

- E. The Old VAERS ID shall be retained in a data table linked to the primary VAERS database to allow for the search and identification of any specific VAERS report by either the first VAERS ID assigned (the Primary Report ID until a report is identified as Duplicate or Redundant) or subsequently reassigned Linked Report ID.
- F. The Contractor shall develop, demonstrate, document, and implement a coding variable (Patient Continuity Code) which shall be used to link a patient identified in a report to other reports in which that particular patient has been identified. Such reports may include Redundant and Duplicate Reports but may also include different "person vaccination events" regarding the same person, but a different vaccination and/or event. The Patient Continuity Code shall be included in the primary system database and in the Government Extract.
- G. The Contractor shall develop, demonstrate, document, and implement measures for batch-matching to identify redundant or secondary reports. The Contractor shall evaluate a variety of methods including "fuzzy logic" (http://en.wikipedia.org/wiki/Fuzzy_logic) for identifying possible duplicate or redundant reports, including reports linked with minor name variations, and implement them at the Government's discretion. An example of the use of fuzzy logic would be linking two different VAERS reports of a very rare occurrence in two patients who have the same birthdate and same date of vaccination but no name reported, into one VAERS report if the Contractor believes the two reports pertain to the same patient.
- H. The Contractor shall develop and maintain methods for confirming the quality of submitted data through standardized quality control and quality assurance procedures designed to reduce or eliminate the presence of more than one record concerning the same adverse event, data inconsistencies or deficiencies.
- I. With data provided by the Government, the Contractor shall develop and implement procedures to provide selection lists for valid vaccine lot identifiers (lot numbers) and data entry masks based on known lot numbers to provide information at the point of data entry as to the validity of the vaccine lot number entered. The Contractor shall develop and implement procedures to detect and specifically demarcate records containing reported vaccine lot identifiers, which are not valid lot numbers, based on comparison with lot identifier data provided by vaccine manufacturers through the FDA and provided to the contractor. These procedures shall be utilized for the Contractor internal data entry system.
- J. Upon provision of SARS-CoV-2 vaccine manufacturers' lot numbers to the Contractor by the FDA, lot numbers in the database shall be flagged if not valid when compared to the manufacturer's master data.
- K. Any errors identified by the Contractor QA checks or Government should be corrected in the data.

QUALITY CONTROL AND ASSURANCE FOR SCANNED DATA QUALITY FOR SARS-CoV-2 VACCINE REPORTS

- A. The Contractor shall develop and maintain methods for assuring the quality of document images for the image database and correct indexing in the image database through standardized quality control and quality assurance procedures designed to confirm that documents are as legible as possible, complete, and capable of retrieval and copying from image base prior to final transfer of original physical document to the Government for archiving.
- B. Any errors identified by the Contractor QA checks or Government should be corrected in the data.

QUALITY CONTROL AND ASSURANCE FOR CODED DATA QUALITY FOR SARS-CoV-2 VACCINE REPORTS

- A. The Contractor shall develop and maintain methods for assuring quality and consistency and the most current version of coding in Medical Dictionary for Regulatory Activities (MedDRA) (or other coding language chosen by the Government) and the accuracy and completeness of MedDRA coding submitted by manufacturers in their reports. The Contractor shall notify the Government of changes made to the

MedDRA codes relevant to the VAERS data coding activities and provide a full report and summary of each updated version of MedDRA.

- B. The Contractor shall develop and implement a training program for all data entry and coding staff which shall require approval by the Government. The Contractor shall enforce a certification process that requires all coders to be trained and become certified coders for current code-based data. This shall include MedDRA, or another coding system chosen by the Government. The data system shall include a coder-signature field to indicate the specific coder staff person who performed the report coding.
- C. The Contractor shall develop or procure and use automated tools, such as auto-coding software, algorithms and aides, when available and approved by the Government, to assist in the coding process.
- D. The Contractor shall provide online manuals for coders to use at any time so that coders can access simulated scenarios and glean applicable codes.
- E. The Contractor shall document any non-standard coding values in use by the VAERS program and submitted in reports.
- F. The Contractor shall implement QA procedures and reviews to ensure that data provided as part of Government data extracts meet pre-specified requirements as directed by the Government. Procedures for data entry error identification, correction and supplemental data entry should be established by the contractor in advance of any error detection by the Government.
- G. The Contractor shall develop and implement a QAP which shall include performance quality measures for each of the elements in this section of the SOW, and which shall require approval by the COR prior to implementation. The Contractor shall perform evaluation of these performance quality measures and report the results to the Government annually or on an alternate schedule as specified by the Government and propose procedure modifications as necessary to ensure data quality. The resultant modifications to QA procedures shall be periodically implemented contingent upon approval by the COR or CO.
- H. Any errors identified by the Contractor QA checks or Government shall be corrected in the data.

QUALITY CONTROL UPDATES FOR SARS-CoV-2 VACCINE REPORTS

- A. The Government reserves the right to direct the Contractor to revise and update QA procedures in the QAP to support changes in reporting procedures, such as changes to the VAERS form, online reporting tool, or standard methods of reporting (i.e., transitioning to fully electronic reporting).
- B. Reasonable accommodations will be made to the Contractor by the Government to allow for implementation of any such revised and updated QA procedures and the Contractor will be allowed to negotiate implementation of changes.

TASK 5: INFORMATION MANAGEMENT FOR SARS-CoV-2 VACCINE REPORTS

- A. VAERS is an integrated system that encompasses information technology, data management, data analysis, software development lifecycle and IT security. The Contractor shall perform the following tasks/activities:
 - 1. Maintain Capability Maturity Model (CMM) Level 3 certification or higher throughout the performance period of the contract and provide the Government current documentation of its CMM Level 3 or higher certification.
 - 2. Maintain current system operations
 - 3. Provide software development, enhancement and progress reviews as requested by the Government.

4. Provide software documentation inclusive but not limited to systems requirements, specifications, architecture details, design details, analytical algorithms, data models, and technical support processes. All documentation shall be submitted to the Government in each annual report and during and following the implementation of system changes.
 5. Provide data extractions and depersonalized data sets requested by the Government on a routine and ad-hoc basis
 6. Provide ad hoc searches of VAERS SARS-CoV-2 vaccine data as requested by the Government
 7. Implement appropriate Government policies and regulatory requirements regarding information management, information technology, software development, and security.
- B. The Contractor shall furnish all necessary personnel, facilities, supplies, and equipment, as appropriate, to provide the Government with required technical, and operational services, within the general work parameters set forth in this Statement of Work.

VAERS SARS-CoV-2 SYSTEM SPECIFICATIONS

- A. The VAERS system shall be hosted on an offsite network consisting of CDC owned software, commercial off the shelf software (COTS), and owned and leased hardware. The VAERS Servers will be categorized into core, non-core and infrastructure systems. Core systems are those identified with core business functionality, non-core provides support for the core systems. The infrastructure servers will provide centralized security, network, authentication, storage, remote access and management of all the VAERS environments. These servers may consist of a combination of physical and virtual servers, though virtual servers are recommended.

The VAERS architecture should consist of two separate Security Sockets Layer (SSL) virtual private networks (VPN), one contains the production and software development lifecycle (SDL) environment, and the second located offsite contains a disaster recovery environment. The disaster recovery site is a duplicate and replication of the production site and provides recovery of the production site within 24 hours (refer to **Task 1: ADMINISTRATIVE** for physical location requirements for the offsite environment for disaster recovery, i.e., the disaster recovery site).

Below is an example of the approximate number of development, testing and user acceptance servers needed for the system:

Environment	Physical	Virtual
Infrastructure	7	5
Production	2	5
Disaster Recovery	6	12
Development	0	6
Testing	4	0
User Acceptance	0	5

- B. Software to be installed on these machines includes but is not limited to:

Activator, ColdFusion, Apache, Biscom FAXCOM, CentOS Enterprise Linux, Chado Software, SpellText, Cisco ASA software, Cisco IOS, CopSSH, Doubletake, Express Metrix, Faxcom, HP Array Configuration Utility, IBM Rational Tools, Itefix CopSSH, Java, Jpeg Wizard, Kofax Capture, Macromedia CFMX, Medical/Pharmaceutical Spellchecker, Microsoft Active Directory, Microsoft Remote Desktop Version 10, Microsoft Windows server 2016, Microsoft IIS, MS Office, MS OS, Microsoft SQL 2017, Microsoft VSS, NSClient++, PHINMS, Python, rDist, Redhat Enterprise Linux, rSync, RSA Authentication Manager, RSA Radius Server, SAS, Screen, SourceForge GNUWin32, SpellText, Stedman's spellchecker, Superflexible, Symantec Backup Exec Agent, Symantic Antivirus, Tripwire for Servers, VMWARE, Zope

Contractor must license or own software (or equivalent) as listed above.

- C. Contractor must develop a VAERS Virtual Private Networks (VPN) which allows authorized users located outside of the Contractor's facility to establish a secure connection to the VAERS application. The VAERS VPNs will provide a secure computer network that uses the Internet to allow remote users secure access to the VAERS application and database. It should encapsulate data transfers each business day, between the authorized users and Contractor's networked devices to keep transferred data private from other devices on one or more intervening local or wide area networks. Depending on the user's access rights to the VAERS database, the individual will either be part of a VPN with full access to the VAERS database or a more restricted VPN only providing access to reports of selected research interest. The Contractor adheres to the following and is expected to create and maintain capabilities to perform these functions:

- Conduct web based query
- Enable viewing of scanned images
- Enable viewing of entered data including Follow up and MedDRA code
- Enable viewing of nurse follow up module

- D. Other VAERS functionality requirements include:

1. Creation of a VAERS SARS-CoV-2 vaccine public website and online reporting tool which includes a mechanism for allowing patients, parents, providers and other partners and stakeholders to electronically submit VAERS reports
2. Creation of an intranet application that allows authorized staff to access SARS-CoV-2 vaccine reports to query, add and modify data, and view linked images
3. Double data entry of specific report types as determined by the Government
4. Scanning of hard copy documents including, but not limited to, VAERS SARS-CoV-2 vaccine report and medical documentation.
5. Receipt of electronic SARS-CoV-2 vaccine reports from manufacturers (eVAERS)
6. Electronic transmission of reports and data extractions to CDC and FDA as specified by the Government
7. Business Intelligence
8. Data warehousing
9. Data editing
10. Duplicate identification
11. Database management system and tools
12. Software for extracting and transmission of Government specified data sets.

DATA MANAGEMENT

- A. All Information Technology (IT) systems must comply with federal regulations and policies regarding IT which includes but are not limited to Enterprise Performance Life Cycle (EPLC), Capital Planning and Investment Control (CPIC), Information Security, Section 508 of the Rehabilitation Act, Enterprise Architecture (EA), etc.

- B. These methods, procedures and processes will accept reports submitted by business partners including manufacturers, state health coordinators, and other immunization programs, other Federal Government agencies and programs, and other parties.
Electronic manufacturer reports include post-marketing adverse drug reaction (ADR) data for individual cases, post-marketing expedited ADR reports and periodic ADR reports. Electronic manufacturer reports shall conform to the format and processes identified and implemented by the US Food and Drug Administration (FDA). This reporting process is referred to as eVAERS.
- C. Under the direction of the CO and COR, the Contractor shall establish and maintain methods, procedures and processes to support a variety of Electronic Data Interchange (EDI) message types to be specified by the Government. The contractor will work with SARS-CoV-2 vaccine manufacturers (approved by Government), to ensure electronic submission of postmarket individual case safety reports (ICSRs) to VAERS using E2B(R3) and submitting via xml format. Electronic reporting of vaccine postmarketing safety reports shall follow the International Council on Harmonisation's (ICH) E2B(R3) ICSR specification : <https://www.federalregister.gov/documents/2014/06/10/2014-13480/postmarketing-safety-reports-for-human-drug-and-biological-products-electronic-submission>

STANDARDIZED METHODS FOR PROVIDING ROUTINE AND REQUESTED REPORTS OF VAERS SARS-CoV-2 VACCINE DATA TO THE GOVERNMENT

- A. The Contractor shall perform ad hoc searches of the VAERS SARS-CoV-2 vaccines databases to address specific surveillance questions and support vaccine safety studies, as requested by the Government.
- B. At the direction of the Government the Contractor shall develop, maintain and update programs to routinely produce specific depersonalized data sets containing originally reported information for the public websites, World Health Organization (WHO), state health coordinators and others as approved by the Government.
- C. The Contractor shall provide a weekly reports of adverse events after SARS-CoV-2 vaccines reported for specific jurisdictions via The Epidemic Information Exchange (Epi-X) to those specific State Health Coordinators as indicated by the Government, upon request by the Government.

These reporting requirements are subject to change at the request of the government.

GOVERNMENT DATA EXTRACTS FOR SARS-CoV-2 VACCINE REPORTS

- A. The quality of the data extract is important to VAERS, therefore, the Contractor shall provide accurate data extract ("Government Extract") to the Government for storage and use at Government sites (both CDC and FDA). The data extract and all available data elements collected from the submission of VAERS reports and collected through follow-up activities are subject to the approval of the Government and should be provided according to the specified timeframes detailed in Appendix A. The complete VAERS SARS-Cov-2 vaccine database, containing both (a) all data elements from the VAERS form which include those data-elements historically used by the Government, and (b) any new and valuable data-elements added by the Contractor by the direction of the Government shall be provided daily. All data elements collected on the VAERS form (and subsequent approved revisions of the VAERS form), and subsequent data elements collected via internal entry system or web system, are subject for inclusion in the data extract to Government. If the data element is a specific field on the form, the data shall be stored in a related specific field in the Government data, with no concatenation of data fields or elements. The following are examples of two processes for important extracts of data from the VAERS system that the Contractor shall follow:
 - 1. VAERS SARS-CoV-2 VACCINE DAILY EXTRACT - Each business day, the Contractor shall send an extract to the CDC and FDA through a low cost data transmission application. Once CDC receives the extract, a confirmatory e-mail is submitted to the Contractor verifying that the extract has been received. The Contractor shall contact the COR if the confirmatory e-mail is not received. The COR

will contact the Contractor if there is a problem uploading and processing the data. The Contractor shall adhere to the following:

- Include initial report data and data obtained in follow up
 - Provide data in a format approved by the Government (CSV format)
 - Maintain manufacturer reports received electronically including postmarketing adverse drug reaction (ADR) data for individual cases, post marketing expedited ADR reports and periodic ADR reports.
2. **VAERS SARS-CoV-2 VACCINE PUBLIC EXTRACTS** - The Contractor shall be required to maintain public redacted databases of VAERS data as specified by the Government. The current VAERS public website (www.vaers.hhs.gov) provides downloadable datasets that are subsets of the VAERS daily extract that is sent to the CDC and FDA. WONDER, a CDC created online tool located at wonder.cdc.gov, is another example of the public databases. This tool allows the public to query a subset of the VAERS data. Standard operating procedures are used to ensure patient privacy. The public website and WONDER shall be updated on a weekly basis. There is a one week lag on data so that quality control measures can be conducted by the Contractor. The datasets on the public website are split into separate CSV files by years dating from 1990 to the current year. Non-domestic (i.e., foreign) reports are placed in a separate CSV file.
 3. **VAERS SARS-CoV-2 VACCINE OTHER GOVERNMENTAL AGENCIES EXTRACTS**- The Contractor shall provide VAERS data in comma separated value (CSV) files on a secure server platform to specified points of contact among other governmental agencies, Department of Defense (DoD), Indian Health Services (IHS), and World Health Organization (WHO), on a weekly basis.
 - a. DoD and non-DoD reports will be identified using specific search criteria as outlined in VAERS CDC DoD Memorandum of Agreement (MOA). Initial and follow-up unredacted information will be provided on DoD reports, while initial redacted information will be provided on non-DoD reports.
 - b. IHS and non-IHS reports will be identified using specific search criteria as outlined in VAERS CDC IHS Memorandum of Understanding (MOU). Initial and follow-up unredacted information will be provided on IHS reports, while initial redacted information will be provided on non-IHS reports.
 - c. WHO will be provided initial redacted information, similar to data publicly available at the CDC WONDER website: <https://wonder.cdc.gov/vaers.html>.
 4. **VAERS SARS-CoV-2 VACCINE JURISDICITON EXTRACTS**- The Contactor shall provide VAERS SARS-CoV-2 vaccine data and summary tables to specified jurisdictions using CDC's Epidemic Information Exchange (*Epi-X*), a secure, web-based network that serves as a powerful information exchange between CDC and public health professionals involved in identifying, investigating, and responding to public health threats. Data will be posted and refreshed on a weekly basis with a one week lag in order to incorporate quality control measures conducted by the Contractor. The VAERS SARS-CoV-2 vaccine data will include initial report data with personal identifiers, no follow-up will be included. Summary tables will also be provided to the jurisdictions, including summary statistics, including but not limited to, serious status and conditions of interest.

VAERS FUTURE SOFTWARE DEVELOPMENT AND ENHANCEMENTS

- A. At the request of the Government, the Contractor shall develop and enhance software for the VAERS system following the HHS, CDC and NCEZID policies and procedures for Enterprise Performance Life Cycle (EPLC), Capital Planning and Investment Control (CPIC) and IT security.
<http://www.hhs.gov/ocio/policy/index.html>

CONTRACTOR COMPLIANCE WITH APPLICABLE LAWS, REGULATIONS, POLICIES AND STANDARDS

- A. The Contractor shall ensure that the Information Technology Architecture (ITA) for the VAERS system is implemented and maintained by the Contractor in compliance with applicable regulations including OMB

Circular A-130, the Federal Information Resources Management Regulation (FIRM), the DHHS Automated Information Systems Security Program (AISSP) Handbook, and applicable portions of the CDC ITA plan, Technical Reference Model and Standards.

- B. IT products and technologies procured through this contract shall meet the applicable accessibility standards at 36 CFR 1194, viewable at <https://www.gpo.gov/fdsys/granule/CFR-2011-title36-vol3/CFR-2011-title36-vol3-part1194/content-detail.html>
- C. The Contractor shall ensure that all systems are in compliance with Section 208, the privacy provisions of the E-Government Act of 2002, and follow the OMB Guidance of September 26, 2003 regarding implementation of the privacy provisions of the E-Government Act.
- D. The Contractor shall be responsible for being aware of and shall comply with all applicable federal information technology and information management laws, regulations, policies, and standards. These include but are not limited to:
- Children's Online Privacy Protection Act (COPPA)
 - Section 508 of the Rehabilitation Act. HHS Section 508 Product Assessment Template (use VPAT version 2.0 or later: <https://www.itic.org/policy/accessibility/vpat>)
 - Clinger-Cohen Act (CCA)
 - Federal Information Security and Management Act (FISMA)
 - Paperwork Reduction Act (PRA)
 - Office of Management and Budget (OMB), National Institute of Standards and Technology (NIST), and General Accounting Office (GAO) policies that can be primarily found at or through the Federal CIO Council website at www.cio.gov.
 - Federal Enterprise Architecture (FEA)
- E. The Contractor shall not develop any Internet web applications that use persistent cookies without explicit authorization by CDC's Chief Information Officer.
- F. The Contractor shall adhere to CDC's Secure Coding Practices guide for developing web-based applications to prevent security vulnerabilities.
- G. Contractor's performance and resulting deliverables shall adhere to all federal, HHS, and/or CDC IT security policies and procedures. Development or implementation of an electronic information system or any electronic data collection effort conducted in the performance of this contract is required to undergo Certification and Accreditation (C&A) prior to operation. When applicable, the Contractor shall be required to complete all security documentation and materials required to obtain an authority to operate (ATO). The Contractor shall comply with all applicable HHS, CDC, FISMA, HIPPA, NIST, and other federal policies and regulations in the performance of the security requirements. If an application or system is operated by the Contractor on behalf of the Government and/or hosted at a Contractor facility, it shall comply with HHS and CDC policies, and is subject to all OMB requirements, including a full Certification and Accreditation (C&A)

V. TASK ORDER DELIVERABLES AND MILESTONES:

Item	Deliverable	Quantity	Time
1.	Program Management Monthly Status Report as specified in the Administrative section of the SOW	1 each to the COR and TR	Monthly, first report due 30 days after contract award
2.	Annual report as specified in the Administrative section of the SOW	1 each to the COR, TR and CO	Annually, due 30 days following the 12 months period covered by report
3.	Draft Final Report as specified in the Administrative section of the SOW.	1 each to the COR and TR	At least 45 days before the contract completion date
4.	Final Report as specified in the Administrative section of the SOW	1 each to the COR, TR and CO	No later than the contract completion date
5.	Report inventory of all hardware and software, including version numbers of software and record of maintenance as specified in Security section of the SOW	1 each to the COR and TR	Include in annual report and upon request
6.	Develop/update and provide standard operating procedures for all aspects of VAERS operations, including complete VAERS report processing, as specified in the Administrative section of the SOW	1 each to the COR and TR	Within 30 days after contract award, within 30 days of implementation of changes, and then annually and upon request
7.	Develop and maintain list of names, phone numbers, fax numbers, and email addresses of contact personnel responsible for reporting from state health agencies, vaccine manufacturers, and immunization programs as specified in Administrative section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually, and upon Government request.
8.	Report number, method of contact, type of contact with VAERS by manufacturers, state health coordinators, immunization programs, and the public.	1 each to the COR and TR	Include in the annual report, and upon Government request
9.	Provide documentation of the technical procedure for data transport to Government as specified in the Information Management section of the SOW.	1 each to the COR and TR	Within 30 days after contract award
10.	Provide Government Extract of VAERS data to both agencies as specified in the Information Management section of the SOW.	1 each to FDA and CDC designees	Beginning 30 days after contract award, and each business day thereafter
11.	Maintain and provide documentation for a current, separate mirror version of the VAERS system and RDBMS as specified in SOW.	1 Each to the COR and TR	Within 90 days after contract award
12.	Provide user-procedure manual(s) and standard operating procedures (manual of operations) for technical aspects of VAERS database operations	1 each to the COR and TR	30 days after contract award and then as specified in SOW
13.	Provide documentation for data verification procedures including standardized letters, forms,	1 each to the COR and TR	Upon Government request

Item	Deliverable	Quantity	Time
	logs, phone scripts and other documents as specified in SOW		
14.	Provide a weekly report of adverse events after SARS-CoV-2 vaccines to Vaccine Safety Coordinators and their designees of specific jurisdictions as indicated by the Government as specified in SOW	1 each to the COR and TR	Weekly, beginning 60 days after contract award
15.	Provide documentation for procedures and rules for Data Quality Control and Assurance as specified in SOW	1 each to the COR and TR	Provide 60 days after contract award then annually or upon request
16.	Provide System Security Plan and training materials for employee AIS security training program as specified in the Information Management section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually
17.	Provide Program Management Plan as specified in the Administrative section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually or upon request
18.	Provide Quality Assurance Program (QAP) plan as specified in SOW	1 each to the COR, TR and CO	Within 30 days after contract award, then annually
19.	Provide list of key project personnel as specified in SOW	1 each to the COR, TR and CO	Within 30 days after contract award, then annually; update within 10 days following key personnel changes
20.	Provide Earned Value Report as specified in Information Management and Administrative sections of SOW	1 each to the COR and TR	Include in monthly reports
21.	Provide Data System Security Plan or information system security plan (SSP) as specified in Information Management section of SOW	1 each to the CO and COR	Draft within 30 days after contract award; final version within 60 days after award.
22.	Provide list of staff who have successfully completed information security training as specified in Information Management section of SOW	1 to COR	Upon request by COR
23.	Provide documentation of Level 3 Security Requirements compliance as specified in the Information Management section of SOW.	1 each to COR and TR	Within 30 days after contract award
24.	Provide Transition-Out Plan for approval as specified in the Administrative section of SOW	1 each to the COR and TR	Within 60 days after contract award
25.	Provide Disaster Recovery Plan for approval as specified in the Information Management section of SOW	1 each to the COR and TR	Within 60 days after contract award
26.	Provide results of IT Security Risk Management Assessment as specified in the Information Management section of SOW	1 each to the COR and TR	Within 45 days of completed assessment
27.	Provide the Government with detailed system documentation. Documentation shall be maintained in two separate volumes: "Volume 1	1 each to the COR and TR	Within 30 days after contract award, then annually thereafter, with new

Item	Deliverable	Quantity	Time
	– VAERS Business Processes” and “Volume 2 – VAERS IT Requirements and Design” as specified in the Administrative section of SOW		sections or documentation revisions provided within 10 days
28.	Provide detailed documentation of the technical procedures for data transport to CDC and FDA as specified in the Administrative section of SOW	1 each to the COR and TR	Within 30 days after contract award, then annually thereafter, with new sections or documentation revisions provided within 10 days

The Contractor shall provide, upon request from the Government, deliverables not specifically listed in this document. The Government will provide the Contractor with sufficient time (i.e., a minimum of 2 business days) to fulfill such requests.

VI. PERFORMANCE MATRIX:

Desired Outcomes	Required Services	SLA Performance Standard (completeness, cost, reliability, accuracy, timeliness, quality)	Acceptable Quality Level (AQL)	Monitoring Method (Quality Assurance Surveillance Plan/QASP)	Incentives/ Disincentives
Execute/perform all required tasks according to performance plan	Meets and complies with defined task requirements	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified in this Statement of Work	100% compliance	COR oversight	Favorable or Unfavorable Performance Evaluation
Send timely VAERS Daily Extracts with correct information	Each business day the Contractor sends an extract to the CDC and FDA through the PHINMS or other specified application.	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified in this Statement of Work	98% compliance	Daily receipt of Extract	Favorable or Unfavorable Performance Evaluation
Process all serious reports within the specified timeframe reflected in	Process serious reports in the established timeframe to electronically migrate VAE	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified	100% compliance All late logging of adverse events reports is	Monthly Quality Reports	Favorable or Unfavorable Performance Evaluation

Desired Outcomes	Required Services	SLA Performance Standard (completeness, cost, reliability, accuracy, timeliness, quality)	Acceptable Quality Level (AQL)	Monitoring Method (Quality Assurance Surveillance Plan/QASP)	Incentives/ Disincentives
Appendix A of this SOW.	data into the database.	in this Statement of Work	reported in monthly report.		

VII. PERIOD OF PERFORMANCE:

The period of performance shall be for two years after date of award.

VIII. PLACE OF PERFORMANCE:

The work will be conducted at the contractor's facility.

IX. EQUIPMENT AND INFORMATION:

The Contractor shall provide hardware, software, office and communications equipment and other resources to be used for data receipt, processing, editing, analysis, reporting, transmission, and storage. The Contractor shall provide the Government with current and detailed system documentation, including SOPs for all aspects of VAERS program operations, including complete VAERS report processing, submitted to the Government for initial review and approval within 30 days after contract award and within 30 days of revision or implementation of changes, and minimally on an annual basis or as requested by the Government thereafter. Please see Task Order 1 (Administrative) for more detail.

Appendix A: VAERS triaging of reports in business days^{1,2}

Category	Serious reports		Serious follow-up initiation	Non-serious reports	
	Scan within	Complete process within ³		Scan within	Complete process within ³
1. US Deaths ⁴	1	1	1	N/A	N/A
2. US 5-day reports	2	2	N/A	N/A	N/A
3. US 15-day reports	2	2	N/A	N/A	N/A
4. US reports ⁵	2	3	3	2	5
5. US 30-day reports	2	20	N/A	2	20
6. Foreign reports	5	90	N/A	5	120

1. Subject to change in response to new public health policies and/or events and/or funding availability after discussion between CDC and FDA

2. Not applicable for GBS reports where a patient is confined to facility longer than the time allowed for follow-up (e.g., patient in rehabilitation after GBS)

3. Completion includes scanning, data entry, and coding

4. If final autopsy report is not received within 2 months, make request every 2 months

5. If no records received within 5 days from the original request, make another request for Covid-19

HHSAR Provision, 352.239-73: Electronic and Information Technology Accessibility Notice

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use

electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/standards.htm>.

(c) The Section 508 accessibility standards applicable to this contract are: 1194.

- 205 WCAG 2.0 Level A & AA Success Criteria
- 302 Functional Performance Criteria
- 502 Inoperability with Assistive Technology
- 503 Applications
- 504 Authoring Tools
- 602 Support Documentation
- 603 Support Services

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and documentation detail - whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site <http://hhs.gov/web/508>.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(e) Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at <http://508.hhs.gov/>, or from the Section 508 Coordinator listed at <https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html>. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.

(End of provision)

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 15 Jul 2021 16:12:34 +0000
To: Brown, Crystal (CDC/OCOO/OFR/OFAS)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: HELP
Attachments: INV# 3852504 PO# 09621 GDIT.pdf

Thanks Crystal. So for this invoice, the amount billed is (b)(4) which includes the credit of (b)(4). Would I enter the invoice without the credit, for (b)(4) and not enter anything for the credited CLIN.? Then CPB will request MISO enter the credit on the appropriate CLIN?

Traci

From: Brown, Crystal (CDC/OCOO/OFR/OFAS) <xlcl1@cdc.gov>
Sent: Thursday, July 15, 2021 10:46 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: HELP
Importance: High

Hi Ms. Traci,

Please see the response below:

Thanks,

Crystal Brown

Commercial Payment Branch (CPB)
Office of Finance and Accounting Services (OFAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Center for Disease Control and Prevention (CDC)



“In dwelling, live close to the ground. In thinking, keep to the simple. In conflict, be fair and generous. In governing, don’t try to control. In work, do what you enjoy. In family life, be completely present” Lao Tzu

From: Berry, Nettie D. (CDC/OCOO/OFR/OFAS) <ndb1@cdc.gov>
Sent: Wednesday, July 14, 2021 5:22 PM
To: Brown, Crystal (CDC/OCOO/OFR/OFAS) <xlcl1@cdc.gov>
Subject: FW: HELP

Hi Crystal,

See Barbara’s response.

Thanks, Nettie

From: O'Neal, Barbara (CDC/OCOO/OFR/OFAS) <fzo2@cdc.gov>
Sent: Wednesday, July 14, 2021 9:26 AM
To: Berry, Nettie D. (CDC/OCOO/OFR/OFAS) <ndb1@cdc.gov>
Subject: RE: HELP

The program (COR) will not have the ability to enter the credit in ICE. CPB will send the request to the MISO Helpdesk to apply the credit memo against an invoice (with same CLIN ,FY, CAN).
Also O&R needs to reduce receipt by the amount of the CM.

Thanks,

Barbara A. O'Neal
Lead Accountant
Commercial Payments Branch
Office of Finance and Accounting Services (OFAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
fzo2@cdc.gov | Office: 678.475.4624 |

From: Berry, Nettie D. (CDC/OCOO/OFR/OFAS) <ndb1@cdc.gov>
Sent: Wednesday, July 14, 2021 9:20 AM
To: O'Neal, Barbara (CDC/OCOO/OFR/OFAS) <fzo2@cdc.gov>
Subject: FW: HELP
Importance: High

Good Morning Barbara,

Based on Credit Memo SOPs, should Program enter Credits in ICE or should this be done by CPB?

Thanks, Nettie

From: Brown, Crystal (CDC/OCOO/OFR/OFAS) <xlc1@cdc.gov>
Sent: Tuesday, July 13, 2021 4:14 PM
To: Berry, Nettie D. (CDC/OCOO/OFR/OFAS) <ndb1@cdc.gov>
Subject: FW: HELP
Importance: High

Hi Ms. Nettie,

Ms. Traci wants to know can she apply this negative amount (credit) to the appropriate CLIN that it belongs to? I mentioned that she could but I wanted to get confirmation first. Please see below:

Thanks,

Crystal Brown

Commercial Payment Branch (CPB)
Office of Finance and Accounting Services (OFAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Center for Disease Control and Prevention (CDC)



"In dwelling, live close to the ground. In thinking, keep to the simple. In conflict, be fair and generous. In governing, don't try to control. In work, do what you enjoy. In family life, be completely present" Lao Tzu

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, July 13, 2021 4:10 PM
To: Brown, Crystal (CDC/OCOO/OFR/OFAS) <xlc1@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: HELP
Importance: High

Hi Crystal,

Do you know if a negative amount can be entered into ICE? There's a (b)(4) credit on the backlog CLIN, page 6 of the pdf (breakdown on page 24). The deliverable for this CLIN has been completed.

Traci

From: Brown, Crystal (CDC/OCOO/OFR/OFAS) <xlc1@cdc.gov>
Sent: Tuesday, July 13, 2021 3:33 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: HELP
Importance: High

Hi Traci,

CDC has received the attached invoice from GDIT in the amount of (b)(4). Would you please review the invoice to see if receiving and acceptance can be entered in ICE? Your assistance with ensuring the agency's vendors are paid accurately and timely is appreciated.

Also, please include the Invoice number in the "Invoice/Comments" field when completing the ICE receiving and acceptance entry.

INVOICE #	AGING BUCKET	LOG DATE	SPD	SUPPLIER	DOCUMENT #	INVOICE AMT	SBF
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F09621

(b)(4)

N
O

Thanks,

Crystal Brown

Commercial Payment Branch (CPB)

Office of Finance and Accounting Services (OFAS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Center for Disease Control and Prevention (CDC)



“In dwelling, live close to the ground. In thinking, keep to the simple. In conflict, be fair and generous. In governing, don't try to control. In work, do what you enjoy. In family life, be completely present” Lao Tzu

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

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Obtained by ICANdecide.org via FOIA

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Obtained by ICANdecide.org via FOIA

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Obtained by ICANdecide.org via FOIA

From: Denis, Philip (CDC/OCOO/OFR/OAS)
Sent: Thu, 25 Feb 2021 17:12:55 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Amador, Nathan (CDC/OCOO/OFR/OAS)
Cc: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: ICE Option Expiration Notification for 47QTCK18D0003 200-2020-F-09621

No action needed. This is generated by ICE and is tied to information that Lindsey inputted while creating the award. There must have been an option period at one time that she removed.

Thanks,
Phil

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Thursday, February 25, 2021 10:18 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: ICE Option Expiration Notification for 47QTCK18D0003 200-2020-F-09621

Good morning Nathan and Phil,

Is the below email related to the VAERES Surge modification in progress? The base contract does not include optional CLINs. Let me know if any action is required on our part.

Thanks,
Traci

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

From: ICEMAIL <icemail@cdc.gov>
Sent: Thursday, February 25, 2021 6:01 AM
To: Crockett, Lindsey M. (CDC/OCOO/OFR/OAS) <ywn1@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: ICE Option Expiration Notification for 47QTCK18D0003 200-2020-F-09621

The following option(s) on 47QTCK18D0003 200-2020-F-09621 will be expiring soon:

Option Name: Surge
CLIN: 2001-00
Line Item Name: VAERS SAR-CoV-2 Surge
Expires on 02/28/21 (3 days)

Option Name: Surge
CLIN: 2002-00
Line Item Name: VAERS Surge ODCs

Expires on 02/28/21 (3 days)

Option Name: Surge

CLIN: 2003-00

Line Item Name: VAERS Surge CAF

Expires on 02/28/21 (3 days)

Please notify the vendor/CIO regarding the possibility of exercising the expiring option(s).

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 29 Mar 2021 21:07:45 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: Janssen Paper 15-day reports

Hi (b)(4)

Yes, please process the paper reports. Thanks!

- John

From: (b)(4)
Sent: Monday, March 29, 2021 4:54 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: Janssen Paper 15-day reports

Hello,

FYI - We received 44 Janssen 15-day paper reports in the mail today. Most are OMIC, but there are about 7 Hospitalizations, a couple Life Threatening Illness and 2 Death reports. We are not processing paper reports, but wanted you to know about these. Should we proceed with processing them? We are asking the FDA to remind the manufacturer to submit electronic reports.

Thanks,

(b)(4)

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.qdit.com

GENERAL DYNAMICS
Information Technology

From: Cason, Cynthia (CDC/OCOO/OFR/OAS)
Sent: Tue, 24 May 2022 18:48:54 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Re compete

So, I guess the question is how definitive the work is. Will there be a set number of employees/hours needed, or would you say the work is more variable based on the volume of input into VAERS?

Thanks,
Luci

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, May 24, 2022 2:14 PM
To: Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Re compete

Hi Lucy,

No not necessarily. We went with Time and Materials because all previous VAERS contracts were considered IT.

Traci

From: Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>
Sent: Tuesday, May 24, 2022 1:57 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Re compete

Hi Traci, one other quick question. Does the team definitely want this one to be a time and materials type contract? Since this is a follow on contract, I'll have to justify why we can't do firm fixed price.

Thanks,
Luci

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, May 24, 2022 12:31 PM
To: Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Re compete

Signed documents attached. Thanks so much for your help.

Traci

From: Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>
Sent: Tuesday, May 24, 2022 10:20 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Recompete

Thank you for doing this so quickly, Traci.

*The Market Research looks great. The only changes I made (attached) were I added the PSC and NAICS codes. I used the same PSC and NAICS that were used for the current VAERS contract and the surge contract. It's ready for signature.

*The changes to the Acquisition Plan look great and it's ready for signature.

Thanks!

Luci Cason
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
CCason@cdc.gov | 678-475-4677 | 678-895-5954 cell



From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Monday, May 23, 2022 3:31 PM
To: Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Recompete

Hi Lucy,

The updated IGCE and unsigned Market Research Report and AP are attached. Please review the report and AP and let me know if okay before I get signatures.

Also, for the market report is the Product Service Code (PSC) and North American Industry Classification System (NAICS) codes the same as included on the v-safe report (Q701 for the PSC and 519190 for the NAICS)?

Thanks,
Traci

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Friday, May 20, 2022 11:31 AM

To: Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Re compete

Hi Cynthia, see responses below in red. I'll get the Market Report, updated AP and reconciled IGCE to you by early next week. Thanks!

From: Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>
Sent: Friday, May 20, 2022 10:48 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Re compete

Hi Traci, I was able to look over the VAERS file and just need a few things/have some questions:

- Are we going to compete the follow-on on Alliant 2? **yes**
- With this dollar level, the Acquisition Plan will have to be approved by Policy and the HCA, so we will need a Market Research to get the Acquisition Plan approved. I've attached the Market research if you don't mind filling that out and sending back to me.
- Are these services severable or non severable? **severable**
- Can you reconcile the IGCE with the PR? PR value is \$21,219,807.12 and IGCE is \$21,219,807.13? Even though it is only one cent, Policy will note that we need to reconcile the two.
- Based on past Policy reviews and what they generally ask us to change, can you make these revisions to the Acquisition Plan?:
 - Please update section I.D. Funding source since the PR has been funded
 - Please update section I.E. Delivery or Performance Period to include a sentence about whether technical criteria will be more important than price, to address any schedule or performance risks, and to address how the use of an IDIQ contract will streamline the acquisition process
 - Please update section II.A. Plan of Action, Market Research Results (Page 2). This should note what the market research showed (i.e. what kind of companies are able to meet the requirement; what IDIQ are we competing this on and why, does the IDIQ we chose to compete on have the labor categories we need, etc., why small business wouldn't be able to perform the requirement).
 - Update Section III (and have re-signed) to show that there are funds that have been committed

As far as timeline, if you could get the Market Research and revised AP back to me by the end of next week, I could submit everything for approval and we would probably get that by June 10th. I can draft the solicitation in the meantime and have that ready to go for approval routing. If we estimate that we can get approval and release the solicitation by June 24th, we can post the solicitation for 3 to 4 weeks. Tech and business evals could happen between July 24th and August 5th. Then we could get approvals for final award and award by August 26th.

Let me know if you want to discuss.

Thanks,

Luci Cason
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
CCason@cdc.gov | 678-475-4677 | 678-895-5954 cell



From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Thursday, May 19, 2022 9:46 AM
To: Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: Late Waiver #20220166 VAERS for Covid-19 Vaccines Recompete

Hi Luci,

Me again! 😊 I know this recompete has just been assigned to you, but I wanted to reach out and ask when do you reasonably think the solicitation will be released? I'm trying to gauge when I'll need to have TEP panel members available before folks start planning their summer leave.

Thanks and have a great day!
Traci

From: Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>
Sent: Wednesday, May 11, 2022 8:51 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>
Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Cason, Cynthia (CDC/OCOO/OFR/OAS) <reo3@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Recompete

Assigned to Luci Cason.

Kris

Kristopher A. Lemaster, MHA, MSS
Team Lead/Contracting Officer
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)
ENE3@cdc.gov | 770-488-2995 | 404-247-3123 cell



From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, May 10, 2022 11:07 AM
To: Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>
Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Recompete

Good Morning,

Funded PR #66765 has been routed for approval.

Thanks,
Traci

From: Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>
Sent: Monday, May 9, 2022 12:04 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>
Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Subject: RE: Late Waiver #20220166 VAERS for Covid-19 Vaccines Recompete

I approved it in the late waiver system. Please send the PR ASAP. Thank you.

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Monday, May 9, 2022 11:43 AM
To: Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>
Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: Late Waiver #20220166 VAERS for Covid-19 Vaccines Recompete

Good Morning Alan and Kris,

Any decision on if and how to move forward with the VAERS for Covid-19 Vaccines Recompete (extension or compete) contract action?

Traci

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Wednesday, April 27, 2022 12:19 PM
To: Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>
Cc: Gallagher, Nancy (CDC/DDID/NCEZID/DHQP) <cvv6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: ALAN PLEASE READ: Late Waiver (b)(6) VAERS for Covid-19 Vaccines Recompete

Hi Alan,

IT/Privacy was just received and attached to PR #66765 which has been RFA.

Thank you for all your help.
Traci

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Wednesday, April 27, 2022 10:53 AM
To: Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>
Cc: Gallagher, Nancy (CDC/DDID/NCEZID/DHQP) <cvv6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: ALAN PLEASE READ: Late Waiver (b)(6) VAERS for Covid-19 Vaccines Recompete

Hi Alan,

Still awaiting IT/Privacy clearance; it is now with the Privacy Office/FITARA for approval. I will route a \$0 PR now.

Thanks,
Traci

From: Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>
Sent: Wednesday, April 27, 2022 9:51 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: Gallagher, Nancy (CDC/DDID/NCEZID/DHQP) <cvv6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>
Subject: RE: ALAN PLEASE READ: Late Waiver (b)(6) VAERS for Covid-19 Vaccines Recompete

Traci – Have you received the final clearances? Please go ahead and send the PR. Kris and I will have to discuss to see whether there is time to compete or if an extension is the only option. Thanks, Alan

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, April 26, 2022 4:59 PM
To: Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>
Cc: Gallagher, Nancy (CDC/DDID/NCEZID/DHQP) <cvv6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)

[<xct6@cdc.gov>](mailto:xct6@cdc.gov)

Subject: ALAN PLEASE READ: Late Waiver (b)(6) VAERS for Covid-19 Vaccines Recompete

Hi Alan,

This is a follow-up email to the voicemail I left this afternoon regarding the late waiver submitted for the VAERS Surge recompetite contract.

Although I did misunderstand that the extended May 17th PR deadline for new contract actions did not apply to FY22 contract actions; the late waiver was submitted due to the still pending IT/Privacy clearance. In my rush to submit the late waiver, I selected the wrong item from the drop down and did not include the clearance status. I realized my error but was unable to edit the late waiver once submitted.

I did reach out to Kris Lemaster on April 14th regarding the pending clearance issue and followed-up in the below email.

The current contract, #200-2020-09621, expires on August 26, 2022. To avoid a break in service, the new contract must be recompetited in FY22 and includes one base year plus one option year.

Base Year = \$10,493,663

Opt Yr 1 = \$10,726,144

Total Estimate Cost = \$21,219,807

Thank you for your consideration of approval. Let me know if there are any other questions or if anything else is needed for your consideration.

Best Regards,

Traci Roberts
404-498-0669

From: Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>

Sent: Friday, April 15, 2022 7:08 PM

To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Sims, Alan (CDC/OCOO/OFR/OAS) <auy0@cdc.gov>

Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>

Subject: RE: VAERS for Covid-19 Vaccines Recompete PR Acceptance

Thank you for your message, Traci.

The late waiver reviews are held at the branch chief level within OAS, but I'll include Alan on this reply so he is aware of your IT clearance challenge.

Best,

Kris

Kristopher A. Lemaster, MHA, MSS
Team Lead/Contracting Officer
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
ENE3@cdc.gov | 770-488-2995 | 404-247-3123 cell



From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Friday, April 15, 2022 3:52 PM
To: Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>
Cc: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Schembri, Christopher P. (CDC/DDID/NCEZID/DHQP) <gmi8@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: VAERS for Covid-19 Vaccines Recompete PR Acceptance

Hi Kris,

The late waiver for the VAERS for Covid-19 Vaccines Recompete is currently awaiting Center approval.

Per today's discussion, please confirm OAS will accept a funded PR for this contract action after April 15th. All clearances except IT/Privacy has been received and funding is pending the Vaccine Task Force (VTF) approval.

Thanks,

Traci

Traci Roberts
Public Health Analyst, Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office 404.498.0669
xct6@cdc.gov

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 13 May 2021 13:37:19 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: need GDIT to prioritize processing of adolescent reports after Pfizer

Yes, the email sent to GDIT by OAS was sufficient for the change; a modification isn't necessary.

Note: OAS is the only one who can send such emails to the contractor.

Let me know if there are any questions.

Traci

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, May 13, 2021 9:21 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: need GDIT to prioritize processing of adolescent reports after Pfizer

So, no modification necessary – email is sufficient to authorize this change in prioritization of processing?

- John

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Thursday, May 13, 2021 8:56 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: need GDIT to prioritize processing of adolescent reports after Pfizer

FYI

From: (b)(4)
Sent: Thursday, May 13, 2021 8:55 AM
To: Crockett, Lindsey M. (CDC/OCOO/OFR/OAS) <ywn1@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
(b)(4)
Subject: RE: need GDIT to prioritize processing of adolescent reports after Pfizer

Hello Lindsey,

The revision is acceptable.

Thank you so very much~

(b)(4)

Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

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From: Crockett, Lindsey M. (CDC/OCOO/OFR/OAS) <ywn1@cdc.gov>

Sent: Thursday, May 13, 2021 7:45 AM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: need GDIT to prioritize processing of adolescent reports after Pfizer

[External Email with Covid-19 Information: Use caution with links & attachments]

Good Afternoon Victoria, please see below with a small edit based upon feedback from program.

1. [Pfizer](#) Covid-19 reports ([all manufacturers](#)) among persons aged 18 years or younger
2. Covid-19 reports with TTS
3. Covid-19 Death/Serious reports
4. Covid-19 pregnancy reports
5. Covid-19 non-serious reports

Thank you!
Lindsey Crockett, CFCM
Sr. Contract Specialist, CDC
Direct Client Support Division
Southeast Sunbelt Region (R4)
GSA Federal Acquisition Service
Comm: 770-488-2815
Cell: 404-747-0868
LCrockett@cdc.gov
Lindsey.crockett@gsa.gov

From: (b)(4)
Sent: Wednesday, May 12, 2021 1:41 PM
To: Crockett, Lindsey M. (CDC/OCOO/OFR/OAS) <ywn1@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
(b)(4)
Subject: RE: need GDIT to prioritize processing of adolescent reports after Pfizer

Lindsey,

GDIT's understanding per the current scope of work is to prioritize the processing of these reports before ALL other Covid-19 reports, not just the Pfizer reports. If this is correct, the processing prioritization would be as follows:

1. Pfizer covid-19 reports among persons aged 18 years or younger
2. Covid-19 reports with TTS
3. Covid-19 Death/Serious reports
4. Covid-19 pregnancy reports
5. Covid-19 non-serious reports

Please confirm this prioritization change and GDIT will revise and prioritize accordingly.

Kindest regards~

(b)(4)

Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

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From: Crockett, Lindsey M. (CDC/OCOO/OFR/OAS) <ywn1@cdc.gov>
Sent: Wednesday, May 12, 2021 12:53 PM
To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: need GDIT to prioritize processing of adolescent reports after Pfizer
Importance: High

[External: Use caution with links & attachments]

Good Afternoon (b)(4) I understand you are now the new POC for this task order effort. Please see below. Thank you!

From: Crockett, Lindsey M. (CDC/OCOO/OFR/OAS)
Sent: Wednesday, May 12, 2021 11:43 AM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: need GDIT to prioritize processing of adolescent reports after Pfizer
Importance: High

Good Afternoon,

Reference the email message below, the CDC is looking to prioritize processing of all reports among persons aged 18 years or younger ahead of all other Pfizer-BioNTech vaccine reports. Please confirm that GDIT finds this currently within scope of the VAERS SARS-CoV-2 task order and that GDIT will be able to quickly prioritize this report. I may be reached via below for any questions or clarifications. Thank you for your prompt attention.

V/R,

Lindsey Crockett, CFCM
Sr. Contract Specialist, CDC
Direct Client Support Division
Southeast Sunbelt Region (R4)
GSA Federal Acquisition Service
Comm: 770-488-2815
Cell: 404-747-0868
LCrockett@cdc.gov
Lindsey.crockett@gsa.gov

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, May 11, 2021 3:33 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: need GDIT to prioritize processing of adolescent reports after Pfizer

Hi Traci,

In the immediate (ie, next 48 hours) future, CDC will need GDIT to process reports after Pfizer-BioNTech vaccines among persons aged 18 years and younger ahead of all other reports. Likewise, we

will need medical records for these reports with corresponding haste (ie, request and upload to VPN **ahead of all other medical records**).

Public attention will be keenly focused on this population. After reports of death, anaphylaxis, and similar highly visible adverse events, public demand for data will be immediate and urgent. CDC must have that data to respond.

Please let me know if you have any questions. Thanks!

- John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 29 Dec 2020 21:54:37 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Dayton, Ana E; Su, John (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: NURFU Guidance Document - VAERS Processing Prioritization via Covid-19 Response
Attachments: VAERS Guidance Document on Report Processing and Clinical Follow-Up 12292020.docx

Hey (b)(4)

While we are waiting to meet about the processing times, I wanted to let you know that we have been working on finalizing the NURFU document. We have made some updates to the prespecified conditions and to the follow-up we would like performed on COVID-19 pregnancy reports. The have provided the draft version, it is still in track changes so you are able to see the proposed updates. I know you guys have been waiting on us for some time now to provide the updated guidance on pregnancy reports so that you can request the desired medical records. I wanted to go ahead and share since we have been receiving more pregnancy reports than expected. Please note this document is in draft version and I understand it will change after our discussion next week about processing times.

Thanks,
Paige

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, December 29, 2020 2:21 PM
To: (b)(4) Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)
(b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: NURFU Guidance Document - VAERS Processing Prioritization via Covid-19 Response

Hi all,

Let's wait until Traci's back from leave, then we can set up a meeting to discuss how best to proceed. Stacey and I spoke, and I think we have a workable interim plan until we can meet. Thanks!

• John

From: (b)(4)
Sent: Tuesday, December 29, 2020 2:16 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)
(b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: NURFU Guidance Document - VAERS Processing Prioritization via Covid-19 Response

Hello,

VAERS is consistently receiving over 1,000 Covid-19 reports per day. I believe we listed over 1,500 reports in today's Covid-19 Priority Report. GDIT expects this trend to increase in the upcoming months as 2nd doses are given, additional doses are released, and new vaccines are approved for EUA.

We would like to meet to discuss temporarily revising the NURFU Guidance document timeframes and prioritizations. Possible considerations could include:

- ORIGIN (Domestic Reports)
- SEVERITY (Death and Serious)
- VACCINE (All Covid-19 Reports)
- Pregnancy Status (All Pregnancy Reports)
- Processing timeframes

Thank you for your consideration.

(b)(4)

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

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Obtained by ICANdecide.org via FOIA

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Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 30 Nov 2021 20:37:41 +0000
To: Brown, Crystal (CDC/OCOO/OFR/OFAS)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: PARTIAL RECEIVING - INV# 3879650R PO# 09621 GDIT (b)(4)

Hi Crystal,

I'm working on reconciling my records with the contractors and will update receiving in ICE as soon as possible.

Thanks,
 Traci

From: Brown, Crystal (CDC/OCOO/OFR/OFAS) <xlcl1@cdc.gov>
Sent: Monday, November 29, 2021 12:41 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: PARTIAL RECEIVING - INV# 3879650R PO# 09621 GDIT (b)(4)
Importance: High

Greetings Ms. Traci,

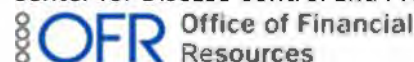
CDC has received the attached invoice from **GDIT** in the amount of (b)(4). Would you please review the invoice to see if receiving and acceptance can be entered in ICE? Your assistance with ensuring the agency's vendors are paid accurately and timely is appreciated.

Also, please include the Invoice number in the "Invoice/Comments" field when completing the ICE receiving and acceptance entry.

INVOICE #	AB	LOG DATE	SPD	SUPPLIER	DOCUME NT #	INVOIC E AMT	SB F
3879650R	07 - 14 Days	19-N OV-2 1	17-D EC-2 1	GENERAL DYNAMICS INFORMATION TECHN	75D30120 F09621	(b)(4)	NO

Crystal Brown

Commercial Payment Branch (CPB)
 Office of Finance and Accounting Services (OFAS)
 Office of Financial Resources (OFR)
 Office of the Chief Operating Officer (OCOO)
 Center for Disease Control and Prevention (CDC)



“In dwelling, live close to the ground. In thinking, keep to the simple. In conflict, be fair and generous. In governing, don't try to control. In work, do what you enjoy. In family life, be completely present” Lao Tzu

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Friday, November 19, 2021 2:10 PM
To: Brown, Crystal (CDC/OCOO/OFR/OFAS) <xlc1@cdc.gov>
Subject: RE: PARTIAL RECEIVING - INV# 3879650R PO# 09621 GDIT (b)(4)

Thanks Crystal. I'll look at it again.

Traci

From: Brown, Crystal (CDC/OCOO/OFR/OFAS) <xlc1@cdc.gov>
Sent: Friday, November 19, 2021 9:53 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: PARTIAL RECEIVING - INV# 3879650R PO# 09621 GDIT (b)(4)
Importance: High

Greetings Ms. Traci,

I want to say thank you for starting the receiving on this invoice. I am not sure if there are any issues preventing you from finishing receiving. If not, would you mind finishing receiving and if there are any issues, would you mind letting me know for my notes.

Thanks,

Project	Top Task/Top Task Name	Current Amount	Cumulative Amount
519485	0000T/CLIN0001	(b)(4)	(b)(4)
519485	0001T/CLIN0002		
519485	0002T/CLIN0003		
519485	0003T/Backlog Labor		
519485	0004T/Backlog ODC		
519485	0005T/Backlog CAF		
519485	0006T/AERS SURGE 2		
519485	0007T/AERS ODC 2		
519485	0008T/AERS CAF 2		
522072	0000T/IWO NBH		
TOTAL INVOICE			

Crystal Brown

Commercial Payment Branch (CPB)
 Office of Finance and Accounting Services (OFAS)
 Office of Financial Resources (OFR)
 Office of the Chief Operating Officer (OCOO)
 Center for Disease Control and Prevention (CDC)



“In dwelling, live close to the ground. In thinking, keep to the simple. In conflict, be fair and generous. In governing, don’t try to control. In work, do what you enjoy. In family life, be completely present” Lao Tzu

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 18 Dec 2020 02:41:39 +0000
To: (b)(4) Zinderman, Craig E (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Woo, Jane (FDA/CBER); Baumblatt, Jane (FDA/CBER); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Myers, Tanya R. (CDC/DDID/NCEZID/DHQP)
Cc: (b)(4) Alimchandani, Meghna (FDA/CBER); Welsh, Kerry (FDA/CBER); Menschik, David (FDA/CBER)
Subject: RE: Please fix the vaccine name for Pfizer-Biontech COVID19 vaccine

Hey everyone,
GDIT please ignore my previous email. I had some more time to think about the structure of vaccine name and we should keep it the way you have it for now. It follows the naming convention we had to use during H1N1 when we did not have brand names. I could go into great detail about the vaccine names but I will keep it short for now. ☺

This is a good time for me to bring up the point that we will be adding Moderna as a COVID19 vaccine to VAERS very soon and we will have to create a third category for COVID19 vaccine, an unknown type. This vaccine name will only be viewed in our data extract, not the dropdowns for the pdf and e-sub form. This is what got me rethinking the vaccine names for the COVID19. For now, since we do not have brand names, we will probably need to use the vax_names listed below in our data extract. Please let me know if you guys have any concerns.

1. COVID19(COVID19(PFIZER-BIONTECH))
2. COVID19(COVID19(MODERNA))
3. COVID19(COVID19(UNKNOWN))

Thanks,
Paige Marquez

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Thursday, December 17, 2020 4:50 PM
To: (b)(4)
Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Cc: (b)(4) Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>
Subject: Please fix the vaccine name for Pfizer-Biontech COVID19 vaccine
Importance: High

Currently, in the CDC data extract the Pfizer-Biontech COVID19 vaccine is showing up as "COVID19 (COVID19 (PFIZER-BIONTECH))" this is incorrect. It should be "COVID19 (PFIZER-BIONTECH)" please fix.

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)

Sent: Friday, December 11, 2020 1:02 PM

To: (b)(4) Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>

Cc: (b)(4) Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>

Subject: RE: VAERS - COVID vaccine variables

Thanks for the clarification (b)(4)

So ignoring the first row, I am good with the rest of the table

From: (b)(4)

Sent: Friday, December 11, 2020 10:52 AM

To: (b)(4) Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>

Cc: (b)(4) Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>

Subject: RE: VAERS - COVID vaccine variables

Hi Paige,

The first highlighted row can be ignored, it is just a header for the table below. It won't be added to VAERS. Also, the manufacturer number will be 590 (instead of 088).

Please let us know if okay to proceed.

Extract Field Names	COVID-19 (BNT162)
VAX_CODE	1200
VAX_TYPE	COVID19
VAX_NAME	COVID19 (PFIZER-BIONTECH)
VAX_MFG	088 (590)
MFG_NAME	PFIZER\BIONTECH
eSub/PDF Drop-down	COVID19 (PFIZER-BIONTECH)

Thanks,

(b)(4)

From: (b)(4)
Sent: Friday, December 11, 2020 10:49 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumbblatt, Jane (FDA/CBER) <Jane.Baumbblatt@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Cc: (b)(4)
 Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>
Subject: RE: VAERS - COVID vaccine variables

Hi Paige,

Currently in VAERS the manufacturer Pfizer will show as Pfizer/Wyeth. Since this vaccine is a collaboration with a different company BIONTECH, we thought it might be best to add it as a separate manufacturer. This way it will show as Pfizer-BIONTECH instead of it being added under Pfizer/Wyeth.

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>
Sent: Friday, December 11, 2020 10:36 AM
To: Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; (b)(4)
 (b)(4) Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumbblatt, Jane (FDA/CBER) <Jane.Baumbblatt@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Cc: (b)(4)
 Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>
Subject: RE: VAERS - COVID vaccine variables

[External Email with Covid-19 Information: Use caution with links & attachments]

Quick question- what does the highlighted row mean? Should that be updated?

Extract Field Names	COVID-19 (BNT162)
VAX_CODE	1200
VAX_TYPE	COVID19
VAX_NAME	COVID19 (PFIZER-BIONTECH)
VAX_MFG	088
MFG_NAME	PFIZER\BIONTECH

eSub/PDF Drop-down

COVID19 (PFIZER-BIONTECH)

From: Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>**Sent:** Friday, December 11, 2020 10:29 AM

To: (b)(4) Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>

Cc: (b)(4) Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>

Subject: RE: VAERS - COVID vaccine variables

Looks good to me.

Thanks,
Craig

From: (b)(4)**Sent:** Friday, December 11, 2020 7:59 AM

To: Marquez, Paige L (CDC) <fgv9@cdc.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>; Su, John (CDC) <ezu2@cdc.gov>; Woo, Jane <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane <Jane.Baumblatt@fda.hhs.gov>; Roberts, Traci S (CDC) <xct6@cdc.gov>; Myers, Tanya R (CDC) <vje9@cdc.gov>

Cc: (b)(4) Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry <Kerry.Welsh@fda.hhs.gov>; Menschik, David <David.Menschik@fda.hhs.gov>

Subject: RE: VAERS - COVID vaccine variables

Hi,

We put together a new set of values/variables for the COVID vaccine, from yesterday's discussion.

Extract Field Names	COVID-19 (BNT162)
VAX_CODE	1200
VAX_TYPE	COVID19
VAX_NAME	COVID19 (PFIZER-BIONTECH)
VAX_MFG	088
MFG_NAME	PFIZER\BIONTECH
eSub/PDF Drop-down	COVID19 (PFIZER-BIONTECH)

Please let us know if approved and we will proceed to add to VAERS today.

(b)(4)

Medical Affairs Advisor/Clinical Lead VAERS
Federal Civilian Division

(b)(4)

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Information Technology

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Thursday, December 10, 2020 5:33 PM

To: Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; (b)(4)

(b)(4) Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>

Cc: (b)(4)
Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>

Subject: RE: VAERS - COVID vaccine variables

[External Email with Covid-19 Information: Use caution with links & attachments]

Craig,

There are a couple of issues with using "PFIZER-BIONTECH COVID-19 VACCINE". I recommend COVID19(PFIZER-BIONTECH).

I am attaching the current list of vaccines for your reference.

Reasons:

1. Our vaccine list is structured in the following format "VAX_TYPE(BRAND_NAME)"
2. We do not use the word "VACCINE" in the vaccine name
3. Vaccine are listed alphabetically. Your recommendations not allow the COVID19 vaccines to be listed in the same area together. If I use your logic then Moderna would be "MODERNA COVID-19 VACCINE", hence nowhere near "PFIZER-BIONTECH COVID-19 VACCINE".
4. When people are using the drop down, they are initially looking for COVID19 not PFIZER.
5. Your recommendation("PFIZER-BIONTECH COVID-19 VACCINE") would be listed between Meningoccal and Pnuemo Vaccines.

From: Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>
Sent: Thursday, December 10, 2020 5:16 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>; (b)(4)
 (b)(4) Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Cc: (b)(4)
 Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>
Subject: RE: VAERS - COVID vaccine variables

The name of the vaccine being used at this stage is "PFIZER-BIONTECH COVID-19 VACCINE", and this is reflected in the Fact Sheet given to Vaccination providers. We suggest using this name in the drop down.

Thanks,
 Craig

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>
Sent: Thursday, December 10, 2020 4:49 PM
To: (b)(4) Shimabukuro, Tom (CDC) <ayv6@cdc.gov>; Su, John (CDC) <ezu2@cdc.gov>; Woo, Jane <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane <Jane.Baumblatt@fda.hhs.gov>; Zinderman, Craig E <Craig.Zinderman@fda.hhs.gov>; Roberts, Traci S (CDC) <xct6@cdc.gov>; Myers, Tanya R (CDC) <vje9@cdc.gov>
Cc: (b)(4)
Subject: RE: VAERS - COVID vaccine variables

Are people really going to know that the Pfizer vaccine is BNT162? Also let's take the dash out of COVID19 in vaccine name.

I propose the following. Depending on how you answer the 3 questions below, the highlighted part may need to change.

With that said, I have a few questions:

1. is there any anticipation that PFIZER would have more than one COVID19 vaccine?
2. Is the manufacturer PFIZER or PFIZER/BIONTECH?
3. Do we need to include WYETH in the MFG_NAME?

Extract Field Names	COVID-19 (BNT162)
VAX_CODE	1200
VAX_TYPE	COVID19
VAX_NAME	COVID19 (PFIZER)
VAX_MFG	088
MFG_NAME	PFIZER\WYETH
eSub/PDF Drop-down	COVID19 (PFIZER)

From: (b)(4)
Sent: Thursday, December 10, 2020 3:36 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>
Cc: (b)(4)
Subject: VAERS - COVID vaccine variables

Hi,

Below are the proposed COVID-19 vaccine variables to be added to VAERS. Note: In Pfizer's EUA application they refer to the vaccine as "COVID-19 (BNT162)".

Extract Field Names	COVID-19 (BNT162)
VAX_CODE	1200
VAX_TYPE	COVID19
VAX_NAME	COVID-19 (BNT162)
VAX_MFG	088
MFG_NAME	PFIZER\WYETH
eSub/PDF Drop-down	COVID-19 (BNT162)

Please let us know if approved and we will proceed to add to VAERS.

(b)(4)

Medical Affairs Advisor/Clinical Lead VAERS
Federal Civilian Division

(b)(4)

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From: Licata, Charles (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 17 Nov 2022 18:00:38 +0000
To: (b)(4) Su, John (CDC/DDID/NCEZID/DHQP)
Cc: (b)(4) VAERS-IT@vaers.org; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); (b)(4)
(b)(4)
Subject: RE: Possible Foreign Manufacturer Reports: PLEASE REVIEW ASAP

(b)(4)

For this week I am going to blank in WONDER the 7 reports. I am going to do this on my side with the data provided from GDIT last night. Please do the same for this week's HHS and WHO.

Fields to be blanked: SYMPTOM_TEXT, LAB_DATA, CUR_ILL, HISTORY, ALLERGIES, SPLTTYE

Please assure the reports are updated in tonight's daily extract.

Thank you,

Charles

From: (b)(4)
Sent: Thursday, November 17, 2022 12:46 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Licata, Charles (CDC/DDID/NCEZID/DHQP) <kui5@cdc.gov>
Cc: (b)(4)
(b)(4) VAERS-IT@vaers.org; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
Subject: RE: Possible Foreign Manufacturer Reports: PLEASE REVIEW ASAP

Charles and John,

These reports are older (reported on the VAERS 1.0 form) before we had to add a state to Box 1. We changed the origin from Domestic to International (FR) and added FR to Box 1.

I am checking to see how this impacts the extract files.

Thanks,

(b)(4)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, November 17, 2022 12:13 PM

To: Licata, Charles (CDC/DDID/NCEZID/DHQP) <kui5@cdc.gov>; (b)(4)
 (b)(4)
Cc: (b)(4)
 (b)(4) VAERS-IT@vaers.org;
 Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Roberts, Traci Sinetta
 (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
Subject: RE: Possible Foreign Manufacturer Reports: PLEASE REVIEW ASAP

[External: Use caution with links & attachments]

Hi Charles,

My two cents: based upon the initial reports, the VAERS IDs highlighted in red below list the patient's country of residence, which are clearly EU; I think you can include these reports with the redacted/suppressed EMA dataset.

The remaining VAERS IDs, I have no data to indicate whether or not they're EU. My bias: if you have reason to believe these reports originated in the EU (e.g., spltttype info), I would go ahead and include them in the redacted/suppressed EMA dataset as well.

Stacey, if you disagree, please let us know. Thanks!

- John

From: Licata, Charles (CDC/DDID/NCEZID/DHQP) <kui5@cdc.gov>
Sent: Thursday, November 17, 2022 11:51 AM
To: (b)(4) Su, John (CDC/DDID/NCEZID/DHQP)
 <ezu2@cdc.gov>
Cc: (b)(4)
 (b)(4) VAERS-IT@vaers.org; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Roberts, Traci Sinetta
 (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; ana.dayton@gdit.com
Subject: Possible Foreign Manufacturer Reports: PLEASE REVIEW ASAP
Importance: High

Hey John and (b)(4)

I have identified 7 non-military manufacturer reports that have unknown state in wonder and a possible EU spltttype. I am concerned that these are foreign manufacturer EU reports. Please review them ASAP and let me know your findings. I am waiting to hear back before proceeding to send the data to the WONDER team.

VAERS_ID	STATE	SPLTTYPE	MILITARY
(b)(6)		FRWYE563907APR05	N
		FRWYE796926JUN06	N

(b)(6)		FRWYE948903JUL06	N
		GB2016013798	N
		GB2018014199	N
		NLWYE347531JAN06	N
		NLWYE986905JUL06	N

From: (b)(4)

Sent: Wednesday, November 16, 2022 8:47 PM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Licata, Charles (CDC/DDID/NCEZID/DHQP) <kui5@cdc.gov>

Cc: (b)(4)

(b)(4) VAERS-IT@vaers.org

Subject: Wonder Weekly Extract 11/11/2022

Hi Paige & Charles,

The WONDER and HHS (1990 to November 11, 2022) data files are on the VPN (in the same location as daily files).

Vaccine	Long	Symptom
2863081	2358465	10184653

Thanks,

Paul

From: (b)(4)
Sent: Sat, 27 Feb 2021 00:28:24 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); (b)(4)
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: prepping for Janssen vaccine's use

Hi John,

We will process Janssen vaccines first. We will let you know if we have any questions.

Thanks,

(b)(4)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, February 26, 2021 7:05 PM
To: (b)(4)
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: prepping for Janssen vaccine's use

[External: Use caution with links & attachments]

Hi folks,

We anticipate the imminent authorization, recommendation, and use of Janssen's vaccine. Because this vaccine is new, please do the following:

1. Prioritize processing of reports after Janssen's vaccine, ahead of reports after Moderna's or Pfizer-BioNTech's vaccines
2. Please resume screening of reports for signs or symptoms suggesting anaphylaxis *prior* to processing, and send the VAERS IDs of potential reports of anaphylaxis to us daily (or more frequently). Pretty much, please resume what we did for Pfizer-BioNTech and Moderna in screening reports for anaphylaxis.

Please let us know if you have any questions. Thanks for your help, and have a terrific weekend!

- John

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 12 Feb 2021 12:19:24 +0000
To: (b)(4) Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: processing of manufacturer reports

Correct; or until (b)(4) responds to Phil's email.

From: (b)(4)
Sent: Thursday, February 11, 2021 6:29 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Subject: RE: processing of manufacturer reports

Hi John,
Traci advised that we would need to wait until a contract modification was in place before we could start development on this task.

Thanks,

(b)(4)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, February 11, 2021 5:58 PM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Subject: processing of manufacturer reports

[External: Use caution with links & attachments]

Hi (b)(4)

I remember you mentioning that you needed an email to begin processing manufacturer reports using their coding. CDC would like GDIT to begin that process. Please advise if there's specific language you need. Thanks!

- John

John R. Su, M.D., Ph.D., M.P.H.
Lead, VAERS Team
CAPT, U.S. Public Health Service
NCEZID/ Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
1600 Clifton Road, MS V18-4
Atlanta, GA 30329-4027

ezu2@cdc.gov

404-498-0698 (office)

404-498-0666 (FAX)

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 22 Apr 2021 00:24:03 +0000
To: (b)(4)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Neloms, Stacey M; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: provider needs help uploading information

Hi Ana,

Good to know – thanks for the update!

- John

From: (b)(4)
Sent: Wednesday, April 21, 2021 7:51 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)
(b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: provider needs help uploading information

Hi,

I just spoke with her and she will have the medical records department send in the MR tomorrow morning.

(b)(4)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, April 21, 2021 7:40 PM
To: (b)(4)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)
(b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: provider needs help uploading information

[External: Use caution with links & attachments]

Thanks!

- John

From: (b)(4)
Sent: Wednesday, April 21, 2021 7:38 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)
(b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: provider needs help uploading information

Hi,

We will reach out to her.

(b)(4)

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

Sent: Wednesday, April 21, 2021 7:27 PM

To: (b)(4)

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)

(b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Subject: provider needs help uploading information

[External: Use caution with links & attachments]

Hi (b)(4)

Dr. Sangli Swathi has been trying to upload data for a reported death after Moderna's vaccine. The patient is (b)(6) I tried,, but wasn't able to find him in VAERS. Dr. Sangli said she was having difficulty using the auto upload keys, and other issues. Would you please contact her?

Swathi.sangli@ahn.org

917-753-5245

Thanks!

- John

From: (b)(4)
Sent: Tue, 18 May 2021 16:36:08 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: pulling pre-processed VAERS IDs
Attachments: COVID_May 1-16_Age18andUnder_20210518.Pre-process.xlsx

Hi,

The attached list is for all domestic COVID-19 vax age 18 & younger reports received from May 1-16 that are still in the workflow (pre-process).

(b)(4)

Medical Affairs Advisor/Clinical Lead VAERS
Federal Civilian Division

(b)(4)

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From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, May 18, 2021 12:18 PM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: pulling pre-processed VAERS IDs

[External Email with Covid-19 Information: Use caution with links & attachments]

To follow up, may we narrow this list to domestic reports only, and only those reports that are pre-process (i.e., haven't been processed yet)?

- John

From: (b)(4)
Sent: Tuesday, May 18, 2021 12:02 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4)
(b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom

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

Subject: RE: pulling pre-processed VAERS IDs

Hi,

Attached is the list of all VAERS IDs for COVID-19 vax age 18 & younger reports received from May 1-16.
Note: this list includes all origins (domestic & foreign), processed or still in processing for all COVID-19 vaccines.

Let us know if there is anything else we can help with,

(b)(4)

Medical Affairs Advisor/Clinical Lead VAERS
Federal Civilian Division

(b)(4)

www.gdit.com

GENERAL DYNAMICS
Information Technology

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

Sent: Tuesday, May 18, 2021 9:12 AM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Subject: pulling pre-processed VAERS IDs

[External: Use caution with links & attachments]

Hi folks,

May we quickly obtain a list of VAERS IDs received (but still waiting processing) during May 1-16? Specifically, about persons age 18 years and younger?

Thanks!

VAERSNbr	Tag	RcptDate	Origin	Severity	Age	InWorkflow
(b)(6)	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	14	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	17.5	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	15	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	15.83	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	18	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	16	1
	1	5/1/2021	D	Non-Serious	17	1
	1	5/1/2021	D	Non-Serious	18	1

[illegible]

(b)(6)

1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Serious	18	1
1	5/2/2021	D	Non-Serious	15	1
1	5/2/2021	D	Non-Serious	16	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	13	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Serious	16	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	15	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	16	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	15	1
1	5/2/2021	D	Non-Serious	16	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	16	1
1	5/2/2021	D	Non-Serious	16	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	16	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	18	1
1	5/2/2021	D	Non-Serious	16	1
1	5/2/2021	D	Non-Serious	17	1
1	5/2/2021	D	Non-Serious	14	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Serious	16	1
1	5/3/2021	D	Non-Serious	17	1

(b)(6)

1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17.58	1
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1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	15.92	1
1	5/3/2021	D	Non-Serious	14.25	1
1	5/3/2021	D	Non-Serious	14.25	1
1	5/3/2021	D	Non-Serious	14.5	1
1	5/3/2021	D	Non-Serious	17.92	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	15	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16.25	1
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1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Serious	17	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	15	1
1	5/3/2021	D	Serious	16	1
1	5/3/2021	D	Non-Serious	18	1

(b)(6)

1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16.17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	15	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16.75	1
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1	5/3/2021	D	Serious	17	1
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1	5/3/2021	D	Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	12	1
1	5/3/2021	D	Non-Serious	15	1
1	5/3/2021	D	Non-Serious	16	1
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1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17.92	1
1	5/3/2021	D	Non-Serious	16.42	1
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1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Serious	18	1
1	5/3/2021	D	Non-Serious	17.5	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1

(b)(6)

1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	15	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	15	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	18	1
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1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	17	1
1	5/3/2021	D	Non-Serious	16	1
1	5/3/2021	D	Non-Serious	18	1
1	5/4/2021	D	Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	15	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	16	1

(b)(6)

1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	15	1
1	5/4/2021	D	Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	15	1
1	5/4/2021	D	Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
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1	5/4/2021	D	Non-Serious	18	1
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1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
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1	5/4/2021	D	Non-Serious	17	1
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1	5/4/2021	D	Serious	16	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
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1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Serious	18	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1

(b)(6)

1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	15	1
1	5/4/2021	D	Non-Serious	15.92	1
1	5/4/2021	D	Non-Serious	15	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	15	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	15	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	17	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	16	1
1	5/4/2021	D	Non-Serious	15	1
1	5/4/2021	D	Non-Serious	18	1
1	5/4/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	16	1

(b)(6)

1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	15.67	1
1	5/5/2021	D	Non-Serious	15.42	1
1	5/5/2021	D	Non-Serious	15.5	1
1	5/5/2021	D	Non-Serious	14.92	1
1	5/5/2021	D	Non-Serious	15.42	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	17	1
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1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	14	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	16.5	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Serious	18	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	16.92	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Serious	17	1
1	5/5/2021	D	Serious	17	1

(b)(6)

1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	16.92	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	18	1
1	5/5/2021	D	Non-Serious	14	1
1	5/5/2021	D	Non-Serious	12	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	18	1
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1	5/5/2021	D	Non-Serious	17	1
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1	5/5/2021	D	Non-Serious	17	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	16	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	15	1
1	5/5/2021	D	Non-Serious	16	1
1	5/6/2021	D	Serious	16	1
1	5/6/2021	D	Non-Serious	17.92	1

(b)(6)

1	5/6/2021	D	Non-Serious	18	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1
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1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	15	1
1	5/6/2021	D	Non-Serious	18	1
1	5/6/2021	D	Non-Serious	18	1
1	5/6/2021	D	Non-Serious	13	1
1	5/6/2021	D	Serious	16	1
1	5/6/2021	D	Non-Serious	15	1
1	5/6/2021	D	Serious	18	1
1	5/6/2021	D	Non-Serious	16	1
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1	5/6/2021	D	Non-Serious	17	1
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1	5/6/2021	D	Non-Serious	17	1
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1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	18	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1
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1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	14	1
1	5/6/2021	D	Non-Serious	15	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17.67	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1

(b)(6)

1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	18	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17	1
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1	5/6/2021	D	Non-Serious	18	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	18	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	14	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16.25	1
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1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	15	1
1	5/6/2021	D	Serious	18	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Serious	18	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1
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1	5/6/2021	D	Non-Serious	18	1
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1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	15	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	17	1

(b)(6)

1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	17	1
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1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16.25	1
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1	5/6/2021	D	Non-Serious	17	1
1	5/6/2021	D	Non-Serious	16	1
1	5/6/2021	D	Non-Serious	18	1
1	5/6/2021	D	Non-Serious	15	1
1	5/6/2021	D	Non-Serious	16	1
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1	5/7/2021	D	Non-Serious	18	1
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1	5/7/2021	D	Serious	18	1
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1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Serious	16	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	15.67	1
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1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	15	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	16	1

(b)(6)

1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	15	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	18	1
1	5/7/2021	D	Non-Serious	15	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	18	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	18	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	15.67	1
1	5/7/2021	D	Non-Serious	18	1
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1	5/7/2021	D	Non-Serious	18	1
1	5/7/2021	D	Non-Serious	17	1
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1	5/7/2021	D	Non-Serious	16	1
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1	5/7/2021	D	Non-Serious	17	1
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1	5/7/2021	D	Serious	17	1
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1	5/7/2021	D	Non-Serious	15	1
1	5/7/2021	D	Non-Serious	17	1
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1	5/7/2021	D	Non-Serious	17	1
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1	5/7/2021	D	Non-Serious	14	1
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1	5/7/2021	D	Non-Serious	15	1
1	5/7/2021	D	Non-Serious	15	1
1	5/7/2021	D	Non-Serious	15	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	15	1

(b)(6)

1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	14	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	16	1
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1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Serious	16	1
1	5/7/2021	D	Non-Serious	15.42	1
1	5/7/2021	D	Non-Serious	15	1
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1	5/7/2021	D	Non-Serious	11	1
1	5/7/2021	D	Non-Serious	16	1
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1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	17	1
1	5/7/2021	D	Non-Serious	17	1

(b)(6)

1	5/7/2021	D	Non-Serious	16	1
1	5/7/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	18	1
1	5/8/2021	D	Non-Serious	18	1
1	5/8/2021	D	Non-Serious	18	1
1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	17.92	1
1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	18	1
1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	18	1
1	5/8/2021	D	Non-Serious	16	1
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1	5/8/2021	D	Non-Serious	16	1
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1	5/8/2021	D	Non-Serious	16	1
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1	5/8/2021	D	Non-Serious	16.5	1
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1	5/8/2021	D	Serious	16	1
1	5/8/2021	D	Non-Serious	18	1
1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	18	1
1	5/8/2021	D	Non-Serious	15	1
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1	5/8/2021	D	Non-Serious	17	1
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1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	16.25	1

(b)(6)

1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	16	1
1	5/8/2021	D	Non-Serious	18	1
1	5/8/2021	D	Non-Serious	17	1
1	5/8/2021	D	Non-Serious	16	1
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1	5/9/2021	D	Non-Serious	16	1
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1	5/9/2021	D	Non-Serious	18	1
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1	5/9/2021	D	Non-Serious	18	1
1	5/9/2021	D	Non-Serious	16	1
1	5/9/2021	D	Serious	18	1
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1	5/9/2021	D	Serious	18	1
1	5/9/2021	D	Non-Serious	16	1
1	5/9/2021	D	Non-Serious	18	1
1	5/10/2021	D	Serious	18	1
1	5/10/2021	D	Non-Serious	17	1

(b)(6)

1	5/10/2021	D	Non-Serious	15	1
1	5/10/2021	D	Non-Serious	17	1
1	5/10/2021	D	Non-Serious	18	1
1	5/10/2021	D	Non-Serious	16	1
1	5/10/2021	D	Non-Serious	15	1
1	5/10/2021	D	Non-Serious	15	1
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1	5/10/2021	D	Non-Serious	16.92	1
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1	5/10/2021	D	Non-Serious	16	1
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1	5/10/2021	D	Non-Serious	17.83	1
1	5/10/2021	D	Non-Serious	17	1
1	5/10/2021	D	Non-Serious	18	1
1	5/10/2021	D	Non-Serious	17	1

(b)(6)

1	5/11/2021	D	Non-Serious	18	1
1	5/11/2021	D	Non-Serious	16	1
1	5/11/2021	D	Non-Serious	15	1
1	5/11/2021	D	Non-Serious	17	1
1	5/11/2021	D	Non-Serious	18	1
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1	5/11/2021	D	Non-Serious	16	1
1	5/11/2021	D	Non-Serious	18	1
1	5/11/2021	D	Non-Serious	17	1
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1	5/11/2021	D	Non-Serious	17	1

(b)(6)

1	5/11/2021	D	Non-Serious	17	1
1	5/11/2021	D	Non-Serious	17	1
1	5/11/2021	D	Non-Serious	18	1
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1	5/11/2021	D	Non-Serious	16	1
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1	5/11/2021	D	Non-Serious	18	1
1	5/11/2021	D	Non-Serious	17	1
1	5/11/2021	D	Non-Serious	16	1
1	5/11/2021	D	Non-Serious	16	1
1	5/11/2021	D	Non-Serious	18	1

(b)(6)

1	5/11/2021	D	Non-Serious	16	1
1	5/11/2021	D	Non-Serious	16	1
1	5/11/2021	D	Non-Serious	17	1
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1	5/11/2021	D	Non-Serious	17	1
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1	5/12/2021	D	Non-Serious	18	1
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1	5/12/2021	D	Non-Serious	17	1
1	5/12/2021	D	Non-Serious	18	1
1	5/12/2021	D	Non-Serious	18	1
1	5/12/2021	D	Non-Serious	13	1
1	5/12/2021	D	Non-Serious	17	1

(b)(6)

1	5/12/2021	D	Non-Serious	16	1
1	5/12/2021	D	Non-Serious	17	1
1	5/12/2021	D	Non-Serious	17	1
1	5/12/2021	D	Non-Serious	17	1
1	5/12/2021	D	Non-Serious	16	1
1	5/12/2021	D	Non-Serious	16	1
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1	5/12/2021	D	Non-Serious	17.58	1
1	5/12/2021	D	Serious	17.33	1
1	5/12/2021	D	Non-Serious	17	1
1	5/12/2021	D	Non-Serious	15	1
1	5/12/2021	D	Non-Serious	18	1
1	5/12/2021	D	Non-Serious	17	1
1	5/12/2021	D	Non-Serious	17	1
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1	5/12/2021	D	Non-Serious	16	1
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1	5/12/2021	D	Non-Serious	16	1
1	5/12/2021	D	Non-Serious	16	1
1	5/12/2021	D	Non-Serious	16	1
1	5/12/2021	D	Non-Serious	18	1
1	5/12/2021	D	Non-Serious	17	1

(b)(6)

1	5/12/2021	D	Non-Serious	17	1
1	5/12/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	17	1
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1	5/13/2021	D	Non-Serious	18	1
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1	5/13/2021	D	Non-Serious	16	1
1	5/13/2021	D	Non-Serious	18	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	15.42	1
1	5/13/2021	D	Serious	18	1
1	5/13/2021	D	Non-Serious	14	1
1	5/13/2021	D	Serious	17	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	12	1
1	5/13/2021	D	Non-Serious	16.92	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	15	1
1	5/13/2021	D	Non-Serious	16	1
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1	5/13/2021	D	Non-Serious	13.67	1
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1	5/13/2021	D	Non-Serious	18	1
1	5/13/2021	D	Non-Serious	13	1
1	5/13/2021	D	Non-Serious	16	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	12	1

(b)(6)

1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	18	1
1	5/13/2021	D	Non-Serious	16	1
1	5/13/2021	D	Non-Serious	16	1
1	5/13/2021	D	Non-Serious	14	1
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1	5/13/2021	D	Non-Serious	17.5	1
1	5/13/2021	D	Non-Serious	17.92	1
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1	5/13/2021	D	Non-Serious	15	1
1	5/13/2021	D	Non-Serious	13	1
1	5/13/2021	D	Non-Serious	14	1
1	5/13/2021	D	Non-Serious	12	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	13	1
1	5/13/2021	D	Serious	17	1
1	5/13/2021	D	Non-Serious	15	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	16	1
1	5/13/2021	D	Non-Serious	12	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	13	1
1	5/13/2021	D	Non-Serious	18	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	18	1
1	5/13/2021	D	Non-Serious	18	1
1	5/13/2021	D	Non-Serious	14	1

(b)(6)

1	5/13/2021	D	Non-Serious	13	1
1	5/13/2021	D	Non-Serious	14	1
1	5/13/2021	D	Non-Serious	14	1
1	5/13/2021	D	Non-Serious	15	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	17	1
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1	5/13/2021	D	Non-Serious	18	1
1	5/13/2021	D	Non-Serious	15	1
1	5/13/2021	D	Non-Serious	12	1
1	5/13/2021	D	Non-Serious	12	1
1	5/13/2021	D	Serious	16	1

(b)(6)

1	5/13/2021	D	Serious	17	1
1	5/13/2021	D	Non-Serious	15	1
1	5/13/2021	D	Non-Serious	17	1
1	5/13/2021	D	Non-Serious	16	1
1	5/13/2021	D	Non-Serious	15	1
1	5/13/2021	D	Non-Serious	18	1
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1	5/14/2021	D	Non-Serious	16	1
1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	16.58	1
1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	18	1
1	5/14/2021	D	Serious	17	1

(b)(6)

1	5/14/2021	D	Serious	17	1
1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	16	1
1	5/14/2021	D	Non-Serious	18	1
1	5/14/2021	D	Non-Serious	14	1
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1	5/14/2021	D	Non-Serious	16	1
1	5/14/2021	D	Non-Serious	15	1
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1	5/14/2021	D	Non-Serious	16	1
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1	5/14/2021	D	Non-Serious	13	1
1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	18	1
1	5/14/2021	D	Non-Serious	14	1
1	5/14/2021	D	Non-Serious	16	1

(b)(6)

1	5/14/2021	D	Non-Serious	12	1
1	5/14/2021	D	Non-Serious	13	1
1	5/14/2021	D	Non-Serious	16	1
1	5/14/2021	D	Non-Serious	15	1
1	5/14/2021	D	Non-Serious	16	1
1	5/14/2021	D	Non-Serious	12	1
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1	5/14/2021	D	Non-Serious	18	1
1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	14	1
1	5/14/2021	D	Non-Serious	14	1
1	5/14/2021	D	Non-Serious	18	1

(b)(6)

1	5/14/2021	D	Non-Serious	14	1
1	5/14/2021	D	Non-Serious	18	1
1	5/14/2021	D	Non-Serious	11	1
1	5/14/2021	D	Non-Serious	15	1
1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	17	1
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1	5/14/2021	D	Non-Serious	17	1
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1	5/14/2021	D	Non-Serious	18	1
1	5/14/2021	D	Non-Serious	17	1
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1	5/14/2021	D	Serious	18	1
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1	5/14/2021	D	Non-Serious	15.58	1
1	5/14/2021	D	Non-Serious	16	1
1	5/14/2021	D	Non-Serious	16	1
1	5/14/2021	D	Non-Serious	12	1
2	5/14/2021	D	Serious	17	1
1	5/14/2021	D	Serious	17	1
1	5/14/2021	D	Non-Serious	16	1
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1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	15	1
1	5/14/2021	D	Non-Serious	15	1
1	5/14/2021	D	Non-Serious	12	1
1	5/14/2021	D	Non-Serious	17	1

(b)(6)

1	5/14/2021	D	Non-Serious	14	1
1	5/14/2021	D	Non-Serious	16	1
1	5/14/2021	D	Non-Serious	18	1
1	5/14/2021	D	Non-Serious	12	1
1	5/14/2021	D	Non-Serious	11	1
1	5/14/2021	D	Non-Serious	17	1
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1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	17	1
1	5/14/2021	D	Non-Serious	18	1
1	5/14/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	12	1

(b)(6)

1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	18	1
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1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	15	1

(b)(6)

1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Serious	17	1
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1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Serious	18	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Serious	17	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	18	1

(b)(6)

1	5/15/2021	D	Non-Serious	11	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Serious	18	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	11	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	11	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	15	1

(b)(6)

1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	17	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	16	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	15	1
1	5/15/2021	D	Non-Serious	13.67	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	12	1
1	5/15/2021	D	Non-Serious	14	1
1	5/15/2021	D	Non-Serious	13	1
1	5/15/2021	D	Non-Serious	18	1
1	5/15/2021	D	Non-Serious	12	1
1	5/16/2021	D	Non-Serious	18	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	18	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	12	1
1	5/16/2021	D	Non-Serious	18	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Serious	16	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	18	1

(b)(6)

1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	18	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	18	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	13.83	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	18	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Serious	17	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	12	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	11	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	18	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	12	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	12	1

(b)(6)

1	5/16/2021	D	Non-Serious	18	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	12	1
1	5/16/2021	D	Non-Serious	17	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	16	1
1	5/16/2021	D	Non-Serious	15	1
1	5/16/2021	D	Non-Serious	14	1
1	5/16/2021	D	Non-Serious	13	1
1	5/16/2021	D	Non-Serious	12	1
1	5/16/2021	D	Serious	17	1
1	5/16/2021	D	Non-Serious	14	1

VAERSNbr	Tag	RcptDate	Origin	Severity	Age	InWorkflow
(b)(6)	1	5/1/2021	D	Non-Serious	18	0
	1	5/1/2021	D	Serious	17	0
	1	5/1/2021	D	Non-Serious	18	0
	1	5/1/2021	D	Non-Serious	17	0
	1	5/1/2021	D	Serious	17	0
	1	5/1/2021	D	Serious	18	0
	1	5/1/2021	D	Serious	16	0
	1	5/1/2021	D	Serious	16	0
	1	5/1/2021	D	Serious	16	0
	1	5/1/2021	D	Serious	17	0
	1	5/1/2021	D	Serious	16	0
	1	5/1/2021	D	Non-Serious	18	0
	1	5/1/2021	D	Serious	17	0
	1	5/1/2021	D	Serious	17	0
	1	5/1/2021	D	Serious	18	0
	1	5/2/2021	D	Non-Serious	18	0
	2	5/2/2021	D	Death	15	0
	1	5/3/2021	D	Non-Serious	18	0
	1	5/3/2021	D	Non-Serious	15	0
	1	5/3/2021	D	Non-Serious	16	0
	1	5/3/2021	D	Non-Serious	17	0
	1	5/3/2021	D	Non-Serious	16	0
	1	5/3/2021	D	Non-Serious	18	0
	1	5/3/2021	D	Non-Serious	16	0
	1	5/3/2021	D	Non-Serious	17	0
	1	5/3/2021	D	Non-Serious	16	0
	1	5/3/2021	D	Non-Serious	17	0
	1	5/3/2021	D	Non-Serious	18	0
	1	5/3/2021	D	Serious	18	0
	1	5/4/2021	D	Non-Serious	16	0
	1	5/4/2021	D	Non-Serious	15	0
	1	5/4/2021	D	Serious	17	0
	1	5/4/2021	D	Serious	17	0
	1	5/4/2021	D	Non-Serious	18	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	16	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	16	0
	1	5/4/2021	D	Non-Serious	16	0
	1	5/4/2021	D	Non-Serious	16	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	17	0
	1	5/4/2021	D	Non-Serious	17	0

(b)(6)

1	5/4/2021	D	Non-Serious	17	0
1	5/4/2021	D	Non-Serious	16	0
1	5/4/2021	D	Non-Serious	16	0
1	5/4/2021	D	Non-Serious	18	0
1	5/4/2021	D	Non-Serious	18	0
1	5/5/2021	D	Non-Serious	18	0
1	5/5/2021	D	Non-Serious	17	0
1	5/5/2021	D	Non-Serious	18	0
1	5/5/2021	D	Non-Serious	18	0
1	5/5/2021	D	Non-Serious	16	0
1	5/5/2021	D	Serious	18	0
1	5/5/2021	D	Serious	18	0
1	5/5/2021	D	Serious	17	0
1	5/5/2021	D	Non-Serious	17	0
1	5/5/2021	D	Non-Serious	17	0
1	5/5/2021	D	Non-Serious	18	0
1	5/5/2021	D	Non-Serious	17	0
1	5/5/2021	D	Non-Serious	16	0
1	5/5/2021	D	Non-Serious	16	0
1	5/5/2021	D	Non-Serious	18	0
1	5/5/2021	D	Non-Serious	17	0
1	5/5/2021	D	Non-Serious	16	0
1	5/5/2021	D	Non-Serious	16	0
1	5/5/2021	D	Non-Serious	17	0
1	5/5/2021	D	Non-Serious	18	0
1	5/5/2021	D	Non-Serious	16	0
1	5/5/2021	D	Serious	16	0
1	5/6/2021	D	Non-Serious	18	0
1	5/6/2021	D	Non-Serious	18	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	16	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	14	0
1	5/6/2021	D	Non-Serious	15	0
1	5/6/2021	D	Non-Serious	16	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	18	0
1	5/6/2021	D	Non-Serious	18	0
1	5/6/2021	D	Non-Serious	18	0
1	5/6/2021	D	Non-Serious	16	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	16	0
1	5/6/2021	D	Non-Serious	16	0
1	5/6/2021	D	Non-Serious	17	0

(b)(6)

1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	17	0
1	5/6/2021	D	Non-Serious	18	0
1	5/6/2021	D	Non-Serious	18	0
1	5/6/2021	D	Non-Serious	17	0
1	5/7/2021	D	Non-Serious	18	0
1	5/7/2021	D	Non-Serious	17	0
1	5/7/2021	D	Serious	18	0
1	5/7/2021	D	Serious	18	0
1	5/7/2021	D	Non-Serious	15	0
1	5/7/2021	D	Non-Serious	16	0
1	5/7/2021	D	Non-Serious	15	0
1	5/7/2021	D	Non-Serious	16	0
1	5/7/2021	D	Non-Serious	18	0
1	5/7/2021	D	Non-Serious	17	0
1	5/7/2021	D	Non-Serious	16	0
1	5/7/2021	D	Non-Serious	16	0
1	5/7/2021	D	Non-Serious	17	0
1	5/7/2021	D	Non-Serious	16	0
1	5/7/2021	D	Non-Serious	17	0
1	5/7/2021	D	Non-Serious	17	0
1	5/7/2021	D	Non-Serious	16	0
1	5/7/2021	D	Non-Serious	18	0
1	5/7/2021	D	Non-Serious	16	0
1	5/8/2021	D	Non-Serious	18	0
1	5/8/2021	D	Non-Serious	18	0
1	5/8/2021	D	Non-Serious	18	0
1	5/8/2021	D	Non-Serious	17	0
1	5/8/2021	D	Serious	18	0
1	5/8/2021	D	Serious	16	0
1	5/8/2021	D	Serious	17	0
1	5/8/2021	D	Serious	17	0
1	5/8/2021	D	Serious	18	0
1	5/8/2021	D	Serious	17	0
1	5/8/2021	D	Serious	16	0
1	5/8/2021	D	Serious	16	0
1	5/8/2021	D	Serious	16	0
1	5/8/2021	D	Serious	12	0
1	5/8/2021	D	Non-Serious	18	0
1	5/8/2021	D	Non-Serious	18	0
1	5/8/2021	D	Non-Serious	18	0
1	5/8/2021	D	Non-Serious	18	0
1	5/8/2021	D	Non-Serious	17	0
1	5/8/2021	D	Non-Serious	17	0
1	5/8/2021	D	Non-Serious	16	0
1	5/8/2021	D	Non-Serious	18	0
1	5/9/2021	D	Non-Serious	18	0
1	5/9/2021	D	Non-Serious	18	0
1	5/9/2021	D	Non-Serious	17	0

[illegible]

(b)(6)

(b)(6)

1	5/10/2021	D	Serious	18	0
1	5/10/2021	D	Non-Serious	17	0
1	5/10/2021	D	Non-Serious	17	0
1	5/10/2021	D	Non-Serious	17	0
1	5/10/2021	D	Non-Serious	16	0
1	5/10/2021	D	Non-Serious	16	0
1	5/11/2021	D	Non-Serious	16	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Serious	17	0
1	5/11/2021	D	Serious	18	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Serious	16	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Serious	16	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Serious	16	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Serious	18	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Serious	18	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Non-Serious	18	0
1	5/11/2021	D	Non-Serious	16	0
1	5/11/2021	D	Serious	18	0
1	5/11/2021	D	Serious	17	0
1	5/11/2021	D	Death	17	0
1	5/11/2021	D	Non-Serious	17	0
1	5/11/2021	D	Serious	18	0
1	5/11/2021	D	Non-Serious	18	0
1	5/12/2021	D	Non-Serious	18	0
1	5/12/2021	D	Non-Serious	16	0
1	5/12/2021	D	Serious	18	0
1	5/12/2021	D	Serious	18	0
1	5/12/2021	D	Serious	18	0
1	5/12/2021	D	Non-Serious	18	0
2	5/12/2021	D	Serious	16	0
1	5/12/2021	D	Serious	16	0
1	5/12/2021	D	Serious	16	0

(b)(6)

1	5/12/2021	D	Serious	18	0
1	5/12/2021	D	Serious	17	0
1	5/12/2021	D	Serious	18	0
1	5/12/2021	D	Non-Serious	18	0
1	5/12/2021	D	Non-Serious	16	0
1	5/12/2021	D	Non-Serious	16	0
1	5/12/2021	D	Non-Serious	16	0
1	5/12/2021	D	Non-Serious	16	0
1	5/12/2021	D	Non-Serious	17	0
1	5/12/2021	D	Non-Serious	18	0
1	5/12/2021	D	Non-Serious	17	0
1	5/12/2021	D	Non-Serious	15	0
1	5/12/2021	D	Non-Serious	17	0
1	5/13/2021	D	Non-Serious	16	0
1	5/13/2021	D	Non-Serious	16	0
1	5/13/2021	D	Non-Serious	18	0
1	5/13/2021	D	Serious	17	0
1	5/13/2021	D	Serious	18	0
1	5/13/2021	D	Non-Serious	16	0
1	5/13/2021	D	Non-Serious	17	0
1	5/13/2021	D	Non-Serious	17	0
1	5/13/2021	D	Non-Serious	17	0
1	5/13/2021	D	Non-Serious	17	0
1	5/13/2021	D	Non-Serious	16	0
1	5/14/2021	D	Non-Serious	17	0
1	5/14/2021	D	Serious	17	0
1	5/14/2021	D	Serious	16	0
1	5/14/2021	D	Non-Serious	17	0
1	5/14/2021	D	Non-Serious	12	0
1	5/14/2021	D	Non-Serious	18	0
1	5/14/2021	D	Non-Serious	16	0
1	5/14/2021	D	Non-Serious	16	0
1	5/14/2021	D	Non-Serious	17	0
1	5/14/2021	D	Non-Serious	16	0
1	5/14/2021	D	Non-Serious	17	0
1	5/14/2021	D	Non-Serious	17	0
1	5/14/2021	D	Non-Serious	16	0
1	5/14/2021	D	Non-Serious	17	0
1	5/14/2021	D	Non-Serious	15	0
1	5/14/2021	D	Non-Serious	18	0
1	5/14/2021	D	Non-Serious	12	0
1	5/14/2021	D	Non-Serious	16	0
1	5/14/2021	D	Non-Serious	15	0
1	5/14/2021	D	Non-Serious	17	0
1	5/14/2021	D	Non-Serious	16	0
1	5/15/2021	D	Serious	16	0
1	5/15/2021	D	Serious	16	0
1	5/15/2021	D	Serious	16	0
1	5/15/2021	D	Serious	18	0

(b)(6)	1	5/15/2021	D	Non-Serious	16	0
	1	5/15/2021	D	Non-Serious	18	0
	1	5/15/2021	D	Non-Serious	16	0
	1	5/15/2021	D	Serious	18	0
	1	5/15/2021	D	Death	11	0
	1	5/15/2021	D	Serious	17	0
	1	5/15/2021	D	Non-Serious	18	0
	1	5/16/2021	D	Non-Serious	18	0
	1	5/16/2021	D	Non-Serious	17	0
	1	5/16/2021	D	Non-Serious	18	0
	1	5/16/2021	D	Non-Serious	18	0
	1	5/16/2021	D	Non-Serious	15	0

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 18 Feb 2021 22:38:34 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: quantifying backlog

Yes. Thanks!

- John

From: (b)(4)
Sent: Thursday, February 18, 2021 4:16 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: quantifying backlog

Hi John,

I'll send some data. Just to make sure we are on the same page: we are currently defining backlog as a report that has expired, per the current timeframes in the NURFU guidance document.

Thanks,

(b)(4)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, February 18, 2021 4:14 PM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: quantifying backlog

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

FDA reached out to us with a couple of questions:

- For COVID-19 vaccines, what is the latest date for which all domestic reports (death, serious-non-death, non-serious) have been processed?
- For non-COVID-19 vaccines, what is the backlog for processing – days, weeks, months? They're seeking a more quantitative measure.

Please let us know. Thanks!

- John

From: (b)(4)
Sent: Tue, 29 Mar 2022 14:37:02 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Cc: (b)(4) Moro, Pedro (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); (b)(4)
Subject: RE: Quarantined Reports
Attachments: SysDoc_QuarantineSectionOnly_ResearcherFup.docx

Hi Paige,

The updated SOP you submitted included our comments and we do not have additional questions. Attached is the internal SOP we are using to quarantine reports. This section was added to our System Documentation.

Thank you,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Friday, March 25, 2022 1:00 PM
To: (b)(4)
Cc: (b)(4)
Subject: RE: GDIT please let us know the status of (b)(6) in HHS download

[External: Use caution with links & attachments]

Hey (b)(4)

Are you able to share your formal documentation on quarantining reports?

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

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Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 10 Jun 2021 18:32:26 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: records GDIT is not requesting

Aha! Thanks for the reminder.

- John

From: (b)(4)
Sent: Thursday, June 10, 2021 2:30 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: records GDIT is not requesting

Yes, you are correct with the following exceptions sent from Elaine:

"Hi (b)(4)

As you are aware, the current plan is for CDC to follow up on all TTS reports of all ages, and myocarditis reports in persons aged ≤30 years.

We will send you a list each day of myocarditis (in persons aged ≤30 years) and TTS reports that:

1. CDC is following up so GDIT should NOT follow up
2. CDC was not able to obtain records so GDIT SHOULD follow up.
3. Deaths reports that GDIT SHOULD follow up on. (GDIT has more expertise in death follow up so we are sending these to GDIT to follow up)

Please contact me for questions.

Thanks,
Elaine"

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, June 10, 2021 12:59 PM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: records GDIT is not requesting

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

I've gotten a bit lost with requests for records. To my recollection, GDIT is requesting records after any serious report after COVID-19 vaccine. There is one specific exception: reports of myopericarditis, for which CDC is directly requesting records.

Is my recollection correct?

Thanks!

- John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 13 Oct 2021 15:48:01 +0000
To: (b)(4)
Cc: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP);
(b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Request for an additional column indicating Myopericarditis cases per jurisdiction - Epi-X weekly spreadsheet

This looks good. Thank you for working on it!

From: (b)(4)
Sent: Friday, October 8, 2021 9:02 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: (b)(4) Roberts, Traci Sinetta
(CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
(b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
<erm4@cdc.gov>
Subject: FW: Request for an additional column indicating Myopericarditis cases per jurisdiction - Epi-X weekly spreadsheet

Hi Paige,

Your request has been completed. The new column will be deployed today and will be capture data on the Weekly files that are created on Monday, 10/11/21. These files will be sent to the jurisdictions on Friday, 10/15/21. We have attached a template with the new column.

Please note that if you try to compare the total Myopericarditis from the Table 2 - Conditions tab with the new column in the Table 1 - Jurisdiction tab, it probably will be a few reports off due to:

- If case counts <5, replace number with "NA" in cell.

Please let us know if you have questions. I am out of the office until next week, so please feel free to send any inquiries to (b)(4)

Thank you,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Tuesday, September 28, 2021 1:25 AM
To: (b)(4)
Cc: (b)(4)
Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: Request for an additional column indicating Myopericarditis cases per jurisdiction - Epi-X weekly spreadsheet

[External: Use caution with links & attachments]

Hey (b)(4)

CDC previously verbally requested an additional column be added to worksheet "Cumulative Table 1- Jurisdiction" of the Epi-X weekly spreadsheet. I do not think I followed up with an official email.

The additional column would provide case counts (all ages) for Myopericarditis cases per jurisdiction. (CDC would like to suppress counts less than 5, in its place provide "NA" response.)

Please find attached template for more information. Do you have an estimated timeframe of when this could be completed?

Thanks,
Paige

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 22 Feb 2021 18:29:01 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621

Paige – We are going with the max amount, 25,000 per week. It will be \$21 million. Given the urgency and our desire to manage risk, we felt like we had to go as big as possible.
Tom

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Monday, February 22, 2021 1:26 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Subject: RE: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621

Hey Traci,
I know we are still waiting to get more detail on the backlog reports but I looked over the proposal as it stands now. I have provided 2 comments (pg. 6,7) and 2 issues (pg 4,9).

Issues:

1. We have requested GDIT surge up to receive 25,000 reports a week. (b)(4)

(b)(4)
2. We need to make sure GDIT has the prioritization of the reports consistently documented in their proposal.

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Monday, February 22, 2021 9:20 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621

Good morning Paige,

GDIT's proposal for the VAERS Surge modification is attached for technical review. Let me know if there are any questions or concerns.

Thanks,
Traci

From: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Sent: Friday, February 19, 2021 5:58 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Cc: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Subject: FW: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621

Here is the final proposal from GDIT. Pricing is little higher but inline with what they discussed with me.

Thanks,
Phil

From: (b)(4)
Sent: Friday, February 19, 2021 5:28 PM
To: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Cc: (b)(4)
(b)(4)
Subject: RE: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621

Hello Phil and Nathan,

The attached is in response to the request for the modification proposal from GDIT pertaining to the subject line contract. We greatly appreciate the opportunity to present this proposal in order to provide support to this important mission that has far exceeded expectations in November/December.

Please let me know if you have any questions.

Kindest regards~

(b)(4)
Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

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From: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Sent: Tuesday, February 16, 2021 4:34 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621 Due No Later than 2/17/2021

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

Please see another updated revision of the PWS. This version clarifies that the Government requires a minimum of 5,000 reports completed in a day. I included a screenshot below of the change.

Thanks,
Phil

Philip Denis, MPA

Team Lead/Contracting Officer

Branch 3 Team 2

Office of Acquisition Services (OAS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)

icx2@cdc.gov | 770-488-2934 office

 **OFR** Office of Financial Resources
Office of Acquisition Services (OAS)

Current VAERS plans, protocols, procedures, manuals, standard operating procedures (SOPs), software, some hardware, etc. may be provided by the Government for adoption/modification (i.e., the contractor would not have to develop all entirely new products, but would have the option of rolling over/adopting/modifying existing ones). Additionally, scanning reports for the image database, certain manual data entry tasks, and other processes clearly related to paper reports shall only apply to paper reports (i.e., electronic reports do not require scanning and manual data entry, but may require redaction).

(b)(5)

From: (b)(4)

Sent: Tuesday, February 16, 2021 11:13 AM

To: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621 Due No Later than 2/17/2021

Good Morning Phil,

This is to confirm receipt and will let you know if we have any further questions.

Kindest regards~

(b)(4)

Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.qdit.com

Upcoming Out of Office: None

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From: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Sent: Tuesday, February 16, 2021 7:58 AM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621 Due No Later than 2/17/2021

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

Please see an updated version of the PWS from this weekend. Feel free to respond with any questions or concerns.

Thanks,
Phil

Philip Denis, MPA

Team Lead/Contracting Officer

Branch 3 Team 2

Office of Acquisition Services (OAS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)

icx2@cdc.gov | 770-488-2934 office



From: (b)(4)

Sent: Friday, February 12, 2021 3:57 PM

To: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621 Due No Later than 2/17/2021

Hi Phil,

This is to confirm receipt and I will let you know if we have any additional questions. You may expect our response by the requested due date.

Kindest regards~

(b)(4)

Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: Monday, February 15, 2021

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From: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Sent: Friday, February 12, 2021 3:08 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>

Subject: Request for Modification Proposal - Contract 47QTCK18D0003 / 75D30120F09621 Due No Later than 2/17/2021

Importance: High

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

I just got off a phone call with the program office and we would like to receive a technical (no longer than 5 pages) and a price proposal to add two CLINs to the contract. One will be for the backlog requirement for domestic and foreign reports (estimated 3 – 6 months to complete) and the other will be for a 6 month surge of services to cover the additional reports received. CDC believes that the reports will be in the range of 4,000 – 5,000 a day.

I've attached the revised SOW to this email and we are requesting to receive your response by **No Later Than 2/17/2021 by Close of Business** with the goal of awarding on 2/19/2021 at the earliest.

Thank you for your assistance throughout this process and feel free to call me with any questions or concerns.

Phil

Philip Denis, MPA

Team Lead/Contracting Officer

Branch 3 Team 2

Office of Acquisition Services (OAS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)

lcx2@cdc.gov | 770-488-2934 office



From: (b)(4)
Sent: Friday, February 12, 2021 1:39 PM
To: Denis, Philip (CDC/OCOO/OFR/OAS) <lcx2@cdc.gov>
Subject: RE: Corrected Version - Contract 47QTCK18D0003 / 75D30120F09621 Response
Importance: High

Good Afternoon Phil,

We submit the following attachment in response to your email below and our conversation. I will send the LCATs in a separate email. Wanted to get this to you soonest.

Please let me know if you have any questions.

Kindest regards~

(b)(4)
Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: Monday, February 15, 2021

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From: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Sent: Friday, February 12, 2021 11:02 AM
To: (b)(4)
Subject: RE: Contract 47QTCK18D0003 / 75D30120F09621
Importance: High

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

Hope you are doing well! I spoke with the COR today and she made mention that GDIT was going to respond to the backlog request with a labor category and an estimate of how many hours would be needed to complete the task. My goal is to have a basic understanding of how we would staff the backlog CLIN. Again, I will allow a new labor category for the task. These new positions will be dedicated to just removing the backlog.

Thanks,
Phil

Philip Denis, MPA
Team Lead/Contracting Officer
Branch 3 Team 2
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
icx2@cdc.gov | 770-488-2934 office



From: (b)(4)
Sent: Wednesday, February 10, 2021 3:48 PM
To: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Subject: RE: Contract 47QTCK18D0003 / 75D30120F09621

Hi Phil,

Do you have time this afternoon for a call?

(b)(4)

From: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Sent: Wednesday, February 10, 2021 2:58 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Contract 47QTCK18D0003 / 75D30120F09621

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi

(b)(4)

I have a few additional questions to add to the ones in my previous email. How many resources (provide the labor category title) are currently staffed to perform the task associated with the backlog? Is this their sole responsibility? If not, how many hours do they dedicate to this task? If you are currently staffed for a worst case scenario of 1,000 a day, how many are you processing on average in a day? What are you doing currently to improve efficiencies?

Thank you for your help with these questions. This will help us get a better picture of the issue.

Thanks,
Phil

Philip Denis, MPA

Team Lead/Contracting Officer

Branch 3 Team 2

Office of Acquisition Services (OAS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)

icx2@cdc.gov | 770-488-2934 office



From: (b)(4)

Sent: Wednesday, February 10, 2021 10:50 AM

To: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Contract 47QTCK18D0003 / 75D30120F09621

Hi Phil,

Thank you for your response. I will get greater details before I respond with follow-up phone call.

(b)(4)

Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: Monday, February 15, 2021

GENERAL DYNAMICS
Information Technology

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From: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Sent: Wednesday, February 10, 2021 10:40 AM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Contract 47QTCK18D0003 / 75D30120F09621

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

How many reports associated with the backlog (on average) can a resource work in one day? For just the backlog, what would be the best resource to perform this work? This can be a labor category that is not included on this contract. The Government is looking for GDIT to provide us with efficiencies and cost savings. An option we are considering is to have a standalone CLIN to clear the backlog to the end of this current PoP. We are still interested in making the change I sent concerning the quality assurance work to provide efficiencies where they can be found.

Looking forward to your response. If you have time today, I would like to discuss this with you over the phone as well.

Thanks,
Phil

Philip Denis, MPA
Team Lead/Contracting Officer

Branch 3 Team 2
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
lcx2@cdc.gov | 770-488-2934 office



From: (b)(4)
Sent: Wednesday, February 10, 2021 9:39 AM
To: Denis, Philip (CDC/OCOO/OFR/OAS) <lcx2@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
(b)(4)
Subject: RE: Contract 47QTCK18D0003 / 75D30120F09621

Good Morning Phil,

Below is a summary from the GDIT Team to clarify the current status of incoming reports, backlog, and MedDRA. After your review, we can get on a call to discuss further as well as options to move this forward to accommodate the surge. Please note, the GDIT Team confirms the Quality Assurance is not the main issue at hand.

1. GDIT is unable to process all of the incoming reports in a timely manner. This scenario is unprecedented and incoming reports are significantly above the government's "worst case scenario" estimate of 1,000 covid-19 reports per day.
2. GDIT is unable to process the "worst case scenario" of 1,000 reports per day.
3. There is an ever growing backlog of expired unprocessed reports, currently over 70,000.
4. CDC suggested GDIT use the manufacturer coding provided on the non-serious manufacturer reports. This will help but the following considerations should be noted:
 - a. So far, the majority of incoming reports are not manufacturer reports. This profile is different from pre-covid-19 reporting.
 - b. These reports will still require some processing, since they need to be redacted (have PII/PHI removed from the text fields).

(b)(4)

Thank you for your time and effort on this high priority situation. GDIT strives to continue to provide excellent customer support on this project.

(b)(4)

Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: Monday, February 15, 2021

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From: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Sent: Tuesday, February 9, 2021 4:06 PM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: Contract 47QTCK18D0003 / 75D30120F09621

[External: Use caution with links & attachments]

Hi (b)(4)

We spoke earlier about Contract 47QTCK18D0003 / 75D30120F09621 and changing the quality assurance requirement noted on page 23. Please see the current language below for the proposed change. We feel like this should free up necessary resources to assist with our backlog of reports. A formal modification request will be following this email but I wanted to send you a draft first for GDIT comment.

(b)(5)

Thanks,
Phil

Philip Denis, MPA
Team Lead/Contracting Officer
Branch 3 Team 2
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
icx2@cdc.gov | 770-488-2934 office



From: Amador, Nathan (CDC/OCOO/OFR/OAS)
Sent: Tue, 5 Jul 2022 17:19:26 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: Request Guidance: GSA letter requested for SQL License purchase

Good Afternoon,

One point of clarification. CDC was sent a sample form from **another contract**, one that appears to be from a GSA task order. There was nothing for the CO to refuse per the statement "CDC will not sign the form" as there was no form to sign, there was instead a request to create something entirely new that was not allowable under either VAERS task order. The sample form and request to create something similar are both outside the scope of either active VAERS task orders.

Per our discussions, this order is not eligible for post-award incorporation of GSA scheduled purchasing authority clauses. For future reference, if that need is foreseeable, it has to be part of the solicitation and award process, not added via modification at the end of two years of performance. This should have been raised at the Q&A level of the solicitation.

If these licenses were previously purchased as OCDs against the current task order, which I believe is 75D30120F09621 VAERS-SARS-COV-2, then they could be purchased again utilizing current contract funds, as this request began with a statement that no additional funds were needed. With that in mind, it makes these request make even less sense, as how have the licenses been purchased/utilized to date if this new mechanism is being requested at the end of task order performance to fulfil an ongoing need?

The other important factor to keep in mind is that this task order expires on 08/26/2022, are we sure new licenses are even worth the effort for just under 2-months of additional support? MS licenses are typically annual in nature, seems like a lot of potential waste, and we should be covered under the expiring licenses until end of performance, if purchased in support of this task order.

If GDIT is currently utilizing CDC equipment that needs a software upgrade, that can be done via a help desk ticket to CDC IT Support at : http://itsoservicedesk.cdc.gov/?s_cid=website_connects_010 or by calling 404-639-6000. There should not exist a Government requirement to purchase new licenses at the end of task order performance. And 08/26/2022 was the original award end date, this is not an extension or new requirement.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(4)
Sent: Tuesday, July 5, 2022 12:07 PM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Subject: Request Guidance: GSA letter requested for SQL License purchase
Importance: High

Hi Nathan,

Thought we had this behind us until this email came through. Please read through the thread and recommend next plan of action.

Would the government just purchase the licenses directly then if government has a current licensing agreement with Microsoft?

Please advise.

(b)(4)

Contracts Administrator Sr. Advisor
Federal Health Sector

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

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From: (b)(4)
Sent: Tuesday, July 5, 2022 12:02 PM
To: (b)(4)
Cc: (b)(4)
(b)(4)
Subject: FW: AIR: 23296---GSA letter requested for SQL License purchase

Hello (b)(4)

Can you provide some feedback? Per purchasing, we are still not able to purchase the SQL License without the GSA letter.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

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OOO: July 18 - 25

From: (b)(4)
Sent: Tuesday, July 5, 2022 11:29 AM
To: (b)(4)
Cc: (b)(4)
(b)(4)
Subject: RE: AIR: 23296---GSA letter requested for SQL License purchase

Based off the attached emails there is no path to purchase this without a GSA LOA.

Thank you,

(b)(4)

From: (b)(4)
Sent: Tuesday, July 5, 2022 10:12 AM
To: (b)(4)
Cc: (b)(4)

(b)(4)

Subject: AIR: 23296---GSA letter requested for SQL License purchase

Good morning,

As requested we have been trying to obtain a GSA letter to proceed to submit this PR. We had no luck with our contacts in GDIT so we forwarded the request to the client. The CDC COR forwarded the form to the CDC Contracts Officer. He stated that the form is not necessary because this is not part of the Task Order. CDC will not sign the form.

Also we were asked if we could make the purchase under CDC, since they have a licensing agreement with Microsoft. Are we able to purchase the licenses at a discounted rate because they are for the CDC/Government? Attached is the temporary budgetary quote you had forwarded to us.

Thank you,

(b)(4)

Project/Task Supervisor
Federal Civilian Group

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 2 Jul 2021 19:47:49 +0000
To: (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); (b)(4)
Subject: RE: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [VACCINE ADVERSE EVENTS] [CDC-1771271-X0B6B3] CRM:09863038

Hi (b)(4)

Please let me know if you all are able to reach him.

Thanks,

Elaine

From: (b)(4)
Sent: Friday, July 2, 2021 3:37 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
Subject: RE: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [VACCINE ADVERSE EVENTS] [CDC-1771271-X0B6B3] CRM:09863038

Staff had to leave a voicemail but we alerted the remaining staff to be on the lookout and provide the case number for reference. We will make 2 more attempts to contact the caller

(b)(4)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Friday, July 2, 2021 3:29 PM
To: (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
Subject: RE: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [VACCINE ADVERSE EVENTS] [CDC-1771271-X0B6B3] CRM:09863038

[External: Use caution with links & attachments]

Thanks (b)(4)

Elaine

From: (b)(4)
Sent: Friday, July 2, 2021 3:27 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
Subject: RE: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [VACCINE ADVERSE EVENTS] [CDC-1771271-X0B6B3] CRM:09863038

Good afternoon,

Our staff is working on the call back now.

(b)(4)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Friday, July 2, 2021 1:56 PM
To: (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: RESPONSE REQUIRED; Priority Medium; Mode Phone; Topic [VACCINE ADVERSE EVENTS] [CDC-1771271-X0B6B3] CRM:09863038

[External: Use caution with links & attachments]

Hi (b)(4)

I am sending this to you since Stacey is out of the office.

Is anyone there able to call (b)(6) to help him get his VAERS report sent? He dose not have a computer.

This was sent to CDC on June 11 and just got directed to our office today, **so is it possible to have someone call him ASAP, today?**

Thanks,
Elaine

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

Name: (b)(6)

E-mail: NONE

Phone: (b)(6)

Date, Time ET: 06/11/2021 1:30 PM EST

General Public: I have been calling VAERS and FDA for several weeks to report the side effects I got from the vaccine, and nobody answers when I call and I have left my information but nobody calls me back. I need to speak with someone and report this.

Caller's insulin spiked after getting vaccinated and it has been several weeks and they have not been able to normalize him, caller wants to report this side effects, but has been trying to contact VAERS and FDA for several weeks, leaving his information and nobody calls him back. I instructed caller by reading PR how to report his side effects, but caller said he has not access to a computer, therefore he would like to speak with someone via phone.

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 16 Feb 2022 17:59:36 +0000
To: Amador, Nathan (CDC/OCOO/OFR/OAS)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: SBI COVID19 Special Emphasis Review - response required by Friday, February 18, 2022

Awesome. Let me know if you need anything else.

FYA, I am out of country Feb 24th – Mar 2nd and won't have access to email. My out of office will include contact information for two Level 3 CORs who are familiar with the VAERS contracts.

From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Sent: Wednesday, February 16, 2022 12:42 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: SBI COVID19 Special Emphasis Review - response required by Friday, February 18, 2022

Wow. Thank you for the quick response. That's an item I can take off of my calendar.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Wednesday, February 16, 2022 11:53 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: SBI COVID19 Special Emphasis Review - response required by Friday, February 18, 2022

Hi Nathan,

A picture of the meeting invite and the monthly reports are attached. Agenda items are provided to GDIT informally via email. Let me know if I should forward them to you or if you need anything else.

Thanks,
Traci

From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Sent: Wednesday, February 16, 2022 9:59 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: SBI COVID19 Special Emphasis Review - response required by Friday, February 18, 2022

This is the audit I was referring to. Can you please provide me copies of these two items: Nathan Amador 47QTCK18D0003 GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC. 75D30120F09621, 200-2020-F-09621

1. Evidence of Program Office (PO) oversight through meetings as required (status meeting invites/meeting minutes/agendas)
2. Evidence of reporting (monthly/interim reports) as required in the scope of the contract

I need to have this ready to submit on Tuesday, February 22, and Monday is a Holiday, so requesting this be submitted by COB on Friday, February 18, 2022.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: Kang, Michael (CDC/OCOO/OFR/OAS) <nhf6@cdc.gov>
Sent: Tuesday, February 15, 2022 2:02 PM
To: Alldredge, Berta (CDC/OCOO/OFR/OAS) <boh9@cdc.gov>; Simmons, Candice L. (CDC/OCOO/OFR/OAS) <iie3@cdc.gov>; McMichael, Christina (CDC/OCOO/OFR/OAS) <wpn6@cdc.gov>; Dombeck, David (CDC/OCOO/OFR/OAS) <vwj8@cdc.gov>; Battle, Donald (CDC/OCOO/OFR/OAS) <gag5@cdc.gov>; Lyons, Eric (CDC/OCOO/OFR/OAS) <kpy2@cdc.gov>; Barritt, Gordon D. (CDC/OCOO/OFR/OAS) <ins4@cdc.gov>; Pace, Gwendolyn A. (CDC/OCOO/OFR/OAS) <dvv1@cdc.gov>; Hartnett, Jennifer (CDC/OCOO/OFR/OAS) <rju8@cdc.gov>; Houston, Joshua (CDC/OCOO/OFR/OAS) <pkf5@cdc.gov>; Marshall, Kourtney (CDC/OCOO/OFR/OAS) <qrz9@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>; Doan, Le (CDC/OCOO/OFR/OAS) <kuj3@cdc.gov>; Kennedy, Lee Catherine (CDC/OCOO/OFR/OAS) <vhg0@cdc.gov>; Shamburger, Maria (CDC/OCOO/OFR/OAS) <hag9@cdc.gov>; Bartkevicius, Marie F. (CDC/OCOO/OFR/OAS) <vji6@cdc.gov>; Draluck, Mark (CDC/OCOO/OFR/OAS) <syq1@cdc.gov>; Crow, Michael J. (CDC/OCOO/OFR/OAS) <wv2@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Taylor, Paula (CDC/OCOO/OFR/OAS) <vga8@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; Alexander, Phillip (CDC/OCOO/OFR/OAS) <pfa5@cdc.gov>; Williams, Ronnie (CDC/OCOO/OFR/OAS) <oga3@cdc.gov>; Kahn, Spencer (CDC/OCOO/OFR/OAS) <qnt8@cdc.gov>; Lester, Stephen (Steve)

(CDC/OCOO/OFR/OAS) <svl3@cdc.gov>; Tucker, Tailee C. (CDC/OCOO/OFR/OAS) <ijk8@cdc.gov>;
Wade, Terri (CDC/OCOO/OFR/OAS) (CTR) <svo9@cdc.gov>
Cc: DeFilipps, Dale F. (CDC/OCOO/OFR/OAS) <ded3@cdc.gov>
Subject: SBI COVID19 Special Emphasis Review

Hello All,

SBI is conducting a review of COVID-19 contracts. If you are receiving this email, you are identified as the owner of one (or more) of the randomly selected contracts. Please take a look at the attached file and provide the following for your contracts:

1. Copy of the contract to include the scope & statement of work
2. Evidence of PO oversight through meetings as required (status meeting invites/meeting minutes/agendas)
3. Evidence of reporting (monthly/interim reports) as required in the scope of the contract
4. Completed file review which includes a completed technical & cost evaluation
5. Evidence of file review and approval by OAS (e.g., File Review Checklist containing signatures/ or approval documented in emails)

If you are no longer the current owner, please let me know as soon as possible. It looks like we may need to contact the COR for some of these items. If so, please notate and I will follow up with the COR to request any missing items.

We have a very short turnaround for this request so we asking you provide the documentation by **COB Tuesday Feb 22**. Let me know if you have any questions.

Thanks,

Michael Kang

Auditor

Office of Acquisition Services (OAS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)

2900 Woodcock Blvd

Atlanta, GA 30341

Email:nhf6@cdc.gov

Office: 678-475-4943



From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 16 Feb 2022 16:52:58 +0000
To: Amador, Nathan (CDC/OCOO/OFR/OAS)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: SBI COVID19 Special Emphasis Review - response required by Friday, February 18, 2022
Attachments: VAERS Surge Meeting.png, RE: VAERS SARS-CoV-2 Monthly Status Report (July 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (August 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (September 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (October 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (November 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (December 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (January 2022)

Hi Nathan,

A picture of the meeting invite and the monthly reports are attached. Agenda items are provided to GDIT informally via email. Let me know if I should forward them to you or if you need anything else.

Thanks,
Traci

From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Sent: Wednesday, February 16, 2022 9:59 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: SBI COVID19 Special Emphasis Review - response required by Friday, February 18, 2022

This is the audit I was referring to. Can you please provide me copies of these two items: Nathan Amador 47QTCK18D0003 GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC. 75D30120F09621, 200-2020-F-09621

1. Evidence of Program Office (PO) oversight through meetings as required (status meeting invites/meeting minutes/agendas)
2. Evidence of reporting (monthly/interim reports) as required in the scope of the contract

I need to have this ready to submit on Tuesday, February 22, and Monday is a Holiday, so requesting this be submitted by COB on Friday, February 18, 2022.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: Kang, Michael (CDC/OCOO/OFR/OAS) <nhf6@cdc.gov>
Sent: Tuesday, February 15, 2022 2:02 PM
To: Alldredge, Berta (CDC/OCOO/OFR/OAS) <boh9@cdc.gov>; Simmons, Candice L. (CDC/OCOO/OFR/OAS) <iie3@cdc.gov>; McMichael, Christina (CDC/OCOO/OFR/OAS) <wpm6@cdc.gov>; Dombeck, David (CDC/OCOO/OFR/OAS) <vwj8@cdc.gov>; Battle, Donald (CDC/OCOO/OFR/OAS) <gaq5@cdc.gov>; Lyons, Eric (CDC/OCOO/OFR/OAS) <kpy2@cdc.gov>; Barritt, Gordon D. (CDC/OCOO/OFR/OAS) <ins4@cdc.gov>; Pace, Gwendolyn A. (CDC/OCOO/OFR/OAS) <dvv1@cdc.gov>; Hartnett, Jennifer (CDC/OCOO/OFR/OAS) <rju8@cdc.gov>; Houston, Joshua (CDC/OCOO/OFR/OAS) <pkf5@cdc.gov>; Marshall, Kourtney (CDC/OCOO/OFR/OAS) <grz9@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>; Doan, Le (CDC/OCOO/OFR/OAS) <kuj3@cdc.gov>; Kennedy, Lee Catherine (CDC/OCOO/OFR/OAS) <vhg0@cdc.gov>; Shamburger, Maria (CDC/OCOO/OFR/OAS) <heg9@cdc.gov>; Bartkevicius, Marie F. (CDC/OCOO/OFR/OAS) <vji6@cdc.gov>; Draluck, Mark (CDC/OCOO/OFR/OAS) <syq1@cdc.gov>; Crow, Michael J. (CDC/OCOO/OFR/OAS) <wv2@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Taylor, Paula (CDC/OCOO/OFR/OAS) <vga8@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; Alexander, Phillip (CDC/OCOO/OFR/OAS) <pfa5@cdc.gov>; Williams, Ronnie (CDC/OCOO/OFR/OAS) <oga3@cdc.gov>; Kahn, Spencer (CDC/OCOO/OFR/OAS) <qnt8@cdc.gov>; Lester, Stephen (Steve) (CDC/OCOO/OFR/OAS) <svl3@cdc.gov>; Tucker, Tailee C. (CDC/OCOO/OFR/OAS) <ijk8@cdc.gov>; Wade, Terri (CDC/OCOO/OFR/OAS) (CTR) <svo9@cdc.gov>
Cc: DeFilipps, Dale F. (CDC/OCOO/OFR/OAS) <ded3@cdc.gov>
Subject: SBI COVID19 Special Emphasis Review

Hello All,

SBI is conducting a review of COVID-19 contracts. If you are receiving this email, you are identified as the owner of one (or more) of the randomly selected contracts. Please take a look at the attached file and provide the following for your contracts:

1. Copy of the contract to include the scope & statement of work
2. Evidence of PO oversight through meetings as required (status meeting invites/meeting minutes/agendas)
3. Evidence of reporting (monthly/interim reports) as required in the scope of the contract
4. Completed file review which includes a completed technical & cost evaluation
5. Evidence of file review and approval by OAS (e.g., File Review Checklist containing signatures/ or approval documented in emails)

If you are no longer the current owner, please let me know as soon as possible. It looks like we may need to contact the COR for some of these items. If so, please notate and I will follow up with the COR to request any missing items.

We have a very short turnaround for this request so we asking you provide the documentation by **COB Tuesday Feb 22**. Let me know if you have any questions.

Thanks,

Michael Kang

Auditor

Office of Acquisition Services (OAS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)

2900 Woodcock Blvd

Atlanta, GA 30341

Email: nhf6@cdc.gov

Office: 678-475-4943



The screenshot shows a Microsoft Teams meeting invitation window. The title is 'VAERS Surge Weekly Update'. The 'Required' list includes Neloms, Stacey M., Su, John, Marquet, Paige L., and Miller, Elaine B., all with CDC email addresses. The 'Optional' list includes Moro, Pedro and Diveley, Ray. The recurrence is 'Occurs every Wednesday effective 5/12/2021 from 1:30 PM to 2:30 PM'. The location is 'Microsoft Teams Meeting'. A note at the bottom says 'Please accept this meeting request, switching the VAERS Surge Weekly Update meeting from Zoom to Teams.' Below the note, there are links to 'Join on your computer or mobile app' and 'Click here to join the meeting'. There are also fields for 'Or call in (audio only)' with a phone number (703) 601-1111 and a 'Phone Conference ID' (703) 601-1111. The Windows taskbar at the bottom shows the date as 2/16/2022 and the time as 11:43 AM.

VAERS Surge Weekly Update - Meeting Series

File Meeting Series Scheduling Assistant Tracking Insert Draw Format Text Review Help Tell me what you want to do

Join Teams Meeting TH Meeting Options Show As Busy Reminder: 15 minutes Viva Insights Add a Zoom Meeting Settings

These recipients are outside your organization: Neloms, Stacey M. X Diveley, Ray X

Attendee responses: 3 accepted, 0 tentatively accepted, 0 declined
All instances of this recurring appointment are next to other appointments on your calendar.

Title: VAERS Surge Weekly Update

Required: Neloms, Stacey M. (CDC/DDO/NCEZID/DHQ2) Marquet, Paige L. (CDC/DDO/NCEZID/DHQ2) Miller, Elaine B. (CDC/DDO/NCEZID/DHQ2)

Optional: Moro, Pedro (CDC/DDO/NCEZID/DHQ2) Diveley, Ray (Ray.Diveley@psh.com)

Recurrence: Occurs every Wednesday effective 5/12/2021 from 1:30 PM to 2:30 PM Edit Recurrence

Location: Microsoft Teams Meeting Room Finder

Please accept this meeting request, switching the VAERS Surge Weekly Update meeting from Zoom to Teams.

Microsoft Teams meeting

Join on your computer or mobile app
[Click here to join the meeting](#)

Or call in (audio only)

(703) 601-1111 United States, Atlanta
(703) 601-1111 United States (Toll-free)

Phone Conference ID: (703) 601-1111
[Find a local number](#) | [Reset PIN](#)

[Learn More](#) | [Meeting options](#)

VAERS Surge Weekly Update - Meeting Series

FileMeeting SeriesScheduling AssistantTrackingInsertDrawFormat TextReviewHelpTell me what you want to do

Join Teams Meeting

Meeting Options

Show As:Busy

Reminder:15 minutes

Viva Insights

Add a Zoom Meeting

Settings

These recipients are outside your organization: (b)(4)

Attendee responses: 5 accepted, 0 tentatively accepted, 0 declined.
48 instances of this recurring appointment are next to other appointments on your Calendar.

Send Update

Title

VAERS Surge Weekly Update

Required

(b)(4) Su, John (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Optional

Moro, Pedro (CDC/DDID/NCEZID/DHQP); (b)(4)

Recurrence

Occurs every Wednesday effective 5/12/2021 from 1:30 PM to 2:30 PM Edit Recurrence

Location

Microsoft Teams Meeting

Room Finder

Please accept this meeting request; switching the VAERS Surge Weekly Update meeting from Zoom to Teams.

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

Or call in (audio only)

(b)(6)

United States, Atlanta

(b)(6)

United States (Toll-free)

Phone Conference ID: (b)(6)
Find a local number | Reset PIN

Learn More | Meeting options

Type here to search

11:43 AM
2/16/2022

From: (b)(4)
Sent: Mon, 16 Aug 2021 03:04:56 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (July 2021)
Attachments: SAR Cov-2 MSR - July 2021.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (July 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

August 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (July 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We exceeded the 25,000 reports per week processing requirement each week during the month of July. In addition, a daily report summarizing the processing of covid reports was submitted each business day in July, for government review.

3. Communications

The GDIT PD and CDC VAERS PO continued to hold daily “touch-base” meetings. Weekly CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Reviewed and updated user permissions
- Automated the Medical COVID records daily report
- Performed data requests and system troubleshooting/updates, as required

5. Earned Value Report

The following are the Earned Value metrics for July:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis

ITEM 00001 Information Management Services for Vaccine Adverse Events Reporting System COVID

	MAY	JUN	JUL
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Thu, 16 Sep 2021 03:28:51 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (August 2021)
Attachments: SAR Cov-2 MSR - August 2021.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (August 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

September 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (August 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We exceeded the 25,000 reports per week processing requirement each week during the month of August. In addition, a daily report summarizing the processing of covid reports was submitted each business day in August, for government review.

- There was a significant increase in the number of covid eVAERS manufacturer reports received.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and weekly CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Reviewed and updated user permissions
- Performed data requests and system troubleshooting/updates, as required

5. Earned Value Report

The following are the Earned Value metrics for August:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis			
	JUN	JUL	AUG
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Sat, 16 Oct 2021 03:28:11 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (September 2021)
Attachments: SAR Cov-2 MSR - September 2021.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (September 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

October 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (September 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We met the 25,000 reports per week processing requirement each week during the month of September. In addition, a daily report summarizing the processing of covid reports was submitted each business day in September, for government review.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and weekly CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis to improve processing efficiencies and performance

5. Earned Value Report

The following are the Earned Value metrics for September:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis

	JUL	AUG	SEP
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Tue, 16 Nov 2021 04:09:48 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (October 2021)
Attachments: SAR Cov-2 MSR - October 2021.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (October 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

November 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (October 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We met the 18,000 reports per week processing requirement each week during the month of October. In addition, a daily report summarizing the processing of covid reports was submitted each business day in October, for government review.

- The decreasing number of incoming reports seen since August continues.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and weekly CDC/GDIT team meetings were also held during the reporting period.

4. *IT/ User Support Activities*

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis to improve processing efficiencies and performance

5. Earned Value Report

The following are the Earned Value metrics for October:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis			
	AUG	SEP	OCT
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Thu, 16 Dec 2021 04:42:03 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (November 2021)
Attachments: SAR Cov-2 MSR - November 2021.pdf

Dear Mrs. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (November 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

December 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (November 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We met the 18,000 reports per week processing requirement each week during the month of November, except for the week of Thanksgiving (with government approval). In addition, a daily report summarizing the processing of covid reports was submitted each business day in November (except holidays), for government review.

- The decreasing number of incoming reports seen since August continues.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and weekly CDC/GDIT team meetings were also held during the reporting period.

4. *IT/ User Support Activities*

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis to improve processing efficiencies and performance

5. Earned Value Report

The following are the Earned Value metrics for November:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis Vaccine Adverse Events Reporting System COVID			
	SEP	OCT	NOV
Baseline Budgeted Cost	(b)(4)	(b)(4)	(b)(4)
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Sun, 16 Jan 2022 04:51:30 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (December 2021)
Attachments: SAR Cov-2 MSR - December 2021.pdf

Dear Mrs. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (December 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS
Information Technology

GENERAL DYNAMICS

Information Technology

January 15, 2022

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (December 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We met the 18,000 reports per week processing requirement each week during the month of December, except for the weeks of December 19 and December 26th (with government approval due to the holiday). We processed more reports to adjust for the holidays during the other weeks. In addition, a daily report summarizing the processing of covid reports was submitted each business day in December (except holidays), for government review.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis to improve processing efficiencies and performance. GDIT will provide information regarding our assessment and recommended actions in January, 2022.

5. Earned Value Report

The following are the Earned Value metrics for December:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis			
Information Management Services for Vaccine Adverse Events Reporting System COVID			
	OCT	NOV	DEC
Baseline Budgeted Cost	(b)(4)	(b)(4)	(b)(4)
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Wed, 16 Feb 2022 04:39:26 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (January 2022)
Attachments: SAR Cov-2 MSR - January 2022.pdf

Dear Mrs. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (January 2022) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

February 15, 2022

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (January 2022)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT met the 18,000 reports per week processing requirement each week (as reports were available) during the month of January. It should be noted that the number of incoming reports decreased and there were some weeks where 18,000 reports were not received. A daily report summarizing the processing of covid reports was submitted each business day in January, for government review.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis and updates to improve processing efficiencies and performance

5. Earned Value Report

The following are the Earned Value metrics for January.

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis			
	NOV	DEC	JAN
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 16 Feb 2022 19:23:13 +0000
To: Kang, Michael (CDC/OCOO/OFR/OAS)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: SBI COVID19 Special Emphasis Review
Attachments: VAERS Surge Meeting.png, RE: VAERS SARS-CoV-2 Monthly Status Report (July 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (August 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (September 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (October 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (November 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (December 2021), RE: VAERS SARS-CoV-2 Monthly Status Report (January 2022)

Hi Michael,

A picture of the meeting invite and the monthly reports are attached. Agenda items are provided to GDIT informally via email. Let me know if I should forward them to you or if you need anything else.

Thanks,
Traci Roberts
404-498-0669

From: Kang, Michael (CDC/OCOO/OFR/OAS) <nhf6@cdc.gov>
Sent: Wednesday, February 16, 2022 2:17 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: SBI COVID19 Special Emphasis Review

Hello Traci,

Strategic Business Initiatives (SBI) is conducting a review of COVID-19 contracts. If you are receiving this email, you are identified as the COR for one of the randomly selected contracts. For each contract shown below, can you please provide the following:

GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.	200-2020-F-09621
---	------------------

1. Evidence of PO oversight through meetings as required (status meeting invites/meeting minutes/agendas)
2. Evidence of reporting (monthly/interim reports) as required in the scope of the contract

If any of these items are not available, please provide adequate explanation.

We have a very short turnaround for this request from SBI so we asking you provide the documentation by **COB Tuesday Feb 22**. Please let me know if you have any questions.

Thanks,

Michael Kang

Auditor

Office of Acquisition Services (OAS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)

2900 Woodcock Blvd

Atlanta, GA 30341

Email: nhf6@cdc.gov

Office: 678-475-4943



VAERS Surge Weekly Update - Meeting Series

File Meeting Series Scheduling Assistant Tracking Insert Draw Format Text Review Help Tell me what you want to do

Join Teams Meeting Meeting Options Show As: Busy Reminder: 15 minutes Viva Insights Add a Zoom Meeting Settings

These recipients are outside your organization: (b)(4)

Attendee responses: 5 accepted, 0 tentatively accepted, 0 declined
48 instances of this recurring appointment are next to other appointments on your calendar.

Title: VAERS Surge Weekly Update

Required: (b)(4) • Su, John (CDC/DDID/NCEZID/DHQP) • Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) • Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Optional: • Mero, Pedro (CDC/DDID/NCEZID/DHQP) (b)(4)

Recurrence: Occurs every Wednesday effective 5/12/2021 from 1:30 PM to 2:30 PM [Edit Recurrence](#)

Location: Microsoft Teams Meeting [Room Finder](#)

Please accept this meeting request, switching the VAERS Surge Weekly Update meeting from Zoom to Teams.

Microsoft Teams meeting

Join on your computer or mobile app
[Click here to join the meeting](#)

Or call in (audio only)
(b)(6) United States, Atlanta
(b)(6) United States (Toll free)
Phone Conference ID: (b)(6)
[Find a local number](#) | [Reset PIN](#)

[Learn More](#) | [Meeting options](#)

VAERS Surge Weekly Update - Meeting Series

FileMeeting SeriesScheduling AssistantTrackingInsertDrawFormat TextReviewHelpTell me what you want to do

Join Teams Meeting

Meeting Options

Show As:Busy

Reminder:15 minutes

Viva Insights

Add a Zoom Meeting

Settings

These recipients are outside your organization: (b)(4)

Attendee responses: 5 accepted, 0 tentatively accepted, 0 declined.
48 instances of this recurring appointment are next to other appointments on your Calendar.

Send Update

Title

VAERS Surge Weekly Update

Required

(b)(4) Su, John (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Optional

More, Pedro (CDC/DDID/NCEZID/DHQP); (b)(4)

Recurrence

Occurs every Wednesday effective 5/12/2021 from 1:30 PM to 2:30 PM Edit Recurrence

Location

Microsoft Teams Meeting

Room Finder

Please accept this meeting request; switching the VAERS Surge Weekly Update meeting from Zoom to Teams.

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

Or call in (audio only)

(b)(6)

United States, Atlanta

(b)(6)

United States (Toll-free)

Phone Conference ID: (b)(6)

Find a local number | Reset PIN

Learn More | Meeting options

Type here to search

11:43 AM
2/16/2022

From: (b)(4)
Sent: Mon, 16 Aug 2021 03:04:56 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (July 2021)
Attachments: SAR Cov-2 MSR - July 2021.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (July 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

August 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (July 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We exceeded the 25,000 reports per week processing requirement each week during the month of July. In addition, a daily report summarizing the processing of covid reports was submitted each business day in July, for government review.

3. Communications

The GDIT PD and CDC VAERS PO continued to hold daily “touch-base” meetings. Weekly CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Reviewed and updated user permissions
- Automated the Medical COVID records daily report
- Performed data requests and system troubleshooting/updates, as required

5. Earned Value Report

The following are the Earned Value metrics for July:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis

ITEM 00001 Information Management Services for Vaccine Adverse Events Reporting System COVID

	MAY	JUN	JUL
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Thu, 16 Sep 2021 03:28:51 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (August 2021)
Attachments: SAR Cov-2 MSR - August 2021.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (August 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

September 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (August 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We exceeded the 25,000 reports per week processing requirement each week during the month of August. In addition, a daily report summarizing the processing of covid reports was submitted each business day in August, for government review.

- There was a significant increase in the number of covid eVAERS manufacturer reports received.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and weekly CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Reviewed and updated user permissions
- Performed data requests and system troubleshooting/updates, as required

5. Earned Value Report

The following are the Earned Value metrics for August:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis			
	JUN	JUL	AUG
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Sat, 16 Oct 2021 03:28:11 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (September 2021)
Attachments: SAR Cov-2 MSR - September 2021.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (September 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS
Information Technology

GENERAL DYNAMICS

Information Technology

October 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (September 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We met the 25,000 reports per week processing requirement each week during the month of September. In addition, a daily report summarizing the processing of covid reports was submitted each business day in September, for government review.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and weekly CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis to improve processing efficiencies and performance

5. Earned Value Report

The following are the Earned Value metrics for September:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis

	JUL	AUG	SEP
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Tue, 16 Nov 2021 04:09:48 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (October 2021)
Attachments: SAR Cov-2 MSR - October 2021.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (October 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

November 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (October 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We met the 18,000 reports per week processing requirement each week during the month of October. In addition, a daily report summarizing the processing of covid reports was submitted each business day in October, for government review.

- The decreasing number of incoming reports seen since August continues.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and weekly CDC/GDIT team meetings were also held during the reporting period.

4. *IT/ User Support Activities*

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis to improve processing efficiencies and performance

5. Earned Value Report

The following are the Earned Value metrics for October:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis			
	AUG	SEP	OCT
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Thu, 16 Dec 2021 04:42:03 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (November 2021)
Attachments: SAR Cov-2 MSR - November 2021.pdf

Dear Mrs. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (November 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

December 15, 2021

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (November 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We met the 18,000 reports per week processing requirement each week during the month of November, except for the week of Thanksgiving (with government approval). In addition, a daily report summarizing the processing of covid reports was submitted each business day in November (except holidays), for government review.

- The decreasing number of incoming reports seen since August continues.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and weekly CDC/GDIT team meetings were also held during the reporting period.

4. *IT/ User Support Activities*

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis to improve processing efficiencies and performance

5. Earned Value Report

The following are the Earned Value metrics for November:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis Vaccine Adverse Events Reporting System COVID			
	SEP	OCT	NOV
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Sun, 16 Jan 2022 04:51:30 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (December 2021)
Attachments: SAR Cov-2 MSR - December 2021.pdf

Dear Mrs. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (December 2021) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.qdit.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

January 15, 2022

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (December 2021)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT also hired staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). We met the 18,000 reports per week processing requirement each week during the month of December, except for the weeks of December 19 and December 26th (with government approval due to the holiday). We processed more reports to adjust for the holidays during the other weeks. In addition, a daily report summarizing the processing of covid reports was submitted each business day in December (except holidays), for government review.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis to improve processing efficiencies and performance. GDIT will provide information regarding our assessment and recommended actions in January, 2022.

5. Earned Value Report

The following are the Earned Value metrics for December:

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis			
Information Management Services for Vaccine Adverse Events Reporting System COVID			
	OCT	NOV	DEC
Baseline Budgeted Cost	(b)(4)	(b)(4)	(b)(4)
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: (b)(4)
Sent: Wed, 16 Feb 2022 04:39:26 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); (b)(4) Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (January 2022)
Attachments: SAR Cov-2 MSR - January 2022.pdf

Dear Mrs. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (January 2022) is attached. Please let me know if you have any questions.

Thank you,

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gditi.com

GENERAL DYNAMICS

GENERAL DYNAMICS

Information Technology

February 15, 2022

Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (January 2022)

1. Processing of Backlog Reports

A contract modification, to provide for backlog remediation, was issued in March. GDIT completed processing the backlog, ahead of schedule, during the month of May 2021.

2. Processing of Incoming Surge Reports

GDIT met the 18,000 reports per week processing requirement each week (as reports were available) during the month of January. It should be noted that the number of incoming reports decreased and there were some weeks where 18,000 reports were not received. A daily report summarizing the processing of covid reports was submitted each business day in January, for government review.

3. Communications

The GDIT PD and CDC VAERS PO conducted check-in meetings and CDC/GDIT team meetings were also held during the reporting period.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet
- Performed data requests and system troubleshooting/updates, as required
- Continued system analysis and updates to improve processing efficiencies and performance

5. Earned Value Report

The following are the Earned Value metrics for January.

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis			
	NOV	DEC	JAN
Baseline Budgeted Cost	(b)(4)		
Budgeted Cost of Work Performed (BCWP) or Earned Value (EV)			
Actual Cost of Work Performed (AC)			
Budgeted Cost of Work Scheduled or Planned Value (PV)			
Cost Variance (CV)			
Schedule Variance (SV)			
Cost Performance Index (CPI)			
Schedule Performance Index (SPI)			
Estimate to Completion (ETC)			
Estimate at Completion (EAC)			
Variance at Completion (VAC)			
Average Index			
Status based on Average Performance Index			

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 28 Jun 2021 12:26:42 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: Suspension Notification for 00HCVLDE-2021-58061 - NCE VAERS Surge/Medical Records Update

Hi John, you are correct. I'm speaking with Nathan today on how we can move forward. I'll let you know if I need anything from you.

Traci

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

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Friday, June 25, 2021 2:22 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Suspension Notification for 00HCVLDE-2021-58061 - NCE VAERS Surge/Medical Records Update

Hi Traci,

FYI: I spoke with Phil to get caught up on where we are. The impression I get is that you and Stacey are already working on this topic, and that what we need to do is look at what the current level of performance has cost, and use that data to project what our needs will be going forward, and modify the contract accordingly.

Please correct me if I'm mistaken, and let me know if there's anything I should be doing re: this topic. Thanks!

-- John

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

From: ICEMAIL <icemail@cdc.gov>
Sent: Friday, June 25, 2021 11:31 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: Suspension Notification for 00HCVLDE-2021-58061 - NCE VAERS Surge/Medical Records Update

00HCVLDE-2021-58061 - NCE VAERS Surge/Medical Records Update has been suspended by Philip Denis for the following reason:

Other: Modification requires additoinal information. Please work with Nathan Amador to finalize.[22]

PIIN:47QTCK18D0003

SPIIN:200-2020-F-09621

Funding:

None.

The below users are associated with this Purchase Request:

OAS:

Project Officer: Traci Sinetta Roberts
COR: Traci Sinetta Roberts
End User: John Su
CO (Contracting Officer): Nathan Amador
Team Lead: Philip Denis
Contract Specialist: Nathan Amador

Program:

Project Officer: Traci Sinetta Roberts

End User: John Su

Requisitioner: Traci Sinetta Roberts

From: (b)(4)
Sent: Wed, 17 Feb 2021 19:33:14 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: Time Sensitive Request- Number of COVID-19 reports per day (January 24-February 16)
Attachments: COVIDDailyTotals_021721.xlsx

Hi Paige,

Here are the numbers – January 1, 2021 – February 16, 2021. Weekends and holidays are highlighted.

Thanks,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Wednesday, February 17, 2021 2:08 PM
To: (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: Time Sensitive Request- Number of COVID-19 reports per day (January 24-February 16)
Importance: High

[External Email with Covid-19 Information: Use caution with links & attachments]

Hey (b)(4)

CDC needs to know the number of COVID-19 reports you guys have received daily from January 24-February 16, 2021. If you can add in serious status, manufacturer, and foreign/domestic status information per day that would be great. If that takes a lot of time, please just provide total report counts per day from January 24- February 16.

Thanks,
Paige

Day	Received
01/01/2021	494
01/02/2021	466
01/03/2021	408
01/04/2021	1472
01/05/2021	2178
01/06/2021	2391
01/07/2021	3081
01/08/2021	3601
01/09/2021	1733
01/10/2021	972
01/11/2021	2607
01/12/2021	2736
01/13/2021	2803
01/14/2021	2805
01/15/2021	2775
01/16/2021	906
01/17/2021	897
01/18/2021	2103
01/19/2021	2697
01/20/2021	2312
01/21/2021	3243
01/22/2021	2902
01/23/2021	1066
01/24/2021	990
01/25/2021	2864
01/26/2021	2791
01/27/2021	3081
01/28/2021	3154
01/29/2021	3196
01/30/2021	1156
01/31/2021	1136
02/01/2021	2720
02/02/2021	3170
02/03/2021	2633
02/04/2021	3993
02/05/2021	3435
02/06/2021	1458
02/07/2021	1220
02/08/2021	3444
02/09/2021	3133
02/10/2021	2783
02/11/2021	3259
02/12/2021	2331
02/13/2021	1227
02/14/2021	1031
02/15/2021	2343
02/16/2021	1870

Highlighted rows represent weekends and/or holidays.

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 15 Dec 2020 04:29:25 +0000
To: (b)(4)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Lara, Elisa G; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: Uploading Epi-X data -SOP and attachments needed

Hey (b)(4)

I hope to send you the items later this week. Please note that CDC is still waiting to get the MOU approved and signed by appropriate parties before we are allowed to post VAERS data or reports to Epi-X.

Also just to clarify, CDC is not expecting GDIT to post anything to Epi-X until December 28. (You will cut the data as of December 18th around 2pm, then have one week to process it before posting to Epi-X the following Friday. Since that Friday is December 25, we are anticipating you guys posting the following Monday.) Now in regards to VAERS death/anaphylaxis reports (pdf images) you could post those before December 28 but then again we are waiting for the MOU to be finalized.

From: (b)(4)
Sent: Monday, December 14, 2020 11:12 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)
Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Uploading Epi-X data -SOP and attachments needed

Hi Paige,

Do you know when the Epi-X SOPs and attachments will be finalized? We would like to receive these items no later than Thursday in order to post the files on Friday.

Thank you,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Thursday, December 10, 2020 10:03 PM
To: (b)(4)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)
Subject: RE: Uploading Epi-X data

[External: Use caution with links & attachments]

Thanks (b)(4) Also, if you could tell us how much time Epi-X will need to do their part of the posting, that would be great.

We would like for the Epi-X data to be posted on Friday to align with the posting of the public data. I'm trying to get a sense of when GDIT needs to complete their process of the upload so that Epi-X can

perform their part so that the data is posted Friday. Would it be that GDIT will need to complete their part by Thursday?

From: (b)(4)

Sent: Thursday, December 10, 2020 9:45 PM

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

Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)

Subject: RE: Uploading Epi-X data

Hi Paige,

I believe Epi-X staff do play a role after GDIT submits the report. I have cc'ed Elisa, who currently submits most of our reports and is our liaison to the Epi-X team for her input.

FYI – here is text from the previous SOP (2017?):

- After you submit the report, *Epi-X* staff will cut the first paragraph from the “Description” field and paste it into the “Brief Summary” field. They will then post the report. When the report is posted, persons who have the “State Health Coordinator” role in the specified state will be notified by immediate e-mail and through *Epi-X Today*. The email notification will include a link to the report.

Thanks,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Thursday, December 10, 2020 9:28 PM

To: (b)(4)

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

Subject: Uploading Epi-X data

[External: Use caution with links & attachments]

Hey (b)(4)

Can you confirm the process for GDIT to upload Epi-X data? Do you guys basically upload all the vaers data to Epi-X and then shortly afterwards the jurisdictions are able to access it? Does Epi-X staff have to do anything in this process?

From: Amador, Nathan (CDC/OCOO/OFR/OAS)
Sent: Fri, 22 Apr 2022 18:27:20 +0000
To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: (b)(4)
(b)(4) Denis, Philip (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS 47QTCK18D0003/75D30119F06120 and VAERS SAR CoV-2
47QTCK18D0003/75D30120F09621 - GDIT Request Invoice Assistance
Attachments: 75D30119F06120 00004_IPP_Signed.pdf, 75D30120F09621
00007_IPP_Signed.pdf

Good Afternoon,

Please find attached the two fully executed modifications. I do not know how long it will take for the changes in FPDS to be reported to Treasury. I have reached out to my fellow COs who were having similar issues and have let them know the process and changes I made for these two actions, so if this works, please let me know so I can help as needed on other activities.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(4)
Sent: Friday, April 22, 2022 1:42 PM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: (b)(4)
(b)(4)
(CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Subject: RE: VAERS 47QTCK18D0003/75D30119F06120 and VAERS SAR CoV-2
47QTCK18D0003/75D30120F09621 - GDIT Request Invoice Assistance
Importance: High

Hello Nathan,

Attached is the GDIT signed contracts for VAERS and VAERS SARS Cov-2.

Thank you~

(b)(4)

Contracts Administrator Sr. Advisor
Federal Health Sector

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.qdit.com

Upcoming Out of Office: May 25-27, 2022

GENERAL DYNAMICS
Information Technology

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From: Amador, Nathan (CDC/OCOO/OFr/OAS) <wlv7@cdc.gov>

Sent: Friday, April 22, 2022 1:33 PM

To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
<xct6@cdc.gov>

Cc: (b)(4)

(b)(4)

(CDC/OCOO/OFr/OAS) <icx2@cdc.gov>

Subject: RE: VAERS 47QTCK18D0003/75D30119F06120 and VAERS SAR CoV-2
47QTCK18D0003/75D30120F09621 - GDIT Request Invoice Assistance

[External: Use caution with links & attachments]

Good Morning,

I will proceed with both of this modifications. I thought the option exercise for 75D30119F06120 was forthcoming, so was waiting on that, but the funding is still being brought together, so the attached modification is only for the HHSAR clause.

The reporting issue showing these changes had already occurred should have been been resolved, so hopefully these two bilateral modifications will resolve the issue with Treasury. Please sign and return the two attached modifications (75D30119F06120 00004 and 75D30120F09621 00007) and I will fully execute and then we'll see if this actually resolves the issues.

I finally found a link for it posted online: [D HHSAR 352.232-71 Electronic Submission of Payment Requests \(Feb 2022\).pdf - GovTribe](#)

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(4)
Sent: Friday, April 22, 2022 12:33 PM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Cc: (b)(4)

(b)(4)

Subject: RE: VAERS 47QTCK18D0003/75D30119F06120 and VAERS SAR CoV-2
47QTCK18D0003/75D30120F09621 - GDIT Request Invoice Assistance
Importance: High

Good Afternoon Phil,

This is a follow-up to the voicemail I left you. I've tried to reach out to Nathan but he may be out of the office this week.

GDIT has encountered issues with entering invoices into the new CDC IPP system with both of these contracts. My understanding is that a modification is to be issued to the contract to include HHSAR 352.232-71 clause which when fully executed, then triggers the Treasury Dept. to initiate the email sent to GDIT to register that contract number to begin submitting the invoices into the new IPP system.

Our invoices have been rejected which is the purpose of this request for a modification to add the HHSAR clause. GDIT has contacted the IPP Help Desk as this contract is not recognized in the IPP system and recommended contacting the Contracting Officer for further assistance.

Please let me know if you have any questions.

Kindest regards~

(b)(4)

Contracts Administrator Sr. Advisor

Federal Health Sector

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: May 25-27, 2022

GENERAL DYNAMICS
Information Technology

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AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

Obtained by ICANDecide.org via FOIA

1. CONTRACT ID CODE

PAGE OF PAGES
1 2

2. AMENDMENT/MODIFICATION NO.
00004

3. EFFECTIVE DATE
04/22/2022

4. REQUISITION/PURCHASE REQ. NO.
N/A

5. PROJECT NO. (If applicable)

6. ISSUED BY CODE 8219
Centers for Disease Control and Prevention (CDC)
Office of Acquisition Services (OAS)
2900 Woodcock Blvd, MS TCU-4
Atlanta, GA 30341-4004

7. ADMINISTERED BY (If other than Item 6) CODE
CO: Nathan R. Amador, wlv7@cdc.gov, 770.488.2690
COR: Traci Sinetta Roberts, xct6@cdc.gov, 404.498.0669
CTR: (b)(4)

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)
GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.
3150 FAIRVIEW PARK DR STE 100
FALLS CHURCH, VA 22042-4504

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (See Item 11)

10A. MODIFICATION OF CONTRACT/ORDER NO.
75D30119F06120

10B. DATED (See Item 13)
09/30/2019

CODE SMNWM6HN79X5

FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ___ is extended, ___ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
(a) By completing Items 8 and 15, and returning ___ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)
N/A

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(√) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X D. OTHER (Specify type of modification and authority)
Bilateral Modification to add HHSAR 352.232-71 Electronic Submission of Payment Requests

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 digital copy to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this bilateral administrative modification 00004 is to add HHSAR 352.232-71 Electronic Submission of Payment Requests to the contract and to trigger payment of invoices via www.ipp.gov.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)

16A. NAME OF CONTRACTING OFFICER
Nathan R. Amador

(b)(4) Contracts Administrator Sr. Advisor

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED
22 APRIL 2022

16B. UNITED STATES OF AMERICA

BY Nathan R. Amador - S Digitally signed by Nathan R. Amador - S
(Signature of Contracting Officer) Date: 2022.04.22 13:59:19 -04'00'

16C. DATE SIGNED

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**Option 2 Line Items:**

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	NOT TO EXCEED
2001	Opt 2: VAERS The contractor shall provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs), and facilitate reporting to VAERS. Reference the SOW and all associated deliverables. This is a T&M, severable line item. PoP: 09/30/2021 - 09/30/2022		(b)(4)	

HHSAR 352. 232-71 Electronic Submission of Payment Requests

(a) *Definitions.* As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system.

Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

Obtained by ICANDecide.org via FOIA

1. CONTRACT ID CODE

PAGE OF PAGES

1 2

2. AMENDMENT/MODIFICATION NO.
00007

3. EFFECTIVE DATE
04/22/2022

4. REQUISITION/PURCHASE REQ. NO.
N/A

5. PROJECT NO. (If applicable)

6. ISSUED BY
Centers for Disease Control and Prevention (CDC)
Office of Acquisition Services (OAS)
2900 Woodcock Blvd, MS TCU-4
Atlanta, GA 30341-4004

CODE

8219

7. ADMINISTERED BY (If other than Item 6)
CO: Nathan R. Amador, wlv7@cdc.gov, 770.488.2690
COR: Traci Sinetta Roberts, xct6@cdc.gov, 404.498.0669
CTR: (b)(4)

CODE

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)
GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.
3150 FAIRVIEW PARK DR STE 100
FALLS CHURCH, VA 22042-4504

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (See Item 11)

10A. MODIFICATION OF CONTRACT/ORDER NO.
75D30120F09621

10B. DATED (See Item 13)
08/27/2020

CODE SMNWM6HN79X5

FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ___ is extended, ___ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
(a) By completing Items 8 and 15, and returning ___ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

N/A

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(√) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X D. OTHER (Specify type of modification and authority)
Bilateral Modification to add HHSAR 352.232-71 Electronic Submission of Payment Requests

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 digital copy to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this bilateral administrative modification 00004 is to add HHSAR 352.232-71 Electronic Submission of Payment Requests to the contract and to trigger payment of invoices via www.ipp.gov.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)

16A. NAME OF CONTRACTING OFFICER

Nathan R. Amador

(b)(4) Contracts Administrator Sr. Advisor

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED

(b)(4)
(Signature of person authorized to sign)

22 APRIL 2022

BY Nathan R. Amador -S Digitally signed by Nathan R. Amador -S
(Signature of Contracting Officer) Date: 2022.04.22 14:00:21 -04'00'

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	NOT TO EXCEED
0001	VAERS SARS-CoV-2 The contractor shall provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs), and facilitate reporting to VAERSspecifically pertaining to SARS-CoV-2. Reference the SOW and all associated deliverables. This is a T&M, severable line item. PoP: 08/27/2020 – 08/26/2022		(b)(4)	

HHSAR 352. 232-71 Electronic Submission of Payment Requests

(a) *Definitions.* As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

From: (b)(4)
Sent: Mon, 26 Apr 2021 16:27:30 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); VAERS; (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS (b)(6)

Hi Elaine,

We have removed the report from f/up. At this time we are only able to trace reports if a valid email address is provided. Unfortunately, we did not get one for this report.

(b)(4)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Monday, April 26, 2021 8:41 AM
To: (b)(4) VAERS <nurfu@vaers.org>; (b)(4)
(b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS (b)(6)

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi all,

Upon further review, the report appears to be a hoax.

The patient name is a Brazilian athlete and the reporter name is the Brazilian leader.

Please let us know if you can determine who filed the report or the email address where the report was sent from.

Thanks,

Elaine

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Friday, April 23, 2021 12:53 PM
To: (b)(4) VAERS <nurfu@vaers.org>
Cc: (b)(4) Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: VAERS (b)(6)
Importance: High

Hi (b)(4)

Please have follow up started on VAERS (b)(6) This is a death after COVID vaccine that was received in VAERS on 3/5/21. Follow up was not yet started.

The report states the page is 2 years old so I assume the age is an error.

Thanks,

Elaine

From: (b)(4)
Sent: Mon, 10 May 2021 18:04:05 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); VAERS
Cc: (b)(4) Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS (b)(6)

Hi,

I'll take a look and make sure we initiate right away.

(b)(4)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Monday, May 10, 2021 2:01 PM
To: VAERS <nurfu@vaers.org>; (b)(4)
Cc: (b)(4) Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: VAERS (b)(6)

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi Ana,
VAERS (b)(6) is a COVID vaccine report of death that was received 3/25/21 and has no follow up started.
Please have records requested.

Thanks,

Elaine

From: (b)(4)
Sent: Wed, 19 May 2021 12:03:29 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Jazwa, Amelia (CDC/DDID/NCEZID/DHQP); Johnson, Tara (CDC/DDNID/NCEH/DEHSP); (b)(4)
Subject: RE: VAERS COVID reports -myocarditis - 5/18/2021

Hi John,

Our clinical team reviews the images of incoming reports (Enhanced Surveillance). This allows us to identify cases/symptom text of interest prior to report processing.

Thanks,

(b)(4)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, May 19, 2021 12:19 AM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Johnson, Tara (CDC/DDNID/NCEH/DEHSP) <qph3@cdc.gov>; (b)(4)
(b)(4)
(b)(4)
Subject: RE: VAERS COVID reports -myocarditis - 5/18/2021

[External Email with Covid-19 Information: Use caution with links & attachments]

Ok, thanks. Just wondering how these IDs were identified.

- John

From: (b)(4)
Sent: Tuesday, May 18, 2021 11:32 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP) <wev7@cdc.gov>; Johnson, Tara (CDC/DDNID/NCEH/DEHSP) <qph3@cdc.gov>; (b)(4)
(b)(4)
(b)(4)
Subject: RE: VAERS COVID reports -myocarditis - 5/18/2021

I would have to go back and check, but I believe there is a mix of both.

(b)(4)

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

Sent: Tuesday, May 18, 2021 10:33 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP)

<wev7@cdc.gov>; Johnson, Tara (CDC/DDNID/NCEH/DEHSP) <gph3@cdc.gov>; (b)(4)

(b)(4)

(b)(4)

Subject: RE: VAERS COVID reports -myocarditis - 5/18/2021

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

Thanks for sharing! Are all of the below reports pre-process (e.g., prior to medical coding with MedDRA codes)?

- John

From: (b)(4)

Sent: Tuesday, May 18, 2021 10:04 PM

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

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Jazwa, Amelia (CDC/DDID/NCEZID/DHQP)

<wev7@cdc.gov>; Johnson, Tara (CDC/DDNID/NCEH/DEHSP) <gph3@cdc.gov>; (b)(4)

(b)(4)

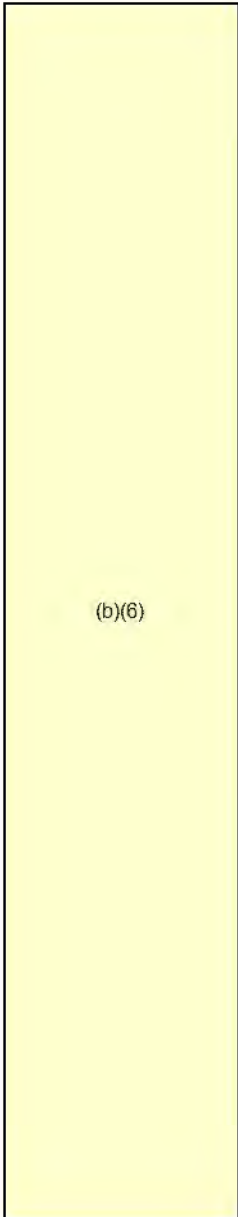
(b)(4)

Subject: VAERS COVID reports -myocarditis - 5/18/2021

Hi,

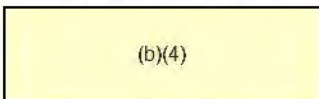
Below are VAERS reports for myocarditis or symptoms related to it, after receiving the COVID-19 vaccine.

(b)(6)



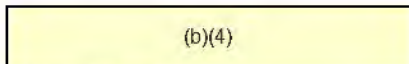
(b)(6)

Let us know if you have any questions.



(b)(4)

Medical Affairs Advisor/Clinical Lead VAERS
Federal Civilian Division



(b)(4)

www.gdit.com

GENERAL DYNAMICS

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 22 Jan 2021 17:55:55 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Kripalani, Kavita; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); (b)(4) Suragh, Tiffany (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X - Draft Template and directions
Attachments: VAERS Images Extraction Directions.docx, VAERS COVID19 Excel File Extraction Directions 2021Jan19.pdf

Hey (b)(4)

Can you guys update your VAERS Images Extraction Directions (word doc attached) with the changes/updates you made available today to the jurisdictions for Excel File Extraction Directions (pdf attached)? You guys added some extra wording and screenshots for the jurisdictions.

Thanks,

Paige

From: (b)(4)
Sent: Wednesday, January 13, 2021 12:53 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4) Suragh, Tiffany (CDC/DDID/NCEZID/DHQP) <xxi5@cdc.gov>
Subject: FW: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X - Draft Template and directions

Hi Paige,

Here is the proposed template for the Epi-X postings for the Death reports. Attached are the draft extraction directions that would accompany the posting—please note we made minor changes to the approved COVID-19 version.

Also, please note the PDF images will not be individually password protected; the folder containing them will be password protected instead with 7-zip. This will facilitate processing but also standardize how we encrypt files for Epi-X delivery.

We will be able to submit a test file once the questions are addressed and the template approved.

Thank you,

(b)(4)

(b)(4)

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Thursday, January 7, 2021 12:41 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4) Miller,

Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4) Suragh,

Tiffany (CDC/DDID/NCEZID/DHQP) <xxi5@cdc.gov>

Subject: RE: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X - GDIT Response

[External Email with Covid-19 Information: Use caution with links & attachments]

Hello (b)(4)

This is great news. Please find our responses to your questions.

- VCS Password: Can CDC send all the VSCs a password they can use to open the files? This is similar to what is done for the current Epi-X postings. – Yes, CDC will be able to send a password to the VSCs once GDIT provides the password. Do you guys plan to provide an updated password every 90 days per CDC security procedures?
- Image clarification: Can CDC define which image they would like GDIT to send? Is it the initial/primary report only? Is it the View Image page? -CDC initially thought we would request GDIT to send the primary VAERS DEATH report (COVID19/FLU) via VIEW IMAGE. We had not considered eVAERS reports and the multiple tabs that would have to be provided. After some discussion, we are now leaning towards requesting GDIT to send the primary VAERS DEATH report via VIEW DATA for ALL reporter types. In order to confirm this option, we would like to know how soon after GDIT receives the report will VIEW DATA be available? Is it within minutes or hours? Please note, CDC would like GDIT to inform the jurisdictions of DEATH reports following COVID19 rather quickly and are ok with expanding the timeframe some for FLU DEATH reports. Hopefully, VIEW DATA is available rather quickly and we will be able to base the report off of this option. Please let us know the timing so we can confirm which option to request from GDIT.
- Sample image: Is it possible for CDC to provide GDIT with a sample image of what is currently sent? - CDC basically opens up the report via VIEW DATA/IMAGE, clicks on print and chooses pdf. CDC then applies a password to the pdf. Do you still need a sample copy?

Does GDIT have a proposed start date for this task? The sooner the better for CDC. 😊

Thanks,
Paige Marquez

From: (b)(4)
Sent: Tuesday, January 5, 2021 8:36 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4) Suragh, Tiffany (CDC/DDID/NCEZID/DHQP) <xxi5@cdc.gov>
Subject: RE: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X - GDIT Response

Hi Paige,

GDIT is able to send VAERS death reports following seasonal flu and COVID-19 to jurisdictions via Epi-X. In order to plan, could CDC answer the following questions?

- VCS Password: Can CDC send all the VSCs a password they can use to open the files? This is similar to what is done for the current Epi-X postings.

- Image clarification: Can CDC define which image they would like GDIT to send? Is it the initial/primary report only? Is it the View Image page?
- eVAERS manufacturer reports: Does CDC want the information on every tab sent? When printing View Image, eVAERS reports are usually 20+ pages long.
- Sample image: Is it possible for CDC to provide GDIT with a sample image of what is currently sent?

GDIT will draft a SOP for or internal process and will submit to CDC for review.

Thank you,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Wednesday, December 30, 2020 4:52 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4) Miller,

Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4) Suragh,

Tiffany (CDC/DDID/NCEZID/DHQP) <xxi5@cdc.gov>

Subject: RE: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X - GDIT Response

[External Email with Covid-19 Information: Use caution with links & attachments]

Hey (b)(4)

We look forward hearing back from you in regards to posting the VAERS forms (pdfs) to Epi-X to the jurisdictions next week. After some discussion, CDC would like to only request GDIT send VAERS Death reports following Seasonal flu and COVID-19 to jurisdictions via Epi-X. We would like the jurisdictions to be notified about the COVID-19 Deaths in a timely manner but there can be some flexibility in the timing of notification for FLU. There is no need for GDIT to send COVID-19 Anaphylaxis reports to the jurisdictions, CDC plans to continue this task for the next couple of months and then phase it out. Hopefully this additional information will help you in your response next week.

Thanks,

Paige Marquez

From: (b)(4)

Sent: Tuesday, December 29, 2020 1:11 PM

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

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4) Miller,

Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4) Suragh,

Tiffany (CDC/DDID/NCEZID/DHQP) <xxi5@cdc.gov>

Subject: RE: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X - GDIT Response

Hi Paige,

We will define the work on our end and let CDC know our thoughts. I will be able to respond next week.

Thanks,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Tuesday, December 29, 2020 12:51 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4) Miller,

Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4) Suragh,

Tiffany (CDC/DDID/NCEZID/DHQP) <xxi5@cdc.gov>

Subject: RE: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X - GDIT Response

Importance: High

[External Email with Covid-19 Information: Use caution with links & attachments]

Hey (b)(4)

I wanted to follow-up with you on GDIT sending images of all VAERS death reports following seasonal flu and COVID-19, as well as, all VAERS anaphylaxis (serious and nonserious) reports following COVID-19 vaccination to Epi-X for each jurisdiction, once identified. Last week you provided the following response "This is a new requirement, an addition to the current Epi-X SOP, and will take time to discuss with CDC and plan for, especially since it was not included in the contract. We will not be able to have this process in place by 12/28."

I know there have been a lot of emails and discussions about new requested task for GDIT, but I thought we discussed this additional task with you previously. Please let us know what we need to do in order for you guys to start work on this request and if you can provide any tentative start date. I can arrange a call to discuss details, if you like. Traci will be back from leave on Monday. For now, CDC can continue to provide the VAERS reports (password protected pdf) to the jurisdictions. We do appreciate GDIT's hard work on this COVID-19 response.

Thanks,

Paige

From: (b)(4)

Sent: Wednesday, December 23, 2020 10:38 AM

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

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4) Miller,

Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)

Subject: Re: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X - GDIT Response

Hi Paige,

Thank you for the information. I have divided our response into two sections: Epi-X data posting and Epi-X VAERS image submission.

1. Epi-X Data Posting: To be able to post the data files on 12/28, GDIT is requesting the following actions from CDC:

- A finalized recipient list. (b)(4)

(b)(4)
- CDC approves the cover letter that will accompany the 12/28 Epi-X data posting by 5:00 PM today, 12/23. The text for your approval is below and is based on the SOP and our current process for the current Epi-X postings.

A. Template

Brief Summary: The attachment to this report contains a summary of all VAERS reports for COVID-19 vaccines received from your jurisdiction during the specified period.

Report Description:

This *Epi-X* report summarizes all Vaccine Adverse Event Reporting System (VAERS) reports received from your jurisdiction during the reporting period specified above. The following attachments are included:

1. VAERS COVID-19 Jurisdiction data in Excel format. This file is password protected; approved recipients receive the password from the ISO.
2. VAERS COVID-19 Excel File Extraction Directions.
3. Informational Document for VAERS-19 Jurisdiction Excel Sheet.

Should you have any questions about the posting please contact VAERS via email at info@vaers.org.

Vaccine Adverse Event Reporting System

P.O. Box 1100

Rockville, MD 20849-1100

Confidentiality Notices:

- All jurisdictions receiving data/reports are required to sign a non-disclosure agreement, one NDA per public health jurisdiction will be signed. The NDA is kept on file at the Immunization Safety Office (ISO). Request for access should also be submitted to the ISO.
- VAERS reports are being sent to state health authorities in selected metropolitan health departments and U.S. territories only for public health purposes related to vaccine safety. All health authorities who receive these VAERS reports are required under the National Childhood Vaccine Injury Act, at section 2125(c) of the Public Health Service Act [42 U.S.C. 300aa-25c], to

protect the confidentiality of VAERS information as follows: prior to any public release of a VAERS report, redact the name and date of birth.

B. Epi-X Sample Posting

Epi-X: The Epidemic Information Exchange

COVID-19 Vaccine Safety Weekly Summary--American Samoa, December 11 - December 18, 2020

Access and Notification: Make available to all Epi-X users
Click to see who has viewed this report.

Distribution: Do not distribute further

Description: This Epi-X report summarizes all Vaccine Adverse Event Reporting System (VAERS) reports received from your jurisdiction during the reporting period specified above. The following attachments are included:

1. VAERS COVID-19 Jurisdiction data in Excel format. This file is password protected; approved recipients receive the password from the ISO.
2. VAERS COVID-19 Excel File Extraction Directions.
3. Informational Document for VAERS-19 Jurisdiction Excel Sheet.

Should you have any questions about the posting please contact VAERS via email at info@vaers.gov

Vaccine Adverse Event Reporting System
P.O. Box 1100
Rockville, MD 20849-1100

Confidentiality Notice:

- ▶ All jurisdictions receiving data/reports are required to sign a non-disclosure agreement, one NDA per public health jurisdiction will be signed. The NDA is kept on file at the Immunization Safety Office (ISO). Request for access should also be submitted to the ISO.
- ▶ VAERS reports are being sent to state health authorities in selected metropolitan health departments and U.S. territories only for public health purposes related to vaccine safety. All health authorities who receive these VAERS reports are required under the National Childhood Vaccine Injury Act, at section 2125(c) of the Public Health Service Act [42 U.S.C. 300aa-29(c)], to protect the confidentiality of VAERS information as follows: prior to any public release of a VAERS report, redact the name and date of birth.

Report Category: Vaccine-Preventable: Vaccine Safety

Setting: Other

Location: American Samoa

Public Health Actions Taken: Vaccination / Prophylaxis Program

Attachments: Descriptive information, graphs, spreadsheets, or pictures

- ▶ COVID-19 Vaccine Safety Weekly Summary--American Samoa, December 11 - December 18, 2020 (ZIP - 15 KB)
- ▶ Informational Document for VAERS COVID-19 Jurisdiction Excel Sheet (PDF - 237 KB)
- ▶ VAERS COVID-19 Excel file Extraction Directions (PDF - 165 KB)

2. Sending images (unredacted) of all VAERS death reports following seasonal flu and COVID-19 vaccination, as well as, all VAERS anaphylaxis (serious and nonserious) reports following COVID-19 vaccination to Epi-X for each jurisdiction, once identified.

This is a new requirement, an addition to the current Epi-X SOP, and will take time to discuss with CDC and plan for, especially since it was not included in the contract. We will not be able to have this process in place by 12/28.

Please let me know if you would like to meet to discuss.

Thank you,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Wednesday, December 23, 2020 1:19 AM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John

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

(b)(4)

Miller,

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

Subject: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X

[External Email with Covid-19 Information: Use caution with links & attachments]

Please find the following documents attached for your review:

1. SOP for VAERS Data Sharing with Jurisdictions via Epi-X
2. Informational Document for VAERS COVID19 Jurisdiction Excel Sheet (previously referenced as data dictionary)
3. VAERS COVID19 excel file extraction directions

I have also attached a draft Vaccine Safety Weekly Report from Epi-X. Do you have the template for the Epi-X message for the Excel file and Reports already created? If you do, can you please update the document appropriately? If not, CDC will need to develop the language for the report rather quickly. Please let us know.

Can you confirm you will be able to start sending data to jurisdictions on December 28? Also when can you start sending VAERS reports (death/anaphylaxis- COVID19 and death only- FLU)? Please confirm the occurrence you will send the VAERS reports: sent once identified or sent on a weekly basis?

Thanks,
Paige

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

(b)(4)

Obtained by ICANdecide.org via FOIA

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 17 Dec 2020 05:16:11 +0000
To: (b)(4) Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Myers, Tanya R. (CDC/DDID/NCEZID/DHQP); Zinderman, Craig E (FDA/CBER); Woo, Jane (FDA/CBER); Baumblatt, Jane (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Menschik, David (FDA/CBER); Welsh, Kerry (FDA/CBER)
Cc: (b)(4)
Subject: RE: VAERS- COVID19 Moderna vaccine variables

Makes total sense (b)(4) Please ignore my comment about eSub/PDF Drop-down then and only update the vax_name.

Field Name	Value
VAX_CODE	1201
VAX_TYPE	COVID19
VAX_NAME	COVID19 (MODERNA)
VAX_MFG	591
MFG_NAME	MODERNA
eSub/PDF Drop-down	COVID19 (Moderna)

From: (b)(4)
Sent: Wednesday, December 16, 2020 8:26 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; (b)(4)
 (b)(4) Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xt6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vje9@cdc.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>
Cc: (b)(4)
Subject: RE: VAERS- COVID19 Moderna vaccine variables

Hi Paige,

Currently, on the eSub/PDF drop down, vaccines and manufacturers are mixed case. Thus, we did not capitalize it.

Thanks,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Wednesday, December 16, 2020 4:54 PM
To: (b)(4) Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)

<ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vie9@cdc.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>

Cc: (b)(4)

Subject: RE: VAERS- COVID19 Moderna vaccine variables

[External Email with Covid-19 Information: Use caution with links & attachments]

Is there a reason you did not capitalize MODERNA for eSub?

Please update the VAX_NAME to COVID19 (MODERNA) and eSub to COVID19 (MODERNA)

Field Name	Value
VAX_CODE	1201
VAX_TYPE	COVID19
VAX_NAME	COVID19 (MODERNA)
VAX_MFG	591
MFG_NAME	MODERNA
eSub/PDF Drop-down	COVID19 (MODERNA)

From: (b)(4)

Sent: Wednesday, December 16, 2020 4:36 PM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Myers, Tanya R. (CDC/DDID/NCEZID/DHQP) <vie9@cdc.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Baumblatt, Jane (FDA/CBER) <Jane.Baumblatt@fda.hhs.gov>; Alimchandani, Meghna (FDA/CBER) <Meghna.Alimchandani@fda.hhs.gov>; Menschik, David (FDA/CBER) <David.Menschik@fda.hhs.gov>; Welsh, Kerry (FDA/CBER) <Kerry.Welsh@fda.hhs.gov>

Cc: (b)(4)

Subject: VAERS- COVID19 Moderna vaccine variables

Importance: High

Good afternoon,

Below are the proposed variables for the COVID19 Moderna vaccine to be added to VAERS.

Field Name	Value
VAX_CODE	1201

VAX_TYPE	COVID19
VAX_NAME	COVID19 (COVID19 (MODERNA))
VAX_MFG	591
MFG_NAME	MODERNA
eSub/PDF Drop-down	COVID19 (Moderna)

Please let us know if approved and we will proceed to add to the system.

Thanks

(b)(4)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 16 Dec 2020 21:10:20 +0000
To: (b)(4)
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS Covid-related website text 2nd update
Importance: High

Hi (b)(4)

We have already received comments on the website update.

Please make one additional change: when you click on the tab that says: [Click here for guidance to healthcare providers on reporting adverse events to VAERS after COVID-19 vaccination](#) please have the link take you directly to the question: **What adverse events should healthcare providers report to VAERS after Covid-19 vaccination.**

Thanks,
Elaine

From: (b)(4)
Sent: Wednesday, December 16, 2020 2:31 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltid8@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: VAERS Covid-related website text 2nd update

Elaine,

The changes have been moved to Production. This has been completed.

Thanks,
(b)(4)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Wednesday, December 16, 2020 12:56 PM
To: (b)(4)
Cc: Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltid8@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: VAERS Covid-related website text 2nd update
Importance: High

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

This looks great. Please move to production and let me know when this is completed.
Thanks,

Elaine

From: (b)(4)
Sent: Wednesday, December 16, 2020 10:36 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS Covid-related website text 2nd update

Hi Elaine,

Here is the revised update. We added a "click here" in the link under the picture. Please let me know when we can move this to Production.

Thank you,

(b)(4)

<https://www-ua2.vaers.org/reportevent.html>

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

VAERS Home

Home | Report an Adverse Event | en Español

Report an Adverse Event to VAERS

VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

Healthcare providers are required by law to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Click here for guidance to healthcare providers on reporting adverse events to VAERS after COVID-19 vaccination

<https://www-ua2.vaers.org/faq.html>

Privacy

What adverse events should healthcare providers report to Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccination?

Healthcare professionals are **encouraged** to report any clinically significant adverse event following vaccination to VAERS, even if they are not sure if vaccination caused the event.

Healthcare providers are **required** to report the following adverse events after COVID-19 vaccination, and other adverse events if later revised by CDC, to VAERS:

- Vaccination administration errors, whether or not associated with an adverse event
- Severe COVID-19 illness (e.g., resulting in hospitalization)
- Serious adverse events (AEs) regardless of causality. Serious AEs are defined as:
 1. Death;
 2. A life-threatening adverse event;
 3. Inpatient hospitalization or prolongation of existing hospitalization;
 4. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
 5. A congenital anomaly/birth defect;
 6. Cases of observed Multisystem Inflammatory Syndrome.
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

Also report any additional select adverse events and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Wednesday, December 16, 2020 8:25 AM
To: (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS Covid-related website text update
Importance: High

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)
Please see comments below regarding the website update.
Please let us know when this has been completed.
Thanks,
Elaine

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Sent: Tuesday, December 15, 2020 5:49 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS Covid-related website text update

Elaine –

The box on the main VAERS webpage looks good; assume that hovering over that box will reveal that you can click on it to be sent to the VAERS FAQ webpage, correct? For the technological luddites out there, I suggest adding “Click here” in the box to make it more obvious.

The content of the FAQ is also correct.

Thank you.

Kevin

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, December 15, 2020 3:21 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Cc: Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS Covid-related website text update

Agreed. I might suggest bolding the corresponding text in the COVID-19 language, for consistency, but it's not a deal-breaker. Thanks!

■ John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Tuesday, December 15, 2020 3:19 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS Covid-related website text update
Importance: High

John and Kevin,
This looks good to me. Please let me know if you agree.
Thanks,
Elaine

From: (b)(4)
Sent: Tuesday, December 15, 2020 3:13 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>;

Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Subject: FW: VAERS Covid-related website text update

Hi Elaine,

Here are new screenshots for your review. We have added a label below the image that takes user to the FAQ page, as requested. Please let me know if we can move these changes to Production.

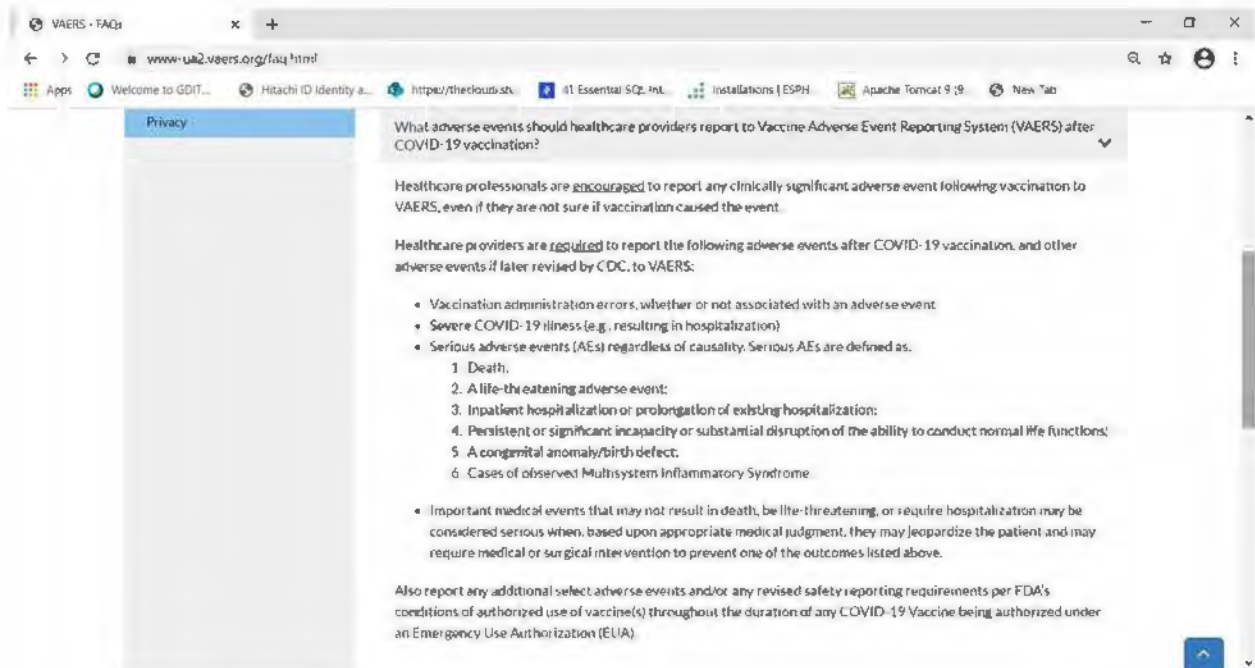
Thank you,

(b)(4)

<https://www-ua2.vaers.org/reportevent.html>



<https://www-ua2.vaers.org/faq.html>



From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Tuesday, December 15, 2020 1:07 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>; (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fisy1@cdc.gov>
Subject: RE: VAERS Covid-related website text update

[External Email with Covid-19 Information: Use caution with links & attachments]

Thanks Kevin---I am adding (b)(4) to this email. Her team will post this to info to the HHS website.

Hi (b)(4) -Please see box below for edits to the posting. Also see the emails below (red circled area) showing what we want this to look like and **let us know if you have questions.**

What adverse events should healthcare providers report to Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccination?

Healthcare professionals are encouraged to report any clinically significant adverse event following vaccination to VAERS, even if they are not sure if vaccination caused the event.

Healthcare providers are required to report the following adverse events after COVID-19 vaccination, and other adverse events if later revised by CDC, to VAERS:

- Vaccination administration errors, whether or not associated with an adverse event
- Severe COVID-19 illness (e.g., resulting in hospitalization)
- Serious adverse events (AEs) regardless of causality. Serious AEs are defined as:
 - 1) Death;
 - 2) A life-threatening adverse event;
 - 3) Inpatient hospitalization or prolongation of existing hospitalization;
 - 4) Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
 - 5) A congenital anomaly/birth defect;
 - 6) Cases of observed Multisystem Inflammatory Syndrome
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

Also report any additional select adverse events and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).

From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>

Sent: Tuesday, December 15, 2020 1:01 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>

Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Thombley, Melisa L. (CDC/OCOO/OGC) <fsy1@cdc.gov>

Subject: RE: VAERS Covid-related website text update

Elaine –

This looks good. Let me know if you have any questions about the content of the referral box (with the weblink to the VAERS FAQ webpage) that will appear on the main VAERS webpage.

Thank you.

Kevin

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

Sent: Tuesday, December 15, 2020 10:45 AM

To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>; Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>

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

<ltd8@cdc.gov>

Subject: RE: VAERS Covid-related website text update

Kevin and Valerie,

Please see revisions in box below and let me know if correct.

We will also send the photo underneath to help VAERS know what we want it to look like.

Thanks,

Elaine

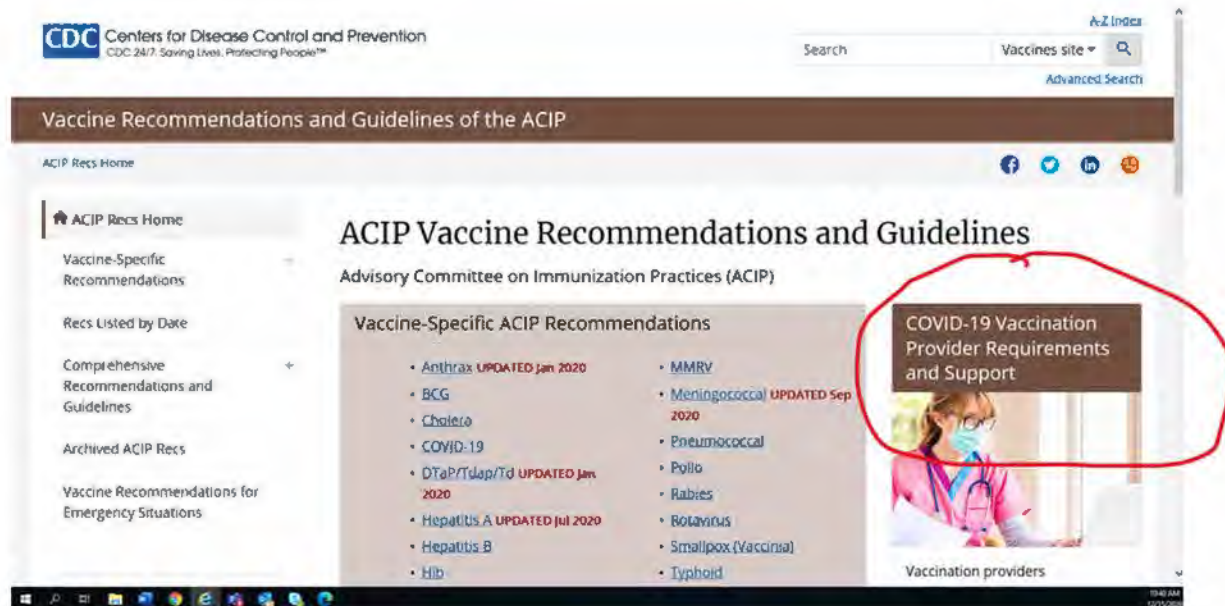
What adverse events should healthcare providers report to Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccination?

Healthcare professionals are encouraged to report any clinically significant adverse event following vaccination to VAERS, even if they are not sure if vaccination caused the event.

Healthcare providers are required to report the following adverse events after COVID-19 vaccination, and other adverse events if later revised by CDC, to VAERS:

- Vaccination administration errors, whether or not associated with an adverse event
- Severe COVID-19 illness (e.g., resulting in hospitalization)
- Serious adverse events (AEs) regardless of causality. Serious AEs are defined as:
 1. Death;
 2. A life-threatening adverse event;
 3. Inpatient hospitalization or prolongation of existing hospitalization;
 4. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
 5. A congenital anomaly/birth defect;
 6. Cases of observed Multisystem Inflammatory Syndrome
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

Also report any additional select adverse events and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).



From: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>

Sent: Tuesday, December 15, 2020 1:53 AM

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

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>; Morelli, Valerie (CDC/DDID/NCIRD/ISD) <vxm4@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Subject: RE: VAERS Covid-related website text update

Elaine –

As you know, since COVID-19 vaccines are not included in the VICP, VAERS reporting for COVID-19 vaccines is not required under the National Childhood Vaccine Injury Act. However, by making VAERS reporting a requirement in the provider agreements for the CDC COVID-19 vaccination program, the providers enrolled in the program are contractually required to file such VAERS reports. The more recent provider agreements for the program already include the AE list below (except for reporting Multisystem Inflammatory Syndrome). The earlier provider agreements more generically just require reporting of moderate and severe adverse events without further elaboration. The purpose of the online posting through the VAERS website is to explicitly require the reporting listed below for all providers in the program.

To be consistent in the layout to the VAERS reporting references on the CDC COVID-19 Vaccination Program Provider Requirements and Support webpage, please move “Multisystem Inflammatory Syndrome” to # 6 under serious adverse events and make the current # 6 a bullet.

In addition, since the main VAERS webpage (<https://vaers.hhs.gov/reportevent.html>) is referenced in the COVID-19 vaccination provider agreements, please add a box, or other reference, on that main VAERS webpage that includes a weblink through to the VAERS FAQ webpage that will include the COVID-

19 vaccine AE reporting to VAERS as listed below. An example of that box can be seen on the ACIP website at: www.cdc.gov/vaccines/hcp/acip-recs/index.html and is titled "COVID-19 Vaccination Provider Requirements and Support." Clicking on that box goes to a CDC COVID-19 Vaccination Program Provider Requirements and Support webpage where updated requirements for the provider agreements are listed. Rather than having the VAERS cover page box click through to that webpage, you could have it click through to the VAERS FAQ webpage you list below. Please talk with Valerie Morelli regarding your preferences and the possible layout for the click-through box on the VAERS main webpage. Note that the COVID-19 Vaccination Provider Requirements and Support webpage, under "Requirements for Reporting to VAERS," will also include the same VAERS reporting requirements listed on the VAERS FAQ webpage. In addition, that section could include a weblink to the VAERS FAQ webpage.

Let me know if you have any questions.

Thanks.

Kevin

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Monday, December 14, 2020 4:06 PM
To: Malone, Kevin M. (CDC/OCOO/OGC) <kmm2@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>
Subject: RE: VAERS Covid-related website text update
Importance: High

Hi Kevin,
Please see the updates to VAERS regarding reporting requirements for COVID-19 vaccine.
Let us know if you have any edits. Once you clear, we will have this posted to the VAERS website.
Thanks,
Elaine

From: (b)(4)
Sent: Monday, December 14, 2020 3:21 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Gallego, Ruth (CDC/DDID/NCEZID/DHQP) <ltd8@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: Re: VAERS Covid-related website text update

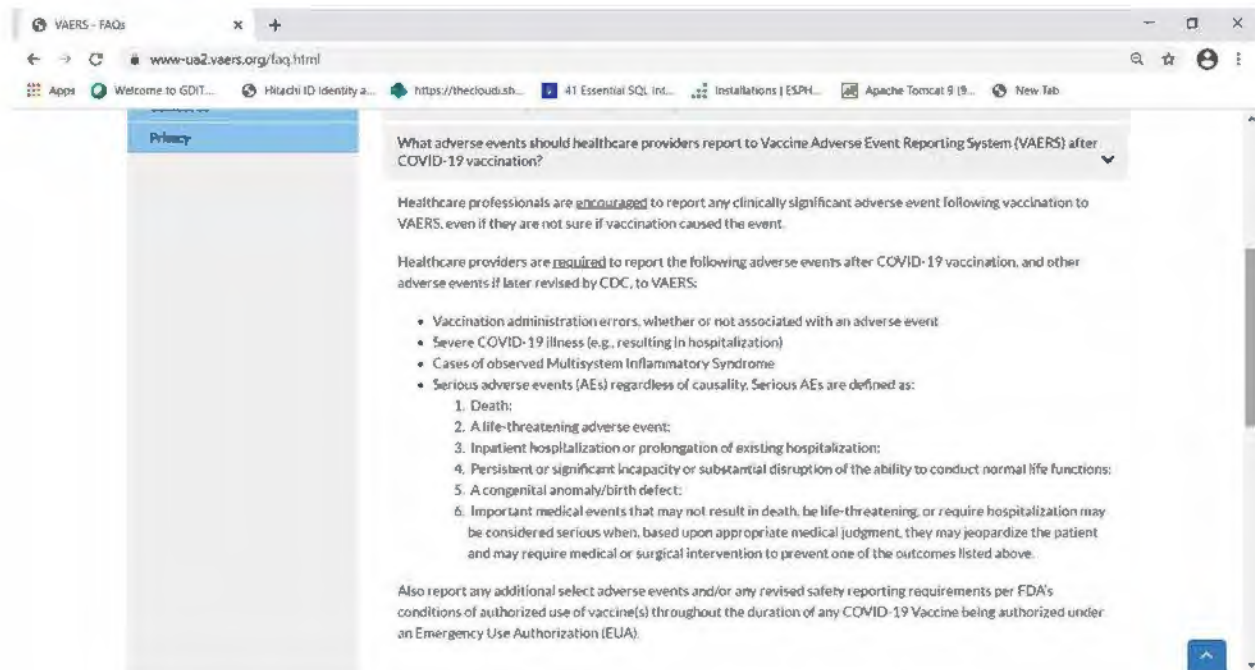
Hi Elaine,

Here is the draft for CDC's review. You can access the draft pages using the links below. Please let me know when it is ready to go live as soon as possible.

Thanks,

(b)(4)

<https://www-ua2.vaers.org/faq.html>



VAERS - FAQs

What adverse events should healthcare providers report to Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccination?

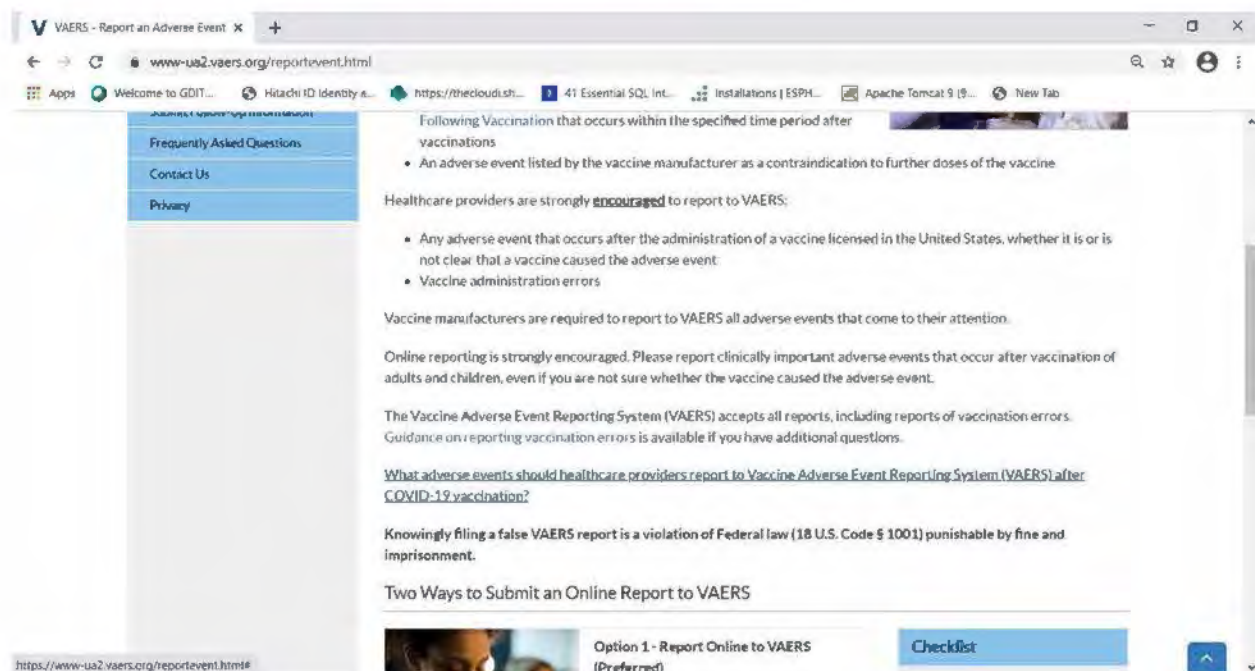
Healthcare professionals are **encouraged** to report any clinically significant adverse event following vaccination to VAERS, even if they are not sure if vaccination caused the event.

Healthcare providers are **required** to report the following adverse events after COVID-19 vaccination, and other adverse events if later revised by CDC, to VAERS:

- Vaccination administration errors, whether or not associated with an adverse event
- Severe COVID-19 illness (e.g., resulting in hospitalization)
- Cases of observed Multisystem Inflammatory Syndrome
- Serious adverse events (AEs) regardless of causality. Serious AEs are defined as:
 1. Death;
 2. A life-threatening adverse event;
 3. Inpatient hospitalization or prolongation of existing hospitalization;
 4. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
 5. A congenital anomaly/birth defect;
 6. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

Also report any additional select adverse events and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).

<https://www-ua2.vaers.org/reportevent.html>



VAERS - Report an Adverse Event

Following Vaccination that occurs within the specified time period after vaccinations

- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

Online reporting is strongly encouraged. Please report clinically important adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

The Vaccine Adverse Event Reporting System (VAERS) accepts all reports, including reports of vaccination errors. Guidance on reporting vaccination errors is available if you have additional questions.

What adverse events should healthcare providers report to Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccination?

Knowingly filing a false VAERS report is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

Two Ways to Submit an Online Report to VAERS

Option 1 - Report Online to VAERS (Preferred)

Checklist

The screenshot shows a web browser window with the address bar displaying `www.va2.vaers.org/reportevent.html`. The browser's tab bar shows several open tabs, including "VAERS - Report an Adverse Event", "Welcome to GDIT...", "Hitachi ID Identity a...", "https://thecloudish...", "41 Essential SQL Int...", "Installations | ESPH...", "Apache Tomcat 9 (9...", and "New Tab".

The main content area of the browser displays a "Guidance on Reporting Adverse Events after COVID-19 Vaccination" pop-up window. The pop-up has a blue header with the title and a close button. The content is organized into sections:

- Frequently Asked Questions** (link)
- Contact Us** (link)
- Privacy** (link)

Guidance on Reporting Adverse Events after COVID-19 Vaccination

Healthcare professionals are **encouraged** to report any clinically significant adverse event following vaccination to VAERS, even if they are not sure if vaccination caused the event.

Healthcare providers are **required** to report the following adverse events after COVID-19 vaccination and other adverse events if later reviewed by CDC to VAERS:

- Vaccination administration errors, whether or not associated with an adverse event
- Severe COVID-19 illness (e.g., resulting in hospitalization)
- Cases of observed Multisystem Inflammatory Syndrome
- Serious adverse events (AEs) regardless of causality. Serious AEs are defined as:
 1. Death;
 2. A life-threatening adverse event;
 3. Inpatient hospitalization or prolongation of existing hospitalization;
 4. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
 5. A congenital anomaly/birth defect;
 6. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

Also report any additional select adverse events and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).

Checklist

What information do I need to report?

- Patient information (age, sex, etc.)
- Vaccine information (date, lot, etc.)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 24 Mar 2021 17:40:18 +0000
To: (b)(4)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS Death report id=(b)(6) (unable to locate in HI weekly spreadsheet via Epi-X)

Thanks for the update Stacey.

Just to clarify, the reporter said "I do not know which Covid-19 vaccine my mother had received" and you guys edited/updated the government data to unknown COVID19 vaccine. The public data and epi-x weekly spreadsheet will show the originally reported vaccine "VACCINE NOT SPECIFIED (NO BRAND NAME)".

From: (b)(4)
Sent: Wednesday, March 24, 2021 1:15 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS Death report id=(b)(6) (unable to locate in HI weekly spreadsheet via Epi-X)

Paige,

As a follow-up: in Box 18 reporter says they don't know which vaccine it was. Such reports should be changed to Unknown COVID vax in Original report the first time the report is redacted since EpiX uses Original data. The vaccine was then corrected so it was included in the priority emails and sent via Epi-X on 1/27.

The EpiX sheets are incremental & the requirement is to use the first time the report is processed as the cutoff date for the weekly file.

Thanks,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Monday, March 15, 2021 12:26 AM
To: (b)(4)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)
(b)(4)
Subject: VAERS Death report id=(b)(6) (unable to locate in HI weekly spreadsheet via Epi-X)

[External: Use caution with links & attachments]

Hey (b)(4)

The VSC from Hawaii contacted Elaine last week about the VAERS Death report id=(b)(6) They were not able to locate this id in their weekly Epi-X spreadsheet.

I investigated, hoping I could solve the issue myself. I was able to see (b)(6) was received by VAERS on Jan. 25th at 6:54pm via web. GDIT posted the VAERS Image via Epi-X to Hawaii on January 27th. I looked at the spreadsheet HI received on Feb 5, 2021 since that spreadsheet includes reports received and processed Jan 22-29. It's not there. I also looked at the spreadsheet sent out the following week, it is not in there either. The cumulative worksheet that shows the number of deaths per jurisdictions for both versions (data posted on Epi-X Feb 5 and 12) only show 5 deaths when it should say 6 for these specific time frames.

Do you know why this id was not in the spreadsheet for reports received and processed Jan 22-29 (posted on Epi-X Feb 5)?

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 19 Apr 2021 16:54:55 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS electronic document request

No-we will deal with it as it. I think there are other more important priorities. I didn't realize it would require this.

From: (b)(4)
Sent: Monday, April 19, 2021 12:40 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: VAERS electronic document request

Hi Elaine,

(b)(4)

Thanks,

(b)(4)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Monday, April 19, 2021 12:17 PM
To: (b)(4)
Subject: RE: VAERS electronic document request

[External: Use caution with links & attachments]

Thank you

From: (b)(4)
Sent: Monday, April 19, 2021 12:12 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: RE: VAERS electronic document request

Hi Elaine,

This is automated. We are discussing how best to approach your request.

Thanks,

(b)(4)

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

Sent: Monday, April 19, 2021 11:04 AM

To: (b)(4)

Subject: FW: VAERS electronic document request

[External: Use caution with links & attachments]

(b)(4)

Please ask your staff to include the **VAERS ID numbers** in the title or somewhere in the email that contains the auto-upload key..

Thanks,
Elaine

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

From: info@vaers.org <info@vaers.org>

Sent: Monday, April 19, 2021 9:53 AM

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

Subject: VAERS electronic document request

Thank you for contacting the Vaccine Adverse Event Reporting System (VAERS) program.

We have received a report of possible adverse reactions following a patient's vaccination. You are welcome to use the VAERS Auto Upload online tool to submit additional information. In order to maintain confidentiality a one-time-use secure key has been created for this case.

* Upload Patient Information Using the Link Below:

<https://vaers.hhs.gov/upload>

(b)(6)

* If you have trouble accessing this link please visit <https://vaers.hhs.gov/upload>

and use Upload Session Key:

(b)(6)

For additional information about the VAERS Auto Upload tool please visit the following page <http://vaers.hhs.gov/autoupload> or contact us.

Thank you again for your collaboration.

VAERS

Tel: (800) 822-7967

Fax: (877) 721-0366

E-mail: info@vaers.org

Website: <http://vaers.hhs.gov>

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 19 Nov 2021 15:53:14 +0000
To: (b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP); (b)(4) Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS hoax reports ?

Hi (b)(4)

In the case of these two specific VAERS IDs (b)(6) I think CDC can remove them from the extract on our end (Paige, please check me on that). Please remove them from the CDC WONDER and vaers.hhs.gov .csv data if they haven't already been updated; the data typically refresh on Fridays (?), so if they just went out today, I think we can remove them without issue. If they've been out a week or so already, maybe just leave it alone.

Going forward, if we (GDIT and/or CDC) identify such questionable reports, please manage them in such a way *that they do not enter the publicly available data* (and the governmental database either). The whole goal is to prevent potentially false/hoax/fake reports from corrupting the VAERS database and undermining the usability of VAERS data – publicly, and on the government side.

We'd proposed a "quarantine folder" in which such reports would reside, where these reports would not show up in either the public or government data, but would be accessible for review or other action (e.g., referral to legal authorities). I understand developing such a folder and the coding to route to it will take time to develop. I'm not wedded to any process – but what is imperative is that we identify and prevent from reaching the VAERS database any reports of a potentially false or deceptive nature.

How that process occurs in the immediate, shorter, and longer-term, I think can be at GDIT's discretion; just please keep us informed of what and how you're doing. But especially for reported deaths, and among 5-11 yo persons in particular, *we need to be vigilant about keeping these potentially false reports from entering the database.*

(b)(5) We are in the process of drafting an addendum to the disclaimer to make public that VAERS has the jurisdiction to set aside potentially false reports. Once that language is added, I understand we can quarantine any potentially false reports of which we are aware – both prospectively, and retrospectively. I recognize that operationalizing this approach will require navigating details the scope of which is beyond this email; we can discuss those details later.

Please let me know if you have any questions. Thanks!

• John

From: (b)(4)
Sent: Friday, November 19, 2021 10:32 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; (b)(4)
Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Roberts, Traci Sinetta
(CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS hoax reports ?

Good Morning,

Are you asking GDIT to remove these reports from all extracts? I think some have already gone out but will need to check.

Also, please note that we do not have a quarantine" process folder yet. These reports will need to be manually removed.

Thanks for your guidance.

(b)(4)

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com
OOO: 11/22 – 11/26

GENERAL DYNAMICS
Information Technology

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Friday, November 19, 2021 8:21 AM
To: (b)(4) Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: (b)(4) Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: FW: VAERS hoax reports ?

[External: Use caution with links & attachments]

Thanks John.

Ana-how did you all identify these hoax reports?

Thanks,

Elaine

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

Sent: Thursday, November 18, 2021 5:58 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; (b)(4)

(b)(4) Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: VAERS hoax reports ?

Hi Elaine,

(b)(5)

• John

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

Sent: Thursday, November 18, 2021 4:54 PM

To: (b)(4) Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>;

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

Subject: RE: VAERS hoax reports ?

Pedro, John:

I think these reports are probably false. Do you agree?

Thanks,

Elaine

From: (b)(4)

Sent: Thursday, November 18, 2021 1:26 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: VAERS hoax reports ?

Hi,

We've come across the following reports for which we are unsure if they should be considered hoax reports.

(b)(6)

Your input is appreciated.

Thanks

(b)(4)

Medical Affairs Advisor/Clinical Lead VAERS
Federal Civilian Division

(b)(4)

www.gdit.com

GENERAL DYNAMICS
Information Technology

From: (b)(4)
Sent: Wed, 23 Jun 2021 16:30:12 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); (b)(4)
Subject: RE: VAERS IDs for GBS reports after Janssen COVID-19 vaccine - GDIT
Attachments: Copy of janssen-gbs-vaersID_GDIT Update.xlsx

Hi John,

An update for each case is attached.

Thank you,

(b)(4)

From: (b)(4)
Sent: Wednesday, June 23, 2021 10:30 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; (b)(4)
Subject: RE: VAERS IDs for GBS reports after Janssen COVID-19 vaccine

Hi John,

We will check and let you know.

Thanks,

(b)(4)

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Wednesday, June 23, 2021 9:32 AM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: VAERS IDs for GBS reports after Janssen COVID-19 vaccine

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4)

Just thought I'd follow up on the below email. Public attention to GBS is rapidly growing (see enclosed), and we need to obtain medical records for reported GBS as quickly as possible for review. For how many of these reports (the Excel spreadsheet) do we have records at the moment?

- John

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tuesday, June 15, 2021 11:26 AM
To: [REDACTED] (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: VAERS IDs for GBS reports after Janssen COVID-19 vaccine

Hi folks,

There's growing interest among multiple stakeholders (CDC, ACIP, etc.) about Guillain-Barre Syndrome (GBS) after Janssen vaccine. Please see the enclosed list of VAERS IDs. May we prioritize obtaining records for these VAERS IDs? I realize just about everything is a priority right now, but I'm hoping this request will be a one-time ask.

If I had to rank priorities:

1. This list of reported GBS
2. Myopericarditis
3. TTS
4. Serious reports after COVID-19 vaccines

Please let me know if you have any questions. Thanks!

- John

From: Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>
Sent: Tuesday, June 15, 2021 9:56 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Nair, Narayan (FDA/CBER) <Narayan.Nair@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: VAERS IDs for GBS reports after Janssen COVID-19 vaccine

Hello John,

As discussed, we are providing the VAERS IDs for the 80 reports of GBS after Janssen (attached). Appreciate it if GDIT could try to prioritize obtaining follow-up/medical records for these cases. Thanks.

Best regards,
Meghna

VAERS ID	RECS REQUESTED	RECS RECEIVED	NOTES
(b)(6)	Y	SOME	Received all records except DC Summary for 3/23/21. Requested that record on 6/8/21. All current records have been abstracted and coded.
	Y	N	Records requested with a response back of patient not in their system. No records available.
	Y	N	Have vaccine rec and an email from patient. Waiting on medical records.
	Y	SOME	Facility emailed records on 6/21/21. Not in Initial records received, abstracted and coded. Waiting on records from patient's transfer to ICU and D/C Summary.
	Y	N	No records received. Have emailed and faxed record requests with no response currently.
	Made several calls to patient.		
	LVM.	N	No records. Have called patient (reporter) many times x 2 days with no response.
	Y	N	Records received per Julie Turnage.
	Y	SOME	Waiting on upload from DE Team.
	Y	Y	Received some records. All current records have been abstracted and coded.
	Y	Y	Waiting on additional recs in order to close All records abstracted and coded. Case closed.
	Y	Y	All records abstracted and coded. Case closed.
	Y	SOME	Have vaccine record. Medical records were mailed on 6/17/21 per facility.
	Y	Y	All records abstracted and coded. Case closed.
	Y	SOME	Have vaccine record. Have emailed and called for status of medical records. Had to leave voice mail and no response from email.
	Y	SOME	All records abstracted and coded. Waiting on death certificate.
	Y	SOME	D/C Summary received abstracted and coded. Waiting on in-patient records from facility in order to close case.
	Y	N	No records received. Have faxed request several times with no records received.
	Y	N	No records received. Have emailed and faxed record requests with no response currently.

(b)(6)

Y	SOME	All records received abstracted and coded. Waiting on most recent records from facility in order to close case.
Y	SOME	All records received abstracted and coded. Waiting on additional records from facility in order to close case.
Y	N	No records received. Faxed request sent. No records received. Spoke with facility on 6/21/21. "Request will be escalated today to be faxed. Previously mailed recs on 6/18/21."
Y	N	No records received. Spoke with facility on 6/15/21 "sent recs back on 4/20/21 but will resend by email today."
Y	N	No records received. Fax and email rec requests sent. Call made to PCP office rec medical records. No response.
Y	N	No records received. Fax and email rec requests sent. No response.
Y	SOME	Vaccine rec received. Spoke with facility on 6/15/21: refaxed medical records.
Y	N	Recs requested several times, only vax rec received, reminder emailed
Y	N	Recs requested several times, none received, reminder emailed
Y	Y	Recs received, abstracted, closed
Y	N	Recs requested several times, none received, reminder emailed
Y	SOME	Recs requested several times, only vax rec received, reminder emailed
Y	SOME	Recs requested several times, only vax rec received, reminder emailed
Y	N	Recs received but not on case other than vax, emailed to find MR
Y	N	Recs requested 6/15, nothing received.
Y	N	Emailed to re-req
Y	Y	Recs received, abstracted, closed
Y	Y	Recs received, abstracted, closed
Y	N	Recs requested 5/16, nothing received, Emailed to re-req
Y	SOME	Recs received, abstracted, closed w missing, neuro f/u recs being sent by today, instructed to reopen and check on the missing MR
Y	Y	Recs received, abstracted, closed
Y	SOME	Recs requested, have vax, missing hosp.
Y	Y	Emailed to re-req
Y	Y	Recs received closed

(b)(6)

Y	N	Recs requested several times, none received, reminder emailed
Y	N	Recs requested 6/15, nothing received.
Y	Y	Emailed to re-req
Y	Y	Recs received, abstracted, closed
Y	Y	Recs received, abstracted, closed
Y	N	Recs requested several times, none received, reminder emailed
Y	N	Recs requested several times, none received, reminder emailed
Y	N	Recs requested several times, none received, reminder emailed
Y	Y	Recs received, abstracted, closed
Y	SOME	Recs received, abstracted, missing DC - requested, reminder emailed
Y	N	Recs requested 6/15, nothing received.
Y	N	Emailed to re-req
Y	SOME	Vax recs received, hosp recs req 5/6, emailed to request
Y	Y	Recs received, not abstracted, emailed to abstract
Y	N	Recs requested 2x, nothing received.
Y	N	Emailed reminder
Y	N	
Y	N	
Y	N	
Y	N	Recd other corresp w/missing info
Y	N	
Y	Y	Recd vax, missing hosp
Y	Y	Recd hosp, vax, OB/GYN
Y	Y	Recd hosp, missing vax
Y	N	
Y	Y	Recd hosp, missing vax
Y	Y	Recd hosp, missing vax
Y	N	
Y	Y	Recd pcp, hosp. Missing vax
Y	Y	Recd vax, hosp. COMPLETE
Y	N	
Y	Y	Recd vax, hosp. COMPLETE
Y	Y	Recd hosp. Missing vax
Y	Y	Recd vax and hosp
Y	N	
Y	Y	Recd vax. Missing hosp
Y	N	
Y	N	

(b)(6)

Y
Y
Y
Y

Y
N
N
N

Recd PCP, Hosp

Recd email from Pt

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 23 Jun 2021 13:31:36 +0000
To: (b)(6)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS IDs for GBS reports after Janssen COVID-19 vaccine
Attachments: FW: AZ vaccine and GBS, janssen-gbs-vaersID.xlsx

Hi (b)(6)

Just thought I'd follow up on the below email. Public attention to GBS is rapidly growing (see enclosed), and we need to obtain medical records for reported GBS as quickly as possible for review. For how many of these reports (the Excel spreadsheet) do we have records at the moment?

• John

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tuesday, June 15, 2021 11:26 AM
To: (b)(6)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: VAERS IDs for GBS reports after Janssen COVID-19 vaccine

Hi folks,

There's growing interest among multiple stakeholders (CDC, ACIP, etc.) about Guillain-Barre Syndrome (GBS) after Janssen vaccine. Please see the enclosed list of VAERS IDs. May we prioritize obtaining records for these VAERS IDs? I realize just about everything is a priority right now, but I'm hoping this request will be a one-time ask.

If I had to rank priorities:

1. This list of reported GBS
2. Myopericarditis
3. TTS
4. Serious reports after COVID-19 vaccines

Please let me know if you have any questions. Thanks!

• John

From: Alimchandani, Meghna <Meghna.Alimchandani@fda.hhs.gov>
Sent: Tuesday, June 15, 2021 9:56 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Nair, Narayan (FDA/CBER) <Narayan.Nair@fda.hhs.gov>; Zinderman, Craig E (FDA/CBER) <Craig.Zinderman@fda.hhs.gov>; Woo, Jane (FDA/CBER) <Jane.Woo@fda.hhs.gov>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <Adamma.Mba-Jonas@fda.hhs.gov>; Shimabukuro, Tom

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

Subject: VAERS IDs for GBS reports after Janssen COVID-19 vaccine

Hello John,

As discussed, we are providing the VAERS IDs for the 80 reports of GBS after Janssen (attached).
Appreciate it if GDIT could try to prioritize obtaining follow-up/medical records for these cases. Thanks.

Best regards,
Meghna

VAERS ID

(b)(6)

(b)(6)

From: (b)(6)
Sent: Tue, 23 Nov 2021 15:19:18 +0000
To: Amador, Nathan (CDC/OCOO/OFR/OAS)
Cc: (b)(6) Roberts, Traci Sinetta
(CDC/DDID/NCEZID/DHQP); Schreiber, David
Subject: RE: VAERS SARS-CoV-2 75D30120F09621 - GDIT Request

Nathan,

This is to confirm receipt and thank you so very much for the response.

Kindest regards~

(b)(6)

Contracts Administrator Advisor
Federal Civilian

(b)(6)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: November 25-29, 2021
December 24 – 31, 2021

GENERAL DYNAMICS
Information Technology

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From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Sent: Tuesday, November 23, 2021 10:04 AM
To: (b)(6)
Cc: (b)(6) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS SARS-CoV-2 75D30120F09621 - GDIT Request

[External: Use caution with links & attachments]

Good Morning,

Pursuant to the terms of your contract, contractor employees are excused for Federal Holidays:

“CDCA_H037 Observance of Legal Holidays and Administrative Leave (Government Facilities Performance) (Jul 2021)

(a) Holidays

Government personnel observe the following listed days as holidays:

Washington's
Birthday
Memorial Day
Juneteenth
Independence
Day Labor Day
Veterans'
Day
Thanksgivin
g Day
Christmas
Day New
Year's Day
Columbus
Day
Martin Luther King Day

Any other day designated by Federal
Statute Any other day designated by
Executive Order
Any other day designated by Presidential proclamation

For purposes of contract performance, the Contractor shall observe the above holidays on the date observed by the Government. Observance of such days shall not be cause for an additional period of performance or entitlement to compensation except as otherwise set forth in the contract. No form of holiday or other premium compensation will be reimbursed; however this does not preclude reimbursement for overtime work authorized in writing by the Contracting Officer.

(b) Unscheduled Facility Closures

In the event Government facilities are closed due to inclement weather, potentially hazardous or unsafe conditions, or other special circumstances, contractor personnel assigned to work within those facilities are automatically dismissed. Notwithstanding the terms herein, the contractor shall comply with any specific contract terms that require a level of ongoing support for critical operations during times of facility closure. The contractor may also continue to provide support under a scheduled telework arrangement in accordance with the terms of the contract if the contract expressly authorizes telework in writing.

(c) Cost Impact

Accounting for costs associated with an unscheduled facility closure is unique to each contract and depends upon a number of factors such as:

- i) Contract type, e.g. Fixed Price, Time and Materials, or Cost Reimbursement.
- ii) Contractor's established management and accounting practices for unproductive time.
- iii) The inclusion and applicability of other contract terms & conditions.
- iv) The ability of the contractor to mitigate costs by reassigning employees to work on other contracts, to work from a different facility, or to work remotely from home in accordance with contract telework provisions."

As for the work load and contract goals of the contract, as these are T&M, it is understood that the level of effort and output will fluctuate and may be lower during the Holiday season, and that an increased level of effort is appropriate to make up for efforts after Holiday weeks, where there may be an understandable drop-off due to CTR employee leave.

This is not written authorization for overtime work during Holidays.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(6)
Sent: Tuesday, November 23, 2021 9:26 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Cc: (b)(6)
Subject: RE: VAERS SARS-CoV-2 75D30120F09621 - GDIT Request
Importance: High

Good Morning Nathan,

Per my email below and our recent conversation, we kindly request response so we can communicate to our team and plan accordingly.

Kindest regards~

(b)(6)

Contracts Administrator Advisor
Federal Civilian

(b)(6)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: November 25-29, 2021
December 24 – 31, 2021

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Information Technology

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From: (b)(6)
Sent: Monday, November 15, 2021 8:24 PM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Cc: (b)(6)
Subject: RE: VAERS SARS-CoV-2 75D30120F09621 - GDIT Request

Good Evening Nathan,

With the upcoming holidays and how it pertains to the contract deliverables, GDIT kindly requests relief during holiday weeks. GDIT PM will let the COR know that we will be short during the holiday weeks, but will meet the volume requirement in November and December on an average basis.

Please reply to this email to confirm receipt and let me know if you wish to discuss on a call.

Thank you for your time and consideration.

(b)(6)

Contracts Administrator Advisor
Federal Civilian

(b)(6)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: November 17-18, 2021 (Training)
November 24-26, 2021
December 24 – 31, 2021

GENERAL DYNAMICS
Information Technology

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From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 18 Feb 2022 18:11:08 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SOP for Quarantined reports
Attachments: (b)(6).pdf

(b)(5)

• John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Wednesday, February 16, 2022 3:52 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: VAERS SOP for Quarantined reports
Importance: High

Hello John,

On today's VAERS Surge call, we discussed the VAERS SOP for quarantined reports (attached). We need to get your feedback on what to do with these quarantined reports? Will they be adjudicated for a final disposition? (Delete, restore, or remain in quarantine)? Can CDC designate someone to serve as a POC for reviewing these reports? If so, can CDC propose a timeframe for feedback to GDIT to reinstate the vaers_id as valid?

FYI: GDIT currently provides a monthly consolidated list of quarantined reports to CDC and they send a weekly report (Wednesday) to CDC with IDs of cases quarantined and restored in the past week.

Paige Marquez
Statistician | Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office 404.639-4709
fqv9@cdc.gov

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 23 Feb 2022 01:54:24 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SOP for Quarantined Reports
Attachments: VAERS SOP for Quarantined Reports.docx

Hello,

I discussed the timeline of holding quarantined reports with John after the call. For now, CDC requests to quarantine suspected reports indefinitely. CDC will discuss with their leadership to develop firmer guidelines knowing the amount of quarantine reports will accumulate over time. Please see revised version attached.

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Monday, February 7, 2022 2:50 PM
To: (b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4)
(b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS SOP for Quarantined Reports

Hey (b)(4)

Do you think your timeframes will differ if you identify a hoax report internally at GDIT? I would think you guys would still use the Friday before 2pm or after 2pm cutoff but maybe you have a different set.... (2pm is an approximation, if you have the exact time, please share). Please do share though... the more information the better.

Ohhh and please note I did update the Table in the document after I sent you guys the document on the 28th but forgot to send updated version. (thanks for reminding me Jennifer)

This version has some corrections to the table and some feedback provided by Jennifer for CDC to consider on page 1.

From: (b)(4)
Sent: Monday, February 7, 2022 11:46 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; (b)(4)
(b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS SOP for Quarantined Reports

Hi Paige,

We will send today. My question is that this document covers the process for when the government requests a report be quarantined. Do you think timeframes should be included for when GDIT quarantines a report as well?

Thanks,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>

Sent: Monday, February 7, 2022 10:54 AM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>;

(b)(4)

(b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Subject: FW: VAERS SOP for Quarantined Reports

[External: Use caution with links & attachments]

Reminder to send comments/edits by COB today. Thanks!

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)

Sent: Friday, January 28, 2022 8:11 PM

To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>;

(b)(4)

(b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Subject: VAERS SOP for Quarantined Reports

I have attached my draft version of VAERS SOP for Quarantined reports. Please make comments and edits as you see fit by February 7. THANKS!!!

Paige Marquez

Statistician | Immunization Safety Office

CDC | Division of Healthcare Quality Promotion

Office 404.639-4709

fqv9@cdc.gov

Version: 02.22.2022

VAERS SOP for Quarantined Reports

When a VAERS_id is requested to be quarantined by CDC, GDIT reviews the report and moves the VAERS_id (all orders) to a restricted location. Once moved the VAERS_id will not be available in the data extracts. GDIT currently sends a monthly report of consolidated quarantined reports to CDC for review. In the future, GDIT will send a weekly report (Wednesday) to CDC with IDs of cases quarantined and restored in the past week. For now, CDC requests to quarantine suspected reports indefinitely. CDC will discuss with their leadership to develop firmer guidelines knowing the amount of quarantine reports will accumulate over time.

If CDC request a VAERS_id to be quarantined

- before public data starts processing (Friday 2pm), GDIT will confirm it is not in the public data extracts (WONDER, HHS, and Epi-X)
- after public data starts processing (Friday 2pm), GDIT will perform the following steps
 - posting of public data may be delayed if a VAERS_ID removal request is submitted late (i.e after 2pm on Thursday)

Steps:

1. Manually update WONDER file
 - a. If the file has not been sent to CDC, GDIT will manually remove the id(s) from 3 WONDER files (events_long\symptoms\vaccines)
 - b. If the file has already been sent to CDC, CDC will manually remove the id(s) from 3 WONDER files and make data available to WONDER team
2. Manually update HHS files
 - a. GDIT will manually remove the id(s) from 3 HHS files (events\symptoms\vaccines) and post new file to VAERS site
3. Manually update Epi-X files
 - a. GDIT will manually remove the id(s) from directly related Epi-X files prior to posting to Epi-X. This includes the following task*:
 - i. Remove the id(s) from the affected jurisdiction Epi-X linelist tab
 - ii. Remove the id(s) from the affected jurisdiction Epi-X row on the "Cumulative Table 1- Jurisdiction" Tab
 - iii. Remove the id(s) from related conditions rows per age group and cumulative age on the "Cumulative Table 2- Conditions" Tab

Version: 02.22.2022

*CDC is not requesting GDIT manually update Cumulative Tables 1 & 2 for every Epi-X jurisdiction file. Since there are over 60 different jurisdictions, requesting all jurisdictions files to be manual updated may introduce additional errors. GDIT should only update directly related jurisdictions. If a jurisdiction is part of another jurisdiction (NYC is included in NY) then all affected jurisdictions will be updated.

Note datasets are sent to WHO, DoD, and IHS on a weekly basis. (see table below). These datasets will not be updated if a VAERS_ID is quarantined after the public data has started processing. Data will be updated the following week.

High Level View of VAERS Datasets (updated 01.2021)

Dataset	Data Type	Files Sent	Includes Follow-up	Report Types	Variables
CDC	CSV	Nightly (M-F)	Yes	Primary and Secondary	-All Variables
FDA	CSV	Nightly (M-F)	Yes	Primary and Secondary	-All variables
DoD	CSV	Weekly (F)	Yes-Military No-NonMilitary	Primary and Secondary	-Military reports include all variables -NonMilitary reports include most variables (Excludes Names, Addresses, DOB; Includes Patient & Facility State)
IHS (sent to IHS)	CSV	Weekly (F) Implementation November 2020	Yes-IHS No-NonIHS	Primary and Secondary	-IHS reports include all variables -NonIHS reports include most variables (Excludes Names, Addresses, DOB; Includes Patient & Facility State)
IHS (sent to Tribal Epi-Center)*	XLS	Weekly (F) Implementation 2021	No	Primary	-IHS report includes only IHS vaers_id and state
WONDER	CSV	Weekly (one week data lag)	No	Primary	-Restricted list** (Excludes Names, Addresses, DOB, Patient State; Includes Facility State)
HHS	CSV	Weekly (one week data lag)	No	Primary	-Restricted list** (Excludes Names, Addresses, DOB, Patient State; Includes Facility State)
WHO	XML	Weekly (one week data lag)	No	Primary and Secondary	-Restricted list** (Excludes Names, Addresses (State and Zip Code), DOB)

* Created by CDC; all other data created by contractor

** Restricted list are similar but not exact copies

Version: 02.22.2022

Obtained by ICANdecide.org via FOIA

From: (b)(4)
Sent: Wed, 8 Dec 2021 15:48:34 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP); (b)(4)
Subject: RE: VAERS Surge Call Discussion Items

Traci,

Here is our response to Paige's questions regarding follow-up.

Thanks,

(b)(4)

1. 1. How does GDIT define (search strategy) myocarditis? TTS? CDC most likely uses a different search strategy for these conditions so how to ensure that you do not perform initial follow-up on these cases?
- 2.
- 3.

(b)(6)

(b)(4)

Obtained by ICANdecide.org via FOIA

- *Platelet count (Thrombocyte count) - code as in narrative (use lab book for values)*

2. If the person had myocarditis and another condition, does GDIT not follow up on the person because one of the conditions was myocarditis?

GDIT Response: We follow-up on any cases that fall under the NURFU guidelines from the CDC. If the case presents with other conditions that meet Follow-up criteria then these are assigned for Follow-up.

3. What about myocarditis and death, does GDIT not follow-up on this person either even though it is a death case?

GDIT Response: We follow-up on all Death including those which may have myocarditis or TTS within the narrative.

4. When CDC sends a list of myocarditis/TTS cases to follow-up on, are these cases prioritized OR do they just go to the bottom of the pull to follow-up on?

GDIT Response: All CDC lists are prioritized daily. They are at the top of the list for follow-up.

5. Are there other conditions you **are not** following up on per CDC?

GDIT Response: No, CDC has not provided anything we are not to f/u on if Serious. We follow-up on any cases that fall under the guidelines from the CDC.

6. Are there nonserious conditions you **are** following up on per CDC?

GDIT Response: Per CDC request, we are not following up on COVID non-serious cases.

7. What is the current backlog date for follow-up? Oldest receive date for the following categories: COVID Death, COVID Serious.

(b)(4)

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Sent: Tuesday, December 7, 2021 5:01 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Subject: FW: VAERS Surge Call Discussion Items

[External Email with Covid-19 Information: Use caution with links & attachments]

Hi (b)(4) please see below for tomorrow's agenda items. ~Traci

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Tuesday, December 7, 2021 4:56 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: VAERS Surge Call Discussion Items

Hey Traci,

We have three items to discuss on the Surge call tomorrow with Stacey.

1. I would like to discuss GDITs COVID-19 follow up procedures (email attached).
2. I would like GDIT to provide follow up on how an id that was requested to not be included in the extracts (b)(6) was added recently.
3. Elaine would like to rediscuss Washington state sending death certificate files in the CSV format and GDIT's ability to receive the files and display the information on VAERS VPN in a user-friendly format. It may be useful to have a standard template: 1. In case other states wish to send CSV files 2. Ease in mapping variables to display form on VPN

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 22 Mar 2022 20:34:18 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS Surge Need Beyond 8/26/22
Attachments: 75D30120F09621 00006 - for bilateral review, signature, and return.pdf

Contract attached for reference.

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, March 22, 2022 4:19 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS Surge Need Beyond 8/26/22

Hi John,

This task order applies to the VAERS Surge contract and services provided by GDIT.

Traci

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, March 22, 2022 4:06 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Subject: RE: VAERS Surge Need Beyond 8/26/22

Hi Traci,

If this task order applies to our contractors performing medical record abstraction, need is anticipated to continue beyond Aug 26, 2022. Please let me know if there's any other info you need, or any action needed on my part.

- John

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, March 22, 2022 2:54 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Johnson, Bonita C.

(CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Subject: VAERS Surge Need Beyond 8/26/22

Good Afternoon,

As you're aware, the final modification (increase) to the VAERS Surge contract was awarded on Feb 28th with a POP of 3/1/2022 – 8/26/2022. Per OAS, if the services under this task order are to continue, they must do so under a **competitively awarded separate task order**.

Questions:

1. Is the current need expected to continue beyond the Aug 26th expiration date requiring a new task order?
2. Or, is need expected to be at a level that services can be provided under the base VAERS contract?

Thanks,
Traci

Traci Roberts
Public Health Analyst | Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office 404.498.0669
xct6@cdc.gov

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

Obtained from AND only via FOIA

1. CONTRACT ID CODE

PAGE OF PAGES

1 6

2. AMENDMENT/MODIFICATION NO.
00006

3. EFFECTIVE DATE
02/28/2022

4. REQUISITION/PURCHASE REQ. NO.
00HCVLDE-2022-62059

5. PROJECT NO. (If applicable)

6. ISSUED BY
Centers for Disease Control and Prevention (CDC)
Office of Acquisition Services (OAS)
2900 Woodcock Blvd, MS TCU-4
Atlanta, GA 30341-4004

CODE

8219

7. ADMINISTERED BY (If other than Item 6)
CO: Nathan R. Amador, wlv7@cdc.gov, 770.488.2690
COR: Traci Sinetta Roberts, xct6@cdc.gov, 404.498.0669

CODE

CTR:

(b)(4)

(b)(4)

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)
GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.
3150 FAIRVIEW PARK DR STE 100

FALLS CHURCH, VA 22042-4504

(✓)

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (See Item 11)

10A. MODIFICATION OF CONTRACT/ORDER NO.

75D30120F09621

X

10B. DATED (See Item 13)

08/27/2020

CODE 067641597

FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ___ is extended, ___ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
(a) By completing Items 8 and 15, and returning ___ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

9390GLY 2512 2022 75-2124-G943 C5B8111101 Increase (b)(4)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(✓) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
FAR 43.103(a)(3) Reelect other agreements of the parties modifying the terms of contracts.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 digital copy to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

See Page 2 for Description of Amendment/Modification.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)

16A. NAME OF CONTRACTING OFFICER

Nathan R. Amador

(b)(4) Contracts Administrator Sr. Advisor

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED

(b)(4)
(Signature of person authorized to sign)

28 February 2022

BY
(Signature of Contracting Officer)

The following modifications are hereby made via 75D30120F09621 00006 and apply thereafter:

- A. Recognize the Novation Agreement completed on May 27, 2021 between the Defense Contract Management Agency (DCMA) and General Dynamics Information Technology (GDIT), Inc., the successor-in-interest of CSRA, LLC, the signed modification and Novation Agreement between DCMA and GDIT is included as a relevant attachment;
- B. Update the SOW standard certification requirement from “CMM Level 3” to “CMMI Level 3 or industry equivalent” throughout the task order;
- C. Update the SOW as highlighted below to account for the VAERS SARS-Cov-2 Increased Capacity, minimum 13,000 extra reports per week (18,000 total) for the period of 03/01/2022 to task order end-date of 08/26/2022;
- D. Add and fully fund CLIN 3001 Increased Capacity, PoP 03/01/2022 to 08/26/2022, in the amount of (b)(4)
- E. Add and fully fund CLIN 3002 Increased Capacity ODCs, PoP 03/01/2022 to 08/26/2022, in the amount of (b)(4)
- F. Add and fully fund CLIN 3003 CAF, PoP 03/01/2022 to 08/26/2022, in the amount of (b)(4)
- G. Increase total contract value and funded amount by (b)(4) from (b)(4) to \$35,425,642.37.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**VAERS SAR-CoV-2 Increased Capacity: Period of Performance 03/01/2022 to 08/26/2022 (end of task order)**

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
3001	VAERS SARS-CoV-2 Increased Capacity until end of task order. The contractor shall provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs), and facilitate reporting to VAERS specifically pertaining to SARS-CoV-2. Reference the SOW and all associated deliverables. This line item is based an estimation of a minimum of 13,000 extra reports per week to be cleared for 6-months from 03/01/2022 - 08/26/2022. This is a T&M, severable line item. See Table B.2 PoP: 03/01/2022 – 08/26/2022		(b)(4)	
	3001 Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101	(b)(4)		
3002	VAERS SARS-CoV-2 Increased Capacity ODCs All travel must be in accordance with the Federal Travel Regulations (FTR). The Contractor shall obtain COR pre-approval of estimated travel expenses prior to travel occurrence. Charges will be submitted for actual costs incurred. The contractor shall ensure that the requested travel costs will not exceed the amount authorized in this task order. Other direct costs include travel, approved training requirements, and items shown in table B.3. All other direct costs must be pre-approved by the CO and COR prior to occurrence. T&M, severable line item See Table B.3 PoP: 03/01/2022 – 08/26/2022		(b)(4)	
	3002 Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101	(b)(4)		

3003	VAERS SARS-CoV-2 Increased Capacity CAF The Contract Access Fee (CAF) is 0.75% to be applied to the total price for contractor performance as billed to the government on each Task Order. The CAF is paid by the Ordering Agency, but remitted to GSA by the Contractor. Based on the established CAF rate, the Contractor shall include the CAF in each proposal. The Contractor shall include the CAF as a separate cost element per year on all quotes to the government, regardless of contract type. The CAF shall never be treated as a negotiable element between the Contractor and the Ordering Agency. The CAF Rate, effective at time of the Task Order award, shall remain the same for that Task Order for the full term of the Order. Not to Exceed a Total of \$150K for orders with total value greater than \$20M per year. PoP: 03/01/2022 – 08/26/2022	(b)(4)		
	3003 Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101	(b)(4)		

Task Order Total: \$35,425,642.37

SECTION B.2 – Level of Effort for Increased Capacity

March 01, 2022 – August 26, 2022				
LCAT	LCAT \$	STAFF	Hours	COST
(b)(4)				
TOTAL				(b)(4)

SECTION B.3 – ODCs for CLIN 3002

ODCs	CLIN 3002
(b)(4)	
TOTAL	(b)(4)

STATEMENT OF WORK FOR
VACCINE ADVERSE EVENT REPORTING SYSTEM
(VAERS) FOR SARS-COV-2 VACCINES

Updated Language is highlighted in yellow below:

IV. DESCRIPTION OF WORK:

- a. The contractor shall implement a staffing and operations plan focusing only on vaccine adverse event (VAE) reports after SARS-CoV-2 vaccines. The total number of reports received during periods of peak activity (which are not expected to reflect sustained activity) is expected to be 1,000 reports per day, with up to 40% of the reports serious in nature. This constitutes the base capacity expectation of up to 5,000 reports per week (CLIN 0001, 0002, and 0003).
- b. The contractor shall implement a staffing and operations plan focusing only on vaccine adverse event (VAE) reports after SARS-CoV-2 vaccines to clear the backlog of SARS-CoV-2 VAE reports that has been projected to accumulate through February 28, 2021. The contractor shall prioritize clearing the backlog of reports at the direction of the Government. The domestic report backlog shall be processed and cleared within 3 months from the start of the March 2021. The foreign report backlog shall be processed and cleared within 3–6 months from the start of the March 2021. (refer to “ACKNOWLEDGMENT, VERIFICATION, CODING AND DATA COLLECTION FOR ADVERSE EVENTS REPORTED AFTER SARS-CoV-2 VACCINES” Section C; 3a, 3b, 3c, and 3d).
- c. The contractor’s staffing and operations for increased capacity (CLIN 2001, 2002, and 2003) shall be sufficient to fully process within specified timelines a minimum of 20,000 extra reports per calendar week (25,000 total) for a 6-month period from March 01, 2021 to August 31, 2021, with up to 30% of the reports classified as serious. No additional funding is to be allocated, but work is estimated continue with a decrease from the average pace established in the initial 6-month period throughout September 2021 to an estimated minimum of 13,000 extra reports per calendar week (18,000 total) for the 5-month period from October 01, 2021 to February 28, 2022 or until such time as funds for CLIN 2001, 2002, and 2003 are invoiced* if the Government need for weekly reports exceeds the estimated minimum. With Modification 00006, continue the minimum of 13,000 extra reports calendar week (18,000 total) for the 6-month period from March 01, 2022 to task order end-date of August 26, 2022 or until such time as funds for CLIN 3001, 3002, and 3003 are fully invoiced* should the Government need for weekly reports exceed the estimated minimum.

*FAR 52.232-7 Payments under Time-and-Materials and Labor-Hour Contracts – see (d) *Total cost*.

Estimated levels of effort (LoE) by invoice as of Modification 00006:

CLIN 2001

Description of Effort	Period of Time	Estimated LoE invoice value
Already Invoiced (min 25k)	March 01, 2021 to July 31, 2021	
Estimated Invoice (min 25k)	August 01, 2021 to September 30, 2021	(b)(4)
To Be Invoiced (min 13k)	October 01, 2021 to February 28, 2021	
TOTAL NTE VALUE	March 01, 2021 to February 28, 2022	(b)(4)

CLIN 3001

Description of Effort	Period of Time	Estimated LoE invoice value
To Be Invoiced (min 13k)	March 01, 2022 to August 26, 2022	(b)(4)
TOTAL NTE VALUE	March 01, 2022 to August 26, 2022	

From: (b)(4)
Sent: Thu, 3 Feb 2022 18:41:36 +0000
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); (b)(4) Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS Surge Weekly Update - GDIT DRAFT

Thanks, I've incorporated it into the notification.

(b)(4)
Research Supervisor
General Dynamics Information Technology
Federal Civilian Group

Tuscaloosa, AL

(b)(4)
www.gdit.com

GENERAL DYNAMICS
Information Technology

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Thursday, February 3, 2022 1:40 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; (b)(4)
(b)(4) Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: VAERS Surge Weekly Update - GDIT DRAFT

[External Email with Covid-19 Information: Use caution with links & attachments]

I had a minor suggested edit in red below.

Thanks,

Elaine

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Thursday, February 3, 2022 1:30 PM
To: (b)(4)
(b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John

(CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: VAERS Surge Weekly Update - GDIT DRAFT

Awesome! Thanks (b)(4)
Looks good to me.

From: (b)(4)
Sent: Thursday, February 3, 2022 1:17 PM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; (b)(4)
(b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: VAERS Surge Weekly Update - GDIT DRAFT

I have made some modifications to capture Paige's point. See below:

DRAFT

(b)(5)

END of DRAFT

Awaiting your feedback,

(b)(4)

Research Supervisor
General Dynamics Information Technology
Federal Civilian Group

Tuscaloosa, AL

(b)(4)

www.gdit.com

GENERAL DYNAMICS
Information Technology

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>
Sent: Thursday, February 3, 2022 12:58 PM
To: (b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: (b)(4)
Subject: RE: VAERS Surge Weekly Update - GDIT DRAFT

[External Email with Covid-19 Information: Use caution with links & attachments]

For those that updated from non-serious to death, the VAERS form has already been sent to the jurisdiction, correct?

If so, we may want to tell them that cases where severity changed from non-serious to death, the VAERS form has already been provided to them via Epi-X.... (you may want to tweak the language)

From: (b)(4)
Sent: Thursday, February 3, 2022 12:45 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Cc: (b)(4)
Subject: RE: VAERS Surge Weekly Update - GDIT DRAFT

Hello Team,

We are all set to send out the weekly updates. We propose the following text (slightly modified the previous version). Please let us know if this is acceptable.

Thank you,

(b)(4)

DRAFT

(b)(5)

End of DRAFT

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

Sent: Monday, January 31, 2022 8:15 AM

To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)

(b)(4) Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>

Subject: RE: VAERS Surge Weekly Update

[External Email with Covid-19 Information: Use caution with links & attachments]

Thanks John.

If anyone has further edits, please reply to this email.

Thanks,

Elaine

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

Sent: Saturday, January 29, 2022 6:26 PM

To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4) Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: VAERS Surge Weekly Update

Hi folks,

Just substituting a bit less colloquial language for "glitch". Thanks!

- John

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>
Sent: Friday, January 28, 2022 7:06 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4) (b)(4) Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: VAERS Surge Weekly Update

Comments in blue

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Friday, January 28, 2022 1:57 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4) Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <psm9@cdc.gov>
Subject: RE: VAERS Surge Weekly Update

Below is sample language for the info that GDIT will send to inform jurisdictions regarding the data glitch.

Please send edits.

Thanks,
Elaine

(b)(5)

The current Epi-X weekly report includes the corrected numbers for Cumulative tables (Table 1&2), no action is needed.

You may use the above updated serious status to revise previously received line listing that includes your affected VAERS ID for your internal use.

If you have questions about this, please email covid19vaxsafety@cdc.gov

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

Sent: Friday, January 28, 2022 1:02 PM

To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)

(b)(4) Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fgv9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>

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

Subject: RE: VAERS Surge Weekly Update

Hi folks,

I've gotten looped into another call from 1-1:30 p.m. Please proceed without me, and I can catch up when I join, or offline if y'all finish early. Thanks!

- John

-----Original Appointment-----

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Sent: Wednesday, May 5, 2021 3:31 PM

To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); (b)(4) Su, John (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)

Cc: Moro, Pedro (CDC/DDID/NCEZID/DHQP)

Subject: VAERS Surge Weekly Update

When: Friday, January 28, 2022 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Microsoft Teams Meeting

Meeting rescheduled.

Microsoft Teams meeting

Join on your computer or mobile app

[Click here to join the meeting](#)

Or call in (audio only)

(b)(6) United States, Atlanta

(b)(6)

United States (Toll-free)

Phone Conference ID: (b)(6)

[Find a local number](#) | [Reset PIN](#)

[Learn More](#) | [Meeting options](#)

From: (b)(4)
Sent: Mon, 12 Jul 2021 21:34:11 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS VPN- older medical records access after migration

Hi Paige,

The restoration has not been completed yet – my apologies for the delay.. We discussed last week – the GDIT hosting team are working on this but there has been an unexpected issue that they are addressing. It does not affect the images – they are safe. They understand the need by CDC for the images.

Thanks,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Monday, July 12, 2021 4:54 PM
To: (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS VPN- older medical records access after migration

[External: Use caution with links & attachments]

Hey (b)(4)

You previously informed us that the Image Restoration task is scheduled to be completed during the week of 6/21 – 6/25. Can you confirm this task has been completed?

Pedro has informed me that there are Varivax reports prior to 2011 that are not accessible. When you try to view the image, you get an error that says “ File not found.”

Here are some examples:

0255329-1
0257684-1
0259715-1
0275428-1
0290970-1
0291678-1
0306817-1
0307009-1
0336785-1
0337669-1
0338667-1
0338821-1
0339027-1

0341593-1
0347248-1
0359358-1
0360751-1
0365786-1
0366004-1
0382602-1
0382746-1
0386283-1
0388098-1
0388916-1

From: (b)(4)
Sent: Monday, June 14, 2021 10:02 AM
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: VAERS VPN- older medical records access after migration

Hi Paige,

The Image Restoration task is scheduled to be completed during the week of 6/21 – 6/25. Please let me know if this is an issue.

Thanks,

(b)(4)

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Sent: Monday, June 14, 2021 7:48 AM
To: (b)(4)
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: VAERS VPN- older medical records access after migration

[External: Use caution with links & attachments]

Hey (b)(4)

Can you refresh our memories of when older medical records (prior to 2010) will be accessible again on the VAERS VPN? Since the migration is complete, we assumed we would be able to access those records soon. We have a manuscript we need to finish with Varicella and it includes cases of special interest starting in 2006 that Pedro needs access to on the VPN.

Thanks,
Paige

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 14 Sep 2021 14:28:51 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: Voice Mail (25 seconds)

Hi John and Elaine,

Yes, GDIT obtains death certificates with funds already allocated via the VAERS contracts.

Traci

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Thursday, September 2, 2021 11:15 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Voice Mail (25 seconds)

Traci's on leave; let's wait to discuss until she's back. Typically, GDIT handles obtaining death certificates and/or autopsy reports, and I've never encountered the challenges we've seen as of late. Because we're discussing fees, etc., that GDIT might typically pay using funding that's already been allocated to them, I don't want to run the risk of "double dipping" by obligating CDC to pay those fees.

As an aside, Tom was going to discuss with state and territorial partners about this issue; leadership suggested he not, opining that few jurisdictions were putting up such roadblocks, and bringing attention to the issue might encourage other jurisdictions to act likewise.

To date, NY, VA, SC, WA, and now NV have been requesting data sharing agreements... that's 10% of the U.S. Makes me wonder how many more are coming...

- John

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Thursday, September 2, 2021 10:38 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: Voice Mail (25 seconds)

Hi John and Traci,

I have been in communication with the Nevada DOH regarding VAERS requests for death certificates. They will not waive fees for us. They charge \$10 per death certificate or we could get a data use agreement with them for a one time fee of \$500.

I suggest we move forward with the data use agreement so that we can get death certificates as needed.

Please let me know if you agree and if there is \$500 available to do so.

Thanks,

Elaine

From: Julie Dickerson <jdickerson@health.nv.gov>
Sent: Thursday, September 2, 2021 10:19 AM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Cc: Stephanie Herrera <s.herrera@health.nv.gov>; Debbie Charlton <dcharlton@health.nv.gov>; Julie Dickerson <jdickerson@health.nv.gov>
Subject: RE: Voice Mail (25 seconds)

Hello Elaine.

It was a pleasure speaking with you. Per our conversation it seems there are some options we can provide to help you with the information you need.

You can apply by mail and include payment of \$10.00 for a black and white not legal copy of a death certificate.

We will need an ID of the person requesting the information along with your normal cover letter. You can pay by check or by CC.

Or you can sign up for a data share with us which is \$500.00 and requires some extensive paperwork but once set up there are no additional fees unless the items requested changes.

Or if you would like a certified copy of a death certificate you will need to request by mail and the cost varies from \$22.00-\$25.00 depending on which county the death occurred. Instructions are the same as above.

Please let me know how you would like us to handle the requests we currently have. Will you send payment or wait and have them as part of a data share?

Thank you and have a wonderful day.



Julie Dickerson

Administrative Assistant IV
Nevada Department of Health and Human Services
Division of Public & Behavioral Health | Office of
Vital Records
4150 Technology Way, Suite 104 | Carson City,
NV 89706
T: (775) 684-4158 | F: (775) 684-4156
E: jdickerson@health.nv.gov
www.dhhs.nv.gov | www.dpbh.nv.gov



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From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Tuesday, August 31, 2021 12:16 PM
To: Julie Dickerson <jdickerson@health.nv.gov>; Stephanie Herrera <s.herrera@health.nv.gov>; Debbie Charlton <dcharlton@health.nv.gov>
Cc: Blaise Satariano <bsatariano@health.nv.gov>
Subject: RE: Voice Mail (25 seconds)

Hi Julie,
I have not been able to reach you by phone.
Please call me at 404-498-4458

Thanks,

Elaine

Elaine R. Miller, RN, MPH
Immunization Safety Office
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Atlanta, GA
Email: emiller@cdc.gov
Phone: 404-498-4458

From: Blaise Satariano <bsatariano@health.nv.gov>
Sent: Friday, August 27, 2021 3:48 PM
To: Julie Dickerson <jdickerson@health.nv.gov>; Stephanie Herrera <s.herrera@health.nv.gov>; Debbie Charlton <dcharlton@health.nv.gov>
Cc: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; OVRPAC <OVRPAC@health.nv.gov>
Subject: FW: Voice Mail (25 seconds)

Hi Julie,

I am forwarding this email to you with Elaine attached. She also left a voicemail as well.

Thank you!



Blaise Satariano

Registration/Amendments Clerk

Nevada Department of Health and Human Services

Division of Public and Behavioral Health | Vital Records

4150 Technology Way Ste 104|Carson City, NV 89706

T: (775)684-4163 | F: (775)684-4156|

E: ovrpac@health.nv.gov

www.dhhs.nv.gov | www.division website.nv.gov

Helping People. It's who we are and what we do.

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

Sent: Friday, August 27, 2021 12:39 PM

To: OVRPAC <OVRPAC@health.nv.gov>

Subject: RE: Voice Mail (25 seconds)

Hi,

I received a phone call from Julie in the Nevada Office of Vital Records. When I returned the call , I got a fast busy signal.

The CDC and FDA co-manage the VAERS program and we need to work with you to obtain death certificates for VAERS reports.

Please contact me again by phone or email.

Thanks,

Elaine

Elaine R. Miller, RN, MPH

Immunization Safety Office

Division of Healthcare Quality Promotion

Centers for Disease Control and Prevention

Atlanta, GA

Email: emiller@cdc.gov
Phone: 404-498-4458

From: NEVADA STATE OF <+17756877101>
Sent: Tuesday, August 17, 2021 2:55 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: Voice Mail (25 seconds)

Hi Elaine, this is Julie. I'm with the state of Nevada Office of Vital Records and I'm calling you with regard to the request for certificates through there's. I think the question isn't so much whether you have the authority to get them, but how you will be paying for them in the future. We have a couple different options. I'd like to talk to you about. You can call me back at 775-684-4158. Thank u.

You received a voice mail from [NEVADA STATE OF](#).

Thank you for using Transcription! If you don't see a transcript above, it's because the audio quality was not clear enough to transcribe.

[Set Up Voice Mail](#)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 7 Apr 2021 16:57:44 +0000
To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly VAERS Call

Thanks (b)(4) Will do.

From: (b)(4)
Sent: Wednesday, April 7, 2021 12:52 PM
To: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Subject: RE: Weekly VAERS Call

Hi Elaine,

Using Auto-Upload is the best way to submit the reports.

Thanks,

(b)(4)

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Sent: Wednesday, April 7, 2021 8:41 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: (b)(4)
Subject: RE: Weekly VAERS Call

[External Email with Covid-19 Information: Use caution with links & attachments]

We have a huge number of pages of medical records for about 5 important Covid cases. I just want to know the best way to get the records to GDIT. We can probably cover by email or discuss in the meeting if Paige has issues to discuss.

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Wednesday, April 7, 2021 8:34 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: Weekly VAERS Call

Thanks John.

Paige and Elaine - (b)(4) is copied on this email, please let her know if you have any agenda topics for today's meeting.

Traci

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Sent: Tuesday, April 6, 2021 11:33 PM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Subject: RE: Weekly VAERS Call

Hi Traci,

I don't have anything specific at this time. Thanks!

• John

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, April 6, 2021 6:37 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: Weekly VAERS Call

Good afternoon,

Please advise if you have any agenda items for tomorrow's meeting.

Thanks,
Traci

Traci Roberts
Public Health Analyst | Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office 404.498.0669
xct6@cdc.gov

From: Amador, Nathan (CDC/OCOO/OFR/OAS)
Sent: Mon, 28 Feb 2022 15:26:14 +0000
To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP)
Cc: (b)(4) Denis, Philip (CDC/OCOO/OFR/OAS)
Subject: Release of fully executed Modification 75D30120F09621 00006
Attachments: 75D30120F09621 00006_signed_02.28.2022.pdf

Good Morning,

Please find attached for your records a fully executed copy of modification 75D30120F09621 00006. This modification marks the last increased effort available to this task order. Please focus over the next 6-months on improving efficiencies and ensuring that this work winds down to a well-documented and clear transition out.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(4)
Sent: Monday, February 28, 2022 10:06 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)
(b)(4)
Subject: RE: Bilateral Modification 75D30120F09621 00006 - Clarification Requested

Hello Nathan,

Attached is the GDIT signed modification. Please sign and return a final executed copy.

Thank you so very much for getting this one pushed through.

Kindest regards~

(b)(4)

Contracts Administrator Sr. Advisor
Federal Health Sector

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

GENERAL DYNAMICS
Information Technology

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From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>

Sent: Monday, February 28, 2022 9:57 AM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Bilateral Modification 75D30120F09621 00006 - Clarification Requested

[External Email with Covid-19 Information: Use caution with links & attachments]

Good Morning,

That is correct. This work has been identified as a Time & Material CLIN, allowing all the controls and freedoms provided by that contract type. The Level of Effort on Section B is an estimate to justify the Not to Exceed amount of the CLIN.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile

 **Office of Financial Resources**
Office of Acquisition Services (OAS)

From: (b)(4)

Sent: Monday, February 28, 2022 9:54 AM

To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Bilateral Modification 75D30120F09621 00006 - Clarification Requested

Importance: High

Good Morning Nathan,

Just want to confirm that GDIT is held to the CLIN line funding and that we are able to utilize the Section B.2 Level of Effort across all the LCATs listed as long as we remain within the total value of each CLIN.

Please confirm and respond soonest to complete our review.

Thank you so much~

(b)(4)

Contracts Administrator Sr. Advisor
Federal Health Sector

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

GENERAL DYNAMICS
Information Technology

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From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>

Sent: Friday, February 25, 2022 10:45 PM

To: (b)(4)

Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>

Subject: Bilateral Modification 75D30120F09621 00006 for review, signature, and return

[External Email with Covid-19 Information: Use caution with links & attachments]

Good Evening,

I apologize for the late email, but I finally received authorization from the Competition Advocate to proceed with bilateral modification 00006, adding increased reporting in the amount of 13k extra reports a week from March 1, 2022 to August 26, 2022.

All parties involved understand that the current task order will expire on August 26, 2022, and that the services under this task order if they are to continue, must do so under a competitively awarded separate task order.

I want to personally thank everyone for their patience and perseverance in getting this modification pulled together, and the ongoing support of the COVID-19 pandemic response.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

Obtained by OAND on 01/07/2022 via FOIA

1. CONTRACT ID CODE

PAGE OF PAGES

1 6

2. AMENDMENT/MODIFICATION NO.
00006

3. EFFECTIVE DATE
02/28/2022

4. REQUISITION/PURCHASE REQ. NO.
00HCVLDE-2022-62059

5. PROJECT NO. (If applicable)

6. ISSUED BY
Centers for Disease Control and Prevention (CDC)
Office of Acquisition Services (OAS)
2900 Woodcock Blvd, MS TCU-4
Atlanta, GA 30341-4004

CODE

8219

7. ADMINISTERED BY (If other than Item 6)
CO: Nathan R. Amador, nlv7@cdc.gov, 770.488.2690
COR: Traci Sinetta Roberts, xct6@cdc.gov, 404.498.0669

CODE

CTR: (b)(4)

(b)(4)

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)
GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.
3150 FAIRVIEW PARK DR STE 100

FALLS CHURCH, VA 22042-4504

(✓)

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (See Item 11)

10A. MODIFICATION OF CONTRACT/ORDER NO.

75D30120F09621

X

10B. DATED (See Item 13)

08/27/2020

CODE 067641597

FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ___ is extended, ___ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
(a) By completing Items 8 and 15, and returning ___ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

9390GLY 2512 2022 75-2124-G943 C5B8111101 Increase

(b)(4)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(✓) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
FAR 43.103(a) (3) Refelect other agreements of the parties modifying the terms of contracts.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 digital copy to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

See Page 2 for Description of Amendment/Modification.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)

16A. NAME OF CONTRACTING OFFICER

Nathan R. Amador

(b)(4) Contracts Administrator Sr. Advisor

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED

(b)(4)
(Signature of person authorized to sign)

28 February 2022

BY Nathan R. Amador -S Digitally signed by Nathan R. Amador -S
(Signature of Contracting Officer) Date: 2022.02.28 10:07:48 -05'00'

The following modifications are hereby made via 75D30120F09621 00006 and apply thereafter:

- A. Recognize the Novation Agreement completed on May 27, 2021 between the Defense Contract Management Agency (DCMA) and General Dynamics Information Technology (GDIT), Inc., the successor-in-interest of CSRA, LLC, the signed modification and Novation Agreement between DCMA and GDIT is included as a relevant attachment;
- B. Update the SOW standard certification requirement from “CMM Level 3” to “CMMI Level 3 or industry equivalent” throughout the task order;
- C. Update the SOW as highlighted below to account for the VAERS SARS-Cov-2 Increased Capacity, minimum 13,000 extra reports per week (18,000 total) for the period of 03/01/2022 to task order end-date of 08/26/2022;
- D. Add and fully fund CLIN 3001 Increased Capacity, PoP 03/01/2022 to 08/26/2022, in the amount of (b)(4)
- E. Add and fully fund CLIN 3002 Increased Capacity ODCs, PoP 03/01/2022 to 08/26/2022, in the amount of (b)(4)
- F. Add and fully fund CLIN 3003 CAF, PoP 03/01/2022 to 08/26/2022, in the amount of (b)(4)
- G. Increase total contract value and funded amount by (b)(4) from (b)(4) to \$35,425,642.37.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**VAERS SAR-CoV-2 Increased Capacity: Period of Performance 03/01/2022 to 08/26/2022 (end of task order)**

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
3001	VAERS SARS-CoV-2 Increased Capacity until end of task order. The contractor shall provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs), and facilitate reporting to VAERS specifically pertaining to SARS-CoV-2. Reference the SOW and all associated deliverables. This line item is based an estimation of a minimum of 13,000 extra reports per week to be cleared for 6-months from 03/01/2022 - 08/26/2022. This is a T&M, severable line item. See Table B.2 PoP: 03/01/2022 – 08/26/2022		(b)(4)	
	3001 Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101 (b)(4)			
3002	VAERS SARS-CoV-2 Increased Capacity ODCs All travel must be in accordance with the Federal Travel Regulations (FTR). The Contractor shall obtain COR pre-approval of estimated travel expenses prior to travel occurrence. Charges will be submitted for actual costs incurred. The contractor shall ensure that the requested travel costs will not exceed the amount authorized in this task order. Other direct costs include travel, approved training requirements, and items shown in table B.3. All other direct costs must be pre-approved by the CO and COR prior to occurrence. T&M, severable line item See Table B.3 PoP: 03/01/2022 – 08/26/2022		(b)(4)	
	3002 Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101 (b)(4)			

3003	VAERS SARS-CoV-2 Increased Capacity CAF The Contract Access Fee (CAF) is 0.75% to be applied to the total price for contractor performance as billed to the government on each Task Order. The CAF is paid by the Ordering Agency, but remitted to GSA by the Contractor. Based on the established CAF rate, the Contractor shall include the CAF in each proposal. The Contractor shall include the CAF as a separate cost element per year on all quotes to the government, regardless of contract type. The CAF shall never be treated as a negotiable element between the Contractor and the Ordering Agency. The CAF Rate, effective at time of the Task Order award, shall remain the same for that Task Order for the full term of the Order. Not to Exceed a Total of \$150K for orders with total value greater than \$20M per year. PoP: 03/01/2022 – 08/26/2022	(b)(4)		
	3003 Line(s) Of Accounting: 9390GLY 2512 2022 75-2124-0943 C5B8111101	(b)(4)		

Task Order Total: \$35,425,642.37

SECTION B.2 – Level of Effort for Increased Capacity

March 01, 2022 – August 26, 2022				
LCAT	LCAT \$	STAFF	Hours	COST
(b)(4)				
TOTAL				(b)(4)

SECTION B.3 – ODCs for CLIN 3002

ODCs	CLIN 3002
(b)(4)	
TOTAL	
	(b)(4)

STATEMENT OF WORK FOR
VACCINE ADVERSE EVENT REPORTING SYSTEM
(VAERS) FOR SARS-COV-2 VACCINES

Updated Language is highlighted in yellow below:

IV. DESCRIPTION OF WORK:

- a. The contractor shall implement a staffing and operations plan focusing only on vaccine adverse event (VAE) reports after SARS-CoV-2 vaccines. The total number of reports received during periods of peak activity (which are not expected to reflect sustained activity) is expected to be 1,000 reports per day, with up to 40% of the reports serious in nature. This constitutes the base capacity expectation of up to 5,000 reports per week (CLIN 0001, 0002, and 0003).
- b. The contractor shall implement a staffing and operations plan focusing only on vaccine adverse event (VAE) reports after SARS-CoV-2 vaccines to clear the backlog of SARS-CoV-2 VAE reports that has been projected to accumulate through February 28, 2021. The contractor shall prioritize clearing the backlog of reports at the direction of the Government. The domestic report backlog shall be processed and cleared within 3 months from the start of the March 2021. The foreign report backlog shall be processed and cleared within 3–6 months from the start of the March 2021. (refer to “ACKNOWLEDGMENT, VERIFICATION, CODING AND DATA COLLECTION FOR ADVERSE EVENTS REPORTED AFTER SARS-CoV-2 VACCINES” Section C; 3a, 3b, 3c, and 3d).
- c. The contractor’s staffing and operations for increased capacity (CLIN 2001, 2002, and 2003) shall be sufficient to fully process within specified timelines a minimum of 20,000 extra reports per calendar week (25,000 total) for a 6-month period from March 01, 2021 to August 31, 2021, with up to 30% of the reports classified as serious. No additional funding is to be allocated, but work is estimated continue with a decrease from the average pace established in the initial 6-month period throughout September 2021 to an estimated minimum of 13,000 extra reports per calendar week (18,000 total) for the 5-month period from October 01, 2021 to February 28, 2022 or until such time as funds for CLIN 2001, 2002, and 2003 are invoiced* if the Government need for weekly reports exceeds the estimated minimum. With Modification 00006, continue the minimum of 13,000 extra reports calendar week (18,000 total) for the 6-month period from March 01, 2022 to task order end-date of August 26, 2022 or until such time as funds for CLIN 3001, 3002, and 3003 are fully invoiced* should the Government need for weekly reports exceed the estimated minimum.

*FAR 52.232-7 Payments under Time-and-Materials and Labor-Hour Contracts – see (d) *Total cost*.

Estimated levels of effort (LoE) by invoice as of Modification 0006:

CLIN 2001

Description of Effort	Period of Time	Estimated LoE invoice value
Already Invoiced (min 25k)	March 01, 2021 to July 31, 2021	(b)(4)
Estimated Invoice (min 25k)	August 01, 2021 to September 30, 2021	
To Be Invoiced (min 13k)	October 01, 2021 to February 28, 2021	
TOTAL NTE VALUE	March 01, 2021 to February 28, 2022	(b)(4)

CLIN 3001

Description of Effort	Period of Time	Estimated LoE invoice value
To Be Invoiced (min 13k)	March 01, 2022 to August 26, 2022	(b)(4)
TOTAL NTE VALUE	March 01, 2022 to August 26, 2022	

From: (b)(4)
Sent: Wed, 6 Apr 2022 18:46:03 +0000
To: OFR Service Desk (CDC)
Cc: Amador, Nathan (CDC/OCOO/OFR/OAS); (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: Request Assistance: VAERS COVID19 TO# 75D30120F09621 Invoice Issues

Good Afternoon,

GDIT Billing has reached out to the IPP helpdesk to assist with our invoicing issues and was told we need to have CDC enroll us on their end in IPP. Currently General Dynamics Information Technology, Inc. (GDIT) is not matched to Health and Human Services (HHS) in IPP.

Once GDIT is enrolled, we will be matched with our existing company profile in IPP. Our profile is under General Dynamics Information Technology, Inc. and our IPP POC is (b)(4) ("cc'd" above).

Nathan Amador, CO and Traci Roberts, COR are copied on this email if you require additional assistance for the IPP setup from them on this task order.

GDIT greatly appreciates everyone's time and effort in getting these invoices processed.

Kindest regards~

(b)(4)
Contracts Administrator Sr. Advisor
Federal Health Sector

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: May 25-27, 2022

GENERAL DYNAMICS
Information Technology

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From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 13 Apr 2022 22:40:25 +0000
To: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP);
Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: SIGNATURE REQUEST: Acquisition Package - VAERS for COVID-19 Vaccines
Attachments: VAERS for Covid-19 Vaccines Streamlined-AP-Revised-03252020.pdf, SOW
VAERS SARS-CoV-2.docx, IGCE VAERS Surge Recompete 4 13 22.xlsx

Hi Bonita,

Attached for signature is the acquisition plan for the VAERS for Covid-19 Vaccines recompetete. Please let me know if there are any questions or concerns.

Thanks,
Traci

Traci Roberts
Public Health Analyst, Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office 404.498.0669
xct6@cdc.gov

**HHS Streamlined Acquisition Plan
Related to COVID-19 Acquisitions
(IAW FAR Part 7)**

**This document must be placed in all contract files
OFFICIAL USE ONLY**

Program/Project Title: Vaccine Adverse Events Reporting System (VAERS) for Covid-19 Vaccines

OPDIV/STAFFDIV/Division: NCEZID/DHQP/ISO

Program/Project Manager: Bonita Johnson, PMO

Acquisition Year: 2022

***Acquisition Plan # (if applicable):**
(Completed by the contracting officer)

Type of Acquisition:

☐ Commercial (if applicable FAR Part 12)

☒ Service ☐ Supply ☒ IT ☐ Other (describe)

Independent Government Cost Estimate (Inclusion of options -- including optional quantities or option to purchase additional requirements. Proposed price schedule and basis for evaluation of price. Fair and reasonable pricing determination.):

\$21,219,807.13

I. Acquisition Background (FAR 7.105(a))

A. Brief Description of Requirement/Statement of Need:

The purpose of this task order is to provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs) after administration of COVID-19 vaccines and facilitate reporting to VAERS. The objectives of the VAERS Project are divided into three categories: programmatic (mainly CDC), scientific (CDC and FDA), and regulatory (FDA).

Programmatic Project Objectives:

1. Create and/or maintain an online reporting website for VAEs following receipt of COVID-19 vaccines
2. Implement an electronic submission gateway for manufacturers to submit VAE reports on COVID-19 vaccines
3. Provide a reporting mechanism for VAEs that maintains submitted COVID-19 vaccines reports, including images of reports and medical documentation;

B. Conditions:

C. Background and Contracting History (if applicable):

The Vaccine Adverse Event Reporting System (VAERS) is a mandated program sponsored jointly by the Centers for

D. Funding Source:

At the time of the development of this AP, the budget to fully fund this task order has not been approved. However, we intend to use COVID-19 funding to fund this task order in FY22.

E. Delivery or Performance Period (Trade-offs/Risks/Streamlining):

This award will be for 24 months (1 base year plus 1 option year). Funding is subject to availability of funds.

II. Plan of Action

A. Market Research Results/Interested Sources:

Market research was conducted as part of the solicitation of the current Vaccine Adverse Events Reporting System (VAERS) contract #200-2019-06120 and historical data from VAERS Surge contract #200-2020-09621.

B. Types of Small Businesses Considered (check all that apply)

(No foreign contractors will be permitted to participate at the prime contractor level, as no awards were made to foreign contractors.)

- ☐ Small Business ☐ HUBZone ☐ Small Disadvantaged Business 8(a)
☐ Service-Disabled Veteran-Owned Small Business
☐ Women Owned Small Business ☐ Other
☐ Disaster Response Registry Search (<https://www.sam.gov>, Search Records, Advanced Search, Disaster Response Registry Search)

C. Acquisition Approach:

(1) Solicitation method to be utilized

- ☐ GWAC/Best-in-Class/Strategic Source ☒ Competitive
☐ Sole Source ☐ Other (Describe)

(2) Contract Type

- ☐ Fixed-Price ☐ Cost Plus Fixed Fee ☐ Cost Reimbursement
☒ Time and Material/Labor Hour ☐ Cost Plus Award Fee
☐ Letter Contract ☐ Other (Specify)

(3) Brief rationale for selecting the contract type:

Competition:

- ☒ Competitive – Results (abstract, summary, etc.) attached.
☐ Sole/Limited Source - FAR required justifications must be attached
☐ FAR 6: ☐ 6.302-2 Unusual & Compelling ☐ 6.302-1 Only One Source ☐ FAR 6 Other: (Insert FAR ref)
☐ FAR 8: ☐ 8.405-6 - Urgent & Compelling ☐ 8.405-6 Only One Source ☐ FAR 8 Other: (Insert FAR ref)
☐ FAR 13: ☐ 13.106-1(b) Soliciting From a Single Source
☐ FAR 16: ☐ 16.505(b)(2) Exception to the fair opportunity process
☐ Micro-Purchase (≤\$10,000.00) - FAR 13.203(a)(2)
☐ Other Sole or Limited Source Justification: (Must insert FAR ref/authority)

E. Government-Furnished Property/Information:

NA

F. Inherently Governmental Functions:

☐ Yes (explain)

☒ No

G. Other Considerations (Security, Information Technology, Personnel/ Organizational Conflicts of Interest, Price Reasonableness, Price Gauging/ Hoarding, Steps taken to ensure vaccines, therapeutics, and diagnostics developed are affordable in the commercial market, PII, etc.):

H. Attachments:

☒ SOW/PWS/SOO ☒ IGCE ☐ D&F

☐ Class J&A (applicable): ☐ Yes ☒ No

III. Coordination/Approval

☐ I hereby certify that (a) this requirement represents a bona fide need of the fiscal year or years for which the appropriation was made and complies with the Anti-deficiency Act; and (b) funds are committed for the entire performance period of this acquisition.

☐ I hereby certify that (a) this requirement represents a bona fide need of the fiscal year or years for which the appropriation was made and complies with the Anti-deficiency Act; and (b) funds are committed for the base period or first increment of performance of this acquisition.

☒ Funds are not currently committed for this acquisition.

Program/Project Manager (P/PM)

Date

Contracting Officer (CO)

Date

Head Contracting Authority (HCA)

Date

*Senior Procurement Executive (SPE)

Date

*IAW Acquisition Alert 2020-04 SPE approval is required for actions exceeding \$150 million.

STATEMENT OF WORK FOR VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FOR COVID-19 VACCINES

I. BACKGROUND:

The Vaccine Adverse Event Reporting System (VAERS) is a mandated program sponsored jointly by the Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA). The purpose of this project as authorized by the National Childhood Vaccine Injury Act (NCVIA), P.L. 99-660, is to provide a single nationwide mechanism to report, analyze and monitor vaccine adverse events (VAEs) that occur after receipt of vaccines. VAERS also provides a vehicle for disseminating vaccine safety information to vaccinated patients, family members, health care providers, vaccine manufacturers, government agencies, and other partners.

Vaccines represent one of the most cost-effective means of reducing or eliminating morbidity and mortality from selected infectious diseases. However, no vaccine is completely effective or safe. Recommendations for the use of vaccines are based on careful weighing of benefits of vaccination and risks of both the disease being vaccinated against and the immunization itself. Vaccines currently in routine use have been determined by various expert groups and FDA to have benefits that outweigh their risks. As part of any vaccination program, ongoing monitoring is essential to ensure that new or rare VAEs are recognized and appropriate measures taken. Vaccines undergo safety and efficacy testing in the laboratory and in controlled clinical studies before licensure or authorization (in the case of Emergency Use Authorization). Because these trials are limited in size, duration, and heterogeneity, rare, delayed, or unusual events caused by a vaccine may not be detected. Once a vaccine is used in the general population, post marketing surveillance is necessary to evaluate such VAEs.

To meet each agency's needs for vaccine safety monitoring data, CDC and FDA have jointly sponsored VAERS since 1990. The needs relate to CDC's public health responsibility for developing and issuing national vaccine policy recommendations and FDA's responsibility for licensing and regulating vaccines.

VAERS contains reports of VAEs based on two criteria, mandated and voluntary reports. The events mandated for healthcare provider and vaccine manufacturer reporting are listed in the Reportable Adverse Events Table (RET) available at https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf US-manufacturers of vaccines are mandated by 21 CFR Part 600.80 (Attachment 3) to submit reports routinely on a periodic basis, as well as in an expedited manner for more serious events. In addition, healthcare providers are encouraged to report all other clinically significant VAEs following the administration of any US vaccine in all age groups. For all reports, the impetus for reporting is not a presumed causal relationship between the vaccination and the event but may be based simply on the occurrence of the event temporally following vaccination and the lack of other obvious causes.

Since 1990, and prior to the COVID-19 pandemic, VAERS had received over 740,000 reports, most of which described mild and self-limited adverse events such as injection site reactions and fever. (VAERS government data archive January 18, 2019.) During 2014 through 2018 alone, VAERS received on average 53,000 reports per year (of which 45,500 were domestic (U.S.) reports). However, **as of April 12, 2022, VAERS has received over 820,000 U.S. reports after COVID-19 vaccines alone**, of which 13.8% were classified as serious (i.e., associated with disability, hospitalization, prolongation of existing hospitalization, life-threatening illness, congenital anomaly/birth defect, or death [21 CFR 600.80]). VAERS helps to identify important new safety concerns and thereby can help inform vaccine policymakers and healthcare providers. In addition, the data are valuable for regulatory actions and vaccine research studies. The US Government considers post-licensure/authorization surveillance for any licensed and new vaccines through VAERS to be a nationally critical function, and the US Government considers the requirements of the VAERS activity to constitute essential services for which any lapse in coverage of services would be unacceptable.

The COVID-19 vaccination program has created additional requirements for VAERS. Unanticipated project needs have materialized, requiring efforts beyond routine VAERS functions. Task requirements in support of public health emergencies (e.g., pandemic influenza, natural disasters and terrorist activities) and unanticipated federal mandates necessitated an increase in Contractor staffing. These new requirements resulted in increased workloads for any of the tasks listed in the SOW Tasks 1-5; the potential for unforeseen events/circumstances remains. The

Contractor shall be prepared to address unforeseen events/circumstances and meet the needs of the Government as it relates to such events. Reasonable accommodations will be made to the Contractor by the Government to address unforeseen events/circumstances and the Contractor will be allowed to negotiate the implementation of changes.

II. OBJECTIVES:

The Vaccine Adverse Event Reporting System (VAERS) is the nation's frontline system for detecting potential vaccine safety concerns after vaccines are licensed or authorized for use in the United States. It is a nationwide mechanism by which VAEs may be reported, analyzed, and made available to the public. It provides a vehicle for disseminating vaccine safety information to vaccinees, family members, health care providers, vaccine manufacturers, government agencies, and other partners. VAERS is a collaboration between CDC and FDA.

The purpose of this task order is to provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs) after administration of COVID-19 vaccines and facilitate reporting to VAERS. The objectives of the VAERS Project are divided into three categories: programmatic (mainly CDC), scientific (CDC and FDA), and regulatory (FDA).

Programmatic Project Objectives:

1. Create and/or maintain an online reporting website for VAEs following receipt of COVID-19 vaccines
2. Implement an electronic submission gateway for manufacturers to submit VAE reports on COVID-19 vaccines
3. Provide a reporting mechanism for VAEs that maintains submitted COVID-19 vaccines reports, including images of reports and medical documentation;
4. Ensure data in the VAERS reports are accessible to the public as required by law (P.L. 99-660, Section 2125), in accordance with policies to protect individuals' privacy;
5. Support CDC and FDA scientific staff in using VAERS data on VAEs after COVID-19 vaccines to rapidly respond to vaccine safety concerns or public health emergencies and in conducting epidemiologic and other scientific studies

Scientific Project objectives:

1. Rapidly detect new, unusual, or rare VAEs after COVID-19 vaccines;
2. Assess the safety of COVID-19 vaccines; or assess the safety in specific populations or situations where a new recommendation for COVID-19 vaccines occur;
3. Rapidly identify vaccine lots for COVID-19 vaccines with increased numbers or types of reported adverse events (FDA lead); and
4. Monitor trends in known VAEs after COVID-19 vaccines, particularly increases in reported VAEs

Regulatory Project Objectives:

1. Implement regulatory requirements related to VAERS, especially regarding reports from manufacturers after COVID-19 vaccines. [21 CFR 600.80].

III. SCOPE OF WORK:

The contractor shall provide support and technical assistance to CDC and FDA by supporting work in the following areas. The tasks below are not in order of priority. These tasks include:

1. Administrative
2. Report Receipt/Processing
3. VAERS Follow Up Activities and Enhanced Surveillance
4. Quality Control for VAERS Data

5. Information Management

Current VAERS plans, protocols, procedures, manuals, standard operating procedures (SOPs), software, some hardware, etc. may be provided by the Government for adoption/modification (i.e., the contractor would not have to develop all entirely new products, but would have the option of rolling over/adopting/modifying existing ones). Additionally, scanning reports for the image database, certain manual data entry tasks, and other processes clearly related to paper reports shall only apply to paper reports (i.e., electronic reports do not require scanning and manual data entry, but may require redaction).

IV. DESCRIPTION OF WORK:

The contractor shall implement a staffing and operations plan focusing only on vaccine adverse event (VAE) reports after COVID-19 vaccines to help process an estimated 770,000 digital reports per year. Periods of heavier and lighter reporting volume are anticipated throughout the year. Contractor is responsible for maintaining active monitoring and adjusting of the number of reports processed on an annual basis.

TASK 1. ADMINISTRATIVE

STANDARDIZED METHODS FOR PROVIDING OPERATIONAL SUPPORT FOR THE VAERS PROGRAM.

- A. The Contractor shall maintain Capability Maturity Model Integration (CMMI) Level 3 certification (or equivalent) or higher throughout the performance period of the contract and shall provide the Government current documentation of its CMMI Level 3 (or equivalent) or higher certification.
- B. The Contractor shall have staff available for program operations, systems maintenance and consultation during normal business hours (8:30 AM Eastern to 5:00 PM Pacific) to accommodate all four time zones within the continental United States. The rationale for this requirement is that it is essential for VAERS to be fully operational and for staff to be available to conduct systems maintenance and recovery during both east and west coast business hours and to also provide a reasonable level of service for the Hawaii-Aleutian time zone, since VAERS is a national spontaneous surveillance system.
- C. The Contractor shall maintain a disaster recovery site for data management, data storage and all other VAERS data and IT functions that duplicates and replicates the primary production site and provides recovery of the production site within 24 hours (refer to **Task 5: INFORMATION MANAGEMENT** for capability requirements). This site shall be at least 100 miles away from the primary production site. The rationale for this requirement is that the disaster recovery site must be sufficiently distanced from the immediate area of the primary production site, but realistically within a business day's drive during an emergency.
- D. The Contractor shall provide hardware, software, office and communications equipment and other resources to be used for data receipt, processing, editing, analysis, reporting, transmission, and storage. The Contractor shall ensure systems compatibility with CDC and FDA software and hardware requirements. The Contractor shall ensure that applicable technology is capable of upgrade or provide for replacement with later technology if necessary. Hardware, software and equipment shall be maintained and upgraded in accordance with industry standards for IT and telecommunications equipment including routine maintenance.
- E. The Contractor shall upgrade VAERS program and related applications at the Government's direction through official modification signed by the Contracting Officer (CO), based on requirements gathered from Government and other program stakeholders, using structured, phased software development methodology.
- F. The Contractor shall provide the Government with current and detailed system documentation. Documentation shall be maintained in two separate volumes: "Volume 1 – VAERS Business Processes" and "Volume 2 – VAERS IT Requirements and Design". Requirements shall be maintained in a formal requirements database, to be prioritized by a change control board consisting of CDC, FDA and Contractor personnel. Work will be prioritized using this process, in both a routine and expedited manner as appropriate. The Contractor must demonstrate adherence to formal CMM Level 3 methodology as the

standard for project performance. System documentation will be presented in standardized text format, generated in Microsoft Word document format (or other word processing format as specified by the Government), with all diagrams and other graphics contained as embedded objects with no external files or links, and presented in legible paper form or electronic form if requested by the Government. The Contractor shall provide detailed documentation of the technical procedures for data transport to the CDC and FDA, and documentation of technical details for source code and code relation, library dependencies, and data transport mechanisms. The Contractor shall provide the Government with this documentation within 30 days after contract award and annually or as requested thereafter, and new sections or documentation revisions will be provided to the Government upon implementation of changes in the system or procedures.

- G. The contractor shall communicate with CDC and FDA, any requested changes to the system (including, but not limited to database structure, and data processes) prior to implementation. Modifications/changes will not be performed until approval from CDC and FDA.
- H. The Contractor shall write standard operating procedures (SOPs) and modify them as needed. SOPs for all aspects of VAERS program operations, including complete VAERS report processing, shall be updated and provided to the Government annually or as requested. All SOPs shall be submitted to the Government for initial review and approval within 30 days after contract award and within 30 days of revision or implementation of changes, and minimally on an annual basis or as requested by the Government thereafter. SOPs shall be provided in a volume or series of volumes organized by subject, and will be presented in standardized text format, generated in Microsoft Word document format (or other word processing format as specified by the Government), with all diagrams and other graphics contained as embedded objects with no external files or links.
- I. The Contractor shall provide VAERS operations and system orientation for Government employees as necessary (minimum once per year).
- J. The Contractor shall produce and distribute the VAERS reporting form (Attachment A) and other forms as required for the operation of the VAERS program and reporting to VAERS. The VAERS program shall be identified as a Government program and the corporate name of the Contractor shall not be used on any form or correspondence to any entity other than CDC, FDA, or VICP, or used in any communication to represent the VAERS program unless approved by the Government.
- K. The Contractor shall maintain lists of names, phone numbers, fax numbers, and E-mail addresses of contact personnel responsible for reporting from state health agencies, vaccine manufacturers, and immunization programs, limiting access and use to VAERS purposes only. The Contractor shall update this list on a quarterly basis and maintain this list for access by the Government in a manner specified by the Government.
- L. The contractor shall shred all incoming documents once they are permanently saved electronically.
- M. The Contractor shall establish, implement and maintain selected work groups as required by the Government throughout the life cycle of the contract, as needed and directed by the Government, and shall take and distribute minutes for working group meetings at the direction of the Government.

TRANSITION OF CONTRACT SERVICES

The Government considers VAERS an essential service; any lapse in coverage is considered unacceptable and can result in possible termination of contract. The Government requires a smooth and orderly transition of services.

- A. No later than 60 days after the contract award the Contractor shall have established a system of operations as described elsewhere in this SOW and perform a functional evaluation of the system. Furthermore, the Contractor shall be able to receive VAERS reports after COVID-19 vaccines via any of the means specified in this contract (including electronically submitted reports from manufactures (eVAERS) and public (website). The Contractor shall also be able to perform all activities involving the handling and processing

of reports submitted to VAERS including report receipt, processing, data entry, coding, quality control, and report follow-up and verification. Contractor shall be able to provide data to the Government in the manners specified within this SOW, including the provision of data extracts, reports and report images, and meet this timeline development requirement as indicated for other activities and functions described within this SOW.

- B. No later than 60 days after contract award the VAERS system maintained by the Contractor shall be fully operational and shall meet the satisfaction of the Government as to operational functionality.
- C. No later than 60 days after contract award the Contractor shall meet all developmental and operational requirements in this SOW unless other specific timeline requirements for those requirements have been specified in the SOW.
- D. No later than 60 days after contract award, the Contractor shall provide a Transition-Out Plan (end of performance period). The plan shall include a technical and management transition approach that is clear and complete and include a timeline and list of resources required for the transition. The Transition-Out Plan shall detail the planned transition methodology in logical sequence to ensure a smooth transition of all tasks and subtasks without interruption or decline in service quality. The plan shall also include a detailed description of risks (cost, technical, and performance) to both the Contractor and the Government, as well as risk mitigation strategies. Contractors shall also include all transition costs within their proposals. Please note that the continuity of services clause 52.237-3 is applicable and should be considered in developing the transition plan.

All documents and materials developed by the Contractor for the fulfillment of this contract, including all SOPs, manuals, security plans, management plans and plans of operations, and hardware shall be considered the property of the Government and may be disposed of by the Government in any manner at the Government's discretion.

CHANGES TO INFORMATION MANAGEMENT PROCEDURES AND TASKS

- A. All tasks and activities specified in this SOW that pertain Information Management are subject to change, at the Government's discretion, to accommodate and support fully electronic reporting to VAERS.
- B. Reasonable accommodations will be made to the Contractor by the Government to allow for implementation of any such revised and updated Information Management procedures and the Contractor will be allowed to negotiate implementation of changes within the scope via official modification.

UNFORESEEN EVENTS/CIRCUMSTANCES

Unanticipated project needs may materialize, requiring efforts beyond those described in this SOW. The Government may modify the contract to add task requirements (or enhance/expand current requirements) in support of public health emergencies (e.g. pandemic flu, natural disasters and terrorist activities) and unknown Federal mandates which are unpredictable and can initiate a workload surge, necessitating an increase in Contractor staffing. These new requirements may result in increased workload for any of the tasks listed in the SOW Tasks 1-5.

- A. **Approval Process for Unforeseen Events and Circumstances**
CDC will provide the new work requirements and deliverables for each of the optional support services to the Contracting Officer (CO) as a revision to the SOW. The CO will send the contractor the revised SOW containing the new requirements. The contractor will review the requirements and provide a technical and cost proposal with the appropriate labor categories, number of hours, and labor rates to the CO. A contract modification (SF30) must be awarded by the CO to add any new optional support requirement. The contractor must not work outside of the SOW without authorization from the CO.
- B. The Contractor shall be prepared to address unforeseen events/circumstances and meet the needs of the Government as it relates to any unforeseen events/circumstances. Reasonable accommodations will be made to the Contractor by the Government to address unforeseen events/circumstances and the Contractor will be allowed to negotiate the implementation of changes.

- C. The implementation of activities to address unforeseen events/circumstances specified by the Government is dependent on the availability of core and supplemental funding to support such activities.
- D. Examples of unforeseen events/circumstances that have impacted VAERS operations include (1) changes in the IT certification and accreditation process, (2) changes in regulatory requirements for reporting VAEs and transmitting data to CDC and FDA, (3) introduction of new vaccines resulting in necessary coding and database architecture changes, (4) changes in reporting requirements, report processing procedures, and data availability timelines to meet current public health needs, (5) urgently needed IT capability during public health emergencies or in preparation for anticipated public health emergencies, and (6) hardware and software upgrades to accommodate unforeseen events/circumstances. This is not an exhaustive list and other unforeseen events/circumstances may occur throughout the course of the contract performance period.

PROGRAM MANAGEMENT PLAN FOR CONTRACT ACTIVITIES

- A. The Contractor shall develop and maintain a Program Management Plan (PMP). The Contractor shall prepare and maintain a phased Program Management Plan describing the tasks, milestones, risk management strategy, organizational resources, performance measures and management control to be employed to meet the cost, performance requirements and schedule of each phase of the VAERS project. The plan shall define the Contractor's governance process and include:
 - 1. The management structure of the Program Management Team, organizational charts, key personnel and main points of contact, and identification of project teams and their roles and responsibilities.
 - 2. Identification of all partners, sub-contracts, sub-contractor management, criteria for selection of sub-contractors, and description of services to be performed by sub-contractors. The Contractor shall not sub-contract out more than 25% of the work described in this SOW (i.e., 75% of the work requirements described in this SOW must be completed by the prime Contractor). Sub-contracting out clinical services tasks, report processing and data entry, coding, report follow-up activities, core IT activities, quality assurance, and core business and administrative tasks is strongly discouraged and will be viewed unfavorably and result in possible termination of contract.
 - 3. Detailed mitigation response procedures in the event of unsatisfactory performance of program/project team members or sub-contractors.
 - 4. Specification of strategies to include detailed timelines with critical milestones to ensure that both long-term, strategic goals as well as specific, targeted objectives are met efficiently and effectively.
 - 5. The Contractor shall submit the PMP to the Government within 30 days after contract award and shall provide updates to the PMP annually or as requested by the Government. The PMP shall be in accordance with OMB Circular A-11, and the Federal IT Capital Programming Guide, Supplement to Part 7 of Circular No. A-11. Approval of the PMP by the Government shall be required.
- B. Key Project Personnel: The Contractor shall employ and retain competent, qualified personnel to perform services of this contract in an effective, prompt, accurate, courteous and efficient manner. The Contractor shall provide a plan for staffing key positions for this project, providing detail about the criteria and selection process used to fulfill the requirements of this contract, and shall notify CDC in the event of changes in staffing of key positions. Staffing of these key positions shall be subject to Government approval. The Contractor shall provide all necessary supervisory, project management, managerial, clinical, technical and administrative support to meet the planning, implementation, operational and management requirements of this contract.

**NOTE FOR ALL TASKS

Qualifications for personnel performing clinical activity (clinical staff) shall be subject to approval by the Government; the minimal education and experience qualifications for this activity shall be a nurse or other

clinical healthcare provider, with a minimum of 2 years of clinical or public health related experience. The manager of the follow-up activity shall be, at a minimum, an RN, PA, MD, DO or equivalent (e.g., MD from a foreign country who is not licensed to practice in the United States). The manager is required to have at least 2 years of clinical experience. The manager shall work closely with the Government to ensure that follow-up is conducted according to Government expectations.

REPORTING REQUIREMENTS:

- A. **PROGRAM MANAGEMENT MONTHLY STATUS REPORT** - The contractor shall provide the Government with a monthly Program Management Monthly Status Report electronically to include the project's cost, progress, and issues in a format as directed by the Government. A copy of each monthly report shall be sent to the COR, the CO, and the FDA Technical Representative. The contractor shall document in the report the efforts performed in the completion of each project task. The report shall be due on the 15th day of each month following the month reported upon.

The Contractor shall propose format and data element recommendations for this report. The final format of the report shall be determined upon contract award.

- B. **ANNUAL REPORT** - On an annual basis, the Contractor shall provide a written report to the Government documenting significant work activities and accomplishments for the preceding 12-month period. This report shall provide a historical record of major work activities accomplished, those ongoing and those not accomplished for the reporting period. As an appendix to the annual report, the Contractor shall deliver to the Government the current database dictionaries, standard operating procedures, and user manuals. The annual report shall be delivered to the Government no later than 30 days following the specified reporting period. One report shall be sent to the COR, the CO, and the FDA Technical Representative.
- C. **DRAFT FINAL REPORT** - The Contractor shall provide a draft final contract report no later than 45 days prior to the expiration date of year 2 of this contract for review by the Government. The report shall include a written narrative highlighting major accomplishments under the contract. The report shall address each year of performance under the contract and document significant contractor findings, conclusions, recommendations, etc., to provide an objective review of contract activities. The Contractor shall provide copies of each draft final report electronically, and optional paper copies at the Government's request. One report shall be sent to the COR, the CO, and the FDA Technical Representative.
- D. **FINAL REPORT** - Following review of the draft final report by the Government and receipt by the Contractor of the Government's written comments, the contractor shall provide a final report on or before the expiration date of the contract. The Contractor shall provide copies of each final report electronically, and optional paper copies at the Government's request. The report shall be sent to the COR, the CO, and the FDA Technical Representative.

FORMAT OF DELIVERABLES

Specific form format and additional content requirements of the delivery schedule items shall be coordinated between the Contractor and the Government, with a continued focus on providing useful and accurate reporting. The COR will provide the Contractor with disposal instructions for all technical documents (including, but not limited to all database dictionaries, databases, software, computer code, documentation, questionnaires, electronic files, etc.) in possession of the contractor at contract completion.

TASK 2. REPORT RECEIPT/PROCESSING

REPORTING TO THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) AFTER COVID-19 VACCINES

The Contractor shall perform the following tasks/activities:

- A. Maintain communication protocols to provide assistance to the public for Vaccine Adverse Event Reporting System (VAERS) after COVID-19 vaccine-related questions. Communication protocols shall

involve appropriate telecommunication and electronic mechanisms for answering questions related to VAERS COVID-19 vaccine reporting and the VAERS system (e.g., how to obtain reporting forms, options for reporting, information referrals), and allowing for filing of VAERS reports over the phone in English or Spanish. The Contractor shall maintain communication protocols including, but not limited to: a toll-free telephone number and toll-free telefacsimile number to be listed as VAERS; a web site identified as VAERS, and an e-mail address (e-mail address may be specified by Government). The Contractor shall have staff available for consultation during normal business hours (8:30 AM to 5:00 PM) that accommodate all four time zones within the continental United States (refer to Task 1:

ADMINISTRATIVE for options for active time zone coverage during normal business hours in the continental United States). The Contractor shall implement, maintain, and upgrade as necessary, telecommunication and electronic reporting systems to be available 24 hours-per-day (the toll-free telephone number is answered by machine after business hours). After-hours automated support shall be available 24 hours-per-day through the web and fax. See Emergency Preparedness section for after-hours support details. Contractor staff shall respond to messages received at the VAERS telephone number and messages sent to the VAERS e-mail address within one business day of receipt.

- B. Staff the telephone system to provide telephone support for reporting during hours that accommodate normal business hours in the four time zones in the continental United States. The Contractor shall maintain a telephone voice message system, available at all times, which shall:
 1. Provide a mechanism for callers to contact VAERS toll-free by telephone;
 2. Provide coverage by automated menu choices for those times when Contractor staff does not immediately respond to calls to the telephone system;
 3. Provide instructions to callers on ways to obtain the VAERS form and instructions on how to submit a VAERS report;
 4. Provide directions to find the VAERS website and to submit a VAERS report using the internet-based reporting form;
 5. Take messages at those times the telephone system is not actively staffed;
 6. Provide information on the National Vaccine Injury Compensation Program (VICP) (website information: www.hrsa.gov/vaccinecompensation) and Countermeasures Injury Compensation Program (CICP): <https://www.hrsa.gov/cicp/>;
 7. Provide additional information to callers as directed by the Government.
- C. Maintain a United States Postal Service post office box identified as Vaccine Adverse Event Reporting System (VAERS) for COVID-19 vaccines and ensure, at a minimum, retrieval and logging of all mail from the post office box during each business day.
- D. Maintain VAERS for COVID-19 vaccine electronic internet-based reporting system, utilizing appropriate system security precautions. This includes reports submitted by VAERS users such as state health coordinators, immunization programs, other Federal Government agencies and programs, and other parties. The procedures shall include methods for receipt of reports via the Internet and shall allow for reporters to submit an initial VAERS report for COVID-19 vaccines or a non-primary report using an Internet-based application, including an electronic version of the VAERS form for COVID-19 vaccines.
- E. Maintain procedures to migrate data from VAERS COVID-19 vaccine manufacturer reports received electronically into the database, utilizing appropriate system security precautions. Manufacturer reports that must be received electronically include -marketing expedited individual case safety reports (ICSRs), periodic ICSR, as well as malfunction reports and 5-day reports required by the Combination product Post-market Safety Reporting Rule. Electronic manufacturer reporting using ICH E2B (R3) is referred to as eVAERS.

- F. All methods for electronic transmission of reports developed and maintained for this project shall be based upon the HL7/ISO 27953-2 specification available at: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=53825, the ICH E2B(R3) Implementation Guide available at: <http://www.ich.org/products/electronic-standards.html>, the FDA E2B(R3) Implementation Technical Specification that will be available on CBER's ICSR website at: <https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation>, or other formats as specified by the Government.
- G. Develop, document and implement procedures for the entry and processing of COVID-19 vaccine report data to ensure that the VAERS public data that is made available to the public is redacted of all protected health information (PHI) and other information that is protected under the Health Insurance Portability and Accountability Act (HIPAA) (<http://www.hhs.gov/ocr/privacy/>), or otherwise not publicly releasable for reasons of commercial confidentiality (as directed by the Government), regardless of the report source (paper/fax/other, web, e-report). Government users of VAERS COVID-19 vaccine data shall have access to personal identifiers from the specific fields for names, addresses, telephone numbers, etc. through the internet-based report viewing system created and maintained by the Contractor. Such data containing PHI shall be included at the direction of the Government in the Government Extract for the CDC, FDA or both.
- H. Maintain a methodology to permanently archive electronically submitted VAERS COVID-19 vaccine reports as originally submitted, prior to any editing or redaction. The method shall allow for identification and retrieval of the reports from the archive database by specific report identifiers and by organization source of origin for reports submitted by manufacturers, state health coordinators, immunization programs, other Federal Government agencies and programs, and other parties.
- I. Maintain methods to support a variety of Electronic Data Interchange (EDI) message types specified by the Government. The Contractor shall have the capability to both receive and transmit VAERS COVID-19 vaccine reports electronically in EDI formats specified by the Government and in additional electronic report submission formats consistent with electronic submission requirements based upon the HL7/ISO 27953-2 specification available at: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=53825, the ICH E2B(R3) Implementation Guide available at: <http://www.ich.org/products/electronic-standards.html>, the FDA E2B(R3) Implementation Technical Specification that will be available on CBER's ICSR website at: <https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation>, and other formats specified by the Government.
- J. Under the direction and approval of the Government, the Contractor shall support additional EDI interface products for VAERS users. These include products from other vendors that use the VAERS web-reporting form, commercial off-the-shelf products, and other products as they are developed. An EDI interface product has been developed, utilizing the VAERS internet-based electronic submission form as a means for EDI electronic submission of VAEs by VAERS users from their immunizations databases. The Contractor shall successfully complete this task for existing, supported EDI interface products within 30 days after contract award. The contractor shall successfully complete this task for new EDI interface products of this nature within 30 days following direction from Government to perform this task.

STANDARDIZED METHODS FOR ENTERING AND PROCESSING VAERS COVID-19 VACCINE REPORTS

A. Report Data Entry and Processing Timeline Requirements:

The Contractor shall perform all necessary data entry for information submitted on VAERS forms for COVID-19 vaccine reports and related documents, and editing of the database, with all entry and edits tracked by date and entry staff and editors' individual identification. The Contractor shall be able to perform these activities within 30 days after contract award. See Appendix A (also in the section under Task 3) for information on scanning, data entry and coding timelines.

The timeline requirements for processing reports for VAEs of special interest to the Government (e.g., seizure) may differ from the above requirements and will be determined or otherwise agreed upon in SOPs approved by the Government. Timelines will be adjusted in response to changing public health needs, such as during a public health emergency or if a vaccine recommendation changes (e.g., a vaccine that was not previously recommended for children becomes recommended).

B. Documentation, SOPs, and user procedure manuals:

The Contractor shall perform the following tasks/activities related to adverse events reported after COVID-19 vaccines:

1. Maintain and update comprehensive documentation of database structure; design and analysis, including dictionaries, edits, report processing, and computer programs (including menu driven programs); user procedure manuals; and other tasks and functions and any modifications set forth in this SOW. Documentation shall adhere to the standards set forth elsewhere within this statement of work, to include Capability Maturity Model (CMM) standards.
2. Provide user-procedure manual(s) and SOP manuals for technical aspects of VAERS COVID-19 vaccine database operations to the Government within 30 days after contract award. Implementation of all procedures is contingent on Government review and approval.
3. Maintain, update and provide to the Government as requested complete documentation of the COVID-19 vaccines database and all regularly produced extracts. The documentation shall be readily available to the Government for use or reference and include data dictionaries for the datasets (including variable names, formats, descriptions, comprehensive list of legal codes) versions of the Medical Dictionary for Regulatory Activities (MedDRA) terms, (www.medramssso.com) or other coding language chosen by the Government, and look-up tables for vaccine, manufacturer, and MedDRA terms.
4. Maintain full, detailed documentation for all business and technical aspects of the VAERS COVID-19 vaccine program. Documentation shall be updated annually or as requested by the Government, and maintained in two separate volumes: "Volume 1 – VAERS Business Processes" and "Volume 2 – VAERS IT Requirements and Design" as detailed in the Administrative section of this SOW.
5. Maintain a formal "requirements" database, to be prioritized by a "change request board" consisting of CDC, FDA and Contractor personnel. Work shall be prioritized by this process, in both a routine and expedited manner as appropriate to the requirement.

ACKNOWLEDGMENT, VERIFICATION, CODING AND DATA COLLECTION FOR ADVERSE EVENTS REPORTED AFTER COVID-19 VACCINES

The Contractor shall perform the following tasks/activities:

- A. Review all documents received daily through all channels to prioritize processing, and assign a unique index number to each report received and initiate processing based on SOPs for the report category and method of transmission. The unique index number (VAERS ID number) shall appear in the personal data files and in files created for other information.

For electronically submitted reports and reports submitted using the internet-based reporting application, a unique index Electronic Report Number (ERN) shall be generated at the time the report is received, and shall be communicated back to the originator of the report using a formal acknowledgement or EDI submission confirmation message integrating the E-Report Number into the message. The ERN shall be included in the primary system database and in the Government extract, and in relational data tables providing linkage between the ERN and VAERS ID number assigned to each report and may be used to query the VAERS report in the master database and Government extract. For electronically submitted EDI reports, sufficient information shall be retained from the EDI VAE message to uniquely identify the report and enable tracking and identification of the report within the primary system database.

- B. Enter into the database all data submitted on report forms and related documents within the time limits specified in this SOW.
- C. Code VAE data after COVID-19 vaccines on the VAERS report form (paper or electronic form/data), from related documents/records, and from additional information sources related to the report (i.e., records obtained during follow-up) using the most updated version of MedDRA (<http://www.meddra.org/>) or other coding source specified by the Government. Codes shall be entered into the database. Relational tables and data dictionaries shall be provided to the Government for all coding used throughout the system. The Government reserves the right to update and replace coding standards as required for the data elements, and reserves the right to introduce requirements for standardized coding for data elements not included in this SOW.
 - 1. The Contractor shall enter into the database COVID-19 vaccine VAE descriptive clinical information and other symptoms, signs, lab data and/or disease entities, including text fields contained in Boxes 9, 10 11, 12, 18, and 19 on the VAERS reporting form (Available at <https://vaers.hhs.gov/uploadFile/index.jsp>) and code this information using MedDRA (or other coding language chosen by the Government). The specific boxes may change if the VAERS form is modified.
 - 2. At the direction of the Government, the Contractor shall assess and potentially implement alternative methods for coding reports (computer assisted, automated, algorithm generated, etc.), and conduct post-implementation quality assurance. The implementation of alternative coding methods is dependent on the availability of core and supplemental funding to support such activities.
- D. If requested by the Government, in the event that FDA approves new or modified labeling for a COVID-19 vaccine, the Contractor shall identify VAEs from the Adverse Reaction, Precautions, and Contraindications sections of the labeling and translate them into MedDRA (or other coding language chosen by the Government) terminology (known as labeled event data). When there is a change in labeling, the Contractor shall submit proposed modifications to the Government and modify the list of terms at the direction of the Government. All code lists or labeling changes submitted by the COVID-19 vaccine manufacturers must be approved by the Government before implementation.
- E. At the direction of the Government, the Contractor shall develop, update, maintain, and provide data dictionaries for all data tables provided to the Government including the tables associated with vaccines, adverse event coding (MedDRA, or other coding language chosen by the Government), manufacturers, and labeled events associated w/vaccines. The labeled event dataset shall indicate labeled events associated with COVID-19 vaccines as identified in vaccine package inserts and product labels. The contractor shall enter labeled events within 10 working days following the introduction of a new vaccine or at the direction of the Government. The Contractor shall review and update the labeled events table annually or as necessary.
- F. Comply with the safeguarding procedures for report forms as required by the NCVIA – 42 U.S.C. 300aa-25, and the safeguarding guidelines of the Privacy Act. The Contractor shall ensure that information which could identify an individual (such as name, street address, telephone number and email address of the person who received the vaccine and that person's legal representative) shall not be made available to any person other than the person who received the vaccine or the legal representative of such person and duly authorized staff of CDC, FDA and other participating federal entities. The restriction on access to identifying information applies to all information received by the VAERS activity, regardless of physical format (paper, electronic, other). The process shall be subject to review and approval by the Government.
- G. Maintain storage of original and depersonalized data separately. Records shall be maintained in accordance with Privacy Act regulations and procedures and defined in the Automated Information Systems Security Program Handbook. Separate physical and electronic storage of original and redacted report data shall be maintained.

DATA AND DOCUMENT ACCESS, TRANSMISSION, STORAGE AND RETRIEVAL

(See Appendix A for detailed information on scanning, data entry and coding timelines).

The Contractor shall perform the following tasks/functions:

- A. Maintain procedures to complete processing of death, 5-day, 15-day, serious, or other priority reports as specified in Appendix A, or upon request of the Government.
- B. Make available to the Government an electronic copy of all received documents within the specified timeframes detailed in Appendix A. The Contractor system (currently a virtual private network [VPN] containing scanned images) enables Government staff electronic access to reports/documents while preserving the integrity of the original document.
- C. Scanned reports and other documents that the Contractor makes available to the Government on the VPN do not require redaction unless specified by the Government.
- D. Provide a data extract (Government Extract) of the VAERS COVID-19 vaccine data to the Government for storage and use at Government sites (both CDC and FDA) each business day, in accordance with this SOW.
- E. Redact all PHI from reports to the VAERS database after COVID-19 vaccines that appear anywhere on the VAERS report form except boxes specifically asking for PHI. For example, if Box 18 on the VAERS 2.0 form states "I gave Mr. Jones his flu shot and then he had a reaction," the words "Mr. Jones" should be redacted from the VAERS database.

CHANGES TO REPORT RECEIPT AND PROCESSING

- A. All tasks and activities specified in this SOW that pertain VAERS report receipt and processing are subject to change, at the Government's discretion.
- B. Reasonable accommodations will be made to the Contractor by the Government to allow for implementation of any such revised and updated report receipt and processing procedures and the Contractor will be allowed to negotiate implementation of changes.

TASK 3: VAERS FOLLOW-UP ACTIVITIES AND ENHANCED SURVEILLANCE

The Contractor shall conduct follow-up on VAERS COVID-19 vaccine reports as specified by the Government in this SOW. Follow-up consists of the 3 parts outlined below:

- Communication Activities and Automated Record Collection
- Record Collection and Data Clarification
- Clinical Activities

COMMUNICATION ACTIVITIES AND AUTOMATED RECORD COLLECTION FOR VAERS COVID-19 VACCINE REPORTS

The Contractor shall:

- A. Upon receipt of a death report from a family member, provide a condolence letter to express sympathy and explain VAERS procedures.
- B. Provide immediate electronic acknowledgement to all persons who submitted VAERS reports via the Internet using the online reporting tool.
- C. Provide acknowledgement in the form of a thank-you notification to all persons who submitted VAERS reports via paper format. Exceptions to this requirement are family members who report deaths, all manufacturers, and all state health coordinator reporters.

- D. Develop and implement standardized letters, forms, logs, phone scripts and other documents, subject to approval by the Government, and implement documents developed by the Government at the direction of the Government, in order to verify the accuracy of submitted data.
- E. Maintain procedures to request additional information from reporters or providers if information from essential items (2-6, 17, 18, and 21) on the initial VAERS report are missing, inconsistent or invalid. (See https://vaers.hhs.gov/pdf/vaers_form.pdf). Essential item numbers are subject to change if the VAERS form is altered or updated by the Government.
- F. Maintain procedures to request disposition updates from reporters at 60 days and 1 year after report receipt for all serious reports with recovery status listed as not recovered. Include a request for any additional information. No 60-day update is required if routine follow-up has been conducted on the report.

RECORD COLLECTION AND DATA CLARIFICATION FOR COVID-19 VACCINE REPORTS

- A. For all COVID-19 vaccine reports designated as serious by regulatory definition (death, life-threatening illness, hospitalization, prolongation of existing hospital stay, permanent disability, or congenital anomaly/birth defect), the Contractor shall attempt to collect follow-up records and additional documentation of the event (includes clarification of the event if necessary). In addition, for other adverse events of importance as determined by the Government, the Contractor shall attempt to collect follow-up records and additional documentation of the event. Follow-up activities include:
 - 1. Identification and resolution of conflicting or incorrect information in the VAERS database and annotation in the VAERS graphic image file.
 - 2. Retrieval of pertinent medical records including hospital discharge summary, labs, history and physical reports, medical, death certificates and/or autopsy reports. In addition, if the vaccination information is missing or unclear (e.g., a report states “flu vaccine” but the brand or manufacturer name is missing) the vaccination record shall be obtained.
 - 3. Scanning of all collected documents/records into the VAERS image base.
 - 4. Other follow-up activities as directed by the Government.

Upon award of the contract, the Government will provide detailed, standard procedures for follow-up, which are subject to change based on the needs of the Government. See Appendix A for required timeframes for follow-up. VAERS correspondence can be via email or hardcopy letters.

Report Confirmation for COVID-19 Vaccine Reports

Confirmation correspondence is sent on receipt of a VAERS COVID-19 vaccine report submitted by a consumer or healthcare professional. Hardcopy letters or email correspondence are sent, depending on the person’s communications preferences (specified in the VAERS report). Vaccine manufacturers do not receive these communications.

<u>REPORT TYPE</u>	<u>FOLLOW-UP</u>	<u>CORRESPONDENCE TYPE</u>
STANDARD - NO MISSING INFORMATION	Send letter or email	Confirmation*
STANDARD - INFORMATION MISSING	Send letter or email	Confirmation with request for missing information*
SERIOUS WITH “NO” FOR RECOVERY STATUS	Send letter or email	60 day follow-up and one year follow-up*
DEATH REPORTS FROM FAMILY MEMBERS	Send letter only	Condolence letter; consumers only*

**The Government will provide the format and wording of the letters for the contractor's use*

Medical Record Requests for COVID-19 vaccine Reports

Requests for medical records are sent in follow-up* to a VAERS COVID-19 vaccine report.

<u>REPORT TYPE</u>	<u>FOLLOW-UP</u>	<u>CORRESPONDENCE TYPE</u>
SERIOUS REPORTS AFTER COVID-19 VACCINE	Send request for medical records for COVID-19 vaccine reports letter*	Request for medical records for COVID-19 vaccine reports**
NON SERIOUS REPORTS OF SPECIAL INTEREST	Send request for medical records letter*	Request for medical records**
DEATH	Send request for death certificate letter	Request for death certificate**
FOREIGN	None	
MANUFACTURER REPORTS	None except death or if requested by the Government (of special interest).	
CLINICAL TRIALS	None	

**The Government will provide a guidance document to specify what records the contractor needs to obtain.*

***The Government will provide the format and wording of the letters for the contractor's use*

CLINICAL ACTIVITIES FOR COVID-19 VACCINE REPORTS

- A. Clinical staff shall review follow-up records and add a narrative summary to the Government data for each report to reflect follow-up records collected. If records are not available, clinical staff may need to contact providers or patients to obtain follow-up information. For example, if a patient reports a serious adverse event but does not seek medical care, the patient or parent would need to be called to obtain the details and outcome of the event.
- B. Clinical staff shall add appropriate MedDRA codes to the record to reflect data from the follow-up. An indicator variable will be provided to distinguish between initial and follow-up MedDRA codes, as well as, item number on the VAERS form.
- C. Clinical staff shall edit or supplement as needed the relevant VAERS database record based on documents collected in follow-up (e.g., if the vaccine records differ from what is on the VAERS report, the vaccine information shall be corrected in the VAERS data).
- D. Clinical staff shall complete Government-developed forms for specific reports which are intended to obtain supplemental information as directed by the Government.
- E. Clinical staff are expected to pursue any leads that become apparent during the follow-up process and obtain information beyond what is detailed on any standard questionnaire that may contribute to an understanding of the underlying cause(s) of the adverse event in question. The information obtained from these leads shall be documented in narrative format by the follow-up staff. For example, if during follow-up the clinician learns that the patient had to be readmitted to the hospital, those records should be obtained and summarized in addition to the initial hospital admission records.
- F. Information obtained during follow-up shall be clearly separated from information in the VAERS report when entering follow-up data into the VAERS database. The Government will provide instructions on how this will be accomplished. Follow-up information will NOT be included in the VAERS public data.

- G. When unexpected, significant, or unusual findings are identified during the performance of follow-up activities, findings shall be shared with FDA and CDC VAERS staff as determined by the professional judgment of the clinical staff.
- H. Clinical staff shall stay current on vaccine recommendations and VAEs. A useful resource is the Advisory Committee on Immunization Practices website: <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>
- I. Provide an indicator variable in the database that will specify if the medical records were collected and the type of records obtained.

TASK 4: QUALITY CONTROL FOR VAERS COVID-19 VACCINE DATA

The Contractor shall develop and implement a Quality Assurance Program (QAP). The QAP is applicable to all functional areas of this SOW and will allow the Government to verify that contract performance objectives are met, the best possible contract performance is being provided, and there is continuous improvement in the quality of contract services. The QAP is an important tool for using and monitoring performance indicators and ensuring the achievement of desired performance measure outcomes. The QAP shall establish quantitative evaluation strategies to ensure that contract performance measurements meet or exceed the highest levels of service.

The Contractor shall work with the Contracting Officer (CO) and Contracting Officer's Representative (COR) to develop standardized tools for assessing contract/project activities and provide consistent evaluation scoring. The Contractor shall conduct self-assessment and evaluation quarterly through the QAP and other strategies and methodologies to ensure quality performance of contract activities.

The QAP shall establish quantitative evaluation strategies to ensure compliance to the contract performance measurements and meet or exceed the highest levels of service. The plan should specify who within the Contractor's organization has oversight for quality initiatives. The Contractor shall provide this plan to the Government within 30 days after contract award. The plan should be updated as necessary (at a minimum annually) or as instructed by the Government to ensure that it remains current.

Quality control procedures shall be developed and implemented, subject to review and approval by the COR, for submitted data, entered data, scanned images, follow-up data and coded data. The areas to be addressed shall include completeness and accuracy of data, recovery status, follow-up, timelines of report processing for serious reports, unexpected occurrences (e.g., pandemic influenza, new recommendations), and completeness and accuracy of vaccine lot information on all VAERS COVID-19 vaccine reports.

QUALITY CONTROL AND ASSURANCE FOR ENTERED AND PROCESSED DATA FOR COVID-19 VACCINE REPORTS

- A. The Contractor shall establish, implement, update and maintain standardized methods for confirming the quality of processed data through standardized quality control and quality assurance procedures designed to reduce or eliminate duplicate entries, data inconsistencies or deficiencies.
- B. Subject to Government approval, the Contractor shall develop, demonstrate, document, and implement procedures to maintain data quality at a level adequate to support data analysis. The procedures shall include:
 - 1. Automated editing procedures for data entered by the contractor using the Contractor's internal data entry system, including double-entry verification of entered data for select fields in reports as specified by this SOW.
 - 2. Automated spelling checks for all text fields on the forms that undergo data entry by the contractor using the Contractor's internal data entry system. Automated spelling check functions shall include standard and custom dictionary spell check, including abbreviations and medical terminology. This process shall detect and alert the operator to possible spelling errors at the time of data entry, so that the operator can immediately implement appropriate corrections.

3. Incorporation of appropriate field restrictions, legal value checks, and background logic checks in the data entry software to ensure that the entered information is logical and appropriate before it is accepted. These procedures shall include, but will not be limited to, the following edit-checks listed below :
 - a. Keystroke edit checks to ensure only correct values for the field are accepted. All other values cause the system to post an error/warning message.
 - b. Within-field checks to ensure that data are valid for that field (e.g., entering numbers in a Name field is invalid and shall be flagged in error/warning). In addition, unusual values in fields, for example: 1) adverse event onset date before vaccination; 2) interval between vaccination date and onset date greater than 10 years, shall be flagged.
 - c. Cross-field checks to ensure that information does not conflict with previously entered data (e.g., a death date is invalid if it is entered with a value prior to the date of birth or vaccination date/onset date prior to date of birth).

All edit checks procedures shall have the ability to be modified as needed. The data entry system shall display warnings or error messages when unusual or incorrect information is entered for new records or for existing records which are retrieved and updated.

4. Automated spelling checks and edit-checks, as described above, used on the web data entry system and implemented in a manner that does not impede or significantly increase form completion time by users.
 5. Development, implementation, utilization, documentation and reporting of internally calculated variables to define the quality of the data records entered. These variables shall be made available to the Government and shall be utilized in quality assurance programs and assessments by the Contractor and by the Government.
 6. Establishment of an edit program that outputs missing and non-plausible data for visual verification with the corresponding VAERS form image record.
 7. Establishment and implementation of a mechanism for correcting data errors detected in the previous steps.
 8. Review of all data on a quarterly basis to examine frequencies of categorical fields and the distribution qualities of continuous variables for any non-plausible data, and verification of any non-plausible data indicated in this step.
 - a. Establishment and implementation of a mechanism for data corrections indicated in the above review processes.
- C. The Contractor shall perform double data entry on all US serious COVID-19 vaccine reports and other reports as specified by the Government. The verification process shall include data entry into two independent data files by different personnel unless otherwise approved by the Government. Report entries shall be matched by identification number and discrepancies shall be resolved. Target permissible data entry effort rates shall be subject to review and approval by the Government. If the Government identifies significant data entry quality concerns, then the requirement for double-data shall be increased to include all reports received until further notice from the Government.
- D. All data entry procedures shall include real-time automated checks for illogical date relationships, invalid vaccine types, unavailable vaccines, invalid vaccine manufacturer combinations, invalid manufacturer or lot number, and other invalid data element combinations. Documentation of programming of these edit checks shall be submitted to the Government upon request. The data entry process shall be configured so initial data entry of records cannot be completed until all flagged data have been accepted as corrected or

moved to a queue for subsequent follow-up within one week. These later stages could include, at the discretion of the Government:

1. Addition of a module for acknowledgement letters sent to individual reporters to request clarification of missing or erroneous data; and
 2. Referral of records to follow-up staff as described in the Follow-Up Section in this SOW for correction or completion of missing or erroneous data through follow-up activities.
- E. The Contractor shall maintain and update a list of currently available COVID-19 vaccines during the contract period.
- F. The Contractor shall maintain within the Relational Database Management System (RDBMS), a log of all manual edits of processed data, including deleted files, with date, editor, and nature of edit identified. All data contained in files deleted from the database shall be moved to a separate data set that shall remain available for review and retrieval.
- G. Any errors identified by the Contractor QA checks or Government shall be corrected in the database.
- H. The Contractor will develop an SOP for identifying reports that are potentially or obviously false or “hoax” reports. Examples include, but are not limited to, reports where the reporter or reported vaccinated person are celebrities (e.g., Vladimir Putin, President of the Russian Federation), or where the reported adverse event is obviously not credible (e.g., attained an ethereal state and traveled through a wormhole to the beginning of the universe). The SOP will include guidance on adjudicating more subtle potentially false reports (e.g., the reported person’s residence is a place of business, or the address carries symbolic meaning, such as “1776 Independence Avenue”), a “quarantine” folder where such reports will be stored outside of other VAERS data, and metrics to track how many such reports have been received, and over what period of time.

QUALITY CONTROL AND ASSURANCE FOR SUBMITTED DATA QUALITY FOR COVID-19 VACCINE REPORTS

- A. The Contractor shall develop, demonstrate, document, and implement mechanisms to detect and request missing or discrepant data from the reporter. The requests shall be made in the form of report acknowledgment letters or other methods at the direction of or with the approval of the Government and shall present incomplete data fields and discrepant data for review and completion or correction by the reporter.
- B. The Contractor shall develop, demonstrate, document and implement mechanisms to detect, confirm, and link duplicate or redundant VAERS COVID-19 vaccine reports concerning the same adverse event. These mechanisms will be implemented as follows:
1. Initial data entry duplication search based on several key identifiers (e.g. name, date of birth, sex, vaccination date)
 2. Two times per week (or as specified by the Government) data entry duplication search on key identifiers, and adverse event. An adverse event is defined as a single “person vaccination event” or the combination of a patient, reported vaccine(s), and adverse event(s), submitted by one or more reporters.

The following business rules and definitions shall apply to this activity:

- a. The first COVID-19 vaccine report received by VAERS for a given adverse event shall be defined as the Primary Report. Other reports received after the Primary Report has been received and processed by the system shall be defined as Secondary Reports.

- b. Any COVID-19 vaccine reports received by VAERS after the Primary Report has been received, which are exact duplicates (photocopies or identical printouts or identical web based reports) of the Primary Report, shall be defined as Exact Duplicate Reports. These Exact Duplicate Reports shall be destroyed upon recognition.
 - c. Any COVID-19 vaccine reports received by VAERS after the Primary Report has been received, which relate to the same "person vaccination event", but which are not exact duplicates of the Primary Report, shall be defined as Redundant Reports. Redundant reports may originate from different reporters reporting the same "person vaccination event", or may originate from the same reporter as the Primary Report, or may provide different information about the adverse event, including information updates.
 - d. All COVID-19 vaccine reports that relate to the same "person vaccination event" shall be grouped together based on the VAERS ID for the Primary Report.
 - e. The manner of identifying the Primary COVID-19 vaccine Report and all subsequent (Secondary) reports shall be as follows, unless otherwise indicated by the Government. The Primary Report shall have the VAERS ID assigned at the time the report is entered into the system, followed by the identifier "-1". The first subsequent VAERS report concerning the same "person vaccination event" shall be assigned a "Linked Report" VAERS ID, which shall be the VAERS ID for the Primary Report, followed by the identifier "-2", at the time the report is identified as a redundant report. The second subsequent VAERS report concerning the same "person vaccination event" shall be assigned a VAERS ID, which shall be the VAERS ID for the Primary Report, followed by the identifier "-3", at the time the report is identified as a redundant report. Subsequent redundant reports shall continue to be numbered according to this pattern. The identifier digit following the hyphen shall be known as the "order number".
 - f. Assigning status regarding the serious nature (Item 21) on the VAERS form: death, life threatening illness, emergency room/department or urgent care visit, , hospitalization, prolongation of existing hospitalization, disability or permanent damage, congenital anomaly or birth defect, doctor or other health care professional office visit, none of the above) of the "person vaccination event" reported, as defined in 21 CFR 600.80, shall be based on the highest degree of severity for any of the reports received for a specific "person vaccination event". The report with the highest degree of severity shall take precedence in the determination of serious/non-serious status if discrepancies exist between the original report and subsequent reports. If there is uncertainty regarding a report's status as being serious or non-serious, reports should generally be adjudicated in favor of serious status.
- C. As required, the Contractor shall develop, demonstrate, document, and implement a methodology by which data submitted by multiple reporters, in multiple documents from the same reporter, or obtained through follow-up or verification activities regarding the same event, are combined to create a composite table or tables which include the reconciliation of conflicting information through follow-up with the reporter, health care provider or parent/vaccine recipient. The Contractor shall amend the primary report with information from subsequent multiple reports on the same adverse event ("person vaccination event"), based on the accuracy of the information (e.g. medical records, follow-up information) or Government approval.
- D. When a VAERS COVID-19 vaccine report is identified as being a Redundant Report or Duplicate Report and has been reassigned a VAERS report identification number based on the VAERS ID for the Primary Report with appropriate identifier tag (e.g., VAERS ID = 123456-2), the Contractor shall retain the VAERS ID number which has been replaced (referred to here as "Old VAERS ID") for the specific report in an accessible file for mapping to the current VAERS ID.

- E. The Old VAERS ID shall be retained in a data table linked to the primary VAERS database to allow for the search and identification of any specific VAERS report by either the first VAERS ID assigned (the Primary Report ID until a report is identified as Duplicate or Redundant) or subsequently reassigned Linked Report ID.
- F. The Contractor shall develop, demonstrate, document, and implement a coding variable (Patient Continuity Code) which shall be used to link a patient identified in a report to other reports in which that particular patient has been identified. Such reports may include Redundant and Duplicate Reports but may also include different "person vaccination events" regarding the same person, but a different vaccination and/or event. The Patient Continuity Code shall be included in the primary system database and in the Government Extract.
- G. The Contractor shall develop, demonstrate, document, and implement measures for batch-matching to identify redundant or secondary reports. The Contractor shall evaluate a variety of methods including "fuzzy logic" (http://en.wikipedia.org/wiki/Fuzzy_logic) for identifying possible duplicate or redundant reports, including reports linked with minor name variations, and implement them at the Government's discretion. An example of the use of fuzzy logic would be linking two different VAERS reports of a very rare occurrence in two patients who have the same birthdate and same date of vaccination but no name reported, into one VAERS report if the Contractor believes the two reports pertain to the same patient.
- H. The Contractor shall develop and maintain methods for confirming the quality of submitted data through standardized quality control and quality assurance procedures designed to reduce or eliminate the presence of more than one record concerning the same adverse event, data inconsistencies or deficiencies.
- I. With data provided by the Government, the Contractor shall develop and implement procedures to provide selection lists for valid vaccine lot identifiers (lot numbers) and data entry masks based on known lot numbers to provide information at the point of data entry as to the validity of the vaccine lot number entered. The Contractor shall develop and implement procedures to detect and specifically demarcate records containing reported vaccine lot identifiers, which are not valid lot numbers, based on comparison with lot identifier data provided by vaccine manufacturers through the FDA and provided to the contractor. These procedures shall be utilized for the Contractor internal data entry system.
- J. Upon provision of COVID-19 vaccine manufacturers' lot numbers to the Contractor by the FDA, lot numbers in the database shall be flagged if not valid when compared to the manufacturer's master data.
- K. Any errors identified by the Contractor QA checks or Government should be corrected in the data.

QUALITY CONTROL AND ASSURANCE FOR SCANNED DATA QUALITY FOR COVID-19 VACCINE REPORTS

- A. The Contractor shall develop and maintain methods for assuring the quality of document images for the image database and correct indexing in the image database through standardized quality control and quality assurance procedures designed to confirm that documents are as legible as possible, complete, and capable of retrieval and copying from image base prior to final transfer of original physical document to the Government for archiving.
- B. Any errors identified by the Contractor QA checks or Government should be corrected in the data.

QUALITY CONTROL AND ASSURANCE FOR CODED DATA QUALITY FOR COVID-19 VACCINE REPORTS

- A. The Contractor shall develop and maintain methods for assuring quality and consistency and the most current version of coding in Medical Dictionary for Regulatory Activities (MedDRA) (or other coding language chosen by the Government) and the accuracy and completeness of MedDRA coding submitted by manufacturers in their reports. The Contractor shall notify the Government of changes made to the MedDRA codes relevant to the VAERS data coding activities and provide a full report and summary of each updated version of MedDRA.

- B. The Contractor shall develop and implement a training program for all data entry and coding staff which shall require approval by the Government. The Contractor shall enforce a certification process that requires all coders to be trained and become certified coders for current code-based data. This shall include MedDRA, or another coding system chosen by the Government. The data system shall include a coder-signature field to indicate the specific coder staff person who performed the report coding.
- C. The Contractor shall develop or procure and use automated tools, such as auto-coding software, algorithms and aides, when available and approved by the Government, to assist in the coding process.
- D. The Contractor shall provide online manuals for coders to use at any time so that coders can access simulated scenarios and glean applicable codes.
- E. The Contractor shall document any non-standard coding values in use by the VAERS program and submitted in reports.
- F. The Contractor shall implement QA procedures and reviews to ensure that data provided as part of Government data extracts meet pre-specified requirements as directed by the Government. Procedures for data entry error identification, correction and supplemental data entry should be established by the contractor in advance of any error detection by the Government.
- G. The Contractor shall develop and implement a QAP which shall include performance quality measures for each of the elements in this section of the SOW, and which shall require approval by the COR prior to implementation. The Contractor shall perform evaluation of these performance quality measures and report the results to the Government annually or on an alternate schedule as specified by the Government and propose procedure modifications as necessary to ensure data quality. The resultant modifications to QA procedures shall be periodically implemented contingent upon approval by the COR or CO.
- H. Any errors identified by the Contractor QA checks or Government shall be corrected in the data.

QUALITY CONTROL UPDATES FOR COVID-19 vaccine REPORTS

- A. The Government reserves the right to direct the Contractor to revise and update QA procedures in the QAP to support changes in reporting procedures, such as changes to the VAERS form, online reporting tool, or standard methods of reporting (i.e., transitioning to fully electronic reporting).
- B. Reasonable accommodations will be made to the Contractor by the Government to allow for implementation of any such revised and updated QA procedures and the Contractor will be allowed to negotiate implementation of changes.

TASK 5: INFORMATION MANAGEMENT FOR COVID-19 VACCINE REPORTS

- A. VAERS is an integrated system that encompasses information technology, data management, data analysis, software development lifecycle and IT security. The Contractor shall perform the following tasks/activities:
 - 1. Maintain Capability Maturity Model (CMM) Level 3 certification or higher throughout the performance period of the contract and provide the Government current documentation of its CMM Level 3 or higher certification.
 - 2. Maintain current system operations
 - 3. Provide software development, enhancement and progress reviews as requested by the Government.
 - 4. Provide software documentation inclusive but not limited to systems requirements, specifications, architecture details, design details, analytical algorithms, data models, and technical support processes.

All documentation shall be submitted to the Government in each annual report and during and following the implementation of system changes.

5. Provide data extractions and depersonalized data sets requested by the Government on a routine and ad-hoc basis
 6. Provide ad hoc searches of VAERS COVID-19 vaccine data as requested by the Government
 7. Implement appropriate Government policies and regulatory requirements regarding information management, information technology, software development, and security.
- B. The Contractor shall furnish all necessary personnel, facilities, supplies, and equipment, as appropriate, to provide the Government with required technical, and operational services, within the general work parameters set forth in this Statement of Work.

VAERS COVID-19 SYSTEM SPECIFICATIONS

- A. The VAERS system shall be hosted on an offsite network consisting of CDC owned software, commercial off the shelf software (COTS), and owned and leased hardware. The VAERS Servers will be categorized into core, non-core and infrastructure systems. Core systems are those identified with core business functionality, non-core provides support for the core systems. The infrastructure servers will provide centralized security, network, authentication, storage, remote access and management of all the VAERS environments. These servers may consist of a combination of physical and virtual servers, though virtual servers are recommended.

The VAERS architecture should consist of two separate Security Sockets Layer (SSL) virtual private networks (VPN), one contains the production and software development lifecycle (SDL) environment, and the second located offsite contains a disaster recovery environment. The disaster recovery site is a duplicate and replication of the production site and provides recovery of the production site within 24 hours (refer to **Task 1: ADMINISTRATIVE** for physical location requirements for the offsite environment for disaster recovery, i.e., the disaster recovery site).

Below is an example of the approximate number of development, testing and user acceptance servers needed for the system:

Environment	Physical	Virtual
Infrastructure	7	5
Production	2	5
Disaster Recovery	6	12
Development	0	6
Testing	4	0
User Acceptance	0	5

- B. Software to be installed on these machines includes but is not limited to:

Activator, ColdFusion, Apache, Biscom FAXCOM, CentOS Enterprise Linux, Chado Software, SpellText, Cisco ASA software, Cisco IOS, CopSSH, Doubletake, Express Metrix, Faxcom, HP Array Configuration Utility, IBM Rational Tools, Itefix CopSSH, Java, Jpeg Wizard, Kofax Capture, Macromedia CFMX, Medical/Pharmaceutical Spellchecker, Microsoft Active Directory, Microsoft Remote Desktop Version 10, Microsoft Windows server 2016, Microsoft IIS, MS Office, MS OS, Microsoft SQL 2017, Microsoft VSS, NSClient++, PHINMS, Python, rDist, Redhat Enterprise Linux, rSync, RSA Authentication Manager, RSA Radius Server, SAS, Screen, SourceForge GNUWin32, SpellText, Stedman's spellchecker, Superflexible, Symantec Backup Exec Agent, Symantic Antivirus, Tripwire for Servers, VMWARE, Zope

Contractor must license or own software (or equivalent) as listed above.

- C. Contractor must develop a VAERS Virtual Private Networks (VPN) which allows authorized users located outside of the Contractor's facility to establish a secure connection to the VAERS application. The VAERS VPNs will provide a secure computer network that uses the Internet to allow remote users secure access to the VAERS application and database. It should encapsulate data transfers each business day, between the authorized users and Contractor's networked devices to keep transferred data private from other devices on one or more intervening local or wide area networks. Depending on the user's access rights to the VAERS database, the individual will either be part of a VPN with full access to the VAERS database or a more restricted VPN only providing access to reports of selected research interest. The Contractor adheres to the following and is expected to create and maintain capabilities to perform these functions:

- Conduct web based query
- Enable viewing of scanned images
- Enable viewing of entered data including Follow up and MedDRA code
- Enable viewing of nurse follow up module

- D. Other VAERS functionality requirements include:

1. Creation of a VAERS COVID-19 vaccine public website and online reporting tool which includes a mechanism for allowing patients, parents, providers and other partners and stakeholders to electronically submit VAERS reports
2. Creation of an intranet application that allows authorized staff to access COVID-19 vaccine reports to query, add and modify data, and view linked images
3. Double data entry of specific report types as determined by the Government
4. Scanning of hard copy documents including, but not limited to, VAERS COVID-19 vaccine report and medical documentation.
5. Receipt of electronic COVID-19 vaccine reports from manufacturers (eVAERS)
6. Electronic transmission of reports and data extractions to CDC and FDA as specified by the Government
7. Business Intelligence
8. Data warehousing
9. Data editing
10. Duplicate identification
11. Database management system and tools
12. Software for extracting and transmission of Government specified data sets.

DATA MANAGEMENT

- A. All Information Technology (IT) systems must comply with federal regulations and policies regarding IT which includes but are not limited to Enterprise Performance Life Cycle (EPLC), Capital Planning and Investment Control (CPIC), Information Security, Section 508 of the Rehabilitation Act, Enterprise Architecture (EA), etc.

- B. These methods, procedures and processes will accept reports submitted by business partners including manufacturers, state health coordinators, and other immunization programs, other Federal Government agencies and programs, and other parties.
Electronic manufacturer reports include post-marketing adverse drug reaction (ADR) data for individual cases, post-marketing expedited ADR reports and periodic ADR reports. Electronic manufacturer reports shall conform to the format and processes identified and implemented by the US Food and Drug Administration (FDA). This reporting process is referred to as eVAERS.
- C. Under the direction of the CO and COR, the Contractor shall establish and maintain methods, procedures and processes to support a variety of Electronic Data Interchange (EDI) message types to be specified by the Government. The contractor will work with COVID-19 vaccine manufacturers (approved by Government), to ensure electronic submission of postmarket individual case safety reports (ICSRs) to VAERS using E2B(R3) and submitting via xml format. Electronic reporting of vaccine postmarketing safety reports shall follow the International Council on Harmonisation's (ICH) E2B(R3) ICSR specification : <https://www.federalregister.gov/documents/2014/06/10/2014-13480/postmarketing-safety-reports-for-human-drug-and-biological-products-electronic-submission>

STANDARDIZED METHODS FOR PROVIDING ROUTINE AND REQUESTED REPORTS OF VAERS COVID-19 VACCINE DATA TO THE GOVERNMENT

- A. The Contractor shall perform ad hoc searches of the VAERS COVID-19 vaccines databases to address specific surveillance questions and support vaccine safety studies, as requested by the Government.
- B. At the direction of the Government the Contractor shall develop, maintain and update programs to routinely produce specific depersonalized data sets containing originally reported information for the public websites, World Health Organization (WHO), state health coordinators and others as approved by the Government.
- C. The Contractor shall provide a weekly reports of adverse events after COVID-19 vaccines reported for specific jurisdictions via The Epidemic Information Exchange (Epi-X) to those specific State Health Coordinators as indicated by the Government, upon request by the Government.

These reporting requirements are subject to change at the request of the government.

GOVERNMENT DATA EXTRACTS FOR COVID-19 VACCINE REPORTS

- A. The quality of the data extract is important to VAERS, therefore, the Contractor shall provide accurate data extract ("Government Extract") to the Government for storage and use at Government sites (both CDC and FDA). The data extract and all available data elements collected from the submission of VAERS reports and collected through follow-up activities are subject to the approval of the Government and should be provided according to the specified timeframes detailed in Appendix A. The complete VAERS COVID-19 vaccine database, containing both (a) all data elements from the VAERS form which include those data-elements historically used by the Government, and (b) any new and valuable data-elements added by the Contractor by the direction of the Government shall be provided daily. All data elements collected on the VAERS form (and subsequent approved revisions of the VAERS form), and subsequent data elements collected via internal entry system or web system, are subject for inclusion in the data extract to Government. If the data element is a specific field on the form, the data shall be stored in a related specific field in the Government data, with no concatenation of data fields or elements. The following are examples of two processes for important extracts of data from the VAERS system that the Contractor shall follow:
 - 1. VAERS COVID-19 vaccine DAILY EXTRACT - Each business day, the Contractor shall send an extract to the CDC and FDA through a low cost data transmission application. Once CDC receives the extract, a confirmatory e-mail is submitted to the Contractor verifying that the extract has been received. The Contractor shall contact the COR if the confirmatory e-mail is not received. The COR will contact the Contractor if there is a problem uploading and processing the data. The Contractor shall adhere to the following:

- Include initial report data and data obtained in follow up
 - Provide data in a format approved by the Government (CSV format)
 - Maintain manufacturer reports received electronically including postmarketing adverse drug reaction (ADR) data for individual cases, post marketing expedited ADR reports and periodic ADR reports.
2. VAERS COVID-19 vaccine PUBLIC EXTRACTS - The Contractor shall be required to maintain public redacted databases of VAERS data as specified by the Government. The current VAERS public website (www.vaers.hhs.gov) provides downloadable datasets that are subsets of the VAERS daily extract that is sent to the CDC and FDA. WONDER, a CDC created online tool located at wonder.cdc.gov, is another example of the public databases. This tool allows the public to query a subset of the VAERS data. Standard operating procedures are used to ensure patient privacy. The public website and WONDER shall be updated on a weekly basis. There is a one week lag on data so that quality control measures can be conducted by the Contractor. The datasets on the public website are split into separate CSV files by years dating from 1990 to the current year. Non-domestic (i.e., foreign) reports are placed in a separate CSV file.
 3. VAERS COVID-19 vaccine OTHER GOVERNMENTAL AGENCIES EXTRACTS- The Contractor shall provide VAERS data in comma separated value (CSV) files on a secure server platform to specified points of contact among other governmental agencies, Department of Defense (DoD), Indian Health Services (IHS), and World Health Organization (WHO), on a weekly basis.
 - a. DoD and non-DoD reports will be identified using specific search criteria as outlined in VAERS CDC DoD Memorandum of Agreement (MOA). Initial and follow-up unredacted information will be provided on DoD reports, while initial redacted information will be provided on non-DoD reports.
 - b. IHS and non-IHS reports will be identified using specific search criteria as outlined in VAERS CDC IHS Memorandum of Understanding (MOU). Initial and follow-up unredacted information will be provided on IHS reports, while initial redacted information will be provided on non-IHS reports.
 - c. WHO will be provided initial redacted information, similar to data publicly available at the CDC WONDER website: <https://wonder.cdc.gov/vaers.html>.
 4. VAERS COVID-19 vaccine JURISDICITON EXTRACTS- The Contactor shall provide VAERS COVID-19 vaccine data and summary tables to specified jurisdictions using CDC's Epidemic Information Exchange (*Epi-X*), a secure, web-based network that serves as a powerful information exchange between CDC and public health professionals involved in identifying, investigating, and responding to public health threats. Data will be posted and refreshed on a weekly basis with a one week lag in order to incorporate quality control measures conducted by the Contractor. The VAERS COVID-19 vaccine data will include initial report data with personal identifiers, no follow-up will be included. Summary tables will also be provided to the jurisdictions, including summary statistics, including but not limited to, serious status and conditions of interest.

VAERS FUTURE SOFTWARE DEVELOPMENT AND ENHANCEMENTS

- A. At the request of the Government, the Contractor shall develop and enhance software for the VAERS system following the HHS, CDC and NCEZID policies and procedures for Enterprise Performance Life Cycle (EPLC), Capital Planning and Investment Control (CPIC) and IT security.
<http://www.hhs.gov/ocio/policy/index.html>

CONTRACTOR COMPLIANCE WITH APPLICABLE LAWS, REGULATIONS, POLICIES AND STANDARDS

- A. The Contractor shall ensure that the Information Technology Architecture (ITA) for the VAERS system is implemented and maintained by the Contractor in compliance with applicable regulations including OMB Circular A-130, the Federal Information Resources Management Regulation (FIRMR), the DHHS

Automated Information Systems Security Program (AISSP) Handbook, and applicable portions of the CDC ITA plan, Technical Reference Model and Standards.

- B. IT products and technologies procured through this contract shall meet the applicable accessibility standards at 36 CFR 1194, viewable at <https://www.gpo.gov/fdsys/granule/CFR-2011-title36-vol3/CFR-2011-title36-vol3-part1194/content-detail.html>
- C. The Contractor shall ensure that all systems are in compliance with Section 208, the privacy provisions of the E-Government Act of 2002, and follow the OMB Guidance of September 26, 2003 regarding implementation of the privacy provisions of the E-Government Act.
- D. The Contractor shall be responsible for being aware of and shall comply with all applicable federal information technology and information management laws, regulations, policies, and standards. These include but are not limited to:
 - Children's Online Privacy Protection Act (COPPA)
 - Section 508 of the Rehabilitation Act. HHS Section 508 Product Assessment Template (use VPAT version 2.0 or later: <https://www.itic.org/policy/accessibility/vpat>)
 - Clinger-Cohen Act (CCA)
 - Federal Information Security and Management Act (FISMA)
 - Paperwork Reduction Act (PRA)
 - Office of Management and Budget (OMB), National Institute of Standards and Technology (NIST), and General Accounting Office (GAO) policies that can be primarily found at or through the Federal CIO Council website at www.cio.gov.
 - Federal Enterprise Architecture (FEA)
- E. The Contractor shall not develop any Internet web applications that use persistent cookies without explicit authorization by CDC's Chief Information Officer.
- F. The Contractor shall adhere to CDC's Secure Coding Practices guide for developing web-based applications to prevent security vulnerabilities.
- G. Contractor's performance and resulting deliverables shall adhere to all federal, HHS, and/or CDC IT security policies and procedures. Development or implementation of an electronic information system or any electronic data collection effort conducted in the performance of this contract is required to undergo Certification and Accreditation (C&A) prior to operation. When applicable, the Contractor shall be required to complete all security documentation and materials required to obtain an authority to operate (ATO). The Contractor shall comply with all applicable HHS, CDC, FISMA, HIPPA, NIST, and other federal policies and regulations in the performance of the security requirements. If an application or system is operated by the Contractor on behalf of the Government and/or hosted at a Contractor facility, it shall comply with HHS and CDC policies, and is subject to all OMB requirements, including a full Certification and Accreditation (C&A)

V. TASK ORDER DELIVERABLES AND MILESTONES:

Item	Deliverable	Quantity	Time
1.	Program Management Monthly Status Report as specified in the Administrative section of the SOW	1 each to the COR and TR	Monthly, first report due 30 days after contract award
2.	Annual report as specified in the Administrative section of the SOW	1 each to the COR, TR and CO	Annually, due 30 days following the 12 months period covered by report

Item	Deliverable	Quantity	Time
3.	Draft Final Report as specified in the Administrative section of the SOW.	1 each to the COR and TR	At least 45 days before the contract completion date
4.	Final Report as specified in the Administrative section of the SOW	1 each to the COR, TR and CO	No later than the contract completion date
5.	Report inventory of all hardware and software, including version numbers of software and record of maintenance as specified in Security section of the SOW	1 each to the COR and TR	Include in annual report and upon request
6.	Develop/update and provide standard operating procedures for all aspects of VAERS operations, including complete VAERS report processing, as specified in the Administrative section of the SOW	1 each to the COR and TR	Within 30 days after contract award, within 30 days of implementation of changes, and then annually and upon request
7.	Develop and maintain list of names, phone numbers, fax numbers, and email addresses of contact personnel responsible for reporting from state health agencies, vaccine manufacturers, and immunization programs as specified in Administrative section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually, and upon Government request.
8.	Report number, method of contact, type of contact with VAERS by manufacturers, state health coordinators, immunization programs, and the public.	1 each to the COR and TR	Include in the annual report, and upon Government request
9.	Provide documentation of the technical procedure for data transport to Government as specified in the Information Management section of the SOW.	1 each to the COR and TR	Within 30 days after contract award
10.	Provide Government Extract of VAERS data to both agencies as specified in the Information Management section of the SOW.	1 each to FDA and CDC designees	Beginning 30 days after contract award, and each business day thereafter
11.	Maintain and provide documentation for a current, separate mirror version of the VAERS system and RDBMS as specified in SOW.	1 Each to the COR and TR	Within 90 days after contract award
12.	Provide user-procedure manual(s) and standard operating procedures (manual of operations) for technical aspects of VAERS database operations	1 each to the COR and TR	30 days after contract award and then as specified in SOW
13.	Provide documentation for data verification procedures including standardized letters, forms, logs, phone scripts and other documents as specified in SOW	1 each to the COR and TR	Upon Government request
14.	Provide a weekly report of adverse events after COVID-19 vaccines to Vaccine Safety Coordinators and their designees of specific jurisdictions as indicated by the Government as specified in SOW	1 each to the COR and TR	Weekly, beginning 60 days after contract award

Item	Deliverable	Quantity	Time
15.	Provide documentation for procedures and rules for Data Quality Control and Assurance as specified in SOW	1 each to the COR and TR	Provide 60 days after contract award then annually or upon request
16.	Provide System Security Plan and training materials for employee AIS security training program as specified in the Information Management section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually
17.	Provide Program Management Plan as specified in the Administrative section of the SOW	1 each to the COR and TR	Within 30 days after contract award, then annually or upon request
18.	Provide Quality Assurance Program (QAP) plan as specified in SOW	1 each to the COR, TR and CO	Within 30 days after contract award, then annually
19.	Provide list of key project personnel as specified in SOW	1 each to the COR, TR and CO	Within 30 days after contract award, then annually; update within 10 days following key personnel changes
20.	Provide Earned Value Report as specified in Information Management and Administrative sections of SOW	1 each to the COR and TR	Include in monthly reports
21.	Provide Data System Security Plan or information system security plan (SSP) as specified in Information Management section of SOW	1 each to the CO and COR	Draft within 30 days after contract award; final version within 60 days after award.
22.	Provide list of staff who have successfully completed information security training as specified in Information Management section of SOW	1 to COR	Upon request by COR
23.	Provide documentation of Level 3 Security Requirements compliance as specified in the Information Management section of SOW.	1 each to COR and TR	Within 30 days after contract award
24.	Provide Transition-Out Plan for approval as specified in the Administrative section of SOW	1 each to the COR and TR	Within 60 days after contract award
25.	Provide Disaster Recovery Plan for approval as specified in the Information Management section of SOW	1 each to the COR and TR	Within 60 days after contract award
26.	Provide results of IT Security Risk Management Assessment as specified in the Information Management section of SOW	1 each to the COR and TR	Within 45 days of completed assessment
27.	Provide the Government with detailed system documentation. Documentation shall be maintained in two separate volumes: "Volume 1 – VAERS Business Processes" and "Volume 2 – VAERS IT Requirements and Design" as specified in the Administrative section of SOW	1 each to the COR and TR	Within 30 days after contract award, then annually thereafter, with new sections or documentation revisions provided within 10 days
28.	Provide detailed documentation of the technical procedures for data transport to CDC and FDA as specified in the Administrative section of SOW	1 each to the COR and TR	Within 30 days after contract award, then annually thereafter, with new sections or documentation revisions provided within 10 days

The Contractor shall provide, upon request from the Government, deliverables not specifically listed in this document. The Government will provide the Contractor with sufficient time (i.e., a minimum of 2 business days) to fulfill such requests.

VI. PERFORMANCE MATRIX:

Desired Outcomes	Required Services	SLA Performance Standard (completeness, cost, reliability, accuracy, timeliness, quality)	Acceptable Quality Level (AQL)	Monitoring Method (Quality Assurance Surveillance Plan/QASP)	Incentives/ Disincentives
Execute/perform all required tasks according to performance plan	Meets and complies with defined task requirements	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified in this Statement of Work	100% compliance	COR oversight	Favorable or Unfavorable Performance Evaluation
Send timely VAERS Daily Extracts with correct information	Each business day the Contractor sends an extract to the CDC and FDA through the PHINMS or other specified application.	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified in this Statement of Work	98% compliance	Daily receipt of Extract	Favorable or Unfavorable Performance Evaluation
Process all serious reports within the specified timeframe reflected in Appendix A of this SOW.	Process serious reports in the established timeframe to electronically migrate VAE data into the database.	All required tasks, milestones and deliverables will be achieved within the agreed-upon schedule specified in this Statement of Work	100% compliance All late logging of adverse events reports is reported in monthly report.	Monthly Quality Reports	Favorable or Unfavorable Performance Evaluation

VII. PERIOD OF PERFORMANCE:

Base: 27 August 2022 – 26 August 2023

Option: 27 August 2023 – 26 August 2024

VIII. PLACE OF PERFORMANCE:

The work will be conducted at the contractor's facility.

IX. EQUIPMENT AND INFORMATION:

The Contractor shall provide hardware, software, office and communications equipment and other resources to be used for data receipt, processing, editing, analysis, reporting, transmission, and storage. The Contractor shall provide the Government with current and detailed system documentation, including SOPs for all aspects of VAERS program operations, including complete VAERS report processing, submitted to the Government for initial review and approval within 30 days after contract award and within 30 days of revision or implementation of changes, and minimally on an annual basis or as requested by the Government thereafter. Please see Task Order 1 (Administrative) for more detail.

Appendix A: VAERS triaging of reports in business days^{1, 2}

Category	<u>Serious</u> reports		<u>Serious</u> follow-up initiation	<u>Non-serious</u> reports	
	Scan within	Complete process within ³		Scan within	Complete process within ³
1. US Deaths ⁴	1	1	1	N/A	N/A
2. US 5-day reports	2	2	N/A	N/A	N/A
3. US 15-day reports	2	2	N/A	N/A	N/A
4. US reports ⁵	2	3	3	2	5
5. US 30-day reports	2	20	N/A	2	20
6. Foreign reports	5	90	N/A	5	120

1. Subject to change in response to new public health policies and/or events and/or funding availability after discussion between CDC and FDA

2. Not applicable for GBS reports where a patient is confined to facility longer than the time allowed for follow-up (e.g., patient in rehabilitation after GBS)

3. Completion includes scanning, data entry, and coding

4. If final autopsy report is not received within 2 months, make request every 2 months

5. If no records received within 5 days from the original request, make another request for Covid-19

PROJECT TITLE: VACCINE ADVERSE EVENT REPORTING SYSTEM
(VAERS) FOR COVID-19 VACCINES

Detailed Price Summary

Contract Line Item Description	Base Period 8/27/2022 - 8/26/2023	Option Year 1 8/27/2023 -8/26/2024
(b)(4)		
TOTAL ESTIMATED VALUE OF CONTRACT	\$ (b)(4)	(b)(4)
Assumptions:	Percent	
Inflation Rate Per Year	(b)(4)	
Fringe Benefits Rate		

From: Amador, Nathan (CDC/OCOO/OFR/OAS)
Sent: Mon, 8 Mar 2021 17:22:07 +0000
To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: (b)(4) Denis, Philip
(CDC/OCOO/OFR/OAS)
Subject: Signed copy of Modification 75D301020F09621 00004 - VAERS SARS-CoV-2 Increased Capacity executed 03/08/2021.
Attachments: 75D30120F09621 00004_Increased Capacity_Signed_03.08.2021.pdf

Good Afternoon,

Please find for your records a fully executed copy of modification 75D30120F09621 00004, for a 6-month increased capacity of the VAERS SARS-CoV-2 support.

Thank you to everyone for getting both of these actions completed. Please let me know if any additional contractual assistance is required.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(4)
Sent: Monday, March 8, 2021 11:24 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: (b)(4)
(b)(4) Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Subject: RE: Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog fully executed 02.26.2021

Good Morning Nathan,

Attached is the signed modification. Please sign and return for final execution.

Kindest regards~

(b)(4)

(b)(4)
Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

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Information Technology

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From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Sent: Monday, March 8, 2021 9:50 AM
To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: (b)(4)
(b)(4) Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Subject: RE: Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog fully executed 02.26.2021

[External Email with Covid-19 Information: Use caution with links & attachments]

Good Morning,

Program is requesting an update on this modification. Beyond the confusion with the Alliant 2 annual cap for contract access fees, is there anything else holding up the signature and return?

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile

 **OFR** Office of Financial Resources
Office of Acquisition Services (OAS)

From: (b)(4)
Sent: Friday, March 5, 2021 10:12 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: (b)(4)
(b)(4) Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Subject: RE: Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog fully executed 02.26.2021

Nathan,

Thank you for your due diligence and response.

(b)(4)

Contracts Administrator Advisor
Federal Civilian

T 703.270.1996
Victoria.lemieux@gdit.com

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

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From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Sent: Friday, March 5, 2021 10:10 AM
To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: (b)(4)
(b)(4) Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Subject: RE: Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog fully executed 02.26.2021

[External Email with Covid-19 Information: Use caution with links & attachments]

Good Morning,

I confirmed with GSA that since the base year exceeds (b)(4) the CAP for the 1st year is \$150K for the entire year. Therefore, it is not set by the line item cost, by the task order costs.

CLIN 0003 accounted for (b)(4) of the \$150K cap. (b)(4) total cap.

CLIN 1003 accounted for (b)(4) of the \$150K cap. (b)(4) total cap.

\$150,000.00 - (b)(4) = (b)(4)

CLIN 2003 accounted for (b)(4) of the \$150K cap. \$150,000.00 total cap.

CDC will not be increasing the Contract Access Fee based on the information received from GSA about annual CAP rates for Alliant 2 contract access fees.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(4)

Sent: Friday, March 5, 2021 9:51 AM

To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>

Cc: (b)(4)

(b)(4) Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>

Subject: RE: Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog fully executed 02.26.2021

Good Morning Nathan,

Please double check the CAF amount. Our calculation total of these 2 CLINS at (b)(4) CAF is .75%, that would be a CAF CLIN of (b)(4) If you confirm this amount, please revise the mod and return.

Thank you~

(b)(4)

Contracts Administrator Advisor
Federal Civilian

(b)(4)

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

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From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>

Sent: Thursday, March 4, 2021 5:44 PM

To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
<xct6@cdc.gov>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP)
<ezu2@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; (b)(4)

(b)(4)

Subject: RE: Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog fully executed
02.26.2021

[External: Use caution with links & attachments]

Good Evening,

Please find attached for bilateral review, signature, and return a copy of modification 75D301020F09621 00004. This modification increases the capacity for all task order tasks from an expectation of 5,000 reports processed per week (that work is still covered by the initial base CLIN) and creates a 6-month increased level of effort with an expectation of 25,000 reports processed per week. This separately priced line item Period of Performance runs from 03/05/2021 to 08/31/2021, total increase of funding in the amount of (b)(4)

That start date is tomorrow, Friday, March 5, 2021, so if possible, please return a signed copy to Nathan R. Amador at wlv7@cdc.gov (reply to this email is fine) as soon as possible.

Thank you in advance for everyone's hard work in turning around these past two modifications so quickly.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(4)
Sent: Friday, February 26, 2021 4:38 PM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; (b)(4)
(b)(4)
Subject: RE: Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog fully executed 02.26.2021

This is to confirm receipt and thank you so very much.

(b)(4)
Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

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From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Sent: Friday, February 26, 2021 4:32 PM
To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; (b)(4)
(b)(4)
Subject: Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog fully executed 02.26.2021

[External: Use caution with links & attachments]

Good Afternoon,

Please find attached a fully executed copy of modification 75D301020F09621 00003 for your records. Thank you for your efforts.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: (b)(4)
Sent: Friday, February 26, 2021 4:19 PM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; (b)(4)
(b)(4)
Subject: RE: Bilateral Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog for review, signature and return

Dear Nathan,

Attached is the signed modification for the subject line contract. Please sign and return the final executed copy for our records.

We look forward to providing continued support to meet the immediate needs of the project.

Kindest regards~

(b)(4)
Contracts Administrator Advisor
Federal Civilian

(b)(4)

3150 Fairview Park Drive
Falls Church, VA 22042
www.gdit.com

Upcoming Out of Office: None

GENERAL DYNAMICS
Information Technology

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From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>

Sent: Friday, February 26, 2021 3:23 PM

To: (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; (b)(4)

(b)(4)
Subject: Bilateral Modification 75D301020F09621 00003 - VAERS SARS-CoV-2 Backlog for review, signature and return

[External: Use caution with links & attachments]

Good Afternoon (b)(4)

Please find attached a copy of bilateral modification 75D30120F09621 00003, which adds CLIN 1001, 1002, 1003 for VAERS SARS-CoV-2 Backlog support, ODCs, and the contract access fee, total value (b)(4). Upon review, please return a signed copy via email so that CDC can full execute and award this modification. Please contact the undersigned immediately with any questions or concerns.

Normally, I do not include so many parties on a bilateral modification release, but am doing so now as a thank you to all parties who worked so hard to get this modification to this point. The Increased Capacity modification is still under review at OAS, should be approved for release or further editing between Monday March 1 and Monday March 8.

I'll keep on eye out for the signed copy of this modification and will award it as soon as possible, but otherwise, I hope everyone has a great weekend.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile

 **OFR** Office of Financial Resources
Office of Acquisition Services (OAS)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

Obtained from OAND on 01/01/2021 via FOIA

1. CONTRACT ID CODE

PAGE OF PAGES

1 5

2. AMENDMENT/MODIFICATION NO.
00004

3. EFFECTIVE DATE
03/05/2021

4. REQUISITION/PURCHASE REQ. NO.
00HCAJ1W-2021-53908

5. PROJECT NO. (If applicable)

6. ISSUED BY
Centers for Disease Control and Prevention (CDC)
Office of Acquisition Services (OAS)
2900 Woodcock Blvd, MS TCU-4
Atlanta, GA 30341-4004

CODE 8219

7. ADMINISTERED BY (If other than Item 6)

CODE

Points of Contact:

CO: Nathan R. Amador, wlv7@cdc.gov, 770.488.2690

COR: Traci Sinetta Roberts, xt6@cdc.gov, 404.498.0669

CTR: (b)(4)

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)
GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.
3150 FAIRVIEW PARK DR STE 100

FALLS CHURCH, VA 22042-4504

(✓)

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (See Item 11)

10A. MODIFICATION OF CONTRACT/ORDER NO.

75D30120F09621

X

10B. DATED (See Item 13)

08/27/2020

CODE 067641597

FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ___ is extended, ___ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
(a) By completing Items 8 and 15, and returning ___ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

9390GLY 2512 2021 75-2124-G943 C5B8111101 Increase (b)(4)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

- (✓) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
- B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
- C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
- X D. OTHER (Specify type of modification and authority)
FAR 43.103(a) (3) Reflect other agreements of the parties modifying the terms of contracts

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copy (digital) to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The following modifications are hereby made via 75D30120F09621 00004 and apply thereafter;

- A. Update the SOW as highlighted below to account for the VAERS SARS-CoV-2 Increased Capacity, minimum 25,000 reports per week for 6-months of additional support;
- B. Add and Fully Fund CLIN 2001, VAERS SARS-CoV-2 Increased Capacity, PoP 03/05/2021 to 08/31/2021, in the amount of (b)(4)
- C. Add and Fully Fund CLIN 2002, VAERS SARS-CoV-2 ODCs, PoP 03/05/2021 to 08/31/2021, in the amount of (b)(4)
- D. Add and Fully Fund CLIN 2003, VAERS SARS-CoV-2 CAF, PoP 03/05/2021 to 08/31/2021, in the amount of (b)(4)
- E. Increase total contract value and funded amount by (b)(4) from (b)(4) to \$30,187,996.11.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)

(b)(4) Contracts Administrator Advisor

16A. NAME OF CONTRACTING OFFICER

Nathan R. Amador

15B. CONTRACTOR/OFFEROR

(b)(4)
(Signature of person authorized to sign)

15C. DATE SIGNED

08 March 2021

16B. UNITED STATES OF AMERICA

BY Nathan R. Amador -S Digitally signed by Nathan R. Amador -S
(Signature of Contracting Officer) Date: 2021.03.08 12:02:12 -05'00'

16C. DATE SIGNED

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**VAERS SAR-CoV-2 Increased Capacity: Period of Performance 03/05/2021 to 08/31/2021**

ITEM	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	NOT TO EXCEED
2001	VAERS SAR-CoV-2 Increased Capacity The contractor shall provide CDC and FDA technical and programmatic support to collect and analyze information on vaccine adverse events (VAEs), and facilitate reporting to VAERS specifically pertaining to SARS-CoV-2. Reference the SOW and all associated deliverables. This line item is based an expectation of 25,000 reports per week to be cleared over a 6-month period. This is a T&M, severable line item. See Table B.2 for LOE PoP: 03/05/2021 – 08/31/2021		(b)(4)	
	2001 Line(s) Of Accounting: 9390GLY 2512 2021 75-2124-0943 C5B8111101	(b)(4)		
2002	VAERS SAR-CoV-2 Increased Capacity ODCs All travel must be in accordance with the Federal Travel Regulations (FTR). The Contractor shall obtain COR pre-approval of estimated travel expenses prior to travel occurrence. Charges will be submitted for actual costs incurred. The contractor shall ensure that the requested travel costs will not exceed the amount authorized in this task order. Other direct costs include travel, approved training requirements, and items shown in table B.3. All other direct costs must be pre-approved by the CO and COR prior to occurrence. T&M, severable line item See Table B.3 approved ODCs PoP: 03/05/2021 – 08/31/2021		(b)(4)	
	2002 Line(s) Of Accounting: 9390GLY 2512 2021 75-2124-0943 C5B8111101	(b)(4)		

2003	VAERS SAR-CoV-2 Increased Capacity CAF The Contract Access Fee (CAF) is 0.75% to be applied to the total price for contractor performance as billed to the government on each Task Order. The CAF is paid by the Ordering Agency, but remitted to GSA by the Contractor. Based on the established CAF rate, the Contractor shall include the CAF in each proposal. The Contractor shall include the CAF as a separate cost element per year on all quotes to the government, regardless of contract type. The CAF shall never be treated as a negotiable element between the Contractor and the Ordering Agency. The CAF Rate, effective at time of the Task Order award, shall remain the same for that Task Order for the full term of the Order. Not to Exceed a Total of \$150K for orders with total value greater than \$20M per year PoP: 03/05/2021 – 08/31/2021		(b)(4)	
	2003 Line(s) Of Accounting: 9390GLY 2512 2021 75-2124-0943 C5B8111101	(b)(4)		

Task Order Total:\$30,187,996.11

SECTION B.2 – Level of Effort for Backlog and Increased Capacity

LCAT	LCAT \$	STAFF	Hours	COST
(b)(4)				

LCAT	LCAT \$	STAFF	Hours	COST
(b)(4)				

SECTION B.3 – Backlog and Increased Capacity ODCs

ODC	Backlog	25,000 Reports
(b)(4)		

STATEMENT OF WORK FOR
VACCINE ADVERSE EVENT REPORTING SYSTEM
(VAERS) FOR SARS-COV-2 VACCINES

Updated Language is highlighted in yellow below:

IV. DESCRIPTION OF WORK:

- a. The contractor shall implement a staffing and operations plan focusing only on vaccine adverse event (VAE) reports after SARS-CoV-2 vaccines. The total number of reports received during periods of peak activity (which are not expected to reflect sustained activity) is expected to be 1,000 reports per day, with up to 40% of the reports serious in nature. This constitutes the base capacity expectation of up to 5,000 reports per week.
- b. The contractor shall implement a staffing and operations plan focusing only on vaccine adverse event (VAE) reports after SARS-CoV-2 vaccines to clear the backlog of SARS-CoV-2 VAE reports that has been projected to accumulate through February 28, 2021. The contractor shall prioritize clearing the backlog of reports at the direction of the Government. The backlog shall be processed and cleared within 3–6 months from the start of March 2021. (refer to “ACKNOWLEDGMENT, VERIFICATION, CODING AND DATA COLLECTION FOR ADVERSE EVENTS REPORTED AFTER SARS-CoV-2 VACCINES” Section C; 3a, 3b, 3c, and 3d).
- c. The contractor’s staffing and operations for increased capacity (CLIN 2001, 2002, and 2003) shall be sufficient to fully process within specified timelines with an expectation of 25,000 reports processed per calendar week for a 6-month period, with up to 30% of the reports classified as serious.

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 6 May 2021 13:09:25 +0000
To: (b)(4) VAERS
Cc: Su, John (CDC/DDID/NCEZID/DHQP); (b)(4) Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: VAERS (b)(6)
Importance: High

Hi Ana,
Please have follow up records requested as soon as possible on VAERS (b)(6)
This report was received on 4.22.21 and states death in a 15 y/o 2 days after Pfizer. He had no prior health problems.

Thanks,

Elaine

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 23 Dec 2020 06:19:17 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); (b)(4) Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: VAERS COVID-19 Data Sharing with jurisdictions via Epi-X
Attachments: SOP for VAERS Data Sharing with Jurisdictions via Epi-X.docx, VAERS COVID19 excel file extraction directions.docx, Informational Document for VAERS COVID19 Jurisdiction Excel Sheet.docx, DRAFT Vaccine Safety Weekly Report for COVID19_22_DEC_2020.docx
Importance: High

Please find the following documents attached for your review:

1. SOP for VAERS Data Sharing with Jurisdictions via Epi-X
2. Informational Document for VAERS COVID19 Jurisdiction Excel Sheet (previously referenced as data dictionary)
3. VAERS COVID19 excel file extraction directions

I have also attached a draft Vaccine Safety Weekly Report from Epi-X. Do you have the template for the Epi-X message for the Excel file and Reports already created? If you do, can you please update the document appropriately? If not, CDC will need to develop the language for the report rather quickly. Please let us know.

Can you confirm you will be able to start sending data to jurisdictions on December 28? Also when can you start sending VAERS reports (death/anaphylaxis- COVID19 and death only- FLU)? Please confirm the occurrence you will send the VAERS reports: sent once identified or sent on a weekly basis?

Thanks,
Paige

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

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Obtained by ICANdecide.org via FOIA

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Obtained by ICANdecide.org via FOIA

(b)(5)

(b)(5)

(b)(5)

Obtained by ICANdecide.org via FOIA

(b)(5)

Obtained by ICANdecide.org via FOIA

From: (b)(4)
Sent: Mon, 8 Feb 2021 14:29:16 +0000
To: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Myers, Tanya R. (CDC/DDID/NCEZID/DHQP); Zinderman, Craig E (FDA/CBER); Woo, Jane (FDA/CBER); Baumblatt, Jane (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Menschik, David (FDA/CBER); Welsh, Kerry (FDA/CBER)
Cc: (b)(4)
Subject: VAERS- COVID19 JnJ vaccine variables

Good morning,

Below are the proposed variables for the COVID19 Johnson and Johnson vaccine to be added to VAERS.

Extract Field Names	COVID-19
VAX_CODE	(b)(5)
VAX_TYPE	
VAX_NAME	
VAX_MFG	
MFG_NAME	
eSub/PDF Drop-down	

Please let us know if approved and we will proceed to add to the system.

Thanks

(b)(4)

From: Amador, Nathan (CDC/OCOO/OFR/OAS)
Sent: Wed, 16 Feb 2022 14:59:01 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: FW: SBI COVID19 Special Emphasis Review - response required by Friday, February 18, 2022
Attachments: SBI COVID Special Emphasis Review Sample.xlsx

This is the audit I was referring to. Can you please provide me copies of these two items: Nathan Amador 47QTCK18D0003 GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC. 75D30120F09621, 200-2020-F-09621

1. Evidence of Program Office (PO) oversight through meetings as required (status meeting invites/meeting minutes/agendas)
2. Evidence of reporting (monthly/interim reports) as required in the scope of the contract

I need to have this ready to submit on Tuesday, February 22, and Monday is a Holiday, so requesting this be submitted by COB on Friday, February 18, 2022.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: Kang, Michael (CDC/OCOO/OFR/OAS) <nfh6@cdc.gov>
Sent: Tuesday, February 15, 2022 2:02 PM
To: Alldredge, Berta (CDC/OCOO/OFR/OAS) <boh9@cdc.gov>; Simmons, Candice L. (CDC/OCOO/OFR/OAS) <iie3@cdc.gov>; McMichael, Christina (CDC/OCOO/OFR/OAS) <wpm6@cdc.gov>; Dombeck, David (CDC/OCOO/OFR/OAS) <vwj8@cdc.gov>; Battle, Donald (CDC/OCOO/OFR/OAS) <qaq5@cdc.gov>; Lyons, Eric (CDC/OCOO/OFR/OAS) <kpy2@cdc.gov>; Barritt, Gordon D. (CDC/OCOO/OFR/OAS) <ins4@cdc.gov>; Pace, Gwendolyn A. (CDC/OCOO/OFR/OAS) <dvv1@cdc.gov>; Hartnett, Jennifer (CDC/OCOO/OFR/OAS) <rju8@cdc.gov>; Houston, Joshua (CDC/OCOO/OFR/OAS) <pkf5@cdc.gov>; Marshall, Kourtney (CDC/OCOO/OFR/OAS) <qrz9@cdc.gov>; Lemaster, Kristopher (Kris) (CDC/OCOO/OFR/OAS) <ene3@cdc.gov>; Doan, Le (CDC/OCOO/OFR/OAS) <kuj3@cdc.gov>; Kennedy, Lee Catherine (CDC/OCOO/OFR/OAS) <vhg0@cdc.gov>; Shamburger, Maria (CDC/OCOO/OFR/OAS) <heg9@cdc.gov>; Bartkevicius, Marie F. (CDC/OCOO/OFR/OAS) <vgj6@cdc.gov>; Draluck, Mark (CDC/OCOO/OFR/OAS) <syq1@cdc.gov>; Crow, Michael J. (CDC/OCOO/OFR/OAS) <wyv2@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Taylor, Paula (CDC/OCOO/OFR/OAS) <vga8@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>;

Alexander, Phillip (CDC/OCOO/OFR/OAS) <pfa5@cdc.gov>; Williams, Ronnie (CDC/OCOO/OFR/OAS) <oga3@cdc.gov>; Kahn, Spencer (CDC/OCOO/OFR/OAS) <qnt8@cdc.gov>; Lester, Stephen (Steve) (CDC/OCOO/OFR/OAS) <svl3@cdc.gov>; Tucker, Tailee C. (CDC/OCOO/OFR/OAS) <ijk8@cdc.gov>; Wade, Terri (CDC/OCOO/OFR/OAS) (CTR) <svo9@cdc.gov>
Cc: DeFilipps, Dale F. (CDC/OCOO/OFR/OAS) <ded3@cdc.gov>
Subject: SBI COVID19 Special Emphasis Review

Hello All,

SBI is conducting a review of COVID-19 contracts. If you are receiving this email, you are identified as the owner of one (or more) of the randomly selected contracts. Please take a look at the attached file and provide the following for your contracts:

1. Copy of the contract to include the scope & statement of work
2. Evidence of PO oversight through meetings as required (status meeting invites/meeting minutes/agendas)
3. Evidence of reporting (monthly/interim reports) as required in the scope of the contract
4. Completed file review which includes a completed technical & cost evaluation
5. Evidence of file review and approval by OAS (e.g., File Review Checklist containing signatures/ or approval documented in emails)

If you are no longer the current owner, please let me know as soon as possible. It looks like we may need to contact the COR for some of these items. If so, please notate and I will follow up with the COR to request any missing items.

We have a very short turnaround for this request so we asking you provide the documentation by **COB Tuesday Feb 22**. Let me know if you have any questions.

Thanks,

Michael Kang

Auditor

Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
2900 Woodcock Blvd
Atlanta, GA 30341
Email: nhf6@cdc.gov
Office: 678-475-4943

Sample Number	Current Owner in ICE	Contract Number	Contractor	Comments
25	Berta Alldredge	200-2020-07643	John Hopkins University Applied Physics Lab	
28	Berta Alldredge	GS02Q16DCR0064	GUIDEHOUSE LLP	75D30120F08685, 200-2020-F-08685
33	Berta Alldredge	200-2018-03379	John Hopkins University Applied Physics Lab	
8	Candice Simmons	200-2020-09275	Goldbelt C6, LLC	
11	Candice Simmons	200-2021-10795	Aegis Sciences Corp	
45	Candice Simmons	200-2019-04370	Kapili Services, Inc.	
12	Christina McMichael	200-2017-92968	McKesson Specialty Distribution, LLC	
10	David Dombeck	47QTCK18D0008	LEIDOS, INC.	75D30119F05492, 200-2019-F-05492
20	Donald Battle	200-2021-10501	Clinical Research Sequencing Platform	
5	Eric Lyons	75D30119A06643	SRA INTERNATIONAL, INC.	75D30120F07677, 200-2020-F-07677
21	Eric Lyons	200-2021-10593	Fulgent Therapeutics LLC	
26	Eric Lyons	200-2021-M-10261	Laboratory Corporation of America	
32	Eric Lyons	GS-35F-004GA	AGILE SIX APPLICATIONS, INC.	75D30121F10287, 200-2021-F-10287
7	Gordon Barritt	200-2021-10659	Mako Medical Laboratories	
34	Gordon Barritt	200-2012-53662	Kaiser Foundation Hospitals	
13	Gwendolyn Pace	200-2017-95101	Children's Hospital Corp	
18	Gwendolyn Pace	200-2021-10149	Tanaq Support Services, LLC	
29	Gwendolyn Pace	200-2021-M-10369	Eagle Global Scientific, LLC	
3	Jennifer Hartnett	200-2020-09554	Nova Southeastern University, Inc.	
27	Joshua Houston	200-2020-08186	Icahn School of Medicine at Mount Sinai	
42	Joshua Houston	200-2020-09190	University of Washington	
39	Kourtney Marshall	200-2020-08325	Seattle Children's Hospital	
19	Kris Lemaster	200-2020-09605	Broad Institute Inc.	
22	Kris Lemaster	GS-35F-386DA	BOOZ ALLEN HAMILTON INC.	200-2021-F-10772
6	Le Doan	HHSN316201200170W	SEKON ENTERPRISE, INC.	75D30120F09619, 200-2020-F-09619
15	Lee Kennedy	200-2020-08653	John Hopkins University Applied Physics Lab	
2	Maria Shamburger	200-2019-04205	American Type Culture Collection	
37	Marie Bartkevicius	GS00Q14OADU113	DELOITTE CONSULTING LLP	75D30119F04824, 200-2019-F-04824
14	Mark Draluck	200-2021-10297	Children's Hospital Corp	
16	Mark Draluck	200-2020-08008	Rush University Medical Center	
41	Michael Crow	V797D30199	CADUCEUS HEALTHCARE INC	75D30120F08081, 200-2020-F-08081
4	Nathan Amador	47QTCK18D0003	GENERAL DYNAMICS INFORMATION TECHNOLOGY, INC.	75D30120F09621, 200-2020-F-09621
44	Paula Taylor	HHSD2002013M53964B	RESEARCH TRIANGLE INSTITUTE	HHSD2002017F96261, 200-201-F-96261
23	Philip Denis	47QTCK18D0011	NORTHROP GRUMMAN SYSTEMS CORPORATION	75D30120F08294, 200-2020-F-08294
36	Philip Denis	47QTCK18D0004	BOOZ ALLEN HAMILTON INC.	75D30120F09333, 200-2020-F-09333
24	Phillip Alexander	200-2021-10273	University of Louisville	
17	Ronnie Williams	200-2020-09551	Duke University	
30	Ronnie Williams	200-2021-10530	Claros Technologies, Inc.	
31	Spencer Kahn	200-2020-09086	Lundquist Institute for Biomedical Innovation	
43	Steve Lester	200-2018-02611	Palantir Technologies, Inc.	
40	Tailee Tucker	200-2016-91787	Rush University Medical Center	
35	Terri Wade	200-2021-11163	University of Georgia Research Foundation	
1	William Brannen	200-2021-10030	Audacious Inquiry, LLC	
9	William Brannen	200-2020-09030	Tanaq Support Services, LLC	
38	William Brannen	200-2020-08004	International Business Machines Corporation	

From: ICEMAIL
Sent: Thu, 25 Feb 2021 06:01:09 -0500
To: Crockett, Lindsey M. (CDC/OCOO/OFR/OAS)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: ICE Option Expiration Notification for 47QTCK18D0003 200-2020-F-09621
Importance: Normal

The following option(s) on 47QTCK18D0003 200-2020-F-09621 will be expiring soon:

Option Name: Surge
CLIN: 2001-00
Line Item Name: VAERS SAR-CoV-2 Surge
Expires on 02/28/21 (3 days)

Option Name: Surge
CLIN: 2002-00
Line Item Name: VAERS Surge ODCs
Expires on 02/28/21 (3 days)

Option Name: Surge
CLIN: 2003-00
Line Item Name: VAERS Surge CAF
Expires on 02/28/21 (3 days)

Please notify the vendor/CIO regarding the possibility of exercising the expiring option(s).

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 5 Oct 2021 15:30:04 +0000
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP); Marquez, Paige L. (CDC/DDID/NCEZID/DHQP); Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Subject: RE: Auto Upload for Surge Meeting

Belay that – we've got a solution already. Thanks!

- John

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tuesday, October 5, 2021 11:20 AM
To: (b)(4)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; Miller, Elaine R. (CDC/DDID/NCEZID/DHQP) <erm4@cdc.gov>
Subject: Auto Upload for Surge Meeting

Hi (b)(4)

May we discuss this topic tomorrow? We're referring medical providers to Auto Upload to share medical records, but the 20 Mb upload limit is posing issues.

- John

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 18 Feb 2021 14:09:50 +0000
To: Sparrow, Rae (CDC/OCOO/OFR/OBS)
Cc: Fedrick, Angela (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP)
Subject: RE: ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

Will do and thank you! Have a great day all.

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

From: Sparrow, Rae (CDC/OCOO/OFR/OBS) <hcq4@cdc.gov>
Sent: Thursday, February 18, 2021 9:09 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Cc: Fedrick, Angela (CDC/DDID/NCEZID/DHQP) <kya8@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Subject: RE: ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports
Importance: High

Hi Traci,

Good morning! I'm going to approve them. Make sure when you fund them, to break the ODC cost in a separate CLIN.

Thanks,
Rae

Rae Sparrow
Budget Analyst
Budget Execution Services (BES1)
Team 2 supporting NCEZID
Office of Budget Services (OBS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO) Centers for Disease Control and Prevention (CDC)
RSparrow@cdc.gov | 770-488-5495 office

Telework: 6:30-3:00, 770-488-5495

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

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Thursday, February 18, 2021 8:52 AM
To: Sparrow, Rae (CDC/OCOO/OFR/OBS) <hcq4@cdc.gov>
Cc: Fedrick, Angela (CDC/DDID/NCEZID/DHQP) <kya8@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

Good morning,

When the PR was initially routed, the plan was to award a funded PR by 2/19. OAS has been actively working with

us and the vendor on this very urgent covid-19 need. It appears now, the PR may be funded early next week.

Traci

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

From: Fedrick, Angela (CDC/DDID/NCEZID/DHQP) <kya8@cdc.gov>
Sent: Thursday, February 18, 2021 7:47 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Cc: Sparrow, Rae (CDC/OCOO/OFR/OBS) <hcq4@cdc.gov>
Subject: RE: ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

See Rae's email

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

From: Sparrow, Rae (CDC/OCOO/OFR/OBS) <hcq4@cdc.gov>
Sent: Thursday, February 18, 2021 7:29 AM
To: Fedrick, Angela (CDC/DDID/NCEZID/DHQP) <kya8@cdc.gov>
Subject: FW: ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports
Importance: High

Hi Angela,

Good morning! I'm reviewing the below PR. It has a start date of 2/19/2021, and is for zero dollars. When do you expect it to be funded?

Thanks,
Rae

Rae Sparrow
Budget Analyst
Budget Execution Services (BES1)
Team 2 supporting NCEZID
Office of Budget Services (OBS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO) Centers for Disease Control and Prevention (CDC)
RSparrow@cdc.gov | 770-488-5495 office

Telework: 6:30-3:00, 770-488-5495

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

From: ICEMAIL <icemail@cdc.gov>
Sent: Tuesday, February 16, 2021 4:00 PM
To: Floyd, Altovise (CDC/OCOO/OFR/OBS) <atf2@cdc.gov>; Hammond, Belinda B. (CDC/OCOO/OFR/OBS) <bnh4@cdc.gov>; Benitez, Cheryl (CDC/OCOO/OFR/OBS) <ziy1@cdc.gov>; Sparrow, Rae (CDC/OCOO/OFR/OBS) <hcq4@cdc.gov>; David, Donna (CDC/OCOO/OFR/OBS) <kyc5@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

You currently have the following Modification Request Folder to review in your ICE inbox:
PR #: 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports
Requisitioner: Traci Sioetta Roberts
Funding:

None.

PIIN: 47QTCK18D0003

SPIIN: 200-2020-F-09621

From: Amador, Nathan (CDC/OCOO/OFR/OAS)
Sent: Wed, 23 Jun 2021 14:04:21 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: ICE Review Notification for 00HCVLDE-2021-58061 - NCE VAERS Surge/Medical Records Update

Good Morning Traci,

We'll get both VAERS contracts properly sorted. Thank you for working with me to get me caught up and straightened out.

Regards,

Nathan R. Amador, JD
Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO
Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile

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

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Wednesday, June 23, 2021 9:51 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: FW: ICE Review Notification for 00HCVLDE-2021-58061 - NCE VAERS Surge/Medical Records Update

Hi Nathan,

Welcome back! Wanted to let you know the PR to extend the increased capacity CLIN is routing; it was stuck in my PMO's que while she was on leave.

Also, I've spoken with GDIT regarding the updated GSA Alliant 2 labor rates we discussed prior to your leave. To clarify, GDIT is not requesting additional funds, but want to ensure the modification reflects the new rates effective in Sept/Oct. Please let me know if there are any questions.

Thanks,
Traci

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

From: ICEMAIL <icemail@cdc.gov>
Sent: Wednesday, June 23, 2021 7:26 AM
To: Floyd, Altovise (CDC/OCOO/OFR/OBS) <atf2@cdc.gov>; Hammond, Belinda B. (CDC/OCOO/OFR/OBS) <bnh4@cdc.gov>; Benitez, Cheryl (CDC/OCOO/OFR/OBS) <ziyl@cdc.gov>; Sparrow, Rae (CDC/OCOO/OFR/OBS) <hcq4@cdc.gov>; David, Donna (CDC/OCOO/OFR/OBS) <kyc5@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: ICE Review Notification for 00HCVLDE-2021-58061 - NCE VAERS Surge/Medical Records Update

You currently have the following Modification Request Folder to review in your ICE inbox:
PR #: 00HCVLDE-2021-58061 - NCE VAERS Surge/Medical Records Update

Requisitioner: Traci Sinetta Roberts

Funding:

None.

PIIN: 47QTCK18D0003

SPIIN: 200-2020-F-09621

From: Marquez, Paige L. (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 24 Jun 2022 11:57:39 +0000
To: (b)(4)
Cc: Diveley, Ray; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: Medical Records COVID Spreadsheet 06/24/2022

Hey (b)(4)

CDC would like to receive the medical records file that is sent every morning via email in the CDC nightly extract, if possible. This would ensure it was processed with the other data at night. Do you think this would be doable?

Thanks,
Paige Marquez

From: VAERS-IT@vaers.org <VAERS-IT@vaers.org>
Sent: Friday, June 24, 2022 7:46 AM
To: VAERS-IT@vaers.org; (b)(4) Marquez, Paige L.
(CDC/DDID/NCEZID/DHQP) <fqv9@cdc.gov>; (b)(4)
Subject: Medical Records COVID Spreadsheet 06/24/2022

The current list of medical records received for COVID reports is attached.

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 16 Feb 2021 16:05:09 +0000
To: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP)
Subject: RE: TRACI - ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

Okay and thanks

From: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Sent: Tuesday, February 16, 2021 10:51 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: TRACI - ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

I'll go ahead and approve since this may be minor.

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, February 16, 2021 10:50 AM
To: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Subject: RE: TRACI - ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

Ok. I'm having trouble getting into ICE again. I'm on the phone with Phil now but will pull back again to check when I can access ICE.

From: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Sent: Tuesday, February 16, 2021 10:46 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: RE: TRACI - ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

Phil Denis' name is reflected twice in block 19.

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, February 16, 2021 10:41 AM
To: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Subject: RE: TRACI - ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

Hi Bonita – I did edit Phil's last name. I cannot change to severable. See previous email.

From: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>
Sent: Tuesday, February 16, 2021 10:37 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>

Subject: RE: TRACI - ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

From: Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP)
Sent: Friday, February 12, 2021 3:58 PM
To: Roberts, Traci Sinetta (CDC/OID/NCEZID) (CTR) (xct6@cdc.gov) <xct6@cdc.gov>
Subject: TRACI - ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

Hi Traci - please pull PR 53669 back to in-process and:

1. Block 19 - Correct spelling for name "Phil Denis"
2. Line item - select "severable" since you have severability memo attached with PR (otherwise - Rae Sparrow may return)

Thanks,

Bonita
498-0646

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

From: ICEMAIL <icemail@cdc.gov>
Sent: Friday, February 12, 2021 3:38 PM
To: Goggins, Nicole J. (CDC/DDID/NCEZID/DHQP) <naj4@cdc.gov>; Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP) <bcj1@cdc.gov>; Denson, Charissa (CDC/DDID/NCEZID/DHQP) <bvn5@cdc.gov>; Blue, Shanda L. (CDC/DDID/NCEZID/DHQP) <gvr6@cdc.gov>; Dobson, Kimberley (CDC/DDID/NCEZID/DHQP) <ihj6@cdc.gov>; Woodard, Tiffanee (CDC/DDID/NCEZID/DHQP) <tow4@cdc.gov>; Gallagher, Nancy (CDC/DDID/NCEZID/DHQP) <cvv6@cdc.gov>; Wilkins, E. Elizabeth (CDC/DDID/NCEZID/DHQP) <bvl5@cdc.gov>; Shams, Alicia (CDC/DDID/NCEZID/DHQP) <aop9@cdc.gov>; Wuichet, John W. (CDC/DDID/NCEZID/DHQP) <uwl2@cdc.gov>; Outin-Blenman, Sajata (CDC/DDID/NCEZID/DHQP) <sao7@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: ICE Review Notification for 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

You currently have the following Modification Request Folder to review in your ICE inbox:

PR #: 00HCVLDE-2021-53669 - VAERSSurge Mod - Backlog Reports

Requisitioner: Traci Sinetta Roberts

Funding:

None.

PIIN: 47QTK18D0003

SPIIN: 200-2020-F-09621

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 30 Sep 2021 16:06:17 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS - Response Needed Today: Division Contract List - Possible Government Shutdown

Hi Traci,

Given Nathan's response, the impression I have is that all VAERS activity can continue per norm (in part because everyone's doing something related to COVID-19 vaccines). Is that understanding correct?

--- John

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Thursday, September 30, 2021 11:42 AM
To: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: VAERS - Response Needed Today: Division Contract List - Possible Government Shutdown

Thanks!

From: Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Sent: Thursday, September 30, 2021 11:41 AM
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>; Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>
Subject: RE: VAERS - Response Needed Today: Division Contract List - Possible Government Shutdown

Good Morning,

In the event of a Federal Government shutdown, funded CDC contracts should proceed as normal until contractors receive instructions directly from:

1. HHS leadership;
2. CDC leadership; or
3. Directly from OAS (most likely source).

To specifically confirm, as of the time of this email, work can continue as normal for VAERS contracts 47QTCK18D0003 75D30119F06120 and 47QTCK18D0003 75D30120F09621 with GDIT.

Regards,

Nathan R. Amador, JD

Contracting Officer, Branch 3, Team 2, in support of CPMO and OCIO

Office of Acquisition Services (OAS)
Office of Financial Resources (OFR)
Office of the Chief Operating Officer (OCOO)
Centers for Disease Control and Prevention (CDC)
wlv7@cdc.gov | 770.488.2690 office | 678.237.1700 mobile



From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Thursday, September 30, 2021 11:27 AM
To: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; Amador, Nathan (CDC/OCOO/OFR/OAS) <wlv7@cdc.gov>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: VAERS - Response Needed Today: Division Contract List - Possible Government Shutdown

Good morning Phil and Nathan,

I just wanted to confirm with you that in the event of a government shutdown, the below VAERS contracts should continue work. The base VAERS contract has continued to work during previous shut downs.

Please respond by 1pm today, I need to provide a response to DHQP today.

VAERS Contract - Option 1/Year 2	47QTCK18D0003/TO 200-2019F-6120	Continue Work	9/29/2020 - 9/28/2021
VAERS for SARS-COV-2 VACCINES	47QTCK18D0003/200-2 020-F-09621	Continue Work	8/27/2020 - 8/26/2022

Thanks,
Traci

Traci Roberts
Public Health Analyst | Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office 404.498.0669
xct6@cdc.gov

From: Denis, Philip (CDC/OCOO/OFR/OAS)
Sent: Wed, 27 Jan 2021 00:49:00 +0000
To: Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: Re: VAERS Covid-19 Contact Modification

Hi Traci,

I'm available tomorrow morning to discuss. Talk to you soon.

Thanks
Phil

Sent from my Verizon, Samsung Galaxy smartphone
Get [Outlook for Android](#)

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Sent: Tuesday, January 26, 2021 12:39:50 PM
To: Denis, Philip (CDC/OCOO/OFR/OAS) <icx2@cdc.gov>; Crockett, Lindsey M. (CDC/OCOO/OFR/OAS) <ywn1@cdc.gov>
Cc: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP) <xct6@cdc.gov>
Subject: VAERS Covid-19 Contact Modification

Hi Phil and Lindsey,

I wanted to give you a heads up that due to substantially higher than expected response, we need to increase the contractor's capacity to fulfill the requirements of the VAERS Surge contract (attached). We have been in ongoing technical discussions regarding the potential modification of both the VAERS Covid-19 Surge Contract (200-2020-F-09621) and the VAERS Covid-19 Call Center contract (200-2021-F-10131). I'd like to bring you up to date and discuss the plan we have in place.

Please let me know if you're available for a quick call today, I'm available until 4:30pm.

Thanks and have a great day.

Traci Roberts
Public Health Analyst | Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office 404.498.0669 | Cel: 404.387.1296 | Fax 404.498.0666
xct6@cdc.gov

From: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 30 Sep 2021 15:27:08 +0000
To: Denis, Philip (CDC/OCOO/OFR/OAS); Amador, Nathan (CDC/OCOO/OFR/OAS)
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: VAERS - Response Needed Today: Division Contract List - Possible Government Shutdown

Good morning Phil and Nathan,

I just wanted to confirm with you that in the event of a government shutdown, the below VAERS contracts should continue work. The base VAERS contract has continued to work during previous shut downs.

Please respond by 1pm today, I need to provide a response to DHQP today.

VAERS Contract - Option 1/Year 2	47QTCK18D0003/TO 200-2019F-6120	Continue Work	9/29/2020 - 9/28/2021
VAERS for SARS-COV-2 VACCINES	47QTCK18D0003/200-2020-F-09621	Continue Work	8/27/2020 - 8/26/2022

Thanks,
Traci

Traci Roberts
Public Health Analyst | Immunization Safety Office
CDC | Division of Healthcare Quality Promotion
Office 404 498 0669
xct6@cdc.gov

From: Miller, Elaine R. (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 21 Dec 2020 20:18:35 +0000
To: Stacey Neloms
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Gallego, Ruth (CDC/DDID/NCEZID/DHQP);
Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Subject: VAERS website update

Hi Stacey,

We request a link for the VAERS COVID vaccine reporting requirements for healthcare providers be moved to the opening page of the VAERS website.

Thanks,

Elaine R. Miller, RN, MPH
Immunization Safety Office
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Atlanta, GA
Email: emiller@cdc.gov
Phone: 404-498-0662