


General Information		
PTA / PIA Name:	FDA - GMVS - QTR3 - 2025 - FDA4949998	PTA / PIA ID: 3639723
Component Name:	FDA - HFP GenomeTrakr Metadata Validation System	ATO Boundary Name: HFP Amazon Web Services East Applications
Overall Status:	Complete 	# of Days - Open: 21
Submitter:		Submit Date: 8/12/2025
Next Assessment Date:	08/28/2028	Expiration Date: 8/28/2028
Office:		OpDiv: FDA
Security Categorization:	Low	
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.	7/3/2025
General 05:	Is the system or electronic information collection, agency or contractor operated?	Agency
History Log:	View History Log	

Privacy Threshold Analysis		
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PTA 01:	Point of Contact (POC) Name	Ruth Timme
PTA 01A:	POC Title and Organization	FDA Project Manager, HFP
PTA 01B:	POC Email Address	Ruth.Timme@fda.hhs.gov
PTA 01C:	POC Phone Number	240-381-6974
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.	N/A
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.	<p>GMVS is available to the public and internal FDA users to automate the metadata validation process. The GMVS system has two interfaces, one that is externally facing and provides external registered users the ability to submit sequencing requests for sequencing that is to be done by HFP staff members. The external interface also provides metadata validation capabilities for both sequencing requests as well as sequencing that will be completed by the external user's institution. The external interface does not provide any administrative functionality and is not granted any modification privileges.</p> <p>The second interface for the GMVS system provides the administrative functionality for the application including defining the metadata validation schema, approving requests, etc. This interface is only accessible from the FDA's Intranet and only by specific FDA staff members</p>
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.	<p>GMVS collects the following PII information: (a) First Name; (b) Last Name; (c) Business Email Address and; (d) Institution. The PII data is / is not shared with any other system or organization.</p> <p>GMVS also collects the following non-PII data: (a) HFP Contact; (b) HFP Project; (c) NCBI Bio Project; (d) Sample Type; (e) Number of Isolates; (f) Sequencing Platform; (g) CARTS ID; (h) Shipping Date; (i) Tracking Number. This data is shared/sent with the GIMS system. Additionally, the system allows users to upload the NCBI metadata sample sheet for validation and submission to GIMS/NCBI, and the BioNumerics metadata sample sheet for validation and submission to the CDC. The metadata sample sheets do not contain PII.</p>
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.	<p>For internal FDA users it is in AD / FDA's SSO.</p> <p>For External users its AWS Cognito.</p>
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.	PII contact information is collected for users who register to use the system include their First Name, Last Name, Business contact email, and Institution.
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://gmvs.fda.gov/
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	Yes

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.	GMVS is a web-based online application available to the public and internal FDA users that automates the metadata validation process. The GMVS externally facing system provides external registered users the ability to submit sequencing requests for sequencing that is to be done by HFP staff members. The external interface also provides metadata validation capabilities for both sequencing requests as well as sequencing that will be completed by the external user's institution.
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 Contact Information Email Address (Business) Other Other
PIA 22A:	Identify the "other" type(s) of personally identifiable information (PII) not mentioned in the above list.	Institution
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.	<100
PIA 25:	For what primary purpose is the PII used?	The system requests the First Name, Last Name, Institution, and Business Email address so users can register for access to the system.
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.	N/A
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.	<p>Directly from an individual about whom the information pertains</p> <ul style="list-style-type: none"> Online Government Sources <ul style="list-style-type: none"> Within the OPDIV Other Non-Government Sources <ul style="list-style-type: none"> Members of the Public
PIA 30A:	Identify the "other" sources of PII in the system not mentioned in the above list.	N/A
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.	N/A
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.	The Agency will provide any required notice and obtain consent from the specific individuals regarding the collection of their PII data. This may be conducted via e-mail to individuals, adding or updating forms and/or online notices.
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.	No such changes are planned or anticipated. However, Should the FDA's use of PII in the system change, the Agency will provide any required notice and obtain consent from the specific individuals regarding the collection of their PII data. This may be conducted via e-mail to individuals, adding or updating forms and/or online notices.
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 may contact HFP officials and/or the FDA Privacy Office by phone, mail, or e-mail using the contact information provided on fda.gov .
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.	The system will be included in the annual ATO assessment process for the HFP AWS East Applications (FAWSEA) boundary which hosts this application.
PIA 38:	Identify who will have access to the PII in the system.	<ul style="list-style-type: none"> Administrators 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.	<p>Administrators: To track and follow up on orders submitted through the system.</p> <p>Contractors: Direct FDA contractors who provide technical and development support to the system</p>
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	The GMVS Admin System leverages FDA Active Directory security groups in order to control access to the GMVS internal administrative site. Access is controlled via the FDA active directory group RB-CFSAN-GMVS-ADM-PRD. Users can only be added to this group if they are authorized by the group manager who will then add them to the group.
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 GMVS Admin System leverages FDA Active Directory security groups in order to control access to the GMVS internal administrative site. Access is controlled via the FDA active directory group RB-CFSAN-GMVS-ADM-PRD. Users can only be added to this group if they are authorized by the group manager who will then add them to the group.
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.	No system-specific training is received by users
PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	No additional system-specific training is received by users
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).	<p>General Records Schedule (GRS) 4.2 File Code: 010</p> <p>General Information Request Files: Requests for information, publications, photographs, and other information involving no administrative action, policy decision, or special compilations or research. Also includes acknowledgments, replies, and referrals of inquiries to other offices for response. Disposition: Disposition: DAA-GRS-2013-0007-0001. Temporary. Destroy when 90 days old, but longer retention is authorized if required for business use.</p> <p>General Records Schedule (GRS) 6.5 File Code: 020</p> <p>Consumer/client records: Distribution lists used by an agency to deliver specific goods or services. Records include contact information for customers or clients, subscription databases for distributing information such as publications and data sets produced by the agency, files and databases related to constituent and community outreach or relations, and sign-up, request, and opt-out forms.</p> <p>Disposition: DAA-GRS-2017-0002-0002</p> <p>Temporary. Delete when superseded, obsolete, or when customer requests the agency to remove the records.</p>

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.

The data hosted for GMVS is contained within the DynamoDB service. The DynamoDB tables contains the metadata related to the electronic publications as well as the request data for orders that need to be fulfilled. All user data stored in Amazon DynamoDB is fully encrypted at rest. DynamoDB encryption at rest provides enhanced security by encrypting all your data at rest using encryption keys stored in AWS Key Management Service (AWS KMS). This functionality helps reduce the operational burden and complexity involved in protecting sensitive data. With encryption at rest, you can build security-sensitive applications that meet strict encryption compliance and regulatory requirements. DynamoDB is also a managed service, where AWS takes on the responsibility of patching and maintaining the infrastructure required to host this service and they have achieved the FedRAMP compliancy at the moderate level for this service. In addition to encryption, the data is also secured by using a "least-privileged" architecture for access control by using AWS's Identity and Access Management service. Each microservice that accesses the data within this application is assigned a role with a policy that only gives that microservice the minimum / exact privileges required to provide the functionality needed.

Data protection is also built into the user interface for the GMVS Admin system. The GMVS Admin System leverages FDA Active Directory security groups in order to control access to the GMVS internal administrative site. Access is controlled via the FDA active directory group RB-CFSAN-GMVS-ADM-PRD. Users can only be added to this group if they are authorized by the group manager who will then add them to the group.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	Privacy Analyst Review Date:	8/12/2025
Privacy Analyst Review Comments:		# of Days - PA Review:	0

SOP Review

SOP Review Decision:	Approved	SOP Review Date:	8/12/2025
SOP Review Comments:		# of Days - SOP Review:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	Agency Privacy Analyst Review Date:	8/21/2025
Agency Privacy Analyst Review Comments:	Reviewer: Crystal Bland 8/21/2025 This PIA is ready for SAOP review and approval.	# of Days - APA Review:	9

SAOP Review

SAOP Review Decision:	Approved	SAOP Review Date:	8/29/2025
SAOP Review Comments:		# of Days - SAOP Review:	8

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/29/2025 1:35 PM	BAUR, VANESSA	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	8/13/2025	<p>8/13/2025 Per FDA's Email:</p> <p>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)?"</p> <p>The FDA instance of Archer is automatically entering the answer "No," which is incorrect. The ATO date is 7/3/2025. At this time, we are unable to update Archer to reflect the correct answer "Yes."</p>	<p>8-13-2025 EMAIL_HFP GenomeTrakr Metadata Validation System FDA- (HFP - GMVS - QTR3 - 2025 - FDA4949998).pdf</p> <p>BEST_PTA_PIA_12-6-2024_SAOP Approved.docx</p>