# Exhibit D

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745 Fifth Ave, Suite 500, New York, NY 10151
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

**FDA FREEDOM OF INFORMATION ACT REQUEST**
**EXPEDITED PROCESSING REQUESTED**

**VIA ONLINE PORTAL** October 23, 2023

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: *Data Sets, Study Designs, and Analysis Plans for Study of Safety of COVID-19 Vaccines in U.S. Children (IR#2001B)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, we submit this FOIA request to the Food and Drug Administration ("**FDA**"):

## I. The Request

Please provide the following records to foia@sirillp.com in electronic form:

> **All data sets, study designs, and analysis plans for the study titled, "Safety of Monovalent BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and NVX-CoV2373 (Novavax) COVID-19 Vaccines in US Children Aged 6 months to 17 years." (Attachment A.)**
>
> **Responsive records should include all drafts, amendments, and final versions of the study designs and analysis plans.**

## II. Expedited Processing Request

We ask that you provide expedited processing for this request. The information requested concerns matters of urgent public concern. ICAN's request for expedited processing should be granted because it qualifies under the "compelling need" analysis, as defined by FOIA. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning

actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

**1. The requester is primarily engaged in disseminating information**

ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. (**Attachment B**.) In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website[1] hosts the organization's largest education program, The HighWire with Del Bigtree.[2] Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 189,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and BitChute, The HighWire has approximately 135,000 followers and growing. Additionally, ICAN has approximately 29,000 text subscribers and 194,245 email subscribers. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts and their impacts on civil rights.

**2. There is an urgency to inform the public concerning actual or alleged Federal Government activity**

In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (i) whether the request concerns a matter of current exigency to the American public; (ii) whether the consequences of delaying a response would compromise a significant recognized interest; and (iii) whether the request concerns federal government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of ICAN's FOIA request.

**(i) ICAN's request concerns a matter of current exigency to the American public**

First, ICAN's request concerns a matter of current exigency to the American public because CDC added COVID-19 vaccines to the routine childhood immunization schedule,[3] which opens the door for states or organizations to make access to certain services, such as public school, day care, and pediatric visits, contingent upon a child's COVID-19 vaccination status. The records requested by ICAN will significantly contribute to the public's understanding of the potential risks associated with the COVID-19 vaccines, which is paramount to the fundamental right of informed

[1] https://www.icandecide.org/.

[2] https://thehighwire.com/.

[3] https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

consent.[4] It is critical for decisionmakers to have access to all available safety data when considering establishment of a mandate, and it is equally important for the public to have access to the data in order to make an informed decision regarding mandate compliance.

Second, even without vaccine mandates, based on the recommendations of federal public health agencies, all Americans six months of age and older are recommended to "*stay up to date* with COVID-19 vaccines of their age group"[5] (emphasis added). For example, CDC recommends children from 6 months to 4 years of age to receive 3 doses of the Pfizer-BioNTech COVID-19 vaccine.[6] For children ages 5 to 17 years old, CDC recommends 1 dose of the updated Pfizer-BioNTech COVID-19 vaccine. The broad application and frequency at which federal health agencies are recommending Americans to receive COVID-19 vaccines demands immediate transparency regarding any information concerning their safety and efficacy.

For these reasons, ICAN has demonstrated that its request significantly concerns matters of current exigency to the American public. Therefore, the first factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

**(ii) Consequences of delaying a response would compromise significant recognized interests**

The American public has a significant recognized interest in informed consent.[7] Understanding the ongoing studies for the COVID-19 vaccines is a key component of informed consent because it provides consumers insight into the thoroughness of the manufacturers' data supporting the reported safety and effectiveness. The manufacturers are protected from liability by the Public Readiness and Emergency Preparedness (PREP) Act[8], and without the threat of liability for harms caused by products, manufacturers have less incentives to prioritize greater investment into product safety.[9] Therefore, the public must have access to all available safety data in order to fully assess the risks involved in using the vaccines. Delaying a response to ICAN's request would compromise Americans' significant recognized interest in informed consent for medical procedures that are recommended, and in the case of COVID-19 vaccines, mandated by the government.

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[4] For example, notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . ." 10NYCRR § 405.7 (b)(9).

[5] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

[6] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#children.

[7] *See* footnote 8 for examples of informed consent codified.

[8] https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf#:~:text=Public%20Readiness%20and%20Emergency%20Preparedness%20Act%20%28PREP%20Act%29,Declaration%20is%20subject%20to%20amendment%20as%20circumstances%20warrant.

[9] *See generally* Restat 3d of Torts: Products Liability, §2.

American taxpayers also have a significant recognized interest in the safety data for COVID-19 vaccines, especially for our youngest and most vulnerable populations, because compensation for COVID-19 vaccine-related injuries and deaths are funded and limited by the Countermeasures Injury Compensation Program (CICP).[10] Under CICP, the American taxpayers are directly responsible for compensation for those who suffer vaccine-related injuries or deaths via emergency appropriations to the Covered Countermeasures Process Fund. [11] Therefore, the American taxpayer has a significant recognized interest in understanding the safety of the COVID-19 vaccines.

For the reasons set forth above, ICAN has demonstrated that delaying a response to its request would compromise significant recognized interests. Thus, the second factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

**(iii) ICAN's request concerns federal government activity**

ICAN's request concerns federal government activity because the information requested is directly linked to scientific conclusions federal health agencies made regarding the safety of the COVID-19 vaccine booster. As previously described, CDC recommends that everyone over 6 months of age receive an updated booster[12], and both the White House and CDC Director Mandy Cohen actively promote and effectively advertise the COVID-19 vaccines on social media.[13] Therefore, the requested information will assist the public and the scientific community in evaluating the appropriateness of these recommendations and outreach efforts carried out by the federal government.

For the reasons set forth above, ICAN has demonstrated that the request concerns federal government activity. Thus, the third and final factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

ICAN has demonstrated (i) the request concerns a matter of current exigency to the American public, (ii) the consequences of delaying a response would compromise a significant recognized interest, and (iii) the request concerns federal government activity. Therefore, ICAN has reasonably established under FOIA a "compelling need" for the expedited processing of its request. 5 U.S.C. § 552(a)(6)(E)(v)(II).

## III. Fee Waiver Request

We also ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). As stated above,[14] ICAN is a not-for-profit news media organization whose

[10] https://www.hrsa.gov/cicp.

[11] https://crsreports.congress.gov/product/pdf/LSB/LSB10584.

[12] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

[13] https://twitter.com/WhiteHouse/status/1701739977367818397; https://twitter.com/CDCDirector/status/1715012612750987465; https://twitter.com/CDCDirector/status/1714706433231519841; https://twitter.com/CDCDirector/status/1712852744875155864; https://twitter.com/CDCDirector/status/1712268748705698218.

[14] *See* page 2.

mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. (**Attachment B**.) As part of its mission, ICAN actively investigates and disseminates scientifically based health information regarding the safety of vaccines and other medical treatments, for free through its website, a weekly health news and talk show, and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

## IV. Estimated Date of Completion Request

Pursuant 5 U.S.C. § 552 (a)(7)(B)(ii), we specifically request that FDA provide us with an estimated date of completion for this request. The estimated completion date can be emailed to foia@sirillp.com when it has been determined.

## V. Conclusion

A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately take further administrative or legal action.

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

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

Very truly yours,

*/s/ Aaron Siri*
Aaron Siri, Esq.

# Attachment A

# Safety of Monovalent BNT162b2 (Pfizer-BioNTech), mRNA-1273 (Moderna), and NVX-CoV2373 (Novavax) COVID-19 Vaccines in US Children Aged 6 months to 17 years

Mao Hu, BS[1]; Azadeh Shoaibi, PhD, MHS[2]; Yuhui Feng, MS[1]; Patricia C. Lloyd, PhD, ScM[2]; Hui Lee Wong, PhD, MSc[2]; Elizabeth R. Smith, BS[1]; Kandace L. Amend, PhD[3]; Annemarie Kline, MS[4]; Daniel C. Beachler, PhD, MPH[5]; Joann F. Gruber, PhD[2]; Mahasweta Mitra, MPH[1]; John D. Seeger, DrPH, PharmD[3]; Charlalynn Harris, MPH, PhD[4]; Alex Secora, PhD[6]; Joyce Obidi, PhD[2]; Jing Wang, BA[1]; Jennifer Song, MA, MURP[3]; Cheryl N. McMahill-Walraven[4]; Christian Reich, MD, PhD[6]; Rowan McEvoy, BS[1]; Rose Do, MD[1]; Yoganand Chillarige, MPA[1]; Robin Clifford, MS, BS[3]; Danielle D Cooper[4]; Richard Forshee, PhD[2]; Steven A. Anderson, PhD, MPP[2]

[1] Acumen LLC, Burlingame, CA, USA

[2] US Food and Drug Administration, Silver Spring, MD, USA

[3] Optum Epidemiology, Boston, MA, USA

[4] Carelon Research, Wilmington, DE, USA

[5] CVS Health/Aetna, Blue Bell, PA, USA

[6] IQVIA, Falls Church, VA, USA

**Corresponding Author**:

Patricia C. Lloyd, PhD, ScM

Health Statistician

Office of Biostatistics and Pharmacovigilance

Center for Biologics Evaluation and Research

U.S. Food & Drug Administration

10903 New Hampshire Ave., Building 71

Silver Spring, MD 20993

Email: patricia.lloyd@fda.hhs.gov

**Word Count:** 2,964

## Key Points

### *Question*

Did active monitoring detect statistical signals for health outcomes following monovalent COVID-19 vaccination in the US children aged 6 months to 17 years?

### *Findings*

In this study including 4,102,106 vaccinated enrollees from three commercial claims databases, myocarditis or pericarditis signaled after BNT162b2 (12-17 years) and a new signal was detected for seizures/convulsions after BNT162b2 (2-4 years) and mRNA1273 COVID-19 vaccinations (2-5 years).

### *Meaning*

Near real-time monitoring of vaccines can rapidly identify potential safety concerns. While the myocarditis or pericarditis signal is consistent with existing evidence, the new seizures/convulsions signal should be interpreted cautiously given study limitations.

## Abstract

### *Importance*

Active monitoring of health outcomes after COVID-19 vaccination provides early detection of rare outcomes that may not be identified in prelicensure trials.

### *Objective*

To conduct near real-time monitoring of health outcomes following COVID-19 vaccination in the United States (US) pediatric population aged 6 months to 17 years.

### *Design*

We evaluated 21 pre-specified health outcomes; 15 were sequentially tested through near real-time surveillance, and 6 were monitored descriptively within a cohort of vaccinated children. We tested for increased rate of each outcome following vaccination compared to a historical comparator cohort.

### *Setting*

This population-based study was conducted under the US Food and Drug Administration public health surveillance mandate using three commercial claims databases.

### *Participants*

Children aged 6 months to 17 years were included if they received a monovalent COVID-19 vaccine dose before early 2023 and had continuous enrollment in a medical health insurance plan from the start of an outcome-specific clean window to the COVID-19 vaccination dose.

### *Exposure*

Exposure was defined as receipt of a monovalent BNT162b2, mRNA-1273, or NVX-CoV2373 COVID-19 vaccine dose. The primary analysis evaluated dose 1 and dose 2 combined, and secondary analyses

evaluated each dose separately. Follow-up time was censored at death, disenrollment, end of risk window, end of study period, or a subsequent dose administration.

***Main Outcomes***

Twenty-one prespecified health outcomes.

***Results***

The study included 4,102,016 enrollees aged 6 months to17 years. Thirteen of 15 outcomes sequentially tested did not meet the threshold for a statistical signal. In the primary analysis, myocarditis or pericarditis signals were detected following BNT162b2 vaccine in children aged 12-17 years old and seizures/convulsions signals were detected following vaccination with BNT162b2 and mRNA-1273 in children aged 2-4/5 years. However, in a post-hoc sensitivity analysis, the seizures/convulsions signal was sensitive to background rates selection and was not observed when 2022 background rates were selected instead of 2020 rates.

***Conclusions and Relevance***

Of the two signaled outcomes, the myocarditis or pericarditis signals are consistent with previously published reports. The new signal detected for seizures/convulsions among younger children should be further investigated in a robust epidemiological study with better confounding adjustment.

## Introduction

Three vaccines against COVID-19 are currently available for use in children in the United States (US) including the Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273) COVID-19 mRNA vaccines for those aged 6 months to 17 years and the protein-based Novavax COVID-19 vaccine (NVX-CoV2373) for those aged 12 to 17 years.[1-3] As of May 2023, the Centers for Disease Control and Prevention (CDC) reported 31.78 million children had received at least one COVID-19 vaccine dose and 26.2 million children had completed the primary series out of approximately 73 million children aged 6 months to 17 years in the US.[4] The US Food and Drug Administration (FDA), utilizing the Biologics Effectiveness and Safety (BEST) Initiative, has been monitoring the safety of COVID-19 vaccines in children since their authorization by applying a near real-time monitoring framework to evaluate the safety of COVID-19 vaccines. This process is a signal detection or screening method and the first step in safety monitoring of these vaccines. This framework is designed to be sensitive enough to rapidly detect less common safety signals. However, results of such study design do not establish a causal relationship between the vaccines and health outcomes and need to be interpreted with caution because of the limited adjustment for confounding and other forms of bias.

The BEST analysis of COVID-19 vaccines in children initially focused on the BNT162b2 COVID-19 monovalent vaccine authorized for use in children aged 5 to 17 years. Surveillance has since been expanded as additional pediatric age groups and vaccine brands received authorization through late 2022. Results of the initial, more limited, safety surveillance in children have been previously published.[5] In this report, we present results from the expanded monitoring of health outcomes in children after exposure to the ancestral monovalent COVID-19 vaccines in the US targeting the original COVID-19 strain.

## Methods

***Study Objective***

This study evaluated 21 pre-specified health outcomes after exposure to BNT162b2, mRNA-1273, or NVX-CoV2373 monovalent COVID-19 vaccines in children 6 months to 17 years old by applying a near real-time monitoring framework using health care data from three commercial claims databases in the US. Fifteen outcomes underwent sequential testing, and 6 outcomes were only monitored descriptively due to lack of historical rates.

***Data Sources***

The study used commercial administrative claims data from Optum, Carelon Research, and CVS Health containing longitudinal medical and pharmacy claims data supplemented with vaccination data from participating local and state Immunization Information Systems (IIS) (Supplemental Table 1).[6]

***Study Population and Period***

The study included pediatric enrollees aged 6 months to 17 years who received a monovalent COVID-19 vaccine from the earliest date of its Emergency Use Authorization by age group through April 2023 (Optum), March 2023 (Carelon Research), and February 2023 (CVS Health) (Supplemental Table 2). The surveillance concluded on these respective dates because of limited accrual of exposures and health outcomes. The sequential analyses for most outcomes did not reach the expected number of events that was pre-specified based on anticipated vaccination uptake in a 6-month period post-authorization of individual vaccine products. Another contributing factor to halting surveillance was the de-authorization of the original monovalent mRNA-1273 and BNT162b2 doses for persons of all ages on April 18, 2023.[7]

The inclusion criteria for the study included enrollment on the vaccination date and continuous enrollment in a participating medical health insurance plan from the start of an outcome-specific clean window to the COVID-19 vaccination date so that only new incident diagnosis of an outcome in the

post-vaccination risk window would contribute to the analysis (Supplemental Table 3).

***Exposures and Follow Up***

Exposure was defined as the receipt of a BNT162b2, mRNA-1273, or NVX-CoV2373 monovalent COVID-19 vaccine dose identified using brand and dose-specific Current Procedural Terminology/ Healthcare Common Procedure Coding System codes[8] and National Drug Codes (Supplemental Table 4). Dose number was assigned based on the chronological order in which vaccinations were observed since administration codes were not available in pharmacy claims. The primary analyses included all follow-up time accrued after dose 1 and dose 2 combined. Secondary analyses included stratification by dose number and follow-up time accrued after the individual dose (including monovalent third/booster doses) through censoring at subsequent vaccination, death, disenrollment, end of risk window, or end of study period.

***Health Outcomes***

Twenty-one pre-specified health outcomes were defined using claims-based algorithms[9-10]. Outcomes were selected through clinical consultation and literature review. Fifteen health outcomes were assessed using sequential testing comparing rates to historical outcome rates (additional information on historical rates below), and 6 were only monitored descriptively due to lack of historical rates.[10] The outcome myocarditis, pericarditis, or co-occurring myocarditis and pericarditis (hereafter referred to as myocarditis/pericarditis) was assessed using four different definitions with varying risk windows and care settings (included in Supplemental Table 3) based on evidence from prior surveillance efforts and clinical input.

***Descriptive Monitoring***

We estimated outcome rates in the vaccinated population stratified by age, sex, region, urban/rural status, data source, and vaccine brand on a monthly basis.

***Sequential Testing***

Monthly sequential testing was conducted using the Poisson Maximized Sequential Probability Ratio Test (PMaxSPRT) to detect statistical signals by generating the incidence rate ratio (IRR) comparing outcome rates following vaccination to database-specific historical (expected) rates for 15 health outcomes.[11]

We estimated annual historical rates for 2019 and 2020 as well as during the COVID-19 pandemic between April and December 2020. Historical rates were adjusted for claims processing delay to account for observation delay and standardized by age and sex where case counts permitted.[12] Selection of the historical comparator rate was based on the overlap between the 95% confidence intervals (CI) for the periods prior to and during the COVID-19 pandemic. If rates in these two historical periods differed substantially, we selected either the minimum or more stable rate as a more conservative approach.

Tests were stratified by age based on age-group-specific authorizations by vaccine brand as well as availability of background rates using historical comparator data. For BNT162b2, this included ages 6 months-4 years, 6 months-1 year and 2-4 years (for seizure/convulsions only), 5-11 years, 12-15 years, and 16-17 years. For mRNA-1273, this included 6 months-5 years, 6 months-1 year and 2-5 years (for seizure or convulsions only), 6-11 years, 12-15 years, and 16-17 years. For NVX-CoV2373, the age groups were 12-15 years and 16-17 years.

Sequential testing for each outcome commenced when a minimum of three cases accrued in the risk window. One-tailed tests were used with the null hypothesis that the observed rate was no greater than the historical comparator rate beyond a pre-specified test margin for each outcome-dose-age group being sequentially tested, with an alpha level of 1%. A stringent alpha level was selected to increase the specificity of signals detected from testing multiple outcomes across different analyses. The log likelihood ratio was calculated comparing the likelihood of the observed IRR and the null hypothesis.

At each test, if the log likelihood ratio exceeded a pre-specified critical value, the null hypothesis was rejected, and a signal was declared. Surveillance continued until a signal was detected, the pre-specified maximum surveillance length was reached, or the end of study period was reached.[10]

### *Signal Characterization*

Signal characterization was conducted after a signal was identified to provide data quality assessment.[13] We conducted quality checks to rule out database errors or changes in the patterns of diagnosis codes used to identify events in the study period; estimated the relative risk of outcomes within demographic strata by age and sex; examined the timing of outcomes occurrence during the pre-specified risk window; and assessed whether the signal was sensitive to changes in background rates selection by conducting a post-hoc sensitivity analysis using the updated 2022 background rates as the historical comparator in sequential testing.

### *Medical Record Review*

Medical record review was conducted for the myocarditis/pericarditis outcome following identification of a signal. Brighton Collaboration case definitions were used to adjudicate cases.[14] Records meeting the confirmed or probable Brighton classifications were considered true myocarditis/pericarditis cases for the validation analyses.

## Results

### *Descriptive Monitoring*

A total of 8,444,355 monovalent COVID-19 vaccine doses were administered to 4,102,016 enrollees aged 6 months -17 years (Figure 1). This included 8,121,591 BNT162b2 (Dose 1: 3,843,778, Dose 2: 3,235,442, Dose 3/ Monovalent Booster: 1,033,036 and Unknown/Unclear: 9,335), and 322,628 mRNA-1273 doses (Dose 1: 173,857, Dose 2: 140,734, Dose 3/Monovalent Booster: 5,284 and

Unknown/Unclear: 2,753) administered to children aged 6 months-17 years, as well as 136 NVX-CoV2373 doses (Dose 1: 63, Dose 2: 43, Dose 3/Monovalent Booster and Unknown/Unclear: 30) administered to children aged 12-17 years (Table 1a). Demographic characteristics of the vaccinated population except age reported at first dose were largely similar across vaccine brands. While majority (93.4%) of BNT162b2-vaccinated individuals were 5 years old and older; majority (97.6%) of mRNA-1273-vaccinated individuals were younger than 5 years old. Across all vaccine brands, 2,058,142 (50.2%) were males and 3,901,370 (95.2%) lived in an urban area (Table 1b). We observed low case counts for outcomes that were monitored descriptively only (<80 cases of any given outcome in all three databases combined) (Supplemental Table 5).

***Sequential Testing***

Among 15 outcomes that were sequentially tested, two outcomes met the statistical threshold for a signal including myocarditis/pericarditis in ages 12-15 and 16-17 years, and seizures/convulsions in ages 2-4/5 years.

Myocarditis/pericarditis signaled for all definitions in the primary analysis following BNT162b2 COVID-19 vaccination among children aged 12-15 and 16-17 years in all three databases. Additionally, dose-specific signals for one or more definitions of the outcomes were detected in ages 12-17 years following dose 1, dose 2, and dose 3 of BNT162b2 vaccine in at least one of the three databases (Table 2).

In the primary analysis, seizures/convulsions met the statistical threshold for a signal in children aged 2-4 years following BNT162b2 vaccination in all three databases, and in children aged 2-5 years following mRNA-1273 vaccination in two of the three databases. Dose-specific signals for seizures/convulsions were detected in two of the three databases following dose 1 and dose 2 BNT162b2 vaccination in ages 2-4 years and following dose 2 mRNA-1273 vaccination in ages 2-5

years (Table 2).

Sequential testing did not initiate for any of the 15 outcomes for mRNA-1273 in ages 5-17 years and NVX-CoV2373 in ages 12-17 years, because no outcomes were observed in any databases.

***Signal Characterization***

Since myocarditis/pericarditis is a known adverse outcome following COVID-19 mRNA vaccinations, further signal characterization activities were not conducted. In the evaluation of the seizures/convulsions signal among children aged 2-4/5 years, none of the pre-specified data quality checks, including claims duplication, timing of events within pre-specified risk window, and IRR estimates, raised any data quality concerns.

There were 72 observed seizures/convulsions cases among children aged 2-4/5 years and >50% of these cases met the definition of febrile seizures. No differences in rates of seizures/convulsions by sex were identified. The timing of cases did not indicate substantial clustering with cases distributed across the 0-7-day risk window; 31.9% of the seizures/convulsions cases occurred within the 0-1 days following COVID-19 vaccination. The median time between vaccination and diagnosis of seizures/convulsions was 2 days. (Supplemental Figure 1).

The seizures/convulsions signal was sensitive to changes in the selection of comparator rates. Evaluation of the annual background rate of seizures/convulsions indicated that the rates used in the primary analyses (2020) were substantially lower than rates in 2022. Background rates in 2022 ranged from approximately 2.2-2.4 times the 2020 rates across three databases (Supplemental Table 6). A post-hoc sensitivity analysis using 2022 background rates as the comparator in sequential testing did not identify any seizures/convulsions signals.

***Medical Record Review***

Of the 153 cases of myocarditis/pericarditis after COVID-19 vaccination among children aged 12-17 years, medical record review was conducted for a sample of 40 cases whose records could be obtained. Twenty-nine of these cases (72.5%) were confirmed as true cases of myocarditis/pericarditis, of which 27 patients were male, and 19 were hospitalized with a median length of hospital stay of 2 days (interquartile range: 1, 3). The median time from vaccination to presentation of myocarditis/pericarditis event was 3 days (interquartile range: 2, 5). Medical record review and further validation efforts for seizures/convulsions are currently underway.

**Discussion**

Our near real-time monitoring of 21 pre-specified health outcomes following monovalent COVID-19 vaccines detected signals for myocarditis/pericarditis in the age group 12-17 years and seizures/convulsions in the age group 2-4/5 years. We did not detect signals for other outcomes that were sequentially tested.

The myocarditis/pericarditis signal is consistent with peer-reviewed publication reports demonstrating an elevated risk of this outcome following mRNA vaccines among younger males aged 12 to 29 years.[15-17] Myocarditis/pericarditis is a rare event with a reported average incidence of 39.3 cases per one million vaccine doses administered in children aged 5-17 years within 7 days after BNT162b2 vaccination.[18-19] We did not detect a signal for myocarditis/pericarditis in children younger than 12 years old which is consistent with reports from other surveillance systems.[20-21]

The seizures/convulsions signal in children aged 2-4/5 years has not been previously reported for this age group in active surveillance studies of mRNA COVID-19 vaccines. However, there are reports from the Vaccine Adverse Events Reporting System (VAERS) database which is a passive reporting system and has limitations. In an analysis of VAERS data, only 8 seizures were identified following approximately one million mRNA vaccinations through August 2022 in the age group 6 months to 5

years. Six of the 8 seizures were afebrile on medical evaluation.[22] Pre-licensure vaccine safety data indicate that among young children, seizures/convulsions following mRNA COVID-19 vaccines are rare; clinical trial of 3,013 BNT162b2 vaccine recipients in children aged 6 months to 4 years reported only 5 febrile convulsions cases and only one of those (in a 6-month-old participant) was considered possibly related to the vaccine or may also have been caused by a concurrent viral infection.[23] Among studies conducted in children with childhood epilepsy (<18 years), no increased risk of medically attended seizures was identified following immunization with COVID-19 vaccines. Seizure risk after COVID-19 vaccination was lower in children who were seizure free for more than six months before vaccination. However, the incidence of general adverse events after vaccination was low with no severe adverse events recorded. [24-25] Generally, there is limited evidence linking the mRNA COVID-19 vaccines to a seizure onset among vaccinated children aged 2-4/5 years.

The new seizures/convulsions signal observed in our study should be interpreted with caution and further investigated in a more robust epidemiological study. Our study utilized a broad seizures/convulsions outcome definition with a 0-7-day risk window because of its applicability to older children. However, in children younger than 5 years, vaccine-related seizures typically manifest as a febrile seizure.[26] Although the majority of seizures/convulsions cases met the febrile seizure definition, there was no statistically significant clustering observed at days 0-1. Since febrile seizures can be common in young children for a variety of reasons; the analysis may have identified febrile seizures unrelated to the vaccination later in the risk window.

The post-hoc sensitivity analyses using the 2022 background rates as comparators in sequential testing did not yield any seizures/convulsions signals which suggest that our results are sensitive to comparator rate selection. The decision to use 2020 seizures/convulsions rates as comparators was to maximize sensitivity in the primary analysis. However, seizures/convulsions rates in this age group in 2022 were twice as high as 2020 rates. There could be a couple of potential reasons for elevated outcome rates in

2022 compared to 2020. First, there was an increased incidence of respiratory infections (influenza and respiratory syncytial virus) which are shown to be associated with febrile seizure in younger children, during the study period (mid-2022 to mid-2023) compared to 2020.[27-30] Second, in 2020, there were likely fewer emergency department visits for seizure-related events compared to 2022 because of COVID-19 pandemic healthcare resource limitations.[31]

Our study has a number of strengths. First, the study included a large, geographically diverse population from three US commercial health insurance databases. Due to availability of more complete information from claims supplemented with IIS data and a short data lag from health encounters, we monitored monovalent COVID-19 vaccines safety in a near real-time manner. Additionally, a subset of the identified myocarditis/pericarditis cases were confirmed through medical record review.

The study also has some limitations. We used a near–real-time surveillance method which may be sensitive to comparator rate selection and does not include controlling for bias and confounding. Therefore, results from this study do not establish a causal relationship between the vaccines and health outcomes, and signals should be further evaluated. Secondly, this study only includes data from a commercially insured pediatric population and may not be nationally representative. Furthermore, the study may have limited power to detect small increases in risk of outcomes in certain subgroups or in the cases of more recently authorized vaccines, such as NVX-CoV2373 in children aged 12-17 years as well as mRNA-1273 in those aged 5-17 years.

**Conclusion**

Our study detected a signal for myocarditis/pericarditis in older children which is consistent with existing literature, and a new signal for seizures/convulsions in young children that is being further evaluated in a more robust study. FDA concludes that the known and potential benefits of COVID-19 vaccination outweigh the known and potential risks of COVID-19 infection. This study was conducted

under the FDA BEST Initiative which plays a major role in the larger US federal government vaccine safety monitoring efforts and further supports regulatory decision-making regarding COVID-19 vaccines.

**Acknowledgements**

**Funder**: The US Food and Drug Administration provided funding for this study and contributed as follows: led the design of the study, interpretation of the results, writing of the manuscript, decision to submit, and made contributions to the coordination of data collection and analysis of the data.

**Disclosures:**

Annemarie Kline, Cheryl McMahill-Walraven, Djeneba Audrey Djibo worked on grants, subcontracts, or contracts from Harvard Pilgrim Health Care Institute, Brown University (National Institute on Aging/ IMPACT Collaboratory), Reagan Udall Foundation for the FDA, Academy of Managed Care pharmacy's Biologics and Biosimilar Collective Intelligence Consortium (BBCIC), TherapeuticsMD, Reachnet (Louisiana Public Health Institute), IQVIA, Pfizer, Carelon Research (formerly Healthcore), and Patient Centered Outcomes Research Institute as employees of CVS Health and report stock or stock options from CVS Health; Carelon Research; Kandace Amend, Robin Clifford, John Seeger, and Jennifer Song reports stock or stock options in UnitedHealth Group; Daniel C. Beachler is an employee of Carelon Research who has previously contracted with Pfizer Inc. for separate projects. No other authors report relevant disclosures.

**Additional Contributions**: We thank Tainya C. Clarke, Sylvia Cho and Carla E. Zelaya of the US Food and Drug Administration; Anchi Lo, Bing Lyu, Nimesh Shah, Derek Phan, Gyanada Acharya, Kamakshi Sirpal, Laurie Feinberg, Lloyd Marks, Minisha Kochar, Sandia Akhtar, Shruti Parulekar, Stella Zhu, William (Trey) Minter, Yeerae Kim, Yixin Jiao, and Zhiruo (Cassie) Wan of Acumen; Nancy B Shaik, Ana M Martinez-Baquero, Smita Bhatia, Vaibhav Sharma, Carla Brannan of CVS Health and Charlalynn Harris and Danielle Cooper formerly CVS Health; Shiva Vojjala, Ramya Avula,

Shiva Chaudhary, Shanthi P Sagare, Ramin Riahi, Navyatha Namburu, and Grace Stockbower of Carelon Research; Michael Goodman, Michael Bruhn, and Ruth Weed of IQVIA; Grace Yang, Sarah Sargen, Alexandra Stone, Wafa Tarazi, Megan Ketchell, Kathryn Federici, Amaka Ume, Emily Myers, Eli Wolter, Jackson Slaney, Bobby Smith, Lauren Peetluk, and Elizabeth Bell of Optum.

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***Table 1a. Vaccine Dose Counts for Monovalent BNT162b2, mRNA-1273, NVX-CoV2373 COVID-19 Vaccines Administered to the Pediatric Population, All Data Sources[a]***

| Vaccine Dose | BNT162b2 | | mRNA-1273 | | NVX-CoV2373 | |
|---|---|---|---|---|---|---|
| | N | % | N | % | N | % |
| **Total** | 8,121,591 | 100 | 322,628 | 100 | 136 | 100 |
| **Dose 1** | 3,843,778 | 47.33 | 173,857 | 53.89 | 63 | 46.32 |
| **Dose 2** | 3,235,442 | 39.84 | 140,734 | 43.62 | 43 | 31.62 |
| **Dose 3/Monovalent Booster** | 1,033,036 | 12.72 | 5,284 | 1.64 | § | § |
| **Unknown/Unclear** | 9,335 | 0.11 | 2,753 | 0.85 | § | § |

[a] Combines Optum data through 4/2023, Carelon Research data through 3/2023, CVS Health data through 2/2023
[§] Cell sizes 1-10 and cells that can be used to back-calculate small cell sizes were masked for confidentiality

***Table 1b. Characteristics of Pediatric Population Receiving Monovalent BNT162b2, mRNA-1273, and NVX-CoV2373 COVID-19 Vaccines, All Data Sources***

| Patient Characteristics[#] | BNT162b2 | | mRNA-1273 | | NVX-CoV2373 | | Multiple Brands | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| **Total No. Persons Vaccinated** | 3,920,563 | 100 | 176,427 | 100 | 53 | 100 | 4,973 | 100 |
| **Age at First Dose (y)** | | | | | | | | |
| 6 months-4/5* | 256,958 | 6.55 | 172,161 | 97.58 | 0 | 0.00 | 2,299 | 46.23 |
| 5/6-11* | 1,558,895 | 39.76 | 1,687 | 0.96 | 0 | 0.00 | 1,471 | 29.58 |
| 12-15 | 1,389,351 | 35.44 | 1,420 | 0.80 | 27 | 50.94 | 945 | 19.00 |
| 16-17 | 715,359 | 18.25 | 1,159 | 0.66 | 26 | 49.06 | 258 | 5.19 |
| **Sex** | | | | | | | | |
| Female | 1,954,260 | 49.85 | 86,588 | 49.08 | 24 | 45.28 | 2,521 | 50.69 |
| Male | 1,965,853 | 50.14 | 89,808 | 50.90 | 29 | 54.72 | 2,452 | 49.31 |
| Missing/Unknown | 450 | 0.01 | 31 | 0.02 | 0 | 0.00 | 0 | 0.00 |
| **Urban/Rural** | | | | | | | | |
| Rural | 191,550 | 4.89 | 4,465 | 2.53 | § | § | § | § |
| Urban | 3,724,798 | 95.01 | 171,771 | 97.36 | 50 | 94.34 | 4,751 | 95.54 |
| Missing/Unknown | 4,215 | 0.11 | 191 | 0.11 | § | § | § | § |
| **United States Department of Health and Human Services (HHS) Region** | | | | | | | | |
| 1: CT, ME, NH, RI, VT | 252,282 | 6.43 | 15,436 | 8.75 | § | § | 287 | 5.77 |
| 2: NJ, NY, PR, VI | 481,296 | 12.28 | 25,927 | 14.70 | § | § | 1,844 | 37.08 |
| 3: DE, DC, MD, PA, VA, WV | 421,390 | 10.75 | 21,765 | 12.34 | § | § | 455 | 9.15 |
| 4: AL, FL, GA, KY, MS, NC, SC, TN | 610,942 | 15.58 | 16,869 | 9.56 | § | § | 523 | 10.52 |
| 5: IL, IN, MI, MN, OH, WI | 644,718 | 16.4 | 24,061 | 13.64 | § | § | 465 | 9.35 |
| 6: AR, LA, NM, OK, TX | 330,374 | 8.43 | 11,142 | 6.32 | § | § | 263 | 5.29 |
| 7: IA, KS, MO, NE | 159,328 | 4.06 | 6,401 | 3.63 | § | § | § | § |
| 8: CO, MT, ND, SD, UT, WY | 168,549 | 4.30 | 6,998 | 3.97 | § | § | 203 | 4.08 |
| 9: AZ, CA, HI, NV, AS, MP, FM, GU, MH, PW | 720,576 | 18.38 | 37,394 | 21.20 | § | § | 621 | 12.49 |
| 10: AK, ID, OR, WA | 127,558 | 3.25 | 10,260 | 5.82 | § | § | 203 | 4.08 |
| Missing/Unknown | 3,550 | 0.09 | 174 | 0.10 | 0 | 0.00 | § | § |
| **Facility/Provider Type** | | | | | | | | |
| Hospital | 194,886 | 4.97 | 11,492 | 6.51 | § | § | § | § |
| Office | 1,115,926 | 28.46 | 125,781 | 71.29 | § | § | 3,559 | 71.57 |
| Pharmacy | 1,610,036 | 41.07 | 9,940 | 5.63 | 32 | 60.38 | 337 | 6.78 |
| Skilled Nursing Facility | § | § | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| Home Health Agency | § | § | 73 | 0.04 | 0 | 0.00 | § | § |
| Mass Immunization Center | 110,794 | 2.83 | 2,448 | 1.39 | § | § | 121 | 2.43 |
| Other | 135,842 | 3.46 | 3,851 | 2.18 | § | § | 151 | 3.04 |
| Missing/Unknown | 751,900 | 19.18 | 22,842 | 12.95 | § | § | 710 | 14.28 |

Combines Optum data through 4/2023, Carelon Research data through 3/2023, CVS Health data through 2/2023

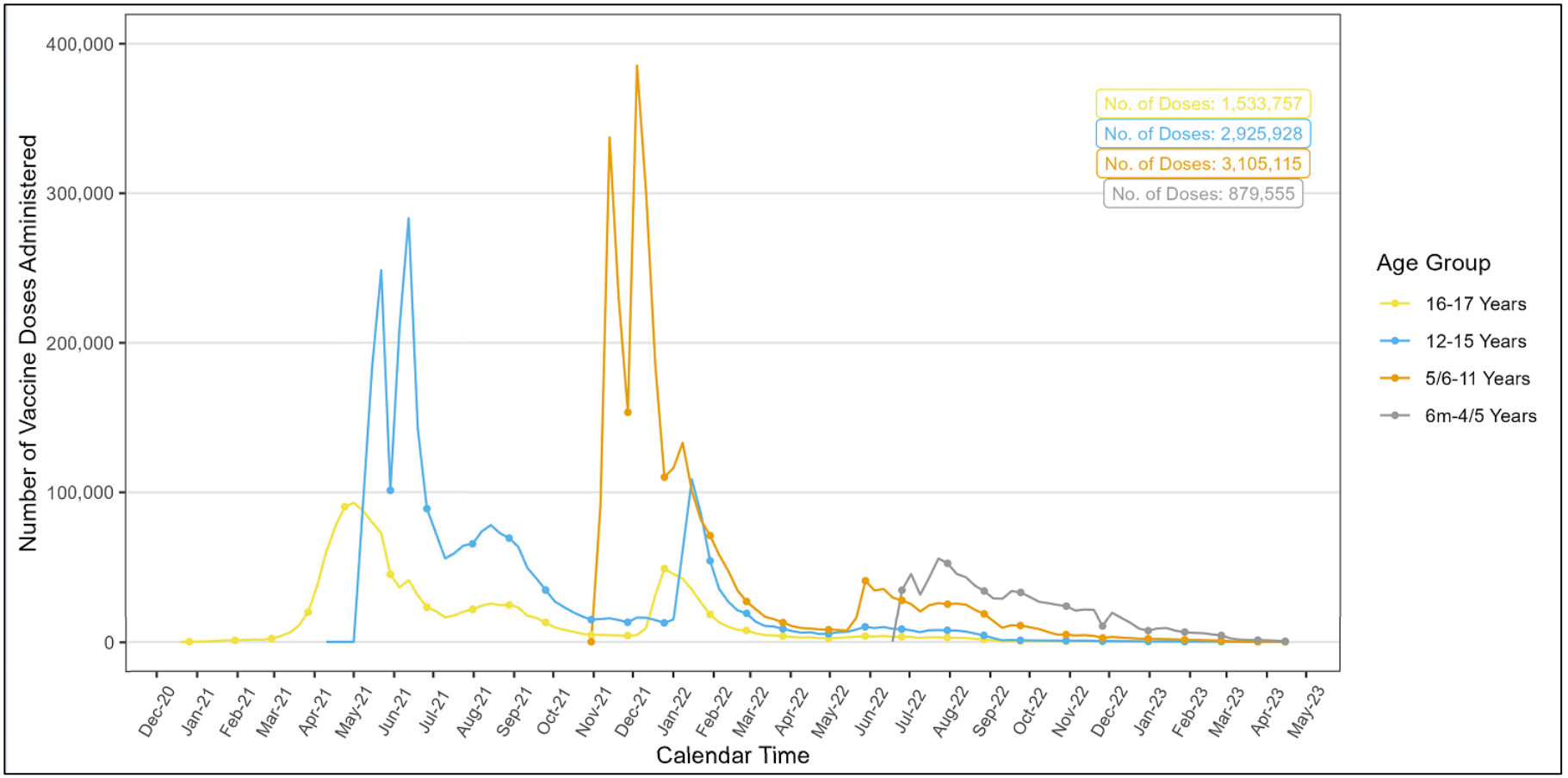
[#] Patient characteristics were assessed at the time of first vaccine dose which was either Dose1 or Dose 2 depending on the dose that met EUA-specific dose eligibility criteria; persons who received a different brand of vaccine from their Dose 1 are categorized in the "Multiple Brands" category

[§] Cell sizes 1-10 and cells that can be used to back-calculate small cell sizes were masked for confidentiality

Percentages may not sum up to 100% due to rounding.

* Children aged 6 months – 4 years that were vaccinated with BNT162b2 COVID-19 vaccine are included in 6 months – 4/5 years age group; children aged 6-months – 5 years that were vaccinated with mRNA1273 COVID-19 vaccine are included in the 6 months – 4/5 years age group. Children aged 5 – 11 years that were vaccinated with BNT162b2 COVID-19 vaccine are included in the 5/6 – 11 years age group; children aged 6 – 11 years that were vaccinated with mRNA1273 COVID-19 vaccine are included in the 5/6 -11 years age group.

***Figure 1. Distribution of Monovalent Doses of BNT162b2, mRNA-1273, and NVX-CoV2373 COVID-19 Vaccines Administered Over Time by Age Group, All Data Sources***




Combines Optum data through 4/2023, Carelon Research data through 3/2023, CVS Health data through 2/2023

***Table 2. Sequential Testing Results for the Pediatric Population Receiving BNT162b2 or mRNA-1273 Monovalent COVID-19 Vaccines Stratified by Vaccine dose and Outcome***

| Outcome | Dose | Age Group (years) | BNT162b2 | | | | mRNA-1273 | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | No. Vaccine Doses | No. Outcomes | Person-Time (Days) | Signal Status* | No. Doses | No. Outcomes | Person-Time (Days) | Signal Status* |
| Anaphylaxis | Dose 1 + Dose 2 | 6months(m)-4/5 | 454,003 | § | 903,139 | NT | 304,501 | § | 606,089 | NT |
| | | 5/6-11 | 2,715,842 | § | 5,428,277 | NS | 1,687 | 0 | 3,346 | NT |
| | | 12-15 | 2,444,395 | § | 4,887,562 | NS | 1,558 | 0 | 3,093 | NT |
| | | 16-17 | 1,245,735 | § | 2,490,728 | NT | 1,315 | 0 | 2,604 | NT |
| | Dose 1 | 6m-4/5 | 248,106 | § | 493,859 | NT | 166,491 | 0 | 331,645 | NT |
| | | 5/6-11 | 1,467,128 | § | 2,932,681 | NT | 1,068 | 0 | 2,120 | NT |
| | | 12-15 | 1,309,249 | § | 2,617,844 | NS | 957 | 0 | 1,896 | NT |
| | | 16-17 | 676,147 | § | 1,351,857 | NT | 834 | 0 | 1,646 | NT |
| | Dose 2 | 6m-4/5 | 205,897 | § | 409,280 | NT | 138,010 | § | 274,444 | NT |
| | | 5/6-11 | 1,248,714 | § | 2,495,596 | NT | 619 | 0 | 1,226 | NT |
| | | 12-15 | 1,135,146 | § | 2,269,718 | NT | 601 | 0 | 1,197 | NT |
| | | 16-17 | 569,588 | 0 | 1,138,871 | NT | 481 | 0 | 958 | NT |
| | Dose 3 | 6m-4/5 | 102,335 | 0 | 204,292 | NT | 3,391 | 0 | 6,671 | NT |
| | | 5/6-11 | 269,600 | 0 | 538,724 | NT | 725 | 0 | 1,448 | NT |
| | | 12-15 | 383,763 | § | 767,272 | NT | 589 | 0 | 1,178 | NT |
| | | 16-17 | 237,024 | § | 473,794 | NT | 320 | 0 | 640 | NT |
| Appendicitis | Dose 1 + Dose 2 | 6m-4/5 | 351,986 | § | 11,874,618 | NT | 241,915 | § | 8,789,224 | NT |
| | | 5/6-11 | 2,213,650 | 206 | 72,789,318 | NS | 1,212 | 0 | 43,060 | NT |
| | | 12-15 | 2,035,023 | 302 | 66,600,250 | NS | 1,187 | 0 | 42,059 | NT |
| | | 16-17 | 1,043,311 | 166 | 34,406,004 | NS | 1,013 | 0 | 34,656 | NT |
| | Dose 1 | 6m-4/5 | 190,648 | § | 5,463,829 | NT | 131,372 | § | 4,385,416 | NT |
| | | 5/6-11 | 1,182,865 | 92 | 30,910,940 | NS | 755 | 0 | 26,302 | NT |
| | | 12-15 | 1,078,396 | 130 | 27,055,551 | NS | 703 | 0 | 23,821 | NT |
| | | 16-17 | 559,908 | 74 | 14,413,948 | NS | 632 | 0 | 20,186 | NT |
| | Dose 2 | 6m-4/5 | 161,338 | § | 6,410,789 | NT | 110,543 | § | 4,403,808 | NT |
| | | 5/6-11 | 1,030,785 | 114 | 41,878,378 | NS | 457 | 0 | 16,758 | NT |
| | | 12-15 | 956,627 | 172 | 39,544,699 | NS | 484 | 0 | 18,238 | NT |
| | | 16-17 | 483,403 | 92 | 19,992,056 | NS | 381 | 0 | 14,470 | NT |
| | Dose 3 | 6m-4/5 | 83,010 | § | 3,397,223 | NT | 2,845 | 0 | 92,282 | NT |
| | | 5/6-11 | 239,487 | 27 | 9,790,542 | NS | 645 | 0 | 23,859 | NT |
| | | 12-15 | 352,339 | 54 | 14,545,967 | NS | 532 | 0 | 20,146 | NT |
| | | 16-17 | 214,951 | 41 | 8,754,099 | NS | 285 | 0 | 10,536 | NT |
| Bell's Palsy | | 6m-4/5 | 410,400 | § | 14,065,149 | NS | 277,737 | § | 10,222,194 | NS |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Dose 1 + Dose 2 | 5/6-11 | 2,485,011 | 35 | 81,704,667 | NS | 1,467 | 0 | 53,845 | NT |
| | | 12-15 | 2,223,492 | 56 | 72,869,846 | NS | 1,410 | 0 | 51,392 | NT |
| | | 16-17 | 1,129,439 | 24 | 37,292,252 | NS | 1,216 | 0 | 43,061 | NT |
| | Dose 1 | 6m-4/5 | 221,585 | § | 6,444,275 | NT | 150,082 | § | 5,063,381 | NT |
| | | 5/6-11 | 1,334,662 | 14 | 35,013,473 | NS | 916 | 0 | 32,855 | NT |
| | | 12-15 | 1,179,765 | 18 | 29,755,101 | NS | 849 | 0 | 29,484 | NT |
| | | 16-17 | 607,786 | § | 15,737,104 | NS | 760 | 0 | 25,173 | NT |
| | Dose 2 | 6m-4/5 | 188,815 | § | 7,620,874 | NT | 127,655 | § | 5,158,813 | NT |
| | | 5/6-11 | 1,150,349 | 22 | 46,691,194 | NS | 551 | 0 | 20,990 | NT |
| | | 12-15 | 1,043,727 | 38 | 43,114,745 | NS | 561 | 0 | 21,908 | NT |
| | | 16-17 | 521,653 | § | 21,555,148 | NS | 456 | 0 | 17,888 | NT |
| | Dose 3 | 6m-4/5 | 96,939 | § | 3,984,353 | NT | 3,233 | 0 | 110,964 | NT |
| | | 5/6-11 | 259,078 | § | 10,618,052 | NS | 699 | 0 | 27,077 | NT |
| | | 12-15 | 370,606 | 16 | 15,297,175 | NS | 562 | 0 | 22,080 | NT |
| | | 16-17 | 229,588 | § | 9,335,942 | NS | 310 | 0 | 12,020 | NT |
| Common Site Thrombosis with Thrombocytopenia[†] | Dose 1 + Dose 2 | 6m-4/5[#] | 244,267 | 0 | 6,241,793 | NT | 81,661 | 0 | 2,219,079 | NT |
| | | 5-6/11[#] | 2,215,973 | § | 55,992,946 | NT | 621 | 0 | 16,404 | NT |
| | | 12-15 | 2,038,360 | § | 51,169,805 | NT | 1,188 | 0 | 31,617 | NT |
| | | 16-17 | 1,045,098 | § | 26,329,445 | NT | 1,016 | 0 | 26,702 | NT |
| | Dose 1 | 6m-4/5[#] | 131,743 | 0 | 3,201,944 | NT | 43,906 | 0 | 1,196,821 | NT |
| | | 5-6/11[#] | 1,184,106 | § | 27,642,091 | NT | 398 | 0 | 10,492 | NT |
| | | 12-15 | 1,080,146 | 0 | 24,623,090 | NT | 704 | 0 | 18,802 | NT |
| | | 16-17 | 560,874 | § | 12,913,395 | NT | 634 | 0 | 16,526 | NT |
| | Dose 2 | 6m-4/5[#] | 112,524 | 0 | 3,039,849 | NT | 37,755 | 0 | 1,022,258 | NT |
| | | 5-6/11[#] | 1,031,867 | 0 | 28,350,855 | NT | 223 | 0 | 5,912 | NT |
| | | 12-15 | 958,214 | § | 26,546,715 | NT | 484 | 0 | 12,815 | NT |
| | | 16-17 | 484,224 | § | 13,416,050 | NT | 382 | 0 | 10,176 | NT |
| | Dose 3 | 6m-4/5[#] | 59,404 | 0 | 1,638,795 | NT | 778 | 0 | 19,250 | NT |
| | | 5-6/11[#] | 239,716 | § | 6,602,510 | NT | 352 | 0 | 9,147 | NT |
| | | 12-15 | 352,878 | 0 | 9,765,325 | NT | 533 | 0 | 14,234 | NT |
| | | 16-17 | 215,309 | 0 | 5,886,780 | NT | 285 | 0 | 7,596 | NT |
| Deep Vein Thrombosis | Dose 1 + Dose 2 | 6m-4/5 | 351,932 | § | 9,020,709 | NT | 241,877 | 0 | 6,579,967 | NT |
| | | 5/6-11 | 2,215,893 | § | 55,988,930 | NT | 1,212 | 0 | 32,099 | NT |
| | | 12-15 | 2,038,235 | § | 51,163,432 | NS | 1,188 | 0 | 31,617 | NT |
| | | 16-17 | 1,044,870 | § | 26,321,797 | NS | 1,016 | 0 | 26,702 | NT |
| | Dose 1 | 6m-4/5 | 190,617 | 0 | 4,651,184 | NT | 131,352 | 0 | 3,581,264 | NT |
| | | 5/6-11 | 1,184,060 | § | 27,640,017 | NT | 755 | 0 | 20,038 | NT |
| | | 12-15 | 1,080,081 | § | 24,620,103 | NS | 704 | 0 | 18,802 | NT |
| | | 16-17 | 560,752 | § | 12,909,608 | NS | 634 | 0 | 16,526 | NT |
| | Dose 2 | 6m-4/5 | 161,315 | § | 4,369,525 | NT | 110,525 | 0 | 2,998,703 | NT |
| | | 5/6-11 | 1,031,833 | 0 | 28,348,913 | NT | 457 | 0 | 12,061 | NT |

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|---|---|---|---|---|---|---|---|---|---|---|
| | | 12-15 | 958,154 | § | 26,543,329 | NT | 484 | 0 | 12,815 | NT |
| | | 16-17 | 484,118 | § | 13,412,189 | NT | 382 | 0 | 10,176 | NT |
| | Dose 3 | 6m-4/5 | 83,015 | 0 | 2,291,244 | NT | 2,845 | 0 | 68,640 | NT |
| | | 5/6-11 | 239,708 | 0 | 6,601,838 | NT | 648 | 0 | 17,106 | NT |
| | | 12-15 | 352,852 | § | 9,763,925 | NT | 533 | 0 | 14,234 | NT |
| | | 16-17 | 215,265 | § | 5,885,237 | NT | 285 | 0 | 7,596 | NT |
| Disseminated Intravascular Coagulation | Dose 1 + Dose 2 | 6m-4/5 | 352,017 | § | 8,897,561 | NT | 241,928 | 0 | 6,501,186 | NT |
| | | 5/6-11 | 2,215,973 | § | 55,933,013 | NT | 1,212 | 0 | 30,713 | NT |
| | | 12-15 | 2,038,363 | 0 | 51,163,245 | NT | 1,188 | 0 | 30,749 | NT |
| | | 16-17 | 1,045,113 | 0 | 26,325,916 | NT | 1,018 | 0 | 25,832 | NT |
| | Dose 1 | 6m-4/5 | 190,665 | § | 4,597,312 | NT | 131,380 | 0 | 3,546,479 | NT |
| | | 5/6-11 | 1,184,106 | § | 27,614,907 | NT | 755 | 0 | 19,448 | NT |
| | | 12-15 | 1,080,148 | 0 | 24,619,938 | NT | 704 | 0 | 18,402 | NT |
| | | 16-17 | 560,883 | 0 | 12,911,429 | NT | 635 | 0 | 15,982 | NT |
| | Dose 2 | 6m-4/5 | 161,352 | 0 | 4,300,249 | NT | 110,548 | 0 | 2,954,707 | NT |
| | | 5/6-11 | 1,031,867 | § | 28,318,106 | NT | 457 | 0 | 11,265 | NT |
| | | 12-15 | 958,215 | 0 | 26,543,307 | NT | 484 | 0 | 12,347 | NT |
| | | 16-17 | 484,230 | 0 | 13,414,487 | NT | 383 | 0 | 9,850 | NT |
| | Dose 3 | 6m-4/5 | 83,022 | 0 | 2,278,221 | NT | 2,845 | 0 | 64,854 | NT |
| | | 5/6-11 | 239,717 | 0 | 6,579,046 | NT | 648 | 0 | 16,295 | NT |
| | | 12-15 | 352,881 | § | 9,759,909 | NT | 533 | 0 | 13,650 | NT |
| | | 16-17 | 215,316 | 0 | 5,884,863 | NT | 285 | 0 | 7,132 | NT |
| Encephalitis or Encephalomyelitis | Dose 1 + Dose 2 | 6m-4/5 | 410,448 | 0 | 13,758,825 | NT | 277,773 | § | 10,024,797 | NT |
| | | 5/6-11 | 2,485,324 | § | 81,547,753 | NT | 1,469 | 0 | 49,843 | NT |
| | | 12-15 | 2,223,796 | § | 72,859,944 | NS | 1,410 | 0 | 48,910 | NT |
| | | 16-17 | 1,129,627 | § | 37,287,987 | NT | 1,216 | 0 | 40,559 | NT |
| | Dose 1 | 6m-4/5 | 221,610 | 0 | 6,325,107 | NT | 150,101 | § | 4,984,704 | NT |
| | | 5/6-11 | 1,334,839 | § | 34,943,578 | NT | 916 | 0 | 30,912 | NT |
| | | 12-15 | 1,179,935 | § | 29,750,039 | NT | 849 | 0 | 28,438 | NT |
| | | 16-17 | 607,886 | § | 15,734,035 | NT | 760 | 0 | 23,715 | NT |
| | Dose 2 | 6m-4/5 | 188,838 | 0 | 7,433,718 | NT | 127,672 | § | 5,040,093 | NT |
| | | 5/6-11 | 1,150,485 | § | 46,604,175 | NT | 553 | 0 | 18,931 | NT |
| | | 12-15 | 1,043,861 | § | 43,109,905 | NS | 561 | 0 | 20,472 | NT |
| | | 16-17 | 521,741 | § | 21,553,952 | NT | 456 | 0 | 16,844 | NT |
| | Dose 3 | 6m-4/5 | 96,950 | 0 | 3,945,744 | NT | 3,233 | 0 | 101,347 | NT |
| | | 5/6-11 | 259,110 | § | 10,548,412 | NT | 699 | 0 | 24,341 | NT |
| | | 12-15 | 370,652 | 0 | 15,282,789 | NT | 563 | 0 | 20,192 | NT |
| | | 16-17 | 229,634 | 0 | 9,331,463 | NT | 310 | 0 | 10,873 | NT |
| Guillain-Barré Syndrome | Dose 1 + Dose 2 | 6m-4/5 | 352,025 | 0 | 11,830,401 | NT | 241,936 | 0 | 8,761,303 | NT |
| | Dose 1 | 6m-4/5 | 190,670 | 0 | 5,446,456 | NT | 131,384 | 0 | 4,374,485 | NT |

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|---|---|---|---|---|---|---|---|---|---|---|
| | Dose 2 | 6m-4/5 | 161,355 | 0 | 6,383,945 | NT | 110,552 | 0 | 4,386,818 | NT |
| | Dose 3 | 6m-4/5 | 83,022 | 0 | 3,391,294 | NT | 2,845 | 0 | 90,746 | NT |
| Hemorrhagic Stroke | Dose 1 + Dose 2 | 6m-4/5 | 351,997 | § | 8,970,006 | NT | 241,927 | 0 | 6,548,151 | NT |
| | Dose 1 | 6m-4/5 | 190,654 | § | 4,629,520 | NT | 131,379 | 0 | 3,567,371 | NT |
| | Dose 2 | 6m-4/5 | 161,343 | 0 | 4,340,486 | NT | 110,548 | 0 | 2,980,780 | NT |
| | Dose 3 | 6m-4/5 | 83,017 | 0 | 2,285,757 | NT | 2,845 | 0 | 66,970 | NT |
| Immune Thrombocytopenia | Dose 1 + Dose 2 | 6m-4/5 | 351,972 | § | 12,028,216 | NT | 241,891 | § | 8,887,610 | NS |
| | | 5/6-11 | 2,215,661 | 23 | 72,925,239 | NS | 1,212 | 0 | 44,796 | NT |
| | | 12-15 | 2,038,029 | 25 | 66,706,657 | NS | 1,188 | 0 | 43,176 | NT |
| | | 16-17 | 1,044,876 | 15 | 34,462,183 | NS | 1,018 | 0 | 35,938 | NT |
| | Dose 1 | 6m-4/5 | 190,643 | 0 | 5,522,961 | NT | 131,361 | § | 4,424,088 | NT |
| | | 5/6-11 | 1,183,941 | § | 30,969,110 | NS | 755 | 0 | 27,077 | NT |
| | | 12-15 | 1,079,968 | § | 27,098,483 | NS | 704 | 0 | 24,320 | NT |
| | | 16-17 | 560,757 | § | 14,438,389 | NS | 635 | 0 | 20,921 | NT |
| | Dose 2 | 6m-4/5 | 161,329 | § | 6,505,255 | NT | 110,530 | § | 4,463,522 | NT |
| | | 5/6-11 | 1,031,720 | § | 41,956,129 | NS | 457 | 0 | 17,719 | NT |
| | | 12-15 | 958,061 | § | 39,608,174 | NS | 484 | 0 | 18,856 | NT |
| | | 16-17 | 484,119 | § | 20,023,794 | NS | 383 | 0 | 15,017 | NT |
| | Dose 3 | 6m-4/5 | 83,012 | 0 | 3,415,558 | NT | 2,845 | 0 | 97,403 | NT |
| | | 5/6-11 | 239,675 | 0 | 9,830,404 | NT | 647 | 0 | 24,998 | NT |
| | | 12-15 | 352,826 | 0 | 14,573,683 | NT | 533 | 0 | 21,004 | NT |
| | | 16-17 | 215,255 | § | 8,769,474 | NT | 285 | 0 | 11,128 | NT |
| Myocarditis/pericarditis (All settings) (1-7 day) | Dose 1 + Dose 2 | 6m-4/5 | 351,988 | 0 | 2,443,114 | NT | 241,924 | 0 | 1,679,814 | NT |
| | | 5/6-11 | 2,215,815 | § | 15,455,303 | NS | 1,212 | 0 | 8,392 | NT |
| | | 12-15 | 2,038,160 | 72 | 14,241,393 | S | 1,188 | 0 | 8,197 | NT |
| | | 16-17 | 1,044,928 | 56 | 7,299,458 | S | 1,018 | 0 | 7,014 | NT |
| | Dose 1 | 6m-4/5 | 190,650 | 0 | 1,323,939 | NT | 131,378 | 0 | 912,801 | NT |
| | | 5/6-11 | 1,184,019 | § | 8,261,973 | NT | 755 | 0 | 5,244 | NT |
| | | 12-15 | 1,080,046 | § | 7,547,573 | NS | 704 | 0 | 4,859 | NT |
| | | 16-17 | 560,782 | § | 3,917,140 | NS | 635 | 0 | 4,355 | NT |
| | Dose 2 | 6m-4/5 | 161,338 | 0 | 1,119,175 | NT | 110,546 | 0 | 767,013 | NT |
| | | 5/6-11 | 1,031,796 | § | 7,193,330 | NS | 457 | 0 | 3,148 | NT |
| | | 12-15 | 958,114 | § | 6,693,820 | S | 484 | 0 | 3,338 | NT |
| | | 16-17 | 484,146 | § | 3,382,318 | S | 383 | 0 | 2,659 | NT |
| | Dose 3 | 6m-4/5 | 83,014 | 0 | 579,161 | NT | 2,845 | 0 | 19,413 | NT |
| | | 5/6-11 | 239,708 | 0 | 1,672,699 | NT | 648 | 0 | 4,517 | NT |
| | | 12-15 | 352,832 | § | 2,465,354 | S | 533 | 0 | 3,719 | NT |
| | | 16-17 | 215,272 | 13 | 1,497,801 | S | 285 | 0 | 1,990 | NT |
| Myocarditis/pericarditis (All | | 6m-4/5 | 351,988 | § | 7,252,205 | NT | 241,924 | 0 | 4,987,361 | NT |
| | | 5/6-11 | 2,215,815 | 12 | 45,978,229 | NS | 1,212 | 0 | 24,750 | NT |

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|---|---|---|---|---|---|---|---|---|---|---|
| Settings) (1-21 day) | Dose 1 + Dose 2 | 12-15 | 2,038,160 | 103 | 42,443,102 | S | 1,188 | 0 | 24,182 | NT |
| | | 16-17 | 1,044,928 | 71 | 21,746,581 | S | 1,018 | 0 | 20,541 | NT |
| | Dose 1 | 6m-4/5 | 190,650 | 0 | 3,932,631 | NT | 131,378 | 0 | 2,711,909 | NT |
| | | 5/6-11 | 1,184,019 | § | 24,573,073 | NT | 755 | 0 | 15,431 | NT |
| | | 12-15 | 1,080,046 | 19 | 22,468,619 | S | 704 | 0 | 14,352 | NT |
| | | 16-17 | 560,782 | 16 | 11,655,098 | S | 635 | 0 | 12,742 | NT |
| | Dose 2 | 6m-4/5 | 161,338 | § | 3,319,574 | NT | 110,546 | 0 | 2,275,452 | NT |
| | | 5/6-11 | 1,031,796 | § | 21,405,156 | NS | 457 | 0 | 9,319 | NT |
| | | 12-15 | 958,114 | 84 | 19,974,483 | S | 484 | 0 | 9,830 | NT |
| | | 16-17 | 484,146 | 56 | 10,091,483 | S | 383 | 0 | 7,799 | NT |
| | Dose 3 | 6m-4/5 | 83,014 | 0 | 1,728,090 | NT | 2,845 | 0 | 54,542 | NT |
| | | 5/6-11 | 239,708 | 0 | 4,980,481 | NT | 648 | 0 | 13,186 | NT |
| | | 12-15 | 352,832 | § | 7,349,009 | S | 533 | 0 | 10,924 | NT |
| | | 16-17 | 215,272 | 14 | 4,436,604 | S | 285 | 0 | 5,871 | NT |
| Myocarditis/pericarditis (IP/OP-ED) (1-7 day) | Dose 1 + Dose 2 | 6m-4/5[#] | 352,019 | 0 | 2,427,241 | NT | 152,637 | 0 | 1,053,032 | NT |
| | | 5-6/11[#] | 2,215,967 | § | 15,450,396 | NT | 621 | 0 | 4,208 | NT |
| | | 12-15 | 2,038,335 | 55 | 14,242,747 | S | 1,188 | 0 | 8,114 | NT |
| | | 16-17 | 1,045,077 | 40 | 7,300,604 | S | 1,018 | 0 | 6,924 | NT |
| | Dose 1 | 6m-4/5[#] | 190,667 | 0 | 1,316,715 | NT | 82,934 | 0 | 573,125 | NT |
| | | 5-6/11[#] | 1,184,102 | § | 8,259,674 | NT | 398 | 0 | 2,691 | NT |
| | | 12-15 | 1,080,136 | § | 7,548,270 | NT | 704 | 0 | 4,819 | NT |
| | | 16-17 | 560,863 | § | 3,917,764 | NS | 635 | 0 | 4,297 | NT |
| | Dose 2 | 6m-4/5[#] | 161,352 | 0 | 1,110,526 | NT | 69,703 | 0 | 479,907 | NT |
| | | 5-6/11[#] | 1,031,865 | § | 7,190,722 | NT | 223 | 0 | 1,517 | NT |
| | | 12-15 | 958,199 | § | 6,694,477 | S | 484 | 0 | 3,295 | NT |
| | | 16-17 | 484,214 | § | 3,382,840 | S | 383 | 0 | 2,627 | NT |
| | Dose 3 | 6m-4/5[#] | 83,021 | 0 | 578,025 | NT | 1,185 | 0 | 7,882 | NT |
| | | 5-6/11[#] | 239,718 | 0 | 1,671,051 | NT | 352 | 0 | 2,405 | NT |
| | | 12-15 | 352,870 | § | 2,465,157 | S | 533 | 0 | 3,707 | NT |
| | | 16-17 | 215,311 | § | 1,498,007 | S | 285 | 0 | 1,966 | NT |
| Myocarditis/pericarditis (IP/OP-ED) (1-21 day) | Dose 1 + Dose 2 | 6m-4/5[#] | 352,019 | 0 | 7,198,601 | NT | 152,637 | 0 | 3,125,323 | NT |
| | | 5-6/11[#] | 2,215,967 | § | 45,959,404 | NT | 621 | 0 | 12,298 | NT |
| | | 12-15 | 2,038,335 | 61 | 42,446,709 | S | 1,188 | 0 | 23,893 | NT |
| | | 16-17 | 1,045,077 | 46 | 21,749,769 | S | 1,018 | 0 | 20,217 | NT |
| | Dose 1 | 6m-4/5[#] | 190,667 | 0 | 3,908,994 | NT | 82,934 | 0 | 1,702,556 | NT |
| | | 5-6/11[#] | 1,184,102 | § | 24,564,532 | NT | 398 | 0 | 7,883 | NT |
| | | 12-15 | 1,080,136 | § | 22,470,533 | NS | 704 | 0 | 14,199 | NT |
| | | 16-17 | 560,863 | 12 | 11,656,804 | S | 635 | 0 | 12,513 | NT |
| | Dose 2 | 6m-4/5[#] | 161,352 | 0 | 3,289,607 | NT | 69,703 | 0 | 1,422,767 | NT |
| | | 5-6/11[#] | 1,031,865 | § | 21,394,872 | NT | 223 | 0 | 4,415 | NT |
| | | 12-15 | 958,199 | § | 19,976,176 | S | 484 | 0 | 9,694 | NT |

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|---|---|---|---|---|---|---|---|---|---|---|
| | | 16-17 | 484,214 | 35 | 10,092,965 | S | 383 | 0 | 7,704 | NT |
| | Dose 3 | 6m-4/5[#] | 83,021 | 0 | 1,723,572 | NT | 1,185 | 0 | 22,367 | NT |
| | | 5-6/11[#] | 239,718 | 0 | 4,973,111 | NT | 352 | 0 | 6,892 | NT |
| | | 12-15 | 352,870 | § | 7,348,086 | S | 533 | 0 | 10,753 | NT |
| | | 16-17 | 215,311 | § | 4,437,033 | S | 285 | 0 | 5,721 | NT |
| Narcolepsy | Dose 1 + Dose 2 | 5/6-11 | 2,215,928 | § | 72,934,272 | NS | 1,212 | 0 | 44,796 | NT |
| | | 12-15 | 2,038,107 | 16 | 66,709,380 | NS | 1,188 | 0 | 43,176 | NT |
| | | 16-17 | 1,044,699 | 24 | 34,456,767 | NS | 1,017 | 0 | 35,896 | NT |
| | Dose 1 | 5/6-11 | 1,184,080 | § | 30,972,795 | NT | 755 | 0 | 27,077 | NT |
| | | 12-15 | 1,080,018 | § | 27,099,946 | NS | 704 | 0 | 24,320 | NT |
| | | 16-17 | 560,647 | § | 14,435,556 | NT | 635 | 0 | 20,921 | NT |
| | Dose 2 | 5/6-11 | 1,031,848 | § | 41,961,477 | NS | 457 | 0 | 17,719 | NT |
| | | 12-15 | 958,089 | § | 39,609,434 | NS | 484 | 0 | 18,856 | NT |
| | | 16-17 | 484,052 | § | 20,021,211 | NS | 382 | 0 | 14,975 | NT |
| | Dose 3 | 5/6-11 | 239,715 | 0 | 9,832,012 | NT | 648 | 0 | 25,021 | NT |
| | | 12-15 | 352,841 | § | 14,574,277 | NS | 533 | 0 | 21,004 | NT |
| | | 16-17 | 215,221 | 12 | 8,768,192 | NS | 285 | 0 | 11,128 | NT |
| Non-Hemorrhagic Stroke | Dose 1 + Dose 2 | 6m-4/5 | 352,009 | 0 | 8,942,566 | NT | 241,930 | § | 6,530,082 | NT |
| | | 5/6-11 | 2,215,960 | § | 55,955,653 | NT | 1,212 | 0 | 31,259 | NT |
| | | 12-15 | 2,038,354 | 0 | 51,165,669 | NT | 1,188 | 0 | 31,151 | NT |
| | | 16-17 | 1,045,115 | § | 26,327,584 | NT | 1,018 | 0 | 26,192 | NT |
| | Dose 1 | 6m-4/5 | 190,661 | 0 | 4,617,655 | NT | 131,381 | § | 3,559,300 | NT |
| | | 5/6-11 | 1,184,098 | § | 27,625,211 | NT | 755 | 0 | 19,695 | NT |
| | | 12-15 | 1,080,143 | 0 | 24,621,154 | NT | 704 | 0 | 18,574 | NT |
| | | 16-17 | 560,884 | § | 12,912,371 | NT | 635 | 0 | 16,176 | NT |
| | Dose 2 | 6m-4/5 | 161,348 | 0 | 4,324,911 | NT | 110,549 | 0 | 2,970,782 | NT |
| | | 5/6-11 | 1,031,862 | 0 | 28,330,442 | NT | 457 | 0 | 11,564 | NT |
| | | 12-15 | 958,211 | 0 | 26,544,515 | NT | 484 | 0 | 12,577 | NT |
| | | 16-17 | 484,231 | § | 13,415,213 | NT | 383 | 0 | 10,016 | NT |
| | Dose 3 | 6m-4/5 | 83,019 | § | 2,282,885 | NT | 2,845 | 0 | 66,156 | NT |
| | | 5/6-11 | 239,722 | 0 | 6,587,840 | NT | 648 | 0 | 16,549 | NT |
| | | 12-15 | 352,881 | 0 | 9,761,993 | NT | 533 | 0 | 13,822 | NT |
| | | 16-17 | 215,317 | § | 5,885,718 | NT | 285 | 0 | 7,299 | NT |
| Pulmonary Embolism | Dose 1 + Dose 2 | 6m-4/5[#] | 239,532 | 0 | 6,178,317 | NT | 160,273 | 0 | 4,377,689 | NT |
| | | 5/6-11 | 2,215,976 | 0 | 56,012,340 | NT | 1,212 | 0 | 32,579 | NT |
| | | 12-15 | 2,038,334 | § | 51,168,510 | NT | 1,188 | 0 | 31,876 | NT |
| | | 16-17 | 1,044,978 | § | 26,326,099 | NS | 1,018 | 0 | 27,082 | NT |
| | Dose 1 | 6m-4/5[#] | 130,125 | 0 | 3,196,420 | NT | 87,477 | 0 | 2,391,693 | NT |
| | | 5/6-11 | 1,184,108 | 0 | 27,650,979 | NT | 755 | 0 | 20,295 | NT |
| | | 12-15 | 1,080,133 | 0 | 24,622,518 | NT | 704 | 0 | 18,935 | NT |
| | | 16-17 | 560,809 | § | 12,911,833 | NS | 635 | 0 | 16,775 | NT |

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|---|---|---|---|---|---|---|---|---|---|---|
| | Dose 2 | 6m-4/5[#] | 109,407 | 0 | 2,981,897 | NT | 72,796 | 0 | 1,985,996 | NT |
| | | 5/6-11 | 1,031,868 | 0 | 28,361,361 | NT | 457 | 0 | 12,284 | NT |
| | | 12-15 | 958,201 | § | 26,545,992 | NT | 484 | 0 | 12,941 | NT |
| | | 16-17 | 484,169 | § | 13,414,266 | NT | 383 | 0 | 10,307 | NT |
| | Dose 3 | 6m-4/5[#] | 55,239 | 0 | 1,527,770 | NT | 2,067 | 0 | 50,277 | NT |
| | | 5/6-11 | 239,722 | § | 6,610,019 | NT | 648 | 0 | 17,308 | NT |
| | | 12-15 | 352,879 | 0 | 9,766,897 | NT | 533 | 0 | 14,393 | NT |
| | | 16-17 | 215,293 | § | 5,886,669 | NT | 285 | 0 | 7,721 | NT |
| Seizures/Convulsions[ϕ] | Dose 1 + Dose 2 | 6m-1 | 450,140 | 25 | 1,191,471 | NS | 302,275 | 15 | 872,958 | NS |
| | | 2-4/5 | 450,140 | 36 | 2,373,696 | S | 302,275 | 29 | 1,522,577 | S |
| | | 5/6-11 | 2,692,535 | 71 | 21,462,208 | NS | 1,667 | 0 | 13,078 | NT |
| | | 12-15 | 2,430,285 | 52 | 19,407,961 | NS | 1,545 | 0 | 12,180 | NT |
| | | 16-17 | 1,238,940 | 38 | 9,890,880 | NS | 1,300 | 0 | 10,220 | NT |
| | Dose 1 | 6m-1 | 245,400 | 14 | 660,359 | NS | 164,942 | § | 486,994 | NS |
| | | 2-4/5 | 245,400 | 21 | 1,284,771 | S | 164,942 | § | 821,447 | NS |
| | | 5/6-11 | 1,454,544 | 41 | 11,598,717 | NS | 1,051 | 0 | 8,240 | NT |
| | | 12-15 | 1,301,389 | 27 | 10,393,770 | NS | 947 | 0 | 7,458 | NT |
| | | 16-17 | 671,951 | 24 | 5,363,845 | NS | 821 | 0 | 6,431 | NT |
| | Dose 2 | 6m-1 | 204,740 | 11 | 531,112 | NS | 137,333 | § | 385,964 | NS |
| | | 2-4/5 | 204,740 | 15 | 1,088,925 | S | 137,333 | § | 701,130 | S |
| | | 5/6-11 | 1,237,991 | 30 | 9,863,491 | NS | 616 | 0 | 4,838 | NT |
| | | 12-15 | 1,128,896 | 25 | 9,014,191 | NS | 598 | 0 | 4,722 | NT |
| | | 16-17 | 566,989 | 16 | 4,527,035 | NS | 479 | 0 | 3,789 | NT |
| | Dose 3 | 6m-1 | 102,099 | § | 231,518 | NT | 3,376 | § | 8,115 | NT |
| | | 2-4/5 | 102,099 | § | 581,953 | NS | 3,376 | 0 | 18,177 | NT |
| | | 5/6-11 | 268,990 | § | 2,145,055 | NS | 725 | 0 | 5,768 | NT |
| | | 12-15 | 382,249 | § | 3,052,406 | NS | 587 | 0 | 4,684 | NT |
| | | 16-17 | 236,352 | § | 1,879,834 | NS | 318 | 0 | 2,532 | NT |

*** Signal Status Definitions**:
- NS: Test was initiated (cases > 3) but no signal was observed.
- S: Test met the statistical threshold for a signal.
- NT: Test did not initiate due to low outcome counts (cases <3).

§ Cell sizes 1-10 and cells that can be used to back-calculate small cell sizes were masked for confidentiality

† Common site thrombosis with thrombocytopenia is combined with unusual site thrombosis (broad) with thrombocytopenia consisting of a thrombotic event (made up of other events such as acute myocardial infarction, deep vein thrombosis etc.) and a thrombocytopenia event (defined in the IP, OP/PB setting). The overall setting definition for the outcome depends on individual setting definitions for each of these components.

# For these outcome-age combinations, testing occurred in fewer than three data sources because one or more data source did not have available background rates; for these outcome-age combinations, no. of doses are reported for the data sources where sequential testing data was available.

ϕ For the outcome seizures/convulsions, the number of doses reported in both ages 6 months-1 year and 2-4/5 years corresponds to the total number of doses monitored descriptively in ages 6 months-4/5 years; all other statistics from sequential testing (number of outcomes, person-time, and signal status) are reported for the corresponding age stratifications listed in the table above due to availability of background rates for those age strata.

Sequential testing ended earlier in ages 5/6-17 years due to limited accrual of new exposures; therefore, the data cuts used are different from ages 6 months-4/5 years.

- Ages 5/6-17 years: Optum data through 4/2023, Carelon Research data through 1/2023, CVS Health data through 12/2022.
- Ages 6 months-4/5 years: Optum data through 1/2023, Carelon Research data through 3/2023, CVS Health data through 2/2023

# Attachment B

# DECLARATION OF CATHARINE LAYTON

STATE OF TEXAS

COUNTY OF Hays

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

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

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

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

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

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

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

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

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

Signed 3 day of May 2022

Signature of Catharine Layton

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

Notary Public for

AMY MARIE BLACKWELL
Notary ID #132597493
My Commission Expires
July 30, 2024