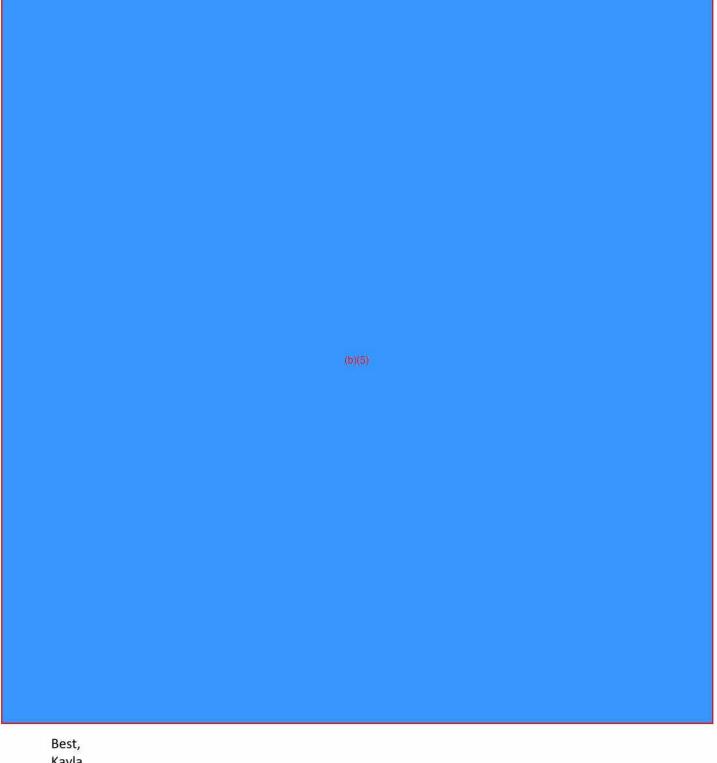
(kristin.x.goddard@kp.org) < kristin.x.goddard@kp.org>

Cc: Donahue, James G DVM/PhD < Donahue. James@marshfieldresearch.org>

Subject: RCA Outcome Questions/Recommendations

Hi Kristin and Eric,





Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute | → 1000 North Oak Avenue (ML2), Marshfield, WI 54449
1-715-221-6482 | 1-715-389-3880 | hanson.kayla@marshfieldresearch.org

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From: Kristin X. Goddard

**Sent:** Tue, 27 Oct 2020 23:09:59 +0000

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Hanson, Kayla E

Cc: Donahue, James G DVM/PhD; NICOLA P KLEIN; Bruce Fireman; Ned Lewis;

Ousseny Zerbo

Subject: RE: RCA Outcome Questions/Recommendations

Attachments: Summary\_COVID-19 RCA AEs incident\_definition\_exclusions10-21-

2020.KPNC.docx, COVID-19 RCA Outcomes Draft Table 2020-10-22.KPNC.docx

Hi there,

(b)(5)

Kristin

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

Sent: Monday, October 26, 2020 10:51 AM

To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard

<Kristin.X.Goddard@kp.org>

Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>

Subject: RE: RCA Outcome Questions/Recommendations

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(b)(5)

From: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>

Sent: Monday, October 26, 2020 1:40 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov >; Kristin Goddard, MPH

(kristin.x.goddard@kp.org) < kristin.x.goddard@kp.org>

Cc: Donahue, James G DVM/PhD < <u>Donahue.James@marshfieldresearch.org</u>>

Subject: RE: RCA Outcome Questions/Recommendations

(b)(5

-Kayla

From: Hanson, Kayla E

Sent: Thursday, October 22, 2020 1:59 PM

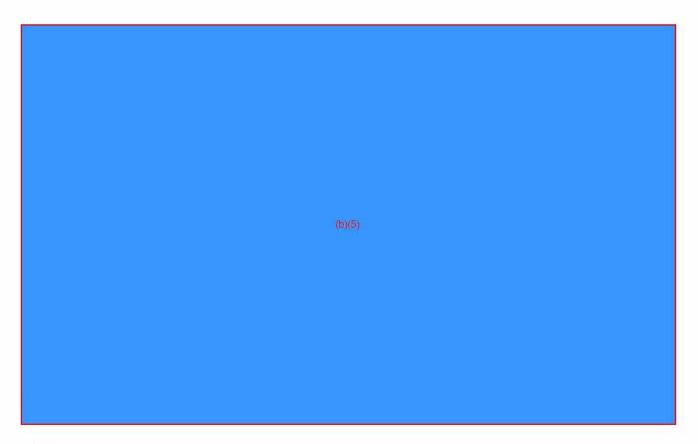
To: Weintraub, Eric (CDC/OID/NCEZID) < eiw8@cdc.gov>; Kristin Goddard, MPH

(kristin.x.goddard@kp.org) < kristin.x.goddard@kp.org>

**Cc:** Donahue, James G DVM/PhD < <u>Donahue</u>.<u>James@marshfieldresearch.org</u>> **Subject:** RCA Outcome Questions/Recommendations

Hi Kristin and Eric,

Jim and I have a list of outstanding questions	(b)(5)
	(b)(5)



Best, Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health

Marshfield Clinic Research Institute | → 1000 North Oak Avenue (ML2), Marshfield, WI 54449

1-715-221-6482 | 1-715-389-3880 | △ hanson.kayla@marshfieldresearch.org

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(b)(5)		

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Sent:** Thu, 21 Jan 2021 18:07:18 +0000 **To:** Su, John (CDC/DDID/NCEZID/DHQP)

Subject: FW: RESPONSE REQUREID: Priority Medium; Mode Phone; Topic [Insert Topic]

[CDC-1255677-W2H7Z7] CRM:08001179

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Sent: Tuesday, January 19, 2021 1:54 PM

**To:** Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> **Cc:** Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>

Subject: RE: RESPONSE REQUREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-

W2H7Z7] CRM:08001179

John,

Please see revised response and let me know if you want edits.

(b)(5)

Thanks, Elaine

(b)(5)

(b)(5)

Sent: Tuesday, January 19, 2021 10:05 AM To: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov> Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < <a href="ttd8@cdc.gov">ttd8@cdc.gov</a>> Subject: FW: RESPONSE REQUREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-W2H7Z7] CRM:08001179 Hi John, Please let me know if this response needs edits. Thanks, **Elaine** 

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

(b)(5), (b)(6)
Sincerely,
From: CISA Response (CDC) Sent: Monday, January 18, 2021 9:54:58 AM (UTC-05:00) Eastern Time (US & Canada) To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management; COVID19VaxSafety Cc: CISA Response (CDC) Subject: RE: RESPONSE REQUREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-W2H7Z7] CRM:08001179
Hi COVID Vaccine Inquiry Management Team (Sarah),
(b)(5)
Thank you.
Theresa
From: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management < <u>eocevent168@cdc.gov</u> > Sent: Sunday, January 17, 2021 3:30 PM To: COVID19VaxSafety < <u>COVID19VaxSafety@cdc.gov</u> >; CISA Response (CDC) < <u>cisaresponse@cdc.gov</u> > Subject: Re: RESPONSE REQUREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-W2H7Z7] CRM:08001179
Hi CISA and Vaccine Safety colleagues,
(b)(5)
Sincerely. Sarah Reagan-Steiner
(b)(5)

COVID-19 Vaccine Clinical Inquiries Management Team | Vaccine Task Force CDC Coronavirus Disease 2019 (COVID-19) Response | eocevent168@cdc.gov

### **Further CDC Resources:**



From: CDC IMS 2019 NCOV Response MCCM INFO < eocevent355@cdc.gov >

Sent: Friday, January 15, 2021 10:37 AM

To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <eocevent168@cdc.gov>

Cc: CDCInfoResponse < cdcinforesponse@cdcinquiry.onmicrosoft.com >

Subject: Fw: RESPONSE REQUREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-

W2H7Z7] CRM:08001179

See the below request

Thanks

Health Systems and Worker Safety (HSWS, formerly MCCM) Task Force CDC COVID-19 Response

From: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>

Sent: Thursday, January 14, 2021 10:05 PM

To: CDC IMS 2019 NCOV Response MCCM INFO < eocevent355@cdc.gov >

Subject: RESPONSE REQUREID: Priority Medium; Mode Phone; Topic [Insert Topic] [CDC-1255677-

W2H7Z7] CRM:08001179

Please let us know if you are able to respond to this inquiry or if you would like us to forward the inquiry to another program.

Things to note about this case: Phone call being escalated about covid-19 vaccines and people who have had Thrombocytopenia

1. This inquiry is being escalated because the answer could not be found in CDC resources,.

To close the case, you may reply directly to this e-mail, keeping the original subject line and historical e-mail thread in your reply. Please let us know if your group will provide the answer

directly to the inquirer below, or provide a reply for us to send back. To better serve the inquirer, please reply within 3 business days of receipt of this escalation. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Thank you for your assistance.

MD PR# 11109

----- Original Message -----

From: COVID-19 MCCM;

Received: Tue Jan 12 2021 12:49:13 GMT-0600 (Central Standard Time)

To: CDC Info Response; CDC Inbound Email;

Subject: Fw: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [Vaccine Side

Effects] [CDC-1255677-W2H7Z7] CRM:06132319

CDC Info,

This is a vaccine-related question and should be sent to Vaccine Inquiry Management (VIM).

Thanks, HSWS

From: CDCInfoResponse < cdcinforesponse@cdcinquiry.onmicrosoft.com>

Sent: Tuesday, January 12, 2021 11:30 AM

To: CDC IMS 2019 NCOV Response MCCM INFO < eocevent355@cdc.gov >

Subject: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [Vaccine Side

Effects] [CDC-1255677-W2H7Z7] CRM:06132319

Please let us know if you are able to respond to this inquiry or if you would like us to forward the inquiry to another program.

Things to note about this case: None

 This inquiry is being escalated because the answer could not be found in CDC resources,. 1. During the call, phone agent provided PRs #11109 to inquirer.

To close the case, you may reply directly to this e-mail, keeping the original subject line and historical e-mail thread in your reply. Please let us know if your group will provide the answer directly to the inquirer below, or provide a reply for us to send back. To better serve the inquirer, please reply within 3 business days of receipt of this escalation. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Thank you for your assistance.

## JJ/LD PR# 11109/14312

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

------ Call Description ------

Name (b)(6)

E-mail: (b)(6)

Phone: (b)(6)

Date, Time ET:1/11/2021, 10:29 AM

General Public: (My son took the covid-19 vaccine. I want to know if there's any information about people having Thrombocytopenia have there been any cases?)

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

**Sent:** Mon, 8 Mar 2021 23:12:36 +0000

To: Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Berger, Sherri (CDC/OCOO/OD);

Brooks, John T. (CDC/DDID/NCHHSTP/DHP); Butler, Jay C. (CDC/DDID/OD); Christie, Athalia

(CDC/DDPHSIS/CGH/OD); Goldstein, Robert (CDC/OD/OADPS); McDonald, Clifford

(CDC/DDID/NCEZID/DHQP); Ogden, Cynthia L. (CDC/DDPHSS/NCHS/DHNES); Schuchat, Anne MD

(CDC/OD); Walensky, Rochelle (CDC/OD); Walke, Henry (CDC/DDID/NCEZID/DPEI)

**Subject:** FW: Director's Daily Update March 8, 2021

Happy Monday!

# CMOU Director's Daily Update

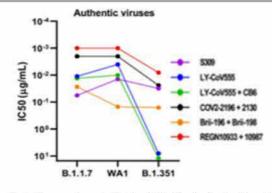


COVID-19 SCIENCE

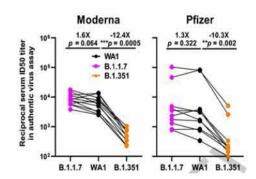
# March 8, 2021, 5 Articles

B.1.351, which has the E484K mutation, is resistant to multiple monoclonal antibodies and threatens the protection of current mRNA vaccines.

Antibody Resistance of SARS-CoV-2 Variants
B.1.351 and B.1.1.7. Nature Wang et al. (March 8, 2021)



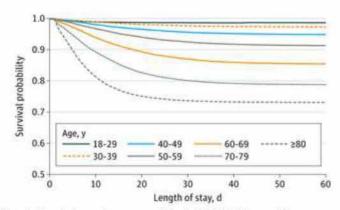
*Note:* Changes in neutralization IC50 of authorized or investigational therapeutic monoclonal antibodies against B.1.1.7, WT (WA1), B.1.351 viruses.



 $\it Note:$  Changes in neutralization IC50 of sera from vaccinees against B.1.1.7, WT (WA1), B.1.351 viruses.

Among 192,550 adults hospitalized with COVID-19 in 555 US medical centers from March-August 2020, in-hospital mortality was high (13.6%) and increased with increasing age; there was a significant reduction in mortality from March (22.1%) to August (6.5%).

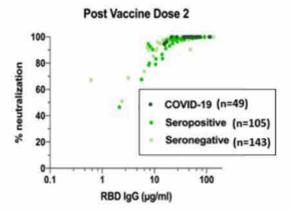
Outcomes and Mortality Among Adults
Hospitalized With COVID-19 at US Medical
Centers. JAMA Nguyen et al. (March 5, 2021)



Note: In-hospital mortality among adults with COVID-19 by age: US

Two doses of mRNA vaccine are needed to reach equivalently high levels of IgG and neutralization activity among seropositive, with and without history of prior COVID-19, and seronegative persons.

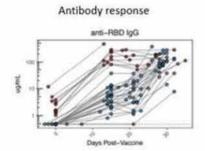
Comparison of IgG and neutralizing antibody responses after one or two doses of COVID-19 mRNA vaccine in previously infected and uninfected persons. medRxiv Demonbreun et al. (Preprint, March 8, 2021)

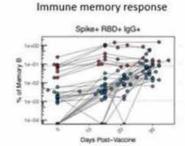


*Note:* Anti-RBD IgG concentration and % neutralization increased dramatically after two doses among seropositive and seronegative samples.

mRNA vaccine induced significant antibody immunological memory responses following two doses among seronegative persons and one dose among seropositive persons.

Longitudinal Analysis Reveals
Distinct Antibody and Memory B
Cell Responses in SARS-CoV2
Naïve and Recovered Individuals
Following mRNA
Vaccination. medRxiv Goel et al.
(Preprint, March 6, 2021)





Note: Concentration of anti-RBD IgG antibodies and immune response as frequency of antigen specific IgG+ memory B cells over time in SARS-CoV2 naïve and SARS-CoV2 recovered vaccinated individuals.

Dotted lines indicate the limit of detection for the assay.

Professional athletes with prior COVID-19 illness have low prevalence of inflammatory heart disease and can safely return to play with implementation of current cardiovascular risk stratification practices.

Cross-sectional study of 789 professional athletes who underwent return-to-play cardiac screening.

Prevalence of inflammatory heart disease among professional athletes with prior COVID-19 infection who received systematic return-to-play cardiac screening. JAMA Cardiology Martinez et al. (March 4, 2021)

30 (3.8%) athletes received additional testing after screening; of whom 5 (0.6%) has inflammatory heart disease: 3 with myocarditis and 2 with pericarditis.

All 5 athletes had preceding symptoms consistent with moderate COVID-19 illness (such as loss of taste and smell, nonspecific fatigue, and cough without dyspnea).

Disclaimer: for internal CDC use only

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Wed, 17 Mar 2021 19:56:00 +0000

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Licata, Charles (CDC/DDID/NCEZID/DHQP); Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR)

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP)

Subject: FW: WHO GACVS sub-committee - request for information

Attachments: COVID\_cerebral venous sinus thrombosis\_details.rtf, COVID\_cerebral venous

sinus thrombosis.rtf

Hi folks,

Please see below email chain. (b)(5) ?

Tom (b)(5) Thanks!

John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Wednesday, March 17, 2021 1:24 PM

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

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

Subject: RE: WHO GACVS sub-committee - request for information

(b)(5)

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

Sent: Wednesday, March 17, 2021 12:26 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

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

Subject: RE: WHO GACVS sub-committee - request for information

(b)(5) . Thanks.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Wednesday, March 17, 2021 12:24 PM

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

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

**Subject:** RE: WHO GACVS sub-committee - request for information

Tom,

John is out today. (b)(5)

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

Sent: Wednesday, March 17, 2021 12:09 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) < <a href="mailto:cezu2@cdc.gov">ce: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:cerm4@cdc.gov">cerm4@cdc.gov</a>>
Subject: FW: WHO GACVS sub-committee - request for information

(b)(5) Thanks.

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Wednesday, March 17, 2021 3:47 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov</a>>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <<a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov">dvj3@cdc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <<a href="mailto:jvk3@cdc.gov">jvk3@cdc.gov</a>; PAL, Shanthi Narayan <<a href="mailto:pals@who.int">pals@who.int</a>; ;

JANIN, Annick < janina@who.int>

Subject: Re: WHO GACVS sub-committee - request for information

#### Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopaenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

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

Sent: Wednesday, 17 March 2021 6:43 AM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<a href="mailto:</a>, conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov</a>; conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov</a>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < <u>iyk3@cdc.gov</u>> **Subject:** RE: WHO GACVS sub-committee - request for information

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I'm happy to talk when convenient. I'm Cc'ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

## Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Monday, March 8, 2021 10:05 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>

Subject: WHO GACVS sub-committee - request for information

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM

Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia

Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)

E: anastasia.phillips@health.wa.gov.au

Ph: +61 417 172 936

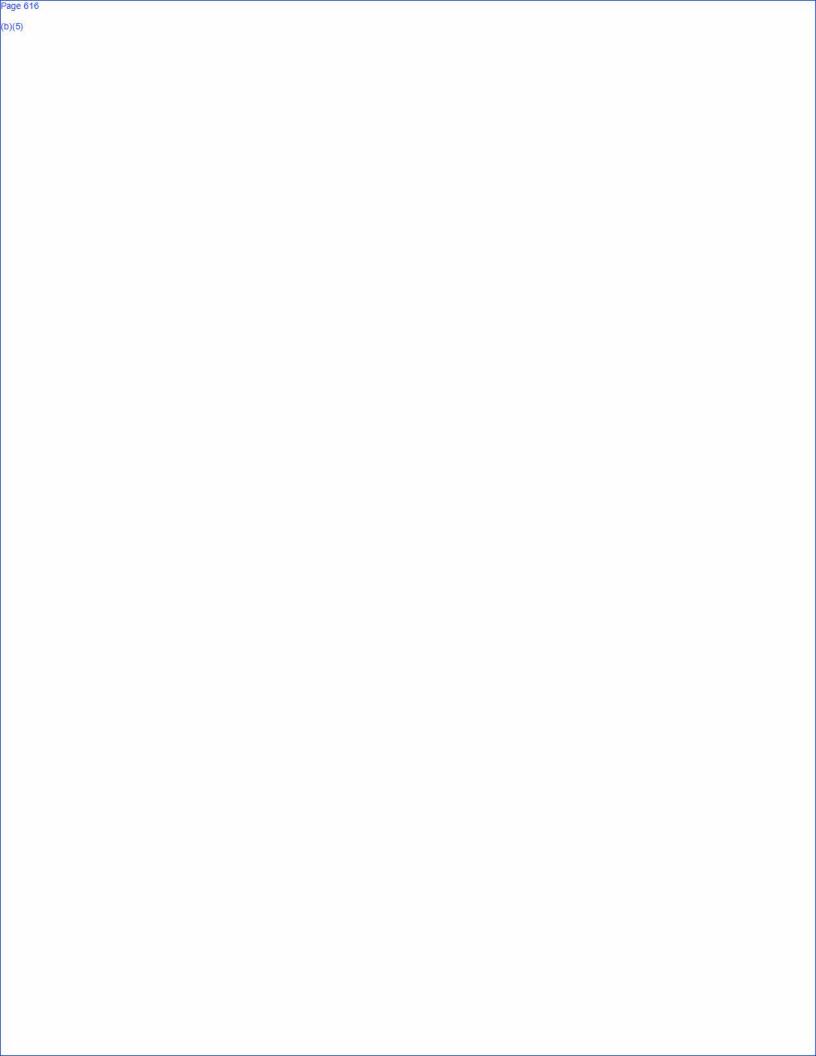












From: Rao, Agam K. (CDC/DDID/NCEZID/DHCPP)

**Sent:** Fri, 15 Jan 2021 15:06:16 +0000 **To:** Su, John (CDC/DDID/NCEZID/DHQP)

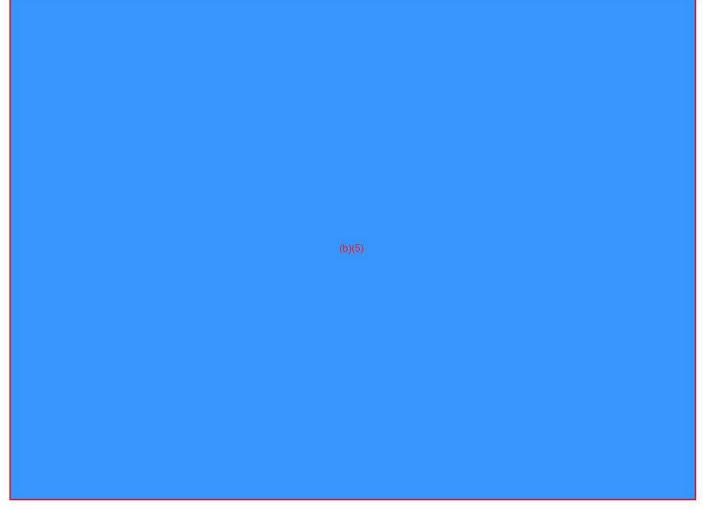
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP); Malluche, Tiffany

(CDC/DDID/NCEZID/DHQP)

Subject: RE: VaST update

Attachments: ITP cases\_1.13.2021\_tojohnsu.pptx

Hi John,



Agam

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

Sent: Thursday, January 14, 2021 11:41 PM

To: Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov> Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>

Subject: RE: VaST update

Hi Agam,

Please see results of a search I did a bit ago. From what I see, there are:

(b)(5) (b)(5)

John

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov>

Sent: Thursday, January 14, 2021 11:24 PM

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

**Cc:** Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov">; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <a href="mailto:fxd1@cdc.gov">fxd1@cdc.gov</a>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

<erm4@cdc.gov>; Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>; Harrington, Theresa

(CDC/DDID/NCEZID/DHQP) < tsh3@cdc.gov>

Subject: RE: VaST update

Agam, can you and John connect

b)(5)

Thanks Karen

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

Sent: Thursday, January 14, 2021 11:06 PM

To: Broder, Karen (CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:square">ayv6@cdc.gov</a>; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

<erm4@cdc.gov>; Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>; Harrington, Theresa

(CDC/DDID/NCEZID/DHQP) < tsh3@cdc.gov>

Subject: RE: VaST update

Hi Karen,

Thanks for the heads up! Looking forward to presenting with you.

(b)(5)

John

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov>

Sent: Thursday, January 14, 2021 10:35 PM

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

Subject: VaST update

Hello. For the VaST meeting TUES, I was asked		(b)(5)
	(b)(5)	
	(6)(0)	

Thanks, Karen



































(CDC/DDID/NCEZID/DHQP)		
Subject:	RE: To be sure you are aware	
Attachments:	All vax_myocarditis.rtf	
Tom, John:		
FYI-	(b)(5)	
	(b)(5)	
Elaine		
Sent: Saturday, April 17	The Conference of the Conferen	
<ezu2@cdc.gov>; Mille</ezu2@cdc.gov>	neissner@tuftsmedicalcenter.org>; Su, John (CDC/DDID/NCEZID/DHQP) r, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov></erm4@cdc.gov>	
Cc: dbalaguru@mgh.ha Subject: RE: To be sure		
Hi Cody,		
Good to hear from you and I hope you are doing well. There have been reports of myocarditis following mRNA vaccines (b)(5)  I'm including John Su,		
	is awareness. Take care.	
Regards,		
Tom		
도 보통한 수요는 교육적인 교육에 한글일에 나타가 하나요요 얼마나 사내에서의 (2007년) 등 1	cmeissner@tuftsmedicalcenter.org>	
Sent: Thursday, April 15	(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov></ayv6@cdc.gov>	
Cc: dbalaguru@mgh.ha	The control of the co	
Subject: To be sure you		
Tom		
(b)(5)		
MAR IN CREATE SECOND	CID	
Great presentation to A Regards,	ICIP yesterday,	

Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John

Sun, 18 Apr 2021 14:32:55 +0000

From:

Sent:

To:

## Cody

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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Mon, 19 Apr 2021 16:06:25 +0000

To: Scotty, Erica J
Cc: Hanson, Kayla E

Subject: RE: VSD COVID19 DXIDs

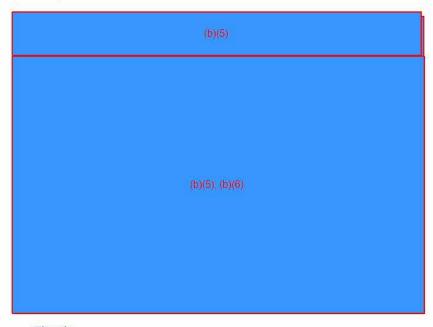
Thanks for the reminder that I need to update our master list!

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>

Sent: Monday, April 19, 2021 12:05 PM

**To:** Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov> **Cc:** Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs



Thanks,

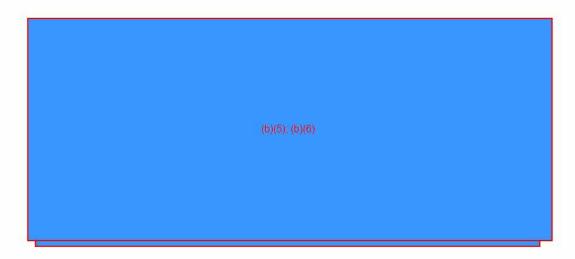
Erica

From: Scotty, Erica J

Sent: Monday, March 15, 2021 11:04 AM

Subject: RE: VSD COVID19 DXIDs

(b)(5)



Erica

From: Scotty, Erica J

Sent: Thursday, February 11, 2021 1:40 PM

Subject: RE: VSD COVID19 DXIDs

(b)(5) (b)(5) (b)(6)

Thanks,

Erica

From: Scotty, Erica J

Sent: Monday, January 11, 2021 11:41 AM

Subject: RE: VSD COVID19 DXIDs

Here are a few more:

(b)(5), (b)(6)

(b)(5), (b)(6)

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Monday, December 21, 2020 3:58 PM

To: Scotty, Erica J <<u>SCOTTY.ERICA@marshfieldresearch.org</u>>
Cc: Hanson, Kayla E <<u>hanson.kayla@marshfieldresearch.org</u>>

Subject: [EXTERNAL] Re: VSD COVID19 DXIDs

Crazy!!

From: Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org>

Sent: Monday, December 21, 2020 4:54:43 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov> Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Here are new DXIDs for the week:

(b)(5), (b)(6

(b)(5) (b)(6)	

Erica

From: Scotty, Erica J

Sent: Tuesday, December 15, 2020 7:56 AM

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We had an issue with our DXID and lab file refresh yesterday. They should be up-to-date now.

(b)(5); (b)(6)

Thanks,

Erica

From: Scotty, Erica J

Sent: Monday, November 30, 2020 9:29 AM

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

Here are the new DXIDs for this week:

(b)(6), (b)(6)

Thanks,

Erica

From: Scotty, Erica J

Sent: Monday, November 16, 2020 12:36 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >; Scotty, Erica J

<<u>SCOTTY.ERICA@mcrf.mfldclin.edu</u>>
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

Here are a few more:



		(b)(5), (b)(6)	
Thanks,			
Erica			
From: Scotty, Erica J < S Sent: Monday, Novemb To: Weintraub, Eric (CD Cc: Hanson, Kayla E < ha < SCOTTY.ERICA@marsh Subject: RE: VSD COVID Hi Eric,	er 02, 2020 3:27 PM C/DDID/NCEZID/DHQP) nson.kayla@marshfield fieldresearch.org> 19 DXIDs		Ĵ
	(b)	(5) (b)(6)	

### Erica

From: Scotty, Erica J <<u>SCOTTY.ERICA@marshfieldresearch.org</u>>

Sent: Monday, October 12, 2020 2:31 PM

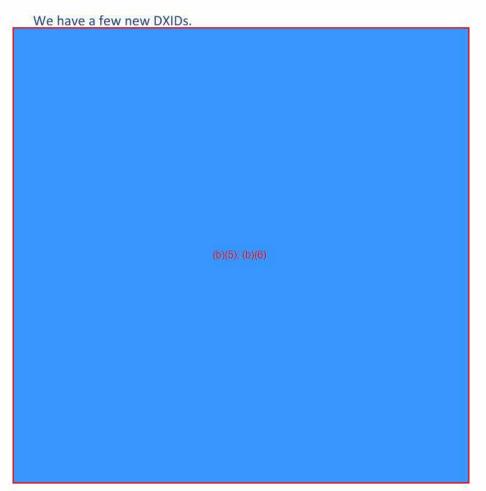
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>; Scotty, Erica J

<SCOTTY.ERICA@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Hi Eric,



Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Wednesday, September 02, 2020 10:20 AM

To: Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org>
Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

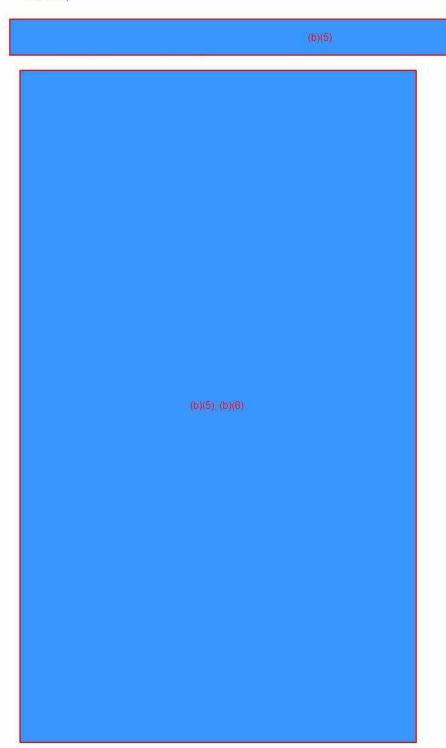


From: Scotty, Erica J < <a href="mailto:SCOTTY.ERICA@marshfieldresearch.org">SCOTTY.ERICA@marshfieldresearch.org</a>

**Sent:** Tuesday, August 18, 2020 12:04 PM

Subject: RE: VSD COVID19 DXIDs

Hi Eric,



(b)(5) (b)(6)

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Tuesday, August 11, 2020 9:24 AM

To: Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org > Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

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Do you mind sending over the text for these as well – I'll make the changes and add them in:

From: Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org>

Sent: Monday, August 10, 2020 11:06 AM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >; Scotty, Erica J

<SCOTTY.ERICA@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

(b)(5)

Thanks,

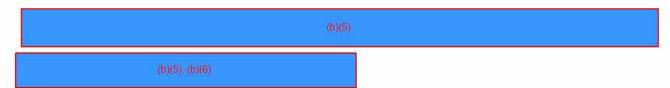
#### Erica

From: Scotty, Erica J

Sent: Monday, July 20, 2020 12:54 PM

Subject: VSD COVID19 DXIDs

Hi Eric,



Thanks,



# **Erica Scotty**

Research Programmer/Analyst Senior | Office of Research Computing & Analytics

Marshfield Clinic Health System

Office: 715-221-8066 | Ext: 1-8066

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contained within. Please contact the sender and advise of the erroneous delivery by return e-mail or telephone. Thank you for your cooperation.

The contents of this message may contain private, protected and/or privileged information. If you received this message in error, you should destroy the e-mail message and any attachments or copies, and you are prohibited from retaining, distributing, disclosing or using any information contained within. Please contact the sender and advise of the erroneous delivery by return e-mail or telephone. Thank you for your cooperation.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Sent:** Thu, 4 Mar 2021 14:33:09 +0000

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19

vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Yes

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Thursday, March 4, 2021 9:29 AM

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

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <a href="mailto:check-accessor-color: blue-color: blue-color:

<ezu2@cdc.gov>

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401



From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Sent: Thursday, March 4, 2021 9:24 AM

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

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP)

< krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) < tsh3@cdc.gov>; Dua, Anamika

(CDC/DDID/NCEZID/DHQP) < atv2@cdc.gov>

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < <a href="td8@cdc.gov">!td8@cdc.gov">!td8@cdc.gov</a>

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401

Thanks Tom

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

Sent: Thursday, March 4, 2021 9:17 AM

**To:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov"> ; Su, John (CDC/DDID/NCEZID/DHQP)</a> < <a href="mailto:ezu2@cdc.gov">ezu2@cdc.gov"> ; Broder, Karen (CDC/DDID/NCEZID/DHQP) < <a href="mailto:krb2@cdc.gov">krb2@cdc.gov"> ; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) < <a href="mailto:krb2@cdc.gov">etsh3@cdc.gov</a> ; Dua, Anamika (CDC/DDID/NCEZID/DHQP) < <a href="mailto:qutv2@cdc.gov">qtv2@cdc.gov</a> >

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < Itd8@cdc.gov>

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Thursday, March 4, 2021 8:52 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ezu2@cdc.gov">ezu2@cdc.gov</a>; Broder, Karen (CDC/DDID/NCEZID/DHQP) < <a href="mailto:krb2@cdc.gov">krb2@cdc.gov</a>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) < <a href="mailto:kstarto:ksta

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ltd8@cdc.gov">ltd8@cdc.gov</a>>

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401

Hi all,

(b)(5)

Is anyone able to talk to this MD from the Israel Ministry of Health? Thanks,

Elaine

From: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management

Sent: Wednesday, March 3, 2021 8:31:15 PM (UTC-05:00) Eastern Time (US & Canada)

To: CDC IMS 2019 NCOV Response VTF Global

Cc: COVID19VaxSafety; CISA Response (CDC); CDC IMS 2019 NCOV Response VTF Communications;

CDC IMS 2019 NCOV Response International Task Force

Subject: Fw: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401

Hello VTF Global colleagues,

Please see the inquiry from the Deputy Director, Division of Epidemiology, MoH Israel below. Could you please respond?

Thank you,

Kate

(b)(5)

COVID-19 Vaccine Clinical Inquiries Management Team | Vaccine Task Force CDC Coronavirus Disease 2019 (COVID-19) Response | eocevent168@cdc.gov

### **Further CDC Resources:**

COVID-19 What's New CDC Health Alert Network (HAN)

### **CDC Vaccines**

### CDC Clinician Outreach and Communication Activity (COCA)

From: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>

Sent: Wednesday, March 3, 2021 1:50 PM

To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management < eocevent168@cdc.gov>

Subject: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events;

[CDC-1460726-X0X9M8] CRM:09092401

Please let us know if you are able to respond to this inquiry or if you would like us to forward the inquiry to another program. This inquiry is being escalated because the answer could not be found in CDC resources.

To close the case, you may reply directly to this e-mail, keeping the original subject line and historical e-mail thread in your reply. Please let us know if your group will provide the answer directly to the inquirer below, or provide a reply for us to send back.

To better serve the inquirer, please reply within 3 business days of receipt of this escalation. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Thank you for your assistance.

# OO/PR#14312/17771/11109

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Message-----

Sent: 3/3/2021 From: Clinician

Subject: COVID-19 vaccine adverse events
Email Address: (b)(6)

Question: From the Israel vaccine adverse event monitoring team:

We are seeing a large number of myocarditis and pericarditis cases in young individuals soon after Pfizer COVID-19 vaccine. We would like to discuss the issue with a relevant expert at CDC.

### **Optional Information**

Name: Dr. Roee Singer

Title: Deputy Director, Division of Epidemiology, MoH Israel

Organization: SLHD - Israel Ministry of Health

Phone: (b)(6)

Other Email: (b)(6)

Address:

Jerusalem, Israel PII Extraction:

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Mon, 11 Jan 2021 17:45:16 +0000

To: Scotty, Erica J
Cc: Hanson, Kayla E

Subject: RE: VSD COVID19 DXIDs

Yea, I'll be updating the list this week - have a bunch to update!!!

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>

Sent: Monday, January 11, 2021 12:41 PM

**To:** Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov> **Cc:** Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Here are a few more:

(b)(b) (b)(5)

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Monday, December 21, 2020 3:58 PM

To: Scotty, Erica J <<u>SCOTTY.ERICA@marshfieldresearch.org</u>>
Cc: Hanson, Kayla E <<u>hanson.kayla@marshfieldresearch.org</u>>

Subject: [EXTERNAL] Re: VSD COVID19 DXIDs

Crazy!!

From: Scotty, Erica J <<u>SCOTTY.ERICA@marshfieldresearch.org</u>>

Sent: Monday, December 21, 2020 4:54:43 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov > Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Subject: RE: VSD COVID19 DXIDs

Here are new DXIDs for the week:

(b)(5); (b)(6)

Thanks,

Erica

From: Scotty, Erica J

Sent: Tuesday, December 15, 2020 7:56 AM

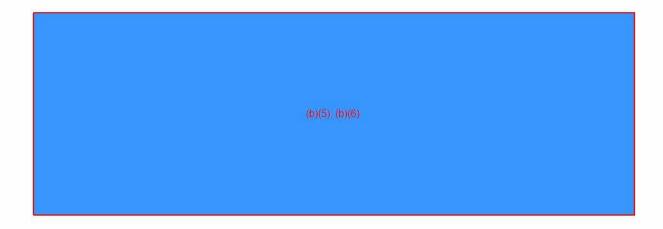
Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We had an issue with our DXID and lab file refresh yesterday. They should be up-to-date now.

Here are some new DXIDs for this week:

(b)(5) (b)(6



Erica

From: Scotty, Erica J

Sent: Monday, November 30, 2020 9:29 AM

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

Here are the new DXIDs for this week:

(b)(5), (b)(8)

Thanks,

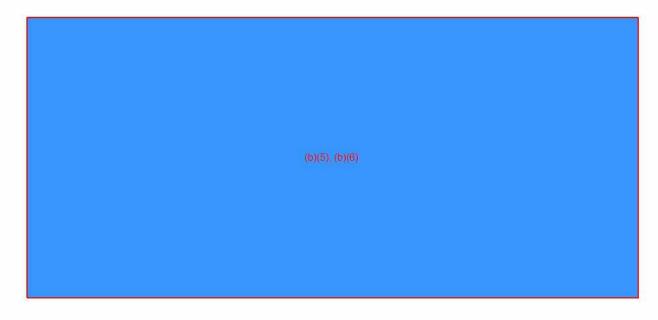
Erica

From: Scotty, Erica J

Sent: Monday, November 16, 2020 12:36 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >; Scotty, Erica J <SCOTTY.ERICA@mcrf.mfldclin.edu> Subject: RE: VSD COVID19 DXIDs Hi Eric, Here are a few more: Thanks, Erica From: Scotty, Erica J < <a href="mailto:SCOTTY.ERICA@marshfieldresearch.org">SCOTTY.ERICA@marshfieldresearch.org</a> Sent: Monday, November 02, 2020 3:27 PM To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov> Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>; Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org> Subject: RE: VSD COVID19 DXIDs Hi Eric, We have more to add again.



Erica

From: Scotty, Erica J < <a href="mailto:SCOTTY.ERICA@marshfieldresearch.org">SCOTTY.ERICA@marshfieldresearch.org</a>

Sent: Monday, October 12, 2020 2:31 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >; Scotty, Erica J

<SCOTTY.ERICA@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We have a few new DXIDs.

(b)(5), (b)(6)



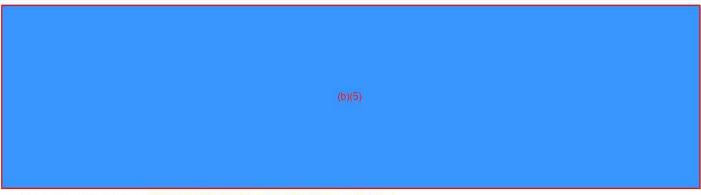
Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Wednesday, September 02, 2020 10:20 AM

To: Scotty, Erica J <<u>SCOTTY.ERICA@marshfieldresearch.org</u>>
Cc: Hanson, Kayla E <<u>hanson.kayla@marshfieldresearch.org</u>>

Subject: [EXTERNAL] RE: VSD COVID19 DXIDs



From: Scotty, Erica J < <a href="mailto:SCOTTY.ERICA@marshfieldresearch.org">SCOTTY.ERICA@marshfieldresearch.org</a>

Sent: Wednesday, September 2, 2020 11:17 AM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov > Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Subject: RE: VSD COVID19 DXIDs

(b)(5)

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Wednesday, September 02, 2020 7:03 AM

To: Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org >

Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>
Subject: [EXTERNAL] RE: VSD COVID19 DXIDs



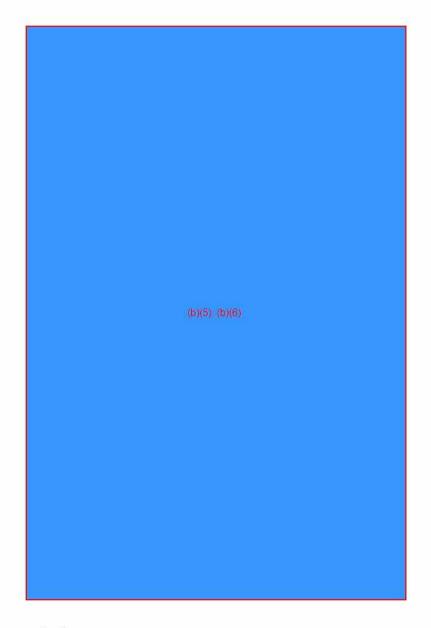
From: Scotty, Erica J < <a href="mailto:SCOTTY.ERICA@marshfieldresearch.org">SCOTTY.ERICA@marshfieldresearch.org</a>

Sent: Tuesday, August 18, 2020 12:04 PM

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

(b)(5) (b)(5), (b)(6)



Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Tuesday, August 11, 2020 9:24 AM

To: Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org>
Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

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(b)(5)

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>

Sent: Monday, August 10, 2020 11:06 AM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov >

Cc: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Scotty, Erica J

<SCOTTY.ERICA@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

(b)(5)

(b)(5) (b)(6)

Thanks,

Erica

From: Scotty, Erica J

Sent: Monday, July 20, 2020 12:54 PM

Subject: VSD COVID19 DXIDs

Hi Eric,

(b)(5)

(b)(5); (b)(6)

Thanks,



## **Erica Scotty**

Research Programmer/Analyst Senior | Office of Research Computing & Analytics

Marshfield Clinic Health System

Office: 715-221-8066 | Ext: 1-8066

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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

Sent: Thu, 11 Feb 2021 19:41:12 +0000

To: Scotty, Erica J

Cc: Hanson, Kayla E

Subject: RE: VSD COVID19 DXIDs

Perfect – updating the list tomorrow morning! thanks

From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>

Sent: Thursday, February 11, 2021 2:40 PM

**To:** Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov> **Cc:** Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Here are a couple more DXIDs:

(b)(5); (b)(6)

Thanks,

Erica

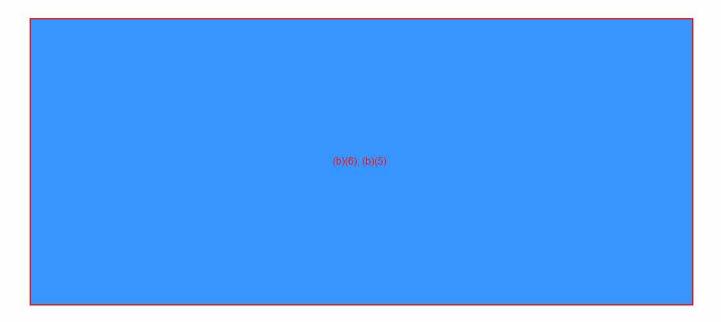
From: Scotty, Erica J

Sent: Monday, January 11, 2021 11:41 AM

Subject: RE: VSD COVID19 DXIDs

Here are a few more:

(b)(5); (b)(6)



### Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Monday, December 21, 2020 3:58 PM

**To:** Scotty, Erica J <<u>SCOTTY.ERICA@marshfieldresearch.org</u>> **Cc:** Hanson, Kayla E <<u>hanson.kayla@marshfieldresearch.org</u>>

Subject: [EXTERNAL] Re: VSD COVID19 DXIDs

Crazy!!

From: Scotty, Erica J <<u>SCOTTY.ERICA@marshfieldresearch.org</u>>

Sent: Monday, December 21, 2020 4:54:43 PM

**To:** Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov> **Cc:** Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Here are new DXIDs for the week:

(b)(6), (b)(5)

Erica

From: Scotty, Erica J

Sent: Tuesday, December 15, 2020 7:56 AM

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We had an issue with our DXID and lab file refresh yesterday. They should be up-to-date now.

Here are some new DXIDs for this week:

(b)(5), (b)(6)

Thanks,

Erica

From: Scotty, Erica J

Sent: Monday, November 30, 2020 9:29 AM

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

Here are the new DXIDs for the	115 Weeki	
	(b)(5), (b)(6)	
Thanks,		
Erica		
< <u>SCOTTY.ERICA@mcrf.mfldcl</u> Subject: RE: VSD COVID19 DX Hi Eric,		inca J
Here are a few more:		
	(b)(5) (b)(6)	
	(b)(5), (b)(6)	
	(b)(5), (b)(6)	

#### Erica

From: Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org>

Sent: Monday, November 02, 2020 3:27 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

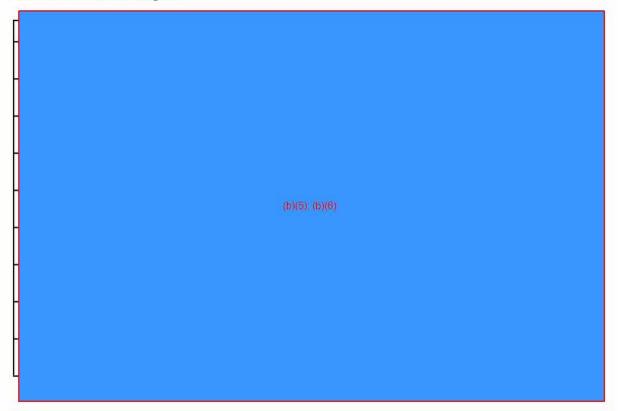
Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >; Scotty, Erica J

<SCOTTY.ERICA@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

We have more to add again.



Thanks,

Erica

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Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >; Scotty, Erica J

## <SCOTTY.ERICA@marshfieldresearch.org> Subject: RE: VSD COVID19 DXIDs Hi Eric, We have a few new DXIDs. Thanks, Erica From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov> Sent: Wednesday, September 02, 2020 10:20 AM To: Scotty, Erica J < <a href="mailto:SCOTTY.ERICA@marshfieldresearch.org">SCOTTY.ERICA@marshfieldresearch.org</a>> Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org> Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

(b)(5)

From: Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org >

Sent: Wednesday, September 2, 2020 11:17 AM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov > Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Subject: RE: VSD COVID19 DXIDs

(b)(5)

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Wednesday, September 02, 2020 7:03 AM

**To:** Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org > **Cc:** Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

(b)(5)

(b)(5) (b)(6)

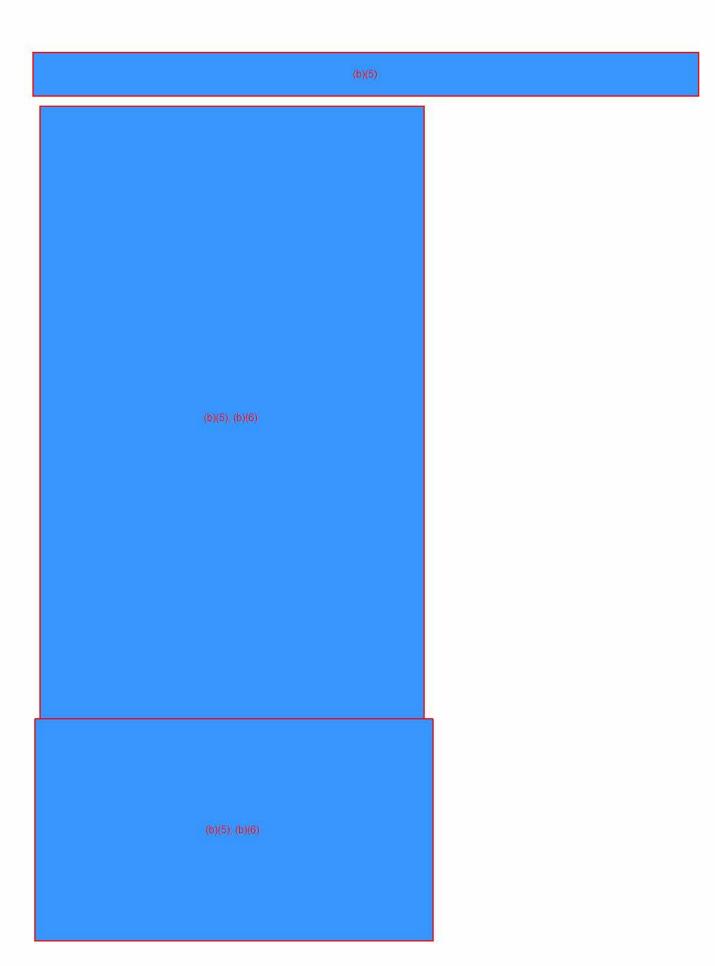
From: Scotty, Erica J < <a href="mailto:SCOTTY.ERICA@marshfieldresearch.org">SCOTTY.ERICA@marshfieldresearch.org</a>

Sent: Tuesday, August 18, 2020 12:04 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov > Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Subject: RE: VSD COVID19 DXIDs

Hi Eric,



(b)(5), (b)(6)

Thanks,

Erica

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Tuesday, August 11, 2020 9:24 AM

**To:** Scotty, Erica J < SCOTTY.ERICA@marshfieldresearch.org > Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Subject: [EXTERNAL] RE: VSD COVID19 DXIDs

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From: Scotty, Erica J <SCOTTY.ERICA@marshfieldresearch.org>

Sent: Monday, August 10, 2020 11:06 AM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >; Scotty, Erica J

<SCOTTY.ERICA@marshfieldresearch.org>

Subject: RE: VSD COVID19 DXIDs

Hi Eric,

(b)(5)

(b)(5); (b)(6)

Thanks,

Erica

From: Scotty, Erica J

Sent: Monday, July 20, 2020 12:54 PM

Subject: VSD COVID19 DXIDs

b)(5)

(b)(5) (b)(6)

Thanks,



## **Erica Scotty**

Research Programmer/Analyst Senior | Office of Research Computing & Analytics

Marshfield Clinic Health System

Office: 715-221-8066 | Ext: 1-8066

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From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP)

**Sent:** Thu, 4 Mar 2021 15:21:02 +0000

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Broder, Karen

(CDC/DDID/NCEZID/DHQP); Dua, Anamika (CDC/DDID/NCEZID/DHQP)

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP)

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19

vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Thanks, Tom.

Theresa

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Thursday, March 4, 2021 9:24 AM

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

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP)

<krb2@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Dua, Anamika

(CDC/DDID/NCEZID/DHQP) <qtv2@cdc.gov>

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < Itd8@cdc.gov>

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401

Thanks Tom

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Thursday, March 4, 2021 9:17 AM

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < <a href="td8@cdc.gov">!td8@cdc.gov</a>>

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401

(b)(5)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Thursday, March 4, 2021 8:52 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >; Broder, Karen (CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov >; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) < tsh3@cdc.gov >; Dua, Anamika (CDC/DDID/NCEZID/DHQP) < avv6@cdc.gov >; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < avv6@cdc.gov >

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < Itd8@cdc.gov>

**Subject:** RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi all.

(b)(5)

Is anyone able to talk to this MD from the Israel Ministry of Health? Thanks, Elaine

From: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management

Sent: Wednesday, March 3, 2021 8:31:15 PM (UTC-05:00) Eastern Time (US & Canada)

To: CDC IMS 2019 NCOV Response VTF Global

Cc: COVID19VaxSafety; CISA Response (CDC); CDC IMS 2019 NCOV Response VTF Communications;

CDC IMS 2019 NCOV Response International Task Force

Subject: Fw: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401

Hello VTF Global colleagues,

Please see the inquiry from the Deputy Director, Division of Epidemiology, MoH Israel below. Could you please respond?

Thank you,

Kate

(b)(5)

COVID-19 Vaccine Clinical Inquiries Management Team | Vaccine Task Force CDC Coronavirus Disease 2019 (COVID-19) Response | eocevent168@cdc.gov

## **Further CDC Resources:**

COVID-19 What's New CDC Health Alert Network (HAN)

**CDC Vaccines** 

CDC Clinician Outreach and Communication Activity (COCA)

From: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>

Sent: Wednesday, March 3, 2021 1:50 PM

**To:** CDC IMS 2019 NCOV COVID Vaccine Inquiry Management < <a href="mailto:eocevent168@cdc.gov">eocevent168@cdc.gov</a> **Subject:** RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Please let us know if you are able to respond to this inquiry or if you would like us to forward the inquiry to another program. This inquiry is being escalated because the answer could not be found in CDC resources.

To close the case, you may reply directly to this e-mail, keeping the original subject line and historical e-mail thread in your reply. Please let us know if your group will provide the answer directly to the inquirer below, or provide a reply for us to send back.

To better serve the inquirer, please reply within 3 business days of receipt of this escalation. A reminder will be sent in 8 days; the inquiry will be closed after 10 days. Thank you for your assistance.

## OO/PR#14312/17771/11109

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Message-----

Sent: 3/3/2021 From: Clinician

Subject: COVID-19 vaccine adverse events Email Address: (b)(6)

Question: From the Israel vaccine adverse event monitoring team:

We are seeing a large number of myocarditis and pericarditis cases in young individuals soon after Pfizer COVID-19 vaccine. We would like to discuss the issue with a relevant expert at CDC.

## **Optional Information**

Name: Dr. Roee Singer

Title: Deputy Director, Division of Epidemiology, MoH Israel

Organization: SLHD - Israel Ministry of Health

Phone:

(6)(0)

Other Email:

Address:

Jerusalem, Israel PII Extraction:

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Mon, 12 Apr 2021 22:58:32 +0000

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP)

Subject: RE: April 12 VaST call - draft agenda and presentations

(b)(5)

John

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Monday, April 12, 2021 6:48 PM

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

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>

Subject: FW: April 12 VaST call - draft agenda and presentations

FYI - let me know your thoughts.

From: Jay Montgomery (b)(6)

Sent: Monday, April 12, 2021 6:41 PM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>; Renata Engler

(b)(6) LC COLLINS < limone.c.collins.civ@mail.mil>

Subject: Re: April 12 VaST call - draft agenda and presentations

Dear Dr. Markowitz,

(b)(5)

Respectfully, Jay Montgomery

## Sent from the all new AOL app for iOS

On Monday, April 12, 2021, 11:14 AM, Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a> wrote:

Dear Jay and Renata,

Thank you again for your presentations. (b)(5)
(b)(5)

Lauri

## Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

1600 Clifton Rd MS H24-5

Atlanta, GA 30329-4027

Phone: 404-639-8359

Cell: 404-384-3767

Email: lem2@cdc.gov

From: Jay Montgomery (5)(6)
Sent: Sunday, April 11, 2021 7:14 PM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a> 
Cc: Gee, Julianne (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dzg2@cdc.gov">dzg2@cdc.gov</a> 
Subject: Re: April 12 VaST call - draft agenda and presentations

Dear Drs. Markowitz and Gee,

Please find attached my slide deck for Monday's VaST presentation on Myocarditis following COVID-19 Vaccination. Please let me know if anything else is required.

I assume I will be receiving a Zoom Invite for Monday? Please be sure to send it to my civilian e-mail address (b)(6) as my government laptop cannot accept ZOOM conferences. As I am on the road, I would appreciate the opportunity to call in early to be sure we have a good connection and everything works as expected.

I very much look forward to sharing with the VaST team the findings of our review. R/ Dr. Jay Montgomery In a message dated 4/9/2021 12:22:41 PM Eastern Standard Time, lem2@cdc.gov writes: Dear all, Thank you for agreeing to present to the VaST next week. Attached is the current agenda, with times. Please send your PowerPoint presentations to me and Julianne Gee (copied here), by Monday morning at 10 am. I will send pdfs of presentations to the VaST members and other call attendees. Our administrative assistant will advance slides for you during the call. Thank you and let me know if you have any questions.

Lauri

Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Thursday, April 8, 2021 2:01 PM

**To:** Forshee, Richard (FDA/CBER) < Richard.Forshee@fda.hhs.gov >; Cunningham, Fran < Fran.Cunningham@va.gov >; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov >; Su, John R CAPT USPHS (USA) < ezu2@cdc.gov >; Collins, Limone C Jr CIV DHA HEALTH OPNS (USA) < limone.c.collins.civ@mail.mil >

Cc: Shimabukuro, Tom T CAPT USPHS (USA) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">; Gee, Julianne

(CDC/DDID/NCEZID/DHQP) < dzg2@cdc.gov>

Subject: [Non-DoD Source] April 12 VaST draft agenda and proposed times

Dear all,

Please see below the approximate times planned for your talks on the VaST call next Monday. Let me know if you feel any revisions are needed.

## April 12



Thank you all for presenting to VaST.

Lauri

Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Sent:** Thu, 1 Apr 2021 13:12:02 +0000 **To:** Su, John (CDC/DDID/NCEZID/DHQP)

Subject: FW: [EXT] RE: WHO GACVS sub-committee - request for information

From: JANIN, Annick <janina@who.int> Sent: Thursday, April 1, 2021 8:44 AM

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

Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura

(CDC/DDPHSIS/CGH/GID) < dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < iyk3@cdc.gov>; Bennett, S

PAL, Shanthi Narayan <pals@who.int>; Phillips, Anastasia <anastasia.phillips@health.wa.gov.au>;

Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>

Subject: RE: [EXT] RE: WHO GACVS sub-committee - request for information

Dear Tom,

Thank you these data are very useful.

I have one question related to thrombotic events (I have highlighted relevant sections below):

(b)(5)

(b)(5)

Would it be possible

Kind regards Annick Annick JANIN, MD Technical Officer - Pharmacovigilance (PVG) World Health Organization

Geneva, Switzerland Office: +41 22 791 1478 Mobile: +33 6 29 54 71 90

janina@who.int

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

Sent: Tuesday, 30 March 2021 22:14

To: Phillips, Anastasia <anastasia.phillips@health.wa.gov.au>; Helfand, Rita (CDC/DDID/NCEZID/OD)

<rzh7@cdc.gov>

**Cc:** Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura

(CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>;

PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int> Subject: [EXT] RE: WHO GACVS sub-committee - request for information

Hi Anastasia,

Could it be shared with the GACVS COVID-19 subcommittee members first and then shared with the broader GACVS if the subcommittee member think it will be helpful? Also, attached are some ACIP COVID-19 vaccine safety technical subgroup presentations. Please treat these as confidential as well. Thanks.

Tom

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Sent: Tuesday, March 30, 2021 5:49 AM

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

(CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>

Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura

(CDC/DDPHSIS/CGH/GID) < <a href="https://dvi3.org/dvj3.org/dc.gov">dvj3.org/dc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < <a href="https://dvi3.org/dc.gov">iyk3.org/dc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) </a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <a href="https://dvi3.org/dc.gov">iyk3.org/dc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) </a>; Bennett, Sarah D. (CDC/DD

PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>

Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for providing this information. Are you happy for this to be provided to the GACVS members in writing (in strict confidence), or would you prefer a verbal update be provided?

Many thanks again Anastasia

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Tuesday, 30 March 2021 6:07 AM

**To:** Phillips, Anastasia <<u>Anastasia.Phillips@health.wa.gov.au</u>>; Helfand, Rita (CDC/DDID/NCEZID/OD) <<u>rzh7@cdc.gov</u>>

Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">ivk3@cdc.gov</a>; PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <a href="mailto:janina@who.int">janina@who.int</a>

Subject: RE: WHO GACVS sub-committee - request for information

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Hi Anastasia – Please keep this information close hold.
Tom

(b)(5)

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Sent: Friday, March 19, 2021 1:01 AM

To: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <a y v 6@cdc.gov>

Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura

(CDC/DDPHSIS/CGH/GID) < dvj3@cdc.gov >; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < iyk3@cdc.gov >;

PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>

Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for sharing this comprehensive piece of work. I have shared it with GACVS sub-committee members only and in confidence.

I have set up a meeting via MS Teams for next week. It would be helpful to discuss what analyses CDC may be able to share with GACVS members going forward, in response to further issues identified internationally.

I have also included Kristine Macartney in the meeting request (GACVS member and NCIRS Director) as there may be a couple of other related issues to discuss. Please feel free to forward the invitation to anyone else in your organization as required. Rita, I have included you in the invitation in case you would like to join.

Many thanks again Anastasia

From: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov>

Sent: Friday, 19 March 2021 12:40 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">; Phillips, Anastasia

<Anastasia.Phillips@health.wa.gov.au>

Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura

(CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>;

PAL, Shanthi Narayan <<u>pals@who.int</u>>; JANIN, Annick <<u>janina@who.int</u>> **Subject:** RE: WHO GACVS sub-committee - request for information

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Thanks, Tom! Anastasia, I would interpret this as being that it could go to the GACVS sub-committee but not the larger group of participants.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Thursday, March 18, 2021 12:29 PM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov">dvj3@cdc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">iyk3@cdc.gov</a>; PAL, Shanthi Narayan <a href="mailto:pals@who.int">pals@who.int</a>;

JANIN, Annick <janina@who.int>

Subject: RE: WHO GACVS sub-committee - request for information

Dear Anastasia,

I have received permission to confidentially share this draft manuscript with is under review at Vaccine. Please do not share outside of you need-to-know group. We hope it will be published soon. (b)(5)

b)(5)

. I have standing meetings

starting at 8am, but could do 7:30am next week if that works.

Regards,

Tom

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Wednesday, March 17, 2021 3:47 AM

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

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">iyk3@cdc.gov</a>; PAL, Shanthi Narayan <a href="mailto:pals@who.int">pals@who.int</a>;

JANIN, Annick < janina@who.int>

Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopaenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again Anastasia

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, 17 March 2021 6:43 AM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I'm happy to talk when convenient. I'm Cc'ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

## Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Sent: Monday, March 8, 2021 10:05 PM

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

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>

Subject: WHO GACVS sub-committee - request for information

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

## Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM

Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia

Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)

E: anastasia.phillips@health.wa.gov.au

Ph: +61 417 172 936

Markowitz, Lauri (CDC/DDID/NCIRD/DVD) From:

Sent: Tue, 13 Apr 2021 01:17:52 +0000

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John

(CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP)

RE: April 12 VaST call - draft agenda and presentations Subject:

Thanks to both of you for your comments. I know everyone is busy with other things at the moment (b)(5)

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

Sent: Monday, April 12, 2021 7:13 PM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>

Subject: RE: April 12 VaST call - draft agenda and presentations

Hi Lauri,

Tom

## Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service **Deputy Director** Immunization Safety Office Centers for Disease Control and Prevention (CDC) 1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a>>

Sent: Monday, April 12, 2021 6:48 PM

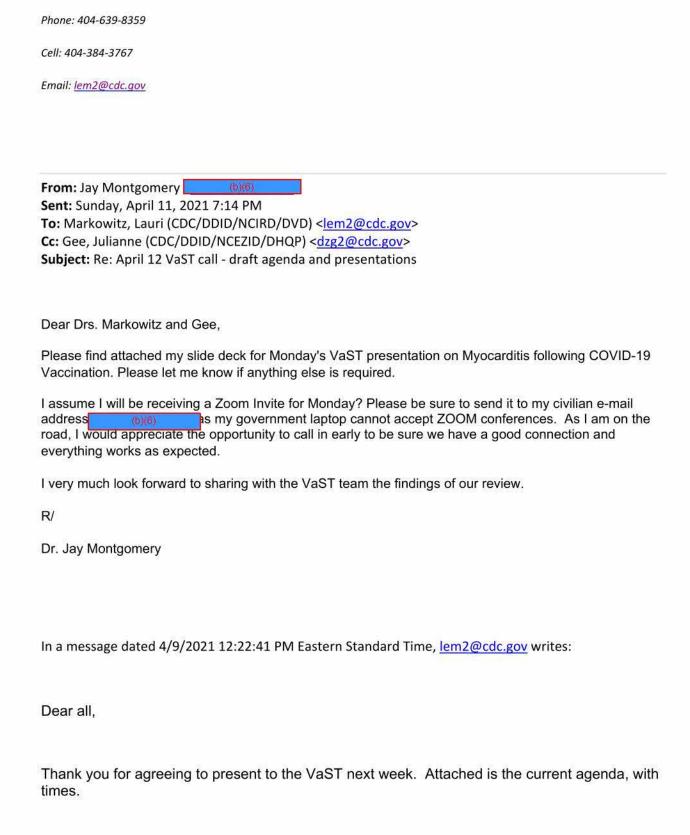
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v 6@cdc.gov >; Su, John

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>

Subject: FW: April 12 VaST call - draft agenda and presentations

FYI – let me know your thoughts.

From: Jay Montgomery Sent: Monday, April 12, 2021 6:41 PM To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">!em2@cdc.gov</a>; Renata Engler LC COLLINS < limone.c.collins.civ@mail.mil> Subject: Re: April 12 VaST call - draft agenda and presentations Dear Dr. Markowitz, Respectfully, Jay Montgomery Sent from the all new AOL app for iOS On Monday, April 12, 2021, 11:14 AM, Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov> wrote: Dear Jay and Renata, Thank you again for your presentations. Lauri Lauri Markowitz, MD VaST Co-Lead Division of Viral Diseases National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention 1600 Clifton Rd MS H24-5 Atlanta, GA 30329-4027



Please send your PowerPoint presentations to me and Julianne Gee (copied here), by Monday morning at 10 am.

I will send pdfs of presentations to the VaST members and other call attendees. Our administrative assistant will advance slides for you during the call.

Thank you and let me know if you have any questions.

Lauri

## Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Thursday, April 8, 2021 2:01 PM

**To:** Forshee, Richard (FDA/CBER) < Richard.Forshee@fda.hhs.gov >; Cunningham, Fran < Fran.Cunningham@va.gov >; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov >; Su, John R CAPT USPHS (USA) < ezu2@cdc.gov >; Collins, Limone C Jr CIV DHA HEALTH OPNS (USA) limone.c.collins.civ@mail.mil >

Cc: Shimabukuro, Tom T CAPT USPHS (USA) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">; Gee, Julianne

(CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>

Subject: [Non-DoD Source] April 12 VaST draft agenda and proposed times

Dear all,

Please see below the approximate times planned for your talks on the VaST call next Monday. Let me know if you feel any revisions are needed.

## April 12

(b)(5)

Thank you all for presenting to VaST.

Lauri

## Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Sent:** Wed, 10 Mar 2021 12:38:12 +0000

To: Su, John (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP);

Destefano, Frank (CDC/DDID/NCEZID/DHQP)

Subject: FW: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to

the Israeli National Focal Point to discuss Pfizer vaccine **Attachments:** Myocarditis Response.docx

This is for that joint FDA-CDC to the Israeli MOH. Please let me know if you have any thoughts. Thanks. Tom

From: Nair, Narayan < Narayan. Nair@fda.hhs.gov>

Sent: Tuesday, March 9, 2021 9:10 AM

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

Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli

National Focal Point to discuss Pfizer vaccine

Hi Tom,

Here are some draft responses to the Israeli Ministry of Health's inquiry.

(b)(5)

(b)(5)

Narayan

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

Sent: Sunday, February 28, 2021 3:06 PM

**To:** Anderson, Steven < Steven.Anderson@fda.hhs.gov>; Forshee, Richard < Richard.Forshee@fda.hhs.gov>; Nair, Narayan < Narayan.Nair@fda.hhs.gov>

Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National

Focal Point to discuss Pfizer vaccine

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

FYI.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov>

Sent: Sunday, February 28, 2021 2:28 PM

To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) <zmt0@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < <a href="mailto:dpl9@cdc.gov">dpl9@cdc.gov">dpl9@cdc.gov</a>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < <a href="mailto:dealer:decdc.gov">dealer:decdc.gov</a>; Beauvais, Denise (CDC/DDID/NCIRD/OD) < <a href="mailto:decdc.gov">cry2@cdc.gov</a>; CDC IMS 2019 NCOV Response VTF Policy < <a href="mailto:decdc.gov">decdc.gov</a>; McClure, Susan (CDC/DDPHSIS/CGH/OD)

<zur1@cdc.gov>

**Subject:** RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Seeing that Denise is out. + Susan

Susan – can you please help coordinate?

Thanks,

-d

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID)
Sent: Sunday, February 28, 2021 2:26 PM

To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < zmt0@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < <a href="mailto:dpl9@cdc.gov">dpl9@cdc.gov">dpl9@cdc.gov</a>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < <a href="mailto:dealer:debrace;">kaf6@cdc.gov</a>; Beauvais, Denise (CDC/DDID/NCIRD/OD) < <a href="mailto:cry2@cdc.gov">cry2@cdc.gov</a>; CDC IMS 2019 NCOV Response VTF Policy < <a href="mailto:coceent417@cdc.gov">ccry2@cdc.gov</a>; CDC IMS 2019 NCOV

**Subject:** RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

Thanks, Stacey.

(b)(5)

Best, David

From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < zmt0@cdc.gov>

Sent: Sunday, February 28, 2021 1:35 PM

To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov >; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < <a href="mailto:dpl9@cdc.gov">dpl9@cdc.gov</a>; Fox, Kimberley (CDC/DDID/NCIRD/DBD)

<kaf6@cdc.gov>

Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point

to discuss Pfizer vaccine

Thanks David (b)(5) ? 1 (b)(5)

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov>

Sent: Sunday, February 28, 2021 11:15 AM

To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < zmt0@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < <a href="mailto:dpl9@cdc.gov">dpl9@cdc.gov">dpl9@cdc.gov</a>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < <a href="mailto:kaf6@cdc.gov">kaf6@cdc.gov</a>>

Subject: FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point

to discuss Pfizer vaccine

Importance: High

Stacey and Tom,

Please see below re discussing with Israeli Vaccine FP re myocarditis in people receiving Pfizer vaccine.

Thanks, David

From: CDC IMS Task Tracker (CDC) <eoctasktracker@cdc.gov>

Sent: Sunday, February 28, 2021 1:13 PM

To: CDC IMS 2019 NCOV Response VTF Vaccine Safety <<u>eocevent416@cdc.gov</u>>; CDC IMS 2019 NCOV Response VTF Policy <<u>eocevent417@cdc.gov</u>>; CDC IMS 2019 NCOV Response VTF Chief Medical Officer <<u>eocevent516@cdc.gov</u>>; CDC IMS 2019 NCOV Response VTF Operations <<u>eocvtftask@cdc.gov</u>>
Cc: CDC IMS Task Tracker (CDC) <<u>eoctasktracker@cdc.gov</u>>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <<u>kaf6@cdc.gov</u>>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <<u>vid3@cdc.gov</u>>; Lubar, Debra (CDC/DDID/NCEZID/OD) <<u>dpl9@cdc.gov</u>>

Subject: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to

discuss Pfizer vaccine Importance: High

Task ID: 42633

Suspense: 3/2/2021 17:00:00

Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety

Requestor's Name: Dr. Roee Singer MD, MPH (b)(6)

Phone #:

**Subject:** HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss Pfizer vaccine

**Description:** The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine. The

Israeli National	Focal Point is	requesting a	Point of	Contact from	the CDC a	nd FDA to	discuss
the issue							

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".

## Summary of VAERS Reports of myocarditis, pericarditis and myopericarditis following vaccination with mRNA COVID-19 vaccines

## **Background:**

This memo responds to questions posed from the Israeli Ministry of Health to the FDA and CDC. They are investigating a safety signal of myocarditis /myopericarditis in a younger population (16 -30 years old) following administration of Pfizer-BioNTech Covid-19 vaccine. The Ministry of Health stated they received reports of around 40 cases of this adverse event. They did not provide additional details about these cases.

## **Questions Posed by Israeli Ministry of Health:**

- 1. How many doses of the vaccine were administered to this age group? CDC to provide this data
- 2. How many cases of myocarditis / peri-myocarditis were reported in your country?

  A search of the U.S. Vaccine Adverse Event Reporting System (VAERS) conducted on February 23, 2021 revealed 27 cases (6 cases of myocarditis, 7 cases of myopericarditis, 14 cases pericarditis).

The following Medical Dictionary for Regulatory Activities (MedDRA) preferred terms were used to conduct the search: myocarditis; eosinophilic myocarditis; hypersensitivity myocarditis; pericarditis; pericarditis; pericarditis adhesive; pericarditis constrictive; pleuropericarditis; pericardial disease; pericardial effusion; pericardial rub; myopericarditis. Reports with sufficient information were reviewed and categorized based on case definitions previously used for surveillance of myopericarditis after smallpox vaccine (https://www.cdc.gov/mmwr/PDF/wk/mm5221.pdf).

Reports were included if they contained a diagnosis by of myocarditis, pericarditis or

myopericarditis. Reports with pericardial effusion and no other signs of myopericarditis were excluded. If the diagnosis in the narrative was pericarditis but the patient also had elevated troponin they were categorized as myopericarditis.

## 3. Could you elaborate details on these AE cases (time of diagnosis from the vaccine, first/second dose, risk factors, etc.)?

Twelve cases occurred after dose 1, 7 cases after dose 2, and the dose was not reported for 8 cases. Four patients had comorbid conditions that could suggest alternate etiologies for the adverse event. These included:

- One patient with subacute pericarditis noted on cardiac MRI. The clinical impression was this pre-dated vaccination
- One patient had a history of recurrent pericarditis
- One patient had recent SARS CoV-2 infection
- One patient had psoriatic arthritis and was on Adalimumab

None of the cases reported other risk factors or causes such as preceding viral infections or other vaccines administered concurrently. However, due to the nature of passive surveillance reports, it is not possible to completely exclude these due to potential incompleteness of reports.

The following table displays additional information about the cases of myopericarditis.

Characteristics	Reports of Myopericarditis/Myocarditis/Pericarditis (N = 27)		
Median age, years (range)*	36 (21–84)		
Female (%)	10(37)		
Male (%)	16 (59)		
Gender not reported (%)	1(4)		
Median Time to Onset in Days (range)	3 (0-20)		

## **4.** Have you assessed the causality between the AE and the vaccine for each of the cases? During this analysis period the reporting rate of myopericarditis following administration of the mRNA COVID-19 vaccines was low and estimated to be 0.7 per million doses of vaccine administered. However, the limitations of passive surveillance such as under-reporting, lack of a control group, missing and incomplete data make it challenging to assess causation. Thus, FDA has not made a final determination regarding the causality between myopericarditis and the mRNA COVID-19 vaccines. We will continue to monitor this outcome in active and passive surveillance.

Sent:	Mon, 12 Apr 2021 22:44:03 +0000						
To:	Wharton, Melinda (CDC/DDID/NCIRD/ISD)						
Subject:	FW: April 12 VaST call - draft agenda and presentations						
Something else v	ve need to discuss.						
From: Jay Montg	omery (b)(6)						
200	pril 12, 2021 6:41 PM						
ACCURACIONAL MARKET AND ACCUSATION OF THE SECOND	auri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Renata Engler</lem2@cdc.gov>						
Subject: Re: Apri	LC COLLINS < limone.c.collins.civ@mail.mil> 12 VaST call - draft agenda and presentations						
	22 ras can draw agenda and presentations						
Dear Dr. Markov	itz,						
	(b)(5)						
Respectfully,							
Jay Montgomery							
Sent from the all	new AOL app for iOS						
Serie morn the un	New Modago 101 100						
5000 (5)	ril 12, 2021, 11:14 AM, Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <u>lem2@cdc.g</u>	₹ <mark>OV</mark> >					
wrote:							
Dear Jay and Rer	ata,						
Thank you again	for your presentations. (b)(5)	-					
The state of the s	(b)(5)						
Lauri							
Lauri							
Lauri Markowitz, M	ז						
-uair markowitz, Wi							
VaST Co-Lead							
Division of Viral Dise	ases						

Markowitz, Lauri (CDC/DDID/NCIRD/DVD)

From:

National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention 1600 Clifton Rd MS H24-5 Atlanta, GA 30329-4027 Phone: 404-639-8359 Cell: 404-384-3767 Email: lem2@cdc.gov From: Jay Montgomery Sent: Sunday, April 11, 2021 7:14 PM To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov> Cc: Gee, Julianne (CDC/DDID/NCEZID/DHQP) < dzg2@cdc.gov> Subject: Re: April 12 VaST call - draft agenda and presentations Dear Drs. Markowitz and Gee, Please find attached my slide deck for Monday's VaST presentation on Myocarditis following COVID-19 Vaccination. Please let me know if anything else is required. I assume I will be receiving a Zoom Invite for Monday? Please be sure to send it to my civilian e-mail address as my government laptop cannot accept ZOOM conferences. As I am on the road, I would appreciate the opportunity to call in early to be sure we have a good connection and everything works as expected. I very much look forward to sharing with the VaST team the findings of our review. R/ Dr. Jay Montgomery

In a message dated 4/9/2021 12:22:41 PM Eastern Standard Time, <a href="lem2@cdc.gov">lem2@cdc.gov</a> writes:

Dear all,

Thank you for agreeing to present to the VaST next week. Attached is the current agenda, with times.

Please send your PowerPoint presentations to me and Julianne Gee (copied here), by Monday morning at 10 am.

I will send pdfs of presentations to the VaST members and other call attendees. Our administrative assistant will advance slides for you during the call.

Thank you and let me know if you have any questions.

Lauri

## Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Thursday, April 8, 2021 2:01 PM

**To:** Forshee, Richard (FDA/CBER) < Richard.Forshee@fda.hhs.gov >; Cunningham, Fran < Fran.Cunningham@va.gov >; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov >; Su, John R CAPT USPHS (USA) < ezu2@cdc.gov >; Collins, Limone C Jr CIV DHA HEALTH OPNS (USA) limone.c.collins.civ@mail.mil >

Cc: Shimabukuro, Tom T CAPT USPHS (USA) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">; Gee, Julianne

(CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>

Subject: [Non-DoD Source] April 12 VaST draft agenda and proposed times

Dear all,

Please see below the approximate times planned for your talks on the VaST call next Monday. Let me know if you feel any revisions are needed.

## April 12



Thank you all for presenting to VaST.

Lauri

## Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

From: Wharton, Melinda (CDC/DDID/NCIRD/ISD)

**Sent:** Thu, 1 Apr 2021 13:32:47 +0000

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)

**Subject:** RE: Covid-19 vaccine safety data

## (b)(5)

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Thursday, April 1, 2021 9:04 AM

To: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>

Subject: RE: Covid-19 vaccine safety data

## (b)(5)

From: Wharton, Melinda (CDC/DDID/NCIRD/ISD) < mew2@cdc.gov>

Sent: Thursday, April 1, 2021 9:00 AM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a>>

Subject: RE: Covid-19 vaccine safety data

### (b)(5)

## (b)(5)

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Thursday, April 1, 2021 8:57 AM

To: Wharton, Melinda (CDC/DDID/NCIRD/ISD) < mew2@cdc.gov>

Subject: FW: Covid-19 vaccine safety data

# Melinda, (b)(5)

This is the schedule - (t

(b)(5

From: 2'2 2222 222222 < EMILIA. ANIS@MOH. GOV.IL>

Sent: Thursday, April 1, 2021 4:24 AM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a>>

Cc: 2727 P27 <hadas.rotem@MOH.GOV.IL>; 272 P27 <BOAZ.LEV@MOH.GOV.IL>; 272 P272

<dana.arad@MOH.GOV.IL>; ?????? ????? <sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Laurie,

I think we will need another 5-10 minutes for our presentation.

We prefer to have these discussions by zoom. Will your invitation be by zoom or would you prefer us to send?

Regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel

Tel. 972-2-5080521 Fax: 972-2-5655950 Mobile: 972-50-6242145

E-mail: emilia.anis@moh.health.gov.il

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Wednesday, March 31, 2021 7:20 PM

To: 2'2 2222 222222 < EMILIA.ANIS@MOH.GOV.IL>

Cc: 2727 ?77 <hadas.rotem@MOH.GOV.IL>; 27 ?77 <BOAZ.LEV@MOH.GOV.IL>; 777 272

<dana.arad@MOH.GOV.IL>; ?????? ????? <sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Emilia,

For the VaST call next Monday, April 5, you will receive a calendar invitation from the VaST call scheduler either on Friday this week or on Monday morning.

We have several items on the agenda and would like the presentation from Israel to be first. We have scheduled 15 minutes for the presentation and 10 minutes for discussion. Will 15 minutes be enough time? It would be great if you can send slides to me before Monday, but if not, Monday morning is OK.

Regards, Lauri

### Lauri Markowitz, MD

VaST Co-Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)

Sent: Wednesday, March 24, 2021 12:17 PM

To: '2'2 2222 222222' < EMILIA.ANIS@MOH.GOV.IL>

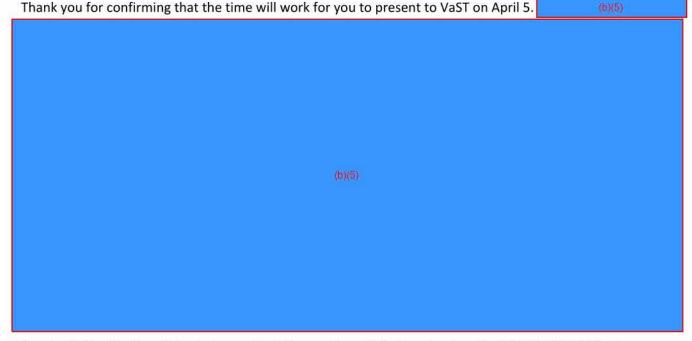
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; 2222 222

<a href="https://www.ncbc/ld.scotter-general-color: blue-section-color: blue-section-c

<ayv6@cdc.gov>

Subject: RE: Covid-19 vaccine safety data

Dear Emilia,



I'm also Cc'ing Dr. Tom Shimabukuro who is the vaccine safety team lead on the CDC COVID-19 Vaccine Task Force who can provide additional information, if needed.

### Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

From: 2'? ???? ??????<EMILIA.ANIS@MOH.GOV.IL>

Sent: Monday, March 22, 2021 12:51 PM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) < mew2@cdc.gov >; ????? ???

<hadas.rotem@MOH.GOV.IL>; ??? ???
BOAZ.LEV@MOH.GOV.IL>; ??? ???
dana.arad@MOH.GOV.IL>;

????? ????? ????<sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Lauri,

(b)(5)

Best regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel

Tel. 972-2-5080521 Fax: 972-2-5655950 Mobile: 972-50-6242145

E-mail: emilia.anis@moh.health.gov.il

From: 2'? ???? ??????

Sent: Saturday, March 20, 2021 4:18 PM

To: 'Markowitz, Lauri (CDC/DDID/NCIRD/DVD)' < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a>>

Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; 2222 222

<a href="mailto:</a><a href="mailto://www.ncov.il">hadas.rotem@MOH.GOV.IL</a>; 22 222<a href="mailto://www.ncov.il">22 222

????? ????? ????? sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Lauri,

I will check with my colleagues and get back to you tomorrow.

Best regards,



Emilia Anis, MD, MPH
Director
Division of Epidemiology
Ministry of Health, Israel
Tel. 972-2-5080521

Fax: 972-2-5655950 Mobile: 972-50-6242145

E-mail: emilia.anis@moh.health.gov.il

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Tuesday, March 16, 2021 11:48 PM

To: 2'2 2222 222222< EMILIA. ANIS@MOH.GOV.IL>

Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) < mew2@cdc.gov >; 2222 222

<hadas.rotem@MOH.GOV.IL>; 22 222<BOAZ.LEV@MOH.GOV.IL>; 222 222<dana.arad@MOH.GOV.IL>;

????? ????? ????<sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Dr. Anis,

Thank you for this note and for your willingness to present to VaST. We were hoping you could present on Monday, April 5. Our calls are at 1:30 PM EDT. I know this is the early evening in Jerusalem, so let me know if this will work of you.

Warm regards, Lauri

### Lauri Markowitz, MD

VaST Co-Lead
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: 2'? ???? ?????< EMILIA.ANIS@MOH.GOV.IL>

Sent: Tuesday, March 16, 2021 9:28 AM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) < mew2@cdc.gov>; 2222 222

<a href="mailto:specification-color: blue-specification-color: blue-sp

?????? ?????? ????? < sharon.alroy@MOH.GOV.IL>

Subject: RE: Covid-19 vaccine safety data

Dear Dr. Markowitz,

Thank you for the invitation.

We will be happy to share our data. Please let us know enough time in advance and note that there are Passover holidays from 27.3 until 3.4.

Best regards from Jerusalem,



Emilia Anis, MD, MPH Director Division of Epidemiology Ministry of Health, Israel

Tel. 972-2-5080521 Fax: 972-2-5655950 Mobile: 972-50-6242145

E-mail: emilia.anis@moh.health.gov.il

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a>>

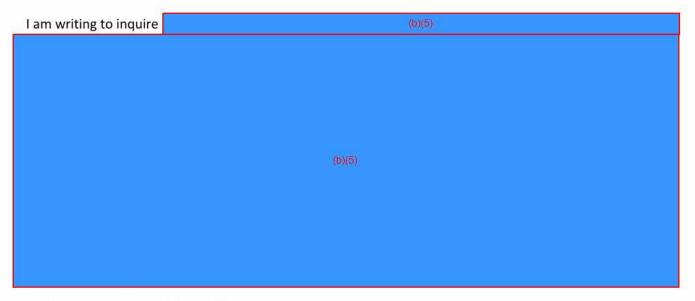
Sent: Monday, March 15, 2021 4:06 PM

To: 2'? ???? ??????<EMILIA.ANIS@MOH.GOV.IL>

Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) < <a href="mew2@cdc.gov">mew2@cdc.gov">mew2@cdc.gov</a>

Subject: Covid-19 vaccine safety data

Dear Dr. Emilia Anis,



Thank you and I hope all is well there, Lauri

### Lauri Markowitz, MD

VaST Co-Lead

Division of Viral Diseases

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

1600 Clifton Rd MS H24-5

Atlanta, GA 30329-4027 Phone: 404-639-8359 Cell: 404-384-3767 Email: lem2@cdc.gov From: Hanson, Kayla E

**Sent:** Mon, 26 Oct 2020 17:39:47 +0000

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Kristin Goddard, MPH

(kristin.x.goddard@kp.org)

Cc: Donahue, James G DVM/PhD

Subject: RE: RCA Outcome Questions/Recommendations

Attachments: Abstraction Tool Inventory.docx

(b)(5)

-Kayla

From: Hanson, Kayla E

Sent: Thursday, October 22, 2020 1:59 PM

To: Weintraub, Eric (CDC/OID/NCEZID) <eiw8@cdc.gov>; Kristin Goddard, MPH

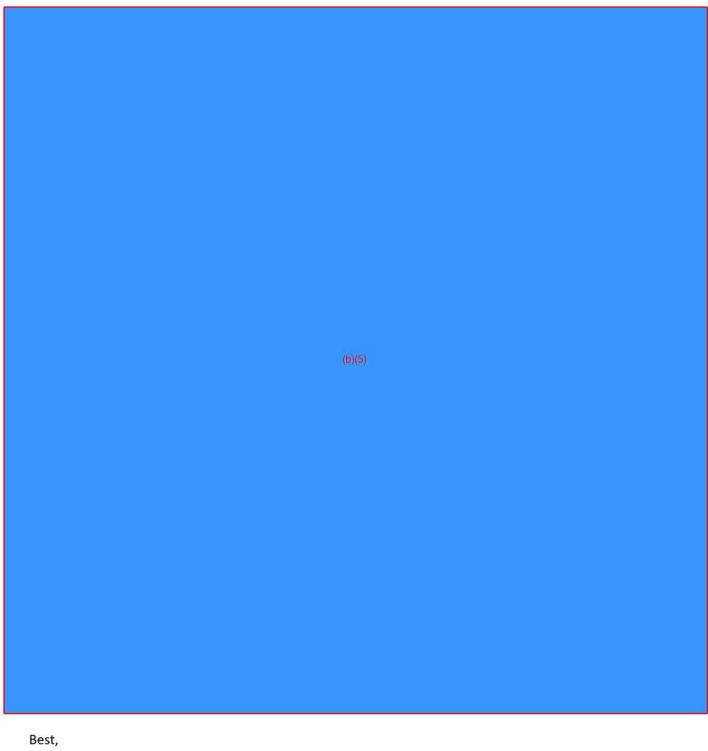
(kristin.x.goddard@kp.org) < kristin.x.goddard@kp.org>

Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>

Subject: RCA Outcome Questions/Recommendations

Hi Kristin and Eric,



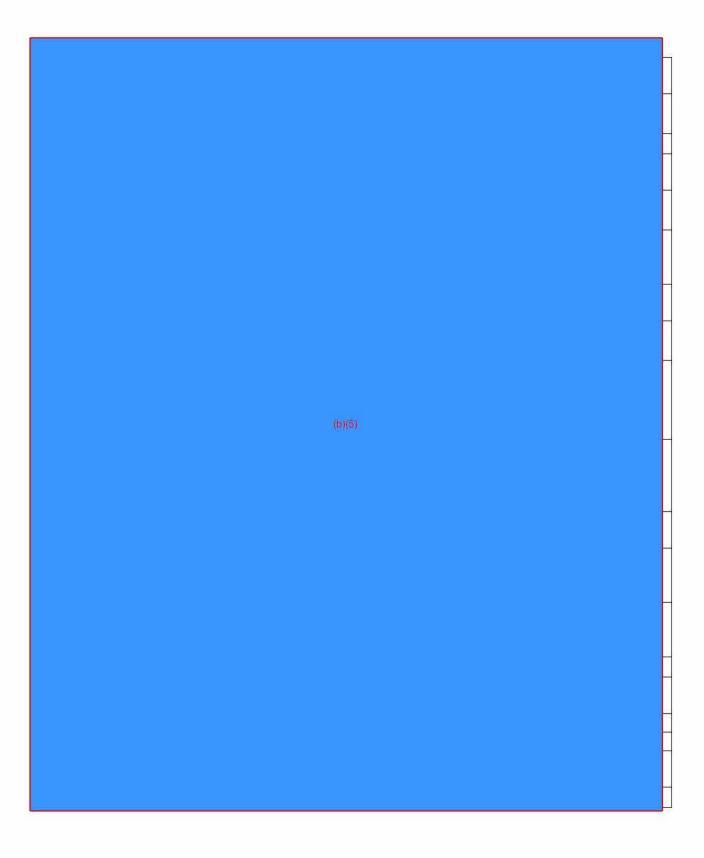


Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health

Marshfield Clinic Research Institute | 1000 North Oak Avenue (ML2), Marshfield, WI 54449 1-715-221-6482 | ■ 1-715-389-3880 | Manson.kayla@marshfieldresearch.org

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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Fri, 30 Apr 2021 00:35:05 +0000

To: NICOLA P KLEIN

**Subject:** RE: updated VaST slideset

Attachments: VSD slides ACIP April 23 2021 - final.pptx

From: NICOLA P KLEIN < Nicola. Klein@kp.org> Sent: Thursday, April 29, 2021 7:35 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

Subject: RE: updated VaST slideset

Excellent. Give me 5 minutes

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Thursday, April 29, 2021 4:33 PM
To: NICOLA P KLEIN < Nicola. Klein@kp.org>

Subject: RE: updated VaST slideset

Nicky - I'm ready now if you are, my evening "session" ended early. Otherwise, I can wait till 8:30 est

From: NICOLA P KLEIN < Nicola. Klein@kp.org>
Sent: Thursday, April 29, 2021 3:56 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Subject: RE: updated VaST slideset

Yes if we do it at 5:30 PT/8:30 ET?

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Thursday, April 29, 2021 12:54 PM
To: NICOLA P KLEIN < Nicola. Klein@kp.org>

Subject: RE: updated VaST slideset

I'm running out right now and probably won't be back available until around 8:30 - 9:00 est?

Does that work?

From: NICOLA P KLEIN < Nicola.Klein@kp.org>
Sent: Thursday, April 29, 2021 3:52 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Subject: RE: updated VaST slideset

(b)(5) ? I won't be able to tomorrow. Hopefully it won't take too

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov> Sent: Thursday, April 29, 2021 6:58 AM To: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard < Kristin.X.Goddard@kp.org>; NICOLA P KLEIN < Nicola.Klein@kp.org>; Ned Lewis < Ned.Lewis@kp.org> Subject: updated VaST slideset Caution: This email came from outside Kaiser Permanente. Do not open attachments or click on links if you do not recognize the sender. Attached is the updated VaST slideset.

NOTICE TO RECIPIENT: If you are not the intended recipient of this e-mail, you are prohibited from sharing, copying, or otherwise using or disclosing its contents. If you have received this e-mail in error, please notify the sender immediately by reply e-mail and permanently delete this e-mail and any attachments without reading, forwarding or saving them. v.173.295 Thank you.





From: John Auerbach

**Sent:** Wed, 28 Apr 2021 13:27:20 +0000

To: John Auerbach

Subject: TFAH's Covid-19 News Update - April 28, 2021

# PH Mitigation/Suppression

- With, by his own admission, "zero background in infectious disease modeling," the young data scientist (he's only 27) Youyang Gu built a Covid-19 modeling site that proved remarkably accurate, and has become an indispensable resource for scientists and government officials. On October 6, Gu posted his final death forecast, just before the fall wave. The model projected there would be 231,000 deaths in the US by November 1. The total recorded by that date: 230,995. He's profiled here.
- India on Wednesday reported another record number of coronavirus cases and deaths, nudging its official Covid-19 death toll past 200,000 as the virus coursed through urban centers and out into rural areas, leaving broken families and communities in its wake. In a new global record, Indian authorities logged 360,960 infections in a 24-hour period, bringing the total number of cases to more than 17.9 million. India also reported 3,293 deaths, even as experts warned that many virus fatalities were going uncounted.
  - Vidya Krishnan in the Atlantic: India's experience of the pandemic will be defined by this enormous second wave. But the chamber of horrors the country now finds itself in was not caused by any one man, or any single government. It is the greatest moral failure of our generation. India may be classified as a developing or middle-income country, and by international standards, it does not spend enough on the health of its people. Yet this masks many of India's strengths in the health-care sector: Our doctors are among the best trained on the planet, and as is well known by now, our country is a pharmacy for the world, thanks to an industry built around making cost-effective medicines and vaccines. What is evident, however, is that we suffer from moral malnutrition—none of us more so than the rich, the upper class, the upper caste of India. And nowhere is this more evident than in the health-care sector.
- In a prospective evaluation involving 3 rounds of testing in 1 nursing home, researchers compared antigen test performance (using BinaxNOW) versus virus culture and real-time reverse transcription polymerase chain reaction (RT-PCR). As expected, the antigen test performed less well in late infection than RT-PCR. Of note, however, it performed very well compared with RT-PCR and virus culture in early infection (percentage of positive agreement, 86% and 95%, respectively). These results provide additional support to the idea that antigen testing could be useful to identify people who are likely to be contagious and may transmit SARS-CoV-2, as well as the idea that rapid antigen tests can be a useful screening tool to limit infectious outbreaks. The rapid time to results, and thus public health mitigation, cannot be overstated. Once a result is obtained in less than a half hour, action can be taken to limit further contacts, and thus further spread of the virus. In the study, researchers also found that false positives were not a significant problem.

- The failure of U.S. authorities to test adult migrants for the coronavirus in jam-packed border processing centers is creating a potential for new transmissions, public health officials and shelter operators warn, even among migrants who may have arrived healthy at America's door. More than 170,000 migrants crossed the border in March—many coming from countries still grappling with high infection rates—but the Border Patrol is conducting no testing for the coronavirus during the several days that the newly arrived migrants are in U.S. custody except in cases where migrants show obvious symptoms. The government says it has insufficient time and space to test migrants upon their arrival. So while migrants get a basic health screening, testing is being postponed until their release to local community groups, cities and counties, usually after the new arrivals have spent days confined in tight spaces with scores of strangers, often sleeping shoulder to shoulder on mats on the floor. Unaccompanied children are being tested, but only after they have spent around three days in custody, just before being loaded onto buses or planes for transport to government-run shelters. U.S. officials say the challenges to testing all the new arrivals when they are first apprehended are insurmountable. There have been no instances of mass spread at U.S. border facilities, and overall numbers of cases are relatively low, according to the Department of Homeland Security. About 5 percent of all single adults and families tested after their release since March showed a positive result, according to the agency, while among the thousands of unaccompanied minors now in custody, the rate has been about 12 percent. But local officials and shelter operators said they feared that the actual number of infections could be much higher.
- While coronavirus cases are falling in much of the United States, <u>infections are spiking in Oregon</u>, where a new wave is set to push a third of counties into the most severe level of restrictions. In the past two weeks, virus cases have risen 54 percent and hospitalizations are up 39 percent.
- Federal health officials said Tuesday that fully vaccinated people can go without masks
  outdoors when walking, jogging or biking, or dining with friends at outdoor restaurants—
  a milestone development for tens of millions of pandemic-weary Americans after more
  than a year of masking up and locking down.
  - The common six-foot social distancing guidance on its own may not be enough to protect people from contracting the coronavirus while spending time indoors, according to a report that examined the virus's airborne transmission risk. Researchers from the Massachusetts Institute of Technology argued that not all indoor settings are the same, varying by size, ventilation, air filtration, occupancy and the nature of the activity. While the core premise of the study isn't new, the research offers more details (and a handy online risk-assessment calculator) to help people better understand what factors in a given indoor setting may increase their risk for catching the coronavirus.

### **Herd Immunity**

Peter Hotez in Nature: I have a long-standing disagreement with many of my US public-health colleagues. I admire their commitment to disease prevention, but when I ask for a more direct way to counter anti-vaccine aggression, I'm told, "that's not our approach;

confrontation gives them a platform and oxygen." In my opinion, this attitude reflects a time when we had dial-up modems. Today, the anti-vaccine empire has hundreds of websites and perhaps 58 million followers on social media. The bad guys are winning, in part because health agencies either underestimate or deny the reach of anti-science forces, and are ill-equipped to counter it. Accurate, targeted counter-messaging from the global health community is important but insufficient, as is public pressure on social-media companies. The United Nations and the highest levels of governments must take direct, even confrontational, approaches with Russia, and move to dismantle anti-vaccine groups in the United States. Efforts must expand into the realm of cyber security, law enforcement, public education and international relations. A high-level inter-agency task force reporting to the UN secretary-general could assess the full impact of anti-vaccine aggression, and propose tough, balanced measures.

- <u>Thread</u> by Center for Countering Digital Hate: "Yesterday, tech CEOs told Congress they had acted on the Disinformation Dozen—12 people responsible for 65% of vaccine disinformation. It's not true. Our new report shows they are still online, posting lies viewed up to 29m times in the last month." (Link to report here.)
- Thread by Igor Bobic on the 2-minute PSA featuring Republican members of Congress who are also doctors, arguing for Americans to get vaccinated. "What we've found is if we put on our white coat, it literally moves the needle," Sen. Roger Marshall said.
- In 19 detailed steps—with photos, video, and illustrations—how Pfizer makes its Covid-19 vaccine.
- Paul Sax blogs on the decision to lift the pause on the J&J vaccine: "I confess this decision surprised me. My hunch was that they would advise limiting the vaccine in the U.S. to women older than 50, with no age criterion for men. Instead, it's now available for all... [But now] It's possible that [a] young healthy woman might end up getting the J&J vaccine. And while the odds are overwhelmingly in her favor that everything will be fine, in practice, this would be giving a vaccine with a recognized safety issue when two highly effective and safe alternatives exist."
- The White House's decision to send millions of doses of AstraZeneca's Covid-19 vaccine overseas has <u>split top Biden administration officials</u>—with many arguing that the government cannot reduce its stockpile of doses on hand given recent disruptions in U.S. vaccine production.

#### Health

• The CDC has not found a link between heart inflammation and Covid-19 vaccines, the agency's Director Rochelle Walensky said on Tuesday. "We have not seen a signal and we've actually looked intentionally for the signal in the over 200 million doses we've given," Walensky said in a press briefing. She said the CDC is in touch with the U.S. Department of Defense over its investigation of 14 cases of heart inflammation or myocarditis among people who were vaccinated through the military's health services.

• Covid survivors are at risk from a possible second pandemic, this time of opioid addiction, given the high rate of painkillers being prescribed to these patients, health experts say. A new study in Nature found alarmingly high rates of opioid use among covid survivors with lingering symptoms at Veterans Health Administration facilities. About 10% of covid survivors develop "long covid," struggling with often disabling health problems even six months or longer after a diagnosis. For every 1,000 long-covid patients, known as "long haulers," who were treated at a Veterans Affairs facility, doctors wrote nine more prescriptions for opioids than they otherwise would have, along with 22 additional prescriptions for benzodiazepines, which include Xanax and other addictive pills used to treat anxiety.

## **Equity**

• In part because of their family histories, many Tuskegee descendants are making a point of getting vaccinated and encouraging others to do the same.

# Cross-cutting/Other

- This is what American health care looks like to people from other countries. A short video.
- As vaccination rates go up, the floodgates of social life are poised to reopen. But not everyone will want to use this newfound freedom in the same way. Even before the pandemic, introverts and extroverts disagreed on the optimal size and frequency of gatherings. Post-vaccine life may breed some misunderstandings between the extroverts who want to dive headfirst into a sea of other people and the introverts who are excited to see their friends but don't want to pack their schedules so full that they have no time to just be. The Atlantic hosts a conversation with an introvert and an extrovert. Quote from Katharine Wu, the self-described introvert: "I think small talk is the tax that God exacted for the privilege of human speech."

# Some good news

• A new survey of native bees and the plants they need offers an encouraging sign that bees can bounce back if we throw them a lifeline in the form of carefully selected plants in our gardens.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Sent:** Fri, 9 Apr 2021 21:58:14 +0000

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP)

Cc: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC); Su, John

(CDC/DDID/NCEZID/DHQP)

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

### Thanks!

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Sent: Friday, April 9, 2021 5:55 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Cc: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Elaine,

### (b)(5)

**Thanks** 

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Friday, April 9, 2021 5:50 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>

Cc: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

### Pedro,

Also, note that John asked

(b)(5)

(b)(5)

Thanks, Elaine

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

Sent: Friday, April 9, 2021 5:35 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov >; Lagarde, Melanie (CDC/OCOO/OSSAM/OHC)

<mvl3@cdc.gov>

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine



John

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>

Sent: Friday, April 9, 2021 5:32 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Lagarde, Melanie

(CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Elaine,

(b)(5)

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>

Sent: Friday, April 9, 2021 5:10 PM

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

(CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

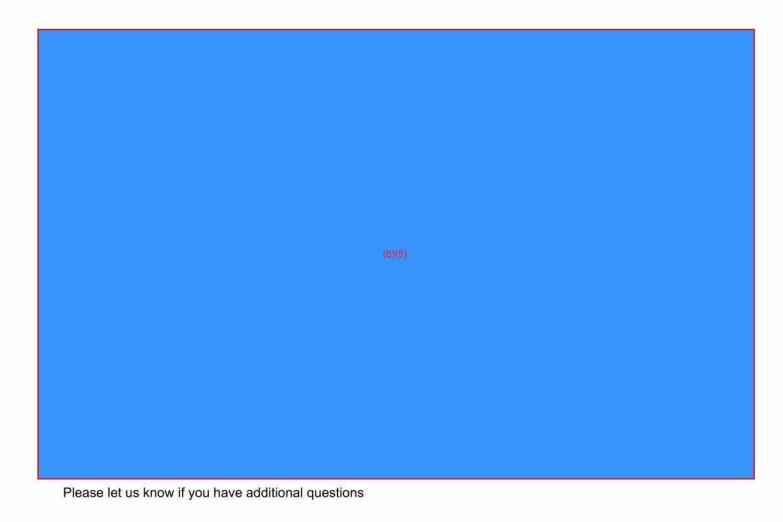
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Please let me know your edits:

(b)(5)

Sincerely, Pedro

(b)(5)



From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Sent: Friday, April 9, 2021 4:13 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov; Lagarde, Melanie

(CDC/OCOO/OSSAM/OHC) < mvi3@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,

(b)(5)

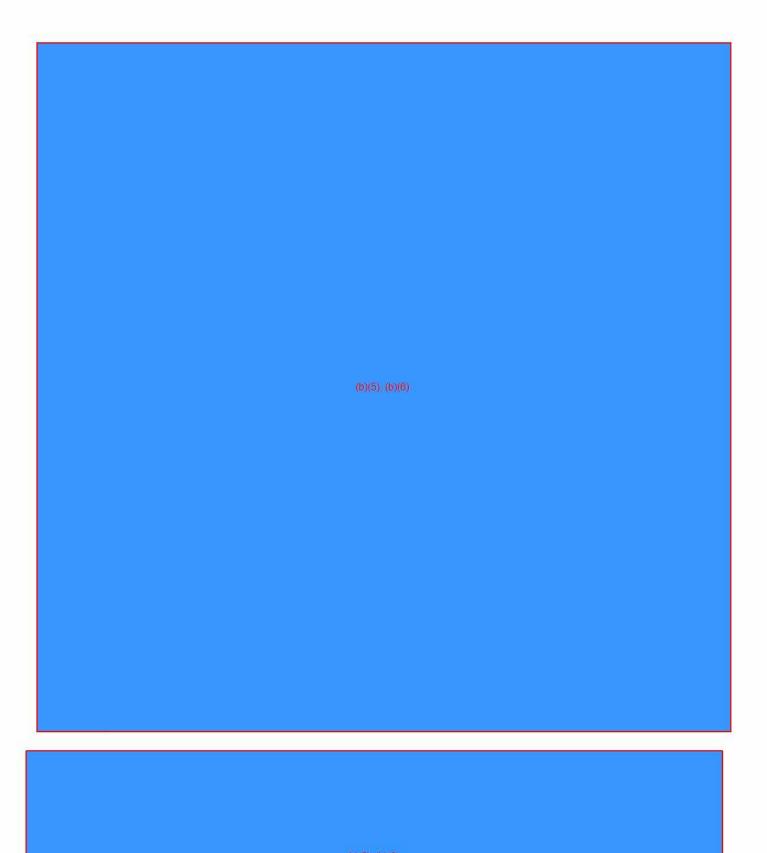
Thanks, Elaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Sent: Friday, April 9, 2021 4:09 PM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov >; Miller, Elaine R.

Elaine or John, do you have any edits?  Thanks for sending this  Pedro  From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov>  Sent: Friday, April 9, 2021 3:48 PM  To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov> Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine	•	:ZID/DHQP) < <u>erm4@cdc.gov</u> >; Su, John (CDC/DDID/NCEZID/DHQP) < <u>ezu2@cdc.gov</u> > DO: RE: DRAFT RE: Autoimmune dx post vaccine
Thanks for sending this  Pedro  From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov> Sent: Friday, April 9, 2021 3:48 PM  To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov> Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine  (b)(5)  Sincerely, Pedro	Hi Melanie,	
Pedro  From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov> Sent: Friday, April 9, 2021 3:48 PM To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) < eru2@cdc.gov> Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine  (DIS)  Sincerely, Pedro	(b)(5)	Elaine or John, do you have any edits?
From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <a href="mailto:smaller.com/mula@cdc.gov">mula@cdc.gov</a> Sent: Friday, April 9, 2021 3:48 PM To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <a href="mailto:smaller.com/psm9@cdc.gov">psm9@cdc.gov</a> ; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <a href="mailto:seru/a@cdc.gov">ezuu2@cdc.gov</a> Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine  (b)(6)  Sincerely, Pedro	Thanks for send	ing this
Sent: Friday, April 9, 2021 3:48 PM To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov> Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine  (b)(5)  Sincerely, Pedro	Pedro	
Sincerely, Pedro	Sent: Friday, Ap To: Moro, Pedro (CDC/DDID/NCE	oril 9, 2021 3:48 PM o (CDC/DDID/NCEZID/DHQP) < <u>psm9@cdc.gov</u> >; Miller, Elaine R. EZID/DHQP) < <u>erm4@cdc.gov</u> >; Su, John (CDC/DDID/NCEZID/DHQP) < <u>ezu2@cdc.gov</u> >
Pedro		(b)(5)
	Sincerely, Pedro	
(b)(S)		
(b)(S):		
(b)(5)		
		(b)(5)



(b)(5)

### Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC)

Sent: Thursday, April 8, 2021 1:13 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,

Thank you. Got it. Makes sense. Happy to work on this. I'll send another draft.

Thanks again.

Melanie

# Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>

Sent: Thursday, April 8, 2021 1:09 PM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

Thanks for sending this. I have a few questions and suggestions

(b)(5) (b)(6

(b)(5) (b)(6)

Thanks again
Pedro
From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov > Sent: Thursday, April 8, 2021 12:56 PM  To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov > Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov > Subject: DRAFT RE: Autoimmune dx post vaccine
(b)(5)
(b)(5) (b)(6)
NG MEDICAN PART

Please let us know if you have additional questions.

Sincerely, CDC Immunization Safety Office Staff Atlanta, GA

### Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Thursday, April 8, 2021 9:15 AM

**To:** Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < <a href="mailto:mvl3@cdc.gov">mvl3@cdc.gov</a> **Cc:** Moro, Pedro (CDC/DDID/NCEZID/DHQP) < <a href="mailto:psm9@cdc.gov">psm9@cdc.gov</a>>

Subject: RE: Autoimmune dx post vaccine

Hi Melanie,

Please let me know if you can draft a response for this inquiry.

Thanks, ELaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>

Sent: Wednesday, April 7, 2021 6:19 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: FW: Autoimmune dx post vaccine

Elaine,

(b)(5)

Pedro

From: dale nordenberg (b)(6)

Sent: Wednesday, April 7, 2021 5:16 PM
To: Robert Chen (b)(6)

Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** Re: Autoimmune dx post vaccine

Hi

(b)(5)

	(b)(5)
Thanks !	
Sent from my	Phone
On Apr 7, 202	L, at 5:08 PM, Robert Chen (b)(6) wrote:
Dale?	
Land: 1-404-2 email:	Chen MD MA Stor, Brighton Collaboration 18-0536 Cell: 1-678-662-0516 (b)(6)  7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQP) <pre>psm9@cdc.gov</pre> wrote:
Hi Bob,	
	200 April 200 Ap
	(b)(5) ?
Pedro	
From: Robert Sent: Wednes To: Nordenbe Cc: Moro, Ped	(b)(5) ?
From: Robert Sent: Wednes To: Nordenbe Cc: Moro, Ped	(b)(5)  Chen (b)(6)  day, April 7, 2021 3:33 PM  rg, Dale (CDC gmail.com) (b)(6)  ro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>
From: Robert Sent: Wednes To: Nordenbe Cc: Moro, Ped Subject: Re: A	Chen (b)(6)  day, April 7, 2021 3:33 PM  rg, Dale (CDC gmail.com) (b)(6)  ro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov> utoimmune dx post vaccine
From: Robert Sent: Wednes To: Nordenbe Cc: Moro, Ped Subject: Re: A	Chen (b)(6)  day, April 7, 2021 3:33 PM  rg, Dale (CDC gmail.com) (b)(6)  ro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov> utoimmune dx post vaccine  (b)(5)  Bob
From: Robert Sent: Wednes To: Nordenbe Cc: Moro, Ped Subject: Re: A	Chen (b)(6)  day, April 7, 2021 3:33 PM  rg, Dale (CDC gmail.com) (b)(6)  ro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov> utoimmune dx post vaccine  (b)(5)  Bob

# Dale

Sent from my iPhone

--

Robert (Bob) Chen MD MA Scientific Director, Brighton Collaboration Land: 1-404-248-0536 Cell: 1-678-662-0516

email:

(b)(6)

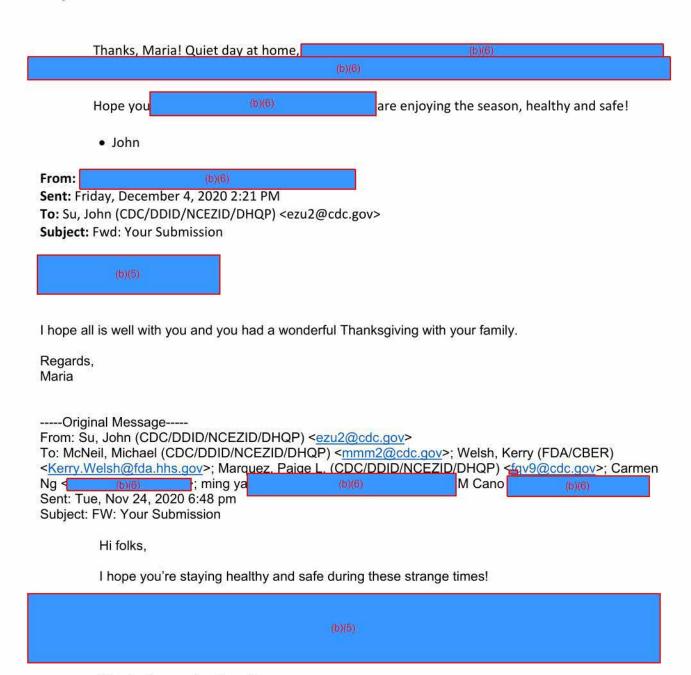
 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Fri, 4 Dec 2020 19:27:04 +0000

To:

(b)(6)

Subject: RE: Your Submission

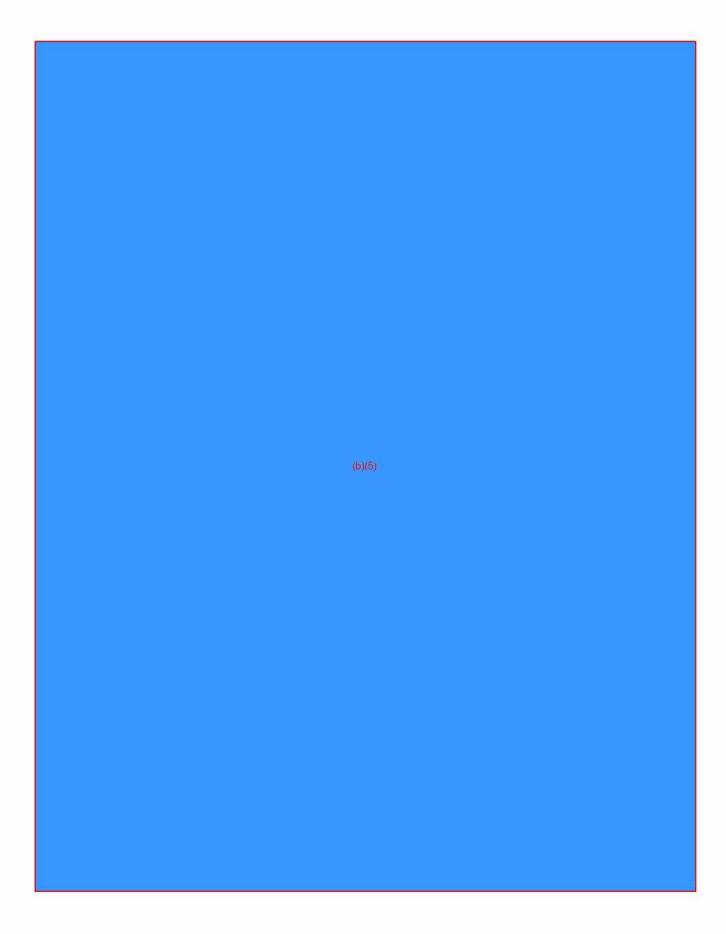


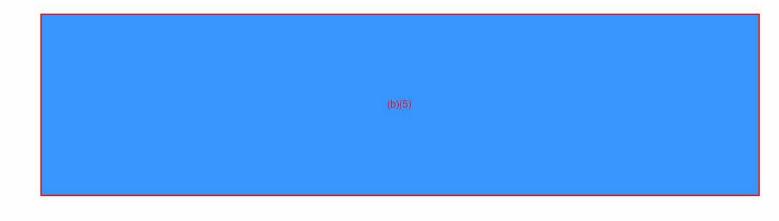
Thanks for your hard work!

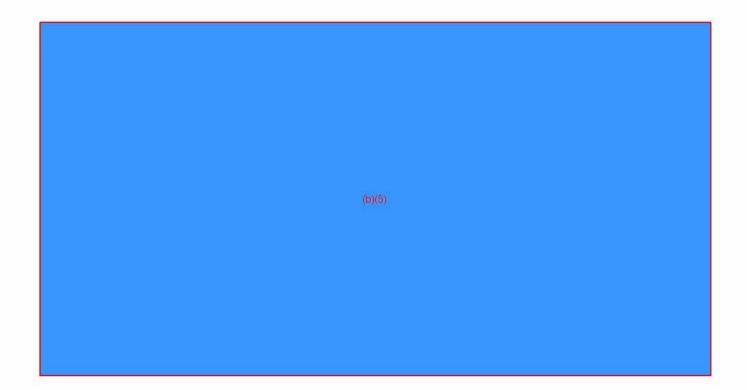
-- John

-----Original Message-----From: eesserver@eesmail.elsevier.com <eesserver@eesmail.elsevier.com>
Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> Subject: Your Submission Ms. Ref. No.: JVAC-D-20-01671 Title: Dear John,

(b)(5)
Yours sincoroly
Yours sincerely,  Robert T Chen, MD MA Associate Editor Vaccine or its open access mirror
view the files
Reviewers' comments:
(b)(5)







From: CDC IMS 2019 NCOV Response VTF Global

**Sent:** Thu, 4 Mar 2021 21:24:22 +0000

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Conklin, Laura

(CDC/DDPHSIS/CGH/GID); CDC IMS 2019 NCOV Response VTF Global; COVID19VaxSafety; CDC IMS 2019

NCOV COVID Vaccine Inquiry Management; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Cc: CISA Response (CDC); CDC IMS 2019 NCOV Response VTF Communications; CDC

IMS 2019 NCOV Response International Task Force; Su, John (CDC/DDID/NCEZID/DHQP)

Subject: RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19

vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi Elaine,

Thank you so much for your response. It may be important for VTF Global to also be looped into these discussions given our global work. I am adding Laura Conklin to this thread as our POC for vaccine safety on the VTF Global Team.

Best,

Prianca Reddi, MSPH
Public Health Advisor | Presidential Management Fellow
COVID19 Vaccine Task Force – Global Team
Centers for Disease Control and Prevention (CDC)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Thursday, March 4, 2021 10:50 AM

**To:** CDC IMS 2019 NCOV Response VTF Global <eocevent445@cdc.gov>; COVID19VaxSafety <COVID19VaxSafety@cdc.gov>; CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <eocevent168@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Cc: CISA Response (CDC) <cisaresponse@cdc.gov>; CDC IMS 2019 NCOV Response VTF Communications

<eocvtfcommteam@cdc.gov>; CDC IMS 2019 NCOV Response International Task Force

<eocevent223@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

**Subject:** RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi Prianca,

Tom Shimabukuro is working with FDA to respond.

There is no action required for VTF Global.

Thanks, Elaine

From: CDC IMS 2019 NCOV Response VTF Global <eocevent445@cdc.gov>

Sent: Thursday, March 4, 2021 10:27 AM

To: COVID19VaxSafety < COVID19VaxSafety@cdc.gov >; CDC IMS 2019 NCOV COVID Vaccine Inquiry

Management <eocevent168@cdc.gov>

Cc: CISA Response (CDC) <cisaresponse@cdc.gov>; CDC IMS 2019 NCOV Response VTF Communications

<eocvtfcommteam@cdc.gov>; CDC IMS 2019 NCOV Response International Task Force
<eocevent223@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom
(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

**Subject:** RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi Elaine,

(b)(5)

Best,

Prianca Reddi, MSPH
Public Health Advisor | Presidential Management Fellow
COVID19 Vaccine Task Force – Global Team
Centers for Disease Control and Prevention (CDC)

From: COVID19VaxSafety < COVID19VaxSafety@cdc.gov >

Sent: Thursday, March 4, 2021 9:41 AM

To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management < <a href="mailto:eocevent168@cdc.gov">eocevent168@cdc.gov</a>>; CDC IMS 2019

NCOV Response VTF Global <eocevent445@cdc.gov>

**Cc:** COVID19VaxSafety < COVID19VaxSafety@cdc.gov >; CISA Response (CDC) < cisaresponse@cdc.gov >; CDC IMS 2019 NCOV Response VTF Communications < eocvtfcommteam@cdc.gov >; CDC IMS 2019 NCOV Response International Task Force < eocevent223@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov >

**Subject:** RE: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events; [CDC-1460726-X0X9M8] CRM:09092401

Hi all,

(b)(5)

Thanks, Elaine

Elaine R. Miller, RN, MPH Immunization Safety Office Division of Healthcare Quality Promotion Centers for Disease Control and Prevention Atlanta, GA

Email: emiller@cdc.gov

From: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management <eocevent168@cdc.gov>

Sent: Wednesday, March 3, 2021 8:31 PM

To: CDC IMS 2019 NCOV Response VTF Global <eocevent445@cdc.gov>

**Cc:** COVID19VaxSafety < COVID19VaxSafety@cdc.gov >; CISA Response (CDC) < cisaresponse@cdc.gov >; CDC IMS 2019 NCOV Response VTF Communications < eocvtfcommteam@cdc.gov >; CDC IMS 2019 NCOV Response International Task Force < eocevent223@cdc.gov >

Subject: Fw: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse

events; [CDC-1460726-X0X9M8] CRM:09092401

Hello VTF Global colleagues,

Please see the inquiry from the Deputy Director, Division of Epidemiology, MoH Israel below. Could you please respond?

Thank you,

Kate

(b)(5)

COVID-19 Vaccine Clinical Inquiries Management Team | Vaccine Task Force CDC Coronavirus Disease 2019 (COVID-19) Response | eocevent168@cdc.gov

#### **Further CDC Resources:**

COVID-19 What's New
CDC Health Alert Network (HAN)

**CDC Vaccines** 

CDC Clinician Outreach and Communication Activity (COCA)

From: CDCInfoResponse <cdcinforesponse@cdcinquiry.onmicrosoft.com>

Sent: Wednesday, March 3, 2021 1:50 PM

To: CDC IMS 2019 NCOV COVID Vaccine Inquiry Management < eocevent168@cdc.gov>

Subject: RESPONSE REQUIRED: Priority HIGH; Mode WebForm; Topic COVID-19 vaccine adverse events;

[CDC-1460726-X0X9M8] CRM:09092401

Please let us know if you are able to respond to this inquiry or if you would like us to forward the inquiry to another program. This inquiry is being escalated because the answer could not be found in CDC resources.

To close the case, you may reply directly to this e-mail, keeping the original subject line and historical e-mail thread in your reply. Please let us know if your group will provide the answer directly to the inquirer below, or provide a reply for us to send back.

To better serve the inquirer, please reply within 3 business days of receipt of this escalation. A reminder will be sent in 8 days; the inquiry will be closed after 10 days. Thank you for your assistance.

## OO/PR#14312/17771/11109

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Message-----

Sent: 3/3/2021 From: Clinician

Subject: COVID-19 vaccine adverse events Email Address (b)(6)

Question: From the Israel vaccine adverse event monitoring team:

We are seeing a large number of myocarditis and pericarditis cases in young individuals soon after Pfizer COVID-19 vaccine. We would like to discuss the issue with a relevant expert at CDC.

# **Optional Information**

Name: Dr. Roee Singer

Title: Deputy Director, Division of Epidemiology, MoH Israel

Organization: SLHD - Israel Ministry of Health

Phone: (b)(6)

Other Email: (b)(6)

Address:

Jerusalem, Israel PII Extraction:

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) Sent: Fri, 9 Apr 2021 21:31:47 +0000 Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Moro, Pedro To: (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP) Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine Thank you, Elaine. Thanks again. Melanie Melanie Carmel Lagarde, DNP, MPH, RN, CHES MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov> Sent: Friday, April 9, 2021 5:10 PM To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine Please let me know your edits: Sincerely, Pedro

(b)(5)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Sent: Friday, April 9, 2021 4:13 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov; Lagarde, Melanie

(CDC/OCOO/OSSAM/OHC) < mvi3@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,

Melanie and I discussed

(b)(5)

(b)(5)

I will get back to you with a revised response soon.

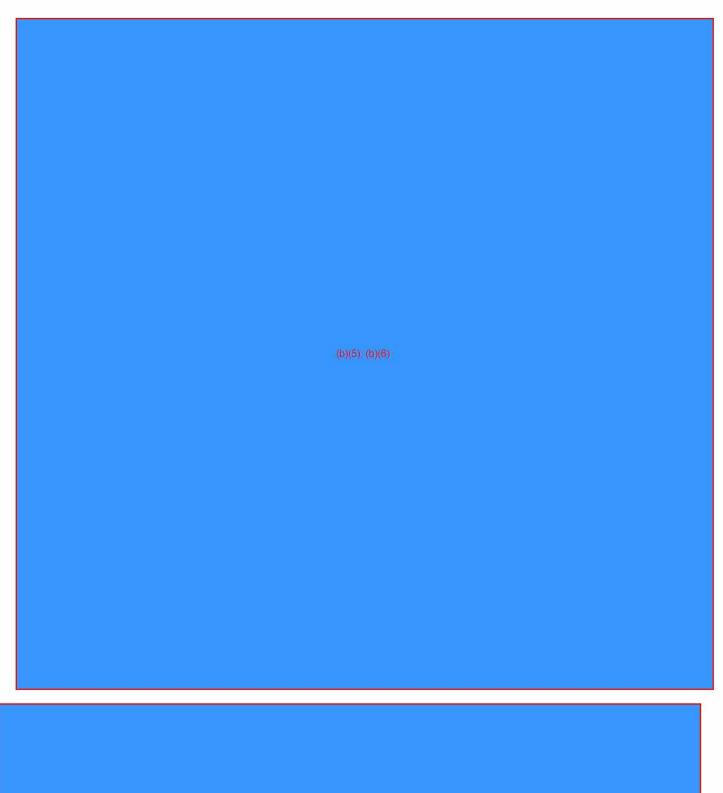
Thanks, Elaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Sent: Friday, April 9, 2021 4:09 PM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> ; Su, John (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ezu2@cdc.gov">ezu2@cdc.gov</a> > Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine
Hi Melanie,
(b)(5) any edits?
Thanks for sending this
Pedro
From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov > Sent: Friday, April 9, 2021 3:48 PM To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov > Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine
(b)(5)
Sincerely, Pedro
(b)(5)



(b)(5)

## Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC)

Sent: Thursday, April 8, 2021 1:13 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,

Thank you. Got it. Makes sense. Happy to work on this. I'll send another draft.

Thanks again.

Melanie

# Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>

Sent: Thursday, April 8, 2021 1:09 PM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

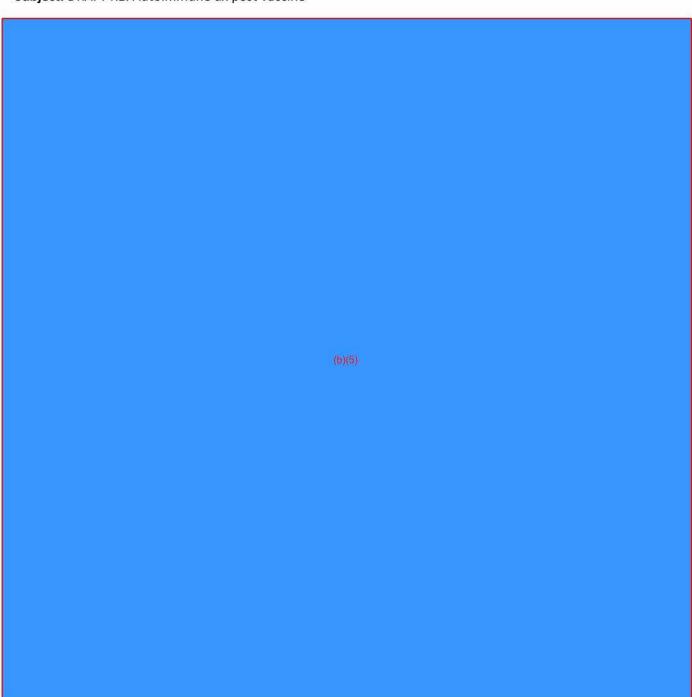
Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

Thanks for sending this. I have a few questions and suggestions.

(b)(5

Thanks again	
Pedro	
From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov > Sent: Thursday, April 8, 2021 12:56 PM	
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov >  Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >  Subject: DRAFT RE: Autoimmune dx post vaccine	





## Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Thursday, April 8, 2021 9:15 AM

**To:** Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov > Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >

Subject: RE: Autoimmune dx post vaccine

Hi Melanie,

Please let me know if you can draft a response for this inquiry.

Thanks, ELaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>

Sent: Wednesday, April 7, 2021 6:19 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: FW: Autoimmune dx post vaccine

Elaine,

(b)(5)

Pedro

From: dale nordenberg (b)(6)

Sent: Wednesday, April 7, 2021 5:16 PM
To: Robert Chen (b)(6)

Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** Re: Autoimmune dx post vaccine

Hi

(b)(5)

# Dale

Sent from my iPhone

--

Robert (Bob) Chen MD MA Scientific Director, Brighton Collaboration

Land: 1-404-248-0536 Cell: 1-678-662-0516

email: [

(b)(5)

From: Kristin X. Goddard

**Sent:** Thu, 22 Oct 2020 20:11:18 +0000

To: Hanson, Kayla E; Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

Cc: Donahue, James G DVM/PhD

Subject: RE: RCA Outcome Questions/Recommendations

Great, we'll review and discuss internally before next Wednesday.

Kristin

From: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

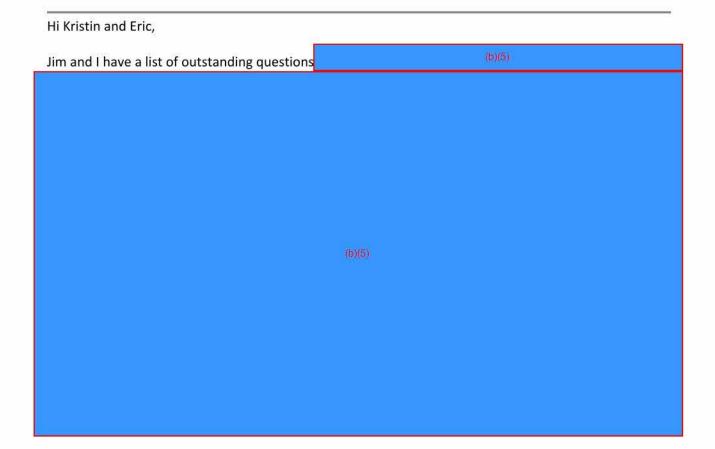
Sent: Thursday, October 22, 2020 11:59 AM

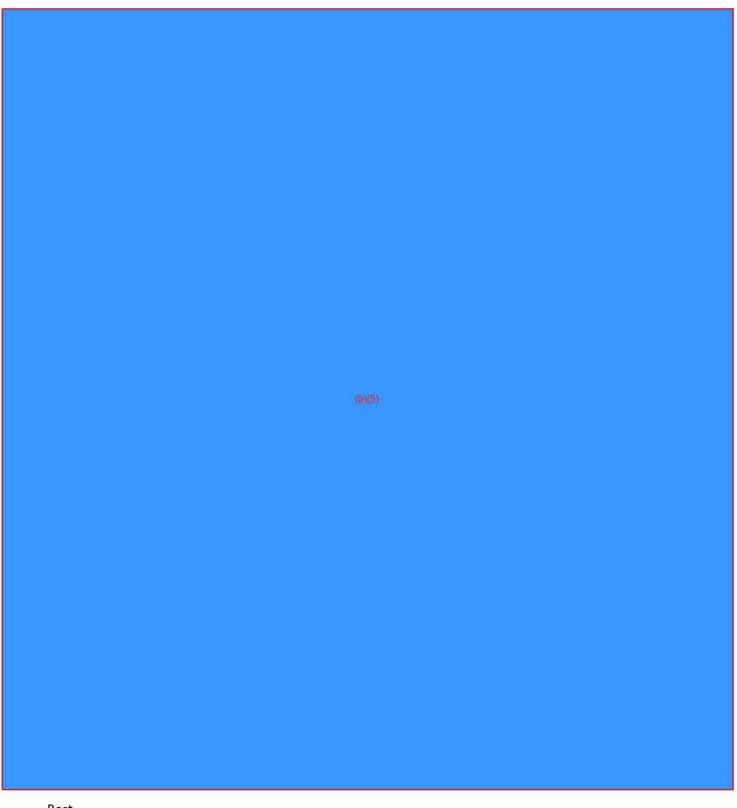
To: Weintraub, Eric (CDC/OID/NCEZID) <eiw8@cdc.gov>; Kristin X. Goddard <Kristin.X.Goddard@kp.org>

Cc: Donahue, James G DVM/PhD < Donahue. James@marshfieldresearch.org>

Subject: RCA Outcome Questions/Recommendations

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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Thu, 29 Apr 2021 19:16:13 +0000 **To:** Hanson, Kayla E; Kristin X. Goddard

Cc: NICOLA P KLEIN; Ned Lewis
Subject: RE: updated VaST slideset

Sure. Thanks! Eric

From: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Sent: Thursday, April 29, 2021 3:11 PM

To: Kristin X. Goddard < Kristin.X.Goddard@kp.org>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

<eiw8@cdc.gov>

Cc: NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org>

Subject: RE: updated VaST slideset

(b)(5) ?

From: Kristin X. Goddard < Kristin.X.Goddard@kp.org>

Sent: Thursday, April 29, 2021 12:31 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov >; Hanson, Kayla E

<a href="mailto:</a><a href="mailto:hanson.kayla@marshfieldresearch.org">hanson.kayla@marshfieldresearch.org</a>

Cc: NICOLA P KLEIN < Nicola. Klein@kp.org >; Ned Lewis < Ned. Lewis@kp.org >

Subject: [EXTERNAL] RE: updated VaST slideset

(b)(5)

Eric – I'll have those slides updated to you tomorrow (offline later today, flying back to CA shortly)

Kristin

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Thursday, April 29, 2021 7:48 AM

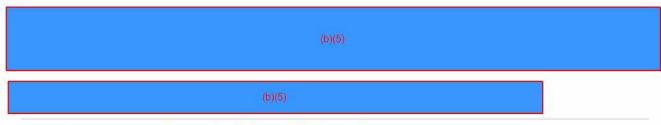
To: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Cc: Kristin X. Goddard < Kristin.X.Goddard@kp.org>; NICOLA P KLEIN < Nicola.Klein@kp.org>; Ned Lewis

<Ned.Lewis@kp.org>

Subject: RE: updated VaST slideset

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From: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

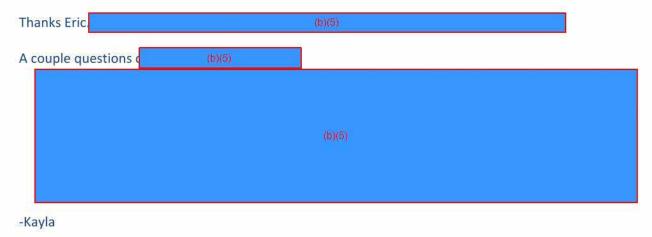
Sent: Thursday, April 29, 2021 10:13 AM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Kristin X. Goddard < Kristin.X. Goddard@kp.org>; NICOLA P KLEIN < Nicola.Klein@kp.org>; Ned Lewis

<Ned.Lewis@kp.org>

Subject: RE: updated VaST slideset



From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

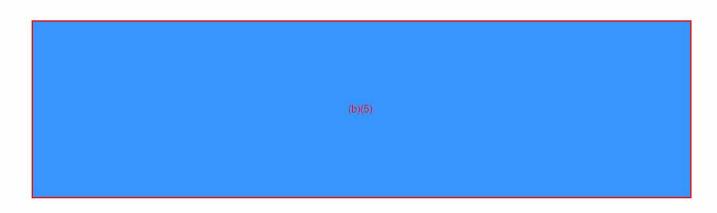
Sent: Thursday, April 29, 2021 8:58 AM

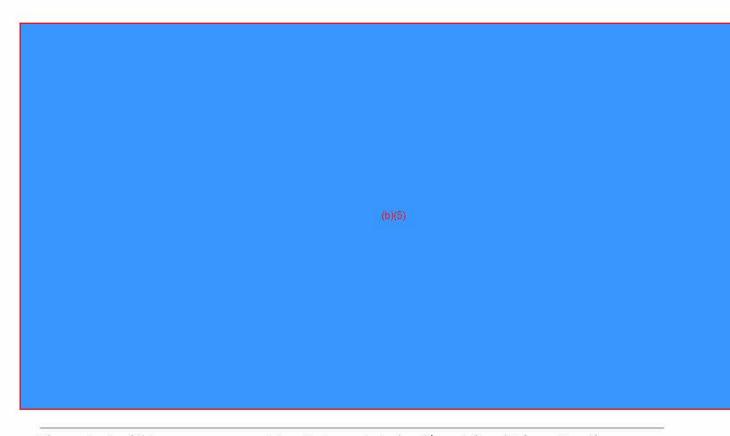
To: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >; Kristin X. Goddard

< Kristin.X.Goddard@kp.org>; NICOLA P KLEIN < Nicola.Klein@kp.org>; Ned Lewis < Ned.Lewis@kp.org>

Subject: [EXTERNAL] updated VaST slideset

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The contents of this message may contain private, protected and/or privileged information. If you received this message in error, you should destroy the e-mail message and any attachments or copies, and you are prohibited from retaining, distributing, disclosing or using any information contained within. Please contact the sender and advise of the erroneous delivery by return e-mail or telephone. Thank you for your cooperation.

From: Gallego, Ruth (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 20 Jan 2021 15:20:19 +0000

To: Su, John (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [

ref:\_00Dt0CmwY.\_500t0bPyvA:ref]

# Thank you

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

Sent: Wednesday, January 20, 2021 9:36 AM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Gallego, Ruth

(CDC/DDID/NCEZID/DHQP) < ltd8@cdc.gov>

Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [

ref:\_00Dt0CmwY.\_500t0bPyvA:ref]



John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Wednesday, January 20, 2021 9:33 AM

To: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ltd8@cdc.gov">!td8@cdc.gov</a>; Su, John (CDC/DDID/NCEZID/DHQP)

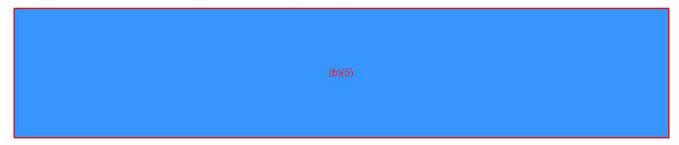
<ezu2@cdc.gov>

Subject: RE: Case 00008665: Illinois Request for Adverse Events Data [

ref: 00Dt0CmwY.\_500t0bPyvA:ref]

## Ruth,

I suggest we send the following info to add to your response:

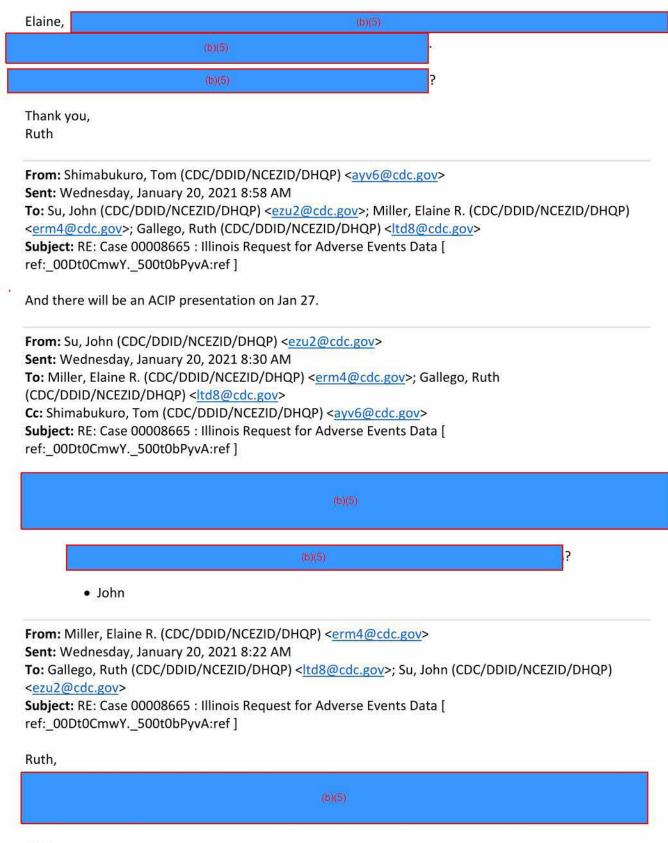


From: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < <a href="ttd8@cdc.gov">ttd8@cdc.gov">ttd8@cdc.gov</a>>

Sent: Wednesday, January 20, 2021 9:21 AM

**To:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** RE: Case 00008665 : Illinois Request for Adverse Events Data [

ref:\_00Dt0CmwY.\_500t0bPyvA:ref]



John,

(b)(5)

(b)(5)

Thanks Elaine

From: Byrne, Jennifer (CDC/DDID/NCEZID/DPEI) <br/> <br/> <br/> <br/> dg0@cdc.gov>

Sent: Wednesday, January 20, 2021 7:54 AM

To: COVID19VaxSafety < COVID19VaxSafety@cdc.gov>

Cc: CDC IMS 2019 NCOV Response STLT Comms < <a href="mailto:eocevent411@cdc.gov">eocevent411@cdc.gov</a>; CDC IMS 2019 NCOV Response STLT TF HDS Comms Section < <a href="mailto:eocevent501@cdc.gov">eocevent501@cdc.gov</a>; CDC IMS 2019 NCOV Response VTF

Communications < eocvtfcommteam@cdc.gov>; Dixon, Nickell (CDC/DDID/NCEZID/DPEI)

<<u>ipi3@cdc.gov</u>>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <<u>erm4@cdc.gov</u>>

Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [

ref:\_00Dt0CmwY.\_500t0bPyvA:ref]

Thank you, Ruth! It was last Friday's MMWR (1/15). Yes, I will take care of getting the response to the original sender.

Warm regards, Jennifer

#### Jennifer Byrne, MPH

Task Force Liaison Officer
Health Department Section
State, Tribal, Local & Territorial Support Task Force
COVID-19 Emergency Response
US Centers for Disease Control and Prevention
Cell: (678) 575-8184
bgq0@cdc.gov
eocevent441@cdc.gov

From: COVID19VaxSafety < COVID19VaxSafety@cdc.gov>

Sent: Tuesday, January 19, 2021 6:26 PM

To: Byrne, Jennifer (CDC/DDID/NCEZID/DPEI) < bgq0@cdc.gov >; COVID19VaxSafety

<COVID19VaxSafety@cdc.gov>

Cc: CDC IMS 2019 NCOV Response STLT Comms < <a href="mailto:eocevent411@cdc.gov">eocevent411@cdc.gov</a>; CDC IMS 2019 NCOV Response STLT TF HDS Comms Section < <a href="mailto:eocevent501@cdc.gov">eocevent501@cdc.gov</a>; CDC IMS 2019 NCOV Response VTF Communications < <a href="mailto:eocevent501@cdc.gov">eocevent501@cdc.gov</a>; Dixon, Nickell (CDC/DDID/NCEZID/DPEI)

<jpi3@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [

ref: 00Dt0CmwY.\_500t0bPyvA:ref]

Good evening Jennifer,

Can you tell me which Friday MMWR are they referring to?

(b)(5)

-?

Thank you, Ruth

Ruth Gallego RN, MPH, CHES<sup>®</sup>
Immunization Safety Office
Division of Healthcare Quality Promotion, NCEZID
Centers for Disease Control and Prevention

404.718.5084 RGallego@cdc.gov

Vaccine Safety coordinators for Illinois are <u>Sarah.Patrick@Illinois.gov</u> and <u>Heidi.Clark@illinois.gov</u>; and city of Chicago is <u>Van.Quach@cityofchicago.org</u>

They receive weekly data on VAERS reports in their jurisdiction through EPIX. Data is presented in the format shown in the attached excel shell tables.

Unfortunately, v-safe data is not made available to jurisdictions.

### To the question

- How frequently will this national analysis be done and where will the data be located?
   As stated, this data will be provided to vaccine safety coordinators on a weekly basis (saturdays).
  - The 3<sup>rd</sup> tab of this data file makes a comparison of number of VAERS on death, serious, and non-serious reports among states and nationwide.
  - The 4<sup>th</sup> tab shows data of the following adverse events of special interest
    - i. Acute myocardial infarction
    - ii. Anaphylaxis
    - iii. Coagulopathy
    - iv. COVID-19 Disease
    - v. Death
    - vi. Guillain-Barré syndrome
    - vii. Kawasaki disease
    - viii. Multisystem Inflammatory Syndrome in Children
    - ix. Myocarditis / Pericarditis
    - x. Narcolepsy / Cateplexy
    - xi. Pregnancy and Prespecified Conditions
    - xii. Seizures / Convulsions
    - xiii. Stroke
    - xiv. Transverse myelitis
- 2) Is it possible to receive state specific reports? See above response



From: Jennifer Byrne < bgq0@cdc.gov>
Sent: Tuesday, January 19, 2021 5:50 PM

To: COVID19VaxSafety < COVID19VaxSafety@cdc.gov>

Cc: CDC IMS 2019 NCOV Response STLT Comms < <a href="mailto:eocevent411@cdc.gov">eocevent411@cdc.gov</a>; CDC IMS 2019 NCOV Response STLT TF HDS Comms Section < <a href="mailto:eocevent501@cdc.gov">eocevent501@cdc.gov</a>; CDC IMS 2019 NCOV Response VTF Communications < <a href="mailto:eocvtfcommteam@cdc.gov">eocvtfcommteam@cdc.gov</a>; Dixon, Nickell (CDC/DDID/NCEZID/DPEI)

<jpi3@cdc.gov>

Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [

ref:\_00Dt0CmwY.\_500t0bPyvA:ref ]

Dear Vaccine Safety Team:

Please note the original inquiry below, sent in error to eocevent416.

Please include the HD LNO, Nickell Dixon, on all responses.

Thank you, Jennifer Byrne

TF LNO - Vaccine & HSWS

----- Original Message -----From: Jennifer Byrne [bgq0@cdc.gov]

**Sent:** 1/19/2021 9:45 AM **To:** eocevent416@cdc.gov

Cc: eocevent411@cdc.gov; jpi3@cdc.gov; eocvtfcommteam@cdc.gov; eocevent501@cdc.gov

Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [

ref:\_00Dt0CmwY.\_500t0bPyvA:ref]

Dear VTF Vaccine Safety Team:

Friday's MMWR on adverse events reported in VAERS was shared with Illinois, to assist with this inquiry. They have responded with these follow up questions:

- 1) How frequently will this national analysis be done and where will the data be located?
- 2) Is it possible to receive state specific reports?
- 3) Will this be dis-aggregated by vaccine type going forward?

Please let us know how best to respond to Illinois' inquiry. Please include the HD LNO for IL, Nickell

Dixon, on all responses.
Thank you, Jennifer Byrne
TF LNO - Vaccine & HSWS
From: Jennifer Byrne [bgq0@cdc.gov] Sent: 1/17/2021 2:42 PM To: jpi3@cdc.gov Cc: eocevent411@cdc.gov Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0CmwY500t0bPyvA:ref]
Dear Nickell,
Friday's MMWR gives some data on adverse events reported to VAERS thus far, that could assist IDPH with their report (see transcript attached).
Warm regards, Jennifer Byrne
TF LNO - Vaccine & HSWS
From: Diamond Elston [qta6@cdc.gov] Sent: 1/15/2021 12:08 PM To: jpi3@cdc.gov Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [ref:_00Dt0CmwY500t0bPyvA:ref]
Thank you for your inquiry regarding the Communications Team of the Vaccine Task Force, however, the Contact Tracing Program Support (CTPS) team is not part of the Vaccine Task Force so does not provide vaccine communications, guidance or technical assistance
From: Jennifer Byrne [bgq0@cdc.gov] Sent: 1/15/2021 11:55 AM To: vtr9@cdc.gov; eocvtfcommteam@cdc.gov; eocevent416@cdc.gov Cc: eocevent441@cdc.gov; eocevent501@cdc.gov; jpi3@cdc.gov; qpu9@cdc.gov Subject: RE: Case 00008665 : Illinois Request for Adverse Events Data [

Dear Nancy/VTF Comms and VTF Vaccine Safety Teams:

ref:\_00Dt0CmwY.\_500t0bPyvA:ref ]

We have received a request for adverse events data from Illinois. Here are the specifics:

IDPH needs to give a presentation to stakeholders about what kind of adverse events have been reported to date in VAERS and V-Safe and compare that to Illinois.

(b)(5)

Thank you, Jennifer Byrne

TF LNO - Vaccine & HSWS

----- Original Message -----From: Nickell Dixon [jpi3@cdc.gov]

Sent: 1/15/2021 10:29 AM
To: eocevent441@cdc.gov
Cc: eocevent508@cdc.gov

Subject: Case 00008665 [ ref:\_00Dt0CmwY.\_500t0bPyvA:ref ]

Hello,

I just put in case#00008665. IDPH needs to give a presentation to stakeholders about what kind of adverse events have been reported to date in VAERS and V-Safe and compare that to Illinois and need us to help collect information on this for them.

ref:\_00Dt0CmwY.\_500t0bPyvA:ref



 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Tue, 30 Mar 2021 22:04:21 +0000

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: WHO GACVS sub-committee - request for information

Awesome! (b)(5)

(b)(5)

John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Tuesday, March 30, 2021 5:52 PM

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

Subject: RE: WHO GACVS sub-committee - request for information

(b)(5)

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

Sent: Tuesday, March 30, 2021 5:39 PM

**To:** Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov > **Subject:** RE: WHO GACVS sub-committee - request for information

Hi Paige,

(b)(5)

John

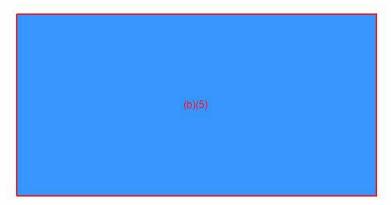
From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>

Sent: Tuesday, March 30, 2021 2:19 PM

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

(CDC/DDID/NCEZID/DHQP) <a y v 6 @ cdc.gov >

Subject: RE: WHO GACVS sub-committee - request for information



From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> Sent: Tuesday, March 30, 2021 12:54 PM To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov >; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov> Subject: Re: WHO GACVS sub-committee - request for information Hi Tom, I'll have to check when I'm back by a computer. — 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: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>> Sent: Tuesday, March 30, 2021 12:49:35 PM To: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov> Subject: FW: WHO GACVS sub-committee - request for information From: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov> Sent: Tuesday, March 30, 2021 12:32 PM To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Subject: RE: WHO GACVS sub-committee - request for information

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Tuesday, March 30, 2021 9:26 AM

To: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

(b)(5)

From: Helfand, Rita (CDC/DDID/NCEZID/OD) < <a href="rzh7@cdc.gov">rzh7@cdc.gov</a>>

Sent: Tuesday, March 30, 2021 8:46 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov> Subject: RE: WHO GACVS sub-committee - request for information

(b)(5) ?

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:agv6@cdc.gov">agv6@cdc.gov</a>

Sent: Monday, March 29, 2021 6:08 PM

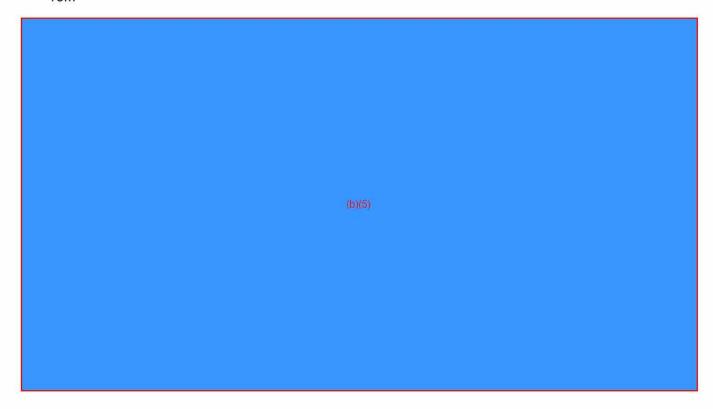
To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >; Helfand, Rita (CDC/DDID/NCEZID/OD)

<rzh7@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

Hi Anastasia – Please keep this information close hold.

Tom



From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Friday, March 19, 2021 1:01 AM

To: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura

(CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>;

PAL, Shanthi Narayan <pals@who.int</pre>>; JANIN, Annick <<u>janina@who.int</u>>
Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for sharing this comprehensive piece of work. I have shared it with GACVS sub-committee members only and in confidence.

I have set up a meeting via MS Teams for next week. It would be helpful to discuss what analyses CDC may be able to share with GACVS members going forward, in response to further issues identified internationally.

I have also included Kristine Macartney in the meeting request (GACVS member and NCIRS Director) as there may be a couple of other related issues to discuss. Please feel free to forward the invitation to anyone else in your organization as required. Rita, I have included you in the invitation in case you would like to join.

Many thanks again Anastasia

From: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov>

Sent: Friday, 19 March 2021 12:40 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">; Phillips, Anastasia

<Anastasia.Phillips@health.wa.gov.au>

Cc: Alexis Pillsbury (SCHN) <alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura

(CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>;

PAL, Shanthi Narayan <pals@who.int>; JANIN, Annick <janina@who.int>

Subject: RE: WHO GACVS sub-committee - request for information

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Thanks, Tom! Anastasia, I would interpret this as being that it could go to the GACVS sub-committee but not the larger group of participants.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Thursday, March 18, 2021 12:29 PM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov</a>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>;

JANIN, Annick < janina@who.int >

Subject: RE: WHO GACVS sub-committee - request for information

Dear Anastasia,

I have received permission to confidentially share this draft manuscript with is under review at Vaccine Please do not share outside of you need-to-know group. We hope it will be published soon (b)(5)

(b)(5)

(b)(5)

I nave standing meetings

starting at 8am, but could do 7:30am next week if that works.

Regards,

Tom

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Sent: Wednesday, March 17, 2021 3:47 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov</a>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) < dvj3@cdc.gov>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < iyk3@cdc.gov >; PAL, Shanthi Narayan < pals@who.int >;

JANIN, Annick <janina@who.int>

Subject: Re: WHO GACVS sub-committee - request for information

Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopaenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again Anastasia

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, 17 March 2021 6:43 AM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < <u>iyk3@cdc.gov</u>> **Subject:** RE: WHO GACVS sub-committee - request for information

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Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I'm happy to talk when convenient. I'm Cc'ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

#### Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Sent: Monday, March 8, 2021 10:05 PM

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

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>

Subject: WHO GACVS sub-committee - request for information

Dear Tom

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM

Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia

Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)

E: anastasia.phillips@health.wa.gov.au

Ph: +61 417 172 936

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Tue, 13 Apr 2021 19:48:08 +0000

**To:** Woo, Jane; Nair, Narayan (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Ahima, Ohenewaa (FDA/CDER);

Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Subject: RE: [EXTERNAL] RE: Janssen - 4/13

Sounds great – thanks!

John

From: Woo, Jane <Jane.Woo@fda.hhs.gov> Sent: Tuesday, April 13, 2021 3:40 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Nair, Narayan (FDA/CBER) <Narayan.Nair@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <Adamma.Mba-

Jonas@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) < Craig.Zinderman@fda.hhs.gov>; Alimchandani,

Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Ahima, Ohenewaa (FDA/CDER)

<Ohenewaa.Ahima@fda.hhs.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Subject: RE: [EXTERNAL] RE: Janssen - 4/13

Thanks. (b)(5)

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

Sent: Tuesday, April 13, 2021 3:37 PM

To: Woo, Jane <a href="mailto:Jane.Woo@fda.hhs.gov">Jane.Woo@fda.hhs.gov</a>; Marayan <a href="mailto:Narayan.Nair@fda.hhs.gov">Nair.Narayan.Nair@fda.hhs.gov</a>; Mba-Jonas,

Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Zinderman, Craig E

<<u>Craig.Zinderman@fda.hhs.gov</u>>; Alimchandani, Meghna <<u>Meghna.Alimchandani@fda.hhs.gov</u>>; Ahima,

Ohenewaa < Ohenewaa. Ahima@fda.hhs.gov >; Shimabukuro, Tom (CDC) < ayv6@cdc.gov >

Subject: RE: [EXTERNAL] RE: Janssen - 4/13

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(b)(5)

John

From: Woo, Jane < <u>Jane.Woo@fda.hhs.gov</u>> Sent: Tuesday, April 13, 2021 3:34 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>; Nair, Narayan (FDA/CBER) < Narayan.Nair@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) (FDA/CBER) < Adamma.Mba-Jonas@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) < Craig.Zinderman@fda.hhs.gov>; Alimchandani,

Meghna (FDA/CBER) < <a href="Meghna.Alimchandani@fda.hhs.gov">Meghna.Alimchandani@fda.hhs.gov</a>; Ahima, Ohenewaa (FDA/CDER) < <a href="Meghna.Ahima@fda.hhs.gov">Meghna.Alimchandani@fda.hhs.gov</a>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < <a href="megayv6@cdc.gov">ayv6@cdc.gov</a>> Subject: RE: [EXTERNAL] RE: Janssen - 4/13

Hi. (b)(5), (b)(3) 21 U S C 379h (b)(5), (b)(3) 21 U S C 379h

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

Sent: Tuesday, April 13, 2021 3:28 PM

To: Nair, Narayan <a href="Nairayan.Nair@fda.hhs.gov">Nair@fda.hhs.gov">Nair. Nair. Nairayan <a href="Nairayan.Nair@fda.hhs.gov">Nair. Nair. Nai

Subject: [EXTERNAL] RE: Janssen - 4/13

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(b)(5) ? (b)(5)

From: Nair, Narayan < Narayan. Nair@fda.hhs.gov>

Sent: Tuesday, April 13, 2021 3:15 PM

To: Mba-Jonas, Adamma (CBER) (FDA/CBER) < Adamma. Mba-Jonas@fda.hhs.gov >; Zinderman, Craig E

(FDA/CBER) < Craig. Zinderman@fda.hhs.gov>; Alimchandani, Meghna (FDA/CBER)

<<u>Meghna.Alimchandani@fda.hhs.gov</u>>; Woo, Jane (FDA/CBER) <<u>Jane.Woo@fda.hhs.gov</u>>; Ahima, Ohenewaa (FDA/CDER) <<u>Ohenewaa.Ahima@fda.hhs.gov</u>>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Subject: RE: Janssen - 4/13

John

Thanks Adamma and Craig,

(b)(5

I think we should Narayan From: Mba-Jonas, Adamma (CBER) < Adamma. Mba-Jonas@fda.hhs.gov>

Sent: Tuesday, April 13, 2021 3:06 PM

To: Zinderman, Craig E < Craig. Zinderman@fda.hhs.gov >; Alimchandani, Meghna

< Meghna. Alimchandani@fda.hhs.gov>; Woo, Jane < Jane. Woo@fda.hhs.gov>; Ahima, Ohenewaa

<Ohenewaa.Ahima@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Su, John (CDC)

<ezu2@cdc.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>

Subject: Re: Janssen - 4/13

(b)(5)

#### Adamma

From: Zinderman, Craig E < Craig.Zinderman@fda.hhs.gov>

Sent: Tuesday, April 13, 2021 3:03:56 PM

**To:** Alimchandani, Meghna < Meghna. Alimchandani@fda.hhs.gov>; Woo, Jane

<<u>Jane.Woo@fda.hhs.gov</u>>; Mba-Jonas, Adamma (CBER) <<u>Adamma.Mba-Jonas@fda.hhs.gov</u>>; Ahima, Ohenewaa <<u>Ohenewaa.Ahima@fda.hhs.gov</u>>; Nair, Narayan <<u>Narayan.Nair@fda.hhs.gov</u>>; Su, John

(CDC) <<u>ezu2@cdc.gov</u>>; Shimabukuro, Tom (CDC) <<u>ayv6@cdc.gov</u>>

Subject: RE: Janssen - 4/13

(b)(5) (b)(5)

Thanks, Craig

From: Alimchandani, Meghna < Meghna. Alimchandani@fda.hhs.gov >

Sent: Tuesday, April 13, 2021 1:03 PM

To: Woo, Jane <<u>Jane.Woo@fda.hhs.gov</u>>; Mba-Jonas, Adamma (CBER) <<u>Adamma.Mba-Jonas@fda.hhs.gov</u>>; Ahima, Ohenewaa <<u>Ohenewaa.Ahima@fda.hhs.gov</u>>; Nair, Narayan <<u>Narayan.Nair@fda.hhs.gov</u>>; Su, John (CDC) <<u>ezu2@cdc.gov</u>>; Shimabukuro, Tom (CDC)

<ayv6@cdc.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>

Subject: RE: Janssen - 4/13

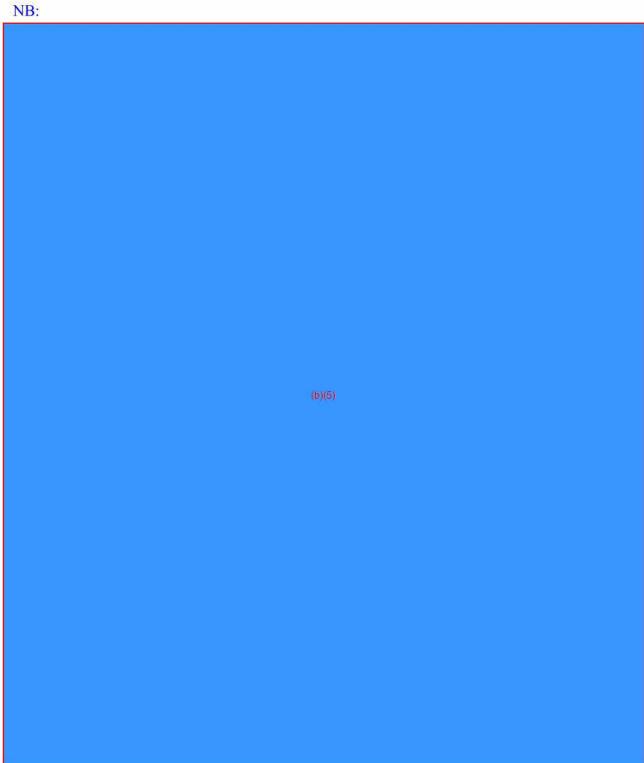
Jane, thank you (b)(5)

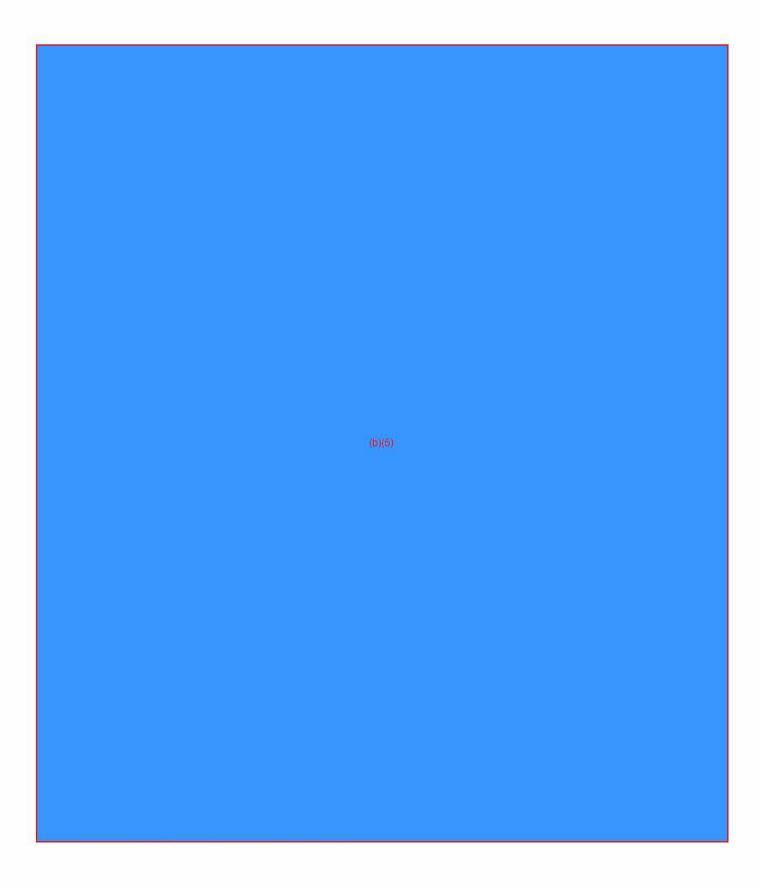
Thanks Meghna

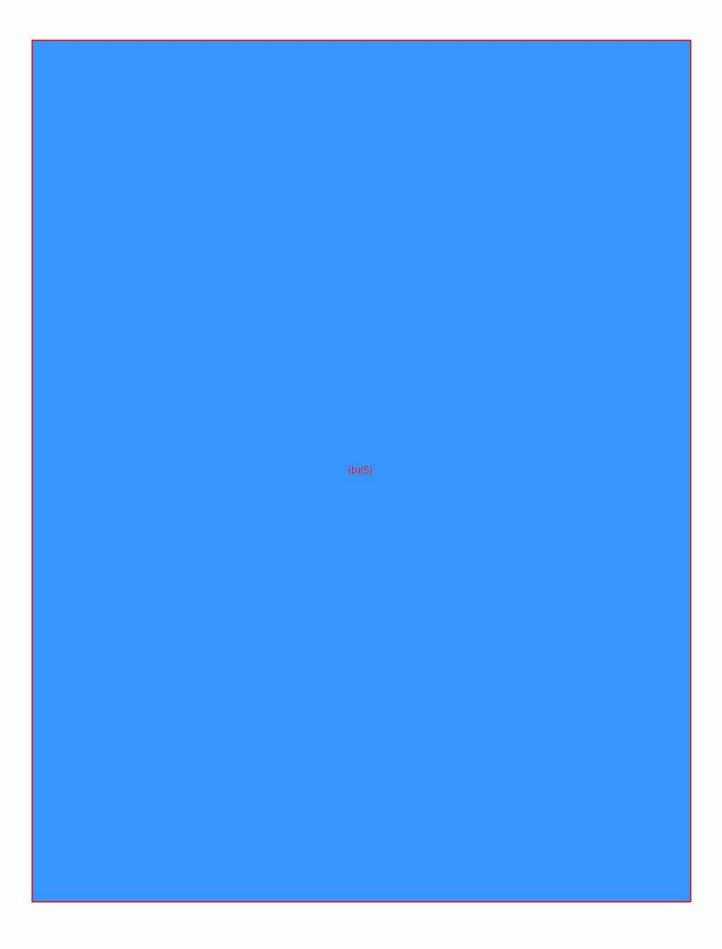
From: Woo, Jane < Jane. Woo@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 12:59 PM

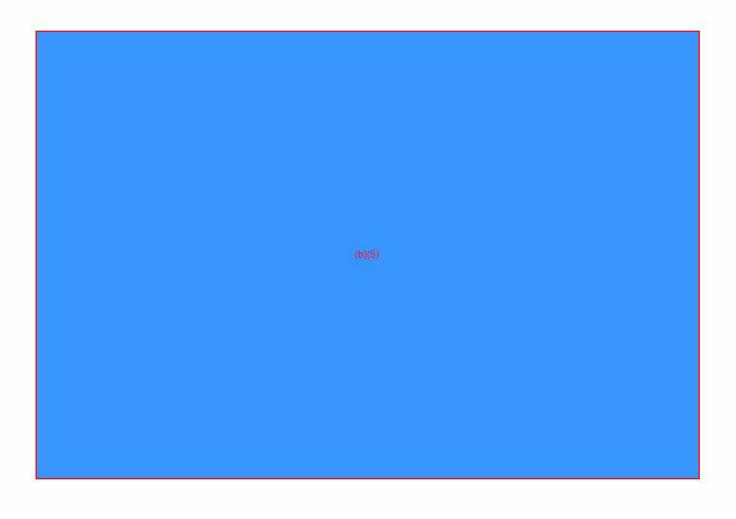
To: Mba-Jonas, Adamma (CBER) <<u>Adamma.Mba-Jonas@fda.hhs.gov</u>>; Ahima, Ohenewaa <<u>Ohenewaa.Ahima@fda.hhs.gov</u>>; Alimchandani, Meghna <<u>Meghna.Alimchandani@fda.hhs.gov</u>>; Nair, Narayan <<u>Narayan.Nair@fda.hhs.gov</u>>; Su, John (CDC) <<u>ezu2@cdc.gov</u>>; Shimabukuro, Tom (CDC) <<u>ayv6@cdc.gov</u>>; Zinderman, Craig E <<u>Craig.Zinderman@fda.hhs.gov</u>>
Subject: Janssen - 4/13

G18240









From: Hanson, Kayla E

**Sent:** Thu, 29 Apr 2021 17:16:08 +0000

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: updated VaST slideset

(b)(5)

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

Sent: Thursday, April 29, 2021 12:13 PM

To: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Subject: [EXTERNAL] RE: updated VaST slideset

Yea, I think

(b)(5)

From: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Sent: Thursday, April 29, 2021 1:11 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Subject: RE: updated VaST slideset

I've never worked with him, but the name has come up in discussion. Looks like he is still with the health system, but not in research.

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

Sent: Thursday, April 29, 2021 12:09 PM

To: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

**Subject:** [EXTERNAL] RE: updated VaST slideset

Ha!! is Nick still at Marshfield?

From: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Sent: Thursday, April 29, 2021 1:02 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Subject: RE: updated VaST slideset

### Nope!

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Thursday, April 29, 2021 12:02 PM

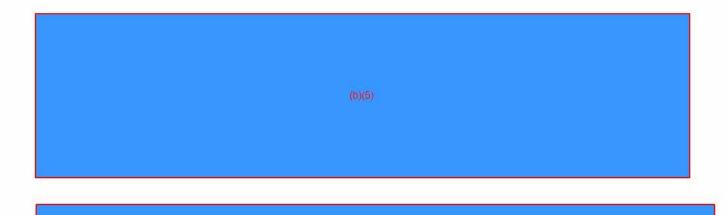
To: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org >

Subject: [EXTERNAL] RE: updated VaST slideset

Unrelated question:

(b)(6)

From: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org > Sent: Thursday, April 29, 2021 10:13 AM To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov> Cc: Kristin X. Goddard < Kristin.X.Goddard@kp.org>; NICOLA P KLEIN < Nicola.Klein@kp.org>; Ned Lewis <Ned.Lewis@kp.org> Subject: RE: updated VaST slideset Thanks Eric. A couple questions on anaphylaxis: -Kayla From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov> Sent: Thursday, April 29, 2021 8:58 AM To: Hanson, Kayla E <hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard < Kristin.X.Goddard@kp.org>; NICOLA P KLEIN < Nicola.Klein@kp.org>; Ned Lewis < Ned.Lewis@kp.org> Subject: [EXTERNAL] updated VaST slideset **CAUTION:** This email originated from outside of the Marshfield Clinic Health System. Do not click links or open attachments unless you recognize the sender and know the content is safe.



(b)(5)

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The contents of this message may contain private, protected and/or privileged information. If you received this message in error, you should destroy the e-mail message and any attachments or copies, and you are prohibited from retaining, distributing, disclosing or using any information contained within. Please contact the sender and advise of the erroneous delivery by return e-mail or telephone. Thank you for your cooperation.

The contents of this message may contain private, protected and/or privileged information. If you received this message in error, you should destroy the e-mail message and any attachments or copies, and you are prohibited from retaining, distributing, disclosing or using any information contained within. Please contact the sender and advise of the erroneous delivery by return e-mail or telephone. Thank you for your cooperation.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Sent:** Wed, 21 Apr 2021 14:54:20 +0000 **To:** Moro, Pedro (CDC/DDID/NCEZID/DHQP)

Cc: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP)

Subject: RE: Question re VAERS Reports Rec'd

Thanks-will send this as final

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Sent: Wednesday, April 21, 2021 10:52 AM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

<ayv6@cdc.gov>

Subject: RE: Question re VAERS Reports Rec'd

Elaine,

I have no comments or edits

**Thanks** 

Pedro

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

Sent: Wednesday, April 21, 2021 10:45 AM

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

Cc: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

<ayv6@cdc.gov>

Subject: FW: Question re VAERS Reports Rec'd

Pedro.

Please let me know if this response needs edits.

I am cc'ing Tom and John for awareness

(b)(5)

Thanks,

Elaine

Dear Kris,

Thanks for your email.

I did not find either of these reports in VAERS yet, but due to processing delays, VAERS may have received them but not processed them yet.

To date, CDC vaccine safety monitoring systems have not found evidence of a concerning pattern of reports of myocarditis after COVID-19 vaccination.

From: Carter, Kris K. < Kris. Carter@dhw.idaho.gov>

Sent: Tuesday, April 20, 2021 7:19 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Cc: Kingsbury, Jeff < Jeff. Kingsbury@dhw.idaho.gov>

Subject: Question re VAERS Reports Rec'd

### Hello, Elaine -

Can you tell us if CDC has received any VAERS reports from Idaho regarding:

- 2<sup>nd</sup> Pfizer COVID-19 vaccine dose administered 4/2, ED visit (b)(6) ID on 4/4, myocarditis, female in her twenties
- 2<sup>nd</sup> Pfizer COVID-19 vaccine dose administered 3 days before 4/11 ED visit to (b)(6)

  (b)(6)

  ID, myocarditis, female in her fifties

If you have not, we will follow up with the provider to stimulate reporting.

Are you seeing any VAERS signals around second dose Pfizer and myocarditis? This is our third.

Thank you for your help,

Kris

Kris K. Carter, DVM, MPVM, DACVPM
CAPT, USPHS; Career Epidemiology Field Officer, CDC
Epidemiology Program and Immunization Program
Bureau of Communicable Disease Prevention
Division of Public Health
Idaho Department of Health and Welfare

Desk Number: (208)334-5939 Fax Number: (208)332-7307

Kris.Carter@dhw.idaho.gov



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 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Fri, 9 Apr 2021 20:29:48 +0000

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC); Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)

Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Zhang, Bicheng (Tony)

(CDC/DDID/NCEZID/DHQP) (CTR)

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi all,



Thanks!

John

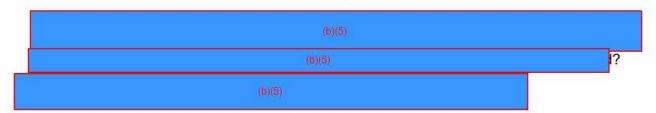
From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>

Sent: Friday, April 9, 2021 4:25 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Moro, Pedro

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

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine



Melanie

### Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

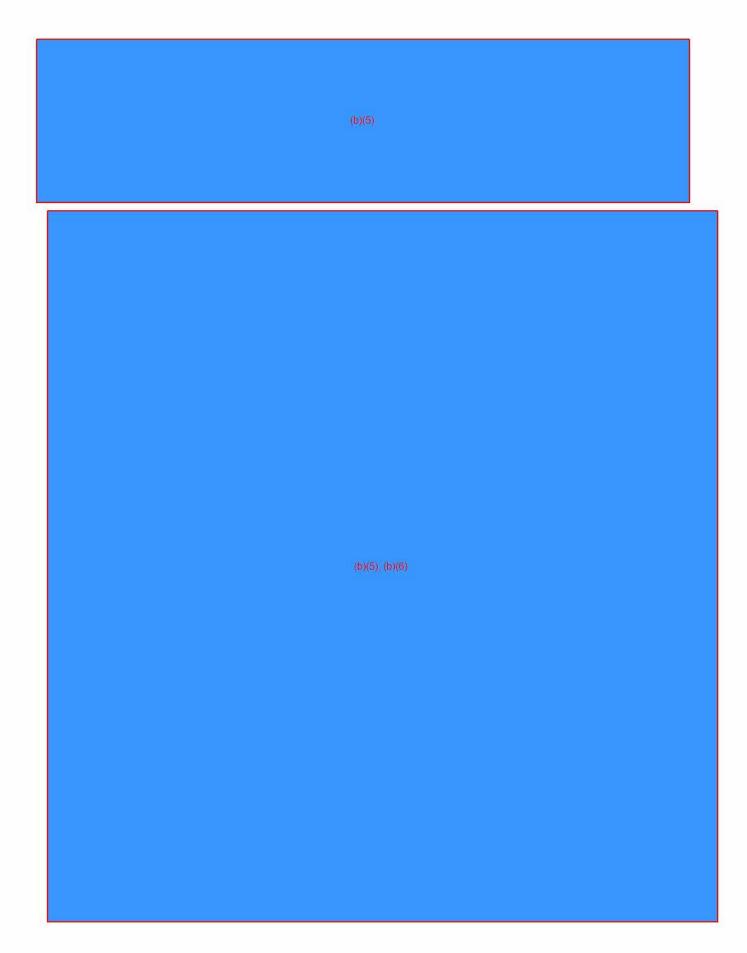
Sent: Friday, April 9, 2021 4:13 PM

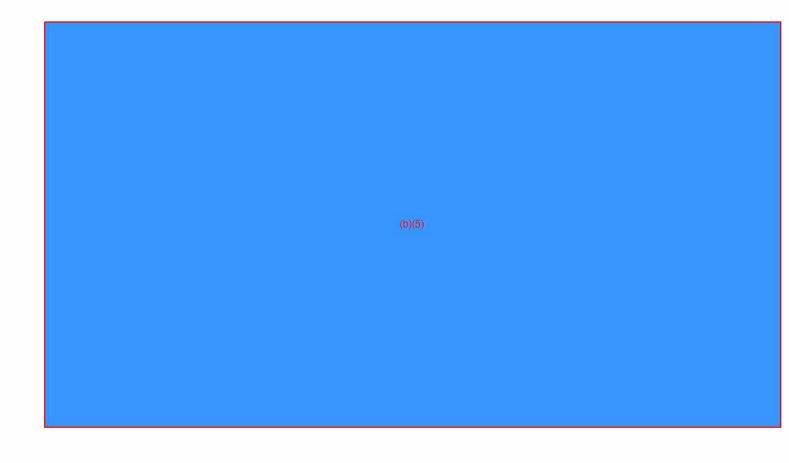
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >; Lagarde, Melanie

(CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,
(b)(5)
Thanks,
Elaine
From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>
Sent: Friday, April 9, 2021 4:09 PM  To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov>; Miller, Elaine R.
(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>
Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine
Hi Melanie,
(b)(5) ?
Thanks for sending this
Pedro
From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov >
<b>Sent:</b> Friday, April 9, 2021 3:48 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <pre>cpsm9@cdc.gov&gt;; Miller, Elaine R.</pre>
(CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> ; Su, John (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ezu2@cdc.gov">ezu2@cdc.gov</a> > Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine
TO COMPANY STATE COMPANY CONTROL CONTR
Dear Bob.
(b)(5)
Sincerely,
Pedro
(b)(5)





### Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC)

Sent: Thursday, April 8, 2021 1:13 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro,

Thank you. Got it. Makes sense. Happy to work on this. I'll send another draft.

Thanks again.

Melanie

Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>

Sent: Thursday, April 8, 2021 1:09 PM

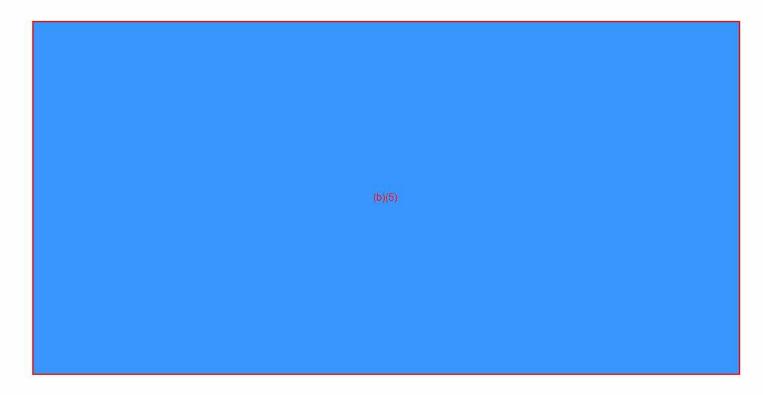
To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

Thanks for sending this. I have a few questions and suggest	ions. (b)(5)
(b)(5)	
Thanks again  Pedro  From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@	Dodg gov
Sent: Thursday, April 8, 2021 12:56 PM  To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gc Subject: DRAFT RE: Autoimmune dx post vaccine	c.gov>
(b)(5)	
(b)(5)	



# Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Thursday, April 8, 2021 9:15 AM

**To:** Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < <a href="mvl3@cdc.gov">mvl3@cdc.gov</a> **Cc:** Moro, Pedro (CDC/DDID/NCEZID/DHQP) < <a href="mvpsm9@cdc.gov">psm9@cdc.gov</a>>

Subject: RE: Autoimmune dx post vaccine

Hi Melanie,

Please let me know if you can draft a response for this inquiry.

Thanks, ELaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>

Sent: Wednesday, April 7, 2021 6:19 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: FW: Autoimmune dx post vaccine

Elaine,

(b)(5)

Pedro

From: dale nordenberg (b)(6)  Sent: Wednesday, April 7, 2021 5:16 PM  To: Robert Chen (b)(6)  Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>  Subject: Re: Autoimmune dx post vaccine
\Hi
(b)(5)
Thanks!
Sent from my iPhone
On Apr 7, 2021, at 5:08 PM, Robert Chen (b)(6) wrote:
Dale?
Robert (Bob) Chen MD MA Scientific Director, Brighton Collaboration Land: 1-404-248-0536 Cell: 1-678-662-0516 email: (b)(6)
On Wed, Apr 7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov > wrote: Hi Bob,
(b)(5)
Pedro
From: Robert Chen (b)(6)  Sent: Wednesday, April 7, 2021 3:33 PM  To: Nordenberg, Dale (CDC gmail.com) (b)(6)  Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>  Subject: Re: Autoimmune dx post vaccine
(b)(5) Bob

On Wed, Apr 7, 2021 at 1:07 AM dale nordenberg (b)(6) wrote:
Bob (b)(5)

Dale

Sent from my iPhone

...

Robert (Bob) Chen MD MA Scientific Director, Brighton Collaboration

Land: 1-404-248-0536 Cell: 1-678-662-0516

email: (b)(6)

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Thu, 22 Oct 2020 19:22:50 +0000

To: Hanson, Kayla E; Kristin Goddard, MPH (kristin.x.goddard@kp.org)

Cc: Donahue, James G DVM/PhD

Subject: Re: RCA Outcome Questions/Recommendations

# This excellent thanks! Get Outlook for iOS

From: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>

Sent: Thursday, October 22, 2020 2:58:49 PM

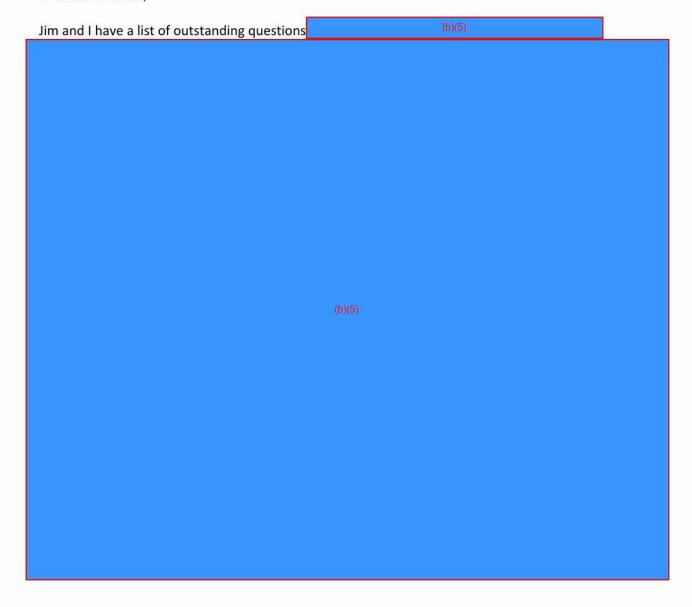
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Kristin Goddard, MPH

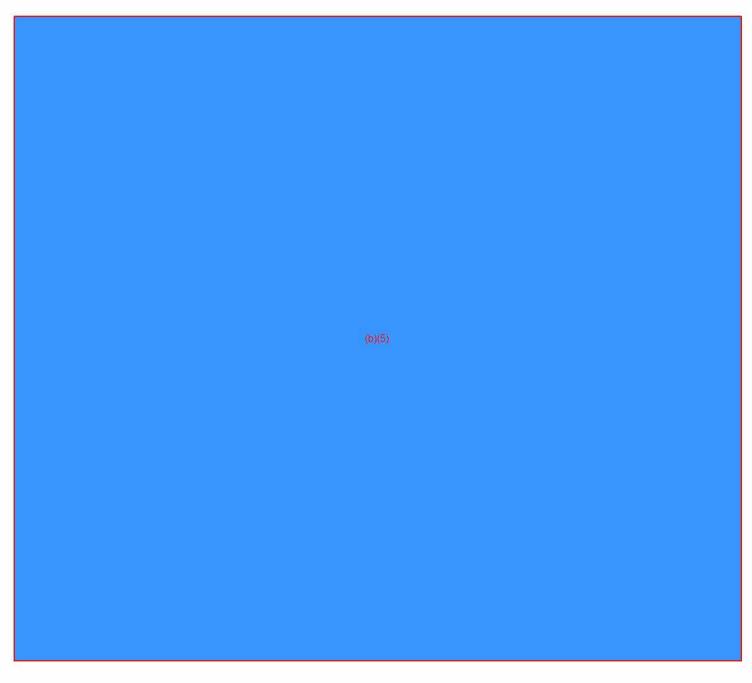
(kristin.x.goddard@kp.org) < kristin.x.goddard@kp.org>

Cc: Donahue, James G DVM/PhD <Donahue.James@marshfieldresearch.org>

Subject: RCA Outcome Questions/Recommendations

Hi Kristin and Eric,





Best, Kayla

Kayla Hanson, MPH
Epidemiologist | Center for Clinical Epidemiology & Population Health
Marshfield Clinic Research Institute | 1000 North Oak Avenue (ML2), Marshfield, WI 54449
1-715-221-6482 | 1715-389-3880 | hanson.kayla@marshfieldresearch.org

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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Mon, 19 Apr 2021 22:04:47 +0000

To: Ned Lewis

Cc: Berwick Chan; Joan Bartlett; Arnold Yee

Subject: RE: Covid-19 RCA data collection programs with minor revisions



From: Ned Lewis <Ned.Lewis@kp.org> Sent: Monday, April 19, 2021 6:03 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

Cc: Berwick Chan <Berwick.Chan@kp.org>; Joan Bartlett <Joan.Bartlett@kp.org>; Arnold Yee

<Arnold.Yee@kp.org>

Subject: RE: Covid-19 RCA data collection programs with minor revisions



Ned

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

**Sent:** Monday, April 19, 2021 2:58 PM **To:** Ned Lewis < Ned.Lewis@kp.org >

Cc: Berwick Chan <Berwick.Chan@kp.org>; Joan Bartlett <Joan.Bartlett@kp.org>; Arnold Yee

<Arnold.Yee@kp.org>

Subject: RE: Covid-19 RCA data collection programs with minor revisions

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Thanks!

Ned, (b)(5) (b)(5)

From: Ned Lewis < Ned.Lewis@kp.org>
Sent: Monday, April 19, 2021 5:48 PM

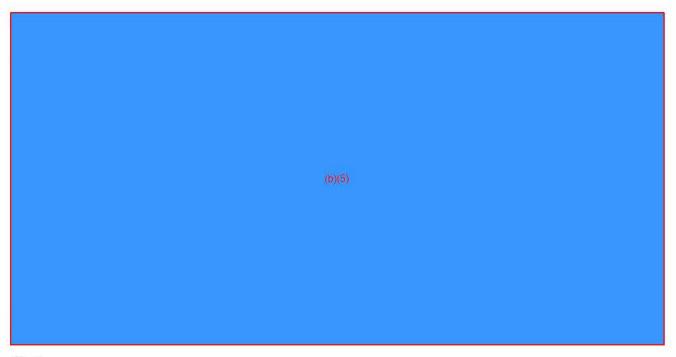
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

**Cc:** Berwick Chan < <u>Berwick.Chan@kp.org</u>>; Joan Bartlett < <u>Joan.Bartlett@kp.org</u>>; Arnold Yee

<Arnold.Yee@kp.org>

Subject: Covid-19 RCA data collection programs with minor revisions

Hi Eric,



## -Ned

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 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

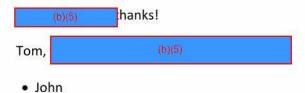
 Sent:
 Mon, 29 Mar 2021 20:50:36 +0000

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP)

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: WHO GACVS sub-committee - request for information



From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Monday, March 29, 2021 4:34 PM

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

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov> **Subject:** RE: WHO GACVS sub-committee - request for information

Hey John,

(b)(5)

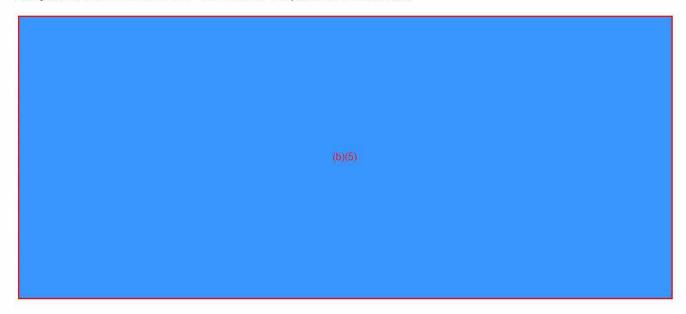
From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)

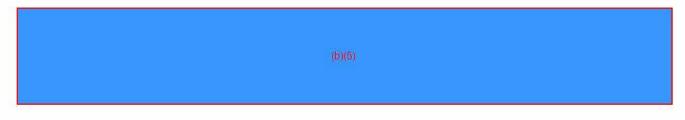
Sent: Monday, March 29, 2021 2:13 PM

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

(CDC/DDID/NCEZID/DHQP) <a y v 6@cdc.gov>

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** RE: WHO GACVS sub-committee - request for information





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

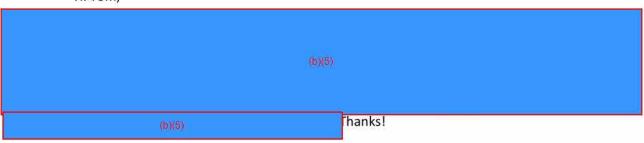
Sent: Friday, March 26, 2021 8:17 AM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov >; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** RE: WHO GACVS sub-committee - request for information

Hi Tom,



John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>

Sent: Thursday, March 25, 2021 5:09 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:square">ayv6@cdc.gov></a>

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

Hey Tom,

(b)(5)

Thanks,

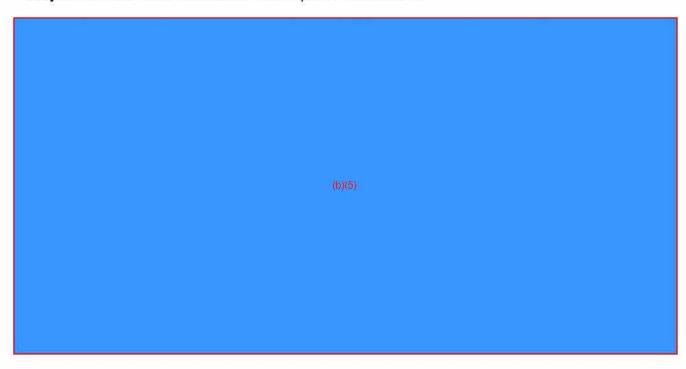
From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>

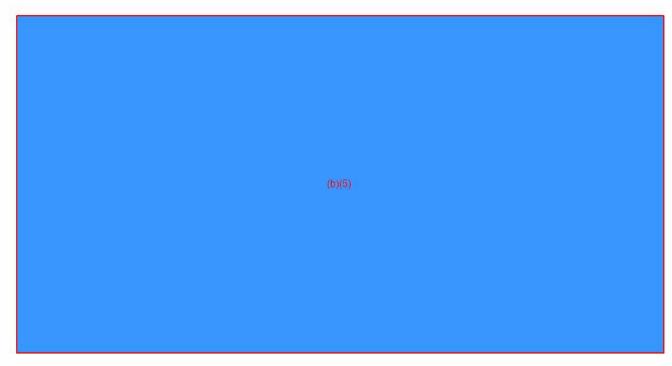
Sent: Thursday, March 25, 2021 2:17 PM

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

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** RE: WHO GACVS sub-committee - request for information





From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> Sent: Wednesday, March 17, 2021 3:56 PM To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>; Licata, Charles (CDC/DDID/NCEZID/DHQP) < kui5@cdc.gov >; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) <qsq2@cdc.gov> Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Subject: FW: WHO GACVS sub-committee - request for information Hi folks, Please see below email chain. Tom, Thanks! John From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov> Sent: Wednesday, March 17, 2021 1:24 PM To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Cc: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov> Subject: RE: WHO GACVS sub-committee - request for information From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a> Sent: Wednesday, March 17, 2021 12:26 PM To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:cerm4@cdc.gov">erm4@cdc.gov</a>> Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> **Subject:** RE: WHO GACVS sub-committee - request for information Thanks. From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov> Sent: Wednesday, March 17, 2021 12:24 PM To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov> Cc: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

Tom,

Elaine

John is out today.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a you say to a you say

Sent: Wednesday, March 17, 2021 12:09 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ezu2@cdc.gov">ezu2@cdc.gov</a>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>
Subject: FW: WHO GACVS sub-committee - request for information

(b)(5) Thanks.

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Wednesday, March 17, 2021 3:47 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov</a>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <iyk3@cdc.gov>; PAL, Shanthi Narayan <pals@who.int>;

JANIN, Annick <janina@who.int>

Subject: Re: WHO GACVS sub-committee - request for information

#### Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopaenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again Anastasia

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Sent: Wednesday, 17 March 2021 6:43 AM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < iyk3@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

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Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I'm happy to talk when convenient. I'm Cc'ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

### Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Monday, March 8, 2021 10:05 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:square">ayv6@cdc.gov></a>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>

Subject: WHO GACVS sub-committee - request for information

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The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM

Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia

Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)

E: anastasia.phillips@health.wa.gov.au

Ph: +61 417 172 936

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Fri, 9 Apr 2021 20:16:11 +0000

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Lagarde, Melanie

(CDC/OCOO/OSSAM/OHC); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

(b)(5) Thanks!

John

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Sent: Friday, April 9, 2021 4:09 PM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Subject: RE: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

(b)(5)

Thanks for sending this

Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < <a href="mvl3@cdc.gov">mvl3@cdc.gov">mvl3@cdc.gov</a>

Sent: Friday, April 9, 2021 3:48 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov >; Miller, Elaine R.

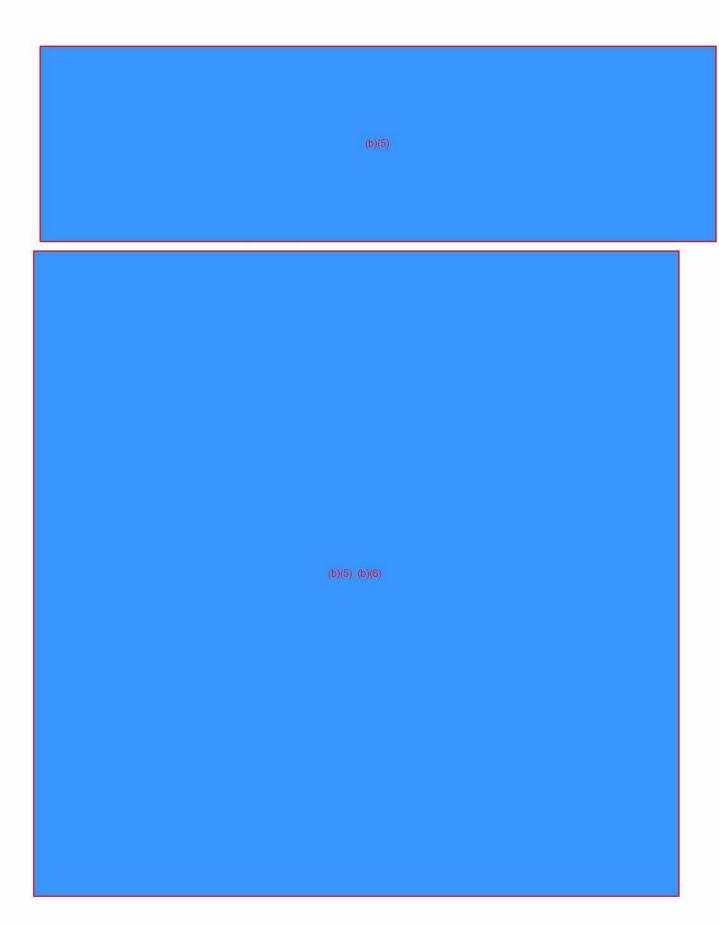
(CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

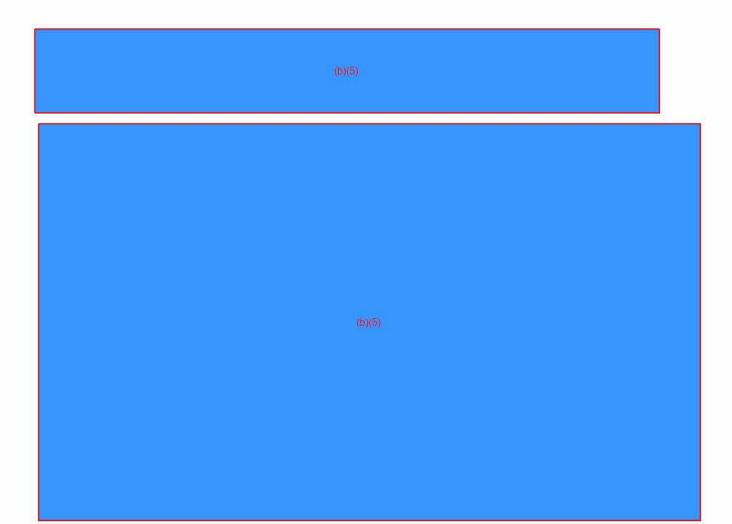
Subject: REDO: RE: DRAFT RE: Autoimmune dx post vaccine

(b)(5)

Sincerely, Pedro

(h)(5)





## Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC)

Sent: Thursday, April 8, 2021 1:13 PM

To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Pedro.

Thank you. Got it. Makes sense. Happy to work on this. I'll send another draft.

Thanks again.

Melanie

# Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) psm9@cdc.gov>

Sent: Thursday, April 8, 2021 1:09 PM

To: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < mvl3@cdc.gov >; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: RE: DRAFT RE: Autoimmune dx post vaccine

Hi Melanie,

Thanks for sending this. I have a few questions and suggestions.	(b)(5)
(b)(5)	
MONEY.	

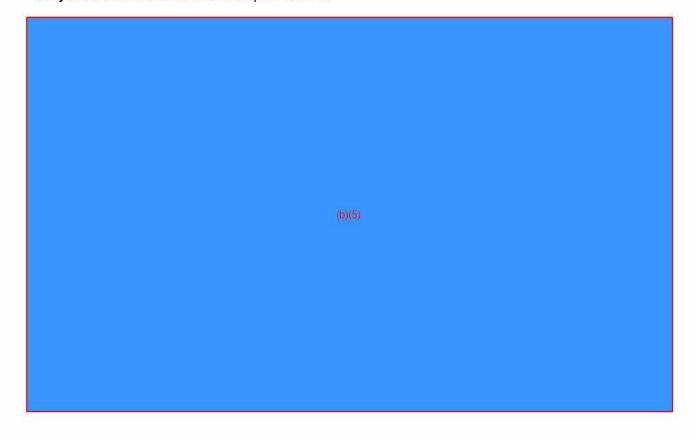
Thanks again

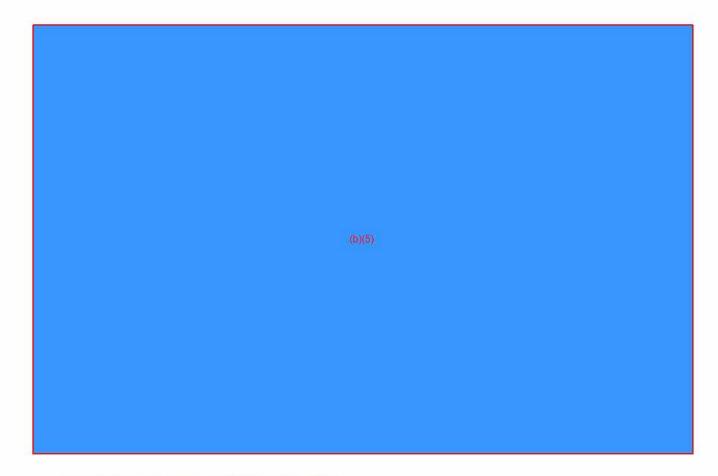
Pedro

From: Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) <mvl3@cdc.gov>

Sent: Thursday, April 8, 2021 12:56 PM

**Subject:** DRAFT RE: Autoimmune dx post vaccine





## Melanie Carmel Lagarde, DNP, MPH, RN, CHES

MVL3@cdc.gov | 404-639-4856 office | 470-773-8733 cell

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Thursday, April 8, 2021 9:15 AM

**To:** Lagarde, Melanie (CDC/OCOO/OSSAM/OHC) < <a href="mvl3@cdc.gov">mvl3@cdc.gov</a> **Cc:** Moro, Pedro (CDC/DDID/NCEZID/DHQP) < <a href="mvpsm9@cdc.gov">psm9@cdc.gov</a>>

Subject: RE: Autoimmune dx post vaccine

Hi Melanie,

Please let me know if you can draft a response for this inquiry.

Thanks, ELaine

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Sent: Wednesday, April 7, 2021 6:19 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: FW: Autoimmune dx post vaccine

Elaine,

	(b)(5)
P	edro
Se Te Ce (C	com: dale nordenberg (b)(6) ent: Wednesday, April 7, 2021 5:16 PM co: Robert Chen (b)(6) c: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>; Miller, Elaine R. CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov> ubject: Re: Autoimmune dx post vaccine
Н	i
	(b)(5)
TI	hanks !
Se	ent from my iPhone
0	n Apr 7, 2021, at 5:08 PM, Robert Chen (b)(6) wrote:
D	ale?
So La	obert (Bob) Chen MD MA cientific Director, Brighton Collaboration and: 1-404-248-0536 Cell: 1-678-662-0516 mail: (b)(6)
	n Wed, Apr 7, 2021 at 3:55 PM Moro, Pedro (CDC/DDID/NCEZID/DHQP) < <a href="mailto:psm9@cdc.gov">psm9@cdc.gov</a> > wrote: i Bob,
	(b)(5)
	(b)(5)
P	edro
	rom: Robert Chen (b)(6) ent: Wednesday, April 7, 2021 3:33 PM

Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) < psm9@cdc.gov>

Subject: Re: Autoimmune dx post vaccine



Sent from my iPhone

---

Robert (Bob) Chen MD MA Scientific Director, Brighton Collaboration

Land: 1-404-248-0536 Cell: 1-678-662-0516

email: (b)(6)

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)

**Sent:** Thu, 8 Apr 2021 02:39:13 +0000

**To:** Wharton, Melinda (CDC/DDID/NCIRD/ISD); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Gee, Julianne (CDC/DDID/NCEZID/DHQP); Shay, David

(CDC/DDID/NCIRD/ID); Clark, Thomas A. (CDC/DDID/NCIRD/DVD)

Subject: RE: Signal eval considerations- feel free to comment/edit/share

Hi all,

I have had a few email exchanges with some of you about this email.

(b)(5)

(b)(5)

Lauri

# Questions to VaST members



- How do we communicate these RCA results to the public?
- How to address the trade-off of the uncertainty of self-controlled studies using pre-vaccination intervals versus more timely analyses?
- Any suggestions for adjustment of risk factors for cardiovascular events during PMaxRT runs? We currently are standardizing the expected rates to nursing home status, age, sex, race/ethnicity.
- Should we consider incorporating severity of the AESIs in determination of our clinical margin and if so, how do we do that? The clinical margins are currently selected based on whether the AESIs are common (signal faster) or rare

For internal Deliberation Only, Do Not Share,

14

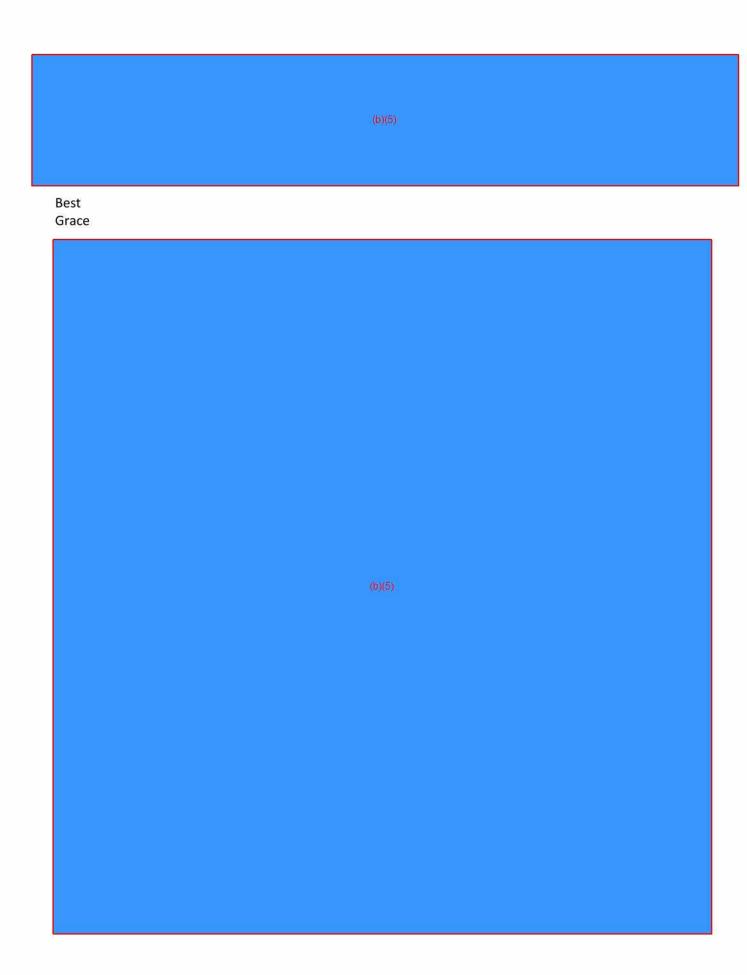
From: Lee, Grace <GMLee@stanfordchildrens.org>

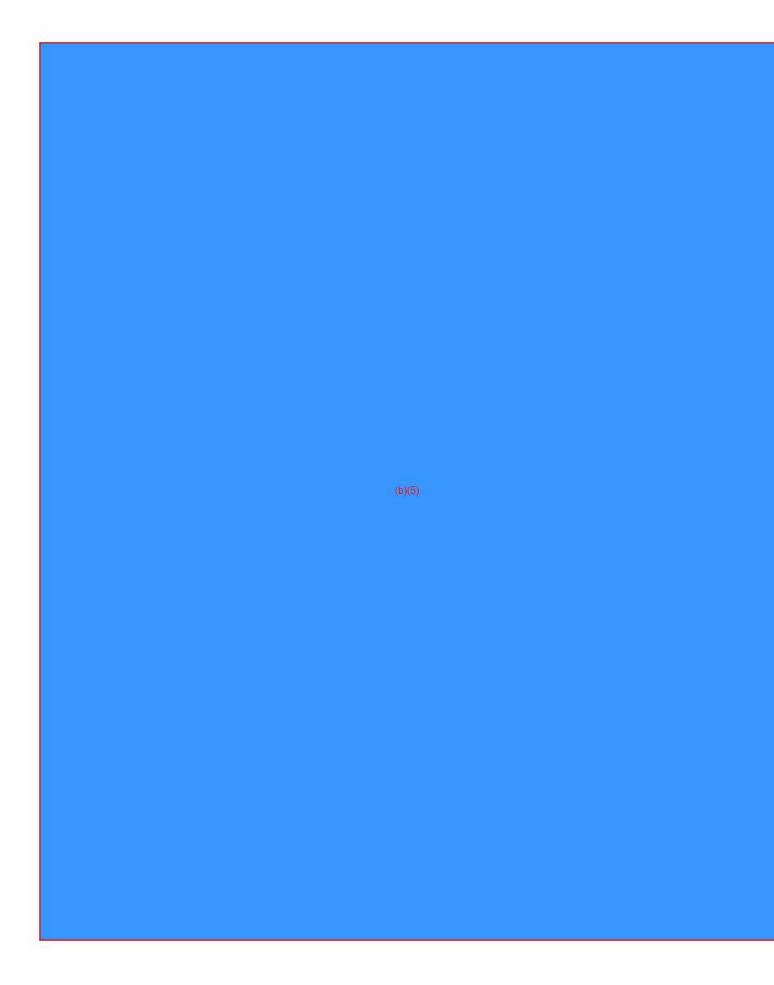
Sent: Tuesday, April 6, 2021 12:56 PM

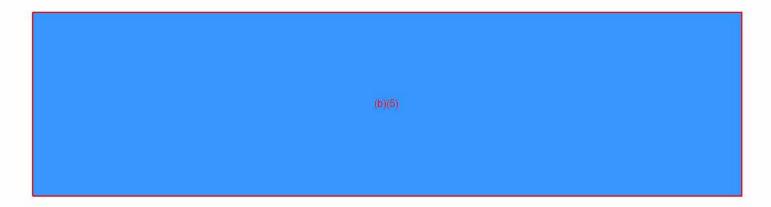
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Hopkins, Bob <hopkinsroberth@uams.edu>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>

**Subject:** Signal eval considerations- feel free to comment/edit/share

Hi Team







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From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)

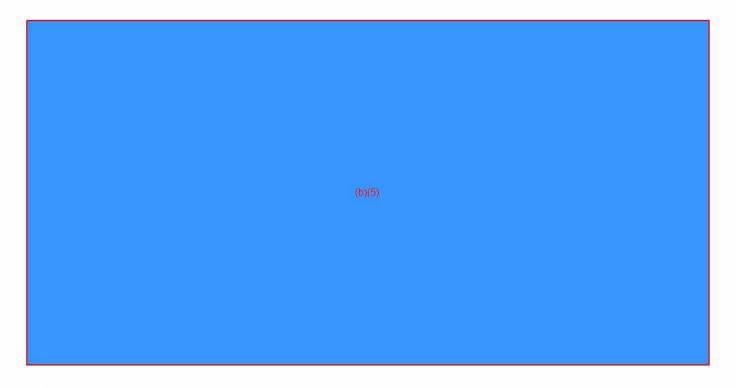
**Sent:** Mon, 29 Mar 2021 18:13:14 +0000

To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP)

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: WHO GACVS sub-committee - request for information



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

Sent: Friday, March 26, 2021 8:17 AM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov> **Subject:** RE: WHO GACVS sub-committee - request for information



From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>

Sent: Thursday, March 25, 2021 5:09 PM

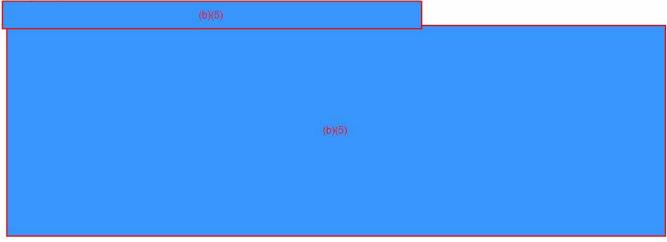
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov>

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

Hey Tom,



Thanks, Paige

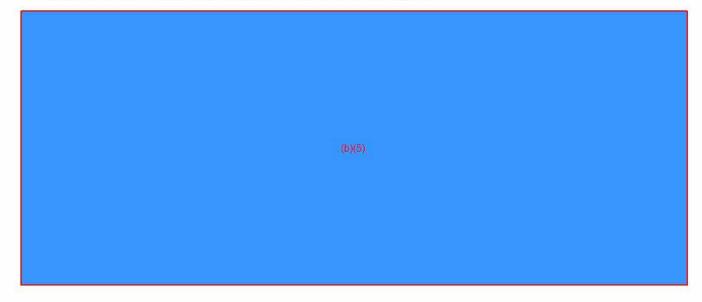
From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>

Sent: Thursday, March 25, 2021 2:17 PM

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

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

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

Sent: Wednesday, March 17, 2021 3:56 PM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>; Licata, Charles

(CDC/DDID/NCEZID/DHQP) < kui5@cdc.gov >; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR)

<qsq2@cdc.gov>

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:crm4@cdc.gov">erm4@cdc.gov</a>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <a y v 6 @ cdc.gov >

Subject: FW: WHO GACVS sub-committee - request for information

Hi folks,

Please see below email chain. Tom, Thanks! John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Wednesday, March 17, 2021 1:24 PM

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

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

Subject: RE: WHO GACVS sub-committee - request for information

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

Sent: Wednesday, March 17, 2021 12:26 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

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

Subject: RE: WHO GACVS sub-committee - request for information

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To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov</a>

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

Subject: RE: WHO GACVS sub-committee - request for information

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Sent: Wednesday, March 17, 2021 12:09 PM

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**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** FW: WHO GACVS sub-committee - request for information

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Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<a href="mailto:square-representation-left"><a href="mailto:square-representation

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < <u>iyk3@cdc.gov</u>>; PAL, Shanthi Narayan < <u>pals@who.int</u>>;

JANIN, Annick < janina@who.int >

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**Dear Tom** 

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Sent: Wednesday, 17 March 2021 6:43 AM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<a href="mailto:</a><a href="mailto:aura"><a href="mailto:aura"><a

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < iyk3@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

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Dear Anastasia,

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Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA Captain, U.S. Public Health Service Deputy Director Immunization Safety Office Centers for Disease Control and Prevention (CDC) 1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Monday, March 8, 2021 10:05 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>

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Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM

Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia

Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)

E: anastasia.phillips@health.wa.gov.au

Ph: +61 417 172 936

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Thu, 29 Apr 2021 23:35:29 +0000

To: NICOLA P KLEIN

**Subject:** RE: updated VaST slideset

Perfect: I'll call the teams at 7:40 est

From: NICOLA P KLEIN < Nicola. Klein@kp.org> Sent: Thursday, April 29, 2021 7:35 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

Subject: RE: updated VaST slideset

Excellent. Give me 5 minutes

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Thursday, April 29, 2021 4:33 PM
To: NICOLA P KLEIN < Nicola. Klein@kp.org>

Subject: RE: updated VaST slideset

Nicky - I'm ready now if you are, my evening "session" ended early. Otherwise, I can wait till 8:30 est

From: NICOLA P KLEIN < Nicola.Klein@kp.org > Sent: Thursday, April 29, 2021 3:56 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Subject: RE: updated VaST slideset

Yes if we do it at 5:30 PT/8:30 ET?

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Thursday, April 29, 2021 12:54 PM
To: NICOLA P KLEIN < Nicola. Klein@kp.org>

Subject: RE: updated VaST slideset

I'm running out right now and probably won't be back available until around 8:30 - 9:00 est?

Does that work?

From: NICOLA P KLEIN < Nicola. Klein@kp.org>

Sent: Thursday, April 29, 2021 3:52 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

**Subject:** RE: updated VaST slideset

Do you have time to over the slides today? I won't be able to tomorrow. Hopefully it won't take too long. I am available now until my next meeting at 4pm PT

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

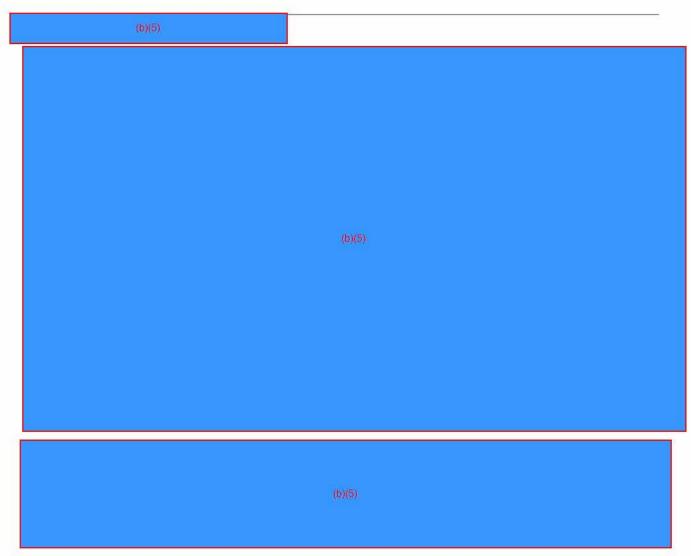
Sent: Thursday, April 29, 2021 6:58 AM

To: Hanson, Kayla E < hanson.kayla@marshfieldresearch.org>; Kristin X. Goddard

<Kristin.X.Goddard@kp.org>; NICOLA P KLEIN < Nicola.Klein@kp.org>; Ned Lewis < Ned.Lewis@kp.org>

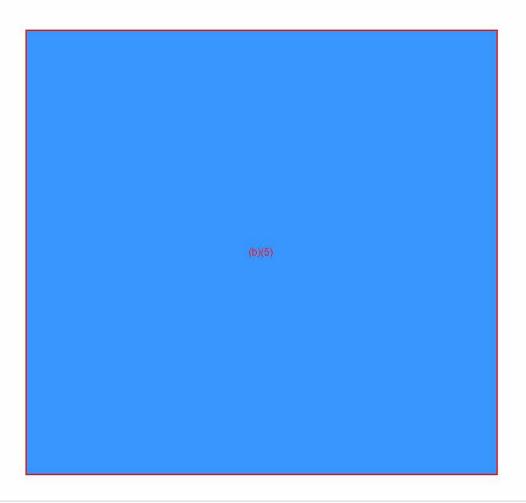
Subject: updated VaST slideset

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McNeil, Michael (CDC/DDID/NCEZID/DHQP) From: Sent: Thu, 22 Oct 2020 17:52:25 +0000 Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom To: (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP) Taylor, Allan W. (CDC/DDPHSIS/CGH/OD); Harrington, Theresa Cc: (CDC/DDID/NCEZID/DHQP) Subject: RE: AESI Attachments: COVID-19 RCA Outcomes Draft Table & Questions.docx This is the current draft table Mike From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> Sent: Thursday, October 22, 2020 1:22 PM To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov> Cc: Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <avt0@cdc.gov>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov> Subject: RE: AESI Hi all, John



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

Sent: Thursday, October 22, 2020 12:39 PM

To: Broder, Karen (CDC/DDID/NCEZID/DHQP) < <a href="mailto:krb2@cdc.gov">krb2@cdc.gov</a>>

Cc: Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <a href="mailto:avt0@cdc.gov">avt0@cdc.gov</a>; Harrington, Theresa

(CDC/DDID/NCEZID/DHQP) < tsh3@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >;

McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov>

Subject: RE: AESI

(b)(5)

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) <a href="mailto:krb2@cdc.gov">krb2@cdc.gov</a>

Sent: Thursday, October 22, 2020 12:29 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">ayv6@cdc.gov</a>

Cc: Taylor, Allan W. (CDC/DDPHSIS/CGH/OD) <a href="mailto:avt0@cdc.gov">avt0@cdc.gov</a>; Harrington, Theresa

(CDC/DDID/NCEZID/DHQP) < tsh3@cdc.gov>

Subject: AESI

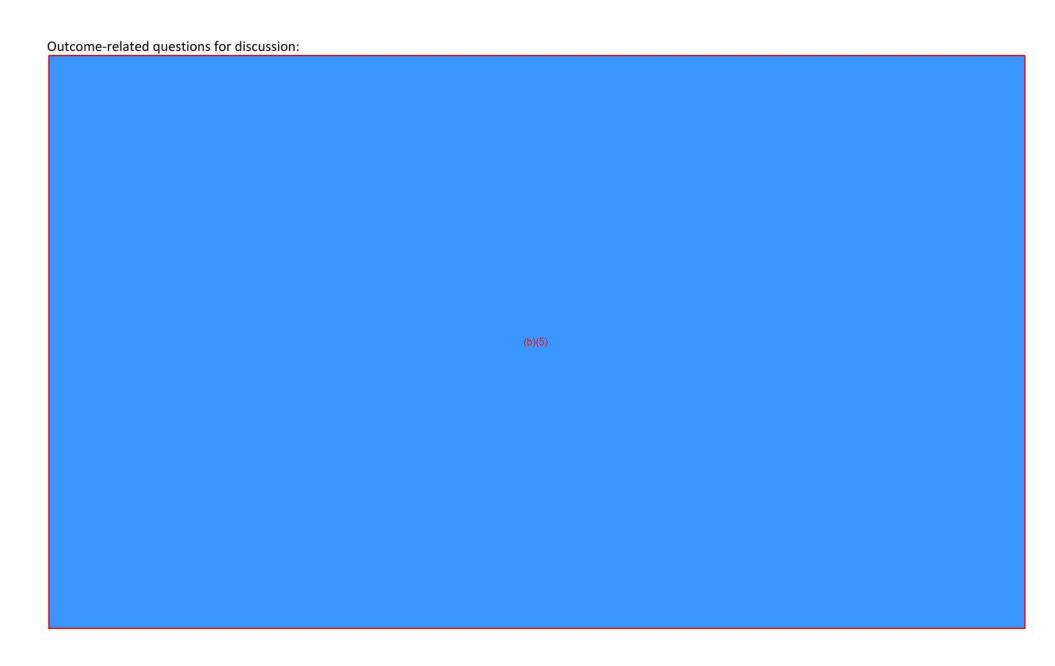
Tom,

(b)(5)

Thanks,

# Karen

Outcome	ICD-10 Code(s)	Exposure Window	Setting(s)	A priori Chart Review	First in what period?	Exclusions
		(b)(5)				



From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Sent:** Fri, 26 Mar 2021 11:49:22 +0000 **To:** Su, John (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: WHO GACVS sub-committee - request for information

So it this correct now?

(b)(5)·

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

Sent: Thursday, March 25, 2021 11:35 PM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov> **Subject:** RE: WHO GACVS sub-committee - request for information

Hi folks,

(b)(5)

Please let me know if you have any questions.

• John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>

Sent: Thursday, March 25, 2021 5:09 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">ayv6@cdc.gov</a>

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

## <ezu2@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

Hey Tom		
	(b)(5)	

Thanks, Paige

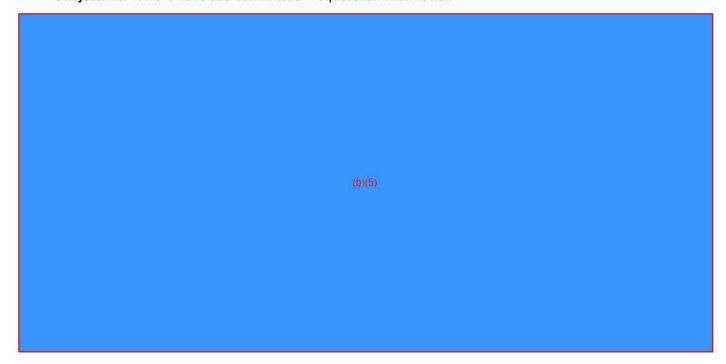
From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>

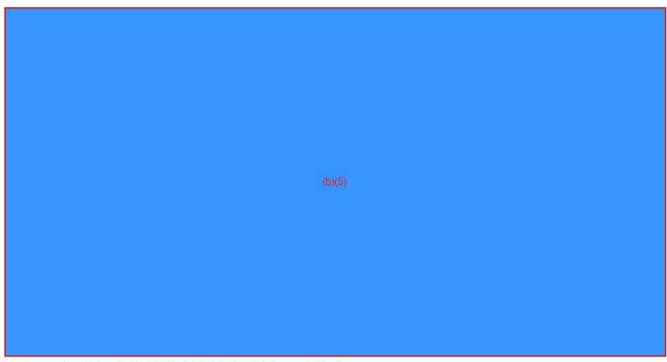
Sent: Thursday, March 25, 2021 2:17 PM

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

(CDC/DDID/NCEZID/DHQP) <a yv6@cdc.gov>

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** RE: WHO GACVS sub-committee - request for information





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

Sent: Wednesday, March 17, 2021 3:56 PM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>; Licata, Charles

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:kui5@cdc.gov">kui5@cdc.gov">kui5@cdc.gov</a>; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR) < <a href="mailto:kui5@cdc.gov">kui5@cdc.gov</a>; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR)

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov >; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Subject: FW: WHO GACVS sub-committee - request for information

Hi folks,

Please see below email chain. (b)(5)

Tom, (b)(5) Thanks!

John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Wednesday, March 17, 2021 1:24 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

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

Subject: RE: WHO GACVS sub-committee - request for information

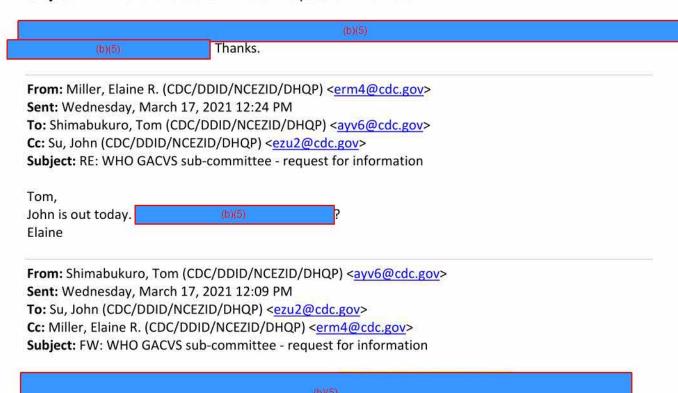
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, March 17, 2021 12:26 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

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

Subject: RE: WHO GACVS sub-committee - request for information



From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Wednesday, March 17, 2021 3:47 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov</a>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov">dvj3@cdc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <a href="mailto:dvj3@cdc.gov">iyk3@cdc.gov</a>; PAL, Shanthi Narayan <a href="mailto:pals@who.int">pals@who.int</a>;

JANIN, Annick < janina@who.int>

manks.

Subject: Re: WHO GACVS sub-committee - request for information

#### Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopaenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again Anastasia

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, 17 March 2021 6:43 AM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) < dvj3@cdc.gov>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < iyk3@cdc.gov>

**Subject:** RE: WHO GACVS sub-committee - request for information

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I'm happy to talk when convenient. I'm Cc'ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

### Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Sent: Monday, March 8, 2021 10:05 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>

Subject: WHO GACVS sub-committee - request for information

**Dear Tom** 

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM

Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia

Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)

E: anastasia.phillips@health.wa.gov.au

Ph: +61 417 172 936

From: Mullen, Jennifer (CDC/DDID/NCEZID/DHQP)

**Sent:** Mon, 26 Apr 2021 16:52:52 +0000

**To:** Sharan, Martha (CDC/DDID/NCEZID/DHQP); Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); McNeil, Michael

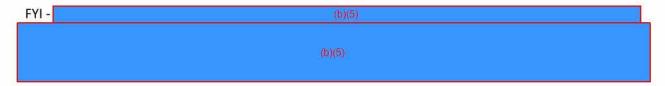
(CDC/DDID/NCEZID/DHQP); Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Grusich, Katherina (Kate)

(CDC/DDID/NCIRD/OD)

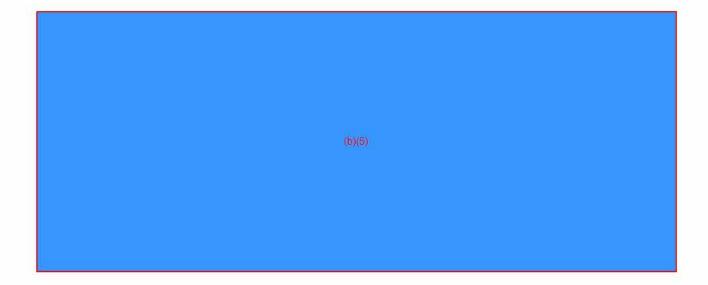
Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP); Burns, Erin (CDC/DDID/NCIRD/ID);

Spratling, Robin (CDC/DDID/NCIRD/ID) (CTR); Jordan, Douglas E. (CDC/DDID/NCIRD/ID)

Subject: RE: Myocarditis



Thanks!



From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) <liu4@cdc.gov>

Sent: Monday, April 26, 2021 12:19 PM

To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Mullen, Jennifer

(CDC/DDID/NCEZID/DHQP) <jjk7@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>;

Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP)

<mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Grusich, Katherina
(Kate) (CDC/DDID/NCIRD/OD) <yhb3@cdc.gov>

**Cc:** Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; Burns, Erin (CDC/DDID/NCIRD/ID) <eub5@cdc.gov>; Spratling, Robin (CDC/DDID/NCIRD/ID) (CTR) <qbm9@cdc.gov>; Jordan, Douglas E.

(CDC/DDID/NCIRD/ID) < fud7@cdc.gov>

Subject: RE: Myocarditis

Thank you... sending to OADC.

Appreciate it, Martha

Martha Sharan Public Affairs

CDC/Division of Healthcare Quality Promotion

Off.: 404-639-2683 Cell: 404-998-1787

From: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Sent: Monday, April 26, 2021 12:17 PM

To: Mullen, Jennifer (CDC/DDID/NCEZID/DHQP) < ijik7@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) < yhb3@cdc.gov>; Sharan, Martha (CDC/DDID/NCEZID/DHQP) < liu4@cdc.gov>

Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) < <a href="mailto:fxd1@cdc.gov">fxd1@cdc.gov</a>; Burns, Erin (CDC/DDID/NCIRD/ID) < <a href="mailto:qeub5@cdc.gov">qeub5@cdc.gov</a>; Jordan, Douglas E. (CDC/DDID/NCIRD/ID) < <a href="mailto:fud7@cdc.gov">fud7@cdc.gov</a>>

Subject: RE: Myocarditis

(b)(5)

tom

From: Mullen, Jennifer (CDC/DDID/NCEZID/DHQP) < jjk7@cdc.gov>

Sent: Monday, April 26, 2021 12:12 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) < <u>ezu2@cdc.gov</u>>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

<<u>erm4@cdc.gov</u>>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <<u>mmm2@cdc.gov</u>>; Weintraub, Eric

(CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD)

<<u>tnc4@cdc.gov</u>>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) <<u>yhb3@cdc.gov</u>>; Sharan, Martha (CDC/DDID/NCEZID/DHQP) <<u>liu4@cdc.gov</u>>

Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) < <a href="mailto:fxd1@cdc.gov">fxd1@cdc.gov">fxd1@cdc.gov</a>; Burns, Erin (CDC/DDID/NCIRD/ID) < <a href="mailto:eub5@cdc.gov">eub5@cdc.gov</a>; Spratling, Robin (CDC/DDID/NCIRD/ID) (CTR) < <a href="mailto:qbm9@cdc.gov">qbm9@cdc.gov</a>; Jordan, Douglas E. (CDC/DDID/NCIRD/ID) < <a href="mailto:fud7@cdc.gov">fud7@cdc.gov</a>>

Subject: RE: Myocarditis

The draft		(b)(5)
		(b)(5)
	(b)(5)	7

(b)(5)

Thanks! Jenny

From: Mullen, Jennifer (CDC/DDID/NCEZID/DHQP)

Sent: Monday, April 26, 2021 12:01 PM

**To:** Su, John (CDC/DDID/NCEZID/DHQP) < <u>ezu2@cdc.gov</u>>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < <u>ayv6@cdc.gov</u>>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

<<u>erm4@cdc.gov</u>>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <<u>mmm2@cdc.gov</u>>; Weintraub, Eric

(CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) < yhb3@cdc.gov>

Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) < <a href="mailto:fxd1@cdc.gov">fxd1@cdc.gov">fxd1@cdc.gov</a>; Burns, Erin (CDC/DDID/NCIRD/ID) < <a href="mailto:qubm9@cdc.gov">qubm9@cdc.gov</a>; Jordan, Douglas E. (CDC/DDID/NCIRD/ID) < <a href="mailto:fud7@cdc.gov">fud7@cdc.gov</a>

Subject: RE: Myocarditis

+ Comms co-leads and deputy for awareness

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

Sent: Monday, April 26, 2021 11:40 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:square">ayv6@cdc.gov</a>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <a href="mailto:square">erm4@cdc.gov</a>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <a href="mailto:square">eiw8@cdc.gov</a>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <a href="mailto:square">tnc4@cdc.gov</a>; Mullen, Jennifer (CDC/DDID/NCEZID/DHQP) <a href="mailto:square">jjk7@cdc.gov</a>;

Subject: RE: Myocarditis

Hi Tom,

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Sent: Monday, April 26, 2021 10:55 AM To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Mullen, Jennifer (CDC/DDID/NCEZID/DHQP) <jjk7@cdc.gov>; Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) < hb3@cdc.gov> Cc: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov> Subject: RE: Myocarditis Below is my first attempt. From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov> Sent: Monday, April 26, 2021 10:41 AM To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov >; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> Subject: RE: Myocarditis Importance: High Hi all, Please advise:

If not, please edit as needed:

(b)(5)

From: McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov>

Sent: Monday, April 26, 2021 9:50 AM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

<erm4@cdc.gov>

Subject: RE: Myocarditis



From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Monday, April 26, 2021 9:43 AM

To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov >

Cc: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

<erm4@cdc.gov>

Subject: RE: Myocarditis

(b)(5)

From: McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov>

Sent: Monday, April 26, 2021 9:24 AM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Cc: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

<erm4@cdc.gov>

Subject: RE: Myocarditis

Eric,

(b)(5)

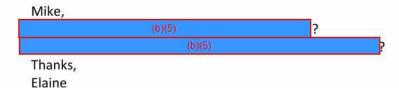
Thanks, Mike From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

**Sent:** Monday, April 26, 2021 9:12 AM

To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov>

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

Subject: RE: Myocarditis

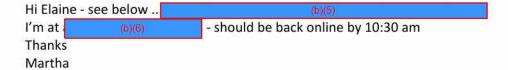


From: Sharan, Martha (CDC/DDID/NCEZID/DHQP) < liu4@cdc.gov>

Sent: Monday, April 26, 2021 9:05 AM

**To:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> <a href="mailto:cc: CDC/DDID/NCEZID/DHQP">cc: Mullen, Jennifer (CDC/DDID/NCEZID/DHQP) < <a href="mailto:jik7@cdc.gov">jik7@cdc.gov</a> <a href="mailto:gov">jik7@cdc.gov</a> <a href="mailto:com/mailto:jik7@cdc.gov">gov</a>

Subject: Fwd: Myocarditis



#### Get Outlook for iOS

From: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>

Sent: Monday, April 26, 2021 8:41:09 AM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>; Grusich, Katherina (Kate)

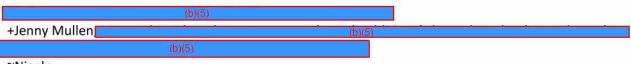
(CDC/DDID/NCIRD/OD) < <a href="mailto:yhb3@cdc.gov">yhb3@cdc.gov</a>; Sharan, Martha (CDC/DDID/NCEZID/DHQP) < <a href="mailto:liu4@cdc.gov">liu4@cdc.gov</a>; ; Sharan, Martha (CDC/DDID/NCEZID/DHQP) < <a href="mailto:liu4@cdc.gov">liu4@cdc.gov</a>; <a href="mailto:

Schindelar, Jessica (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ghq1@cdc.gov">ghq1@cdc.gov</a>>

Cc: Haynes, Benjamin (CDC/OD/OADC) < fxq2@cdc.gov >; Heldman, Amy B. (CDC/OD/OADC) < evd4@cdc.gov >; McDonald, Jason (CDC/OD/OADC) < gnf0@cdc.gov >; Mullen, Jennifer

(CDC/DDID/NCEZID/DHQP) < jjk7@cdc.gov>

Subject: RE: Myocarditis



~Nicole

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov">aws8@cdc.gov</a>

Sent: Monday, April 26, 2021 6:03 AM

**To:** Grusich, Katherina (Kate) (CDC/DDID/NCIRD/OD) < <a href="mailto:yhb3@cdc.gov">yhb3@cdc.gov</a>; Sharan, Martha (CDC/DDID/NCEZID/DHQP) < <a href="mailto:huda@cdc.gov">huda@cdc.gov</a>; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < <a href="mailto:huda@cdc.gov">huda@cdc.gov</a>; Coffin,

Schindelar, Jessica (CDC/DDID/NCEZID/DHQP) < ghq1@cdc.gov>

Cc: Haynes, Benjamin (CDC/OD/OADC) < fxq2@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC)

<evd4@cdc.gov>; McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>

Subject: FW: Myocarditis



Adam

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Thu, 25 Mar 2021 22:11:24 +0000

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP)

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: WHO GACVS sub-committee - request for information

Hi folks,

(b)(5)

John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Thursday, March 25, 2021 5:09 PM

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

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

Hey Tom,

(b)(5)

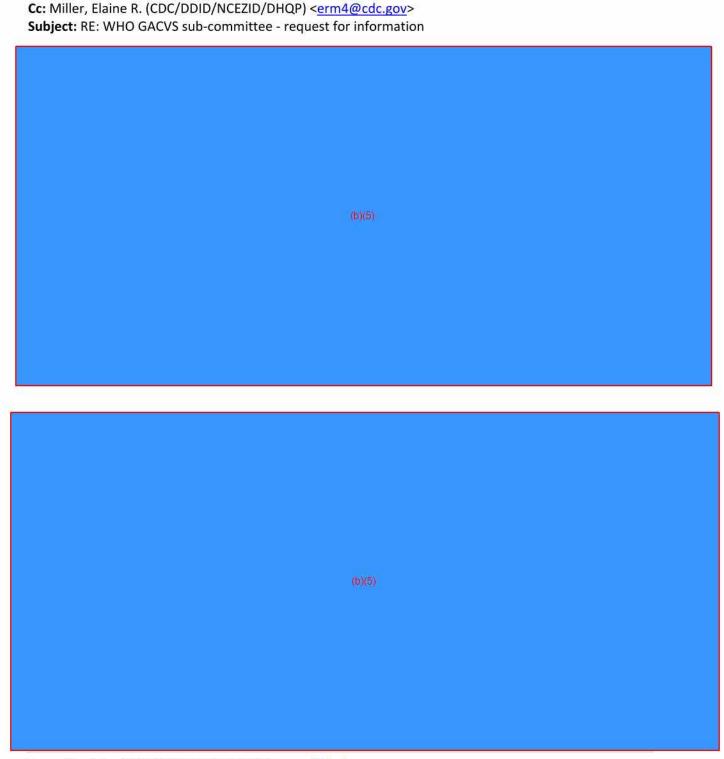
Thanks, Paige

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>

Sent: Thursday, March 25, 2021 2:17 PM

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

(CDC/DDID/NCEZID/DHQP) <a y v 6@cdc.gov>



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

Sent: Wednesday, March 17, 2021 3:56 PM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov>; Licata, Charles

(CDC/DDID/NCEZID/DHQP) < kui5@cdc.gov >; Zhang, Bicheng (Tony) (CDC/DDID/NCEZID/DHQP) (CTR)

<qsq2@cdc.gov>

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:crm4@cdc.gov">erm4@cdc.gov</a>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <a y v 6 @ cdc.gov >

Subject: FW: WHO GACVS sub-committee - request for information

Hi folks,

Please see below email chain. (b)(5) ?

Tom, (b)(5) (b)(5)

Thanks!

John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>

Sent: Wednesday, March 17, 2021 1:24 PM

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

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

**Subject:** RE: WHO GACVS sub-committee - request for information

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, March 17, 2021 12:26 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

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

Subject: RE: WHO GACVS sub-committee - request for information

	(b)(5)
(b)(5)	Thanks.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Sent: Wednesday, March 17, 2021 12:24 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a yo 6 @cdc.gov>

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

**Subject:** RE: WHO GACVS sub-committee - request for information

Tom,
John is out today.

Elaine

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, March 17, 2021 12:09 PM

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

**Cc:** Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> **Subject:** FW: WHO GACVS sub-committee - request for information

(b)(5)

Thanks.

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au>

Sent: Wednesday, March 17, 2021 3:47 AM

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

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) < rzh7@cdc.gov >; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <<a href="mailto:dvj3@cdc.gov">dvj3@cdc.gov">dvj3@cdc.gov</a>; Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) <<a href="mailto:jvjk3@cdc.gov">jvjk3@cdc.gov</a>; PAL, Shanthi Narayan <<a href="mailto:pals@who.int">pals@who.int</a>;

JANIN, Annick < janina@who.int>

Subject: Re: WHO GACVS sub-committee - request for information

#### Dear Tom

Thank you for your response. As you can imagine, the issue of thromboembolic events has taken priority since my earlier email about myocarditis/appendicitis. While the focus in Europe is on Astrazeneca, there is still interest from the sub-committee in any data you are able to share from the US on cerebral venous sinus thrombosis, thrombocytopaenia and thromboembolism. I appreciate this data may be confidential.

We are still interested in presenting information to the GACVS sub-committee on any background rates and O/E analyses you have conducted on myocarditis/appendicitis for the next or subsequent GACVS meeting.

If you would prefer to chat about this first, I am happy to set up a Teams meeting. Given the time difference, options might be 8 or 9am Atlanta time, potentially Thursday this week or Tuesday next week. I have cc'd the WHO team (Shanthi and Annick).

Rita, please do comment if you would like to add or clarify anything.

Many thanks again Anastasia

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

Sent: Wednesday, 17 March 2021 6:43 AM

To: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>; Conklin, Laura (CDC/DDPHSIS/CGH/GID) <dvj3@cdc.gov>;

Bennett, Sarah D. (CDC/DDPHSIS/CGH/GID) < iyk3@cdc.gov>

Subject: RE: WHO GACVS sub-committee - request for information

**CAUTION External Communication:** This email originated from outside of the organisation. Do not click links or open attachments unless you recognise the sender and know the content is safe.

Dear Anastasia,

I hope you are doing well and sorry for my delayed response. I'm happy to talk when convenient. I'm Cc'ing Laura Conklin and Sarah Bennett from our Global Immunization Division for awareness. Take care.

Regards,

Tom

## Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Phillips, Anastasia < Anastasia. Phillips@health.wa.gov.au >

Sent: Monday, March 8, 2021 10:05 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">ayv6@cdc.gov</a>

Cc: Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Alexis Pillsbury (SCHN)

<alexis.pillsbury@health.nsw.gov.au>

Subject: WHO GACVS sub-committee - request for information

**Dear Tom** 

Rita Helfand suggested that I contact you. I am writing on behalf of the GACVS COVID-19 sub-committee. The committee is considering reports of myocarditis and appendicitis following COVID-19 vaccines. I was wondering whether you have information on background rates and observed/expected analyses for these conditions that you might be able to share with the sub-committee? I noticed some preliminary results from the VSD concurrent comparator analysis in your ACIP presentation from 1 March.

The sub-committee is also interested in whether you have identified and/or examined any issues related to myocarditis or appendicitis during post-marketing surveillance in the US?

Many thanks

Anastasia

Dr Anastasia Phillips MBBS MPH FAFPHM

Public Health Physician – Immunisation, Metropolitan Communicable Disease Control, Western Australia

Public Health Physician, National Centre for Immunisation Research and Surveillance, Sydney, Australia (GACVS COVID-19 Subcommittee secretariat)

E: anastasia.phillips@health.wa.gov.au

Ph: +61 417 172 936

CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP)   Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss	Sent: Wed, 10 Mar 2021 14:45:02 +0000	
RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (D)(5)  Frank DeStefano, MD, MPH  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Sent: Wednesday, March 10, 2021 7:38 AM  For: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov> Subject: FW: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (D)(5)  This is for that joint FDA-CDC to the Israeli MOH. Please let me know if you have any thoughts. Thanks. From: Nair, Narayan <narayan.nair@fda.hhs.gov> Sent: Tuesday, March 9, 2021 9:10 AM  To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (D)(5)  Narayan  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (D)(5)  Narayan  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Sent: Sunday, February 28, 2021 3:366 PM  To: Anderson, Steven <steven.anderson@fda.hhs.gov>; Forshee, Richard  (Richard.Forshee@fda.hhs.gov): Nair, Narayan <ayrayan.nair@fda.hhs.gov> Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (D)(5)  OXAMINITARY TO CONTACT TO CONTACT TO CONTACT TO The Israeli National Focal Point to discuss  (D)(5)</ayrayan.nair@fda.hhs.gov></steven.anderson@fda.hhs.gov></ayv6@cdc.gov></ayv6@cdc.gov></ayv6@cdc.gov></narayan.nair@fda.hhs.gov></fxd1@cdc.gov></krb2@cdc.gov></ezu2@cdc.gov></ayv6@cdc.gov>	To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John	
the Israeli National Focal Point to discuss  (D)(5)  Frank DeStefano, MD, MPH  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Sent: Wednesday, March 10, 2021 7:38 AM  To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP)  kkrb2@cdc.gov&gt;; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov> Subject: FW: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (D)(6)  This is for that joint FDA-CDC to the Israeli MOH. Please let me know if you have any thoughts. Thanks. Tom  From: Nair, Narayan <a href="Narayan.Nair@fda.hhs.gov">Nair@fda.hhs.gov</a> Sent: Tuesday, March 9, 2021 9:10 AM  To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="qayv6@cdc.gov">qayv6@cdc.gov</a> Subject: RE: (EXTERNAL) FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (D)(5)  Narayan  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="qayv6@cdc.gov">qayv6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM  To: Anderson, Steven <a href="qayv6@cdc.gov">Stent: Sunday, February 28, 2021 3:06 PM Io: Anderson, Steven <a href="qayv6@cdc.gov">Stent: Sunday, February 28, 2021 3:06 PM Io: Anderson, Steven <a href="qayv6@cdc.gov">Stent: Sunday, February 28, 2021 3:06 PM Io: Anderson, Steven <a href="qayv6@cdc.gov">Stent: Sunday, February 28, 2021 3:06 PM Io: Anderson, Steven <a href="qayv6@cdc.gov">Stent: Sunday, February 28, 2021 3:06 PM Io: Anderson, Steven <a href="qayv6@cdc.gov">Stent: Sunday, February 28, 2021 3:06 PM Io: Anderson, Steven <a href="qayv6@cdc.gov">Stent: Sunday, February 28, 2021 3:06 PM Io: Anderson, Steven <a href="qayv6@cdc.gov">Steven <a href="qa&lt;/th&gt;&lt;th&gt;&lt;/th&gt;&lt;th&gt;&lt;/th&gt;&lt;/tr&gt;&lt;tr&gt;&lt;th&gt;From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) &lt;ayv6@cdc.gov&gt; Sent: Wednesday, March 10, 2021 7:38 AM To: Su, John (CDC/DDID/NCEZID/DHQP) &lt;ezu2@cdc.gov&gt;; Broder, Karen (CDC/DDID/NCEZID/DHQP) &lt;kr/&gt; skrb2@cdc.gov&gt;; Destefano, Frank (CDC/DDID/NCEZID/DHQP) &lt;fr/&gt; skrb2@cdc.gov&gt;; Destefano, Frank (CDC/DDID/NCEZID/DHQP) &lt;fractional focal point of Contact to the Israeli National Focal Point of discuss (0)(6)  This is for that joint FDA-CDC to the Israeli MOH. Please let me know if you have any thoughts. Thanks. Tom  From: Nair, Narayan &lt;a href=" narayan.nair@fda.hhs.gov"="">Narayan.Nair@fda.hhs.gov</a> Sent: Tuesday, March 9, 2021 9:10 AM To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (0)(6)  Hi Tom, Here are some draft responses to the Israeli Ministry of Health's inquiry. (0)(5)  Narayan  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Yavy6@cdc.gov">Navy6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM To: Anderson, Steven <a href="Y&lt;/th&gt;&lt;th&gt;-&lt;/th&gt;&lt;th&gt;nt of Contact to&lt;/th&gt;&lt;/tr&gt;&lt;tr&gt;&lt;th&gt;Frank DeStefano, MD, MPH  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) &lt;ayv6@cdc.gov&gt; Sent: Wednesday, March 10, 2021 7:38 AM  To: Su, John (CDC/DDID/NCEZID/DHQP) &lt;ezu2@cdc.gov&gt;; Broder, Karen (CDC/DDID/NCEZID/DHQP) \  kirb2@cdc.gov&gt;; Destefano, Frank (CDC/DDID/NCEZID/DHQP) &lt; kird1@cdc.gov&gt; Subject: FW: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (b)(6)  This is for that joint FDA-CDC to the Israeli MOH. 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Narayan  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a> a y &lt; 6 @ cdc.gov &gt; Sent: Sunday, February 28, 2021 3:06 PM  To: Anderson, Steven &lt; Steven.Anderson@fda.hhs.gov &gt;; Forshee, Richard <a> Richard.Forshee@fda.hhs.gov &gt;; Nair, Narayan <a> Narayan.Nair@fda.hhs.gov &gt; Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (b)(5)  CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless</a></a></a>	To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a 6="" @cdc.gov="" v="" y=""> Subject: RE: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to National Focal Point to discuss (b)(5)  Hi Tom,</a>	
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Narayan  From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov"&gt;ayv6@cdc.gov"&gt;ayv6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM  To: Anderson, Steven <a href="mailto:Steven.Anderson@fda.hhs.gov">ateven.Anderson@fda.hhs.gov</a> ; Forshee, Richard <a href="mailto:Richard.Forshee@fda.hhs.gov">ateven.Anderson@fda.hhs.gov</a> ; Nair, Narayan <a href="mailto:Narayan.Nair@fda.hhs.gov">Nair@fda.hhs.gov</a> Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (b)(5)  CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless	(bV5)	
From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov"&gt;ayv6@cdc.gov</a> Sent: Sunday, February 28, 2021 3:06 PM  To: Anderson, Steven <a href="mailto:Steven.Anderson@fda.hhs.gov">ayv6@cdc.gov</a> Forshee, Richard  Richard.Forshee@fda.hhs.gov; Nair, Narayan <a href="mailto:Narayan.Nair@fda.hhs.gov">Nair@fda.hhs.gov</a> Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss  (b)(5)  CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless	(O)(O)	
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To: Anderson, Steven < Steven.Anderson@fda.hhs.gov>; Forshee, Richard < Richard.Forshee@fda.hhs.gov>; Nair, Narayan < Narayan.Nair@fda.hhs.gov> Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (b)(5)  CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless	Trom: Shimabakaro, Tom (ebej bbib) Necezib) brian / sayvoe cac.gov	
<a href="mailto:kindedge-state-"><a href="mailto:kindedge-state-">Richard.Forshee@fda.hhs.gov</a>; Nair, Narayan &lt; <a href="mailto:kindedge-state-">Narayan.Nair@fda.hhs.gov</a></a> <a href="mailto:kindedge-state-">Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (b)(5)</a> <a href="mailto:kindedge-state-">CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless</a>	Sent: Sunday February 28, 2021 3:06 PM	
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Focal Point to discuss (b)(5)  CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless	To: Anderson, Steven < <a href="mailto:Steven.Anderson@fda.hhs.gov">Steven.Anderson@fda.hhs.gov</a> >; Forshee, Richard	
CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless	<b>To:</b> Anderson, Steven < Steven.Anderson@fda.hhs.gov >; Forshee, Richard < Richard.Forshee@fda.hhs.gov >; Nair, Narayan < Narayan.Nair@fda.hhs.gov >	lova oli Niskis v - L
	To: Anderson, Steven < <u>Steven.Anderson@fda.hhs.gov</u> >; Forshee, Richard < <u>Richard.Forshee@fda.hhs.gov</u> >; Nair, Narayan < <u>Narayan.Nair@fda.hhs.gov</u> > <b>Subject:</b> [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the	Israeli National
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you recognize the sender and know the content is safe.	To: Anderson, Steven < Steven.Anderson@fda.hhs.gov >; Forshee, Richard < Richard.Forshee@fda.hhs.gov >; Nair, Narayan < Narayan.Nair@fda.hhs.gov > Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Focal Point to discuss (b)(5)	energie in Casa de Arectorio de Audocumentales
	To: Anderson, Steven < Steven.Anderson@fda.hhs.gov >; Forshee, Richard < Richard.Forshee@fda.hhs.gov >; Nair, Narayan < Narayan.Nair@fda.hhs.gov > Subject: [EXTERNAL] FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Focal Point to discuss (b)(5)  CAUTION: This email originated from outside of the organization. Do not click links or open attack.	

Destefano, Frank (CDC/DDID/NCEZID/DHQP)

From:

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov>

Sent: Sunday, February 28, 2021 2:28 PM

To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < zmt0@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <avv6@cdc.gov> Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) <dpl9@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Beauvais, Denise (CDC/DDID/NCIRD/OD) <cry2@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy <eocevent417@cdc.gov>; McClure, Susan (CDC/DDPHSIS/CGH/OD) <zur1@cdc.gov> Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (b)(5)Seeing that Denise is out. + Susan Susan – can you please help coordinate? Thanks, -d From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) Sent: Sunday, February 28, 2021 2:26 PM To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < zmt0@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < dpl9@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Beauvais, Denise (CDC/DDID/NCIRD/OD) <cry2@cdc.gov>; CDC IMS 2019 NCOV Response VTF Policy < eocevent 417@cdc.gov > Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discus (b)(5) Thanks, Stacey. Denise – can you help set this up via policy? Best, David From: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < zmt0@cdc.gov> Sent: Sunday, February 28, 2021 1:35 PM To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < dpl9@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov> Subject: RE: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (b)(5)Thanks David. Do you want Tom and I to coordinate a call? This was sent to multiple units.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov >
Sent: Sunday, February 28, 2021 11:15 AM  To: Martin, Stacey (CDC/DDID/NCEZID/DVBD) < zmt0@cdc.gov>; Shimabukuro, Tom
(CDC/DDID/NCEZID/DHQP) <a 6="" @="" cdc.gov="" v="" y=""></a>
Cc: Lubar, Debra (CDC/DDID/NCEZID/OD) < dpl9@cdc.gov >; Fox, Kimberley (CDC/DDID/NCIRD/DBD)
< kaf6@cdc.gov>
Subject: FW: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (b)(5)
Importance: High
Stacey and Tom,
Please see below re discussing with Israeli Vaccine FP (b)(5)
Thanks, David
From: CDC IMS Task Tracker (CDC) < eoctasktracker@cdc.gov > Sent: Sunday, February 28, 2021 1:13 PM  To: CDC IMS 2019 NCOV Response VTF Vaccine Safety < eocevent416@cdc.gov >; CDC IMS 2019 NCOV Response VTF Policy < eocevent417@cdc.gov >; CDC IMS 2019 NCOV Response VTF Chief Medical Officer < eocevent516@cdc.gov >; CDC IMS 2019 NCOV Response VTF Operations < eocvtftask@cdc.gov > Cc: CDC IMS Task Tracker (CDC) < eoctasktracker@cdc.gov >; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < kaf6@cdc.gov >; Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov >; Lubar, Debra (CDC/DDID/NCEZID/OD) < dpl9@cdc.gov > Subject: Task ID: 42633 - HHS SOC RFI: Provide a Point of Contact to the Israeli National Focal Point to discuss (b)(5) Importance: High
Task ID: 42633
Suspense: 3/2/2021 17:00:00
Assigned To: CDC IMS 2019 NCOV Response VTF Chief Medical Officer, CDC IMS 2019 NCOV Response VTF Operations, CDC IMS 2019 NCOV Response VTF Policy, CDC IMS 2019 NCOV Response VTF Vaccine Safety
Requestor's Name: Dr. Roee Singer MD, MPH (b)(6)
Phone #: (b)(6)

E <del>-</del>	
Description: (b)(5)	
(b)(5)	

Please coordinate with the appropriate IMS Desk(s) and provide coordinated response to the requestor by the suspense. If clarification on the task is required, please contact the requestor. Reply back to this email noting that you have completed this task.

Please include the original task ID number in the email. The subject line should include Event Name, Task #, Team Name and "Open Task" or "Close Task".

From: Hamburger, Tanya (CDC/DDNID/NCCDPHP/DDT)

**Sent:** Thu, 17 Dec 2020 23:22:49 +0000

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP); McNeil, Michael

(CDC/DDID/NCEZID/DHQP); Gee, Julianne (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: telehealth and vaccine safety

## Thanks, Eric!

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

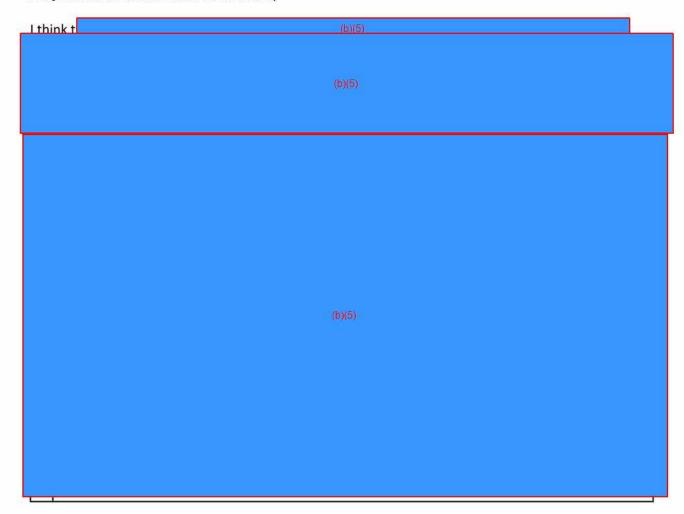
Sent: Thursday, December 17, 2020 5:52 PM

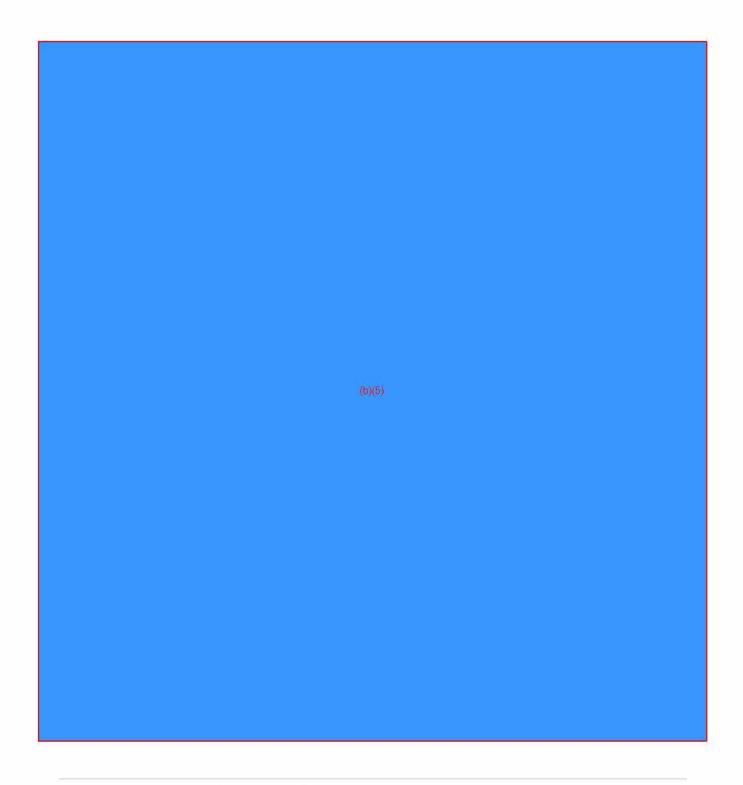
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>; Hamburger, Tanya

(CDC/DDNID/NCCDPHP/DDT) <dln7@cdc.gov>

Cc: Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) <lzd5@cdc.gov>; McNeil, Michael

(CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov> **Subject:** RE: telehealth and vaccine safety





From: Gee, Julianne (CDC/DDID/NCEZID/DHQP) < dzg2@cdc.gov>

Sent: Thursday, December 17, 2020 5:35 PM

To: Hamburger, Tanya (CDC/DDNID/NCCDPHP/DDT) < dln7@cdc.gov>

**Cc:** Duffy, Jonathan M. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:lzd5@cdc.gov">! McNeil, Michael">!zd5@cdc.gov</a>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) < <a href="mailto:mmm2@cdc.gov">!mmm2@cdc.gov</a>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

<eiw8@cdc.gov>

Subject: RE: telehealth and vaccine safety

Tanya,

I am connecting you with Jonathan, Mike, and EW. Maybe they can give you info.

Thanks, Julianne

From: Hamburger, Tanya (CDC/DDNID/NCCDPHP/DDT) <dln7@cdc.gov>

Sent: Thursday, December 17, 2020 5:02 PM

To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dzg2@cdc.gov">dzg2@cdc.gov</a>>

Subject: FW: telehealth and vaccine safety

She is on it...mentioned I would try to get it to her tonight. Want to tell me by phone what to relay?

From: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov>

Sent: Thursday, December 17, 2020 4:15 PM

**To:** Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">dbc0@cdc.gov">dbc0@cdc.gov</a>; Joshi, Cecilia (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">any9@cdc.gov</a>; Bell, Michael MD (CDC/DDID/NCEZID/DHQP) < <a href="mailto:zzb8@cdc.gov">zzb8@cdc.gov</a>>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov>; Hamburger, Tanya (CDC/DDNID/NCCDPHP/DDT) < dln7@cdc.gov>; Moran, Kerri (CDC/DDID/NCEZID/DHQP) < ytb5@cdc.gov>

Subject: RE: telehealth and vaccine safety

+Tanya Hamburger (b)(5)

Tanya is going to look into this further and may have more information later tonight or tomorrow. ~Nicole

From: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">dbc0@cdc.gov</a>>

Sent: Thursday, December 17, 2020 2:55 PM

To: Joshi, Cecilia (CDC/DDID/NCEZID/DHQP) <any9@cdc.gov>; Bell, Michael MD

(CDC/DDID/NCEZID/DHQP) < zzb8@cdc.gov>

Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <ndc3@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov>
Subject: RE: telehealth and vaccine safety

(b)(

Thanks, Denise.

From: Joshi, Cecilia (CDC/DDID/NCEZID/DHQP) <any9@cdc.gov>

Sent: Thursday, December 17, 2020 2:37 PM

To: Bell, Michael MD (CDC/DDID/NCEZID/DHQP) <zzb8@cdc.gov>; Cardo, Denise M. MD

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">dbc0@cdc.gov</a> Subject: telehealth and vaccine safety

Cecilia W. Joshi, Ph.D. LTC State Support & Coordination Unit | Infection Prevention and Control Team Health Systems and Worker Safety Task Force (HSWSTF) COVID-19 Response Centers for Disease Control and Prevention (CDC)

eocevent467@cdc.gov https://www.cdc.gov/COVID19

Associate Director for State Strategy, Division of Healthcare Quality Promotion & Director, State Strategy and Evaluation Team National Center for Emerging and Zoonotic Infectious Diseases Centers for Disease Control and Prevention Address: 1600 Clifton Road, Bldg 16, room 3143-B, Atlanta, Ga 30329 Phone: 404-639-7303 cjoshi@cdc.gov

I telework on Tuesdays and can be reached at 404-643-0177 (cell) or by email

From: Broder, Karen (CDC/DDID/NCEZID/DHQP)

Sent: Sat, 10 Apr 2021 22:34:18 +0000

Paulin, Heather N. (CDC/DDPHSIS/CGH/DGHT); McCormick, David To: (CDC/DDID/NCEZID/DVBD); Agyemang, Elfriede (CDC/DDPHSIS/CGH/DGHT); Beavers, Suzanne

(CDC/DDPHSS/CSELS/DSEPD); Byrd, Kathy K. (CDC/DDID/NCHHSTP/DHP)

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Destefano, Frank (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCEZID/DHQP); Nguyen, Duong T. (CDC/DDPHSS/NCHS/DHNES); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Gee, Julianne (CDC/DDID/NCEZID/DHQP); Museru, Oidda I. (CDC/DDID/NCEZID/DHQP); Cortese, Margaret (CDC/DDID/NCIRD/DVD); Rao, Agam K. (CDC/DDID/NCEZID/DHCPP); Lale, Allison

(CDC/DDID/NCEZID/DHQP); Sharma, Shashi (CDC/DDID/NCEZID/DHQP); Young, Mardia (CDC/DDID/NCEZID/DHQP) (CTR); Su, John (CDC/DDID/NCEZID/DHQP); McNeil, Michael

(CDC/DDID/NCEZID/DHQP)

Subject: Thank you departing March/April CISA deployers

## Dear Colleagues,

On behalf of the CISA Project COVID-19 Team/ Vaccine Safety Team/ VTF I am writing to thank you for your service on our team. You played a valuable role during a time of expanding COVID-19 vaccination and increasing complexity of CISA inquiries. Below are some specific achievements.

- David (EISO) –You helped us with multiple special projects, including helping us close out a high priority death case following ITP, review myocarditis, and respond to multiple requests for emergency consults.
- Heather Thanks for a third rotation with CISA! You served in one of the toughest roles on the team – Deputy CMO, responsible for managing the clinical staffing, 24/7 on-call operations (and staff morale) and partnerships. You helped us recruit talented officers and kept the service running. We can't wait to have you back for night float later in the month.
- Elfriede thanks for returning to CISA and jumping in during spring break to help with a staffing crunch and serving as Day supervisor. We are impressed how quickly you have learned the medical areas needed to supervise to these complicated inquiries. Thanks for volunteering for this role again in May!
- Suzanne (rotating off this week). Thanks for coming back for this deployment. I think you had the most diverse set up duties on the team, ranging from fielding inquiries, preparing consults and taking on Deputy CMO to manage operations and staffing, after Heather left. Your ER background is super useful.
- Kathy Bryd You served as an outstanding on-call clinician and responded to complex inquiries from all areas of medicine. You provided expertise in allergy that was very useful, and along with Margaret is the best on the team.

The pandemic work has been hard work, but working with you guys has been a bright spot. Theresa and I have been impressed by your work ethic and we have learned a great deal from you. You are part of the CISA family and we look forward to continued collaboration. We hope you get a break before your next deployment.

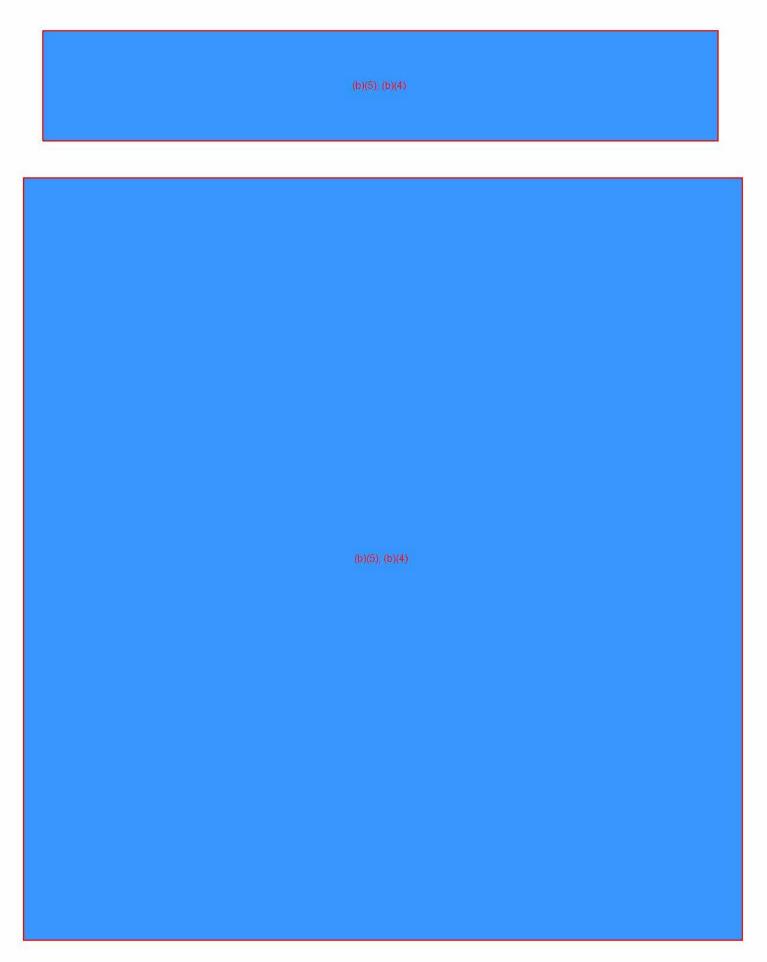
# Sincerely,

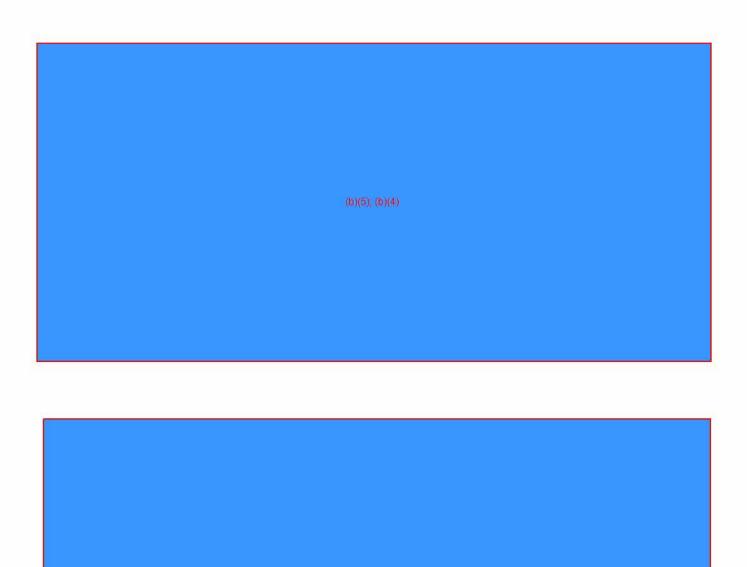
Karen R. Broder, MD
Captain, United States Public Health Service
Team Lead
Clinical Immunization Safety Assessment (CISA) Project
Immunization Safety Office
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Phone: 404-498-0632 Fax: 404-498-0666

email: Kbroder@cdc.gov

From:	Su, John (CDC/DDID/NCEZID/DHQP)				
Sent: To:	Fri, 30 Oct 2020 12:55:52 +0000 Vaccine				
Subject:	RE: Your Submission				
Good morning,					
	feedback! We will address the reviewers comments as soon as we can. (b)(5)				
(b)(5)	I just wanted to acknowledge your email and explain the delay in our ence in the interim is most appreciated.				
Stay healthy, ar	nd safe. Thanks!				
John					
Sent: Thursday, Octo	esmail.elsevier.com <eesserver@eesmail.elsevier.com> ober 15, 2020 11:03 PM DDID/NCEZID/DHQP) <ezu2@cdc.gov></ezu2@cdc.gov></eesserver@eesmail.elsevier.com>				
Ms. Ref. No.: JVAC	C-D-20-01671				
	(b)(5) (b)(4)				
	Annual Control				
Dear John,					
	(b)(5), (b)(4)				
-					
	(b)(5), (b)(4)				

(b)(5), (b)(	4)
Yours sincerely,  Robert T Chen, MD MA Associate Editor Vaccine or its open access mirror	
view the files	
Reviewers' comments:	
(b)(5), (b)(4)	





From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Sent:** Tue, 13 Apr 2021 17:04:53 +0000

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)

Subject: RE: Janssen - 4/13

(b)(5)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Tuesday, April 13, 2021 1:04 PM

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

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Subject: RE: Janssen - 4/13

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a you will be a second of the control of the cont

Sent: Tuesday, April 13, 2021 1:01 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

Subject: FW: Janssen - 4/13

(b)(5)

I'm in the office.

From: Woo, Jane < Jane. Woo@fda.hhs.gov>
Sent: Tuesday, April 13, 2021 12:59 PM

To: Mba-Jonas, Adamma (CBER) (FDA/CBER) < Adamma. Mba-Jonas@fda.hhs.gov >; Ahima, Ohenewaa

(FDA/CDER) < Ohenewaa. Ahima@fda.hhs.gov>; Alimchandani, Meghna (FDA/CBER)

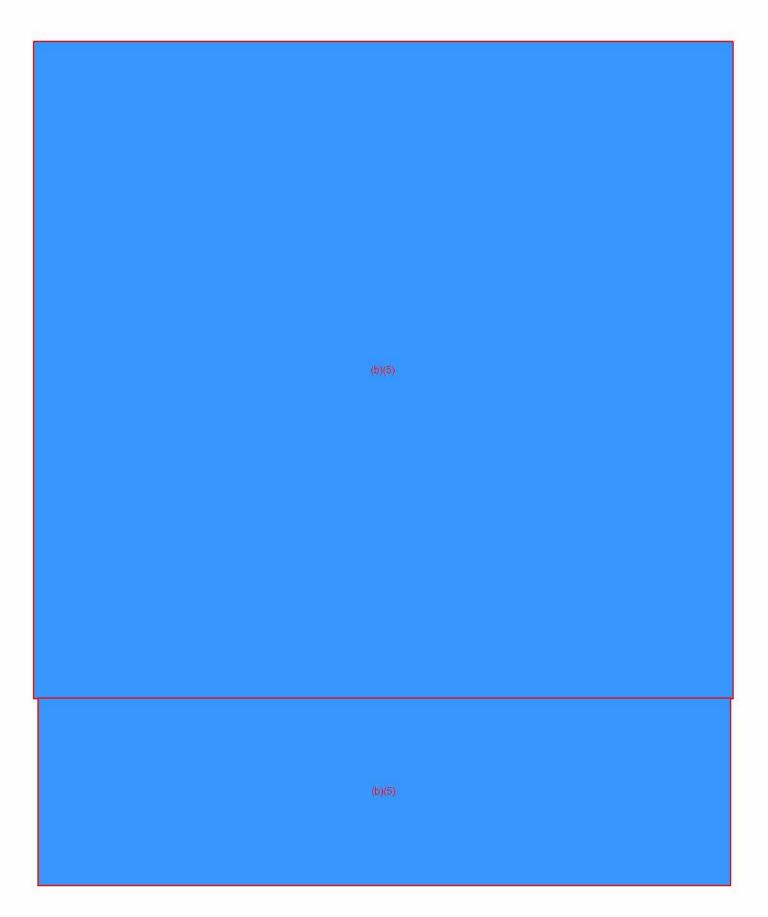
<<u>Meghna.Alimchandani@fda.hhs.gov</u>>; Nair, Narayan (FDA/CBER) <<u>Narayan.Nair@fda.hhs.gov</u>>; Su, John (CDC/DDID/NCEZID/DHQP) <<u>ezu2@cdc.gov</u>>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

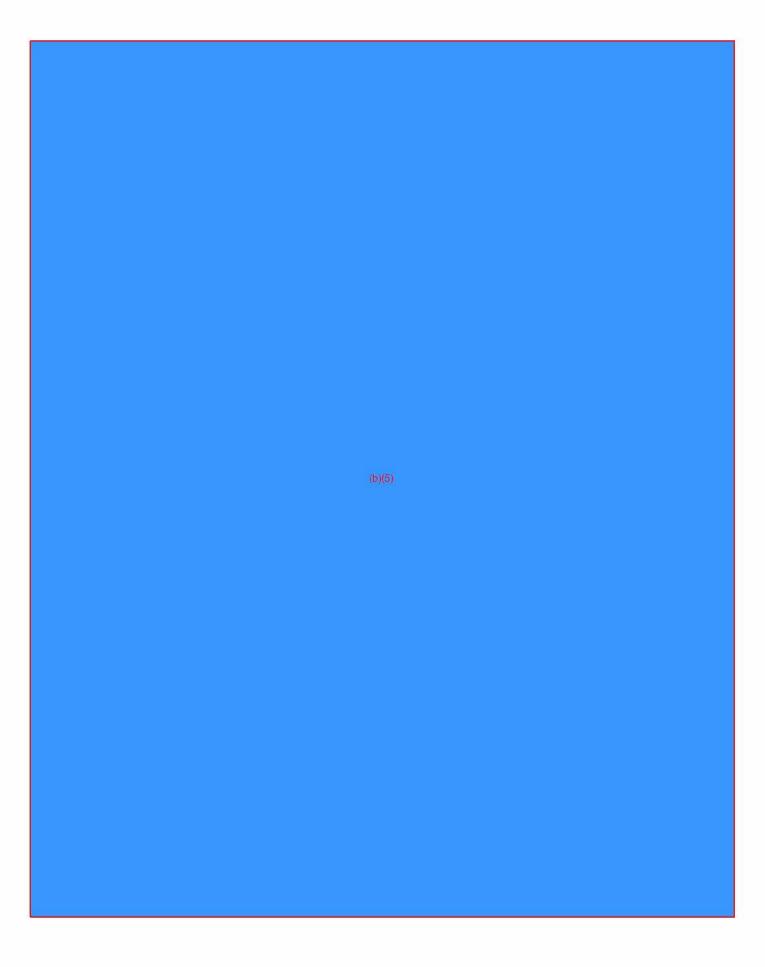
<avv6@cdc.gov>; Zinderman, Craig E (FDA/CBER) < Craig.Zinderman@fda.hhs.gov>

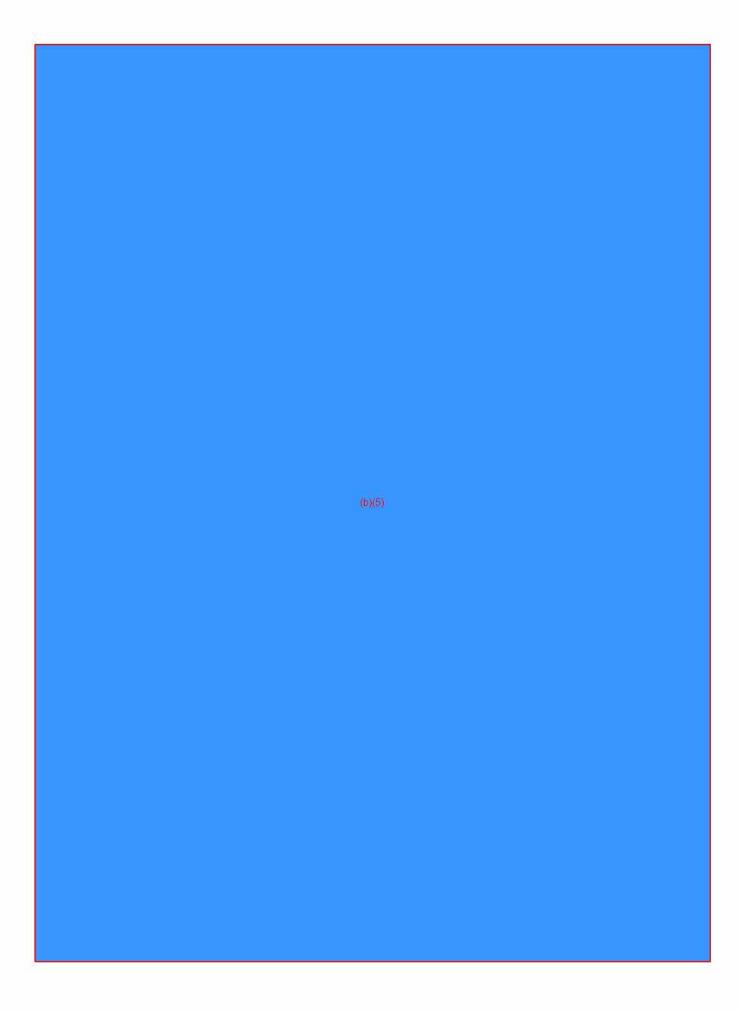
Subject: Janssen - 4/13

NB:

(b)(5)







From: Woo, Jane

**Sent:** Tue, 13 Apr 2021 17:46:34 +0000

To: Alimchandani, Meghna (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER);

Ahima, Ohenewaa (FDA/CDER); Nair, Narayan (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP);

Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Zinderman, Craig E (FDA/CBER)

Subject: RE: Janssen - 4/13



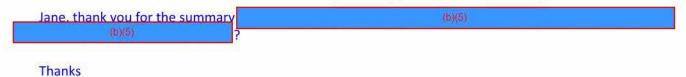
From: Alimchandani, Meghna < Meghna. Alimchandani@fda.hhs.gov>

Sent: Tuesday, April 13, 2021 1:03 PM

**To:** Woo, Jane <Jane.Woo@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Ahima, Ohenewaa <Ohenewaa.Ahima@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Su, John (CDC) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC)

<ayv6@cdc.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>

Subject: RE: Janssen - 4/13



From: Woo, Jane <<u>Jane.Woo@fda.hhs.gov</u>>
Sent: Tuesday, April 13, 2021 12:59 PM

To: Mba-Jonas, Adamma (CBER) < Adamma. Mba-Jonas@fda.hhs.gov >; Ahima, Ohenewaa

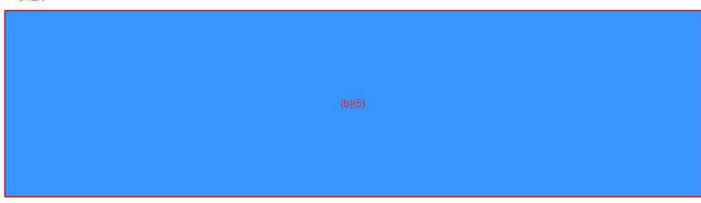
<<u>Ohenewaa.Ahima@fda.hhs.gov</u>>; Alimchandani, Meghna <<u>Meghna.Alimchandani@fda.hhs.gov</u>>; Nair, Narayan <<u>Narayan.Nair@fda.hhs.gov</u>>; Su, John (CDC) <<u>ezu2@cdc.gov</u>>; Shimabukuro, Tom (CDC)

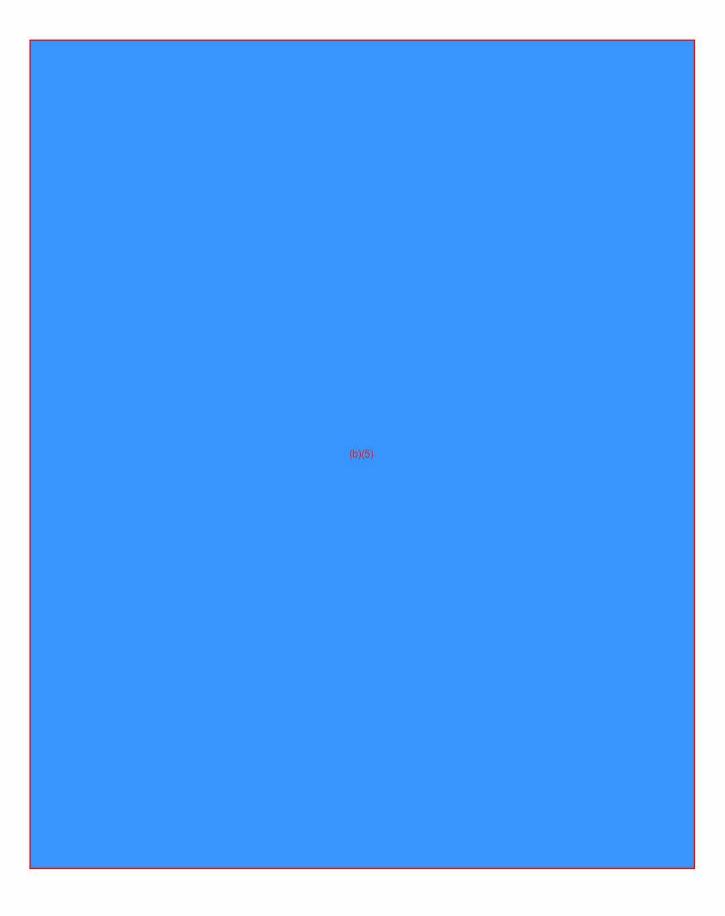
<avv6@cdc.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>

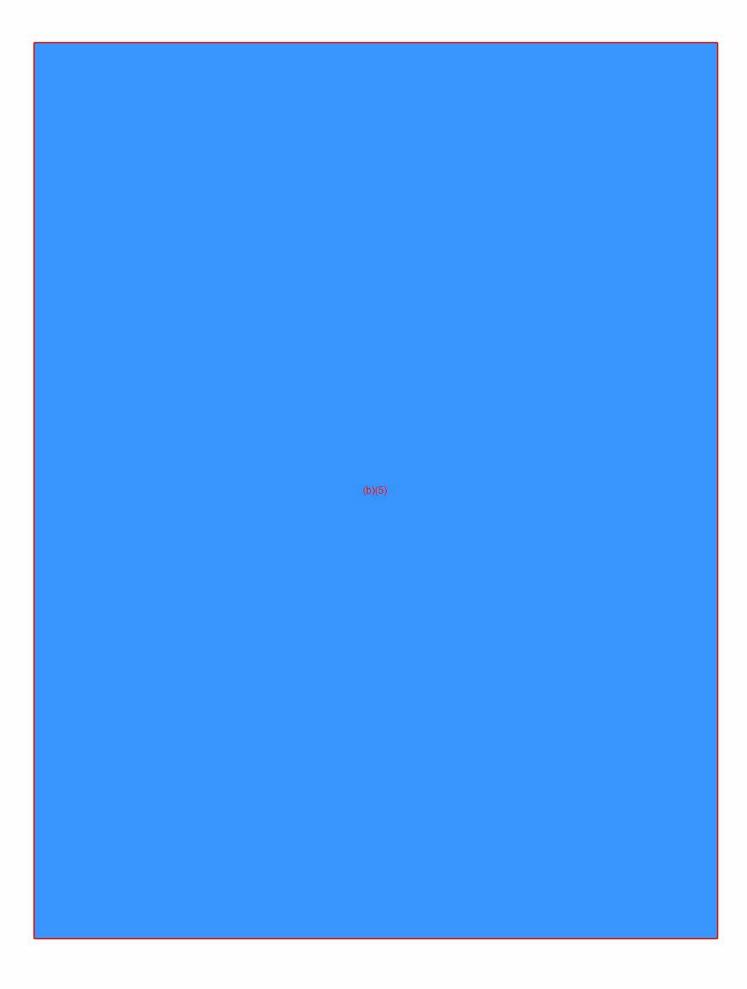
Subject: Janssen - 4/13

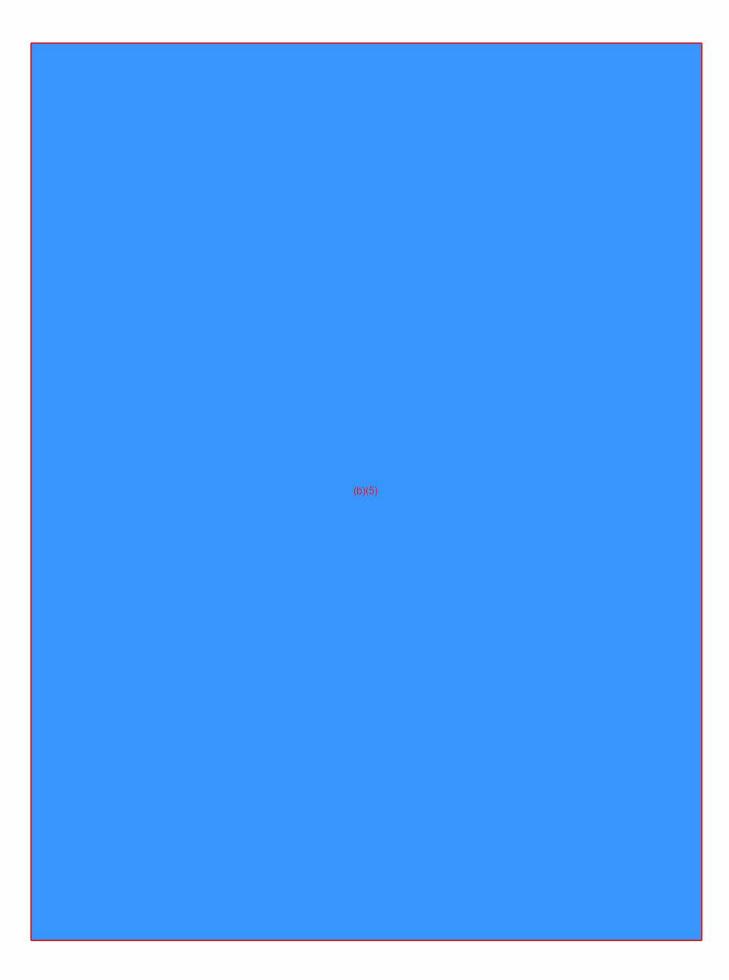
NB:

Meghna









From: COVID19VaxSafety

**Sent:** Tue, 27 Apr 2021 20:49:55 +0000

To:

Subject: RE: Reported Pfizer adverse event not appearing in VAERS

Dear (b)(6)

Thank you for contacting the CDC. We are very sorry to hear that you son developed myocarditis after his COVID vaccination and we hope that he fully recovers.

We did locate your son's report in VAERS. The permanent VAERS ID number is 1238456. The reason that the report is not in the VAERS public data is because the report must be processed before we can share it publicly. For example, we remove the patient name, address, birthday, hospital name, etc. in order to keep the patient identifying information confidential. Additionally due to the large number of reports that we are receiving at this time, processing is taking longer than usual.

Your son's report is included in the government data used to analyze the safety of the COVID-19 vaccine and will eventually be viewable in the VAERS public data site.

Please let us know if we can be of additional assistance.

Sincerely,

CDC Immunization Safety Office staff Atlanta, GA

From: (b)(6)

Sent: Tuesday, April 27, 2021 1:55 PM

To: CDC Wonder Customer Support <cwus@cdc.gov>; NIPINFO (CDC) <NIPINFO@cdc.gov>

Subject: Reported Pfizer adverse event not appearing in VAERS

Importance: High

I am writing because a filed report is not showing up in the VAERS system online. This is concerning to me given questions that are arising concerning heart problems associated with the Pfizer vaccine for covid.

My 16yo son was hospitalized with myopericarditis after receiving his first shot of the Pfizer BioN-Tech vaccination for covid-19. He was diagnosed with covid on Jan. 14. He complained of his heart pounding but had a normal EKG when seen by his pediatrician on March 31. He got the first Pfizer shot on Friday, April 16. On Sunday, April 18, he was admitted to the PICU at the

(b)(6) His troponin levels reached a high of 16.7 but it was successfully reduced with prednisone and other interventions. He was discharged on Thursday, April 22.

The hospital filed a report with VAERS on April 21 (I have a photo of the confirmation email), but all it listed was the Temporary VAERS E-Report Number. When I enter that number in VAERS, I get data for a 60yo man vaccinated in 2012.

I have requested the non-temporary report number from <a href="mailto:info@vaers.org">info@vaers.org</a> but I am wondering why <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:info@vaers.org">info@vaers.org</a> but I am wondering why <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:info@vaers.org">info@vaers.org</a> but I am wondering why <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:info@vaers.org">info@vaers.org</a> but I am wondering why <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:his-align: left) have requested to his-align: left

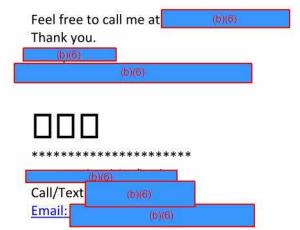
Specifically, when I do a data request, the following parameters yield 0 total events:

- •
- 10028650 (MYOPERICARDITIS)
- .
- 1200 (COVID19 (COVID19 (PFIZER-BIONTECH)))
- Hospitalized

When I change the symptom to "10028606 (MYOCARDITIS)" and keep the other two parameters the same, I get 22 events, but in the 6-17 age range there are zero events.

This is very distressing amid reports that "CDC, FDA see no Pfizer vaccine link to heart problem." <a href="https://www.newsobserver.com/news/coronavirus/article250965424.html">https://www.newsobserver.com/news/coronavirus/article250965424.html</a>

How are CDC and FDA able to monitor this situation if they don't have the information being submitted by hospitals?



From: Nair, Narayan

**Sent:** Tue, 13 Apr 2021 17:03:30 +0000

**To:** Woo, Jane (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER); Ahima, Ohenewaa (FDA/CDER); Alimchandani, Meghna (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP);

Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Zinderman, Craig E (FDA/CBER)

Subject: RE: Janssen - 4/13

Thanks Jane,

Tom/John - it looks like a seventh case of CVST - just double checking that for these cases there was

(5)

would be good to know if they had thrombocytopenia.

## Narayan

From: Woo, Jane <Jane.Woo@fda.hhs.gov> Sent: Tuesday, April 13, 2021 12:59 PM

To: Mba-Jonas, Adamma (CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Ahima, Ohenewaa <Ohenewaa.Ahima@fda.hhs.gov>; Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>; Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Su, John (CDC) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC)

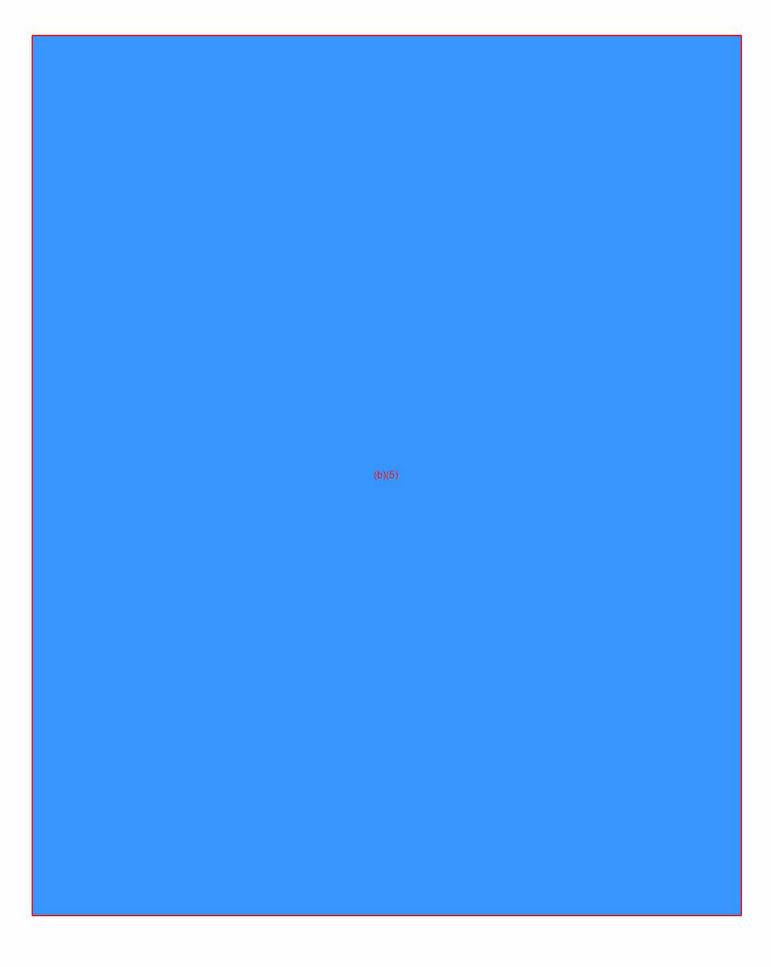
<ayv6@cdc.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>

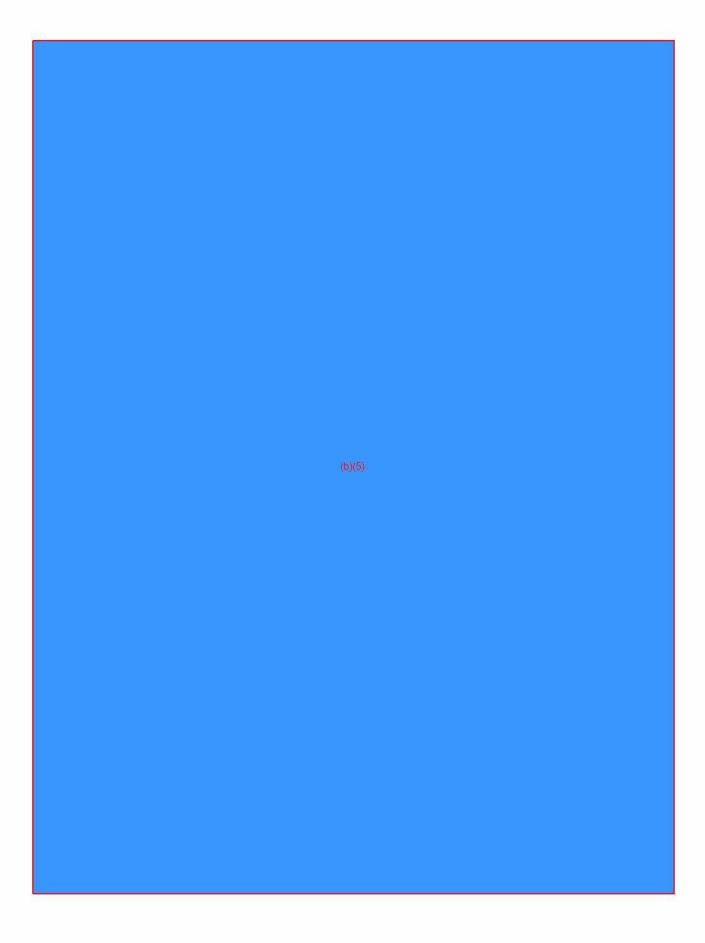
Subject: Janssen - 4/13

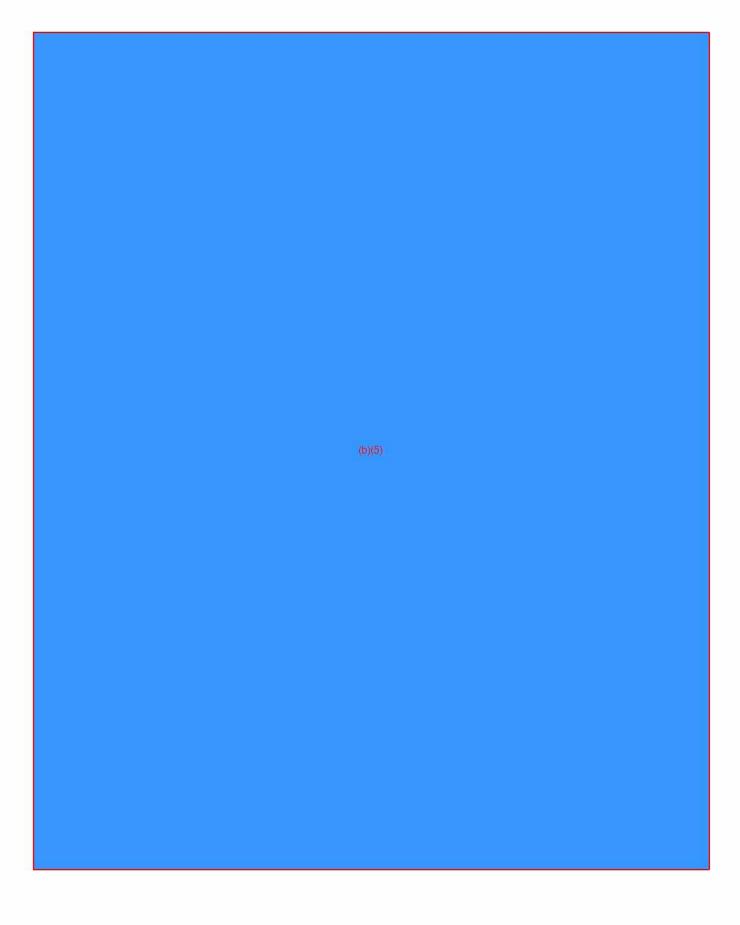
NB:

b)(5)

(b)(5)







From: Broder, Karen (CDC/DDID/NCEZID/DHQP)

**Sent:** Mon, 26 Apr 2021 16:04:17 +0000 **To:** Su, John (CDC/DDID/NCEZID/DHQP)

Cc: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES)

Subject: FW: question - confidential Attachments: CISA SBAR AB 4 24 2021.docx

(b)(5)

Karen

From: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES) <srl2@cdc.gov>

Sent: Monday, April 26, 2021 11:31 AM

To: Broder, Karen (CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov>; Nguyen, Duong T.

(CDC/DDPHSS/NCHS/DHNES) <ydi0@cdc.gov>

Subject: RE: question

Karen.

(b)(5)

Susan

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) < <a href="mailto:krb2@cdc.gov">krb2@cdc.gov</a>>

Sent: Monday, April 26, 2021 11:19 AM

To: Nguyen, Duong T. (CDC/DDPHSS/NCHS/DHNES) <ydi0@cdc.gov>; Lukacs, Susan

(CDC/DDPHSS/NCHS/DHNES) < sri2@cdc.gov>

Subject: question

(b)(5)

(b)(5)

(b)(5)

Karen

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Wed, 3 Mar 2021 19:05:50 +0000

To: Pettrone, Kristen (CDC/DDPHSS/NCHS/DVS); Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP)

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP)

Subject: RE: Add MI/Myocarditis abstraction: (b)(5)

Hi Kristen,

Let's wait for records. Thanks!

John

From: Pettrone, Kristen (CDC/DDPHSS/NCHS/DVS) <pho3@cdc.gov>

Sent: Wednesday, March 3, 2021 9:32 AM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) < ltd8@cdc.gov>

Subject: Add MI/Myocarditis abstraction (b)(5)

Hi all

(b)(5) ?

#### Kristen

## Kristen Pettrone, MD MPH

EIS Officer, Global Civil Registration and Vital Statistics Team Division of Vital Statistics National Center for Health Statistics Centers for Disease Control and Prevention 3311 Toledo Rd., MS P08 Hyattsville, MD 20782 (301) 458-4679 From: McCormick, David (CDC/DDID/NCEZID/DVBD)

**Sent:** Thu, 1 Apr 2021 17:53:43 +0000

To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP); Miller, Elaine R.

(CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: Can you please send VAERS definition of Serious to David?

Thanks Elaine and Theresa!		(b)(5)
	(b)(5)	
Best,		
David		
From: Harrington, Theresa	(CDC/DDID/NCEZID/DHQP) <	tsh3@cdc.gov>
Sent: Thursday, April 1, 202	1 11:53 AM	
To: Miller, Elaine R. (CDC/D <ezu2@cdc.gov></ezu2@cdc.gov>	DID/NCEZID/DHQP) <erm4@< td=""><td>ocdc.gov&gt;; Su, John (CDC/DDID/NCEZID/DHQP)</td></erm4@<>	ocdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)
그리 경에 가장 맛있다면 하다 보다 보고 그 사람이 되었다.	/DDID/NCEZID/DVBD) <yup1< td=""><td>@cdc.gov&gt;</td></yup1<>	@cdc.gov>
	rana varionima amena rana de la fina finalida a	
Subject: RE: Can you please	send VAERS definition of Se	
Subject: RE: Can you please	e send VAERS definition of Se	
Subject: RE: Can you please Hi Elaine,	e send VAERS definition of Se	3
tur far i fina ett i kan kantera eta kantera fak arrenda fike dikada eta eta bira iki bira ilikan ilikan ilika I	e send VAERS definition of Se	3
tur far i fina ett i kan kantera eta kantera fak arrenda fike dikada eta eta bira iki bira ilikan ilikan ilika I	e send VAERS definition of Se	3
Hi Elaine,	e send VAERS definition of Se	rious to David?
Hi Elaine, Thanks for the reply.		rious to David?
Hi Elaine, Thanks for the reply. David	(b)(	rious to David?
Hi Elaine, Thanks for the reply.	(b)(	rious to David?
Hi Elaine, Thanks for the reply. David Yes, Elaine,	(b)(5)	rious to David?
Hi Elaine, Thanks for the reply. David	(b)(5)	rious to David?
Hi Elaine, Thanks for the reply. David  Yes, Elaine, David, please update.	(b)(5)	rious to David?
Hi Elaine, Thanks for the reply. David Yes, Elaine,	(b)(5)	rious to David?
Hi Elaine, Thanks for the reply. David  Yes, Elaine, David, please update.	(b)(5)	rious to David?

Sent: Thursday, April 1, 2021 1:24 PM

To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) < tsh3@cdc.gov >; Su, John

(CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>

Cc: McCormick, David (CDC/DDID/NCEZID/DVBD) < <a href="mailto:yup1@cdc.gov">yup1@cdc.gov</a> Subject: RE: Can you please send VAERS definition of Serious to David?

Hi Theresa,

Please see responses in red below.

Thanks, Elaine From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) < tsh3@cdc.gov>

Sent: Thursday, April 1, 2021 1:15 PM

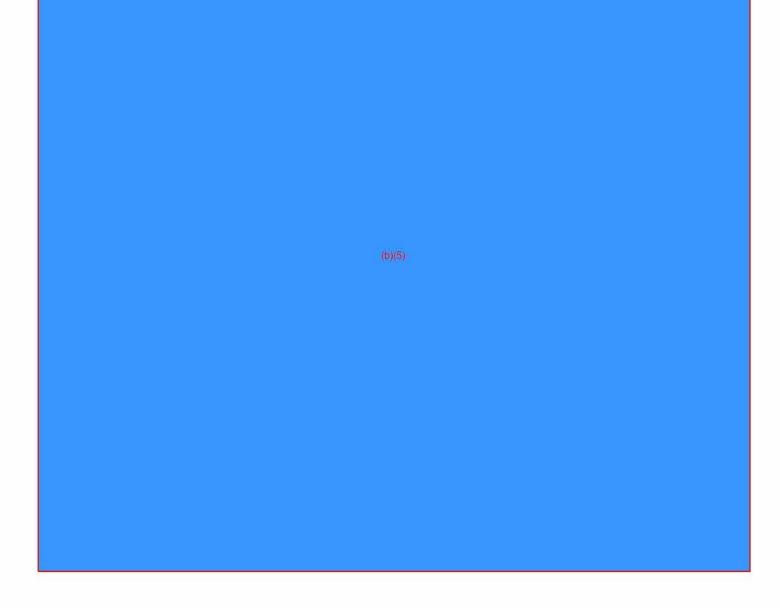
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

**Cc:** McCormick, David (CDC/DDID/NCEZID/DVBD) < yup1@cdc.gov > **Subject:** Can you please send VAERS definition of Serious to David?

Importance: High

Hi Elaine,



(b)(5)

# Thank you!

## Theresa

Theresa Harrington, MD, MPH&TM
CAPT, US Public Health Service
Medical Officer, Clinical Immunization Safety Assessment (CISA) Team
Immunization Safety Office, Division of Healthcare Quality Promotion (DHQP)
Centers for Disease Control and Prevention

office: 404-639-2877 cell: 404-751-6389

email: tharrington@cdc.gov

Subject:	RE: RCA outcomes w/ low platelet counts	
	(b)(5)	
	(b)(5)	
	(b)(5)	
	(b)(5)	

Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

Wed, 28 Apr 2021 19:53:39 +0000

**Ned Lewis** 

From:

Sent: To: (b)(5)

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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Sat, 3 Apr 2021 22:48:20 +0000

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: Re: VSD methods advantages/limitations for vast call

# Sounds good.

Sent: Saturday, April 3, 2021 4:29:57 PM

**To:** Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov> **Subject:** RE: VSD methods advantages/limitations for vast call

Thanks. Due to time constraints I will be providing the slides as read only and Fran and I will verbally

update VaST, but I'll be briefing off these slides. (b)(5)

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

Sent: Saturday, April 3, 2021 8:36 AM

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

Subject: VSD methods advantages/limitations for vast call

(b)(5) (b)(5)

(b)(5)

(b)(5)

Page 900			
(b)(5)			
TATAL			



Page 902			
(b)(5)			
1707C			

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Sent: Wed, 21 Apr 2021 14:56:05 +0000

To: Carter, Kris (CDC dhw.idaho.gov)

Cc: Jeff.Kingsbury@dhw.idaho.gov

Subject: RE: Question re VAERS Reports Rec'd

Dear Kris.

Thanks for your email.

I did not find either of these reports in VAERS yet, but due to processing delays, VAERS may have received them but not processed them yet.

To date, CDC vaccine safety monitoring systems have not found evidence of a concerning pattern of reports of myocarditis after COVID-19 vaccination.

Best, Elaine

From: Carter, Kris K. < <a href="mailto:Kris.Carter@dhw.idaho.gov">Kris.Carter@dhw.idaho.gov</a>>

Sent: Tuesday, April 20, 2021 7:19 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a>>

Cc: Kingsbury, Jeff < Jeff.Kingsbury@dhw.idaho.gov>

Subject: Question re VAERS Reports Rec'd

Hello, Elaine -

Can you tell us if CDC has received any VAERS reports from Idaho regarding:

- 2<sup>nd</sup> Pfizer COVID-19 vaccine dose administered 4/2, ED visit (b)(6)
   ID on 4/4, myocarditis, female in her twenties
- 2<sup>nd</sup> Pfizer COVID-19 vaccine dose administered 3 days before 4/11 ED visit to (b)(6)

  ID, myocarditis, female in her fifties

If you have not, we will follow up with the provider to stimulate reporting.

Are you seeing any VAERS signals around second dose Pfizer and myocarditis? This is our third.

Thank you for your help,

Kris

Kris K. Carter, DVM, MPVM, DACVPM CAPT, USPHS; Career Epidemiology Field Officer, CDC Epidemiology Program and Immunization Program

Bureau of Communicable Disease Prevention

Division of Public Health

Idaho Department of Health and Welfare

Desk Number: (208)334-5939 Fax Number: (208)332-7307

Kris.Carter@dhw.idaho.gov



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 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Wed, 16 Dec 2020 13:15:16 +0000

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Subject: Re: Table 2 Condition Updates- please advise

## Hi Paige,

Excorcising CITGO demons again — will address your above comments when I'm online.

(b)(5)

(b)(5) Thanks!

— 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)

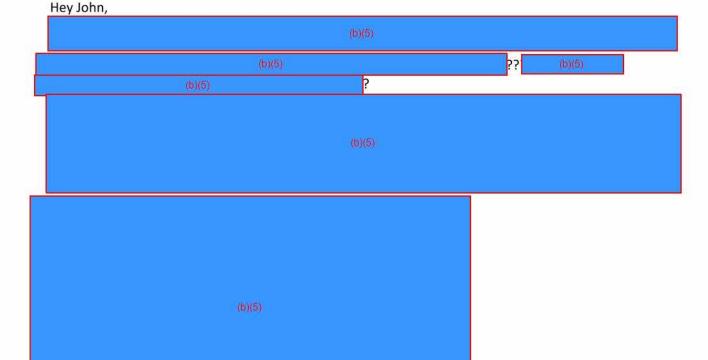
(404) 498-0666 (fax)

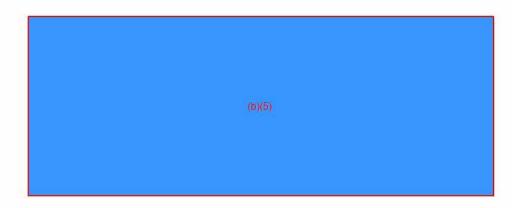
From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Wednesday, December 16, 2020 7:51:49 AM

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

Subject: Table 2 Condition Updates- please advise





 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Sun, 18 Apr 2021 14:39:39 +0000

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP)

**Subject:** Re: To be sure you are aware

## Hi Elaine,

Thanks for the info! I (b)(5)

— 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: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Sunday, April 18, 2021 10:32:55 AM

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

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Subject: RE: To be sure you are aware

Tom, John:



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

Sent: Saturday, April 17, 2021 10:09 PM

To: Meissner, Cody <cmeissner@tuftsmedicalcenter.org>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Cc: dbalaguru@mgh.harvard.edu
Subject: RE: To be sure you are aware

Hi Cody,

Good to hear from you and I hope you are doing well. There have been reports of myocarditis following mRNA vaccines (b)(5)

I'm including John Su,

VAERS team lead, for his awareness. Take care.

Regards,

From: Meissner, Cody < cmeissner@tuftsmedicalcenter.org>

Sent: Thursday, April 15, 2021 2:21 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

Cc: dbalaguru@mgh.harvard.edu
Subject: To be sure you are aware

Tom

(b)(5); (b)(6)

Writing to be sure you are aware and to ask if myocarditis has been reported in other vaccinees? Great presentation to ACIP yesterday,

Regards,

Cody

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Tufts Medical Center HIPAA Hotline at (617) 636-4422. If the e-mail was sent to you in error but does not contain patient information, contact the sender and properly dispose of the e-mail.

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From:	Su, John (CDC/DDID/NCEZID/DHQP)		
Sent:	Mon, 30 Nov 2020 14:54:01 +0000		
To: Welsh, Kerry			
Subject:	RE: Your Submission		
ні к	erry,		
Tha water, and g	nks for letting me know! I bet things are getting busy at FDA. :P Keep your head above ood luck!		
• J	ohn		
	, Kerry <kerry.welsh@fda.hhs.gov></kerry.welsh@fda.hhs.gov>		
	(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov></ezu2@cdc.gov>		
	Your Submission		
# 1 - Lander on the - The Property Colonic Section (1887) (1887). The section (1887)			
Hi John,			
11222272792	also dei accordi 18/a boso bassociab aba ELIA acastica acida		
ACTION AND ACTION AND ACTION AND ACTIONS	also doing well. It's busy here with the EUAs getting going. (b)(5) Thanks for putting all of this together!		
(0)(0)	Haliks for putting an of this together:		
Best,			
Kerry			
From: Su, Joh	nn (CDC/DDID/NCEZID/DHQP) < <u>ezu2@cdc.gov</u> >		
	y, November 24, 2020 6:49 PM		
	Michael M (CDC) < mmm2@cdc.gov>; Welsh, Kerry < Kerry.Welsh@fda.hhs.gov>; Marquez,		
Paige L (CDC)	(b)(6)     M Cano       (b)(6)     ming yan		
Subject: FW:	(b)(6) M Cano (b)(6) Your Submission		
Subject: 1 vv.	Todi Sabilission		
Hi fo	olks,		
I hope you're staying healthy and safe during these strange times!			
1110	pe you re staying healthy and sale during these straffge times:		
	(b)(5)		
	(6)(6)		

-- John

Thanks for your hard work!

-----Original Message-----

From: <u>eesserver@eesmail.elsevier.com</u> <<u>eesserver@eesmail.elsevier.com</u>>

Sent: Thursday, October 15, 2020 11:03 PM

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

**Subject: Your Submission** 

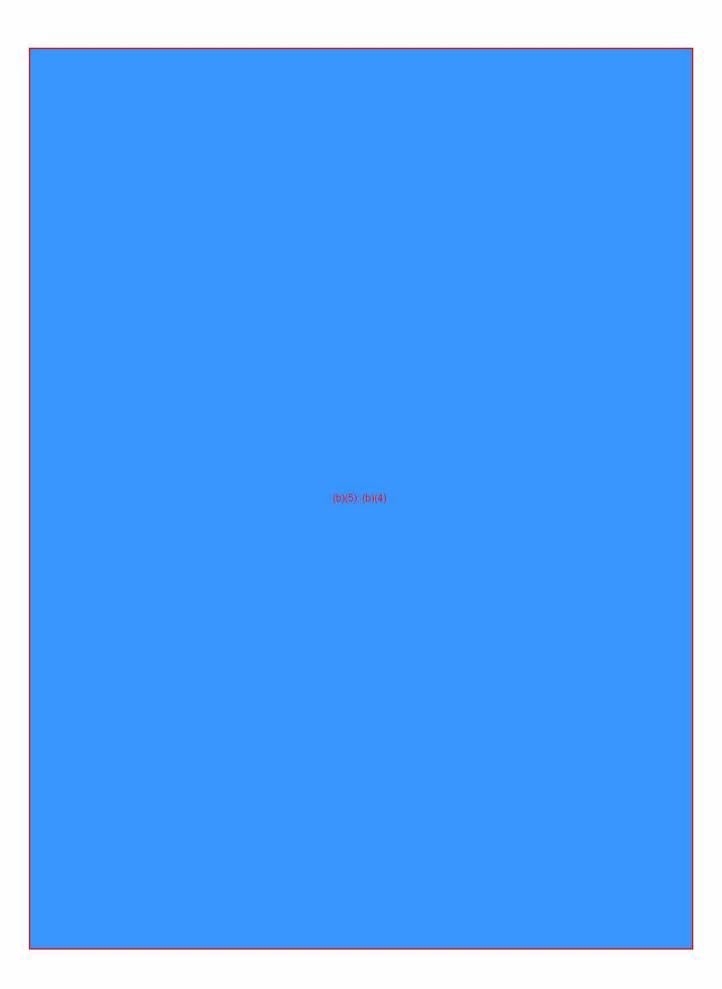
Ms. Ref. No.: JVAC-D-20-01671

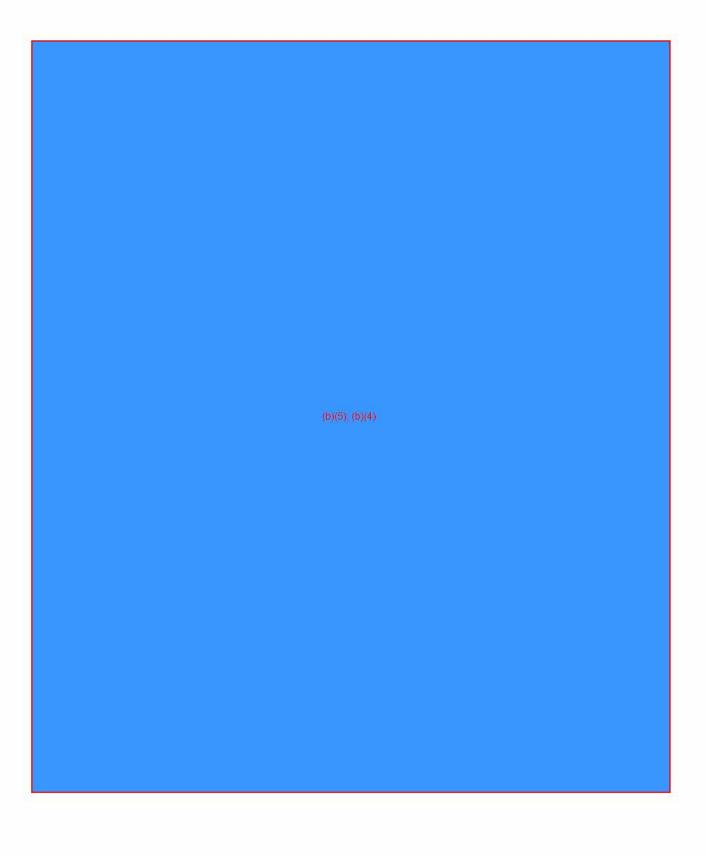
(b)(5)
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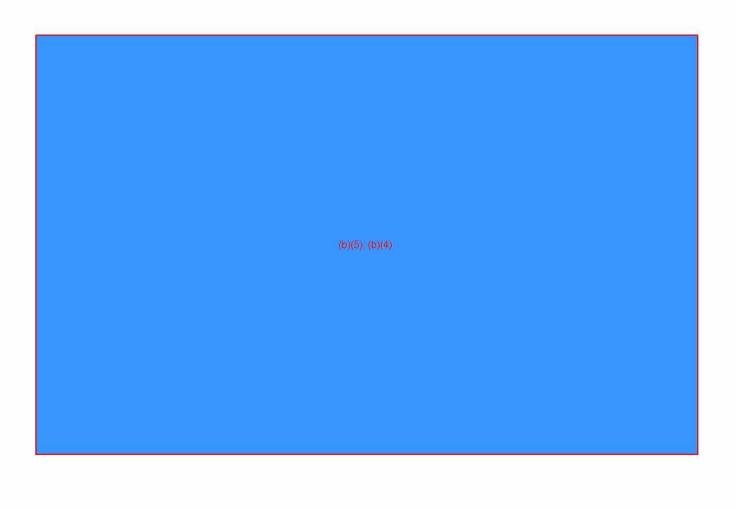
Dear John,

-	
	(b)(5), (b)(4)
300 × 1	
Yours sincerely,	
Robert T Chen, MD MA	
Associate Editor	
Vaccine or its open access mirror	
view the files	

Reviewers' comments:







Sent:	Sun, 18 Apr 2021 11:51:51 +0000
To: Cc:	Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) Su, John (CDC/DDID/NCEZID/DHQP); Miller, Elaine R.
	IQP); dbalaguru@mgh.harvard.edu
Subject:	Re: [EXT] RE: To be sure you are aware
,	
Thanks for your reply	
Everyone is so appreceduring these unpreceduring	ciative of the exemplary leadership you and your colleagues are providing
Remember to save so	
Best regards	ine time for yourself
Cody	
Sent from my iPhone	
On Apr 17 2021 at 1	0:08 PM, Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
<ayv6@cdc.gov> wro</ayv6@cdc.gov>	도보고 생각 보고 있다. 전에 보고 있는데 이번에 되었다면 보고 있는데 되었다면 보고 있는데 되었다면 되었다면 되었다면 보고 있는데 되었다면 보고 있는데 보고 있는데 보고 있는데 보고 있는데
EXTERNAL MESSAGE -	TREAT LINKS/FILES WITH CARE
Hi Cody,	
Til Cody,	
	and I hope you are doing well. There have been reports of myocarditis following
mRNA vaccines,	(b)(5) I'm including John Su,
VAERS team lead, for n	is awareness. Take care.
Regards,	
Tom	
From: Meissner, Cody <	<pre><cmeissner@tuftsmedicalcenter.org></cmeissner@tuftsmedicalcenter.org></pre>
Sent: Thursday, April 15	
	(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov></ayv6@cdc.gov>
Cc: dbalaguru@mgh.ha Subject: To be sure you	
Subject. To be sure you	Tale aware
Tom	
	(b)(5). (b)(6)

Meissner, Cody

From:

Writing to be sure you are aware and to ask if myocarditis has been reported in other vaccinees? Great presentation to ACIP yesterday, Regards, Cody

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Tufts Medical Center HIPAA Hotline at (617) 636-4422. If the e-mail was sent to you in error but does not contain patient information, contact the sender and properly dispose of the e-mail.

Please consider the environment and the security of the information contained within or attached to this e-mail before printing or saving to an insecure location.

The information in this e-mail is intended only for the person to whom it is addressed. If you believe this e-mail was sent to you in error and the e-mail contains patient information, please contact the Tufts Medical Center HIPAA Hotline at (617) 636-4422. If the e-mail was sent to you in error but does not contain patient information, contact the sender and properly dispose of the e-mail.

Please consider the environment and the security of the information contained within or attached to this e-mail before printing or saving to an insecure location.

Su, John (CDC/DDID/NCEZID/DHQP) From: Sent: Fri, 16 Oct 2020 15:14:03 +0000 McNeil, Michael (CDC/DDID/NCEZID/DHQP); Welsh, Kerry (FDA/CBER); To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Carmen Ng; ming yan; M Cano Subject: **RE: Your Submission** Sure will, Mike. Thanks! John From: McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov> Sent: Friday, October 16, 2020 11:00 AM To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Carmen Ng M Cano ming yan Subject: RE: Your Submission Hi John, Good news! Please let us know if we can assist in any way? Thanks, Mike From: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov> Sent: Friday, October 16, 2020 10:40 AM To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <a href="mmn2@cdc.gov">mmn2@cdc.gov</a>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Carmen Ng ming yan M Cano Subject: FW: Your Submission Hi folks, I hope you're staying safe and well! Thanks, and Happy Friday, all! -- John ----Original Message-----From: eesserver@eesmail.elsevier.com <eesserver@eesmail.elsevier.com>

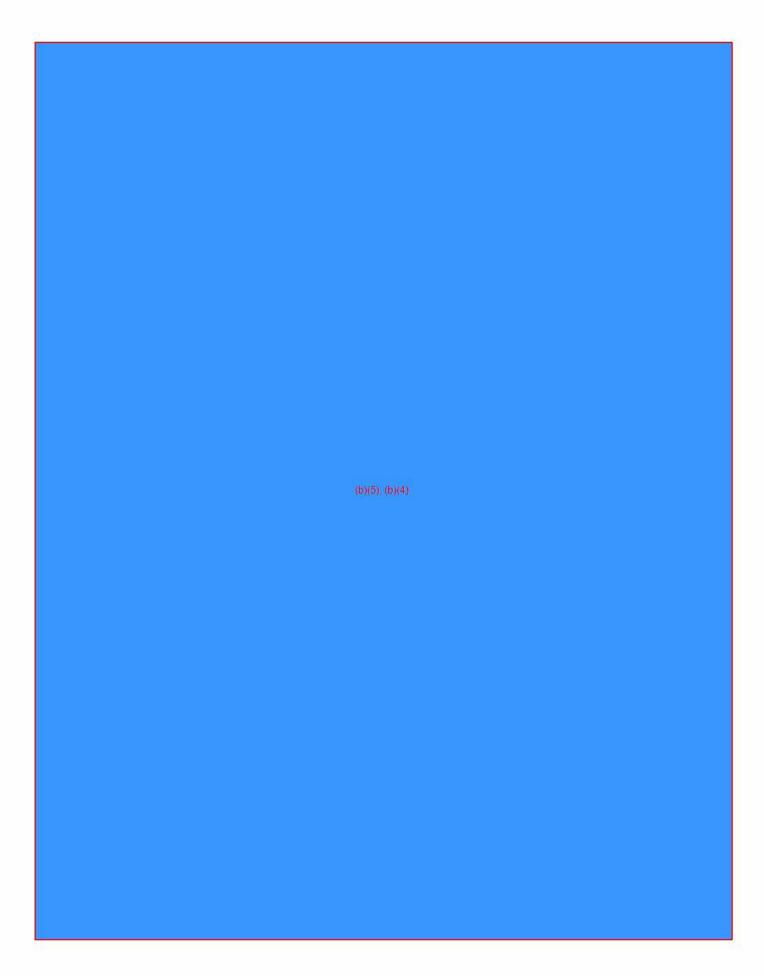
Sent: Thursday, October 15, 2020 11:03 PM

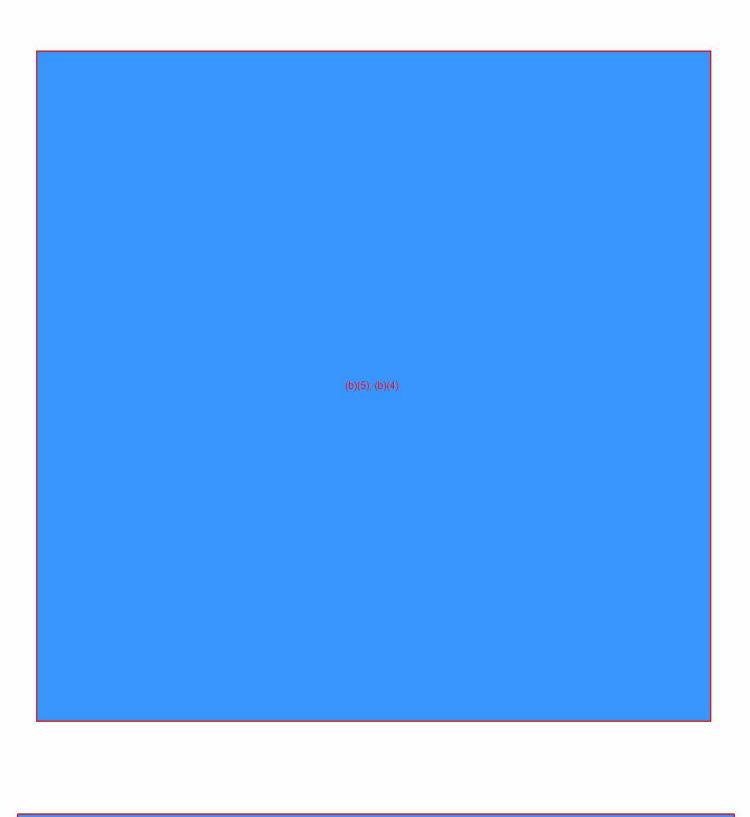
Ms. Ref. No.: JVAC-D-20-01671 Title: (b)(5); (b)(4) Dear John, (b)(5); (b)(4)

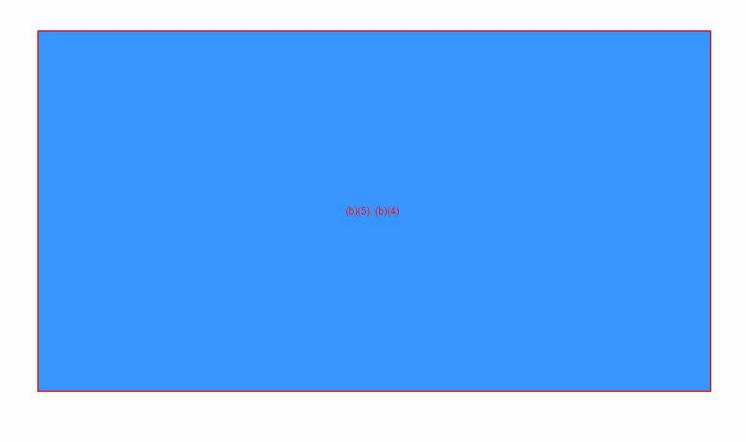
To: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>

Subject: Your Submission

	(b)(5), (b)(4)
Yours sincerely,	
Robert T Chen, MD MA Associate Editor Vaccine or its open access mirror	
view the files	
Reviewers' comments:	
	(b)(5), (b)(4)







 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Fri, 16 Oct 2020 21:22:43 +0000

To: ming yan

Subject: RE: FW: Your Submission

Thanks, Ming! I hope you're doing well.

John

From: ming yan

Sent: Friday, October 16, 2020 5:07 PM

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

Subject: Re: FW: Your Submission

Congrats John! Thanks for your hard work!

On Fri, Oct 16, 2020 at 10:39 Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov > wrote:

Hi folks,

I hope you're staying safe and well!

(b)(5)

Thanks, and Happy Friday, all!

-- John

----Original Message----

From: eesserver@eesmail.elsevier.com <eesserver@eesmail.elsevier.com>

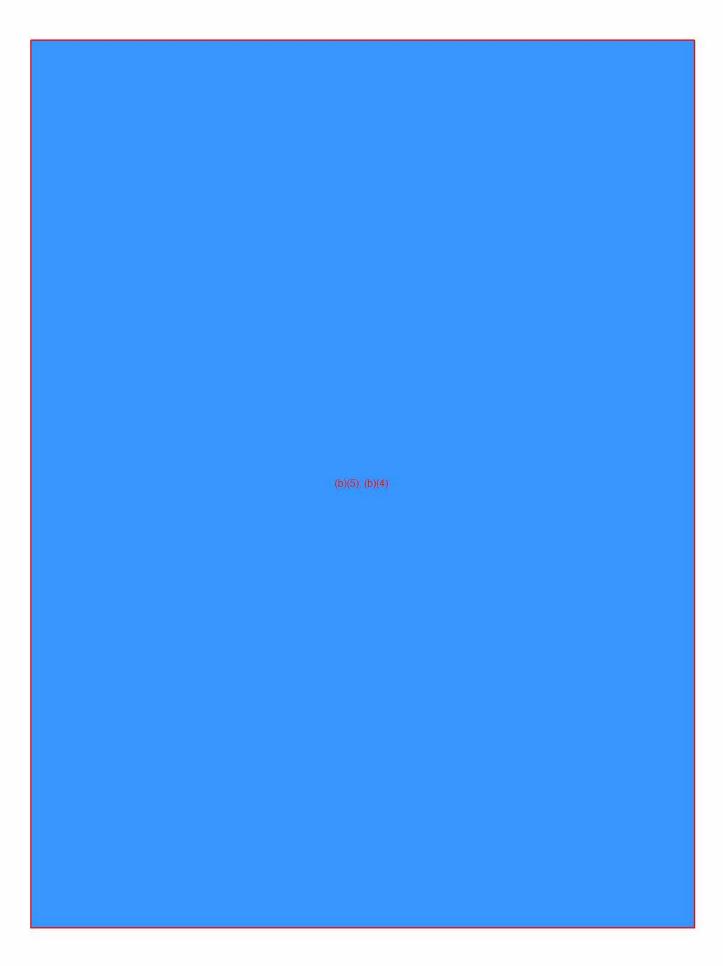
Sent: Thursday, October 15, 2020 11:03 PM

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

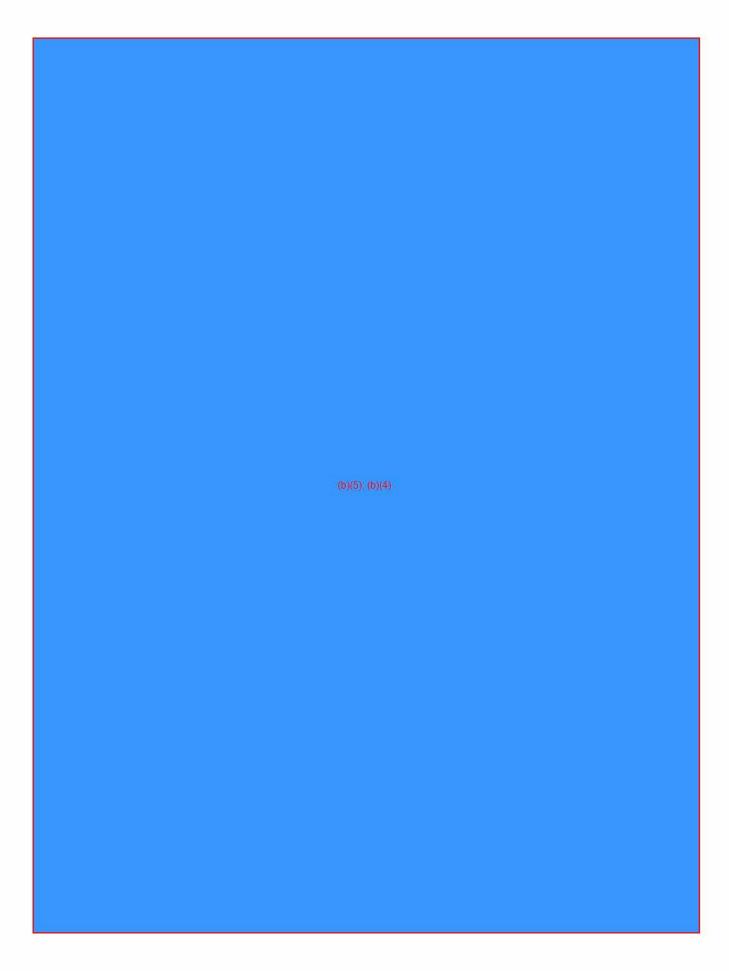
Subject: Your Submission

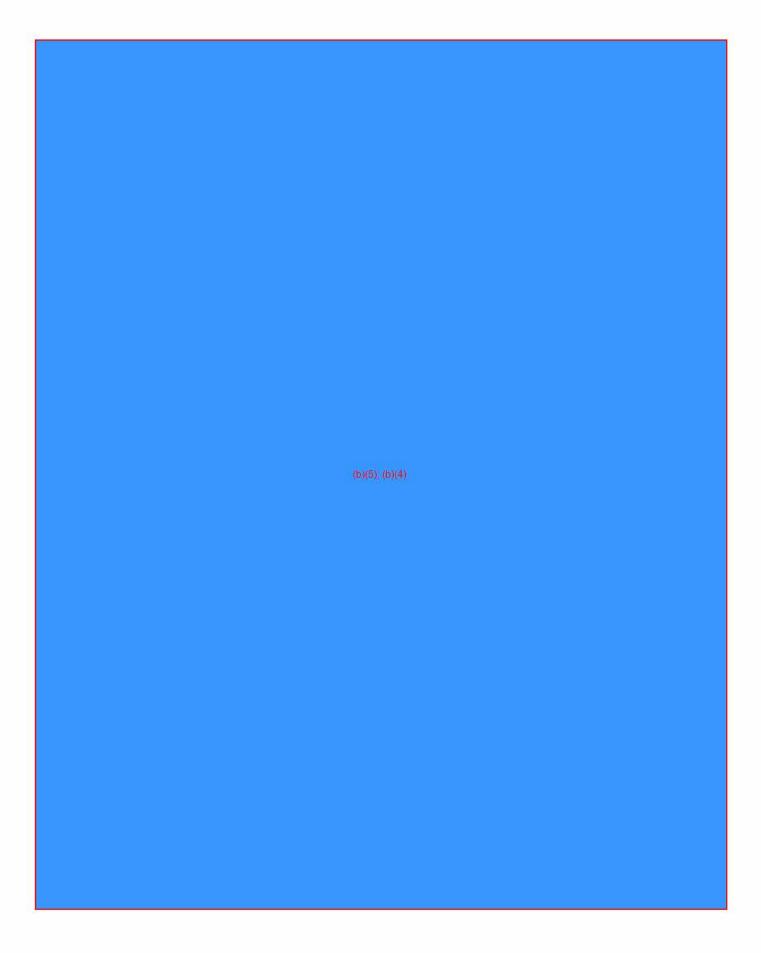
Ms. Ref. No.: JVAC-D-20-01671

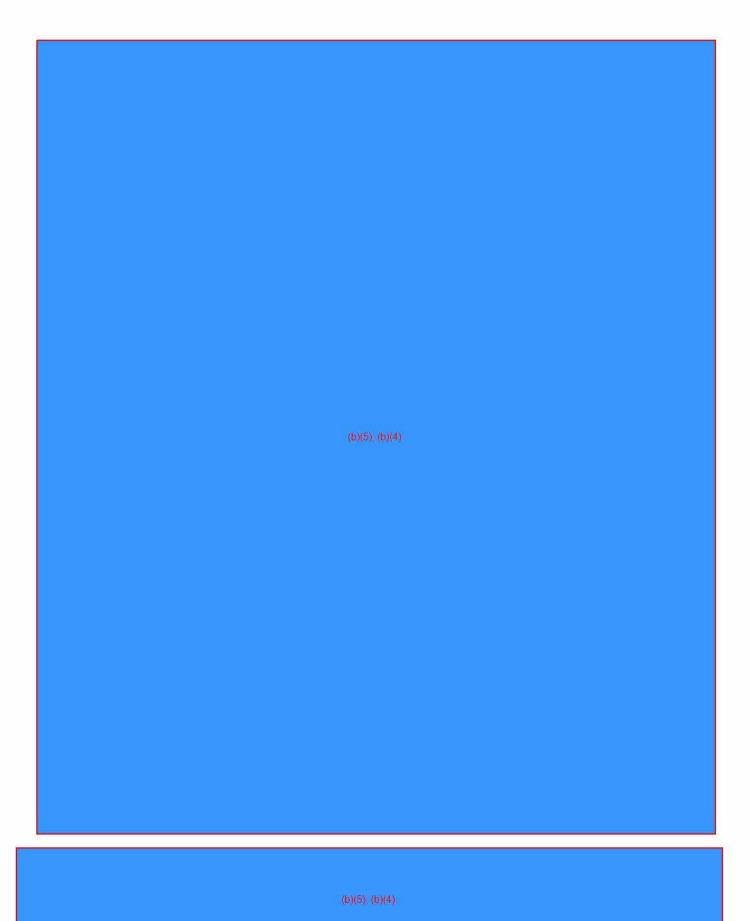
Title	(b)(5), (b)(4)
(b)(5), (b)(4)	- 2
Special Control (March March M	I
E	
Dear John,	
2	
	(b)(5), (b)(4)



Yours sincerely,	
Robert T Chen, MD MA	
Associate Editor	
Vaccine or its open access mirror	
view the files	
Reviewers' comments:	
	(b)(5), (b)(4)







From: Hopkins jr., Robert H

**Sent:** Wed, 14 Apr 2021 12:41:45 +0000

To: 'Lee, Grace'; Markowitz, Lauri (CDC/DDID/NCIRD/DVD); Wharton, Melinda

(CDC/DDID/NCIRD/ISD)

Subject: RE: DoD and myocarditis

(b)(5)

From: Lee, Grace [mailto:GMLee@stanfordchildrens.org]

Sent: Tuesday, April 13, 2021 6:48 PM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>; Wharton, Melinda

(CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Hopkins jr., Robert H <HopkinsRobertH@uams.edu>

Subject: Re: DoD and myocarditis

Okay – (b)(5)

(b)(5)

Thank you Grace

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Date: Tuesday, April 13, 2021 at 3:16 PM

**To:** Wharton, Melinda (CDC/DDID/NCIRD/ISD) < <a href="mailto:mew2@cdc.gov">mew2@cdc.gov</a>, Lee, Grace < <a href="mailto:GMLee@stanfordchildrens.org">GMLee@stanfordchildrens.org</a>, Hopkins, Bob < <a href="mailto:HopkinsRobertH@uams.edu">HopkinsRobertH@uams.edu</a>>

Subject: DoD and myocarditis

Warning: This email originated from outside of Stanford Medicine. Do not open attachments or click on links unless you recognize the sender and know the content is safe. Remember to never provide your username or password via email. Please forward the email to <a href="mailto:spamcontrol@stanfordchildrens.org">spamcontrol@stanfordchildrens.org</a> if you are unsure and would like it reviewed.

DoD has submitted manuscripts on post-COVID-19 vaccine-associated myocarditis to both JACC and JAMA Cardiology.

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From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)

**Sent:** Mon, 25 Jan 2021 17:20:34 +0000

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Gee, Julianne

(CDC/DDID/NCEZID/DHQP)

Subject: RE: ACIP\_VaxSafety\_Shimabukuro\_1-27-2021\_v3.pptx

Ok. Lets touch base tomorrow.

(b)(5)

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

Sent: Monday, January 25, 2021 12:01 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Gee, Julianne

(CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>

Subject: RE: ACIP\_VaxSafety\_Shimabukuro\_1-27-2021\_v3.pptx

(b)(6)

I'll just need to touch base with you before the Wednesday meeting.

(b)(5)

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

Sent: Monday, January 25, 2021 8:24 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov</a>; Gee, Julianne

(CDC/DDID/NCEZID/DHQP) < dzg2@cdc.gov>

Subject: RE: ACIP\_VaxSafety\_Shimabukuro\_1-27-2021\_v3.pptx

Tom – do you want to chat during the 10:00 vsd meeting? If not feel free to give me a call.

(b)(6)

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

Sent: Sunday, January 24, 2021 9:04 PM

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; Gee, Julianne

(CDC/DDID/NCEZID/DHQP) < dzg2@cdc.gov>

Subject: RE: ACIP\_VaxSafety\_Shimabukuro\_1-27-2021\_v3.pptx

Thanks. I added the summary slide back in, but I need to talk to you about

(b)(5

(b)(5)

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov>

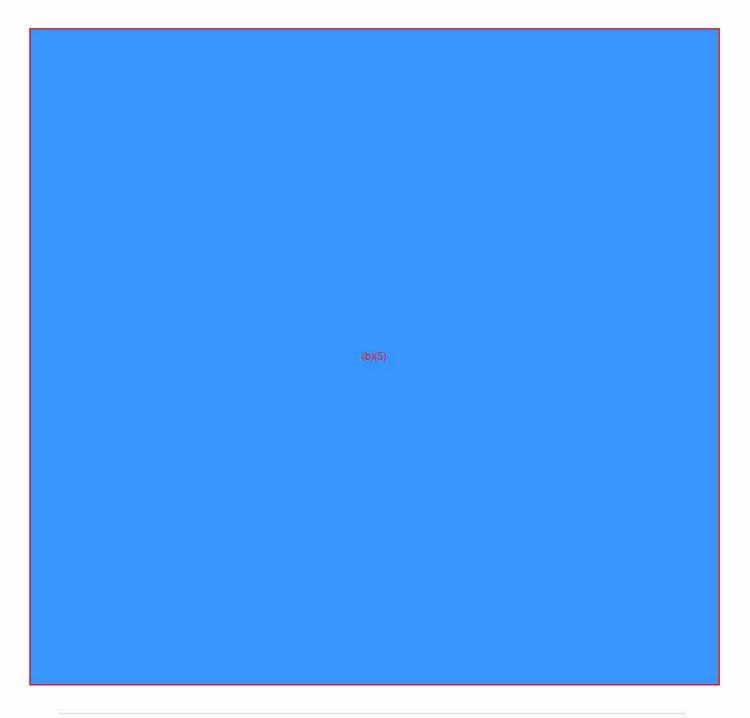
Sent: Sunday, January 24, 2021 5:43 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">; Gee, Julianne

(CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>

**Subject:** FW: ACIP\_VaxSafety\_Shimabukuro\_1-27-2021\_v3.pptx

(b)(5)



From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Sunday, January 24, 2021 5:21 PM

 $\label{eq:to:constraint} \textbf{To:} \ Shimabukuro, \ Tom \ (CDC/DDID/NCEZID/DHQP) < \underbrace{ayv6@cdc.gov}; \ Wharton, \ Melinda \ (CDC/DDID/NCIRD/ISD) < \underbrace{mew2@cdc.gov}; \ Destefano, \ Frank \ (CDC/DDID/NCEZID/DHQP) < \underbrace{mew2@cdc.gov}; \ Destefano, \ Destefano,$ 

<<u>fxd1@cdc.gov</u>>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <<u>dzg2@cdc.gov</u>>

Cc: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov >; Calvert, Geoffrey M. (CDC/NIOSH/WTCHP) < iac6@cdc.gov >; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) < fqv9@cdc.gov >; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) < vje9@cdc.gov >; McNeil, Michael (CDC/DDID/NCEZID/DHQP) < mmm2@cdc.gov >; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov >; Broder, Karen

(CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov>

Subject: RE: ACIP\_VaxSafety\_Shimabukuro\_1-27-2021\_v3.pptx



Lauri

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a you say to a you say

Sent: Sunday, January 24, 2021 2:48 PM

**To:** Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">! Wharton, Melinda (CDC/DDID/NCIRD/ISD) < <a href="mailto:mew2@cdc.gov">! Destefano, Frank (CDC/DDID/NCEZID/DHQP)</a>

<fxd1@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>

Cc: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>; Calvert, Geoffrey M. (CDC/NIOSH/WTCHP)

<<u>iac6@cdc.gov</u>>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <<u>fqv9@cdc.gov</u>>; Myers, Tanya R.

(CDC/DDID/NCEZID/DHQP) < vje9@cdc.gov >; McNeil, Michael (CDC/DDID/NCEZID/DHQP)

<<u>mmm2@cdc.gov</u>>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <<u>eiw8@cdc.gov</u>>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <<u>krb2@cdc.gov</u>>

Subjects ACID Versefets Chimabulana 1 27 2021 v2

**Subject:** ACIP\_VaxSafety\_Shimabukuro\_1-27-2021\_v3.pptx



what you think.

From: Montgomery, Jay R CIV DHA HEALTHCARE OPS (USA)

**Sent:** Wed, 28 Apr 2021 22:23:06 +0000

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Engler, Renata J CTR (USA);

Collins, Limone C Jr CIV DHA HEALTH OPNS (USA)

Cc: Su, John (CDC/DDID/NCEZID/DHQP)

Subject: RE: [Non-DoD Source] RE: Myocarditis cases

(b)(5)

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

Sent: Wednesday, April 28, 2021 6:22 PM

**To:** Montgomery, Jay R CIV DHA HEALTHCARE OPS (USA) <jay.r.montgomery.civ@mail.mil>; Engler, Renata J CTR (USA) <renata.j.engler.ctr@mail.mil>; Collins, Limone C Jr CIV DHA HEALTH OPNS (USA)

limone.c.collins.civ@mail.mil>

Cc: Su, John R CAPT USPHS (USA) <ezu2@cdc.gov>
Subject: [Non-DoD Source] RE: Myocarditis cases

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Sorry. (b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Sent: Wednesday, April 28, 2021 2:49 PM

To: Montgomery, Jay R CIV DHA HEALTHCARE OPS (USA) < jay.r.montgomery.civ@mail.mil>; Engler,

Renata J CTR (USA) < renata.j.engler.ctr@mail.mil > Cc: Su, John (CDC/DDID/NCEZID/DHQP) < revere < rev

Subject: Myocarditis cases

Dear Dr. Montgomery and Colleagues,

(b)(5) . Thanks.

Regards,

Tom

Tom Shimabukuro, MD, MPH, MBA Captain, U.S. Public Health Service Deputy Director Immunization Safety Office Centers for Disease Control and Prevention (CDC) 1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email:TShimabukuro@cdc.gov < Caution-mailto:TShimabukuro@cdc.gov >

Sent: Fri, 16 Oct 2020 20:12:51 +0000 canmz007; McNeil, Michael (CDC/DDID/NCEZID/DHQP); Welsh, Kerry To: (FDA/CBER); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Carmen Ng; ming yan Subject: **RE: Your Submission** Thanks, Maria! John From: canmz007 **Sent:** Friday, October 16, 2020 4:09 PM To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Carmen Ng Subject: RE: Your Submission Congratulations! Sent from my Verizon 4G LTE smartphone ----- Original message -----From: "Su, John (CDC/DDID/NCEZID/DHQP)" <ezu2@cdc.gov> Date: 10/16/20 11:14 AM (GMT-05:00) To: "McNeil, Michael (CDC/DDID/NCEZID/DHQP)" < mmm2@cdc.gov>, "Welsh, Kerry (FDA/CBER)" <Kerry.Welsh@fda.hhs.gov>, "Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)" <fqv9@cdc.gov>, Carmen Ng (b)(6) M Cano ming yan Subject: RE: Your Submission Sure will, Mike. Thanks! \* John From: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov> Sent: Friday, October 16, 2020 11:00 AM To: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Carmen Ng ming yan M Cano Subject: RE: Your Submission Hi John,

Su, John (CDC/DDID/NCEZID/DHQP)

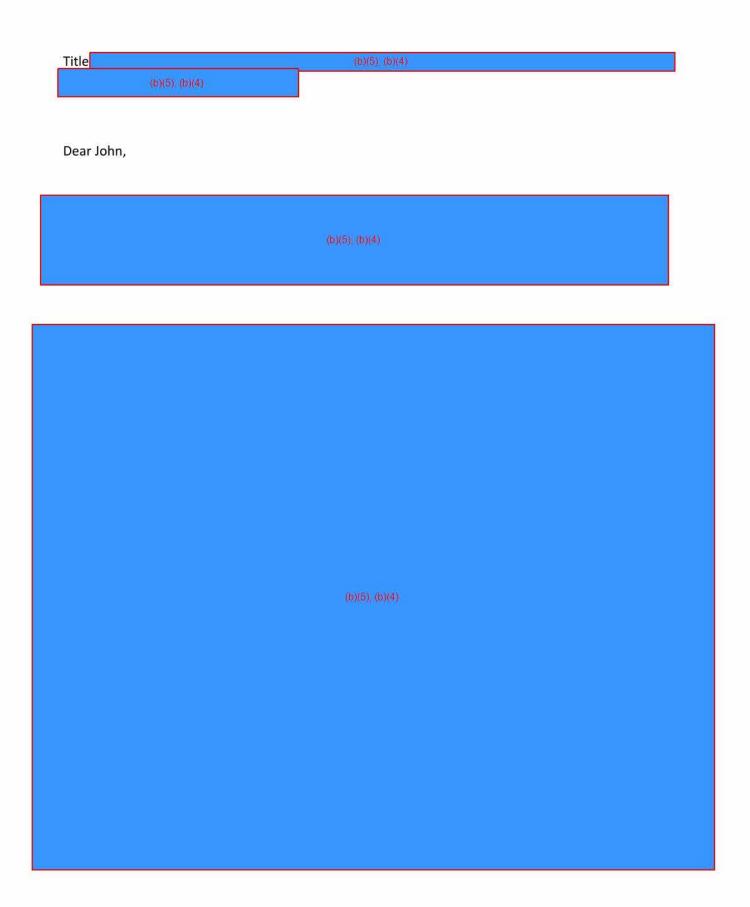
From:

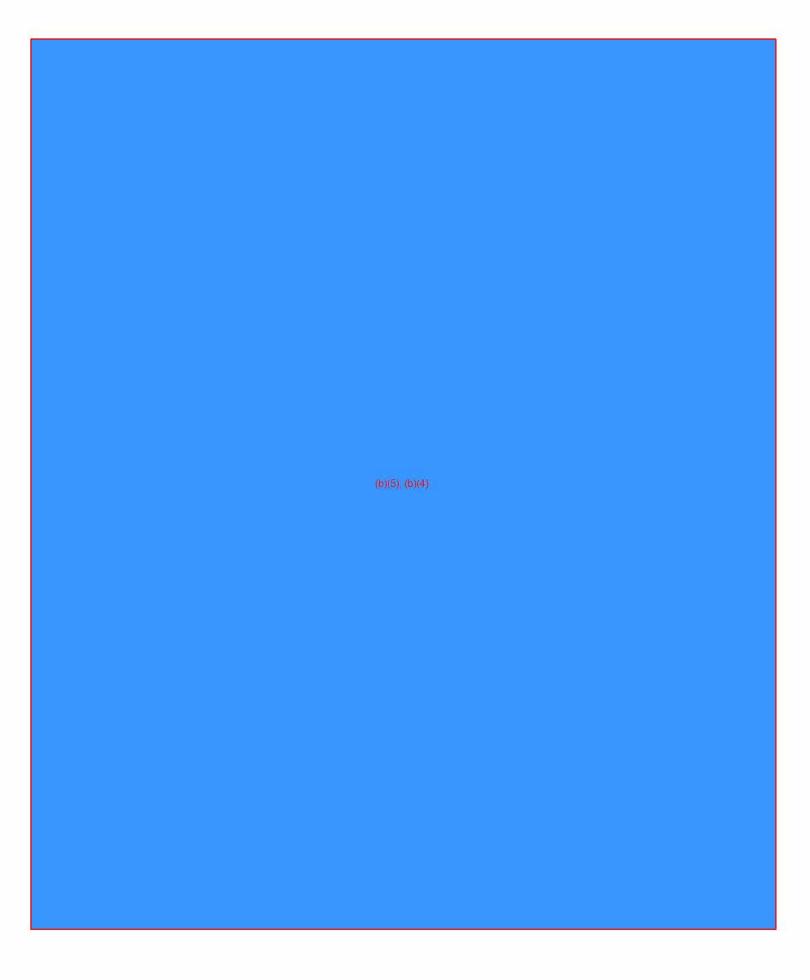
Good news! Please let us know if we can assist in any way? Thanks, Mike From: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov<mailto:ezu2@cdc.gov>>> Sent: Friday, October 16, 2020 10:40 AM To: McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov<mailto:mmm2@cdc.gov>>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov<mailto:Kerry.Welsh@fda.hhs.gov>>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov<mailto:fqv9@cdc.gov>>; Carmen Ng ming yan M Cano Subject: FW: Your Submission Hi folks, I hope you're staying safe and well! Thanks, and Happy Friday, all! -- John ----Original Message-----From: eesserver@eesmail.elsevier.com<mailto:eesserver@eesmail.elsevier.com> <eesserver@eesmail.elsevier.com<mailto:eesserver@eesmail.elsevier.com>>>

Sent: Thursday, October 15, 2020 11:03 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov<mailto:ezu2@cdc.gov>>>

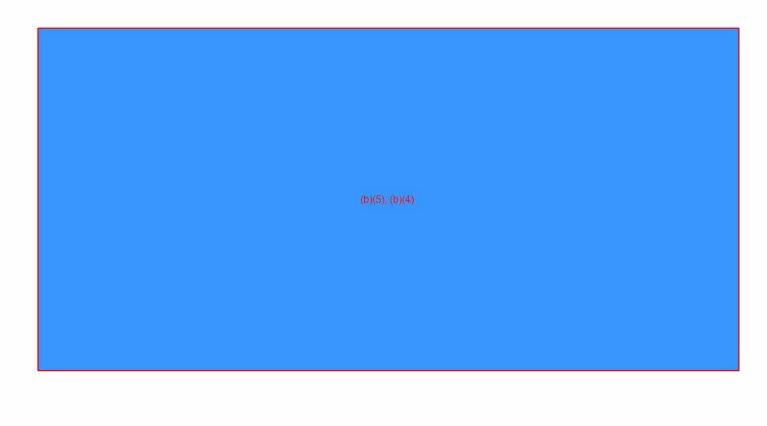
Subject: Your Submission

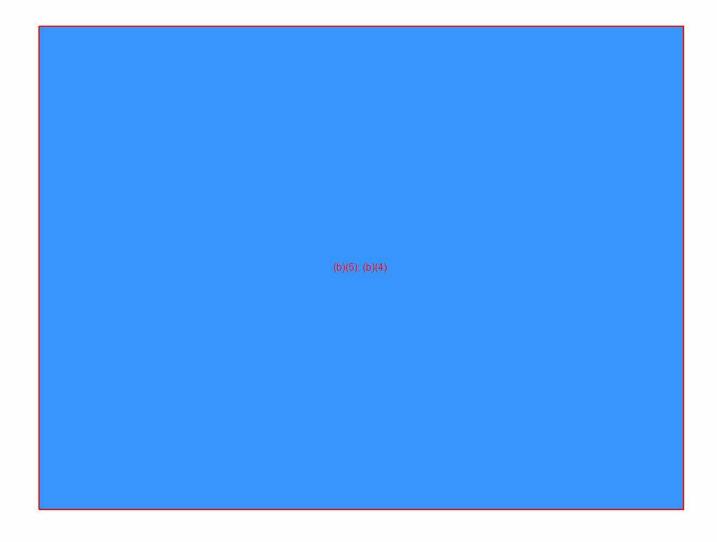
Ms. Ref. No.: JVAC-D-20-01671

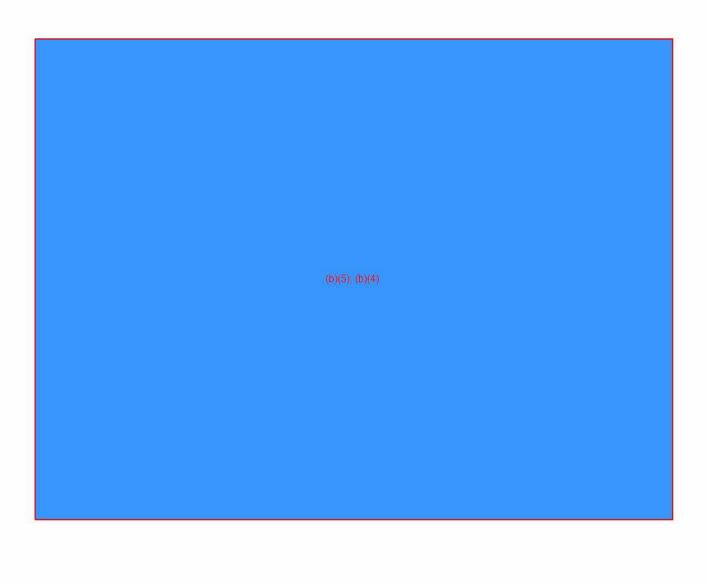




	(b)(5), (b)(4)
Yours sincerely,	
Robert T Chen, MD MA Associate Editor	
Vaccine or its open access mirror	
view the files	
Reviewers' comments:	
	(b)(5) (b)(4)







From: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Sent: Tue, 27 Apr 2021 14:33:40 +0000

To: Walensky, Rochelle (CDC/OD)

valensky, Nochelle (CDC/OD)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD)

Subject: FW: Myocarditis

## See below

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Sent: Tuesday, April 27, 2021 10:22 AM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:kfw3@cdc.gov">hfw3@cdc.gov</a>; Schuchat, Anne MD (CDC/OD)

<acs1@cdc.gov>

Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Cardo, Denise M. MD

(CDC/DDID/NCEZID/DHQP) < dbc0@cdc.gov>

Subject: Myocarditis

Henry

I think I sent this to you yesterday. Denise C and I discussed.

Hope this is what you need.

Best

Dana

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Monday, April 26, 2021 2:43 PM

To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov >; Cardo, Denise M. MD

(CDC/DDID/NCEZID/DHQP) < dbc0@cdc.gov >

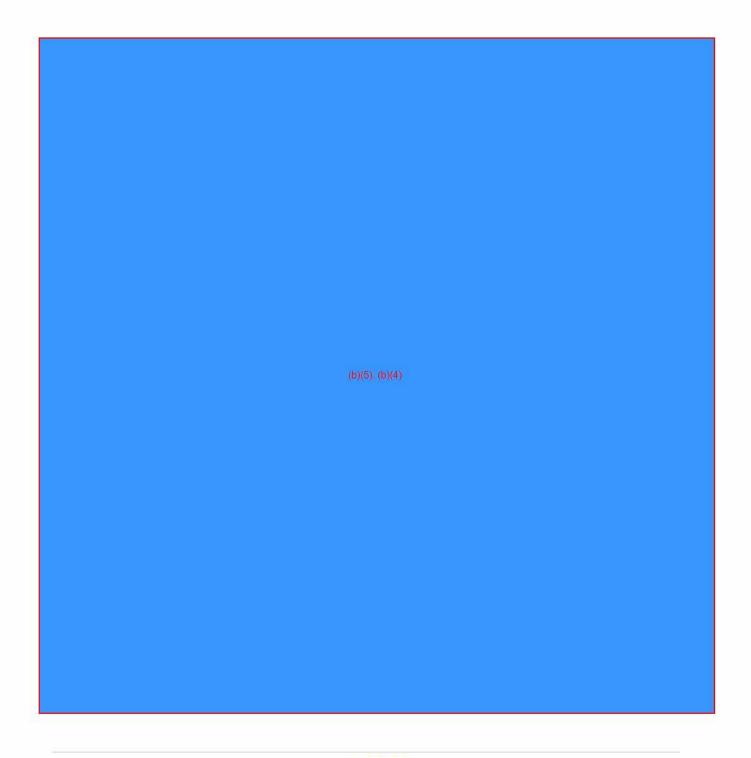
Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov>; Tumpey, Abbigail

(CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

<vmo0@cdc.gov>

Subject: RE: Please read: Myocarditis

(b)(5) (b)(4)



From: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Sent: Monday, April 26, 2021 1:59 PM

To: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">dbc0@cdc.gov</a>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <a y v 6 @ cdc.gov >

Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov >; Tumpey, Abbigail

(CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

<vmo0@cdc.gov>

Subject: RE: Please read: Myocarditis

Thanks, Denise. tom From: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) <dbc0@cdc.gov> Sent: Monday, April 26, 2021 1:42 PM To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v 6 @ cdc.gov > Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov>; Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) <vmo0@cdc.gov> Subject: Please read: Myocarditis Importance: High Tom C and Tom S, Thanks, Denise. From: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov> Sent: Monday, April 26, 2021 1:13 PM To: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">dbc0@cdc.gov</a>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) <wpw7@cdc.gov>; Moran, Kerri (CDC/DDID/NCEZID/DHQP) <ytb5@cdc.gov>; Joshi, Cecilia (CDC/DDID/NCEZID/DHQP) <any9@cdc.gov> Cc: Schindelar, Jessica (CDC/DDID/NCEZID/DHQP) <ghq1@cdc.gov> Subject: FW: Myocarditis FYSA, in case asked in other channels.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Sent:** Fri, 15 Jan 2021 20:46:44 +0000

To: Su, John (CDC/DDID/NCEZID/DHQP); Gallego, Ruth (CDC/DDID/NCEZID/DHQP)

Subject: RE: Covid 19 vaccine and thrombocytopenia

Importance: High

Hi John -I know you are very busy, but I would

(b)(5)

(b)(5)

Thanks, Elaine

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Sent: Friday, January 15, 2021 11:17 AM

**To:** Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov> **Cc:** Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>

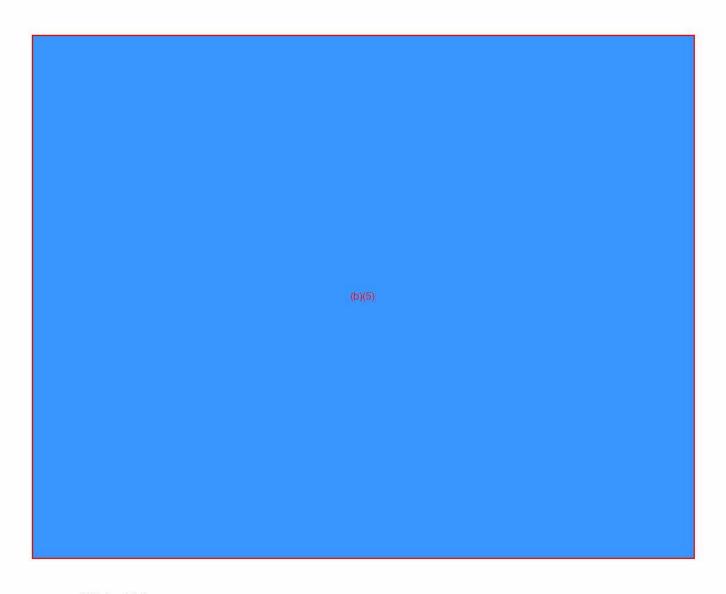
Subject: RE: Covid 19 vaccine and thrombocytopenia

Hi John,

Please let me know your edits. This question is from BETH HIBBS!

Thanks, Elaine

(b)(5)



----Original Message----

From: Beth (b)(6)

Sent: Friday, January 15, 2021 10:12 AM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>

Subject: Re: Covid 19 vaccine and thrombocytopenia

## Hi Elaine,

Thank you so much. I tried to get through to Moderna to ask but they only had a recording to leave a message. I know it is too early to draw any conclusions about any rare AEs. But I was interested in the number of reports VAERS had about it for Pfizer and Moderna vaccines. I really appreciate it!

Beth

> On Jan 15, 2021, at 8:36 AM, Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> wrote:

>

> Hi Beth,

- > So sorry I didn't get back to you earlier.
  > We will look into VAERS and get back to you.
  > Best,
  > Elaine
  >
  > -----Original Message----> From: Beth Hibbs (b)(6)
  > Sent: Thursday, January 14, 2021 7:25 PM
  > To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>
  > Subject: Covid 19 vaccine and thrombocytopenia
- > Hi Elaine,
- > When you get a chance. Just wanted to ask you about if you have heard of any unusual reporting about Moderna Covid 19 vaccine and thrombocytopenia. I know there has been a report with Pfizer's vax. Not sure if you all are seeing more reports of this. I know it is too soon but wanted to see if you had heard anything. Bob has an appointment for the Moderna vaccine and he has thrombocytopenia and I am hesitant since these vaccines are similar and so new.
- > Thanks millions > Beth

From: Walensky, Rochelle (CDC/OD)

Sent: Wed, 28 Apr 2021 19:43:13 +0000

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

Cc: McDonald, Jason (CDC/OD/OADC); Berger, Sherri (CDC/OCOO/OD); Goldstein,

Robert (CDC/OD/OADPS); Warner, Agnes (CDC/OD/OCS)

Subject: RE: Myocarditis TPs

Great – thanks, (b)(5)

Thank you for running this down...

R

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Sent: Wednesday, April 28, 2021 3:13 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Warner, Agnes (CDC/OD/OCS)

<bli><bli>dc.gov>

Subject: RE: Myocarditis TPs

Rochelle,

Re: (b)(5)

Please let me know if you need more.

Regards,

Abbigail

From: Walensky, Rochelle (CDC/OD) <a href="mailto:aux7@cdc.gov">aux7@cdc.gov</a>

Sent: Wednesday, April 28, 2021 1:59 PM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Cc: McDonald, Jason (CDC/OD/OADC) < gnf0@cdc.gov >; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Warner, Agnes (CDC/OD/OCS)

<bli><bli>dcdc.gov>

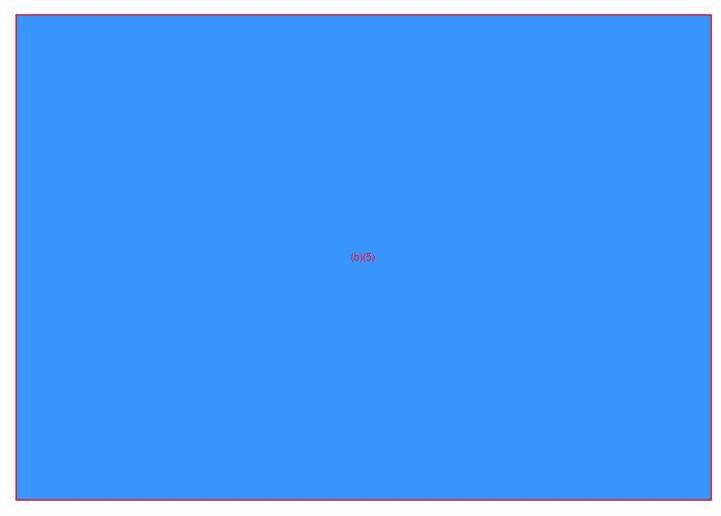
Subject: RE: Myocarditis TPs

Very helpful... (b)(5) ?

Thank you!

R

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov">aws8@cdc.gov</a> Sent: Wednesday, April 28, 2021 1:49 PM To: Walensky, Rochelle (CDC/OD) <a href="mailto:aux7@cdc.gov">aux7@cdc.gov</a>> Cc: McDonald, Jason (CDC/OD/OADC) < gnf0@cdc.gov >; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Warner, Agnes (CDC/OD/OCS) <bli><bli>di8@cdc.gov> Subject: RE: Myocarditis TPs Rochelle,



Regards,

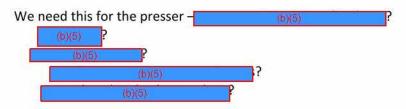
Abbigail

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Wednesday, April 28, 2021 9:56 AM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>

**Subject:** Myocarditis TPs



Thanks!

R

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Sent:** Wed, 6 Jan 2021 16:54:20 +0000

To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP)
Cc: McNeil, Michael (CDC/DDID/NCEZID/DHQP)
Subject: RE: Standing federal agency coordination meeting

(b)(5) M

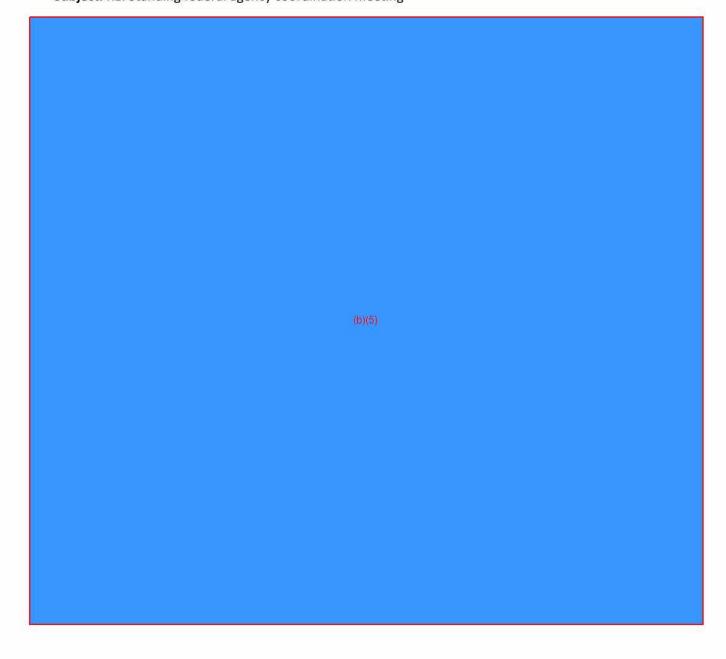
we should discuss on the call.

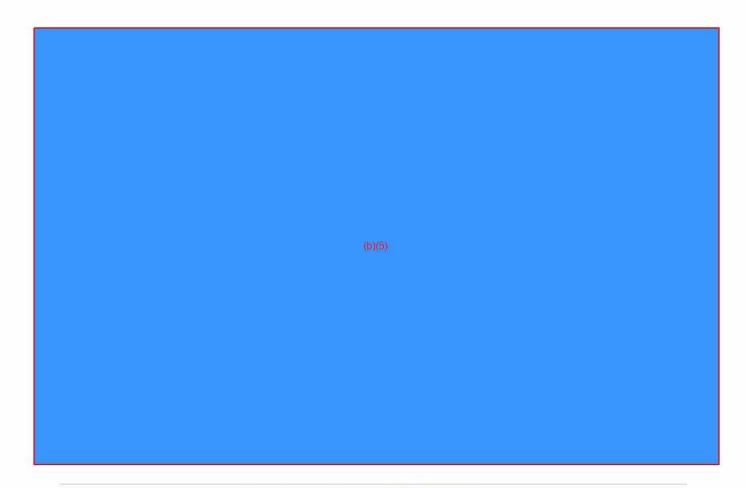
From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>

Sent: Wednesday, January 6, 2021 11:41 AM

**To:** Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> **Cc:** McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>

Subject: RE: Standing federal agency coordination meeting

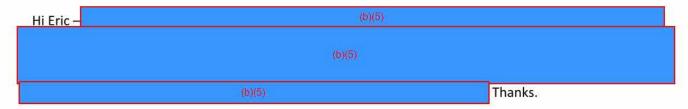




From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v 6 @cdc.gov >

Sent: Wednesday, January 6, 2021 10:32 AM

Subject: RE: Standing federal agency coordination meeting



Tom

From: Forshee, Richard < Richard. Forshee@fda.hhs.gov>

Sent: Wednesday, January 6, 2021 8:46 AM

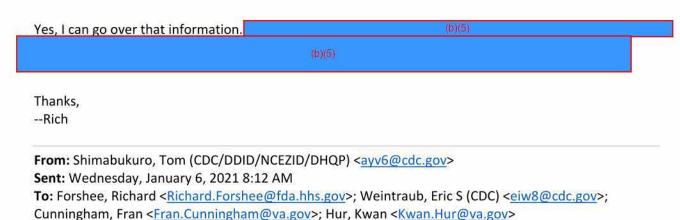
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov">; Weintraub, Eric

(CDC/DDID/NCEZID/DHQP) < eiw8@cdc.gov >; Cunningham, Fran < Fran.Cunningham@va.gov >; Hur,

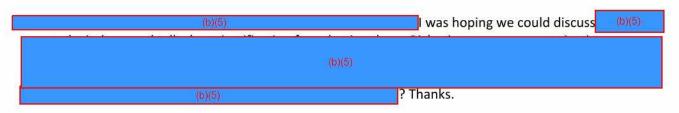
Kwan < Kwan. Hur@va.gov>

Subject: RE: Standing federal agency coordination meeting

Hi Tom,



Subject: RE: Standing federal agency coordination meeting



Tom

----Original Appointment----

From: Gee, Julianne (CDC/DDID/NCEZID/DHQP) < dzg2@cdc.gov>

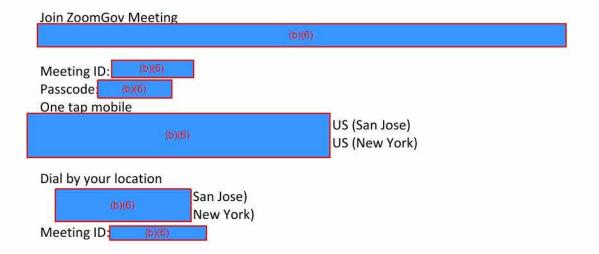
Sent: Wednesday, December 30, 2020 8:41 AM

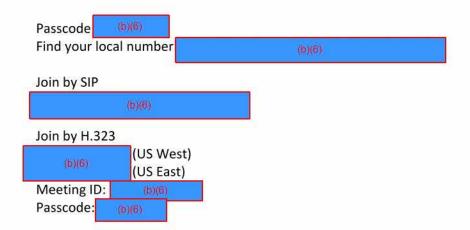
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Weintraub, Eric (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Clark, Matthew (IHS/ALB); Destefano, Frank (CDC/DDID/NCEZID/DHQP); Anderson, Steven (FDA/CBER); Forshee, Richard (FDA/CBER); Collins, Limone C Jr CIV (US); Cunningham, Fran; Hur, Kwan Cc: Kenigsberg, Tat'Yana A. (CDC/DDID/NCEZID/DHQP); Clark, Thomas A. (CDC/DDID/NCIRD/DVD)

Subject: Standing federal agency coordination meeting

When: Wednesday, January 6, 2021 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: zoom





From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Sent:** Sun, 17 Jan 2021 15:06:58 +0000

To: (b)(6)

Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)

Subject: RE: Covid 19 vaccine and thrombocytopenia

Hi Beth,

It is great to hear from you!

I understand that you have question	(b)(6)	
d))	You want to know what	
we are seeing in VAERS and if	(b)(6) can receive	e the vaccine.

As of 1/14/21, VAERS contains 7 reports with the MedDRA codes: IMMUNE THROMBOCYTOPENIA, IMMUNE THROMBOCYTOPENIC PURPURA, THROMBOCYTOPENIA, or THROMBOCYTOPENIC PURPURA after either COVID-19 vaccination. The patient ages ranged from 25 to 56 with a median of 42 years. Five reports were after Pfizer and 2 were after Moderna. A brief summary of the reports is listed below.

- 1) A 56 year old male with no prior medical history received PFIZER-BIONTECH and had onset of symptoms about 4 days later and died 13 days after vaccination.
- 2) A 36 year old female with no reported medical problems received PFIZER-BIONTECH and has onset of symptoms about 13 days later. Hospitalized 2 days.
- 3) A 41 year old male with a prior history of ITP in 2014 that was in remission received PFIZER-BIONTECH and has onset of symptoms about 3 days later. Hospitalized 1 day
- 4) A 25 year old female with history of anti-thyroglobulin antibodies received Moderna vaccine and had onset of symptoms about 10 days later. Hospitalized 3 days.
- 5) A 43 year old female with history of GERD received Moderna vaccine and had onset of symptoms about 8 days later. Hospitalized.
- 6) A 44 year old female with no history received PFIZER-BIONTECH vaccine and had onset of nausea, vomiting, diarrhea, fever on the same day. The following day was hospitalized for chest pain and platelets found to be low. Diagnosed with myocarditis and thrombocytopenia. Hospitalized 2 days
- 7) A patient with unreported history received PFIZER-BIONTECH vaccine and died from thrombopenia; pulmonary embolism; neutropenia fever. There is no information to determine if this is a duplicate of the other death report or if this is a different patient.

CDC Clinical Guidance on the use of the COVID-19 vaccines is available at this link: <a href="https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html">https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</a> It states the following:

Persons with autoimmune conditions

No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials. No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

(b)(6)			
(b)(G)			
(b)(6)			
Best,			
Elaine			
Original Massaga			
From: Beth (b)(6)			
Sent: Friday, January 15, 2021 10:12 AM			
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < <a href="mailto:erm4@cdc.gov">erm4@cdc.gov</a> >			
Subject: Re: Covid 19 vaccine and thrombocytopenia			
Hi Elaina			
Hi Elaine, Thank you so much. I tried to get through to Moderna to ask but they only had a recording to			
leave a message. I know it is too early to draw any conclusions about any rare AEs. But I was			
interested in the number of reports VAERS had about it for Pfizer and Moderna vaccines.			
I really appreciate it!			
Beth			
> On Jan 15, 2021, at 8:36 AM, Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov></erm4@cdc.gov>			
wrote:			
>			
> Hi Beth,			
> So sorry I didn't get back to you earlier.			
> We will look into VAERS and get back to you. > Best,			
> Elaine			
>			
>Original Message			
> From: (b)(6) (b)(6)			
> Sent: Thursday, January 14, 2021 7:25 PM > To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov>			
> Subject: Covid 19 vaccine and thrombocytopenia			
>			

> Hi Elaine,

> When you get a chance. Just wanted to ask you about if you have heard of any unusual reporting about Moderna Covid 19 vaccine and thrombocytopenia. I know there has been a report with Pfizer's vax. Not sure if you all are seeing more reports of this. I know it is too soon but wanted to see if you had heard anything. (b)(6)

>

> Thanks millions

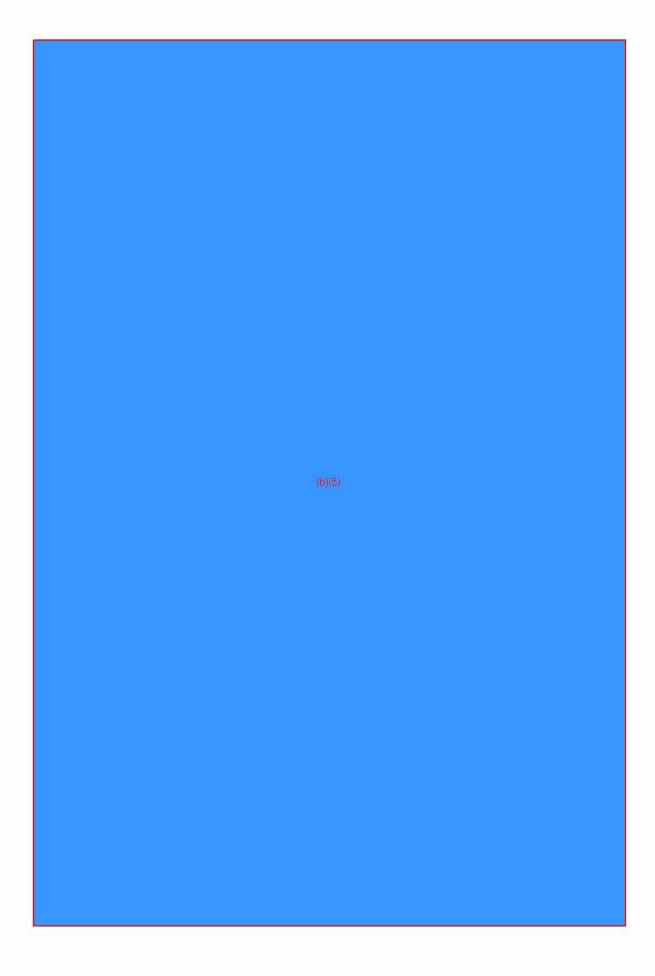
> Beth

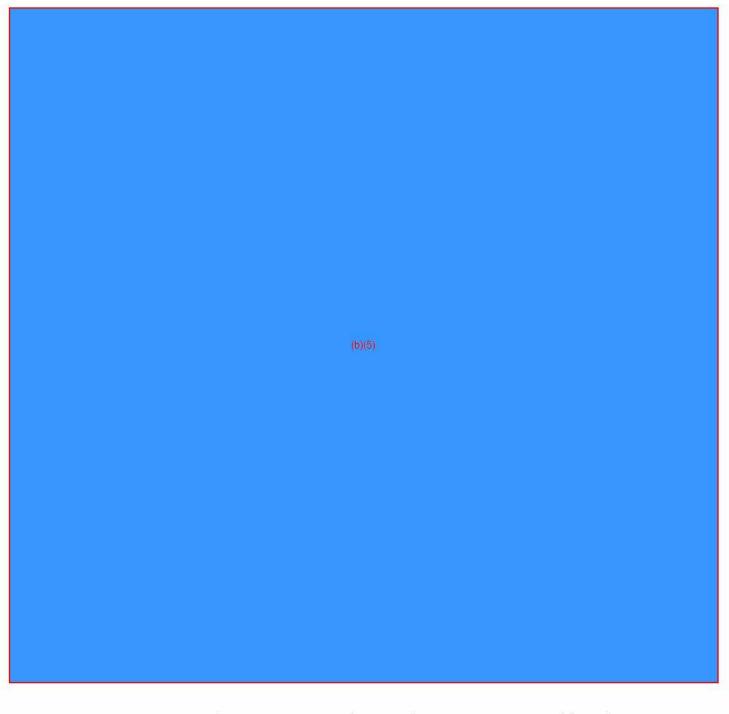
To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) Subject: RE: Signal eval considerations- feel free to comment/edit/share From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov> Sent: Tuesday, April 6, 2021 10:49 PM To: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov> Subject: FW: Signal eval considerations- feel free to comment/edit/share From: Lee, Grace < GMLee@stanfordchildrens.org> Sent: Tuesday, April 6, 2021 12:56 PM To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">! Wharton, Melinda">!em2@cdc.gov</a>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; Hopkins, Bob <hopkinsroberth@uams.edu>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov> Subject: Signal eval considerations- feel free to comment/edit/share Hi Team I started drafting just what came from the closed meeting but added some thoughts below. Best Grace

Wharton, Melinda (CDC/DDID/NCIRD/ISD)

Wed, 7 Apr 2021 23:38:19 +0000

From: Sent:





CONFIDENTIALITY NOTICE: This communication and any attachments may contain confidential or privileged information for the use by the designated recipient(s) named above. If you are not the intended recipient, you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or the attachments is strictly prohibited. If you have received this communication in error, please contact me and destroy all copies of the communication and attachments. Thank you.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

**Sent:** Tue, 27 Apr 2021 19:09:18 +0000

To: NIPINFO (CDC)

Cc: Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP);

Economou, Sigrid A. (CDC/DDPHSS/CSELS/DHIS)

Subject: RE: Reported Pfizer adverse event not appearing in VAERS

Hi Tina,

We will respond and cc you.

Thanks, Elaine

From: NIPINFO (CDC) <NIPINFO@cdc.gov> Sent: Tuesday, April 27, 2021 2:06 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

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

Subject: FW: Reported Pfizer adverse event not appearing in VAERS

Importance: High

Hello,

Please see below. Of note this was also sent to Wonder Customer Support. Please let us know if you will address (or copy us when you send the response) and we can close the loop on our end.

Thanks,

Tina (for NIPINFO)

From: (b)(6)

Sent: Tuesday, April 27, 2021 1:55 PM

To: CDC Wonder Customer Support <cwus@cdc.gov>; NIPINFO (CDC) <NIPINFO@cdc.gov>

Subject: Reported Pfizer adverse event not appearing in VAERS

Importance: High

I am writing because a filed report is not showing up in the VAERS system online. This is concerning to me given questions that are arising concerning heart problems associated with the Pfizer vaccine for covid.

My 16yo son was hospitalized with myopericarditis after receiving his first shot of the Pfizer BioN-Tech vaccination for covid-19. He was diagnosed with covid on Jan. 14. He complained of his heart pounding but had a normal EKG when seen by his pediatrician on March 31. He got the first Pfizer shot on Friday, April 16. On Sunday, April 18, he was admitted to the PICU at the

(b)(6) His troponin levels reached a high of 16.7 but it was successfully reduced with prednisone and other interventions. He was discharged on Thursday, April 22.

The hospital filed a report with VAERS on April 21 (I have a photo of the confirmation email), but all it listed was the Temporary VAERS E-Report Number. When I enter that number in VAERS, I get data for a 60yo man vaccinated in 2012.

I have requested the non-temporary report number from <a href="mailto:info@vaers.org">info@vaers.org</a> but I am wondering why <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:info@vaers.org">info@vaers.org</a> but I am wondering why <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:info@vaers.org">info@vaers.org</a> but I am wondering why <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:info@vaers.org">info@vaers.org</a> but I am wondering why <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:his-align: left) have requested the non-temporary report number from <a href="mailto:his-align: left) have requested to his-align: left

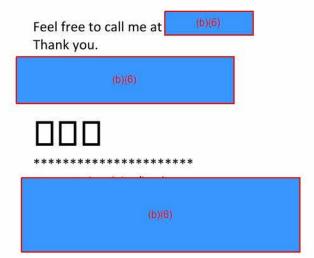
Specifically, when I do a data request, the following parameters yield 0 total events:

- .
- 10028650 (MYOPERICARDITIS)
- •
- 1200 (COVID19 (COVID19 (PFIZER-BIONTECH)))
- Hospitalized

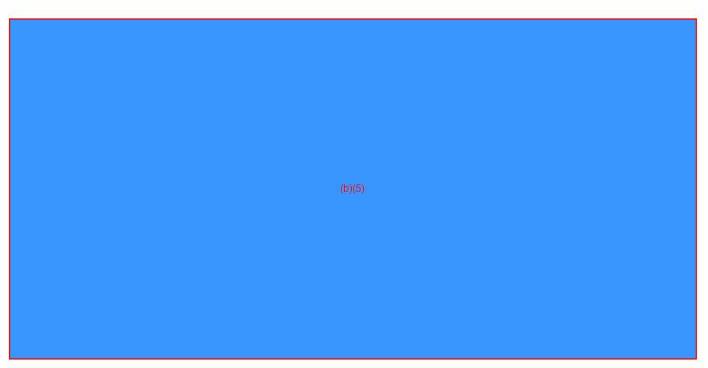
When I change the symptom to "10028606 (MYOCARDITIS)" and keep the other two parameters the same, I get 22 events, but in the 6-17 age range there are zero events.

This is very distressing amid reports that "CDC, FDA see no Pfizer vaccine link to heart problem." <a href="https://www.newsobserver.com/news/coronavirus/article250965424.html">https://www.newsobserver.com/news/coronavirus/article250965424.html</a>

How are CDC and FDA able to monitor this situation if they don't have the information being submitted by hospitals?



Harrington, Theresa (CDC/DDID/NCEZID/DHQP) From: Sent: Fri, 29 Jan 2021 18:16:41 +0000 Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Su, John To: (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP) Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED) Cc: Subject: RE: Please review VAERS search and give approval for pericarditis after COVID disease case Thanks so much. Theresa From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov> Sent: Friday, January 29, 2021 12:42 PM To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov> Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED) <oqk3@cdc.gov> Subject: RE: Please review VAERS search and give approval for pericarditis after COVID disease case Hi Theresa, I can check these searches. I will get back to you. Thanks, Elaine From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov> Sent: Friday, January 29, 2021 12:08 PM To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <a href="mailto:krb2@cdc.gov">krb2@cdc.gov">krb2@cdc.gov</a>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <a href="mailto:krb2@cdc.gov">erm4@cdc.gov</a>> Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED) < oqk3@cdc.gov> Subject: Please review VAERS search and give approval for pericarditis after COVID disease case Importance: High Hi all,



Thank you.

## Theresa

Theresa Harrington, MD, MPH&TM
CAPT, US Public Health Service
Medical Officer, Clinical Immunization Safety Assessment (CISA) Team
Immunization Safety Office, Division of Healthcare Quality Promotion (DHQP)
Centers for Disease Control and Prevention

office: 404-639-2877 cell: 404-751-6389

email: tharrington@cdc.gov

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP)

**Sent:** Fri, 29 Jan 2021 17:44:28 +0000

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Su, John

(CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP)

Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED)

Subject: RE: Please review VAERS search and give approval for pericarditis after COVID

disease case

Thanks, Elaine.

Theresa

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Sent: Friday, January 29, 2021 12:42 PM

To: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Su, John

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>

Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED) < oqk3@cdc.gov>

Subject: RE: Please review VAERS search and give approval for pericarditis after COVID disease case

Hi Theresa,

I can check these searches. I will get back to you.

Thanks, Elaine

From: Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>

Sent: Friday, January 29, 2021 12:08 PM

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

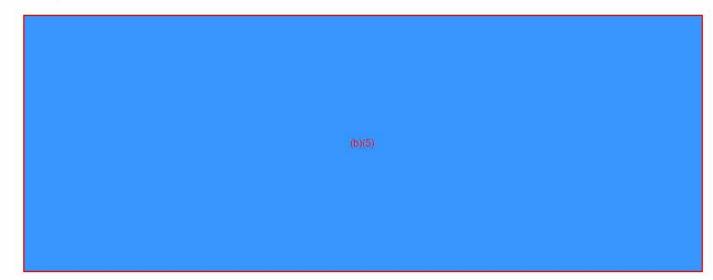
<<u>krb2@cdc.gov</u>>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <<u>erm4@cdc.gov</u>>

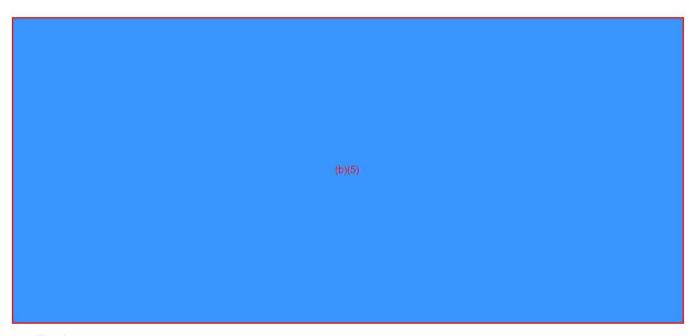
Cc: Tobolowsky, Farrell (CDC/DDID/NCEZID/DFWED) <oqk3@cdc.gov>

Subject: Please review VAERS search and give approval for pericarditis after COVID disease case

Importance: High

Hi all,





Thank you.

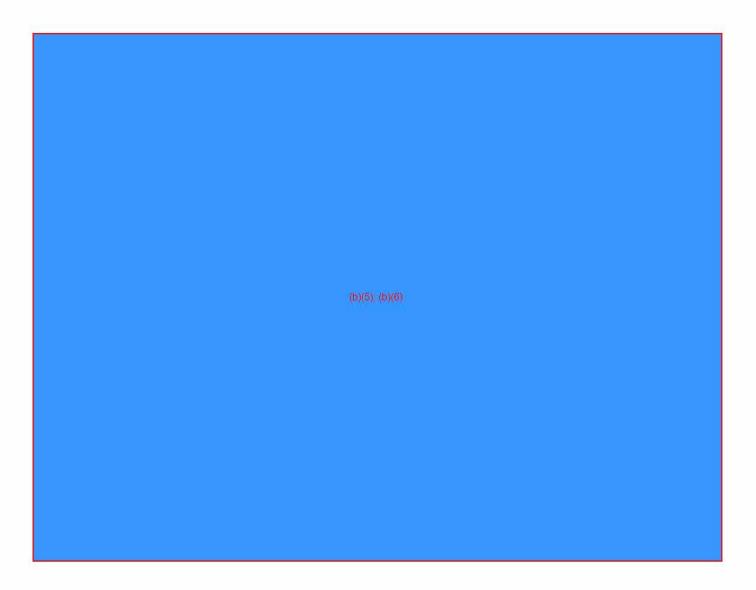
## Theresa

Theresa Harrington, MD, MPH&TM
CAPT, US Public Health Service
Medical Officer, Clinical Immunization Safety Assessment (CISA) Team
Immunization Safety Office, Division of Healthcare Quality Promotion (DHQP)
Centers for Disease Control and Prevention

office: 404-639-2877 cell: 404-751-6389

email: tharrington@cdc.gov

From:	Su, John (CDC/DDID/NCEZID/DHQP)	
Sent:	Wed, 24 Feb 2021 21:07:37 +0000	
То:	Calvert, Geoffrey M. (CDC/NIOSH/WTCHP)	
Cc:	Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)	
Subject:	(b)(5)	
Hi Geof	f,	
Thanks	for sharing!	
• John		
Sent: Wednesda To: Su, John (CD	eoffrey M. (CDC/NIOSH/WTCHP) < jac6@cdc.gov> y, February 24, 2021 3:58 PM C/DDID/NCEZID/DHQP) < ezu2@cdc.gov> R. (CDC/DDID/NCEZID/DHQP) < erm4@cdc.gov> (b)(5)	
	(b)(5), (b)(6)	
		-
	(b)(5)	



Geoffrey M. Calvert, MD, MPH
Vaccine Task Force
CDC COVID-19 Response
and
Associate Director for Clinical Quality
World Trade Center Health Program
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
1090 Tusculum Avenue, R-12
Cincinnati, OH 45226
513-841-4448

Fax: 513-841-4489

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Sent:** Wed, 28 Apr 2021 14:41:01 +0000 **To:** Su, John (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: myocarditis cases



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

Sent: Wednesday, April 28, 2021 10:35 AM

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

Subject: RE: myocarditis cases

(b)(5)

John

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a yo 6 @cdc.gov>

Sent: Wednesday, April 28, 2021 9:58 AM

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

Subject: RE: myocarditis cases

We need to expedite these reviews and get ahead of the situation before it starts dictating our actions.

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

Sent: Wednesday, April 28, 2021 9:28 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:syv6@cdc.gov">ayv6@cdc.gov</a>

Subject: RE: myocarditis cases

Hi Tom,

(b)(5)

(b)(5)

(b)(5)

Please let me know if you need any other information.

John

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Wednesday, April 28, 2021 8:09 AM

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

Subject: myocarditis cases

Importance: High

(b)(5)

# Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Sent:** Fri, 9 Apr 2021 20:13:47 +0000

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD); Gee, Julianne

(CDC/DDID/NCEZID/DHQP); Wharton, Melinda (CDC/DDID/NCIRD/ISD)

Subject: RE: Call re: CVST cases in VAERS

(b)(5)

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>

Sent: Friday, April 9, 2021 4:13 PM

**To:** Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD)

<mew2@cdc.gov>

Subject: RE: Call re: CVST cases in VAERS

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Friday, April 9, 2021 4:01 PM

To: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">!em2@cdc.gov">: Gee, Julianne</a>

(CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD)

<mew2@cdc.gov>

Subject: RE: Call re: CVST cases in VAERS

(b)(5)

# Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service
Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, MS V18-4, Atlanta, GA 30329

Phone: 404-498-0679, Fax: 404-498-0666

Email: TShimabukuro@cdc.gov

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>

Sent: Friday, April 9, 2021 2:57 PM

To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < <a href="mailto:tnc4@cdc.gov">tnc4@cdc.gov</a>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < <a href="mailto:tnc4@cdc.gov">tnc4@cdc.gov</a>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < <a href="mailto:tnc4@cdc.gov">tnc4@cdc.gov</a>; Shimabukuro, Tom (CDC/DDID/NCIRD/DVD) < <a href="mailto:tnc4@cdc.gov">tnc4@cdc.gov</a>; Sotir, Mark (CDC/DDID/NCIRD/DVD) < <a href="mailto:tnc4@cdc.gov">mps6@cdc.gov</a>; Wharton, Melinda

(CDC/DDID/NCIRD/ISD) < mew2@cdc.gov >; Anderson, Steven (FDA/CBER)

<<u>Steven.Anderson@fda.hhs.gov</u>>; Forshee, Richard (FDA/CBER) <<u>Richard.Forshee@fda.hhs.gov</u>>; Nair,

Narayan (FDA/CBER) < Narayan.Nair@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER)

<<u>Craig.Zinderman@fda.hhs.gov</u>>; Su, John (CDC/DDID/NCEZID/DHQP) <<u>ezu2@cdc.gov</u>>; Broder, Karen

(CDC/DDID/NCEZID/DHQP) < <a href="mailto:krb2@cdc.gov">krb2@cdc.gov">krb2@cdc.gov</a>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) < <a href="mailto:mm2@cdc.gov">mm2@cdc.gov</a>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dzg2@cdc.gov">dzg2@cdc.gov</a>; Shay, David (CDC/DDID/NCIRD/ID) < <a href="mailto:dks4@cdc.gov">dks4@cdc.gov</a>>

Subject: RE: Call re: CVST cases in VAERS

(b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:agv6@cdc.gov">agv6@cdc.gov</a>>

Sent: Friday, April 9, 2021 2:43 PM

To: Destefano, Frank (CDC/DDID/NCEZID/DHQP) < fxd1@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < fxd2@cdc.gov>; Sotir, Mark (CDC/DDID/NCIRD/DVD) < fxd2@cdc.gov>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < fxd2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) < fxew2@cdc.gov>; Anderson, Steven (FDA/CBER) < fxeven.Anderson@fda.hhs.gov>; Forshee, Richard (FDA/CBER) < fxeven.Anderson@fda.hhs.gov>; Su, John (CDC/DDID/NCEZID/DHQP) < fxeven.Anderson@fda.hhs.gov

Subject: Call re: CVST cases in VAERS

Are folks available from 5-6pm Monday to discuss the CVST issue. I think (b)(5)
(b)(5)
Thanks.

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Thu, 1 Apr 2021 20:25:42 +0000

To: McCormick, David (CDC/DDID/NCEZID/DVBD); Destefano, Frank

(CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa

(CDC/DDID/NCEZID/DHQP); Rao, Agam K. (CDC/DDID/NCEZID/DHCPP)

Subject: RE: VAERS Review of Myocarditis/Myopericarditis for DoD Discussion Tomorrow

Hi David,

(b)(5)

John

## Restricted Use /CDC FTE Only

From: McCormick, David (CDC/DDID/NCEZID/DVBD) <yup1@cdc.gov>

Sent: Thursday, April 1, 2021 1:59 PM

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

<fxd1@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov> Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <krb2@cdc.gov>; Harrington, Theresa

(CDC/DDID/NCEZID/DHQP) <tsh3@cdc.gov>; Rao, Agam K. (CDC/DDID/NCEZID/DHCPP) <ige4@cdc.gov>

Subject: VAERS Review of Myocarditis/Myopericarditis for DoD Discussion Tomorrow

Hi all,

(b)(5)

Any comments or suggestions for improvement are welcome

(b)(£

(b)(5)

Please send any comments by 10AM 4/2 so that I

have a chance to incorporate them into the presentation.

(b)(5)

Best, David

## David McCormick, MD, MPH

LCDR, US Public Health Service

EIS Officer

Centers for Disease Control and Prevention

Bacterial Diseases Branch | Division of Vector-Borne Diseases

Fort Collins, CO yup1@cdc.gov | Office 970-225-4272 | Cell 970-787-5036

Restricted Use /CDC FTE Only

From: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES)

**Sent:** Mon, 26 Apr 2021 18:04:29 +0000

To: Su, John (CDC/DDID/NCEZID/DHQP); Broder, Karen (CDC/DDID/NCEZID/DHQP)

Subject: RE: question - confidential

(b)(5)

Susan

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

Sent: Monday, April 26, 2021 12:16 PM

**To:** Broder, Karen (CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov> **Cc:** Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES) < srl2@cdc.gov>

Subject: RE: question - confidential

Thanks for sharing, Karen!

(b)(5

John

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) <a href="mailto:krb2@cdc.gov">krb2@cdc.gov</a>

Sent: Monday, April 26, 2021 12:04 PM

To: Su, John (CDC/DDID/NCEZID/DHQP) < ezu2@cdc.gov > Cc: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES) < srl2@cdc.gov >

Subject: FW: question - confidential

(b)(5

Karen

From: Lukacs, Susan (CDC/DDPHSS/NCHS/DHNES) <srl2@cdc.gov>

Sent: Monday, April 26, 2021 11:31 AM

To: Broder, Karen (CDC/DDID/NCEZID/DHQP) < <a href="mailto:krb2@cdc.gov">krb2@cdc.gov</a>; Nguyen, Duong T.

(CDC/DDPHSS/NCHS/DHNES) < ydi0@cdc.gov>

Subject: RE: question

Karen,

(b)(5)

Susan

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) < <a href="mailto:krb2@cdc.gov">krb2@cdc.gov</a>>

Sent: Monday, April 26, 2021 11:19 AM

To: Nguyen, Duong T. (CDC/DDPHSS/NCHS/DHNES) <ydi0@cdc.gov>; Lukacs, Susan

(CDC/DDPHSS/NCHS/DHNES) <srl2@cdc.gov>

Subject: question

(b)(5)

Karen

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Wed, 7 Apr 2021 03:33:53 +0000

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

**Subject:** RE: USG vax safety coordination call

#### Thanks for the reminder!

John

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

**Sent:** Tuesday, April 6, 2021 6:44 PM

To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <dzg2@cdc.gov>; Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <eiw8@cdc.gov>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Clark, Matthew (IHS/ALB) <Matthew.Clark@ihs.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; Anderson, Steven (FDA/CBER) <Steven.Anderson@fda.hhs.gov>; Forshee, Richard (FDA/CBER) <Richard.Forshee@fda.hhs.gov>; Collins, Limone C Jr CIV (US Limone.c.collins.civ@mail.mil>; Cunningham, Fran <Fran.Cunningham@va.gov>; Hur, Kwan <Kwan.Hur@va.gov>; Kenigsberg, Tat'Yana A. (CDC/DDID/NCEZID/DHQP) <ynf1@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Wong, Hui-Lee (FDA/CBER) <Huilee.Wong@fda.hhs.gov>; Shay, David (CDC/DDID/NCIRD/ID) <dks4@cdc.gov>; Martin, Stacey (CDC/DDID/NCEZID/DVBD) <zmt0@cdc.gov> Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>

Subject: USG vax safety coordination call

#### Agenda for tomorrow:

- General updates
- DoD myocarditis case series preview
- VSD and VA efforts for signal refinement for PE and AMI
- CDC update on CVST epi and CVST reports to VAERS
- Agency updates

 From:
 Su, John (CDC/DDID/NCEZID/DHQP)

 Sent:
 Fri, 12 Mar 2021 14:35:53 +0000

To: Broder, Karen (CDC/DDID/NCEZID/DHQP)

Subject: RE: Call with DoD

Hi Karen,

I'm (supposedly) out of the office today. I'll try to catch up offline. Thanks!

John

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) < krb2@cdc.gov>

Sent: Friday, March 12, 2021 7:13 AM

To: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <fxd1@cdc.gov>; McNeil, Michael

(CDC/DDID/NCEZID/DHQP) <mmm2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Cc: Paulin, Heather N. (CDC/DDPHSIS/CGH/DGHT) <ydi2@cdc.gov>; McCormick, David

(CDC/DDID/NCEZID/DVBD) < yup1@cdc.gov>

Subject: Call with DoD

Hello - (b)(5) call with DoD (b)(5) at 10a today.

Let me know if you want to be added.

Tom is on the invite.

**Thanks** 

Karen

Get Outlook for iOS

From: Sent: To: (CDC/DDID/NCIRD/OD) Subject:	Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) Mon, 26 Apr 2021 13:42:58 +0000 Hesse, Elisabeth (CDC/DDID/NCEZID/DPEI); Mbaeyi, Sarah ; Clark, Thomas A. (CDC/DDID/NCIRD/DVD); Su, John (CDC/DDID/NCEZID/DHQP) RE  (b)(5)
	(b)(5)
<b>Sent:</b> Monday, April 26, <b>To:</b> Mbaeyi, Sarah (CDC	/DDID/NCIRD/OD) <vif6@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) abukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John</ayv6@cdc.gov></vif6@cdc.gov>
	(b)(5)
(b)(5	- Control - Cont
Thanks,	

-Lisa

Elisabeth Hesse, MD, MTM&H LCDR, USPHS CDC LNO to the Vaccine Operations Center COVID-19 Vaccine Task Force Centers for Disease Control and Prevention 404-498-5084 nrn3@cdc.gov

From: Walensky, Rochelle (CDC/OD)

Sent: Wed, 28 Apr 2021 14:03:28 +0000

To: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Cc: Schuchat, Anne MD (CDC/OD)

Subject: RE: follow-up

## Thanks much!

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Wednesday, April 28, 2021 10:00 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Subject: follow-up

Will pull together talking points on myocarditis and share. Henry

Henry Walke, MD, MPH Incident Manager CDC COVID-19 Response +1-404-639-3582 (office) +1-404-452-9624 (mobile) hwalke@cdc.gov From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)

**Sent:** Tue, 13 Apr 2021 22:15:48 +0000

To: Wharton, Melinda (CDC/DDID/NCIRD/ISD); Lee, Grace; Hopkins, Bob

**Subject:** DoD and myocarditis

DoD has submitted manuscripts on post-COVID-19 vaccine-associated myocarditis to both JACC and JAMA Cardiology.