


General Information		
PTA / PIA Name:	FDA - DDT - QTR4 - 2025 - FDA5001361	PTA / PIA ID: 3966625
Component Name:	FDA - CDER Drug Development Tools	ATO Boundary Name: OC Digital Solution Partners Appian
Overall Status:	Complete 	# of Days - Open: 36
Submitter:		Submit Date: 11/3/2025
Next Assessment Date:	12/08/2028	Expiration Date: 12/8/2028
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.	9/8/2023
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	Jeffrey Siegel
PTA 01A:	POC Title and Organization	POC Title: Office Director POC Organization: Office of New Drugs (OND)/Office of Drug Evaluation Science (ODES)
PTA 01B:	POC Email Address	jeffrey.siegel@fda.hhs.gov
PTA 01C:	POC Phone Number	301-796-8921
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.

In support of the Food and Drug Administration's (FDA's) modernization efforts, the Center for Drug Evaluation and Research (CDER) established the Drug Development Tool (DDT) Qualification Program in accordance with Section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C), as added by Section 3011 of the 21st Century Cures Act. Under the law, the agency is required to provide consistent, efficient and transparent review processes when qualifying new drug tools. To enhance the user experience for all stakeholders CDER's Division of Biomedical Informatics, Research, and Biomarker Development within the Office of Drug Evaluation Science (ODES), Office of New Drugs (OND), has developed a new web interface, the DDT Transparency Database.

The CDER DDT system provides a secure and standardized submission gateway for external users (also known as requestors) to submit qualification materials, and search and filter across DDT Qualification Programs based on criteria such as submission stage, qualification status, applicable disease, and determination status.

The CDER DDT Transparency Database is hosted by Appian and Salesforce cloud platforms. Both Appian and Salesforce are hosted within the Amazon Web Service (AWS) government cloud environment. Appian is fully integrated with Salesforce, leveraging Web Application Programming Interface (API) calls with API key authentication for seamless communication between the platforms. The CDER DDT transparency database sources data from FDA's Nexus system (the subject of a separate assessment). Specifically, business data entered by business entities and submission documents maintained in FDA's NextGen Portal (the subject of a separate assessment) is transmitted to FDA's Nexus system which then transmits this data via API to CDER DDT. This data is then manually entered into the CDER DDT transparency database by ODES regulatory project managers/qualification program staff (first in the Appian system for internal use and then to the Salesforce system via API for public posting). The API does not act as a data repository.

Business data and submissions contain personally identifiable information (PII). Data consists of point of contact (POC) and business partner information (name, business email address, business mailing address, business phone number, and Dun and Bradstreet (DUNS) number). Program staff may also upload several document types that contain requestor information, such as Letters of Intent (LOI), Qualification Plan (QP) executive summaries, and Final Qualification Plan (FQP) executive summaries. Executive summaries typically include the requestor's contact information. When uploaded into the database, this information becomes accessible to authorized

users in Appian (internal) and the public in Salesforce (external).

CDER DDT also collects PII in the form of usernames of FDA permanent employees and Direct Contractors who access the system. This information is captured and included as part of system access log records.

The CDER DDT Transparency Database is used by both internal and external stakeholders. Internal users of the system include FDA permanent employees and Direct Contractors. Internal users (e.g., reviewers, system administrators) access the system via the Appian uniform resource locator (URL) using single sign-on (SSO) authentication and use of their personal identity verification (PIV) cards. External users of the system include members of the public (e.g., industry professionals, academics, researchers, etc.). External users access the system via a publicly available Salesforce uniform resource locator (URL).

CDER DDT does not collect any PII directly from FDA employees, Direct contractors, or members of the public. PII is collected via an API that interfaces with FDA's Nexus system. Once data is transmitted from FDA Nexus to CDER DDT, this data is then manually entered into the CDER DDT Transparency Database.

The types of information transmitted into the system includes PII and non-PII. PII about points of contact (POCs) and business partners may include name, business email address, business mailing address, business phone number, and Dun and Bradstreet (DUNS) number.

Executive summaries and qualification review documents may also include the following requestor PII: name, business email address, business mailing address, and business phone number.

CDER DDT also collects PII in the form of usernames of FDA permanent employees and Direct Contractors who access the system. This information is captured and included as part of system access log records.

Non-PII maintained by the system may include company name, and submission figures/tables.

PII in the system is retained on a temporary basis per National Archives and Records Administration (NARA) retention and disposal schedules. The PII in the system is not shared with any other system or organization.

Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this 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.

PTA 05A:

Are user credentials used to access the 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.	<p>The 21st Century Cures Act transparency provisions under section 507 require that FDA make publicly available and update on a biannual basis, information with respect to each DDT qualification submission. This requirement applies to Letters of Intent (LOI) and Letters of Support (LOS), Qualification Plans (QPs), and Full Qualification Packages (FQPs) sent to FDA after December 13, 2016.</p> <p>Documents may include PII and non-PII about external users (requestors). The CBER Drug Development Tool Qualification database also includes legacy projects (those submitted prior to passage of the 21st Century Cures Act). PII about POCs and business partners may include name, business mailing address, business phone number, business email address, and DUNS number. This PII may also be found in executive summaries and qualification review documents.</p> <p>CDER DDT also collects PII in the form of usernames of FDA permanent employees and Direct Contractors who access the system. This information is captured and included as part of system access log records.</p> <p>Non-PII maintained by the system may include company name and submission figures/tables.</p> <p>No information from the transparency database is shared with other systems</p>
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).	<p>Internal-facing (Appian): https://appian-dsc.fda.gov/suite/sites/ddt</p> <p>External-facing (Salesforce): https://force-dsc.my.site.com/ddt/s/</p>
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	Yes

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.	<p>The website serves as a public transparency portal for the FDA's DDT Qualification Program. Its primary purpose is to provide public access to comprehensive information about submissions made to the DDT Qualification Program, including Letters of Intent (LOIs), Qualification Plans (QPs), and Full Qualification Packages (FQPs). The platform enhances transparency in regulatory decision-making by publishing FDA's acceptance or non-acceptance determinations for each submission type, along with official FDA communications to requestors regarding these decisions. Additionally, the website functions as a submission tracking and history resource, allowing users to access summary information about what was submitted by requestors, including contact details and addresses of recipients who previously submitted materials through FDA's NextGen Portal.</p> <p>The website is publicly accessible to anyone without restrictions. This includes general members of the public, industry stakeholders, researchers and academics, healthcare professionals, regulatory professionals, and any other interested parties seeking information about DDT qualification activities. No special credentials, organizational affiliation, or approval process is required to access the information contained on the public website.</p> <p>Users access the website through a public URL without requiring login credentials or special permissions. The specific URL is https://force-dsc.my.site.com/ddt/s/, which is hosted on the Salesforce platform. No registration, authentication, or special software is required for access-users simply need a standard web browser to view all available information on the site.</p>
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.	Identifying Numbers DUNS Biographical Information Name User Credentials 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.	Business Partners/Contacts (Federal state, local agencies) Members of the public
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999
PIA 25:	For what primary purpose is the PII used?	The PII that is transmitted through DDT is used primarily for business contact purposes.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The FDA makes no secondary use of the PII.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	Federal Food, Drug & Cosmetic Act at 21 U.S.C. 301 including sections 353, 355, 356b, 360; Departmental Regulations 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.	Government Sources Within the OPDIV
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 DDT does not require an OMB approval number because this is not an information collection request as defined by the Paperwork Reduction Act.
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 (permanent employees and Direct Contractors) are notified at the time of hire of the Agency's collection, creation, and use of their PII in the context of their work with the Agency. At every instance of logging on to the FDA network, they must read and acknowledge a warning message advising that they have no expectation of privacy when using government systems and resources. For other systems that are the source of PII in CDER DDT, individuals may be provided additional notice in the context of those other systems. This PIA provides additional notice.

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 FDA or CDER changes its practices regarding the collection or handling of PII related to the CDER DDT system (or source system), the Agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include email 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.	<p>Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have a number of avenues available to resolve the situation. Employees may submit concerns to their supervisor, the FDA Privacy Office, Employee Resource and Information Center (ERIC), and FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC).</p> <p>All FDA personnel are required to immediately report any suspected data breaches and security incidents to CIOCC.</p>
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.	CDER DDT is an entirely cloud-based, production ready system that provides the infrastructure to support innovative knowledge management. Any PII collected is stored on a temporary basis. Source systems which provide the data are responsible for the periodic reviews of PII contained within their systems to ensure data integrity, accuracy and relevancy.
PIA 38:	Identify who will have access to the PII in the system.	<p>Users</p> <p>Administrators</p> <p>Developers</p> <p>Contractors</p>
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.	<p>Users: Will have access to their own PII in the system and can edit it for changes.</p> <p>Administrators: Will have access to user PII when needed for account management purposes.</p> <p>Developers: Will have access to user PII for system development, implementation, and operations and maintenance tasks.</p> <p>Contractors: Some of the Developers are Direct Contractors</p>

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	FDA users and Direct Contractors with valid network accounts who require access to DDT must have supervisor approval before access is granted. The Agency reviews the system access list on a quarterly basis to adjust users' access roles and permissions and delete unneeded accounts from the system.
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 relevant supervisor indicates on the user account creation form the minimum access that is required in order for the user to complete his/her job. The scope of access is restricted based on role based criteria.
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.	Additional privacy guidance is available on the FDA intranet and from Privacy office staff.
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).	<p>FDA maintains records in accordance with the following National Archives and Records Administration (NARA) General Records Schedules (GRS):</p> <p>GRS 3.2: Information System Security Records</p> <p>Item 30: System Access Records – systems not requiring special accountability for access. The GRS disposition authority is DAA-GRS-2013-0006-0003 with the records being destroyed when business use ceases.</p> <p>Item 40: System backups and tape library records – incremental backup files The GRS disposition authority is DAA-GRS-2013-0006-0005 with the records being destroyed when superseded by a full backup, or when no longer needed for system restoration, whichever is later.</p>

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.

The administrative safeguards applied 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 maintenance of data servers 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:	11/3/2025
Privacy Analyst Review Comments:	Due to an Archer error, General Q 03: "Does the system have or is it covered by a Security Authorization to Operate (ATO)?" erroneously reports that no ATO is in place. The correct response should be "Yes" and ATO date is 9/8/2023., At this time, we are unable to update Archer to reflect the correct answer "Yes."	# of Days - PA Review:	0

SOP Review

SOP Review Decision:	Approved	SOP Review Date:	11/4/2025
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:	1

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	Agency Privacy Analyst Review Date:	11/26/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 11/26/2025 Comment regarding ATO was addressed. This PIA is ready for SAOP review and approval.	# of Days - APA Review:	22

SAOP Review

SAOP Review Decision:	Approved	SAOP Review Date:	12/9/2025
SAOP Review Comments:		# of Days - SAOP Review:	13

SAOP Signature

Date	User	Type	Name	Original Value	New Value
12/9/2025 2:11 PM	BAUR, VANESSA	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	VILLAFUERTE, NESTOR	11/17/2025	Q3 states that the PIA does not have an ATO however, the ATO listed is in 2023.	
PTA 01	BLAND, CRYSTAL	11/26/2025	11/26/2025 Q3 should be marked Yes and ATO is 9/8/2023.	CDER DDT SOP approved 11.4.2025.pdf