

Copy PIA (Privacy Impact Assessment)

Do you want to copy this PIA ?

Please select the user, who would be submitting the copied PIA.

Instructions


Review the following steps to complete this questionnaire:

- 1) Answer questions.** Select the appropriate answer to each question. Question specific help text may be available via the  icon. If your answer dictates an explanation, a required text box will become available for you to add further information.
- 2) Add Comments.** You may add question specific comments or attach supporting evidence for your answers by clicking on the  icon next to each question. Once you have saved the comment, the icon will change to the  icon to show that a comment has been added.
- 3) Change the Status.** You may keep the questionnaire in the "In Process" status until you are ready to submit it for review. When you have completed the assessment, change the Submission Status to "Submitted". This will route the assessment to the proper reviewer. Please note that all values list questions must be answered before submitting the questionnaire.
- 4) Save/Exit the Questionnaire.** You may use any of the four buttons at the top and bottom of the screen to save or exit the questionnaire. The button allows you to complete the questionnaire. The button allows you to save your work and close the questionnaire. The button allows you to save your work and remain in the questionnaire. The button closes the questionnaire without saving your work.

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

PIA Name:	FDA - CTS - QTR1 - 2025 - FDA4914341	PIA ID:	2841534
Name of Component:	FDA - CDRH Center Tracking System	Name of ATO Boundary:	CDRH Regulatory Review
Overall Status:		PIA Queue:	
Submitter:		# Days Open:	4
Submission Status:	Submitted	Submit Date:	3/7/2025
Next Assessment Date:	N/A	Expiration Date:	3/10/2028
Office:		OPDIV:	FDA
Security Categorization:		OpDiv PIA ID:	FDA4914341
Legacy PIA ID:		Make PIA available to Public?:	Yes
1:	Identify the Enterprise Performance Lifecycle Phase of the system.		Operations and Maintenance
2:	Is this a FISMA-Reportable system?		No
3:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?		No
4:	ATO Date or Planned ATO Date.		10/12/2022
5:	Is the system or electronic information collection, agency or contractor operated?		Agency

PTA

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.	Since this Privacy Threshold Analysis/Privacy Impact Assessment (PTA/PIA) was last approved, the Premarket Applications (APPS) component was removed from CTS-Centry.
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's (FDA's) Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health. Among its responsibilities, CDRH approves medical devices before manufacturers and retailers are permitted to sell or otherwise provide these devices to health care providers. To receive these approvals, known as "pre-market approvals," manufacturers and sellers must submit applications providing information about the devices. The applications may include information about complying with the Clinical Laboratory Improvement Act (CLIA), requests for designations (e.g., to designate a product as a "medical device," to confirm which Center within the FDA will regulate the product), information about post-market safety surveillance (e.g., whether there have been reports of adverse events associated with the use of the device), and other information as described in this assessment.

The subject of this assessment is the CDRH Center Tracking System (CTS). This work-flow management system supports CDRH business processes and rules during all stages of the product life cycle for medical devices. CDRH CTS is used to process, track and respond to pre-market and post-market industry submissions, as well complaints submitted by the general public.

CDRH CTS encompasses CDRH Entry (CEntry) which is a data submission tool. The main difference between CEntry and CTS is that CTS is a workflow management system whereas CEntry is a data submission tool. CEntry is the data submission tool of the CTS system where device information submitted by manufacturers is stored. It is used by internal users to enter data into the CTS system. Any data maintained in CTS is likely being maintained in CEntry. CEntry has the same business owner as CTS, and CEntry does not maintain a separate PIA. CTS is also used to maintain complaint records submitted by the general public or industry via email, standard mail, or through the online "Allegations of Misconduct" web form.

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.	<p>Among its responsibilities, CDRH approves medical devices before manufacturers and retailers are permitted to sell or otherwise provide these devices to health care providers. CDRH CTS collects and maintains manufacturer and seller applications consisting of information about the devices. The applications may include information about complying with the Clinical Laboratory Improvement Act (CLIA), requests for designations, information about post-market safety surveillance, and other information as described in this assessment.</p> <p>CDRH CTS data will vary with each submitted application. The following PII may be collected and maintained about submitters (e.g., industry personnel): (a) name; (b) business email address; (c) business phone number; and (d) business mailing address. PII collected and maintained about members of the public submitting complaints may include name, email address and unique device identifiers.</p> <p>Non-PII data collected and maintained may include non-unique device identifiers and status (e.g., under review, approved/denied), and details regarding specific activities or processes currently supported by CTS for premarket and post-market approvals (e.g., premarket division tracking, Clinical Laboratory Improvement Act submissions, requests for designations, condition of approvals, device nomenclature data, post-market surveillance studies, compliance operation program support which consists of allegations of regulatory misconduct or Complaints, and consult functionality (eConsults)).</p>
PTA - 5A:	Are user credentials used to access the system?	Yes
PTA - 5B:	Please identify the type of user credentials used to access the system.	<p>HHS User Credentials</p> <p>HHS/OpDiv PIV Card</p>

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.	<p>The CDRH CTS work-flow management system supports CDRH business processes and rules associated with pre-market and post-market approvals. All information collected and maintained in the system is needed to process premarket and post market approvals. Information is also used to communicate with entities whose activities are regulated by the FDA. The information collected and maintained by the system varies with each new submission. Information includes both PII and Non-PII.</p> <p>The following point of contact (POC) information is collected from submitters (e.g., industry personnel): (a) name; (b) business email address; (c) business phone number; and (d) business mailing address.</p> <p>The following personal contact information may be collected from members of the public who submit complaints: (a) name; (b) email address; and (c) unique device identifiers.</p> <p>Non-PII data collected and maintained may include non-unique device identifiers and status (e.g., under review, approved/denied), and details regarding specific activities or processes currently supported by CTS for premarket and post-market approvals (e.g., premarket division tracking, Clinical Laboratory Improvement Act submissions, requests for designations, condition of approvals, device nomenclature data, post-market surveillance studies, compliance operation program support which consists of allegations of regulatory misconduct or Complaints, and consult functionality (eConsults)).</p>
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?	Yes
PTA - 8A:	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	No
PTA - 9:	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.	CDRH CTS is a web-based system and is accessed via the CTS website. Users of the system (FDA employees and Direct Contractors) access CTS via Single Sign-On (SSO) authentication using Personal Identity Verification cards (PIV cards).
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 - 11A:	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	
PTA - 12:	Does the website use web measurement and customization technology?	No
PTA - 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	

PTA - 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA - 13A:	Does the website collect PII from children under the age thirteen?	
PTA - 13B:	Is there a unique privacy policy for the website and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
PTA - 14:	Does the system have a mobile application?	No
PTA - 14A:	Is the mobile application HHS developed and managed or a third-party application?	
PTA - 15:	Describe the purpose of the mobile application, who has access to it, and how users access it. Please address each element in your response.	
PTA - 16:	Does the mobile application/ have a privacy notice?	
PTA - 17:	Does the mobile application contain links to non-federal government websites external to HHS?	
PTA - 17A:	Is a disclaimer notice provided to users that follow external links to resources not owned or operated by HHS?	
PTA - 18:	Does the mobile application use measurement and customization technology?	
PTA - 18A:	Describe the type(s) of measurement and customization technologies or techniques in use and what information is collected.	
PTA - 19:	Does the mobile application have any information or pages directed at children under the age of thirteen?	
PTA - 19A:	Does the mobile application collect PII from children under the age thirteen?	
PTA - 19B:	Is there a unique privacy policy for the mobile application and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
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		
PIA - 1:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Name Email Address Phone numbers Mailing Address Devices Identifiers
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?	The FDA uses the PII in CTS to process, track and respond to industry submissions and complaints.
PIA - 5:	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 - 6:	Describe the function of the SSN, Truncated SSN, and/or Taxpayer ID.	

PIA - 6A:	Cite the legal authority to use the SSN, Truncated SSN, and/or Taxpayer ID.	
PIA - 7:	Identify legal authorities governing information use and disclosure specific to the system and program.	<p>All submissions maintained in CDRH CTS are necessary for FDA activities as authorized by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301.</p> <p>44 U.S.C. 3506 which supports the FDA by allowing the ability for the collection, review and approval of submitted information.</p> <p>The implementation of this system is also authorized by 5 U.S.C. 301 which permits agency heads to create the usual and expected infrastructure necessary for the organization to accomplish its purposes and mission.</p>
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	No
PIA - 8A:	Please specify which PII data elements are used to retrieve records.	
PIA - 8B:	Provide the number, title, and URL of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or indicate whether a new or revised SORN is in development.	
PIA - 9:	Identify the sources of PII in the system.	<p>Directly from an individual about whom the information pertains</p> <ul style="list-style-type: none"> Hard Copy Mail/Fax Email Online <p>Government Sources</p> <ul style="list-style-type: none"> Within the OPDIV <p>Non-Government Sources</p> <ul style="list-style-type: none"> 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.	<p>OMB No. 0910-0120, expires 07/31/2026</p> <p>OMB Number 0910-0769, expires 11/30/2026</p>
PIA - 10B:	Identify the OMB information collection approval number expiration date.	7/31/2026
PIA - 10C:	Explain why an OMB information collection approval number is not required.	
PIA - 11:	Is the PII shared with other organizations outside the system's Operating Division?	No
PIA - 11A:	Identify with whom the PII is shared or disclosed.	
PIA - 11B:	Please provide the purpose(s) for the disclosures described in PIA - 11A.	
PIA - 11C:	List any agreements in place that authorizes the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	
PIA - 11D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	

PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 12A:	If PII submission is mandatory, provide the specific legal requirement that requires individuals to provide information or face potential civil or criminal penalties.	
PIA - 13:	Describe the method for notifying individuals that their information will be collected and how they can opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.	<p>Submitters provide their contact information as a practical requirement in order to communicate with FDA about submissions. There are no opt-out procedures specific to CTS. While FDA requires that regulated entities supply the PII of a point of contact, that person can be anyone who is authorized to send and receive communications on behalf of the regulated entity.</p> <p>For the Allegations of Regulatory Misconduct (Complaints), individuals can opt-out from including their PII by choosing only to submit information regarding their complaint.</p>
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.	No such changes are anticipated. If FDA changes its practices with regard to the collection or handling of PII related to CTS, 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 - 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.	<p>Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have many avenues available for assistance. These individuals may contact FDA offices, including the FDA Privacy Office, via email, phone and standard mail avenues (all listed on fda.gov).</p> <p>FDA personnel may contact their Center supervisor, FDA Privacy Office, the Employee Resource and Information Center (ERIC), the Cybersecurity Infrastructure Operations Coordination Center (CIOCC), and other agency offices.</p> <p>In the event of a suspected incident or data breach, FDA personnel must report that without delay to the FDA's CIOCC.</p>

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 submitting individual is responsible for providing accurate information. PII relevance is supported through the design of the system and processes to require, collect and handle only the minimum necessary PII to allow for system use and operation. Integrity and availability are protected by privacy and 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. CDRH performs annual reviews to evaluate user access. Data discrepancies identified in the course of system use are addressed when discovered. PII relevancy is subject to submitter control and is supported by agency forms and guidance designed to ensure only relevant and necessary PII is provided.
PIA - 17:	Identify who will have access to the PII in the system.	Users Administrators Developers 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.	<p>Users: Reviewers (FDA personnel) require access to the system to create, update and perform routine tasks pertaining to their job responsibilities using the systems granted access to.</p> <p>Administrators: May be application administrators who require access to conduct business functions, or application administrators who require access to create and manage user accounts for specific applications.</p> <p>Developers: will not normally have access to PII but may while maintaining the systems or providing technical assistance.</p> <p>Contractors: Some developers may be Direct Contractors and will have access under the same circumstances as developers.</p>
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	FDA employees and Direct Contractors with valid network accounts who require access to CTS must have supervisory approval and signature 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 - 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.	All users including administrators, developers, and Direct Contractors are granted only the minimal privileges that they require to do their job. The users' supervisor indicates on the account creation form the minimum system access that is required.
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.	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 - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	Personnel are trained on the use of the system and review the Rules of Behavior. Additional role-based training on privacy is available via 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).	Records are maintained according to National Archives and Records Administration (NARA) citation N1-088-08-1, Items 2.1-2.5 and General Records Schedule 5.1 and 5.2. Temporary-Cutoff at the end of the calendar year after final action is completed or product is withdrawn from the market. Delete/Destroy when no longer needed for business and regulatory purposes, or 20 years after cutoff, whichever is later.
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.	<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 role-based access settings, firewalls, passwords and others. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls.</p> <p>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.</p>

Review & Comments

Privacy Analyst Review

OpDiv Privacy Analyst Review Status:	Approved	Privacy Analyst Review Date:	3/7/2025
Privacy Analyst Comments:		Privacy Analyst Days Open:	

SOP Review

SOP Review Status:	Approved	SOP Signature:	
SOP 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.	SOP Review Date:	3/7/2025
		SOP Days Open:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	Agency Privacy Analyst Review Date:	3/11/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 3/11/2025 The following PIA is ready for SAOP review and approval.	Agency Privacy Analyst Days Open:	4

SAOP Review

SAOP Review Status:	Approved	SAOP Signature:	Archer Signature_Bridget Guenther.docx
SAOP Comments:		SAOP Review Date:	3/11/2025
		SAOP Days Open:	0

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
CDRH Center Tracking System_SOP Approved.pdf	170103	.pdf	3/10/2025 12:55 PM	0
PIAs in your Queue (CDRH Center Tracking System and CBER Connect) .pdf	396656	.pdf	3/10/2025 12:55 PM	0

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 10B	Data Feed Service, piafrmfda	3/7/2025	<p>OMB No. 0910-0120, expires 07/31/2026</p> <p>OMB Number 0910-0769, expires 11/30/2026</p>	
PIA - 1	BLAND, CRYSTAL	3/10/2025	<p>3/7/2025 Per FDA's email:</p> <p>For the CDRH Center Tracking System PIA:</p> <p>Q-3 "Does the system have or is it covered by a Security Authorization to Operate (ATO)?"</p> <ul style="list-style-type: none"> The FDA instance of Archer is automatically entering the answer "No," which is incorrect. The ATO date is 10/12/2022. At this time, we are unable to update Archer to reflect the correct answer "Yes." 	

Admin Section

Is OpDiv Privacy Analyst Approved ?:	1	Is OpDiv Privacy Analyst Return ? :	0
Is Agency Privacy Analyst Approve ?:	1	Is SOP Return ?:	0
Is SAOP Approved?:	1	Is Agency Privacy Analyst Return ?:	0
Total Approved:	4	Is SAOP Return ?:	0
Total Approval Required:	4	Total Return:	0

Miscellaneous Fields

Last Updated:	3/11/2025 11:01 AM	History Log:	View History Log
---------------	--------------------	--------------	----------------------------------