PTA / PIA: FDA - LX - QTR2 - 2025 - FDA4941549

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General Information

PTA / PIA Name:	FDA - LX - QTR2 - 2025 - FDA4941549	**PTA / PIA ID:**	3386749
Component Name:	FDA - CDER Legacy Refresh	**ATO Boundary Name:**	CDER Regulatory Tracking and Quality Management Systems
Overall Status:	Complete	**# of Days - Open:**	8
Submitter:		**Submit Date:**	6/23/2025
Next Assessment Date:	06/24/2028	**Expiration Date:**	6/24/2028
Office:		**OpDiv:**	FDA
Security Categorization:	Moderate		
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.	10/21/2022
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	Andriy Chut
PTA 01A:	POC Title and Organization	POC Title: Information Technology Specialist POC Organization: OIMT/OTD/DAS/MPB
PTA 01B:	POC Email Address	andriy.chut@fda.hhs.gov
PTA 01C:	POC Phone Number	240-338-7846
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 Center for Drug Evaluation and Research (CDER) Legacy Refresh (LX) consists of legacy CDER tracking systems that have been upgraded over time. These legacy applications are being maintained through the LX project. These applications track information such as application sponsor data, compliance of clinical investigators with clinical trial standards, adverse events associated with drugs or manufacturing sites, and the management of physical volumes of applications received by the U.S. Food and Drug Administration (FDA). All the LX applications are written in Oracle Forms and are accessed from a single uniform resource locator (URL) leading to a central menu. Each application appears as an option on the LX Main menu. LX includes the following Active Applications: CIS - Clinical Investigators System – Tracks information on clinical investigators registering clinical trial Investigational New Drug Applications (INDs) with FDA. Also includes inspection results and any adverse findings. DADS – Developers and Distributors System - Provides the dataset of sponsor, manufacturer, and drug firms. Includes all manufacturers and their addresses and roles. INVAS – The Investigational New Drug (IND) /New Drug Application (NDA) Volume Accountability System is an administrative system. It functions as a library for physical paper volumes. INVAS tracks physical volume location in Document Rooms. It also tracks check-in/check-out of physical volumes by CDER reviewer staff. Information from DADS is shared with Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) to add information about the application's sponsor to the regulatory review data for the particular NDA, IND, or other application. DARRTS is covered by a separate privacy assessment. User access to the LX applications is controlled via the User Access Control (UAC) and User Access Management (UAM) systems. UAC and UAM are covered by a separate privacy assessment.

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.	The types of data that are maintained in and/or shared from the system are about FDA employees, FDA Direct Contractors, and members of the public. CIS – Tracks information on clinical investigators registering clinical trial INDs with FDA. Also includes inspection results and any adverse findings. DADS – Provides the dataset of sponsor, manufacturer, and drug firms. Includes all manufacturers and their addresses and roles. INVAS - is an administrative system. It functions as a library for physical paper volumes. INVAS tracks physical volume location in Document Rooms. It also tracks check-in/check-out of physical volumes by CDER reviewer staff. CIS collects the following personally identifiable information (PII): names, work email address, and work phone number of clinical investigators who are FDA Employees and Direct Contractors. DADS collects the following PII: names (company or individual), mailing addresses, and phone numbers of drug firms (sponsors), manufacturers, repackagers, and distributors of pharmaceuticals and pharmaceutical components, and individual IND and Drug Master File (DMF) holders. Where sponsors are individuals, the sponsor's name is considered to be PII. INVAS may collect the following PII: name, work email, and work phone number of CDER reviewer staff who are FDA Employees and Direct Contractors. PII is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The amount of time that the PII is stored in the system is in accordance with the National Archives and Records Administration (NARA) retention standards. Data is disposition is temporary; data is not archived.
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 (AD).

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.	CIS tracks information on clinical investigators registering clinical trial INDs with FDA. Also includes inspection results and any adverse findings. DADS - PII, members of the public: The DADS sponsor and contact information (address and phone number) is used to provide information on particular drug manufacturers. The use of the names, addresses, and phone number aids in the communication between the FDA and the manufacturer or individual. DADS information is provided to DARRTS to add information about the application's sponsor to the regulatory review data for the particular NDA, IND, or other application. PII, FDA employees: The PII collected on FDA employees (name and work contact information that includes email address and phone number) serves to provide accountability for data quality; that is, the staff member entering data is responsibility for its quality. INVAS – IND/NDA Volume Accountability System - INVAS tracks physical volume location in Document Rooms. It also tracks check-in/check-out of physical volumes by CDER reviewer staff. CDER reviewer staff name and work contact information that includes email address and phone number is used to provide accountability for tracking and retention of physical sponsor documents. INVAS for the Office of Compliance (INVAS-OC) tracks the location of application volumes for the Office of Compliance. It includes such information as the title of the volume, the drug product, and keywords associated with the volume.)
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://lxmain.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.	CDER Legacy Refresh (LX) consists of legacy CDER tracking systems that have been upgraded over time. These legacy applications are being maintained through the LX project. These applications track information such as application sponsor data, compliance of clinical investigators with clinical trial standards, adverse events associated with drugs or manufacturing sites, and the management of physical volumes of applications received by the FDA. User access to the LX applications is controlled via the User Access Control (UAC) and User Access Management (UAM) systems. UAC and UAM are covered by a separate privacy assessment. The following categories of individuals have access to the website: Users: The users of the legacy applications include application business owners, system administrators, developers, Document Room data entry staff, drug reviewers, project managers, and safety reviewers. Most users are in the CDER Office of New Drugs and Office of Compliance, with some in the Office of Regulatory Affairs field offices. Users access the website via (intranet Uniform Resource Locator (URL), Single Sign-On (SSO) enabled) https://lxmain.fda.gov.
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.	Biographical Information Name Contact Information Email Address (Business) Mailing Address (Business) Phone Numbers (Business)
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors Members of the public
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	5,000 – 9,999

PIA 25:	For what primary purpose is the PII used?	The primary purpose of the PII collected on FDA Employees and Direct Contractors (name and work contact information that includes email address and phone number) serves to provide accountability for data quality and to provide accountability for tracking and retention of physical sponsor documents. The sponsor and business contact information are used to provide information on particular drug manufacturers. The use of the names and business contact information (email address and phone number) is to aid in the communication between the FDA and the manufacturer or individual.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The secondary use of the DADS PII is to link regulatory review application information collected in DARRTS to the application sponsors.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	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. In addition, the security and privacy measures of the system are required by the Federal Information Security Modernization Act (FISMA) and the statutes underlying OMB Circular A-130 for the secure and efficient use of government systems and resources.
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 Email Online Government Sources Within the OPDIV
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA 31A:	Provide the information collection approval number(s) and expiration date(s).	OMB Information Collection Approve Number: OMB No. 0910-0338. Expiration Date: 10/31/2026 OMB Information Collection Approve Number: OMB No. 0910-0014. Expiration Date: 09/30/2026
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.	Submission of PII is voluntary as that term is used by the Privacy Act. However, the submission of PII is necessary in order for FDA Employees and Direct Contractors to access and use applications owned and operated by CDER. The PII is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). Individuals can elect to not provide the information which may impact FDA-related work.
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. If the agency changes the collection, use, or sharing of PII data in this system, the affected individuals will be notified by the most efficient and effective means available and appropriate to the specific change(s). This may include a notice on the web site, or e-mail notice to the individuals.
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.	Users who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have a number of avenues available to raise their concerns. They can work with their supervisor(s), a 24-hour FDA technical assistance line, FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC), the FDA Privacy Office, and other offices.
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.	All FDA personnel, including users of this application, are responsible for providing accurate information and may independently update and correct their information at any time. All information is relevant to the authentication and authorization process. Integrity and availability are protected by security safeguards selected based on guidance from the National Institute of Standards and Technology (NIST) appropriate to the level of risk associated with the application.
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.	The reason the following groups need access to PII is: Users: The front-end users include the FDA Employees and Direct Contractors who require access to the PII to enter information about the application sponsor, which includes PII. CDER analytic staff may require access to PII for analysis and reporting. Administrators: Administrators are application administrators who require access to manage application releases. This work requires access to the PII data. Developers: Developers need read-only access to the component, which may include access to PII. (In the development environment, developers have full access to all database objects). Contractors: Some administrators, users, and developers may be Direct Contractors.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	All system administrators require access to all PII submitted by users. Administrators require this access to create and manage access credential accounts. Users do not have access to any PII from the UAC application itself. A system owner therefore grants administrator credentials to authorized individuals, and then administrators create user profiles, with much more limited privileges, for all other users that apply by submitting a User Access Request form.
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 (the system owner and administrators) establishes roles for individual personnel for each CDER application, with technically and administratively enforced role-based restrictions permitting access only to information that is required for each individual to perform his/her job.
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 personnel must complete FDA's mandatory Computer Security Awareness Training at a minimum of every twelve months. This course includes privacy training. The Office of Digital Transformation (ODT) tracks completion of the course.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	Additional on-the-job or informal training provided by the program office or Privacy Office may be received.

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).	PII, FDA personnel: Logon credentials remain available as long as each user has authorized access to the system. Credentials are revoked immediately when access is no longer needed, including if the individual leaves FDA employment. These are maintained under the National Archives and Records Administration (NARA) general records schedule (GRS) 3.2, Item 030-System Access Records. Disposition: TEMPORARY. Destroy when business use ceases. PII, public: The retention requirements for DADS fall under an approved FDA Records Control Schedule (RCS). The retention schedule is FDA File Code 7222, Compliance Database Records (NARA citation N1-88-07-2, Items 6.2, 6.2.2). Disposition: TEMPORARY. The relevant cutoff date for these records is the date after the establishment goes out of business or the product is no longer commercially marketed. Records are to be deleted or destroyed 10 years after the cutoff date or when no longer needed for legal, research, historical or reference purposes, whichever is the latest. If data is migrated into a new system or replaced by a successor system, it is to be deleted or destroyed after the verification of successful data migration.
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 uses of firewalls; Single Sign-on (SSO) protocols; and regular testing of information technology systems. 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 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:**	6/23/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	6/23/2025
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:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	6/25/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 6/25/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	2

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	6/25/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
6/25/2025 7:55 AM	BLAND, CRYSTAL	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	6/24/2025	6/24/2025 Per FDA's Email: The PIA is experiencing an Archer error with question General 03: “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 *10/21/2022*. 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.	6-24-2025 EMAIL_PIA In Queue (CDER Legacy Refresh (LX)).pdf CDER Legacy Refresh_SOP Approved.pdf