Privacy Impact Assessment (PIA): FDA - CBER Connect - QTR1 - 2025 - FDA4914345

Created Date: 3/7/2025 11:22 AM Last Updated: 3/11/2025 10:22 AM

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 - CBER Connect - QTR1 - 2025 - FDA4914345	**PIA ID:**	2841396
Name of Component:	FDA - CBER Connect	**Name of ATO Boundary:**	CBER Office of Regulatory Operations
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:**	FDA4914345
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.	11/21/2022
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.	FDA has made no changes to the system since the last Privacy Impact Assessment (PIA) 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 purpose of the Center for Biologics Evaluation and Research (CBER) Connect system is to provide CBER's Regulatory Project Managers (RPM) the ability to electronically search, view and upload industry submissions, communications and CBER Programmatic Items as part of the industry submission review process. CBER Connect v1.0 was the initial release of CBER's modernized User Interface (UI) for accessing regulatory review functions. It provides document access, search, and upload capabilities. Key features include screens for accessing industry submissions and Food and Drug Administration (FDA) generated communications. CBER Connect provides the ability to conduct full-text searches by keyword for FDA generated communications and public Programmatic Items in the CBER Search Home Screen. CBER Connect also introduces a modernized UI for users when interacting with another system, CBER's Electronic Records (CER). CBER Connect users (FDA employees and Direct Contractors) access the system via Single Sign-On (SSO) multifactor authentication.
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.	CBER Connect is the primary point of entry for CBER staff to conduct regulatory and non-regulatory business, resulting in fewer UIs for users to navigate. As part of the CBER modernization initiative, CBER Connect provides regulatory reviewers access to submission data for submission processing. CBER Connect users (FDA employees and Direct Contractors) access the system via a SSO process using multi-factor authentication. To facilitate the submission review activity, CBER Connect processes personally identifiable information (PII) that includes: (a) name; (b) email address; (c) phone numbers; (d) medical notes; (e) date of birth; (f) certificates; (g) clinical study data; and patient identifiers such as (h) photographic identifiers; (i) biometric identifiers; and (j) and medical records numbers. PII data is collected from regulated industry facility contacts and patients who submit adverse event reports. The PII data is not directly collected from patients and this data is not shared with any other system or organization. Additional information about the information technology (IT) systems and product application artifacts processed using CBER Connect during the submission review include: Premarket Approvals (PMAs): FDA approvals to manufacture or distribute certain medical devices. PMAs include new drug applications for a device under section 520(l) of the Federal Food Drug and

		Cosmetics (FD&C) Act. Premarket Notifications 510(k): FDA premarket approvals for devices, not subject to a PMA themselves, to demonstrate that the devices to be marketed are at least as safe and effective (that is, substantially equivalent) to an already-legally marketed device. Investigational Device Exemptions (IDEs): FDA approvals for producers to use investigational devices in clinical studies, in order to collect safety and effectiveness data. Investigational New Drug applications (INDs): FDA approvals for producers to use new biological compounds, vaccines, blood and blood components, as well as human and non- human tissues and factors in clinical studies, in order to collect safety and effectiveness data. Biologic License Application (BLA): FDA approvals to manufacture or distribute certain new biological compounds, vaccines, blood and blood components, as well as human and non-human tissues and factors. BLA includes a new biologic application for the entities covered in 21 CFR 600 series. Master Files (MF): FDA approvals to manufacture certain new biological compounds, vaccines, blood and blood components, as well as human and non-human tissues and factors. These documents are not reviewed until they are cross-referenced in a BLA or IND application. New Drug Applications (NDAs) and abbreviated New Drug Applications (ANDAs): FDA approvals to manufacture or distribute certain new biological compounds.
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.	HHS User Credentials HHS/OpDiv PIV Card
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.	CBER Connect is the primary point of entry for CBER staff to conduct regulatory and non-regulatory business, resulting in fewer UIs for users to navigate. CBER Connect provides regulatory reviewers access to submission data for submission processing. CBER Connect maintains the following PII about individuals (e.g., patients submitting adverse event reports): (a) name; (b) email address; (c) phone numbers; (d) medical notes; (e) date of birth; (f) certificates; (g) clinical study data; and patient identifiers such as (h) photographic identifiers; (i) biometric identifiers; and (j) and medical records numbers. The PII data is not directly collected from patients and are not shared with any other system or organization. Additional information about the IT systems and product application

		artifacts processed using CBER Connect during the submission review include: Premarket Approvals (PMAs): FDA approvals to manufacture or distribute certain medical devices. PMAs include new drug applications for a device under section 520(l) of the FD&C Act. Premarket Notifications 510(k): FDA premarket approvals for devices, not subject to a PMA themselves, to demonstrate that the devices to be marketed are at least as safe and effective (that is, substantially equivalent) to an already-legally marketed device. Investigational Device Exemptions (IDEs): FDA approvals for producers to use investigational devices in clinical studies, in order to collect safety and effectiveness data. Investigational New Drug applications (INDs): FDA approvals for producers to use new biological compounds, vaccines, blood and blood components, as well as human and non- human tissues and factors in clinical studies, in order to collect safety and effectiveness data. Biologic License Application (BLA): FDA approvals to manufacture or distribute certain new biological compounds, vaccines, blood and blood components, as well as human and non-human tissues and factors. BLA includes a new biologic application for the entities covered in 21 CFR 600 series. Master Files (MF): FDA approvals to manufacture certain new biological compounds, vaccines, blood and blood components, as well as human and non-human tissues and factors. These documents are not reviewed until they are cross-referenced in a BLA or IND application. New Drug Applications (NDAs) and abbreviated New Drug Applications (ANDAs): FDA approvals to manufacture or distribute certain new biological compounds.
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.	The purpose of the website is to provide system users (FDA permanent employees and Direct Contractors) with the information required to support the managed review process. Users access the website via SSO/multifactor 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 - 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 Medical records (PHI) Date of Birth Photographic Identifiers Medical Records Number Other - Free text Field

PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Employees/ HHS Direct Contractors Patients Members of the public Vendors/Suppliers/Third-Party Contractors (Contractors other than HHS Direct Contractors)
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?	PII is used to contact regulated industry establishments regarding their applications while they are under review, during reviews of adverse event reports, when conducting trend analysis, and for analyzing outliers in clinical study data.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	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.	Collecting this information is necessary to meet the FDA's requirements for conducting market submission review and post market surveillance under the provisions of the Federal Food, Drug, and Cosmetic Act at 21 U.S.C. 301, see especially sections 505A, 506B, and 522. Additional information concerning these activities may be found in CBER's regulations at 21 CFR 600.80.
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.	Directly from an individual about whom the information pertains Online Government Sources Within the OPDIV Non-Government Sources 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 Approval number 0910-0014 with expiration date 03/31/2025. OMB Approval number 0910-0001 with expiration date 03/31/2027.
PIA - 10B:	Identify the OMB information collection approval number expiration date.	3/31/2025
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.	Individuals can opt out of the clinical trials that record the relevant PII patient data. This option and the process for doing so are provided to these individuals via consent forms provided by the trial sponsor. This occurs prior to submitting this information to FDA, and FDA does not have oversight of this part of the consent process. Industry points of contact provide PII as a mere convenience. No individual is required to provide this information, although FDA requests this information to facilitate communications with regulated industries. FDA personnel whose PII is in the system would be unable to perform their duties if they opted not to provide their PII.
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 FDA changes its practices with regard to the collection or handling of PII related to the website, 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 e-mail 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.	Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system may contact FDA offices, including the Privacy Office, the Employee Resource and Information Center (ERIC, FDA personnel only), the Cybersecurity Infrastructure Operations Coordination Center (CIOCC) and other agency offices, via email, phone and standard mail (all listed on fda.gov and the FDA intranet). In the event of a suspected incident or data breach, FDA personnel must report immediately to the FDA's CIOCC.

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.	FDA personnel may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. PII relevancy is supported through the design of the system to require and collect only the PII elements necessary to administer the system and enable its intended use. 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.
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.	Users have access to PII in the course of reviewing applications for regulatory and scientific merit. Administrators ensure the proper controls are in place for user access, but administrators do not review industry-submitted content or FDA analysis of that content. Developers build new capabilities for reviewers to use, but they do not review industry-submitted content or FDA analysis of that content. Direct Contractors are sometimes developers and have access only to such material as developers have.
PIA - 19:	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 the system must obtain 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.	The relevant supervisor will indicate 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 - 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 Control schedules are maintained for all data that traverses CBER Connect during the submission review process. Updating and maintaining those records schedules is the responsibility of CBER's Document Control Center (DCC) staff. The records schedules for the data processed in CBER Connect as follows: Investigational Files: FDA Schedule item B-10 N1-088-03-05 Biologic License Applications Files: The records are destroyed 30 years after being withdrawn or terminated. FDA Schedule item B-31 N1-088-03-05: The records are destroyed or revoked after 10 years. Master Files (FDA Schedule item B- 20 N1-088-03-05): The destruction of records in the system is done by withdrawing or terminating the records after 30 years. New Drug Applications (FDA Schedule item B-21 N1-088-03-05): The records are destroyed, revoked, or withdrawn after 10 years. Pre-Market Devices (510K) (FDA Schedule item B-22 N1-088-03-05: The records are destroyed, revoked, or withdrawn after 20 years. Pre-Market Application (PMA) (FDA Schedule item B-23 N1-088-03-05): The records are destroyed, revoked, or withdrawn after 30 years. Pre-Application Submissions: This is an unscheduled item with the Records Control Schedule under development.

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.	Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.

Review & 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:**	3/10/2025
Agency Privacy Analyst Review Comments:	Reviewer: Shanai Shobowale 3/10/2025 This PIA is ready for SAOP review and approval.	**Agency Privacy Analyst Days Open:**	3

SAOP Review

SAOP Review Status:	Approved	**SAOP Signature:**	Archer Signature_Bridget Guenther.docx
SAOP Comments:		**SAOP Review Date:**	3/11/2025
		SAOP Days Open:	1

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
CBER Connect_SOP Approved.rtf	806114	.rtf	3/7/2025 1:27 PM	0
PIAs in your Queue (CDRH Center Tracking System and CBER Connect) .pdf	396656	.pdf	3/7/2025 1:27 PM	0

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 10B	Data Feed Service, piafrmfda	3/7/2025	OMB Approval number 0910-0014 with expiration date 03/31/2025. OMB Approval number 0910-0001 with expiration date 03/31/2027.	
PIA - 1	BLAND, CRYSTAL	3/7/2025	Per FDA's Email, For the CBER Connect PIA: Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” • The FDA instance of Archer is automatically entering the answer “*No*,” which is incorrect. The ATO date is *11/21/2022*. • At this time, we are unable to update Archer to reflect the correct answer “Yes.”	
PIA - 1	BLAND, CRYSTAL	3/10/2025	On the next iteration of the PIA: PIA-1: Please check or include " Biometric Identifiers and Medical notes," as mentioned in PTA-5.	

Admin Section

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

Miscellaneous Fields

Last Updated:	3/11/2025 10:22 AM	**History Log:**	View History Log