Exhibit 1

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL June 24, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852
Email: FOIARequests@cdc.gov

Re: V-Safe de-identified data (IR#0519)

Dear Mr. Andoh:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("FOIA").

By this letter, please provide the following records in your possession via email to foia@sirillp.com:

All de-identified data submitted to v-safe since January 1, 2020.

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

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 of course reserves all rights to appeal the withholding or deletion of any information.

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

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

Very truly yours,

/s/ Elizabeth A. Brehm
Elizabeth A. Brehm, Esq.

Exhibit 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

June 29, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your clarified June 24, 2021, Freedom of Information Act (FOIA) request on June 25, 2021, seeking:

> "All de-identified data submitted to v-safe since January 1, 2020."

Your FOIA request number is #21-01506-FOIA, and it has been placed in our complex processing queue.

In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request. We will require more than thirty working days to respond to your request because:

☒ We reasonably expect that two or more CDC centers, institutes, and offices (C/I/Os) may have responsive records.

☒ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Carolyn Okpewho, at 770-488-6332 or our FOIA Public Liaison, Roger Andoh, at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

☒ The disclosure of the records will not contribute significantly to public understanding of the operations or activities of the government.

☒ You have failed to demonstrate that you disseminate information to the public.

☒ You have failed to provide enough information to warrant a waiver of fees.

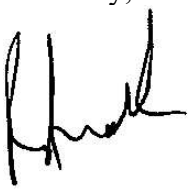
Because Informed Consent Action Network (ICAN) is considered an "All Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Since you did provide us with a date range for your request, the search cut-off date for your request will be the date provided.

You have the right to appeal the agency's fee waiver response to your request. You may mail your appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Your appeal must be postmarked or electronically transmitted by September 27, 2021.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number.

Sincerely,



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

#21-01506-FOIA

Exhibit 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

July 29, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your clarified June 24, 2021, Freedom of Information Act (FOIA) request on June 25, 2021, seeking:

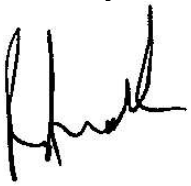
> "All de-identified data submitted to v-safe since January 1, 2020."

A search of our records failed to reveal any documents pertaining to your request. The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) communicated that the v-safe data contains approximately 119 million medical entries. The information in the app is not de-identified.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by October 27, 2021.

Sincerely,



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

#21-01506-FOIA

Exhibit 4

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
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CDC FREEDOM OF INFORMATION ACT APPEAL

VIA ONLINE PORTAL August 25, 2021

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201

Re: Appeal of FOIA Request Case Number #21-01506-FOIA (IR#0519)

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, on June 24, 2021, we requested records from the files of the Centers for Disease Control and Prevention ("**CDC**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). The CDC assigned the request as Request Number 21-01506-FOIA (the "**FOIA Request**"). In a letter dated July 29, 2021, Roger Andoh, CDC/ATSDR FOIA Officer (the "**CDC Officer**"), responded to the request and stated, *inter alia*, that CDC has no documents responsive to the FOIA Request. ICAN now writes to appeal this determination.

A. The FOIA Request

In the FOIA Request, ICAN requested the following documents:

> **All de-identified data submitted to v-safe since January 1, 2020.**

(**Exhibit A**.)[1]

[1] All "Exhibits" referenced herein are appended to this letter.

B. Correspondence Regarding the FOIA Request

On June 29, 2021, the CDC acknowledged the FOIA Request and stated, in relevant part:

> The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your clarified[2] June 24, 2021, Freedom of Information Act (FOIA) request on June 25, 2021. Your FOIA request number is #21-01506-FOIA, and it has been placed in our complex processing queue.

(**Exhibit B**.)

C. The Final Response to the FOIA Request

On July 29, 2021, the CDC responded to the FOIA Request and stated in relevant part:

> A search of our records failed to reveal any documents pertaining to your request. The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) communicated that the v-safe data contains approximately 119 million medical entries. The information in the app is not de-identified.

(**Exhibit C**.)

D. Appellate Request

The CDC has failed to conduct an adequate search of the data requested. An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. EPA*, 767 F.2d 569, 571 (9th Cir. 1985) (quoting *Weisberg v. U.S. Dept. of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984)) (internal quotation marks omitted). In the FOIA Request, ICAN requested "All de-identified data submitted to v-safe since January 1, 2020." The agency's response acknowledges that data has been submitted to v-safe: approximately 119 million medical entries exist. ICAN has requested that data in a de-identified form. The FOIA Request is broad enough to capture data submitted to v-safe and subsequently de-identified by the CDC.

In response to the FOIA Request, the CDC simply stated that "[t]he information in the [v-safe] app is not de-identified." ICAN assumes that the CDC interprets ICAN's use of the word "submitted" as if the FOIA Request is a request for information that was de-identified at the time it was submitted to v-safe. CDC's interpretation of the FOIA Request is unreasonable because, as the CDC is aware, individuals must provide personally identifiable information, including name, phone number, date of birth, sex, and zip code, in order to register for the v-safe program. However, FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. ICAN therefore requested that it be provided with all non-exempt

[2] The CDC, in what appears to be an error, refers to the FOIA Request as a "clarified" request however ICAN submitted its original request and did not otherwise alter, revise, or clarify same.

portions which are reasonably segregable – here, that is the equivalent of de-identified data. ICAN's request clearly encompasses data submitted and subsequently de-identified.

On May 20, 2021, CDC published a document titled "V-safe active surveillance for COVID-19 vaccine safety" (the "**V-Safe Protocol**").[3] The V-Safe Protocol indicates that "V-safe data will be collected, managed, and housed on a secure server by Oracle."[4] The V-Safe Protocol further provides:

> Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, **will have access to aggregate deidentified data for reporting**. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), **these survey data will be accessible to CDC** through downloads from the secure server.[5]

In the V-Safe Protocol, the CDC states that "[n]o PII will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests,"[6] that "[r]egular updates will be provided to advisory committees and data review groups" and that "[i]t is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports."[7] Therefore, according to the V-Safe Protocol: (1) de-identified data submitted to v-safe exists; (2) CDC, and only CDC, has access to the de-identified data; and (3) CDC has shared or anticipates sharing the de-identified data outside of the agency. Therefore, de-identified data submitted to v-safe exists and should have been produced by the CDC in response to the FOIA Request. Alternatively, data provided to v-safe can be de-identified and then produced in response to the FOIA Request pursuant to FOIA.

Given the foregoing, ICAN hereby appeals and requests that all documents responsive to the FOIA Request be produced within 20 days of this appeal.

Thank you for your time and attention to this matter. If you require any additional information, please contact me at (212) 532-1091 or through email at foia@sirillp.com.

Very truly yours,

/s/ Gabrielle G. Palmer
Gabrielle G. Palmer, Esq.

Enclosures

[3] A copy of the V-Safe Protocol is attached hereto as **Exhibit D**.

[4] Ex. D at 8.

[5] Ex. D at 9.

[6] Ex. D at 10.

[7] Ex. D at 12.

Exhibit A

Siri | Glimstad

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FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL June 24, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
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Fax: (404) 235-1852
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/s/ Elizabeth A. Brehm
Elizabeth A. Brehm, Esq.

Exhibit B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

June 29, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

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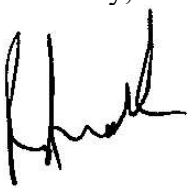
Sincerely,



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

#21-01506-FOIA

Exhibit C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

July 29, 2021

SENT VIA EMAIL

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Siri & Glimstad
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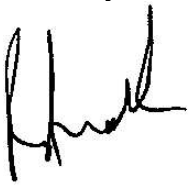

Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
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#21-01506-FOIA

Exhibit D

V-safe active surveillance for COVID-19 vaccine safety

Version 3
May 20, 2021

Protocol Change History

Version	Date	Change
1	Dec 8, 2021	N/A – Original
2	Jan 28, 2021	Added race and ethnicity question to survey (Attachment 1) Modified Attachment 1 to clarify timepoints that include pregnancy questions
3	May 12, 2021	Modified protocol and survey language to reflect enhancement to v-safe that allows registration of dependents and completion of surveys for dependents Revised language to reflect revision of CDC follow-up calls to be specific to medically attended health events Additional language to reflect enhancements to the v-safe platform (ability to delete account on participant request, text reminders for 2nd dose) Minor edits to reflect current survey language and completion messages viewed at end of survey

v-safe protocol: May 20, 2021, version 3

Protocol summary

V-safe is an active surveillance program to monitor the safety of COVID-19 vaccines during the period when the vaccines are authorized for use under Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and possibly early after vaccine licensure. V-safe is a new smartphone-based system that uses text messaging to initiate web-based survey monitoring in the form of periodic health check-ins to assess for potential adverse events following vaccination. CDC will use the follow-up capability of the existing Vaccine Adverse Event Reporting System (VAERS) call center to conduct active telephone follow-up on recipients reporting a significant, medically attended health impacts during v-safe health check-ins. The purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions.

Background and significance

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Following the emergence of COVID-19 in China in late 2019, the first confirmed U.S. cases were detected in January 2020. With rapid human-to-human transmission occurring, the United States declared a public health emergency in February 2020, followed by a national emergency in March 2020 (1). As of November 18, 2020, there have been 11,300,635 cases of COVID-19 disease in the United States and 247,834 deaths (2). A key U.S. pandemic response initiative is Operation Warp Speed, a public-private partnership established in May 2020, with a goal to develop and deliver safe and effective COVID-19 vaccine(s) to the U.S. population by early 2021 (3).

Post-authorization/post-approval vaccine safety monitoring is a federal government responsibility, with the Centers for Disease Control and Prevention (CDC) and the FDA sharing most of the responsibility along with other federal agencies involved in healthcare delivery (e.g., Veterans Affairs, Department of Defense, Indian Health Service). Initial safety assessment begins in early vaccine development and expands during phased clinical trials in humans. Clinical trials are effective at identifying and characterizing common adverse events, such as local and systemic reactions. However, even large clinical trials, like the COVID-19 vaccine

clinical trials that are enrolling tens of thousands of volunteers, might not be large enough to detect rare adverse events (for example, those occurring at rates of <1 per 100,000 people vaccinated). Furthermore, for some clinical trials of COVID-19 vaccines, the follow-up period to monitor for possible adverse events with delayed onset may not be completed for all subjects prior to issuance of an EUA or licensure. Additionally, exclusion criteria for clinical trials may limit generalizability of safety and efficacy findings to special populations, such as those with certain chronic illnesses or pregnant women (4). For these reasons, robust post-authorization/approval safety monitoring of COVID-19 vaccines is a public health priority.

To meet the safety data needs for COVID-19 vaccine pharmacovigilance during the post-authorization/approval period, CDC will implement v-safe, a smartphone-based system that uses text messaging to initiate web-based surveys to monitor for adverse events following vaccination. The surveillance process triggers active telephone follow-up on vaccinated individuals reporting a significant, medically attended health impact during v-safe health check-ins.

Goals and objectives

Goals

- Characterize the safety profile of COVID-19 vaccines.

- Rapidly monitor and identify potential safety problems associated with COVID-19 vaccines that would impact policy or regulatory decisions.

Objectives

- Characterize the local and systemic reactogenicity of COVID-19 vaccines during the first week post-vaccination (days 0-7).

- Identify and characterize clinically important adverse events following COVID-19 vaccination during a 6-week post-vaccination follow-up period.

- Monitor the long(er)-term (3, 6, and 12 months post-vaccination) safety of COVID-19 vaccines.

Methods

Surveillance population

All people in the United States who receive a COVID-19 vaccination will be eligible to enroll in v-safe for the duration of the v-safe program. Surveys will be available in English, Spanish, Simplified Chinese, Vietnamese, and Korean languages.

Enrollment criteria:

- Participants must have received a COVID-19 vaccination.
- Participants or their parent/guardian must possess a smartphone with a valid US telephone number. More than one individual may use the same smartphone/telephone number (i.e., shared smartphone).

Enrollment

The v-safe program will commence when COVID-19 vaccines are authorized or approved for use and become available to the U.S. population. Vaccination may occur at a mass vaccination clinic, an occupational health clinic, a public health clinic, a healthcare provider's office, a pharmacy, or other setting. At the time of vaccination, the healthcare provider will briefly describe the v-safe program using a prescribed script. In addition, the healthcare provider will provide the vaccinated patient with an information sheet that includes a brief description of the program, a URL and a scannable QR code, and enrollment instructions.

Vaccinated individuals can enroll in v-safe immediately following vaccination or at a later date; surveys will be timed appropriately based on vaccination date(s). For vaccine recipients whose vaccination information is captured in CDC's Vaccine Administration Management System (VAMS), VAMS will send recipients a reminder text message about v-safe 24 hours after vaccination (5). For vaccine recipients receiving a 2-dose vaccine, v-safe will send a text reminder to participants that they should schedule their second dose. Participation in v-safe is

voluntary and people can opt out at any time by texting “STOP” when v-safe sends a reminder text message; people can also start v-safe again by texting “UNSTOP.”

Once a vaccinated individual decides to enroll in v-safe, the individual will either scan his/her mobile phone camera over the QR code on the information sheet or type in the v-safe URL to access the v-safe registration website.

Registration information includes:

- First name
- Last name
- Mobile phone number
- Date of birth
- Sex
- Zip code

If registering in v-safe on behalf of a dependent, the original registrant will also be asked to supply the following:

- First name of dependent
- Last name of dependent
- Date of birth of dependent
- Sex of dependent
- Zip code of dependent
- Relationship to dependent (child or adolescent, adult friend or relative, other)

The registration system will ask the participant to verify their phone number by sending a text message with a verification code. The participant will enter the texted code to verify their identity. After that, the participant will be asked to record information on their first COVID-19 vaccination (or that of their dependent), including the vaccine manufacturer and the vaccination date. If the v-safe participant does not know this information, they are encouraged to refer to the vaccination record card they received or to contact their healthcare provider.

Once a participant has registered and provided information on their COVID-19 vaccination, they will be prompted to take an initial v-safe health check-in survey for themselves or their dependent. The survey will be dependent on the vaccination date and dose number (if applicable)

entered during registration. Subsequently, text messages will be sent to their smartphone with a link to a web-based survey at 2:00 pm (local time based on zip code entered at registration) on the schedule listed below. Surveys for all timepoints are included in Attachment 1.

Electronic health check-in schedule

The schedule for electronic health check-ins is as follows:

1. Day 0 (day of vaccination)

2. Daily on days 1-7 (the 1st week post-vaccination)

3. Weekly starting day 14 (2nd week post-vaccination) to up to day 42 (6th week post-vaccination) if no 2nd dose of COVID-19 vaccine is received

    a. If participant receive a 2nd COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the 2nd dose and continue through steps 1-3 above based on time since the 2nd dose.

4. At 3, 6, and 12 months post-vaccination following 2nd dose vaccination or following first dose if no 2nd dose is received

Daily surveys expire at midnight on the day of the survey and weekly surveys expire at midnight on the last day of the week before the next weekly survey period. The day 42 survey will expire on day 48 at midnight. Monthly surveys will be available for 6 full days following receipt of the survey, expiring at midnight. A participant cannot go back and complete surveys for timepoints prior to their registration (i.e., surveys will be prospective from the time of enrollment). In addition, a participant cannot revise their survey once it has been submitted. After submission, the participant is told that depending on his/her answers, someone from CDC might call to follow up.

Active telephone follow-up

If, during any v-safe health check-in, a participant reports a significant, medically-attended health impact event for themselves or their dependent, including but not exclusive to requiring care in a hospital or emergency room setting, VAERS call center staff will be informed and active telephone follow-up will be initiated to check on the patient and take a VAERS report if appropriate. VAERS is an existing national spontaneous reporting system that is co-managed by FDA and CDC. It serves as an early warning system for adverse events following vaccination (6).

VAERS call center staff will be notified of participants who have reported a significant health impact event via a data set that will be created from the v-safe survey system. The data set will include the following variables:

- Unique v-safe id
- First name
- Last name
- Phone number
- Sex
- Age
- Zip code
- First name of guardian, if applicable
- Last name of guardian, if applicable
- Relationship to guardian, if applicable
- Flagged health impact question
- Flagged health impact response(s) survey number (dose/survey [i.e., Dose2D0])

Using this information, the VAERS call center staff will call participants identified in the data set and complete a VAERS report (located at https://vaers.hhs.gov) by phone if appropriate.

Data collection, quality, and management

V-safe data will be collected, managed, and housed on a secure server by Oracle. Through Health and Human Services (HHS), Oracle has donated IT services to any agency conducting COVID-19 related activities. Oracle is providing IT support for v-safe. All data will be stored, processed, and transmitted in accordance with the Federal Information Security Modernization Act (FISMA) and based on NIST standards. Data will be housed in *Oracle Cloud Infrastructure (OCI) U.S. Government Cloud tenancy*; the OCI U.S. government tenancy is Federal Risk and Authorization Management Program (FEDRAMP) approved (7).

Per Oracle's internal policies, Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the secure server. The v-safe system employs strict security measures appropriate for the level of sensitivity of the data. Data received by CDC will be stored on an internal secure CDC/ISO server and access will be limited to authorized personnel.

Oracle will create a data set for the VAERS call center that includes those participants who reported having a heath impact event that requires call follow-up. CDC-badged contractors will access these data in order to provide call center representatives with information needed to follow up with participants (see "Active telephone follow-up" above). The VAERS call center staff is employed specifically for v-safe follow-up and is associated with the overall VAERS contractor.

VAERS reports will be obtained during active telephone follow-up with v-safe participants and will be processed, handled, stored, and accessed in accordance with existing approved VAERS procedures and policies.

Data from all components of v-safe, as well as VAERS reports obtained through the call center, may be combined into a master data set behind the CDC firewall using unique identification numbers assigned at registration.

Preapproved CDC investigators and data managers, including CDC contractors, will be the only individuals with access to the full data (v-safe, linked VAERS reports). All electronic documents, data sets, and files relevant to the project will be stored on network folders with restricted access on CDC computers. The v-safe team at CDC will be primarily responsible for data management activities, including data extraction, documentation, and archival of a final data set for data sharing purposes. The archive will include the protocol, statistical programs, human

subjects review documents, statistical output, analytical data sets, and manuscripts. It will clearly identify the permanent storage location for these files.

A final data set at the end of the v-safe program with deidentified aggregate data will be made available for external data requests or through Freedom of Information Act (FOIA) requests.

Analysis plan

Descriptive analyses will be conducted using the data collected through surveys on a weekly basis during the surveillance period. Participation rates over time will also be calculated.

For v-safe participants who have a VAERS report submitted through the VAERS call center, additional analyses will be conducted. Rates of serious events as well as adverse events of special interest (AESI) following COVID-19 vaccination will be generated using VAERS reports solicited via v-safe to define the numerator and v-safe participants as the denominator (Attachment 2). VAERS reports that are considered serious or AESI will be reviewed by medical staff at CDC. Case definitions (Brighton Collaboration or other standard definitions as appropriate) will be applied to the AESIs. Reporting rates for each AESI will be calculated and compared to established background rates. If at any time rates observed in v-safe exceed what is expected from background rates, further investigation will occur within other vaccine safety monitoring systems, including VAERS and Vaccine Safety Datalink (7).

VAERS monitoring for all COVID-19 reports will include VAERS reports solicited from v-safe participants. Reports obtained from v-safe participants during call center outreach will be coded so that they can be distinguished from other VAERS reports and analyzed separately from other VAERS reports if needed.

Human subjects considerations and confidentiality

This protocol will require human subjects determination at CDC since CDC is the lead site and surveillance data will include collection of PII. No PII will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests. Participation is completely voluntary and individuals self-enroll. Participants can elect to stop text notifications at any time

and their data will be used for those surveys completed prior to opting out. Participants who request to be removed entirely from the system will be inactivated in v-safe so that their registration record is deleted, and their health survey data will not be included in future analyses. As an analysis of data collected for non-research purposes, this activity presents minimal risk to subjects, and use of patient data for this purpose will not adversely affect subjects' rights or welfare.

Duration

The anticipated duration of the v-safe program is at least one year of active enrollment, based on anticipated length of emergency use authorizations for COVID-19 vaccines. The decision to discontinue v-safe or to modify v-safe procedures to scale back active telephone follow-up will be made in consultation with the CDC COVID-19 Vaccine Task Force leadership and FDA.

Limitations and challenges

Limitations and challenges for v-safe surveillance include:

- Enrollment and registration will initially be a manual process and will be dependent on healthcare providers sharing information about the system with vaccine recipients. Enrollment might be limited. While VAMS will help promote v-safe enrollment though automated text message reminders, not all jurisdictions will use VAMS, and VAMS text messaging capabilities may not be rolled out until several weeks/months after vaccine becomes available.

- Accurate capture of vaccine manufacturer information will depend on accurate self-report, at least initially. Vaccine recipients are expected to receive vaccination record cards specifying the vaccine they received, which might help to improve accuracy of these data.

- Vaccinated people who choose to participate in v-safe might be different from those who decline; therefore, rates of side effects and adverse events generated from v-safe might not be generalizable to the full population of vaccine recipients.

- V-safe allows people to enter late in the post-vaccination monitoring period. The group of individuals who enroll in v-safe late might be heterogenous–those who simply neglected to enroll early, those who chose to enroll only after experiencing a clinically important adverse event, and others. Data collected from these individuals may need to be analyzed separately from data from those who enrolled early.

- The information provided by v-safe participants at 3, 6, and 12 months after vaccination might be impacted by recall bias.

- Participants will likely be lost to follow-up at later time points, reducing participant numbers and likely creating biases in v-safe analyses of safety out to 12 months.

- Because v-safe relies on vaccine recipients reporting their own experiences after vaccination, v-safe is not conducive to capturing the adverse event of death following vaccination.

Dissemination

Data from v-safe will be important in the beginning phases of the COVID-19 vaccination program. Regular updates will be provided to advisory committees and data review groups. It is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports.

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References

1. *The American Journal of Managed Care*. A Timeline of COVID-19 Developments in 2020. Available at https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020.

2. CDC. CDC COVID Data Tracker. Available at https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days.

3. Slaoui M, Hepburn M. Developing Safe and Effective Covid Vaccines—Operation Warp Speed's Strategy and Approach. *N Engl J Med* 2020; 383:1701–1703.

4. Su JR, Duffy J, Shimabukuro TT (2019). Chapter 1: Vaccine Safety. In Poland GA (Ed.) and Whitaker JA (Assoc. Ed.), *Vaccinations*. St. Louis, MO: Elsevier.

5. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

6. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015; 33(36): 4398–4405.

7. *https://www.gsa.gov/technology/government-it-initiatives/fedramp)?*

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8. McNeil MM, Gee J, Weintraub E, et al. The Vaccine Safety Datalink: successes and challenges monitoring vaccine safety. *Vaccine*. 2014; 32(42):5390–8.

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Attachment 1: V-safe health check-in surveys

Note: language to be used for dependents is itali cized. Pregnancy questions are only asked for those 18 years of age or older.

Day 0 - Dose 1

Text message invitation:
Hi <NAME>. It's time for your first v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the first v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
Hi <NAME>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Since your/*their* vaccination, have you/*they* had a fever or felt feverish?
☐ Yes ☐ No

(If Yes) Do you know your/*their* highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- don't remember the reading
☐ No- didn't take my/*their* temperature

Enter your/*their* highest temperature reading from today (degrees Fahrenheit)
Enter your/*their* highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you/*they* had any of these symptoms today where you/*they* got the shot (injection site)?
select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐None

How would you rate your/*their* symptoms:
(If checked Pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Redness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Swelling) ☐ Mild ☐ Moderate ☐ Severe

(If checked Itching) ☐ Mild ☐ Moderate ☐ Severe

Have you/*they* experienced any of these symptoms today?
Select all that apply.
☐ Chills
☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

How would you rate your/*their* symptoms:

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site) ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the/*their* symptoms or health conditions you reported TODAY cause you/*them* to (select all that apply):

☐ Be unable to work or attend school?

☐ Be unable to do your/*their* normal daily activities?

☐ Get care from a doctor or other healthcare professional?

☐ None of the above

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(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

_____

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1.)*
☐ Yes ☐ No ☐ Don't know

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call.*
If you had/*there were* symptoms or health problems following your/*the* COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report the experience to the Vaccine Adverse Event Reporting System (VAERS).

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We'll be in touch tomorrow.

Days 1-7 post vaccination - Dose 1

Text message invitation:
Hi, <NAME>. It's time for your daily v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder (day 7 only):
Hi <NAME>, Please remember to do your daily v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
Hi <NAME>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Have you/*they* had a fever or felt feverish TODAY?
☐ No ☐ Yes

(If Yes) Do you know your/*their* highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- don't remember the reading
☐ No- didn't take my/*their* temperature

Enter your/*their* highest temperature reading from today (degrees Fahrenheit)
Enter your/*their* highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you/*they* had any of these symptoms at or near the injection site today?
Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

How would you rate your/*their* symptoms:

(If checked Pain)	☐ Mild	☐ Moderate	☐ Severe
(If checked Redness)	☐ Mild	☐ Moderate	☐ Severe
(If checked Swelling)	☐ Mild	☐ Moderate	☐ Severe
(If checked Itching)	☐ Mild	☐ Moderate	☐ Severe

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Have you/*they* experienced any of these symptoms today?
Select all that apply:
☐ Chills
☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None
Any other symptoms or health conditions you want to report_____

Symptoms:
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

How would you rate your/*their* symptoms:
(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the/*their* symptoms or health conditions you reported today cause you/*them* to (Select all that apply):

☐ Be unable to work or attend school?

☐ Be unable to do your/*their* normal daily activities?

☐ Get care from a doctor or other healthcare professional?

☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

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- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

_____

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1.)*

☐ Yes ☐ No ☐ Don't know

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
If you had/*there were* symptoms or health problems following your/*the* COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow. (For Day 7 survey, "tomorrow" is replaced with "for your next check-in".)

Day 14 (2 weeks) post vaccination - Dose 1

Text message invitation:
Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:
Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
Hi <NAME>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe:

_____

(if Yes) Did any of the/*their* symptoms or health conditions cause you/*them* to (check all that apply):

☐ Be unable to work or attend school?

☐ Be unable to do your/*their* normal daily activities?

☐ Get care from a doctor or other healthcare professional?

☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

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- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

_____

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked once for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in.

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Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.

Alternate onscreen completion message for Pfizer and Novavax recipients:

Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
You'll need to get your 2nd COVID-19 vaccine next week./*The 2nd COVID-19 vaccine will be needed next week.* Please remember to make an appointment if you have not done so already!
(Alternate language if >=18 days replaces "next week" with "shortly")
After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your/*the* next check-in.

Day 21 (3 weeks) post vaccination - Dose 1

Text message invitation:
Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:
Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
For Pfizer/Novavax recipients:

Hi <name>.
Hi there.

Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

Did you/*they* get your/*their* 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.

(Survey will end and will be directed to enter Dose 2 information:)

Thank you for letting us know that you/*they* received your/*their* 2nd COVID-19 vaccine. Please click the View My Account button below to view your/*their* account and register your/*their* 2nd COVID-19 vaccine.

For Moderna/AstraZeneca/Janssen-Johnson&Johnson/Pfizer/Novavax recipients who did not get dose 2:

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your/*their* last check in, have you/*they* experienced any new or worsening symptoms or health conditions?
☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

☐ Be unable to work or attend school?

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☐ Be unable to do your/*their* normal daily activities?

☐ Get care from a doctor or other healthcare professional

☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?
☐ Yes ☐ No

(If Yes) When were you/*they* diagnosed? _____ (mm/dd/yyyy)

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Since your/*their* last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive? (A*sked if participant answered no to above pregnancy question in this or previous survey)*

☐ Yes
☐ No

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

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- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

For Janssen/Johnson & Johnson recipients:

Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.

For Moderna/AstraZeneca:
Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
You'll need to get your 2nd COVID-19 vaccine next week./*The 2nd COVID-19 vaccine is due next week.* Please remember to make an appointment if you have not done so already! (Alternate language if >=25 days replaces "next week" with "shortly")
After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your/*their* next check-in.

For Pfizer/Novavax recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your/*the* answers, CDC may call you to check on you/*may call*.
It is time to get your/*the* 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your/*their* next check-in.

Day 28 (4 weeks) post vaccination - Dose 1

Text message invitation:
Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:
Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

For all Moderna/AstraZeneca/Pfizer/Novavax recipients who did not previously report Dose 2:

Hi <NAME>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

Did you/*they* get your/*their* 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you/*they* received your/*their* 2nd COVID-19 vaccine. Please click the View My Account button below to view your/*their* account and register your/*their* 2nd COVID-19 vaccine.

For Janssen/Johnson & Johnson and all 2-dose vaccine recipients who report 'No' above

Hi <name>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new or worsening symptoms or health conditions?

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☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions:

(if Yes) Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

☐ Be unable to work or attend school?

☐ Be unable to do your/*their* normal daily activities?

☐ Get care from a doctor or other healthcare professional?

☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or prefer not to say

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What is your/*their* racial group(s)? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

For Janssen/Johnson & Johnson recipients:
Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.

For Pfizer/Novavax/Moderna/AstraZeneca recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
It is time to get your/*the* 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your next check-in.

Day 35 (5 weeks) post vaccination - Dose 1

Text message invitation:
Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:
Hi <NAME>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*
Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
For all Moderna/AstraZeneca/Pfizer/Novavax who did not previously report receipt of Dose 2:

Hi <NAME>.
Hi there.

Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

Did you/*they* get your/*their* 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you/*they* received your/*their* 2nd COVID-19 vaccine. Please click the View My Account button below to view your/*their* account and register your/*their* 2nd COVID-19 vaccine.

For Janssen/Johnson & Johnson and all 2 dose recipients who report 'No' above
Hi <NAME>.
Hi there.

Let's start today's health check-in .
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new or worsening symptoms or health conditions?
☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

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(if Yes) Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

☐ Be unable to work or attend school?

☐ Be unable to do your/*their* normal daily activities?

☐ Get care from a doctor or other healthcare professional?

☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

☐ Outpatient clinic or urgent care clinic visit

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

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- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

For Janssen/Johnson & Johnson recipients:
Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call you to check on you/*may call*.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.

For Pfizer/Novavax/Moderna/AstraZeneca recipients who did not receive dose 2:
Thanks for completing today's check-in.
Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
It is time to get your/*the* 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your next check-in.

Day 42 (6 weeks) post vaccination - Dose 1

Text message invitation:
Hi <NAME>. It's time for your 6-week v-safe check-in. <URL for survey>
Hi <NAME>. It's time for your 6-week v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:
Hi <NAME>. Please remember to do your 6-week v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the 6-week v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
For all Moderna/AstraZeneca/Pfizer/Novavax who did not previously report receipt of Dose 2:

Hi <name>.
Hi there.

Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

Did you/*they* get your/*their* 2nd COVID-19 vaccination?
☐ Yes ☐ No
(If YES) Thank you.
Survey will end and will be directed to enter Dose 2 information

Thank you for letting us know that you/*they* received your/*their* 2nd COVID-19 vaccine. Please click the View My Account button below to view your/*their* account and register your/*their* 2nd COVID-19 vaccine.

For Janssen/Johnson & Johnson and all 2 dose recipients who report 'No' above
Hi <name>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

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(if Yes) Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

_____

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

How would you describe your/*their* current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your/*their* health now compared to your/*their* heath before your/*their* last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your/*their* health problems might be related to your/*their* COVID-19 vaccination?

- ☐ Yes

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☐ No

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Since your/*their* last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive?(*Asked if participant answered no to above pregnancy question in this or previous survey)*
☐ Yes
☐ No

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian or other Pacific Islander

☐ White

☐ Other

☐ Unknown or prefer not to say

Onscreen completion thank you message:
For Janssen/Johnson & Johnson recipients:
Thanks for completing today's check-in.
Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*..
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe.

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We'll be in touch in a few months.

For Pfizer/Novavax/Moderna/AstraZeneca recipients who did not receive dose 2:
Thanks for completing today's check-in.
Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
It is time to get your/*the* 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you/*they* receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch in a few months.

Day 0 – Dose 2

Text message invitation:
Hi <NAME>. It's time for your first v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the first v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
Hi <NAME>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Since your/*their* second COVID-19 vaccination, have you/*they* had a fever or felt feverish?
☐ No ☐ Yes

(If Yes) Do you know your/*their* highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- don't remember the reading
☐ No- didn't take my/*their* temperature

Enter your/*their* highest temperature reading from today (degrees Fahrenheit)
Enter your/*their* highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you/*they* had any of these symptoms where you/*they* got the shot (injection site)?

Select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐None

How would you rate your/*their* symptoms:

(If checked Pain)	☐ Mild	☐ Moderate	☐ Severe
(If checked Redness)	☐ Mild	☐ Moderate	☐ Severe
(If checked Swelling)	☐ Mild	☐ Moderate	☐ Severe
(If checked Itching)	☐ Mild	☐ Moderate	☐ Severe

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Have you/*they* experienced any of these symptoms today?
Select all that apply.

☐ Chills
☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None

Any other symptoms or health conditions you want to report_____

Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms cause some limitation of your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

How would you rate your/*their* symptoms:

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site) ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the/*their* symptoms or health conditions you reported TODAY cause you/*them* to (Select all that apply):

☐ Be unable to work to attend school?
☐ Be unable to do your/*their* normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

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(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

_____

Were you/*they* pregnant at the time of your/*their* second COVID-19 vaccination? (*This is only asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

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If you had/*there were* symptoms or health problems following your/*the* COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow.

Days 1-7 post vaccination – Dose 2

Text message invitation:
Hi <NAME>. It's time for your daily v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder (day 7 only):
Hi <NAME>. Please remember to do your daily v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
Hi <NAME>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Have you/*they* had a fever or felt feverish TODAY?
☐ No ☐ Yes

(If Yes) Do you know your/*their* highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- don't remember the reading
☐ No- didn't take my/*their* temperature

Enter your/*their* highest temperature reading from today (degrees Fahrenheit)
Enter your/*their* highest temperature reading from today (degrees Celsius)

Symptom check
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

Have you/*they* had any of these symptoms where you/*they* got the shot (injection site)?

Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

How would you rate your/*their* symptoms:

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(If checked Pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Redness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Swelling) ☐ Mild ☐ Moderate ☐ Severe
(If checked Itching) ☐ Mild ☐ Moderate ☐ Severe

Have you/*they* experienced any of these symptoms today?
Select all that apply:
☐ Chills
☐ Headache
☐ Joint pain
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☐ None
Any other symptoms or health conditions you want to report_____

Symptoms:
Symptoms can be classified as:
Mild = you notice symptoms, but they aren't a problem
Moderate = symptoms that limit your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

How would you rate your/*their* symptoms:
(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
(If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
(If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
(If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
(If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
(If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
(If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
(If checked Rash, not including the immediate area around the injection site_ ☐ Mild ☐ Moderate ☐ Severe

Health impact
Did any of the/*their* symptoms or health conditions you reported today cause you/*them* to (Select all that apply):

☐ Be unable to work or attend school?
☐ Be unable to do your/*their* normal daily activities?
☐ Get care from a doctor or other healthcare professional?

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☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization
☐ Other, describe:

_____

Were you/*they* pregnant at the time of your/*their* second COVID-19 vaccination? (*This is only asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

☐ Hispanic or Latino
☐ Not Hispanic or Latino
☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or other Pacific Islander
☐ White
☐ Other
☐ Unknown or prefer not to say

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

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If you had/*there were* symptoms or health problems following your/*the* COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow. (For Day 7 survey, “tomorrow” is replaced with “for your next check-in”.

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Days 14, 21, 28, 35 (2, 3, 4, 5 weeks) post vaccination – Dose 2

Text message invitation:
Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>
Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:
Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:
Hi <NAME>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions:

(if Yes) "Did any of these symptoms or health conditions cause you/*them* to (check all that apply):"

☐ Be unable to work or attend school?
☐ Be unable to do your/*their* normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

(If "Get care…" checked) "What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit

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☐ Hospitalization

☐ Other, describe:

_____

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Were you/*they* pregnant at the time of your/*their* second COVID-19 vaccination? (*This is only asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2)*

☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive? (A*sked at Day 21 if participant answered no to above pregnancy question in this or previous survey)*

☐ Yes

☐ No

Race/Ethnicity

(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian or other Pacific Islander

☐ White

☐ Other

☐ Unknown or prefer not to say

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Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.

Day 42 (6 weeks) post vaccination – Dose 2

Text message invitation:
Hi <NAME>. It's time for your 6 week v-safe check-in. <URL for survey>
Hi <NAME>. It's time for your 6-week v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:
Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the 6-week v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

Hi <NAME>.
Hi there.
Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) "Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

☐ Be unable to work or attend school?
☐ Be unable to do your/*their* normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit

v-safe protocol: May 20, 2021, version 3

☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

_____

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

How would you describe your/*their* current state of health?

☐ Excellent
☐ Good
☐ Fair
☐ Poor

How is your/*their* health now compared to your/*their* health before your/*their* last COVID-19 vaccination?

☐ Better
☐ About the same
☐ Worse

(If Worse) Do you believe your/*their* health problems might be related to your/*their* COVID-19 vaccination?

☐ Yes
☐ No

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 2; if yes, then no more pregnancy questions asked for Dose 2)*
☐ Yes ☐ No ☐ Don't know

Since your/*their* last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive?
(*Asked if participant answered no to above pregnancy question in this or previous survey)*

☐ Yes
☐ No

Race/Ethnicity
(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

☐ Hispanic or Latino

v-safe protocol: May 20, 2021, version 3

- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch in a few months.

3, 6, and 12 month post vaccination – Dose 1 or Dose 2

Text message invitation:
Hi <NAME>. We hope you are doing well! It's time for a v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:
Hi <NAME>. Please remember to do your v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey
Hi <NAME>.
Hi there.

Let's start today's health check-in.
Let's start today's health check-in for <DEPENDENT NAME>.

How are you/*they* feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since we last contacted you, have you/*they* experienced any new symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you/*they* to (check all that apply):

☐ Be unable to work or attend school?
☐ Be unable to do your/*their* normal daily activities?
☐ Get care from a doctor or other healthcare professional?
☐ None of the above

(If "Get care…" checked) What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit

v-safe protocol: May 20, 2021, version 3

☐ Hospitalization

☐ Other, describe:

_____

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐ No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Since your/*their* last check-in, have you/*they* had a home or laboratory pregnancy test that was positive?

☐ Yes
☐ No

How would you describe your/*their* current state of health?

☐ Excellent
☐ Good
☐ Fair
☐ Poor

How is your/*their* health now compared to your/*their* health before your/*their* last COVID-19 vaccination?

☐ Better
☐ About the same
☐ Worse

(If Worse) Do you believe your/*their* health problems might be related to your/*their* COVID-19 vaccination?

☐ Yes
☐ No

Since your/*their* last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive? (A*sked if participant answered no to above pregnancy question in this or previous survey)*

☐ Yes
☐ No

Race/Ethnicity

(*This is only asked once; once data are captured, questions will not display on future surveys)*

What is your/*their* ethnic group?

v-safe protocol: May 20, 2021, version 3

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

3/6 Month:
Thanks for completing today's check in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your answers, someone from CDC may call to check on you/*may call*.
If you/*they* had symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch in a few months.

12 Month:
Congratulations! You have completed your/*the* final v-safe check-in.
Depending on your answers, someone from CDC may call to check on you/*may call*.
If you/*they* had symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).
Thank you for participating in v-safe! Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Take care and stay safe.

v-safe protocol: May 20, 2021, version 3

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

Exhibit 5

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Tracking No. 2021-00256-A-PHS

August 27, 2021

Elizabeth Brehm
Siri & Glimstad
200 Park Ave
17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Ms. Brehm:

This letter acknowledges our receipt of your Freedom of Information Act (FOIA) appeal, which was submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on August 25, 2021. It challenges the CDC's response to your initial request, #21-01506-FOIA. We assigned your appeal the tracking number at the top of this page, based on when it was received in our office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved. For more information about how your appeal will be processed, please refer to the HHS FOIA regulations. They are available at the following web addresses:

- https://www.justice.gov/oip/freedom-information-act-5-usc-552 and
- https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations.

If you have any questions, please call (202) 260-6933, or email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Brandon J. Gaylord
Director, FOI/Privacy Acts Division

Exhibit 6

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL June 24, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852
Email: FOIARequests@cdc.gov

Re: Documents Concerning V-Safe Data (IR#0522)

Dear Mr. Andoh:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("FOIA").

By this letter, please provide the following records in your possession via email to foia@sirillp.com:

> **All documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

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 of course reserves all rights to appeal the withholding or deletion of any information.

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

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

Very truly yours,

/s/ Elizabeth A. Brehm
Elizabeth A. Brehm, Esq.

Exhibit 7

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

June 29, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your clarified June 24, 2021, Freedom of Information Act (FOIA) request on June 25, 2021, seeking:

> "All documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same."

Your FOIA request number is #21-01507-FOIA, and it has been placed in our complex processing queue.

In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request. We will require more than thirty working days to respond to your request because:

☒ We reasonably expect that two or more CDC centers, institutes, and offices (C/I/Os) may have responsive records.

☒ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Carolyn Okpewho, at 770-488-6332 or our FOIA Public Liaison, Roger Andoh, at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

☒ The disclosure of the records will not contribute significantly to public understanding of the operations or activities of the government.

☒ You have failed to demonstrate that you disseminate information to the public.

☒ You have failed to provide enough information to warrant a waiver of fees.

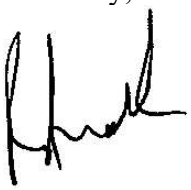
Because Informed Consent Action Network (ICAN) is considered an "All Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Since you did not provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

You have the right to appeal the agency's fee waiver response to your request. You may mail your appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Your appeal must be postmarked or electronically transmitted by September 27, 2021.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number.

Sincerely,



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

#21-01507-FOIA

Exhibit 8

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

August 02, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

Dear Ms. Brehm:

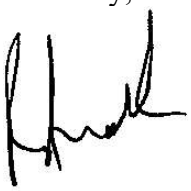
The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your clarified June 24, 2021, Freedom of Information Act (FOIA) request on June 25, 2021, seeking:

> "All documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same."

We located 61 pages and one Excel Spreadsheet of responsive records. After a careful review of these pages, no information was withheld from release.

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 770-488-6277.

Sincerely,



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

Enclosures

#21-01507-FOIA

Exhibit 9

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

CDC FREEDOM OF INFORMATION ACT APPEAL

VIA EMAIL October 28, 2021

Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: ***Appeal of FOIA Request Case Number #21-01507-FOIA (IR#0522)***

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, on June 24, 2021, we requested records from the files of the Centers for Disease Control and Prevention ("**CDC**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). The CDC designated the request as Request Number #21-01507-FOIA (the "**FOIA Request**"). On August 2, 2021, Roger Andoh, the CDC/ATSDR FOIA Officer (the "**CDC Officer**"), issued a final response (the "**Final Response**") to the FOIA Request. ICAN writes now to appeal CDC's final response.

A. The FOIA Request

The FOIA Request sought the following documents (the "**FOIA Request**"):

> **All documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same.**

(**Exhibit A**.)[1]

On June 29, 2021, CDC assigned FOIA request #21-01507 to the FOIA Request. (**Exhibit A.1**.)

[1] All "Exhibits" referenced herein are appended to this letter.

B. The Final Response

On August 2, 2021, the CDC issued the Final Response and stated, in relevant part:

> **We located 61 pages and one Excel Spreadsheet of responsive records. After a careful review of these pages, no information was withheld from release.**

(**Exhibit B**.)

C. Argument

The CDC has failed to conduct an adequate search of the data requested. An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. EPA*, 767 F.2d 569, 571 (9th Cir. 1985) (quoting *Weisberg v. U.S. Dept. of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984)) (internal quotation marks omitted). In the FOIA Request, ICAN requested "[a]ll documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and *communications* regarding same" (emphasis added). CDC did not produce any communications in response to the FOIA Request. Therefore, the Final Response is inadequate.

D. Appellate Request

Given the foregoing, ICAN hereby appeals and requests that the documents responsive to the FOIA Requests be produced within 20 days of this appeal. Thank you for your time and attention to this matter. If you require any additional information, please contact me at **(212) 532-1091** or through email at **foia@sirillp.com**.

Very truly yours,

/s/ Gabrielle G. Palmer
Gabrielle G. Palmer, Esq.

Enclosures

Exhibit A

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL June 24, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852
Email: FOIARequests@cdc.gov

Re: Documents Concerning V-Safe Data (IR#0522)

Dear Mr. Andoh:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("FOIA").

By this letter, please provide the following records in your possession via email to foia@sirillp.com:

> **All documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

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 of course reserves all rights to appeal the withholding or deletion of any information.

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

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

Very truly yours,

/s/ Elizabeth A. Brehm
Elizabeth A. Brehm, Esq.

Exhibit A.1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

June 29, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your clarified June 24, 2021, Freedom of Information Act (FOIA) request on June 25, 2021, seeking:

> "All documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same."

Your FOIA request number is #21-01507-FOIA, and it has been placed in our complex processing queue.

In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request. We will require more than thirty working days to respond to your request because:

☒ We reasonably expect that two or more CDC centers, institutes, and offices (C/I/Os) may have responsive records.

☒ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Carolyn Okpewho, at 770-488-6332 or our FOIA Public Liaison, Roger Andoh, at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

☒ The disclosure of the records will not contribute significantly to public understanding of the operations or activities of the government.

☒ You have failed to demonstrate that you disseminate information to the public.

☒ You have failed to provide enough information to warrant a waiver of fees.

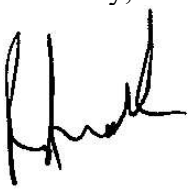
Because Informed Consent Action Network (ICAN) is considered an "All Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Since you did not provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

You have the right to appeal the agency's fee waiver response to your request. You may mail your appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Your appeal must be postmarked or electronically transmitted by September 27, 2021.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number.

Sincerely,



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

#21-01507-FOIA

Exhibit B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

August 02, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your clarified June 24, 2021, Freedom of Information Act (FOIA) request on June 25, 2021, seeking:

> "All documents concerning v-safe data including but not limited to policies, procedures, processes related to v-safe, and communications regarding same."

We located 61 pages and one Excel Spreadsheet of responsive records. After a careful review of these pages, no information was withheld from release.

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 770-488-6277.

Sincerely,

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

Enclosures

#21-01507-FOIA

Exhibit 10

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2022-00010-A-PHS

November 2, 2021

Gabrielle Palmer
Siri & Glimstad
200 Park Ave
17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Ms. Palmer:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on October 28, 2021. It challenges the Centers for Disease Control and Prevention (CDC) response to your client's initial request, 21-01507-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 421 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

Exhibit 11

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL September 1, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852

Re: V-Safe de-identified data (IR#0547)

Dear Mr. Andoh:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**").

On behalf of ICAN, please provide the following records via email to foia@sirillp.com:

> **Produce all data submitted to v-safe and subsequently deidentified by the CDC and/or Oracle from January 1, 2020 forward.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii). ICAN is a not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. As part of their mission, ICAN actively investigates and disseminates information regarding vaccine safety issues, including through their website, and through press events and releases. They are seeking the information in this FOIA request to allow them to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information we are requesting will not contribute to any commercial activities.

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 of course reserves all rights to appeal the withholding or deletion of any information.

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

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or via email at 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.
Gabrielle G. Palmer, Esq.

Exhibit 12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

September 03, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

1st Letter Subject: Acknowledgement Letter

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your September 01, 2021, Freedom of Information Act (FOIA) request on September 01, 2021, seeking:

> "Produce all data submitted to v-safe and subsequently deidentified by the CDC and/or Oracle from January 1, 2020 forward."

Your FOIA request number is #21-02128-FOIA, and it has been placed in our complex processing queue.

In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request. We will require more than thirty working days to respond to your request because:

> ☒ We reasonably expect that two or more CDC centers, institutes, and offices (C/I/Os) may have responsive records.
>
> ☒ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, Carolyn Okpewho, at 770-488-6332 or our FOIA Public Liaison, Roger Andoh, at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:

☒ The disclosure of the records will not contribute significantly to public understanding of the operations or activities of the government.

☒ You have failed to demonstrate that you disseminate information to the public.

☒ You have failed to provide enough information to warrant a waiver of fees.

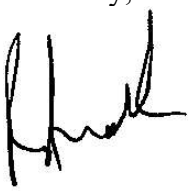
Because Informed Consent Action Network (ICAN) is considered an "All Other requester" you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages. (10 cents/page).

Since you did provide us with a date range for your request, the search cut-off date for your request will be the date provided.

You have the right to appeal the agency's fee waiver response to your request. You may mail your appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Your appeal must be postmarked or electronically transmitted by December 02, 2021.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number.

Sincerely,



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

#21-02128-FOIA

Exhibit 13

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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

September 03, 2021

SENT VIA EMAIL

Elizabeth Brehm
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

2nd Letter Subject: Duplicate Request Letter

Dear Ms. Brehm:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your September 01, 2021, Freedom of Information Act (FOIA) request on September 01, 2021, seeking:

> "Produce all data submitted to v-safe and subsequently deidentified by the CDC and/or Oracle from January 1, 2020 forward."

This request is a duplicate of your June 24, 2021, request, assigned #21-01506-FOIA, seeking *"All de-identified data submitted to v-safe since January 1, 2020."* and therefore has been administratively closed as a duplicate request.

Sincerely,

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

#21-02128-FOIA

Exhibit 14

From: Okpewho, Carolyn (CDC/OCOO/OD)
To: Gabrielle Palmer
Cc: S&G Information Request Staff; Annalise Beube
Subject: RE: CDC FOIA #21-02128 Acknowledgement Letter and Duplicate Request Letter {Brehm}
Date: Thursday, September 9, 2021 5:12:52 AM

Good morning Ms. Palmer,

Happy Thursday! Thank you for your response. You stated that you seek data that was "and subsequently deidentified." Your previous request seeks "de-identified data." Since you have already appealed your request seeking said data, permit them to finish their analysis and respond to you.

Should you seek a different set of data or something else, you may submit a new FOIA request.

Thank you for your time Ms. Palmer.

Please enjoy the rest of your week.

Remain Safe !

Have a*´¨)
,.·´,.·*´¨) ,.·*¨)
(,.·´ (,.·´ * Wonderful Day!

V/R

Carolyn Sanchang-Fon Okpewho
CDC/ATSDR Workstream Leader
Freedom of Information Act Office
Centers for Disease Control and Prevention
Agency for Toxic Substances and Disease Registry
☎ 770-488-6332 (Direct) | ☎ 770-488-6399 (Main)
404-235-1852 | xxo5@cdc.gov
Telework ~ Monday through Friday

From: Gabrielle Palmer <gpalmer@sirillp.com>
Sent: Wednesday, September 8, 2021 4:30 PM
To: Okpewho, Carolyn (CDC/OCOO/OD) <xxo5@cdc.gov>
Cc: S&G Information Request Staff <foia@sirillp.com>; Annalise Beube <abeube@sirillp.com>

Subject: RE: CDC FOIA #21-02128 Acknowledgement Letter and Duplicate Request Letter {Brehm}

Ms. Okpewho,

Your email indicates that "if de-identified records exist," a search under both FOIA requests would yield the same results. However, your statement misinterprets both of our requests. If responsive documents (i.e., documents showing the data submitted to v-safe) exist, they should be redacted and de-identified as necessary and then produced.

With that in mind, please confirm that the CDC understands request no. 21-01506 to encompass all v-safe data (with appropriate information redacted, e.g., deidentified) regardless of when the deidentification took place or who deidentified the data (whether CDC or Oracle).

Gabrielle G. Palmer, Attorney

Siri | Glimstad

200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

From: Okpewho, Carolyn (CDC/OCOO/OD) <xxo5@cdc.gov>
Sent: Wednesday, September 8, 2021 1:18 PM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: S&G Information Request Staff <foia@sirillp.com>; Annalise Beube <abeube@sirillp.com>
Subject: RE: CDC FOIA #21-02128 Acknowledgement Letter and Duplicate Request Letter {Brehm}

Good afternoon Ms. Palmer,

Hope that all is well with you today. In response to your communication below:

#21-01506 ⇨ "All de-identified data submitted to v-safe since January 1, 2020."
#21-02128 ⇨ "Produce all data submitted to v-safe and subsequently deidentified by the CDC and/or Oracle from January 1, 2020 forward."

Should the de-identified records exist, they would yield the same results for both requests.

Thank you for your time Ms. Palmer.

Enjoy the rest of your week!

Remain Safe !

Have a*´¨)
,.·´,.·*´¨) ,.·*¨)
(,.·´ (,.·´ * Wonderful Day!

V/R

Carolyn Sanchang-Fon Okpewho
CDC/ATSDR Workstream Leader
Freedom of Information Act Office
Centers for Disease Control and Prevention
Agency for Toxic Substances and Disease Registry
☎ 770-488-6332 (Direct) | ☎ 770-488-6399 (Main)
🖷 404-235-1852 | xxo5@cdc.gov
Telework ~ Monday through Friday

From: Gabrielle Palmer <gpalmer@sirillp.com>
Sent: Tuesday, September 7, 2021 10:23 PM
To: Okpewho, Carolyn (CDC/OCOO/OD) <xxo5@cdc.gov>
Cc: S&G Information Request Staff <foia@sirillp.com>; Annalise Beube <abeube@sirillp.com>
Subject: RE: CDC FOIA #21-02128 Acknowledgement Letter and Duplicate Request Letter {Brehm}

Dear Sir or Madam,

On June 24, 2021, we submitted a FOIA request to CDC for "all de-identified data submitted to v-safe since January 1, 2020" (the "First Request"). On July 29, 2021, CDC issued a final response to the First Request and stated that no responsive records existed. CDC's response to the first request is subject to a pending appeal.

On September 1, 2021, we submitted a second FOIA request for "all data submitted to v-safe and subsequently deidentified by the CDC and/or Oracle from January 1, 2020 forward."

We understand by your letter dated September 3, 2021, that CDC understands the First Request to mean that ICAN seeks all v-safe data (with appropriate information redacted, e.g., deidentified) regardless of when the deidentification took place or who deidentified the data (whether CDC or Oracle). Please confirm that CDC agrees with our understanding.

Sincerely,

Gabrielle G. Palmer, Attorney

Siri | Glimstad

200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

From: xxo5@cdc.gov <xxo5@cdc.gov>
Sent: Friday, September 3, 2021 9:13 AM
To: S&G Information Request Staff <foia@sirillp.com>
Subject: CDC FOIA #21-02128 Acknowledgement Letter and Duplicate Request Letter {Brehm}

September 3, 2021

Request Number: 21-02128-FOIA

Dear Ms. Brehm:

This is regarding your Freedom of Information Act (FOIA) request of September 1, 2021, seeking

"Produce all data submitted to v-safe and subsequently deidentified by the CDC and/or Oracle from January 1, 2020 forward."

Please see the attached letters.

Sincerely,
CDC/ATSDR FOIA Office
770-488-6399