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El independiente canadiense

Los contratos de los CDC y la FDA muestran que se prepararon para cantidades masivas de eventos adversos graves meses antes de que se implementaran las vacunas Covid-19.



El independiente canadiense

30 de marzo de 2023

Una <u>solicitud</u> de libertad de información de 142 páginas revela impactantes documentos contractuales sobre eventos adversos de la vacuna Covid-19 entre los CDC, la FDA y General Dynamics Information Technology con fecha del 27 de agosto de 2020, cuatro meses **ANTES de que** se introdujeran las vacunas Covid-19 a la población general.

		PAGE 1	OF PAGES								
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	for technical and programmatic suppor related to the Vaccine Adverse Event Reporting System (VARRS) SARS-CGV-2 vaccines. This task order will be pla on GSA Alliant 2. OFR/OAS: Lindsey Crockett, ywn18cdc.go										
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Como se puede ver el contrato tiene fecha del 27 de agosto de 2020, las vacunas contra el Covid-19 comenzaron a llegar a la población a mediados de diciembre de 2020.

El contrato muestra que los CDC y la FDA están buscando asistencia de General Dynamics Information Technology para brindar apoyo relacionado con el Sistema de notificación de eventos adversos a las vacunas (VAERS) para las vacunas Covid-19.

Lo que resulta extremadamente alarmante es la sección "descripción del trabajo" del contrato. Dice: "El contratista implementará un plan de operaciones y dotación de personal que se centre únicamente en los informes de eventos adversos de las vacunas (EVA) después de las vacunas contra el SARS-CoV-2. Se espera que el número total de informes recibidos durante los períodos de máxima actividad (que no se espera que reflejen una actividad sostenida) sea de 1.000 informes por día, y hasta el 40% de los informes son de naturaleza grave".

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 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 patters.

TASK 1. ADMINISTRATIVE

STANDARDIZED METHODS FOR PROVIDING OPERATIONAL SUPPORT FOR THE VAERS PROGRAM.

- A. The Contractor shall maintain Capability Maturity Model (CMM) Level 3 certification (or equivalent) or higher throughout the performance period of the contract and shall provide the Government current documentation of its CMM 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.

Entonces, en resumen, los CDC y la FDA prepararon un contrato 4 meses antes del lanzamiento de la vacuna y esperaban 1.000 eventos adversos por día (7.000 por semana), el 40% de los cuales se estimaba que eran graves.

En marzo de 2021, aproximadamente tres meses y medio después de que se presentaran al público las vacunas Covid-19, los CDC y la FDA modificaron el contrato con General Dynamics Information Technology. La enmienda buscaba 6 meses de asistencia para hacer frente a un retraso de aproximadamente 115.000 informes de eventos adversos.

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E. Increase total contract value and funded amount by (b)(4) from (b)(4) to	
additional support to clear it	.115 0
Except as provided herein, all lerms and conditions of the document referenced in item SA or 10A, as hererofore changed, remains unchanged and in full torce and effect	

Cuatro días después, el contrato se modifica nuevamente solicitando a General Dynamics Information Technology que ayude a lidiar con un mínimo de 25 000 informes de eventos adversos por semana durante los próximos 6 meses.

00004	3. EFFECTIVE DATE	4 REQUISITION/PURCHA	SE RE	Q. NO.	5. PROJECT	NO (if applicable)
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ISSUED BY CODE	8219	7. ADMINISTERED BY (#	other th	an Itom G)	COUL	
enters for Disease Control and CDC)		Points of Contact: CO: Nathan R. Amador				
Office of Acquisition Services 1900 Woodcock Blvd, MS TCU-4 Ulanta, GA 30341-4004	(OAS)	COR: Traci Sinetta Rob	oerts, y	(b)(4)	404.498.0069	
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Otro contrato modificado varios meses después, el 24 de septiembre de 2021, entre los CDC, la FDA y General Dynamics Information Technology muestra que los CDC y la FDA ahora están pidiendo a la compañía que procese un mínimo de 13 000 informes de eventos adversos adicionales por semana durante los próximos seis meses. .

1	AMENDMENT OF SOLICITATION	DIVINODII ICA IIO		_			1	- 1
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(CI	nters for Disease Control and DC) fice of Acquisition Services		CO: Nathan R. As COR: Traci Sines 404.498.0669					2690
	00 Woodcock Blvd, MS TCU-4	(mm)	CTR:		(b)(4)			
	lanta, GA 30341-4004		(b)(4)					
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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 October 01, 2021 to February 28, 2022

Modificaron el contrato nuevamente en febrero de 2022, solicitando a General Dynamics Information Technology que continuara ayudando con un mínimo de 13,000 informes de eventos adversos por semana durante otros seis meses.

	ON/MODIFICATIO	N OF CONTRACT	1.0	ONTRACT ID CO	ADC.	PAGE OF	6	
2. AMENDMENT/MODIFICATION NO. 00006	3. EFFECTIVE DATE 02/28/2022	REQUISITION/PURCHA 00HCVLDE-20				NO. (If applic	able)	
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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
- G. Increase total contract value and funded amount by (b)(4) from (b)(4) to

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.

No está claro si se firmaron contratos nuevos o modificados entre los CDC, la FDA y General Dynamics Information Technology más allá de este último contrato modificado el 28 de febrero de 2022.

Además, descubrí que los CDC y la FDA otorgaron a Eagle Health Analytics un **contrato** separado con fecha del 8 de julio de 2021. Como parte de este contrato, están buscando ayuda con varias cosas, incluido el apoyo de funcionarios médicos y epidemiólogos para el programa VAERS.

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En el contrato de la página 5, los CDC dicen: "VAERS ha tenido un aumento en la notificación de eventos adversos en comparación con años anteriores y con otras vacunas".

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 ohyious causes.

From 2015 through 2019, VAERS received an annual average of 58,000 reports, of which 49,000 were US reports. Of the US reports, 5.3% 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]). Since 1990 to 2019, VAERS has received over 810,000 reports, most of which describe mild and self-limited adverse events such as injection site reactions and fever. (VAERS government data archive January 29, 2021.) 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 current COVID-19 pandemic and COVID-19 vaccination program have created additional requirements for VAERS. Specifically, as part of a mass immunization program with a goal to immunize every adult by May 2021, VAERS has had a surge in reporting of adverse events as compared to previous years and to other vaccines. In addition, CDC reviews reports that are coded as Adverse Events of Special Interest (AESI). These AESI include: acute myocardial infarction, anaphylaxis, coagulopathy, death, Guillain-Barré Syndrome, Kawasaki Disease, Multisystem Inflammatory Syndrome (in adults and in children), myopericarditis, narcolepsy, pregnancy, seizure, stroke, transverse myelitis, Bell's palsy, and appendicitis. Additional outcomes are added, as potential concerns following COVID-19 vaccination are identified.

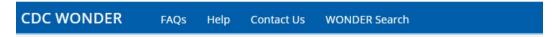
Clinical Immunization Safety Assessments (CISA)

<u>CISA</u> Project is a national network of vaccine safety experts from CDC's Immunization Safety Office (ISO) and seven medical research centers. CISA conducts clinical research, assesses complex adverse events following vaccination, and provides consultations to United States healthcare providers and public health partners.

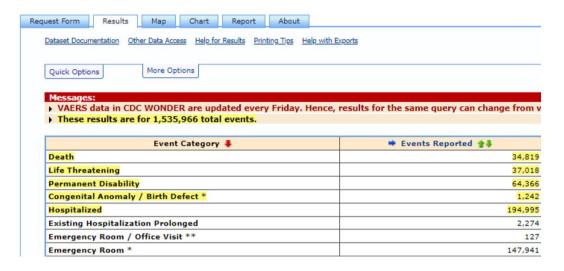
El Sistema de Notificación de Eventos Adversos a las Vacunas ha recibido más de 1,5 millones de informes de eventos adversos relacionados con las vacunas Covid-19 desde diciembre de 2020 hasta marzo de 2023. Los informes incluyen poco menos de 35.000 muertes, casi 200.000 hospitalizaciones, más de 64.000 incapacidades permanentes y más de 1200 defectos de nacimiento.

Covid-19 Vaccines ONLY

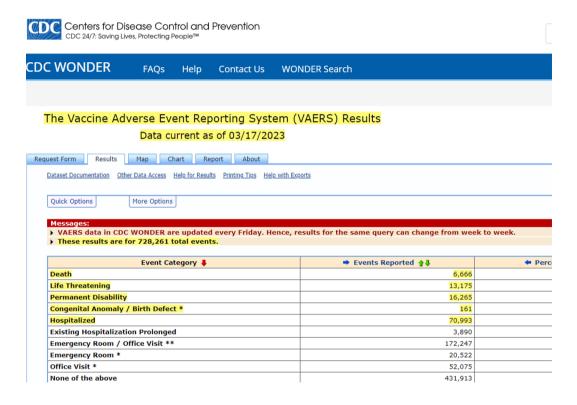




The Vaccine Adverse Event Reporting System (VAERS) Results Data current as of 03/17/2023



97 Historical Vaccines 1990 to 2023 (33 Years) Excluding the Covid-19 Vaccines



Los datos del VAERS muestran que las vacunas Covid-19 tienen informes de eventos adversos extremadamente altos, incluidas hospitalizaciones, discapacidad permanente, defectos de nacimiento y muerte, en comparación con todas las demás vacunas históricas combinadas durante 33 años.

Vale la pena señalar que según la <u>FDA</u>. "No recibe la mayoría de los informes de eventos adversos que ocurren en los Estados Unidos. Las estimaciones sugieren que la FDA recibe informes de alrededor del 1 al 10 por ciento de los eventos adversos que ocurren".

WORLD OF DRUG SAFETY MODULE



AERS has just as many limitations:

- Underreporting; FDA does not get most reports of adverse events that occur in the United States.
 Estimates suggest that FDA receives reports of about 1 to 10 percent of the adverse events that occur.
- Duplicate reporting. FDA can get the same report about the same event from the same person if they
 send it to the company and FDA, if manufacturers submit follow-up reports as new reports, or if more
 than one report is sent to the company or FDA by the patient, family member or healthcare providers.
 There's a manual process to remove duplicate entries but it is time-consuming.
- Variable reporting quality. Some reports are very good; some are not. If reports don't have important clinical information, then it is difficult to determine if the drug was related to the adverse event.
- Reporting biases. Some people report some things more than others.
- Spontaneous report numbers cannot be used to determine incidence of adverse events. Without the total number of cases that occur in the United States, OSE cannot use the data to determine incidence rates of adverse events -- how commonly the event occurs in the population.
- Difficult to attribute events with high background rate and long latency.

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