Privacy Impact Assessment (PIA): FDA - BITS-PTS - QTR1 - 2025 - FDA4915058

Created Date: 3/19/2025 4:25 PM Last Updated: 3/24/2025 4:12 PM

Copy PIA (Privacy Impact Assessment)

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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 - BITS-PTS - QTR1 - 2025 - FDA4915058	**PIA ID:**	2887851
Name of Component:	FDA - CBER Biologics Information Tracking System_PTS	**Name of ATO Boundary:**	CBER Office of Regulatory Operations
Overall Status:		**PIA Queue:**	
Submitter:		**# Days Open:**	6
Submission Status:	Submitted	**Submit Date:**	3/19/2025
Next Assessment Date:	03/23/2028	**Expiration Date:**	3/23/2028
Office:		**OPDIV:**	FDA
Security Categorization:		**OpDiv PIA ID:**	FDA4915058
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.	New
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	
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) Center for Biologics Evaluation and Research (CBER) Office of Regulatory Operations (ORO) supports CBER's mission to protect and enhance public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, cellular and gene therapies, and tracking of Post Marketing commitments related to these approved products. A wide range of users at CBER and the FDA utilize CBER ORO and the system's associated components and tools to support the FDA/CBER mission. The subject of this assessment is the CBER Pre-Application Tracking System (BITS-PTS) module. CBER BITS-PTS tracks regulatory documents and associated correspondence submitted by applicants/sponsors (firms) to obtain feedback from CBER subject matter experts (SMEs) prior to the submission of an Investigational New Drug (IND), Investigational Device Exemption (IDE), Master File (MF), Biologics License Application (BLA), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Product Development Protocol (PDP), Special Protocol Assessment (SPA) or other uncategorized submissions (e.g., draft protocol not associated with an IND or IDE). The BITS-PTS module encompasses all functions needed to support Pre-Application tracking procedures and has extensive links to the following existing CBER systems (all of which have been assessed separately): CBER Regulatory Meetings Tracking System (CRMTS), CBER Regulatory Management System-Document Accountability and Tracking System (RMS-DATS), CBER Biologics Investigational and Related Applications Management Systems (BIRAMS) (to include Biologics IND (Investigational New Drug Applications), CBER RMS- Biologics Licensing Application (RMS-BLA), CBER Electronic Repository (CER) and the CBER Connect User Interface (UI). System users are FDA permanent employees and Direct Contractors.

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 BITS-PTS provides users with the ability to track sponsor materials, CBER documents, and meeting requests associated with a submission that is not an application type defined in the Code of Federal Regulations. The data is submitted by applicants to obtain feedback from CBER prior to the submission of a valid application, and the submission may or may not be associated with a future regulatory application. The Pre-Applications Module enables CBER wide insight into this Pre-Application work and facilitates the sharing of relevant information across offices. Information collected by the system includes personally identifiable information (PII). The system collects the following PII about applicants, points of contact (POC) and/or sponsors/authorized representatives: (a) name; (b) business address; (c) business phone number; (d) business fax number; (e) DUNS #; and (f) business email address. Non-PII includes details regarding clinical investigations, product information and facility information. PII is not used to retrieve system records. Users can search for a specific Pre-Application by the Receipt Date, Product Name, Indication, Product Class (RRS), Product Office, PTS# (firm case number). Information collected is stored according to approved CBER Records Control Schedule as approved by the National Archives and Records Administration (NARA).
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 BITS-PTS tracks applicant/sponsor(firms) materials and CBER documents associated with a submission that is not an application type defined in the Code of Federal Regulations. The submission may or may not be associated with a future regulatory application. Information collected includes Pre-Application, Pre-Submission, Communications, and Amendment data. The system collects the following PII about applicants/sponsor (firms) point of contact (POC) and/or authorized representatives: (a) name; (b) business address; (c) business phone number; (d) business fax number; (e) DUNS #; and (f) business email address.
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.	CBER BITS-PTS is a front-end web application that allows the end user to enter data and track sponsor materials and CBER documents associated with a submission that is not an application type defined in the Code of Federal Regulations. The submission may or may not be associated with a future regulatory application. Only CBER full- time employees and Direct Contractors with specific access and role will be able to access the system. Users' login to CBER BITS-PTS via Uniform Resource Locator (URL) using Single Sign-On (SSO) authentication.
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 Other - Free text Field Others - Chart No., TIN, DUNS, Provider License #
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	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?	The FDA uses the PII in BITS-PTS for the primary purpose of tracking the Applicant/Sponsor POC for Pre-Application submissions.
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.	The implementation of this application is authorized by 5 U.S.C. 301, Federal Food, Drug and Cosmetic Act, 21 USC 353, 356b, 360; and the Public Health Service Act, 42 USC 263a. In addition, the security and privacy measures of the applications are required by the Federal Information Security Modernization Act (FISMA) and the statutes underlying OMB Circular A-130 for the secure and efficient use of government systems and resources.
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 Hard Copy Mail/Fax Email

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 Information Collection Approval Numbers are: 1) 0910-0014 2) 0910-0001
PIA - 10B:	Identify the OMB information collection approval number expiration date.	9/30/2026
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.	External individuals submitting biologic product reports are not mandated to submit any PII except for a point of contact name and telephone number. This information is used to contact people to clarify data regarding their submissions. This information is provided as a convenience to aid in communications and is "voluntary" as that term is used by the Privacy Act. There is no method for employees to opt out of submitting their PII. While submission is "voluntary" as that term is used by the Privacy Act, permanent employees, Direct Contract employees, fellows and other personnel must provide their PII in order for the Agency to process administrative materials and securely administer access to Agency information and property.
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 a major change in the collection and use or sharing of PII data for this application occurs, users will be notified via individual e-mail notification or in updated notice statements on submission forms and Federal Register publications. However, no such changes that would affect the rights or interests of the individuals are anticipated.

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 have many avenues available for assistance. These individuals may contact FDA offices, including the Privacy Office, the Employee Resource and Information Center (ERIC, FDA personnel only), the Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) (FDA personnel only) and other agency offices, via email, phone, and standard mail (all listed on FDA.gov and the FDA intranet). Any changes to an individual's name or address would need to be updated using a Standard Form 50 or 52, which is the process used to make such changes used by all FDA employees, and the data would be updated in the separate human resources information system. In the event of a suspected incident or data breach, FDA personnel must report without delay to the FDA's Cybersecurity and Infrastructure Operations Coordination Center (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.	PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of reporting. FDA personnel may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. 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 security controls selected and implemented during 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. CBER performs annual reviews to evaluate user access. One of the controls includes information system backups reflecting the requirements in contingency plans as well as other agency requirements for backing up information. Data discrepancies identified during system use are addressed when discovered.
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 require access in order to view pre/post application. Administrators require access to provide assistance to users unable to submit applications; troubleshoot system issues and perform job duties. Developers require access to the system to perform job duties. Direct Contractors require use to perform job duties (some administrators and developers are Direct Contractors).
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	System users (FDA employees 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.	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. All users are FDA network users and must have a current Personal Identity Verification (PIV) compliant badge.
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).	System users receive system-specific training and review the Department of Health and Human Services (HHS) 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).	CBER Records Control Schedule (National Archives and Records Administration NARA Schedule No. N1-088-03-05) Items b-34, Post Marketing Products Safety Reviews and Adverse Event Summaries, and b-35, Post-Marketing Surveillance Lot Analysis Reports. Records are retired to the Washington National Records Center three years after the cutoff date and destroyed 20 years after the cutoff date.

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:**	3/19/2025
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:**	3/19/2025
		SOP Days Open:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	**Agency Privacy Analyst Review Date:**	3/20/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 3/20/2025 This PIA is ready for SAOP review and approval.	**Agency Privacy Analyst Days Open:**	1

SAOP Review

SAOP Review Status:	Approved	**SAOP Signature:**	Archer Signature_Bridget Guenther.docx
SAOP Comments:		**SAOP Review Date:**	3/24/2025
		SAOP Days Open:	4

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
PIA IN QUEUE (CBER BITS-PTS_FDA - BITS-PTS - QTR1 - 2025 - FDA4915058).pdf	243061	.pdf	3/20/2025 9:44 AM	1

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 10B	Data Feed Service, piafrmfda	3/19/2025	Note: There are two expiration dates associated with this collection. As users are not able to enter multiple expiration dates using the drop-down menu provided, I have included the additional date below: 0910-0001 expires 8/31/2028	
PIA - 1	BLAND, CRYSTAL	3/20/2025	The subject PIA is SOP approved and should be in your queue. Please note the PIA is experiencing an Archer error when reporting the response for Question #3 of the general information section. 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.” The FDA Archer Team is aware of this occurrence and is working on a solution.	
PIA - 1	VILLAFUERTE, NESTOR	3/20/2025	Reviewer notes that Chart number and TIN was not mentioned in the PTA.	
PIA - 1	BLAND, CRYSTAL	3/20/2025	TIN and Chart Number are not collected but the DUNS number is collected which is why the category was selected.	

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:	3/24/2025 4:12 PM	**History Log:**	View History Log