Biomedical Advanced Research and Development Authority (BARDA) Request for Project Proposals (RPP) for

"Project NextGen: Innovation in Clinical Manufacturing of COVID-19 Vaccines"

RPP #: RRPV-24-05- NGClinMfg

Issued: January 16, 2024

Amendment No. 02 Issue Date: March 7, 2024

Due: April 19, 2024, by 1pm Eastern

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

Amendment No. 02 does the following:

Extends the proposal due date from March 15, 2024 to April 19, 2024 at 1pm Eastern.

All other terms and conditions remain unchanged.

1 Executive Summary

1.1 Rapid Response Partnership Vehicle Consortium

The Rapid Response Partnership Vehicle (RRPV) Consortium is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Biomedical 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 countermeasures products prior to and during a pandemic or public health emergency. The RRPV will focus on the acceleration of products and technology development, regulatory approval, commercialization, and sustainment to address pandemic influenza, emerging infectious diseases, and other biological threats.

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

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

1.2 Purpose

BARDA is requesting project proposals for the implementation of new, innovative solutions to overcome manufacturing hurdles to produce current good manufacturing practice (cGMP) clinical trial material (CTM) of next-generation COVID-19 vaccine candidates that will decrease costs, speed production, increase efficacy, and/or improve access of COVID-19 vaccines. BARDA has previously identified that response to an emerging infectious disease is enabled by robust and flexible platform technologies that can be pivoted to address the new pathogen. However, there exist challenges and gaps within cGMP clinical manufacturing of vaccines. Enabling vaccine developers to improve the yield, scale, speed, performance, affordability, and/or accessibility of next-generation vaccine candidates will increase readiness to not only manufacture COVID-19 vaccines but also prepare and respond to emerging threats. In addition, overcoming such challenges could improve the vaccine manufacturing enterprise as a whole.

The purpose of this initiative is to partner with developers and other organizations to implement novel solutions to cGMP manufacturing hurdles and enable clinical trials for next-generation COVID-19 vaccines. The goal of these Project Awards is to advance innovative capabilities and improve the vaccine manufacturing enterprise to provide better COVID-19 solutions and bolster preparedness and response against future health security threats. Innovative technologies could encompass all aspects of manufacturing as well as analytical support, from excipients and other materials that may facilitate better production, to upstream and downstream processing, through final formulation. Final formulation challenges around the transition away from traditional needle/syringe administration may be addressed with this project. In addition,

associated and intertwined analytical support challenges can be identified and overcome to enable innovative vaccine manufacturing.

Figure 1 illustrates the overall vision and goals of this Project NextGen initiative through several possible applications in COVID-19 vaccine manufacturing that would enable increased efficacy, faster manufacturing speeds, lower costs, and/or improve access for the public.

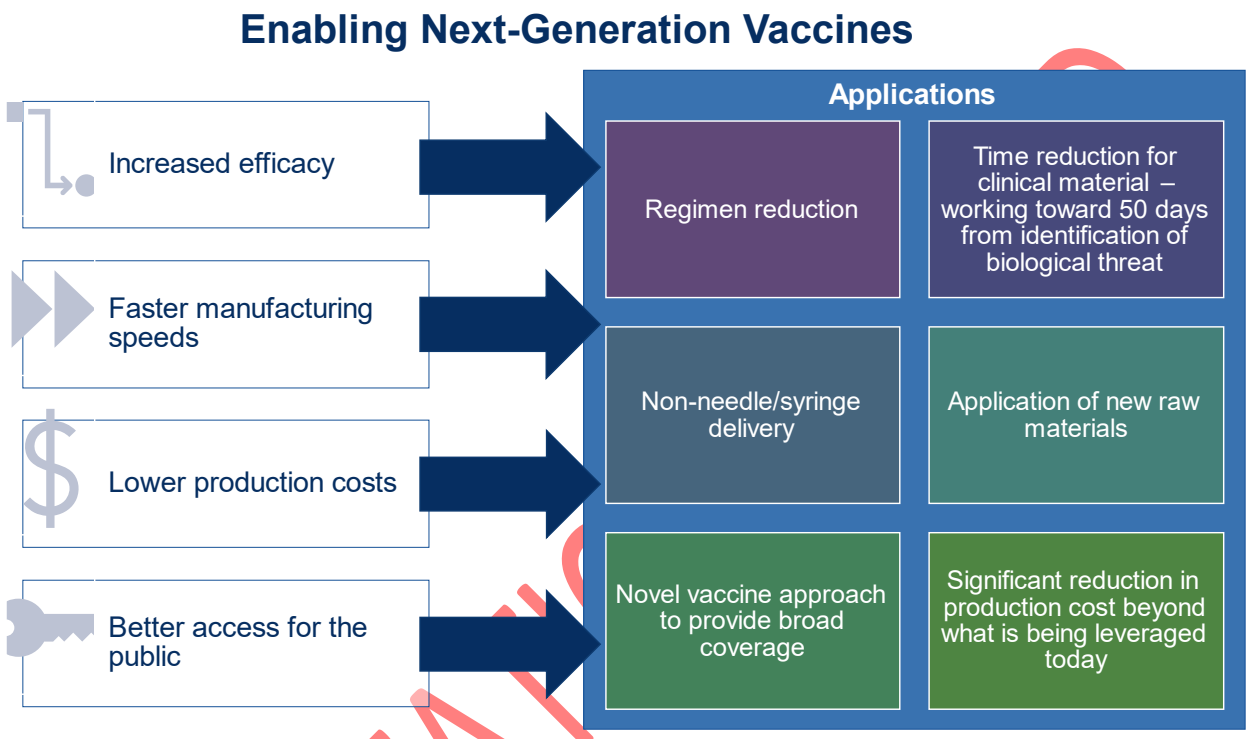

Figure 1. Success for this initiative can be defined by the enabling technology applications shown here that achieve at least one of the Project NextGen enabler goals.

For these Project Awards, proposals should consider the following:

- Recommendations from the National Biodefense Science Board (NBSB): Prioritization of Product Attribute Categories to Maximize Access for Next Generation COVID-19 Vaccines and Therapeutics, focused on increasing access to diverse and broad populations
- Goal 1 of American Pandemic Preparedness: Transforming Our Capabilities supporting the ability to make effective vaccines rapidly
- Objectives and key milestones in the BARDA 2022–2026 Strategic Plan

2 Administrative Overview

2.1 Request for Project Proposals (RPP)

Each response submitted to this RPP shall contain a Technical Proposal, Cost Proposal, and Statement of Work as described in Section 3 of this request.

2.2 RPP Approach
It is expected that there will be a total of one or more qualified respondents to accomplish the statement of objectives.

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

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

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

2.3 Period of Performance and Type of Funding Instrument Issued
The anticipated Period of Performance for this effort is estimated to be four (4) years. Specific dates are to be negotiated. It is anticipated that the primary place of performance will be the performers' facilities, however this aspect can be negotiated as part of each Performers' submission.

The total Government funding amount anticipated to be available for Project Awards is expected to be approximately $160M, and the Government anticipates making up to 20 awards. All funding and award estimates are subject to change and realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

2.4 Expected Award Date
Offeror should plan on the period of performance beginning sometime in the third quarter of fiscal year 2024. Government reserves the right to change the proposed period of performance start date through negotiations via the RRPV CMF and prior to issuing a Project Award.

2.5 Anticipated Proposal Selection Notification
As the basis of selection is completed, the Government will forward their selections to the RRPV CMF to notify Offerors. Proposers will be notified of the decision via email from the RRPV CMF of the results of the evaluation. All Offerors will receive feedback on eligible submissions.

2.6 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.

2.7 Eligibility Criteria

Offerors submitting proposals 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.

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

2.8 Special Considerations

The following are special considerations in the selection and/or negotiation process; however, these are not required in order to be eligible to receive an award under this RPP.

- **Small Business Utilization.** Small Businesses utilization is encouraged to the maximum extent practicable as a means to build an agile and resilient industrial and manufacturing base, which ultimately supports economic growth and development.
- **Cost Sharing.** Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment B.

2.9 Intellectual Property and Data Rights

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

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

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

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

3 Proposals

3.1 Proposal General Instructions

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

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

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

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

3.2 Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page.

Do not submit any classified information in the Proposal submission.

Offerors shall submit files in Microsoft Word, Microsoft Excel, or Adobe Acrobat (PDF – portable document format) formats as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension (.docx, .doc, .xlsx, or .pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters.

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

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.

3.3 Proposal Preparation Cost

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

3.4 Submission Format

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

- **Technical Proposal submission (30-page limit, unless noted*) – See Attachment A:** One signed Technical Proposal (.pdf, .doc or .docx). The mandatory template is provided as Attachment A, and includes mandatory sections for a cover page*, information sheet*, executive summary, technical approach, cost realism, current and pending support, data rights*, and key personnel resumes*.
- **Cost Proposal Narrative (no page limit) – See Attachment B:** One Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative is required using the mandatory template. Separately, Section II: Cost Proposal Format is required in Excel (.xlsx) format, with working formulas to the maximum extent practicable. See Section 3.5 for additional information.
- **Cost Proposal Formats (no page limit) – See Attachment B:** One Excel (.xlsx) document is required, with working formulas to the maximum extent practicable. See Section 3.5 for additional information.
- **Statement of Work/Milestone Payment Schedule (no page limit) – See Attachment C**: One Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the mandatory template provided as Attachment C.

3.5 Cost Proposal

The Cost Proposal must include two sections, a Cost Proposal Narrative and a Cost Proposal Format. Offerors are encouraged to use their own cost formats such that the necessary detail is provided. The RRPV CMF will make optional cost proposal formats available on the Members-Only RRPV website. The provided Cost Proposal format template is **NOT** mandatory if the Offeror's formats provide the same level of detail.

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

3.6 Special Requirements

Offerors must be prepared to comply with restrictions and reporting requirements for the use of animal and human subjects, as addressed in further detail in the RRPV Base Agreement.

Additional information on the applicable regulatory terms is provided in the RRPV Base Agreement.

These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.

4 Technical Requirements

4.1 Introduction

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

For scheduling and pricing purposes, Offerors should assume that a go/no-go decision will be made at the end of Stage 1. For awareness, Stage 1 defines success criteria that will be the key go/no go or down select for Stage 2.

4.2 Scope

This project supports the implementation of innovative solutions to manufacture Clinical Trial Material (CTM) for next-generation COVID-19 vaccines that decrease costs, speed production, increase efficacy, and/or improve access.

Figure 2 illustrates the project stages intended to improve COVID-19 vaccine manufacturing and produce material to enable clinical trials for next-generation vaccines.

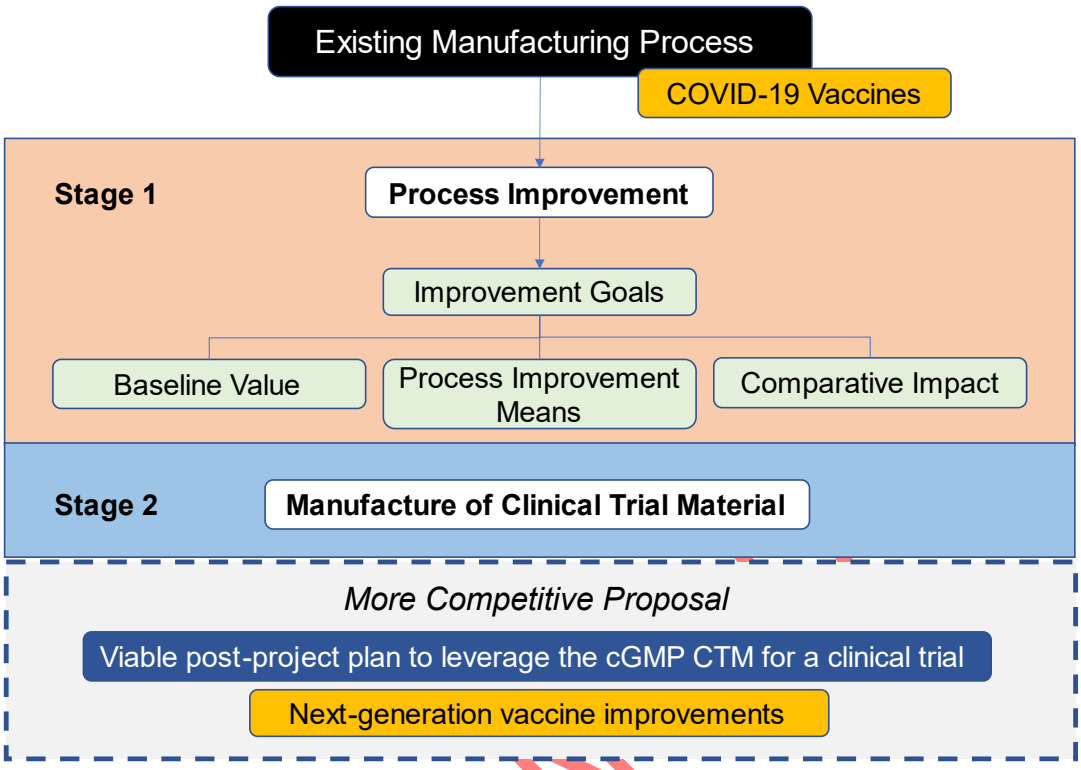

Figure 2. The two project stages aim to improve upon existing vaccine manufacturing gaps/challenges to enable clinical trials for next-generation COVID-19 vaccines.

4.3 Project Criteria

Proposals must meet the below Project Criteria to be considered within the scope of this solicitation:

1. Process improvement means:
    a. In scope:
        i. In-process and release assay improvements that reduce the requirement for specialized reagents and shorten release times
        ii. Identification of and transition to new raw materials
        iii. Use of a new platform/technology to enable improvement
        iv. Integration of continuous bioprocessing/biomanufacturing into units of operation
        v. Utilization of artificial intelligence/machine learning for process improvements
        vi. Other solutions to overcome challenges/gaps within the scope of this effort and excluding out-of-scope means described below (1.b)
    b. Out of scope:
        i. Development of new platforms/technologies
        ii. Development or production of new raw materials
        iii. Expansion of manufacturing capacity
        iv. Process improvements that are focused solely on supply chain, supply chain improvements, supply chain analysis, or any other supply chain-focused solutions

2. Vaccine characteristics:
    a. In scope:
        i. COVID-19 vaccine
        ii. Next-generation vaccine characteristics that will improve the competitiveness of a proposal:
            1. New formulation that expands options for administration or distribution (e.g., reduced number of doses to achieve protection, non-needle/syringe delivery)
            2. Novel vaccine approaches to provide broad coverage (e.g., SARS-CoV-2 variant-resistant, pan-sarbecovirus, pan-betacoronavirus)
    b. Out of scope:
        i. Non-COVID-19 vaccine

4.4 Project Objectives

The objective of this project is for an Offeror to (1) identify a challenge/gap in their existing vaccine cGMP manufacturing process and (2) implement a technical solution to address the challenge/gap that (3) results in a significant improvement in one or more of the following improvement goals:

- Shortening the time for cGMP manufacturing of CTM from sequencing of a new threat
- Increasing the number of vaccine doses per batch
- Increasing the number of batches produced within the current production timeline
- Reduction in production cost beyond what is being leveraged today

4.5 Technical Requirements

The Offeror must describe, technically justify, and provide supportive data to:

- Define your current cGMP manufacturing process as well as providing supporting data to establish and technically justify a starting baseline value for the selected improvement goal(s) to clearly illustrate the value of improvement
- Identify the process improvement means by which you will significantly improve on the selected improvement goal(s) (see Project Criteria above for list of in-scope and out-of-scope process improvement means)
- Specify how your process improvement means will result in a significant improvement and the degree of the improvement, i.e., the comparative impact. The Offeror must propose and technically justify a specific value for the degree of improvement over the baseline value; the Offeror and BARDA will come to agreement to set this success metric value prior to award.
    - What constitutes a significant improvement will be evaluated on a proposal-specific basis. An example of a significant improvement would be but not limited to shortening the time for cGMP manufacturing of clinical material, working toward a target of 50 days from identification of a biological threat.

The long-term objective of this project is to manufacture sufficient cGMP CTM to enable a COVID-19 vaccine clinical trial. Conducting a clinical trial is out of scope for this project; however, a viable

post-project strategy to leverage the cGMP CTM for a clinical trial is required and will increase the competitiveness of a proposal. As part of the technical proposal, the Offeror should describe:

- Offeror's strategy for how the cGMP CTM will be leveraged in a future clinical trial. This strategy should be reasonably achievable by means of internal, private investor, and/or existing funding opportunity (government or non-government).
- Where the work funded under this project fits into Offeror's regulatory pathway. For example, update to existing Chemical, Manufacturing, and Control (CMC) section in Offeror's Investigational New Drug (IND) application and/or support submission of Offeror's IND. If available, provide evidence of an active registered IND to evaluate the manufactured material in a clinical study.

4.6 Project Tasks

Awardees will be responsible for the following:

1. **Stage 1 – Process Development**
    a. Implement cGMP process improvement in line with the selected improvement goal(s) and process improvement mean(s).
    b. Demonstrate at the pilot scale that development activities are successful.
    c. Collect and provide data on the novel manufacturing process/process improvement.
    d. Identify and report potential constraints that may delay manufacturing of the product in future public health emergency response scenarios.
    e. Success criteria:
        i. Pilot-scale run must meet the defined degree of improvement over the established baseline value.
2. **Stage 2 – Manufacture of cGMP CTM**
    a. If desired outcome metrics are achieved in Stage 1, manufacture sufficient cGMP material to enable clinical trials in accordance with the vaccine product sponsor's regulatory pathway, implementing the improvements developed in Stage 1.
        i. Manufacturing activities will include upstream, downstream, and formulation dependent on the manufacturing platform used.
        ii. Analytical activities will be required to support the manufacturing of CTM.
    b. Collect and provide data on the novel manufacturing process/process improvement.
    c. Identify and report potential constraints that may delay manufacturing of the product in future public health emergency response scenarios.
    d. Success criteria:
        i. cGMP CTM-scale run that meets the defined degree of improvement over the established baseline value.

4.7 Project Management Objectives

It is anticipated that the performer will be required to submit a number of documents to capture the progression of the project, post-award. See Attachment C for full listing of anticipated deliverables. Requirements may include but are not limited to the following:

> **Reporting:** The performer shall deliver monthly technical and financial reports and progress reports. Annual reports shall also be provided. At the end of the effort, the performer shall provide a detailed final report of process development and manufacturing efforts.
>
> **Meetings:** The performer shall schedule regular, recurring progress meetings with the Government. The meeting agenda shall be submitted to the Government in advance and meeting minutes will be submitted following meetings.

The successful Offeror shall provide deliverables as included in Attachment C, Statement of Work.

4.8 Logistics Objectives

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

5 Selection/Evaluation

5.1 Compliance Screening

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

5.2 Proposal Evaluation Process

Following the preliminary screening, the Government sponsor will perform evaluation and source selection 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. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors as described below.

5.3 Evaluation Factors

The Government will evaluate each proposal against the following evaluation factors, which are listed in descending order of importance:

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

  Relevancy: Relevance of the proposed solution and its alignment with the RPP's topic area and the program objectives described in Section 4, which include:

  (1) identify a challenge/gap in their existing vaccine cGMP manufacturing process and
  (2) implement a technical solution to address the challenge/gap that
  (3) results in a significant improvement in one or more of the following improvement goals:

  - Shortening the time for cGMP manufacturing of CTM from sequencing of a new threat
  - Increasing the number of vaccine doses per batch
  - Increasing the number of batches produced within the current production timeline
  - Reduction in production cost beyond what is being leveraged today

  Thoroughness: The proposal provides sufficient detail and indicates a thorough understanding of the technical requirements set forth in this RPP.

  Completeness: The proposal addresses all technical requirements as described in Section 4.

  Feasibility: Feasibility of the Offeror's regulatory strategy and post-project strategy including the degree to which the proposed process improvement will result in cGMP clinical trial material that can be leveraged in a future clinical trial.

- Factor 2 – Cost/Price: See Section 5.5 below.
- Factor 3 – Relevant Experience: This factor evaluates the offeror's demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS) and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems.

5.4 Evaluation Ratings

The Government will assign one of the following adjectival merit ratings to each of the non-cost/price factors:

- Outstanding
- Good
- Acceptable
- Marginal

- Unacceptable

5.5 Cost/Price Evaluation

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

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

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

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

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

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

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

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized, and systematic manner.

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

c) Completeness. The RRPV CMF will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

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

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

5.6 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, the Source Selection Authority may:

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

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 (at the Government's sole discretion) for 2 years and eligible for award during that time. Proposals rated as Unacceptable will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal best meets its needs.

6 Points of Contact

Questions related to this RPP should be directed to rrpv-contracts@ati.org. All technical questions must be submitted by **February 23, 2024,** to allow for Government response. The Government will respond to questions at its discretion. All questions and responses will be posted to the RRPV Solicitation webpage. Questions received after the stated deadline are not guaranteed a response.

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.

ATTACHMENT A – 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 & Eligibility
4. Technical Approach
5. Cost Realism
6. Current & Pending Support
7. Data Rights*
8. Resumes of Key Personnel*

***Excluded from page limitation**

1. Technical Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[Proposal Title]

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

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

[As detailed in Section 2.6 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample: *This Proposal includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).*]

_____ _____
Signature of responsible party for the Offeror DATE

2. Member Information Sheet

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

OFFEROR NAME:	
ALL PLACES OF PERFORMANCE:	
TITLE OF PROPOSED EFFORT:	
UEI # (if applicable):	
CAGE CODE (if applicable):	
SMALL BUSINESS (YES/NO):	
SMALL/DISADVANTAGED BUSINESS (YES/NO): SOCIOECONOMIC CATEGORY?	
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):	
CONTRACT/NEGOTIATION CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
TECHNICAL/PRINCIPAL INVESTIGATOR CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
COGNIZANT RATE AUDIT AGENCY OFFICE (IF KNOWN, INCLUDE POC, ADDRESS, PHONE #, E-MAIL):	

3. Executive Summary & Eligibility

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

[Clearly indicate how the proposal is within the "Project Criteria" listed in Section 4.3 of this RPP.]

4. Technical Approach

[Provide sufficient technical detail and analysis to support the technical solution being proposed for the project. Clearly identify the core of the intended approach. It is not effective simply to address a variety of possible solutions to the technology problems. Provide the following information:]

1. **Background:** [Describe the problem that the proposal is addressing.]
2. **General Approach:** [Briefly describe your overarching approach and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform or solution and list the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Relevant Experience:** [Identify relevant past experience, as well as the technical and management experience of the proposed team, to perform the proposed work.]
5. **Technical Strategy**: [Thoroughly describe the detailed and stepwise approach on how your organization intends to address each technical requirement set forth in the RPP and show a clear course of action. Be sure to clearly show Stage 1 versus Stage 2.]
6. **Regulatory Strategy**: [Provide a description of the proposed regulatory strategy.]
7. **Key Personnel:** [Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified.]

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

8. **Risk & Mitigation:** [Identify key technical, schedule, and cost risks, their potential impact and mitigation.]
9. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur, but is not limited to, 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. **Period of Performance:** [Identify the proposed Period of Performance (PoP) in months from award. Also identify the number of months for Stage 1 and Stage 2, separately.]
11. **Offeror Resources**: [Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.]
12. **Government Resources**: [Identify any key Government facilities, Government equipment, Government property, etc. that your organization requests to use for the effort.]
13. **Post-Project Strategy: [Per Section 4.5 Technical Requirements Offerors are required to provide a viable post-project strategy to leverage the cGMP CTM for a clinical trial.]**
14. **Cost Realism:** [This section provides technical evaluators with high-level cost data in order for the evaluators to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by cost element.]

Cost Realism Form EXAMPLE This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as samples only. Offeror must complete table with the applicable information.				
Cost Element	**Stage 1 Cost**	**Stage 2 Cost**	**Total**	**Description/Explanation**
Labor	*$XXXX*	*$XXXX*	*$XXXX*	*XXX hrs of XXX; XXX hrs of XXX; XXX hrs of XXX; XXX hrs of XXX*
Labor Hours	*XXX*	*XXX*	*XXX*	
Subcontractors	*$XXXX*	*$XXXX*	*$XXXX*	*Sub A - $$$$; XXX hrs of XXX* *Sub B - $$$; XXX hrs of XXX*
Subcontractor Hours	*XXX*	*XXX*	*XXX*	
Consultants	*$XXXX*	*$XXXX*	*$XXXX*	*____ consultant supporting all phases*
Consultant Hours	*XXX*	*XXX*	*XXX*	
Material/Equipment	*$XXXX*	*$XXXX*	*$XXXX*	*XXX, YYY, ZZZ*
Other Direct Costs	*$XXXX*	*$XXXX*	*$XXXX*	*YYYYY*
Travel	*$XXXX*	*$XXXX*	*$XXXX*	*## trips for # people for # days from _____ to ____ for _____*
Indirect Costs	*$XXXX*	*$XXXX*	*$XXXX*	*approved by DHHS 30 Sept 23*
Fee	*$XXXX*	*$XXXX*	*$XXXX*	*Not applicable if cost share proposed*
Total Cost to Government	*$XXXXXX*	*$XXXXXX*	*$XXXXXX*	
Additional Offeror-Provided Cost Share	*$XXXX*	*$XXXX*	*$XXXX*	
Total Project Value	***$XXXXXX***	***$XXXXXX***	***$XXXXXX***	

5. Current & Pending Support

Current
Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

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

Pending
Title of Proposal:
Funding Agency/Requiring Activity:
Estimated Dates of Funding:
Proposed Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Title of Proposal:
Funding Agency/Requiring Activity:
Estimated Dates of Funding:
Proposed Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

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

6. Data Rights

[Failure to complete this attachment in its entirety (including a failure to provide the required signature) may result in removal from the competition and the proposal determined to be ineligible for award]

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.

☐ If Offeror WILL be asserting data rights for the proposed effort, check this box and complete the table below, adding rows as necessary.

Technical Data to Be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Asserting Organization	Milestone Affected

☐ If the Offeror will NOT be asserting data rights for the proposed effort, check this box.

_____ _____

Signature of responsible party for the proposing Prime Offeror DATE

7. 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.

ATTACHMENT B – COST PROPOSAL TEMPLATE

General Instructions

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

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

Section I: Cost Proposal Narrative

a. Cover Page
b. Overview
c. Cost Information

Section II: Cost Proposal Format

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

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

1. Cost Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[Proposal Title]

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

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

[As detailed in Section 2.6 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample:
This Proposal includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

_____ _____
Signature of responsible party for the Offeror DATE

2. Cost Proposal Section I: Cost Proposal Narrative Template

1. Cost Proposal Narrative Overview

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

1. **Overall Approach.** [Provide an overall and succinct explanation of how this Proposal is justified.]
2. **Assumptions.** [Provide any assumptions. Note that assumptions should be limited to cost or pricing. Technical assumptions are better captured in the Statement of Work.]
3. **Preferred Payment Method.** [Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones (with ceiling), (2) Cost Reimbursable/Cost Share (with ceiling), (3) Cost Plus Fixed Fee Milestones (with ceiling) and (4) Fixed Price Milestones (with ceiling).]
4. **Total Cost Elements by Stage.** [Include a cost-by-cost element breakout of the costs in Stage 1 and Stage 2, separately.]

2. Cost Proposal Narrative Cost Data

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

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

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

   Provide an explanation for any proposed labor escalation.

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

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

   For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary." An individual's direct salary is the annual compensation that the entity pays for an individual's direct effort (costs). Direct salary excludes any income that an individual may be permitted to earn outside of duties to the entity. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [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 website for Federal Executive Schedule salary levels that apply to the current period. See the RRPV Base Agreement for further details.]

3. **Fringe Benefits.** [Identify whether or not the proposed labor rates include fringe costs. If so, then identify the percentage rate. If not, then provide a statement to that effect and include the fringe costs in the indirect section instead.]

4. **Travel.** [Portions of travel information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the total travel amount proposed. Provide an estimate of the cost per trip; number of trips; number of days; number of persons; departure city, destination city; approximate travel time frames; and the purpose of the travel. The key is to apply best estimating techniques that are auditable. Include a brief explanation of the methodology used to estimate travel costs. If exact destination is unknown at time of proposal, for pricing purposes use a potential location using best known information. Note that RRPV project awardees are expected to be cost-conscious regarding travel (e.g., using coach rather than first class accommodations and, whenever possible, using Government per diem, or similar regulations, as a guideline for lodging and subsistence costs). If travel is estimated based on an approved methodology, then state as such.]

5. **Subcontractors/Consultants.** [Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide a list of all subcontractors/consultants 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, catalogue 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 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;
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. Provide a 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. The fees shall be specific to the individual RRPV project and negotiated on a project-by-project basis.]

10. **Cost Share.** [Identify if any Cost Share is proposed. 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, 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 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.).]

11. **Small Business Utilization:** [Small businesses utilization is encouraged to the maximum extent practicable under the RRPV OTA. To be a small business, an organization must first be a for-profit legal structure. Next, it must qualify with the Small Business Association's (SBA) size standards, which are structured by NAICS Code (see https://www.sba.gov/document/support-table-size-standards for more details). Lastly, some small businesses participate in one or more additional programs with the Small Business Administration (see https://www.hhs.gov/grants-contracts/small-business-support/programs-supporting-small-businesses/index.html for more details).

    As part of the Cost Narrative, provide details on any significant small business utilization proposed, similar to the below chart. Participation can include the Offeror, subcontractors, consultants, material providers, service providers, etc.

Small Business Name	NAICS Code	Proposed $ Value	Task Involvement	SBA Program*

*[*Can include: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; and/or Women-owned-small-business. Otherwise, list N/A.]*

3. Cost Proposal Section II: Cost Proposal Format

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

The Cost Proposal Format section must include cost-by-element detail broken out by the Offeror's fiscal year. **As required by the RPP, costs must also be broken out by Stage 1 versus Stage 2 to match the technical requirements and objectives**.

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 C – 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 (*RPP NUMBER*)
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	The Performer must complete an initial teleconference after the initiation of the Project Award period of performance. 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting	•Within 5 business days after the initiation of the Project Award period of performance •Performer must submit agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply a teleconference number •Project Award Representative (PAR) edits/approves and instructs Performer to distribute agenda at least 2 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	Kickoff Meeting	The Performer must complete a Kickoff meeting after the initiation of the Project Award period of performance.	•Within 10 business days after the initiation of the Project Award period of performance, pending concurrence by the Other Transaction Agreements Officer (OTAO) •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
1.3	Regular Teleconference	The Performer must participate in regular teleconferences with BARDA, at a frequency to be determined at the Kickoff Meeting, to discuss the technical performance on the Project Award. 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 business days in advance of meeting •Performer must submit meeting minutes to PAR within 3 business days of the meeting

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			•PAR reviews, comments, and approves minutes within 10 business days
1.4	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 Project Award. 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 2 business 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 6 business days
1.5	Periodic Review Meetings	At the discretion of the Government, the Performer must hold up to four per year recurring Project Review Meetings, held by teleconference or face to face either in Washington, D.C., or at work sites of the Performer or sub-performers. Face-to-face meetings shall alternate between Washington, D.C., and Performer or sub-performer sites. The meetings will be used to discuss Project Award progress in relation to the Program Management deliverables described in this Project Award as well as technical, regulatory, and ethical aspects of the program.	•Performer must submit an agenda and itinerary, if applicable, at least 5 business days, and Performer must provide presentation materials at least 3 business days, in advance of the meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting by at least 3 business days •Performer provides meeting minutes to PAR within 3 business days after the meeting •PAR reviews, comments, and approves minutes within 10 business days

Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
2.1	Enabling Technology Management and Development Plan	The Performer must develop an integrated Enabling Technology Management and Development Plan. The Plan must be inclusive of management and development activities performed and completed prior to the Project Award and the activities to be performed post-award. The Enabling Technology Management and Development Plan should define the overall plan for how the project will be executed, monitored, and controlled. The Plan 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. The Plan must also include a draft regulatory strategy/plan for the product, if applicable. Each of the subsidiary planning documents should be detailed to the extent required by the specific project.	•The Performer must submit the Enabling Technology Management and Development Plan within 30 calendar days after the initiation of the period of performance (within 45 calendar days for the draft regulatory strategy/plan). •The Performer must submit proposed vaccine constructs *prior* to Plan finalization. ○ BARDA will provide input within 5 business days of receipt of construct design. ○ The Performer must respond in writing to BARDA comments and recommendations within 5 business days of receipt and must be addressed prior to finalization. ○ BARDA must approve the final construct design. •BARDA will provide Performer with a list of concerns in response to draft regulatory strategy/plan submitted, if applicable. ○ The Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's regulatory strategy/plan concerns.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		The Plan must provide a high-level overview of development activities and include the following elements: •Gantt chart timeline or equivalent. •Description of the process development and scale-up of vaccine manufacturing to support process validation, clinical evaluation and U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) product licensure. •Proposed vaccine constructs. Subtype/strain selection must be at the discretion of BARDA. •Description of the assay development plan including development and validation of the potency assay(s). •Description of product lot characterization, release and stability assay development including assay specifications and qualification/validation. •Risk mitigation plan 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.	•Plan updates should be provided to reflect any key changes and reviewed at least annually (regulatory strategy/plan excepted; see below). •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 to the regulatory strategy/plan from the prior submission, and not submit an update.
2.2	Enabling Technology Management and Development Plan Amendment for Stage 2	If the project proceeds to Stage 2, the Performer must leverage existing manufacturing facilities and capabilities to manufacture investigational lots of vaccines for clinical trials. The Enabling Technology Management and Development Plan must be amended to include Stage 2 activities, as well as the following additions, as applicable: •Draft regulatory strategy/plan •Technology transfer plan •Schedule for technology transfer, making bulk drug substance, and manufacturing drug product	•The Performer must submit the Enabling Technology Management and Development Plan Amendment for Stage 2, as applicable, within 30 calendar days after BARDA approval to begin Stage 2. •BARDA will provide Performer with a list of concerns in response to draft regulatory strategy/plan submitted. ○ The Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's regulatory strategy/plan concerns. •Plan updates should be provided to reflect any key changes and reviewed at least annually (regulatory strategy/plan excepted; see below). •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 to the regulatory strategy/plan from the prior submission, and not submit an update.
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 ○ Within 30 calendar days after the initiation of the Project Award period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
2.4	Performer Locations	The Performer must submit detailed data regarding locations where work will be performed under this Project Award, including addresses, points of contact, and work	•Performer must submit Work Locations Report: ○ Within 5 business days after the initiation of the Project Award period of performance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		performed per location, to include sub-performers and critical vendors of reagents and supplies.	○ Within 30 business days after a substantive location or capabilities change
2.5	Request for Information (RFI) Responses	Upon request of the Government, the Performer must provide complete responses to ad hoc RFIs. RFIs may address key cost, schedule, and technical updates. Responses may be shared with senior Government leaders and should be provided on a non-confidential basis, unless the response includes confidential information in which case Performer must provide the response in both confidential and non-confidential formats.	•Performer must submit an RFI response to BARDA by email within 24 hours after Performer receipt of the RFI.
2.6	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 Statement of Work (SOW) based on the Statement of Objectives (SOO) – or as applicable. 1. An Executive Summary highlighting the progress, issues, and relevant manufacturing, regulatory, and publication activities. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages 2. Progress in meeting Project Award milestones, 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 3. A three-month rolling forecast of the key planned activities 4. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission, and next steps 5. Estimated and Actual Expenses • 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 6. Results of any audits or site visits that the Performer conducts at CDMO facilities, as BARDA deems necessary 7. Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and	•The Performer must submit Monthly Reports on the 15th day of the month covering the preceding month and Annual Reports on the last calendar day of the month after each Project Award anniversary. Monthly 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 OTAO will review all 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 or major deviations to the OTAO and PAR within 24 hours of being notified of the event

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		other public-facing material or information containing data generated under this Project Award	
2.7	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 Project Award. 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 Project Award. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The report must also provide data on the manufacturing process and potential constraints that may delay manufacturing of the product in future public health emergency response scenarios. The draft report must be duly marked as 'Draft.' The Final Technical Progress Report must incorporate feedback received from BARDA and contain a summation of the work performed and the results obtained for the entire Project Award PoP. The final report must document the results of the entire Project Award. 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 Project Award.	• The Performer must submit the Draft Final Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP • PAR will provide feedback on draft report within 21 calendar days of receipt, which the Performer must consider incorporating into the Final Report

Technical Reporting: Manufacturing

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
3.1	Clinical Lots of Vaccines	To achieve Stage 2, the Performer must leverage existing manufacturing facilities and capabilities to manufacture investigational lots of vaccines for clinical trials.	The Performer must submit batch records, major/critical deviations, change controls, corrective and preventative action (CAPA), and certificate of analysis (COA) within 15 calendar days after lot release.

Quality Assurance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.1	Quality Management Plan (QMP)	For Stage 2 clinical manufacturing, 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 sub-performer quality management plans specifically addressing how sub-performer quality will be managed. All sub-performers must	• Performer must submit a Quality Management Plan ○ Within 30 calendar days after the initiation of the Project Award period of performance ○ 6 months after the start of the period of performance to include any updates.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		have a current quality agreement with the Performer and a recent vendor qualification audit.	
4.2	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 GMP-related 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 Project Award 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 GMP-related 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 OTAO 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
4.3	FDA Inspections/Site visits	In the event of an FDA inspection that occurs in relation to this Project Award and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this Project Award, including, but not limited to manufacturing facilities, the Performer must provide the USG with an exact copy (non-redacted) of the FDA Form 483 or summary and the Establishment Inspection Report (EIR). The Performer must provide the PAR and OTAO with copies of the plan and FDA submissions for addressing areas of non-conformance to FDA regulations for GMP 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 sub-performers that occur as a result of this Project Award 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 OTAO 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 sub-performers that occur as a result of this Project Award or for this product within 1 business day of receiving correspondence from the FDA, a sub-performer, or third party •Within 10 business days of inspection report, Performer must provide OTAO with a plan for addressing areas of nonconformance, if any are identified
4.4	Quality Assurance Audits and Sub-performer Monitoring Visits	BARDA reserves the right to participate in QA audits performed by the Performer, as applicable. Upon completion of the audit/site visit the Performer must provide a report capturing the findings, results and next steps in proceeding with the sub-performer. If action is requested of the sub-performer, detailed concerns for addressing areas of non-conformance to FDA regulations for GMP guidelines, as identified in the audit report, must be provided to BARDA. The Performer must provide responses from the sub-performers to address these concerns and plans for corrective action.	•Performer must notify OTAO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of sub-performers •Performer must notify the PAR and OTAO within 5 business days of report completion and provide Draft Report. •PAR and OTAO will review the report and provide a response to the Performer with 10 business days before audit can be finalized. •Performer must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		The Performer must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight.	•Performer must provide a final closeout report that all CAPAs were addressed to PAR and OTAO •Performer must notify BARDA within 24 hours of any critical and/or major findings
4.5	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 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 must also be reported.	•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 OTAO •Additional updates due to PAR and OTAO 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
4.6	Quality Agreement	BARDA will issue a draft Quality Agreement to the Performer to review and sign. The terms of the Quality Agreement shall set forth the requirements under the contract.	•The Performer must respond to updates and inquiries within 5 business days of receiving the draft Quality Agreement

Advanced R&D Products

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
5.1	Technical Documents	Upon request, Performer must provide OTAO and PAR with deliverables from the following activities: quality agreements between Performer and sub-performers, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis. The OTAO and PAR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government.	•Performer must provide technical document within 10 business days of OTAO 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

Regulatory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
6.1	FDA Correspondence	The Performer must memorialize all original and unredacted correspondence between Performer and FDA and, if applicable, 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, if applicable, within 2 business days of correspondence

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
6.2	FDA Submissions	The Performer must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA, if applicable. 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, if applicable, 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

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

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

The milestones and associated deliverables proposed should, in general:

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

RRPV Milestone Payment Schedule Example						
RRPV Milestone Number	Stage #	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	#	Kick-Off Meeting	XX/XX/XXXX	$ -	$ -	$ -
2	#		XX/XX/XXXX	$ -	$ -	$ -
4	#		XX/XX/XXXX	$ -	$ -	$ -
5	#	Final Reports (PoP End)	XX/XX/XXXX	$ -	$ -	$ -
			Total	**$ -**	**$ -**	**$ -**

Please Note:

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Expenditure Based Contracts – You may invoice for actual costs incurred and providing a progress report on technical milestones.
3. Cannot receive payment for a report (i.e., Monthly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount).
4. Monthly 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.