Privacy Impact Assessment (PIA): FDA - VAERS-VEII - QTR1 - 2025 - FDA4914126

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Copy PIA (Privacy Impact Assessment)

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Instructions

Review the following steps to complete this questionnaire:

1) Answer questions. Select the appropriate answer to each question. Question specific help text may be available via the icon. If your answer dictates an explanation, a required text box will become available for you to add further information.

2) Add Comments. You may add question specific comments or attach supporting evidence for your answers by clicking on the icon next to each question. Once you have saved the comment, the icon will change to the icon to show that a comment has been added.

3) Change the Status. You may keep the questionnaire in the "In Process" status until you are ready to submit it for review. When you have completed the assessment, change the Submission Status to "Submitted". This will route the assessment to the proper reviewer. Please note that all values list questions must be answered before submitting the questionnaire.

4) Save/Exit the Questionnaire. You may use any of the four buttons at the top and bottom of the screen to save or exit the questionnaire. The button allows you to complete the questionnaire. The button allows you to save your work and close the questionnaire. The button allows you to save your work and remain in the questionnaire. The button closes the questionnaire without saving your work.

Acronyms
ATO - Authorization to Operate
CAC - Common Access Card
FISMA - Federal Information Security Management Act
ISA - Information Sharing Agreement
HHS - Department of Health and Human Services
MOU - Memorandum of Understanding
NARA - National Archives and Record Administration
OMB - Office of Management and Budget
PIA - Privacy Impact Assessment
PII - Personally Identifiable Information
POC - Point of Contact
PTA - Privacy Threshold Assessment
SORN - System of Records Notice
SSN - Social Security Number
URL - Uniform Resource Locator

General Information

PIA Name:	FDA - VAERS-VEII - QTR1 - 2025 - FDA4914126	**PIA ID:**	2820888
Name of Component:	FDA - CBER VAERS Explorer II	**Name of ATO Boundary:**	CBER Office of Regulatory Operations
Overall Status:		**PIA Queue:**	
Submitter:		**# Days Open:**	10
Submission Status:	Submitted	**Submit Date:**	2/28/2025
Next Assessment Date:	03/09/2028	**Expiration Date:**	3/9/2028
Office:		**OPDIV:**	FDA
Security Categorization:		**OpDiv PIA ID:**	FDA4914126
Legacy PIA ID:		**Make PIA available to Public?:**	Yes

1:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
2:	Is this a FISMA-Reportable system?	No
3:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
4:	ATO Date or Planned ATO Date.	11/21/2022
5:	Is the system or electronic information collection, agency or contractor operated?	Agency

PTA

PTA

PTA - 2:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	The Food and Drug Administration (FDA) has made no changes to this component since the last Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) was approved.
PTA - 3:	Is the data contained in the system owned by the agency or contractor?	Agency

PTA - 4:	Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions.	The Food and Drug Administrations (FDA) Center for Biologics Evaluation and Research (CBER) administers the Vaccine Adverse Events System (VAERS) Program an outgrowth of the National Childhood Vaccine Injury Act of 1986 (NCVIA). VAERS accepts reports of adverse events that may be associated with United States (U.S.) licensed vaccines from health care providers, manufacturers, and the public. The FDA continually monitors VAERS reports for any unexpected patterns or changes in rates of adverse events. CBER maintains a VAERS DataMart populated with data from the broader joint FDA & CDC managed VAERS program, which allows both fixed-format and ad-hoc analysis of individual vaccine adverse-events, as well as aggregated adverse-event cases. The VAERS DataMart is known colloquially as CBER VAERS Explorer II (VAERS-VEII) at FDA but should not be confused with the CDC-managed VAERS program. The subject of this assessment is CBER VAERS Explorer II (VAERS-VEII). CBER VAERS-VEII is one of the primary data sources for the larger CBER Office of Regulatory Operations (ORO) system under which VAERS-VEII falls. This data source is established, and data is provided via system-level connections with the source systems at CDC (VAERS) and FDA's Adverse Event Reporting System (FAERS, the subject of a separate assessment). The data contained in the CBER ORO system is refreshed daily; data is overwritten and updated with the latest available data from VAERS and FAERS.

PTA - 5:	List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored.	The CBER ORO system exists to provide a central location to collect, review, and analyze Adverse Event Reports for all CBER regulated products. Each component of the ORO system captures different information from different data sources. CBER VAERS-VEII receives information from CDC VAERS and provides CBER users with a means for performing analysis and ad hoc data querying of vaccine adverse events. Data includes information about vaccine adverse events that have been reported to the CDC, including vaccine, dosage and adverse event information about the reporter and the patient experiencing the adverse event. Personally identifiable information (PII) may include contact information such as name, telephone number, email address, mailing address, date of birth, patient identification (I.D.) and/or other patient identifiers such as patient initials, age, sex, weight, race and ethnicity. Device identifiers may also be disclosed, as well as time and location information related to the adverse event. CBER VAERS also has an electronic submission process that allows manufacturers of vaccines to report directly to FDA concurrently with reports to CDC using the individual case safety report (ICSR) electronic submission format. These reports come in through the FDA Electronic Submission Gateway (ESG, the subject of a separate assessment). All data collected in the CBER ORO System is provided to users "as-is" in that it shares information that it has received from other source systems but does not create or modify any data it contains. Information about the users themselves (the medical reviewers, systems administrators) are managed through network access protocols and all have FDA system access credentials. All users are authorized FDA network users and access to this system is granted via the CBER Menu application (the subject of a separate assessment) using single sign-on (SSO) authentication. Users of the system are full time employees of the federal government and Direct Contractors with FDA badges and smart cards.
PTA - 5A:	Are user credentials used to access the system?	Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this system. The system providing credentials is
PTA - 5B:	Please identify the type of user credentials used to access the system.	

PTA - 6:	Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual.	CBER VAERS-VEII consists of adverse event reports associated with U.S. licensed vaccines submitted by health care providers, manufacturers, and the public. VAERS-VEII is populated with data from the broader joint FDA and CDC managed VAERS program, which allows both fixed-format and ad hoc analysis of individual vaccine adverse events, as well as aggregated adverse event cases for FDA reporting purposes. Information in VAERS-VEII is provided by CDC and is shared with CDER as a data extract file to Empirica Signal (a CDER system covered in a separate PIA) in support of wider post-market surveillance. Data may include the following PII: name, telephone number, email address, mailing address, date of birth (reporter or patient experiencing the adverse event), patient i.d. and/or other patient identifiers such as patient initials, age, sex, weight, race and ethnicity. Device identifiers may also be disclosed, as well as time and location information related to the adverse event.
PTA - 7:	Does the system collect, maintain, use or share PII?	Yes
PTA - 7A:	Does this include Sensitive PII as defined by HHS?	Yes
PTA - 8:	Does the system include a website or online application?	Yes
PTA - 8A:	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	No
PTA - 9:	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	The internal uniform resource locator (URL) provides CBER users with access to the information provided from CDC VAERS and provides a means for performing analysis and ad hoc data querying of vaccine adverse events. Users are authorized FDA permanent employees and Direct Contractors. Access to this system is granted through the CBER Menu application using SSO authentication.
PTA - 10:	Does the website have a posted privacy notice?	Yes
PTA - 11:	Does the website contain links to non-federal government websites external to HHS?	No
PTA - 11A:	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	
PTA - 12:	Does the website use web measurement and customization technology?	No
PTA - 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	
PTA - 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA - 13A:	Does the website collect PII from children under the age thirteen?	
PTA - 13B:	Is there a unique privacy policy for the website and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
PTA - 14:	Does the system have a mobile application?	No
PTA - 14A:	Is the mobile application HHS developed and managed or a third-party application?	

PTA - 15:	Describe the purpose of the mobile application, who has access to it, and how users access it. Please address each element in your response.	
PTA - 16:	Does the mobile application/ have a privacy notice?	
PTA - 17:	Does the mobile application contain links to non-federal government websites external to HHS?	
PTA - 17A:	Is a disclaimer notice provided to users that follow external links to resources not owned or operated by HHS?	
PTA - 18:	Does the mobile application use measurement and customization technology?	
PTA - 18A:	Describe the type(s) of measurement and customization technologies or techniques in use and what information is collected.	
PTA - 19:	Does the mobile application have any information or pages directed at children under the age of thirteen?	
PTA - 19A:	Does the mobile application collect PII from children under the age thirteen?	
PTA - 19B:	Is there a unique privacy policy for the mobile application and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
PTA - 20:	Is there a third-party website or application (TPWA) associated with the system?	No
PTA - 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

PIA

PIA

PIA - 1:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Name Email Address Phone numbers Mailing Address Devices Identifiers Patient ID Number Other - Free text Field - Other patient identifiers such as patient initials, age, sex, weight, race and ethnicity.
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Patients Members of the public
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system.	Above 2000
PIA - 4:	For what primary purpose is the PII used?	The information (if provided) is used to contact people to clarify data regarding their submissions and to assist in follow-up analysis of the data.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	The FDA makes no secondary use of the PII.
PIA - 6:	Describe the function of the SSN, Truncated SSN, and/or Taxpayer ID.	
PIA - 6A:	Cite the legal authority to use the SSN, Truncated SSN, and/or Taxpayer ID.	

PIA - 7:	Identify legal authorities governing information use and disclosure specific to the system and program.	Provisions of the Food, Drug, and Cosmetic Act, 21 U.S.C. 301, including sections 353, 356b, 360; Public Health Service Act, 42 U.S.C. 201 including sections 262, 263a; 5 U.S.C. 301.
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	No
PIA - 8A:	Please specify which PII data elements are used to retrieve records.	
PIA - 8B:	Provide the number, title, and URL of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or indicate whether a new or revised SORN is in development.	
PIA - 9:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Email Online Government Sources Within the OPDIV Other HHS OPDIV State/Local/Tribal Foreign Non-Government Sources Members of the Public Private Sector
PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA - 10A:	Provide the information collection approval number.	OMB No. 0910-0291
PIA - 10B:	Identify the OMB information collection approval number expiration date.	6/30/2025
PIA - 10C:	Explain why an OMB information collection approval number is not required.	
PIA - 11:	Is the PII shared with other organizations outside the system's Operating Division?	Yes
PIA - 11A:	Identify with whom the PII is shared or disclosed.	Within HHS
PIA - 11B:	Please provide the purpose(s) for the disclosures described in PIA - 11A.	Information is shared with CDER and the Center for Disease Control (CDC) for joint handling of adverse events regarding vaccines.
PIA - 11C:	List any agreements in place that authorizes the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	Interagency agreement with CDC, IAG # 224-08-1093. This joint agreement stems from a joint FDA-CDC project required under the National Childhood Vaccine Injury Act (NCVIA), P.L. 99-660.
PIA - 11D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	Data is not disclosed outside of the Department of Health and Human Services (HHS). Personnel requiring access are provided with disclosure accounting guidance and resources, however, these applications are not subject to the Privacy Act, and its requirement to maintain an accounting of certain disclosures.

PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 12A:	If PII submission is mandatory, provide the specific legal requirement that requires individuals to provide information or face potential civil or criminal penalties.	
PIA - 13:	Describe the method for notifying individuals that their information will be collected and how they can opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.	HHS and FDA personnel that use the systems are notified, and as a condition of employment and use of the systems, consent to the use of their information by FDA and HHS at the time they are hired. Voluntary Reporters are not required to report PII of the affected individuals, and have full control over the submission of PII, if any. Mandatory reporters (e.g. manufacturers) do not have a choice regarding the submission of information including PII about themselves. This information is essential for FDA to effectively analyze and respond to event reports, and thereby protect against unsafe biologic products in the marketplace. However, those mandatory submissions are made to systems maintained by the CDC and FDA CDER, and the collection of that information is addressed in dedicated PIAs for those other systems. PII about the individuals affected by adverse events is not required and is not expected to be reported. Information provided (adverse event experienced, dates of events, relevant health conditions) is not sufficient to identify the individual, alone or in combination with other reasonably available information.
PIA - 14:	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained.	PII data maintained in CBER ORO is obtained directly from CDC's VAERS and FDA's FAERS. Operators of those systems are responsible for notifying the individuals of any changes to the collection or distribution of PII data. System updates to CBER VAERS-VEII and CBAERS systems are communicated to the users of those systems through system update notices and through the points of contact as needed for the CDC VAERs or CDER FAERS systems. Lot Distribution Data (LDD) PII data consists of the reporters' contact information only, and changes to the LDD system are communicated to its users through the CBER LDD Coordinator. This may include a formal process involving written and/or electronic notice, or informal processes such as email notice to the individuals.

PIA - 15:	Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.	Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have many avenues available for assistance. These individuals may contact FDA offices, including the Privacy Office, the Employee Resource and Information Center (ERIC-FDA personnel only), the Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) and other agency offices, via email, phone and standard mail avenues (all listed on FDA.gov and the FDA intranet). In the event of a suspected incident or data breach, FDA personnel must report that without delay to the FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC).
PIA - 16:	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. Please address each element in your response. If no processes are in place, explain why not.	Reporter's PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of reporting. FDA personnel may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Integrity and availability are protected by security controls selected and implemented during providing the system with an authority to operate (ATO). Controls are selected based on National Institute of Standards and Technology (NIST) guidance concerning the ATO process, appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standards (FIPS) 199. CBER performs annual reviews to evaluate user access. One of the controls includes information system backups reflecting the requirements in contingency plans as well as other agency requirements for backing up information. Data discrepancies identified during system use are addressed when discovered.
PIA - 17:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA - 17A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA - 17B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes

PIA - 18:	Provide the reason why each of the groups identified in PIA - 17 needs access to PII.	OBPV Users : The Office of Biostatistics and Pharmacovigilance (OBPV) users will have access to PII under the same circumstances as FDA employees in those roles. Administrators: System administrators require access to users account information to conduct system maintenance and provide quality control. Developers: Developers may have access to user or Adverse Event Report (AERs) subject PII incidentally to unit and system testing and development. Contractors: Some system administrators or developers may be Direct Contractors and will have access to PII under the same circumstances as FDA employees in those roles.
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	FDA users and Direct Contractors with valid network accounts who require access to the system must obtain supervisory approval and signature before access is granted. The agency reviews the system access list on a quarterly basis to adjust users' access roles and permissions and delete unneeded accounts from the system.
PIA - 20:	Describe the technical methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.	All users including administrators, developers, and Direct Contractors are granted only the minimal privileges that they require to do their job. Users' supervisor indicates on the account creation form the minimum system access that is required. All users are FDA network users and must have a current Personal Identity Verification (PIV) compliant badge.
PIA - 21:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.	All system users at FDA take annual mandatory computer security and privacy awareness training. This training includes guidance on Federal laws, policies, and regulations relating to privacy and data confidentiality, integrity and availability, as well as the handling of data (including any special restrictions on data use and/or disclosure). The FDA Office of Digital Transformation (ODT) verifies that training has been successfully completed.
PIA - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	System users receive system-specific training, review the HHS Rules of Behavior. Additional role-based training on privacy is available via FDA's privacy office.

PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	All adverse event files are temporary, and destroyed according to the instructions cited in the following records schedules: FDA 5, Adverse Event/Experience and Product Defect Reports; 5.1 Adverse Event Management Files; 5.2 Adverse Event Reports or Forms; 5.3 Adverse Events Reporting Systems; 5.3.2 AERS Database Records; 5.3.3 Extracts of the Adverse Data for Public Access; Output Records; General Records Schedule, Electronic Records GRS 4.3, item 020, 030, 031; GRS 3.1, item 051. CBER Records Control Schedule (NARA Schedule No. N1-088-03-05) Items B-34, Post Marketing Products Safety Reviewers and Adverse Event Summaries, and B-35 Post Marketing Surveillance Lot Analysis Reports. Records are retired to the Washington National Records Center three years after the cut-off date and destroyed 20 years after the cut-off date.
PIA - 24:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

Review & Comments

Privacy Analyst Review

OpDiv Privacy Analyst Review Status:	Approved	**Privacy Analyst Review Date:**	2/28/2025
Privacy Analyst Comments:		**Privacy Analyst Days Open:**	

SOP Review

SOP Review Status:	Approved	**SOP Signature:**	
SOP Comments:	The FDA's Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls.	**SOP Review Date:**	2/28/2025
		SOP Days Open:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	**Agency Privacy Analyst Review Date:**	3/3/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 3/3/2025 This PIA is ready for SAOP review and approval.	**Agency Privacy Analyst Days Open:**	3

SAOP Review

SAOP Review Status:	Approved	**SAOP Signature:**	Archer Signature_Bridget Guenther.docx
SAOP Comments:		**SAOP Review Date:**	3/10/2025
		SAOP Days Open:	7

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
2-28-2025 EMAIL_PIA in Queue (CBER VAERS Explorer II).pdf	331397	.pdf	3/3/2025 11:51 AM	0
CBER VAERS Explorer II_SOP Approved.rtf	802703	.rtf	3/3/2025 11:51 AM	0

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 1	BLAND, CRYSTAL	3/3/2025	There are two Archer issues impacting this PIA. • The Answer to PTA-5A is entered on the PTA but does not show on the PIA. • Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this system. The system providing credentials is **Active Directory.** The PIA is also experiencing an Archer error with Question #3 of the general information. • Q-3 "Does the system have or is it covered by a Security Authorization to Operate (ATO)?" • The FDA instance of Archer is automatically entering the answer "*No*," which is incorrect. The ATO date is *11/21/2022*. • At this time, we are unable to update Archer to reflect the correct answer "Yes." The FDA Archer Team is aware of this occurrence and is working on a solution.	

Admin Section

Is OpDiv Privacy Analyst Approved ?:	1	**Is OpDiv Privacy Analyst Return ? :**	0
		Is SOP Return ?:	0
Is Agency Privacy Analyst Approve ?:	1	**Is Agency Privacy Analyst Return ?:**	0
Is SAOP Approved?:	1	**Is SAOP Return ?:**	0
Total Approved:	4	**Total Return:**	0
Total Approval Required:	4		

Miscellaneous Fields

Last Updated:	3/10/2025 2:14 PM	**History Log:**	View History Log