

From: Neloms, Stacey M
Sent: Mon, 16 Nov 2020 04:37:27 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lotspeich, Dana M
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (October 2020)
Attachments: SAR_Cov-2 MSR_October 2020.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Senior Project Manager
Federal Civilian Division

M 240.620.9679
6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com

GENERAL DYNAMICS
Information Technology

November 15, 2020

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

A. SAR-CoV-2 Monthly Status Report

1. Overview

This document will provide an overview of GDIT's activities related to the VAERS SAR-CoV-2 response. Given that vaccines have not yet been released and, consequently, no adverse events reported, our focus will be on the preparatory activities currently underway. GDIT will meet with CDC to determine and agree on future report content, as the vaccine release schedule evolves.

2. Staffing

Using our previous experiences with high-volume events, such as during the influenza season and during the 2009 H1N1 pandemic surge, GDIT estimated, with Government guidance, the number of staff needed. To this end, we developed a three stage hiring strategy. Phase one focused on staff required for key operational functions (data entry, medical coding, clinicians, call center agents).

- Medical Coders: All new medical coders have been trained in MedDRA coding terminology and VAERS coding conventions. They are actively coding reports. Their work is being monitored and feedback provided by senior staff.
- Call Center Agents (CSR): All of the CSRs have completed customer service and call handling training. They are all "live" and are processing inbound VAERS calls while they continue to train for other tasks, including clinical case follow up.
- Clinicians: All new clinicians have completed training and are abstracting records.
- Data Entry: All new data entry staff have been trained and are actively entering reports. They have been paired with a mentor and their work is being monitored.

3. IT Activities (Data Extracts and State Submissions, HIS extract)

- Development of the COVID excel jurisdiction sheets is in progress;
- Development of Public, Wonder, WHO weekly extracts is in progress; and

GENERAL DYNAMICS
Information Technology

- Development of the weekly Indian Health extract is complete and a test file was submitted.

B. Earned Value Report

The following is the Earned Value metrics for October financials, the first full month of billing.

Project Earned Value Analysis	
	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: Neloms, Stacey M
Sent: Wed, 16 Dec 2020 04:19:18 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (November 2020)
Attachments: SAR Cov-2 MSR - November 2020.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (November 2020) is attached. Please let me know if you have any questions.

Thank you,
Stacey

STACEY NELOMS, MPH

Senior Project Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

GENERAL DYNAMICS

Information Technology

December 15, 2020

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 2020)

A. SAR-CoV-2 Monthly Status Report – November 2020

1. Overview

This document will provide an overview of GDIT's activities related to the VAERS SAR-CoV-2 response. Given that vaccines have not yet been released and, consequently, no adverse events reported, our focus will be on the preparatory activities currently underway. GDIT will meet with CDC to determine and agree on future report content, as the vaccine release schedule evolves.

2. Staffing

Phase one staffing focused on staff required for key operational functions (data entry, medical coding, clinicians, call center agents). Information on the number of COVID-19 doses to be administered is evolving and reforecasting of staffing needs may be necessary.

3. IT Activities (Data Extracts and State Submissions, HIS extract)

- Development of the COVID excel jurisdiction sheets is complete.
- Development of Public, Wonder, WHO weekly extracts has been completed. Testing of the Wonder extract with the CDC is in process.
- Development of the weekly Indian Health extract is complete and extract files are being delivered weekly.

B. Earned Value Report

The following is the Earned Value metrics for November financials, the second full month of billing.

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis

ITEM 00001 Information Management Services for VAERS COVID

	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: Neloms, Stacey M
Sent: Sat, 16 Jan 2021 04:37:43 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (December 2020)
Attachments: SAR_Cov-2 MSR_December 2020.pdf

Dear Ms. Roberts,

The VAERS SARS-CoV-2 Monthly Status Report (December 2020) is attached. Please let me know if you have any questions.

Thank you,
Stacey

STACEY NELOMS, MPH

Senior Project Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

January 15, 2020

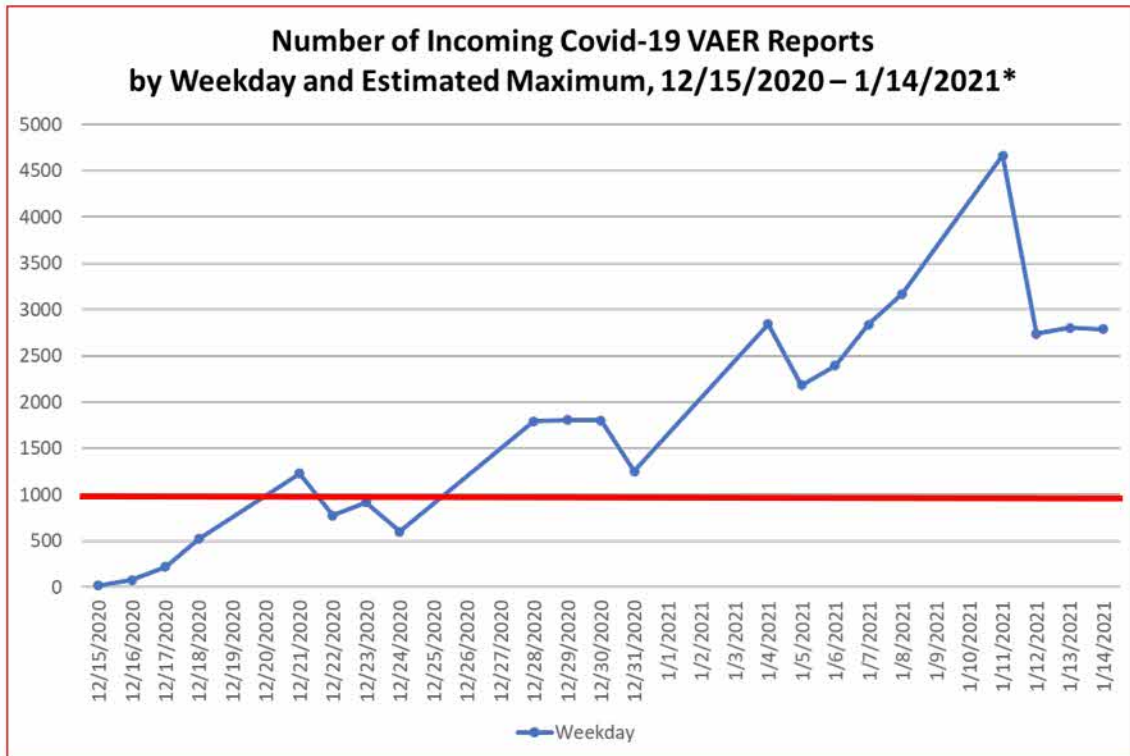
Traci Roberts, COR
Immunization Safety Office
1600 Clifton Road, Mailstop D-26
Atlanta, GA 30333

RE: SAR-CoV-2 Contract Monthly Status Report and Earned Value Report (December 2020)

A. SAR-CoV-2 Monthly Status Report – December 2020

1. Overview

This document will provide an overview of GDIT’s activities related to the VAERS SAR-CoV-2 response. Two vaccines have been released since the last report. Since release the number of incoming COVID-19 reports has significantly exceeded the estimated maximum of 1,000 reports per day (per the chart below). As a result, GDIT is unable to meet processing and other timeframes (data processing, telephone inquiries, clinical inquiries, etc.). GDIT has reached out to the Program office and OAS for guidance and support.



*Red line = estimated “worst case” scenario of 1,000 reports per day

GENERAL DYNAMICS

Information Technology

December Covid reports have also resulted in record metrics in multiple categories including:

- Number of incoming reports: 19,046
- Number of Web reports received: 11,266
- Number of website visits: 343,964
- Number of inquiries: 2,683
- Number of medical records requested: 2,526

2. Staffing

Phase one staffing focused on staff required for key operational functions (data entry, medical coding, clinicians, call center agents). Information on the number of COVID-19 doses to be administered is evolving and reforecasting of staffing needs will be necessary.

3. IT Activities

- Added 2 COVID vaccines to the Electronic Submission form and the Writable PDF form
- Deployed the COVID weekly excel jurisdiction sheets for all states and jurisdictions.
- Public, Wonder, and WHO extracts are now being delivered weekly.
- Added new internal and external users to VAERS VPN

B. Earned Value Report

The following is the Earned Value metrics for December financials, the third full month of billing.

Project Earned Value Analysis			
ITEM 00001 Information Management Services for Vaccine Adverse Events Reporting System COVID			
	OCT	NOV	DEC
Baseline Budgeted Cost			
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)		(b)(4)	
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: Neloms, Stacey M
Sent: Tue, 16 Feb 2021 04:48:24 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (January 2021)
Attachments: SAR_Cov-2 MSR_January 2021.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

February 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 (January 2021)

A. SAR-CoV-2 Monthly Status Report – January 2021

1. Overview

This document will provide an overview of GDIT's activities related to the VAERS SAR-CoV-2 response. Two vaccines have been released since the last report. There continues to be record setting metrics in multiple categories including:

- Number of incoming reports: 76,067
- Number of Web reports received: 54,684 (most of them are Covid-19 reports)
- Number of website visits: 1,555,875
- Number of datasets downloaded: 198,517
- Number of inquiries from the public (phone, etc): 14,857

GDIT is working with the Program Office and OAS for guidance and support.

2. IT Activities

- Expanded the VAERS-IDs in all six extracts to support a 7-digit field
- Updated the COVID excel sheet deliverables application to include additional symptom codes.
- Worked on expanding the columns in the Persons.csv daily extract for CDC, DoD and the Indian Health Service extracts

B. Earned Value Report

The following is the Earned Value metrics for January financials.

GENERAL DYNAMICS

Information Technology

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

	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: Neloms, Stacey M
Sent: Tue, 16 Mar 2021 03:51:11 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (February 2021)
Attachments: SAR_Cov-2 MSR_February 2021.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

March 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 (February 2021)

A. SAR-CoV-2 Monthly Status Report – February 2021

1. Overview

This document will provide an overview of GDIT's activities related to the VAERS SAR-CoV-2 response. Two vaccines have been released since the last reporting period. While some numbers have decreased since January 2021, there continues to be record setting metrics in multiple categories including:

- Number of incoming reports: 74,357 (slight decrease from January 2021)
- Number of Web reports received: 48,128 (decrease from January, most of the reports are Covid-19)
- Number of website visits: 1,433,924 (decrease from January 2021)
- Number of datasets downloaded: 167,696 (decrease from January 2021)
- Number of inquiries from the public (phone, etc): 20,851 (increase from January 2021).

Although staff processed over 40,000 reports in February, a record high, they are unable to keep up with the increased surge in reports at current staffing levels. A contract modification, to provide for surge and backlog remediation, should be issued in March 2021. GDIT is working with the Program Office and OAS for guidance and support.

2. IT Activities

- Created custom daily reports for COVID
- Updated priority report email to include COVID report counts
- Worked on application to move all eVAERS COVID reports to bypass medical coding and instead use manufacturer provided codes, to be launched in March 2021.
- Updated the Medical Coding queues search criteria and display
- Added new users to the VAERS intranet

GENERAL DYNAMICS

Information Technology

3. Earned Value Report

The following is the Earned Value metrics for February financials.

Project Earned Value Analysis
ITEM 00001 Information Management Services for Vaccine Adverse Events Reporting System COVID

	DEC	JAN	FEB
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: Neloms, Stacey M
Sent: Fri, 16 Apr 2021 03:42:23 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baublatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (March 2021)
Attachments: SAR_Cov-2 MSR_March 2021.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

April 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 (March 2021)

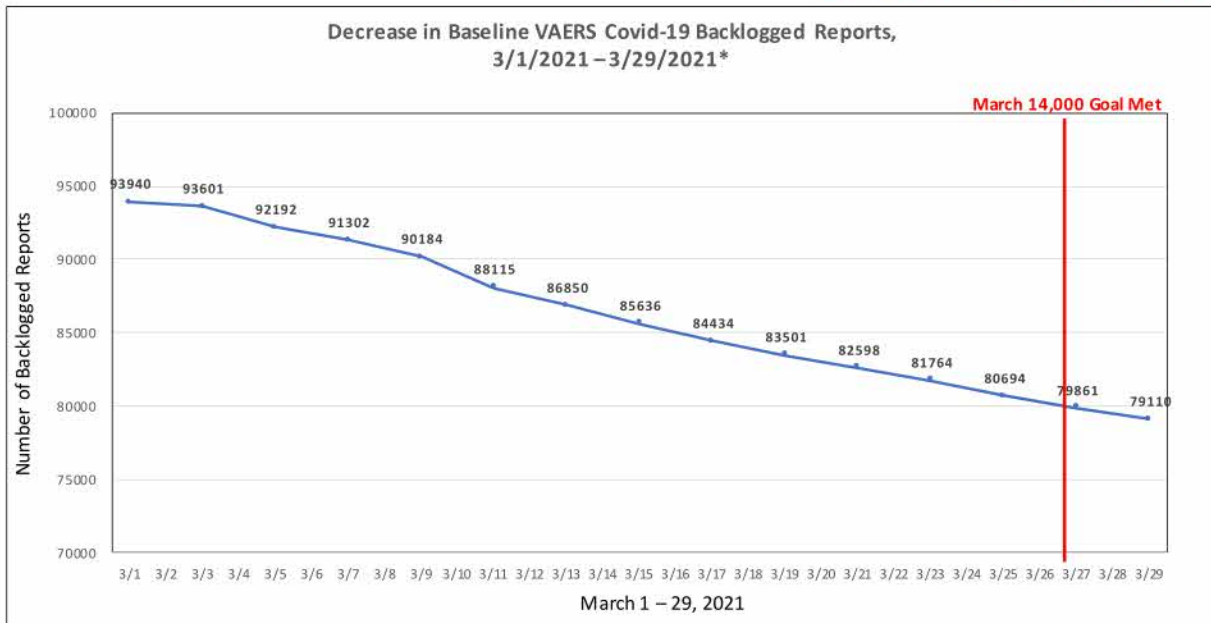
During the reporting period, VAERS continued to be impacted by the surge in Covid-19 related reports, as evidenced by the following metrics:

- Number of incoming reports: 98,687 (increase from February 2021)
- Number of website visits: 1,963,535 (increase from February 2021)
- Number of datasets downloaded: 169,783 (increase from February 2021)
- Number of inquiries from the public: 28,472 (increase from February 2021).

While staff processed over 60,200 reports in March, a record high, they were unable to keep up with the increased surge in reports. Additional surge hiring began with the receipt of additional funding.

1. Processing of Backlog Reports A contract modification, to provide for backlog remediation, was issued in March. During the reporting period, GDIT filled over 90 backlog staffing positions and began processing the backlogged reports. We exceeded the March 14,000 processing goal by over 2,000 reports.

*Total number of processed reports = 15,216
14,000+ reports to be processed in March 2021.



GENERAL DYNAMICS

Information Technology

2. Processing of Incoming Surge Reports

GDIT also began hiring staff to assist in the processing of incoming surge reports and related activities (medical record receipt, enhanced surveillance, etc.). Over 200 staff have been hired and are in training. **GDIT will begin processing 25,000 reports per week during the week of April 19th.**

3. IT/ User Support Activities

- Continued work on VAERS migration. Once completed, this will improve processing efficiencies and increase system storage, among other benefits;
- Created custom daily reports for COVID report monitoring;
- Updated priority report email to include COVID report counts;
- Launched application to move all eVAERS COVID reports to bypass medical coding and instead use manufacturer provided codes;
- Created separate backlog and Covid-Surge queues for processing teams;
- Updated the Medical Coding queues search criteria and display;
- Added new users to the VAERS intranet; and
- Provided user support to government users.

4. Earned Value Report

The following are the Earned Value metrics for March.

Project Earned Value Analysis			
ITEM 00001 Information Management Services for Vaccine Adverse Events Reporting System COVID			
	JAN	FEB	MAR
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: Neloms, Stacey M
Sent: Sun, 16 May 2021 03:43:11 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (April 2021)
Attachments: SAR_Cov-2 MSR_April 2021.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

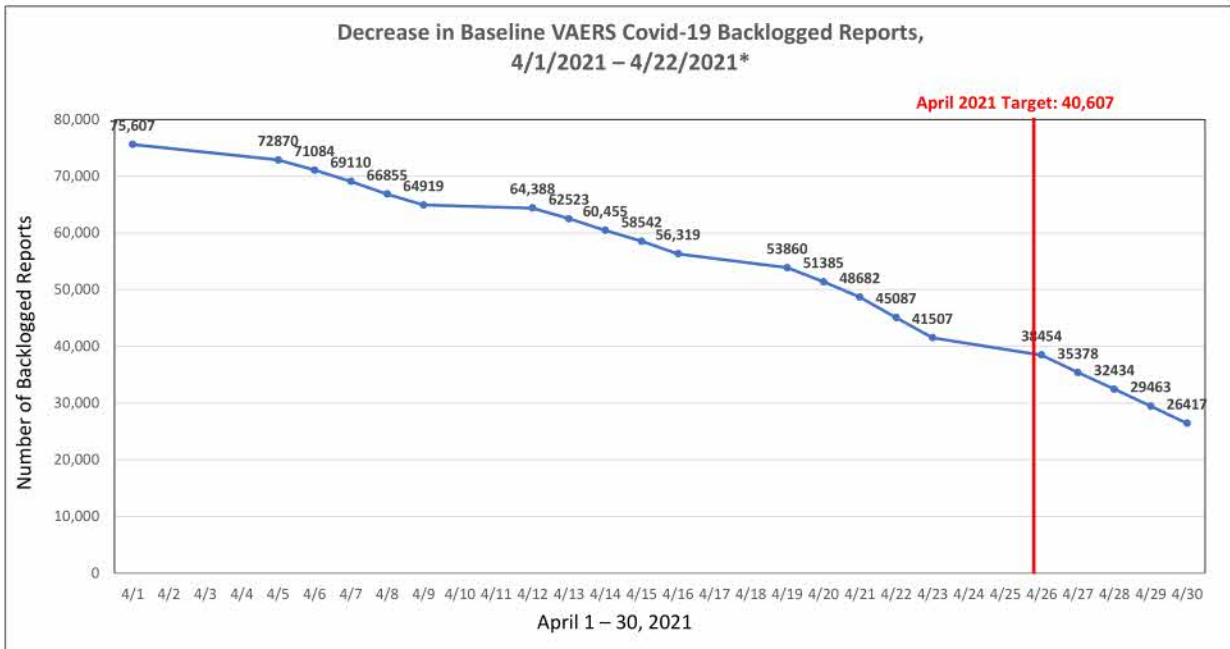
May 15, 2021

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 (April 2021)

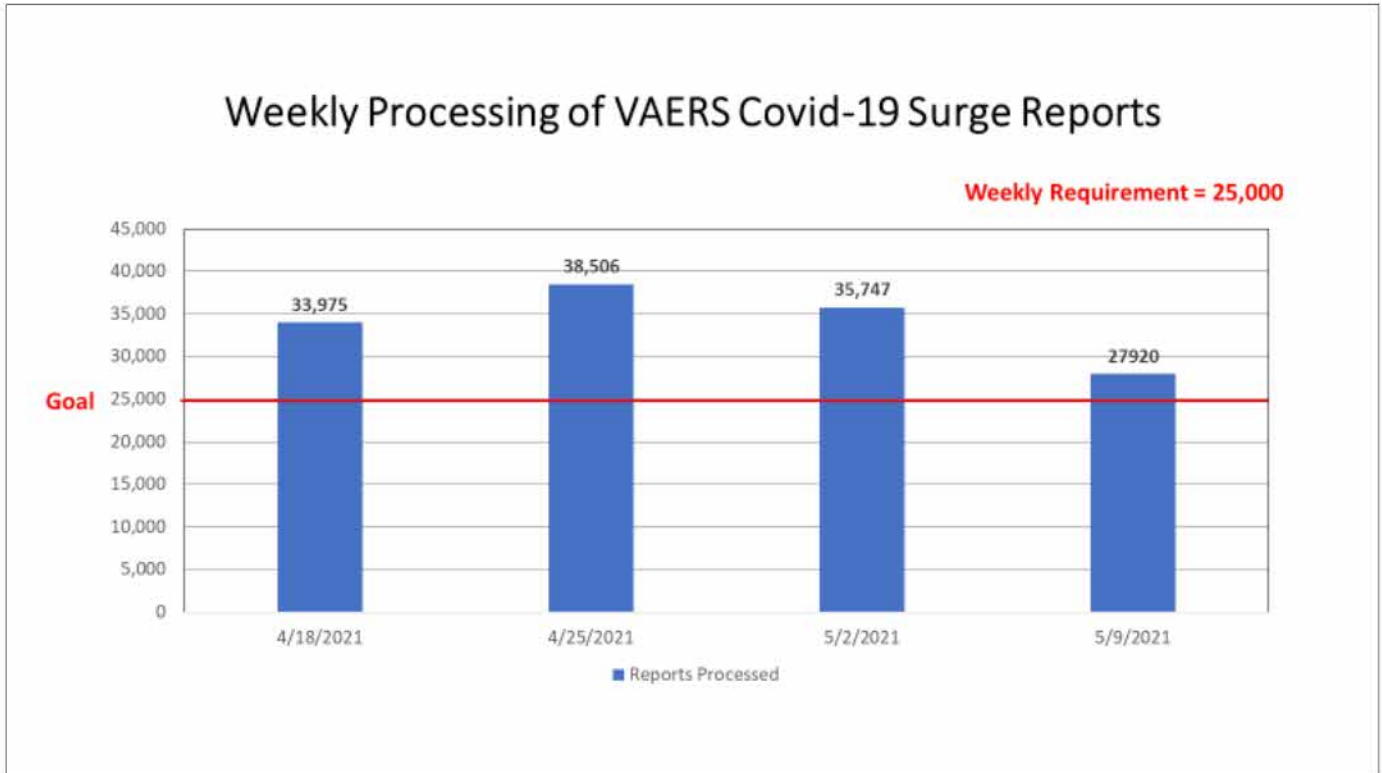
- 1. Processing of Backlog Reports** A contract modification, to provide for backlog remediation, was issued in March. During the reporting period, GDIT exceeded the April 35,000 processing goal.

*Total number of processed reports = 64,733
35,000 reports to be processed in April 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 since we began this task (the week of April 19th).



3. *IT/ User Support Activities*

- Continued work on VAERS migration. Once completed, this will improve processing efficiencies and increase system storage, among other benefits;
- Updated Jurisdiction and State Excel sheets to allow for individual passwords;
- Provided a list of secure, unique passwords to utilize in State sheets and images to be sent to states;
- Updated the Medical Coding, Redaction queues search criteria and display;
- Added new users to the VAERS intranet; and
- Provided user support to government users.

4. **Earned Value Report**

The following are the Earned Value metrics for April.

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis

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

	FEB	MAR	APR
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: Neloms, Stacey M
Sent: Wed, 16 Jun 2021 02:47:41 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Crockett, Lindsey M. (CDC/OCOO/OFR/OAS); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (May 2021)
Attachments: SAR_Cov-2 MSR_May 2021.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

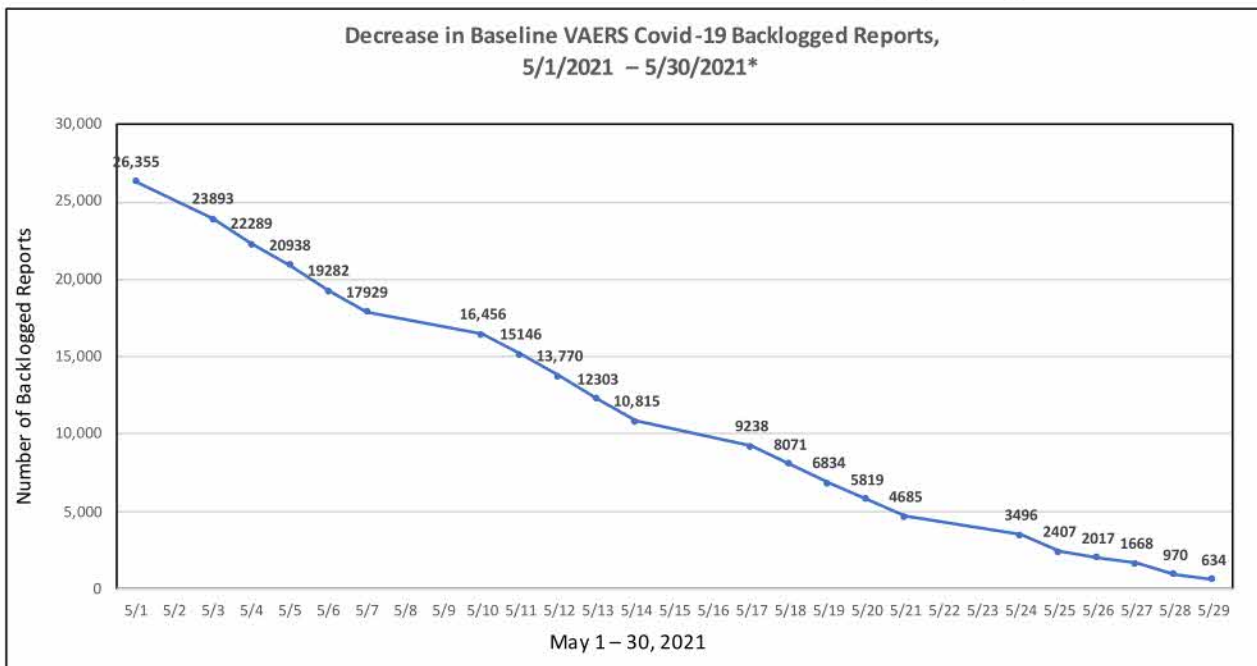
June 15, 2021

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 (May 2021)

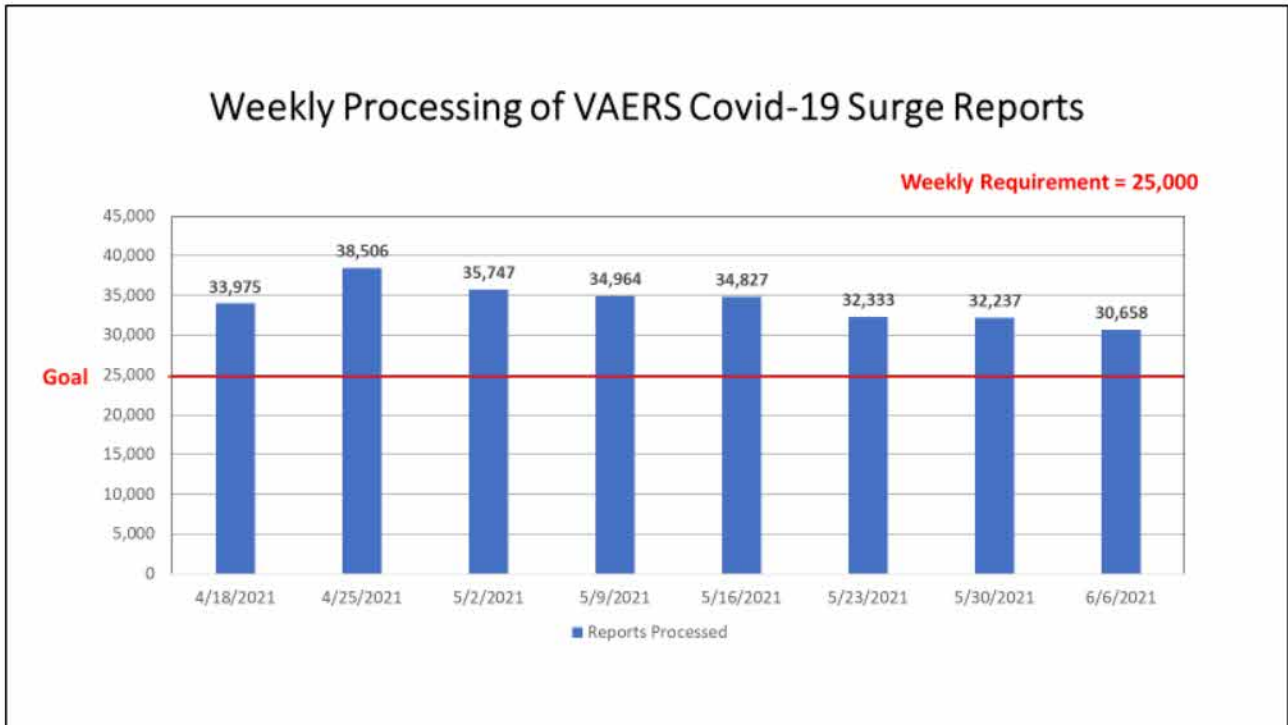
- 1. Processing of Backlog Reports** A contract modification, to provide for backlog remediation, was issued in March. During the reporting period, GDIT completed processing the backlog, ahead of schedule.

*Total number of processed reports = 92,458
Backlog completed May 30, 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 since we began this task (the week of April 19th).



3. IT/ User Support Activities

- Continued work on VAERS migration. Once completed, this will improve processing efficiencies and increase system storage, among other benefits;
- Posted death images to states and weekly Covid data files;
- Continued to updated the Medical Coding, Data entry and Redaction queues search criteria and display screens for staff;
- Added new users to the VAERS intranet; and
- Provided user support to government users.

4. Earned Value Report

The following are the Earned Value metrics for May.

GENERAL DYNAMICS
Information Technology

Project Earned Value Analysis			
ITEM 00001 Information Management Services for Vaccine Adverse Events Reporting System COVID			
	MAR	APR	MAY
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: Neloms, Stacey M
Sent: Fri, 16 Jul 2021 03:22:41 +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); Lemieux, Victoria; Amador, Nathan (CDC/OCOO/OFR/OAS)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (June 2021)
Attachments: SAR Cov-2 MSR - June 2021.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

July 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 (June 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 previous reporting month (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 June.

Number of Covid-19 VAERS Reports Processed by Week, June 2021	
Week	Number Processed*
5/30 – 6/05/2021	31,788
6/06 – 6/12/2021	30,658
6/13 – 6/19/2021	28,987
6/20 – 6/26/2021	25,009
6/27 – 7/03/2021	26,649

*Does not include backlog reports completed in May 2021

In addition, a daily report summarizing the processing of covid reports was submitted each business day in June, 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

- Created custom reports to identify key terms related to death in Box 1. This will assist the team in fulfilling the CDC SOP for identifying death reports.

GENERAL DYNAMICS

Information Technology

- Continued to update the Medical Coding, Data entry and Redaction queues search criteria and display screens for leads
- Added new Government users to the VAERS intranet.

5. Earned Value Report

The following are the Earned Value metrics for June.

Project Earned Value Analysis			
ITEM 00001 Information Management Services for Vaccine Adverse Events Reporting System COVID			
	APR	MAY	JUN
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: Neloms, Stacey M
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); Lemieux, Victoria; 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,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

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: Neloms, Stacey M
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); Lemieux, Victoria; 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,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

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: Neloms, Stacey M
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); Lemieux, Victoria; 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,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

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			
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)		(b)(4)	
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: Neloms, Stacey M
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); Lemieux, Victoria; 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,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

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: Neloms, Stacey M
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); Lemieux, Victoria; 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,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

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: Neloms, Stacey M
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); Lemieux, Victoria; 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,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

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			
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)		(b)(4)	
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: Neloms, Stacey M
Sent: Wed, 16 Feb 2022 04:39:26 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baublatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria; 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,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

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: Neloms, Stacey M
Sent: Wed, 16 Mar 2022 01:05:14 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baublatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria; Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (February 2022)
Attachments: SAR Cov-2 MSR - February 2022.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

GENERAL DYNAMICS

Information Technology

March 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 (February 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 February. A daily report summarizing the processing of covid reports was submitted each business day in February, 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;
- Continued system analysis and updates (i.e., duplicate check) to improve processing efficiencies and performance;
- Ran the weekly covid EpiX s state/jurisdiction XLS files creation process; updated totals for files; and
- Created new custom passwords for covid EpiX state/jurisdiction XLS files.

5. Earned Value Report

The following are the Earned Value metrics for February.

GENERAL DYNAMICS
 Information Technology

Project Earned Value Analysis			
	DEC	JAN	FEB
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: Neloms, Stacey M
Sent: Sat, 16 Apr 2022 03:20:39 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baublatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria; Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (March 2022)
Attachments: SAR Cov-2 MSR - March 2022.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

April 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 (March 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 March. A daily report summarizing the processing of covid reports was submitted each business day in March, 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;
- Continued system analysis and updates to improve processing efficiencies and performance;
- Ran the weekly covid EpiX state/jurisdiction XLS files creation process; updated totals for files; and;
- Researched storage issues, including deleting daily extract output files due to lack of space.

5. System Storage Issues

The VAERS system experienced a significant increase in users/images/incoming files during the COVID-19 response. To handle the current user load, increased volume, and increased stored reports, the VAERS infrastructure needs an upgrade. There is an urgent need for additional storage and a new server.

6. Earned Value Report

The following are the Earned Value metrics for March.

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis ITEM 00001 Information Management Services for Vaccine Adverse Events Reporting System COVID			
	JAN	FEB	MAR
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: Neloms, Stacey M
Sent: Mon, 16 May 2022 03:39:16 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baublatt, Jane (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria; Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (April 2022)
Attachments: SAR Cov-2 MSR - April 2022.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

May 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 (April 2022)

1. Processing of Incoming Surge Reports

GDIT met the reports per week processing requirement each week (as reports were available) during the month of April. A daily report summarizing the processing of covid reports was submitted each business day in April, for government review.

2. Communications

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

3. Covid Updates

- There was a drop in the number of initial reports received. April was the lowest number of reports received since the pandemic started
- The drop in website visits continues. This is the lowest since the pandemic started.
- There was an increase in the number of phone inquiries.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet;
- Performed data requests and system troubleshooting/updates;
- Continued system analysis and updates to improve processing efficiencies and performance; and
- Ran the weekly covid EpiX state/jurisdiction XLS files creation process; updated totals for files.

5. System Storage Issues

The VAERS system experienced a significant increase in users/images/incoming files during the COVID-19 response. To handle the current user load, increased volume, and increased stored reports, the VAERS infrastructure needs an upgrade. There is an urgent need for additional storage and a new server.

GENERAL DYNAMICS
Information Technology

6. Earned Value Report

The following are the Earned Value metrics for April.

Project Earned Value Analysis			
Vaccine Adverse Events Reporting System COVID			
	FEB	MAR	APR
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: Neloms, Stacey M
Sent: Thu, 16 Jun 2022 03:03:04 +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); Lemieux, Victoria; Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (May 2022)
Attachments: SAR Cov-2 MSR - May 2022.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

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

GENERAL DYNAMICS
Information Technology

June 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 (May 2022)

1. Processing of Incoming Surge Reports

GDIT met the reports per week processing requirement each week (as reports were available) during the month of May. A daily report summarizing the processing of covid reports was submitted each business day in May, for government review.

2. Communications

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

3. Covid Updates

- The downward trend in the number of initial reports continued.
- The drop in website visits continues.
- There was an increase in the number of phone inquiries.

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet;
- Performed data requests and system troubleshooting/updates;
- Ran the weekly covid EpiX state/jurisdiction XLS files creation process; updated totals for files.

5. System Storage Issues

The VAERS system experienced a significant increase in users/images/incoming files during the COVID-19 response. To handle the current user load, increased volume, and increased stored reports, the VAERS infrastructure needs an upgrade. There is an urgent need for additional storage and a new server.

6. Earned Value Report

The following are the Earned Value metrics for May.

GENERAL DYNAMICS

Information Technology

Project Earned Value Analysis Vaccine Adverse Events Reporting System COVID			
	MAR	APR	MAY
Baseline Budgeted Cost			
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)		(b)(4)	
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: Neloms, Stacey M
Sent: Sat, 16 Jul 2022 03:22:34 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane; Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria; Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (June 2022)
Attachments: SAR Cov-2 MSR - June 2022.pdf

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852

www.gdit.com

OOO: July 18-25

GENERAL DYNAMICS
Information Technology

GENERAL DYNAMICS

Information Technology

July 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 (June 2022)

1. Processing of Incoming Surge Reports

GDIT met the reports per week processing requirement each week (as reports were available) during the month of June. A daily report summarizing the processing of covid reports was submitted each business day in June, for government review.

2. Communications

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

3. Covid Updates

- The downward trend in the number of initial reports continued.
- The drop in website visits continues.
- Average daily images sent to states/jurisdictions remains low compared to previous quarter
 - We sent ~ 11 images per day to about 6 jurisdictions per day

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet;
- Performed data requests and system troubleshooting/updates;
- Ran the weekly covid EpiX state/jurisdiction XLS files creation process; updated totals for files.

5. System Storage Issues

The VAERS system experienced a significant increase in users/images/incoming files during the COVID-19 response. To handle the current user load, increased volume, and increased stored reports, the VAERS infrastructure needs an upgrade.

6. Earned Value Report

The following are the Earned Value metrics for June.

GENERAL DYNAMICS
Information Technology

Project Earned Value Analysis			
Vaccine Adverse Events Reporting System COVID			
	APR	MAY	JUN
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: Neloms, Stacey M
Sent: Tue, 16 Aug 2022 04:00:21 +0000
To: Roberts, Traci Sinetta (CDC/DDID/NCEZID/DHQP)
Cc: Baumblatt, Jane; Su, John (CDC/DDID/NCEZID/DHQP); Johnson, Bonita C. (CDC/DDID/NCEZID/DHQP); Lemieux, Victoria; Amador, Nathan (CDC/OCOO/OFR/OAS); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: VAERS SARS-CoV-2 Monthly Status Report (July 2022)
Attachments: SARS Cov-2 MSR - July 2022.docx

Dear Ms. Roberts,

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

Thank you,
Stacey

STACEY NELOMS, MPH

Program Manager
Federal Civilian Division

6003 Executive Blvd., 4th Floor
Rockville, MD 20852
www.gdit.com
OOO: July 18-25

GENERAL DYNAMICS
Information Technology

August 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 (July 2022)

1. Processing of Incoming Surge Reports

GDIT met the reports per week processing requirement each week (as reports were available) during the month of July. A daily report summarizing the processing of covid reports was submitted each business day in July, for government review.

2. Communications

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

3. Covid Updates

- The downward trend in the number of initial reports continued.
- The drop in website visits continues.
- Averaged 10 death certificate reports/day to about 6 jurisdictions/day with 100% on-time delivery and no errors.
 - Last year, during the same reporting period, we distributed 25 reports/day to about 17 jurisdictions/day
 - We have not seen any increase with the widening vaccine age range to younger children

4. IT/ User Support Activities

- Added new Government users to the VAERS intranet;
- Performed data requests and system troubleshooting/updates;
- Ran the weekly covid EpiX state/jurisdiction XLS files creation process; updated totals for files.

5. Challenges

System Storage Issues

The VAERS system experienced a significant increase in users/images/incoming files during the COVID-19 response. This is affecting multiple parts of the system To handle the current user load,

GENERAL DYNAMICS

Information Technology

increased volume, and increased stored reports, the VAERS infrastructure needs an upgrade and, at a minimum, a new server.

2. Processing of Incoming Medical Records

We have experienced a backlog in processing of incoming faxes and medical records sent to the Rockville office. We have technical and operational teams working on the issue and have identified the following root causes:

Root Causes:

- Increase in hard copy reports sent to Rockville Office
- Volume Capacity of Fax lines and machines
- Staffing levels for Rockville onsite and remote staff assigned to Rockville processing
- Increase in emailed inquiries, including those with medical record attachments
- Uploading image errors and image queue refresh delays in system.

Corrective Actions (Current, Planned and Investigating):

We are implementing and/or investigating the following actions to address the issue. We have seen an increase in the number of medical records processed during the month of August:

- Increase in staffing to upload records to VAERS
- Added additional fax lines
- Increase Rockville staff to include possibly evening/overnight shift, when faxes are less active.
- For paper records, bypass fax lines but send scanned images to centralized folder in secure server location
- For electronic records (Auto-Upload & email), add possible batch image uploads to database
- For electronic records (Auto-Upload & email), send images to centralized folder in secure server location bypassing Upload tool in system which allows individual uploads only.
- Process records received via Auto-Upload by having robots download attachments to secure centralized folder
- Process records received via email by having robots download attachments to secure centralized folder
- Identify VAERS ID by having the robots work on centralized queue identifying possible VAERS IDs by looking up name and date of birth.

3. Clinical Follow

Root Causes

1. Increase in Serious and other reports requiring follow-up
2. Staffing levels
3. Delay in processing of incoming medical records received (see #2 Medical Records)

Corrective Actions

1. Work on processing of incoming medical records
2. Increase in staffing to help with calls

GENERAL DYNAMICS

Information Technology

6. Earned Value Report

The following are the Earned Value metrics for July.

ITEM 00001 Information Management Services for Vaccine	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			