

**Biomedical Advanced Research and Development Authority (BARDA)  
Rapid Response Partnership Vehicle (RRPV)**



**Request for Project Proposals (RPP)**

**Solicitation Number: 24-06-DxR2**

**“Biothreat Diagnostic Rapid Response”**

**Original Issue Date: March 27, 2024**

***Amendment No. 3 Issue Date: April 23, 2024***

***Due Date: May 17, 2024, 1PM ET***

Issued by:

Biomedical Advanced Research and Development Authority (BARDA)  
Contracts Management & Acquisition (CMA)  
400 7th Street, SW, Washington, DC 20024

[MedicalCountermeasures.gov](https://www.mediccountermeasures.gov)

**Amendment No. 03 does the following:**

**Extends the proposal due date from May 10, 2024, to May 17, 2024, at 1pm Eastern.**

**All other terms and conditions remain unchanged.**

Request for Project Proposals 24-06-DxR2  
BARDA Rapid Response Partnership Vehicle

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**Table of Contents**

<b>1</b>	<b>EXECUTIVE SUMMARY</b> .....	<b>3</b>
1.1.	RAPID RESPONSE PARTNERSHIP VEHICLE CONSORTIUM .....	3
1.2.	PURPOSE .....	3
<b>2</b>	<b>ADMINISTRATIVE OVERVIEW</b> .....	<b>4</b>
2.1.	ACQUISITION APPROACH .....	4
2.2.	FUNDING AVAILABILITY AND PERIOD OF PERFORMANCE .....	4
2.3.	EXPECTED AWARD DATE .....	4
2.4.	PROPRIETARY INFORMATION .....	4
2.5.	OFFEROR ELIGIBILITY CRITERIA .....	5
2.6.	COST SHARING.....	5
2.7.	INTELLECTUAL PROPERTY AND DATA RIGHTS.....	5
<b>3</b>	<b>PROPOSALS</b> .....	<b>6</b>
3.1.	QUESTION AND ANSWER PERIOD.....	6
3.2.	PROPOSAL GENERAL INSTRUCTIONS .....	6
3.3.	PROPOSAL SUBMISSION .....	7
3.4.	PROPOSAL PREPARATION COST .....	7
3.5.	SUBMISSION DOCUMENTS AND FORMAT.....	7
3.6.	COST PROPOSAL.....	8
3.7.	REGULATORY TERMS.....	8
3.8.	SECURITY REQUIREMENTS .....	8
<b>4</b>	<b>TECHNICAL REQUIREMENTS</b> .....	<b>8</b>
4.1.	INTRODUCTION .....	8
4.2.	OVERVIEW .....	9
4.3.	TECHNICAL REQUIREMENTS.....	9
<b>5</b>	<b>EVALUATION/SELECTION</b> .....	<b>12</b>
5.1.	COMPLIANCE SCREENING .....	12
5.2.	PROPOSAL EVALUATION PROCESS.....	12
5.3.	EVALUATION FACTORS.....	12
5.4.	COST/PRICE ESTIMATE AND EVALUATION.....	13
5.5.	EVALUATION OUTCOME.....	14
5.6.	BASKET PROVISION .....	14
<b>6</b>	<b>POINTS OF CONTACT</b> .....	<b>15</b>
	<b>ATTACHMENT 1 – TECHNICAL PROPOSAL TEMPLATE</b> .....	<b>16</b>
	<b>ATTACHMENT 2 – COST PROPOSAL TEMPLATE</b> .....	<b>25</b>
	<b>ATTACHMENT 3 – STATEMENT OF WORK (SOW) TEMPLATE</b> .....	<b>33</b>

## 1 Executive Summary

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### 1.1. Rapid Response Partnership Vehicle Consortium

The Biomedical Advanced Research and Development Authority's (BARDA) Rapid Response Partnership Vehicle (RRPV) Consortium is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities to:

- Help fortify national health security by developing medical countermeasures products prior to and during a pandemic or public health emergency; and
- Accelerate technology development, regulatory approval, commercialization, and sustainment to address pandemic influenza, emerging infectious diseases, and other biological threats.

Advanced Technology International (ATI) has been awarded an Other Transaction Agreement (OTA) by BARDA to serve as the Consortium Management Firm (CMF) for the RRPV.

RRPV is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from all organizations who work within stated technical focus areas; for more information on the RRPV mission, refer to the RRPV website at [RRPV.org](http://RRPV.org). For entities interested in joining the RRPV Consortium and responding to this solicitation, please visit [www.rrpv.org/how-to-join](http://www.rrpv.org/how-to-join).

Strategic oversight for the Project Agreement(s) supported by this RPP will be provided by BARDA.

### 1.2. Purpose

BARDA's product portfolio has capability readiness gaps for rapid biothreat diagnostic test development and ready-production capacity to quickly produce tests in lieu of stockpiling. To address these gaps, biothreat tests will be developed and pilot program(s) will be established to assess the feasibility of rapid response capabilities, leveraging existing domestic manufacturing capacities. BARDA is seeking support for the first of three distinct phases through this Request for Project Proposals (RPP):

- Phase I (Base) - Biothreat Test Development: Develop and obtain regulatory clearance of the biothreat diagnostic tests in addition to design transfer to manufacturing activities, such as limited production runs for validation, quality checks, stability studies, early adopter training, and manufacturing capacity studies.

Should additional funding become available, BARDA may seek support for the two additional phases below. As such, proposals are not required for Phase II and Phase III at this time.

- Phase II (Option) - Warm-base Surge Capacity: Maintain a warm-base surge capacity via low-rate initial production to produce biothreat tests for use in a public health emergency or large-scale government exercises, or for use in public health laboratory proficiency training, or for use in long-term storage and stability studies of tests and test components.
- Phase III (Option) – Manufacturing Capacity Modifications: Execute on the manufacturing capacity study analysis with line modifications to ensure rapid, scalable production capacity in the event of another public health emergency. The overall goal is to build a biothreat diagnostic portfolio, maintain domestic test manufacturing facilities and to enable just-in-time manufacturing practices to be able to rapidly

produce biothreat tests at scale, or other tests needed by the U.S. Government (USG), along with the supplies needed, and to achieve aggressive test delivery schedules.

## **2 Administrative Overview**

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### **2.1. Acquisition Approach**

RRPV is utilizing the Full Technical Proposal and Full Cost Proposal approach to award for this RPP. The Government will evaluate responses submitted and will select the Proposal(s) that best meets their current priorities using the criteria in Section 5.

Each proposal selected for award under this RPP will be executed as a Project Award under the RRPV by the RRPV CMF and be funded under the OTA Number 75A50123D00005. The same provisions will govern this Base Agreement as the OTA between the USG and ATI, unless otherwise noted in the Project Award.

**At the time of the submission, Offerors must certify on the cover page of their Proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the RRPV Base Agreement.** Base Agreements are typically not executed until the Offeror is selected for award.

Offerors are advised to check the RRPV website periodically during the proposal preparation period for any changes to the RRPV Base Agreement terms and conditions.

### **2.2. Funding Availability and Period of Performance**

The total USG funding amount anticipated to be available for Phase I Project Awards is approximately \$40 million (M), and the USG anticipates making 4 awards. Award and funding from the Government is expected to be limited to the funding specified above and is contingent upon the availability of federal funds for this program. Dependent on the results and deliverables of Phase I, additional dollars and time may be added to the period of performance for Phase II and Phase III follow-on tasks.

It is expected that there will be a total of one or more qualified respondents to accomplish the statement of objectives. If an optimal team is not identified, then BARDA may direct the RRPV CMF to make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

The anticipated Period of Performance for Phase I is estimated to be 36 months. Specific dates are to be negotiated. It is anticipated that the primary place of performance will be the Offeror's facilities, however this aspect can be negotiated as part of each Offeror's submission.

### **2.3. Expected Award Date**

Offeror should plan for the period of performance to begin June 2024. The USG reserves the right to change the proposed period of performance start date through negotiations via the CMF and prior to issuing a Project Award.

### **2.4. Proprietary Information**

The RRPV CMF will oversee submission of proposals submitted in response to this RPP. The RRPV CMF shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than proposal evaluation and agreement administration. Offerors should mark all

Request for Project Proposals 24-06-DxR2  
BARDA Rapid Response Partnership Vehicle

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Confidential or Proprietary Information as such. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CMF responsibilities.

## 2.5. Offeror Eligibility Criteria

Offerors must be RRPV Members to be eligible to submit a proposal. Subcontractors (including all lower tier awardees) do not need to be RRPV members. To join RRPV, please visit [www.rrpv.org/how-to-join](http://www.rrpv.org/how-to-join).

Offerors should show evidence in their proposal of the following "Preferred Capabilities". Please note and expand on the "Preferred Capabilities" status. Proposals with "Preferred capabilities" will be reviewed more favorably:

1. Have a minimum of 1 (one) FDA approved or CE Marked in vitro diagnostic (IVD) product commercially available
2. Have a current production capacity of >1M tests/annually
3. Have US-based manufacturing (21 CFR 820 / ISO 13485)
4. Install base >300 domestic placements (applies only to instrument-based products)

Proposals that do not meet minimum eligibility of RRPV membership detailed above may be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

## 2.6. Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). The extent of cost sharing is a consideration in the evaluation of proposals; however, this is not required in order to be eligible to receive an award under this RPP. If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment 2.

## 2.7. Intellectual Property and Data Rights

Intellectual Property (IP) rights for RRPV Project Awards will be defined in the terms of a the RRPV Base Agreement. The RRPV CMF reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the Project Awardees during the entire award period.

The Offeror shall comply with the terms and conditions defined in the RRPV Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights as defined in the RRPV Base Agreement unless otherwise specified in the proposal and agreed to by the Government. All proposed data rights are subject to Government review and approval.** Rights in technical data agreed to by the Government will be incorporated into the Project Award.

The Offeror shall indicate in its proposal submission its acceptance of the terms and conditions defined in the RRPV Base Agreement regarding intellectual property and data rights.

Request for Project Proposals 24-06-DxR2  
BARDA Rapid Response Partnership Vehicle

The Offeror shall complete the table provided in Section 6 of the SOW, for any items to be furnished to the Government with restrictions. An example is provided below.

Technical Data to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2

### 3 Proposals

#### 3.1. Question and Answer Period

Table 1. Key dates related to this RPP.

Date	Event
27 Mar 2024	RPP released
11 Apr 2024 COB	Questions due from potential Offerors
18 Apr 2024 COB	Questions & Answers released (can be approx.)
17 May 2024 1PM ET	Proposals due

Please submit questions to [rrpv-contracts@ati.org](mailto:rrpv-contracts@ati.org).

#### 3.2. Proposal General Instructions

The templates provided in this RPP are mandatory and shall reference this RPP number. **Do not submit any classified information in the submission.** Offerors are encouraged to contact the Point of Contact (POC) identified herein up until the Proposal submission date/time to clarify requirements.

All eligible Offerors shall submit Proposals for evaluation according to the criteria set forth in this RPP. Offerors are advised that only ATI, as the RRPV CMF, with the approval of the Other Transaction Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

### 3.3. Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page. Do not submit any classified information in the proposal submission.

A receipt confirmation will be provided by email. Offerors may submit, or re-submit, in advance of the deadline. Neither the Government nor the RRPV CMF will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror fails to submit the full submission prior to the deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.

### 3.4. Proposal Preparation Cost

The cost of preparing submissions in response to this RPP is not considered a direct charge to any resulting award or any other contract.

### 3.5. Submission Documents and Format

Proposals shall reference this RPP number. Each document below (e.g., Technical Proposal, Cost Proposal Narrative, Cost Proposal Format, and Statement of Work) is mandatory and must each be submitted as separate files and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact the RRPV CMF with any questions so that all aspects are clearly understood by both parties. The proposal should include the following:

- Technical Proposal (30-page limit, unless noted\*) – See Attachment 1: One Technical Proposal (.pdf, .doc or .docx). The mandatory template is provided as Attachment 1, and includes mandatory sections for a cover page\*, information sheet\*, executive summary and preferred capabilities, technical approach, current and pending support, Success Criteria\*, and key personnel resumes/CV.\* While no template is required for the resume/CV, each resume/CV is limited to 3 pages.
- Cost Proposal (no page limit) – See Attachment 2: One Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative is required using the mandatory template. Separately, Section II: Cost Proposal Format is required in Excel (.xlsx) format, with working formulas to the maximum extent practicable. See Section 3.5 of this RPP for additional information.
- Statement of Work/Milestone Payment Schedule (no page limit) – See Attachment 3: One Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the mandatory template provided as Attachment 3.

The following formatting requirements apply:

- 12-point font (or larger), single-spaced, single-sided, 8.5 by 11 inches
- Smaller type may be used in figures and tables, but must be 8-point font (or larger)
- Margins on all sides (top, bottom, left, and right) should be at least 1-inch
- Submit files in Microsoft Word, Microsoft Excel, or Adobe Acrobat (PDF – portable and searchable document format) formats as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension (.docx, .doc, .xlsx, or .pdf). Filenames should not contain special

Request for Project Proposals 24-06-DxR2  
BARDA Rapid Response Partnership Vehicle

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characters. IOS users must ensure the entire filename and path are free of spaces and special characters.

### 3.6. Cost Proposal

The Cost Proposal must include two sections, a Cost Proposal Narrative and a Cost Proposal Format. Offerors are encouraged to use their own cost formats such that the necessary detail is provided. The RRPV CMF will make optional cost proposal formats available on the Members-Only RRPV website. The Cost Proposal formats are NOT mandatory.

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

### 3.7. Regulatory Terms

Project Awardees must be prepared to comply with the following regulatory terms:

- The Performer shall serve as regulatory product sponsor and be responsible for all documents and submissions to FDA necessary to achieve authorization or clearance.
- Support and maintain regulatory submissions domestically throughout the life of the agreement.
- The Performer must submit to the Government all supporting documentation related to assay feasibility, verification, and validation, manufacturing activities, as well as other related documentation. All information in the Device Master Record (DMR) associated with this effort is also included.
- The Performer shall cross-reference any applicable regulatory files prior to the conduct of the studies, and shall allow cross-referencing of these documents associated with this effort.
- All nonclinical (if required) and clinical studies should be approved in accordance with industry standards, and HHS's Animal Welfare Assurance and HHS' Office of Human Research Protection (OHRP), respectively.

Additional information on the applicable regulatory terms is provided in the RRPV Base Agreement. ***These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.***

### 3.8. Security Requirements

Security Requirements have not been identified at this time. Project Awardees may be provided further security requirements during negotiations prior to award.

## 4 Technical Requirements

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### 4.1. Introduction

The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable, unless specifically stated otherwise.



Request for Project Proposals 24-06-DxR2  
BARDA Rapid Response Partnership Vehicle

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For scheduling and pricing purposes, Offerors should assume that some elements of the Base Period may occur concurrently to support cost and schedule savings; however, an Agreement modification will be required to begin an option period.

#### 4.2. Overview

The overall goal of this program is to build a biothreat diagnostic portfolio, maintain domestic test manufacturing facilities and to enable just-in-time manufacturing practices to be able to rapidly produce biothreat tests at scale, or other tests needed by the USG, along with the supplies needed, and to achieve aggressive test delivery schedules. Therefore, an awarded project resulting from this RPP will develop biothreat diagnostic tests and establish a pilot program(s) to assess the feasibility of rapid response capabilities, leveraging existing domestic manufacturing capacities. BARDA is seeking support for the first of three distinct phases under this program and are described below. **Note that offerors are required to only address Phase I at this time.**

Phase I - Biothreat Test Development (Base Period): This phase focuses on the i) development and regulatory clearance of biothreat tests, and ii) design transfer to manufacturing activities, such as limited production runs for validation, quality checks, stability studies, early adopter training, and manufacturing capacity studies.

Should additional funding become available, BARDA may seek support for the two additional phases below. As such, proposals are not required for Phase II and Phase III at this time.

Phase II – Maintain Warm-Base Surge Capacity (Option Period): This phase focuses on establishing a domestic warm-base surge capacity via low-rate initial production to:

- Maintain the supplies needed to rapidly produce the biothreat test,
- Conduct long-term storage and stability studies of tests and test components (i.e., primers, probes, consumable plastic components) for biothreat assays with potential agreements in place to rapidly manufacture tests from these components, if a public health emergency is declared, and
- Produce biothreat tests for use in a public health emergency or large-scale government exercises and public health laboratory competency and proficiency training.

Phase III – Manufacturing Capacity Modifications (Option Period): The overall goal of phase III is to maintain domestic test manufacturing facilities and to enable just-in-time manufacturing practices to be able to rapidly produce biothreat tests, or other tests needed by the USG, along with the supplies needed and to achieve aggressive test delivery schedules. The phase focuses on expanding the capacity preservation program i to enable scaled volume shipment of product within days to weeks from order, and to achieve the equivalent of stockpiling of multiple threat tests in one manufacturing facility. This phase includes the execution of capacity expansion based on the manufacturing capacity study report which provides an analysis of the current state of the Offeror's manufacturing capabilities along with recommendations for modifications that would be required to ensure rapid, scalable domestic production capacity in the event of another public health emergency.

#### 4.3. Technical Requirements

At this time, offerors are required to submit proposals that **address only Phase I** described below; future work may include Phase II and III activities. The Offeror shall address any circumstances where an aspect described below is not relevant to the Offeror's proposal.

Request for Project Proposals 24-06-DxR2  
BARDA Rapid Response Partnership Vehicle

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**PHASE I - Biothreat Test Development (Base Period):** This phase includes the following tasks:

- Assay Feasibility: The biothreat test assay is designed and optimized followed by preliminary analytical studies performed to demonstrate the assay meets the performance specifications described in the Offeror's Design Input Requirements. The assay design is locked for development under design/change control in the verification and validation (V&V) phases.
  - Planning
    - Product definition (Design input requirements, customer, market requirements)
    - Project Plan
    - Risk Management Plan
    - Regulatory Plan
  - Assay Design
    - In silico and bioinformatic designs
    - Assay reagent design and parameters
    - Software development to establish detection algorithm for making calls
  - Assay Optimization
    - Design of Experiments to optimize performance of all critical reagents
    - Sample preparation and detection conditions are defined and optimized
    - Define internal and external controls for V&V
    - Define limits of failure
  - Preclinical Performance Testing
    - Analytical Studies, including limit of detection (LoD), linearity, inclusivity, and exclusivity will be conducted to demonstrate that the assay meets the performance specifications described in the Design Input Requirements (DIR).
  - Instrument Support
    - Evaluate, calibrate, and optimize assay performance on requisite instruments
  - Assay Design Freeze: future modifications in V&V phases will occur under change control
- Assay Verification
  - Development is performed under design control. Work performed during verification will require manufacturing of at least three independent test lots. The critical raw material lots (plastic components, critical reagents) are varied between Design Lots to ensure robustness of design for manufacturing. The results, or design outputs, must meet the design input requirements described in the DIR.
  - Assay verification studies include all analytical studies to support non-clinical performance claims in the package insert: LoD, Linearity, Precision, Reproducibility, Inclusivity, Exclusivity, Interfering substances, and Failure mode testing.
  - Sample stability studies will be performed at -20°C, 4°C, 28°C, and 37°C to establish the allowable storage time and temperatures for clinical samples.
  - Kit stability studies should be performed at 2°C, 28°C, 35°C, 45°C, and 50°C.
  - Manufacturing quality control (QC) procedures and acceptance criteria will be evaluated by a two-step process: (i) control limit studies where R&D defines the test methods, test material, and acceptance criteria used for kit release during manufacturing; (ii) test method validation performed by manufacturing. Three independent lots are used for each set of studies.
  - External beta (pre-clinical) study will be conducted to obtain preliminary performance data in the hands of the end user on the final product configuration.
  - External QC will be developed to monitor shifts, trends, operator errors, and systematic variation.

Request for Project Proposals 24-06-DxR2  
BARDA Rapid Response Partnership Vehicle

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- Assay Validation: Assay validation is the final task areas to achieve regulatory clearance which will include manufacturing process validation, clinical trials and regulatory submission.
  - Manufacturing process validation: Three independent process validation lots are built to demonstrate the reproducibility of the manufacturing process including validating QC release procedures and acceptance criteria.
  - Clinical Trials: Conduct all tasks required to execute a clinical trial in accordance with the FDA and the intended clinical indication. This includes but is not limited to: planning and protocols, review by the Institutional Review Board, site management, recruitment, screening, enrollment of subjects, quality and data management, data management and biostatistics, and clinical trial reports.
  - Regulatory Plan Execution: Conduct appropriate meetings (e.g., pre-sub meetings) and submission to the FDA with the intent to obtain clearance.
  - Manufacturing for Regulatory Clearance: Execute on manufacturing activities in preparation for FDA authorization or clearance and post-clearance monitoring to include:
    - Limited production runs for validation studies, stability studies, quality checks, line efficiency exercises
    - Limited post clearance production for performance monitoring and early adopter training and testing.
- Manufacturing Capacity Study: Conduct a study of the current state of manufacturing capacity and optimization to keep manufacturing capacity available and ensure rapid response times. The deliverable is a study report for improving capacity across manufacturing processes and operations. Key elements of the deliverable may include:
  - Determine improvements to existing production practices without implementing automation (such as batch sizes, raw material inventory management, or replication of current lines).
  - Determine production practices or modifications that will lead to long-term preservation of manufacturing capacity in terms of cost, performance, workforce, and other factors.
  - Determine production practices or modifications that will increase the speed to pivot production to another test (i.e., pivot production from a commercial influenza test to a USG biothreat test). The goal is to ship tests within 1 week of order placement.
  - Determine production practices or modifications that could be put in place to better manage the forecast and supply chain needs for your primary diagnostic product lines in conjunction with forecasts required for products sold during seasonal or surge-related times (i.e., pandemic or emergency event).
  - Determine how implementation of any production practices or modifications may impact workforce headcount and determine your plans for redeploying/rehiring/retaining, if any.

**PHASE II – Maintain Warm-Base Surge Capacity (Option Period):** This phase is focused on manufacturing of lots and includes the following tasks:

- Long term storage and stability studies
- Delivery and proficiency training for certified labs
- Production for warm base maintenance and calibration
- Production for process optimization and scaling studies
- Production for a public health emergency or large-scale government exercises

### **PHASE III - Manufacturing Capacity Modifications (Option Period)**

- Execute plan for improving capacity across manufacturing processes and operations.
- Initiate and deliver improvements to existing production infrastructure without implementing automation (such as batch sizes, raw material inventory management, or replication of current production lines).
- Initiate and deliver improvements to existing production infrastructure with automation upgrades (such as robotic systems, injection molding, chip production, reel-to-reel assembly systems, fill and finish systems).

## **5 Evaluation/Selection**

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### **5.1. Compliance Screening**

The RRPV CMF will conduct a preliminary screening of submitted Proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, Proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the RRPV CMF. The Government reserves the right to request additional information or eliminate Proposals that do not meet these requirements from further consideration.

### **5.2. Proposal Evaluation Process**

Following the preliminary screening, the Government sponsor will perform source selection evaluation of all qualified Proposals. Such review may include a panel of subject matter experts (SMEs), to include the use of contractor consultants or SMEs, who will make recommendations to a Source Selection Authority. Where appropriate, the USG will employ non-disclosure agreements to protect information. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs. Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each Proposal against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s).

The Government will evaluate the information provided in each Offeror's Proposal to determine which Proposal(s) provide(s) the best value to the Government. Such a determination will be based on the following criteria, in addition to cost/price.

### **5.3. Evaluation Factors**

The following Evaluation factors are listed in descending order of importance:

**Evaluation Factor 1 - Technical Approach:** This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.

**Evaluation Factor 2 – Relevant Experience:** This factor evaluates the offeror's demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems.

**Evaluation Factor 3 – Cost Reasonableness:** Assessment of the cost of the project to determine i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed.

For each evaluated proposal, the non-cost/price factors will each be assigned one of the following adjectival merit ratings:

- Outstanding
- Good
- Acceptable
- Marginal
- Unacceptable

#### **5.4. Cost/Price Estimate and Evaluation**

The Cost Proposal will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

If a proposal is selected for award, the RRPV CMF will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP. Evaluation will include analysis of the proposed cost together with all supporting information. The RRPV CMF will request additional information or clarification as necessary. The RRPV CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the project value is fair and reasonable, subject to final Government negotiations.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

**a) Realism.** Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

Estimates are “realistic” when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each phase of the proposed project when compared to the total proposed cost.

The RRPV CMF will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

**b) Reasonableness.** The Offeror’s cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror’s cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical

Request for Project Proposals 24-06-DxR2  
BARDA Rapid Response Partnership Vehicle

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cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down in the Cost Proposal Format. An optional template is located on the Members-Only RRPV website.

**c) Completeness.** The RRPV CMF will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation. The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The RRPV CMF will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The RRPV CMF will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal may not be selected for award.

**Best Value**

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Funding recommendations depend on various factors and programmatic relevance. Based on the evaluation of the Technical Approach, Relevant Experience, and Cost/Price, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offerors will have the opportunity to concur with the requested changes, propose further changes and revise cost proposals, as necessary.

**5.5. Evaluation Outcome**

Following the evaluation, the Source Selection Authority may:

1. Select the proposal (or some portion of the proposal) for award;
2. Place the proposal in the Basket if funding currently is unavailable; or
3. Reject the proposal (will not be considered for award and will not be placed in the Basket)

As the basis of selections are completed, the Government will forward their selections to the RRPV CMF to notify Offerors. Offerors will be notified of the decision via email from the RRPV CMF of the results of the evaluation. All Offerors will receive feedback on eligible submissions.

**5.6. Basket Provision**

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately selected for award, may be placed in the Basket for 2 years and are eligible for award during that time. Proposals rated as Unacceptable will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal best meets its needs.

## **6 Points of Contact**

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Questions related to this RPP should be directed to [RRPV-contracts@ati.org](mailto:RRPV-contracts@ati.org).

**Once an Offeror has submitted a Proposal, the Government and the RRPV CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.**

SOLICITATION CLOSED

## ATTACHMENT 1 – TECHNICAL PROPOSAL TEMPLATE

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### **General Instructions**

The Technical Proposal must address the technical requirements described in the RPP in sufficient detail to permit evaluation from a technical perspective in accordance with the evaluation factors set forth in the RPP. The Technical Proposal shall be single-spaced, single-sided, and 8.5 x 11 inches, and 12-point font. Smaller type may be used in figures and tables but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc.

The Technical Proposal shall be limited to 30 pages (unless otherwise noted below). Pages in excess of this limitation may not be considered. Offerors are advised that the number of pages should be commensurate with the degree of complexity of the proposed effort. It is expected, and encouraged, that less complex, less expensive proposals will be significantly less than 30 pages in length.

To ensure Technical Proposals receive proper consideration, **the Technical Proposal format shown below is mandatory**. If there are any items which are not applicable to a specific proposal, include the section topic in the proposal with a short explanation as to why it is not applicable.

1. Cover Page\*
2. RRPV Member Organization Information Sheet\*
3. Executive Summary & Preferred Capabilities
4. Technical Approach
5. Current & Pending Support
6. Success Criteria\*
7. Resumes/CV of Key Personnel (each no greater than 3 pages)\*

**\*Excluded from page limitation**



# 1. Technical Proposal Cover Page

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[Name of Offeror]  
[Address of Offeror]

**RPP Number RPP-24-06-DxR2**

**[Proposal Title]**

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the RRPV Base Agreement.

[Offeror] certifies that this Proposal is valid for 180 days from the close of the applicable RPP, unless otherwise stated.

[As detailed in Section 2.4 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample:

*This Proposal includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]*

## 2. Member Information Sheet

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If an item is not applicable, then that section should be listed as “not applicable.”

OFFEROR NAME:	
ALL PLACES OF PERFORMANCE:	
TITLE OF PROPOSED EFFORT:	
UEI # (if applicable):	
CAGE CODE (if applicable):	
SMALL BUSINESS (YES/NO):	
CONFLICT OF INTEREST (YES/NO):	
TOTAL COST OF PROPOSAL:	
PROPOSED PERIOD OF PERFORMANCE IN MONTHS:	
PREFERRED PAYMENT METHOD (FFP, CPFF, Cost Reimbursable (CR), CR/COST SHARE):	
REQUESTED USE OF GOVERNMENT RESOURCES, PROPERTY, LABS, ETC. (YES/NO):	
PROPOSED USE OF ANIMAL SUBJECTS (YES/NO):	
PROPOSED USE OF HUMAN SUBJECT (YES/NO):	
PROPOSED USE OF HUMAN SPECIMEN MATERIAL (YES/NO):	
PROPOSED USE OF HUMAN FETAL TISSUE (YES/NO):	
PROPOSED USE OF LIVE VERTABRATE ANIMALS (YES/NO):	
PROPOSED USE OF SELECT BIOLOGICAL AGENTS OR TOXINS (YES/NO):	
CONTRACT/NEGOTIATION CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
TECHNICAL/PRINCIPAL INVESTIGATOR CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
COGNIZANT RATE AUDIT AGENCY OFFICE (IF KNOWN, INCLUDE POC, ADDRESS, PHONE #, E-MAIL):	

### 3. Executive Summary & Preferred Capabilities

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[The Executive Summary allows Offerors to present briefly and concisely present the important aspects of their proposals to evaluators. The summary should present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core concepts of the proposed project.]

[Additionally, this section must address how the Offeror currently satisfies any of the preferred capabilities:]

1. Have a minimum of 1 (one) FDA-approved or CE-Marked in vitro diagnostic (IVD) product commercially available.
2. Have a current production capacity of >1M tests/annually
3. Have US-based manufacturing (21 CFR 820 / ISO 13485)
4. Install base >300 domestic placements (applies only to instrument-based products)

### 4. Technical Approach

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[Provide sufficient technical detail and analysis to support the technical solution being proposed for the project. Clearly identify the core of the intended approach. It is not effective simply to address a variety of possible solutions to the technology problems. Include citation to each Deliverable identified in the Statement of Work throughout the Technical Approach (e.g. (1.1)). Provide the following information:]

1. **Background:** [Describe the problem that the proposal is addressing.]
2. **Approach:** [Describe your approach to solving the problem, broken out by Phase as outlined in Section 4 (Technical Requirements) of the RPP. Include relevant background data about your approach. Include the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Past Experience:** [Describe relative corporate and capabilities past experience, as well as the technical and management experience of the proposed team, to perform the proposed work. Past experience should be recent, relevant and similar in size and scope to offeror's proposed effort.]
5. **Technical Strategy:** [Describe the proposed methodology, including development and manufacturing approach, in sufficient detail to show a clear course of action.]
6. **Anticipated Outcomes:** [Provide a description of the anticipated outcomes from the proposed work.]
7. **Technical Maturity and Commercialization Strategy:** [Provide a description and justification of the maturity of the proposed technology, anticipated regulatory pathway and commercialization plans. Include high-level information about Intellectual Property/Data Rights Assertions. Describe the planned indication for the product label, if appropriate, and include an outline of the development plan required to support that indication. The application should describe a transition plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful

completion of this award.]

- 8. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur when an individual or an entity is unable, or potentially unable, to provide impartial advice or service to the Government or separate entity because of other business activities or relationships. Disclose any potential conflict of interest pertaining to this opportunity. If none, state as such.]
- 9. **Key Personnel:** [Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified].

Key Personnel	Organization	Role and Key Contribution	Level of Effort
Name (Principal Investigator)			%
Name			%
Name			%

[Address the qualifications, capabilities, and experience of the proposed personnel who will be assigned to carry out the project. Ensure resumes/CVs of key personnel are provided in the “Resumes/CVs of Key Personnel” section.]

- 10. **Schedule:** [Identify key technical, schedule, and cost risks, their potential impact and mitigation.]
- 11. **Offeror Resources:** [Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.]
- 12. **Government Resources:** [Identify any key Government facilities, Government equipment, Government property, etc. that your organization requests to use for the effort.]
- 13. **Proposed Cost Share:** [If applicable, this section provides technical evaluators with information on any additional cost share proposed by the Offeror. If proposing cost share, identify deliverables that are associated with cost shared resources as well as the technical benefit resulting from this resource.]
- 14. **Cost Realism:** [This section provides technical evaluators with high-level cost data in order for them to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by cost element.]

**Cost Realism Form EXAMPLE**

This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as samples only. Offeror must complete table with the applicable information. Add or delete columns/rows as needed.

<b>Cost Element</b>	<b>Total Project Value</b>	<b>Description/Explanation</b>
<b>Labor</b>	\$750,000	<i>3000 hrs of senior scientist; 2500 hours of program management; 1000 of hours of contracts management; 1750 hours of scientist</i>
<b>Labor Hours</b>	7,500	
<b>Subcontractors</b>	\$200,000	<i>Sub A - \$25,000; 250 legal advisor hours – each task Sub B - \$25,000; 250 hours of Testing – each task</i>
<b>Subcontractor Hours</b>	2,000	
<b>Consultants</b>	\$40,000	<i>Financial consultant supporting all phases</i>
<b>Consultant Hours</b>	400	
<b>Material/Equipment</b>	\$375,000	<i>pipettes, gloves, computer software – each phase</i>
<b>Other Direct Costs</b>	\$9,000	<i>ship testing materials to lab – each phase</i>
<b>Travel</b>	\$20,000	<i>2 trips for 2 people for 2 days to Washington, DC from Charleston, for program meetings – each task</i>
<b>Indirect Costs</b>	\$278,800	<i>approved by DHHS 30 Sept 23</i>
<b>Fee</b>	\$0	<i>Not applicable if cost share proposed</i>
<b>Total Cost to Government</b>	\$1,672,800	
<b>Cost Share</b>	\$1,160,000	<i>5,000 hours of lab assistant – each task</i>
<b>Total Project Value</b>	<b>\$2,832,800</b>	

## 5. Current & Pending Support

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### Current

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

*[Add additional fields, if needed, to report all current support]*

### Pending

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

*[Add additional fields, if needed, to report all pending support]*

## 6. Success Criteria\*

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[Please complete the table below for each element listed to provide the Success Criteria and anticipated Due Dates]

Biothreat Test Development Milestone	Deliverable	Success Criteria	Due Date (Month from Award)
Assay Feasibility	Customer and Market Requirements Report		
	Design Input Requirements (DIR) Report		
	Pre-Alpha Study Plan		
	Design Review Report		
Assay Verification	Update Customer and Market Requirements Report		
	Update DIR		
	Assay Optimization Deliverables		
	Mid-Technical Feasibility Design Review & Report		
	FDA Pre-Submission		
	Alpha Study Report		
	Beta Study Protocol		
	Clinical Plan Draft		
	Alpha Study Report		
	Clinical Trial Plan		
	Clinical Trial protocol		
	FDA Pre-Submission		
	Technical Feasibility Design Review Report		
Assay Validation	LoD, Analytical Specificity & Sensitivity studies Deliverable		
	Beta Study Report		
	Process Validation Report		
	Assay Stability Report		
	Clinical report		
	Validation Design Review Report		
	FDA Submission Package		
	Receive 510(k) Clearance		
Manufacturing Activities	Deliver tests in preparation for FDA authorization or clearance and post-clearance monitoring		
Capacity Analysis Study	Study Report		

## **7. Resumes/CV of Key Personnel\***

Include the resumes/CV of key personnel from the Offeror's organization, as well as subcontractors or consultants, who will work on this project if selected. The Principal Investigator must be identified.

SOLICITATION CLOSED



## ATTACHMENT 2 – COST PROPOSAL TEMPLATE

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### **General Instructions**

The objective of the Cost Proposal is to provide sufficient cost information to substantiate that the proposed cost is realistic, reasonable and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the Technical Proposal (e.g., costs, cost share, dates). Proposals that deviate substantially from these guidelines or that omit substantial parts or sections may be found non-responsive and may be eliminated from further review and funding consideration.

**To ensure Cost Proposals receive proper consideration, it is mandatory that the Cost Proposal include the information below.**

#### Section I: Cost Proposal Narrative

- a. Cover Page
- b. Overview
- c. Cost Information

#### Section II: Cost Proposal Format

The Cost Proposal Narrative is used to assess various criteria. This section will be used to determine reasonableness, allowability, and allocability of costs. The Cost Proposal Narrative section should provide a more detailed breakdown of the figures that are contained in the Cost Proposal Format. The Cost Proposal Narrative section also should give substantiation and written explanation of proposed costs. Breakdowns should be as accurate and specific as possible. Ensure that any figures presented in this part are consistent with the figures in the Cost Proposal Format.

Separately, the Cost Proposal Format must be provided in Excel, with working formulas to the maximum extent practicable. Optional formats are available on the Members Only website. However, Offerors are encouraged to use their own formats so long as the required level of detail is provided.

# 1. Cost Proposal Cover Page

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[Name of Offeror]  
[Address of Offeror]

**RPP Number RPP-24-06-DxR2**

**[Proposal Title]**

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the RRPV Base Agreement.

[Offeror] certifies that this Proposal is valid for 180 days from the close of the applicable RPP, unless otherwise stated.

[As detailed in Section 2.4 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample:

*This Proposal includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]*

## 2. Cost Proposal Section I: Cost Proposal Narrative Template

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### 1. Cost Proposal Narrative Overview

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[The Cost Proposal Narrative must include sufficient information to evaluate the proposed value through cost information. This information is required to properly perform the cost and/or price analysis of a proposal. Proposals without this information cannot be properly evaluated and may be eliminated from selection for award. All Proposals must provide the following information as part of the Cost Proposal Narrative Overview:]

1. **Overall Approach.** [Provide an overall and succinct explanation of how this Proposal is justified.]
2. **Assumptions.** [Provide any assumptions. Note that assumptions should be limited to cost or pricing. Technical assumptions are better captured in the Statement of Work.]
3. **Preferred Payment Method.** [Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones (with ceiling), (2) Cost Reimbursable/Cost Sharing Milestones (with ceiling), (3) Cost Plus Fixed Fee Milestones (with ceiling) and (4) Fixed Price Milestones (with ceiling).]
4. **Total Cost by Phase Cost Elements.** [Include a list of each phase that is stated in the Statement of Work and its associated total cost by year. The sum of the phases must equal the total listed in the Cost Proposal Formats.]
5. **Cost Share.** [Cost Share includes any costs a reasonable person would incur to carry out (necessary to) proposed project's Statement of Work not directly paid for by the Government. If a proposal includes cost share, then it cannot include fee. Cost Share may be proposed only on cost type agreements. There are two types of cost sharing: Cash Contribution and In-Kind Contribution.]

#### **Cash Contribution:**

Cash Contribution means the Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Project Award. The cash contribution may be derived from the Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Project Award or specific tasks identified within the SOW of a Project Award. Prior IR&D funds will not be considered as part of the Offeror's Cost Share.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Project Award, and restocking the parts and material consumed.

**In-Kind Contribution:**

In Kind Contribution means the Offeror's non-financial resources expended s to perform a Project Award such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Project Award, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Project Award.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on cost share.

If cost share is proposed, the following must be provided:

- A description of each cost share item proposed;
- Proposed dollar value of each cost share item proposed; and
- The valuation technique used to derive the cost share amounts (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).]

## 2. Cost Proposal Narrative Cost Data

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[The Cost Proposal Narrative must include the following cost categories and details, at a minimum.]

1. **Labor Rates.** [Portions of labor information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the position title of all personnel, the labor category description, the hourly rate for each individual, and show estimated hours for each labor category proposed. If an approved organizational estimating procedure use average labor rates for specific labor categories, this would be acceptable.

It is recognized that an organization may not be able to identify all of the personnel to be assigned to the project several years in advance. Where this cannot be done, use generic position titles such as "scientist." If direct labor costs include allocated direct costs or other direct costs in accordance with established accounting and estimating practices and systems, identify these costs separately and provide an explanation and basis for proposed costs.

Provide an explanation for any proposed labor escalation.

Offerors are expected to avoid overtime as much as practicable, except when lower overall costs to the Government will result or when it is necessary to meet urgent program needs. If overtime is proposed, provide an explanation as to why.]

- 2. Salary Rate Limitation.** [Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level is an unallowable cost under the RRPV OTA and shall be addressed in accordance the RRPV Base Agreement.

For purposes of the salary rate limitation, the terms “direct salary,” “salary,” and “institutional base salary” have the same meaning and are collectively referred to as “direct salary.” An individual’s direct salary is the annual compensation that the entity pays for an individual’s direct effort (costs). Direct salary excludes any income that an individual may be permitted to earn outside of duties to the entity. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or [F&A] costs).

The salary rate limitation does not restrict the salary that an entity may pay an individual, it merely limits the portion of that salary that may be paid with Federal funds.

See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current period. See the RRPV Base Agreement for further details.]

- 3. Fringe Benefits.** [Identify whether or not the proposed labor rates include fringe costs. If so, then identify the percentage rate. If not, then provide a statement to that effect and include the fringe costs in the indirect section instead.]
- 4. Travel.** [Portions of travel information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the total travel amount proposed. Provide an estimate of the cost per trip; number of trips; number of days; number of persons; departure city, destination city; approximate travel time frames; and the purpose of the travel. The key is to apply best estimating techniques that are auditable. Include a brief explanation of the methodology used to estimate travel costs. If exact destination is unknown at time of proposal, for pricing purposes use a potential location using best known information. Note that RRPV project awardees are expected to be cost-conscious regarding travel (e.g., using coach rather than first class accommodations and, whenever possible, using Government per diem, or similar regulations, as a guideline for lodging and subsistence costs). If travel is estimated based on an approved methodology, then state as such.]

- 5. Subcontractors/Consultants.** [Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide a list of all subcontractor/consultant and a total cost for each. If a cost and/or price analysis has been performed, provide a copy or summary of results.

Support is required for each subcontractor/consultant as follows:

- If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalog pricing)
- For a subcontractor/consultant less than \$250,000, provide a brief explanation of the work to be performed.
- For a subcontractor/consultant greater than \$250,000 and less than or equal to \$2,000,000, provide a supporting quote and confirmation of compliance with the Salary Rate Limitation.
- If a subcontractor/consultant over \$2,000,000 was competitively solicited, provide the price analysis showing how the price was determined reasonable, summary of competition, and copies of the competitive quotes.
- Absent any of the above, if relying on cost data for a subcontractor/consultant greater than \$2,000,000, a cost-by-cost element breakout must be provided to the same level of detail as the Offeror.]

- 6. Material/Equipment/Other Direct Costs.** [Portions of the material/equipment/other direct cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an itemized list of the material/equipment/other direct costs, including the itemized unit cost and quantity. Identify the supplier/manufacturer and basis of cost (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) for each item, if known. Additionally, a copy of the basis of cost documentation for each piece of proposed material/equipment/other direct cost with a unit cost greater than or equal to \$25,000; or total cost greater than or equal to \$150,000; must be provided. If material/equipment/other direct cost is estimated based on an approved methodology, then state as such.

If any sort of usage cost is determined by a rate, identify the basis and rationale used to derive the rate.

Only in extraordinary circumstances will government funds be used to purchase equipment. Examples of acceptable equipment might include special test equipment, special tooling, or other specialized equipment specific to the research effort. This award is not an assistance agreement/instrument and Offerors should normally have the required equipment to perform.

The value of equipment should be prorated according to the share of total use dedicated to carrying out the proposed work. Include a brief explanation of the prorating methodology used.]

- 7. Indirect Costs.** [Portions of the indirect cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an estimate of the total indirect costs, identify each rate used in the proposal, and provide documentation to support the indirect cost rates by one of the below methods.
- a. Provide a copy of certification from a Federal agency indicating these indirect rates are approved by the Federal agency; or
  - b. Provide a letter from the Offeror's Administrative Contracting Officer, in lieu of a rate certificate, stating these indirect rates are approved by a Federal agency;
  - c. Copy of current forward pricing rate proposal with date proposal was submitted to the Administrative Contracting Officer; or
  - d. Absent Government approved rates, provide detailed supporting data to include (1) indirect rates and all pricing factors that were used; (2) methodology used for determining the rates (e.g., current experience in the organization or the history base used); and, (3) all factors, by year, applied to derive the proposed rates.

Alternately, in lieu of providing indirect rates, if the Offeror can obtain appropriate Government assistance, it may provide a letter from the cognizant Federal audit agency stating that, based upon their review of the Offeror's proposal, the indirect rates used in the proposal are approved by a Federal agency and were applied correctly in this specific proposal. If the Offeror elects to rely on these Government inputs, it is responsible for ensuring any Government agency cooperation is obtained so that the proposal is complete when submitted.]

- 8. Cost of Money.** [If applicable, Cost of Money should be proposed separately from indirect costs.]
- 9. Fee/Profit.** [State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted when cost share is not being contributed. The fees shall be specific to the individual RRPV project and negotiated on a project-by-project basis.]

### **3. Cost Proposal Section II: Cost Proposal Format**

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[The Cost Proposal Format must be provided as a separate Excel document. Offerors are encouraged to use their own Excel cost formats so long as the necessary cost detail is provided. Working formulas should be included to the maximum extent possible. The Cost Proposal Formats provided on the RRPV Members Only Site are **NOT** mandatory.

The Cost Proposal Format section must include a breakout of the total cost proposed by cost element for each year of the program. If required by the RPP, costs must also be broken out by Phase stated in the Statement of Work. The sum of the Phases must equal the total.

Supporting data and justification for labor, equipment/material, team member/subcontractor, consultants, travel, other direct costs, indirect costs, and profit used in developing the cost breakdown also must be included. The Offeror must provide sufficient details to allow a full understanding of and justification for the proposed costs. Offerors must refer to the RPP for a start date for cost estimating purposes.]

SOLICITATION CLOSED



## Attachment 3 – Statement of Work (SOW) Template

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[The SOW developed by the Lead RRPV member organization and included in the proposal (also submitted as a separate document) is intended to be incorporated into a binding agreement if the proposal is selected for award. If no SOW is submitted with the proposal, there may be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. The following is the required format for the SOW.]

### Statement of Work

**RPP#:** (RPP NUMBER)

**Project Identifier:** RRPV24-06-DxR2-XXX

**Project Title:**

**Member Organization Name:**

**1.0 Introduction/Background** (To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)

**2.0 Scope/Project Objective** (To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

**3.0 Requirements** (To be provided initially by the Offeror at the time of proposal submission to be finalized by the Government based on negotiation of Scope/Project Objective).

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

**4.0 Deliverables** (To be provided initially by the Offeror at the time of proposal submission.

Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Below are the following minimum deliverables for this RPP:

**4.1 Meetings**

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.1.1	Post Award Teleconference	<p>The Performer must complete an initial teleconference after the initiation of the agreement period of performance.</p> <ol style="list-style-type: none"> <li>1. Outline activities for the next 30 days</li> <li>2. Discuss agenda items for the post-award Kickoff Meeting</li> </ol>	<ul style="list-style-type: none"> <li>• Within 5 business days after the initiation of the agreement period of performance</li> <li>• Performer must submit agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply a teleconference number</li> <li>• PAR edits/approves and instructs Performer to distribute agenda at least 2 business days prior to meeting</li> <li>• Performer submits meeting minutes to PAR within 3 business days after the meeting</li> <li>• PAR reviews, comments, and approves minutes within 10 business days</li> </ul>
4.1.2	Kickoff Meeting	The Performer must complete a Kickoff meeting after the initiation of	<ul style="list-style-type: none"> <li>• Within 10 business days after the initiation of the</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		the agreement period of performance.	<p>agreement period of performance, pending concurrence by the Agreements Officer</p> <ul style="list-style-type: none"> <li>• Performer must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference</li> <li>• PAR edits/approves and instructs Performer to distribute agenda at least 3 business days prior to meeting</li> <li>• Performer submits meeting minutes to PAR within 3 business days after the meeting</li> <li>• PAR reviews, comments, and approves minutes within 10 business days</li> </ul>
4.1.3	Weekly Teleconference	<p>The Performer must participate in teleconferences weekly with BARDA to discuss the technical performance on the agreement. Meeting frequency may be increased or decreased as needed during the course of the project.</p>	<ul style="list-style-type: none"> <li>• Performer must submit agenda to PAR no later than 2 business days in advance of meeting</li> <li>• PAR edits/approves and instructs Performer to distribute agenda prior to meeting</li> <li>• Performer must distribute agenda and presentation materials at least 2 calendar days in advance of meeting</li> <li>• Performer must submit meeting minutes to PAR within 3 business days of the meeting</li> <li>• PAR reviews, comments, and approves minutes within 10 business days</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.1.4	Technical, Subgroup, Ad Hoc Teleconference(s)	<p>The Performer must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the agreement.</p> <p>Meeting frequency may be defined as needed during the course of the project.</p>	<ul style="list-style-type: none"> <li>• Performer must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting</li> <li>• PAR edits/approves and instructs Performer to distribute agenda prior to meeting</li> <li>• Performer must distribute agenda and presentation materials at least 24 hours in advance of meeting</li> <li>• Performer must submit meeting minutes to PAR within 3 business days of the meeting</li> <li>• PAR reviews, comments, and approves minutes within 6 business days</li> </ul>
4.1.5	Periodic Review Meetings	<p>At the discretion of the Government, the Performer must hold up to four per year recurring Project Review Meetings, held by teleconference or face-to face either in Washington, D.C. or at work sites of the Performer or sub-performers. Face-to-face meetings shall alternate between Washington, D.C. and Performer, sub-performer sites. The meetings will be used to discuss agreement progress in relation to the Program Management deliverables described in this agreement as well as nonclinical, technical, regulatory, and ethical aspects of the program.</p>	<ul style="list-style-type: none"> <li>• Performer must submit an agenda and itinerary, if applicable, at least 5 business days, and Performer must provide presentation materials at least 3 business days, in advance of the meeting</li> <li>• PAR edits/approves and instructs Performer to distribute agenda prior to meeting by at least 3 business days</li> <li>• Performer provides meeting minutes to PAR within 3 business days after the meeting</li> <li>• PAR reviews, comments, and approves minutes within 10 business days</li> </ul>

#### 4.2 Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.2.1	Project Management Plan (PMP)	<p>The Project Management Plan should define the overall plan for how the project will be executed, monitored and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer team(s).</p> <p>The PMP may be a single detailed document or composed of one or more subsidiary planning documents. These additional planning documents provide guidance and direction for specific management, planning, and control activities such as schedule, cost, risk, staffing, change control, communications, quality, procurement, deployment, etc. Each of the subsidiary planning documents should be detailed to the extent required by the specific project.</p>	<ul style="list-style-type: none"> <li>• Performer must submit a Project Management Plan (PMP) <ul style="list-style-type: none"> <li>○ Within 30 calendar days after the initiation of the agreement period of performance</li> <li>○ Updates should be provided to reflect any key changes and reviewed at least annually.</li> </ul> </li> </ul>
4.2.2	Gantt Chart/Timeline	<p>The Gantt Chart/Timeline should be detailed to the extent required by the specific project.</p>	<ul style="list-style-type: none"> <li>• At first project meeting and as updated no later than every 30 calendar days. Provided in pdf.</li> </ul>
4.2.3	Communication Plan	<p>The Performer must develop and implement an effective Communication Plan that details the flow of information between BARDA, Performer, collaborators, vendors, and other organizations.</p> <p>The Communication Plan must also include a press release review process.</p>	<ul style="list-style-type: none"> <li>• Performer must submit a Communication Plan <ul style="list-style-type: none"> <li>○ Within 30 calendar days after the initiation of the agreement period of performance</li> <li>○ Updates should be provided to reflect any key changes and reviewed at least annually.</li> </ul> </li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.2.4	Performer Locations	The Performer must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location, to include sub-performer and critical vendors of reagents and supplies. Performers must include vendors for critical infrastructure protection.	<ul style="list-style-type: none"> <li>• Performer must submit Work Locations Report: <ul style="list-style-type: none"> <li>○ Within 5 business days after the initiation of the agreement period of performance</li> <li>○ Within 30 business days after a substantive location or capabilities change <ul style="list-style-type: none"> <li>• Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO</li> </ul> </li> </ul> </li> </ul>
4.2.5	Pandemic/Public Health Emergency Facility and Operational Management Plan	Performer must develop a Pandemic Facility and Operational Management Plan, including change procedures from normal to pandemic operations and continuity of operations in the event of a declared pandemic emergency. Performer must identify critical infrastructure.	<ul style="list-style-type: none"> <li>• Performer must submit Pandemic Management Plan: <ul style="list-style-type: none"> <li>○ Draft within 15 days of award</li> <li>○ Final within 30 days of award</li> </ul> </li> </ul>
4.2.6	Request for Information (RFI) Responses	Upon request of the Government, the Performer must provide complete responses to ad hoc RFIs. RFIs may address key cost, schedule, and technical updates. Responses may be shared with senior Government leaders and should be provided	<ul style="list-style-type: none"> <li>• Performer must submit an RFI response to BARDA by email within 24 hours after Performer receipt of the RFI.</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>on a non-confidential basis unless the response includes confidential information in which case Performer must provide the response in both confidential and non-confidential formats.</p>	
4.2.7	<p>Monthly &amp; Annual Technical Progress Reports/Annual Meeting</p>	<p>The Monthly and Annual Technical Progress reports must address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS) – or as applicable.</p> <ol style="list-style-type: none"> <li>1. An Executive Summary highlighting the progress, issues and relevant manufacturing, nonclinical, regulatory, and publication activities. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages</li> <li>2. Progress in meeting agreement milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports must detail the planned and actual progress during the period covered, explaining any differences between</li> </ol>	<ul style="list-style-type: none"> <li>• The Performer must submit monthly reports on the 15<sup>th</sup> day of the month covering the preceding month; Annual Reports submitted on the last calendar day of the month after each agreement anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable 4.2.8 Draft and Final Technical Progress Report). The PAR and AO will review the monthly reports with the Performer and provide feedback</li> <li>• Performer must provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits</li> <li>• Performer must provide notification of designated safety events to the AO and PAR within 24 hours of being notified of the event</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>the two and the corrective steps</p> <p>3. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS</p> <p>4. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission, and next steps</p> <p>5. Estimated and Actual Expenses</p> <ul style="list-style-type: none"> <li>This report must also contain a narrative or table detailing whether there is a significant discrepancy (&gt;10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subperformer expenses from the previous month if the Subperformer did not submit a bill in the previous month. If the Subperformer(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be</li> </ul>	



#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>included in this report for those respective Subperformers. If the PAR and AO are satisfied that the Performer's reporting is sufficient to convey this information, this section may be waived.</p> <p>6. Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and other public-facing material or information containing data generated under this agreement</p>	
4.2.8	Draft and Final Technical Progress Report	<p>A draft Final Technical Progress Report must contain a summation of the work performed and the results obtained over the entire agreement. This report must be in sufficient detail to fully describe the progress achieved under all milestones. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report must be duly marked as 'Draft.' The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results</p>	<ul style="list-style-type: none"> <li>• The Performer must submit the Draft Final Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP</li> <li>• PAR will provide feedback on draft report within 21 calendar days of receipt, which the Performer must consider incorporating into the Final Report</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>obtained for the entire agreement PoP. The final report must document the results of the entire agreement. The final report must be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the agreement.</p>	

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**4.3 Technical Reporting: Manufacturing**

Technical Reporting: Manufacturing			
4.3.1	Supply Chain Resiliency Plan	<p>The Performer must develop and submit within 30 calendar days after the initiation of the agreement period of performance, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with all components, hardware, reagents, supplies, and work-in-process through to finished goods.</p> <p>a. A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.</p> <p>Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a product, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.</p> <p>The performer must identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of</p>	<p>Due within 30 calendar days after the initiation of the agreement period of performance</p> <p>Reports for critical items must be provided within ten (10) calendar days after AO issues the request. The Performer may arrange for additional time if deemed necessary, and agreed to by the AO.</p>

		<p>award. This document must address planning and scheduling for the necessary components, upstream, downstream, component assembly, finished product and delivery events as necessary for the delivery of product.</p> <ul style="list-style-type: none"> <li>a. Communication for these requirements must be updated as part of an annual review, or as necessary, as part of regular communications.</li> <li>b. For hardware components, all electronics, fabrication, ingredients, and other materials must be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery must be addressed taking into account capacity capabilities.</li> <li>c. The focus on the aspects of resiliency must be on critical components and aspects of complying with the agreement delivery schedule. Delivery methods must be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the agreed deliveries.</li> </ul> <p>The performer must articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.</p> <ul style="list-style-type: none"> <li>a. Production rates and lead times must be understood and communicated to the Agreements Officer (AO) or the Agreements Officer's</li> </ul>	
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		<p>Representative (PAR) as necessary.</p> <p>b. Production throughput critical constraints must be well understood by activity and by design, and communicated to agreement personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.</p> <p>Reports for critical items must include the following information:</p> <ul style="list-style-type: none"> <li>a. Critical Material</li> <li>b. Vendor</li> <li>c. Supplier, Manufacturing / Distribution Location</li> <li>d. Supplier Lead Time</li> <li>e. Shelf Life</li> <li>f. Transportation / Shipping restrictions</li> </ul> <p>The AO and PAR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government.</p>	
4.3.2	Performer Locations	<p>Using a BARDA-supplied template, the Performer must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location, to include sub-performer and critical vendors of reagents and supplies.</p> <p>Performers must include vendors for critical infrastructure protection.</p>	<ul style="list-style-type: none"> <li>• Performer must submit Work Locations Report: <ul style="list-style-type: none"> <li>○ Within 5 business days after the initiation of the agreement period of performance</li> <li>○ Within 30 business days after a substantive location or capabilities change</li> <li>○ Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health</li> </ul> </li> </ul>

			Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
4.3.3	Pandemic/Public Health Emergency Facility and Operational Management Plan	<p>Performer must develop a Pandemic Facility and Operational Management Plan, including change procedures from normal to pandemic operations and continuity of operations in the event of a declared pandemic emergency. Performer must identify critical infrastructure.</p>	<p>Performer must submit Pandemic Management Plan:</p> <ul style="list-style-type: none"> <li>• Draft within 15 days of award</li> <li>• Final within 30 days of award</li> </ul>
4.3.4	Product Development Source Material Report	<p>The Performer must submit detailed data regarding critical project materials, materials sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: Bill of Materials (BOM), physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of nonclinical. The BOM submitted must include at minimum the manufacturer part and/or lot numbers, part names, descriptions, unit(s) of measure, procurement type (e.g., off-the shelf, manufactured according to specification), consumables. The BOM must include the quantity required per production run and a schedule for consumable procurement and production.</p> <p>In the event of a Public Health Emergency, HHS may require daily reporting of manufacturing campaigns during response operations. BARDA may provide a table in tabular format for Performer to be used to submit</p>	<ul style="list-style-type: none"> <li>• Performer must submit a Product Development Source Material Report <ul style="list-style-type: none"> <li>○ Within 30 calendar days after the initiation of the agreement period of performance</li> <li>○ Within 30 calendar days of changes made to sources and/or materials</li> <li>○ On the 6<sup>th</sup> month agreement anniversary.</li> </ul> </li> <li>• The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission</li> <li>• If corrective action is recommended, Performer must address all concerns raised by BARDA in writing</li> <li>• The Performer must submit Product Development and Source Material report via spreadsheet.</li> </ul>

		<p>such data which would include but not be limited to the following:</p> <ul style="list-style-type: none"> <li>• Manufacturing locations</li> <li>• Seed development or other starting material manufacturing</li> <li>• Critical materials, consumables, and components</li> <li>• Storage/inventory of starting materials</li> </ul>	
4.3.5	Manufacturing Reports and Projections	<p>The Contractor must submit detailed data regarding manufacturing and manufacturing finished product projections/actuals, including product for clinical study use.</p> <p>BARDA may provide a table in tabular format for Performer to be used to submit such data which would include but not be limited to the following:</p> <ul style="list-style-type: none"> <li>• Storage/inventory of consumable materials (e.g., reagents, primer, batteries, swabs, etc.)</li> <li>• Shipment of ancillary materials (e.g., reagents, primer, batteries, swabs, etc.)</li> <li>• Disposal of ancillary materials (e.g., reagents, primer, batteries, swabs, etc.)</li> <li>• Starting or raw material for manufacturing</li> <li>• Manufacturing production projections</li> <li>• Production of finished and packaged devices</li> <li>• Storage/inventory of starting materials, consumable materials and finished product</li> </ul>	<ul style="list-style-type: none"> <li>• Performer must update the manufacturing data at minimum weekly during manufacturing campaigns and daily during response operations (i.e., where a Public Health Emergency has been declared) with the first deliverable submission within 15 days of award. Updates must be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture.</li> <li>• Dose Tracking must be completed via spreadsheet or other format (e.g., XML or JSON) as agreed to by USG and Performer.</li> </ul>

		<ul style="list-style-type: none"> <li>• Stability information of all components including reagents and biological material (if any)</li> <li>• Shipment of components or final finished product</li> <li>• Disposal of components or finished product</li> </ul> <p>In the event of a Public Health Emergency, HHS may require daily reporting of manufacturing campaigns during response operations.</p>	
4.3.6	Manufacturing Campaign Reports	<p>In the event of a <u>large-scale</u> manufacturing campaign, the Performer must provide Manufacturing Campaign Reports to BARDA as described under 4.3.5 Manufacturing Reports and Projections. The Manufacturing Campaign Reports should include lot history, major deviations, PPQ reports, CoAs, batch reports, storage location, purity, potency, yield.</p> <p>If Manufacturing Campaign Reports are provided to FDA, the Performer must provide Reports to BARDA for review and comment prior to submission to FDA.</p> <p>The PAR and AO reserve the right to request within the Period of Performance (PoP) a non-proprietary Manufacturing Campaign Report for distribution within the USG.</p>	<ul style="list-style-type: none"> <li>• Performer must submit Manufacturing Reports at least 15 business days prior to FDA submission in an agreed-upon electronic format.</li> <li>• The Government will provide written comments to the manufacturing report within 15 business days after the submission</li> <li>• If corrective action is recommended, Performer must address, in writing, the concerns raised by BARDA.</li> <li>• Performer must revise the reports to address BARDA's concerns and/or recommendations prior to FDA submission.</li> <li>• The Performer must submit Final FDA submission to BARDA concurrently or no later than 1 business day after submission to the FDA.</li> </ul>



4.3.7	Supply Chain and Distribution Tracking <sup>4</sup>	<p>Distribution Concept of Operations. BARDA, CDC, and MCM Manufacturers play an important role in the distribution of medical countermeasures to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline. BARDA will relay final medical technology product specifications as it is being released to the CDC for allocation and ordering by the jurisdiction public health departments. This information will be returned to BARDA as CDC replenishment orders (CDC Purchase Order, PO) on a daily basis with shipping instructions on where to send final product.</p> <p>Order quantity will be determined by the USG based on need. Order quantity may not be limited to lot-sized shipments or pallet-sized shipments. Manufacturers will use the PO information to ship final product as bulk shipments to designated distribution centers for final distribution to end users and end user networks. BARDA will provide the Performer with a list of distribution centers and contact information prior to the start of a distribution campaign.</p>	<p>Performer must provide the following information in order to coordinate the movement and delivery of final product from manufacturing locations to USG distribution centers:</p> <ul style="list-style-type: none"> <li>• Shipment Plan to include detailed timelines between PO receipt and delivery of final medical technology product at the distribution center. Upon USG request, Performer must support expedited shipments. Ultracold storage conditions should be planned to be direct-shipped to end users from the manufacturer.</li> <li>• Provide Points of Contact information (name, title, phone, email) for manufacturing / supply chain personnel for each manufacturing, CMO, storage, and distribution locations: <ul style="list-style-type: none"> <li>• Head of Manufacturing</li> <li>• Production Planning</li> <li>• Logistics</li> <li>• Distribution</li> <li>• Labeling</li> </ul> </li> <li>• Provide labeling, packaging, and distribution information as soon as it becomes available. Plan to support CDC Immunization Information Systems (IIS) codeset development. At a minimum, provide the following: <ul style="list-style-type: none"> <li>• MSDS / Specification Sheet</li> <li>• Health Distribution Alliance (HDA) Form</li> <li>• Primary Container Information</li> <li>• Quantity Unit of Sale per pallet</li> <li>• Quantity cartons per pallet</li> </ul> </li> </ul>
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4.3.8	Packing List	<p>Performer must include the following data elements on the packing lists sent with all bulk shipments to centralized depots:</p> <ul style="list-style-type: none"> <li>• Transaction Information (TI), Transaction History (TH), Transaction Statement (TS)</li> <li>• CDC Purchase Order (PO) number (which BARDA will provide at the time the bulk order is submitted)</li> <li>• Agreement number</li> <li>• Copy of the MSDS (with QR code) in the packing list envelope</li> </ul>	
4.3.9	Advance Shipment Notices (ASNs)	Performer must transmit bulk shipment ASNs to CDC via Electronic Data Interchange (EDI)	Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. CDC will provide EDI

		Rationale: Required for receiving at centralized distributor.	mapping specifications that include the CDC generated PO number
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#### 4.4 Technical Reporting: Nonclinical and/or Analytical Studies

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.4.1	Draft and Final Nonclinical and Analytical Study Report(s)	Performer must provide Draft and Final Nonclinical Study Reports and/or Draft and Final Analytical Study Reports to BARDA for review and comment.	<ul style="list-style-type: none"> <li>• Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA</li> <li>• The Performer must submit Subperformer-prepared reports received by the Performer to the PAR and AO for review and comment no later than 5 business days after receipt by Performer</li> <li>• The Government will provide written comments to the Draft Report for Nonclinical Study Reports and/or Analytical Study Report within 15 business days after the submission</li> <li>• Final report due 30 calendar days after receiving comments on the Draft Report; If corrective action is recommended, Performer must address all concerns raised by BARDA in writing</li> <li>• Performer must consider revising reports to address BARDA's recommendations prior to FDA submission</li> </ul>
4.4.2	Nonclinical and Analytical Study Protocols	The Performer must submit draft and final nonclinical and/or analytical study protocols to AO and PAR.	<p>The Performer must submit Draft nonclinical study protocols to PAR electronically prior to finalization.</p> <ul style="list-style-type: none"> <li>○ BARDA will provide comments within 10 business days of receipt of draft protocol</li> <li>○ Performer must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol.</li> <li>○ PAR must approve the final protocol <ul style="list-style-type: none"> <li>• The Performer must submit Final nonclinical</li> </ul> </li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			study protocols to PAR electronically no later than 10 business days prior to FDA submission.
4.4.3	Nonclinical Study Final Data Submission Package	<p>BARDA must have access to methods.</p> <p>BARDA must have unlimited rights to all nonclinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this agreement.</p> <p>At BARDA's request, the Performer must provide any nonclinical-related agreement deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the nonclinical-related deliverables, as BARDA deems necessary.</p>	<ul style="list-style-type: none"> <li>• Performer must submit at least 15 business days prior to agreement end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.</li> </ul>

#### 4.5 Technical Reporting: Clinical Studies and/or Trials

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.5.1	Clinical Study/Trial Protocols	The Performer must submit draft and final clinical protocols to AO and PAR.	<p>The Performer must submit Draft study protocols to PAR electronically prior to finalization.</p> <ul style="list-style-type: none"> <li>○ BARDA will provide comments within 10 business days of receipt of draft protocol</li> <li>○ Performer must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol.</li> <li>○ PAR must approve the final protocol. <ul style="list-style-type: none"> <li>• The Performer must submit Final study protocols to PAR</li> </ul> </li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			electronically no later than 10 business days prior to FDA submission.
4.5.2	Clinical Study/Trial Documentation	<p>The Performer must provide the following documents for any portion of a study funded under this agreement:</p> <ul style="list-style-type: none"> <li>• Investigational Product Accountability Plan</li> <li>• Study Supplies Procurement Plan</li> <li>• Site selection questionnaire</li> <li>• Overall Recruitment and Retention plan</li> <li>• Informed Consent Form (ICF) template</li> <li>• eConsent</li> <li>• Data Management Plan</li> <li>• Data Validation/Quality Plan</li> <li>• Statistical Analysis Plan</li> <li>• Sample/Specimen Management Plan</li> <li>• Diversity inclusion plan to enroll based on US demographic based on most recent census</li> <li>• Investigator Brochure</li> <li>• eCRF</li> </ul>	<ul style="list-style-type: none"> <li>• The Performer must submit Draft study documents to PAR electronically prior to finalization. <ul style="list-style-type: none"> <li>○ BARDA will provide comments within 10 business days of receipt of draft document</li> <li>○ Performer must respond in writing to BARDA comments and recommendations prior to finalization of protocol.</li> </ul> </li> <li>• The Performer must submit Final study documents to PAR electronically no later than 10 business days prior to FDA submission.</li> <li>• Performer must submit draft Statistical Analysis Plan no later than 20 business days after protocol is finalized. The final Statistical Analysis Plan must be submitted 5 business days prior to study database unblinding.</li> <li>• Performer must submit final version Investigational Product and Clinical Supplies Management Plan at</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<ul style="list-style-type: none"> <li>• Community engagement materials, posters, media advertisements, animations, graphics, etc.</li> <li>• Clinical Trial Agreements</li> <li>• Monitoring Plan</li> <li>• Safety Monitoring Plan (processes to provide 24-7 pharmacovigilance and safety monitoring)</li> <li>• SAE Reconciliation SOP (if safety database separate from clinical database)</li> <li>• Processes to manage and support an independent DSMB</li> <li>• DSMB Charter</li> <li>• DSMB template reports and DSMB reports</li> <li>• Draft and Final Tables, Listings, and Figures (TLFs), ad hoc TLFs</li> <li>• Plan for notifying participants of his/her treatment assignment</li> <li>• Essential Regulatory Documents that demonstrate compliance with</li> </ul>	<p>least 6 weeks prior to investigational product shipments to clinical sites.</p> <ul style="list-style-type: none"> <li>• Performer must retain the capability to procure, ship, deliver, install, and train on the use of all required supplies, including, but not limited to, documents, files, and equipment.</li> <li>• Final TLFs must be submitted to the PAR 3 weeks after database lock.</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>the standards of ICH E6 (R2) Good Clinical Practice and with all applicable regulatory requirements</p> <ul style="list-style-type: none"> <li>Pharmacy Manual</li> </ul> <p>The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during clinical site monitoring visits.</p>	
4.5.3	ClinicalTrials.Gov Posting and Results Reporting	Per clinicaltrials.gov registration and reporting requirements.	<p>Performer must post results:</p> <ul style="list-style-type: none"> <li>3 months from any interim analysis</li> <li>3 months from primary analysis</li> <li>3 months from final analysis</li> </ul>
4.5.4	Draft and Final Clinical Study/Trial Report(s)	Performer must provide Draft and Final Clinical Study/Trial Reports to BARDA for review and comment.	<ul style="list-style-type: none"> <li>Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA</li> <li>The Performer must submit Subperformer-prepared reports received by the Performer to the PAR and AO for review and comment no later than 5 business days after receipt by Performer</li> <li>The Government will provide written comments to the Draft Report for Clinical Study Reports within 15 business days after the submission</li> <li>Final report due 30 calendar days after receiving comments on the Draft Final Report for Clinical Trial; If corrective</li> </ul>



#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<p>action is recommended, Performer must address all concerns raised by BARDA in writing</p> <ul style="list-style-type: none"> <li>• Performer must consider revising reports to address BARDA's recommendations prior to FDA submission</li> </ul>
4.5.5	Project-Specific First Site Activated for First Subject First Visit	Performer should have all pre-study planning complete and be ready to enroll subjects.	<ul style="list-style-type: none"> <li>• Within five days of IRB approval</li> </ul>
4.5.6	Clinical Report During Active Enrollment Periods <sup>1</sup>	<p>The Performer must submit daily the data specs in the attached document during active clinical trial enrollment.</p> <p>Clinical Report submission must be by electronic transfer, e.g., from Performer Electronic Data Capture (EDC) system/Interactive Voice Response System (IVRS) to USG.</p>	<ul style="list-style-type: none"> <li>• Performer must submit, in a format and to a location agreed to by BARDA, data specs on a daily basis starting when first subject is enrolled and ending when last subject is enrolled.</li> </ul>
4.5.7	Access to Electronic Systems Used in Trial Conduct	The Performer must provide access to systems used in trial conduct.	<ul style="list-style-type: none"> <li>• Due within 20 calendar days of PAR request, no later than ten calendar days prior to first site activated</li> </ul>
4.5.8	Specimen Collection for Future Use	<p>The sample types, timepoints, volume collected, and collection, transfer, and storage procedures must be conducted as defined by the AO or PAR and must be defined in the study protocol.</p> <p>These samples and associated clinical data (metadata) must be transferred to a BARDA-managed repository according to a schedule to be determined by the AO or PAR.</p> <p>The Performer must remove any personal identifying</p>	<ul style="list-style-type: none"> <li>• Performer must provide weekly specimen inventory reports during the course of the clinical trial.</li> <li>• Specimens and associated clinical data must be transferred to BARDA upon request from the AO or PAR according to a schedule to be determined by the AO or PAR.</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>information (PII) from the samples and assign each with a unique subject identification number before transferring to BARDA. The Performer must provide a specimen disposition report prior to transferring the material to the repository. Testing on samples can include but will not be limited to in vitro biochemical, biophysical, and cell-based assays. BARDA will establish a Deliverables Table, Technology Transfer and Evaluation Agreement (TTEA) and Data Distribution Agreement (DDA) with appropriate partners as applicable (i.e., manufacturer, repository, testing labs, data analysis services), necessary to secure execution, timelines, materials and preserve intellectual property.</p>	
4.5.9	Clinical Study/Trial Final Study Package	<p>BARDA must have unlimited rights to all clinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this agreement.</p> <p>At BARDA's request, the Performer must provide any clinical-related agreement deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the clinical-related deliverables, as BARDA deems necessary.</p> <p>If clinical study/trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).</p>	<ul style="list-style-type: none"> <li>• Performer must submit the Clinical Study/Trial Final Study Package at least 15 business days prior to agreement end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.</li> </ul>
4.5.10	Data Exchange Package(s)	As part of Final or Draft Submission Package(s), upon BARDA request,	<ul style="list-style-type: none"> <li>• Performer must provide the Technical Documents and/or</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Submitted to Regulatory Agency(s)	and also as part of deliverables, the Performer must provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), Analysis Datasets (e.g., CDISC-compliant ADaM SAS XPT datasets), and any additional documents including but not limited to Reviewer's Guide (PDF), SDTM annotated CRF(s) (PDF), and data definition file(s) (XML) to BARDA. Other data exchange standards or file formats might be used if discussed with and agreed by BARDA. The Performer must provide the software programs (e.g., SAS programs, R programs) used to create any ADaM datasets and generate tables and figures associated with all analyses, including primary and secondary efficacy analyses. <i>List of abbreviations: XPT = SAS Transport Format (XPORT) Version 5; PDF = Portable Document Format; XML = Extensible Mark-up Language; CDISC = Clinical Data Interchange Standards Consortium</i>	datasets within 20 business days of request from the AO or PAR
4.5.11	Clinical Trial Datasets	Performer must make clinical trial datasets publicly available.	Performer must post clinical trial datasets on a web-based platform easily accessible by the public: <ul style="list-style-type: none"> <li>○ 3 months from any interim analysis <b>supporting any action (e.g., regulatory filing, protocol change), if applicable</b></li> <li>○ 3 months from primary analysis</li> <li>○ 3 months from final analysis</li> </ul>
4.5.12	Additional Data Package(s)	Upon request, the Performer must provide raw data, tabulation Data	<ul style="list-style-type: none"> <li>● Performer must provide the data package(s) within 20</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		and/or analysis data in a BARDA-agreed upon format and supporting documents that might be including but not limit to the list of files in package, technical specification documents, data analysis programs. Data exchange standards and file formats must be discussed and agreed upon with BARDA.	business days of request from the AO or PAR

#### 4.6 Quality Assurance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.6.1	Quality Management Plan (QMP)	<p>Performer must develop an overall project Quality Management Plan to include a description of all quality activities and personnel involved in ensuring all activities are conducted and data are maintained under cGMP (where relevant) and ISO standards for relevant Medical Technologies (e.g. IVD and/or IDE), and all products are managed to ensure that all regulatory requirements are met.</p> <p>All quality management plans must include Subperformer quality management plans specifically addressing how Subperformer quality will be managed. All Subperformers must have a current quality agreement with the Performer and a recent vendor qualification audit.</p>	<ul style="list-style-type: none"> <li>• Performer must submit a Quality Management Plan <ul style="list-style-type: none"> <li>○ Within 30 calendar days after the initiation of the agreement period of performance</li> <li>○ On the 6<sup>th</sup> month agreement anniversary to include any updates.</li> </ul> </li> </ul>
4.6.2	BARDA Audit	Performer must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by	<ul style="list-style-type: none"> <li>• If issues are identified during the audit, Performer must submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>HHS. If BARDA, the Performer, or other parties identify any issues during an audit, the Performer must capture the issues, identify potential solutions and submit a report to BARDA detailing the finding and corrective action(s). HHS reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this agreement and all records related to the manufacture, testing (including but not limited to analytical testing, nonclinical study), and storage of the product.</p>	<ul style="list-style-type: none"> <li>• PAR and AO will review the report and provide a response to the Performer with 10 business days</li> <li>• Once corrective action is completed, the Performer will provide a final report to BARDA</li> </ul>
4.6.3	FDA Inspections/Site visits	<p>In the event of an FDA inspection that occurs in relation to this agreement and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this agreement, including, but not limited to manufacturing facilities, the Performer must provide the USG with an exact copy (non-redacted) of the FDA Form 483 or summary and the Establishment Inspection Report (EIR). The Performer must provide the PAR and AO with copies of the plan and FDA submissions for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the inspection report, status updates during the plan's execution and a copy of all final responses to the FDA. The</p>	<ul style="list-style-type: none"> <li>• Performer must notify AO and PAR within 10 business days of the scheduling of a scheduled FDA inspection/site visit or within 24 hours after inspection/site visit if the FDA does not provide advanced notice</li> <li>• Performer must provide copies of any FDA inspection report received from Subperformers that occur as a result of this agreement or for this product within 1 business day of receiving correspondence from the FDA, a Subperformer, or third party</li> <li>• Within 10 business days of inspection report, Performer must provide AO with a plan for addressing areas of nonconformance, if any are identified</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>Performer must also provide redacted copies of any FDA inspection reports received from Subperformers that occur as a result of this agreement or for this product.</p> <p>The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during the opening, any daily debriefs, and the final debrief by the regulatory inspector.</p>	
4.6.4	Quality Assurance Audits and Subperformer Monitoring Visits	<p>BARDA reserves the right to participate in QA audits performed by the Performer. Upon completion of the audit/site visit the Performer must provide a report capturing the findings, results and next steps in proceeding with the Subperformer. If action is requested of the Subperformer, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, ISO, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Performer must provide responses from the Subperformers to address these concerns and plans for corrective action.</p> <p>The Performer must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, including manufacturing person in plant, at nonclinical sites, CROs, and any other</p>	<ul style="list-style-type: none"> <li>• Performer must notify AO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of Subperformers</li> <li>• Performer must notify the PAR and AO within 5 business days of report completion and provide Draft Report.</li> <li>• PAR and AO will review the report and provide a response to the Performer with 10 business days before audit can be finalized.</li> <li>• Performer must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report.</li> <li>• Performer must provide a final closeout report that all CAPAs were addressed to PAR and AO</li> <li>• Performer must notify BARDA within 24 hours of any critical and/or major findings</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>vendor involved in the conduct of the nonclinical study under agreement.</p>	
4.6.5	Risk Management Plan (RMP)	<p>The Performer must provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan must include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule, and performance.</p>	<ul style="list-style-type: none"> <li>• A Draft is due within 45 calendar days after the initiation of the agreement period of performance; updates to the RMP are due concurrent with Monthly Technical Progress Reports, but may be communicated more frequently. The Performer may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update</li> <li>• BARDA will provide Performer with a list of concerns in response plan submitted</li> <li>• Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns</li> <li>• The Performer must submit updates at minimum of every three months.</li> </ul>
4.6.6	Integrated Master Schedule (IMS)	<p>The Performer must provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks.</p>	<ul style="list-style-type: none"> <li>• The Performer must submit the IMS in both PDF and an agreed-upon electronic format (e.g., Microsoft Project) to the PAR</li> <li>• The first Draft of the IMS is due within 30 business days after the initiation of the agreement period of performance</li> <li>• The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<ul style="list-style-type: none"> <li>• Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports</li> <li>• During a declared Public Health Emergency, the Performer must submit the IMS within 10 business days after the initiation of the agreement period of performance, updates are due weekly, and any significant change (i.e., a change which would impact the schedule by greater than one week) must be reported immediately to the PAR and/or designee.</li> </ul>
4.6.7	Deviation Notification and Mitigation Strategy	<p>Process for changing IMS activities associated with cost and schedule as baselined. Performer must notify BARDA of significant proposed changes to the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Performer must provide a high-level management strategy for risk mitigation.</p>	<ul style="list-style-type: none"> <li>• The Performer must submit Deviation Notification and Mitigation Strategy at least 10 business days prior to the Performer anticipating the need to implement changes</li> </ul>
4.6.8	Incident Report	<p>Performer must communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance. "Significant" is defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the PAR. Incidents that present liability</p>	<ul style="list-style-type: none"> <li>• Due within 48 hours of activity or incident or within 24 hours for a security activity or incident</li> <li>• Email or telephone with written follow-up to PAR and AO</li> <li>• Additional updates due to PAR and AO within 48 hours of additional developments</li> <li>• Performer must submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues</li> <li>• If corrective action is deemed necessary, Performer must</li> </ul>



#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		to the project even without cost/schedule impact.	address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

**4.7 Advanced R&D Products**

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.7.1	Technical Documents	<p>Upon request, Performer must provide AO and PAR with deliverables from the following activities: quality agreements between Performers and sub-performer, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis. The AO and PAR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government.</p>	<ul style="list-style-type: none"> <li>• Performer must provide technical document within 10 business days of AO or PAR request. Performer can request additional time on an as needed basis</li> <li>• If corrective action is recommended, the Performer must address, in writing, concerns raised by BARDA in writing</li> </ul>
4.7.2	Publications	<p>The Performer must submit any manuscript, scientific meeting abstract, poster, presentation, and any other public-facing material or information disseminated outside the purview of other deliverables, containing data generated under this agreement, to</p>	<ul style="list-style-type: none"> <li>• Performer must submit all manuscript or scientific meeting abstracts to PAR and AO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts, posters, or any other material</li> <li>• Performer must address in writing all concerns raised by BARDA in writing</li> <li>• Final submissions must be submitted to BARDA concurrently or no later than within one (1) calendar day of its submission</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>BARDA for review prior to submission.</p> <p>Acknowledgment of BARDA funding must be included as noted in agreement article 11.</p>	<ul style="list-style-type: none"> <li>• Performer must list all publication material in the Monthly Technical Progress Report</li> </ul>
4.7.3	<p>Performer Nonclinical Publication Timeline and USG Right to Publish Data</p>	<p>The Performer and Government are committed to transparent and timely publication of nonclinical data to ensure rapid distribution of information, particularly during a Public Health Emergency.</p> <p>Within 90 days of the of study end date [audited or quality-controlled draft final report prepared and reviewed by the Government] for studies funded in part or whole under this agreement and consistent with Good Publication Practices, Sponsor must submit nonclinical study data for publication to a peer reviewed journal.</p> <p>If the Performer does not elect to publish data, Performer must provide AO and PAR with nonclinical data to support the government publication of data as deemed appropriate by the government, without the Performer involvement. The government reserves the</p>	<ul style="list-style-type: none"> <li>• Performer must notify AO within 30 calendar days of study end date [audited or quality-controlled draft final report prepared and submitted for Government review] if they plan not to publish data.</li> <li>• Within 10 calendar days of a request for nonclinical data from the AO, the Performer must provide AO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the nonclinical trial data funded in part or whole under this agreement</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		right to publish a counter-analysis of the data.	

#### 4.8 Regulatory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.8.1	Regulatory Strategy/Plan	The Performer must provide a Regulatory Plan that outlines the regulatory strategy for the product. The plan must include information leading to commercialization readiness.	<ul style="list-style-type: none"> <li>• The Performer must submit a Draft within 45 calendar days after the initiation of the agreement period of performance; updates to the Regulatory Strategy/Plan must be submitted concurrently with Monthly Technical Progress Reports. The Performer may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update</li> <li>• BARDA will provide Performer with a list of concerns in response to plan submitted</li> <li>• Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns</li> </ul>
4.8.2	FDA Correspondence	The Performer must memorialize all original and unredacted correspondence between Performer and FDA and submit to BARDA, including formal and informal emails, correspondence, telephone calls, and official information requests (IRs).	<ul style="list-style-type: none"> <li>• Performer must provide copies of all original and unredacted FDA correspondence within 2 business days of correspondence</li> </ul>
4.8.3	FDA Submissions	The Performer must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Performer must provide BARDA with an electronic copy of the final FDA submission. All	<ul style="list-style-type: none"> <li>• Performer must submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission</li> <li>• BARDA will provide feedback to Performer within 10 business days of receipt</li> </ul>

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		documents must be duly marked as either "Draft" or "Final."	<ul style="list-style-type: none"> <li>• The Performer must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission</li> <li>• The Performer must submit Final FDA submissions to BARDA concurrently or no later than five (5) calendar days of submission</li> </ul>

SOLICITATION CLOSED

**4.9 Press Releases**

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.9.1	Press Releases	Performer agrees to accurately and factually represent the work conducted under this agreement in all press releases.	<ul style="list-style-type: none"> <li>• Performer must submit to the PO an advance copy of any press release to this agreement no fewer than 5 business days prior to the issuance of the press release. Performer must also send the advance copy to the AO for awareness.</li> <li>• If corrective action is required, the Performer agrees to accurately and factually represent the work conducted under this agreement in all press releases</li> <li>• The Performer must submit any final press release to BARDA no later than one (1) calendar day prior to its release</li> </ul>

SOLICITATION CLOSED

**5.0 Milestone Payment Schedule** (To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture))

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the RRPV member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the RRPV member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Monthly Reports which include both Technical Status and Business Status Reports (due the 25th of each month), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

**RRPV Milestone Payment Schedule Example**

Milestone Number	Task Number	Milestone Description	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	\$20,000		\$20,000

2	N/A	Monthly Report (Technical and Business Reports)	1/15/2020	\$ -		\$ -
3	N/A	Monthly Report (Technical and Business Reports)	2/15/2020	\$ -		\$ -
4	1	Protocol Synopsis	2/28/2020	\$21,075		\$21,075
5	2	Submission for Program Office Approval	2/28/2020	\$21,075		\$21,075
6	N/A	Monthly Report (Technical and Business Reports)	3/15/2020	\$ -		\$ -
7	N/A	Monthly Report (Technical and Business Reports)	4/15/2020	\$ -		\$ -
8	3	Submission of Device Testing Reports	4/30/2020	\$210,757	\$187,457	\$398,214
9	N/A	Monthly Report (Technical and Business Reports)	5/15/2020	\$ -		\$ -
10	N/A	Monthly Report (Technical and Business Reports)	6/15/2020	\$ -		\$ -
11	N/A	Monthly Report (Technical and Business Reports)	7/15/2020	\$ -		\$ -
12	N/A	Monthly Report (Technical and Business Reports)	8/15/2020	\$ -		\$ -
13	N/A	Monthly Report (Technical and Business Reports)	9/15/2020	\$ -		\$ -
14	4	Assay Validation	10/1/2020	\$63,227		\$63,227
15	N/A	Annual Report 1	10/25/2020	\$ -		\$ -

16	N/A	Monthly Report (Technical and Business Reports)	11/15/2020	\$ -		\$ -
17	5	Authorization trial	11/30/2020	\$84,303		\$84,303
18	6	Research staff trained	11/30/2020	\$ -		\$ -
19	7	Data Management system completed	11/30/2020	\$ -		\$ -
20	N/A	Monthly Report (Technical and Business Reports)	12/15/2020	\$ -		\$ -
21	8	Study Reports	1/1/2021	\$150,000	\$187,457	\$337,457
22	N/A	Monthly Report (Technical and Business Reports)	1/15/2021	\$ -		\$ -
23	N/A	Monthly Report (Technical and Business Reports)	2/15/2021	\$ -		\$ -
24	9	Completion of dip molding apparatus	3/1/2021	\$ 157,829	\$ 187,457	\$ 345,286
25	N/A	Monthly Report (Technical and Business Reports)	3/15/2021	\$ -		\$ -
26	N/A	Monthly Report (Technical and Business Reports)	4/15/2021	\$ -		\$ -
27	N/A	Monthly Report (Technical and Business Reports)	5/15/2021	\$ -		\$ -
28	10	Design Reports	6/1/2021	\$157,829		\$157,829
29	N/A	Monthly Report (Technical and Business Reports)	6/15/2021	\$ -		\$ -
30	N/A	Monthly Report (Technical and Business Reports)	7/15/2021	\$ -		\$ -



31	N/A	Monthly Report (Technical and Business Reports)	8/15/2021	\$ -		\$ -
32	N/A	Monthly Report (Technical and Business Reports)	9/15/2021	\$ -		\$ -
33	11	Complete 50% patient enrollment	10/1/2021	\$350,000	\$187,457	\$537,457
34	N/A	Annual Report 1	10/25/2021	\$ -		\$ -
35	N/A	Monthly Report (Technical and Business Reports)	11/15/2021	\$ -		\$ -
36	N/A	Monthly Report (Technical and Business Reports)	12/15/2021	\$ -		\$ -
37	N/A	Monthly Report (Technical and Business Reports)	1/15/2022	\$ -		\$ -
38	N/A	Monthly Report (Technical and Business Reports)	2/15/2022	\$ -		\$ -
39	12	Electronic Report Forms Developed	3/1/2022	\$315,658	\$187,457	\$503,115
40	N/A	Monthly Report (Technical and Business Reports)	3/15/2022	\$ -		\$ -
41	N/A	Monthly Report (Technical and Business Reports)	4/15/2022	\$ -		\$ -
42	N/A	Monthly Report (Technical and Business Reports)	5/15/2022	\$ -		\$ -
43	N/A	Monthly Report (Technical and Business Reports)	6/15/2022	\$ -		\$ -

44	N/A	Monthly Report (Technical and Business Reports)	7/15/2022	\$ -		\$ -
45	13	Complete 100% patient enrollment	8/1/2022	\$315,658	\$187,457	\$503,115
46	N/A	Monthly Report (Technical and Business Reports)	8/15/2022	\$ -		\$ -
47	N/A	Monthly Report (Technical and Business Reports)	9/15/2022	\$ -		\$ -
48	N/A	Annual Report 1	10/25/2022	\$ -		\$ -
49	14	Report results from data analysis	11/1/2022	\$157,829		\$157,829
50	N/A	Final Reports (POP End)	11/30/2022	\$ -		\$ -
<b>Total</b>				<b>\$2,025,240</b>	\$1,124,742	\$3,149,982
<b>Period of Performance (Months)</b>						<b>XX Months</b>
<b>Contract Type</b>						<b>FFP/CPFF/CR</b>

**Please Note:**

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Expenditure Based Contracts – You may invoice for actual costs incurred and providing a progress report on technical milestones.
3. Cannot receive payment for a report (i.e., Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)
4. Monthly, Quarterly, and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be the POP end noted in Project Award.
6. Milestone Numbers are used for administrative purposes and should be sequential.

7. Task Numbers are used to reference the statement of work if they are different from the Milestone Number.

**6.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS**

*If the Offeror intends to provide technical data which existed prior to, or was produced outside of the proposed effort, to which the Offeror wishes to maintain additional rights, these rights should be asserted through the completion of the table below.*

*Note that this assertion is subject to negotiation prior to award.*

Rights in such Data shall be as established under the terms of the Base Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The below table lists the Awardee’s assertions.

<b>Technical Data or Computer Software to be Furnished with Restrictions</b>	<b>Basis for Assertion</b>	<b>Asserted Rights</b>	<b>Name of Organization Asserting Restrictions</b>	<b>Deliverables Affected</b>