PTA / PIA: FDA - DARRTS - QTR3 - 2025 - FDA4949900

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General Information

PTA / PIA Name:	FDA - DARRTS - QTR3 - 2025 - FDA4949900	**PTA / PIA ID:**	3604581
Component Name:	FDA - CDER Document Archiving Reporting Regulatory Tracking System	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	3
Submitter:		**Submit Date:**	8/5/2025
Next Assessment Date:	08/07/2028	**Expiration Date:**	8/7/2028
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?	Yes
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	Karina Kuhn
PTA 01A:	POC Title and Organization	Title: RR/System Owner Organization: CDER
PTA 01B:	POC Email Address	Karina.Kuhn@FDA.HHS.gov
PTA 01C:	POC Phone Number	301-796-4059
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 (PTA)/Privacy Impact Assessment (PIA) was last 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.	The Food and Drug Administration (FDA) uses the Center for Drug Evaluation and Research (CDER) Regulatory Tracking and Quality Management system (RTQMS) for tracking, reporting, and maintaining an archival record of the drug and biological product materials submitted to the FDA for review. CDER reports to Congress on a number of issues, including performance on the Prescription Drug User Fee Act (PDUFA), Biosimilar User Fee Act (BsUFA), and related goals. The CDER RTQMS system boundary includes several sub-systems. The subject of this assessment is the CDER Document Archiving Reporting Regulatory Tracking (DARRTS) sub-system, an internal web-based application used for tracking, reporting, and maintaining archival records of drug and biological products submitted to FDA for review. DARRTS is a component-based, multi-tier enterprise application that provides FDA users (permanent employees and Direct Contractors) with the ability to receive, manage, track, and report on drug applications. DARRTS helps the FDA provide reports to Congress on several issues, including performance on the Prescription Drug User Fee Act (PDUFA), Generic Drug User Fee Act (GDUFA) and Biosimilar User Fee Act (BsUFA). DARRTS contains data associated with the complete drug approval process and ultimate approval of every application listed below. After approval, the applicant may manufacture and market the drug product to provide a safe, effective, low-cost alternative for the public. DARRTS captures all data submitted by sponsors, and communications between the FDA and Sponsor regarding the drug application which are stored in electronic format (word/pdf) in FDA's Documentum repository (the subject of a separate privacy impact assessment). The following product application types are captured in the DARRTS system: Investigational New Drug (INDs): Current federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. To obtain an investigational product for clinical study in the United States (U.S.), an exemption is needed from that legal requirement. Master Files (MFs): The MF is a submission to the FDA that may be used to provide detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. Emergency Use Authorization (EUAs): The Project

		Bio Shield Act of 2004 gives the FDA commissioner authority to authorize use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency. New Drug Application (NDA): The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA. Abbreviated New Drug Application (ANDA): An Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Biologic License Application (BLA): The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2). The BLA is regulated under 21 CFR 600 – 680. Marketing and Advertising General Tracking Record (MAGTR): The Marketing and Advertising General Tracking Record (MAGTR) will be used to track reviews on Marketing and Advertising Supporting Documents that cannot or should not be linked to an existing Application. This system is used exclusively by FDA employees and Direct Contractors. DARRTS is not available for use by the general public.
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 data collected and maintained in DARRTS includes information regarding the receipt, management, and reporting of clinical investigational and marketing submissions for human drugs and therapeutics. Personally identifiable information (PII) data is collected by the system. The following information is collected and maintained about company/organization points of contact (POCs) filing required information with the FDA: business e-mail address, business mailing address, and business phone numbers. Additionally, DARRTS also collects and maintains sponsor information to include name, organization information, email address, and phone number. Employee PII may also be collected. As DARRTS is used to send copies of e-mail communications to and from FDA employees (including communications between employees), employee PII such as name and e-mail address may be incidentally captured in these communications. Every CDER drug submission reviewers using DARRTS for the purposes of reviewing and processing clinical investigational and marketing submissions for human drugs and therapeutics is

		assigned a review number. This review number is collected and maintained by the system. DARRTS and the systems with which it interfaces, track information such as application sponsor data, products, advertising submissions, registration and listing submissions, site inspections, and the volume of workflow handled by CDER's drug submission reviewers. DARRTS also stores communications (decisions on the review of submissions submitted by industry) in Documentum (a separate application within CDER RQMS, assessed separately). Some of these communications are internal (sent from FDA employees to other FDA employees) and are generated as part of the review process, and others might be issued to the industry and related to specific submissions being reviewed. These external communications are likely to contain the contact information for institutional points of contact and may contain the name of the Director of the division where the review is being conducted (but not the names or other PII of any other FDA staff). DARRTS is configured to work with FDA's Single Sign-On (SSO) authentication process and thus does not require username and password. Access to DARRTS is available for read-only actions or to perform specific functions such as adding supporting documents, applications, and checking in communications. This access is granted via a separate application called User Access Control (UAC). The CDER User Access application is covered under a separate CDER RTQMS sub-system PIA. Access by FDA personnel to the DARRTS backend functionality, such as application servers or database servers, follows the standard FDA security process and requires an FDA Active Directory (AD) account for application and database administrators (administrators and system users do not directly access the DARRTS system). While FDA employees can use a drug reviewer's number to identify an FDA drug reviewer, this requires use of a reference model that is maintained outside the CDER RTQMS system boundary. Use of a reviewer number in this context is strictly done so for identification purposes only (e.g., identify who is working on a specific submission). CDER employees do not retrieve information from DARRTS using an individual's name nor any other personal identifier.
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.	Information collected and maintained in DARRTS is used for tracking, reporting, and maintaining an archival record of the drug and biological products submitted to the FDA for review. This system is used exclusively by FDA employees and not available to the general public. It also provides administrative and regulatory reporting capabilities; tracking of product and site quality control processes; and functionality for monitoring the CDER library of drug review documents. The three main areas of DARRTS where it collects information are related to: New Drug Applications from sponsors; submissions and supporting documents for the application; and communications back to sponsors as part of the review process. Among the areas mentioned above, PII information collected is specifically limited to sponsors and FDA permanent employee/Direct Contractor contact information (name, email address, phone number and mailing address). This contact information is used by FDA to communicate with external parties regarding the submissions. As part of that process, DARRTS executes business rules for supporting documents and communications to create goals, assignments and make changes to the status of the applications accordingly. All the supporting documents that DARRTS references are stored in a system called Electronic Document Room (EDR, assessed separately as a sub-system of the CDER RTQMS system boundary) and referenced via secure shell connection between DARRTS and EDR. All the communication documents (office documents/pdfs) are stored in Documentum and referenced from the DARRTS interface for both upload and view.
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://darrts.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 DARRTS is a web-based application used by FDA personnel to receive, manage, track, and report on drug applications. It is accessed using an internal only uniform resource locator (URL) and SSO authentication process.
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 (Personal) Mailing Address (Personal) Phone Numbers (Personal) Email Address (Business) Mailing Address (Business) Phone Numbers (Business) Other Other
PIA 22A:	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Reviewer Number
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Business Partners/Contacts (Federal state, local agencies) 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?	PII is collected to appropriately regulate NDAs and other regulatory submissions to FDA, and for communication purposes.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The FDA does not use PII for any secondary purposes.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	Provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, including sections 353, 355, 356b, 360. 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 Email Online Government Sources Within the OPDIV Non-Government Sources Members of the Public
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 No. 0910-0338; Expires 3/31/2026 (FDA Form 356h) OMB No. 0910-0014; Expires 9/30/2026 (FDA Form 1571) OMB No. 0910-0014; Expires 9/30/2026 (FDA Form 1572) OMB No. 0910-0001; Expires 8/31/2025 (FDA Forms 2252, 2253).
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 in the Privacy Act, but submitters are required to include the name of a point of contact who can communicate on behalf of the organization (i.e., an industry submitter point of contact). This PII is necessary for project managers to process and act on submitted applications. FDA personnel may opt out of providing their PII to the FDA. Should an individual choose to do this, they will not be able to perform their job duties 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 FDA changes its practices with regard to the collection or handling of PII for DARRTS, FDA 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.
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.	FDA employees may contact a system administrator or the Employee Resource and Information Center (ERIC). Additionally, employees may work with their supervisors, the Privacy Office, and FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC). External individuals may contact the FDA Privacy Office, or their FDA point of contact or general points of informational contact at the FDA. Contact information for these offices and resources is available across FDA's internet and intranet pages. All personnel are required to report suspected instances of PII compromise or misuse to FDA's CIOCC.

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.	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 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. FDA's Office of Information Management and Technology (OIMT) performs annual reviews to evaluate user access. One of the controls includes information system backups reflecting the requirements in contingency plans as well as other agency requirements for backing up information. 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: To communicate with POCs of companies/organizations applying for drug approval and determine compliance with clinical trial ethics. Administrators: System operation monitoring and troubleshooting purposes. Contractors: Some of the Administrators are Direct Contractors. Access to PII in DARRTS Production System required to perform their work duties.

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Users who require access to the information system need to have supervisor approval and sign off before access is granted. A User Access Request form is sent to a System Administrator, who reviews the application and provides access if appropriate and maintains a record of those who have been granted access. Access is granted using the CDER RTQMS Legacy User Access application which is the subject of a separate PIA.
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 user's supervisor will indicate on the account creation form the minimum information system access that is required in order for the user to complete his/her job. The access list is also reviewed twice a year at which time users' access permissions are reviewed and adjusted or removed for lack of system use. Unneeded accounts are purged 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.	Personnel must complete FDA's mandatory Computer Security and Privacy Awareness Training on an annual basis. FDA 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.	Annual Security Training and Privacy Awareness is reiterated in the DARRTS training sessions. Agency 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).	System records are maintained under the following FDA schedules. These schedules are consistent with the record keeping guidance issued by the National Archives and Records Administration (NARA). CDER File Code 2000; Record Series 2310, Database Records; Data input from or about incoming and outgoing documents submitted or created as part of the review process. Includes information about the initial application and supplements/amendments such as document types, review assignments, status of applications and reviews, dates initiated and completed, and other related information. The disposition: TEMPORARY. Cut off at the end of the calendar year when final action occurs. Destroy/delete 30 years after cutoff or when no longer needed for reference or research, whichever is later. N1-088-08-02. CDER File Code 2000; Record Series 2320, Output Records; disposition: TEMPORARY. Destroy upon verification of successful creation of the final document or file, or when no longer needed for business use, whichever is later. This is covered by General Records Schedule (GRS) 5.2 item 20. CDER File Code 2000; Record Series 2330, System Documentation; disposition: TEMPORARY. Destroy/delete when superseded or obsolete, or upon authorized deletion of the related master file or system, whichever is later. This is covered by General Records Schedule (GRS) 3.1 item 51.
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, encryption, network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, key cards, cipher locks, and climate controls. Other appropriate controls have been selected from NIST's Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199. The Rules of Behavior for using FDA systems are clarified and mandated to the user by the HHS guidelines and security documentation. Users agree to abided by these rules when receiving access to FDA system and upon passing a background clearance check.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	8/5/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	8/5/2025
SOP Review Comments:		**# of Days - SOP Review:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	8/8/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 8/8/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	3

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	8/8/2025
SAOP Review Comments:	Approved on behalf of the SAOP	**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/8/2025 9:16 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	8/6/2025	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. Please also note that the following SOP confirmation was inadvertently omitted from the PIA and it included here to confirm the following: "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."	8-5-2025 EMAIL_CDER Document Archiving Reporting Regulatory Tracking System (DARRTS) PIA.pdf CDER DARRTS SOP Approved 8.5.2025.pdf