

Biomedical Advanced Research and Development Authority
(BARDA)

Request for Project Proposals (RPP)

RPP Name: Antibody (Ab) Advanced Manufacturing
Capability Improvement: Smart Technologies



RPP Identifier: 25-11-Smart Ab

RPP Issue Date: September 10, 2025

Amendment No. 2 Issue Date: September 29, 2025

Enhanced White Paper Due: October 22, 2025, 1 PM ET

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

[MedicalCountermeasures.gov](https://www.mediccountermeasures.gov)

Amendment No. 02 does the following:

Extends the proposal submission due date from October 1, 2025 to October 22, 2025, 1PM ET

All other terms and conditions remain unchanged.

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Solicitation Closed

1 Executive Summary

1.1 Biopharmaceutical Manufacturing Preparedness Consortium

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

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

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

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

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

1.2 Purpose

Monoclonal Antibodies (mAbs) played a central role in the US response to the outbreaks of important human pathogens such as anthrax, Ebola, RSV and SARS CoV-2. Advancing beyond the demonstrated manufacturing performance of mAbs for a rapid response, BARDA is seeking to improve (enhance) the speed and efficiency of antibody production. This effort is directed at developing and implementing FDA Advanced Manufacturing goals within the antibody manufacturing environment. Innovations of most interest are those that rapidly scale manufacturing capabilities (scalability), create a distributed network of manufacturing sites (portability), improve cost-efficiency of manufacturing processes, and create new tools that can address drug shortages in support of the emergency preparedness and response mission of the Biomedical Advanced Research and Development Authority (BARDA).

Improvements of consideration in this solicitation apply the use of automation, digitization, and artificial intelligence to; streamline production methods, collection of more process control data, and ultimately design and deployment of smart algorithms that adaptively control

or make decisions about production or release. The effort must be directed at an improvement which can be used across multiple biologics (applicability).

The effort must be focused on the manufacturing improvement of a product in the BARDA portfolio.

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 will be conducted using the Enhanced White Paper approach. In Stage 1, Offerors are invited to submit Enhanced White Papers using the mandatory format contained in this RPP (see Attachment A of this RPP). The Government will evaluate Enhanced White Papers submitted and will recommend those that best meet their current technology priorities using the criteria in Section 5 of this RPP. Offerors whose proposed solution is recommended for further consideration based on the Enhanced White Paper evaluation will be invited to submit a Statement of Work (SOW) and Full Cost Proposal in Stage 2 (and may be required to submit additional documentation or supplemental information). Notification letters will contain specific Stage 2 proposal submission requirements.

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 (Statement of Work and Full Cost Proposal): The recommended Offeror(s) will receive a request from the CMF to submit a Statement of Work (see Attachment B) and Full Cost Proposal (see Attachment C).

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

The anticipated period of performance shall not exceed 36 months. Offerors should plan for the period of performance to begin in late Quarter 1 or early Quarter 2 of Government Fiscal Year 2026. Government reserves the right to change the proposed period of performance start date through negotiations via the CMF and prior to issuing a Project Agreement.

2.4 Estimated Funding

The total estimated funding for this project is approximately \$13.2 million. This amount is approximate and subject to adjustment based on program requirements and the availability of funds. Funding of proposals submitted in response to this RPP is contingent upon the availability of federal funds for this program. The Government anticipates making one or more awards under this RPP.

2.5 Proprietary Information

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

2.6 Minimum Criteria

To respond to this RPP, Offerors must show evidence they satisfy the following minimum 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.

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

2.7 Special Considerations

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

United States Industrial Base. Consistent with BioMaP-Consortium's focus to expand the United States' domestic industrial and manufacturing base for medical countermeasures, proposals are expected to be focused on United States investments, and all work and/or capacity expansion shall be focused on US soil (including United States territories) to satisfy domestic requirements. This does not preclude offers from non-US companies, provided they meet the minimum eligibility criteria and work supports US domestic purposes, nor does it preclude non-US companies from utilizing non-US employees to provide subject matter expertise.

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

2.8 Cost Sharing

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

However, this is not required in order to be eligible to receive an award under this RPP. If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment C.

2.9 Intellectual Property and Data Rights

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

The BioMaP-Consortium Base Agreement contains general provisions regarding Data Rights. For this specific RPP, it is anticipated that anything delivered under this proposed effort would be delivered to the Government with government purpose rights, unless otherwise specified in the proposal and agreed to by the Government. All proposed data rights are subject to

Government review and approval. Rights in technical data agreed to by the Government will be incorporated into the Project Agreement.

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

2.10 Regulatory Terms

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

While additional regulatory terms have not been identified at this time for this project, information on potential regulatory terms is provided in the BioMaP-Consortium Base Agreement.

2.11 Special Requirements

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

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

2.12 Security Requirements

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

2.13 Preparation Cost

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

3 Proposals

3.1 Question and Answer Period

All questions regarding this RPP must be submitted via email to biomap-contracts@ati.org no later than 3:00 PM ET on September 16, 2025. Please note that questions will not be addressed during the Solicitation Webinar.

Key Dates for this RPP

Date	Event
9/10/2025	RPP Released
9/15/2025	Solicitation Webinar (no live Q&A)
9/16/2025	Virtual Teaming Speed Networking Event
9/16/2025	Deadline for submitting questions to biomap-contracts@ati.org (by 3:00 PM ET)
Notification sent via email	Questions & Answers posted on the BioMaP-Consortium website
10/22/2025	Proposals Due

3.2 Proposal General Instructions

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

The proposal format provided in this RPP is mandatory and shall reference this RPP number. Offerors are encouraged to contact the Point of Contact (POC), identified herein up until the Proposal submission date/time to clarify requirements (Section 7 of this RPP).

The Government will evaluate proposals submitted and will select the proposal(s) that best meets their current technology priorities using the criteria in Section 5 of this RPP.

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

3.3 Proposal Submission

Proposals must be submitted online via BIDS at

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

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

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

Files submitted in BIDS must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename 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.

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

3.4 Stage 1 (Enhanced White Paper): Submission Format

The Enhanced White Paper must be submitted in Word format (.docx or .doc) or as a PDF, and must follow the mandatory template in Attachment A of this RPP. The Enhanced White Paper is limited to 15 pages excluding the 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, .doc, or pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters.

3.5 Stage 2 (Statement of Work and Full Cost Proposal): Submission Format

- **Statement of Work – See Attachment B:** Recommended Offeror(s) will be requested to submit 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.
- **Cost Proposal submission – See Attachment C:** Recommended Offeror(s) will be requested to provide a Full Cost Proposal, which includes a Cost Proposal and Narrative.

4 Technical Requirements

4.1 Overview

Monoclonal Antibodies (mAbs) played a central role in the US response to the outbreaks of important human pathogens such as anthrax, Ebola, RSV and SARS CoV-2. Advancing beyond the demonstrated manufacturing performance of mAbs for a rapid response, BARDA is seeking to improve (enhance) the speed and efficiency of antibody production. This effort is directed at developing and implementing FDA Advanced (See Section 8, Reference #2) goals within the antibody manufacturing environment. Innovations of most interest are those that rapidly scale manufacturing capabilities (scalability), create a distributed network of manufacturing sites (portability), improve cost-efficiency of manufacturing processes, and create new tools that can address drug shortages in support of the emergency preparedness and response mission of the Biomedical Advanced Research and Development Authority (BARDA).

Improvements of consideration in this solicitation apply the use of automation, digitization, and artificial intelligence to; streamline production methods, collection of more process control data, and ultimately design and deployment of smart algorithms that adaptively control or make decisions about production or release. The effort must be directed at an improvement which can be used across multiple biologics (applicability).

The effort must be focused on the manufacturing improvement of a product in the BARDA portfolio.

4.2 Technical Objectives

4.2.1 General Objectives:

This program aims to utilize FDA Advanced Manufacturing concepts to identify, develop, and optimize qualifiable novel, as well as existing manufacturing technologies that will improve quality, decrease manufacturing times, improve manufacturing flexibility, and reduce cost, for antibody-based MCMs that address the BARDA threat space. Offerors must be actively developing the drug candidate and must be funded for continued development to licensure. The development effort must be post Phase 2. Offerors can also propose improvements to the manufacture of drug products that are in BARDA's mission and intended for the National Stockpile.

Results of improvements should be in the areas of efficiency and productivity, cost-effectiveness, portability (multiple sites), applicability (multiple product types), scalability, data utilization and insights affecting product quality monitoring and improvement, cost reduction, and/or cycle time reductions.

Technology Readiness Levels (TRL) are a type of measurement system used to assess the maturity level of a particular technology. Each technology project is evaluated against the parameters for each technology level and is then assigned a TRL rating based on the progress of the project.

For this program, the government will assess the maturity of the proposed technology and decide on the suitability for continued development under this program. The government will use TRLs 4-6 as a guideline for determining suitability. The goal is to have innovations demonstrated at a technology maturity of TRL 6 (See Section 8, Reference #2 and Attachment E: TRL for Smart Manufacturing of Antibodies) qualifiable for GMP1 (See Section 8, Reference #4). A GMP batch is not required.

4.2.2 Specific Objectives:

4.2.2.1 Advanced development and implementation of innovations in the antibody manufacturing process to meet one or more of the goals of FDA Advanced Manufacturing, qualifiable on a scalable system, within three years of project award (See Section 8, Reference #1). Achievement of this objective will include a GMP-qualifiable successful proof of approach, operational data showing what the improvement is and its return on investment, as well as documentation to meet all the requirements of the proposed TRL and preceding TRLs.

4.2.2.2 Application of smart manufacturing concepts that use automation, digitization, and artificial intelligence to streamline production methods, collect increased process control data, and would ultimately use a smart algorithm to adaptively control or make decisions about production or release, which could be used across multiple biologics within the BARDA portfolio. Considerations for success in this solicitation include the quality and the quantity of the data used, the degree of networking of the unit operation, the algorithm's adaptivity, and the level of autonomous control designed into the application.

- For the purposes of this requirement, the government interprets “qualifiable” to mean that the equipment, software or other changes implemented and used in the manufacture should be of appropriate design and adequate size, and suitably located for its intended use, cleaning, sanitation (where appropriate), validation and maintenance and be supported by appropriate documentation (See Section 8, Reference #3).

There are some general specifications in the GMP regulations that apply to every GMP compliant equipment design:

- The system may not influence the product Critical Quality Attributes in a negative way. This could include product contact surfaces, temperature control, shear force, etc., as documented with a Quality Risk Assessment
- The system must be easy to clean and sterilize. Cleanability not only includes product contact surfaces, but also the

entire equipment, according to the environmental classification requirements.

- The system must comply with applicable technical rules. This includes manufacturing and quality standards for the equipment, from entities such as ASTM (E2500), ISPE or PDA.
- The system must be suitable for its purpose. The suitability of a system is proven by its qualification. Qualification process shall be documented by the development of a user requirement specification (URS) and continues in the phases DQ, IQ, and OQ. PQ is not required unless necessary to demonstrate suitability for purpose.
- The offeror must provide data driven evidence to support claims of process improvement relative to a baseline process. In addition, the offeror must provide baseline data from which improvements have been demonstrated.
- Focus areas for improvement can be (but not limited to):
 - Efficiency and Productivity (Cycle time, Throughput and Overall effectiveness)
 - Cost-effectiveness (ROI, Cost per gram (g), maintenance)
 - Scalability and Flexibility (Changeover time, Capacity utilization, Adaptability to process change)
 - Data Utilization and Insights (Predictive analytics, Decision making speed and Data accuracy)
 - Regulatory Compliance (Audit findings, Deviation rates, CAPA timelines)
 - Product Quality Monitoring
- The government reserves the right to decide on best value to the government.

4.3 Project Agreement Deliverables

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

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

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

Deliverable Description	Content Requirements and Instructions ⁱ	Reporting Frequency ⁱⁱⁱⁱⁱ
Kick Off Meeting	<p>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.</p> <p>Provide meeting minutes.</p>	<p>Kickoff meeting conducted within 5 days of award.</p> <p>Minutes to be submitted within 3 business days of meeting.</p>
Ad-hoc Project Team Meetings	<p>Recipient to schedule and create an agenda. Follows Agenda mutually agreed upon in advance of meeting. Recipient to provide meeting minutes within 3 business days from date of meeting.</p>	<p>As needed for special topics, when specifically requested by the OTA0 or OTTR.</p>
Monthly Project Team Meetings	<p>Purpose is to review monthly progress report findings, any changes since last month and any projected risks, issues or challenges.</p> <p>Recipient to provide meeting minutes within 3 business days from date of meeting.</p>	<p>Virtual. Monthly, 5 business days after the monthly report deliverable. 1 hour duration, hosted by the recipient.</p>
Monthly Project Progress Report	<p>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, Regulatory progress, and deviations from proposed Return on Investment. Level of detail for various aspects of project may decrease or increase in detail as the project moves through the various phases of execution.</p>	<p>Monthly. Due 15th of the month. Contractor format acceptable, in PDF.</p>

Bi-Annual 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.	Every 6 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. Submitted with the Monthly Project Progress Report.
Project Budget	Excel Detailed Project Budget, full detailed budget for entire Project	Notify USG via e-mail whenever Project Budget is revised/updated and post to shared documents site
Project Documentation	Project Design and other related project execution related documents	Included in the Monthly Project Progress Report
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 Project Progress Report.
Project Action Items List	Actions identified throughout the project, which are not tracked by some other project management tool, and which require follow up and monitoring for completion, will be captured in an Action Items List. (Or similar list/tracking tool.) List should contain information regarding identification date, target completion, responsible individuals/groups, etc.	Submitted if/as required with Monthly Project Progress Report.
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	<p>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.</p>	<p>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</p>
Final Report	<p>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.</p> <p>A section shall be included that details the effort, any changes made from initial processes, and reduction to practical evidence. Include any changes to training requirements necessitated by implementing the process changes conducted in this program.</p> <p>A section shall be included that details any improvements realized by implementation of the project. Report shall include improvements in terms of dollar savings, flexibility, speed, output, and/or any other areas</p>	<p>Initial submission to be submitted within 30 days after 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.</p>

<p>Security Plan</p>	<p>The Security Plan must detail how the RECIPIENT will adhere to established ASPR Informational Technology (IT) and Operational Security (OPSEC) policies and requirements.</p> <p>The Security Plan must include but is not limited to;</p> <ul style="list-style-type: none"> • Internal management security measures that meet the ASPR, IT, and OPSEC security requirements • Plan to ensure Project Agreement security compliance, to include roles and responsibilities • Plan to manage Consortium member physical, IT, and OPSEC security compliance as a contingency of Consortium membership 	<p>Initial submission 30 Days after Award, updated as necessary</p> <p>See BARDA Security Plan checklist</p>
<p>Quality Management Plan</p>	<p>The recipient shall develop and submit a Quality Management Plan that details the approach to regulatory compliance appropriate to the proposed innovations.</p>	<p>Initial submission 30 Days after Award, updated as necessary</p> <p>Report format: Microsoft Word and PDF</p>
<p>Infrastructure and Management Structure Organizational Chart</p>	<p>The recipient shall complete description of the infrastructure and management structure (organizational chart) including but not limited to addressing all elements that will accomplish the program’s goals and milestones. The recipient shall propose a workforce management plan, e.g., how workforce will train, maintain, etc., that reflects the ability to meet the requirements.</p>	<p>Initial submission 30 Days after Award, updated as necessary Report format: Microsoft Word and PDF</p>

4.4 Program Management

The Awardee is responsible for overall management and execution of the work to achieve the objectives of the agreement. The Awardee must provide the overall management, integration, and coordination of all agreement activities to ensure the efficient planning, initiation, implementation, and direction of all agreement activities.

The Awardee will be responsible for establishing and managing project milestones for the effort. The Awardee will ensure that any changes or deviations planned or incurred by the Awardee in pursuing the objectives of any resulting agreement are reported to the USG. While primary responsibility for management and execution of the effort resides with the Awardee, the USG will provide input to the milestone review process and any changes to the objectives of any resulting agreement.

4.5 Risk Management Objectives

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

5 Stage 1 (Enhanced White Paper): Evaluation and Selection

5.1 Compliance Screening

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

5.2 Evaluation Process

Following the preliminary screening, the Government sponsor will perform an evaluation of all qualified Enhanced White Papers. The Government sponsor team may include a panel of subject matter experts (SMEs), to include the use of contractor consultants, who will make recommendations to the Government during the evaluation. Where appropriate, the Government will employ non-disclosure agreements to protect information. An Offeror's submission of an Enhanced White Paper under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of Enhanced White Papers will be based on a comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each Enhanced White Paper against the evaluation factors detailed below.

5.3 Evaluation Factors Overview

The Government will evaluate the information provided in each Offeror's Enhanced White Paper and/or Proposal to determine which Enhanced White Paper(s) and/or Proposal(s)

provide(s) the most advantageous solution to the Government. Such a determination will be based on the following criteria:

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

5.4 Adjectival Merit Rating

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

- Technical Approach/Solution
- Relevant Experience

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

5.5 Evaluation Factors

Factor 1 – Technical Approach/Solution (Adjectival Rating): This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.

- **Factor 2 – Cost:** The proposed cost/price will be reviewed for cost/price realism, and overall, most advantageous solution to the Government and will be given a narrative rating. Proposals will be reviewed to ascertain if the costs proposed are based on realistic assumptions, reflect a sufficient understanding of the technical goals and the objectives of the proposed work, and are consistent with the Offeror’s technical approach. Quotes from proposed subcontractors and suppliers to help substantiate the

project expenses are recommended. Similarly, a breakdown of significant costs in order to show realism is also recommended.

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

The respondent shall provide relevant and recent evidence of their experience in mAb manufacturing. The respondent shall provide at least one (1) and no more than five (5) recent and relevant experience examples. Experience is considered current for performance within the past 5 years. Relevant experience shall be captured in the RPP’s Attachment A, Relevant Experience Appendix.

The Government reserves the right to contact customer references to verify performance and assess quality of that performance, and to perform independent relevant experience analysis.

5.6 Evaluation Outcome

The Government will recommend project(s) based on an evaluation of the information provided in the applicable Enhanced White Paper (Stage 1). Following the evaluation, the Project Agreement Evaluation Team (PAET) Chairperson may:

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

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

5.7 Basket Provision

The electronic “Basket” is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately recommended for award, may be placed in the Basket for 2 years and are eligible for award during that time. Proposals rated as Unacceptable will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal

best meets its needs after it has received and reviewed a Full Cost Proposal and Statement of Work.

6 Stage 2: SOW, Full Cost Proposal

6.1 Statement of Work

Recommended Offeror(s) will be requested to submit 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.

6.2 Cost/Price Estimate and Evaluation

Recommended Offeror(s) will be requested to provide a Full Cost Proposal. The Full 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 C 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 task of the proposed project when compared to the total proposed cost.

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

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

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

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

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

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

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

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

6.3 Award Determination

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

7 Points of Contact

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

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

8 References

1. Advanced Manufacturing: <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing#guidance>
2. Technology Readiness Levels: <https://medicalcountermeasures.gov/trl/integrated-trls/>
3. Qualifiable: GMP-compliant equipment design: [GMP-compliant equipment design: The GMP Equipment Design Guide - GMP Journal](#)
4. The GMP Equipment Design Guide: <https://www.gmp-journal.com/current-articles/details/gmp-compliant-equipment-design-the-gmp-equipment-design-guide.html>

9 Attachments

Attachment A: Enhanced White Paper Template (Stage 1)

Attachment B: Statement of Work Template (Stage 2)

Attachment C: Full Cost Proposal Template (Stage 2)

Attachment D: ASPR Security Requirements

Attachment E: TRL for Smart Manufacturing of Antibodies

Attachment A: Enhanced White Paper Template (Stage 1)

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.

Solicitation Closed

[Name of Offeror]

[Address of Offeror]

RPP Identifier: 25-11-Smart Ab

[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).]

[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 as described in Section 4 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.]

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 4]

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	Total Estimate
Labor	\$XXX
Labor Hours	XX
Subcontractors	\$XXX
Subcontractor Hours	XX
Consultants	\$XXX
Consultant Hours	XX
Material/Equipment	\$XXX
Other Direct Costs (ODCs)	\$XXX
Travel	\$XXX
Indirect Costs	\$XXX
Fee <i>(Not applicable if cost share proposed)</i>	\$XXX

Total Cost to Government	\$XXX
Additional Offeror-Provided Cost Share	\$XXX
Total Project Value	\$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.]

Respondent's Name and Contract/Example Name			
Contract Number		Contract Type	
Period of Performance		Contract Value	
		(Base and Sub-awards)	
Agency		Customer Points of Contact	
Name & Address of Contracting Organization		Project Officer	
		Phone	
		E-mail	
		Contracting Officer	
		Phone	
		E-mail	
Similarities to this Solicitation			
Brief Description of Project Scope and Customer Expectations			
Brief Description of Approach and Performance			

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 or Computer Software to be Furnished with Restrictions	Basis of Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Affected Deliverable(s)

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

Attachment B: Statement of Work Template (Stage 2)

Statement of Work

Submitted under the Request for Project Proposals (RPP):

Proposal/Project Number:

Organization:

Title:

- 1. Background:** [Describe the problem that the solution is addressing.]
- 2. Objective:** [Describe the goal of the project and what you are going to do to achieve the goal, including the final product(s) and/or anticipated outcome(s). Be as concise as possible.]
- 3. Project Team:** [Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified. If you are partnering with additional organizations to execute the proposed technical and programmatic work, provide details prior to the table below identifying those partners with clear roles and responsibilities of each organization.]

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

- 4. General Approach:** [Summarize your overarching approach/solution and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform/facilities or solution and the current state of the solution if previous development/progress has been made.]
- 5. Technical Approach:** [Provide a detailed approach, broken out by major phases/top level tasks and gates/decision points, on how your organization intends to address the requirements set forth in the RPP, showing a clear course of action and roles of organizations (if applicable).]
- 6. Schedule:** [Include a project schedule (e.g., a Gantt chart) that reflects the same level of detail as outlined in the Technical Approach section's work breakdown. For space efficiency, the schedule may be summarized at the task level if needed.]
- 7. Deliverables Table:** [Populate the table below to include all deliverables from the RPP and any additional technical deliverables proposed to support the technical effort. 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. List the data rights assertion as numbered in the data rights assertion table. If not applicable for that deliverable, "N/A".]

Deliverable #	Task # in Section 5 (if applicable)	Deliverable Name	Content Requirements/ Instructions	Due Date/Reporting Frequency	Assertion #

8. Milestone Payment Schedule: [Align project payments with the corresponding deliverables in the Deliverables Table and the associated completion dates.]

Milestone #	Deliverable #	Deliverable Name(s)	Due Date	Total Cost

Total Cost: \$

Total Period of Performance: # Months

Contract Type:

9. Intellectual Property, Data Rights, and Copy Rights: [If the Offeror plans to provide technical data that either pre-existed or was developed outside the proposed effort, and intends to retain additional rights to that data, such rights must be asserted by completing the table below. Please note that all assertions are subject to negotiation prior to award.]

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

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

Attachment C: Cost Proposal Template (Stage 2)

The objective of the Cost Proposal is to provide sufficient cost information to substantiate that the proposed cost is realistic, reasonable, and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the Statement of Work and general technical approach (i.e., costs, cost share, dates, etc.). Proposals that deviate substantially from these guidelines, omit substantial parts or sections, or deviate significantly from the original Enhanced White Paper Rough Order of Magnitude (ROM) estimate may be eliminated from further review and funding consideration.

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

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

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

Cost Proposal Narrative

The Cost Proposal Narrative must include sufficient information to evaluate the proposed value through cost information. This information is required to properly perform the cost and/or price analysis of a proposal. All Proposals must provide the following overview information as part of the Cost Proposal Narrative:

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

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

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

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

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

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

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

Provide an explanation for any proposed labor escalation.

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

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

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

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

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

- c. Fringe Benefits.** Identify whether or not the proposed labor rates include fringe costs. If so, then identify the percentage rate. If not, then provide a statement to that effect and include the fringe costs in the indirect section instead.
- d. Travel.** Portions of travel information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the total travel amount proposed. Provide an estimate of the cost per trip; number of trips; number of days; number of persons; departure city, destination city; approximate travel time frames; and the purpose of the travel. The key is to apply best estimating techniques that are auditable. Include a brief explanation of the methodology used to estimate travel costs. If exact destination is unknown at time of proposal, for pricing purposes use a potential location using best known information. Note that BioMaP-Consortium Project Awardees are expected to be cost-conscious regarding travel (e.g., using coach rather than first class accommodations and, whenever possible, using Government per diem, or similar regulations, as a guideline for lodging and subsistence costs). If travel is estimated based on an approved methodology, then state as such.
- e. Subcontractors/Consultants.** Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide a list of all subcontractor/consultant and a total cost for each. If a cost and/or price analysis has been performed, provide a copy or summary of results.

Support is required for each subcontractor/consultant as follows:

- If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalogue pricing, etc.)
- For a subcontractor/consultant less than \$250,000, provide a brief explanation of the work to be performed.
- For a subcontractor/consultant greater than \$250,000 and less than or equal to \$2,000,000, provide a supporting quote and confirmation of compliance with the Salary Rate Limitation.
- If a subcontractor/consultant over \$2,000,000 was competitively solicited, provide the price analysis showing how the price was determined reasonable, summary of competition, and copies of the competitive quotes.

- Absent any of the above, if relying on cost data for a subcontractor/consultant greater than \$2,000,000, a cost-by-cost element breakout must be provided to the same level of detail as the Offeror.

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

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

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

g. Indirect Costs. Portions of the indirect cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an estimate of the total indirect costs, identify each rate used in the proposal, and provide documentation to support the indirect cost rates by one of the below methods.

- i. Provide a copy of certification from a Federal agency indicating these indirect rates are approved by the Federal agency; or
- ii. Provide a letter from the Offeror's Administrative Agreements Officer, in lieu of a rate certificate, stating these indirect rates are approved by a Federal agency;
- iii. Copy of current forward pricing rate proposal with date proposal was submitted to the Administrative Agreements Officer; or
- iv. Absent Government approved rates, provide detailed supporting data to include (1) indirect rates and all pricing factors that were used; (2) methodology used for determining the rates (e.g., current experience in

the organization or the history base used); and (3) all factors, by year, applied to derive the proposed rates.

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

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

Cash Contribution:

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

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

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

In-Kind Contribution:

In Kind Contribution means the Offeror's non-financial resources expended to perform a Project Award such as wear-and-tear on in-place capital assets like

machinery or the prorated value of space used for performance of the Project Award, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Project Award.

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

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

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

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

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

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

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

Cost Proposal Section II: Cost Proposal Format

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

Proposal Formats provided on the BioMaP-Consortium Members Only Site are **NOT** mandatory.

The Cost Proposal Format section must include cost-by-element detail broken out by the Offeror's fiscal year. If required by the RPP, costs must also be broken out by phase to match the technical requirements and objectives. The sum of the phases must equal the total.

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

Solicitation Closed

Attachment D: ASPR Security Requirements

Mandatory* ASPR Deliverables and Security Requirements

* This list of deliverables and security requirements ASPR-mandated requirements that may be required for any contract or agreement awarded by or on behalf of ASPR. ASPR shall be the sole determiner of the necessity of inclusion of these requirements, or subset thereof, on a case-by-case basis, as identified in the Deliverables Section of each BioMaP-Consortium Project Solicitation. BioMaP-Consortium members should be prepared to include these deliverables and security requirements as part of their Project Proposal submissions. These ASPR deliverables and security requirements are included in the Base Agreement to enable awareness and early planning by Consortium members for their inclusion as performance requirements under Project Awards.

Security Reporting Requirements

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

Security Audits

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

Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the 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 Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.
- b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
- c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

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

Security Requirements:

1. Facility Security Plan	
Description: As part of the partner facility’s overall security program, the contractor shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	<ul style="list-style-type: none"> • organization chart and responsibilities
Personnel Security	<ul style="list-style-type: none"> • policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
Information Security	<ul style="list-style-type: none"> • identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none"> • intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems

	<ul style="list-style-type: none"> • 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. Security Operations	
Description:	
Security Management	<ul style="list-style-type: none"> a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
3. 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	<ul style="list-style-type: none"> a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
4. Information Security	
Description:	
Physical Document Control	<ul style="list-style-type: none"> a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.

Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
5. Information Technology & Cybersecurity	
Description:	
Identity Management	<ul style="list-style-type: none"> a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	<ul style="list-style-type: none"> a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	<ul style="list-style-type: none"> a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	<ul style="list-style-type: none"> a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	<ul style="list-style-type: none"> a) Establish and enforce security configuration settings.

	b) Implement sub networks for 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.
<p>6. Security Reporting Requirements</p> <p>Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.</p>	
<p>7. Security Audits</p> <p>Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.</p>	

Attachment E: TRL for Smart Manufacturing of Antibodies

Supplement: Technical Readiness Levels (TRLs) for Smart Manufacturing of Antibodies

Overview

Technical Readiness Levels (TRLs) provide a standardized framework to assess the maturity of a given technology. Each project is evaluated against defined criteria and assigned a TRL rating that reflects its progress toward operational readiness. For this solicitation, only **manufacturing-related advancements within TRLs 4 through 6** will be considered responsive.

Biomedical TRL Adaptation

The TRL framework has been adapted for the biomedical community to align with the unique requirements of regulated environments. Under this solicitation, proposals must demonstrate:

- **Minimum Entry Requirement:** Completion of **TRL-3** (component and/or breadboard validation in a laboratory environment).
- **Eligibility Requirement:** Capability to advance through **TRL-6**, defined as **system/subsystem model or prototype demonstration in a relevant environment**.

Manufacturing Considerations for TRL-6

It is critical to note that products manufactured at **TRL-6** must be suitable for use in clinical trials. This necessitates compliance with **Good Manufacturing Practices (GMP)**. Specifically:

- **Equipment and Systems Qualification:** Instruments, equipment, or systems must be **qualifiable** for their intended use. While not required to be scaled for full commercial production, they must meet design and performance requirements consistent with equipment qualification standards.
- **GMP Compliance:** Successful completion of TRL-6, within a biomedical context, requires the manufacture of GMP-compliant lots intended for clinical use. By extension, control systems supporting these processes must be designed and manufactured in a manner that enables qualification for such regulated applications.

Demonstration at this stage must include the capability to support GMP-compliant clinical production.

TRL Definitions Relevant to This Solicitation

TRL	Definition	TRL Description
4	Component and/or breadboard validation in laboratory environment	Basic technological components are integrated to establish that they will work together. This is relatively “low fidelity” compared to the eventual system.

5	Component and/or breadboard validation in relevant environment	Breadboard fidelity is significantly improved. Components are integrated with more realistic support elements and tested in a simulated environment
6	System/subsystem model or prototype demonstration in a relevant environment	A representative prototype system, substantially more advanced than TRL 5, is demonstrated in a relevant environment. This represents a critical advancement in demonstrated readiness.

Solicitation Closed