



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

September 2, 2022

Aaron Siri  
Siri & Glimstad LLP  
745 Fifth Ave.  
Suite 500  
New York, NY 10151  
Via email: foia@sirillp.com

Dear Mr. Siri:

This letter is our final response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of June 30, 2022, assigned #22-01789-FOIA, for “[IR#0802F] All “reports of possible concern based on the data mining results” the FDA shared with the CDC pursuant to section 2.5 of the VAERS Standard Operating Procedures for COVID-19. Information helpful to fulfilling the request: The CDC’s Immunization Safety Office is the likely custodian of responsive records.”

We located CDC reports that incorporate FDA data mining results are listed below in the online publicly available listings of TTS and Myocarditis publications as well as links to ACIP Meeting Presentations (October 2021 – May 2022) on Thrombosis with Thrombocytopenia Syndrome and Myocarditis following COVID-19 vaccinations. After a careful review of these pages, no information was withheld from release.

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

#### **TTS publications:**

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

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

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

[https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm?s\\_cid=mm7103a4\\_w](https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm?s_cid=mm7103a4_w)

### **Myocarditis publications:**

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

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

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

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

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

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

October 2021

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/03-COVID-Heaton-Douoguih-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/06-COVID-Shimabukuro-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/09-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/08-COVID-Klein-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/09-COVID-Talbot-508.pdf>

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

November 2021

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

December 2021

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/03-COVID-Talbot-508.pdf>
- [https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/04\\_COVID\\_Oliver\\_2021-12-16.pdf](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/04_COVID_Oliver_2021-12-16.pdf)
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/05-COVID-Su-508.pdf>

January 2022

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/02-COVID-Su-508.pdf>

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/03-COVID-Hause-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/04-COVID-Klein-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/05-COVID-Twentyman-508.pdf>
- [https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/06\\_COVID\\_Oliver\\_2022-01-05.pdf](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/06_COVID_Oliver_2022-01-05.pdf)

#### February 2022

- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/02-COVID-Das-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/03-COVID-Shimabukuro-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04-COVID-Kracalic-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/05-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/05-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/06-COVID-Wallace-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/07-COVID-Oliver-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/09-COVID-Tunis-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/10-COVID-Klein-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/11-COVID-Moulia-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/12-COVID-Oliver-508.pdf>

#### April 2022

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

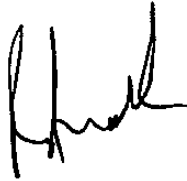
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/04-COVID-Talbot-508.pdf>
- <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-04-20/05-COVID-Oliver-508.pdf>

May 2022

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

If you need any further assistance or would like to discuss any aspect of the records provided please contact either our FOIA Requester Service Center at 770-488-6399 or our FOIA Public Liaison at 770-488-6246.

Sincerely,



Roger Andoh  
CDC/ATSDR FOIA Officer  
Office of the Chief Operating Officer  
(770) 488-6399  
Fax: (404) 235-1852