PTA / PIA: FDA - BITS-URVR - QTR2 - 2025 - FDA4921174

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General Information

PTA / PIA Name:	FDA - BITS-URVR - QTR2 - 2025 - FDA4921174	**PTA / PIA ID:**	3155356
Component Name:	FDA - CBER Biologics Information Tracking System_URVR	**ATO Boundary Name:**	CBER Office of Regulatory Operations
Overall Status:	Complete	**# of Days - Open:**	3
Submitter:		**Submit Date:**	5/9/2025
Next Assessment Date:	05/11/2028	**Expiration Date:**	5/11/2028
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	POC Title: Business Owner POC Organization: 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.	PIA Validation (PIA Refresh)

PTA 02A:	Describe in further detail any changes to the system that have occurred since the last PIA.	FDA has made no changes to this system/component since the last Privacy Threshold Analysis/Privacy Impact Assessment was approved.
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.	This assessment addresses the Biologics Information Tracking System-Unified Requalification and Variance Requests (BITS-URVR) application and associated business tool, the BITS-Device Submission Tracking (DST) application. BITS-URVR is a component of the Center for Biologics Evaluation and Review (CBER) Office of Regulatory Operations (ORO) system. BITS-URVR tracks and stores information on Blood Donor Requalification and Blood Variance Request document types and enables tracking of metadata associated with variance and blood donor requalification requests. The BITS-URVR enables the Office of Blood Research and Review (OBRR) staff to more effectively and efficiently track metadata associated with 21 The Code of Federal Regulations (CFR) 640.120 variance and blood donor requalification requests. BITS-URVR works together with the CBER BITS-DST, a web-based application that enhances BITS-URVR review capabilities. As a business tool, BITS-DSTis used within the URVR component to improve the review processes associated with medical device submission (501ks only). BITS-DTS does not collect, maintain, or store any information.
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.	Filings handled in this system consist of submissions seeking various Food and Drug Administration (FDA) approvals. An Investigational New Drug Application (IND) is a request for FDA to permit the applicant to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application (NDA) or Biologics/Product License Application (BLA). An investigational device exemption (IDE) allows the investigational device to be used in a clinical study to collect safety and effectiveness data. A “510(k)” submission is a premarket submission to FDA to demonstrate that the device to be marketed is, substantially equivalent to (at least as safe and effective) a legally marketed device that is not subject to a pre-market approval, which requires Submitters to compare their device to one or more similar legally marketed devices to support their substantial equivalency claims. A drug/device master file (DMF) is a confidential, detailed document submitted to the FDA by Active Pharmaceutical Ingredient (API) manufacturers. A DMF contains the chemistry, manufacturing, and controls of a drug component or the product (e.g., ingredient, subassembly, or accessory) or facility in the manufacture of the device. The information in a DMF may be used to support other submissions

		such as an IND or NDA. Another type of submission includes requests for an Emergency Use Authorization (EUA). Per the federal Food, Drug and Cosmetics (FD&C) Act, FDA strives to protect against chemical, biological, or radiological/nuclear agent (CBRN) threats by facilitating the availability and use of Medical Countermeasures (MCMs) during public health emergencies. By law, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives. A "Blood Variance Request" is a petition for exemption from requirements (methods, facilities, controls) proposed for the manufacture, packing, storage, and use of a blood product, to ensure the product will be safe and effective for public consumption; a Blood Donor Requalification is a request to allow a previously deferred donor to donate blood if the donor meets the eligibility criteria. The request is submitted to the FDA for approval along with supporting documents and test results. Personally Identifiable information (PII) and Non-PII is maintained in BITS-URVR. Information collected related to the review status of submissions for the approval of devices and products includes the following: applicant name, points of contact, business/personal phone number, fax number, employment status/credentials, product name, facility details and promotional materials, facility/physical address, business/personal e-mail addresses, and CBER contact names. This system also tracks documents and files related to submissions throughout their regulatory and records management lifecycle. BITS-URVR may also contain the PII of patients or subjects that have taken part in a clinical trial (e.g., an adverse event report may be submitted with PII). PII may include name, date of birth, email address, phone number, and mailing address.
PTA 05A:	Are user credentials used to access the system?	Yes
PTA 05B:	Please identify the type of user credentials used to access the system.	HHS User Credentials HHS/OpDiv PIV Card

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.	This Regulatory Filing system maintains information related to the review status of submissions for the approval of devices and products which include applicant name, points of contact, phone number, fax number, credentials, product name, facility details and promotional materials, facility/physical address, e-mail addresses, and CBER contact names. This system also tracks documents and files related to submissions throughout their regulatory and records management lifecycle. BITS-URVR may contain the personally identifiable information (PII) of patients or subjects that have taken part in a clinical trial (e.g., an adverse event report may be submitted with PII). FDA does not request this information from reporters/subjects. Where provided, reporters/subjects provide this information on a voluntary basis.
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.	The purpose of the website is to enable the Office of Blood Research and Review staff to more effectively and efficiently track metadata associated with 21 The Code of Federal Regulations (CFR) 640.120 variance and blood donor requalification requests.
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.	Biographical Information Name Date of Birth Employment Status/History Contact Information Email Address (Personal) Mailing Address (Personal) Phone Numbers (Personal) 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.	Fax number
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors Members of the public
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	500 – 4,999
PIA 25:	For what primary purpose is the PII used?	Data collected by these systems is used for organizing and holding meetings, tracking contacts and subjects, reporting safety progress, tracking submission receipt, tracking quality control and workflow.
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 use of these applications is authorized by various sections of the FD&C Act. It may be helpful to the reader to be familiar with the implementing regulations of that Act that affect each type of submission accepted by FDA's CBER: IND: Title 21 Code of Federal Regulations (CFR) part 312; IDE: Title 21CFR part 812; MF: Title 21CFR parts 814.3 & 314.420 EUA: sections 564, 564A, and 564B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended & added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) See also Title 21 CFR parts 600-680 See also Title 21 CFR parts 640.120 The implementation of these applications 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. In addition, the security and privacy measures of the applications are required by the Federal Information Security Management 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.	Government Sources Within the OPDIV Non-Government Sources Members of the Public Private Sector
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).	OMB# 0910-0338 (10/31/2026) OMB# 0910-0543 (02/28/2026) OMB# 0910-0458 (02/28/2026) OMB# 0910-0308 (09/30/2027)
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.	There is no method for employees to opt out of submitting their PII. Permanent employees, 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. External individuals submitting comments to the Federal Register are not mandated to submit any PII. External individual (non-employees) submitters were notified on forms they submitted (no longer in use), in Federal Register publications (e.g., comment submission guidance and SORNs), privacy statements on the FDA.gov and in other resources provided on FDA.gov. FDA's Federal Register notices inform individuals of the procedures for commenting on a notice and advise that submitted comments may be made public.
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, FDA-wide e-mail and/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.	FDA personnel may resolve such concerns by contacting the appropriate system administrator, FDA's Employee Resources and Information Center (ERIC) or FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC). 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. External individuals may use any of a number of avenues to raise concerns, including contacting FDA offices through FDA.gov (phone, mail, mail and by using information provided on forms submitted by individuals. External individuals submitting comments to the Federal Register are not mandated to submit any PII. FDA's Federal Register notices consistently inform individuals of the procedures for commenting on a notice and advise submitters that submitted comments are published in full, including PII and any other information submitters choose to include in their comments. The need for each item of PII has been assessed as part of the process of accessing public burden in the course of submitting the standard form for OMB Paperwork Reduction Act (PRA) approval and all information collected has been confirmed to be necessary to the business purpose of the application.

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.	Patients' 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 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 to the system in order to track and monitor submissions for regulatory approval. Note that "users" may include subject individuals, supervisors, or business function administrators. Administrators may be application administrators who require access to to conduct business functions, or application administrators who require access in order to create and manage user accounts for specific applications. Some developers may be direct contractors and will have access under the same circumstances as developers. Developers will not normally have access to PII, but may in the course of maintaining the systems or providing technical assistance.

PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Users who require access to the application need to have supervisor approval and sign off before access is granted. The user's supervisor will use an account creation form to specify the minimum application access that is required in order for the user to complete his/her job. The agency reviews the access list for the application on a quarterly basis to review and adjust users' access permissions, and to remove unnecessary accounts from the application.
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.	Management establishes roles for individual personnel, with role-based restrictions permitting access only to information that is required for each individual to perform his/her job.
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 Information Management and Technology (OIMT) verifies that training has been successfully completed and maintains a record of certificates of training on all FDA employees and direct contractors.
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	Help links are available within applications, and instructional materials are available on the FDA intranet for all applications. All users are instructed on adhering to the HHS Rules of Behavior in the context of their work involving this system. For additional privacy guidance, personnel may contact the Agency's privacy office. Privacy program materials are provided to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA.
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).	Files and documents are unscheduled for disposition purposes and must be retained until a new schedule is drafted and approved or a General Records Schedule can be applied.
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.	There are several controls in place for the securing of PII within the system. The administrative controls include system users completing an access request form and an access review/approval process. The technical controls include firewalls, virtual private networks (VPNs), encryption, and intrusion detection systems. The physical controls are comprised of guarded facilities, gated access to these facilities, security barriers, and locked doors.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	5/9/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	5/9/2025
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:**	5/12/2025
Agency Privacy Analyst Review Comments:	Reviewer: Crystal Bland 5/12/2025 This PIA is ready for SAOP review and approval.	**# of Days - APA Review:**	3

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	5/12/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	0

SAOP Signature

Date	User	Type	Name	Original Value	New Value
5/12/2025 1:41 PM	GUENTHER, BRIDGET	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	5/12/2025	The PIA is experiencing an Archer error with Question #3 of the general information. 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 *12/23/2022*. • 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.	5-9-2025 EMAIL_CBER Biologics Information Tracking System -URVR.pdf CBER BITS-URVR SOP approved.pdf