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

"Enabling Technology – Decentralized Clinical Trial – Retail/Pharmacy Focus"

RPP #: RRPV-24-02-Retail
Issued: February 02, 2024
Amendment No. 01 Issue Date: March 11, 2024
Due: March 20, 2024, by 1pm Eastern

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

MedicalCountermeasures.gov

Amendment No. 01 does the following:

Extends the proposal due date from March 15, 2024, to March 20, 2024, at 1pm Eastern.

All other terms and conditions remain unchanged.

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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).

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

Project NextGen is leveraging public-private partnerships to advance the next generation of vaccines, therapeutics, and enabling technologies to address the COVID-19 challenges of today and to enhance future pandemic preparedness and response. Under the Enablers program area, BARDA is focused on technologies and capabilities that decrease costs, speed production, increase efficacy, and improve accessibility. This includes enabling better vaccine correlates of protection (CoP) data by advancing decentralized clinical trial (DCT) capabilities that could improve the collection of samples and data from larger and more diverse populations.

BARDA is looking to partner with early adopters and innovators in the field of decentralized clinical trials. This project aims to stimulate and accelerate the adoption of innovative solutions to decentralized clinical trials by focusing on conducting BARDA's first clinical study exclusively at a retail pharmacy.

During the COVID-19 pandemic response, pharmacies and retail clinics were essential to the distribution of both vaccines and diagnostic tests. Developing and testing clinical trial capabilities at these locations is the next step to bringing clinical studies and research to the patient-centric clinical settings that are accessible to most Americans. This will allow us to better prepare for conducting clinical studies during public health emergencies and to conduct clinical research at real-world locations where medical counter measure products are used.

As the COVID-19 pandemic evolves, characterization of CoP are critical for ongoing vaccine development and optimization as variants and subvariants continue to emerge. As part of Project NextGen, BARDA intends to leverage immunogenicity data from multiple clinical trials of

investigational next-generation COVID-19 vaccines and FDA licensed or authorized COVID-19 vaccines to inform a broader understanding of vaccine effectiveness and immunologic correlates of vaccine protection. In addition to interventional clinical trials of investigational products, establishing a paradigm that allows for the capture of real-world data on both immunologic and clinical endpoints is critical for a continual assessment of thresholds of protection in an immunologically heterogeneous and geographically diverse cross-section of the United States.

The BARDA, Administration for Strategic Preparedness and Response (ASPR), US Department of Health and Human Services (HHS) is requesting project proposals to conduct a study designed to assess CoP using humoral immunogenicity data correlated to symptomatic COVID-19 following vaccination with an FDA licensed/authorized COVID-19 vaccine, leveraging the decentralized clinical study sites. To be eligible for funding, Awardees must have current capabilities to conduct decentralized clinical trials for vaccines as aligned with the project synopsis. The study must be conducted through use of a retail pharmacy or retail clinic where COVID-19 vaccinations are offered as part of standard business practice outside of this study.

2 Administrative Overview

2.1 Request for Project Proposals (RPP)

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

2.2 RPP Approach

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

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 two years for conduct of the proposed study. Specific dates are to be negotiated. The primary place of performance will be the performers' facilities or subcontracted facilities which would include a retail location with

appropriate infrastructure to conduct a clinical trial. Initial recruitment and COVID-19 vaccination of participants will occur during the 2024-2025 respiratory disease season, which starts in Fall 2024.

This study has a fixed budget of $25,000,000 and no further funds will be available for costs over the budget. The U.S. Government (USG) may apply additional dollars for follow-on efforts with appropriate modification of the Project Award.

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

2.4 Expected Award Date
Offeror should plan on the period of performance beginning sometime in April 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 their proposal is submitted. As mentioned above, prospective Offerors may join the consortium at www.rrpv.org/how-to-join.

Additionally, in order to respond to this RPP, Offerors must show evidence they satisfy the following **minimum eligibility criteria**:

- The study must be conducted using retail pharmacy or retail clinic sites where COVID-19 vaccinations are offered as part of the business practice of the site.
    - If applicant is sub-contracting with retail sites, then supporting documentation will need to be provided regarding the teaming arrangement to conduct the study. Current agreements will be reviewed more favorably than planned or in-discussion agreements with sites.
    - The retail locations must intend to distribute and administer COVID-19 vaccines during the 2024-2025 respiratory disease season, which starts in Fall 2024.

- Possess the current capability to conduct clinical trials for vaccines as appropriate for and aligned with the project, which include patient recruitment/enrollment, sample collection and processing and monitoring patient health.
- The ability to successfully conduct a longitudinal clinical trial of an FDA-approved vaccine.
- Possess the current capability to or have a demonstrated partnership with CAP/CLIA collection laboratories, for the collection and analysis of blood specimens for determination of Correlates of Protection (CoP) for vaccines. This includes collection (storage and shipping if necessary) of serum samples.
- The ability to perform on site (at retail site) COVID-19 testing using a molecular test. Samples should not be sent to a central lab nor should testing on-site be performed with antigen nor lateral flow assays.
- The ability to collect from patient in real-time, and especially at time of sample collection for CoPs or COVID testing, a patient health assessment, including reported symptoms and outcomes

Ideal Proposed Capabilities:

- Ability to enroll a diverse set of patients, representative of the US population to include appropriate representation of age (incl. pediatric patients >age 2 years), race/ethnicity, rural and urban populations.
- Ability to collect and isolate peripheral blood mononuclear cells (PBMCs) or collect and transfer blood to be processed for PBMCs for T-cell immune assays. BARDA will not provide services to isolate PBMCs, proposer should either have this capability or have a laboratory partner with this capability.
- Ability to collect retail and pharmacy data on participants, to include OTC medication, prescription medicine relevant to COVID or respiratory illness and COVID test purchases as well as pharmacy COVID-19 treatment medications to trial participants.
- Ability to offer ad-hoc sample collection when patient is either visiting pharmacy for other reasons or is sick.
- Ability to assess CoP data and combine with COVID breakthrough infections. Additionally, the ability to correlate CoP data with other health risks and demographic data, to develop likelihood ratios is strongly desired.

Note – if available, examples should provide National Clinical Trial (NCT) identifier or ClinicalTrial.gov reference.

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. Proposals with the “Ideal Capabilities” will be reviewed more favorably.

2.8 Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). The extent of cost sharing is a consideration in the evaluation of proposals.

This study has a fixed budget of $25,000,000 and no further funds will be available for costs over the budget. Cost sharing is expected, and Offerors should project and account for all potential costs variances in their proposed budget in a cost share plan.

Cost sharing is expected and may include labor, direct costs, and/or other direct costs (ODCs) associated with any aspect of the overall life cycle costs of the program. The cost sharing should be documented and illustrate the full costs sharing for the proposed effort.

For more information regarding cost share, please see Attachment 2.

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

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

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

Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2

3 Proposals

3.1 Question and Answer Period

Date	Event
02 Feb 2024	RPP released
16 Feb 2024	Questions due from proposers
23 Feb 2024	Questions & Answers released (date is approximate)
20 Mar 2024 1PM Eastern	Proposals due

Please submit questions to rrpv-contracts@ati.org.

3.2 Proposal General Instructions

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.

3.3 Proposal Submission
Proposals shall be submitted by the date and time specified on the cover page of this RPP to the following website. Include this RRPV Solicitation Number on each Proposal submitted. Proposals received after the time and date specified may not be evaluated.

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.**

3.4 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.

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

- **Technical Proposal submission (30-page limit, items noted* are not included in the total page count)** – **See Attachment 1:** One signed Technical Proposal (.pdf, .doc or .docx). The mandatory template is provided as Attachment 1, and includes mandatory sections for a cover page*, information sheet*, executive summary and minimum eligibility requirements, technical approach, current and pending support, and key personnel resumes*.

- **Cost Proposal submission (no page limit) – See Attachment 2:** The Government funding available for this project is not to exceed $25,000,000. Any cost proposed beyond the Government funding available would be the responsibility of the proposer. 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 3.6 of this RPP for additional information. Cost proposals should evaluate how many participants *could* be

enrolled based on this SOO and study description while reducing the risk of exceeding the agreement funded amount. Cost proposals should be for study designs where recruitment and enrollment is performed immediately after vaccination, and cost of vaccine and administration is not covered under the study protocol. Correlate of Protection assay costs do not need to be included, only sample collection storage and shipping costs should be included (See Figure 1).

3.6 Cost Proposal

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

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

3.7 Restrictions on Animal and Human Subjects

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

- For research involving human subjects, HHS human subject protection regulations and policies require that any institution engaged in non-exempt human subjects research conducted or supported by HHS must submit a written assurance of compliance to Office for Human Research Protections (OHRP). Under an Federal Wide Assurance, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

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 Project Objectives (Attachment A)

This project aims to develop, execute, and analyze a decentralized clinical study performed at a retail pharmacy or clinic location that is designed to assess vaccine CoP using humoral immunogenicity data correlated to symptomatic COVID-19 infection following vaccination with an FDA licensed/authorized COVID-19 vaccine.

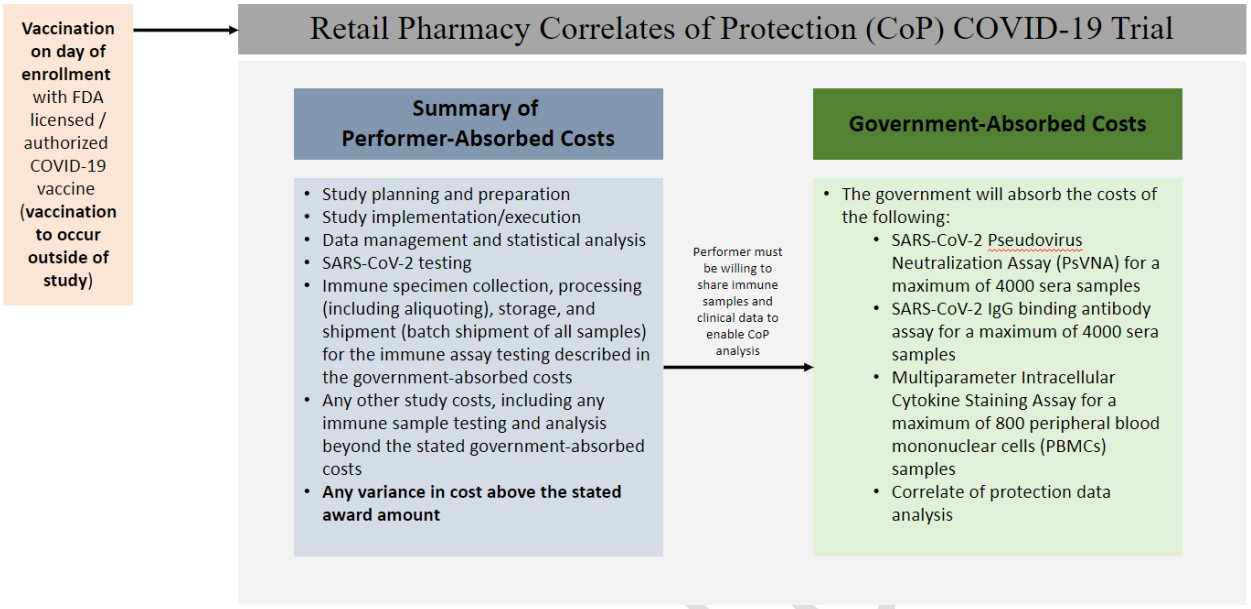
Proposals should evaluate how many participants *could* be enrolled based on this SOO and study description while reducing the risk of exceeding the agreement funded amount. Proposals should be for study designs where recruitment and enrollment is performed immediately after vaccination, and cost of vaccine and administration is not covered under the study protocol. Correlate of Protection assay costs do not need to be included, only sample collection storage and shipping costs should be included (See Figure 1).

Study Enrollment. This decentralized CoP study should enroll subjects on the day of vaccination, with vaccination occurring outside of the study (Figure 1 and Attachment A – Clinical Study Synopsis). Since vaccination will occur outside the study, Offerors should plan to align study enrollment with the Fall 2024 rollout of the COVID-19 vaccine update with a study start (i.e., first subject enrolled) by October 1st, 2024, to minimize timeline and cost risks associated with prolonged enrollment; this is particularly important in proposals with a minimal cost-share plan to cover cost over the budget.

However, Offerors may propose a later trial start if the Offeror includes a cost-share plan to account for any planned or unplanned costs over the stated award. A strongly justified enrollment plan that leverages an established retail pharmacy/clinic network of sufficient size to recruit in a condensed timeline regardless of trial start, thus reducing the cost risk, is also acceptable.

Specimen Collection. The Offeror must be willing to share the requited immune clinical samples and clinical data with BARDA for immune assay and analysis of CoP. The proposed study will require collection of venous blood specimens for sera to assess antibody levels and will perform FDA cleared/authorized Molecular Point of Care test for SARS-CoV-2 virus from nasal swabs. The Offeror may also propose to collect PMBCs on a subset of patients for assessment of PBMC sample quality (e.g., viability) and immune assay of T cells. The Offeror is expected to collaborate, with USG identified central laboratories for testing of sera for correlates of protection assays and PBMC testing assays. Clinical immune samples must be shipped by Offeror to these locations and the cost for shipment should be included in the proposal (See Figure 1 for Government-Absorbed Costs for immune assays and CoP analysis). A Materials Transfer Agreement and Data Transfer Agreement will be needed for CoP testing and data analysis that is to be performed by other members of the RRPV consortium. Assays to detect viral infection will be performed at the clinical site at point of care and must be molecular detection assays with a sensitivity above 90% PPA and specificity above 98% NPA.

Figure 1. Overview of Study and Performer- versus Government-Absorbed Costs.



Study Execution. The Performer should include all aspects of clinical study planning and execution required to successfully meet the required elements, and any additional Offeror-proposed elements, of the study. This may include but is not limited to – program management and administration; study and protocol development/planning; development of other key study plans and study implementation actions (e.g., medical safety and monitoring; Institutional Review Board (IRB) approval; any sub-performer/contractor quality assurance plans/monitoring; etc.); study site management and monitoring; and full clinical data management and statistical analysis.

Technical Proposal. The technical proposal must meet the required elements of the clinical study described below. Offeror must describe their experience and existing capabilities (e.g., project management in clinical research and clinical trials; data management systems; data analytics; etc.) to meet the technical objectives.

In addition to those described above, the required elements of the clinical study that the proposer should address in their Technical Proposal include:

- Conduct assessment of study metrics and data in terms of recruitment time post-vaccination, retention, and sub-analysis on demographic diversity (including age, race/ethnicity, region, education, etc.) and other trial performance metrics that are relevant to the advantages and disadvantages of decentralized clinical trials conducted in the retail pharmacy/clinic setting
- Develop a recruitment plan to recruit both diverse participants and pediatric participants 2 years of age or older.

- Conduct Point of Care molecular COVID-19 testing at the retail/pharmacy site clinic when needed by the patient, antigen testing or lateral flow assays are not acceptable assays for COVID-19 testing. The Performer should propose a plan to ensure patients return to the site for testing within 3 days of symptom onset. This could involve phone calls, emails, electronic alerts, etc.
- Develop an alternative plan for longitudinal monitoring for participants for 12 months, through tracking of possible COVID-19 infection and treatment. There are many possible study designs that may be acceptable. Two examples (this is not a comprehensive list) are: capturing patient prescription information from local pharmacy data, using ePRO software with prompts to measure symptoms and encourage testing, monitoring of patient OTC purchases for medications or products that treat or detect COVID-19.
- Develop a flexible plan to take patient samples, as close to target dates for measurement of CoPs as possible, but reflecting the ability to take samples on patients' schedule when they are visiting the retail location for other reasons (e.g. Rx pickup, sundries, etc.)
- Develop a patient survey to evaluate participant satisfaction with decentralized trial design evaluating; patient preference for study location, ease of participation, willingness to participate in future similar studies, etc.
- The proposed study must collect serum samples from all study subjects at baseline (day (D) 0), D31, and D181 to enable CoP analysis (See Attachment C, Table 2 and 3 for minimum serum volume and required aliquots). Performer must plan for sample collection, processing, storage, and shipment to the government central immune assay laboratory.
    - Establish appropriate material for transfer agreements and data sharing agreements such that data can be shared from the testing site to be included in the clinical analysis and research report.
    - Coordinate biological specimen management with the central clinical laboratory or other designated facilities, and coordinate storage and shipment to a research lab.
    - Serum samples will need to be processed and stored by the proposer during the study awaiting batch shipping to the testing laboratory when the study ends. Sample storage can be managed by the proposer or a sub-contractor chosen by the proposer. The immune sample collection and processing used for traditional clinical trials is described in Attachment C as an example of the standard required for the sample quality necessary for immune assays; Offerors may propose collection devices/procedures that align with the retail pharmacy/clinical setting of this study.

- The government central immune assay laboratory will run a maximum of 4000 Pseudovirus Neutralization Assay (PsVNA) tests and a maximum of 4000 IgG binding antibody tests on sera samples (See Attachment C)).

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

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

This process may involve the use of contractors as SME consultants or reviewers. 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. The Government will evaluate each proposal against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) as discussed below. The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable, unless specifically stated otherwise.

The evaluation factors and evaluation criteria are described below.

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

- Outstanding
- Good
- Acceptable
- Marginal
- Unacceptable

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

5.3 Evaluation Factors

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

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

Factor 2 – Cost/Price: (See Section 5.4 "Cost/Price Evaluation" 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.

Evaluation factors (above) are listed in descending order of importance.

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)*

5.4 Cost/Price Evaluation

The Cost Proposal will receive a narrative rating to determine whether costs are realistic, reasonable, and complete. The extent of cost sharing is a consideration in the evaluation of proposals.

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

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

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

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

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

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

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

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

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

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

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

5.5 Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The 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.

5.6 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately selected for award, may be placed in the Basket (at the Government's sole discretion) for 2 years and remain 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 and rrpv-contracts@ati.org

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

ATTACHMENT 1 – TECHNICAL PROPOSAL TEMPLATE

General Instructions

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

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

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

1. Cover Page*
2. RRPV Member Organization Information Sheet*, including subcontractors that will be needed to complete the study.
3. Executive Summary & Minimum Eligibility Criteria
4. Technical Approach
5. Current & Pending Support
6. Data Rights*
7. Resumes of Key Personnel*
8. Letters of Intent or Sub-agreements with partners*
9. List of retail pharmacy sites that will be used in the study. For each site, please include the following information:*
    - Whether COVID-19 vaccinations are offered as part of standard business practice for the specific site (i.e., outside of this study)
    - If available, number of individuals that received a COVID-19 vaccination at the site during the 2022/2023 Fall/Winter respiratory disease season
    - If available, estimated/protected number of individuals that will receive a COVID-19 vaccination at the site during the 2023/2024 Fall/Winter respiratory disease season

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

3. Executive Summary & Minimum Eligibility Requirements

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

[Additionally, this section must address how the Offeror currently satisfies the following minimum eligibility requirements and ideal capabilities:]

- The study must be conducted using retail pharmacy or retail clinic sites where COVID-19 vaccinations are offered as part of the business practice of the site.
    - If applicant is sub-contracting with retail sites, then supporting documentation will need to be provided regarding the teaming arrangement to conduct the study. Current agreements will be reviewed more favorably than planned or in-discussion agreements with sites.
    - The retail locations must intend to distribute and administer COVID-19 vaccines during the 2024-2025 respiratory season, which starts in Fall 2024.
- Possess the current capability to conduct clinical trials for vaccines as appropriate for and aligned with the project, which include patient recruitment/enrollment, sample collection and processing and monitoring patient health.
- The ability to successfully conduct a longitudinal clinical trial of an FDA-approved vaccine.
- Possess the current capability to or have a demonstrated partnership with CAP/CLIA collection laboratories, for the collection and analysis of blood specimens for determination of Correlates of Protection (CoP) for vaccines. This includes collection (storage and shipping if necessary) of serum samples.
- The ability to perform on site (at retail site) COVID-19 testing using a molecular test. Samples should not be sent to a central lab nor should testing on-site be performed with antigen nor lateral flow assays.
- The ability to collect from patient in real-time, and especially at time of sample collection for CoPs or COVID testing, a patient health assessment, including reported symptoms and outcomes

Ideal Proposed Capabilities:

- Ability to enroll a diverse set of patients, representative of the US population to include appropriate representation of age (incl. pediatric patients >age 2 years), race/ethnicity, rural and urban populations.
- Ability to collect and isolate peripheral blood mononuclear cells (PBMCs) or collect and transfer blood to be processed for PBMCs for T-cell immune assays. BARDA will not provide services to isolate PBMCs, proposer should either have this capability or have a laboratory partner with this capability. The BARDA central laboratory can run a maximum of 800 test for this study (See Attachment C for PBMC sample requirements).

- Ability to collect retail and pharmacy data on participants, to include OTC medication, prescription medicine relevant to COVID or respiratory illness and COVID test purchases as well as pharmacy COVID-19 treatment medications to trial participants.
- Ability to offer ad-hoc sample collection when patient is either visiting pharmacy for other reasons or is sick.
- Ability to assess CoP data and combine with COVID breakthrough infections. Additionally, the ability to correlate CoP data with other health risks and demographic data, to develop likelihood ratios is strongly desired.

Note – if available, examples should provide National Clinical Trial (NCT) identifier or ClinicalTrial.gov reference.

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. Proposals with the "Ideal Capabilities" will be reviewed more favorably.

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. Include citation to each Deliverable identified in the Statement of Work throughout the Technical Approach (e.g. (1.1)). Provide the following information:]

1. **Background:** [Describe the problem that the proposal is addressing.]
2. **Approach:** [Describe your overarching approach and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform or solution and listing the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Relevant Experience:** [Describe relevant past experience, as well as the technical and management experience of the proposed team, to perform the proposed work]
5. **Technical Strategy**: [Provide a detailed and stepwise approach on how your organization intends to address the requirements set forth in the RPP and show a clear course of action.]
6. **Clinical Trial:** [If a clinical trial is proposed as part of Technical Strategy, then include the following information as part of the technical approach. Clinical trials should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to development and testing of biologics. This will include compliance with applicable portions of Title 21 of the US Code of Federal Regulations (CFR) including Title 21 CFR Parts 11, 50, 54, 56, the Health Insurance Portability and Accountability Act (HIPPA) of 1996 (Pub.L. 104-191, 110 Stat. 1936, enacted August 21, 1996), and International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practices (GCPs) (ICH Guidelines for Good Clinical Practice (E6), Published May 9, 1997).]

- **Study Design/Clinical Protocol:**
  - Describe potential challenges and alternative strategies where appropriate.
  - Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (e.g., convenience, simple random, stratified random).
  - Describe specific considerations for the Informed Consent Form (ICF)
  - Describe approach to obtaining IRB approval
- **Statistical Plan and Data Analysis:** Describe the data collection plan, statistical model, and data analysis plan with respect to the study objectives.
- **Technical Risks:** Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.
- **Ethical Issues:** Include a clear and detailed description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.
- **Training/Proficiency Requirements:** Determination to ensure that personnel have appropriate training/competency.

7. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur when an individual or an entity is unable, or potentially unable, to provide impartial advice or service to the Government or separate entity because of other business activities or relationships. Disclose any potential conflict of interest pertaining to this opportunity. If none, state as such.]
8. **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.

9. **Schedule:** Identify key technical, schedule, and cost risks, their potential impact and mitigation.

10. **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.
11. **Government Resources**: Identify any key Government facilities, Government equipment, Government property, etc. that your organization requests to use for the effort.
12. **Proposed Cost Share:** If applicable, this section provides technical evaluators with information on any additional cost share proposed by the Offeror. If proposing cost share, identify deliverables that are associated with cost shared resources as well as the technical benefit resulting from this resource.
13. **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	**Total Proposed Cost**	**Description/Explanation**
Labor	*$1,475,000*	*5000 hrs of senior scientist; 3000 hours of program management; 3000 of hours of contracts management; 3750 hours of scientist*
Labor Hours	*$14,750*	
Subcontractors	*$300,000*	*Sub A - $150,000; 1500 legal advisor hours* *Sub B - $150,000; 1500 hours of Testing*
Subcontractor Hours	*$3,000*	
Consultants	*$60,000*	*Financial consultant supporting all phases*
Consultant Hours	*$600*	
Material/Equipment	*$500,000*	*pipettes, gloves, computer software*
Other Direct Costs	*$12,000*	*ship testing materials to lab*
Travel	*$30,000*	*12 trips for 2 people for 2 days to Washington, DC from Charleston, SC for program meetings*
Indirect Costs	*$475,400*	*approved by DHHS 30 Sept 23*
Fee	*$0*	*Not applicable if cost share proposed*
Total Cost to Government	*$2,852,400*	
Cost Share	*$1,740,000*	*30,000 hours of lab assistant*
Total Project Value	***$4,592,400***	

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. 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. The Principal Investigator must be identified.

ATTACHMENT 2 – COST PROPOSAL TEMPLATE

General Instructions

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

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

Section I: Cost Proposal Narrative

a. Cover Page
b. Overview
c. Cost Information

Section II: Cost Proposal Format

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

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

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 Sharing Milestones (with ceiling), (3) Cost Plus Fixed Fee Milestones (with ceiling) and (4) Fixed Price Milestones (with ceiling).
4. **Total Cost by Phase Cost Elements.** Include a list of each phase that is stated in the Statement of Work and its associated total cost by year. The sum of the phases must equal the total listed in the Cost Proposal Formats.
5. **Cost Share.** Cost Share includes any costs a reasonable person would incur to carry out (necessary to) proposed project's Statement of Work not directly paid for by the Government. If a proposal includes cost share, then it cannot include fee. Cost Share may be proposed only on cost type agreements. There are two types of cost sharing: Cash Contribution and In-Kind Contribution.

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

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

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

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

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

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

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

2. Cost Proposal Narrative Cost Data

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

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

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

   Provide an explanation for any proposed labor escalation.

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

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

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

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

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

5. **Subcontractors/Consultants.** Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical.

Provide a list of all subcontractor/consultant and a total cost for each. If a cost and/or price analysis has been performed, provide a copy or summary of results.

Support is required for each subcontractor/consultant as follows:

- If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, 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 research effort. This award is not an assistance agreement/instrument and Offerors should normally have the required equipment to perform. The value of equipment should be prorated according to the share of total use dedicated to carrying out the proposed work. Include a brief explanation of the prorating methodology used.

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

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

8. **Cost of Money.** If applicable, Cost of Money should be proposed separately from indirect costs.

9. **Fee/Profit.** State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted when cost share is not being contributed. The fees shall be specific to the individual RRPV project and negotiated on a project-by-project basis.

3. Cost Proposal Section II: Cost Proposal Format

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

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

Supporting data and justification for labor, equipment/material, team member/subcontractor, consultants, travel, other direct costs, indirect costs, and profit used in developing the cost breakdown also must be included. The Offeror must provide sufficient details to allow a full

understanding of and justification for the proposed costs. Offerors must refer to the RPP for a start date for cost estimating purposes.

ATTACHMENT 3 – STATEMENT OF WORK (SOW) TEMPLATE

Statement of Work

RPP#: (*RPP NUMBER***)**
Project Identifier: RRPV24-02-retail-XXX (obtain from selection notification)
Project Title:
Member Organization Name:

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

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

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

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

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

Deliverables

- Defines end items to be delivered for each task or phase, such as prototypes, hardware, software, data and reports, analyses, testing reports, etc.

1. For physical prototypes, include type and quantity.
2. For reports, include delivery/acceptance criteria in the SOW (e.g. – The test report shall be delivered to the PAR 30 days after completion of the testing. The PAR shall approve the test report prior to start of Task 2).

Cross-Referencing

- All requirements should be cross-referenced and traceable in Section 4.0, Deliverables, and Section 5.0, Milestone Payment Schedule.

NOTE: Begin sentences indicating action to be taken, by stating "The awardee shall provide/deliver/develop/etc…"

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
	Post Award Teleconference	The Performer must complete an initial teleconference after the initiation of the agreement period of performance. 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting	•Within 5 business days after the initiation of the agreement 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 •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
	Kickoff Meeting	The Performer must complete a Kickoff meeting after the initiation of the agreement period of performance.	•Within 10 business days after the initiation of the agreement period of performance, pending concurrence by the Agreements Officer •Performer must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference •PAR edits/approves and instructs Performer to distribute agenda at least 3 business days prior to meeting •Performer submits meeting minutes to PAR within 3 business days after the meeting •PAR reviews, comments, and approves minutes within 10 business days

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Weekly Teleconference	The Performer must participate in teleconferences weekly with BARDA to discuss the technical performance on the agreement. Meeting frequency may be increased or decreased as needed during the course of the project.	•Performer must submit agenda to PAR no later than 2 business days in advance of meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting •Performer must distribute agenda and presentation materials at least 2 calendar days in advance of meeting •Performer must submit meeting minutes to PAR within 3 business days of the meeting •PAR reviews, comments, and approves minutes within 10 business days
	Technical, Subgroup, Ad Hoc Teleconference(s)	The Performer must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the agreement. Meeting frequency may be defined as needed during the course of the project.	•Performer must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting •Performer must distribute agenda and presentation materials at least 24 hours in advance of meeting •Performer must submit meeting minutes to PAR within 3 business days of the meeting •PAR reviews, comments, and approves minutes within 6 business days
	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-contractors. Face-to-face meetings shall alternate between Washington, D.C. and Performer, sub-contractor sites. The meetings will be used to discuss agreement progress in relation to the Program Management deliverables described in this agreement as well as nonclinical, clinical, technical, regulatory, and ethical aspects of the program.	•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
	FDA Meetings and Interactions	The Performer must forward the dates and times of any meeting with the FDA to BARDA, including formal meetings, site visits, inspections, audits, ad hoc meetings, technical meetings, etc. The Performer must arrange for up to four (4) BARDA staff to attend any FDA meeting. (BARDA staff typically include the PAR and three (3) subject matter experts).	•Performer must notify BARDA of any and all upcoming FDA meeting at minimum within 24 hours of meeting request. This includes formal (Type A, B, or C meetings or any and all other technical meetings). •Performer must provide advance copies of any correspondence it plans to send to FDA. •Performer must provide within 24 hours of its receipt, unredacted copies of all written communications it receives from the FDA. • Performer must notify BARDA within 24 hours of any informal or ad hoc meeting occurrence. •The Performer must forward initial Performer- and FDA-issued draft minutes AND final minutes of **any** meeting with the FDA to BARDA within 2 business days of receipt.

Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Project Management Plan (PMP)	The Project Management Plan should define the overall plan for how the project will be executed, monitored and controlled and must include a Study Responsibility Assignment Matrix for Performer and subPerformer team(s). The PMP may be a single detailed document or composed of one or more subsidiary planning documents. These additional planning documents provide guidance and direction for specific management, planning, and control activities such as schedule, cost, risk, staffing, change control, communications, quality, procurement, deployment, etc. Each of the subsidiary planning documents should be detailed to the extent required by the specific project.	•Performer must submit a Project Management Plan (PMP) ○ Within 30 calendar days after the initiation of the agreement period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
	Gantt Chart/Timeline	The Gantt Chart/Timeline should be detailed to the extent required by the specific project.	•At first project meeting and as updated no later than every 30 calendar days. Provided in pdf.
	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 agreement period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
	Performer Locations	The Performer must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location, to include sub-performers and critical vendors of reagents and supplies. Performers must include vendors for critical infrastructure protection.	•Performer must submit Work Locations Report: ○ Within 5 business days after the initiation of the agreement period of performance ○ Within 30 business days after a substantive location or capabilities change •Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
	Pandemic/Public Health Emergency Facility and Operational Management Plan	Performer must develop a Pandemic Facility and Operational Management Plan, including change procedures from normal to pandemic operations and continuity of operations in the event of a declared pandemic emergency. Performer must identify critical infrastructure.	•Performer must submit Pandemic Management Plan: ○ Draft within 15 days of award ○ Final within 30 days of award
	Request for Information (RFI) Responses	Upon request of the Government, the Performer must provide complete responses to ad hoc RFIs.	•Performer must submit an RFI response to BARDA by email within 24 hours after Performer receipt of the RFI.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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.	
	Monthly & Annual Technical Progress Reports/Annual Meeting	The Monthly and Annual Technical Progress reports must address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS) – or as applicable. 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, nonclinical, clinical, regulatory, and publication activities. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages 2. The Performer must submit monthly detailed clinical reports during active clinical trial enrollment to include at a minimum: •Central IRB approval status •Site IRB approval status •Site information (FWA number, site type (e.g., commercial site, academic site), site activation status) •Number of subjects screened and enrolled by age, race, ethnicity, geographic distribution •Investigational Product status (receipt at depot and receipt on site) •Safety reporting (SAEs) •Protocol deviations •Database management •Status of ancillary supplies e.g., PPE, swabs, syringes, tubes on site •Specimen collection status •Pharmacy manuals The Performer must inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Performer on site visits and/or audits of CROs as BARDA deems necessary. 3. Progress in meeting agreement milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports must detail the planned and actual	•The Performer must submit monthly reports on the 15th day of the month covering the preceding month; Annual Reports submitted on the last calendar day of the month after each agreement anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable XX). The PAR and AO will review the monthly reports with the Performer and provide feedback •Performer must provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits •Performer must provide notification of designated safety events to the AO and PAR within 24 hours of being notified of the event

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		progress during the period covered, explaining any differences between the two and the corrective steps 4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 5. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission, and next steps 6. Estimated and Actual Expenses • This report must also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the SubPerformers expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subPerformer(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subPerformers. If the PAR and AO are satisfied that the Performer's reporting is sufficient to convey this information, this section may be waived. 7. Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and other public-facing material or information containing data generated under this agreement	
	Draft and Final Technical Progress Report	A draft Final Technical Progress Report must contain a summation of the work performed and the results obtained over the entire agreement. This report must be in sufficient detail to fully describe the progress achieved under all milestones. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report must be duly marked as 'Draft.' The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results	• 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

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

	Packing List	Performer must include the following data elements according to the Drug Supply Chain Security Act (DSCSA), required for receiving, on the packing lists sent with all bulk shipments to centralized depots: • Transaction Information (TI), Transaction History (TH), Transaction Statement (TS) • CDC Purchase Order (PO) number (which BARDA will provide at the time the bulk order is submitted) • Contract number • Copy of the MSDS (with QR code) in the packing list envelope	
	Advance Shipment Notices (ASNs)	Performer must transmit bulk shipment ASNs to CDC via Electronic Data Interchange (EDI) Rationale: Required for receiving at centralized distributor.	Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. CDC will provide EDI mapping specifications that include the CDC generated PO number
	Final Transition Plan	Inclusive of transfer of study documents and study specimens to BARDA/BARDA contractor.	No later than 6 months of first subject enrollment.
	Transfer of study documents and study specimens	As per Final Transition Plan.	No later than six months after Final Clinical Study Report submission to BARDA.

Technical Reporting: Nonclinical Studies (if applicable)

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Draft and Final Nonclinical Study Report(s)	Performer must provide Draft and Final Nonclinical Study Reports to BARDA for review and comment.	• Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA • The Performer must submit Subcontractor-prepared reports received by the Performer to the PAR and AO for review and comment no later than 5 business days after receipt by Performer • The Government will provide written comments to the Draft Report for Nonclinical Study Reports within 15 business days after the submission • Final report due 30 calendar days after receiving comments on the Draft Final Report for Non-Clinical Studies; If corrective action is recommended, Performer must address all concerns raised by BARDA in writing • Performer must consider revising reports to address BARDA's recommendations prior to FDA submission
	Nonclinical Study Protocols	The Performer must submit draft and final nonclinical study protocols to AO and PAR.	• The Performer must submit Draft nonclinical study protocols to PAR electronically prior to finalization. o BARDA will provide comments within 10 business days of receipt of draft protocol o Performer must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol. o PAR must approve the final protocol • The Performer must submit Final nonclinical study protocols to PAR electronically no later than 10 business days prior to FDA submission.
	Nonclinical Study Final Data Submission Package	BARDA must have access to methods and reagents. BARDA must have unlimited rights to all nonclinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this agreement At BARDA's request, the Performer must provide any nonclinical-related agreement deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the nonclinical-related deliverables, as BARDA deems necessary.	• Performer must submit at least 15 business days prior to agreement end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.

Technical Reporting: Clinical Trials

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates

	Clinical Trial Protocols	The Performer must submit draft and final clinical study protocols to AO and PAR.	• The Performer must submit Draft study protocols to PAR electronically prior to finalization.
			  ○ BARDA will provide comments within 10 business days of receipt of draft protocol
			  ○ Performer must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol.
			  ○ PAR must approve the final protocol.
			• The Performer must submit Final study protocols to PAR electronically no later than 10 business days prior to FDA submission.

	Clinical Trial Documentation	The Performer must provide the following documents for any portion of a study funded under this agreement:
		• Investigational Product Accountability Plan
		• Study Supplies Procurement Plan
		• Site selection questionnaire
		• Overall Recruitment and Retention plan
		• Informed Consent Form (ICF) template
		• eConsent
		• Data Management Plan
		• Data Validation/Quality Plan
		• Statistical Analysis Plan
		• Sample/Specimen Management Plan
		• Diversity inclusion plan to enroll based on US demographic based on most recent census
		• Investigator Brochure
		• eCRF
		• Community engagement materials, posters, media advertisements, animations, graphics, etc.
		• Clinical Trial Agreements
		• Monitoring Plan
		• Safety Monitoring Plan (processes to provide 24-7 pharmacovigilance and safety monitoring)
		• SAE Reconciliation SOP (if safety database separate from clinical database)
		• Processes to manage and support an independent DSMB
		• DSMB Charter
		• DSMB template reports and DSMB reports
		• Draft and Final Tables, Listings, and Figures (TLFs), ad hoc TLFs
		• Plan for notifying participants of his/her treatment assignment
			• The Performer must submit Draft study documents to PAR electronically prior to finalization.
			  ○ BARDA will provide comments within 10 business days of receipt of draft document
			  ○ Performer must respond in writing to BARDA comments and recommendations prior to finalization of protocol.
			• The Performer must submit Final study documents to PAR electronically no later than 10 business days prior to FDA submission.
			• Performer must submit draft Statistical Analysis Plan no later than 20 business days after protocol is finalized. The final Statistical Analysis Plan must be submitted 5 business days prior to study database unblinding.
			• Performer must submit final version Investigational Product and Clinical Supplies Management Plan at least 6 weeks prior to investigational product shipments to clinical sites.
			• Performer must retain the capability to procure, ship, deliver, install, and train on the use of all required supplies, including, but not limited to, documents, files, and equipment.
			• Final TLFs must be submitted to the PAR 3 weeks after database lock.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		• Essential Regulatory Documents that demonstrate compliance with the standards of ICH E6 (R2) Good Clinical Practice and with all applicable regulatory requirements • Pharmacy Manual The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during clinical site monitoring visits.	
	ClinicalTrials.Gov Posting and Results Reporting	Per clinicaltrials.gov registration and reporting requirements.	• Performer must post results: o 3 months from any interim analysis o 3 months from primary analysis • 3 months from final analysis
	Draft and Final Clinical Study Report(s)	Performer must provide Draft and Final Clinical Study Reports to BARDA for review and comment.	• Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA • The Performer must submit Subcontractor-prepared reports received by the Performer to the PAR and AO for review and comment no later than 5 business days after receipt by Performer • The Government will provide written comments to the Draft Report for Clinical Study Reports within 15 business days after the submission • Final report due 30 calendar days after receiving comments on the Draft Final Report for Clinical Trial; If corrective action is recommended, Performer must address all concerns raised by BARDA in writing • Performer must consider revising reports to address BARDA's recommendations prior to FDA submission
	Project-Specific First Site Activated for First Subject First Visit	Performer should have all pre-study planning complete and be ready to enroll subjects.	• After IND is in effect, within five days of IRB approval
	Clinical Report During Active Enrollment Periods[1]	The Performer must submit daily the data specs in the attached document during active clinical trial enrollment. Deliverables_Active Enrollment Report_Da Clinical Report submission must be by electronic transfer, e.g., from Performer Electronic Data Capture (EDC) system/Interactive Voice Response System (IVRS) to USG.	• Performer must submit, in a format and to a location agreed to by BARDA, data specs on a daily basis starting when first subject is enrolled and ending when last subject is enrolled.

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

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Access to Electronic Systems Used in Trial Conduct	The Performer must provide access to systems used in trial conduct.	•Due within 20 calendar days of PAR request, no later than ten calendar days prior to first site activated
	Blinded Safety Reports, Medical Data Listing, CIOMS Report, Pharmacovigilance Database Listing	The Performer must submit blinded safety data reports, medical data listings, CIOMS reports and listings from the Pharmacovigilance database.	•Performer must provide weekly blinded safety data reports and medical data listings during the treatment period. •CIOMS reports and data listing from Pharmacovigilance database will be provided to the PSRT for review. Meeting frequency may be reduced during the follow up phase.
	Specimen Collection for Future Use	The Performer must collect and store clinical samples at key immune time points for future use in immune assays to be conducted at a central laboratory(s) as determined by BARDA. The sample types, timepoints, volume collected, and collection, transfer, and storage procedures must be conducted as defined by the AO or PAR and must be defined in the study protocol. These samples and associated clinical data (metadata) must be transferred to a BARDA-managed repository according to a schedule to be determined by the AO or PAR. The intended use of these samples is to establish a repository of samples from the vaccine arm(s) at multiple time points for future use in centralized immune assays and analysis. The repository is only available for storage of samples specifically for use in the centralized immune assays according to needs and requirements as determined by BARDA. The Performer must remove any personal identifying information (PII) from the samples and assign each with a unique subject identification number before transferring to BARDA. The Performer must provide a specimen disposition report prior to transferring the material to the repository. Testing on samples can include but will not be limited to in vitro biochemical, biophysical, and cell-based assays. BARDA will establish a Deliverables Table, Technology Transfer and Evaluation Agreement (TTEA) and Data Distribution Agreement (DDA) with appropriate partners as applicable (i.e., vaccine manufacturer, repository, testing labs, data analysis services), necessary to secure execution, timelines, materials and preserve intellectual property.	•Performer must provide weekly specimen inventory reports during the course of the clinical trial. •Specimens and associated clinical data must be transferred to BARDA upon request from the AO or PAR according to a schedule to be determined by the AO or PAR.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Clinical Trial Final Study Package	BARDA must have unlimited rights to all clinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this agreement At BARDA's request, the Performer must provide any clinical-related agreement deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the clinical-related deliverables, as BARDA deems necessary. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	•Performer must submit the Clinical Trial Final Study Package at least 15 business days prior to agreement end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.
	Data Exchange Package(s) Submitted to Regulatory Agency(s)	As part of Final or Draft Submission Package(s), upon BARDA request, and also as part of deliverables, the Performer must provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), Analysis Datasets (e.g., CDISC-compliant ADaM SAS XPT datasets), and any additional documents including but not limited to Reviewer's Guide (PDF), SDTM annotated CRF(s) (PDF), and data definition file(s) (XML) to BARDA. Other data exchange standards or file formats might be used if discussed with and agreed by BARDA. The Performer must provide the software programs (e.g., SAS programs, R programs) used to create any ADaM datasets and generate tables and figures associated with all analyses, including primary and secondary efficacy analyses. *List of abbreviations: XPT = SAS Transport Format (XPORT) Version 5; PDF = Portable Document Format; XML = Extensible Mark-up Language; CDISC = Clinical Data Interchange Standards Consortium*	•Performer must provide the Technical Documents and/or datasets within 20 business days of request from the AO or PAR
	Clinical Trial Datasets	Performer must make clinical trial datasets publicly available.	•Performer must post clinical trial datasets on a web-based platform easily accessible by the public: o 3 months from any interim analysis **supporting any action (e.g., regulatory filing, protocol change), if applicable** o 3 months from primary analysis o 3 months from final analysis
	Additional Data Package(s)	Upon request, the Performer must provide raw data, tabulation Data and/or analysis data in a BARDA-agreed upon format and supporting documents that might be including but not limit to	•Performer must provide the data package(s) within 20 business days of request from the AO or PAR

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		the list of files in package, technical specification documents, data analysis programs. Data exchange standards and file formats must be discussed and agreed upon with BARDA.	

Quality Assurance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Quality Management Plan (QMP)	Performer must develop an overall project Quality Management Plan to include a description of all quality activities and personnel involved in ensuring all activities are conducted and data are maintained under cGXP, and all products are managed to ensure that GMP requirements are met. All quality management plans must include subPerformer quality management plans specifically addressing how subPerformer quality will managed. All subPerformers must have a current quality agreement with the Performer and a recent vendor qualification audit.	•Performer must submit a Quality Management Plan ○ Within 30 calendar days after the initiation of the agreement period of performance ○ On the 6th month agreement anniversary to include any updates.
	BARDA Audit	Performer must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by HHS. If BARDA, the Performer, or other parties identify any issues during an audit, the Performer must capture the issues, identify potential solutions and submit a report to BARDA detailing the finding and corrective action(s). HHS reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this agreement and all records related to the manufacture, testing (including but not limited to analytical testing, nonclinical study, clinical trial), and storage of the product.	•If issues are identified during the audit, Performer must submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit •PAR and AO will review the report and provide a response to the Performer with 10 business days •Once corrective action is completed, the Performer will provide a final report to BARDA
	FDA Inspections/Site visits	In the event of an FDA inspection that occurs in relation to this agreement and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this agreement, including, but not limited to clinical trials and manufacturing facilities, the Performer must provide the USG with an exact copy (non-redacted) of the FDA Form 483 or summary and the Establishment Inspection Report (EIR). The Performer must provide the PAR and AO with copies of the plan and FDA submissions for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the inspection report, status updates during the plan's execution and a copy of all final responses to the FDA. The Performer must also provide redacted copies of any FDA inspection reports received from subPerformers that occur as a result of this agreement or for this product. The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during the opening, any daily debriefs, and the final debrief by the regulatory inspector.	•Performer must notify AO and PAR within 10 business days of the scheduling of a scheduled FDA inspection/site visit or within 24 hours after inspection/site visit if the FDA does not provide advanced notice •Performer must provide copies of any FDA inspection report received from subPerformers that occur as a result of this agreement or for this product within 1 business day of receiving correspondence from the FDA, a subPerformer, or third party •Within 10 business days of inspection report, Performer must provide AO with a plan for addressing areas of nonconformance, if any are identified

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Quality Assurance Audits and Subcontractor Monitoring Visits	BARDA reserves the right to participate in QA audits performed by the Performer. Upon completion of the audit/site visit the Performer must provide a report capturing the findings, results and next steps in proceeding with the subPerformer. If action is requested of the subPerformer, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Performer must provide responses from the subPerformers to address these concerns and plans for corrective action. The Performer must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, including manufacturing person in plant, at nonclinical sites, at clinical sites, CROs, and any other clinical vendor involved in the conduct of the nonclinical study or clinical trial under agreement.	•Performer must notify AO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subPerformers •Performer must notify the PAR and AO within 5 business days of report completion and provide Draft Report. •PAR and AO will review the report and provide a response to the Performer with 10 business days before audit can be finalized. •Performer must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report. •Performer must provide a final closeout report that all CAPAs were addressed to PAR and AO •Performer must notify BARDA within 24 hours of any critical and/or major findings
	Risk Management Plan (RMP)	The Performer must provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan must include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule, and performance.	•A Draft is due within 45 calendar days after the initiation of the agreement period of performance; updates to the RMP are due concurrent with Monthly Technical Progress Reports, but may be communicated more frequently. The Performer may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update •BARDA will provide Performer with a list of concerns in response plan submitted •Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns •The Performer must submit updates at minimum of every three months.
	Integrated Master Schedule (IMS)	The Performer must provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks.	•The Performer must submit the IMS in both PDF and an agreed-upon electronic format (e.g., Microsoft Project) to the PAR •The first Draft of the IMS is due within 30 business days after the initiation of the agreement period of performance •The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set •Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports •During a declared Public Health Emergency, the Performer must submit the IMS within 10 business days after the initiation of the agreement period of performance, updates are due weekly, and any significant change (i.e., a change which would

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			impact the schedule by greater than one week) must be reported immediately to the PAR and/or designee.
	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Performer must notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Performer must provide a high-level management strategy for risk mitigation.	•The Performer must submit Deviation Notification and Mitigation Strategy at least 10 business days prior to the Performer anticipating the need to implement changes
	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, such as breach of GCP during a clinical study, 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 AO •Additional updates due to PAR and AO within 48 hours of additional developments •Performer must submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues •If corrective action is deemed necessary, Performer must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

Technical Documents and Publications

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Technical Documents	Upon request, Performer must provide AO and PAR with deliverables from the following activities: quality agreements between Performers and sub-contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports, clinical trial documents. The AO and PAR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government.	•Performer must provide technical document within 10 business days of AO or PAR request. Performer can request additional time on an as needed basis •If corrective action is recommended, the Performer must address, in writing, concerns raised by BARDA in writing
	Publications	The Performer must submit any manuscript, scientific meeting abstract, poster, presentation, and any other public-facing material or information disseminated outside the purview of other deliverables, containing data generated under this agreement, to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in agreement article X.	• Performer must submit all manuscript or scientific meeting abstracts to PAR and AO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts, posters, or any other material • Performer must address in writing all concerns raised by BARDA in writing

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			• Final submissions must be submitted to BARDA concurrently or no later than within one (1) calendar day of its submission • Performer must list all publication material in the Monthly Technical Progress Report
	Performer Clinical Publication Timeline and USG Right to Publish Data	The Performer and Government are committed to transparent and timely publication of clinical trial data to ensure rapid distribution of information during a Public Health Emergency. Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this agreement and consistent with Good Publications Practices. Sponsor must submit clinical study primary endpoint analysis for publication to a peer reviewed journal. Within 90 days of the of study end date [last subject last visit] for studies funded in part or whole under this agreement and consistent with Good Publication Practices, Sponsor must submit clinical study data for publication to a peer reviewed journal. If the Performer does not elect to publish data, Performer must provide AO and PAR with clinical trial data to support the government publication of data as deemed appropriate by the government, without the Performer involvement. The government reserves the right to publish a counter-analysis of the data.	• Performer must notify AO and PAR within 30 calendar days of primary analysis results and study end date [last subject last visit] if they plan not to publish data. • Within 10 calendar days of a request for clinical data from the AO, the Performer must provide AO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the clinical trial data funded in part or whole under this agreement
	Performer Nonclinical Publication Timeline and USG Right to Publish Data	The Performer and Government are committed to transparent and timely publication of nonclinical data to ensure rapid distribution of information, particularly during a Public Health Emergency. Within 90 days of the of study end date [audited or quality-controlled draft final report prepared and reviewed by the Government] for studies funded in part or whole under this agreement and consistent with Good Publication Practices, Sponsor must submit nonclinical study data for publication to a peer reviewed journal. If the Performer does not elect to publish data, Performer must provide AO and PAR with nonclinical data to support the government publication of data as deemed appropriate by the government, without the Performer involvement. The government reserves the right to publish a counter-analysis of the data.	• Performer must notify AO within 30 calendar days of study end date [audited or quality-controlled draft final report prepared and submitted for Government review] if they plan not to publish data. •Within 10 calendar days of a request for nonclinical data from the AO, the Performer must provide AO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the nonclinical trial data funded in part or whole under this agreement

Regulatory Deliverables (if applicable)

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Regulatory Strategy/Plan	The Performer must provide a Regulatory Plan that outlines the regulatory strategy for the product. The plan must include information leading to commercialization readiness.	•The Performer must submit a Draft within 45 calendar days after the initiation of the agreement period of performance; updates to the Regulatory Strategy/Plan must be submitted concurrently with Monthly Technical Progress Reports. The Performer may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update •BARDA will provide Performer with a list of concerns in response to plan submitted •Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns
	FDA Correspondence	The Performer must memorialize all original and unredacted correspondence between Performer and FDA and submit to BARDA, including formal and informal emails, correspondence, telephone calls, and official information requests (IRs).	•Performer must provide copies of all original and unredacted FDA correspondence within 2 business days of correspondence
	FDA Submissions	The Performer must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Performer must provide BARDA with an electronic copy of the final FDA submission. All documents must be duly marked as either "Draft" or "Final."	•Performer must submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission •BARDA will provide feedback to Performer within 10 business days of receipt •The Performer must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission •The Performer must submit Final FDA submissions to BARDA concurrently or no later than five (5) calendar days of submission

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.. For fixed price agreements, when each milestone is submitted, the RRPV member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the RRPV member is required to assign a

monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

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

RRPV Milestone Payment Schedule Example

Milestone Number	Task Number	Milestone Description	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	$20,000		$20,000
2	N/A	Monthly Report (Technical and Business Reports)	1/25/2020	$ -		$ -
3	N/A	Monthly Report (Technical and Business Reports)	2/25/2020	$ -		$ -
4	1	Protocol Synopsis	2/28/2020	$21,075		$21,075
5	2	Submission for Program Office Approval	2/28/2020	$21,075		$21,075

6	N/A	Monthly Report (Technical and Business Reports)	3/25/2020	$ -		$ -
7	N/A	Monthly Report (Technical and Business Reports)	4/25/2020	$ -		$ -
8	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	$210,757	$187,457	$398,214
9	N/A	Monthly Report (Technical and Business Reports)	5/25/2020	$ -		$ -
10	N/A	Monthly Report (Technical and Business Reports)	6/25/2020	$ -		$ -
11	N/A	Monthly Report (Technical and Business Reports)	7/25/2020	$ -		$ -
12	N/A	Monthly Report (Technical and Business Reports)	8/25/2020	$ -		$ -
13	N/A	Monthly Report (Technical and Business Reports)	9/25/2020	$ -		$ -
14	4	Toxicity Studies	10/1/2020	$63,227		$63,227
15	N/A	Annual Report 1	10/25/2020	$ -		$ -
16	N/A	Monthly Report (Technical and Business Reports)	11/25/2020	$ -		$ -
17	5	FDA authorization trial	11/30/2020	$84,303		$84,303
18	6	Research staff trained	11/30/2020	$ -		$ -
19	7	Data Management system completed	11/30/2020	$ -		$ -
20	N/A	Monthly Report (Technical and Business Reports)	12/25/2020	$ -		$ -

21	8	1st subject screened, randomized, and enrolled in study	1/1/2021	$150,000	$187,457	$337,457
22	N/A	Monthly Report (Technical and Business Reports)	1/25/2021	$ -		$ -
23	N/A	Monthly Report (Technical and Business Reports)	2/25/2021	$ -		$ -
24	9	Completion of dip molding apparatus	3/1/2021	$ 157,829	$ 187,457	$ 345,286
25	N/A	Monthly Report (Technical and Business Reports)	3/25/2021	$ -		$ -
26	N/A	Monthly Report (Technical and Business Reports)	4/25/2021	$ -		$ -
27	N/A	Monthly Report (Technical and Business Reports)	5/25/2021	$ -		$ -
28	10	Assess potential toxicology	6/1/2021	$157,829		$157,829
29	N/A	Monthly Report (Technical and Business Reports)	6/25/2021	$ -		$ -
30	N/A	Monthly Report (Technical and Business Reports)	7/25/2021	$ -		$ -
31	N/A	Monthly Report (Technical and Business Reports)	8/25/2021	$ -		$ -
32	N/A	Monthly Report (Technical and Business Reports)	9/25/2021	$ -		$ -
33	11	Complete 50% patient enrollment	10/1/2021	$350,000	$187,457	$537,457
34	N/A	Annual Report 1	10/25/2021	$ -		$ -

35	N/A	Monthly Report (Technical and Business Reports)	11/25/2021	$ -		$ -
36	N/A	Monthly Report (Technical and Business Reports)	12/25/2021	$ -		$ -
37	N/A	Monthly Report (Technical and Business Reports)	1/25/2022	$ -		$ -
38	N/A	Monthly Report (Technical and Business Reports)	2/25/2022	$ -		$ -
39	12	Electronic Report Forms Developed	3/1/2022	$315,658	$187,457	$503,115
40	N/A	Monthly Report (Technical and Business Reports)	3/25/2022	$ -		$ -
41	N/A	Monthly Report (Technical and Business Reports)	4/25/2022	$ -		$ -
42	N/A	Monthly Report (Technical and Business Reports)	5/25/2022	$ -		$ -
43	N/A	Monthly Report (Technical and Business Reports)	6/25/2022	$ -		$ -
44	N/A	Monthly Report (Technical and Business Reports)	7/25/2022	$ -		$ -
45	13	Complete 100% patient enrollment	8/1/2022	$315,658	$187,457	$503,115
46	N/A	Monthly Report (Technical and Business Reports)	8/25/2022	$ -		$ -
47	N/A	Monthly Report (Technical and Business Reports)	9/25/2022	$ -		$ -
48	N/A	Annual Report 1	10/25/2022	$ -		$ -

49	14	Report results from data analysis	11/1/2022	$157,829		$157,829
50	N/A	Final Reports (POP End)	11/30/2022	$ -		$ -
			Total	**$2,025,240**	$1,124,742	$3,149,982
					Period of Performance (Months)	**XX Months**
					Contract Type	**FFP/CPFF/CR**

Please Note:

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.

2. Expenditure Based Contracts – You may invoice for actual costs incurred and providing a progress report on technical milestones.

3. Cannot receive payment for a report (i.e., Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)

4. Monthly, Quarterly, and Annual Reports include BOTH Technical and Business Reports (separate).

5. Final Report due date must be the POP end noted in Project Award.

6. Milestone Numbers are used for administrative purposes and should be sequential.

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

6.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

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

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

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

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

ATTACHMENT SUMMARY

Attachment A – Project Objectives (see Section 4, page 11)
Attachment B – Retail Pharmacy CoP Clinical Protocol Synopsis (Separate File)
Attachment C– CoP Sample Collection and Processing-Decentralized (Separate File)