

Biomedical Advanced Research and Development Authority (BARDA)
 Request for Project Proposals (RPP) for
 “Rapid Pandemic Influenza and Emerging Infectious Disease Vaccine
 Development and Response Capability”



RPP #: RRPV-24-08-mRNALongTerm *Amendment 04 - Revised*

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RPP AMENDMENTS	
No.	Description
1.	Revises Supplemental Questions Due Date to 11/08/24
1.	Adds Sec. 4.4.0 <i>Out of Scope</i>
2.	Revises Proposal Response Deadline
3.	Revises Proposal Response Deadline
4.	Revises Proposal Response Deadline
4.	Update Section 4, Statement of Objectives
4r.	Update Section 4, Statement of Objectives

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1 Executive Summary

1.1 Rapid Response Partnership Vehicle Consortium

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

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

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

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

1.2 Background

The Biomedical Advanced Research and Development Authority (BARDA), within the Administration for Strategic Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS) is requesting proposals from product developers for establishment of a long-term partnership that develops and provides a sustained mRNA preparedness and response capability for pandemic influenza and emerging infectious diseases.

The development and licensure of mRNA vaccines for COVID-19 has facilitated the development of novel interventions for seasonal influenza, pandemic influenza, and other public health emergencies (PHEs). If proven safe and effective to merit regulatory approval, these vaccines are poised to transform pandemic preparedness strategies moving forward. The mRNA platform has the potential to shorten the time needed to design, prepare, and test vaccine candidates compared to more traditional platforms and provides the most promise toward achieving the goal of having a vaccine authorized within 100 days of recognition of an emerging threat. While filling critical gaps in the nation's preparedness and response capabilities, one lesson learned from COVID-19 is the need to be able to pivot these platform technologies to new threats even faster, and for this capability to be regularly exercised. BARDA seeks to establish a long-term partnership centered around the development of a broad preparedness and response capability that can be rapidly and flexibly leveraged toward vaccine development for pandemic influenza or other priority pathogen threats.

1.3 Purpose

BARDA envisions an initial focus on influenza mRNA vaccine development that complements existing pandemic influenza response capabilities. As the program matures beyond licensure of influenza vaccines, there will be increased focus on continually 'exercising' preparedness and response efforts at small scale to ensure readiness to rapidly pivot to address pandemic influenza

or any other emerging infectious disease that poses a threat. As part of these ongoing efforts, as well as to enable a rapid response, the successful Performer(s)¹ will be expected to have identified staff and capabilities, including domestic manufacturing capability, to immediately pivot for early-stage development work at any time. Various models could be utilized, including sub-contractor support/lab facilities, or a small, dedicated internal team.

The successful Performer(s) will also have the capability to perform clinical and regulatory work internationally to ensure products can be tested, licensed, and distributed in regions where vaccine is needed. The program will also develop and lead innovative platform improvement efforts, including an expectation for collaboration with developers of new technologies, allowing for continued improvement of the mRNA platform attributes to create more effective and accessible vaccines.

This partnership will focus on enabling domestic Current Good Manufacturing Practices (CGMP) manufacturing capability and subsequent annual costs to support the response capability utilizing existing facilities, rather than dedicated new-build construction. Leveraging the smaller footprint and modular capability of mRNA to facilitate meeting and sustaining product goals will be critical for success. Further, vaccine commercialization, whether seasonal influenza or other commercial RNA-based products made in the same facility, will be expected to sustain much of the pandemic influenza vaccine commercial-scale production capabilities.

The Performer is expected to provide high quality data packages, inclusive of randomized controlled clinical trials, to expedite local approvals or World Health Organization (WHO) Emergency Use Listing (EUL) and equitable global access to U.S. Government (USG)-funded countermeasures during outbreak responses.

Following influenza vaccine licensure (which is anticipated to be completed within the first 5 years of award), the program will focus on sustaining the manufacturing capability and continuous 'exercising' of small-scale preparedness efforts. The penultimate goal for this program is to serve as a critical component of the Nation's pandemic response for influenza and any other emerging infectious diseases, collaboratively working with BARDA to develop multiple products using a single, flexible platform capability.

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.***

¹ For the purpose of this document, *Performer* refers to the successful respondent(s) with whom BARDA has entered into an Other Transaction Agreement to fulfill the requirements stated herein.

2.2 RPP Approach

BARDA prefers a Performer or Performer-Team who can successfully perform all Phases of Section 4.0 Attachment A Statement of Objectives (SOO). In the alternative, BARDA may elect to partner with individual Performers 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 / 75A50124F61008 (“TO8”). 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 Order of Precedence

Each proposal selected for award under this RPP will be executed as Project Award under the RRPV Base Agreement 75A50123D00005 (RRPV Base) and OTA Number 75A50123D00005 / 75A50124F61008 (“TO8”) entitled “Rapid Pandemic Influenza and Emerging Infectious Disease Vaccine Development and Response Capability”. The same provisions will govern this Base Agreement as the OTA between the U.S. Government (USG) and ATI (“RRPV Base”) unless otherwise noted in the Project Award. If an ambiguity or conflict arises between these agreements, the following order of precedence applies: 1) TO8 Project Agreements 2) TO8 and 3) RRPV Base.

2.4 Period of Performance and Funding

2.4.1 Period of Performance

BARDA estimates the full program Period of Performance to be up to ten (10) years from date of award, including the base and all option periods. At the unilateral discretion of the U.S. Government, options may be executed throughout the entirety of the period of performance. Specific dates will be negotiated prior to award of the project agreement. It is anticipated that the primary place of performance will be the performers’ facilities, however this aspect can be negotiated as part of each Performers’ submission.

Offeror should plan on the period of performance commencing in May 2025. 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.

2.4.2 Funding

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

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

2.4.3. Funding Eligibility

To be eligible for funding, the Performer will have expertise and demonstrated experience as shown by the following:

- Experience with all aspects of mRNA manufacture under CGMP.
- An active Investigational New Drug (IND) for a vaccine product, with a preference for Biologics License Application (BLA) experience.
- Initiation of a Phase 1 clinical trial with an mRNA viral vaccine candidate.

2.5 Anticipated Proposal Selection Notification

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

2.6 Proprietary Information

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

2.7 Eligibility Criteria

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

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

- a. Demonstrated experience in mRNA vaccine manufacture under CGMP (Performer must provide documentation that clinical material was produced under CGMP).
- b. Evidence that a Phase 1 clinical trial with an mRNA viral vaccine candidate has been initiated.

- c. Demonstrated experience in vaccine development as demonstrated by an active Investigational New Drug (IND) with the U.S. FDA for a vaccine product.²
- d. ASPR Security Requirements Attestation Statement (See Attachment 5).

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

2.7.2 To be eligible to receive a project award, Offerors must show evidence of all criteria in 2.7.1 AND the following:

- a. SAM.gov registration and Unique Entity ID (UEI) number. <https://sam.gov/content/entity-registration>

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, but is not required to be eligible to receive an award under this RPP. If cost sharing is proposed, 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.

² Vaccine under IND may be for any biothreat area, including but not limited to influenza.

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.

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.

Offeror shall complete the table provided in *Attachment 3, Statement of Work Sec 6.0 Intellectual Property, Data Rights and Copyrights* for any items to be furnished to the Government with restrictions. If the Offeror does not assert data rights on any items, a negative response in Attachment 3 is required.

To assist Offerors, the following table is provided as an example:

No.	Technical Data to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
1	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.

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

3.2 Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page to the following website: www.RRPV.HHS.gov. Please be sure to include RRPV Solicitation Number **24-08-mRNALongTerm** 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. File sizes cannot exceed 100Mb.

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

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

3.3 Proposal Preparation Cost

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

3.4 Submission Format

Proposals shall reference RPP number **24-08-mRNALongTerm**. **Each document below (e.g., Technical Proposal, Cost Proposal Narrative, Cost Proposal Format, Statement of Work, Program/Project Management Plan, ASPR Security Requirements Attestation) 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. Offeror's proposal must include the following:

- 3.4.1 Technical Proposal submission (100-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*.

3.4.2 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.

3.4.3 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.

3.4.4 Program/Project Management Plan submission (5-page limit) – See Attachment 4: One Word (.docx or .doc) or PDF file. The Offeror is required to provide details on their proposed approach for Program Management and subperformer management. Submission should include a listing of key personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal (Note: Key personnel resumes must be included in the technical proposal). A summary of related activities must also be provided for key personnel.

An organizational chart for the project with affiliations (who will report to whom). Details on Offeror-provided facilities, infrastructure, and other resources, including, but not limited to the following:

- a. Manufacturing capacity expansion plans to match the proposed manufacturing scale-up;
- b. Overview of the management of Quality Systems at the facility;
- c. List of capabilities for clinical activities conducted in-house and at contract research organizations;
- d. Qualified animal facilities where Good Laboratory Practice (GLP) studies would be conducted and appropriate certifications for humane care and use of vertebrate animals;
- e. Commercial capabilities of the Offeror, including current products, and marketing, distribution, and customer support capabilities (as applicable); and
- f. List of key vendors or service providers, locations, and brief description of their expertise/experience.

3.4.5 ASPR Security Requirements Attestation Statement (no page limit) – See Attachment 5. One Word (.docx or .doc) or PDF file. Included with Project Proposals, Offerors must include a statement attesting to their intent and ability

to comply with the deliverables and security requirements within the deadline dates stated in Attachment 5.

3.5 Cost Proposal

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

Each cost must 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

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

- a. The Performer shall serve as regulatory product sponsor and be responsible for any regulatory submissions to FDA as well as all documents and submissions necessary to enable a World Health Organization Emergency Use Assessment and Listing (WHO EUAL)
- b. Support and maintain regulatory submissions throughout life of the project.
- c. The Performer must submit to the Government all regulatory and supporting documentation related to candidate mRNA vaccine development, to include manufacturing, lot releasing, certificates of analysis, analytical development, stability, nonclinical and clinical testing as well as other related documentation.
- d. The Performer 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.
- e. All nonclinical (if required) should be approved in accordance with industry standards, and HHS's Animal Welfare Assurance
- f. For research involving human subjects, HHS human subject protection regulations and policies require that any institution engaged in non-exempt human subjects research conducted or supported by HHS must submit a written assurance of compliance to Office for Human Research Protections (OHRP). Under an Federal Wide Assurance, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

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

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

4 Attachment A - Statement of Objectives

4.1 Project Objectives

This project supports the establishment of a long-term, shared programmatic and financial partnership that develops and provides a sustained mRNA preparedness and response capability for influenza and emerging infectious diseases. The primary focus of this project is the development of an mRNA vaccine platform production capability applied first to influenza viruses that can be exercised over time to respond rapidly and flexibly to pandemic influenza and develop vaccines to other priority threats. The project will support domestic manufacturing of investigational product and clinical trial(s) to test the safety and immunogenicity of vaccines targeted to various influenza and emerging infectious disease subtypes/strains as specified by BARDA and as required for FDA authorization/approval (emergency use authorization [EUA] or BLA). The project will also support commercial scale-up as necessary in response to a PHE.

4.2 Solution Requirements

Specifically, the Performer will be responsible for:

Phase #	Phase Name	Line Item Number (LIN) Structure ³
1	Product Development Plan – Seasonal and Pandemic Influenza	Firm Fixed Price (FFP)
2	Clinical Development and Regulatory Plan	FFP
3	Design and development of influenza mRNA vaccine candidates	Cost
4	Animal studies (if required)	Cost or FFP
5	Manufacturing of mRNA vaccines for clinical trials	FFP by unit
6	Clinical trials	Cost or FFP
7	Regulatory interactions	Cost
8	Manufacturing Capability	FFP
9	Platform Innovations and Improvement	Cost
10	Prototype Vaccine Development	Cost (per prototype vaccine candidate)
11	Large-scale Response Vaccine Development (Pandemic Influenza or Emerging Pathogen Vaccine)	Cost and FFP

³ To be negotiated with the Performer

Phase #	Phase Name	Line Item Number (LIN) Structure ³
12	Commercial-scale Manufacturing and Distribution (Pandemic Influenza or Emerging Pathogen Vaccine)	FFP by unit

4.2.1 Phase 1: Product Development Plan – Seasonal and Pandemic Influenza [Base Period]

Performer will develop an integrated **Product Development Plan** for seasonal and pandemic influenza vaccines. The Plan shall be inclusive of nonclinical and clinical activities performed and completed prior to an agreement award and those clinical and manufacturing activities to be performed post-agreement award. The Plan shall be a high-level overview and include the following elements:

- a. Gantt chart timeline or equivalent.
- b. Description of the general clinical development plan including development and validation of clinical sample assays.
- c. Description of the process development, scale-up of domestic vaccine manufacturing, and description of clinical and consistency lot manufacturing to support process validation, clinical evaluation and FDA Center for Biologics Evaluation and Research (CBER) product licensure.
- d. Description of product lot characterization, release, and stability assay development including assay specifications and qualification/validation.
- e. Regulatory strategy master plan that focuses on the critical pathway to product licensure. Plan should achieve licensure for children aged 6 months and older, adults, and the elderly.
- f. Risk mitigation plan that includes nonclinical and clinical activities and 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.

4.2.2 Phase 2: Clinical Development and Regulatory Plan [Base Period]

I. Phase 2A: Performer shall develop a Clinical Development and Regulatory Plan for seasonal and pandemic influenza, to include:

- a. A **detailed summary of nonclinical studies** including consultation(s) with CBER incorporated as an appendix to the milestone report.

- b. A **detailed description of clinical evaluation** shall be integrated with the manufacturing plans using the most current and available information including consultation with CBER. Clinical trials performed as a result of this solicitation shall include any Phase 1, Phase 2, and Phase 3 trials needed to achieve U.S. licensure for individuals aged 6 months and older. Trials shall 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 shall 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. **It is expected that the Performer must include the funding for seasonal influenza vaccine clinical trials needed to support dose selection for pivotal Phase 3 trials.** Studies related to pandemic-like vaccine shall be done using an mRNA vaccine developed for subtype and strain to be designated by BARDA (e.g., H5Nx, H7Nx, H9N2). 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 shall be incorporated as an appendix to the milestone report.
- c. A **detailed description of regulatory activities** shall be integrated with all products, clinical testing and manufacturing activities using the most current and available information, including consultation with CBER. 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 EUA shall be included. Issues suitable for risk assessment include recombinant DNA constructs, cell lines, assay development, process yields and facility management. Mitigation plans shall include decision trees where applicable.

II. **Phase 2B: Rapid Pandemic Influenza Response Plan**

Performer shall develop a **Rapid Pandemic Influenza Response Plan** specifically for pandemic influenza vaccines during an emergency response. The plan must aim to meet the objectives and goals as outlined in the [National Biodefense Strategy](#), including vaccine design, testing and authorization within 100 days, and production goals as outlined below. The plan will include clinical trial testing of candidate vaccines (safety

and immunogenicity) to support authorization, 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. Performers should include all assumptions related to implementation of the plan.

The plan shall be inclusive of all activities to be performed in a pandemic influenza response situation, and must include the following elements:

- a. A plan with timelines for all clinical development and regulatory activities to be performed during a response to pandemic influenza as outlined in Phase 2A as well as post-use monitoring of adverse event data as required by USG during an emergency or unexpected usage.
- b. FDA authorization or approval for candidate mRNA vaccine within 100 days of sequence availability for a pandemic influenza strain.
- c. A plan for quickly pivoting from commercial vaccine production to manufacturing, formulation, and fill/finish of up to 100 million doses within 130 days of recognition of a potential emerging pandemic influenza threat at domestic facilities in compliance with FDA 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 phases that will be quickly operationalized. Timelines for operationalizing both the existing commercial capability toward pandemic vaccine production and the new phases to be operationalized in an emergency should be provided.
- d. A Gantt chart timeline or equivalent. Times should reflect the number of days after having a confirmed sequence to produce vaccines, begin clinical studies, manufacture product, and achieve authorization and/or licensure.
- e. Description of a pandemic facility and/or operational management plan including change procedures from routine commercial manufacturing operations to pandemic operations.

III. **Phase 2C: Emerging Pathogen Response Plan**

Performer shall develop an end-to-end **Emerging Pathogen Response** plan. The plan should assume prototype vaccine work has been completed and should aim to meet the objectives and goals as outlined in the National Biodefense Strategy, including vaccine design, testing and authorization within 100 days, and production goals as outlined below. The plan will include clinical trial testing of candidate vaccines (safety

and immunogenicity) to support authorization, 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. Performers should include all assumptions related to implementation of the plan. The plan should include, but not be limited to:

- a. A plan for achieving FDA authorization or approval for candidate mRNA vaccine within 100 days of recognition of a potential emerging pandemic threat. Plan should include the capabilities and timelines for objectives previously described in Phases 4-7 (excluding Phase 6A) with the ability to perform the objectives in those phases either domestically or internationally upon direction from BARDA.
- b. A plan for quickly pivoting from commercial vaccine production to manufacturing, formulation, and fill/finish of up to 100 million doses within 130 days of recognition of a potential emerging pandemic threat at domestic facilities in compliance with FDA CGMP guidelines. This plan should include amount of domestic manufacturing capability that is expected to be available by pivoting commercial manufacturing, as well as number of doses that will be produced using phases that will be quickly operationalized. Timelines for operationalizing both the existing commercial capability toward pandemic vaccine production and the new phases to be operationalized in an emergency should be provided.
- c. A plan for achieving regulatory authorization or approval for a candidate mRNA vaccine internationally to ensure products can be distributed and/or donated in areas where vaccine is needed beyond the United States.
- d. Information leading to distribution readiness, including information needed to support the U.S. Centers for Disease Control and Prevention (CDC) Immunization Information Systems (IIS) data code set development.
- e. A distribution plan for administering vaccines in accordance with CDC-defined population tiers and sub-tiers.
- f. A description of the patient assistance program to be established upon commercialization of the vaccine.
- g. A commercialization plan agreed to by the USG for transitioning vaccine to the commercial market, if applicable. Date of commercialization of a pandemic vaccine will be determined by the USG in consultation with the Performer.

- h. A communications plan agreed to in coordination with the USG that supports broad use of the product, such as direct to consumer advertising (as allowed by the FDA), creation of educational materials for patients and healthcare providers, etc.
- i. A Gantt chart timeline or equivalent. Times should reflect the number of days after having a confirmed sequence to produce vaccines, begin clinical studies, manufacture product, and achieve authorization and/or licensure.

4.2.3 Phase 3: Design and development of influenza mRNA vaccine candidates [Base Period]

- a. Design mRNA constructs for vaccines against influenza viruses, upon agreement with BARDA on selection of the virus subtypes/strains.
- b. Develop a phase-appropriate process and analytical plan for producing and characterizing representative preclinical materials as necessary.
- c. Produce, characterize, and release nonclinical lots of the vaccine candidates under appropriate quality standards for use in animal studies as necessary.
- d. Develop any novel potency testing as needed for antigens of interest. Testing plan timeline should be provided and aligned with ability to achieve authorization or approval for a candidate mRNA vaccine within 100 days of recognition of a potential emerging pandemic threat.
- e. Prepare and release mRNA vaccine plasmid libraries or banks that are suitable for commercial production for rapid response to influenza virus subtypes/strains of pandemic potential upon agreement with BARDA. Material should enable rapid initiation of at-scale manufacturing.

4.2.4 Phase 4: Animal studies (if required) [Base Period]

- a. Perform preclinical studies as required in suitable animal models to collect safety, immunogenicity, and efficacy data that support clinical trials – including animal challenge studies with pathogens regulated under the Select Agents Program (9 CFR part. 121 and 42 C.F.R. Part 73).
- b. Establish and maintain a repository of serum and other appropriate samples from animals vaccinated with each of the vaccine candidates and share samples for testing in laboratories designated by BARDA. Repository samples will be transferred to a BARDA centralized laboratory upon request for potential analyses and future use by the USG.

4.2.5 Phase 5: Manufacturing of mRNA vaccines for clinical trials [Base Period]

- a. Develop or leverage existing manufacturing processes and analytical methods appropriate to supply stage-appropriate clinical trial materials.
- b. Manufacture clinical trial materials using a validated production method following CGMP guidance, including fill-finish, labeling/package, release testing, and storage of the manufactured vaccine lots.
- c. Initiate stability monitoring program to support clinical use.
- d. Perform human factor studies to ensure appropriate extraction and delivery of desired doses for the selected product image, including all required quality assurance studies (e.g., sterility, extractable volume).
- e. Ensure stored materials are compliant with the Performer's internal quality control system and are ready for use in further CGMP-governed manufacturing of clinical materials or licensed doses as directed by BARDA.
- f. Make batch records available for review by BARDA.

4.2.6 Phase 6: Clinical trials

I. Phase 6A: Clinical trials for seasonal influenza mRNA vaccine licensure [Option Period]

- a. Initiate, upon completion of appropriate tasks in Phases 1-5.
- b. Sponsor clinical trials required to achieve licensure following Good Clinical Practice (GCP) guidelines, with successful mRNA vaccine candidates. Performer's cost-share must include most of the funding for seasonal influenza vaccine clinical trials needed to support dose selection for pivotal Phase 3 trials.
- c. Qualify or validate (based on the phase of clinical study) assays for measuring the immune response in vaccinated human subjects.
- d. Collect and store serum samples at key immune time points from all clinical trial participants and test for the immune response unless otherwise directed by BARDA. Seasonal influenza vaccine history should be collected for all trial participants.
- e. Establish and maintain a repository to archive all serum and all other clinical samples from all clinical trial participants. Repository samples will be transferred to a BARDA centralized laboratory for potential clinical analyses and future use by the USG.

- f. Transfer the laboratory and clinical data to BARDA-managed repository.
- g. Provide a Statistical Analysis Plan (SAP) to be reviewed by BARDA prior to data analysis. Immunogenicity results for influenza vaccines will be provided to BARDA based on subjects' prior seasonal influenza virus vaccination history and stratified by age.
- h. A plan to assess the duration of immune response to the vaccine is required.
- i. Plan to publish study findings in a peer-reviewed scientific journal within 12 months of clinical study report finalization.

II. Phase 6B: Clinical trials for pandemic influenza mRNA vaccine licensure [Base funding limited to Phase 1/2 clinical trial]

- a. Initiate, upon completion of appropriate tasks in Phases 1-5.
- b. Sponsor phase-appropriate clinical trials (inclusive as necessary, e.g., Phase I, Phase II, pivotal Phase III, and response-related trials) following GCP guidelines, with successful mRNA vaccine candidates.
- c. Design and pre-position adaptive clinical trials, platform trials, and master protocols when appropriate for testing in multiple subpopulations.
- d. Qualify or validate (based on the phase of clinical study) assays for measuring the immune response in vaccinated human subjects.
- e. Collect and store serum samples at key immune time points from all clinical trial participants and test for the immune response unless otherwise directed by BARDA. Seasonal influenza vaccine history should be collected for all trial participants.
- f. Establish and maintain a repository to archive all serum and all other clinical samples from all clinical trial participants. Repository samples will be transferred to a BARDA centralized laboratory for potential clinical analyses and future use by the USG.
- g. Transfer the laboratory and clinical data to BARDA-managed repository.
- h. Provide an SAP to be reviewed by BARDA prior to data analysis. Immunogenicity results for influenza vaccines will be provided to BARDA based on subjects' prior seasonal influenza virus vaccination history and stratified by age.
- i. Perform interim analysis 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.

- j. A plan to assess the duration of immune response to the vaccine is required.
- k. Plan to publish study findings in a peer-reviewed scientific journal within 12 months of clinical study report finalization.

4.2.7 Phase 7: Regulatory interactions [Base Period limited to 6 years, with additional 4 year Option Period]

- a. Request and participate in regulatory meetings (e.g., pre-Investigational New Drug Application [pIND], End-of-Phase 2) with FDA, as needed.
- b. Submit and maintain Investigational New Drug Applications (INDs) to FDA for all clinical studies.
- c. Submit and maintain BLAs to FDA for product licensure. This agreement will not fund BLA Submission User Fee costs associated with the Prescription Drug User Fee Act (PDUFA) for submittal of the BLA to CBER.
- d. Submit documents as requested by BARDA to support the preparation of a pre-EUA package.
- e. Submit EUA applications to FDA in a PHE as needed.
- f. Provide a Regulatory Plan that outlines the regulatory strategy for the product. The plan must include information leading to distribution readiness, information needed to support the CDC IIS data code set development.
- g. Accommodate up to 4 BARDA personnel to attend all regulatory meetings with the FDA concerning seasonal and pandemic influenza mRNA vaccines.

4.2.8 Phase 8: Manufacturing Capability [Base Period limited to development of Manufacturing Facility Plan and Retrofit/Renovation]

- a. Sustain a manufacturing capability that can produce 100 million doses of vaccine for a pandemic threat within 130 days of recognition of a potential emerging pandemic threat. In accordance with the plans in Phase 2, this capability should also be able to produce a clinical lot for trials within 50 days of recognition of a potential emerging pandemic threat. The manufacturing capability should include the raw materials and supplies, the amount of manufacturing capability that is expected to be available by pivoting commercial vaccine manufacturing toward emergency response, and any warm-base capability that can be operationalized rapidly in an

emergency. Performer should assume that all capacity utilized for commercial vaccine would be leveraged toward emergency response production.

- b. Prepare a detailed Manufacturing Facility Plan describing the design, permit approval, retrofit/renovation, commissioning, qualification, and validation of a U.S.-based facility(s) to produce the Performer's vaccines. The plan must be reasonable, justifiable, and specific to work to be performed in this Statement of Objectives.

While some funding will be available for retrofit and renovation within the Manufacturing Facility Plan, the Performer should consider and implement all opportunities to maximize production capacity using existing facilities. The Plan(s) shall contain the following elements:

1. Architectural/structural plans that include concept functional designs, descriptions, and diagrams of space requirements, adjacency plans, floor plans, mechanical/electrical/plumbing, equipment layouts, material, product and personnel flows, solid, liquid contaminated and other waste flows, and air balance description or diagram detailing zoning, pressurization, air flows and air quality classification.
2. Process and building/mechanical engineering including energy balances, utility flow diagrams, automation plan, equipment lists and a preliminary layout.
3. If retrofit/renovation is proposed, provide a retrofit/renovation schedule including permitting, installation, commissioning and installation/operational/performance qualification and a risk mitigation analysis.
4. A description of the manufacturing facility quality assurance and regulatory acceptance including quality systems, tech transfer plan, the validation master plan (VMP), and regulatory milestones towards facility approval.
5. Plans for supply chain management to ensure consistent production.
6. Environmental Health and Safety plans, including waste and hazardous material management.
7. Personnel training plans.
8. A comprehensive Business Continuity Plan.
9. A comprehensive communication and reporting plan detailing

communication management between stakeholders and reporting mechanisms to track progress and address issues.

10. A Gantt chart or equivalent with the project timeline and key milestones outlines for various phases of facility design, construction and operation.

11. A detailed calculation of the additional production capacity in doses enabled by any retrofit/renovation as described in the plan. The calculation should include what the Performer considers the baseline capability expected to be available by pivoting commercial manufacturing toward emergency response as an initial assumption, so that the added capacity enabled through the proposed retrofit/renovation is clear. A timeline for operationalizing the additional capacity should be included.

- c. Develop plans for additional fill/finish capabilities, as needed to supply pandemic influenza vaccine, particularly during a PHE.
- d. The General Contractor (GC) proposed by the Performer, for the retrofit portion of the anticipated agreement, shall comply with the current edition of all applicable practices, codes, methods, and standards as prepared by technical societies and associations, and other applicable laws, statutes, ordinances, rules and regulations. In case of conflict between applicable building codes and standards of the technical societies and associations, the more stringent regulations shall govern.
- e. The GC shall provide all labor, materials, equipment, tools, supplies, supervision, and general retrofit/renovation services for the retrofit portion of the anticipated agreement. The GC shall accomplish the retrofit objectives as described in the Performer-proposed basis of design, as well as the detailed design plan, drawings and specifications developed during the design stage of the agreement.

4.2.9 Phase 9: Platform Innovations and Improvement [Option Period]

- a. Develop enhancements to the underlying platform to improve vaccine platform efficacy, breadth, accessibility, durability, or reagentogenicity.
- b. Develop enhancements to the platform process and analytics that improve quality, cycle time, control, or characterization of critical quality attributes.
- c. Develop innovations in manufacturing to allow more rapid vaccine deployment and scaling.

- d. Develop alternative delivery technologies for the underlying platform that reduce the need for cold chain distribution and manufacturing of needles and syringes.
- e. Develop improvements in platform stability and storage.
- f. Develop combination products allowing for co-formulated mRNA vaccines that protect against multiple pathogens.
- g. Develop RNA-based platforms beyond mRNA (e.g., circular RNA) that offer substantial improvements on platform characteristics to include, but not limited to, stability, efficacy, breadth, accessibility, durability, or reactogenicity.
- h. Partnerships are encouraged to achieve the objectives in this phase.

4.2.10 Phase 10: Emerging Pathogen Prototype Vaccine Development [Base Period limited to 5 years, with additional 5 year Option Period]

- a. Design mRNA constructs for vaccines against emerging pathogens, upon agreement with BARDA on selection of the virus subtypes/strains, on a regular basis.
- b. Identify effective potential targets for design of vaccine candidates in coordination with BARDA.
- c. Test immunogenicity of candidate vaccines and down-select a lead candidate.
- d. Develop a plan for identification of correlates/surrogates of protection.
- e. Develop a phase-appropriate process and analytical plan for producing and characterizing representative nonclinical materials as necessary.
- f. Produce, characterize, and release CGMP clinical lots of vaccine candidates under appropriate quality standards, including fill-finish, labeling/package, release testing, and storage of the manufactured vaccine lots.
- g. Prepare and release mRNA vaccine plasmid libraries or banks that are suitable for commercial-scale production for rapid response upon agreement with BARDA. Material should enable rapid initiation of domestic manufacturing.
- h. If efficacy trials are conducted, collect, store, analyze and distribute samples and accompanying metadata to support laboratory diagnosis of disease.
- i. In consultation with BARDA, develop and execute a product development plan through licensure. Plan should achieve licensure for children aged 6 months and older, adults, and the elderly. Plan should include the capabilities and timelines for objectives previously described in Phases 4-7, with the ability to achieve the objectives in those phases either domestically or internationally upon direction from BARDA.

- j. Ensure there are identified staff and capabilities to immediately pivot for early-stage development work at any time.

4.2.11 Phase 11: Large-scale Response Vaccine Development (Pandemic Influenza or Emerging Pathogen Vaccine) [Option period]

Implement all aspects, exclusive of commercial-scale manufacturing of the vaccine, of either the **Rapid Pandemic Influenza Response Plan** in Phase 2B or the **Emerging Pathogen Response** plan from Phase 2C, as directed by BARDA.

4.2.12 Phase 12: Commercial-scale Manufacturing and Distribution (Pandemic Influenza or Emerging Pathogen Vaccine) [Option Period]

- a. Implement either the manufacturing plan described in the **Rapid Pandemic Influenza Response Plan** in Phase 2B, or the manufacturing plan described in the **Emerging Pathogen Response Plan** in Phase 2C, as directed by BARDA, for up to 100 million vaccine doses within 130 days of recognition of a potential emerging pandemic threat.
- b. Scale up the manufacturing process to be suitable/ready for manufacturing and releasing commercial-scale bulk lots of successful mRNA vaccines.
- c. Identify lead time from date of order to completion/delivery required by contractor to reach maximum manufacturing production that vendor would be able to provide the USG in the event of a pandemic (identify maximum production capacity).
- d. Manufacture commercial-scale vaccine lot(s) in domestic manufacturing facilities according to CGMP under 21 CFR parts 210, 211, and 600. Date of commercialization of a vaccine distributed under this phase will be determined by the USG in consultation with the Performer.
- e. Perform and provide to HHS lot release product testing of the vaccine including potency using specifications agreed on by the FDA.
- f. Ensure stored materials are compliant with the Performer's internal quality control system and are ready for use in further CGMP-governed manufacturing of clinical materials or licensed doses as directed by BARDA.
- g. Propose a supply chain distribution plan for the product.
- h. Develop a plan to distribute vaccine as directed by BARDA to all U.S. states and territories within 30 days of notification from BARDA.

4.3 Project Management Objectives

After award, Project Awardee will be required to submit several documents to capture the progression of the project. Requirements may include, but are not limited to the following:

4.3.1 Reporting

- a. The Performer shall deliver monthly technical and financial reports and progress reports, to including a master schedule. Annual reports shall also be provided. At the end of the effort, the Offeror shall provide a detailed clinical study report, and a final technical and business report.
- b. Additional deliverables will include:
 1. Those as described in the Deliverables Table below
 2. Draft and final nonclinical and clinical study reports.
 3. Inclusion of the U.S. Government in FDA meetings.
 4. Submission of all read-ahead packages for FDA meetings ahead of time.
 5. Records of any and all communications with the FDA.

4.3.2 Meetings

- a. The Performer shall schedule regular, recurring progress meetings with the Government.
- b. The meeting agenda shall be submitted to the Government in advance and meeting minutes will be submitted following meetings.

4.3.3 Logistics Objectives

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

4.3.4 Performance Requirements

- a. Submission and maintenance of clinical documentation for compliance with Institutional Review Board (IRB)/ Ethics Committee (EC) as per Federal and local regulations to support execution and completion of the clinical study.
- b. **The successful Offeror shall provide deliverables as included in Attachment 3, Statement of Work.**

4.4.0 Out of Scope: The following proposed solutions are considered 'out of scope' and will **not** be considered or evaluated:

- a. Candidates with recombinant protein subunit vaccine platforms.

b. Candidates with LNP-DNA vaccine platforms.

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

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 in Section 5.2.1. 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. 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.

For each evaluated proposal, the factors will each be assigned one of the following adjectival merit ratings:

- Excellent
- Good
- Fair
- Poor
- Unacceptable

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

5.3 Evaluation Factors

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

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

- **Subfactor 1 – Facilities.** This subfactor evaluates facility capabilities, usage/demand as it pertains to the timeliness of response execution, compliance (through documentation of compliance with CGMP), security elements, storage capabilities, physical security, formulation, and fill, finish, and final packaging. Offerors with demonstrated experience in domestic mRNA vaccine manufacture under CGMP are preferred.
- **Subfactor 2 – Delivery Schedule.** This subfactor evaluates the feasibility of schedule for all proposed phases, availability of materials and reagents to complete the work, end-to-end domestic manufacture capabilities, and the feasibility of the plan for production of vaccines at the scale and within the timelines described in the SOO.
- **Subfactor 3 – Sustainment/Adaptability.** To maintain sustainment-need and retain adaptability, Offeror's platform technology must be leveraged for technology transfer domestically and internationally within the scope of the award. Depending on level of development of the technology and system proposed by Offeror, USG intends to enter discussions with successful respondent to meet BARDA mission on sustainability and adaptability in response to a Public Health Event (PHE) defined as organizational willingness/readiness to pivot to novel vaccine development and manufacturing in advance of a PHE declaration domestically and internationally. Offeror must present a willingness to provide the freedom to operate in the event of a PHE to include, at minimum: access to required data, intellectual property, and other dependencies for a response event domestically and internationally. Additionally, this subfactor evaluates the feasibility of Offeror's plan to sustain sufficient capability and expertise beyond vaccine commercialization and Offeror's capability to pivot to early-stage development for a novel threat at any time.

5.3.2 Factor 2 - Relevant Corporate and Capabilities Experience: This factor evaluates the offeror's demonstrated relevant corporate experience and capabilities experience as well as the technical experience and program management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems.

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

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

5.3.4 Factor 4 – Cost/Price (See Section 5.4 below)

Non-Cost/Price Evaluation factors are listed in descending order of importance. Non-Cost/Price factors are more important than Cost/Price, collectively and individually. Following the evaluation, the Source Selection Authority may:

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

THE GOVERNMENT DOES NOT GUARANTEE A MINIMUM OR MAXIMUM NUMBER OF AWARDS WILL RESULT FROM THIS SOLICITATION.

5.4 Cost/Price Evaluation

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

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

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

5.4.1 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.

5.4.2 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.

5.4.3 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 Basis for Award - Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Funding recommendations depend on various factors and programmatic relevance. Based on the evaluation of the Technical Approach, Relevant Experience, and Cost/Price, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offerors will have the opportunity to concur with the requested changes, propose further changes and revise cost proposals, as necessary.

5.6 Basket Provision

The electronic “Basket” is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately selected for award, may be placed in the Basket (at the Government’s sole discretion) for 2 years and eligible for award during that time. Proposals rated as Unacceptable will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal best meets its needs.

6 Points of Contact

Questions related to this RPP should be directed to Ms. Rebecca Harmon (rrpv-contracts@ati.org). All technical questions must be submitted by **27 September 2024** to allow for Government response. The Government will respond to questions at its discretion. All questions and responses will be posted to the RRPV Solicitation webpage (<https://www.rrpv.org/opportunities/>).

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

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 100 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 100 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).]

2. Member Information Sheet

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

OFFEROR NAME:	
ALL PLACES OF PERFORMANCE:	
TITLE OF PROPOSED EFFORT:	
UEI # (if applicable):	
CAGE CODE (if applicable):	
SMALL BUSINESS (YES/NO):	
SMALL/DISADVANTAGED BUSINESS SOCIOECONOMIC CATEGORY? (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 briefly and concisely present the important aspects of their proposals to evaluators. The summary should present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core concepts of the proposed project.]

[Additionally, this section must address how the Offeror currently satisfies the following minimum eligibility requirement(s):]

- a. Demonstrated experience in mRNA vaccine manufacture under CGMP (Performer **must** provide documentation that clinical material was produced under CGMP);
- b. Evidence that a Phase 1 clinical trial with an mRNA viral vaccine candidate has been initiated; and
- c. Demonstrated experience in vaccine development as demonstrated by an active IND with the U.S. FDA for a vaccine product.⁴

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

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 overarching approach and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform or solution and listing the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Relevant Experience:** [Describe relevant past experience, as well as the technical and management experience of the proposed team, to perform the proposed work]
5. **Technical Strategy:** [Provide a detailed and stepwise approach on how your organization intends to address the requirements set forth in the RPP and show a clear course of action.]
6. **Clinical Trial:** [If a clinical trial is proposed as part of Technical Strategy, then include the following information as part of the technical approach. Clinical trials should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements

⁴ Vaccine under IND may be for any biothreat area, including but not limited to influenza.

related to development and testing of biologics. This will include compliance with applicable portions of Title 21 of the US Code of Federal Regulations (CFR) including Title 21 CFR Parts 11, 50, 54, 56, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Pub.L. 104-191, 110 Stat. 1936, enacted August 21, 1996), and International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practices (GCPs) (ICH Guidelines for Good Clinical Practice (E6), Published May 9, 1997).]

- **Clinical Trial History:** [If the proposed clinical trial/testing was initiated using other funding prior to this application, explain the history and background of the clinical trial/testing and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.]
- **On-Going Effort:** [If the proposed clinical trial/testing involves continuation or assumption of an ongoing effort then state the transition plan proposed (e.g., transfer of FDA Sponsorship). In the case of ongoing clinical trials, append or provide reference to previous FDA-regulated studies. Offeror must justify carefully any changes proposed to ongoing FDA-regulated protocols and provide specific rationale for alterations (e.g., FDA feedback, change in clinical resources or study sites, etc.)]
- **FDA Interactions:** [Describe plan to meet all regulatory sponsor responsibilities under 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 the evaluators to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by cost element.]

Cost Realism Form EXAMPLE

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

Cost Element	Total Proposed Cost	Description/Explanation
Labor	<i>\$1,475,000</i>	<i>5000 hrs of senior scientist; 3000 hours of program management; 3000 of hours of contracts management; 3750 hours of scientist</i>
Labor Hours	<i>\$14,750</i>	
Subcontractors	<i>\$300,000</i>	<i>Sub A - \$150,000; 1500 legal advisor hours Sub B - \$150,000; 1500 hours of Testing</i>
Subcontractor Hours	<i>\$3,000</i>	
Consultants	<i>\$60,000</i>	<i>Financial consultant supporting all phases</i>
Consultant Hours	<i>\$600</i>	
Material/Equipment	<i>\$500,000</i>	<i>pipettes, gloves, computer software</i>
Other Direct Costs	<i>\$12,000</i>	<i>ship testing materials to lab</i>
Travel	<i>\$30,000</i>	<i>12 trips for 2 people for 2 days to Washington, DC from Charleston, SC for program meetings</i>
Indirect Costs	<i>\$475,400</i>	<i>approved by DHHS 30 Sept 23</i>
Fee	<i>\$0</i>	<i>Not applicable if cost share proposed</i>
Total Cost to Government	<i>\$2,852,400</i>	
Total Project Value	<i>\$2,852,400.00</i>	

5. Relevant Corporate and Capabilities Experience

Current

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

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

Pending

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

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

6. Resumes of Key Personnel

Include the resumes of key personnel from the Offeror's organization, as well as subcontractors or consultants, who will work on this project if selected. The Principal Investigator must be identified.

SOLICITATION CLOSED

ATTACHMENT 2 – COST PROPOSAL TEMPLATE

General Instructions

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

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

Section I: Cost Proposal Narrative

- a. Cover Page
- b. Overview
- c. Cost Information

Section II: Cost Proposal Format

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

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

1. Cost Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

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).]

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

Cash Contribution:

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

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

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward

efforts expended on the SOW of a Project Award, and restocking the parts and material consumed.

In-Kind Contribution:

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

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

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

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

2. Cost Proposal Narrative Cost Data

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

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

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

Provide an explanation for any proposed labor escalation.

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

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

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

The salary rate limitation does not restrict the salary that an entity may pay an individual, it merely limits the portion of that salary that may be paid with Federal funds.

See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current period. See the RRPV Base Agreement for further details.]

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

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

- 5. Subcontractors/Consultants.** [Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide a list of all subcontractor/consultant and a total cost for each. If a cost and/or price analysis has been performed, provide a copy or summary of results.

Support is required for each subcontractor/consultant as follows:

- If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalogue pricing, etc.)
- For a subcontractor/consultant less than \$250,000, provide a brief explanation of the work to be performed.
- For a subcontractor/consultant greater than \$250,000 and less than or equal to \$2,000,000, provide a supporting quote and confirmation of compliance with the Salary Rate Limitation.
- If a subcontractor/consultant over \$2,000,000 was competitively solicited, provide the price analysis showing how the price was determined reasonable, summary of competition, and copies of the competitive quotes.
- Absent any of the above, if relying on cost data for a subcontractor/consultant greater than \$2,000,000, a cost-by-cost element breakout must be provided to the same level of detail as the Offeror.]

6. Material/Equipment/Other Direct Costs. [Portions of the material/equipment/other direct cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an itemized list of the material/equipment/other direct costs, including the itemized unit cost and quantity. Identify the supplier/manufacturer and basis of cost (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) for each item, if known. Additionally, a copy of the basis of cost documentation for each piece of proposed material/equipment/other direct cost with a unit cost greater than or equal to \$25,000; or total cost greater than or equal to \$150,000; must be provided. If material/equipment/other direct cost is estimated based on an approved methodology, then state as such.]

If any sort of usage cost is determined by a rate, identify the basis and rationale used to derive the rate.

Only in extraordinary circumstances will government funds be used to purchase equipment. Examples of acceptable equipment might include special test equipment, special tooling, or other specialized equipment specific to the research effort. This award is not an assistance agreement/instrument and Offerors should normally have the required equipment to perform. The value of equipment should be prorated according to the share of total use dedicated to carrying out the proposed work. Include a brief explanation of the prorating methodology used.]

7. Indirect Costs. [Portions of the indirect cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an estimate of the total

indirect costs, identify each rate used in the proposal, and provide documentation to support the indirect cost rates by one of the below methods.

- a. Provide a copy of certification from a Federal agency indicating these indirect rates are approved by the Federal agency; or
- b. Provide a letter from the Offeror's Administrative Contracting Officer, in lieu of a rate certificate, stating these indirect rates are approved by a Federal agency;
- c. Copy of current forward pricing rate proposal with date proposal was submitted to the Administrative Contracting Officer; or
- d. Absent Government approved rates, provide detailed supporting data to include (1) indirect rates and all pricing factors that were used; (2) methodology used for determining the rates (e.g., current experience in the organization or the history base used); and (3) all factors, by year, applied to derive the proposed rates.

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

8. **Cost of Money.** [If applicable, Cost of Money should be proposed separately from indirect costs.]
9. **Fee/Profit.** [State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted when cost share is not being contributed. The fees shall be specific to the individual RRPV project and negotiated on a project-by-project basis.]

3. Cost Proposal Section II: Cost Proposal Format

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

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

Supporting data and justification for labor, equipment/material, team member/subcontractor, consultants, travel, other direct costs, indirect costs, and profit used in developing the cost breakdown also must be included. The Offeror must provide sufficient details to allow a full understanding of and justification for the proposed costs. Offerors must refer to the RPP for a start date for cost estimating purposes.]

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 (Attachment B):

Meetings

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
A1	Post-award Teleconference	The Performer must complete an initial teleconference after the initiation of the agreement period of performance. 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting	<ul style="list-style-type: none"> •Within 5 business days after the initiation of the agreement period of performance •Performer must submit agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply a teleconference number •PAR edits/approves and instructs Performer to distribute agenda at least 2 business days prior to meeting •Performer submits meeting minutes to PAR within 3 business days after the meeting •PAR reviews, comments, and approves minutes within 10 business days
A2	Kickoff Meeting	The Performer must complete a Kickoff meeting after the initiation of the agreement period of performance.	<ul style="list-style-type: none"> •Within 10 business days after the initiation of the agreement 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
A3	Regular Teleconference	The Performer must participate in teleconferences at least monthly with BARDA to discuss the technical performance on the agreement.	<ul style="list-style-type: none"> •Performer must submit agenda to PAR no later than 2 business days in advance of meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Meeting frequency may be increased or decreased as needed during the course of the project.	<ul style="list-style-type: none"> • 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
A4	Technical, Subgroup, Ad Hoc Teleconference(s)	<p>The Performer must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the agreement.</p> <p>Meeting frequency may be defined as needed during the course of the project.</p>	<ul style="list-style-type: none"> • Performer must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting • PAR edits/approves and instructs Performer to distribute agenda prior to meeting • Performer must distribute agenda and presentation materials at least 24 hours in advance of meeting • Performer must submit meeting minutes to PAR within 3 business days of the meeting • PAR reviews, comments, and approves minutes within 6 business days
A5	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 subPerformers. Face-to-face meetings should alternate between Washington, D.C. and Performer, subPerformer sites. The meetings will be used to discuss agreement progress in relation to the Program Management deliverables described in this agreement as well as nonclinical, clinical, technical, regulatory, and ethical aspects of the program.	<ul style="list-style-type: none"> • Performer must submit an agenda and itinerary, if applicable, at least 5 business days, and Performer must provide presentation materials at least 3 business days, in advance of the meeting • PAR edits/approves and instructs Performer to distribute agenda prior to meeting by at least 3 business days • Performer provides meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days
A6	FDA Meetings and Interactions	<p>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.</p> <p>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).</p>	<ul style="list-style-type: none"> • Performer must notify BARDA of any and all upcoming FDA meeting at minimum within 24 hours of meeting request. This includes formal (Type A, B, C, D, and INTERACT meetings or any and all other technical meetings). • Performer must provide advance copies of any correspondence it plans to send to FDA. • Performer must provide within 24 hours of its receipt, unredacted copies of all written communications it receives from the FDA. • Performer must notify BARDA within 24 hours of any informal or ad hoc meeting occurrence.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<ul style="list-style-type: none"> The Performer must forward initial Performer- and FDA-issued draft minutes AND final minutes of any meeting with the FDA to BARDA within 2 business days of receipt. FDA-issued meeting minutes must be received in its original and unredacted form.
A7	Daily check in with BARDA	<p>Upon request of the Government, the Performer must participate in a daily check-in update with the project staff (via teleconference or email).</p> <p>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.</p> <p>Daily check-ins may occur on weekdays, excluding federal holidays.</p> <p>Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.</p>	<ul style="list-style-type: none"> A standing agenda must be used, to include key cost, schedule, 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
B1	Project Management Plan (PMP)	<p>The Project Management Plan (PMP) 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).</p> <p>The PMP may be a single detailed document or composed of one or more subsidiary planning documents. These additional planning documents provide guidance and direction for specific management, planning, and control activities such as schedule, cost,</p>	<ul style="list-style-type: none"> Performer must submit a PMP <ul style="list-style-type: none"> Within 30 calendar days after the initiation of the agreement period of performance Updates should be provided to reflect any key changes and reviewed at least annually.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>risk, staffing, change control, communications, quality, procurement, deployment, etc. Each of the subsidiary planning documents should be detailed to the extent required by the specific project.</p>	
B2	Product Development Plan – Seasonal and Pandemic Influenza	<p>The integrated Product Development Plan for seasonal and pandemic influenza vaccines must be inclusive of nonclinical and clinical activities performed and completed prior to an agreement award and those nonclinical, clinical, and manufacturing activities to be performed post-agreement award.</p> <p>The Plan must be a high-level overview and include the following elements:</p> <ul style="list-style-type: none"> • Gantt chart timeline or equivalent. • Description of the general clinical development plan including development and validation of clinical sample assays. • Description of the process development, scale-up of domestic vaccine manufacturing, and clinical and consistency lot manufacturing through to Process Performance Qualification (PPQ) process validation, clinical evaluation and FDA Center for Biologics Evaluation and Research (CBER) product licensure. • Description of product lot characterization, release, and stability assay development including assay specifications and qualification/validation. • Regulatory strategy master plan that focuses on the critical pathway to product licensure. Plan should achieve licensure for children aged 6 months and older, adults, and the elderly. • Risk mitigation plan that includes nonclinical and clinical activities and outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan must include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule, and performance. 	<ul style="list-style-type: none"> • Performer must submit a Product Development plan <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance • Updates should be provided to reflect any key changes and reviewed at least annually
B3	Product Development Plan – Emerging Pathogen(s)	<p>In consultation with BARDA, Performer must develop a product development plan through licensure for an mRNA vaccine for emerging pathogen(s). Plan should achieve licensure for children aged 6 months and older, adults, and the elderly. Plan should include the capabilities and timelines for objectives</p>	<ul style="list-style-type: none"> • Performer must submit a Product Development Plan <ul style="list-style-type: none"> ○ Within 90 calendar days after initiation of the period of performance of this module

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>previously described in Modules 4-7 of the Statement of Objectives, with the ability to achieve the objectives in those modules either domestically or internationally upon direction from BARDA.</p>	
B4	Nonclinical and Clinical Development and Regulatory Plan – Seasonal and Pandemic Influenza	<p>Develop a Clinical Development and Regulatory Plan for seasonal and pandemic influenza, to include</p> <ul style="list-style-type: none"> • A detailed summary of nonclinical studies including consultation(s) with the FDA 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. 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. Studies related to pandemic –like vaccine must be done using an mRNA vaccine developed for subtype and strain to be designated by BARDA (e.g., H5Nx, H7Nx, H9N2) 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 detailed description of regulatory activities must be integrated with all products, clinical testing and manufacturing activities using the most current and available information, including consultation with CBER. A risk assessment and mitigation plan 	<ul style="list-style-type: none"> • Performer must submit a Clinical Development and Regulatory plan for influenza <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance • Updates should be provided to reflect any key changes and reviewed at least annually

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>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 (EUA) 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.</p>	
B5	Rapid Pandemic Influenza Response Plan	<p>The Rapid Pandemic Influenza Response Plan should be written specifically for pandemic influenza vaccines during an emergency response. The plan should aim to meet the objectives and goals as outlined in the National Biodefense Strategy, including vaccine design, testing and authorization within 100 days, and production goals as outlined below. The plan will include clinical trial testing of candidate vaccines (safety and immunogenicity) to support authorization, 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:</p> <ul style="list-style-type: none"> • A plan with timelines for all clinical development and regulatory activities to be performed during a response to pandemic influenza as outlined in Module 2A 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 sequence availability for a pandemic influenza strain • A plan for quickly pivoting from commercial vaccine production to manufacturing, formulation, and fill/finish of up to 100 million vaccine doses within 130 days of recognition of a potential emerging pandemic influenza threat at domestic facilities in 	<ul style="list-style-type: none"> • Performer must submit a Clinical Development and Regulatory plan for influenza <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance • Updates should be provided to reflect any key changes and reviewed at least annually

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>compliance with FDA 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 to be operationalized in an emergency should be provided.</p> <ul style="list-style-type: none"> • A Gantt chart timeline or equivalent. Times should reflect the number of days after having a confirmed sequence to produce vaccines, begin clinical studies, manufacture product, and achieve authorization and/or licensure. <p>Description of a pandemic facility and/or operational management plan including change procedures from normal commercial manufacturing operations to pandemic operations.</p>	
B6	Emerging Pathogen Response Plan	<p>The Performer must develop an end-to-end Emerging Pathogen Response plan. The plan should assume prototype vaccine work has been completed and should aim to meet the objectives and goals as outlined in the National Biodefense Strategy, including vaccine design, testing and authorization within 100 days, and production goals as outlined below. The plan will include clinical trial testing of candidate vaccines (safety and immunogenicity) to support authorization, 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 should include, but not be limited to:</p> <ul style="list-style-type: none"> • A plan for achieving FDA authorization or approval for candidate mRNA vaccine within 100 days of recognition of a potential emerging pandemic threat. Plan should include the capabilities and timelines for objectives previously described in Modules 4-7 with the ability to perform the objectives in those 	<ul style="list-style-type: none"> • Performer must submit a Clinical Development and Regulatory plan for emerging pathogens <ul style="list-style-type: none"> ○ Within 90 calendar days after the initiation of the agreement period of performance • Updates should be provided to reflect any key changes and reviewed at least annually

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>modules either domestically or internationally upon direction from BARDA.</p> <ul style="list-style-type: none"> • A plan for quickly pivoting from commercial vaccine production to manufacturing, formulation, and fill/finish of up to 100 million vaccine doses within 130 days of recognition of a potential emerging pandemic threat at domestic facilities in compliance with FDA CGMP guidelines. This plan should include amount of domestic 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 to be operationalized in an emergency should be provided. • A plan for achieving regulatory authorization or approval for a candidate mRNA vaccine internationally to ensure products can be distributed and/or donated in areas where vaccine is needed beyond the United States. • Information leading to distribution readiness, including information needed to support the U.S. Centers for Disease Control and Prevention (CDC) Immunization Information Systems (IIS) data code set development. • A distribution plan for administering vaccines in accordance with CDC-defined population tiers and sub-tiers. • A description of the patient assistance program to be established upon commercialization of the vaccine. • A commercialization plan agreed to by the USG for transitioning vaccine to the commercial market, if applicable. Date of commercialization of a pandemic vaccine will be determined by the USG in consultation with the Performer. • A consumer communications plan agreed to in coordination with the USG that supports broad use of the product, such as direct to consumer advertising (as allowed by the FDA), creation of educational materials for patients and healthcare providers, etc. • A Gantt chart timeline or equivalent. Times should reflect the number of days after having a confirmed sequence to 	

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#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		produce vaccines, begin clinical studies, manufacture product, and achieve authorization and/or licensure.	
B7	Gantt Chart/Timeline	The Gantt Chart/Timeline should be detailed to the extent required by the specific project.	<ul style="list-style-type: none"> • Performer must provide at the first project meeting and must update no later than every 30 calendar days in PDF format.
B8	Communication Plan	<p>The Performer must develop and implement an effective Communication Plan that details the flow of information between BARDA, Performer, collaborators, vendors, and other organizations, including communications with, as appropriate, regarding label contents, expiry dating, healthcare provider educational materials.</p> <p>The Communication Plan must also include a press release review process.</p>	<ul style="list-style-type: none"> • Performer must submit a Communication Plan <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
B9	Performer Locations	<p>Using BARDA-defined template, the Performer must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location, to include subPerformers and critical vendors of reagents and supplies.</p> <p>Performers must include vendors for critical infrastructure protection.</p>	<ul style="list-style-type: none"> • Performer must submit Work Locations Report: <ul style="list-style-type: none"> ○ Within 5 business days after the initiation of the agreement period of performance ○ Within 30 business days after a substantive location or capabilities change • Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a PHE by the HHS Secretary or a PHE of International Concern (PHEIC) by the WHO
B10	Pandemic/PHE Facility and Operational Management Plan	Performer must develop a Pandemic Facility and Operational Management Plan, including change procedures from routine to pandemic operations and continuity of operations in the event of a declared pandemic/PHE emergency. Performer must identify critical infrastructure.	<ul style="list-style-type: none"> • Performer must submit Pandemic Management Plan: <ul style="list-style-type: none"> ○ Draft within 15 days of award ○ Final within 30 days of award
B11	Request for Information (RFI) Responses	<p>Upon request of the Government, the Performer must provide complete responses to ad hoc RFIs.</p> <p>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</p>	<ul style="list-style-type: none"> • Performer must submit an RFI response to BARDA by email within 24 hours after Performer receipt of the RFI.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		provide the response in both confidential and non-confidential formats.	
B12	Monthly & Annual Technical Progress Reports/Annual Meeting	<p>The Monthly and Annual Technical Progress reports must address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS), and Contract Performance Report (CPR) – or as applicable.</p> <ol style="list-style-type: none"> 1. An Executive Summary highlighting the progress, issues, and relevant Chemistry, Manufacturing, and Controls (CMC), 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: <ul style="list-style-type: none"> •Central Institutional Review Board (IRB) approval status •Site IRB approval status •Site information (FWA number, site type (e.g., commercial site, academic site), site activation status) •Number of subjects screened and enrolled by age, race, ethnicity, geographic distribution •Investigational Product status (receipt at depot and receipt on site) •Safety reporting (Serious Adverse Events) •Protocol deviations •Database management •Status of ancillary supplies, e.g., PPE, swabs, syringes, tubes on site •Specimen collection status <p>The Performer must inform BARDA of any upcoming site visits and/or audits of Contract Research Organization (CRO) facilities funded under this effort. BARDA reserves the right to accompany the</p>	<ul style="list-style-type: none"> •The Performer must submit monthly reports on the 15th day of the month covering the preceding month; Annual Reports submitted on the last calendar day of the month after each agreement anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable B13). The PAR and OIAO 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 OIAO and PAR within 24 hours of being notified of the event

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>Performer on site visits and/or audits of CROs as BARDA deems necessary.</p> <p>3. Progress in meeting agreement milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports must detail the planned and actual progress during the period covered, explaining any differences between the two and the corrective steps</p> <p>4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS</p> <p>5. A tracking log of FDA correspondence and progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission, and next steps</p> <p>6. Estimated and Actual Expenses</p> <ul style="list-style-type: none"> • This report must also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the 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 OTA0 are satisfied that the Performer's reporting is sufficient to convey this information, this section may be waived. <p>7. Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and other public-</p>	

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#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		facing material or information containing data generated under this agreement	
B13	Draft and Final Technical Progress Report	<p>A draft Final Technical Progress Report must contain a summation of the work performed and the results obtained over the entire agreement. This report must be in sufficient detail to fully describe the progress achieved under all milestones. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report must be duly marked as 'Draft.'</p> <p>The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire agreement Period of Performance. The final report must document the results of the entire agreement. The final report must be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the agreement.</p>	<ul style="list-style-type: none"> •The Performer must submit the Draft Final Technical Progress Report 75 calendar days before the end of the Period of Performance and the Final Technical Progress Report on or before the completion date of the Period of Performance •PAR will provide feedback on draft report within 21 calendar days of receipt, which the Performer must consider incorporating into the Final Report
B14	Integrated Master Schedule (IMS)	<p>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.</p>	<ul style="list-style-type: none"> •The Performer must submit the IMS in both PDF and an agreed-upon electronic format (e.g., Microsoft Project) to the PAR •The first Draft of the IMS is due within 30 business days after the initiation of the agreement period of performance •The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set •Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports •During a declared PHE, the Performer must submit the IMS within 10 business days after the initiation of the agreement period of performance, updates are due weekly, and any significant change (i.e., a change which would impact the schedule by greater than

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			one week) must be reported immediately to the PAR and/or designee
B15	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Performer must notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a Period of Performance extension. Performer must provide a high-level management strategy for risk mitigation.	<ul style="list-style-type: none"> The Performer must submit Deviation Notification and Mitigation Strategy at least 10 business days prior to the Performer anticipating the need to implement changes
B16	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.	<ul style="list-style-type: none"> Due within 48 hours of activity or incident or within 24 hours for a security activity or incident Email or telephone with written follow-up to PAR and OTAO Additional updates due to PAR and OTAO within 48 hours of additional developments Performer must submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues If corrective action is deemed necessary, Performer must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

Physical Inventory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
C1	Manufacturing Materials	<p>mRNA-based vaccine seed lots (e.g., CGMP plasmid DNAs) that are fully ready for large scale commercial production</p> <p>Investigational lots (mRNA, lipid nanoparticles, diluents, adjuvants) produced</p> <p>Relevant reference reagents as specified by BARDA</p> <p>In the case of a PHE, drug substance must be fill-finished into final containers as drug product with appropriate labels and packaging.</p>	<ul style="list-style-type: none"> All physical manufacturable deliverables should be accurately reflected in the BARDA dose tracker in a timely manner. Dose tracker must be updated once a week at a minimum. Batch records (MBRs), Certificate(s) of Analysis (CoA), Quality Disposition Letter (CoC), Product Safety Data Sheets, Sample labels and Lot Data for all CGMP batches should be shared with BARDA and Quality/Regulatory prior to product acceptance.

		<p>Performer and USG should have appropriate material agreements in place to allow vaccine use by the Government in future USG-led clinical trials and studies.</p> <p>Product must have authorizations/licensure to ensure the product can be distributed and/or donated internationally if requested</p>	
C2	Serum and Sample Repository – Animal Studies	<p>The Performer must establish and maintain a repository of serum and other appropriate samples (and their associated metadata) from animals vaccinated with any vaccine candidates.</p> <p>Samples must be shared for testing in laboratories designated by BARDA.</p> <p>Samples will be transferred to a BARDA centralized laboratory upon request for potential analyses and future use by the USG</p>	<ul style="list-style-type: none"> • Performer must provide specimen inventory reports from nonclinical 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.
C3	Specimen Collection for Future Use	<p>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 will be provided to BARDA based on the subjects' prior seasonal influenza vaccination history and stratified by age.</p> <p>Clinical samples from all subjects and timepoints 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.</p> <p>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.</p> <p>The intended use of these samples is to establish a repository of samples from multiple time points for future use in centralized immune assays and analysis. The repository is only available for storage of samples specifically for use in the</p>	<ul style="list-style-type: none"> • Performer must provide weekly specimen inventory reports during the course of the clinical trial(s). • 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.

		<p>centralized immune assays according to needs and requirements as determined by BARDA.</p> <p>The Performer must remove any personal identifying information (PII) from the samples and assign each with a unique subject identification number before transferring to BARDA. The Performer must provide a specimen disposition report prior to transferring the material to the repository. Testing on samples can include but will not be limited to in vitro biochemical, biophysical, and cell-based assays. BARDA will establish a Deliverables Table, Technology Transfer and Evaluation Agreement (TTEA) and Data Distribution Agreement (DDA) with appropriate partners as applicable (i.e., vaccine manufacturer, repository, testing labs, data analysis services), necessary to secure execution, timelines, materials and preserve intellectual property.</p>	
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Technical Reporting: Manufacturing

Technical Reporting: Manufacturing			
#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
D1	mRNA vaccine constructs	The Performer must design constructs for mRNA-based vaccines against influenza viruses and emerging pathogens, as requested, of pandemic potential for nonclinical studies and clinical trials. Subtype/strain selection must be at the discretion of BARDA.	<ul style="list-style-type: none"> •The Performer must submit proposed constructs prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide input within five (5) business days of receipt of construct design ○ Performer must respond in writing to BARDA comments and recommendations within five (5) business days of receipt and must be addressed prior to finalization ○ BARDA must approve the final construct design
D2	mRNA vaccine plasmid libraries or banks	The Performer must prepare mRNA vaccine plasmid libraries or banks that are suitable for commercial production for rapid response to influenza virus or emerging pathogen subtypes/strains of pandemic potential. Material should	Within 15 days after agreement with BARDA on the subtypes/strains to be produced

		enable rapid initiation of at-scale manufacturing.	
D3	Production of nonclinical lots of mRNA-based vaccines	The Performer will produce, characterize, and release nonclinical lots of the vaccine candidates under appropriate quality standards for use nonclinical, as necessary.	Within 30 days after notification from BARDA
D4	Manufacturing of clinical lots of mRNA vaccines	<p>The Performer must develop or leverage existing manufacturing processes and analytical methods to manufacture and supply investigational lots of mRNA vaccines for clinical trials.</p> <ul style="list-style-type: none"> • The clinical vaccine lots must be manufactured in accordance with CGMP under 21 CFR parts 201, 211, and 600. • The Performer must conduct lot release testing of the clinical lots per specifications agreed upon by the FDA and provide the testing data to BARDA. • Performer must initiate stability monitoring program to support clinical use. • Develop any novel potency testing as needed for antigens of interest. • Performer must conduct studies to ensure appropriate extraction and delivery of desired doses for the selected product, 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 preventive actions (CAPAs), and CoA available for review by BARDA. 	Clinical lot production must be finished within 50 days of recognition of a potential emerging pandemic threat.
D5	Large-scale manufacturing and distribution in response to an influenza PHE	<p>Performer must implement the manufacturing plan described in the Rapid Pandemic Influenza Response Plan for up to 100 million vaccine doses delivered within 130 days of recognition of a pandemic threat.</p> <ul style="list-style-type: none"> • 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 	Manufacturing of up to 100 million vaccine doses within 130 days of recognition of a potential emerging pandemic threat

		<p>CGMP under 21 CFR parts 210, 211, and 600.</p> <ul style="list-style-type: none"> • 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. • Ensure stored materials are compliant with the Performer's internal quality control system and are ready for use in further CGMP-governed manufacturing of clinical materials or licensed doses as directed by BARDA. • Propose a supply chain distribution for the product. • 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. 	
D6	Commercial-scale Manufacturing and distribution in Response to a non-influenza PHE	<p>Performer must implement the manufacturing plan described in the Emerging Pathogen Response Plan for up to 100 million vaccine doses within 130 days of recognition of a pandemic threat.</p> <ul style="list-style-type: none"> • 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. • 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. • Ensure stored materials are compliant with the Performer's internal quality control system and are ready for use in further CGMP-governed manufacturing of clinical materials or licensed doses as directed by BARDA. 	Manufacturing of up to 100 million vaccine doses within 130 days of recognition of a potential emerging pandemic threat

		<ul style="list-style-type: none"> • Propose a supply chain distribution for the product. • 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. 	
D7	Manufacturing Facility Plan	<p>The Performer must prepare a detailed Manufacturing Facility Plan describing the design, permit approval, retrofit/renovation, commissioning, qualification, and validation of a U.S.-based facility(s) to produce the Performer's vaccines. The Plan(s) must contain the following elements:</p> <ul style="list-style-type: none"> • Architectural/structural plans that include concept functional designs, descriptions, and diagrams of space requirements, adjacency plans, floor plans, mechanical/electrical/plumbing, equipment layouts, material, product and personnel flows, solid, liquid contaminated and other waste flows, and air balance description or diagram detailing zoning, pressurization, air flows and air quality classification. • Process and building/mechanical engineering including energy balances, utility flow diagrams, automation plan, equipment lists and a preliminary layout. • If retrofit/renovation is proposed, provide a retrofit/renovation schedule including permitting, installation, commissioning and installation/operational/performance qualification and a risk mitigation analysis. • A description of the manufacturing facility quality assurance and regulatory acceptance including quality systems, tech transfer plan, the validation master plan (VMP), and regulatory milestones towards facility approval. • Plans for supply chain management to ensure consistent production. • Environmental Health and Safety plans, including waste and hazardous material management. • Personnel training plans. 	<p>Performer must submit a Manufacturing Facility Plan</p> <ul style="list-style-type: none"> • Draft within 15 calendar days after the initiation of the agreement period of performance • BARDA will provide input within ten (10) business days of receipt • Performer must respond in writing to BARDA comments and recommendations within five (5) business days of receipt and must be addressed prior to plan finalization.

		<ul style="list-style-type: none"> • A comprehensive Business Continuity Plan. • A comprehensive communication and reporting plan detailing communication management between stakeholders and reporting mechanisms to track progress and address issues. • A Gantt chart or equivalent with the project timeline and key milestones outlines for various phases of facility design, construction and operation. • A detailed calculation of the additional production capacity in doses enabled by any retrofit/renovation as described in the plan. The calculation should include what the Performer considers the baseline capability expected to be available by pivoting commercial manufacturing toward emergency response as an initial assumption, so that the added capacity enabled through the proposed retrofit/renovation is clear. A timeline for operationalizing the additional capacity should be included. 	
D8	Supply Chain Resiliency Plan	<p>The Performer must develop and submit within 30 calendar days after the initiation of the agreement 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.</p> <p>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.</p> <p>Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling,</p>	<p>Due within 30 calendar days after the initiation of the agreement period of performance</p> <p>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.</p>

		<p>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.</p> <p>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.</p> <ul style="list-style-type: none"> 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 reusable 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. <p>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.</p> <ul style="list-style-type: none"> 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 	
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		<p>communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.</p> <p>Reports for critical items must include the following information:</p> <ul style="list-style-type: none"> a. Critical Material b. Vendor c. Supplier, Manufacturing / Distribution Location d. Supplier Lead Time e. Shelf Life f. Transportation / Shipping restrictions <p>The OTA0 and PAR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government.</p>	
D9	Product Development Source Material Report	<p>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.</p> <p>In the event of a PHE, 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:</p>	<ul style="list-style-type: none"> • Performer must submit a Product Development Source Material Report <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance ○ Within 30 calendar days of changes made to sources and/or materials ○ On the 6th month agreement anniversary • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, Performer must address all concerns raised by BARDA in writing • The Performer must submit Product Development and Source Material report via spreadsheet

		<ul style="list-style-type: none"> • Manufacturing locations • Seed development or other starting material manufacturing • Critical materials, consumables, and components • Storage/inventory of starting materials 	
D10	Manufacturing Reports and Projections	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • Storage/inventory of ancillary materials (e.g., vials, needles, syringes) • Shipment of ancillary materials (e.g., vials, needles, syringes) • Disposal of ancillary materials (e.g., vials, needles, syringes) • 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 • 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. <p>In the event of a PHE, HHS may require daily reporting of manufacturing campaigns during response operations.</p>	<ul style="list-style-type: none"> • Performer must update the “Dose Tracking Template” at minimum weekly during manufacturing campaigns and daily during response operations (i.e., where a PHE 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) as agreed to by USG and Performer.
D11	Manufacturing Campaign Reports	<p>In the event of a <u>large-scale</u> manufacturing campaign, the Performer must provide Manufacturing Campaign</p>	<ul style="list-style-type: none"> • Performer must submit Manufacturing Reports at least 15 business days prior to

		<p>Reports or Quarterly Manufacturing Reports to BARDA as described under deliverable D10 Manufacturing Reports and Projections. The Manufacturing Campaign Reports should include a listing of all drug substance, adjuvants, and drug product lots produced. The report includes lot number and history, manufacturing site, date of manufacture, and lot disposition including lots that are quarantined for investigation or those lots rejected. Information on the reasons for lot quarantine or rejection should be included in the report. Manufacturing reports also include major deviations, change controls, CAPAs, PPQ reports, CoAs, batch reports, storage location, purity, potency, yield.</p> <p>If Manufacturing Campaign Reports are provided to FDA, the Performer must provide Reports to BARDA for review and comment prior to submission to FDA.</p> <p>The PAR and OTAO reserve the right to request within the Period of Performance a non-proprietary Manufacturing Campaign Report for distribution within the USG.</p>	<p>FDA submission in an agreed-upon electronic format.</p> <ul style="list-style-type: none"> • 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.
D12	Supply Chain and Distribution Tracking ⁴	<p>Distribution Concept of Operations. BARDA, ASPR, CDC, and Medical Countermeasure (MCM) Manufacturers play an important role in the distribution of vaccines to the American people under a nationwide response. BARDA will work with the manufacturer 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 CDC for allocation and ordering by the jurisdiction public health departments. This information will be returned to BARDA as CDC replenishment orders (CDC Purchase Order [PO]) on a daily basis with shipping instructions on where to send final drug product.</p> <p>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</p>	<p>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:</p> <ul style="list-style-type: none"> • Shipment Plan to include detailed timelines between PO receipt and delivery of final drug product at the distribution center. Upon USG request, Performer must support expedited shipments. Ultra-cold 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 be provided by the Performer) 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, Contract

		<p>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.</p>	<p>Manufacturing Organization (CMO), storage, and distribution locations:</p> <ul style="list-style-type: none"> • Head of Manufacturing • Production Planning • Logistics • Distribution • Labeling <ul style="list-style-type: none"> • Provide vaccine labeling, packaging, and distribution information as soon as it becomes available. Plan to support CDC IIS codeset development. At a minimum, provide the following: <ul style="list-style-type: none"> • Material Safety Data Sheet (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 data, 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 • Vaccine products should be packaged in 100-dose units to facilitate pick/pack process. • Send electronic/scanned copies of all bulk shipment related documents to the PAR for three-way matching on the day shipment occurs.
D13	Packing List	Performer must include the following data elements according to the Drug	

		<p>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):</p> <ul style="list-style-type: none"> • Transaction Information (TI), Transaction History (TH), Transaction Statement (TS) • PO number (which BARDA will provide at the time the order is submitted) • Agreement number • Copy of the MSDS (with QR code) in the packing list envelope 	
D14	Advance Shipment Notices (ASNs)	<p>Performer must transmit bulk shipment ASNs to CDC via Electronic Data Interchange (EDI)</p> <p>Rationale: Required for receiving at centralized distributor and for tracking shipment in real time.</p>	<p>Send EDI 856 Advanced Shipment Notice for all products shipped to a USG directed location. CDC will provide EDI mapping specifications that include the CDC generated PO number</p>

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Technical Reporting: Nonclinical Studies

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
E1	Nonclinical Study Protocols	The Performer must submit Draft and Final Nonclinical Study Protocols to OTAO and PAR.	<ul style="list-style-type: none"> •The Performer must submit Draft Nonclinical Study Protocols to PAR electronically prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 business days of receipt of draft protocol ○ Performer must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol ○ PAR must approve the final protocol •The Performer must submit Final Nonclinical Study Protocols to PAR electronically no later than 10 business days prior to FDA submission.
E2	Draft and Final Nonclinical Study Report(s)	Performer must provide Draft and Final Nonclinical Study Reports to BARDA for review and comment.	<ul style="list-style-type: none"> •Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA •The Performer must submit 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 Nonclinical Study Reports within 15 business days after the submission •Final report due 30 calendar days after receiving comments on the Draft Final Report for Nonclinical Studies; If corrective action is recommended, Performer must address all concerns raised by BARDA in writing •Performer must consider revising reports to address BARDA's recommendations prior to FDA submission
E3	Nonclinical Study Final Data	BARDA must have access to methods and reagents. ^{5,6}	<ul style="list-style-type: none"> •Performer must submit at least 15 business days prior to agreement end date. Partial datasets may also be requested for delivery

⁵ BARDA may explicitly require data as a deliverable prior to award. The Government unlimited rights in all other data delivered under the agreement. If Performers disagree, BARDA can request "limited rights" to specific data. Under limited rights, the Government can evaluate data, but not use it to manufacture or disclose.

⁶ Language may be included that gives the Performer notice that the Government will have access to methods and reagents. This would be included as an "Advance Understanding" in both the solicitation and agreement. The OTAO should assist in drafting the requirement.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Submission Package	<p>BARDA must have unlimited rights to all nonclinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this agreement.⁷</p> <p>At BARDA's request, the Performer must provide any nonclinical-related agreement deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the nonclinical-related deliverables, as BARDA deems necessary.</p>	prior to submission of the Final Data Submission Package.
E4	Potency Test Protocols and Data	<p>Develop potency testing as needed for antigens of interest</p> <p>Provide a testing plan timeline aligned to the ability to achieve authorization or approval for a candidate mRNA vaccine within 100 days of recognition of a potential emerging pandemic threat</p>	<ul style="list-style-type: none"> • The Performer must submit Potency Test Protocols to OTAR electronically prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 business days of receipt of draft protocol ○ Performer must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol.
E5	Emerging Pathogen Prototype Development Studies	<p>The Performer must develop and execute studies to enable prototype vaccine development studies for emerging pathogen(s). Studies must include:</p> <ul style="list-style-type: none"> • Studies to identify effective potential targets for design of vaccine candidates in coordination with BARDA • Immunogenicity studies of candidate vaccines to enable down-selection for a lead candidate • Studies to identify correlates/surrogates of protection 	

⁷ The Government has unlimited rights to data first produced under the agreement, and the Performer the ability to copyright the data. This means that the Government only has unlimited rights in data that was first produced; an Agreement is able to restrict access to assay data that was produced on their own.

Technical Reporting: Clinical Trials

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
F1	Clinical Trial Protocols	<p>The Performer must submit draft and final clinical trial protocols to OTAO and PAR.</p> <p>A plan to assess the duration of immune response must be included in the protocols.</p> <p>The Statistical Analysis Plan (SAP) must be reviewed by BARDA prior to data analysis.</p>	<ul style="list-style-type: none"> •The Performer must submit Draft clinical trial protocols to PAR electronically prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 business days of receipt of draft protocol. ○ Performer must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol. ○ PAR must approve the final protocol. •The Performer must submit Final clinical trial protocols to PAR electronically no later than 10 business days prior to FDA submission.
F2	Clinical Trial Documentation ⁸	<p>The Performer must provide the following documents for any portion of a study funded under this agreement:</p> <ul style="list-style-type: none"> •Investigational Product Accountability Plan •Study Supplies Procurement Plan •Site selection questionnaire •Overall Recruitment and Retention plan •Informed Consent Form (ICF) template, including consent for sharing clinical samples with BARDA for future use •eConsent •Data Management Plan •Data Validation/Quality Plan •Statistical Analysis Plan •Sample/Specimen Management Plan •Diversity inclusion plan to enroll based on U.S. demographic based on most recent census •Investigator Brochure •eCRF •Community engagement materials, posters, media advertisements, animations, graphics, etc. •Clinical Trial Agreements •Monitoring Plan 	<ul style="list-style-type: none"> •The Performer must submit Draft study documents to PAR electronically prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 business days of receipt of draft document ○ Performer must respond in writing to BARDA comments and recommendations prior to finalization of protocol. •The Performer must submit Final study documents to PAR electronically no later than 10 business days prior to FDA submission. •Performer must submit draft Statistical Analysis Plan no later than 20 business days after protocol is finalized. The final Statistical Analysis Plan must be submitted 5 business days prior to study database unblinding. •Performer must submit final version Investigational Product and Clinical Supplies Management Plan at least 6 weeks prior to investigational product shipments to clinical sites. •Performer must retain the capability to procure, ship, deliver, install, and train on the use of all required supplies, including, but not limited to, documents, files, and equipment.

⁸ To be added at the discretion of the OTAO and the PAR and PCT as appropriate for the agreement, e.g., if the clinical trial utilizes NIH-funded clinical sites: *The Performer must participate in and provide information to a USG-oversight and review committee(s) outside of BARDA. The Performer must submit protocol, ICF, and IB to a Protocol Science Review Committee (PSRC) four (4) business days before the review to the PSRC Chair and USG-designated reviewers.*

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<ul style="list-style-type: none"> •Safety Monitoring Plan (processes to provide 24-7 pharmacovigilance and safety monitoring) •Serious Adverse Events Reconciliation Standard Operating Procedure (SOP) (if safety database separates from clinical database) •Processes to manage and support an independent Data and Safety Monitoring Board (DSMB) •DSMB Charter •DSMB template reports and DSMB reports •Draft and Final Tables, Listings, and Figures (TLFs), ad hoc TLFs •Plan for notifying participants of his/her treatment assignment •Essential Regulatory Documents that demonstrate compliance with the standards of ICH E6 (R2) Good Clinical Practice and with all applicable regulatory requirements •Pharmacy Manual <p>The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during clinical site monitoring visits.</p>	<ul style="list-style-type: none"> •Final TLFs must be submitted to the PAR 3 weeks after database lock.
F3	ClinicalTrials.Gov Posting and Results Reporting	Per clinicaltrials.gov registration and reporting requirements.	<ul style="list-style-type: none"> •Performer must post results: <ul style="list-style-type: none"> ○ 3 months from any interim analysis ○ 3 months from primary analysis ○ 3 months from final analysis
F4	Draft and Final Clinical Study Report(s)	Performer must provide Draft and Final Clinical Study Reports to BARDA for review and comment.	<ul style="list-style-type: none"> •Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA •The Performer must submit 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 •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

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<ul style="list-style-type: none"> • Performer must consider revising reports to address BARDA's recommendations prior to FDA submission
F5	Project-Specific First Site Activated for First Subject First Visit	Performer should have all pre-study planning complete and be ready to enroll subjects.	<ul style="list-style-type: none"> • After IND is in effect, within five days of IRB approval
F6	Clinical Report During Active Enrollment Periods ⁹	<p>The Performer must submit daily the following data specifications during active clinical trial enrollment:</p> <p>Study-level specs:</p> <ul style="list-style-type: none"> • Study ID, name, and sponsor • Target and actual start date • Reporting period • Target and actual number screened and enrolled • File date <p>Site-level specs (for each study):</p> <ul style="list-style-type: none"> • Site ID and status • PI name • Site name and address (including country, state, zip) • Site latitude and longitude • Site enrollment status • Reporting period • Target and actual number screened and enrolled • File date <p>Subject-level specs (for each study site):</p> <ul style="list-style-type: none"> • Subject unique identifier • Subject age category, gender, comorbidities (categorized), ethnicity, and race • First and second boost dose administered (with dates) • Subject reached endpoint (with date) • Subject completed follow-up visits (with date) • Participant dropped from study (with date and reason) • File date 	<ul style="list-style-type: none"> • 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.

⁹ 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
		Clinical Report submission must be by electronic transfer, e.g., from Performer Electronic Data Capture (EDC) system/Interactive Voice Response System (IVRS) to USG.	
F7	Access to Electronic Systems Used in Trial Conduct	The Performer must provide access to systems used in trial conduct.	<ul style="list-style-type: none"> •Due within 20 calendar days of PAR request, no later than ten calendar days prior to first site activated
F8	Blinded Safety Reports, Medical Data Listing, CIOMS Report, Pharmacovigilance Database Listing	The Performer must submit blinded safety data reports, medical data listings, Council for International Organizations of Medical Sciences (CIOMS) reports and listings from the Pharmacovigilance database.	<ul style="list-style-type: none"> •Performer must provide weekly blinded safety data reports and medical data listings during the treatment period. •CIOMS reports and data listing from Pharmacovigilance database will be provided to the Protocol Safety Review Team (PSRT) for review. Meeting frequency may be reduced during the follow-up phase.
F9	Clinical Trial Final Study Package	<p>BARDA must have unlimited rights to all clinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this agreement..</p> <p>At BARDA's request, the Performer must provide any clinical-related agreement deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the clinical-related deliverables, as BARDA deems necessary.</p> <p>If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).</p>	<ul style="list-style-type: none"> •Performer must submit the Clinical Trial Final Study Package at least 15 business days prior to agreement end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.
F10	Data Exchange Package(s) Submitted to Regulatory Agency(s)	As part of Final or Draft Submission Package(s), upon BARDA request, and also as part of deliverables, the Performer must provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), Analysis Datasets (e.g., CDISC-compliant ADaM SAS XPT datasets), and any additional documents including but not limited to Reviewer's Guide (PDF), SDTM annotated CRF(s) (PDF), and data definition file(s) (XML) to BARDA. Other data exchange standards or file formats might be used if discussed with and agreed by BARDA. The Performer must	<ul style="list-style-type: none"> •Performer must provide the Technical Documents and/or datasets within 20 business days of request from the OTAO or PAR

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>provide the software programs (e.g., SAS programs, R programs) used to create any AdAM datasets and generate tables and figures associated with all analyses, including primary and secondary efficacy analyses.</p> <p><i>List of abbreviations: XPT = SAS Transport Format (XPORT) Version 5; PDF = Portable Document Format; XML = Extensible Mark-up Language; CDISC = Clinical Data Interchange Standards Consortium</i></p>	
F11	Clinical Trial Datasets	Performer must make clinical trial datasets publicly available.	<ul style="list-style-type: none"> • Performer must post clinical trial datasets on a web-based platform easily accessible by the public: <ul style="list-style-type: none"> ○ 3 months from any interim analysis ○ 3 months from primary analysis ○ 3 months from final analysis
F12	Additional Data Package(s)	Upon request, the Performer must provide raw data, tabulation Data and/or analysis data in a BARDA-agreed-upon format and supporting documents that might be including but not limit to the list of files in package, technical specification documents, data analysis programs. Data exchange standards and file formats must be discussed and agreed upon with BARDA.	<ul style="list-style-type: none"> • Performer must provide the data package(s) within 20 business days of request from the OIAO or PAR

Quality Assurance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
G1	Quality Management Plan (QMP)	<p>Performer must develop an overall project Quality Management Plan to include a description of all quality activities and personnel involved in ensuring all activities are conducted and data is maintained under CGXP, and all products are managed to ensure that CGMP requirements are met.</p> <p>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.</p>	<ul style="list-style-type: none"> • Performer must submit a Quality Management Plan <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the agreement period of performance ○ On the 6th month agreement anniversary to include any updates.
G2	BARDA Audit	<p>Performer must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by HHS. If BARDA, the Performer, or other parties identify any issues during an audit, the Performer must capture the issues, identify potential solutions and submit a report to BARDA detailing the finding and corrective action(s).</p> <p>HHS reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this agreement and all records related to the manufacture, testing (including but not limited to analytical testing, nonclinical study, clinical trial), and storage of the product.</p> <p>The Performer must allow for up to four (4) USG Quality representative(s) to conduct an audit.</p>	<ul style="list-style-type: none"> • If issues are identified during the audit, Performer must submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit report • PAR and OTAO will review the report and provide a response to the Performer within 10 business days • Once corrective action is completed, the Performer will provide a final report to BARDA
G3	FDA Inspections/Site visits	<p>In the event of an FDA inspection that occurs in relation to this agreement and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this agreement, including, but not limited to clinical trials and manufacturing facilities, the Performer must provide the USG with an exact copy (non-redacted) of the FDA Form 483 or summary and the Establishment Inspection Report (EIR). The Performer must</p>	<ul style="list-style-type: none"> • 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 agreement or for this product within 1

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>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 agreement or for this product.</p> <p>The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during the opening, any daily debriefs, and the final debrief by the regulatory inspector.</p>	<p>business day of receiving correspondence from the FDA, a subPerformer, or third party</p> <ul style="list-style-type: none"> • Within 10 business days of inspection report, Performer must provide OTAO with a plan for addressing areas of non-conformance, if any are identified
G4	Quality Assurance (QA) Audits and SubPerformer Monitoring Visits	<p>BARDA reserves the right to participate in QA audits performed by the Performer. Upon completion of the audit/site visit the Performer must provide a report capturing the findings, results and next steps in proceeding with the 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.</p> <p>The Performer must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, including manufacturing person in plant, at nonclinical sites, at clinical sites, CROs, and any other clinical vendor involved in the conduct of the nonclinical study or clinical trial under agreement.</p>	<ul style="list-style-type: none"> • Performer must notify OTAO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subPerformers. • 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 CAPAs to address all findings in the report. • 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.
G5	Project Risk Management Plan (RMP)	<p>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.</p>	<ul style="list-style-type: none"> • A Draft is due within 45 calendar days after the initiation of the agreement period of performance; updates to the RMP are due concurrent with Monthly Technical Progress Reports, but may be communicated more frequently. The Performer may choose to notify the government up to two times every three months if there are no changes from

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<p>the prior submission, and not submit an update</p> <ul style="list-style-type: none"> •BARDA will provide Performer with a list of concerns in response plan submitted •Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns •The Performer must submit updates at minimum of every three months.
G6	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 agreement.	<ul style="list-style-type: none"> •The Performer must respond to updates and inquiries within 5 business days of receiving the draft Quality Agreement
G7	Vendor Managed Inventory (VMI)	Performer must draft a VMI Plan that defines all aspects of VMI build-up, maintenance, and deployment.	<ul style="list-style-type: none"> •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
G8	Animal Model or Other Technology Transfer Package	Performer must provide Animal Model or Other Technology Transfer Package containing relevant methodology and data sufficient to enable other practitioners in the field to successfully replicate experimental conditions developed and tested with USG support	<ul style="list-style-type: none"> •Performer must provide a draft development plan within 20 business days of execution of this module or PAR/OTAO request •Performer must revise the plan to address BARDA's concerns, recommendations and/or requests for additional detail
G9	Improved RNA constructs	<p>Performer will develop and provide constructs that contain modifications (e.g., better caps, modified bases, UTR sequences, polyA tail; SAM or circular RNA constructs) to existing mRNA constructs. These modifications should provide improvements in characteristics including, but not limited to: vaccine platform efficacy, breadth, accessibility, durability, stability, or reactogenicity.</p> <p>Improved RNA constructs may also include developing and providing combination products allowing for co-formulated mRNA vaccines that protect against multiple pathogens</p>	<ul style="list-style-type: none"> •Performer must provide a draft development plan within 20 business days of execution of this module or PAR/OTAO request •Performer must revise the plan to address BARDA's concerns, recommendations and/or requests for additional detail

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
G10	Improved delivery systems	Performer will develop and provide new delivery systems for RNA vaccines (e.g., LNP composition and properties changes, route of delivery innovations, adjuvants) to existing vaccine constructs. These modifications should provide improvements in characteristics including, but not limited to: vaccine platform efficacy, breadth, accessibility, durability, or reactogenicity.	<ul style="list-style-type: none"> • Performer must provide a draft development plan within 20 business days of execution of this module or PAR/OTAO request • Performer must revise the plan to address BARDA's concerns, recommendations and/or requests for additional detail
G11	Process Innovations	Performer will develop and provide innovations and enhancements to the platform process and analytics that improve quality, cycle time, control, product stability, scaling, vaccine deployment times, product storage, or characterization of critical quality attributes.	<ul style="list-style-type: none"> • Performer must provide a draft development plan within 20 business days of execution of this module or PAR/OTAO request • Performer must revise the plan to address BARDA's concerns, recommendations and/or requests for additional detail
G12	Assay Innovations	Performer will develop and provide innovations and enhancements to assays necessary for vaccine platform innovation, including but not limited to: potency assays, assays to establish novel correlates of protection, immunogenicity assays.	<ul style="list-style-type: none"> • Performer must provide a draft development plan within 20 business days of execution of this module or PAR/OTAO request • Performer must revise the plan to address BARDA's concerns, recommendations and/or requests for additional detail
G13	Technical Documents	<p>Upon request, Performer must provide OTAO and PAR with deliverables from the following activities: quality agreements between Performers 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.</p> <p>The OTAO and PAR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the Government¹⁰.</p>	<ul style="list-style-type: none"> • 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
G14	Publications	The Performer must submit any manuscript, scientific meeting abstract, poster,	<ul style="list-style-type: none"> • Performer must submit all manuscript or scientific meeting abstracts to PAR and

¹⁰ Please see footnotes 5, 6, and 7 under Technical Reporting: Nonclinical Studies.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>presentation, and any other public-facing material or information disseminated outside the purview of other deliverables, containing data generated under this agreement, to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in agreement per BARDA's direction.</p>	<p>OTAO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts, posters, or any other material</p> <ul style="list-style-type: none"> • Performer must address in writing all concerns raised by BARDA in writing • Final submissions must be submitted to BARDA concurrently or no later than within one (1) calendar day of its submission • Performer must list all publication material in the Monthly Technical Progress Report
G15	<p>Performer Clinical Publication Timeline and USG Right to Publish Data</p>	<p>The Performer and Government are committed to transparent and timely publication of clinical trial data to ensure rapid distribution of information during a PHE.</p> <p>Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this agreement and consistent with Good Publications Practices. Sponsor must submit clinical study primary endpoint analysis for publication to a peer-reviewed journal.</p> <p>Within 90 days of the of study end date [last subject last visit] for studies funded in part or whole under this agreement and consistent with Good Publication Practices, Sponsor must submit clinical study data for publication to a peer-reviewed journal.</p> <p>If the Performer does not elect to publish data, Performer must 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.</p>	<ul style="list-style-type: none"> • 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 agreement.
G16	<p>Performer Nonclinical Publication Timeline and USG Right to Publish Data</p>	<p>The Performer and Government are committed to transparent and timely publication of nonclinical data to ensure rapid distribution of information, particularly during a PHE.</p>	<ul style="list-style-type: none"> • 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.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>Within 90 days of the of study end date [audited or quality-controlled draft final report prepared and reviewed by the Government] for studies funded in part or whole under this agreement and consistent with Good Publication Practices, Sponsor must submit nonclinical study data for publication to a peer-reviewed journal.</p> <p>If the Performer does not elect to publish data, Performer must provide 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.</p>	<ul style="list-style-type: none"> •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 agreement.

Regulatory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
H1	Regulatory Strategy	<p>The Performer must provide a Regulatory Strategy that outlines the regulatory strategy for FDA licensure and EUA if applicable, including the CMC and clinical development plans, for the product.</p> <p>The Regulatory Strategy should also outline the plan for achieving licensure/authorization for candidate vaccines internationally to ensure the products can be distributed and/or donated internationally. The strategy must include information leading to commercialization and distribution readiness, and information needed to support the CDC IIS data code set development.</p>	<ul style="list-style-type: none"> •The Performer must submit a Draft upon request of the PAR; updates to the Regulatory Strategy must be submitted concurrently with Monthly Technical Progress Reports and address all products under development. The Performer may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update •BARDA will provide Performer with a list of concerns in response to plan submitted •Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns
H2	FDA Correspondence	<p>The Performer must memorialize all original and unredacted correspondence between Performer and FDA and submit to BARDA, including formal and informal emails, correspondence, telephone calls, and official information requests (IRs).</p>	<ul style="list-style-type: none"> •Performer must provide copies of all original and unredacted FDA correspondence within 2 business days of correspondence
H3	FDA Submissions	<p>The Performer must submit and maintain all the regulatory submissions to the FDA.</p>	<ul style="list-style-type: none"> •Performer must submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission •BARDA will provide feedback to Performer within 10 business days of receipt

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>The Performer must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA.</p> <p>Performer must provide BARDA with an electronic copy of the final FDA submission. All documents must be duly marked as either "Draft" or "Final."</p>	<ul style="list-style-type: none"> •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
H4	WHO Submissions	<p>The Performer must serve as the regulatory product sponsor and be responsible for all documents and submissions necessary to enable a World Health Organization Emergency Use Assessment and Listing</p>	<ul style="list-style-type: none"> • Performer must submit draft WHO submissions to BARDA at least 15 days prior to WHO 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 WHO submissions to BARDA concurrently or within no later than five (5) calendar days of submission.

SOLICITATION

Press Releases

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
11	Press Releases	Performer agrees to accurately and factually represent the work conducted under this agreement in all press releases.	<ul style="list-style-type: none"> • Performer must submit to the PAR an advance copy of any press release to this agreement no fewer than 5 business days prior to the issuance of the press release. Performer must also send the advance copy to the OTAO for awareness • If corrective action is required, the Performer agrees to accurately and factually represent the work conducted under this agreement in all press releases • The Performer must submit any final press release to BARDA no later than one (1) calendar day prior to its release

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

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

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Monthly Reports which include both Technical Status and Business Status Reports (due the 15th of each month), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

RRPV Milestone Payment Schedule Example

RRPV Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	\$20,000		\$20,000
2	N/A	Monthly Report (Technical and Business Reports)	1/15/2020	\$ -		\$ -
3	N/A	Monthly Report (Technical and Business Reports)	2/15/2020	\$ -		\$ -
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)	3/15/2020	\$ -		\$ -
7	N/A	Monthly Report (Technical and Business Reports)	4/15/2020	\$ -		\$ -
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)	5/15/2020	\$ -		\$ -
10	N/A	Monthly Report (Technical and Business Reports)	6/15/2020	\$ -		\$ -
11	N/A	Monthly Report (Technical and Business Reports)	7/15/2020	\$ -		\$ -
12	N/A	Monthly Report (Technical and Business Reports)	8/15/2020	\$ -		\$ -

13	N/A	Monthly Report (Technical and Business Reports)	9/15/2020	\$ -		\$ -
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)	11/15/2020	\$ -		\$ -
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)	12/15/2020	\$ -		\$ -
21	8	1 st subject screened, randomized, and enrolled in study	1/1/2021	\$150,000	\$187,457	\$337,457
22	N/A	Monthly Report (Technical and Business Reports)	1/15/2021	\$ -		\$ -
23	N/A	Monthly Report (Technical and Business Reports)	2/15/2021	\$ -		\$ -
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)	3/15/2021	\$ -		\$ -
26	N/A	Monthly Report (Technical and Business Reports)	4/15/2021	\$ -		\$ -
27	N/A	Monthly Report (Technical and Business Reports)	5/15/2021	\$ -		\$ -

28	10	Assess potential toxicology	6/1/2021	\$157,829		\$157,829
29	N/A	Monthly Report (Technical and Business Reports)	6/15/2021	\$ -		\$ -
30	N/A	Monthly Report (Technical and Business Reports)	7/15/2021	\$ -		\$ -
31	N/A	Monthly Report (Technical and Business Reports)	8/15/2021	\$ -		\$ -
32	N/A	Monthly Report (Technical and Business Reports)	9/15/2021	\$ -		\$ -
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)	11/15/2021	\$ -		\$ -
36	N/A	Monthly Report (Technical and Business Reports)	12/15/2021	\$ -		\$ -
37	N/A	Monthly Report (Technical and Business Reports)	1/15/2022	\$ -		\$ -
38	N/A	Monthly Report (Technical and Business Reports)	2/15/2022	\$ -		\$ -
39	12	Electronic Report Forms Developed	3/1/2022	\$315,658	\$187,457	\$503,115
40	N/A	Monthly Report (Technical and Business Reports)	3/15/2022	\$ -		\$ -
41	N/A	Monthly Report (Technical and Business Reports)	4/15/2022	\$ -		\$ -

42	N/A	Monthly Report (Technical and Business Reports)	5/15/2022	\$ -		\$ -
43	N/A	Monthly Report (Technical and Business Reports)	6/15/2022	\$ -		\$ -
44	N/A	Monthly Report (Technical and Business Reports)	7/15/2022	\$ -		\$ -
45	13	Complete 100% patient enrollment	8/1/2022	\$315,658	\$187,457	\$503,115
46	N/A	Monthly Report (Technical and Business Reports)	8/15/2022	\$ -		\$ -
47	N/A	Monthly Report (Technical and Business Reports)	9/15/2022	\$ -		\$ -
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.

6.0 Intellectual Property, Data Rights, and Copyrights

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

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

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

No.	Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights	Name of Organization Asserting Restrictions	Deliverables Affected
1					
2					
3					
4					

Attachment 4 – Program/Project Management Plan Template

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

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

Attachment 5 – ASPR Security Requirements

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

1. Security Reporting Requirements

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

2. Supply Chain Resiliency Plan

In the event the scope of this award is amended to support manufacture of product fit for human use (at a minimum, manufacturing under GMP)), the contractor shall develop and submit to the PAR and PAO, **no later than 90 calendar days prior to GMP manufacture**, a comprehensive Supply Chain Resiliency Program Plan 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.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall 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 shall 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 shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
- c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall 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 contractor shall 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 shall be understood and communicated to the Contracting Officer or the Contracting Officer's Representative as necessary.
- b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should 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 CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

3. Manufacturing Data Requirements

The Performer shall submit within 30 calendar days after agreement award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Performer to be used to submit such data which would include but not be limited to the following:

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

- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

4. Performer Locations

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

Performer will submit a Work Locations Report:

- Within 5 business days after agreement award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

5. Operational Security (OPSEC)

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

6. Security Plan

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

- a. The Government will perform an internal review in detail and submit comments within ten (10) business days to the PAO and PAR to be forwarded to the Performer. The Performer

shall review the Draft Security Plan comments and submit a Final Security Plan to the U.S. Government within ten (10) calendar days after receipt of the comments.

- b. The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
- c. Upon completion of initiating all security measures, the Performer shall supply to the PAO and PAR a letter certifying compliance to the elements outlined in the Final Security Plan.

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

Security Requirements:

1. Facility Security Plan	
<p>Description: As part of the partner facility’s overall security program, the performer shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the agreement will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:</p>	
Security Administration	<ul style="list-style-type: none"> • organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Physical Security Policies and Procedures	<ul style="list-style-type: none"> • internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers

	<ul style="list-style-type: none"> • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	<ul style="list-style-type: none"> • identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none"> • intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination

	<ul style="list-style-type: none"> • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
<p align="center">2. Site Security Master Plan</p> <p>Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.</p>	
<p align="center">3. Site Threat / Vulnerability / Risk Assessment</p> <p>Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.</p>	
<p align="center">4. Physical Security</p> <p>Description:</p>	
<p>Closed Circuit Television (CCTV) Monitoring</p>	<ul style="list-style-type: none"> a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the agreement. c) Video recordings must be maintained for a minimum of 30 days.

	<ul style="list-style-type: none"> d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the agreement. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	<ul style="list-style-type: none"> a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	<ul style="list-style-type: none"> a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	<ul style="list-style-type: none"> a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the agreement are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.).

	<ul style="list-style-type: none"> d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	<ul style="list-style-type: none"> a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.

5. Security Operations	
Description:	
Security Management	<ul style="list-style-type: none"> a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subperformer compliance with all Government security requirements.
6. Information Security	
Description:	
Physical Document Control	<ul style="list-style-type: none"> a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
7. Information Technology & Cybersecurity	
Description:	
Identity Management	<ul style="list-style-type: none"> a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk.

	<p>f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes.</p> <p>g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)</p>
Access Control	<p>a) Limit information system access to authorized users.</p> <p>b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access.</p> <p>c) Limit physical access to information systems, equipment, and server rooms with electronic access controls.</p> <p>d) Limit access to/ verify access to use of external information systems.</p>
Training	<p>a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.</p>
Audit and Accountability	<p>a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months.</p> <p>b) Ensure the actions of individual information system users can be uniquely traced to those users.</p> <p>c) Update malicious code mechanisms when new releases are available.</p> <p>d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.</p>

Configuration Management	<ul style="list-style-type: none"> a) Establish and enforce security configuration settings. b) Implement sub networks for publicly accessible system components that are physically or logically separated from internal networks.
Contingency Planning	<ul style="list-style-type: none"> a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	<ul style="list-style-type: none"> a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	<ul style="list-style-type: none"> a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	<ul style="list-style-type: none"> a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.

Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
8. Transportation Security	
Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	<ul style="list-style-type: none"> a) Drivers must be vetted in accordance with Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	<ul style="list-style-type: none"> a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	<ul style="list-style-type: none"> a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. <ul style="list-style-type: none"> • Tamper resistant seals must be verified as “secure” after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport,

	<p>and any deviations from planned routes should be investigated and documented.</p> <p>c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.</p>
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9. Security Reporting Requirements

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

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