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

"Accelerating Near-Term Availability of mRNA-based Pandemic Influenza Vaccine"

RPP Solicitation Number: 24-01-mRNA

Issued: 26 October 2023
Amendment No. 04 Issue Date: 14 November 2023
Due: 4 December 2023 by 3pm EST

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

MedicalCountermeasures.gov

Amendment No. 04 does the following:

Extends the proposal due date from 27 November 2023 at 3pm to 4 December 2023 at 3pm

All other terms and conditions remain unchanged.

Contents

1 Executive Summary

1.1 Rapid Response Partnership Vehicle Consortium

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

The RRPV will help fortify national health security by developing medical countermeasures products prior to and during a pandemic or public health emergency. The RRPV will focus on the acceleration of products and technology development, regulatory approval, commercialization, and sustainment to address pandemic influenza, emerging infectious diseases, and other biological threats.

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

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

1.2 Purpose

BARDA is requesting project proposals from product developers for design and manufacturing, as well as nonclinical and clinical testing, of mRNA vaccines against influenza viruses of pandemic potential. BARDA has previously identified that the mRNA-based vaccine production platform has characteristics that could complement currently licensed influenza vaccine manufacturing approaches. In particular, mRNA-based vaccines can be rapidly switched to a new viral strain, as witnessed with the COVID-19 response. This is an important attribute when responding to a new viral strain that emerges and spreads rapidly with little warning. The frequent outbreaks of influenza A(H5Nx) virus infections in poultry and birds worldwide and the recent transmission of avian influenza A(H5N1) virus to multiple mammalian species, underscore the importance of developing complementary vaccine platforms, e.g., mRNA-based vaccines, for rapid pandemic influenza response. The purpose of this project is to partner with existing domestic large-scale commercial mRNA vaccine producer(s) with existing capabilities, including fill/finish and labeling/packaging and as-needed distribution activities that could be readily repurposed for a pandemic influenza response. The goal of this project is to rapidly enable a mRNA-based national pandemic influenza vaccination response capability by generating manufacturing and clinical data with various influenza strains of pandemic potential.

*Note: Project Awards resulting from this RPP may include a procurement option pursuant to BARDA's Other Transaction Authority provided in 42 USC § 247d–7e(c)(5).

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

2 Administrative Overview

2.1 Request for Project Proposals (RPP)

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

2.2 RPP Approach

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

Each proposal selected for award under this RPP will be executed as a Project Award under the RRPV by the RRPV CMF and be funded under the OTA Number 75A50123D00005. 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 up to five (5) years from date of award for design, manufacturing, nonclinical testing, and clinical trials performed only in the U.S. It is anticipated that the overall base period will be three (3) years, with the ability to execute the option periods throughout the entire 5-year period of performance. Specific dates are to be negotiated. It is anticipated that the primary place of performance will be the Project Awardee's facilities.

The U.S. Government (USG) may apply additional dollars for follow-on efforts with appropriate modification of the Project Award.

The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

2.4 Expected Award Date

Offeror should plan on the period of performance beginning January 22, 2024 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the RRPV CMF and prior to issuing a Project Award.

2.5 Anticipated Proposal Selection Notification

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

2.6 Proprietary Information

The RRPV CMF will oversee submission of proposals submitted in response to this RPP. The RRPV CMF shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than proposal evaluation and agreement administration. Please mark all Confidential or Proprietary Information as such. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CMF responsibilities.

2.7 Eligibility Criteria

Offerors submitting proposals must be RRPV members when the proposal is submitted. As mentioned above, prospective Offerors may join the consortium at www.rrpv.org/how-to-join.

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

- Demonstrated experience in mRNA vaccine development, and FDA licensure or Emergency Use Authorization (EUA) for an mRNA vaccine.
- Demonstrated ability to manufacture mRNA vaccines at commercial scale in the United States.
- Demonstrated mRNA-based influenza vaccine candidate in advanced development with plans to submit for FDA licensure. For the purpose of this RPP, "advanced development" is defined as mRNA-based influenza vaccine candidates in Phase 3 clinical trial or later.

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

Additionally, the following proposals may be excluded from consideration:

- Proposal from vaccine developer without domestic commercial mRNA vaccine manufacturing capacity.
- Proposal from vaccine developer without clinical data from mRNA-based influenza vaccine candidate.

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

2.8 Cost Sharing

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

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

2.9 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 Attachment 1, Technical Proposal, for any items to be furnished to the Government with restrictions. An example is provided below. If the Offeror does not assert data rights on any items, a negative response in Attachment 1 is required.

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

3 Proposals

3.1 Proposal General Instructions

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

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

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

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

3.2 Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page to the following website. Include this RRPV Solicitation Number on each Proposal submitted.

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.**

3.3 Proposal Preparation Cost

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

3.4 Submission Format

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

- **Technical Proposal submission (30 page limit, unless noted*) – See Attachment 1:** One 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, data rights*, and key personnel resumes*.

- **Cost Proposal submission (no page limit) – See Attachment 2:** One Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative is required using the mandatory template. Separately, Section II: Cost Proposal Format is required in Excel (.xlsx) format, with working formulas to the maximum extent practicable. See Section 3.5 of this RPP for additional information.

- **Statement of Work/Milestone Payment Schedule (no page limit) – See Attachment 3**: One Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the mandatory template provided as Attachment 3.

3.5 Cost Proposal

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

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

3.6 Restrictions on Animal and Human Subjects

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

- The Project Awardee shall serve as regulatory product sponsor and be responsible for any regulatory submissions to FDA.
- Support and maintain regulatory submissions throughout life of the project.
- The Project Awardee must submit to the Government all regulatory and supporting documentation related to potential pandemic mRNA vaccine development, manufacturing,

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

- The Project Awardee shall cross-reference any applicable regulatory files, such as INDs, Master Files, and BLA prior to the conduct of the studies, and shall allow cross-referencing of these documents associated with this effort.

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

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

4 Technical Requirements

4.1 Introduction

This project supports the development and manufacturing of mRNA vaccines against influenza viruses of pandemic potential by leveraging existing US domestic large-scale commercial manufacturing platforms and capabilities. The primary focus of this project is manufacturing investigational mRNA vaccines targeted to various influenza virus subtypes/strains of pandemic potential upon agreement with BARDA and conducting clinical trials to collect the safety and immunogenicity data for FDA biologics license application (BLA) or emergency use authorization (EUA) as necessary for commercial scale-up in response to a public health emergency (PHE).

4.2 Solution Requirements

The successful Offeror will be responsible for the below. For scheduling and pricing purposes, Offerors should assume that all Base Periods may occur concurrently to support cost and schedule savings. Offerors should assume that an Agreement modification will be required to begin an option period.

Phase 1: Regulatory Interactions - Base Period

- Provide a Product Development, Clinical Development, and Regulatory Plan that outlines the regulatory strategy for the product(s), including both an initial BLA for product licensure, as well as supplements to the BLA for a response scenario. The plan must include timelines for strain changes, information leading to distribution readiness, and information needed to support the CDC Immunization Information Systems (IIS) data code set development.

- Request and participate in regulatory meetings (e.g., Pre-IND, End-of-Phase 2) with FDA, as needed.

- Submit and maintain INDs (Investigational New Drug Applications) to FDA for all clinical studies.

- Submit and maintain BLA to FDA for product licensure.

- Submit EUA application to FDA in response to a PHE as needed.
- Submit documents as requested by BARDA to support the preparation of pre-EUA package for the vaccine.
- Accommodate up to 4 BARDA personnel to attend all regulatory meetings with FDA concerning the pandemic influenza mRNA vaccines.
- This project will not fund BLA Submission User Fee costs associated with the Prescription Drug User Fee Act (PDUFA) for submittal of the BLA to FDA.

Phase 2: Production of mRNA Vaccine Candidates for Nonclinical Studies – Base Period

- Design mRNA constructs for vaccines against influenza viruses of pandemic potential. Subtype/strain selection will be at the discretion of BARDA.
- Develop a phase-appropriate process and analytical plan for producing and characterizing nonclinical materials as necessary.
- Produce, characterize, and release nonclinical lots of the vaccine candidates under appropriate quality standards for use in animal studies as necessary.
- Perform animal studies (if required) in suitable animal models to collect safety, immunogenicity, and efficacy data that support clinical trials.

Phase 3: Manufacturing Candidate mRNA Vaccines for Clinical Trials - Base Period

- Develop or leverage existing manufacturing processes and analytical methods appropriate to supply phase-appropriate pandemic influenza mRNA vaccine clinical trial materials.
- Manufacture the clinical vaccine lots in manufacturing facilities according to CGMP under 21 CFR parts 210, 211, and 600.
- Ensure stored materials are compliant with the Project Awardee's internal quality control system and are ready for use in further CGMP-governed manufacturing of clinical trial materials or licensed doses as directed by BARDA.
- Perform and provide to BARDA lot release testing of the influenza vaccine using specifications that are agreed on by the FDA.
- Develop any novel potency testing as needed for antigens of interest.
- Initiate stability monitoring program to support clinical use.
- Perform studies to ensure appropriate extraction and delivery of desired doses for the selected product image, including all required quality assurance studies (sterility, extractable volume, *etc*.).

Phase 4: Clinical Trials

It is not expected that Phases 4A, 4B, and 4C are dependent on one another; the order of execution is based on USG requirements.

Phase 4A: Clinical trials for pandemic influenza mRNA vaccine licensure - Base Period exclusive of Phase 3 Trial

- Initiate upon completion of appropriate tasks in Phases 2-3.
- Sponsor phase-appropriate clinical trials (inclusive as necessary, *e.g.*, Phase I, Phase II, pivotal Phase III) following Good Clinical Practice (GCP) guidelines, with successful pandemic influenza mRNA vaccine candidates, to support the product licensure by FDA.
- Immunogenicity assays should be qualified or validated (based on the phase of clinical study) for measuring the immune response to the homologous vaccine antigen(s) in vaccinated human subjects. Qualification and/or validation protocols and reports must be reviewed and agreed upon by BARDA prior to assay execution.
- Collect and store serum samples at key immunogenicity time points from vaccinated human subjects and test for the immune response. Samples and associated metadata will be transferred to a BARDA managed repository. Immunogenicity results will be provided to BARDA based on the subjects' prior seasonal influenza vaccination history and stratified by age. Serum samples may be required to be transferred to a BARDA centralized immunogenicity laboratory for clinical endpoint analyses. The remaining serum samples should be stored for future use by BARDA for pandemic readiness purposes (*e.g.*, cross-reactivity to emerging influenza virus strains). These specimens and associated metadata will be transferred to a BARDA-managed repository at a date to be determined.
- Perform interim analysis following the peak immunogenicity time point based on cumulative immunogenicity and safety data when all in-study subjects complete that visit. At the interim analysis, the study database will be monitored, cleaned, and locked. Data for the interim analysis will be unblinded at the group level for preparing interim tables and listings and provided to BARDA.
- The Statistical Analysis Plan (SAP) should be reviewed by BARDA prior to data analysis.
- A plan to assess the duration of immunogenicity is required.
- Plan to publish study findings in peer-reviewed scientific journals within 12 months of clinical study report finalization.

Phase 4B: Clinical trial readiness for influenza strains or other emerging viruses- Base Period

- Initiated as requested by BARDA.
- Sponsor clinical trials for investigational vaccines made from seed lot(s) prepared as described in Phase 5.
- Collect safety and immunogenicity data for EUA or BLA submission to FDA.

Phase 4C: Clinical trials for PHE response - Option Period

- Initiate as an emergency response as requested by BARDA.
- Conduct all necessary studies as described in Phases 2 and 3 and sponsor clinical trials

to prepare data package for EUA submission to FDA.

- Provide a plan for clinical lot production within the first 50 days of recognition of a potential PHE and the clinical trial and FDA EUA authorization within the 100-day total timeframe.

Phase 4D Clinical trials for vaccination regimen - Option Period

- Participate in BARDA-sponsored clinical trials for novel vaccination regimen upon request. The trials will evaluate the safety and immunogenicity of mRNA vaccine candidate(s) as part of a multi-dose regimen with influenza vaccines manufactured with different platforms (e.g., mRNA vaccine plus recombinant HA-based vaccine or split vaccine). Data will support the preparedness against a PHE.

Phase 5: CGMP Manufacturing/Operational Readiness - Option Period

- Prepare and release mRNA vaccine seed lots (*e.g.*, master bacterial cell banks containing plasmids that carry the gene(s) of interest from influenza virus or other emerging viruses, CGMP plasmid batches) annually for virus subtypes/strains upon agreement with BARDA. These seed lots should be fully ready for large scale commercial production for rapid response to a PHE.
- Ensure the manufacturing process is suitable/ready for manufacturing and releasing commercial lots of successful potentially pandemic influenza mRNA vaccines.
- Develop a Pandemic/PHE Facility and Operational Management Plan that includes changing procedures from normal to pandemic operations.

Phase 6: Commercial Scale Manufacturing and Distribution in Response to a PHE - Option Period

- Establish a quality agreement with BARDA within 30 days of exercise of the option.
- Propose and execute a supply chain, manufacturing, and distribution plan for distributing the product to all U.S. states and territories as directed by USG.
- Implement, as appropriate, the required regulatory and clinical requirements and enable the logistics infrastructure for donation/distribution/administration of the product internationally as requested by USG.
- Identify lead time from date of order to completion/delivery required by the performer to reach maximum manufacturing production to provide to the USG in the event of a pandemic/PHE (identify maximum production capacity).
- Work with BARDA and other USG agencies on vaccine commercialization as needed. Commercialization of pandemic vaccines will occur on a date determined by BARDA/FDA in consultation with the Performer.
- Establish a patient assistance program upon commercialization of the vaccine.
- Manufacture commercial scale vaccine lot(s) in U.S. domestic manufacturing facilities

according to CGMP under 21 CFR parts 210, 211, and 600.

- Perform and provide to BARDA lot release testing of the vaccine lot(s) using specifications agreed on by the FDA.
- Execute stability testing of material in a manner consistent with the stability testing plan approved by BARDA.
- Make batch records available for review by BARDA.
- Product acceptance will be contingent on BARDA agreement that product meets all specifications and passes quality inspection.
- Allow onsite BARDA acceptance of product, as required.
- Dispose of all products related to this agreement, as required by BARDA. Disposal of product shall follow all federal and state regulations for the appropriate waste category. Provide documentation and reports on the performed and completed disposal activity.

The successful Offeror shall provide deliverables as included in Attachment 3, Statement of Work.

5 Selection/Evaluation

5.1 Compliance Screening

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

5.2 Proposal Evaluation Process

Following the preliminary screening, the Government sponsor will perform source selection using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified Proposals.

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

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP as outlined in Section 2.8. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each proposal against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) as discussed below. The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable, unless specifically stated otherwise.

The evaluation factors and evaluation criteria are described below.

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

- 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 - 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.

Factor 3 - Cost/Price (See Section 5.4 below)

Evaluation factors 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.

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

6 Points of Contact

- Questions related to this RPP should be directed rrpv-contracts@ati.org. All technical questions must be submitted by **13 November 2023** to allow for Government response. All questions and responses will be posted to the RRPV Solicitation webpage.

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*
3. Executive Summary & Minimum Eligibility Criteria
4. Technical Approach
5. Current & Pending Support
6. Data Rights*
7. Resumes of Key Personnel*

***Excluded from page limitation**

1. Technical Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[Proposal Title]

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

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

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

_____ _____
Signature of responsible party for the Offeror DATE

2. Member Information Sheet

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

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

3. Executive Summary & Minimum Eligibility Requirements

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

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

1. **mRNA vaccine development and either FDA licensure or Emergency Use Authorization (EUA):** [Provide evidence of both]
2. **Ability to manufacture mRNA vaccines at commercial scale in the United States:** [Provide evidence]
3. **mRNA-based influenza vaccine candidate in advanced development (Phase 3 or later) with plans to submit for FDA licensure**: [Provide evidence]

4. Technical Approach

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

1. **Background:** [Describe the problem that the proposal is addressing.]
2. **Approach:** [Describe your approach to solving the problem, broken out by Phase as outlined in Section 4.2 (Solution Requirements) of the RPP. Include relevant background data about your approach. Include the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Past Experience:** [Describe relative past experience, as well as the technical and management experience of the proposed team, to perform the proposed work]
5. **Technical Strategy**: [Describe the proposed methodology in sufficient detail to show a clear course of action.]
6. **Clinical Trial:** [If a clinical trial is proposed as part of Technical Strategy, then include the following information as part of the technical approach. Clinical trials should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to development and testing of biologics. This will include compliance with applicable portions of Title 21 of the US Code of Federal Regulations (CFR) including Title 21 CFR Parts 11, 50, 54, 56, the Health Insurance Portability and Accountability Act (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).]

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

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

7. **Anticipated Outcomes**: [Provide a description of the anticipated outcomes from the proposed work.]
8. **Technical Maturity and Commercialization Strategy:** [Provide a description and justification of the maturity of the proposed technology, anticipated regulatory pathway and commercialization plans. Include high-level information about Intellectual Property/Data Rights Assertions. Describe the planned indication for the product label, if appropriate, and include an outline of the development plan required to support that indication. The application should describe a transition plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of this award.]
9. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur when an individual or an entity is unable, or potentially unable, to provide impartial advice or service to the Government or separate entity because of other business activities or relationships. Disclose any potential conflict of interest pertaining to this opportunity. If none, state as such.]
10. **Key Personnel:** [Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified].

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

Name			%
Name			%

[Address the qualifications, capabilities, and experience of the proposed personnel who will be assigned to carry out the project. Ensure resumes of key personnel are provided in the "Resumes of Key Personnel" section. Resumes are excluded from page count limit]

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

Cost Realism Form EXAMPLE

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

Cost Element	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6	Total Proposed Cost	Description/Explanation
Labor	*$100,000*	*$150,000*	*$200,000*	*$300,000*	*$350,000*	*$375,000*	*$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	*1,000*	*1500*	*2000*	*3000*	*3500*	*3750*	*$14,750*	
Subcontractors	*$50,000*	*$50,000*	*$50,000*	*$50,000*	*$50,000*	*$50,000*	*$300,000*	*Sub A - $25,000; 250 legal advisor hours – each phase*
Subcontractor Hours	*500*	*500*	*500*	*500*	*500*	*500*	*$3,000*	*Sub B - $25,000; 250 hours of Testing – each phase*
Consultants	*$10,000*	*$10,000*	*$10,000*	*$10,000*	*$10,000*	*$10,000*	*$60,000*	*Financial consultant supporting all phases*
Consultant Hours	*100*	*100*	*100*	*100*	*100*	*100*	*$600*	
Material/Equipment	*$75,000*	*$50,000*	*$100,000*	*$150,000*	*$50,000*	*$75,000*	*$500,000*	*pipettes, gloves, computer software – each phase*
Other Direct Costs	*$1,000*	*$1,000*	*$2,000*	*$5,000*	*$1,000*	*$2,000*	*$12,000*	*ship testing materials to lab – each phase*
Travel	*$5,000*	*$5,000*	*$5,000*	*$5,000*	*$5,000*	*$5,000*	*$30,000*	*2 trips for 2 people for 2 days to Washington, DC from Charleston, for program meetings – each phase*
Indirect Costs	*$48,200*	*$53,200*	*$73,400*	*$104,000*	*$93,200*	*$103,400*	*$475,400*	*approved by DHHS 30 Sept 23*

Fee	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*Not applicable if cost share proposed*
Total Cost to Government	*$289,200*	*$319,200*	*$440,400*	*$624,000*	*$559,200*	*$620,400*	*$2,852,400*	
Cost Share	*$290,000*	*$290,000*	*$290,000*	*$290,000*	*$290,000*	*$290,000*	*$1,740,000*	*5,000 hours of lab assistant – each phase*
Total Project Value	***$579,200***	***$609,200***	***$730,400***	***$914,000***	***$849,200***	***$910,400***	***$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 current support]

6. Data Rights

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

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

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

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

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

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

_____ _____

Signature of responsible party for the proposing Prime Offeror DATE

7. Resumes of Key Personnel

Include the resumes of key personnel from the Offeror's organization, as well as subcontractors or consultants, who will work on this project if selected. 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 s to perform a Project Award such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Project Award, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Project Award.

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

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

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

2. Cost Proposal Narrative Cost Data

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

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

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

Provide an explanation for any proposed labor escalation.

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

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

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

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

Statement of Work

Submitted under Request for Project Proposals (*RPP NUMBER*)
Proposed Project Title:
RRPV Member Organization Name:
RRPV Member Primary Place of Performance:

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

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

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

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

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

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

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

Below are the following minimum deliverables for this RPP:

Meetings

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
1.1	Post Award Teleconference	The Performer must complete an initial teleconference after the initiation of the period of performance. 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting	•Within 5 business days after the initiation of the Project Award period of performance •Performer must submit agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply a teleconference number •PAR edits/approves and instructs Performer to distribute agenda at least 2 business days prior to meeting •Performer submits meeting minutes to PAR within 3 business days after the meeting •PAR reviews, comments, and approves minutes within 10 business days
1.2	Kickoff Meeting	The Performer must complete a Kickoff meeting after the initiation of the period of performance.	•Within 10 business days after the initiation of the period of performance, pending concurrence by the OTAO •Performer must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference •PAR edits/approves and instructs Performer to distribute agenda at least 3 business days prior to meeting •Performer submits meeting minutes to PAR within 3 business days after the meeting •PAR reviews, comments, and approves minutes within 10 business days

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
1.3	Regular Teleconference	The Performer must participate in teleconferences at least montly with BARDA to discuss the technical performance on the project. Meeting frequency may be increased or decreased as needed during the course of the project.	•Performer must submit agenda to PAR no later than 3-4 business days in advance of meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting •Performer must distribute agenda and presentation materials at least 2 calendar days in advance of meeting •Performer must submit meeting minutes to PAR within 3 business days of the meeting •PAR reviews, comments, and approves minutes within 10 business days
1.4	Technical, Subgroup, Ad Hoc Teleconference(s)	The Performer must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the Project Award. Meeting frequency may be defined as needed during the course of the project.	•Performer must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting •Performer must distribute agenda and presentation materials at least 24 hours in advance of meeting •Performer must submit meeting minutes to PAR within 3 business days of the meeting •PAR reviews, comments, and approves minutes within 6 business days
1.5	Periodic Review Meetings	At the discretion of the Government, the Performer must hold up to four per year recurring Project Review Meetings, held by teleconference or face-to face either in Washington, D.C. or at work sites of the Performer or subperformer. Face-to-face meetings should alternate between Washington, D.C. and Performer, subperformer sites. The meetings will be used to discuss project progress in relation to the Program Management deliverables described in this Project Award 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
1.6	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.	•Performer must notify BARDA of any and all upcoming FDA meetings at minimum within 24 hours of meeting request. This includes formal (Type A, B, or C meetings or any and all other technical meetings).

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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 provide advance copies of any PAR respondence 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-issued draft minutes AND final minutes of **any** meeting with the FDA to BARDA within 2 business days of receipt.
1.7	Daily check-in with BARDA in the event of a PHE	Upon request of the Government, the Performer must participate in a daily check-in update with the project staff (via teleconference or email). The updates will address key cost, schedule, and technical updates. Daily updates may be shared with senior Government leaders and should be provided on a non-confidential basis, unless the update includes confidential information in which case Performer must provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	•A standing agenda must be used, to include key cost, schedule, technical updates, as well as updates on ad hoc communications between the USG and the Performer. •No meeting minutes are required •Performer must provide bulleted email updates following any call or in lieu of a call by 2:00PM ET for that day.

Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
2.1	Project Management Plan (PMP)	The Project Management Plan should define the overall plan for how the project will be executed, monitored and controlled and must include a Study Responsibility Assignment Matrix for Performer and 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	•The Performer must submit a Project Management Plan (PMP) ○ Within 30 calendar days after the initiation of the period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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.	
2.2	Product Development Plan	The Performer must develop an integrated Product Development Plan for mRNA-based vaccine(s) against influenza subtype(s)/strain(s) (and other emerging viruses) of pandemic potential, selected at the discretion of BARDA. The Plan must be inclusive of product development activities performed and completed prior to the Project Award and the activities to be performed post- award. The Plan must be a high-level overview and include the following elements: • Gantt chart timeline or equivalent. • Description of the process development, scale-up of domestic vaccine manufacturing, and clinical and consistency lot manufacturing to support process validation, clinical evaluation and FDA Center for Biologics Evaluation and Research (CBER) product licensure. • Description of the assay development plan including development and validation of the potency assay(s). • Description of product lot characterization, release and stability assay development including assay specifications and qualification/validation. • Risk mitigation plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan must include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule, and performance.	• The Performer must submit the Product Development Plan within 30 calendar days after the initiation of the period of performance. • Updates should be provided to reflect any key changes and reviewed at least annually
2.3	Clinical Development Plan	Develop a Clinical Development Plan for mRNA-based pandemic influenza vaccine(s), to include: • A **detailed summary of nonclinical studies** including consultation(s) with the FDA Center for Biologics Evaluation and Research (CBER) incorporated as an appendix to the milestone report. • A **detailed description of clinical evaluation** must be integrated with the manufacturing plans using the most current and available information including consultation with CBER.	• The Performer must submit the Clinical Development Plan within 30 calendar days after the initiation of the period of performance. • Updates should be provided to reflect any key changes and reviewed at least annually

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Clinical trials performed should include any Phase 1, Phase 2, and Phase 3 trials needed to achieve U.S. licensure for individuals aged 6 months and older. Trials must include adults, older adults, and children, as needed, to support licensure for both low and high-risk populations. Given the duration, cost, and importance of clinical trials, the plan for each clinical trial must clearly indicate key outcomes, populations, study sites and collaborators, management, and reporting of safety events (local and systemic reactions; Adverse Events, Serious Adverse Events, etc.), analytic strategy, sample size, timelines, and other key components. The plan must include the development and validation of clinical sample assays. A summary of available clinical lot manufacturing results, provisional lot release specifications, completed Phase 1 trials and any additional stages of product development that have been completed must be incorporated as an appendix to the milestone report. • A risk assessment and mitigation plan addressing potential manufacturing, clinical and regulatory obstacles that might prevent or delay licensure as well as a plan for the production and distribution of vaccine in the case of emergency use authorization must be included. Issues suitable for risk assessment include recombinant DNA constructs, cell lines, assay development, process yields and facility management. Mitigation plans must include decision trees where applicable.	
2.4	Gantt Chart/Timeline of the project	The Gantt Chart/Timeline should be detailed to the extent required by the specific project.	•At first project meeting and as updated no later than every 30 calendar days. Provided in pdf.
2.5	Communication Plan	The Performer must develop and implement an effective Communication Plan that details the flow of information between BARDA, Performers, collaborators, vendors, and other organizations, including communications with, as appropriate, regarding label contents, expiry dating, healthcare provider educational materials. 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 period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
2.6	Performer Locations	Using BARDA-defined template, the Performer must submit detailed data regarding locations where work will be performed under this Project Award, including addresses, points of contact, and work	•Performer must submit Work Locations Report: ○ Within 30 calendar days after the initiation of the period of performance ○ Within 30 business days after a substantive location or capabilities change

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		performed per location, to include subperformers and critical vendors of reagents and supplies. Performer must include vendors for critical infrastructure protection.	•Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
2.7	Rapid Pandemic/PHE Response Plan	Develop a Rapid Pandemic/PHE Response Plan for pandemic influenza vaccine(s) during an emergency response. The plan should aim to meet the objectives and goals as outlined in the National Biodefense Strategy and Implementation Plan (2022), including vaccine design, testing, and production goals as outlined below. The plan will include clinical trial testing of candidate vaccines (safety and immunogenicity) to support an EUA, with an expectation that clinical lot production will be completed within the first 50 days and the clinical trial and authorization will be completed subsequently within the 100-day total timeframe. The Performer should include all assumptions related to implementation of the plan. The plan must be inclusive of all activities to be performed in a pandemic influenza response situation, and should include the following elements: • A plan with timelines for all clinical development and regulatory activities to be performed during a response to pandemic influenza as well as post-use monitoring of adverse event data as required by USG during an emergency or unexpected usage. • FDA authorization or approval for candidate mRNA vaccine within 100 days of recognition of a pandemic/PHE. • A plan for quickly pivoting from commercial vaccine production to manufacturing, formulation, and fill/finish of up to enough pandemic influenza vaccine regimens for the entire US population within 130 days of recognition of a potential emerging pandemic influenza threat at domestic facilities in compliance with CGMP guidelines. This plan should include amount of manufacturing capability that is expected to be available by pivoting commercial manufacturing, as well as number of doses that will be produced using modules that will be quickly operationalized. Timelines for operationalizing both the existing commercial capability toward pandemic vaccine production and the new modules	• The Performer must submit the Product/Clinical Development plan within 30 calendar days after the initiation of the period of performance. • Updates should be provided to reflect any key changes and reviewed at least annually.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		to be operationalized in an emergency should be provided. • A Gantt chart timeline or equivalent. Times should reflect the number of days after having a confirmed sequence to produce vaccine(s), begin clinical studies, manufacture product, and achieve authorization and/or licensure. • A description of a pandemic facility and/or operational management plan including change procedures from normal commercial manufacturing operations to pandemic operations.	
2.8	Request for Information (RFI) Responses	Upon request of the Government, the Performer must provide complete responses to ad hoc RFIs. • RFIs may address key cost, schedule, and technical updates. Responses may be shared with senior Government leaders and should be provided on a non-confidential basis, unless the response includes confidential information in which case Performer must provide the response in both confidential and non-confidential formats.	Performer must submit an RFI response to BARDA by email within 24 hours after Performer receipt of the RFI.
2.9	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), and 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)	•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 every twelve months. 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 Draft and Final Technical Progress Report). The PAR and OTAO 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 OTAO and PAR within 24 hours of being notified of the event

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		•Safety reporting (SAEs) •Protocol deviations •Database management •Status of ancillary supplies e.g., PPE, swabs, syringes, tubes on site •Specimen collection status 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 milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports must detail the planned and actual progress during the period covered, explaining any differences between the two and the corrective steps 4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 5. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission, and next steps 6. Estimated and Actual Expenses • 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 Subperformer did not submit a bill in the previous month. If the subperformer(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subperformers. If the PAR and OTAO are satisfied that the Performer's reporting is sufficient to convey this information, this section may be waived.	

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and other public-facing material or information containing data generated under this Project Award	
2.10	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 period of performance. This report must be in sufficient detail to fully describe the progress achieved under all milestones. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the Project Award. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The 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 obtained for the entire Project Award PoP. The final report must document the results of the entire Project Award. The final report must be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the period of performance.	•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

Physical Inventory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
3.1	Manufacturing Materials	mRNA-based pandemic influenza vaccine seed lots (e.g., CGMP plasmid DNAs) that are fully ready for large scale commercial production for rapid response to a PHE Investigational mRNA vaccine lots, adjuvants, diluents, *etc.* mRNA vaccines fill-finished into final containers with appropriate labels and in cartons in the event of a PHE, then stored and distributed under conditions specified in product profile label (insert).	• All physical manufacturable deliverables are accurately reflected in the BARDA dose tracker in a timely manner. Dose tracker must be updated weekly or daily. • Batch records (MBRs) and quality/ release testing results for all CGMP batches must be shared with BARDA and Quality/Regulatory

3.2	Serum and Sample Repository – Animal Studies	If animal studies are conducted, Performer must establish and maintain a repository of serum and other appropriate samples (and their associated metadata) from animals vaccinated with any vaccine candidates. Samples must be shared for testing in laboratories designated by BARDA. Samples will be transferred to a BARDA centralized laboratory upon request for potential analyses and future use by the Government	•Performer must provide specimen inventory reports from animal studies in their monthly technical report • Specimens and associated data must be transferred to BARDA or a BARDA-designated laboratory upon request from the OTAO or PAR according to a schedule to be determined by the OTAO or PAR.
3.3	Clinical Specimen Collection for Future Use	The Performer must collect and store clinical samples at key immune time points from human subjects and test for the immune response endpoint(s). Immunogenicity results most be provided to BARDA based on the subjects' prior seasonal influenza vaccination history and stratified by age. Clinical samples and associated clinical data (metadata) must be transferred to a BARDA-managed repository according to a schedule (including the sample volume and number of aliquots) to be determined by the OTAO or PAR. The sample types, timepoints, volume collected, and collection, transfer, and storage procedures must be conducted as defined by the OTAO or PAR and must be defined in the study protocol. The intended use of these samples and associated clinical data is to establish a repository of samples 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 solely determined by BARDA. Such assays and analysis may be performed by third parties at BARDA's direction. 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 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	• 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 OTAO or PAR according to a schedule to be determined by the OTAO or PAR

		services), necessary to secure execution, timelines, materials and preserve intellectual property.	

Technical Reporting: Manufacturing

4.1	mRNA Vaccine Constructs	The Performer must design constructs for mRNA-based vaccines against influenza viruses (and other emerging viruses, as requested) of pandemic potential for nonclinical studies and clinical trials. Subtype/strain selection must be at the discretion of BARDA.	The Performer must submit proposed constructs prior to finalization. ○ BARDA will provide input within 5 business days of receipt of construct design ○ Performer must respond in writing to BARDA comments and recommendations within 5 business days of receipt and must be addressed prior to finalization. ○ BARDA must approve the final construct design
4.2	Nonclinical lots of mRNA-based Pandemic Influenza Vaccines	The Performer will produce, characterize, and release nonclinical lots of the vaccine candidates under appropriate quality standards for use in *in vitro* and/or animal studies, as necessary.	Within 30 days of notification from BARDA
4.3	Clinical Lots of mRNA-based Pandemic Influenza Vaccines	The Performer must develop or leverage existing manufacturing facilities and capabilities to manufacture investigational lots of mRNA-based vaccines for clinical trials: • The clinical vaccine lots must be manufactured in according to CGMP under 21 CFR parts 201, 211, and 600. • Provide the release testing and stability data of the clinical lots to BARDA. • Develop any novel potency testing as needed for antigens of interest. • Perform studies to ensure appropriate extraction and delivery of desired doses for the selected product image, including all required quality assurance studies (sterility, extractable volume, etc.), and provide data to BARDA. • Make batch records, major/critical deviations, change controls, corrective and preventative action (CAPA), and certificate of analysis (COA) available for review by BARDA.	In the case of a PHE caused by influenza or any other emerging virus, the clinical lot production must be finished within 50 days of recognition of the PHE.
4.4	mRNA Vaccine Seed Library	The Performer must prepare a library of mRNA seed lot targeting influenza virus or other emerging virus subtypes/strains of pandemic potential selected by BARDA. These seed lots should be fully ready for large scale commercial production for rapid response to a PHE.	• Within 15 days after agreement with BARDA on the subtypes/strains to be produced. • The preparation and release of mRNA vaccine seed lots must be done annually or as requested by BARDA.

4.5	Commercial Scale Manufacturing in Response to a Pandemic/PHE	Performer must implement the manufacturing plan described in the Rapid Pandemic/PHE Response Plan in the event of a pandemic/PHE. • The Performer must identify lead time from date of order to completion/delivery required to reach maximum manufacturing production to provide to the USG in the event of a pandemic/PHE (identify maximum production capacity). • Manufacture commercial scale vaccine lot(s) in U.S. domestic manufacturing facilities according to CGMP under 21 CFR parts 210, 211, and 600. • Provide lot release testing and stability data of the vaccine lot(s) to BARDA. • Make batch records available for review by BARDA. • Product acceptance will be contingent on BARDA agreement that product meets all specifications and passes quality inspection. • Allow onsite BARDA acceptance of product, as required.	Manufacturing of up to 300 million vaccine doses within 130 days of recognition of a potential emerging pandemic threat
4.6	Supply Chain Resiliency Plan	The Performer must develop and submit within 30 calendar days after the initiation of the period of performance, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods. a. A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment. Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.	• Due within 30 calendar days after the initiation of the period of performance • Reports for critical items must be provided within ten (10) calendar days after OTAO issues the request. The Performer may arrange for additional time if deemed necessary, and agreed to by the OTAO

		The Performer must identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document must address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product. a. Communication for these requirements must be updated as part of an annual review, or as necessary, as part of regular contractual communications. b. For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also must be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery must be addressed taking into account capacity capabilities. c. The focus on the aspects of resiliency must be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods must be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries. The Performer must articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries. a. Production rates and lead times must be understood and communicated to the OTAO or the PAR as necessary. b. Production throughput critical constraints must be well understood by activity and by design and communicated to personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate. Reports for critical items must include the following information: a. Critical Material b. Vendor c. Supplier, Manufacturing / Distribution Location d. Supplier Lead Time e. Shelf Life f. Transportation / Shipping restrictions	

		The OTAO and PAR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government.	
4.7	Product Development Source Material Report	The Performer must submit detailed data regarding critical project materials, materials sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: Bill of Materials (BOM), physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of nonclinical and clinical study sites. The BOM submitted must include at minimum the manufacturer part and/or lot numbers, part names, descriptions, unit(s) of measure, procurement type (e.g., off-the shelf, manufactured according to specification), consumables. The BOM must include the quantity required per production run and a schedule for consumable procurement and production. In the event of a Public Health Emergency, HHS may require daily reporting of manufacturing campaigns during response operations. BARDA may provide a table in tabular format for Performer to be used to submit such data which would include but not be limited to the following: • Manufacturing locations • Seed development or other starting material manufacturing • Critical materials, consumables, and components • Storage/inventory of starting materials	• Performer must submit a Product Development Source Material Report ○ Within 30 calendar days after the initiation of the period of performance ○ Within 30 calendar days of changes made to sources and/or materials ○ 6 months after the start of the PoP. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, Performer must address all concerns raised by BARDA in writing • The Performer must submit Product Development and Source Material report via spreadsheet.
4.8	Manufacturing Reports and Projections	The Performer must submit detailed data regarding manufacturing and manufacturing dose tracking projections/actuals utilizing the BARDA defined "Dose Tracking Template" or similar, including product for clinical trial use. BARDA may provide a table in tabular format for Performer to be used to submit such data which would include but not be limited to the following: • Storage/inventory of ancillary materials (e.g., vials, needles, syringes, etc.) • Shipment of ancillary materials (e.g., vials, needles, syringes, etc.)	• Performer must update the "Dose Tracking Template" at minimum weekly during manufacturing campaigns and daily during response operations (i.e., where a Public Health Emergency has been declared) and COVID-19 response, with the first deliverable submission within 15 days of award. Updates must be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture. • Dose Tracking must be completed via spreadsheet or other format (e.g., XML or JSON) as agreed to by USG and Performer.

		• Disposal of ancillary materials (e.g., vials, needles, syringes, etc.) • Seed development or other starting material manufacturing • Manufacturing production projections • Bulk drug substance actuals and/or adjuvant production actuals • Fill, finish, and release of product or adjuvant • Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant or diluent • Stability information of bulk substance and/or finished product • Shipment of bulk substance or final finished product • Disposal of bulk substance or final product • Similar details for adjuvant or diluent, if not co-formulated. In the event of a Public Health Emergency, HHS may require daily reporting of manufacturing campaigns during response operations.	
4.9	Manufacturing Campaign Reports	In the event of a large-scale manufacturing campaign, the Performer must provide Manufacturing Campaign Reports to BARDA as described above in Manufacturing Reports and Projections. The Manufacturing Campaign Reports should include lot history, major deviations, PPQ reports, CoAs, batch reports, storage location, purity, potency, yield. If Manufacturing Campaign Reports are provided to FDA, the Performer must provide Reports to BARDA for review and comment prior to submission to FDA. The PAR and OTAO reserve the right to request within the PoP a non- proprietary Manufacturing Campaign Report for distribution within the USG.	• Performer must submit Manufacturing Reports at least 15 business days prior to FDA submission in an agreed-upon electronic format. • The Government will provide written comments to the manufacturing report within 15 business days after the submission • If corrective action is recommended, Performer must address, in writing, the concerns raised by BARDA. • Performer must revise the reports to address BARDA's concerns and/or recommendations prior to FDA submission. • The Performer must submit Final FDA submission to BARDA concurrently or no later than 1 business day after submission to the FDA.
4.10	Supply Chain and Distribution Tracking	Distribution Concept of Operations. BARDA will work with the Performer to monitor what is in the manufacturing pipeline using the "Dose Tracking Templates" (see above). BARDA will relay final drug product information as it is being released to the distributor as required for allocation and ordering by the jurisdiction public health departments. This information will be returned to	Performer must provide the following information in order to coordinate the movement and delivery of final drug product from manufacturing locations to USG distribution centers: • Shipment Plan to include detailed timelines between PO receipt and

		BARDA as replenishment orders (or Purchase Order, PO) on a daily basis with shipping instructions on where to send final drug product. Order quantity will be determined by the USG based on need. Order quantity may not be limited to lot-sized shipments or pallet-sized shipments. Manufacturers will use the PO information to ship final drug product as bulk shipments to designated distribution centers for final distribution to end users and end user networks or as individual shipments to points of use, depending on product logistical considerations (e.g. cold chain or time in transit requirements). BARDA will provide the Performer with a list of distribution centers and contact information and/or an approximate number of points of use prior to the start of a distribution campaign.	delivery of final drug product at the distribution center. Upon USG request, Performer must support expedited shipments. Drug product should be planned to be direct-shipped to end users from the manufacturer under appropriate conditions (ultra-cold, freezer, *etc*) and matched with needed components such as diluent, adjuvant, and necessary ancillaries to facilitate administration at final point of use. • Provide Points of Contact information (name, title, phone, email) for manufacturing / supply chain personnel for each manufacturing, CMO, storage, and distribution locations: • Head of Manufacturing • Production Planning • Logistics • Distribution • Labeling • Provide vaccine labeling, packaging, and distribution information as soon as it becomes available. Plan to support Immunization Information Systems (IIS) codeset development. At a minimum, provide the following: • MSDS • Health Distribution Alliance (HDA) Form • Primary Container Information • Number of doses per primary container • Unit of Sale (carton, box, package, other) • Quantity per Unit of Sale • Quantity per Carton • National Drug Code (NDC) • Structured Product Labeling (SPL) • Unit of Sale dimensions (H, W, L) • Unit of Sale weight • Intermediate Package • Intermediate Package dimensions • Intermediate Package weight • Quantity Unit of Sale per pallet • Quantity cartons per pallet • Pallet dimensions, fully loaded with finished product (H, W, L) • Pallet weight, fully loaded with finished product and inclusive of the pallet • Storage Requirements • Stability Information • The Performer must deliver commercial lots with a minimum of 6 months real-time stability with less possible if

			supporting representative lot and/or accelerated data can be provided • The Performer must obtain concurrence on planned shipment protocols prior to transport • Send electronic/scanned copies of all bulk shipment related documents to the PAR for three-way matching on the day shipment occurs.
4.11	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 (similar data will be required for direct-ship shipments: • Transaction Information (TI), Transaction History (TH), Transaction Statement (TS) • Purchase Order (PO) number (which BARDA will provide at the time the order is submitted) • Project Award number • Copy of the MSDS (with QR code) in the packing list envelope	
4.12	Advance Shipment Notices (ASNs)	Performer must transmit bulk shipment ASNs to BARDA or BARDA's designee via Electronic Data Interchange (EDI)	Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. BARDA or BARDA's designee will provide EDI mapping specifications that include the generated PO number

Technical Reporting: Nonclinical Studies

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
5.1	Nonclinical Study Protocols	The Performer must submit Draft and Final Nonclinical Study Protocols to OTAO and PAR.	•The Performer must submit Draft Nonclinical Study Protocols to OTAO and 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 Nonclinical Study Protocols to PAR electronically no later than 10 business days prior to FDA submission.
5.2	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

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			•The Performer must submit Subperformer reports received by the Performer to the PAR and OTAO 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

Technical Reporting: Clinical Trials

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
6.1	Clinical Trial Protocols	The Performer must submit draft and final clinical trial protocols to OTAO and PAR. A plan to assess the duration of immune response must be included in the protocols. The Statistical Analysis Plan (SAP) must be reviewed by BARDA prior to data analysis.	•The Performer must submit Draft clinical trial protocols to OTAO and 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 clinical trial protocols to PAR electronically no later than 10 business days prior to FDA submission.
6.2	Clinical Trial Documentation	The Performer must provide the following documents for any portion of a study funded under this Project Award: •Investigational Product Accountability Plan •Study Supplies Procurement Plan •Site selection questionnaire •Overall Recruitment and Retention plan •Informed Consent Form (ICF) template, including consent for sharing clinical samples with BARDA for future use •eConsent •Data Management Plan •Data Validation/Quality Plan	•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.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		•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 separates 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 •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.	•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.
6.3	ClinicalTrials.Gov Posting and Results Reporting	Per clinicaltrials.gov registration and reporting requirements.	•must post results: o 3 months from any interim analysis o 3 months from primary analysis o 3 months from final analysis
6.4	Draft and Final Clinical Study Report(s)	The 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 Subperformer-prepared reports received by the Performer to the PAR and OTAO 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

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			•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
6.5	Clinical Report During Active Enrollment Periods[1]	The Performer must submit daily the data specifications as requested by BARDA during active clinical trial enrollment. Clinical Report submission must be by electronic transfer, e.g., from Performer Electronic Data Capture (EDC) system/Interactive Voice Response System (IVRS) to USG.	•Performer must submit, in a format and to a location agreed to by BARDA, data specifications on a daily basis starting when first subject is enrolled and ending when last subject is enrolled.
6.6	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
6.7	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.
6.8	Clinical Trial Final Data Package	Performer must provide the Clinical Trial Final Data Package to BARDA for review and comment. At BARDA's request, the Performer must provide any clinical-related 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 Project Award end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.
6.9	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),	•Performer must provide the Technical Documents and/or datasets within 20 business days of request from the OTAO or PAR

[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
		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 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*	
6.10	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: ○ 3 months from any interim analysis ○ 3 months from primary analysis ○ 3 months from final analysis
6.11	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 limited to the list of files in package, technical specification documents, data analysis programs. Data exchange standards and file formats must be discussed and agreed upon with BARDA.	•Performer must provide the data package(s) within 20 business days of request from the OTAO or PAR

Quality Assurance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
7.1	Quality Management Plan (QMP)	Performer must develop an overall project Quality Management Plan to include a description of all quality activities and personnel involved in ensuring all activities are conducted and data are maintained under CGXP, and all products are managed to ensure that CGMP requirements are met. All quality management plans must include subperformer quality management plans specifically addressing how subperformer quality will be managed. All subperformers must have a current quality agreement with the Performer and a recent vendor qualification audit.	•Performer must submit a Quality Management Plan ○ Within 30-60 calendar days after the initiation of the period of performance ○ 6 months after the start of the period of performance to include any updates.
7.2	BARDA Audit	Performer must accommodate periodic or ad hoc site visits, audits, inspections and review of release	•If issues are identified during the audit, Performer must submit a report to BARDA

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		documents, test results, equipment and facilities when requested by HHS. If BARDA, the Performer 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 Project Award and all records related to the manufacture, testing (including but not limited to analytical testing, nonclinical study, clinical trial), and storage of the product.	detailing the finding and corrective action(s) within 10 business days of the audit •PAR and OTAO will review the report and provide a response to the Performer with 10 business days •Once corrective action is completed, the Performer will provide a final report to BARDA
7.3	FDA Inspections/Site visits	In the event of an FDA inspection that occurs in relation to this Project Award and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this Project Award, including, but not limited to 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 OTAO 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 Project Award or for this product. The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during the opening, any daily debriefs, and the final debrief by the regulatory inspector.	•Performer must notify OTAO and PAR within 10 business days of the scheduling of a scheduled FDA inspection/site visit or within 24 hours after inspection/site visit if the FDA does not provide advanced notice •Performer must provide copies of any FDA inspection report received from subperformers that occur as a result of this Project Award 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 OTAO with a plan for addressing areas of nonconformance, if any are identified
7.4	Quality Assurance Audits and Subperformer Monitoring Visits	BARDA reserves the right to participate in QA audits performed by the Performer. Upon completion of the audit/site visit the Performer 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.	•Performer must notify OTAO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subperformer •Performer must notify the PAR and OTAO within 5 business days of report completion and provide Draft Report. •PAR and OTAO will review the report and provide a response to the Performer with 10 business days before audit can be finalized. •Performer must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		The Performer must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, 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 contract.	•Performer must provide a final closeout report that all CAPAs were addressed to PAR and OTAO •Performer must notify BARDA within 24 hours of any critical and/or major findings
7.5	Risk Management Plan (RMP)	The Performer must provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan must include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule, and performance.	•A Draft is due within 45 calendar days after the initiation of the 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 of BARDA's concerns •The Performer must submit updates at minimum of every three months.
7.6	Integrated Master Schedule (IMS)	The Performer must provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks.	•The Performer must submit the IMS in both PDF and an agreed-upon electronic format (e.g., Microsoft Project) to the PAR •The first Draft of the IMS is due within 30 business days after the initiation of the 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 period of performance, updates are due weekly, and any significant change (i.e., a change which would impact the schedule by greater than one week) must be reported immediately to the PAR and/or designee.
7.7	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Performer must notify BARDA of significant proposed changes the IMS defined	•The Performer must submit Deviation Notification and Mitigation Strategy at least

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		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.	10 business days prior to the Performer anticipating the need to implement changes
7.8	Incident Report	Performer must communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project 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 OTAO •Additional updates due to PAR and OTAO within 48 hours of additional developments •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
7.9	Quality Agreement	BARDA will issue a draft Quality Agreement to the Performer to review and sign. The terms of the Quality Agreement shall set forth the requirements under the contract.	•The Performer must respond to updates and inquiries within 5 business days of receiving the draft Quality Agreement
7.10	Vendor Managed Inventory (VMI)	Performer must draft a VMI Plan that defines all aspects of VMI build-up, maintenance, and deployment.	•The Performer shall submit the VMI Plan and supporting SOPs for approval no later than 90 days from the date of award.

Advanced R&D Products

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
8.1	Technical Documents	Upon request, Performer must provide the PAR with deliverables from the following activities: quality agreements between Performer and subperformers, Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Major/Critical Deviation Investigation Reports, OOS Investigation Reports, Clinical Studies Data or Reports, Clinical Trial Documents. The OTAO and PAR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government.	•Performer must provide technical document within 10 business days of OTAO or PAR request. Performer can request additional time on an as needed basis •If corrective action is recommended, the Performer must address, in writing, concerns raised by BARDA in writing

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
8.2	Performer Clinical Publication Timeline in the Event of PHE and USG Right to Publish Data	Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this Project Agreement and consistent with Good Publications Practices, Performer 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 contract and consistent with Good Publication Practices, Performer must submit clinical study data for publication to a peer reviewed journal. If the Performer does not elect to publish data, Performer provide OTAO 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 OTAO 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 OTAO, the Performer must provide OTAO 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 Project Agreement
8.3	Performer Nonclinical Publication Timeline in the Event of PHE and USG Right to Publish Data	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 Project Agreement and consistent with Good Publication Practices, The Performer must submit nonclinical study data for publication to a peer reviewed journal. If the Performer does not elect to publish data, Performer must provide OTAO 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 OTAO 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 OTAO, the Performer must provide OTAO 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 contract

Regulatory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
9.1	Regulatory Strategy/Plan	The Performer must provide to BARDA a Regulatory Strategy/Plan that outlines the regulatory strategy/plan for FDA licensure or Emergency Use Authorization of the product. The plan must include timelines for strain changes, information leading to commercialization and distribution readiness, and information needed to support the CDC Immunization Information Systems (IIS) data code set development.	•The Performer must submit a Draft within 45 calendar days after the initiation of the contract 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

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			•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
9.2	FDA correspondence	The Performer must memorialize all original and unredacted correspondence between Performer and FDA and submit to BARDA, including formal and informal emails, correspondence, telephone calls, and official information requests (IRs).	•Performer must provide copies of all original and unredacted FDA correspondence within 2 business days of correspondence
9.3	FDA Submissions	The Performer must maintain all the regulatory submissions to the FDA. 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 submissions. 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 and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the RRPV member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the RRPV member is required to assign a monetary value to each milestone. In this case, however, invoice totals

are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

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

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

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

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

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

48	N/A	Annual Report 1	10/25/2022	$ -		$ -
49	14	Report results from data analysis	11/1/2022	$157,829		$157,829
50	N/A	Final Reports (POP End)	11/30/2022	$ -		$ -
			Total	$2,025,240	$1,124,742	$3,149,982

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

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