PTA / PIA: FDA - Sci-Net - QTR2 - 2025 - FDA4928175

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General Information

PTA / PIA Name:	FDA - Sci-Net - QTR2 - 2025 - FDA4928175	**PTA / PIA ID:**	3213570
Component Name:	FDA - CDRH Scientific Network	**ATO Boundary Name:**	CDRH Scientific and Research General Support Systems
Overall Status:	Complete	**# of Days - Open:**	33
Submitter:		**Submit Date:**	5/22/2025
Next Assessment Date:	N/A	**Expiration Date:**	1/1/2100
Office:		**OpDiv:**	FDA
Security Categorization:	Low		
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)?	Yes
General 04:	ATO Date or Planned ATO Date.	8/18/2023
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	Jonathan Boswell
PTA 01A:	POC Title and Organization	POC Title: System Owner POC Organization: FDA/CDRH/OSEL/DIDSR
PTA 01B:	POC Email Address	Jonathan.Boswell@fda.hhs.gov
PTA 01C:	POC Phone Number	301-796-2535
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.	The purpose of Food and Drug Administration's (FDA) Scientific Network is for non-regulatory scientific Research and Development (R&D) that is separate from the FDA Regulatory Network. The network supports the following FDA operations: (a)Center for Devices and Radiological Health (CDRH) Engineering and Physics Lab including research equipment and compute clusters and (b) CDER Labs. The research data collected and stored on the Scientific Network is sometimes called "Open Science", because the inputs and outputs involve no sensitive data, are non-regulatory, and rely on collaborations with external entities such as research universities.
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.	FDA's Scientific Network collects the following PII data: (a)FDA employee/direct contractor first and last name; and (b) user credentials (username, password and single sign-on (SSO) PIV card). FDA Scientific Network collects the following non-PII data elements: (a) non-regulatory publicly available scientific research data; (b) scientific diagrams; (c) synthetic images; (d) gene sequencing; (e) chemical analysis, and (f) raw data to support journal articles. CDRH Scientific Network maintains PII as long as each user has authorized access to the system.
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.	The Scientific Network serves as an alternative option for FDA scientific IT devices that are not able to meet the compliance requirements necessary to access the FDA Regulatory Network that conduct non-production, non-critical, non-regulatory research operations using non-sensitive public and locally generated research data. Ports can be activated for the FDA Scientific Network all over the White Oak Campus. The network is currently deployed supporting the following FDA operations: CDRH Engineering and Physics Labs, and CDER Labs . The assets deployed on the Scientific Network are logically isolated from the FDA Production Network and allows access to the Internet for research and collaboration. Users of the system include FDA employees and Direct Contractors who access the lab equipment through locally-authenticated computer systems using usernames and passwords. CDRH Scientific Network does not use personal identifiers to retrieve records within the system.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes

PTA 08:	Does the system include a website or online application?	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
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.	100 – 499
PIA 25:	For what primary purpose is the PII used?	The FDA uses name and user credentials for the purpose of maintaining authorized users.
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.	5 U.S.C. 301 which permits agency heads to create the usual and expected infrastructure necessary for the organization to accomplish its purposes and mission.
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 information collection approval number is not required for Scientific Network because all data obtained from already existing previously collected information. The system holds no information collected under the PRA.
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 CDRH Scientific Network system. Users provide their information as a requirement to complete the job specific duties. Users can elect to not provide the information which may impact the FDA-related work that they are required to do per their duties.

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 CDRH Scientific Network system. If FDA changes its practices regarding the collection or handling of PII related to CDRH Scientific Network, the Agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII.
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.	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 CDRH Scientific Network 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.
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 - Users have access to the PII about themselves to access the system. Users may include subject individuals, supervisors, or administrators. 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 - Some users, developers, and system administrators may be direct contractors.
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 users, administrators, and developers; 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.	Management establishes roles for individual personnel, with role-based restrictions permitting access only to information that is required for each individual to perform his/her job. When a user no longer requires access to PII to perform their work, management removes that user's permissions from the system.
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; however, privacy guidance is available on the FDA intranet and from Privacy staff.
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).	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. Records are managed in accordance with National Archives and Records Administration (NARA) general records schedule (GRS) 3.2, Item 030-System Access Records. Disposition: TEMPORARY. Destroy when business use ceases.

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:**	5/22/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	5/23/2025
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:**	1

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	6/5/2025
Agency Privacy Analyst Review Comments:	Reviewer: Shanai Shobowale 6/5/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	13

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	6/24/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	19

SAOP Signature

Date	User	Type	Name	Original Value	New Value
6/24/2025 2:55 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	5/27/2025	5=27=2-25 Attached PIA	CDRH Scientific Network_SOP Approved.pdf