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

"Production of Drug Substances and Drug Products at Commercial Scale"

RPP #: 24-02-KSM-API
Issued: February 21, 2024
Due: March 20, 2024 1PM Eastern

Biomedical Advanced Research Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
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MedicalCountermeasures.gov

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

Platform Technologies for Efficient Distributed Scalable Manufacturing of Active Pharmaceutical Ingredients (APIs) Drugs, includes key regulatory/chemical starting material(s) (KSMs), precursor(s), intermediate, enzymes or catalyst necessary, up to and including the synthesis of essential APIs[1], with a preferred application to multiple medicines. Examples of platforms include but are not limited to those that incorporate distributed manufacturing systems with a special focus on vertical integration of the systems with fill and finish lines.

An important strategic goal of the Administration for Strategic Preparedness and Response (ASPR) Industrial Base Management and Supply Chain (IBMSC) Office Advanced Manufacturing Domain is to support and facilitate development of the technological infrastructure within the Domestic pharmaceutical manufacturing industry to provide new materials, products, capabilities, and manufacturing paradigms for the Nation. Specifically, ASPR IBMSC is seeking to develop a drug substance and drug product manufacturing design-build-test cycle at a scale that demonstrates the ability to produce hundreds of millions of doses of drug substances to support

1. Reference for essential medicines to be considered in this solicitation: https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

the American public (population scale), with a focus of sustaining domestic production capacities. This objective will support ASPR IBMSC's broader long-term goal of commercializing infrastructure that will be accessible to a broad community of users for the purpose of producing drug substances and drug products, creating a new manufacturing paradigm that can be competitive in the domestic and global market, with the added benefit of onshoring drug production.

The objective of this project is to commercialize production for at least one (1) drug substance(s) at population scale. To be eligible for consideration, offerors must be:

- Compliant with the DPA definition of a "domestic source" (i.e., 50 U.S.C. 4552(7))

Offerors should also describe the following in their Enhanced White Paper in order to maximize their potential for award:

- Demonstrated experience in the scalable manufacturing of KSMs/APIs and FPF drugs, specifically at or beyond MRL 6
- Proven ability to manage complex projects, encompassing engineering design, technical development, logistics, pricing/costing and infrastructure governance

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

2 Administrative Overview

2.1 Request for Project Proposals (RPP)

This RPP utilizes a two-stage approach, as described below. Based on the Government's evaluation of the Enhanced White Papers in Stage 1, successful Offerors will be invited to participate in Stage 2 Presentations for further evaluation. The Government will then complete source selection, and the selected Offeror(s) will be invited to submit a Full Cost Proposal and Statement of Work.

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

The following two-stage approach is intended to streamline the initial proposal preparation time and effort for Offerors as follows:

Stage 1 (Enhanced White Paper): Enhanced White Papers submitted under this RPP shall follow the template provided in Attachment A. All Offerors will receive feedback on eligible submissions.

Stage 2 (Presentation followed by Statement of Work and Full Cost Proposal): Successful Offerors will receive invitation letters from the CMF to participate in Presentations during Stage 2, which will include instructions, evaluation criteria, and meeting details. All Stage 2 Offerors will receive additional feedback from Stage 2. Based on the Government's evaluation of the Presentations, the selected Offeror(s) will receive a request from the CMF to submit a Statement of Work (see Attachment B) and Full Cost Proposal (see Attachment D).

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. BioMaP-Consortium members typically execute the BioMaP-Consortium Base Agreement with the CMF upon entering the consortium. 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 Enhanced White Paper 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 and Type of Funding Instrument Issued

The anticipated Period of Performance is estimated be 24 months or less. Specific dates are to be negotiated. It is anticipated that the primary place of performance will be the Offeror's facilities, however this aspect can be negotiated as part of each Offeror's submission.

The estimated funding for this project is approximately $34,063,260. The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

2.4 Expected Award Date

Offeror should plan for the period of performance to begin during Quarter 3 of Government Fiscal Year 2024. 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.

2.5 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 Eligibility Criteria

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

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

- Compliance with the DPA definition of a "domestic source" (i.e., 50 U.S.C. 4552(7))

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

2.7 Special Considerations

The following are special considerations in the selection and/or negotiation process; however, are not 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. Priority will be given to proposals with domestic United States focus, including Hawaii, Alaska, and US Territories. This does not preclude offers from non-US companies, provided the work is performed in the US and/or 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.
- **Cost Sharing.** Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment D.

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

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

2.9 Regulatory Terms

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

Additional information on the applicable regulatory terms is provided in the BioMaP-Consortium Base Agreement. These restrictions include mandatory government review and reporting processes that may impact the Offeror's schedule.

2.10 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.

- **Unique Entity ID (UEI).** In accordance with the BioMaP-Consortium Base Agreement, Offerors will be required to obtain a Unique Entity Identifier (UEI) from SAM.gov prior to award of a Project Agreement.

2.11 Security Requirements.

See Attachment C for potential Administration for Strategic Preparedness and Response (ASPR) Deliverables and Security Requirements that may be required for any BioMaP-Consortium Project Agreement. ASPR shall be the sole determiner of the necessity of inclusion of these requirements, or subset thereof, on a case-by-case basis. BioMaP-Consortium members should be prepared to include applicable deliverables and security requirements. Project-specific security deliverables and requirements will be provided prior to award.

2.12 Preparation Cost

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

3 Technical Requirements

3.1 Introduction

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

For scheduling and pricing purposes, Offerors should assume that activities may occur concurrently, where practicable, to support cost and schedule savings.

3.2 Overview

ASPR IBMSC is seeking to develop a drug substance and drug product manufacturing design-build-test cycle at a scale that demonstrates the ability to produce hundreds of millions of doses of drug substances to support the American public (population scale), with a focus of sustaining domestic production capacities. This objective will support ASPR IBMSC's broader long-term goal of commercializing infrastructure that will be accessible to a broad community of users for the purpose of producing drug substances and drug products, creating a new manufacturing paradigm that can be competitive in the domestic and global market, with the added benefit of onshoring drug production.

3.3 Technical Objectives

The objective of this project is to commercialize production for at least one (1) drug substance(s) at population scale. This will be achieved by employing a multi-step approach as described below, with a total period of performance of no more than 24 months.

Objective A

Objective A is an engineering design and study phase to allow the performer to explore, develop and refine an infrastructure design and technical approach, including management, logistics, pricing/costing and other non-technical elements necessary to achieve the primary goal of distributed scalable manufacturing of drug substances at population scale. The following incremental objectives are required:

i. Jointly with the Government, select at least 1 proposed target drug substance(s), with a minimum entry requirement of Manufacturing Readiness Level (MRL) 6 (Manufacturing Proof of Concept Developed, see MRL definitions here). Must include rationale and basis for selection.
ii. Develop a detailed list of molecules and/or molecule classes, as well as other materials and systems and equipment required for each phase of manufacture, for each drug substance.
iii. Develop a proposed analytical/characterization and manufacturing plan for the manufacture of the selected drug substance(s) at population scale that includes automated and integrated processes across all stages of design, manufacturing, testing, and analysis. Plan must increase MRL to 10 and meet U.S. Pharmacopeia standards and ICH guidelines for purity, potency, safety, validation, quality, etc. Concepts to be considered in the analytical/characterization and manufacturing plan development may include, but are not limited to:
    a. Design tool innovations to enable forward engineering of novel synthetic pathways and population scale manufacturing.
    b. Methods for automated, scalable, high-throughput and distributed drug substance and drug product manufacturing.
    c. Design evaluation tools to enable massively parallel testing, analysis, validation, and verification of engineered systems, including analysis of intermediates.
    d. Fully integrated computational and physical infrastructure to optimize design, manufacturing, validation/quality control, and analysis.
    e. Include in the plan an infrastructure governance framework required to achieve population scale manufacturing of the selected drug substances, including considerations of academic and industrial partnerships, schedule requirements for each phase of drug substance development.
iv. Evaluate the maturity of necessary technology and infrastructure in the domestic market.
v. Conduct a risk assessment based on the maturity of domestic capabilities.
vi. Refine and finalize the analytical/characterization and manufacturing plan.
vii. Present final results of Objective A and the Plan for Objective B to the Government for approval to execute Objective B

Objective B

Upon approval from the government to proceed with Objective B at the conclusion of Objective A, develop and execute an analytical model and demonstrate the manufacturing of a KSM/API

including the development from MRL 6/7 to MRL 10, in compliance with U.S. Pharmacopeia standards and ICH guidelines for purity, potency, safety, validation, quality, etc.

i. Execute an analytical model and demonstrate manufacturing of the drug substance under various conditions and assumptions that:
    a. Demonstrates the ability to produce a minimum of 1 drug substance(s) at population scale.
    b. Assesses, through multiple production runs, various scenarios using various assumptions that exercises the limits the model and the assumptions, with a goal of identifying a set of input market conditions that can positively influence best results for drug substance manufacturing at population scale, and those which negatively influence results for drug substance manufacturing at population scale. Outcomes to be considered include, but are not limited to:
        i. Shortest time to market
        ii. Lowest development and deployment costs
        iii. Optimal time to market with cost considerations
        iv. Major influencers in time to market
        v. Major factors and influencers in development and deployment costs
        vi. Recommendations for future investment that can improve real-market ability to enable manufacturing of drug substances at population scale

3.4 Deliverables

Objective A deliverables:

i. Monthly technical progress report
ii. Objective A Project Plan (1 month after award):
    a. Plan should describe in detail the proposed plan to achieve each numbered step in sub-paragraph a above.
    b. Plan should include all analytical assumptions that will be employed in preparing and executing the model.
    c. Plan should include a range of assumptions/variables that can be used to assess various market conditions in Objective B.
    d. Plan should include metrics, variables, and milestones for gauging domestic and global market progress of required technologies and infrastructure that will be needed to validate the model in real world scenarios.
    e. Plan should include all metrics, variables and milestones that define the various gates and decision points in the model (distinct from the bullet above).
    f. Plan should include a detailed analytical and manufacturing (Production) information that will be developed. Details should include the basic steps for each phase of analysis (anticipated to follow the various MRLs from 6-10), and which includes all dependencies and data interfaces between phases.
    g. Plan should include identification of risks associated with execution of the plan.
iii. Drug Substance Selection Report

a. Basis for selection for each drug substance
b. List of required materials for each molecule/molecule class

iv. Analytical/Characterization and Manufacturing Plan (at conclusion of Objective A)
a. Final analytical and manufacturing plan that describes all analytical and manufacturing steps, data interfaces between phases, and other pertinent data and facts that will allow the reader to fully understand the methodology of the proposed plan.
b. Complete description of the infrastructure and management structure, including but not limited to addressing all elements that will accomplish the program's goals and milestones (at conclusion of Objective A)

v. Objective A Review (at conclusion of Objective A)
a. Written briefing and oral presentation to the government team summarizing Objective A results and description of the technical approach and a plan for Objective B.

Objective B deliverables:

i. Monthly technical progress reports
ii. Technical Batch Reports describing the analytical/characterization and manufacturing data of each manufacturing batch
iii. Final Technical Report:
a. Thorough discussion of the analytical/characterization and manufacturing (Production) model and its inherent limitations.
b. Full list of variables
c. Full list of assumptions
d. A discussion of each model "run" that includes:
i. Market scenarios tested
ii. List of assumptions and variable values used in each scenario
iii. Discussion of observations and trends based on changes in assumptions and variables
iv. Detailed discussion of each bulleted item from Objective B requirements i.b above
v. Summary of fundings regarding major influencers identified through the production process
vi. Recommendations for further study
iv. Established Registration Batches for each drug product
v. Completion of environmental, engineering and registration batch runs for each drug product.
vi. Abbreviated New Drug Applications (ANDAs) for each drug product filed with the Food and Drug Administration (FDA)

3.5 Program Management

The performer will be responsible for overall management and oversight of the work necessary to achieve the objectives of this effort. The performer will provide the overall management, integration, and coordination of all objective activities, including a technical and administrative organization that ensures the efficient planning, initiation, implementation, and direction of all activities.

The performer will establish and maintain a project milestone schedule for the entire effort that includes all critical steps, critical path, and phases to include go/no-go and success criteria.

Any changes or deviations planned or incurred by the performer in pursuing the objectives of this effort shall be reported to USG. While primary responsibility for management and execution of the effort resides with the performer, USG shall have input to the milestone review process and any changes to the objectives.

3.6 Risk Management Objectives

The performer shall identify all anticipated project risks and track them via a Risk Register in accordance with deliverables requirements. The performer shall manage all project risks using its in-house risk management capabilities, and report to the USG changes to all identified risks as they occur/arise. USG shall be permitted to participate in the risk management and mitigation processes associated with this project.

3.7 Schedule Objectives

The Government's schedule objective for this effort is a period of performance of no more than 24 months. High-level milestones are outlined below, however responders should include durations for Objective A and Objective B in their response, with anticipated dates of the high-level milestones.

Milestone	***Due Date***
Objective A	
Kickoff meeting	Within 30 days of award
Objective A Project Plan	1 month from the award
Drug Substance Selection	TBD
Draft Analytical/Characterization and Manufacturing Plan	TBD
Objective A Review	TBD
Objective B	
Demonstration of population-scale production of at least one (1) drug substance(s) that meet U.S. Pharmacopeia standards for purity, potency, safety, and quality	21 months from the award
a. Demonstrate the overarching analytical and manufacturing infrastructure to enable end-to-end process.	
b. Demonstrate the analytical and manufacturing (production) Design tool innovations to enable the commercial production of at least (1) small molecule drug substance(s).	

c. Establish validated Methods for automated, scalable, high-throughput distributed manufacturing.	
d. Design evaluation tools to enable massively parallel testing, analysis, validation, and verification of engineered systems, including analysis of intermediates.	
e. Demonstrate a Fully integrated analytical and production infrastructure supporting design, fabrication, validation/quality control, and analysis, the totality of which should be tightly for design, process, manufacturing, and quality control optimization.	
f. Completion of environmental, engineering and registration batch runs for each drug product, including acceptable analytical/characterization data	
g. Technical Batch Report for each Environmental Batch	
h. Technical Batch Report for each Engineering Batch	
i. Technical Batch Reports for each Registration Batch	
j. Filing of an ANDA for each drug product	
Final Report	30 days from completion

3.8 Teaming and Partnerships

It is anticipated that multi-disciplinary teams will approach this program, and that successful implementation will result from collaborations between academia and industry. Teams may be led by industrial, academic, or non-profit entities, and along with other organizations. Teams can incorporate members with experience in fields such as computer science, engineering, automation, regulatory, supply chain, industrial process development, chemistry/chemical engineering, and pharmaceutical sciences, among others. It is expected that the proposed leadership team will include individuals with significant experience and expertise in directing operations and technology development. These teams will lead large and diverse teams with both academic and industrial partners and have significant experience in industrial process design, identify industrial and commercial partners to aid in focusing technology development and identifying target drug substances. This expectation allows the rapid design and prototyping infrastructure to benefit from industrial partner knowledge and allows industrial partners to impact design processes based on experience. Team efforts should be fully integrated and demonstrate that all components are necessary and inseparable.

4 Stage 1: Enhanced White Paper Submission

4.1 General Instructions

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

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

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

4.2 Submission

Enhanced White Papers must be submitted online via BIDS at https://ati2.acqcenter.com/BIOMAP/BIDS.NSF. Offerors are strongly encouraged to register as a new user well in advance of the Enhanced White Paper submission deadline. (Note: Submitter registrations from previous solicitations are still valid.) After registering and logging in, Offerors should select the "Respond to RPP" option on the left menu bar and select "RPP-24-02-KSM-API".

The BIDS Home Page will contain a link to a "Submitter Quick Reference Card" to help with the electronic submission process. The Home Page will also contain contact information for assistance with any problems associated with the electronic submission process.

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. Please allow sufficient time to submit your Enhanced White Paper.

Files submitted in BIDS must be print-capable and without a password required. File names must contain the appropriate extension (.docx, or .doc). File names should not contain special characters. Apple users must ensure the entire file name and path are free of spaces and special characters.

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

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

Once an Offeror has submitted an Enhanced White Paper, the Government and the BioMaP-Consortium CMF will not discuss evaluation/status until the source selection process is complete.

4.3 Submission Documents and Format

The Enhanced White Paper must follow the mandatory template in Attachment A, and is limited to 15 pages excluding Cover Page, Data Rights Appendix, and Relevant Experience Appendix. The section headers in Attachment A are mandatory.

The following formatting requirements apply:

- 12-point font (or larger), single-spaced, single-sided, 8.5 by 11 inches
- Smaller type may be used in figures and tables, but must be 8-point font (or larger)
- Margins on all sides (top, bottom, left, and right) should be at least 1-inch

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

5 Stage 1: Enhanced White Paper Evaluation

5.1 Compliance Screening

The BioMaP-Consortium CMF will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced White Papers 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 Enhanced White Papers 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 Enhanced White Papers. Such review may include a panel of subject matter experts (SMEs), to include the use of contractor consultants or SMEs, who will make recommendations to a Source Selection Authority. Where appropriate, the Government will employ non-disclosure agreements to protect information. An Offeror's submission of an Enhanced White Papers under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of Enhanced White Papers will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each Enhanced White Paper against the evaluation factors detailed below and assign adjectival ratings in order to determine the best value to the Government.

5.3 Evaluation Factors

The following Evaluation factors are listed in descending order of importance:

- Factor 1 - Technical Approach: This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.
- Factor 2 – Relevant Experience: This factor evaluates the Offeror's demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems. 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.
- Factor 3 – Cost/Price Rough Order of Magnitude (ROM) Estimate: The Enhanced White Paper shall include as thorough a cost/price estimate as is possible. During Stage 1, the primary objectives of the Government's evaluation is to assess (1) if the proposed estimate is based on realistic assumptions, (2) if the estimate reflects a sufficient understanding of the technical goals and the objectives, and (3) if the estimate is consistent with the Offeror's technical approach.

5.4 Evaluation Ratings

The Government will assign one of the following adjectival merit ratings to each of the factors:

- Excellent
- Very Good
- Acceptable
- Unacceptable

Note, as described throughout this RPP, selected Offerors will ultimately be requested to provide a Full Cost Proposal which will be evaluated for realism, reasonableness, and completeness and subject to negotiation prior to award. If the Full Cost Proposal varies in any significant manner from the Enhanced White Paper estimate, it will likely be grounds for the Government to reconsider whether the project is suitable for award.

5.5 Evaluation Results

Upon review of the Enhanced White Papers, Offerors may receive feedback and be invited into Stage 2 of the Enhanced White Paper process. Offerors who are not invited to proceed into Stage 2 will be provided feedback.

6 Stage 2: Presentation, SOW, Full Cost Proposal

6.1 Presentation

The successful Stage 1 Offeror(s) will receive an invitation letter from the CMF to participate in a virtual presentation of the proposed project during a meeting with the Government sponsors. The invitation letter will include additional details. While the Government reserves the right to request that additional information related to specific areas of interest be included in the presentation, at a minimum Offerors should be prepared to include the following information:

Executive summary (up to approximately 10 to 15 slides):

- Technical approach overview
- Facilities and personnel qualification

Oral proposal presentation (up to approximately 25 to 30 slides):

- Detailed technical approach
- Detailed risks and mitigation plan
- Details of the cGMP manufacturing facility (can include video)
- Budget estimation
- Teaming/subcontractors
- Data Rights Assertions

The information discussed during the presentation provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the Enhanced White Paper and the Offeror's capabilities. The pitch should be restricted to a maximum of 60 minutes with an additional 30 minutes to address any questions from the Government and discussion (total of 90 minutes). Offerors will be requested to provide advanced copies of their presentation materials prior to the meeting date.

6.2 Presentation Evaluation

The Government will evaluate the information provided in each Offeror's Oral Presentation to determine which Presentation(s) provide(s) the best value to the Government.

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

6.3 Evaluation Outcome

The Government will determine which project(s) provide the greatest value to the Government based on a final evaluation of the information provided in the applicable Enhanced White Paper

(Stage 1) and the Presentation (Step 2). Following the evaluation, the Source Selection Authority may:

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

As the basis of selections are completed, the Government will forward their selections to the BioMaP-Consortium CMF to notify 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. Selected Offeror(s) will receive a request letter detailing the next steps in the award process.

6.4 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Excellent, but not immediately selected 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.

6.5 Statement of Work

If selected for award following the Presentations, the Offeror will be requested to provide a detailed SOW/Milestone Payment Schedule using the mandatory template provided as Attachment B. The Government may collaborate with the Offeror during the development process.

6.6 Cost Proposal

If selected for award following the Presentations, Offerors will be requested to provide a Full Cost Proposal. The Cost Proposal must include two sections, a Cost Proposal Narrative and a Cost Proposal Format. Offerors are encouraged to use their own cost formats such that the necessary detail is provided. The BioMaP-Consortium CMF will make optional cost proposal formats available on the Members-Only BioMaP-Consortium website. The Cost Proposal formats are NOT mandatory.

Each cost proposal should include detailed direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), etc. See Attachment D for full cost proposal requirements.

The BioMaP-Consortium CMF will analyze the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP. Analysis will include proposed cost together with all supporting information. 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 project value is fair and reasonable, subject to final Government negotiations.

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

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

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

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

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

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

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

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

   The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The 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.

7 Points of Contact

Questions related to this RPP should be directed to and 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.

8 Attachments

Attachment A: Enhanced White Paper Template
Attachment B: Statement of Work Template
Attachment C: Potential ASPR Security Requirements
Attachment D: Full Cost Proposal Instructions

ATTACHMENT A: ENHANCED WHITE PAPER TEMPLATE

Directions: The following pages are the mandatory Enhanced Whitepaper template. The template includes mandatory aspects including a cover page, section headers, charts, and appendixes. Guidance indicated in [brackets] is provided to assist the Offeror. Delete the guidance and replace with content.

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[Proposal Title]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the 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 Enhanced White Paper 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).*]

_____ _____
Signature of responsible party for the Offeror DATE

[Title of Enhanced White Paper]

1. **Minimum Eligibility Requirement**: [Address how the Offeror currently satisfies the following minimum eligibility requirements.]

2. **Background**: [Briefly provide background understanding of the problem.]

3. **General Approach:** [Briefly summarize the general approach and how it will solve the problem.]

4. **Technical Strategy**: [Thoroughly describe the proposed technical strategy in detail, with a clear course of action to address the entirety of Objectives A and B as described in Section 3 of this RPP.]

5. **Principal Investigator:** [Identify the Principal Investigator and provide his/her relevant experience and expertise to be leveraged to meet the program's objectives.]

6. **Teaming and Project Management:** [Team Management - If the proposal involves more than one organization, identify the team that will perform the proposed work along with respective qualities or contributions (e.g., qualifications, technical experience, management experience, etc.) Indicate if the team has worked together before.

   Project Management - If the proposal involves more than one organization, clearly identify roles and responsibilities Describe plans for managing communication and conflict resolution.]

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

8. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur, but is not limited to, when an individual or an entity is unable, or potentially unable, to provide impartial advice or service to the Government or separate entity because of other business activities or relationships. Disclose any potential conflict of interest pertaining to this opportunity. If none, state as such.]

9. **Period of Performance:** [Identify the proposed Period of Performance (PoP) in months from award. Also identify the number of months for Objective A and Objective B, separately.]

10. **Timeline**: [Provide a schedule (e.g., Gantt chart) that clearly shows program tasks in an orderly manner. Provide each major task as a separate line. At a minimum, must address the RPP's Schedule Objectives in Section 3]

11. **Rough Order of Magnitude (ROM) Pricing Estimate:** [Complete the following chart to provide sufficient pricing estimation information to substantiate that the estimate reflects a sufficient understanding of the technical goals/objectives and is consistent with the Offeror's technical approach. If subcontractors or consultants are proposed, the estimates for their labor, travel, material, other directs, indirects, and fee should all be included on their respective Subcontractor or Consultant row. As a result, the Labor, Material, Other Direct Costs, Indirect Cost, and Fee rows should only reflect the Offeror's costs.]

Rough Order of Magnitude (ROM) Pricing Estimate			
Cost Element	**Objective A Estimate**	**Objective B Estimate**	**Total Estimate**
Labor	*$XXX*	*$XXX*	*$XXX*
Labor Hours	*XX*	*XX*	*XX*
Subcontractors	*$XXX*	*$XXX*	*$XXX*
Subcontractor Hours	*XX*	*XX*	*XX*
Consultants	*$XXX*	*$XXX*	*$XXX*
Consultant Hours	*XX*	*XX*	*XX*
Material/Equipment	*$XXX*	*$XXX*	*$XXX*
Other Direct Costs (ODCs)	*$XXX*	*$XXX*	*$XXX*
Travel	*$XXX*	*$XXX*	*$XXX*
Indirect Costs	*$XXX*	*$XXX*	*$XXX*
Fee *(Not applicable if cost share proposed)*	*$XXX*	*$XXX*	*$XXX*
Total Cost to Government	*$XXX*	*$XXX*	*$XXX*
Additional Offeror-Provided Cost Share	*$XXX*	*$XXX*	*$XXX*
Total Project Value	**$XXXXXX**	**$XXXXXX**	**$XXXXXX**

12. **Estimate Rationale:** [Provide brief rationale describing how the estimate was calculated and is appropriate for the proposed work. Include list of important pricing assumptions.]

13. **Offeror Resources**: [Identify any key facilities, equipment, cost share, and other resources proposed for the effort. Identified facilities, equipment, and resources should be available and relevant for the technical solution being proposed. If none, state as such.]
14. **Government Resources**: [Identify any key Government facilities, Government equipment, Government property, etc. that requested to use for the effort. If none, state as such.]
15. **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).]

15.1. 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

15.2. 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

15.3. Potential Small Business Utilization: [Identify any additional potential and realistic opportunities with the technical approach/scope to meaningfully involve small

businesses, which have not otherwise been addressed in the previous subsections. If none, state as such.]

Relevant Experience Appendix

[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 enhanced white paper, each relevant experience is limited to three pages.]

Relevant Experience Example #1			
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	
		Agreements Officer	
		Phone	
		E-mail	
Similarities to this Solicitation			
Brief Description of Project Scope and Customer Expectations			
Brief Description of Approach and Performance			

Data Rights Appendix

[Note that this assertion is subject to negotiation prior to award. Failure to complete this appendix in its entirety may result in removal from the competition and the proposal determined to be ineligible for award. This appendix does not count towards the overall page limit of the enhanced white paper.]

Directions: Review and check the appropriate box. Only complete the table if asserting data rights. Add additional rows as needed.

☐ 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 as detailed in the table below.

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

☐ Offeror will NOT be asserting data rights for the proposed effort.

ATTACHMENT B: STATEMENT OF WORK TEMPLATE

[The SOW is to be initially developed by the Lead BioMaP-Consortium member organization, and the Government will ultimately provide collaborative review and input during the pre-award process. The SOW is intended to be incorporated into a binding agreement at time of award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. The following is the required format for the SOW.]

Statement of Work

Submitted under Request for Project Proposals (*RPP NUMBER*)
Proposed Project Title:
BioMaP-Consortium Member Organization Name:
Places of Performance:

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

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

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

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

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

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

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

Below are the following minimum deliverables for this RPP. This may be updated to reflect any additional deliverables as identified in Section 3 of the RPP.

Deliverable Description	Content Requirements and Instructions [i]	Reporting Frequency [ii,iii]
Kick Off Meeting	Recipient to develop Agenda and host an in-person or virtual kick-off meeting to discuss overall project objectives, key personnel, deliverables, risks, schedule and funding/payment procedures. Provide meeting minutes.	Kickoff meeting conducted within 30 days of award. Minutes to be submitted within 3 business days of meeting.
Ad-hoc Project Team Meetings	Recipient to schedule and create and agenda. Follows Agenda mutually agreed upon in advance of meeting. RECIPIENT to provide meeting minutes within 3 business days from date of meeting.	As needed for special topics, when specifically requested by the OTAO or OTTR.
Monthly Project Team Meetings	Purpose is to review monthly progress report findings, any changes since last month and any projected issues or challenges.	Virtual. Monthly, 5 business days after the monthly report deliverable. 1 hour duration, hosted by the recipient. Minutes to be submitted within 3 business days of meeting.
Monthly Project Progress Report	Monthly report of overall status including cost, performance and schedule progress and variance from plan. Include discussion of important design considerations and milestones, such as Process Flow Diagrams complete, P&IDs Issued for Design, Process Description complete, etc. Include status of other engineering disciplines, project delays, risk management, funding issues, Construction, Startup, Commissioning/Validation, and Regulatory progress. Level of detail for various aspects of project may decrease or increase in detail as the project moves through the various phases of execution.	Monthly. Due 15th of the month. Contractor format acceptable, in PDF.

Deliverable Description	Content Requirements and Instructions [i]	Reporting Frequency [ii,iii]
Quarterly In-Process Review (IPR)	Organized, scheduled and hosted by Recipient. May be virtual or physical at the Recipient's facilities based on USG preference. High level project progress review of overall objectives including, but not limited to Schedule, Budget, Quality, Cost Control (i.e. changes), Design, Construction, Validation, Regulatory. Projections against project expectations, including risks and mitigation plans.	Every 3 months from start of project. Recipient to send brief 3 working days in advance of meeting.
Integrated Master Project Schedule	MS Project Detailed Project Schedule, full detailed schedule for entire Project, including all major activities, critical path, and milestones. Status updated regularly.	Status updated monthly and when milestones and/or major events change.
Project Budget	Excel Detailed Project Budget, full detailed budget for entire Project, and overall project financial performance	Provided monthly
Project Documents and List(s)	Full listing of project, documentation organized by engineering discipline or other category (e.g. drawings list, specifications list, procurement packages list, instrument index, URS/FRS, etc.)	Submitted, uploaded and updated as required to USG specified site.
Project Documentation	Project Design, Procurement, Construction, Validation, Regulatory, and other related project execution related documents	When specifically requested via e-mail by USG Project Manager (or designee), post latest version of requested documents to shared documents site
Project Risk Register	Project risks identified throughout the project shall 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.	Updated monthly and submitted with Monthly Technical Progress Report and posted to USG identified document site.
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 with monthly technical progress report.

Deliverable Description	Content Requirements and Instructions [i]	Reporting Frequency [ii,iii]
Site Visits	Host visits from USG following agenda/schedule mutually agreed upon with USG in advance of visits. Provide visit notes within 3 business days from date of visit.	Typically, quarterly, commensurate with quarterly IPR, at the Agreements Officer's discretion.
Annual Project Progress Report	High level project progress review of overall objectives. Updated projections against project expectations, including risks and mitigation plans, should be reported with respect to the previous annual report. Summary of critical changes that took place over the year. Recommended to not exceed 20 pages.	Annually from award. To review progress over the previous 12 months. A Draft to be submitted 30 days after the completion of each year of performance. Within 15 days of receipt, the Government will provide review comments. The Respondent shall respond within 15 days of receipt of comments. Report format: Microsoft Word and PDF
Final Report	Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of production improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.	Initial submission to be submitted 30 days prior to the end of the period of performance. Within 15 days of receipt, the Government will provide review comments. The Respondent shall respond within 15 days of receipt of comments.

Deliverable Description	Content Requirements and Instructions [i]	Reporting Frequency [ii,iii]
Security Plan	The Security Plan must detail how the RECIPIENT will adhere to established ASPR Informational Technology (IT) and Operational Security (OPSEC) policies and requirements. The Security Plan must include but is not limited to; • 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 • Plan to manage Consortium member physical, IT, and OPSEC security compliance as a contingency of Consortium membership	Initial submission 30 Days after Award, updated as necessary See BARDA Security Plan checklist

[i] Unless otherwise specified, RECIPIENT's format is acceptable. Submissions may be in MS Office or PDF format. Funding and schedule information shall be MS Excel and MS Project, respectively.

[ii] Unless otherwise specified, ALL deliverables shall be emailed to the Other Transaction Agreements Officer (OTAO) and Other Transaction Technical Representative (OTTR) listed in the Agreement AND uploaded to USG-specified database/folder.

[iii] All Final Deliverable Submissions are subject to USG review and comment which may result in additional Deliverable submissions by the RECIPIENT.

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

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable.

- For fixed price agreements, when each milestone is submitted, the BioMaP-Consortium member will submit an invoice for the exact amount listed on the milestone payment schedule.
- For cost reimbursable agreements, the BioMaP-Consortium member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a $5M multi-year project may have 20, while a $700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Monthly Reports which include both Technical Status and Business Status Reports (due the 10th of each month), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

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

Please Note:

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

4. Monthly, Quarterly, and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be the POP end noted in Project Award.
6. BioMaP-Consortium Milestone Numbers are used for administrative purposes and should be sequential.
7. Task Numbers are used to reference the statement of work if they are different from the Milestone Number.

ATTACHMENT C: POTENTIAL ASPR SECURITY REQUIREMENTS

This is a potential list of ASPR-mandated security deliverables and requirements that may be required for any BioMaP-Consortium Project Agreement. ASPR shall be the sole determiner of the necessity of inclusion of these requirements, or subset thereof, on a case-by-case basis. BioMaP-Consortium members should be prepared to include these deliverables and security requirements as part of their submissions. Project-specific security deliverables and requirements will be provided prior to award.

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.

Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

a) A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.

b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.

c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The contractor shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

a) Production rates and lead times shall be understood and communicated to the Agreements Officer or the Agreements Officer's Representative as necessary.

b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

a) Critical Material
b) Vendor
c) Supplier, Manufacturing / Distribution Location
d) Supplier Lead Time
e) Shelf Life
f) Transportation / Shipping restrictions

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

Manufacturing Data Requirements

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

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

Contractor Locations

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

Contractor will submit Work Locations Report:

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

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 PAR 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 AO 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 AO 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	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements

Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• 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
2. Site Security Master Plan	

Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products

	by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.

Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations Description:	
Information Sharing	a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security Description:	
Records Checks	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.
Hiring and Retention Standards	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.
7. Information Security Description:	
Physical Document Control	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).
8. Information Technology & Cybersecurity Description:	
Identity Management	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	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. 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	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	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	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	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	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	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	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.
9. **Transportation Security** Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. • Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.

10. Security Reporting Requirements Description: 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. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. 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 subcontractor.	

ATTACHMENT D – FULL COST PROPOSAL INSTRUCTIONS

1. General Instructions

The objective of the Cost Proposal is to provide sufficient cost information to substantiate that the proposed cost is realistic, reasonable, and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the 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.

2. 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:

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

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

2.3 Preferred Payment Method. Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones with Ceiling, (2) Cost Reimbursable/Cost Share with Ceiling, (3) Cost Plus Fixed Fee Milestones with Ceiling and (4) Fixed Price Milestones with Ceiling).

2.4 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 rational used to derive the rate.

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

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

i. 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.

j. 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.).

k. 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.*

3. Cost Proposal Section II: Cost Proposal Format

The Cost Proposal Format must be provided as a separate Excel document. Offerors are encouraged to use their own Excel cost formats so long as the necessary cost detail is provided. Working formulas should be included to the maximum extent possible. The Cost Proposal Formats provided on the 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.