PTA / PIA: FDA - CEDh - QTR2 - 2025 - FDA4925169

Created Date: 5/20/2025 4:35 PM Last Updated: 5/30/2025 4:38 PM

General Information

PTA / PIA Name:	FDA - CEDh - QTR2 - 2025 - FDA4925169	**PTA / PIA ID:**	3199780
Component Name:	FDA - CDRH Enterprise Datahub	**ATO Boundary Name:**	CDRH Reporting and Collection Tools
Overall Status:	Complete	**# of Days - Open:**	11
Submitter:		**Submit Date:**	5/20/2025
Next Assessment Date:	N/A	**Expiration Date:**	1/1/2100
Office:		**OpDiv:**	FDA
Security Categorization:	High		
Make PIA available to Public?:	No	**PIA Required:**	Yes

General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?	No
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
General 04:	ATO Date or Planned ATO Date.	1/23/2023
General 05:	Is the system or electronic information collection, agency or contractor operated?	Agency
History Log:	View History Log	

Privacy Threshold Analysis

Privacy Threshold Analysis

PTA 01:	Point of Contact (POC) Name	POC Name: Jonathan Adams
PTA 01A:	POC Title and Organization	POC Title: System Owner POC Organization: CDRH/OSPTI/DTDS
PTA 01B:	POC Email Address	Jonathan.adams@fda.hhs.gov
PTA 01C:	POC Phone Number	240-402-2604
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	New
PTA 03:	Is the data contained in the system owned by the agency or contractor?	Agency

PTA 04:	Please give a brief overview of the purpose of the system by describing what the functions of the system are and how the system carries out those functions in support of HHS.	Center for Devices and Radiological Health (CDRH) Enterprise Data Hub (CEDh) is a component of the CDRH Reporting and Collection Tools (RCT) system boundary. The purpose of CEDh is to ingest (view-only) data from multiple sources (internal Food and Drug Administration (FDA) / CDRH wide applications). This single all-encompassing repository will simplify data analysis and reporting for internal FDA staff by allowing FDA data scientists to query FDA/CDRH wide applications to perform data analysis and reporting.
PTA 05:	List and/or describe all the types of information that are collected, maintained, and/or shared by the system regardless of whether that information is PII and how long that information is stored.	CDRH CEDh maintains the following PII from internal users of the system (FDA permanent employees and Direct Contractors): a) first and last name, b) work email address, and c) user credentials (username and password). CEDh serves as a single all-encompassing repository that allows FDA data scientists to query FDA/CDRH wide applications to perform data analysis and reporting. The data ingested from the data sources is view-only. The (FDA) / CDRH wide applications used for data analysis and reporting in CEDh include but may not be limited to: CTS - Center Tracking System DNMS - Device Nomenclature System eMDR - Electronic Medical Device Reports System FACS - Facility System PSTS - Center Electronic Submissions (Cesub) Pre-Market Submission Tracking System (PSTS) RHPro - Radiological Health Processor STDS - Recognized Standards GUDID - Global Unique Device Identification Database ITR - Insight Time Reporting The information collected in these data sources include Personally Identifiable Information (PII), Adverse Event Data, Confidential Commercial Information, PreMarket and PostMarket device information, Regulatory Science, Trade Secrets, Pre-decisional Information and Regulatory Compliance data. It is not possible to enumerate all of the potential personally identifiable information (PII) and other information that may be contained in records maintained in the source systems. CEDh does not store the PII maintained in the data sources. The source system teams, and their specific programs identify the primary use of PII for each individual system through system specific

		privacy assessments. The CEDh system will be accessed by FDA Employees and Direct Contractors. CEDh applications are integrated with Enterprise Single Sign-on (SSO). Single sign-on is the primary method to access CEDh. For administrative purposes there is an option for system users to access CEDh using username and password. CEDh retains the PII for the length of the contract, it will be deleted or destroyed after ten years after cutoff or when no longer needed for legal, research, historical or reference purposes, whichever is the latest) which corresponds with the National Archives and Records Administration (NARA) retention schedule.
PTA 05A:	Are user credentials used to access the system?	Yes
PTA 05B:	Please identify the type of user credentials used to access the system.	HHS User Credentials HHS/OpDiv PIV Card HHS Username Password
PTA 06:	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	CDRH CEDh maintains the following PII from internal users of the system (FDA permanent employees and Direct Contractors): a) first and last name, b) work email address, and c) user credentials (username and password) to establish log-in credentials for system access. Information that is ingested (view-only) from multiple sources (internal FDA / CDRH wide applications) is used to facilitate data analysis and reporting across all CDRH applications.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes
PTA 08A:	Provide the URL(s).	https://cdrh-databricks.prod.fda.gov/ https://cedh-pyramidanalytics.fda.gov/ https://cedh-dvsum.fda.gov/ https://cdrh-curate.preprod.fda.gov
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No

PTA 09:	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 purpose of the website is to ingest data from multiple sources (internal Food and Drug Administration (FDA) / CDRH wide applications) to simplify data analysis and reporting for internal FDA staff. FDA personnel (developers, data analysts, administrators) can log in to perform maintenance on the system or access the data collected there to perform analysis. The CEDh system will be accessed by FDA Employees and Direct Contractors. CEDh applications are integrated with Enterprise Single Sign-on (SSO). Single sign-on is the primary method to access CEDh. For administrative purposes there is an option for system users to access CEDh using username and password.
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 12:	Does the website use web measurement and customization technology?	Yes
PTA 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	Session Cookies- Does Not Collect PII
PTA 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA 14:	Does the system have a mobile application?	No
PTA 20:	Are any third-party websites or applications (TPWA) associated with the system?	No
PTA 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

Privacy Impact Assessment

Privacy Impact Assessment

PIA 22:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Biographical Information Name User Credentials Contact Information Email Address (Business)
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999
PIA 25:	For what primary purpose is the PII used?	The primary purpose for the PII maintained in CEDh is to allow users access to the system. The purpose for the view-only PII depends on the source from which it has been ingested. The CeDh serves as a single repository for multiple sources (internal FDA / CDRH wide applications) and makes no direct use of any of the data it ingests.

PIA 26:	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 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The Medical Device Amendments to the Food Drug and Cosmetic Act, including the Medical Device Amendments 21 U.S.C. sections 360, 360c, 360e, 360i, 360j, 360l, 510(k), 515(c), 515(d), 515(f), 519, 520(g), 520(m), and 564. Mammography Quality Standards Act Regulations (MQSA), 42 U.S.C. 263b. Safe Medical Device Act of 1990 (SMDA), 21 U.S.C. 301, 42U.S.C. 263b-n. Medical Device Reporting regulations at 21 CFR 803, 803.32, and 803.40; 21 U.S.C. 352, 360, 360i, 360j, 371, 174. The Radiological Health regulations CFR 1002.1(c)(4), 1002.10-1002.13, 1002.20, 1020.30(d), and 1020.30(d)(1), as well as Table 1 in 21 CFR 1002.1(b); 21 U.S.C. 352, 360, 360i, 360j, 360hh-ss, 371, 174. The Federal Food, Drug, and Cosmetic Act, section 519(f).
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No
PIA 30:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains Online Government Sources Within the OPDIV
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA 31B:	Explain why an OMB information collection approval number is not required.	An OMB number is not required because the system does not collect information from members of the public. It is a datahub that retrieves information from multiple internal FDA / CDRH applications.
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
PIA 33:	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary
PIA 34:	Describe the method in place to notify and obtain consent from individuals whose PII will be collected. If no prior notice is given or consent cannot be obtained, explain why.	There are no opt out procedures specific to the system. Users provide their information as a requirement to access CEDh. Users can elect to not provide the information which may impact the FDA-related work that they are required to do per their duties. For view-only PII, there is no option to object to or opt-out of the information collection because referral of data to CeDh is not explicitly announced to end users of the other applications from which the data is ingested. The mechanism for information collection is adopted from the source system.

PIA 35:	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). If they cannot be notified or have their consent obtained, explain why.	No such changes are anticipated for the CEDh system. If FDA changes its practices regarding the collection or handling of PII related to CEDh, the Agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. For view-only PII. Referral of data to CeDh is not explicitly announced to end users of the other applications from which the data is ingested. Thus, the mechanism for information collection is adopted from the source system.
PIA 36:	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.	Referral of data to CeDh is not explicitly announced to end users of the other applications from which the data is ingested. However, 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), Cybersecurity Infrastructure Operations Coordination Center (CIOCC) and other agency offices, via email, phone and standard mail avenues.

PIA 37:	Describe the process in place for periodic reviews of the system to ensure the integrity, availability, accuracy, and relevancy of the PII in the system. Please address each element in your response. If no processes are in place, explain why not.	The PII maintained in CEDh 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. Relevancy is supported by design of system and related processes to solicit or collect only the PII necessary for the system's purpose and supporting functionality. 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 privacy and security controls selected and implemented in the course of 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. There is no review of the ingested (view-only) PII specific to CeDh because such review is expected to occur within the applications from with data is referred into CeDh. A separate review specific to CeDh would be redundant, as it's meant to consolidate data from other applications without any direct input from users.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA 38A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	Users: Data scientists need access to all data in order to perform their analysis. Administrators: System administrators may have access to PII to support system administration activities. Developers: Developers may have access to PII to maintain the system and provide technical assistance to users. Contractors: FDA Direct Contractors are users, administrators, and developers.

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	The administrative procedures in place to determine which system users may access PII are governed by the Role Based Access Control (RBAC) policy. Access is role based, and system users access the minimum amount of information necessary to perform the job. Procedures include separation of duties between system managers, change control personnel, users, and administrators; access to the application at any level must first be reviewed and approved by management.
PIA 41:	Describe the technical methods in place to allow those with access to PII to access only the minimum amount of information necessary to perform their job.	Access approvals are implemented via technical permission settings. Data scientists will only have access to data meeting the criteria of the analysis they need to perform. The only other users with access to PII would be administrators, and access would only be required when modifying or further developing the system. Individuals in these roles would only be authorized to access PII as needed to accomplish the specific tasks they have been assigned.
PIA 42:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) 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 Information Management and Technology (OIMT) verifies that training has been successfully completed.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	No additional system-specific training is received by users.
PIA 44:	Describe the process and guidelines in place for the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	The current retention schedule is FDA File Code 7222, Database Records, National Archives and Records Administration (NARA) Approval N1-88-07-2. Retention is temporary, with cutoff after the establishment goes out of business or the product is no longer commercially marketed, and the records would be deleted or destroyed after ten years after cutoff or when no longer needed for legal, research, historical or reference purposes, whichever is the latest. System account credentials remain available as long as each user has authorized access to the system. Credentials are revoked when access is no longer needed, including if the individual moves to a different office within FDA or leaves FDA employment. These records are maintained under FDA File Code 9962, General Records Schedule (GRS) 3.2, item 030 (DAA-GRS-2013-0006-0003). Distribution: TEMPORARY. Under this schedule, retention is until "business use ceases." In other words, NARA concurs that agencies may dispose of these records as soon as they are no longer needed.

PIA 45:	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 and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	5/20/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	5/20/2025
SOP Review 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.	**# of Days - SOP Review:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	5/21/2025
Agency Privacy Analyst Review Comments:	Reviewer: Crystal Bland 5/21/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	1

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	5/30/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	9

SAOP Signature

Date	User	Type	Name	Original Value	New Value
5/30/2025 2:04 PM	GUENTHER, BRIDGET	Signature	SAOP (Email PIN)		Content Signed

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments

Question Name	Submitter	Date	Comment	Attachment
PTA 01	BLAND, CRYSTAL	5/21/2025	Per FDA Email, The PIA is experiencing an Archer error with question General 03: Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” o The FDA instance of Archer is automatically entering the answer “No,” which is incorrect. The ATO date is 1/23/2023. o 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.	5-20-2025 EMAIL_PIA in Queue (CDRH Enterprise Datahub).pdf CDRH Enterprise Datahub_SOP Approved_5.20.2025.pdf