PTA / PIA: FDA - BITS-PTS - QTR3 - 2025 - FDA4949895

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General Information

PTA / PIA Name:	FDA - BITS-PTS - QTR3 - 2025 - FDA4949895	**PTA / PIA ID:**	3604202
Component Name:	FDA - CBER Biologics Information Tracking System_PTS	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	3
Submitter:		**Submit Date:**	8/5/2025
Next Assessment Date:	08/07/2028	**Expiration Date:**	8/7/2028
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.	11/21/2022
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	Christopher Kiem
PTA 01A:	POC Title and Organization	System Owner FDA/CBER
PTA 01B:	POC Email Address	Christopher.Kiem@fda.hhs.gov
PTA 01C:	POC Phone Number	240-402-8093
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.	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 (BITSPTS) 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 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.	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 05A:	Are user credentials used to access the system?	Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this system.
PTA 05C:	Please identify the system that maintains the user credentials or controls access to this system.	Active Directory
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.	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 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).	https://cberapex.fda.gov/

PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No
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.	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 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 Contact Information Email Address (Business) Mailing Address (Business) Phone Numbers (Business) Other Other
PIA 22A:	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Other - FAX Number
PIA 23:	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 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	50,000 – 99,999

PIA 25:	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 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.	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 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.	Directly from an individual about whom the information pertains Hard Copy Mail/Fax Email
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
PIA 31A:	Provide the information collection approval number(s) and expiration date(s).	0910-0014 expiration date: 09/30/2026 0910-0001 expiration date: 07/31/2027
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.	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 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.	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 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.	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 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.	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 (rolebased 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 38:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
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.	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 40:	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 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.	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 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.	System users receive system-specific training and review the Department of Health and Human Services (HHS) Rules of Behavior. Additional rolebased training on privacy is available via FDA's privacy office.
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).	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 45:	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 and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	8/5/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	8/5/2025
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:**	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	8/8/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 8/8/2025 No comments, this PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	3

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	8/8/2025
SAOP Review Comments:	Approved on behalf of the SAOP	**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/8/2025 8:43 AM	BLAND, CRYSTAL	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	BLAND, CRYSTAL	8/6/2025	Per FDA's EMAIL: The attached PIA is SOP approved and should be in your queue. This PIA was SAOP approved on 3/24/2025 but needed to be entered in Archer 4.0 because of a sync issue.	8-5-2025 EMAIL_PIA in Queue (CBER Biologics Information Tracking System_PTS).pdf CBER Biologics Information Tracking System_PTS_8.5.2025.pdf FDA - BITS-PTS - QTR1 - 2025 - FDA4915058.pdf