Biomedical Advanced Research and Development Authority (BARDA)

Rapid Response Partnership Vehicle (RRPV)

Request for Project Proposals (RPP)

Solicitation Number: RRPV 26-13-BundiVx

"Bundibugyo Virus Outbreak Response Vaccines (BundiVx)"

Issue Date: 11 June 2026

Questions Due: 16 June 2026

Responses Due: 26 June 2026, by 1pm Eastern

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

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 Center for the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services (HHS).

The RRPV will help fortify national health security by developing medical countermeasure 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 RRPV.org. For entities interested in joining the RRPV Consortium and responding to this solicitation, please visit http://www.rrpv.org/how-to-join.

1.2 Background

Filoviruses, including ebolaviruses and marburgviruses, continue to pose a significant threat to U.S. national health security due to their potential to cause severe hemorrhagic disease, high mortality rates, and rapidly escalating outbreaks. Case fatality rates from past outbreaks range from ~ 25-90%, depending on the species, outbreak setting, and available supportive medical care.

On May 15, 2026, the Ministry of Health of the Democratic Republic of the Congo (DRC) confirmed an outbreak of Ebola virus disease in Ituri Province. On the same day the Africa Centres for Disease Control and Prevention (Africa CDC) specified it was a non-Zaire ebolavirus with, at the time, 46 suspected cases and 65 deaths reported.[1] The causative agent of the ongoing outbreak has since been identified as Bundibugyo ebolavirus (BDBV) and as of June 10th, 2026, there was a total of 598 confirmed cases and 115 confirmed deaths in DRC as well as 19 confirmed cases and 2 confirmed deaths in Uganda.[2]

There are currently no BDBV-specific vaccines licensed or in clinical development that could be leveraged in outbreak response trials.

The only FDA-licensed filovirus vaccine is ERVEBO (Merck), a vesicular stomatitis virus (VSV)-based vaccine indicated for the prevention of disease caused by Zaire ebolavirus (EBOV). A single dose of ERVEBO demonstrated protection during the 2014–2016 West Africa and the 2018 DRC EBOV outbreaks. Additional VSV-based vaccine candidates targeting SUDV and MARV have also demonstrated single-dose protection in nonclinical studies as well as favorable early safety and immunogenicity profiles in Phase 1 clinical studies.

1.3 Purpose

The purpose of this RPP is to advance investigational BDBV vaccine candidates leveraging the VSV vaccine

[1] https://africacdc.org/news-item/africa-cdc-calls-for-urgent-regional-coordination-meeting-following-ebola-virus-disease-outbreak-in-ituri-province-drc/
[2] https://www.cdc.gov/ebola/situation-summary/index.html

platform, which has demonstrated single dose protection in past EBOV outbreaks.

Work includes manufacturing process development through production of initial current Good Manufacturing Practice (cGMP) Phase 1 clinical trial material (CTM), with a goal of up to 10,000 doses. Early regulatory engagement will inform the critical-path IND-enabling nonclinical. The proposed approach must describe how any available platform efficiencies from prior or ongoing platform development and manufacturing to accelerate the path towards cGMP CTM production and IND submission under the U.S. FDA. Additional activities include a Phase 1 safety and immunogenicity trial as well as options for production of up to 100,000 doses of cGMP CTM.

The end goal of this effort is (1) to produce cGMP CTM and meet regulatory requirements to enable use of investigational candidate(s) in a clinical trial for the ongoing 2026 BDBV outbreak and (2) to identify successful BDBV vaccine candidates for potential further development.

2. Administrative Overview

2.1 RPP Approach

A single-stage approach will be employed with submission of a full technical and cost proposal. Submission of a full technical and cost proposal does not guarantee an award. Invitation to negotiations does not guarantee an award. Submissions that are not invited to negotiations, including the basket (see Section 5.5/5.6 below), will receive notification but may not receive feedback on their offer.

It is expected that there will be one or more qualified respondents that can accomplish the objectives.

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.

2.2 Order of Precedence

Each proposal selected for award under this RPP will be executed as a Project Award under the RRPV Base Agreement 75A50123D00005. The same provisions as the OTA between the U.S. Government (USG) and ATI ("RRPV Base") will govern this Base Agreement unless otherwise noted in the Project Award.

2.3 Period of Performance and Funding

2.3.1 Period of Performance

The period of performance should be commensurate with the amount of work proposed. BARDA anticipates the full program Period of Performance to be up to five (5) years from the date of award. Specific dates will be negotiated prior to award of the project agreement.

2.3.2 Funding

The total USG funding amount anticipated to be available is approximately $75M. The USG anticipates making approximately 1-3 awards. Funding may be adjusted based on the Performer's demonstrated progress and program priorities.

Based on program priorities, the USG may provide additional funds to support continued development and manufacturing.

Funding and estimated number of awards is subject to change and dependent on the proposal(s) received, BARDA priorities, and availability of Federal funds for this program.

2.4 Expected Award Date

The government anticipates the period of performance beginning during fiscal year 2026. The government reserves the right to change the notional period of performance start date through negotiations via the RRPV CMF prior to project award.

2.5 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.

2.6 Mandatory Eligibility Criteria

To be eligible for consideration Offerors must be RRPV members when their proposal is submitted. Prospective Offerors may join the consortium at www.rrpv.org/how-to-join.

Offerors must meet the following additional mandatory eligibility criteria:

- Proposed approach must use a VSV-based platform technology
- Developer must have development and manufacturing experience with the platform in the context of a filovirus vaccine
- At the time of proposal submission, the developer and proposed Contract Development and Manufacturing Organization (CDMO) partner must already have a demonstrated manufacturing relationship involving the platform technology and the manufacturing system/process proposed for this effort
- Developer must commit to providing material produced to BARDA, or to a BARDA-selected partner, for testing in nonclinical models, nonclinical assays, and/or clinical assays

Failure to meet the mandatory criteria will result in a rejection of the submission without further review.

2.7 Cost Sharing

Cost sharing is defined as the resources expended by the Project Performer on the proposed Statement of Work (SOW). Cost sharing, while not required, is encouraged, if possible, as it leads to stronger leveraging of Government-Performer collaboration. During negotiations cost sharing may be discussed depending on the potential of future commercial applications.

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.).

2.8 Intellectual Property and Data Rights

Intellectual Property (IP) rights for RRPV Project Awards will be defined in the terms of a Project Performer'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 Performers during the entire award period.

The Offeror must 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 will be delivered to the Government with unlimited data rights as defined in the RRPV Base Agreement unless otherwise specified in Attachment 3, Statement of Work, 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.

3 Submissions

3.1 Question and Answer Period

Key dates related to this RPP are provided below. Please submit questions to Ms. Kathy Garee (rrpv-contracts@ati.org). Answers will be posted publicly to the RRPV website.

Date	Event	Method
11 June 2026	RPP Released	RRPV Website
16 June 3pm Eastern	Questions Due to RRPV	Email to rrpv-contracts@ati.org
18 June 2026	Answers Released on RRPV website (Approximate)	RRPV Website
26 June 2026 1PM Eastern	Proposals Due	RRPV BDR Portal

3.2 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 will 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.

Offerors may request a current copy of the RRPV Base Agreement terms and conditions by emailing RRPV-contracts@ati.org. Base Agreements are typically not executed until Offeror is selected for award. Offerors are

encouraged to contact the Point of Contact (see Section 6), identified herein up until the submission date/time to clarify requirements.

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

An RRPV 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 submit 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 should 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 will not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

3.4 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.

3.5 Submission Format
Proposals shall reference this RPP number. **Each document below (Technical Proposal, Cost Proposal Narrative, Cost Proposal Format, Project Management Plan, 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 must include the following:

- **Technical Proposal submission (30-page limit, unless noted*) – See Attachment 1:** One Word (.docx or .doc) or PDF file for the Technical Proposal. 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.

- **Statement of Work/Milestone Payment Schedule (no page limit) – See Attachment 3**: One Word (.docx or .doc) file. 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. 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).

3.6 Restrictions on Animal and Human Subjects

Project Performers 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 Performer 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 Performer 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 Performer 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.

4 Technical Requirements

4.1 Introduction

The Offeror shall clearly state how they intend to meet and, if possible, exceed the technical requirements. Responses must include quantitative, data-driven justification and clearly describe how prior platform development enables efficiency, scalability, and reuse.

4.2 Scope

Overall objective. The purpose of this RPP is to advance investigational BDBV vaccine candidates leveraging the VSV platform, which has precedent for single dose protective efficacy in past EBOV outbreaks. The end goals are to (1) produce cGMP CTM and meet regulatory requirements to enable use of investigational BDBV vaccine

candidate(s) in the ongoing 2026 BDBV outbreak response trial and to (2) identify successful BDBV vaccine candidates for potential further development. The preference is to support different manufacturing approaches/platforms systems to diversify manufacturing risk.

The project supports manufacturing process development through to production of cGMP Phase 1 CTM (target: up to 10,000 doses); critical path IND-enabling activities to support a Phase 1 trial; a Phase 1 clinical trial; additional manufacturing of up to 100,000 doses of CTM; regulatory engagements and submissions; and necessary logistical support (e.g., dose and sample shipping for outbreak response).

4.3 Performance Objectives and Supporting Technical Justification and Plans

Offerors are encouraged to address the following areas, as applicable to the proposed effort, and may provide any additional technical or other information they deem pertinent.

- Platform technology
    - Provide a technical description of the platform technology, including details of the platform backbone/viral vector engineering and formulation
- Nonclinical
    - Describe the nonclinical efficacy and immunogenicity data generated using the platform for BDBV and any other filoviruses; data supporting rapid onset of single-dose protection is a priority
    - Describe the relevant nonclinical safety data generated by the Offeror for the platform
- Clinical
    - Describe the clinical safety, immunogenicity, and efficacy data generated using the platform for filoviruses; data supporting rapid onset of immunogenicity and/or protection following a single dose is a priority
    - Describe the overall clinical safety database generated with the platform
- Manufacturing
    - Describe the Offeror's manufacturing experience with the platform for filoviruses
    - Describe the manufacturing expression system and process proposed for use under this RPP
        - Provide details on the manufacturing partner and facility (developer-owned or CDMO partner(s)
        - Describe the joint experience of the Offeror with the manufacturing facility/CDMO for the manufacturing expression system and process proposed for use under this RPP
            - Note the mandatory criteria in Section 2.6: at the time of proposal submission, the developer (i.e., Performer) and the proposed Contract Development and Manufacturing Organization (CDMO) partner must already have a demonstrated manufacturing relationship involving the platform technology and the manufacturing system/process proposed for this effort
- Leveraging platform efficiencies
    - Describe any FDA feedback previously received regarding nonclinical, clinical, or platform-based efficiencies that could be leveraged to accelerate development of the proposed candidate
    - Describe the Offeror's manufacturing plan for production of cGMP CTM.
        - Describe the steady-state manufacturing process and timelines
        - Describe the planned accelerated manufacturing process, projected timelines, key critical-path activities, and assumptions required to achieve accelerated production.

        - Targets are
            - Up to 10,000 doses of CTM (Section 4.4, Task 1b)
            - Up to 100,000 doses of CTM (Section 4.4, Task 2)
        - The stated dose targets represent an ideal for the associated Task. Based on the proposed platform and manufacturing process/system, describe the number of doses reasonably anticipated to be produced under each task/subtask and provide the technical justification that supports the estimates. Capture this in the proposed work.
- Regulatory and development plan
    - Propose a regulatory strategy and development plan to achieve U.S. FDA approval of a Phase 1 IND application. The proposal must describe the Offeror's risk management approach, the extent to which efficiencies from past platform development and manufacturing activities can be leveraged, and any appropriate regulatory flexibilities that may be used. The regulatory strategy and accelerated development plan shall focus on production of stage-appropriate cGMP CTM, in line with project tasks, and supporting critical-path nonclinical and clinical studies anticipated to enable use of CTM in an outbreak response trial.

4.4 Project Tasks

All work described below must be included in the proposal and planned for execution. However, pursuant to the mandatory eligibility criteria in Section 2.6, Offerors must commit to providing any materials produced under this effort to BARDA or a BARDA-designated third party. BARDA anticipates potential coordination with partner organizations, as appropriate, to conduct critical-path nonclinical and other supporting studies and to facilitate the potential use of cGMP CTM in outbreak clinical trials conducted in affected countries.

As appropriate, the Performer may be required to engage with international regulatory authorities, local ministries of health, and relevant ethics committees to support the use of investigational CTM in clinical trials conducted in countries affected by the 2026 BDBV outbreak.

All tasks must account for necessary regulatory engagement and submissions.

1 Manufacturing through cGMP Phase 1 CTM

- **Task 1a. Process development to engineering run (Base)**
    - Conduct any necessary process development work through production of an engineering run at scale
    - Conduct analytical assay development and testing to support product release and stability studies
    - Regulatory
        - Conduct early regulatory engagement with the U.S. FDA to identify manufacturing and nonclinical critical-path activities necessary to support submission of a Phase 1 IND
        - Prepare and submit all regulatory documentation required to support the proposed activities, and conduct any necessary regulatory interactions and submissions
- **Task 1b. Production of Phase 1 cGMP CTM (target: up to 10,000 doses) (Option)**
    - Production of up to 10,000 doses of Phase 1 cGMP CTM

- Conduct any analytical development and testing to support release
- Conduct stability studies
- Conduct stage appropriate process, facilities, equipment and analytical qualification
- Support preparation of any regulatory documentation, engagement, and submissions required
- Include any logistical support activities (e.g., labelling, shipping, storage, etc.) both for the Phase 1 and for potential shipment of doses for use in an outbreak clinical trial in countries affected by the 2026 BDBV outbreak

2 **Task 2. IND-enabling nonclinical activities (Option).**

- Conduct all critical path nonclinical activities required for submission of a Phase 1 IND under the U.S. FDA and achieve safe-to-proceed status
  - ◊ Propose all nonclinical activities that could reasonably be required to support successful submission a Phase 1 IND under the U.S. FDA. Note that if awarded, the specific nonclinical activities to be conducted will be finalized as informed by FDA feedback received through a pre-IND meeting or other regulatory interactions.
  - ◊ Note that while all work shall be proposed and planned, per the mandatory eligibility criteria (Section 2.6), Offerors must commit to providing any material produced to BARDA, or a BARDA-selected third party. BARDA anticipates possible coordination with other partner organizations to conduct nonclinical/in vitro studies.
- Prepare and submit all regulatory documentation required to support the proposed activities, and conduct any necessary regulatory interactions and submissions

3 **Task 3. Phase 1 clinical trial (Option).** Plan and execute a Phase 1 study under a U.S. FDA IND. The Propose a placebo-controlled Phase 1 study design and provide a proposed draft protocol synopsis; the final study design will be determined in future discussion with BARDA.

- The Phase 1 study design should consider an initial interim analysis of the safety, tolerability, and rapid immunogenicity profile of the single-dose investigational vaccine from the perspective of future potential use for reactive deployment in an outbreak setting. Given the anticipated use scenario, the principal immunologic objective is to characterize the kinetics of early immune responses associated with rapid onset of protection following a single vaccination to inform decision-making for potential outbreak trial use. Endpoints related to durability of response should be accounted for in exploratory endpoints.
- Conduct all necessary activities, including but not limited to:
  - Conduct trial readiness and execution activities.
  - Propose a plan to accelerate study recruitment and enrollment
  - Conduct immunogenicity assays
  - Conduct safety and immunogenicity analysis
  - Produce interim and final Clinical Study Report
- Prepare and submit all regulatory documentation required to support the proposed activities, and conduct any necessary regulatory interactions and submissions

4 **Task 4. Manufacturing up to 100,000 doses of CTM.**

- Include two separate options as: **Task 4a (option) and Task 4b (option)** that each account for manufacturing of up to 100,000 doses.
- For both options include
    - Conduct of any analytical development and testing to support release and stability studies
    - Any logistical support activities (e.g., labelling, shipping, storage, etc.)

5 **Task 5. Outbreak trial support (Option)**.

- Shipping of clinical immune samples from outbreak clinical, sample storage, and any other required support functions, to enable testing in immune assays developed under the BARDA-funded development program.
- Incorporation of clinical safety data into the Performer's safety database for the platform

4.4 Performance Requirements

Preparation, submission, and maintenance of nonclinical and clinical documentation for regulatory filings (pre-IND/IND) to support regulatory strategies aimed at obtaining FDA approval.

4.5 Deliverables

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

4.6 Special Requirements

- Export Control: The Project Awardee will be expected to be knowledgeable of and comply with any applicable U.S. Export Laws.

- 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.

5 Proposal Selection/Evaluation

5.1 Gain-of-Function Research

In accordance with Executive Order 14292 "Improving the Safety and Security of Biological Research," BARDA does not support gain-of-function research or research involving the manipulation of pathogens that may result in a gain of function.

For purposes of this RPP, gain-of-function research is defined as scientific research on an infectious agent or toxin that has the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility.

Covered research activities include those that could result in significant societal consequences and that seek or achieve one or more of the following outcomes:

- Enhancing the harmful consequences of an agent or toxin
- Disrupting beneficial immunological responses or reducing the effectiveness of immunizations
- Conferring resistance to clinically or agriculturally useful prophylactic or therapeutic interventions, or enabling evasion of detection methodologies

- Increasing the stability, transmissibility, or dissemination potential of an agent or toxin
- Altering the host range or tropism of an agent or toxin
- Enhancing the susceptibility of a human population to an agent or toxin
- Generating or reconstituting an eradicated or extinct agent or toxin

Proposals will be evaluated by BARDA for the appropriate use of strains in proposed studies, in addition to all other evaluation factors. Proposals that include gain-of-function research will be considered unacceptable and will not be eligible for award.

5.2 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, the RRPV CMF will request additional information from proposals that do not meet the requirements of the RPP. If requirements remain not met, a proposal may be eliminated from the competition. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

5.3 Proposal Evaluation Process

An initial review will assess alignment to mandatory criteria; if determined acceptable further review will be conducted as described.

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 2.9. 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 preferred characteristics, technical requirements, 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 Government will evaluate each Proposal against the evaluation factors detailed below and assign one of the following adjectival ratings in order to determine the best value to the Government.

- Outstanding
- Good
- Acceptable
- Marginal
- 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.

5.4 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. Non-Cost/Non-Price Evaluation factors are listed in descending order of importance. Non-Cost/Non-Price factors are more important than Cost/Price, collectively and individually. A determination on best value to the Government 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 this RPP.
b. **Accelerated Development and Manufacturing Approach** including proposed plan to leverage any efficiencies provided by prior platform work and any additional manufacturing efficiencies; joint developer/CDMO experience manufacturing the platform for filoviruses; joint developer/CDMO; demonstration of active and successful manufacturing of the platform technology at developer's with a Contract Development and Manufacturing Organization (CDMO) partner with the propose manufacturing system/process
c. **Clinical approach** plan to assess safety and immunogenicity as aligned to safety and rapid onset to protection demonstration and exploratory endpoints plan for durability of response

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. Demonstrated capability of the Performer's own manufacturing facility or proposed CDMO partner(s) will also be considered.

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 5.5 below): Assessment of the cost of the project to determine i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed.

5.5 Cost/Price Evaluation

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 may 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.

5.6 Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Funding recommendations depend on various factors and programmatic relevance.

Based on the evaluation of the Technical Approach, Relevant Experience, and Cost/Price, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offerors will have the opportunity to concur with the requested changes, propose further changes and revise cost proposals as necessary.

5.7 Evaluation Results
Following the evaluation of proposals, the Source Selection Authority may recommend the following for the CMF's consideration:

1. Select the proposal (or some portion of the proposal) for award;
2. Place the proposal in the Basket; 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.

5.8 Basket Provision
The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately selected for award may be placed in the Basket for 2 years from the date of RPP close and eligible for award during that time. Proposals rated as below Acceptable 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.

5.9 Points of Contact
Questions related to this RPP should be directed to Ms. Kathy Garee (rrpv-contracts@ati.org).

All technical questions must be submitted by 3pm ET on June 16, 2026, to allow for a 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/). Individualized responses or discussions will not be provided to ensure fairness to all Offerors.

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)

* *Sections marked with an asterisk (**)* are excluded from the page limitation.

Technical Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RRPV 26-13-BundiVx

[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 2.5 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).

1. 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):	

2. Executive Summary & Minimum Eligibility Requirements

[The Executive Summary allows Offerors to present briefly and concisely 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.]

[This section must address how the Offeror currently satisfies each aspect of the following minimum eligibility requirements. Proposals will be reviewed to confirm minimum criteria are met.]

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. Developer must have development and manufacturing experience with the platform in the context of a filovirus vaccine.
3. At the time of proposal submission, the developer and proposed Contract Development and Manufacturing Organization (CDMO) partner must already have a demonstrated manufacturing relationship involving the platform technology and the manufacturing system/process proposed for this effort
4. Developer must commit to providing material produced to BARDA, or to a BARDA-selected partner, for testing in nonclinical models, nonclinical assays, and/or clinical assays

3. 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 (Technical Requirements) of the RPP. Include relevant background data about your approach. Include the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Past Experience:** [Describe relative corporate and capabilities past experience, as well as the technical and management experience of the proposed team, to perform the proposed work. Past experience should be recent, relevant and similar in size and scope to offeror's proposed effort.]
5. **Technical Strategy**: [Describe the proposed methodology, including development and manufacturing approach, in sufficient detail to show a clear course of action.]
6. **Manufacturing:** [Include the following information as part of the technical approach. Manufacturing activities must be described in sufficient detail to assess technical feasibility, manufacturing readiness, scalability, regulatory compliance, and the ability to produce cGMP Clinical Trial Material (CTM) within the proposed timelines. The manufacturing approach must address all applicable regulatory requirements and industry standards, including current cGMP regulations, relevant FDA guidance documents, ICH quality guidelines, and demonstrate suitability to support Phase 1 IND submission and outbreak-response deployment.]
    - **Manufacturing Experience**: Describe the Offeror's prior experience developing and

manufacturing filovirus vaccines using the proposed platform technology. Summarize relevant experience with process development, technology transfer, engineering runs, cGMP manufacturing, clinical material production, and regulatory submissions. Describe how prior platform knowledge will be leveraged to reduce manufacturing, quality, and regulatory risk.

- **Manufacturing Partner and Facility:** Identify the proposed manufacturing facility or CDMO partner(s), including facility location, capabilities, cGMP status, relevant inspection history, and manufacturing scale. Describe the manufacturing expression system and process proposed for use under this RPP. Describe the joint experience of the Offeror and the proposed facility/CDMO with the same platform technology, expression system, and manufacturing process. The proposal must demonstrate that, at the time of submission, the developer and proposed CDMO already have a manufacturing relationship involving the proposed platform and manufacturing system/process.
- **Manufacturing Process and Readiness:** Provide an overview of the proposed manufacturing process from starting materials through final drug product, including upstream, downstream, formulation, and fill-finish, as applicable. Describe current process maturity, remaining process development needs, critical process parameters, critical quality attributes, in-process controls, and key assumptions required to proceed to engineering and cGMP production.
- **Process Development Through Engineering Run:** Describe the process development activities, analytical assay development, scale-up parameters as applicable, testing, and engineering run strategy proposed to support cGMP manufacturing readiness. Include engineering run objectives, scale, success criteria, and how results will inform cGMP production.
- **cGMP CTM Production:** Describe the phase-appropriate manufacturing plan for Phase 1 cGMP CTM, including the steady-state process, projected timelines, batch size, yield assumptions, release testing, stability testing, and logistical support. Separately describe the accelerated manufacturing approach, projected timelines, critical-path activities, and assumptions needed to produce CTM. Address production targets of up to 10,000 doses under Task 1b and up to 100,000 doses under each Task 4 option. Based on the proposed platform and process, state the number of doses reasonably expected to be produced and provide the technical justification supporting those estimates.
- **Analytical, Quality, and Supply Chain Strategy:** Describe analytical methods supporting release, characterization, comparability, and stability. Address assay readiness, reference standards, critical reagents, long-lead items, and mitigation strategies. Describe applicable quality systems.
- **Regulatory Strategy and Risk Management:** address a CMC/regulatory strategy to support U.S. FDA Phase 1 IND approval, including early FDA engagement (e.g., INTERACT or pre-IND mechanisms), regulatory submissions, and use of appropriate platform efficiencies, existing Drug Master Files (DMFs), or regulatory flexibilities. Identify manufacturing, analytical, supply chain, facility, regulatory, and schedule risks, and describe mitigation plans, contingencies, and decision points.

7. **Clinical Trial:** [A Phase 1 trial must be proposed as part of Technical Strategy and Include the following information as part of the technical approach. Describe the clinical trial(s) 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).]

- **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.]
- **Study Design/Clinical Protocol**
- **Statistical Plan and Data Analysis**

8. **Anticipated Outcomes**: [Provide a description of the anticipated outcomes from the proposed work.]
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 format below. 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.]

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

4. 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]

5. 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.

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.

Cost Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RRPV 26-13-BundiVx

[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 2.5 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).

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 hourly rate for each individual, and estimated hours for each labor category proposed. Provide job description (i.e. example duties, qualification requirements, years of experience, etc.) for each position proposed. If an approved organizational estimating procedure is used, average labor rates for specific labor categories may 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 with 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 people; 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 accommodation 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 rational 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.]

2. 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.]

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: RRPV 26-13-BundiVx
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	•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.	•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.	•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
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	•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

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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.	days
1.5	Weekly Check-in with BARDA	Upon request of the Government, the Performer must participate in a weekly check-in update with the project staff (via email of, if needed, teleconference). The update will address key costs, schedule, and technical updates. 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. Check-ins may occur on weekdays, excluding federal holidays. If necessary during the outbreak response period, upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24-hours' notice. Check-in frequency may be increased or decreased as needed during the course of the project	•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)	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). 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.	•Performer must submit a PMP o Within 30 calendar days after the initiation of the agreement period of performance o 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.	•At first project meeting and as updated no later than every 30 calendar days. Provided in pdf.
2.3	Communication Plan	The Performer must develop and implement an effective Communication Plan that details the flow of information between BARDA, Performer, collaborators, vendors, and other organizations. The Communication Plan must also include a press release review process.	•Performer must submit a Communication Plan o Within 30 calendar days after the initiation of the agreement period of performance o Updates should be provided to reflect any key changes and reviewed at least annually.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
2.4	Performer Locations	The Performer must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location, to include subcontractors and critical vendors of reagents and supplies. Performer must include vendors for critical infrastructure protection.	•Performer must submit Work Locations Report: o Within 5 business days after the initiation of the agreement period of performance o 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	Monthly & Annual Technical Progress Reports/Annual Meeting	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. 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: •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 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. 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 during the period covered, explaining any differences between the two and the corrective steps 4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 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 6. Estimated and Actual Expenses	•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
		• 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. 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	
2.6	Draft and Final Technical Progress Report	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.' 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.	• 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: 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.	• The Performer must submit Draft study protocols to PAR electronically prior to finalization. o BARDA will provide comments within 10 business days of receipt of draft protocol o 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. o 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[3]	The Performer must provide the following documents for any portion of a study funded under this agreement: • 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) • 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	• The Performer must submit Draft study documents to PAR electronically prior to finalization. o BARDA will provide comments within 10 business days of receipt of draft document o 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.

[3] 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
		• 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 The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during clinical site monitoring visits.	
5.3	ClinicalTrials.Gov Posting and Results Reporting	Per clinicaltrials.gov registration and reporting requirements.	• Performer must post results: o 3 months from any interim analysis o 3 months from primary analysis o 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.	• 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
5.6	Clinical Report During Active Enrollment Periods[4]	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.	• 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.	• Due within 20 calendar days of PAR request, no later than ten calendar days prior to first site activated
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.	• 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	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	• 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

[4] 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
		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. If clinical trial data is included, that data must be provided consistently with applicable privacy laws to protect personally identifiable information (PII).	Submission Package.
5.10	Data Exchange Package(s) Submitted to Regulatory Agency(s)	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. *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*	•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.	•Performer must post clinical trial datasets on a web-based platform easily accessible by the public: o 3 months from any interim analysis **supporting any action (e.g., regulatory filing, protocol change), if applicable** o 3 months from primary analysis o 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.	•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)	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. All quality management plans must include subperformer quality management plans specifically addressing how subcontractor quality will be managed. All subPerformers must have a current quality agreement with the Performer and a recent vendor qualification audit.	• Performer must submit a Quality Management Plan o Within 30 calendar days after the initiation of the agreement period of performance o On the 6th month agreement anniversary to include any updates.
6.2	BARDA Audit	Performer must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by HHS. If BARDA, the Performer, or other parties identify any issues during an audit, the Performer must capture the issues, identify potential solutions and submit a report to BARDA detailing the finding and corrective action(s). HHS reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this agreement and all records related to the manufacture, testing (including but not limited to analytical testing, nonclinical study, clinical trial), and storage of the product.	• 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	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. 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.	• 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	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 GCP guidelines, as identified in the audit report, must be	• 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. • PAR and AO will review the report and provide a response to the Performer with 10 business days before

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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.	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.	•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.	•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.	•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 that have or are likely to significantly impact project	•Due within 48 hours of activity or incident or within 24 hours for a security activity or incident •Email or telephone with written follow-up to PAR and AO

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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.	• 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[5].	• Performer must provide technical documents 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.	• 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.	• 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

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

Regulatory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
8.1	Regulatory Strategy/Plan	The Performer must provide a Regulatory Plan that outlines the regulatory strategy for the product. The plan must include information leading to commercialization readiness.	•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	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).	•Performer must provide copies of all original and unredacted FDA correspondence within 2 business days of correspondence
8.3	FDA Submissions	The Performer must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Performer must provide BARDA with an electronic copy of the final FDA submission. All documents must be duly marked as either "Draft" or "Final."	•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	The Performer shall provide a copy of any request for IND submitted to the FDA	•Within 7 calendar days after submission to the FDA
8.5	EUA Filing	The Performer shall provide a copy of any request for EUA submitted to the FDA	•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 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	1st 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 table below 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.]