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

Status:	Approved	**PIA ID:**	1310881
PIA Name:	OS - BEAM - QTR4 - 2020 - OS1040755	**Title:**	OS - BARDA Enclave for Analytics and Management (BEAM)
OpDiv:	OS		

PTA

PTA - 1A:	Identify the Enterprise Performance Lifecycle Phase of the system	Initiation
PTA - 1B:	Is this a FISMA-Reportable system?	Yes
PTA - 2:	Does the system include a website or online application?	No
PTA - 3A:	Is the data contained in the system owned by the agency or contractor?	Both
PTA - 5:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
PTA - 5B:	If no, Planned Date of ATO	12/4/2020
PTA - 6:	Indicate the following reason(s) for this PTA. Choose from the following options.	New
PTA - 8:	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?	The BARDA (Biomedical Advanced Research and Development Authority) Enclave for Analytics and Management (BEAM) system concept will

eventually underpin and facilitate most of BARDA operations and data analytics, but the initial use-case (called the BARDA Data Infrastructure, or BDI) is much more narrowly targeted on the COVID-19 response, specifically the Operation Warp Speed (OWS) vaccine manufacturing, distribution, and administration effort. BDI within BEAM will receive data files from COVID-19 vaccine manufacturers and the ancillary kit assembler regarding manufacturing status and timelines, will pass these to OWS personnel (including the Centers for Disease Control (CDC) and Strategic National Stockpile (SNS)), will receive and process vaccine and ancillary kit order from the CDC, converting these to purchase orders for the vaccine manufacturers and the ancillary kit order, and will then track the shipments as they move to central distribution and/or administration sites. BDI and BEAM will ensure appropriate quality and contractual oversight of the entire process, as well as facilitate invoicing upon successful delivery of vaccine.

PTA - 9:	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.		There are four main categories of data captured in the BEAM system: 1) BARDA financial and contracting data 2) BARDA project management data

3) Partner organization data and
4) Covid-19 vaccine manufacturing and supply chain data.

The BARDA financial and contracting data is primarily focused on data about BARDA contracts with organizational partners. The data includes contract numbers, funding sources, award amounts, descriptions of purpose of the contract and period of performance data. The data also includes the names of BARDA contracting officers (CO), specialists and contracting office representative (COR) associated with a contract. The data may include the name, phone number and email address of a point of contact for the partner organization.

BARDA Project management data in BEAM overlaps with the financial and contracting data above. It is typically centered on a contract award and includes financial and categorical data including the division or branch that manages the contracts. This data is typically maintained by the BARDA staff in spreadsheets used to track and manage their business processes.

Partner Organization data includes reference data for organizations which have pursued or entered into contracts with BARDA. Using identifiers like Company Tax Identification Number (TIN) and Data Universal Numbering System (DUNS) codes, geographical and categorical data is imported into the BEAM system as reference data. The Dynamics Customer Relationship Management (CRM) component of BEAM also tracks the names and contact information of representatives of partner or prospective partner organizations.

Covid-19 vaccine manufacturing and supply chain data is focused on projected and actual vaccine production metrics as well as inventory, shipping and ordering data for each vaccine product or component. It also includes organizational data about Covid-19 vaccine manufacturers including the location of their production facilities and names, email addresses and phone numbers of points of contact at those facilities. The data also includes supply chain data from the Strategic National Stockpiles (SNS) and Centers for Disease Control (CDC).
All the information types will be stored indefinitely.

PTA -9A:	Are user credentials used to access the system?	Yes
PTA - 9B:	Please identify the type of user credentials used to access the system.	HHS User Credentials
		HHS Email Address
		HHS Password
		HHS Username
		HHS/OpDiv PIV Card

		Non-HHS User Credentials
		Email address
		Password
		Username
PTA - 10:	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	There are four main categories of data captured

in the BEAM system:

1) BARDA financial and contracting data

2) BARDA project management data

3) Partner organization data and

4) Covid-19 vaccine manufacturing and supply chain data.

BARDA financial and contracting data is included in the system to support a broad portfolio analysis effort to inform and optimize BARDA's budgeting and project priorities. It will be used to provide answers to questions like "How much money did BARDA invest in projects focused on "threat X" in 2020?". Contact information for members of the BARDA staff and partner organizations is used to facilitate management of the contracts.

BARDA Project management data is also included in the system to support data analysis and reporting efforts. The system will eventually underpin and facilitate most of BARDA operations and data analytics. Contact information for members of the BARDA staff and partner organizations is used to facilitate management of the contracts.

Partner organization data is used as a reference for data analysis, but is also a focus of the Dynamics Customer Relationship Management (CRM) component of BEAM. The CRM system is used to track and facilitate communication and engagement with partner, and prospective partner organizations. Contact information for partner organizations is used to facilitate management of the contracts.

For Covid-19 vaccine manufacturing and supply chain data, BEAM will serve as a data interchange between BARDA, manufacturers, the Centers for Disease Control (CDC) and Strategic National Stockpile (SNS). In that capacity BEAM will be used to receive data files from COVID-19 vaccine manufacturers and the ancillary kit assembler regarding manufacturing status and timelines, will pass these to OWS personnel (including CDC and SNS), will receive and process vaccine and ancillary kit order from the CDC, converting these to purchase orders for the vaccine manufacturers and the ancillary kit order, and will then track the shipments as they move to central distribution and/or administration sites. Contact information for points of contact in partner organizations is used to facilitate communication necessary to support the supply chain management efforts.

PTA - 10A:	Are records in the system retrieved by one or more PII data elements?	Yes
PTA - 10B:	Please specify which PII data elements are used.	name

		email
		employer
		Phone number
		TIN
PTA - 11:	Does the system collect, maintain, use or share PII?	Yes

PIA		
PIA - 1:	Indicate the type of PII that the system will collect or maintain	Name
		E-Mail Address
		Phone numbers
		Others - Corporate Tax Identification Number (TIN)
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
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system	Above 2000
PIA - 4:	For what primary purpose is the PII used?	Two Primary Uses: 1. Contact information for HHS Staff is used for Portfolio Analysis and to support Biomedical Advanced Research and Development Authority (BARDA) Operations so that when a contract is analyzed, the BARDA staff associated with hat contract like the contract office or Contract Office Representative (COR). 2. The Dynamics platform functions as a Customer Relationship Management (CRM) tool. Its purpose is to facilitate and communication and collaboration with Partner Organizations. This requires the system to have contact information for those organizations.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research)	Personally Identifiable Information (PII) could be used in data normalization efforts. For example,

		Point Of Contact's (POC) email addresses could be analyzed by looking for multiple Organization records that have the same email domain (e.g. @Acme.com) and that would be an indication that the two organizations are related, which could inform data normalization and analysis efforts
PIA - 7:	Identify legal authorities, governing information use and disclosure specific to the system and program	The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA), amends other legislation to provide a 10-year authorization for the Project BioShield Special Reserve Fund, BARDA's Advanced Research and Development (ARD) mission, and BARDA's Influenza Emerging Infectious Diseases countermeasure requirement. This has been integral in the development of 57 Medical Countermeasures (MCMs) supported by BARDA which have received FDA approval, licensure, or clearance. The Pandemic and All-Hazards Preparedness Re-authorization Act of 2013, PL-113-5 - reauthorized public health response programs. Project Bioshield Act of 2004, PL 108-276, to streamline procurement of biomedical countermeasures and biodefense activities. For example, this activity supports the requirement from the Project Bioshield Act for the Secretary to 'devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure' (PL 108-276, Sec. 3(a)(2), amending the Public Health Service Act at 319F-2 (a)(2)(E)). Specifically, these legislation have established in the Public Health Service Act that BARDA shall coordinate the acceleration of countermeasure and product advanced research and development by— (A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development; (B) promoting countermeasure and product advanced research and development; (C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act and under section 351 of this Act; and (D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.
PIA - 9:	Identify the sources of PII in the system	Government Sources

		Within the OPDIV
		Other HHS OPDIV
		State/Local/Tribal
		Other Federal Entities
		Non-Government Sources
		Private Sector
PIA - 9A:	Identify the OMB information collection approval number or explain why it is not applicable.	Office of Management and Budget (OMB) control number 0990-0323
PIA - 9B:	Identify the OMB information collection expiration date.	2/28/2023
PIA - 10:	Is the PII shared with other organizations outside the system's Operating Division?	No
PIA - 11:	Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason	Individuals will be notified via a system use notification that must be acknowledged prior to logging into the system.
PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 13:	Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason	BARDA Staff cannot opt out of collection or use of their PII. The data is acquired from contract management systems like Procurement Information System Management (PRISM). Partner organizations will need to provide contact information but are not required to provide personal contact information. Companies can provide resource/group mailboxes or department/corporate phone numbers.
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	Individuals will be notified via a system use notification that must be acknowledged prior to logging into the system. The notification will describe changes to the use or collection of PII in the system. In the event of a public health emergency, the notification may not be updated, prior to the change in use of the PII.
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	The system will include a link to a BARDA Digital Resources (BDR) Admin resource mailbox that will be monitored by BARDA staff.
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	Through the required periodic conduct of System Certification & Accreditation (C&A) and the Annual Review process, the Agency ensures the integrity, availability, and accuracy and relevance of the information in BARDA Enclave for Analysis and Management (Beam). Data integrity and availability is addressed by continuous diagnostics and security monitoring, annual testing of the Contingency Plan, and annual testing of Security Controls.
PIA - 17:	Identify who will have access to the PII in the system and the reason why they require access	Users Administrators Developers Contractors

Provide the reason of access for each of the groups identified in PIA -17

Standard users will be HHS/ASPR/BARDA employees and contractors engaged in BARDA's standard business processes. These standard business processes include communicating with partner organizations. These users will depend on the standard Customer Relationship Management (CRM) capabilities in the Microsoft Dynamics component of BEAM. The purpose of the CRM is to facilitate communication and collaboration between BARDA and partner organizations.

Administrators and Developers will have access to PII in the system in support of the business users. They may encounter PII in support of data analysis efforts in response to requests from BARDA users or leadership.

Contractors are the external users that will have access to the contact information for the BARDA staff members associated with their project. They won't have broad access to PII, but would be able to find a name, email address and phone number (HHS number, not personal phone number) for their BARDA points of contact.

PIA - 17B:	Select the type of contractor	HHS/OpDiv Direct Contractor
PIA - 18:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII	Levels of access to the system are defined by user roles and documented in the Role Based Access Control (RBAC) plan. HHS employees and contractors who have HHS badges and have signed Non-Disclosure Agreements (NDAs) with BARDA would have broad access to PII. External users accessing the system through Dynamics Portals will have limited access, enough to communicate with BARDA staff and submit proposals, market research etc.
PIA - 19:	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	Authentication protocols are in place to ensure role-based access to minimal information. In addition, encryption certificates are used to protect information transmitted. External users will also be assigned user roles, but they will be far more limited. External user/role management will be implemented using user management capabilities in the Microsoft Dynamics application. External users will not have an HHS Active Directory user account, which would be a prerequisite for broad access to any PII.
PIA - 20:	Identify training and awareness provided to personnel (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	Internal HHS/ASPR/BARDA users are required to complete standard, annual privacy and security training. BEAM technical staff will also complete HHS training for system owners and administrators.
PIA - 21:	Describe training system users receive (above and beyond general security and privacy awareness training).	Administrators are required to complete Role Based Training. BDR Microsoft Dynamics Role Based Workflow training is provided to internal HHS/ASPR/BARDA users.
PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific NARA records retention schedule(s) and include the retention period(s)	The Agency adheres to the Departmental guidance regarding PII data retention and destruction using record disposition authority DAA-0468-2013-0003.

| **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**: Only badged HHS & BARDA staff (employees and contractors) would have broad access to PII in BEAM. That access would have to be approved by the BEAM Program Manager or designee. External Dynamics Portals users will have the ability to enter their own contact information and could have access to the name and contact information of the BARDA staff member assigned to their project. This is part of the core function of the Dynamics CRM system.

Technical: Internal users (badged HHS employees and contractors) could be granted access to the system based on their HHS Active Directory user account. Further system security measures are documented in the System Security Plan (SSP). External users of the Dynamics Portals system would be granted specific roles with limited access.

Physical: The BEAM system is entirely based in the Microsoft cloud environment. Physical controls on the PII would not apply. |