PTA / PIA: FDA - WLIMS - QTR2 - 2025 - FDA4932091

Created Date: 5/29/2025 8:37 AM Last Updated: 6/24/2025 4:45 PM

General Information

PTA / PIA Name:	FDA - WLIMS - QTR2 - 2025 - FDA4932091	**PTA / PIA ID:**	3243493
Component Name:	FDA - CDER DARS Watson LIMS	**ATO Boundary Name:**	CDER Study Data Review Tools
Overall Status:	Complete	**# of Days - Open:**	27
Submitter:		**Submit Date:**	5/28/2025
Next Assessment Date:	N/A	**Expiration Date:**	1/1/2100
Office:		**OpDiv:**	FDA
Security Categorization:	Moderate		
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.	2/13/2025
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 Mashaee
PTA 01A:	POC Title and Organization	POC Title: Pharmacokineticist POC Organization: CDER/OTS/OCP/DARS
PTA 01B:	POC Email Address	manni.mashaee@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) Office of Clinical Pharmacology/Division of Applied Regulatory Science (OCP/DARS) bioanalytical laboratory supports quality integrity, data management and regulatory compliance for laboratory operations. The subject of this assessment is the CDER DARS WATSON Laboratory Information Management System (CDER WLIMS). CDER WLIMS is a software used to track and secure bioanalytical data from collection through analyses ensuring adherence to FDA 21 CFR Part 11 regulations. The system capabilities include automated checks and audit trails, automation of lab workflows, and collection of laboratory study data. The key functional elements of the system include an application server, and a database (DB) server located in the Ashburn Data Center (ADC). WLIMS carries out its functions using configured templates that guide users through the creation, planning and execution of bioanalytical studies. This system has no relationship to any other systems. There are no automated system interfaces to any other FDA or external systems. System users consist of FDA employees (permanent and Direct Contractors) within the Bioanalytical Laboratory and support personnel. Contractors do not have user accounts within the production system.
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 WLIMS collects and maintains personally identifiable information (PII). PII about DARS employees accessing the system includes user credentials (usernames), passwords (not used for authentication purposes and email addresses. The system also collects anonymized and non-anonymized data, all of which is non-PII. Anonymized data includes sample study information and other supporting scientific data that has been deidentified prior to system entry or import. Non-anonymized data includes design data, results associated with analyses of lab instrument data, and inventories of items associated with studies conducted within the laboratory. Users' PIII is stored in the system on a temporary basis per applicable National Archives and Records Administration (NARA) records retention schedules.
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 (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.	Information is collected within CDER WLIMS to support bioanalytical workflow within FDA labs, design and execute studies, and manage lab inventory. PII collected and maintained by the system is used to allow access to and authorize permissions within the system. PII consists of usernames, passwords (not used for authentication), and email addresses.
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://darswatson.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 provide access to data within CDER WLIMS. Authorized users (FDA permanent employees and Direct Contractors) access the system via the single sign-on (SSO) process using their personal identity verification (PIV) cards. Users access the system using an HHS internal uniform resource locator (URL).
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 Contact Information Email Address (Business) Other Other
PIA 22A:	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Other: user credentials include usernames, passwords (not used for authentication purposes) and email addresses.
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
PIA 25:	For what primary purpose is the PII used?	PII is used to establish role-based access control, application of electronic signature for a limited number of system functions, and delivery of alerts and notifications.
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 is 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 Online
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.	The requirements of the Paperwork Reduction Act (PRA) do not apply to CDER WLIMS. The system does not collect and/or maintain any information related to members of the public. Information collected and maintained about FDA permanent employees and Direct Contractors is done so in while in their official capacity as FDA employees.
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.	FDA personnel are required to provide their PII as a requirement of working at the FDA and performing their job functions and therefore there is no opt-out option. If an individual chooses not to provide their PII, they will not be able to work at the FDA.
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 CDER WLIMS, 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, or informal processes such as 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 the SDRT system boundary (includes WLIMS) have multiple options available to resolve the issue. These individuals may contact FDA via email, phone and standard mail avenues (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 the individual submitting the PII is responsible for providing accurate information. Integrity and availability are protected by security controls selected and implemented in the course of providing the system with an authorization 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. 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 access PII about themselves (username, password and email addresses to complete work assignments. Supervisory and management users use usernames to allow assignment of resources within the system to specific users. Administrators require access to PII about users to enable/disable users and perform other administrative tasks. Direct Contractors require access to PII in their role as Administrators.

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	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.
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 CDER WLIMS system use individual role-based accounts to ensure minimum necessary access. Each tool 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.
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.	No additional training is provided.
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 records in CDER WLIMS are maintained under the following National Archives and Records Administration (NARA) citations: General Records Schedule (GRS) 3.2 items 30 and 31. The records disposition is temporary under disposition authority DAA-GRS2013-0006- 0004 and the records are deleted or destroyed 6 years after they are no longer needed or 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:**	5/28/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	5/29/2025
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. NOTE: 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)?" The FDA instance of Archer is automatically entering the answer "No," which is incorrect. The ATO date is 2/13/2025.	**# of Days - SOP Review:**	1

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	6/10/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 6/10/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	12

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	6/24/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	14

SAOP Signature

Date	User	Type	Name	Original Value	New Value
6/24/2025 3:19 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	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)?” The FDA instance of Archer is automatically entering the answer “No,” which is incorrect. **The ATO date is 2/13/2025.** At this time, we are unable to update Archer to reflect the correct answer “Yes.”	5-29-2025 Email_CDER DARS Waston LIMS (FDA - WLIMS - QTR2 - 2025 - FDA4932091).pdf CDER DARS Watson Lims SOP approved.5.29.2025.pdf