


General Information		
PTA / PIA Name:	FDA - LeadScope - QTR2 - 2025 - FDA4928180	PTA / PIA ID: 3213209
Component Name:	FDA - CDER LeadScope Enterprise	ATO Boundary Name: CBER Office of Regulatory Operations
Overall Status:	Complete 	# of Days - Open: 8
Submitter:		Submit Date: 5/22/2025
Next Assessment Date:	N/A	Expiration Date: 1/1/2100
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.	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	Manni Mashae
PTA 01A:	POC Title and Organization	Pharmacokineticist/CDER/OTS/OCP/DARS
PTA 01B:	POC Email Address	Manni.Mashae@fda.hhs.gov
PTA 01C:	POC Phone Number	(240) 402-0748
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 Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER) LeadScope Enterprise system is a cheminformatics

application that provides large-scale warehousing of experimental toxicology data linked to chemical structures.

Data maintained in the application may be retrieved using chemical structure-based queries as well as text and ID-based searches. The database contains compilations of curated data from public sources, provided by the software vendor LeadScope, as well as confidential data compiled by CDER's Computational Toxicology Consultation Service (CTCS) team, using internal review documents.

The CTCS team uses the entire LeadScope Enterprise database on a daily basis to support a consultation-based review workflow. Specifically, the database is searched for experimental toxicology data and related documents to support regulatory recommendations on the safety of untested chemical substances contained in a drug product. The workflow is time sensitive, consistent with the Prescription Drug User Fee Act (PDUFA) and the Generic Drug User Fee Act (GDUFA) timeclocks, and the deliverables are regulatory consultation reports that are subsequently uploaded to the database for future reference.

CTCS team members access LeadScope Enterprise using several local LeadScope Enterprise Client software installations on scientific workstations, where some members have the ability to upload and modify records. Additionally, other groups of reviewers within CDER access the database in a read-only capacity to support their individual review workflows. In this latter case, reviewers use the LeadScope Web Client to access the database without the need for a local software installation. In both cases, LeadScope Enterprise is used to perform mission critical reviews and consultations.

This system does not have any relationship to other FDA systems and/or components/information collections.

The key functional elements of the system include an application server and a database (DB) server in Antibody-Drug Conjugates (ADC).

CDER LeadScope users include FDA permanent employees and Direct Contractors. System "users" consist of the Computational Toxicology group in CDER/Office of Translational Sciences (OTS)/Office of Clinical Pharmacology (OCP)/Division of Applied Regulatory Science (DARS) and drug reviewers within CDER/Office of Pharmaceutical Quality (OPQ).

Users access the system via the Single Sign-On (SSO) authentication process and use of the personal identity verification (PIV) card.

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.	CDER LeadScope collects a very limited amount of PII from users of the system (FDA permanent employees and Direct Contractors). Usernames (in the form of user email addresses) are collected into and maintained by the system. Non-PII collected by the system includes experimental toxicology data and related documentation, as well as administrative log files containing administrative related data (e.g., troubleshooting details, number of access visits). PII is stored in the system on a temporary basis per National Archives and Records Administration general records schedule (GRS).
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.	The system providing credentials is Active Directory for installed client users and Oracle Identity Management for web client users.
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.	Information is collected and maintained in CDER LeadScope to allow access to the system. Usernames of FDA permanent employees and Direct Contractors (Administrators and Non-Administrator users) are collected and maintained by the system. The system also maintains experimental toxicology data and related documentation, as well as administrative log files containing administrative related data (e.g., troubleshooting details, number of access visits).
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://leadscope.fda.gov/webapps/lse_web_client/#/
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 allow access to system data for users in CDER/OPQ. Users are limited to internal FDA users, and users access the website via FDA intranet.
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 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?	PII is used for the primary purpose of system login and providing privileges within the system.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	FDA does not use PII for any secondary uses.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The legal authorities that govern information use and disclosures specific to the system and program are: 5 U.S.C. 301.
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 In-person
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 LeadScope Enterprise does not collect information from any persons other than federal employees/Direct Contractors during the performance of their duties and therefore does not require an OMB information collection approval number.
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 is no option to object to or opt-out of the information collection because FDA personnel are required to provide their PII as a condition of their employment at the FDA and necessary to perform their job functions.
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.	If the Agency makes any major changes in the collection or use of PII in LeadScope, FDA will notify the affected individuals in the most efficient and effective manner available and appropriate, which may include a formal process involving written or electronic notice via email.

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 of the tools comprising Study Data Review Tools (SDRT) have multiple options available to resolve the issue. These individuals may contact FDA via email, phone and/or standard mail (all of the relevant contact information is listed on fda.gov). They may also contact the FDA's Privacy Office or the Cybersecurity Infrastructure Operations Coordination Center (CIOCC). Additionally, individuals may raise concerns through supervisory channels and through the FDA's Employee Resource and Information Center (ERIC).
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.	Individuals voluntarily submit their PII and are responsible for ensuring the accuracy of information submitted. Integrity and availability are protected by security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on National Institutes 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. CDER performs annual reviews to evaluate user access. Data discrepancies identified in the course of system use are addressed when discovered.
PIA 38:	Identify who will have access to the PII in the system.	Users Administrators 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: require access to their own PII to view system data. Administrators (some of whom are Direct Contractors) require access to PII about users to administer the system, including adding/removing users and setting permissions. Direct Contractors: some are Administrators who require access to perform job duties.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Administrators are required to have elevated privileges in order to access the full system and its data. FDA utilizes an Access Control system that requires pre-access approval from system owners and supervisors. Application-specific procedures include requesting access from business, system, and data owners and approval through supervisors.

<p>PIA 41:</p>	<p>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.</p>	<p>LeadScope uses individual role-based accounts to ensure minimum necessary access. LeadScope maintains an access control procedure which outlines the steps to request role-based access. The roles include, at a minimum, “administrator” and “user.” The system, business, and/or data owner will authorize access to the system with supervisory approval. The administrator of the system will set the appropriate degree of access. All users are authenticated by FDA enterprise-wide SSO, Active Directory, or username/password combination. Once a user is authenticated by FDA, credentials are passed to the tool, and the tool will provide access based on the role.</p>
<p>PIA 42:</p>	<p>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.</p>	<p>All system users are required to complete annual FDA Security Awareness Training and Privacy Training.</p>
<p>PIA 43:</p>	<p>Describe the training system users receive above and beyond general security and privacy awareness training.</p>	<p>No additional system-specific training is received by users.</p>
<p>PIA 44:</p>	<p>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>	<p>The records in LeadScope are maintained under the following National Archives and Records Administration (NARA) citations: General Records Schedule (GRS) 3.2 items 30 and 31(System Access Records). The records disposition is temporary under disposition authority DAA-GRS2013-0006-0003/4 and the records are deleted or destroyed 6 years after they are no longer needed or when business use ceases.</p>
<p>PIA 45:</p>	<p>Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.</p>	<p>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.</p> <p>Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools.</p> <p>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 NIST Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.</p>

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	Privacy Analyst Review Date:	5/22/2025
Privacy Analyst Review Comments:	<p>•The PIA is 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)?"</p> <p>The FDA instance of Archer is automatically entering the answer "No," which is incorrect. The ATO date is 1/10/2023.</p>	# of Days - PA Review:	0

SOP Review

SOP Review Decision:	Approved	SOP Review Date:	5/23/2025
SOP Review Comments:	<p>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. 5/22/2025</p>	# of Days - SOP Review:	1

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	Agency Privacy Analyst Review Date:	5/28/2025
Agency Privacy Analyst Review Comments:	<p>Reviewer: Crystal Bland</p> <p>5/28/2025 This PIA is ready for SAOP review and approval.</p>	# of Days - APA Review:	5

SAOP Review

SAOP Review Decision:	Approved	SAOP Review Date:	5/30/2025
SAOP Review Comments:		# of Days - SAOP Review:	2

SAOP Signature

Date	User	Type	Name	Original Value	New Value
5/30/2025 1:38 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	5/23/2025	<p>Per FDA's Email, The PIA is 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)?"</p> <ul style="list-style-type: none">o 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>5-23-2025 EMAIL_FDA - LeadScope - QTR2 - 2025 - FDA4928180.pdf</p> <p>CDER LeadScope SOP approved 5.22.25.pdf</p>