

Biomedical Advanced Research and Development Authority
(BARDA)

Request for Project Proposals (RPP)

RPP Name: Domestic Capability
Building Activity – Onshoring the Manufacturing of Viral
Hemorrhagic Fever Vaccine Candidates



RPP Identifier: 26-10-VHF

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Responses Due: December 11, 2025, 1 PM ET

Biomedical Advanced Research Development
Authority (BARDA) Contracts Management &
Acquisition (CMA)
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[MedicalCountermeasures.gov](https://www.MedicalCountermeasures.gov)

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Solicitation Closed

1 Executive Summary

1.1 Biopharmaceutical Manufacturing Preparedness Consortium

The Biopharmaceutical Manufacturing Preparedness Consortium (BioMaP-Consortium) is a multiple-purpose acquisition vehicle comprised of industry partners across the drug and vaccine manufacturing supply chain, including, but not limited to, drug substance manufacturers of required raw materials and consumables, suppliers of fill-finish services, and developers of innovative manufacturing technologies.

The BioMaP-Consortium brings together pharmaceutical, medical, academic, and scientific organizations working toward successful development and delivery of medical countermeasure materials and products. Cooperative partnerships are maintained to ensure that there are adequate manufacturing capabilities to provide and make available requisite products and materials, so that countermeasures and therapies can be delivered to civilian populations addressing threats to the nation's public health or other security interests.

The BioMaP-Consortium is also focused on expanding the United States' domestic industrial and manufacturing base for medical countermeasures.

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

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

1.2 Purpose

The United States Government (USG) has a requirement to expand domestic commercial biopharmaceutical manufacturing capabilities. To meet this need, the USG is initiating an effort to onshore the manufacturing of Vesicular Stomatitis Virus (VSV) Delta G based vaccine candidates, expressed in Vero cells, for protection against viral hemorrhagic fever viruses such as Marburg virus (MARV) and Sudan virus (SUDV). At present, there is limited domestic capacity for live viral vector manufacturing, including for viral hemorrhagic fever vaccines. Strengthening this capability is critical to enhancing domestic vaccine production to bolster national health security preparedness and ensure a more effective response to known and emerging infectious disease threats. This effort will involve the technology transfer of current candidate vaccine production processes (inclusive of bulk drug substance (upstream and downstream) and drug product (formulation, fill/finish)) from their current manufacturing sites, located outside the U.S., to one or more domestic Contract Development and Manufacturing Organizations (CDMOs) located within the US.

Project Awardees for this effort shall be limited to product sponsors/technology owners that have BARDA-sponsored monovalent filovirus vaccine candidates based on the VSV platform technology.

The scope of this effort is, strictly, to demonstrate tech transfer of manufacturing capability for bulk drug substance and drug product to the U.S. This effort does not include any options dedicated or focused on the procurement of investigational or licensed products.

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.

The Government reserves the right to modify this process if it is determined to be in its best interest at any time during the solicitation process. In such instance, the CMF would provide additional and/or revised requests for information, clarifications, presentations, etc. and include any modified evaluation criteria to be used for the remaining portion of the selection process, if applicable.

2.2 RPP Approach

It is expected that there will be a total of one or more qualified respondents to accomplish the statement of objectives. If an optimal team is not identified, then BARDA may direct the BioMaP-Consortium CMF to make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks. The Government also reserves the right to make one, multiple, or no awards as a result of this RPP.

This RPP is issued under OTA Number 75A50123D00003 between the Government and the CMF. The same provisions are contained in the BioMaP-Consortium Base Agreement. A copy of the Base Agreement can be requested from biomap-contracts@ati.org. Each proposal selected for award under this RPP will be executed as a Project Agreement funded under OTA Number 75A50123D00003 and governed by the Base Agreement terms and conditions, unless otherwise noted in the Project Agreement.

At the time of the submission, Offerors must certify on the cover page of their Technical Proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the BioMaP-Consortium Base Agreement.

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

2.3 Period of Performance

The anticipated period of performance shall not exceed 30 months. Offerors should plan for the period of performance to begin in Quarter 2 of Government Fiscal Year 2026. The Government reserves the right to change the proposed period of performance start date through negotiations via the CMF and prior to issuing a Project Agreement.

2.4 Estimated Funding

Funding of proposals submitted in response to this RPP is contingent upon the availability of federal funds for this program. The Government anticipates making one or more awards under this RPP. Offerors are encouraged to propose budgets commensurate with the nature, scope and complexity of the proposed project. Offerors should submit proposals that include the entire period of performance of the project.

2.5 Proprietary Information

The BioMaP-Consortium CMF will oversee submission of proposals submitted in response to this RPP. The BioMaP-Consortium 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. Offerors should mark all Confidential or Proprietary Information as such. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CMF responsibilities.

2.6 Minimum Eligibility Criteria

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

- Both product sponsor/technology owner and CDMO(s) must be members of the BioMaP-Consortium prior to award of a Project Agreement. Click [here](#) to learn how to join the consortium.
- Only offerors who are product sponsors/technology owners will be considered.
- Only offerors proposing a BARDA-sponsored monovalent filovirus candidate based on the VSV platform technology will be considered.

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

2.7 Special Considerations

The following are special considerations in the evaluation and/or negotiation process; however, neither are required in order to be eligible to receive an award under this RPP.

United States Industrial Base. Consistent with BioMaP-Consortium's focus to expand the United States' domestic industrial and manufacturing base for medical countermeasures, proposals are expected to be focused on United States investments, and all work and/or capacity expansion shall be focused on US soil (including United States territories) to satisfy

domestic requirements. This does not preclude offers from non-US companies, provided they meet the minimum eligibility criteria and work supports US domestic purposes, nor does it preclude non-US companies from utilizing non-US employees to provide subject matter expertise.

Small Business Utilization. Small Businesses utilization is encouraged to the maximum extent practicable as a means to build an agile and resilient industrial and manufacturing base, which ultimately supports economic growth and development in the United States.

2.8 Cost Sharing

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

However, this is not required in order to be eligible to receive an award under this RPP. If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips). 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 C.

2.9 Intellectual Property and Data Rights

Intellectual Property (IP) rights for BioMaP-Consortium Project Agreements are defined in the terms of the BioMaP-Consortium Base Agreement. The BioMaP-Consortium CMF reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the Project Awardees during the entire award period.

The BioMaP-Consortium Base Agreement contains general provisions regarding Data Rights. For this specific RPP, it is anticipated that anything delivered under this proposed effort would be delivered to the Government with government purpose rights, 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 Agreement.

The Offeror shall complete the table provided in this RPP's Attachment A, Data Rights Table, identifying any Intellectual Property or Data Rights to be furnished to the Government with restrictions.

2.10 Regulatory Terms

Project Awardees must be expected to comply with the relevant FDA, DEA, USP and cGMP regulatory practices.

It is anticipated that any Project Agreements would be subject to the following regulatory terms identified in the BioMaP-Consortium Base Agreement with the exclusions identified in Section 4.2.2.10 of this RPP.

18.4. Manufacturing Standards. Where applicable, the Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of products developed under this Base Agreement. If at any time during the life of this contract, the Project Awardee fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of this product (a material failure) as identified by Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER), the Project Awardee shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Project Awardee fails to take such an action within the thirty (30) calendar day period, then the Project Agreement may be terminated.

This is subject to change pending any final direction provided by the Government at the time of Project Award. Information on potential regulatory terms is provided in the BioMaP-Consortium Base Agreement.

2.11 Special Requirements

Offerors must be prepared to comply with the following special requirements:

- **Salary Rate Limitation.** Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II is an unallowable cost under the BioMaP-Consortium OTA. See the BioMaP-Consortium Base Agreement for further details.
- **Expansion.** In accordance with the BioMaP-Consortium Base Agreement, any work for capacity expansion shall be executed within the continental United States and its Territories, whether the company is based domestically or overseas.
- **SAM.gov Registration.** Offerors are required to obtain a Unique Entity Identifier (UEI) from SAM.gov prior to award of a Project Agreement.

2.12 Security Requirements

See Attachment C of this RPP for Administration for Strategic Preparedness and Response (ASPR) Deliverables and Security Requirements that will be required for any resulting projects. BioMaP-Consortium members should be prepared to include the applicable deliverables and security requirements identified in the attachment.

2.13 Preparation Cost

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

3 Proposals

3.1 Question and Answer Period

All questions regarding this RPP must be submitted via email to biomap-contracts@ati.org no later than 3:00 PM ET on November 12, 2025. Please note that questions will not be addressed during the Solicitation Webinar.

Key Dates for this RPP

Date	Event
10/15/2025	RPP Released
11/12/2025	Deadline for submitting questions to biomap-contracts@ati.org
Notification sent via email	Questions & Answers posted on the BioMaP-Consortium website
12/11/2025	Proposals Due

3.2 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 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 (Section 6 of this RPP).

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 of this RPP.

All eligible Offerors shall submit proposals for evaluation according to the criteria set forth in this RPP. Offerors are advised that only ATI, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

3.3 Proposal Submission

Proposals must be submitted online via BIDS at <https://submissions2.ati.org/ATI2/Portal.nsf/Start?ReadForm>. Submissions will not be accepted by any other means. Offerors are strongly encouraged to register as a new user well in advance of the Proposals submission deadline.

The Home Page will contain contact information for assistance with any problems associated with the electronic submission process. You may also reach out to the BioMaP-Consortium CMF.

Neither the Government nor the CMF can make allowances/exceptions for submission problems encountered by the offeror using system-to-system interfaces with BIDS. If the offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted.

Offerors will also be required to provide general submission information in BIDS such as point of contact information.

Receipt confirmations will be e-mailed upon submission of proposals and will include the unique reference number. Submissions can be made in advance of the deadline and updated (replace any of the files) up until the submission deadline.

3.4 Submission Format

Each document listed below is mandatory and must be submitted as separate files. These documents will remain valid for two years unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact the BioMaP Consortium CMF with any questions to ensure that all aspects are clearly understood by both parties. The proposal should include the following items:

- **Technical Proposal submission – See Attachment A:** A Technical Proposal is required in Word (.docx or .doc) or PDF using the mandatory template in Attachment A.
- **Cost Proposal submission – See Attachment B**
 - Section I: Cost Proposal Narrative is required in Word (.docx or .doc) or PDF using the mandatory template in Attachment B.
 - Section II: Cost Proposal Format is required in Excel (.xlsx) format, with working formulas to the maximum extent practicable.
- **Teaming Arrangement Plan – See Attachment D:** One Word or PDF using the template in Attachment D.

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, or pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters.

4 Technical Requirements

4.1 Overview

4.2.1. The United States Government (USG) has a requirement to expand domestic commercial biopharmaceutical manufacturing capabilities. To meet this need, the USG is initiating an effort to onshore the manufacturing of Vesicular Stomatitis Virus (VSV) Delta G based vaccine candidates, expressed in Vero cells, for protection against viral hemorrhagic fever viruses such as Marburg virus (MARV) and Sudan virus (SUDV). At present, there is limited domestic capacity for live viral vector manufacturing, including for viral hemorrhagic fever vaccines. Strengthening this capability is critical to enhancing domestic vaccine production to bolster national health security preparedness and ensure a more effective response to known and emerging infectious disease threats. This effort will involve the technology transfer of current candidate

vaccine production processes (inclusive of bulk drug substance (upstream and downstream) and drug product (formulation, fill/finish)) from their current manufacturing sites, located outside the U.S., to one or more domestic Contract Development and Manufacturing Organizations (CDMOs) located within the US.

- 4.2.2. Offerors for this effort shall be limited to product sponsors/technology owners that have BARDA-sponsored monovalent filovirus vaccine candidates based on the VSV platform technology.
- 4.2.3. The scope of this effort is, strictly, to demonstrate tech transfer of manufacturing capability for bulk drug substance and drug product to the U.S. This effort does not include any options dedicated to or focused on the procurement of investigational or licensed products.
- 4.2.4. Offerors for this effort shall demonstrate consistency between the existing product sponsor/technology owner's process and the newly established process at the domestic CDMO(s). This includes but is not limited to all necessary engineering/demonstration runs, analytical testing, assays, and metrics. Details on the specific types and quantities of runs and tests and their associated acceptance criteria shall be negotiated between the product sponsor/technology owner and the CDMO(s).
- 4.2.5. The goal of this effort is to perform a technology transfer of an existing process. In the event the product sponsor/technology owner(s) performs process development and/or optimization activities concurrent to this effort, incorporation of those activities may be handled under a separate option if/when needed.
- 4.2.6. The product sponsor shall serve as Offeror, with the CDMOs acting as team members.
- 4.2.7. Complete all tech transfer activities within 30 months from project agreement award to achieve specific objectives described.

4.2 Technical Objectives

4.2.1. General Objectives:

- 4.2.1.1. Make awards necessary to onshore drug substance and drug product manufacturing processes (inclusive of formulation, fill/finish) for up to two (2) vaccine candidates for protection against viral hemorrhagic fever viruses, specifically Marburg virus and Sudan virus. The priority candidate for this effort is Marburg virus; proposed work must initially focus on the Marburg virus candidate with optional work proposed for Sudan virus that leverages lessons learned and efficiencies from the initial Marburg virus tech transfer activities.
 - Offerors should propose to perform the tech transfer of one or more vaccine candidates and include separate detailed cost models for drug substance activities and drug product activities respectively.
- 4.2.1.2. The USG expects offerors to face risks and unique technical challenges as a result of this effort. As such, the offerors shall include a teaming arrangement in accordance with sections 4.2.2.8 and 4.4 below.
- 4.2.1.3. Complete all tech transfer activities within 30 months from project agreement award to achieve specific objectives described below in Section 4.2.2.

4.2.2. Specific Objectives:

- 4.2.2.1. Offerors(s) shall propose tech transfer of the existing manufacturing process for vaccine candidates for protection against viral hemorrhagic fever viruses (inclusive of bulk drug substance and drug product to one or more new domestic CDMO site(s).
- 4.2.2.2. The processes that are established at the new domestic manufacturing site(s) shall be identical to the product sponsor/technology owners' current process. The anticipated vaccine dosage is greater than 10⁷ infectivity units (the specific dosage concentration will be provided prior to agreement award). It is expected that bulk Drug Substance titers/quantities produced should account for typical losses during fill/finish operations.
- 4.2.2.3. Domestic CDMO(s) must be capable of manufacturing under qualified cGMP conditions and BSL-2 safety containment (see 4.2.2.10 for details on GMP conditions).
- 4.2.2.4. Offerors shall propose transfer pertinent analytical test methods and establish them at the new domestic CDMO site(s).
- 4.2.2.5. Offerors shall propose to perform all necessary runs, analytical testing, assays, and metrics to ensure consistency between the current processes and the processes established at the new domestic CDMO site(s).
- 4.2.2.6. All manufactured material (both drug substance and drug product) shall be stored frozen at –80°C for potential future use. The storage cost shall be included in the agreement. Stability testing will be performed in accordance with the Milestone table.
- 4.2.2.7. It is expected that the CDMO(s) may need to provide regulatory support to the product sponsor/technology owner for any comparability filings with the FDA. The cost of the support shall be proposed/priced as an option if/when needed.
- 4.2.2.8. The Offeror shall propose a teaming arrangement that will be leveraged for all regular and ad hoc technical meetings with the USG that occur as deliverables under the agreement. The teaming arrangement for such meetings must include, the USG, the product sponsor (i.e., the Offeror), and any sub-awardee CDMO partner(s). As part of the proposal, the Offeror shall submit a Teaming Arrangement Plan (see Attachment D) that outlines the structure of the team, how it will be maintained throughout the period of performance, and the plan must include, but is not limited to, a communications plan detailing role, responsibilities, points of contact, and methods for ensuring timely and transparent information sharing among all parties.

Clarifications:

- The USG is not required to be included in internal technical discussions that occur solely between the product sponsor (i.e., the Offeror) and its sub-awardee CDMO partner(s) outside the context of technical meetings that occur as deliverables under this agreement.
- The product sponsor may request ad hoc technical meetings with only the USG and the product sponsor, if such meetings are technically or programmatically necessary.

- This teaming arrangement does not permit the USG to bypass the product sponsor (i.e., the Offeror) to seek information or engage directly with the CDMO partner(s) without the Offeror's involvement, unless otherwise mutually agreed upon in writing.

4.2.2.9. Both product sponsor/technology owner and CDMO(s) shall be members of the BioMaP-Consortium.

4.2.2.10. The process tech transfer shall be deemed successful with the completion of at least one (1) manufacturing run (inclusive of bulk drug substance and drug product vials), produced at the new domestic CDMO site(s) under GMP conditions for each vaccine candidate with acceptable process results compared to the original manufacturing processes. For the purposes of this effort, "GMP conditions" mean production on qualified equipment using qualified procedures, but no quality release documentation and/or qualified batch records are required.

4.3 Project Agreement Deliverables

The following deliverables are mandatory. Any additional technical deliverables proposed by the Offeror must be clearly identified.

Unless otherwise specified, the Offeror, hereafter referred to as Recipient in the table below, may submit deliverables in its own format. Acceptable submission formats include MS Office or PDF. Funding information shall be submitted in MS Excel, and schedule information may be submitted in either MS Excel or MS Project.

All deliverables are subject to U.S. Government review and comment. This review may require the Offeror to provide additional revisions or submissions.

Meetings

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
Post-Award Teleconference	<p>The Project Awardee must complete a Post-Award Teleconference after the initiation of the Project Award period of performance.</p> <ol style="list-style-type: none"> 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 Project Award period of performance, pending concurrence by the Other Transaction Agreement Officer (OTAO) • Project Awardee must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference unless notified that BARDA will supply a teleconference number • Project Agreement Officer (PAR) edits/approves and instructs Project Awardee to distribute agenda at least 2 business days prior to meeting • Project Awardee submits meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days
Kickoff Meeting	<p>The Project Awardee must complete a Kickoff meeting after the initiation of the Project Award period of performance.</p>	<ul style="list-style-type: none"> • Within 10 business days after the initiation of the Project Award period of performance, pending concurrence by the OTAO • Project Awardee 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 Project Awardee to distribute agenda at least 3 business days prior to meeting • Project Awardee submits meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days
Bi-Weekly Teleconference	<p>The Project Awardee must participate in teleconferences bi-weekly with BARDA to discuss the technical performance on the Project Award.</p>	<ul style="list-style-type: none"> • Project Awardee must submit agenda to PAR no later than 2 business days in advance of meeting • PAR edits/approves and instructs Project Awardee to distribute agenda prior to meeting • Project Awardee must distribute agenda and presentation materials at least 2 calendar days in advance of meeting

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	<p>Meeting frequency may be increased or decreased as needed during the course of the period of performance.</p>	<ul style="list-style-type: none"> • Project Awardee must submit meeting minutes to PAR within 3 business days of the meeting • PAR reviews, comments, and approves minutes within 10 business days
<p>Technical, Subgroup, Ad Hoc Teleconference(s)</p>	<p>The Project Awardee must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the Project Award.</p> <p>Meeting frequency may be defined as needed during the course of the project.</p>	<ul style="list-style-type: none"> • Project Awardee must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting • PAR edits/approves and instructs Project Awardee to distribute agenda prior to meeting • Project Awardee must distribute agenda and presentation materials at least 24 hours in advance of meeting • Project Awardee must submit meeting minutes to PAR within 3 business days of the meeting • PAR reviews, comments, and approves minutes within 6 business days
<p>Periodic Review Meetings</p>	<p>At the discretion of the Government, the Project Awardee must hold up to four (4) per year recurring Periodic Review Meetings, held by teleconference or face-to-face either in Washington, D.C. or at work sites of the Project Awardee or subawardees. Face-to-face meetings shall alternate between Washington, D.C. and Project Awardee, subawardee sites. The meetings will be used to discuss Project Award progress as well as technical and regulatory, aspects of the program.</p>	<ul style="list-style-type: none"> • Project Awardee must submit an agenda and itinerary, if applicable, at least 5 business days, and Project Awardee must provide presentation materials at least 3 business days, in advance of the meeting • PAR edits/approves and instructs Project Awardee to distribute agenda prior to meeting by at least 3 business days • Project Awardee provides meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days

Technical Reporting: General

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
Project Management Plan (PMP)	<p>The Project Management Plan should define the overall plan for how the project will be executed, monitored and controlled and must include a Study Responsibility Assignment Matrix for Project Awardee and subawardee 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, 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>	<p>Project Awardee must submit a PMP:</p> <ul style="list-style-type: none"> • Within 30 calendar days after the initiation of the Project Award period of performance • Updates should be provided to reflect any key changes and reviewed at least annually.
Gantt Chart/Timeline/ Integrated Master Schedule (IMS)	<p>The Gantt Chart/Timeline/IMS should be detailed to the extent required by the specific project. The Gantt Chart/IMS should include an MS Project Detailed Project Schedule, full detailed schedule for entire project, including all major activities, critical path, and milestones. Status updated regularly.</p>	<p>At first Teleconference and as updated no later than every 30 calendar days. Provided in pdf and MS Project.</p>
Communication Plan	<p>The Project Awardee must submit an effective Communication Plan that details the flow of information between BARDA, Project Awardee, collaborators, vendors, and other organizations, including communications with all parties, as appropriate, regarding label contents, expiry dating, and healthcare provider educational materials.</p> <p>The Communication Plan must also include a press release review process.</p>	<p>Project Awardee must submit a Communication Plan:</p> <ul style="list-style-type: none"> • Within 30 calendar days after the initiation of the Project Award period of performance • Updates should be provided to reflect any key changes and reviewed at least annually.
Work Locations	<p>The Project Awardee must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location.</p> <p>Project Awardee must include vendors for critical infrastructure protection.</p>	<p>Project Awardee must submit Work Locations Report:</p> <ul style="list-style-type: none"> • Within 5 business days after the initiation of the Project Award period of performance • Within 30 business days after a substantive location or capabilities change
Request for Information (RFI) Responses	<p>Upon request of the Government, Project Awardee must provide complete responses to ad hoc RFIs.</p>	<p>Project Awardee must submit an RFI response to BARDA by email within 48</p>

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	<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 Project Awardee must provide the response in both confidential and non-confidential formats.</p>	<p>hours after Project Awardee receipt of the RFI.</p>
<p>Monthly & Annual Technical Progress Reports/Annual Meeting</p>	<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)– or as applicable.</p> <ol style="list-style-type: none"> 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, and regulatory. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages 2. Progress in meeting Project Award milestones 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 3. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 4. Estimated and Actual Expenses <ul style="list-style-type: none"> • This report must contain a narrative or table detailing the projected monthly expenses and the cumulative costs incurred to date for the entire period of performance. • The 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 Subawardees' expenses from the previous month if the Subawardee did not submit a bill in the previous month. If the subawardee(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 Subawardee. If the PAR and OTAO are satisfied that the Project Awardee's reporting is sufficient to convey this information, this section may be waived. 5. Publication activities and progress for any manuscript, scientific meeting abstract, poster, 	<ul style="list-style-type: none"> • Project Awardee must submit monthly reports on the 15th day of the month covering the preceding month; Annual Reports submitted on the last calendar day of the month every 12 months. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable 2.7). The PAR and OTAO will review the monthly reports with the Project Awardee and provide feedback • Project Awardee must provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits • The PAR and OTAO will review the monthly reports with Project Awardee and provide feedback

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	presentation, and other public-facing material or information containing data generated under this Project Award	
Project Budget	Excel spreadsheet of Detailed Project Budget	Initial Project Budget to be delivered within thirty (30) days of project award.
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 Project Award. This report must be in sufficient detail to fully describe the progress achieved under all milestones. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the 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 contain a summation of the work performed and the results obtained for the entire Project Award Period of Performance (POP). The final report must document the results of the entire agreement. The final report must document the results of the entire Project Award. The final report must be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the Project Award.</p>	<ul style="list-style-type: none"> • The Project Awardee must submit the Draft Final Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP • PAR will provide feedback on draft report within 21 calendar days of receipt, which the Project Awardee must consider incorporating into the Final Report
Project Action Items List	Actions identified throughout the project, which are not tracked by some other project management tool, and which require follow up and monitoring for completion, will be captured in an Action Items List. (Or similar list/tracking tool.) List should contain information regarding identification date, target completion, responsible individuals/groups, etc.	Submitted if/as required with Monthly Project Progress Report.
Security Plan	<p>The Security Plan must detail how the Project Awardee will adhere to established ASPR Informational Technology (IT) and Operational Security (OPSEC) policies and requirements.</p> <p>The Security Plan must include but is not limited to:</p> <ul style="list-style-type: none"> • Internal management security measures that meet the ASPR, IT, and OPSEC security requirements • Plan to ensure Project Agreement security compliance, to include roles and responsibilities 	<p>Initial submission within thirty (30) days after project award, updated as necessary.</p> <p>See BARDA Security Program and Facility Security Plan Instructions.</p>

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	<ul style="list-style-type: none"> Plan to manage Consortium member physical, IT, and OPSEC security compliance as a contingency of Consortium membership 	
Infrastructure and Management Structure Organizational Chart	The Project Awardee shall complete description of the infrastructure and management structure (organizational chart) including but not limited to addressing all elements that will accomplish the program's goals and milestones. The Project Awardee shall propose a workforce management plan, e.g., how workforce will train, maintain, etc., that reflects the ability to meet the requirements.	Initial submission within (30) days after project award, updated as necessary. Report format: Microsoft Word and PDF
Material Stability Report	The Project Awardee shall develop and submit a Stability Report that details the Project Awardee's Stability Protocol inclusive of parameters, duration, sample time intervals, analytical test metrics, data, results, and conclusions for all material produced during this effort.	To be determined after project award during regular and recurring project team meetings.

Solicitation Closed

Quality Assurance

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
Quality Management Plan (QMP)	<p>Project Awardee must develop an overall project Quality Management Plan to include a description of all quality activities and personnel involved in ensuring all activities are conducted and data are maintained under cGXP, and all products are managed to ensure that GMP requirements are met.</p> <p>All quality management plans must include subawardee quality management plans specifically addressing how subawardee quality will be managed.</p> <p>All subawardees must have a current quality agreement with the Project Awardee and a recent vendor qualification audit.</p>	<p>Project Awardee must submit a Quality Management Plan</p> <ul style="list-style-type: none"> • Within 30 calendar days after the initiation of the Project Award period of performance • 6 months after the initiation of the Project Award period of performance to include any updates. • Report format: Microsoft Word and PDF
Site Visits	<p>Project Awardee(s) to develop Agenda and host in-person visits from USG and/or Product Sponsor/technology owner.</p> <p>Agenda mutually agreed upon with USG in advance of visits.</p> <p>Project Awardee(s) to provide meeting minutes.</p>	<p>Typically, quarterly at the Agreements Officer's discretion.</p> <p>Agenda to be provided minimum of one (1) business day in advance of the meeting.</p> <p>Meeting minutes to be submitted within three (3) business days of meeting.</p>
BARDA Audit	<p>Project Awardee must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by BARDA. If BARDA, the Project Awardee, or other parties identify any issues during an audit, the Project Awardee must capture the issues, identify potential solutions and submit a report to BARDA detailing the finding and corrective action(s).</p> <p>HHS/BARDA reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this Project Award and all records related to the manufacture, testing (including but not limited to analytical testing, nonclinical study, clinical trial), and storage of the product.</p>	<ul style="list-style-type: none"> • If issues are identified during the audit, Project Awardee must submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit • PAR and OTAO will review the report and provide a response to the Project Awardee with 10 business days • Once corrective action is completed, the Project Awardee will provide a final report to BARDA
Quality Assurance (QA) Audits and Subawardee Monitoring Visits	<p>BARDA reserves the right to participate in QA audits performed by the Project Awardee. Upon completion of the audit/site visit the Project Awardee must provide a report capturing the findings, results and next steps in proceeding with the subawardee.</p> <p>If action is requested of the subawardee, 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</p>	<ul style="list-style-type: none"> • Project Awardee must notify OTAO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subawardee • Project Awardee must notify the PAR and OTAO within 5 business days of report completion and provide Draft Report.

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	<p>BARDA. The Project Awardee must provide responses from the subawardee to address these concerns and plans for corrective action.</p> <p>The Project Awardee 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.</p>	<ul style="list-style-type: none"> • PAR and OTAO will review the report and provide a response to the Project Awardee with 10 business days before audit can be finalized. • Project Awardee must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report. • Project Awardee must provide a final closeout report that all CAPAs were addressed to PAR and OTAO • Project Awardee must notify BARDA within 24 hours of any critical and/or major findings
Risk Management Plan (RMP)	<p>The Project Awardee 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> <p>Risks must be tracked via a Risk Register Log (or similar list/tracking vehicle). Log should contain information regarding identification date, severity of risk, mitigation plan(s) and dates for implementation, risk owner, etc.</p>	<ul style="list-style-type: none"> • A Draft is due within 45 calendar days after the initiation of the Project Award period of performance; updates to the RMP are due concurrent with Monthly Technical Progress Reports, but may be communicated more frequently. The Project Awardee 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 Project Awardee with a list of concerns in response plan submitted • Project Awardee must address, in writing, all concerns raised by BARDA within 20 business days of Project Awardee 's receipt of BARDA's concerns • The Project Awardee must submit updates at minimum of every three months.
Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Project Awardee must notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension.	The Project Awardee must submit Deviation Notification and Mitigation Strategy at least 10 business days prior to the Project Awardee anticipating the need to implement changes

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	Project Awardee must provide a high-level management strategy for risk mitigation.	
Incident Report	Project Awardee 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.	<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 • Project Awardee 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, Project Awardee must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

Regulatory Deliverables

Deliverable	Deliverable Description	Reporting Procedures and Due Dates
Technical Documents	<p>Upon request, Project Awardee must provide OTAO and PAR with deliverables from the following activities: quality agreements between Project Awardees and sub-Project Awardee, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis.</p> <p>The OTAO and PAR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government.</p>	<ul style="list-style-type: none"> • Project Awardee must provide technical document within 10 business days of OTAO or PAR request. Project Awardee can request additional time on an as needed basis • If corrective action is recommended, the Project Awardee must address, in writing, concerns raised by BARDA in writing

4.4 Program Management

The Project Awardee(s) is(are) responsible for overall management and execution of the work to achieve the objectives of the agreement. The Project Awardee(s) must provide the overall management, integration, and coordination of all agreement activities to ensure the efficient planning, initiation, implementation, and direction of all agreement activities. The Project Awardee(s) shall be responsible for establishing and managing the project milestones for the effort; however, at a minimum, the milestones described below must be included. The Project Awardee(s) shall ensure that any changes or deviations planned or incurred by the Project Awardee(s) in pursuing the objectives of any resulting agreement are reported to the USG. While primary responsibility for management and execution of the effort resides with the Project Awardee(s), achievement of the technical objectives will be a shared responsibility for the Consortium Management Firm, Project Awardee, its major/minor sub-awardees, teaming partners, and the USG. As such the USG shall be kept informed of the progress against all technical objectives and shall have input to the milestone review process and any changes to the objectives of any resulting agreement. Additionally, the Project Awardee(s) shall ensure the USG remains a key stakeholder in accordance with the Project Awardee(s)' teaming arrangement.

Milestone	Activities	Milestone & Go/No go
1	BDS Tech Transfer – Proof-of-concept <ul style="list-style-type: none"> • Paper transfer • Analytical transfer • Scale-down Engineering run • Release testing • Storage 	Key milestone: Successful TT through first small-scale BDS engineering run Go/no go: Meet minimum titer target based on existing program/process
2	BDS Tech Transfer – Full Demonstration <ul style="list-style-type: none"> • Full-scale Engineering Run • Release testing • Stability testing • Storage 	Key milestone: Successful TT through full-scale BDS engineering run Go/no go: Meet minimum titer target based on existing program/process. Demonstration of process capability (upstream and downstream). Satisfactory completion of release testing and all criteria met.
3	FDP (fill/finish) Tech Transfer – Proof-of-concept <ul style="list-style-type: none"> • Paper transfer • Analytical transfer • Water Run • Engineering Run at 10–20% of target batch size 	Key milestone: Successful TT through FDP engineering run at 10%-20% of target batch size Go/no go: Meet minimum titer target based on existing program/process

	<ul style="list-style-type: none"> • Release testing • Storage 	
4	FDP (fill/finish) Tech Transfer – Full Demonstration <ul style="list-style-type: none"> • Engineering Run conducted at full lot size under GMP conditions • Release testing • Stability testing • Storage 	Key milestone: Successful TT through FDP engineering run at full lot size under GMP conditions Go/no go: Meet minimum titer target based on existing program/process
5	BDS Tech Transfer <ul style="list-style-type: none"> • GMP Run • Storage • Stability testing 	Key milestone: Successful BDS GMP run Go/no go: Meet minimum titer target based on existing program/process. Successful completion of release testing and batch record review.
6	FDP Tech Transfer <ul style="list-style-type: none"> • GMP Run • Storage • Stability testing 	Key milestone: Successful FDP GMP run Go/no go: Meet minimum titer target based on existing program/process. Successful completion of release testing and batch record review.

4.5 Risk Management Objectives

The Project Awardee(s) will establish a Risk Management program that includes development of a Risk Management Plan, Risk Register, and risk mitigation strategies. See Risk Management Requirements in the Deliverables Table. The Project Awardee(s) must manage all project risks, and report changes to all identified risks to the USG as they occur/arise. The USG must be permitted to participate in the risk management and mitigation processes associated with this project.

The Government recognizes that there is a limited pool of US-based CDMOs capable of manufacturing live virus vaccines. This creates a realistic possibility that multiple product sponsors (i.e., Offeror) may propose teaming with the same CDMO. To ensure transparency, avoid conflicts of interest, and mitigate risks associated with similar government-funded efforts, the Offeror should provide the below information for their CDMO partner in the Supporting Project Information Appendix. If necessary, the Government may request additional information for risk mitigation planning.

Disclosure of other USG-funded vaccine efforts. Identification of whether the partner CDMO is currently supporting, has firm plans to support, or is proposing to support (as a prime or sub-awardee/contractor) other USG-funded vaccine manufacturing efforts involving live virus vaccines or closely related products.

Team Composition and Staffing. Provide information on key personnel of the partner CDMO that will support the proposed work. Include a description of how the CDMO will ensure that staffing is adequate to meet technical and project management requirements without reliance on the same individuals supporting other similar vaccine manufacturing efforts that are either current receiving USG funding or are proposing to USG-funded work as either the primary Offeror or as a sub-awardee/contractor to the primary Offeror.

Risk mitigation measures. Description of measures the partner CDMO will employ to keep programs technically, operationally, and administratively distinct, including:

- Physical or procedural segregation of facilities or equipment.
- Firewalls between project teams.
- Documentation practices ensuring product separation.
- Conflict of interest mitigation strategies.

4.6 Physical Property

The U.S. Government does not anticipate the purchase of any physical property under this agreement; however, minor equipment purchases may be considered. No renovations of existing spaces nor construction of new spaces will be considered.

5 Evaluation and Selection

5.1 Compliance Screening

The BioMaP-Consortium 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 BioMaP-Consortium CMF. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

5.2 Evaluation Process

Following the preliminary screening, the Government sponsor will perform an evaluation of all qualified proposals. The Government sponsor team may include a panel of subject matter experts (SMEs), to include the use of contractor consultants, who will make recommendations to the Government during the evaluation. Where appropriate, the Government will employ non-disclosure agreements to protect information. 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 a 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.

5.3 Evaluation Factors Overview

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

- Factor 1: Technical Approach/Solution
- Factor 2: Cost/Price
- Factor 3: Relevant Experience

5.4 Adjectival Merit Rating

Adjectival merit ratings that will be used for the non-cost/price factors.

- Technical Approach/Solution
- Relevant Experience

GENERAL MERIT RATING ASSESSMENTS	
RATING	DESCRIPTION
OUTSTANDING	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
ACCEPTABLE	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
MARGINAL	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
UNACCEPTABLE	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

5.5 Evaluation Factors

- **Factor 1 – Technical Approach/Solution (Adjectival Rating):** This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.
- **Factor 2 – Cost:** The proposed cost/price will be reviewed for cost/price realism, and overall, most advantageous solution to the Government and will be given a narrative rating. Proposals will be reviewed to ascertain if the costs proposed are based on

realistic assumptions, reflect a sufficient understanding of the technical goals and the objectives of the proposed work, and are consistent with the Offeror's technical approach. Quotes from proposed subcontractors and suppliers to help substantiate the project expenses are recommended. Similarly, a breakdown of significant costs in order to show realism is also recommended.

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

The respondent shall provide relevant and recent evidence of experience with Vero cell (or similar adherent cell culture experience) and/or VSV (or similar viral vectors). Additionally, respondent shall provide relevant and recent evidence of the proposed CDMO's experience as a GMP manufacturing CDMO at BSL-2 safety containment. The respondent shall provide at least one (1) and no more than five (5) recent and relevant experience examples for both the CDMO and innovator/developer (1-5 examples for each). Experience is considered current for performance within the past 5 years.

Relevant experience shall be captured in the Technical Proposal (Attachment A), limited to three pages. The Government reserves the right to contact customer references to verify performance and assess quality of that performance, and to perform independent relevant experience analysis.

5.6 Evaluation Outcome

The Government will recommend project(s) based on an evaluation of the information provided in the applicable proposal. Following the evaluation, the Project Agreement Evaluation Team (PAET) Chairperson may:

- Recommend proposal(s) (or some portion of the proposal) for negotiations towards the award.
- Recommend placement of proposal(s) in the Basket if funding currently is unavailable; or
- Recommend rejection of proposal(s) (will not be considered for award and will not be placed in the Basket)

As the basis of the recommendations is completed, the Government will forward its recommendations to the BioMaP-Consortium CMF to notify the Offerors. Offerors will be notified of the decision via email from the BioMaP-Consortium CMF of the results of the evaluation. All Offerors will receive feedback on eligible submissions. Recommended Offeror(s) will receive a request letter detailing the next steps in the award process.

5.7 Basket Provision

The electronic “Basket” is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately recommended for award, may be placed in the Basket for 2 years and are 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

5.8 Cost/Price Estimate and Evaluation

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

If a proposal is recommended for Project Agreement award, the BioMaP-Consortium CMF will review the original cost proposal and the Offeror’s response to a Proposal Update Letter, if applicable. The BioMaP-Consortium CMF will request additional information or clarification as necessary. The BioMaP-Consortium 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 negotiated project value is fair and reasonable.

Full Cost Proposals will be evaluated by CMA using the understanding of cost reasonableness and completeness as outlined below:

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

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

The Project Agreement Representative (PAR) will review the Technical Verification Form (TVF), which includes the proposed costs, to deem the proposed costs are appropriate for technical effort.

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

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

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down to the level of detail outlined in the RPP.

The BioMaP-Consortium CMF will analyze and assess 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.

c) Completeness: The BioMaP-Consortium CMF will make an assessment on whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation, as well as reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The BioMaP-Consortium CMF will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The BioMaP-Consortium 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 eligible for further award.

5.9 Award Determination

Following final negotiations, the Government may determine award(s) based on an evaluation of the information provided in the proposal that provides the best value to the Government. After approval from the Source Selection Authority (SSA), the Government will forward their selection, if any, to the BioMaP-Consortium CMF to notify the applicable Offeror(s). The Offeror(s) will be notified of the decision and/or change in recommendation status via email from the BioMaP-Consortium CMF of the results of the selection.

6 Points of Contact

Questions related to this RPP should be directed to Ms. Rebecca Harmon (biomap-contracts@ati.org)

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

7 Attachments

Attachment A: Technical Proposal Template

Attachment B: Full Cost Proposal Template

Attachment C: ASPR Security Requirements

Attachment D: Teaming Arrangement Plan

Solicitation Closed

Attachment A: Technical Proposal Template

Directions:

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

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

To ensure Technical Proposals receive proper consideration, **the Technical Proposal format shown below and all sections detailed within the template are 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. Organization Information Sheet*
3. Executive Summary and Minimum Eligibility Criteria
4. Technical Approach
5. Supporting Project Information Appendix*

***Excluded from page limitation**

Technical Proposal Cover Page

[Name of Offeror]

[Address of Offeror]

RPP Identifier: 26-10-VHF

[Proposal Title]

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

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

[As detailed in **Section 2.5** of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample:

This Proposal includes data that shall not be disclosed outside the BioMaP-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).]

Organization Information Sheet

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

Offeror Name	
All Places of Performance	
Title of Proposed Effort	
UEI # (if applicable)	
CAGE Code (if applicable)	
Small Business (Yes/No)	
Small/Disadvantaged Business (Yes/No); Socioeconomic Category	
Conflict of Interest (Yes/No)	
Government Funds	
Industry Cost Share	
Total Cost of Proposal	
Proposed Period of Performance (Months)	
Preferred Payment Method (FFP, CPFF, Cost Reimbursable (CR), CR/Cost Share)	
Requested Use of Government Resources, Property, Labs, etc. (Yes/No; list if Yes)	
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, Email)	

Executive Summary & Minimum Eligibility Criteria

Please do not include the instructions in [brackets] in your proposal.

- 1. Executive Summary:** [The Executive Summary allows Offerors to 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.]
- 2. Minimum Eligibility:** [Explain how the Offeror currently meets the minimum eligibility criteria outlined in section 2.6 of the RPP.]

Technical Approach

[If recommended for award, this section will serve as the basis for the Statement of Work, which may be further refined and negotiated. Write this section accordingly, avoiding generic proposal language. Provide enough technical detail and analysis to fully support the proposed solution, and clearly define the core approach. Do not simply list or discuss multiple potential solutions; focus on the intended strategy. The following sections are required.]

- 1. Background:** [Describe the problem that the solution is addressing.]
- 2. Objectives:** [Describe the goal of the project and what you are going to do to achieve the goal, including the final product(s) and/or anticipated outcome(s). Be as concise as possible.]
- 3. Project Team:** [Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified. If you are partnering with additional organizations to execute the proposed technical and programmatic work, provide details prior to the table below identifying those partners with clear roles and responsibilities of each organization. If you are not partnering, state as such.]

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

- 4. General Approach:** [Summarize your overarching approach/solution and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform/facilities or solution and the current state of the solution if previous development/progress has been made.]

5. **Technical Approach:** [Provide a detailed approach, broken out by major phases/top level tasks and gates/decision points, on how your organization intends to address the requirements set forth in the RPP, showing a clear course of action and roles of organizations (if applicable).]
6. **Schedule:** [Include a Gantt chart of the project, developed to include the same level of detail as the work breakdown provided in the Technical Approach section. Gantt can be rolled up to the task level for space efficiency if necessary.]

Solicitation Closed

7. Deliverables and Milestone Payments:

Instructions:

- Submitted information may change during negotiations if the Government recommends the proposal for award.
- The deliverables listed in section 4.3 of the RPP are mandatory. Please populate the table below with all deliverables from section 4.3 of the RPP, as well as any additional technical deliverables you propose to support the technical effort. The results of the technical effort are contractually binding and must be clearly identified. Offerors should carefully read the Base Agreement. Additionally, any hardware or software to be provided to the Government as a result of this project must be specified.
- The proposed milestones and deliverables should be appropriate in number relative to the project's size and duration, and they should hold enough monetary value to justify the generation of a deliverable and any related invoices. Please note that recurring programmatic reporting will not be funded. For cost-reimbursable agreements, the offeror is still required to assign a monetary value to each milestone. However, the total invoice amounts will be based on actual costs incurred and do not have to match the specified amounts exactly.
- List the data rights assertions as numbered in the data rights assertion table. If not applicable for that deliverable, write "N/A".

Deliverable #	Task # <i>(For technical deliverables in Section 5 (Technical Approach), the offeror shall reference the applicable Task # or Paragraph #. For mandatory deliverables specified in Section 4.3 of the RPP, the offeror may indicate "N/A")</i>	Deliverable Name <i>(Include all technical and mandatory deliverables specified in Section 4.3 of the RPP.)</i>	Deliverable Description <i>(All technical deliverables proposed by the offeror must include a description. For mandatory deliverables outlined in Section 4.3 of the RPP, the offeror may instead state "the full description is outlined in the RPP" rather than copying the entire text into the table.)</i>	Due Date (Month)/ Reporting Frequency	Total Cost <i>(If proposing cost share, provide a breakout distinguishing Government funding from cost share contributions.)</i>	Assertion #
1						
2						
3						
4						
Etc.						

Total Period of Performance: # Months

8. Intellectual Property, Data Rights, and Copy Rights

[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.

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

Solicitation Closed

Supporting Project Information Appendix

- 1. Cost Summary:** [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 Summary 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	\$XXX	<i>xx hrs of senior scientist; xx hours of program management; include additional as required.</i>
Labor Hours	XX	
Subcontractors	\$XXX	<i>Sub A - \$xxx; xx legal advisor hours Sub B - \$xxx; xx hours of Testing</i>
Subcontractor Hours	XX	
Consultants	\$XXX	<i>Financial consultant supporting all phases</i>
Consultant Hours	XX	
Material/Equipment	\$XXX	<i>pipettes, gloves, computer software</i>
Other Direct Costs	\$XXX	<i>ship testing materials to lab</i>
Travel	\$XXX	<i>x trips for x people for x days to xx (city), xx (state) from xx (city), xx (state) for program meetings</i>
Indirect Costs	\$XXX	<i>approved by DHHS (provide date)</i>
Fee	\$XXX	<i>Not applicable if cost share proposed</i>
Total Cost to Government	\$XXX	
Total Project Value	\$XXX	

- 2. Risks & Mitigation:** [Identify potential problem areas (e.g., technical, schedule, cost) in the proposed approach. Describe risk mitigation methods.]

*For this RPP, the Government recognizes that there is a limited pool of US-based CDMOs capable of manufacturing live virus vaccines. This creates a realistic possibility that multiple product sponsors (i.e., Offeror) may propose teaming with the same CDMO.

To ensure transparency, avoid conflicts of interest, and mitigate risks associated with similar government-funded efforts, the Offeror should provide the below information for their CDMO partner. If necessary, the Government may request additional information for risk mitigation planning.

Disclosure of other USG-funded vaccine efforts. Identification of whether the partner CDMO is currently supporting, has firm plans to support, or is proposing to support (as a prime or sub-awardee/contractor) other USG-funded vaccine manufacturing efforts involving live virus vaccines or closely related products.

Team Composition and Staffing. Provide information on key personnel of the partner CDMO that will support the proposed work. Include a description of how the CDMO will ensure that staffing is adequate to meet technical and project management requirements without reliance on the same individuals supporting other similar vaccine manufacturing efforts that are either current receiving USG funding or are proposing to USG-funded work as either the primary Offeror or as a sub-awardee/contractor to the primary Offeror.

Risk mitigation measures. Description of measures the partner CDMO will employ to keep programs technically, operationally, and administratively distinct, including:

- Physical or procedural segregation of facilities or equipment.
- Firewalls between project teams.
- Documentation practices ensuring product separation.
- Conflict of interest mitigation strategies.

3. 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.]

4. Small Business Utilization: [Complete the following subsections with as much information as currently known. In accordance with the RPP, this information is not part of the Government's technical evaluation; however, small businesses utilization is encouraged to the maximum extent practicable under the BioMaP-Consortium. To be a small business, an organization must first be a for-profit legal structure. Next, it must qualify with the Small Business Association's (SBA) size standards, which are structured by NAICS Code (see <https://www.sba.gov/document/support-table-size-standards>) for more details). Lastly, some small businesses participate in one or more additional programs with the Small Business Administration (see <https://www.hhs.gov/grants-contracts/small-business-support/programs-supporting-small-businesses/index.html> for more details).]

4.1. Offeror's Business Status: [Select and complete the appropriate option. Delete the other two options which do not apply.]

- Offeror qualifies a small business under NAICS code(s) _____
- Offeror qualifies a small business under NAICS code(s) _____ and further participates in the SBA's [select from following list as appropriate: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; Women-owned-small-business] program.
- Offeror does not qualify as small business

4.2. Teaming with Small Businesses: [Select and complete the appropriate option based on currently proposed teaming plan. Teaming can include subcontractors, consultants, and significant material or service providers. Delete any options with do not apply.]

- Offeror plans to team with _____, who qualifies a small business under NAICS code(s) _____
- Offeror plans to team with _____, who qualifies a small business under NAICS code(s) _____ and further participates in the SBA's [select from following list as appropriate: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; Women-owned-small-business] program.
- Offeror does not plan to partner with any small business
- At this time, it is unknown if Offeror will be able to team with any small businesses

5. Relevant Experience

[Provide at least one (1) and no more than five (5) current and/or relevant experience examples of performance within the past 5 years. Copy and paste the below template as needed. While this appendix does not count towards the overall page limit of the technical proposal, each relevant experience is limited to three pages.]

Respondent's Name and Contract/Example Name			
Contract Number		Contract Type	
Period of Performance		Contract Value	
		(Base and Sub-awards)	
Agency		Customer Points of Contact	
Name & Address of Contracting Organization		Project Officer	
		Phone	
		E-mail	
		Contracting Officer	
		Phone	

		E-mail	
Similarities to this Solicitation			
Brief Description of Project Scope and Customer Expectations			
Brief Description of Approach and Performance			

Solicitation Closed

Attachment B: Cost Proposal Template

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 Statement of Work and general technical approach (i.e., costs, cost share, dates, etc.). Proposals that deviate substantially from these guidelines, omit substantial parts or sections, or deviate significantly from the original Enhanced White Paper Rough Order of Magnitude (ROM) estimate may be eliminated from further review and funding consideration.

To ensure Cost Proposals receive proper consideration, it is mandatory that the Cost Proposal include both Section I: Cost Proposal Narrative and Section II: Cost Proposal Format.

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

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

Cost Proposal Narrative

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. All Proposals must provide the following overview information as part of the Cost Proposal Narrative:

Overall Approach. Provide an overall and succinct explanation of how this Proposal is structured.

Assumptions. Provide any assumptions. Note that assumptions should be limited to cost or pricing. Technical assumptions are better captured in the Statement of Work.

Preferred Payment Method. Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones with Ceiling, (2) Cost Reimbursable/Cost

Share with Ceiling, (3) Cost Plus Fixed Fee Milestones with Ceiling and (4) Fixed Price Milestones with Ceiling.

Detailed Cost Element Explanation: The Cost Proposal Narrative must include the following cost categories and details, at a minimum:

- a. 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.

- b. Salary Rate Limitation.** Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II is an unallowable cost under the BioMaP-Consortium OTA and shall be addressed in accordance the BioMaP-Consortium 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 BioMaP-Consortium Base Agreement for further details.

- c. 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.
- d. 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 BioMaP-Consortium 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.
- e. 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.

f. 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.

g. 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.

- i. Provide a copy of certification from a Federal agency indicating these indirect rates are approved by the Federal agency; or
- ii. Provide a letter from the Offeror's Administrative Agreements Officer, in lieu of a rate certificate, stating these indirect rates are approved by a Federal agency;
- iii. Copy of current forward pricing rate proposal with date proposal was submitted to the Administrative Agreements Officer; or
- iv. 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.

- h. Fee/Profit.** State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted. The fees shall be specific to the individual BioMaP-Consortium project and negotiated on a project-by-project basis.
- i. Cost Share.** Identify if any Cost Share is proposed. Cost Share includes any costs a reasonable person would incur to carry out (necessary to) proposed project's Statement of Work not directly paid for by the Government. If a proposal includes cost share, then it cannot include fee. Cost Share may be proposed only on cost type agreements. There are two types of cost sharing, Cash Contribution and In-Kind Contribution:

Cash Contribution:

Cash Contribution means the Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Project Award. The cash contribution may be derived from the Project Awardee (or Awardees' subawards) funds or outside sources 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.).

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

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

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

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

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 BioMaP-Consortium Members Only Site are **NOT** mandatory.

The Cost Proposal Format section must include cost-by-element detail broken out by the Offeror's fiscal year. If required by the RPP, costs must also be broken out by phase to match the technical requirements and objectives. 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 may refer to the RPP for a start date for cost estimating purposes.

Solicitation Closed

Attachment C: ASPR Security Requirements

Mandatory* ASPR Deliverables and Security Requirements

* This list of deliverables and security requirements ASPR-mandated requirements that 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 each BioMaP-Consortium Project Solicitation. BioMaP-Consortium members should be prepared to include these deliverables and security requirements as part of their Project Proposal submissions. These ASPR deliverables and security requirements are included in the Base Agreement to enable awareness and early planning by Consortium members for their inclusion as performance requirements under Project Awards.

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.

Security Audits

Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractors. Minimum length of notification is 10 business days.

Operational Security (OPSEC)

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

Security Plan

The contractor 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 contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be

delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

- a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (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 Contractor shall supply to the Contracting Officer 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	
Description: As part of the partner facility’s overall security program, the contractor 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 contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	<ul style="list-style-type: none"> • organization chart and responsibilities
Personnel Security	<ul style="list-style-type: none"> • policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
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

<p>Information Technology/Cyber Security Policies and Procedures</p>	<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 • 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>2. Security Operations</p> <p>Description:</p>	
<p>Security Management</p>	<ul style="list-style-type: none"> a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
<p>3. Personnel Security</p> <p>Description:</p>	
<p>Records Checks</p>	<p>Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.</p>
<p>Hiring and Retention Standards</p>	<ul style="list-style-type: none"> a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.

	b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
4. 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).
5. 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. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. 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)
Access Control	<ul style="list-style-type: none"> a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access.

	<ul style="list-style-type: none"> c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	<ul style="list-style-type: none"> 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.
Audit and Accountability	<ul style="list-style-type: none"> 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. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
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.
<p>6. Security Reporting Requirements</p> <p>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.</p>	
<p>7. Security Audits</p> <p>Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.</p>	

Solicitation

Attachment D: Teaming Arrangement Plan

Teaming Organization	Role	Points of Contact

Solicitation Closed