Privacy Impact Assessment (PIA): FDA - FEEDS - QTR2 - 2024 - FDA2128084

Created Date: 4/10/2024 4:04 PM Last Updated: 4/29/2024 3:10 PM

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 - FEEDS - QTR2 - 2024 - FDA2128084	**PIA ID:**	1802231
Name of Component:	FDA - OC Enterprise EDiscovery System	**Name of ATO Boundary:**	OC Enterprise EDiscovery System
Overall Status:		**PIA Queue:**	
Submitter:		**# Days Open:**	19
Submission Status:	Submitted	**Submit Date:**	4/10/2024
Next Assessment Date:	N/A	**Expiration Date:**	4/29/2027
Office:		**OPDIV:**	FDA
Security Categorization:		**OpDiv PIA ID:**	FDA2128084
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?	Yes
3:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	Yes
4:	ATO Date or Planned ATO Date.	1/27/2023
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.	Significant System Management Change
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	Since this Privacy Threshold Analysis (PTA) / Privacy Impact Assessment (PIA) was last approved, the FDA has migrated from an on-premises deployment of Relativity to a FedRAMP approved Cloud Service Provider (CSP) – Relativity One – as its Case Management (CM) solution.
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.	FDA Enterprise eDiscovery System (FEEDS) is an eDiscovery system that provides commercial off the shelf (COTS) tools to search, retrieve, process, and produce Electronically Stored Information (ESI) in response to litigation, administrative, Freedom of Information Act (FOIA), legislative, and investigative activities and proceedings. Requests for searches may be made by Agency attorneys, FOIA professionals, or other designated employees in accordance with Agency policy. These production requests can be extremely burdensome, often reaching back decades and can include thousands of electronic files. The eDiscovery System is designed to facilitate and automate responses to these requests, comply with eDiscovery best practices, and support agency responses in accordance with deadlines and documentation requirements set by courts or by the United States Congress, while minimizing the time and effort required to satisfy these requests and increase the accessibility of ESI. Internal Food and Drug Administration (FDA) requestors identify custodians, search terms, and date ranges likely to return records relevant to requests or investigations. Internal FDA requestors may include FDA staff, Direct Contractors, detailees , and assignees. Custodians are individuals with whom ESI is associated, such as the sender or recipient of an email. Custodians may include current and former FDA employees, Direct Contractors, detailees, assignees, and other individuals who maintain electronic profiles at the Agency. ESI associated with selected custodians is copied to the FEEDS System and, where necessary, converted to text searchable files. Users can then search the ESI using the identified search terms and dates. Responsive records are then reviewed by the internal requestor to determine whether they are relevant to a particular request. The internal requestor may then select, retrieve, and redact those files necessary for production in each request. The eDiscovery Program utilizes applications such as EnCase and Relativity to facilitate this process.
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.	The FEEDS System contains files that may be relevant to support discovery requests as mandated by both law and policy. These files are generally FDA email messages (including any attachments), FDA electronic files, and text messages from FDA phones. Should a case or investigation need it, other electronic records maintained by the Agency may also be included in FEEDS. The system is designed to extract meta data from the files loaded to the system. The FEEDS System commonly collects and stores the following PII data in searchable fields associated with the files: names, email addresses, device identifiers (from ingested mobile device data), and employment status (custodians are marked as active, for current employees / contractors, or departed, for former employees / contractors). The FEEDS System commonly collects and stores

		files that contain the following personally identifiable information (PII) within the text of the file: addresses, legal documents, and phone numbers. The contents of files within FEEDS may include other PII, however because it is not contained within the meta data of the file it is not easily identified. Because of the varied nature of the Agency's work and because electronic records could conceivably include almost any type of PII, it is not possible to list with certainty every type of ESI that will be collected or stored by the system. The most common non-PII that the system collects are all dates and times associated with file, file names, information about attachments, file size, file extension, folder path, and Hash values. FEEDS may collect and store other meta data that is available. FEEDS must collect the following PII information: name and email address for user identification. User profiles are created by system administrators (including provision of access rights). Most users are verified for basic system access using single sign-on (SSO) from Active Directory. Users with elevated privileges use AD_APP accounts and ALT_PIV cards to validate their access. The applications do not have independent passwords established by either administrators or users. The user community is comprised of administrators (a mix of full-time equivalent (FTEs) and Direct Contractors) and end users, both from the eDiscovery program and centers and offices. There are no FEEDS users external to FDA. Access to FEEDS is restricted to people with valid FDA user identification (ID). Data from FEEDS can be disclosed outside of FDA but must be reviewed by staff from Office of Chief Counsel (OCC), Office of Legislation (OL), Office of Regulatory Affairs (ORA), Office of Criminal Investigations (OCI) and Division of Freedom of Information (DFOI) to ensure that any data, including PII, that should not be disclosed is either excluded or redacted. Typically, data is disclosed to Health and Human Services (HHS) Office of Chief Counsel (for employment matters), Department of Justice (for litigation), or Congressional requestors.
PTA - 5A:	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. The system providing credentials is
PTA - 5B:	Please identify the type of user credentials used to access the system.	

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.	The FEEDS Case Management (CM) solution (Relativity) was originally hosted on-premises but has now been replaced by a FedRAMP approved Cloud Service Provider (CSP): Relativity One Government. The data collected into and maintained by Relativity on-premises is now being sent to Relativity One. Though the CSP hosts the software as a service (SaaS) solution underlying infrastructure, ownership of the data within the application and application administration responsibilities are still assigned to FDA personnel.
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)?	Yes
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 Relativity One website is the user interface for the FEEDS Case Management (CM) solution. It is hosted by a FedRAMP approved Cloud Service Provider, with a public-facing URL that is only accessible via authentication with FDA approved authentication mechanisms (i.e., FDA Enterprise SSO). Access is limited to individuals with a need to access workspace-specific legal artifacts and application administrators.
PTA - 10:	Does the website have a posted privacy notice?	No
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 Legal Documents Devices Identifiers Employment Status
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Business Partners/Contacts (Federal, state, local agencies) Employees/ HHS Direct Contractors 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.	501 - 2000
PIA - 4:	For what primary purpose is the PII used?	Although PII is present within the ESI gathered in FEEDS, FDA does not make an affirmative use of such PII other than that of stakeholders/users which is used to support their role in agency responses to litigation, and administrative, legislative, and investigative activities and proceedings (e.g., associating a user's name and office with the relevant case action in FEEDS). To the extent it may be considered a “use,” stakeholder offices disclose the PII contained in ESI in FEEDS as permitted by law and as required to comply with applicable authorities such as the Federal Rules of Civil Procedure (FRCP) and court orders.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	FDA makes no secondary uses for any 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.	5 U.S.C. 301, 44 U.S.C. sections 2904 and 3102 for the authority to conduct actions to maintain and gather records to satisfy legal requirements such as those imposed upon agencies, e.g., the Freedom of Information Act (FOIA), 5 U.S.C. 552; Federal Rules of Civil Procedure (FRCP); and the US Constitution (implied power of Congress to investigate; oversight of government agencies).
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	Yes
PIA - 8A:	Please specify which PII data elements are used to retrieve records.	Name and Email Address.
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.	The following System of Records Notice(s) (SORN) are used to cover this system: 09-10-0002 (Regulated Industry Employee Enforcement Records, HHS/FDA) 09-10-0013 (Employee Conduct Investigative Records, HHS)
PIA - 9:	Identify the sources of PII in the system.	Government Sources Within the OPDIV
PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA - 10A:	Provide the information collection approval number.	
PIA - 10B:	Identify the OMB information collection approval number expiration date.	
PIA - 10C:	Explain why an OMB information collection approval number is not required.	This tool is used interna so there aren't any Paperwork Reduction Act (PRA) implications.
PIA - 11:	Is the PII shared with other organizations outside the system's Operating Division?	Yes
PIA - 11A:	Identify with whom the PII is shared or disclosed.	Other Federal Agency/Agencies Within HHS
PIA - 11B:	Please provide the purpose(s) for the disclosures described in PIA - 11A.	Data is disclosed to HHS Office of Chief Counsel (for employment matters), Department of Justice (for litigation), or Congressional requestors to satisfy legal requirements such as those imposed upon agencies, e.g., the Freedom of Information Act (FOIA). 5 U.S.C. 552; Federal Rules of Civil Procedure (FRCP); and the US Constitution (implied power of Congress to investigate; oversight of government agencies).
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)).	N/A
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.	Disclosures are tracked for content and delivery in eDiscovery case records and the FEEDS system: what data was exported, when it was exported, and to whom it was delivered.
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.	The collection of the PII is necessary for FDA to search, collect, retrieve, process, review and produce data in response to litigation, administrative, FOIA, legislative, and investigative activities and proceedings.
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.	There is no opt-out process for this system. The collection of the PII is necessary for FDA to search, collect, retrieve, process, review and produce data in response to litigation, administrative, FOIA, legislative, and investigative activities and proceedings. Regulated entities are required by law to register and to submit information necessary to administer the registration process. FDA personnel and Direct Contractors consent to the submission and use of their information by HHS/FDA as a condition of employment. Personnel who opt not to provide PII would not be able to perform their assigned duties and maintain employment in their position.
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.	The offices operating systems which are the source of ESI gathered via FEEDS are responsible for providing any required notice to individuals.
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), the Cybersecurity and Infrastructure Operations Coordination Center (CIOCC) and other agency offices, via email, phone and standard mail avenues (all listed on fda.gov and the FDA intranet). In the event of a suspected or confirmed incident or data breach, FDA personnel must report that without delay 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.	The source systems that the FEEDS system collects its data from have their own dedicated processes for the reviews of PII they maintain. Source systems are not within the scope of this PIA. As part of the ongoing ATO process for FEEDS there are controls in place to ensure the integrity and availability of the data in FEEDS. Accuracy of the data is ensured via the standard operating procedures (SOPs) used by the eDiscovery office when collecting and handling the PII.
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: FDA personnel (attorneys, legal staff, FOIA, and Office of Legislation staff) who are authorized to review data housed in the system pursuant to a lawful request. Administrators: Manage the system, control access, helpdesk support and completion reports. Developers: System maintenance and enhancement. Contractors: Project Management and system administrators (eDiscovery team) which may include security cleared Direct Contractors.
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 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 individuals successfully complete the training.
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 (ROB). 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).	Documents and other materials contained within the FEEDS system are copies and are classified as duplicates subject to the authority of 44 U.S.C 3301. As such, there is no applicable retention obligation for data contained within FEEDS. FDA retains materials in the system only for as long as an active litigation hold is in place or as otherwise needed for the short-term support of the user. If, during final production of the data set, new records are created, it is incumbent upon the stakeholder/user (office requesting data collection) to retain the data set in accordance with applicable retention schedules for the type of data sets. Examples of the materials temporarily held in FEEDS and the related records schedules that would be applied by the user offices include: FDA Suit Files with Precedential Value (records control schedule DAA-0468-2012-0009-0005), FDA Suit Files without Precedential Value (DAA-0468-2012-0009-0006), Litigation Case Files with Precedential Value (DAA-0468-2012-0009-0018), Litigation Case Files without Precedential Value (DAA-0468-2012-0009-0019), and, Access and disclosure requests (DAA-GRS-2016-002-001).
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 role bases access restriction, 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 uses of firewalls, access controls, encryption of files, certificates or logs, and regular testing of information technology systems. Physical controls include that all system servers are located at FDA 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:**	4/10/2024
Privacy Analyst Comments:		**Privacy Analyst Days Open:**	

SOP Review

SOP Review Status:	Approved	**SOP Signature:**	
SOP Comments:		**SOP Review Date:**	4/10/2024
		SOP Days Open:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	**Agency Privacy Analyst Review Date:**	4/11/2024
Agency Privacy Analyst Review Comments:	Reviewer: Jim Laskowski 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:**	4/29/2024
		SAOP Days Open:	18

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
4-17-2024_EMAIL_RE_ FDA PIA_ FDA - FEEDS - QTR2 - 2024 - FDA2128084.pdf	251275	.pdf	4/17/2024 2:09 PM	0
OC Enterprise eDiscovery System_PIA_SOP_Approved.pdf	187598	.pdf	4/11/2024 8:05 AM	0

Comments

Question Name	Submitter	Date	Comment	Attachment
No Records Found				

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:	4/29/2024 3:10 PM	**History Log:**	View History Log