Privacy Impact Assessment (PIA): FDA - DARRTS - QTR3 - 2022 - FDA2062706

Date Signed: 8/22/2022

Acronyms

ATO - Authorization to Operate
CAC - Common Access Card
FISMA - Federal Information Security Management Act
ISA - Information Sharing Agreement
HHS - Department of Health and Human Services
MOU - Memorandum of Understanding
NARA - National Archives and Record Administration
OMB - Office of Management and Budget
PIA - Privacy Impact Assessment
PII - Personally Identifiable Information
POC - Point of Contact
PTA - Privacy Threshold Assessment
SORN - System of Records Notice
SSN - Social Security Number
URL - Uniform Resource Locator

General Information

Status:	Approved	**PIA ID:**	1471948
PIA Name:	FDA - DARRTS - QTR3 - 2022 - FDA2062706	**Title:**	CDER Regulatory Tracking and Quality Management Systems
OpDiv:	FDA		

PTA

PTA - 2:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	FDA has made no changes to this [system/component/information collection] since the last Privacy Threshold Analysis/Privacy Impact Assessment was approved.
PTA - 3:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA - 4:	Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions.	The Food and Drug Administration (FDA) uses the Center for Drug Evaluation and Research Regulatory Review (CDER RR) system 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 several issues, including performance on the Prescription Drug User Fee Act (PDUFA), Biosimilar User Fee Act (BsUFA), and related goals. The use of the Document Archiving, Reporting and Regulatory Tracking System (DARRTS), an element of the CDER RR system, encompasses all functions related to tracking application submissions, archiving documents generated during application review, supporting reporting requirements, and providing a template driven generation system for producing standard documents during application review.

Overall, DARRTS is a component-based, multi-tier enterprise application that is accessed via a web-based interface. DARRTS provides FDA users 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 for the complete drug approval process and ultimate approval of each and 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 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 Bioshield 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.

PTA - 5:	List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored.	The data collected in CDER-RR includes information regarding the receipt, management, and reporting of clinical investigational and marketing submissions for human drugs and

therapeutics. CDER-RR contains PII elements about individuals serving as the points of contact at companies and other organizations that file required information with the FDA. This PII includes professional/work e-mail, mailing addresses, and phone numbers. In addition to that it also includes sponsors information i.e. their organization information, email address, contact information, address. FDA reviewers of applications are identified by a reviewer number. FDA employees can use this number to identify the FDA reviewer, but this requires use of a reference model that is maintained outside the boundary of the CDER RR system. DARRTS is also 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 present in these communications.

DARRTS and the systems with which it interacts, track information such as application sponsor data, products, advertising submissions, registration and listing submissions, site inspections, and the volume of work flow 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 RR, addressed in a separate privacy impact assessment). 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).

The DARRTS System Authentication process is configured to work with FDA's Single Sign-On (SSO) 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 in a separate CDER RR PIA.

Access by FDA personnel to the DARRTS backend 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).

CDER employees do not retrieve information from DARRTS using an individual's name nor any other personal identifier.

PTA - 5A:	Are user credentials used to access the system?	No
PTA - 6:	Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual.	CDER uses DARRTS for tracking, reporting, and maintaining an archival record of the drug and biological products submitted to the FDA for review. It provides a flexible, integrated, web-based system that supports the drug review and biologic review product tracking process. 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 permanent FDA employee 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, part of a separate assessment of another set of CDER RR applications) 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 - 7:	Does the system collect, maintain, use or share PII?	Yes
PTA - 7A:	Does this include Sensitive PII as defined by HHS?	No
PTA - 8:	Does the system include a website or online application?	No
PTA - 14:	Does the system have a mobile application?	No
PTA - 20:	Is there a third-party website or application (TPWA) associated with the system?	No
PTA - 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

PIA

PIA - 1:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Email Address Mailing Address

		Name Phone numbers
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Employees/ HHS Direct Contractors Members of the public
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system.	Above 2000
PIA - 4:	For what primary purpose is the PII used?	Personally identifiable information (PII) is collected to appropriately regulate NDAs and other regulatory submissions to FDA, and the clinical investigators who work on those projects.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	There are no secondary uses.
PIA - 7:	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.
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	No
PIA - 9:	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 Private Sector
PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA - 10A:	Provide the information collection approval number.	OMB No. 0910-0338; Expires 3/31/2020 (FDA Form 356h) OMB No. 0910-0014; Expires 2/28/2019 (FDA Form 1571) OMB No. 0910-0014; Expires 2/28/2019 (FDA Form 1572) OMB No. 0910-0001; Expires 03/31/2021 (FDA Forms 2252, 2253)
PIA - 10B:	Identify the OMB information collection approval number expiration date.	3/31/2021
PIA - 11:	Is the PII shared with other organizations outside the system's Operating Division?	No
PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary

PIA - 13:	Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason	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.
PIA - 14:	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). Alternatively, describe why they cannot be notified or have their consent obtained.	If the agency makes a major change in its collection or use of major changes occur to the system (e.g., disclosure PII in CDER RR, FDA will notify affected individuals in the most efficient and effective manner available and appropriate, the time of original collection). Alternatively, describe which may include a formal process involving written or why they cannot be notified or have their consent electronic notice, or informal processes such as e-mail.
PIA - 15:	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.	There is no system-specific process in place. Individuals may contact FDA offices to which they submit their information and/or the FDA Privacy Office should they wish to correct their information or raise concerns about its use or disclosure. Contact information is available on fda.gov.
PIA - 16:	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. Please address each element in your response. If no processes are in place, explain why not.	The Regulatory Review Project Managers within CDER are responsible for ensuring that point of contact information remains accurate and up to date. Minimal PII is collected in DARRTS, consisting of contact information only, because the FDA must communicate with individuals to discuss NDAs and ANDAs, all this information is relevant. Data integrity and availability are safeguarded by the security controls selected and implemented consistently with the Federal Information Security Modernization Act (FISMA) and guidance from the National Institute of Standards and Technology (NIST).
PIA - 17:	Identify who will have access to the PII in the system.	Users Contractors
PIA - 17A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA - 17B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA - 18:	Provide the reason why each of the groups identified in PIA - 17 needs access to PII.	Users: To communicate with points of contact of organizations applying for drug approval, and determine compliance with clinical trial ethics. Contractors: Direct contractors have access to PII in DARRTS Production System to perform their work duties.
PIA - 19:	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 RR Legacy User Access application, which is the subject of a separate PIA.
PIA - 20:	Describe the technical methods in place to allow those with access to PII to only access 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 - 21:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.	Personnel must complete FDA's mandatory Computer Security Awareness Training at a minimum of every twelve months. This course includes privacy training.
PIA - 22:	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 - 23:	Describe the process and guidelines in place with regard to 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). The NARA citation that covers these specific applications is N1-088-08-02. FDA File Code 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. FDA File Code 2320, Output Records; disposition: TEMPORARY. Delete/destroy when no longer needed for reference. This is covered by General Records Schedule (GRS) 5.2 item 20. FDA File Code 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 - 24:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	The information contained in CDER-RR is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from FDA, NIST, and the Office of Management and Budget (OMB). The agency reviews security controls on a periodic basis to ensure they are implemented correctly, operating as intended, and effectively protecting all information within the system. Controls include: user authentication and authorization, firewalls, virtual private networks, encryption, intrusion detection system, smart cards, guards, identification badges, key cards, cipher locks, and closed circuit television.