

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



**Request for Project Proposals (RPP)
Solicitation Number: RRPV 24-03-SmMol**

“COVID-19 Small Molecule Therapeutics for PrEP”

Issue Date: 05 August 2024

Amendment 01 Issue Date: August 20, 2024

Questions Due: 15 August 2024 by 1pm Eastern

Closed: 20 September 2024 by 1pm Eastern

In support of:

OT Task Order No. 3: 75A50123D00005 / 75A50123F61003

“NextGen Therapeutics”

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

RPP AMENDMENTS	
No.	Description
1.	Revises Sec. 4.2.1.C.

Contents

1	Executive Summary	4
1.1	Rapid Response Partnership Vehicle Consortium	4
1.2	Purpose	4
2	Administrative Overview	5
2.1	Request for Project Proposals (RPP)	5
2.2	RPP Approach	5
2.3	Period of Performance and Type of Funding Instrument Issued	5
2.4	Expected Award Date	5
2.5	Anticipated Proposal Selection Notification	6
2.6	Proprietary Information	6
2.7	Eligibility Criteria	6
2.8	Cost Sharing	7
2.9	Intellectual Property and Data Rights	7
3	Proposals	8
3.1	Proposal General Instructions	8
3.2	Proposal Submission	8
3.3	Proposal Preparation Cost	9
3.4	Submission Format	9
3.5	Cost Proposal	10
3.6	Restrictions on Animal and Human Subjects	10
4	Technical Requirements	12
4.1	Scope	12
4.2	Objectives	12
5	Selection/Evaluation	17
5.1	Compliance Screening	17
5.2	Proposal Evaluation Process	17
5.3	Evaluation Factors	17
5.4	Cost/Price Evaluation	18
5.5	Best Value	20
5.6	Basket Provision	20
6	Points of Contact	21
	ATTACHMENT 1 – TECHNICAL PROPOSAL TEMPLATE	22
1.	Technical Proposal Cover Page	23
2.	Member Information Sheet	24
3.	Executive Summary & Minimum Eligibility Requirements	25
4.	Technical Approach	25
5.	Current & Pending Support	30
6.	Resumes of Key Personnel	31
	ATTACHMENT 2 – COST PROPOSAL TEMPLATE	32
1.	Cost Proposal Cover Page	33
2.	Cost Proposal Section I: Cost Proposal Narrative Template	34
3.	Cost Proposal Narrative Overview	34
4.	Cost Proposal Narrative Cost Data	35
5.	Cost Proposal Section II: Cost Proposal Format	38
	ATTACHMENT 3 – STATEMENT OF WORK (SOW) TEMPLATE	40
	ATTACHMENT 4 – PROGRAM/PROJECT MANAGEMENT PLAN TEMPLATE	58

SOLICITATION CLOSED

1 Executive Summary

1.1 Rapid Response Partnership Vehicle Consortium

The Rapid Response Partnership Vehicle (RRPV) Consortium is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Biomedical Research and Development Authority (BARDA).

The RRPV will help fortify national health security by developing medical countermeasures products prior to and during a pandemic or public health emergency. The RRPV will focus on the acceleration of products and 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 www.RRPV.org. For entities interested in joining the RRPV Consortium and responding to this solicitation, please at www.rrpv.org/how-to-join.

1.2 Purpose

BARDA is requesting project proposals from product developers for the advanced clinical development and assessment of Next-Generation Therapeutics for COVID-19. BARDA has previously identified a capability gap for therapeutics that provide protection through Pre-exposure Prophylaxis (PrEP) and treatment against new SARS-CoV-2 variants. The purpose of this project is to partner with developers and other organizations to advance the clinical development of Next-Generation Therapeutics for COVID-19. The goal of this project is to provide better COVID-19 solutions and bolster preparedness and response against future health security threats.

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

2 Administrative Overview

2.1 Request for Project Proposals (RPP)

Each response submitted to this RPP shall contain a Technical Proposal and a Cost Proposal, as well as additional documents described in Section 3 of this request. **White papers are not required for this RPP.**

2.2 RPP Approach

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.

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 / 75A50123F61003 "NextGen Therapeutics"*. The same provisions will govern this Base Agreement as the OTA between the U.S. Government (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 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.

2.3 Order of Precedence

Each proposal selected for award under this RPP will be executed as a Project Award under the *RRPV Base agreement 75A50123D00005 (RRPV Base) and OTA Number 75A50123D00005 / 75A50123F61003 "NextGen Therapeutics" (RRPV TO3)*. The same provisions will govern this Base Agreement as the OTA between the U.S. Government (USG) and ATI, aka RRPV Base, unless otherwise noted in the Project Award. If an ambiguity or conflict arises between these agreements, the following order of precedence will apply: 1) 24-03-SmMol Agreements, 2) RRPV TO3 and 3) RRPV Base.

2.4 Period of Performance, Place of Performance and Type of Funding Instrument Issued

The anticipated Period of Performance for this effort is up to seven (7) years from date of award for design, manufacturing, nonclinical testing, and clinical trials. Specific dates of performance will be negotiated as part of each offeror's submission. The primary place of performance is anticipated to be the Project Awardee's facilities but remains negotiable as part of each offeror's submission.

The USG may apply additional dollars for follow-on efforts with appropriate modification of the Project Award.

Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

2.5 Expected Award Date

Offeror should plan on the period of performance beginning on the date of contract award. The Government reserves the right to change the proposed period of performance start date through negotiations via the RRPV CMF and prior to issuing a Project Award.

2.6 Anticipated Proposal Selection Notification

As the basis of selections is completed, the Government will forward their selections to the RRPV CMF to notify Offerors. Proposers 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.

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

2.8 Eligibility Criteria

Offerors submitting proposals will initially be reviewed for compliance with the following minimum eligibility criteria:

- a) Offerors must be RRPV members when the proposal is submitted. As mentioned above, prospective Offerors may join the consortium at www.rpv.org/how-to-join.
- b) Demonstrated successful history of developing, cGMP manufacturing, release testing, and conduct of clinical trials for therapeutics and/or vaccines.
- c) ASPR Security Requirements Attestation Statement (See Attachment 5).

Proposals found to not meet these minimum eligibility criteria as detailed above **will be** removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

2.9 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, it is not required in order to be eligible to receive an award under this RPP. The Government anticipates a minimum 30% cost-sharing agreement for this effort.

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, etc.). 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.

2.10 Intellectual Property and Data Rights

Intellectual Property (IP) rights for RRPV Project Awards will be defined in the terms of a Project Awardee's 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.

The Offeror shall complete the table provided in Attachment 3, Statement of Work, for any items to be furnished to the Government with restrictions. An example is provided below. If the Offeror does not assert data rights on any items, a negative response in Attachment 3 is required.

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 Proposal General Instructions

Offerors who submit Proposals in response to this RPP must submit by the date on the cover page of this RPP. Proposals received after the time and date specified may not be evaluated.

The Proposal format provided in this RRPV RPP is mandatory and shall reference this RPP number. Offerors are encouraged to contact the Point of Contact (POC) identified herein up until the Proposal submission date/time to clarify requirements.

The Government will evaluate Proposals submitted and will select the Proposal(s) that best meets their current technology priorities using the criteria in Section 5.

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's 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.

3.2 Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page to the following website: www.RRPV.HHS.gov

A BDR Portal account is required before a response can be submitted. A BDR account can be requested by contacting ATI at RRPV@ati.org. The account request process is simple but may take several days for approval and access. Upon confirmation of a BDR Portal account, offerors will be able to complete their account registration to be able to submit a proposal.

Failure to propose your submission on time for any reason (e.g., due to late registration in BDR Portal) will result in the submission not being considered for award. Respondents will be provided an automated confirmation of successful submission.

Do not submit any classified information in the Proposal submission.

Offerors shall 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 characters. IOS users must ensure the entire filename and path are free of spaces and special characters. The file should not exceed 10 Megabytes of storage space. Movie and sound file attachments, URL Links, or other additional files, will not be accepted.

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.

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.**

3.3 Proposal Preparation Cost

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

3.4 Submission 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 submission (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 minimum eligibility requirements, technical approach, current and pending support, data rights*, and key personnel resumes*.
- **Cost Proposal submission (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.
- **Program/Project Management submission (5-page limit) – See Attachment 4:** One Word (.docx or .doc) or PDF file. The Offeror is required to provide details on their proposed approach for Program Management and subcontractor management. Submission should include a listing of key personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal (Note: key personnel resumes to be included in the technical proposal). A summary of related activities must also be provided for key personnel. An organizational chart for the project with affiliations (who will report to whom). Details on Offeror-provided facilities, infrastructure, and other resources, such as:
 - Manufacturing capacity expansion plans to match the proposed manufacturing scale-up;

- Overview of the management of Quality Systems at the facility;
 - List of capabilities for clinical activities conducted in-house and at contract research organizations;
 - Qualified animal facilities where Good Laboratory Practice (GLP) studies would be conducted and appropriate certifications for humane care and use of vertebrate animals;
 - Commercial capabilities of the Offeror, including current products, and marketing, distribution, and customer support capabilities (as applicable); and
 - List of key vendors or service providers, locations, and brief description of their expertise/experience.
- **ASPR Security Requirements Attestation Statement (no page limit) – See Attachment 5.** One Word (.docx or .doc) or PDF file. Included with Project Proposals, Offerors must include a statement attesting to their intent and ability to comply with the deliverables and security requirements within the deadline dates stated in Attachment 5.

3.5 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 provided Cost Proposal format template is NOT mandatory if the Offeror's format provides the same level of detail.

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, travel and ODC costs as applicable.

For scheduling and pricing purposes, Offerors should assume that all Base Period objectives and task may occur concurrently to support cost and schedule savings. If Optional tasks are included in the project award, Offerors should assume that an Agreement modification will be required to begin an option period.

3.6 Restrictions on Animal and Human Subjects

Project Awardees must comply with restrictions and reporting requirements for the use of animal and human subjects, as addressed in further detail in the RRPV Base Agreement. It is anticipated that the Project Award(s) issued under this RPP will require the following:

- The Project Awardee shall serve as regulatory product sponsor and be responsible for any regulatory submissions to the US Food and Drug Administration (FDA).
- Support and maintain regulatory submissions throughout life of the project.
- The Project Awardee must submit to the Government all regulatory and supporting documentation related to therapeutic development, manufacturing, lot releasing, certificates of analysis, analytical development, stability, nonclinical and clinical testing as well as other related documentation.

- The Project Awardee shall cross-reference any applicable regulatory files, such as Investigational New Drug (IND) applications, Master Files, and Biologics License Applications (BLAs) prior to the conduct of the studies, and shall allow cross-referencing of these documents associated with this effort.

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.

SOLICITATION CLOSED

4 Technical Requirements

4.1 Scope

This project supports advancing, either directly or indirectly, the clinical development of COVID-19 medical countermeasures and, where noted, the advancement of new technologies and other capabilities that decrease costs, accelerate production, increase efficacy, and improve access of next-generation COVID-19 therapeutics.

4.2 Objectives

The Offeror will be responsible for the following:

4.2.1 COVID-19 Small Molecule Therapeutics for PrEP

Advanced development of small molecule therapeutics (MW < 1 kDa) with activity against SARS-CoV-2, for a primary indication of pre-exposure prophylaxis (PrEP), through FDA approval. The proposed small molecule(s) should be able to provide rapid pre-exposure protection against SARS-CoV-2 infection, particularly in special populations, such as adults and pediatrics who may be moderately to severely immune compromised and may not be able to mount an adequate immune response to COVID-19 vaccines or for whom vaccination with any available COVID-19 vaccine is not recommended.

A. Pass/Fail Criteria: Proposed small molecule(s) ***must meet the following minimum criteria*** to be considered for award:

1. *In vitro* activity against currently known variants of SARS-CoV-2, as designated by the World Health Organization (WHO) or the U.S. Centers for Disease Control and Prevention (CDC) as a Variant of Concern (VOC) or Variant Being Monitored (VBM) due to shared attributes and characteristics that may necessitate a public health response. Variants should include but are not limited to those listed in *Table 1* below.
 - *In vitro* potency must be in the nanomolar (nM) range.
 - Potency data must be generated from qualified and/or validated live virus and/or pseudo-virus neutralization assays.

Table 1: List of Variants		
WHO Label	Pango Lineage	CDC Status at time of RPP posting:
N/A	Variants containing the F456L spike mutations*	VOI
Omicron	BA.2.86	VBM
Omicron	XBB.1.9.1	VBM
Omicron	XBB.1.9.2	VBM
Omicron	XBB.2.3	VBM
Omicron	XBB.1.16	VBM
Omicron	XBB.1.5	VBM

Omicron	CH.1.1	VBM
Omicron	BA.2.74	VBM
Alpha	B.1.1.7 and Q lineages	VBM
Beta	B.1.351 and descendent lineages	VBM
Gamma	P.1 and descendent lineages	VBM
Delta	B.1.617.2 and descendant lineages	VBM
Epsilon	B.1.427 and B.1.429	VBM
Eta	B.1.525	VBM
Iota	B.1.526	VBM
Kappa	B.1.617.1	VBM
N/A	B.1.617.3	VBM
Omicron (parent lineages) **	B.1.1.529 and descendant lineages	VOC
Zeta	P.2	VBM
Mu	B.1.621, B.1.621.1	VBM

* Many lineages have acquired the F456L mutation and common examples include EG.5, FL.1.51 and XBB.1.16.6.

** Omicron parent lineages include BA.1 or similar.

2. Data demonstrating mechanism of action.
3. Data demonstrating an injectable half-life greater than 24 hours.
4. Data demonstrating low to no drug-drug interaction (DDI) risk.
5. Potency to support intramuscular (IM) and/or subcutaneous (SC) administration with no more than two injections once every three (3) months.
6. Data supporting a unique drug resistance profile relative to other FDA-approved/authorized COVID-19 antivirals.

B. Preferred Criteria: Proposed small molecule(s) that also meet the following preferred criteria will be given preferential consideration:

1. Demonstrated *in vitro* potency against other beta-coronaviruses (e.g., MERS-CoV, SARS-CoV).
2. [Technology readiness level \(TRL\) 6](#) or later.
3. Reduced dosing, administration, and monitoring requirements.
4. Demonstrated manufacturing process to support use in clinical trials at the time of proposal submission.
5. Manufacturing in a cGMP-compliant facility in the United States.

C. Out of Scope: *The following are out of scope and will **not** be considered:

1. Candidate therapeutics with an injectable half-life less than 24 hours.
2. Candidate therapeutics with Phase I failures or withdrawn from market for safety reasons.

3. Candidate therapeutics with black box labels.
4. Host-directed therapeutics.
5. Peptides, fatty acids, or steroid conjugates.
6. Oral or topical sprays.

** Proposals found to be out of scope as detailed above will be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.*

4.2.2 Project Tasks

A. Non-clinical Development Plan

Awardee shall develop and implement a nonclinical development plan, including Investigational New Drug (IND) enabling studies (e.g., toxicology/ADME). If in vivo efficacy studies have not yet been completed, Awardee must develop and implement a plan to complete these activities within six (6) months after project award. Offeror **must** also provide a proposed schedule for any other non-clinical studies that may extend beyond the first six (6) months of work. It is **recommended** that Offerors also identify if any of those studies will be considered IND-enabling.

B. Manufacturing Plan

Awardee shall develop and implement a manufacturing plan to perform at-scale manufacturing and fill-finish using cGMP validated manufacturing processes for bulk Drug Substance and fill and finished Drug Product to support use in clinical trials.

C. Regulatory Strategy and Clinical Development Plan

Awardee shall develop and implement a regulatory strategy and a clinical development plan for obtaining FDA approval, using aggressive risk management, and taking advantage of any regulatory flexibilities. The regulatory strategy and clinical development plan should be focused on achieving FDA approval with an option to submit for Emergency Use Authorization (EUA). Regulatory strategies shall not focus on EUA as the end goal.

D. Clinical Trials

Awardee shall conduct phase-appropriate clinical trials (inclusive as necessary, e.g., phase 1, phase 2, pivotal phase 3), following Good Clinical Practice (GCP) guidelines to support product registration and approval by the FDA.

E. Regulatory Interactions

- Awardee shall serve as regulatory product sponsor and be responsible for all regulatory submissions to the FDA and continue to support and maintain regulatory submissions throughout the life of the project.
- Awardee shall submit to the Government all regulatory and supporting documentation related to candidate therapeutic development, manufacturing, lot

releasing, certificates of analysis, analytical development, stability, nonclinical and clinical testing as well as other related documentation.

- Awardee shall cross-reference any applicable regulatory files, such as INDs, Master Files and New Drug Applications (NDAs) 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 Animal Welfare Assurance and HHS Office of Human Research Protection (OHRP) respectively.

F. Project Management

It is anticipated that the project agreement holder (PAH) will be required to submit a number of documents to capture the progression of the project, post-award. Requirements may include, but are not limited to the following:

1. Reporting

Awardee shall deliver monthly technical and financial reports and progress reports, to including a master schedule. Annual reports shall also be provided. At the end of the effort, the Awardee shall provide a detailed clinical study report, and a final technical and business report.

2. Meetings

- Awardee shall schedule regular, recurring progress meetings with the Government. The meeting agenda shall be submitted to the Government at least 3 business days in advance of the meeting. The meeting minutes shall be submitted to the Government no later than 3 business days following the meeting.
- Awardee shall include the Government in all FDA meetings and submit all 'read-ahead' packages at least 3 business days in advance of the FDA meeting.
- Awardee shall provide to the Government records of all communications with the FDA no later than 3 business days after communications occur.

3. Logistics Objectives

Awardee shall be responsible for (sub)contracting or executing all intellectual property, materiel, and sample shipments and maintenance of all associated records and permits.

4.2.3 Performance Requirements

Submission and maintenance of nonclinical and clinical documentation for regulatory filings (pre-IND/IND) that support a regulatory strategy to achieve FDA approval.

4.2.4 Deliverables

Over the course of this project, Awardee is required to provide the deliverables in Attachment 3 Section 4.0 of this RPP.

NOTE: Technical data deliverables described herein shall be delivered to the Government with unlimited data rights.

4.2.5 Special Requirements

1. **Export Control:** The Project Awardee will be expected to be knowledgeable of and comply with any applicable U.S. Export Laws.
2. **Security and Classified Data:** The security classification level for this effort will be *Unclassified*. If Controlled Unclassified Information is provided or must be generated under this agreement, it will be subject to the safeguarding provisions and reporting requirements of the RRPV Base Agreement and/or Project Award.

SOLICITATION CLOSED

5 Selection/Evaluation

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 using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified Proposals.

Qualified Proposals will be evaluated by a panel of subject matter experts (SMEs) who will make recommendations to a Source Selection Authority.

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP as outlined in Section 2.8. 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) as discussed below. 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.

The evaluation factors and evaluation criteria are described below.

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

- Excellent
- Good
- Fair
- Poor
- Unacceptable

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.

5.3 Evaluation Factors

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:

Factor 1 - Technical Approach: This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach in relation to the following subfactors:

- a. **General Technical Approach** including ability of proposal to meet all requirements as outlined in the Section 4 of this RPP.
- b. **Clinical and Regulatory Approach**
- c. **Development and Manufacturing Approach**

Factor 2 - Relevant Corporate and Capabilities Experience: This factor evaluates the offeror's demonstrated corporate experience and capabilities experience as well as the technical and program 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.

Factor 3 - Program Management Approach: This factor evaluates the quality, thoroughness, completeness and feasibility of the proposed Program Management approach in relation to the following subfactors:

- a. **Key Personnel & Personnel Management**
- b. **Contract/Subcontract Management**

Factor 4 - Cost/Price (See Section 5.4 below)

Non-Cost/Price Evaluation factors are listed in descending order of importance. Non-Cost/Price factors are more important than Cost/Price, collectively and individually. 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)

The Government does not guarantee a minimum or maximum number of awards resulting from this solicitation.

5.4 Cost/Price 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 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.

5.5 Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The Government does not guarantee a minimum or maximum number of awards resulting from this solicitation. If an award is made, 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 Corporate and Capabilities Experience, Project Management Approach 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.

5.6 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Fair through Excellent, but not immediately selected for award, will be placed in the Basket for 2 years and 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

Questions related to this RPP should be directed to Ms. Rebecca Harmon (rrpv-contracts@ati.org). All technical questions must be submitted by **1pm Eastern on 15 August 2024** to allow for Government response. The Government will respond to questions at its discretion. All questions and responses will be posted to the RRPV Solicitation webpage (<https://www.rrpv.org/opportunities/>).

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

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 & Minimum Eligibility Criteria
4. Technical Approach
5. Current & Pending Support
6. Data Rights*
7. Resumes of Key Personnel* (each not to exceed 3 pages)

*Excluded from page limitation

1. Technical Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RRP Number 24-03-SmMol

[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 2.6 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

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 & Minimum Eligibility Requirements

[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 each aspect of the following minimum eligibility requirements:

1. Offerors must be RRPV members when the proposal is submitted. As mentioned above, prospective Offerors may join the consortium at www.rrpv.org/how-to-join.
2. Demonstrated successful history of developing, cGMP manufacturing, release testing, and conduct of clinical trials for therapeutics and/or vaccines.
3. ASPR Security Requirements Attestation Statement (See Attachment 5).

4. Technical Approach

[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 4.2 (Solution 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. **Clinical Trial:** [If a clinical trial is proposed as part of Technical Strategy, then include the following information as part of the technical approach. Clinical trials should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to development and testing of biologics. This will include compliance with applicable portions of Title 21 of the US Code of Federal Regulations (CFR) including Title 21 CFR Parts 11, 50, 54, 56, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Pub.L. 104-191, 110 Stat. 1936, enacted August 21, 1996), and International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practices (GCPs) (ICH Guidelines for Good Clinical Practice (E6),

Published May 9, 1997).]

- **Clinical Trial History:** [If the proposed clinical trial/testing was initiated using other funding prior to this application, explain the history and background of the clinical trial/testing and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.]
- **On-Going Effort:** [If the proposed clinical trial/testing involves continuation or assumption of an ongoing effort then state the transition plan proposed (e.g., transfer of FDA Sponsorship). In the case of ongoing clinical trials, append or provide reference to previous FDA-regulated studies. Offeror must justify carefully any changes proposed to ongoing FDA-regulated protocols and provide specific rationale for alterations (e.g., FDA feedback, change in clinical resources or study sites, etc.)]
- **FDA Interactions:** [Describe plan to meet all regulatory sponsor responsibilities under ICH parts E6, E2A, E8, and 21 Code Federal Regulation parts 312, 11, 50, 54, 56 including regulatory writing and submissions support for clinical efforts, safety reporting, pharmacovigilance, clinical monitoring, data management, regulatory writing and submissions, etc.]
- **Test Materials:**
 - Describe the clinical intervention, medical drug, biologic, device or human exposure model to be tested and the projected outcomes or measures.
 - Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
 - Describe the production/manufacturing plan for the test materials proposed.
- **Study Design/Clinical Protocol:**
 - Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/ hypotheses to include the following details as applicable to the proposed work.
 - Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action.
 - Describe potential challenges and alternative strategies where appropriate. Define the study variables, outline why they were chosen, and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (e.g., convenience, simple random, stratified random).
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

- **Statistical Plan and Data Analysis:** [Describe the data collection plan, statistical model, and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled or number of human samples to be studied. If multiple study sites are involved, state the approximate number to be enrolled or samples collected at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. If a subpopulation of a sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study.]
 - **Technical Risks:** [Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.]
 - **Ethical Issues:** [Include a clear and detailed description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.]
 - **Training/Proficiency Requirements:** [Determination to ensure that personnel have appropriate training/competency.]
- 7. Anticipated Outcomes:** [Provide a description of the anticipated outcomes from the proposed work.]
- 8. 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.]
- 9. 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.]
- 10. 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 of key personnel are provided in the “Resumes of Key Personnel” section. Resumes are excluded from page count limit]

- 11. Schedule:** [Identify key technical, schedule, and cost risks, their potential impact and mitigation.]
- 12. 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.]
- 13. Government Resources:** [Identify any key Government facilities, Government equipment, Government property, etc. that your organization requests to use for the effort.]
- 14. 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.]
- 15. 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.]

SOLICITATION CLOSED

Cost Realism Form EXAMPLE

This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as examples only. Offeror must complete table with the applicable information. Add or delete columns to match optional tasks.

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

5. Current & Pending Support

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 current support]

6. Resumes of Key Personnel

Include the resumes of key personnel from the Offeror's organization, as well as subcontractors or consultants, who will work on this project if selected (each resume not to exceed 3 pages). The Principal Investigator must be identified.

SOLICITATION CLOSED

ATTACHMENT 2 – COST PROPOSAL TEMPLATE

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 (i.e., costs, cost share, dates, etc.). 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

[Name of Offeror]
[Address of Offeror]

RRP Number 24-03-SmMol

[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 2.6 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

1. Cost Proposal Narrative Overview

[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

[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, etc.)
- 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

[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

[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

Submitted under Request for Project Proposals (24-03-SmMol)

Proposed Project Title:

RRPV Member Organization Name:

RRPV Member Primary Place of Performance:

- 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:

Meetings

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
1.1	Post-Award Teleconference/ Kickoff Meeting	The Performer must complete a Post-Award Teleconference/ Kickoff Meeting after the initiation of the agreement period of performance. 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting	<ul style="list-style-type: none"> • Within 10 business days after the initiation of the agreement period of performance, pending concurrence by the Contracting Officer • Performer must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference • PAR edits/approves and instructs Performer to distribute agenda at least 3 business days prior to meeting • Performer submits meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days
1.2	Bi-Weekly Teleconference	The Performer must participate in teleconferences bi-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.	<ul style="list-style-type: none"> • Performer must submit agenda to PAR no later than 2 business days in advance of meeting • PAR edits/approves and instructs Performer to distribute agenda prior to meeting • Performer must distribute agenda and presentation materials at least 2 calendar days in advance of meeting • Performer must submit meeting minutes to PAR within 3 business days of the meeting • PAR reviews, comments, and approves minutes within 10 business days
1.3	Technical, Subgroup, Ad Hoc Teleconference(s)	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. Meeting frequency may be defined as needed during the course of the project.	<ul style="list-style-type: none"> • Performer must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting • PAR edits/approves and instructs Performer to distribute agenda prior to meeting • Performer must distribute agenda and presentation materials at least 24 hours in advance of meeting • Performer must submit meeting minutes to PAR within 3 business days of the meeting • PAR reviews, comments, and approves minutes within 6 business days

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
1.4	Periodic Review Meetings	At the discretion of the Government, the Performer must hold up to four (4) 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 subcontractors. Face-to-face meetings shall alternate between Washington, D.C. and Performer, subcontractor 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, clinical, technical, regulatory, and ethical aspects of the program.	<ul style="list-style-type: none"> • 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 • PAR edits/approves and instructs Performer to distribute agenda prior to meeting by at least 3 business days • Performer provides meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days
1.5	Daily Check-in with BARDA	<p>Upon request of the Government, the Performer must participate in a daily check-in update with the project staff (via teleconference or email). The update will address key cost, schedule, and technical updates. Daily updates may be shared with senior Government leaders and should be provided on a non-confidential basis, unless the update includes confidential information in which case the Performer must provide the update in both confidential and non-confidential formats.</p> <p>Daily check-ins may occur on weekdays, excluding federal holidays.</p> <p>Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24-hours' notice.</p>	<ul style="list-style-type: none"> • A standing agenda must be used, to include key cost, schedule, and technical updates, as well as updates on ad hoc communications between USG and the Performer • No meeting minutes are required • Performer must provide bulleted email updates following any call or in lieu of a call by 2:00PM ET for that day

Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
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 subcontractor 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"> • Performer must submit a PMP <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
2.2	Gantt Chart/Timeline	The Gantt Chart/Timeline should be detailed to the extent required by the specific project.	<ul style="list-style-type: none"> • At first project meeting and as updated no later than every 30 calendar days. Provided in pdf.
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"> • Performer must submit a Communication Plan <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<ul style="list-style-type: none"> ○ Updates should be provided to reflect any key changes and reviewed at least annually.
2.4	Performer Locations	<p>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 subcontractors and critical vendors of reagents and supplies.</p> <p>Performers must include vendors for critical infrastructure protection.</p>	<ul style="list-style-type: none"> ● Performer must submit Work Locations Report: <ul style="list-style-type: none"> ○ Within 5 business days after the initiation of the agreement period of performance ○ Within 30 business days after a substantive location or capabilities change ● 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
2.5	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>	<ul style="list-style-type: none"> ● Performer must submit Pandemic Management Plan: <ul style="list-style-type: none"> ○ Draft within 15 days of award ○ Final within 30 days of award
2.6	Monthly & Annual Technical Progress Reports/Annual Meeting	<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), and Contract Performance Report (CPR) – or as applicable.</p> <ol style="list-style-type: none"> 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, nonclinical, clinical, regulatory, and publication activities. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages 2. The Contractor Performer must submit monthly detailed clinical reports during active clinical trial enrollment to include at a minimum: <ul style="list-style-type: none"> ● Central IRB approval status ● Site IRB approval status ● Site information (FWA number, site type (e.g., commercial site, academic site), site activation status) ● Number of subjects screened and enrolled by age, race, ethnicity, geographic distribution ● Investigational Product status (receipt at depot and receipt on site) ● Safety reporting (SAEs) ● Protocol deviations ● Database management ● Status of ancillary supplies e.g., PPE, swabs, syringes, tubes on site ● Specimen collection status ● Pharmacy manuals <p>The Performer must inform BARDA of any upcoming site visits and/or audits of Contract Research Organization (CRO) facilities funded under this effort. BARDA reserves the right to accompany the Contractor Performer on site visits and/or audits of CROs as BARDA deems necessary.</p> 3. 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 	<ul style="list-style-type: none"> ● The Performer must submit monthly reports on the 15th 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 2.7). The PAR and AO will review the monthly reports with the Performer and provide feedback ● Performer must provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits ● Performer must provide notification of designated safety events to the AO and PAR within 24 hours of being notified of the event

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>during the period covered, explaining any differences between the two and the corrective steps</p> <p>4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS</p> <p>5. 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>6. Estimated and Actual Expenses</p> <ul style="list-style-type: none"> • This report must also contain a narrative or table detailing whether there is a significant discrepancy (>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 Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors. If the AORPAR and AO are satisfied that the Performer's reporting is sufficient to convey this information, this section may be waived. <p>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>	
2.7	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.'</p> <p>7. The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results 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>	<ul style="list-style-type: none"> •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 •PAR will provide feedback on draft report within 21 calendar days of receipt, which the Performer must consider incorporating into the Final Report

Technical Reporting: Manufacturing

3.1	Product Development Source Material and Manufacturing Reports Projections	<p>The Performer shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.</p> <p>The Performer will provide manufacturing reports and manufacturing projections/actuals on any agreement/agreement that is manufacturing product, including product for clinical trial use.</p>	<ul style="list-style-type: none"> • Performer will submit Product Development Source Material Report Within month of Agreement award <ul style="list-style-type: none"> ○ Within 30 days of substantive changes are made to sources and/or materials ○ Or on the 6th month agreement anniversary. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, Performer must address all concerns raised by BARDA in writing • Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and company
-----	---	---	---

Technical Reporting: Nonclinical Studies

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.1	Draft and Final Nonclinical Study Report(s)	Performer must provide Draft and Final Nonclinical Study Reports to BARDA for review and comment.	<ul style="list-style-type: none"> • Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA • The Performer must submit Subcontractor-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 • The Government will provide written comments to the Draft Report for Nonclinical Study Reports within 15 business days after the submission • Final report due 30 calendar days after receiving comments on the Draft Final Report for Nonclinical Studies; If corrective action is recommended, Performer must address all concerns raised by BARDA in writing • Performer must consider revising reports to address BARDA's recommendations prior to FDA submission
4.2	Nonclinical Study Protocols	The Performer must submit draft and final nonclinical study protocols to AO and PAR.	<ul style="list-style-type: none"> • The Performer must submit Draft nonclinical study protocols to PAR electronically prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 business days of receipt of draft protocol ○ 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. ○ PAR must approve the final protocol • The Performer must submit Final nonclinical study protocols to PAR electronically no later than 10 business days prior to FDA submission.
4.3	Nonclinical Study Final Data Submission Package	BARDA must have access to methods and reagents. BARDA must have unlimited rights to all nonclinical-related protocols, data generated from the execution of these	<ul style="list-style-type: none"> • Performer must submit at least 15 business days prior to agreement end date. Partial datasets may also be

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		protocols, and final reports, funded by BARDA under this agreement 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.	requested for delivery prior to submission of the Final Data Submission Package.

Technical Reporting: Clinical Trials

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
5.1	Clinical Trial Protocols	The Performer must submit draft and final clinical study protocols to AO and PAR.	<ul style="list-style-type: none"> •The Performer must submit Draft study protocols to PAR electronically prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 business days of receipt of draft protocol ○ 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. ○ PAR must approve the final protocol. •The Performer must submit Final study protocols to PAR electronically no later than 10 business days prior to FDA submission.
5.2	Clinical Trial Documentation ¹	<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"> • Investigational Product Accountability Plan • Study Supplies Procurement Plan • Site selection questionnaire • Overall Recruitment and Retention plan • Informed Consent Form (ICF) template • eConsent • Data Management Plan • Data Validation/Quality Plan • Statistical Analysis Plan • Sample/Specimen Management Plan • Diversity inclusion plan to enroll based on US demographic based on most recent census • Investigator Brochure • eCRF • Community engagement materials, posters, media advertisements, animations, graphics, etc. • Clinical Trial Agreements • Monitoring Plan • Safety Monitoring Plan (processes to provide 24-7 pharmacovigilance and safety monitoring) • SAE Reconciliation SOP (if safety database separate from clinical database) 	<ul style="list-style-type: none"> •The Performer must submit Draft study documents to PAR electronically prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 business days of receipt of draft document ○ Performer must respond in writing to BARDA comments and recommendations prior to finalization of protocol. •The Performer must submit Final study documents to PAR electronically no later than 10 business days prior to FDA submission. •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. •Performer must submit final version Investigational Product and Clinical Supplies Management Plan at least 6 weeks prior to investigational product shipments to clinical sites. •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. •Final TLFs must be submitted to the PAR within 3 weeks after database lock.

¹ To be added at the discretion of the Agreements Officer and the Agreements Officer's Representative and PCT as appropriate for the contract, e.g., if the clinical trial utilizes NIH-funded clinical sites: *The Performer must participate in and provide information to a USG-oversight and review committee(s) outside of BARDA. The Performer must submit protocol, ICF, and IB to a Protocol Science Review Committee (PSRC) four (4) business days before the review to the PSRC Chair and USG-designated reviewers.*

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<ul style="list-style-type: none"> •Processes to manage and support an independent Data and Safety Monitoring Board (DSMB) •DSMB Charter •DSMB template reports and DSMB reports •Draft and Final Tables, Listings, and Figures (TLFs), ad hoc TLFs •Plan for notifying participants of his/her treatment assignment •Essential Regulatory Documents that demonstrate compliance with the standards of ICH E6 (R2) Good Clinical Practice and with all applicable regulatory requirements •Pharmacy Manual <p>The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during clinical site monitoring visits.</p>	
5.3	ClinicalTrials.Gov Posting and Results Reporting	Per clinicaltrials.gov registration and reporting requirements.	<ul style="list-style-type: none"> •Performer must post results: <ul style="list-style-type: none"> ○ 3 months from any interim analysis ○ 3 months from primary analysis ○ 3 months from final analysis
5.4	Draft and Final Clinical Study Report(s)	Performer must provide Draft and Final Clinical Study Reports to BARDA for review and comment.	<ul style="list-style-type: none"> •Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA •The Performer must submit Subcontractor-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 •The Government will provide written comments to the Draft Report for Clinical Study Reports within 15 business days after the submission •Final report due 30 calendar days after receiving comments on the Draft Final Report for Clinical Trial; If corrective action is recommended, Performer must address all concerns raised by BARDA in writing •Performer must consider revising reports to address BARDA's recommendations prior to FDA submission
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"> •After IND is in effect, within five days of IRB approval
5.6	Clinical Report During Active Enrollment Periods ²	The Performer must submit daily the data specs during active clinical trial enrollment. Clinical Report submission must be by electronic transfer, e.g., from Performer Electronic Data Capture (EDC) system/Interactive Voice Response System (IVRS) to USG.	<ul style="list-style-type: none"> •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.
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"> •Due within 20 calendar days of PAR request, no later than ten calendar days prior to first site activated

² Note that this may be modified to daily, weekly, monthly, etc., reporting as required by the PCT.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
5.8	Blinded Safety Reports, Medical Data Listing, CIOMS Report, Pharmacovigilance Database Listing	The Performer must submit blinded safety data reports, medical data listings, CIOMS reports and listings from the Pharmacovigilance database.	<ul style="list-style-type: none"> • Performer must provide weekly blinded safety data reports and medical data listings during the treatment period. • CIOMS reports and data listing from Pharmacovigilance database will be provided to the PSRT for review. Meeting frequency may be reduced during the follow up phase.
5.9	Clinical 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 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"> • Performer must submit the Clinical 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.
5.10	Data Exchange Package(s) Submitted to Regulatory Agency(s)	<p>As part of Final or Draft Submission Package(s), upon BARDA request, 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.</p> <p><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></p>	<ul style="list-style-type: none"> • Performer must provide the Technical Documents and/or datasets within 20 business days of request from the AO or PAR
5.11	Clinical Trial Datasets	Performer must make clinical trial datasets publicly available.	<ul style="list-style-type: none"> • Performer must post clinical trial datasets on a web-based platform easily accessible by the public: <ul style="list-style-type: none"> ○ 3 months from any interim analysis supporting any action (e.g., regulatory filing, protocol change), if applicable ○ 3 months from primary analysis ○ 3 months from final analysis
5.12	Additional Data Package(s)	Upon request, the Performer must provide raw data, tabulation Data 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.	<ul style="list-style-type: none"> • Performer must provide the data package(s) within 20 business days of request from the AO or PAR

Quality Assurance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
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 cGXP, and all products are managed to ensure that GMP requirements are met.</p> <p>All quality management plans must include subperformer quality management plans specifically addressing how subcontractor quality will 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"> ● Performer must submit a Quality Management Plan <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance ○ On the 6th month agreement anniversary to include any updates.
6.2	BARDA Audit	<p>Performer must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by 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).</p> <p>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, clinical trial), and storage of the product.</p>	<ul style="list-style-type: none"> ● 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 ● PAR and AO will review the report and provide a response to the Performer with 10 business days ● Once corrective action is completed, the Performer will provide a final report to BARDA
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 clinical trials and 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 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>	<ul style="list-style-type: none"> ● 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 ● 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 subcontractor, or third party ● Within 10 business days of inspection report, Performer must provide AO with a plan for addressing areas of non-conformance, if any are identified
6.4	Quality Assurance Audits and Subcontractor 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 subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or</p>	<ul style="list-style-type: none"> ● Performer must notify AO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subcontractors ● Performer must notify the PAR and AO within 5 business days of report completion and provide Draft Report.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		GCP guidelines, as identified in the audit report, must be provided to BARDA. The Performer must provide responses from the subcontractors to address these concerns and plans for corrective action. 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, at clinical sites, CROs, and any other clinical vendor involved in the conduct of the nonclinical study or clinical trial under agreement.	<ul style="list-style-type: none"> • PAR and AO will review the report and provide a response to the Performer with 10 business days before audit can be finalized. • Performer must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report. • Performer must provide a final closeout report that all CAPAs were addressed to PAR and AO • Performer must notify BARDA within 24 hours of any critical and/or major findings
6.5	Risk Management Plan (RMP)	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.	<ul style="list-style-type: none"> • 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 • BARDA will provide Performer with a list of concerns in response plan submitted • Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer 's receipt of BARDA's concerns • The Performer must submit updates at minimum of every three months.
6.6	Integrated Master Schedule (IMS)	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.	<ul style="list-style-type: none"> • The Performer must submit the IMS in both PDF and an agreed-upon electronic format (e.g., Microsoft Project) to the PAR • The first Draft of the IMS is due within 30 business days after the initiation of the agreement period of performance • The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set • Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports • 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.
6.7	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Performer must notify BARDA of significant proposed changes 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.	<ul style="list-style-type: none"> • The Performer must submit Deviation Notification and Mitigation Strategy at least 10 business days prior to the Performer anticipating the need to implement changes
6.8	Incident Report	Performer must communicate to BARDA and document all critical programmatic concerns, issues, or probable risks	<ul style="list-style-type: none"> • Due within 48 hours of activity or incident or within 24 hours for a security activity or incident

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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 to the project even without cost/schedule impact, such as breach of GCP during a clinical study, must also be reported.	<ul style="list-style-type: none"> •Email or telephone with written follow-up to PAR and AO •Additional updates due to PAR and AO within 48 hours of additional developments •Performer must submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues •If corrective action is deemed necessary, Performer must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

Advanced R&D Products

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
7.1	Technical Documents	Upon request, Performer must provide AO and PAR with deliverables from the following activities: quality agreements between Performer s and subPerformers, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports, clinical trial documents. The AO and PAR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government ³ .	<ul style="list-style-type: none"> •Performer must provide technical document within 10 business days of AO or PAR request. Performer can request additional time on an as needed basis •If corrective action is recommended, the Performer must address, in writing, concerns raised by BARDA in writing
7.2	Publications	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 BARDA for review prior to submission. Acknowledgment of BARDA funding must be included.	<ul style="list-style-type: none"> • 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 • Performer must address in writing all concerns raised by BARDA in writing • Final submissions must be submitted to BARDA concurrently or no later than within one (1) calendar day of its submission • Performer must list all publication material in the Monthly Technical Progress Report
7.3	Performer Clinical Publication Timeline and USG Right to Publish Data	The Performer and Government are committed to transparent and timely publication of clinical trial data to ensure rapid distribution of information during a Public Health Emergency. Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this agreement and consistent with Good Publications Practices. Sponsor must submit clinical study primary endpoint analysis for publication to a peer reviewed journal. Within 90 days of the of study end date [last subject last visit] for studies funded in part or whole under this agreement and consistent with Good Publication Practices, Sponsor must submit clinical study data for publication to a peer reviewed journal. If the Performer does not elect to publish data, Performer must provide AO and PAR with clinical trial data to support the government publication of data as deemed appropriate by the government, without the Performer	<ul style="list-style-type: none"> • Performer must notify AO and PAR within 30 calendar days of primary analysis results and study end date [last subject last visit] if they plan not to publish data. • Within 10 calendar days of a request for clinical 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 clinical trial data funded in part or whole under this agreement

³ Please see footnotes **Error! Bookmark not defined.**, **Error! Bookmark not defined.**, and **Error! Bookmark not defined.** under Technical Reporting: Nonclinical Studies.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		involvement. The government reserves the right to publish a counter-analysis of the data.	
7.4	Performer Nonclinical Publication Timeline and USG Right to Publish Data	<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 QAO 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 right to publish a counter-analysis of the data.</p>	<ul style="list-style-type: none"> • 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. • 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

Regulatory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
8.1	Regulatory Strategy/Plan	<p>The Performer must provide a Regulatory Plan that outlines the regulatory strategy for the product.</p> <p>The plan must include information leading to commercialization readiness.</p>	<ul style="list-style-type: none"> • 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 • BARDA will provide Performer with a list of concerns in response to plan submitted • Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns
8.2	FDA Correspondence	<p>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).</p>	<ul style="list-style-type: none"> • Performer must provide copies of all original and unredacted FDA correspondence within 2 business days of correspondence
8.3	FDA Submissions	<p>The Performer must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA.</p> <p>Performer must provide BARDA with an electronic copy of the final FDA submission. All documents must be duly marked as either "Draft" or "Final."</p>	<ul style="list-style-type: none"> • Performer must submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission • BARDA will provide feedback to Performer within 10 business days of receipt • The Performer must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission • The Performer must submit Final FDA submissions to BARDA concurrently or no later than five (5) calendar days of submission
8.4	IND Filing	<p>The Performer shall provide a copy of any request for IND submitted to the FDA</p>	<ul style="list-style-type: none"> • Within 7 calendar days after submission to the FDA
8.5	EUA Filing	<p>The Performer shall provide a copy of any request for EUA submitted to the FDA</p>	<ul style="list-style-type: none"> • Within 7 calendar days after submission to the FDA
8.6	BLA Filing	<p>The Performer shall provide a copy of the BLA submitted to the FDA</p>	<ul style="list-style-type: none"> • Within 7 calendar days after submission to the FDA

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 15th 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

RRPV Milestone Number	Task Number	Significant Event/ Accomplishments	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)	1/25/2020	\$ -		\$ -

3	N/A	Monthly Report (Technical and Business Reports)	2/25/2020	\$ -		\$ -
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)	3/25/2020	\$ -		\$ -
7	N/A	Monthly Report (Technical and Business Reports)	4/25/2020	\$ -		\$ -
8	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	\$210,757	\$187,457	\$398,214
9	N/A	Monthly Report (Technical and Business Reports)	5/25/2020	\$ -		\$ -
10	N/A	Monthly Report (Technical and Business Reports)	6/25/2020	\$ -		\$ -
11	N/A	Monthly Report (Technical and Business Reports)	7/25/2020	\$ -		\$ -
12	N/A	Monthly Report (Technical and Business Reports)	8/25/2020	\$ -		\$ -
13	N/A	Monthly Report (Technical and Business Reports)	9/25/2020	\$ -		\$ -
14	4	Toxicity Studies	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)	11/25/2020	\$ -		\$ -
17	5	FDA 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)	12/25/2020	\$ -		\$ -

21	8	1 st subject screened, randomized and enrolled in study	1/1/2021	\$150,000	\$187,457	\$337,457
22	N/A	Monthly Report (Technical and Business Reports)	1/25/2021	\$ -		\$ -
23	N/A	Monthly Report (Technical and Business Reports)	2/25/2021	\$ -		\$ -
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)	3/25/2021	\$ -		\$ -
26	N/A	Monthly Report (Technical and Business Reports)	4/25/2021	\$ -		\$ -
27	N/A	Monthly Report (Technical and Business Reports)	5/25/2021	\$ -		\$ -
28	10	Assess potential toxicology	6/1/2021	\$157,829		\$157,829
29	N/A	Monthly Report (Technical and Business Reports)	6/25/2021	\$ -		\$ -
30	N/A	Monthly Report (Technical and Business Reports)	7/25/2021	\$ -		\$ -
31	N/A	Monthly Report (Technical and Business Reports)	8/25/2021	\$ -		\$ -

32	N/A	Monthly Report (Technical and Business Reports)	9/25/2021	\$ -		\$ -
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)	11/25/2021	\$ -		\$ -
36	N/A	Monthly Report (Technical and Business Reports)	12/25/2021	\$ -		\$ -
37	N/A	Monthly Report (Technical and Business Reports)	1/25/2022	\$ -		\$ -
38	N/A	Monthly Report (Technical and Business Reports)	2/25/2022	\$ -		\$ -
39	12	Electronic Report Forms Developed	3/1/2022	\$315,658	\$187,457	\$503,115
40	N/A	Monthly Report (Technical and Business Reports)	3/25/2022	\$ -		\$ -
41	N/A	Monthly Report (Technical and Business Reports)	4/25/2022	\$ -		\$ -
42	N/A	Monthly Report (Technical and Business Reports)	5/25/2022	\$ -		\$ -
43	N/A	Monthly Report (Technical and Business Reports)	6/25/2022	\$ -		\$ -
44	N/A	Monthly Report (Technical and Business Reports)	7/25/2022	\$ -		\$ -
45	13	Complete 100% patient enrollment	8/1/2022	\$315,658	\$187,457	\$503,115
46	N/A	Monthly Report (Technical and Business Reports)	8/25/2022	\$ -		\$ -
47	N/A	Monthly Report (Technical and Business Reports)	9/25/2022	\$ -		\$ -
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	\$ -		\$ -
Total				\$2,025,240	\$1,124,742	\$3,149,982
Period of Performance (Months)						XX Months
Contract Type						FFP

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. However, submission of a report may be used as a ‘triggering event’ indicating sufficient work has been completed to allow milestone payment.(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. RRPV 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 RRPV 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.

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

ATTACHMENT 4 – PROGRAM/PROJECT MANAGEMENT PLAN TEMPLATE

[The Offeror is required to provide details on their proposed approach for Program Management and subcontractor management, to include:

- 1. Program Management:** Provide details on proposed Program Management approach.
- 2. Subcontractor Management:** Provide details on proposed Subcontractor Management Approach.
- 3. Key Personnel:** Key personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal (Note: key personnel resumes to be included in the technical proposal). A summary of related activities must also be provided for key personnel.
- 4. Organizational Chart:** Organizational chart for the project with affiliations (who will report to whom).
- 5. Offeror-Provided Facilities:** Details on infrastructure and other resources, such as:
 - Manufacturing capacity expansion plans to match the proposed manufacturing scale-up;
 - Overview of the management of Quality Systems at the facility;
 - List of capabilities for clinical activities conducted in house and at contract research organizations;
 - Qualified animal facilities where Good Laboratory Practice (GLP) studies would be conducted and appropriate certifications for humane care and use of vertebrate animals;
 - Commercial capabilities of the Offeror, including current products, and marketing, distribution, and customer support capabilities (as applicable); and
 - List of key vendors or service providers, locations, and brief description of their expertise/experience.]

ATTACHMENT 5 – ASPR SECURITY REQUIREMENTS

* This list of deliverables and ASPR-mandated security requirements may be required for any contract or agreement awarded by or on behalf of ASPR. ASPR shall be the sole determiner of the necessity of inclusion of these requirements, or subset thereof, on a case-by-case basis, as identified in the Deliverables Section of the RRPV Project Solicitation. Included with Project Proposals, Offerors must include a statement attesting to their intent and ability to comply with these deliverables and security requirements within the deadline dates stated in Attachment 5.

1. Security Reporting Requirements

The partner facility shall notify the Government Security Team within 24-72 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products associated with this Agreement. The facts and circumstances associated with these incidents will be documented in writing for government review.

2. Supply Chain Resiliency Plan - [Removed]

3. Manufacturing Data Requirements

The Contractor shall submit within 30 calendar days after contract award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: 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 non-clinical and clinical studies sites. The Government may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or adjuvant production
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

4. Contractor Locations

The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.

Contractor will submit a Work Locations Report:

- Within 5 business days after contract award
- Within 30 business days after a substantive location or capabilities change

- 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

5. Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days after project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this project agreement, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

6. Security Plan

The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing. The Draft Security Plan shall be delivered to the Government Project Agreement Office (PAO) and Project Agreement Representative (PAR) no later than 30 calendar days after award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

- a) The Government will perform an internal review in detail and submit comments within ten (10) business days to the PAO and PAR to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments and submit a Final Security Plan to the U.S. Government within ten (10) calendar days after receipt of the comments.
- b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
- c) Upon completion of initiating all security measures, the Contractor shall supply to the PAO and PAR a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

<p>1. Facility Security Plan Description: As part of the partner facility’s overall security program, the contractor shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:</p>	
<p>Security Administration</p>	<ul style="list-style-type: none"> • organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats

	<ul style="list-style-type: none"> • liaison procedures with law enforcement • annual employee security education and training program
Physical Security Policies and Procedures	<ul style="list-style-type: none"> • internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	<ul style="list-style-type: none"> • identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none"> • intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability

2. Site Security Master Plan

Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.

3. Site Threat / Vulnerability / Risk Assessment	
Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security	
Description:	
Closed Circuit Television (CCTV) Monitoring	<ul style="list-style-type: none"> a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	<ul style="list-style-type: none"> a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	<ul style="list-style-type: none"> a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	<ul style="list-style-type: none"> a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.).

	<p>d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas.</p> <p>e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months.</p> <p>f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company.</p> <p>g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months.</p> <p>h) Should have written procedures to prevent employee piggybacking access</p> <p>i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access.</p> <p>j) Must have a written manual key accountability and inventory process.</p> <p>k) Physical access controls should present a layered approach to critical assets within the facility.</p>
Employee/Visitor Identification	<p>a) Should issue company photo identification to all employees.</p> <p>b) Photo identification should be displayed above the waist anytime the employee is on company property.</p> <p>c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property.</p> <p>d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.</p>
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
<p>5. Security Operations Description:</p>	
Security Management	<p>a) Designate a knowledgeable security professional to manage the security of the facility.</p> <p>b) Ensure subcontractor compliance with all Government security requirements.</p>
<p>6. Information Security Description:</p>	
Physical Document Control	<p>a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings.</p> <p>b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended.</p>

	c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
7. Information Technology & Cybersecurity	
Description:	
Identity Management	<ul style="list-style-type: none"> a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	<ul style="list-style-type: none"> a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	<ul style="list-style-type: none"> a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	<ul style="list-style-type: none"> a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available.

	<ul style="list-style-type: none"> d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	<ul style="list-style-type: none"> a) Establish and enforce security configuration settings. b) Implement sub networks for publicly accessible system components that are physically or logically separated from internal networks.
Contingency Planning	<ul style="list-style-type: none"> a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	<ul style="list-style-type: none"> a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	<ul style="list-style-type: none"> a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	<ul style="list-style-type: none"> a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	<p>Employ intrusion prevention and detection technology with immediate analysis capabilities.</p>
<p>8. Transportation Security Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.</p>	
Drivers	<ul style="list-style-type: none"> a) Drivers must be vetted in accordance with Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product.

	<p>e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency.</p> <p>f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.</p>
<p>Transport Routes</p>	<p>a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency.</p> <p>b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.</p>
<p>Product Security</p>	<p>a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed.</p> <ul style="list-style-type: none"> • Tamper resistant seals must be verified as “secure” after the product is placed in the transport vehicle. <p>b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented.</p> <p>c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.</p>
<p>9. Security Reporting Requirements Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.</p>	

SOLICITATION