PTA / PIA: FDA - RPAaaS - QTR2 - 2025 - FDA4916509

Created Date: 4/14/2025 8:37 AM Last Updated: 4/16/2025 8:48 PM

## General Information

| | | | |
|---|---|---|---|
| **PTA / PIA Name:** | FDA - RPAaaS - QTR2 - 2025 - FDA4916509 | **PTA / PIA ID:** | 3014532 |
| **Component Name:** | FDA - OC Robotic Process Automation as a Service | **ATO Boundary Name:** | OC Robotic Process Automation as a Service |
| **Overall Status:** | Complete | **# of Days - Open:** | 5 |
| **Submitter:** | | **Submit Date:** | 4/11/2025 |
| **Next Assessment Date:** | N/A | **Expiration Date:** | 1/1/2100 |
| **Office:** | | **OpDiv:** | FDA |
| **Security Categorization:** | Moderate | | |
| **Make PIA available to Public?:** | No | **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? | Yes |
| **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. | 9/8/2023 |
| **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 | Michael T Phillips |
| **PTA 01A:** | POC Title and Organization | POC Title: IT Project Manager<br>POC Organization: OC/OIMT |
| **PTA 01B:** | POC Email Address | michael.phillips@fda.hhs.gov |
| **PTA 01C:** | POC Phone Number | 301-796-7848 |
| **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 purpose(s) of the OC Robotic Process Automation as a Service (RPAaaS) is to provide infrastructure and software for automating FDA business functions by tenant groups. The tenant groups / systems include however:<br><br>1. OC Office of Digital Transformation (ODT) Division of Application Servies Safety Inventory and Protocol System, replaced by ICIMS- Inventory Control and Information Management System<br>2. OC ODT, Division of Infrastructure Operations, Ease Time and Attendance (ETA) Model<br>3. Center for Biologics Evalution and Research (CBER) Business and Tools Analysis Improvement (BPTI) Project<br>4. CBER Division of Information Technology - Technology Integration and Delivery Branch (DIT-TIDB)<br>5. Center for Drug Evaluation and Research (CDER) CDER Budget and Acquisition Planning System (CBAPS)<br>6. Center for Devices and Radiological Health (CDRH) Acquisition and Administrative Planning System (CAAPS)<br>7. CDRH Division of Technology and Data Services (TDS) Operations and Maintenance (O&M)<br>8. Human Foods Program (HFP) (formerly Center for Food Safety and Applied Nutrition (CFSAN)) Core Analytics Research Application (CARA)<br>9. Center for Veterinary Medicine (CVM) Automate<br>10. OC Integrated Budget and Acquisition Planning System (IBAPS)<br><br>This list is not all inclusive because additional FDA tenant groups may be added.<br><br>The relationship of this system to other FDA systems/components/information collections is determined by the owners of those systems when/if they decide to use RPAaaS functionality to automate their operations.<br><br>The key functional elements of the system include a central Orchestrator system and attended or unattended robot systems which run automations. The central Orchestrator system provides licensing and scheduling for UIPath based robotic process automations.<br><br>System “users” consist of FDA employees and 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. | OC RPaaS collects personally identifiable information (PII). The types of information collected and maintained by the system are FDA personnel (permanent employees and Direct Contractors) emails and names.<br><br>The types of data that are maintained in and/or shared from the system is/are: N/A - nothing is maintained or shared.<br><br>The amount of time the PII is stored in the system is: names and email addresses are retained until users offboard. |
| **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. | Email and names of users (FDA permanent employees and Direct Contractors) is collected and/or maintained in order to allow them into the system and keep track of them.<br><br>PII from the system is not shared. |
| **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://rpa.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 provide licensing and scheduling for UIPath based robotic process automations.<br><br>The following categories of individuals have access to the website: automation developers and users.<br><br>Users access the website via an intranet only website with Active Directory integrated single-sign-on. |
| **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 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<br>Name<br>Contact Information<br>Email Address (Business) |
| **PIA 23:** | Indicate the categories of individuals about whom PII is collected, maintained, or shared. | Employees/HHS Direct Contractors |
| **PIA 24:** | Indicate the approximate number of individuals whose PII is maintained in the system. | 100 – 499 |
| **PIA 25:** | For what primary purpose is the PII used? | The FDA uses the PII for the primary purpose of granting access to the application. |
| **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 legal authorities that govern information use and disclosures specific to the system and program is 5 U.S.C.301. |
| **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<br>Online<br>Government Sources<br>Within the OPDIV |
| **PIA 31:** | Is there an Office of Management and Budget (OMB) information collection approval number? | No |
| **PIA 31B:** | Explain why an OMB information collection approval number is not required. | The system does not collect information on members are the public and there are no forms in use. Therefore, the system is not subject to the Paperwork Reduction Act (PRA). |
| **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 users of the application (FDA permanent employees and Direct Contractors) to opt out of submitting their PII. Submission is voluntary and users must provide their PII in order to use OC RPAaaS. |
| **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. | While no major changes are anticipated, if a major change in the system and use of PII occurs, users will be notified via email to their FDA email addresses. |

| | | |
|---|---|---|
| **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), FDA's Cybersecurity and Infrastructure Operations Coordination Center (CIOCC), the FDA Privacy Office, and other FDA offices using contact information provided on all FDA internet and intranet pages.<br><br>All FDA personnel are required to rapidly report any suspected or actual breach of PII or security incident. |
| **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. | Individuals who submit their PII do so voluntary. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at 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 privacy and security controls selected and implemented during the authorization to operate process. 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.<br><br>OC performs quarterly review of user access and removes users who no longer require access. |
| **PIA 38:** | Identify who will have access to the PII in the system. | Users<br><br>Administrators<br><br>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 PII about themselves and other users to for collaboration purposes when working on UIPath automations.<br><br>Administrators require access to PII about users to add and remove users from the system. Some administrators are Direct Contractors. |
| **PIA 40:** | Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII. | Any user in a tenant can see the names and email addresses of other users in the tenant. System administrators can see this for all tenants. Users are added via a ticket or email request to a tenant. System administrators are added via the Role Based Accessed Control (RBAC) process. |

| | | |
|---|---|---|
| **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. | The following technical methods are in place to allow those with access to PII to only access the minimum amount of information necessary to perform the job: users can only view names and email addresses of other in their center specific tenant. |
| **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. The Office of Information Management and Technology (OIMT) verifies that training has been successfully completed. |
| **PIA 43:** | Describe the training system users receive above and beyond general security and privacy awareness training. | There is no additional system-specific training received by users; however they may use the self-service UIPath Academy for self-guided training (available at https://academy.uipath.com/). This is not a formal part of the RPAaaS offering. |
| **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). | Records are managed in accordance with National Archives and Records Administration (NARA) general records schedule (GRS) 3.2, Item 030-System Access Records. Disposition: TEMPORARY. Destroy when business use ceases. |
| **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 securing PII within the system. Administrative controls include user access request and approval process. PII stored in the database is stored and secured via RBAC process. Technical controls include the use of (Amazon Web Services) AWS firewall and security groups. The physical controls are comprised of storage of data in AWS cloud with inherited physical security controls from AWS. |

## Review and Comments

### OpDiv Privacy Analyst Review

| | | | |
|---|---|---|---|
| **Privacy Analyst Review Decision:** | Approved | **Privacy Analyst Review Date:** | 4/11/2025 |
| **Privacy Analyst Review Comments:** | | **# of Days - PA Review:** | 0 |

### SOP Review

| | | | |
|---|---|---|---|
| **SOP Review Decision:** | Approved | **SOP Review Date:** | 4/14/2025 |
| **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:** | 3 |

### Agency Privacy Analyst Review

| | | | |
|---|---|---|---|
| **Agency Privacy Analyst Review Decision:** | Approved | **Agency Privacy Analyst Review Date:** | 4/16/2025 |
| **Agency Privacy Analyst Review Comments:** | Reviewer: Nestor Villafuerte<br><br>4/16/2025 This PIA is ready for SAOP review and approval. | **# of Days - APA Review:** | 2 |

### SAOP Review

| | | | |
|---|---|---|---|
| **SAOP Review Decision:** | Approved | **SAOP Review Date:** | 4/16/2025 |
| **SAOP Review Comments:** | | **# of Days - SAOP Review:** | 0 |

### SAOP Signature

| Date | User | Type | Name | Original Value | New Value |
|---|---|---|---|---|---|
| 4/16/2025 1:30 PM | 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 | 4/15/2025 | Per FDA's EMAIL:<br>• The PIA is experiencing an Archer error with Question #3 of the general information.<br>Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)?”<br>• The FDA instance of Archer is automatically entering the answer “*No*,” which is incorrect. The ATO date is *9/8/2023*.<br>• At this time, we are unable to update Archer to reflect the correct answer “Yes.”<br>The FDA Archer Team is aware of this occurrence and is working on a solution. | |