


General Information			
PTA / PIA Name:	FDA - SARITA - QTR2 - 2025 - FDA4926125	PTA / PIA ID:	3239182
Component Name:		ATO Boundary Name:	
Overall Status:	Complete 	# of Days - Open:	34
Submitter:		Submit Date:	6/11/2025
Next Assessment Date:	06/23/2028	Expiration Date:	6/23/2028
Office:		OpDiv:	
Security Categorization:			
Make PIA available to Public?:	Yes	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.		1/10/2023
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: Gregory Jackson
PTA 01A:	POC Title and Organization		Title: Project Management Officer Organization: CDER
PTA 01B:	POC Email Address		gregory.jackson@fda.hhs.gov
PTA 01C:	POC Phone Number		3017964096
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.		PIA Validation (PIA Refresh)

PTA 02A:	Describe in further detail any changes to the system that have occurred since the last PIA.	FDA has made no changes to this component since the last Privacy Threshold Analysis/Privacy Impact Assessment was approved.
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.	In order to meet the requirements established by the Center for Drug Evaluation and Research (CDER) Research Governance Council (RGC), CDER replaced the CDER Science Project Database (CSPD) database with the Science and Research Investments Tracking Archive (SARITA) in 2020. SARITA, which resides on CDER-owned servers, serves as CDER's central repository for CDER science and research activities and outcomes. SARITA is accessible only to a limited group of authorized FDA employees, and Direct Contractors identified to edit (editors), view (superusers), or approve (approvers) records.
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.	<p>SARITA maintains personally identifiable information (PII) to support system access control, provide contact information and enable CDER awareness of researchers and research efforts. SARITA collects the following PII from and about assigned editors, superusers and approvers (all FDA employees and Direct Contractors): (a) first and last name; (b) work email address; and (c) username information (obtained from a weekly download from FDA's Enterprise Administrative Support Environment (EASE). EASE is the subject of a separate PIA).</p> <p>SARITA collects the following PII entered by assigned editors regarding Project Team members (FDA and non-FDA federal partners): (a) FDA research team first and last names (those associated with a project) and non-FDA collaborator collects name only.</p> <p>SARITA also maintains project information (purpose, status, progress, outcomes); and (e) estimates of full-time equivalent (FTE) personnel assigned to a project.</p> <p>CDER maintains SARITA records applying a temporary disposition of "5 years after the project/activity/ transaction is completed or superseded, or the associated system is terminated, or the associated data is migrated to a successor system, but longer retention is authorized if required for business use."</p> <p>SARITA has incorporated a single sign-on (SSO) user authentication solution, that eliminates the need for passwords or system specific access credentials.</p>
PTA 05A:	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.

PTA 05C:	Please identify the system that maintains the user credentials or controls access to this system.	Active Directory
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.	<p>SARITA is the tool CDER uses to track, monitor, and assist in disseminating information to stakeholders about CDER regulatory science efforts, including research and other science activities undertaken to support its regulatory and public health mission. CDER research staff are requested to provide high-level information about their projects and accomplishments. SARITA supports CDER's strategic plan goal of business modernization. The backend of SARITA is supported by FileMaker Pro Advanced (a commercial off-the-shelf, cross-platform relational database application).</p> <p>SARITA is accessible through a data entry capability provided via FDA's intranet. Access for updating records is limited in time to a few months during an annual data call. Authorized users only have access to view, edit, and/or approve records for which they are assigned. Once the data call is closed, the updating site is also closed, and users no longer have access. In the future, cursory information (project team members, collaborators, project summary, and resultant publication information) will be made available as part of an internal-only search page.</p> <p>The majority of users access the system via web browsers utilizing SSO for user authentication. Full Access and System Administrator users can also use the desktop application.</p> <p>CDER personnel who access or use the system, use first and last name of FDA personnel and Direct Contractors to retrieve records held in the system. Non-FDA individuals are not subject to the Privacy Act since the only information collected about them is name.</p>
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://sarita.fda.gov/SARITA_Launcher.html
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.	<p>The CDER Science and Research Investments Tracking Archive (SARITA) serves to support information requests on CDER's science and research activities from our stakeholders, including the Office of Management and Budget, the General Accountability Office, and Congress.</p> <p>During an annual data call, CDER research project leads are required to update records in SARITA, the center-wide online tool, to provide data on project alignment, details and outcomes from the previous fiscal year activities. After the data call, compiled reports are migrated to the centralized repository SARITA_Reports, an FDA-wide search tool that can be used to retrieve data on demand.</p> <p>FDA Employees and Direct Contractors access CDER SARITA through Single Sign-On via Active Directory.</p>
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?	No
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.	<p>Biographical Information</p> <p style="padding-left: 20px;">Name</p> <p>Contact Information</p> <p style="padding-left: 20px;">Email Address (Business)</p> <p>Other</p> <p style="padding-left: 20px;">Other</p>
PIA 22A:	Identify the "other" type(s) of personally identifiable information (PII) not mentioned in the above list.	Username -Organization name of non-FDA collaborator -Organization location (city, state/country) of non-FDA collaborator
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	<p>Business Partners/Contacts (Federal state, local agencies)</p> <p>Employees/HHS Direct Contractors</p> <p>Vendors/Suppliers/Third-Party Contractors (Contractors other than HHS Direct Contractors)</p>
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?	PII is collected on behalf of FDA employees, Business Partners, and Vendors/Suppliers/Contractors to better understand the extent of collaboration efforts inside and outside FDA. The collected PII is also used to securely administer the system.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	None. FDA/CDER do not use the PII in SARITA for testing training, research or other secondary purpose.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	All submissions maintained in SARITA are in support of FDA activities authorized by the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 301. The implementation of this system is authorized by 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?	Yes
PIA 29A:	Please specify which PII data elements are used to retrieve records.	CDER personnel who access or use the system, use first and last name of FDA personnel and Direct Contractors to retrieve records held in the system.
PIA 29B:	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.	OPM/GOVT-1 (General Personnel Records), 09-90-0777 (Facility and Resource Access Control Records)
PIA 30:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains In-person 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.	CDER SARITA does not collect information using an information collection request as defined by the Paperwork Reduction Act.
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

<p>PIA 34:</p>	<p>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.</p>	<p>FDA personnel (permanent employees and Direct Contractors) are notified at the time of hire of the Agency's collection, creation, and use of their PII in context of their work with the Agency. At every instance of logging on to the FDA network, they must read and acknowledge a warning message advising that they have no expectation of privacy when using government systems and resources.</p> <p>This PIA provides additional notice.</p> <p>The applicable SORN(s) provide notice.</p> <p>A Privacy Act Statement will be displayed.</p> <p>For other systems that are the source of PII in SARITA, individuals may be provided additional notice in the context of those other systems.</p>
<p>PIA 35:</p>	<p>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.</p>	<p>No such changes are anticipated. If FDA changes its practices with regard to the collection or handling of PII related to SARITA the Agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include e-mail to individuals, adding or updating online notices or forms, or other available means to inform the individual.</p>
<p>PIA 36:</p>	<p>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.</p>	<p>Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have a number of avenues available to resolve the situation. Employees may submit concerns to their supervisor, the FDA Privacy Office, a 24-hour technical assistance line, and FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC).</p> <p>All personnel are required to rapidly report potential data breaches and security incidents.</p>

<p>PIA 37:</p>	<p>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.</p>	<p>CDER performs annual reviews to evaluate, update and correct/adjust user access.</p> <p>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 review and correct/update their information themselves</p> <p>PII is relevant and necessary to be granted access to the system and perform assigned duties. The design of the system supports PII minimization by limiting PII fields and other system elements to handling only necessary PII.</p> <p>Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access).</p> <p>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 as appropriate to the system's level of risk determined using NIST's Federal Information Processing Standards (FIPS) 199.</p> <p>One of the controls includes information system backups reflecting the requirements in contingency plans as well as other agency requirements for backing up information.</p> <p>Data discrepancies identified in the course of system use are addressed when discovered.</p>
<p>PIA 38:</p>	<p>Identify who will have access to the PII in the system.</p>	<p>Users</p> <p>Administrators</p> <p>Developers</p> <p>Contractors</p>
<p>PIA 38A:</p>	<p>Select the type of contractor.</p>	<p>HHS/OpDiv Direct Contractors</p>
<p>PIA 38B:</p>	<p>Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?</p>	<p>Yes</p>
<p>PIA 39:</p>	<p>Provide the reason why each of the groups identified in 38 needs access to PII.</p>	<p>Users: To update record data entry or approve records.</p> <p>Administrators: To update record information on behalf of users when appropriate.</p> <p>Developers: To modify backend structures, developers have access to the data.</p> <p>Contractors: Some of the Direct Contractors are administrators and developers.</p>

PIA 40:	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 SARITA must have approval from SARITA Business owner with CDER's Office of Translational Sciences 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 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.	The relevant supervisor indicates on the user account creation form the minimum access that is required in order for the user to complete his/her job. The scope of access is restricted based on role-based criteria.
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 Digital Transformation (ODT) verifies that training has been successfully completed.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	Site administrators receive specialized training on the appropriate use of approval controls to ensure proper use of access controls, data storage, and that data is properly reviewed before any release. Privacy program materials are available to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA. Privacy guidance is also available via the FDA's Privacy Office.
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).	<p>CDER maintains system records under Agency records schedule FDA 9991a2 – Information Technology Development Project Records. The NARA approved citation is GRS 3.1, Item 011, System Development Records.</p> <p>Disposition: Temporary. Destroy 5 years after system is superseded by a new iteration, or is terminated, defunded, or no longer needed for agency/IT administrative purposes, but longer retention is authorized if required for business use.</p>

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 role-based access settings, firewalls, passwords and others.

Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls.

Other appropriate controls have been selected from the 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:	6/11/2025
Privacy Analyst Review Comments:	System owner provided update that personal email address and employment history are not collected.	# of Days - PA Review:	0

SOP Review

SOP Review Decision:	Approved	SOP Review Date:	6/11/2025
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:	6/12/2025
Agency Privacy Analyst Review Comments:	<p>Reviewer: Crystal Bland</p> <p>6/12/2025 All comments have been addressed. This PIA is ready for SAOP review and approval.</p> <p>6/5/2025 Please see comments and update accordingly.</p> <p>In the General Information section is missing the Component Name and OpDiv.</p> <p>PTA-5: Please include the following PII elements in your response Employment Status/History and Personal email address.</p>	# of Days - APA Review:	1

SAOP Review

SAOP Review Decision:	Approved	SAOP Review Date:	6/24/2025
SAOP Review Comments:		# of Days - SAOP Review:	12

SAOP Signature

Date	User	Type	Name	Original Value	New Value
6/24/2025 3:27 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	6/3/2025	<p>Per FDA's Email:</p> <p>The PIA is experiencing an Archer error with question General 03:</p> <p>Q-3 "Does the system have or is it covered by a Security Authorization to Operate (ATO)?"</p> <ul style="list-style-type: none"> The FDA instance of Archer is automatically entering the answer "No," which is incorrect. The ATO date is 1/10/2023. At this time, we are unable to update Archer to reflect the correct answer "Yes." <p>The FDA Archer Team is aware of this occurrence and is working on a solution.</p>	<p>5-28-2025 EMAIL_PIA in Queue (CDER SARITA).pdf</p> <p>CDER SARITA_SOP Approved.pdf</p>
PTA 01	BLAND, CRYSTAL	6/5/2025	In the General Information section is missing the Component Name and OpDiv.	
PTA 05	BLAND, CRYSTAL	6/5/2025	Please include the following PII elements in your response Employment Status/History and Personal email address.	
PTA 01	BLAND, CRYSTAL	6/6/2025	Per FDA's Email, the SARITA PIA is not showing rejected in FDA instance of Archer 4.0.	RE_ FDA SARITA PIA - HHS Returned with Comments.pdf
PTA 01	BLAND, CRYSTAL	6/12/2025	<p>Per FDA's Email, In the General Information section is missing the Component Name and OpDiv. This may be an Archer issue. The Component Name and OpDiv are showing in our instance of Archer.</p> <p>PTA-5: Please include the following PII elements in your response Employment Status/History and Personal email address. The system owner indicated that these PII types are not collected, they were selected in error. The Employment Status/History and personal email address have been removed from PIA-22.</p>	6-11-2025 EMAIL_PIA in Queue (CDER SARITA).pdf