Statement of Objectives (SOO)
BioMaP-Consortium OT Vehicle

Project Title: Domestic Capability Building Activity – Onshoring the Manufacturing of Viral Hemorrhagic Fever Vaccine Candidates

1. SCOPE

Topic Area: BioMaP-Consortium Domain 2– Domestic Capability Building Activity – Onshoring the Manufacturing of Viral Hemorrhagic Fever Vaccine Candidates

1.1. The United States Government (USG) has a requirement to expand domestic commercial biopharmaceutical manufacturing capabilities. To meet this need, the USG is initiating an effort to onshore the manufacturing of novel Vesicular Stomatitis Virus (VSV) Delta G based vaccine candidates, expressed in Vero cells, for protection against viral hemorrhagic fever viruses such as Marburg and Ebola Sudan. At present, there is no domestic manufacturing capability for viral hemorrhagic fever vaccines; therefore, it is in the USG's interest to establish this capability to prepare for and respond to potential viral outbreaks. This effort will involve the technology transfer of the current candidate vaccine production processes (inclusive of bulk drug substance and drug product (formulation, fill/finish)) from their current manufacturing sites, located outside the U.S., to one or more domestic Contract Development and Manufacturing Organizations (CDMOs) located within the US.

1.2. The scope of this effort is strictly to demonstrate tech transfer of manufacturing capability for bulk drug substance and drug product to the U.S. This effort does not include any options dedicated or focused on the procurement of licensed products. Any procurement of licensed products would be handled under a future separate contract or agreement.

1.3. All necessary engineering/demonstration runs, analytical testing, assays, and metrics will be conducted in order to ensure consistency between the current processes at the product sponsor/technology owner(s) site(s), and the processes established at the new domestic CDMO site(s). Details on the specific types and quantities of runs and tests and their associated acceptance criteria shall be negotiated between the product sponsor/technology owner and the CDMO(s).

1.4. The USG expects Awardee(s) to face risks and unique technical challenges as a result of this effort. Specifically, given that the vaccines utilize a viral backbone, it is unlikely any one entity will be able to conduct all of the requested work. Therefore, it is expected bulk production, fill/finish, and testing will require different CDMO(s). A teaming arrangement that includes the USG, the product sponsor/technology owner, and new domestic CDMO(s) as a key stakeholder in all technical discussions shall be included.

1.5. The goal of this effort is to perform a technology transfer of an existing process. In the event the product sponsor/technology owner(s) performs process development and/or optimization activities concurrent to this effort, incorporation of those activities maybe handled under a separate option if/when needed.

1.6. Complete all tech transfer activities within 18 months from project agreement award to achieve specific objectives described.

2. REQUIREMENTS

2.1. General Objectives:

2.1.1. Make awards necessary to onshore drug substance and drug product manufacturing processes (inclusive of formulation, fill/finish) for up to two (2) vaccine candidates for protection against viral hemorrhagic fever viruses.

2.1.1.1. Offerors should propose to perform the tech transfer of one or more vaccine candidates, and include separate detailed cost models for drug substance activities and drug product activities respectively

2.1.2. The USG expects Awardee to face risks and unique technical challenges as a result of this effort. As such, the awardee shall include a teaming arrangement in accordance with paragraph 2.2.8 and 3.0 below.

2.1.3. Complete all tech transfer activities within 18 months from project agreement award to achieve specific objectives described below in Section 2.2.

2.2. Specific Objective(s):

2.2.1. Awardee(s) shall tech transfer the existing manufacturing process for vaccine candidates for protection against viral hemorrhagic fever viruses (inclusive of bulk drug substance and drug product (formulation, fill/finish)) to one or more new domestic CDMO site(s).

2.2.2. The processes that are established at the new domestic manufacturing site(s) shall be identical to the product sponsor/technology owners' current process. The anticipated vaccine dosage is greater than 10^7 infectivity units (the specific dosage concentration will be provided prior to agreement award). It is expected that bulk Drug Substance titers/quantities produced should account for typical losses during fill/finish operations.

2.2.3. Domestic CDMO(s) must be capable of manufacturing under qualified cGMP conditions and BSL-2 safety containment (see 2.2.10 for details on GMP conditions).

2.2.4. Awardee(s) shall transfer pertinent analytical test methods and establish them at the new domestic CDMO site(s).

2.2.5. Awardee(s) shall perform all necessary engineering/demonstration runs, analytical testing, assays, and metrics to ensure consistency between the current processes and the processes established at the new domestic CDMO site(s).

2.2.6. All material shall be stored frozen at –80°C for potential future use. The storage cost shall be included in the base agreement, but any stability or analytical development activities will be priced as an option if/when needed.

2.2.7. It is expected that the CDMO(s) will need to provide regulatory support to the product sponsor/technology owner for any comparability filings with the FDA. The cost of the support shall be proposed/priced as an option if/when needed.

2.2.8. The Awardee(s) shall propose a teaming arrangement that includes full, active participation by the Consortium Management Firm, Awardee, its major/minor subcontractors, teaming partners, and the USG for technical matters and discussions. Awardee's teaming arrangement shall ensure the USG can participate as a key stakeholder in full and transparent technical discussions/meetings. However, this teaming arrangement does not allow the USG to bypass the product sponsor/technology owner, and all engagements between the new domestic CDMO(s) and the USG shall have all parties in attendance.

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

2.2.10. The process tech transfer shall be deemed successful with the completion of at least one (1) manufacturing engineering run (inclusive of bulk drug substance and drug product vials), produced at the new domestic CDMO site(s) under GMP conditions for each vaccine candidate with acceptable process results compared to the original manufacturing processes. For the purposes of this effort, "GMP conditions" means

production on qualified equipment using qualified procedures, but no quality release documentation and/or qualified batch records are required.

3. PROGRAM MANAGEMENT

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

4. DELIVERABLES

See Appendix 1.

5. PHYSICAL PROPERTY

The U.S. Government does not anticipate the purchase of any physical property under this agreement.

6. REQUIRED TERMS RELATED TO USG INVESTMENT

Consider whether the following four (4) regulatory flow downs are required for the proposed project. Each project may require All, None, or a Combination. Please work with your BioMaP-Consortium Sponsor Liaison to mark those that apply or provide additional regulatory requirements as necessary for final submission.

☐ Needle Exchange

☐ Product Licensure

☐ Final Distribution

☒ Manufacturing Standards

☐ All of these

☐ None of these

☐ Other, please provide additional information:

7. SCHEDULE OBJECTIVES

The complete schedule for finalizing Technology Transfer activities is 18 months to achieve specific objective described above.

8. RISK MANAGEMENT OBJECTIVES

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

9. INTELLECTUAL PROPERTY

The Government requires not less than Government Purpose Rights to any intellectual property developed under this effort with USG funds.

APPENDIX 1. Project Agreement Deliverables

Deliverable Description	Content Requirements and Instructions	Reporting Frequency
Kick Off Meeting	Awardee 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. Awardee(s) to provide meeting minutes.	Kickoff meeting conducted within fourteen (14) days of award. Agenda to be provided minimum of one (1) business day in advance of the meeting. Meeting minutes to be submitted within three (3) business days of meeting.
Ad-hoc Project Team Meetings	Awardee to schedule and provide an agenda. Follows Agenda mutually agreed upon in advance of meeting. AWARDEE to provide meeting minutes.	As needed for special topics, when specifically requested by the OTAO or OTTR. Agenda to be provided minimum of one (1) business day in advance of the meeting. Meeting minutes to be submitted within three (3) business days of meeting.
Monthly Project Team Meetings	Awardee(s) to develop Agenda and host an in-person or virtual meeting to review monthly progress report findings, any changes since last month and any projected issues or challenges. Awardee(s) to provide meeting minutes.	Monthly, five (5) business days after the monthly report deliverable. Agenda to be provided minimum of one (1) business day in advance of the meeting. Meeting minutes to be submitted within three (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	Monthly. Due fifteenth (15^{th}) of the month. Contractor format acceptable, provided in PDF and MS Word.

	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.	
Semi-Annual In-Process Review (IPR)	Organized, scheduled and hosted by Awardee. May be virtual or physical at the Awardee's facilities based on USG preference. High level project progress review of overall objectives. Awardee(s) to provide project briefing.	Every six (6) months from start of project. Awardee to send project briefing three (3) working days in advance of meeting.
Integrated Master Project Schedule (IMPS)	MS Project Detailed Project Schedule, full detailed schedule for entire Project, including all major activities, critical path, and milestones. Status updated regularly.	Initial IMPS to be delivered within thirty (30) days after project award. Status updated monthly and when milestones and/or major events change. Submitted with the Monthly Project Progress Report in PDF and MS Project.
Project Budget	Excel spreadsheet of Detailed Project Budget	Initial Project Budget to be delivered within thirty (30) days of project award. Notify USG via e-mail whenever Project Budget is revised/updated. Submitted with the Monthly Project Progress Report.
Project Documentation	Project Design and other related project execution related documents	Submitted if/as required with 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	Awardee(s) to develop Agenda and host an in-person visits from USG and/or Product Sponsor/technology owner. Agenda mutually agreed upon with USG in advance of visits. Awardee(s) to provide meeting minutes.	Typically, quarterly at the Agreements Officer's discretion. Agenda to be provided minimum of one (1) business day in advance of the meeting. Meeting minutes to be submitted within three (3) business days of meeting.
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 twelve (12) months. A draft to be submitted thirty (30) days after the completion of each year of performance. Within fifteen (15) days of receipt, the Government will provide review comments. The Awardee shall respond within fifteen (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	Initial submission to be submitted thirty (30) days prior to the end of the period of performance. Within fifteen (15) days of receipt, the Government will provide review comments. The Respondent shall respond

	schedule to final schedule; recommendations for path forward as applicable.	within fifteen (15) days of receipt of comments. Report format: Microsoft Word and PDF
Security Plan	The Security Plan must detail how the AWARDEE 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 within thirty (30) days after project award, updated as necessary. See BARDA Security Plan checklist.
Quality Management Plan	The Awardee shall develop and submit a Quality Management Plan that details the approach to regulatory compliance	Initial submission within thirty (30) days after project award, updated as necessary Report format: Microsoft Word and PDF
Material Stability Report (Option)	The Awardee shall develop and submit a Stability Report that details the Awardee's Stability Protocol inclusive of parameters, duration, sample time intervals, analytical test metrics, data, results, and conclusions for all material produced during this effort.	To be determined after project award during regular and recurring project team meetings.
Infrastructure and Management Structure Organizational Chart	The Awardee shall complete description of the infrastructure and management structure (organizational chart) including but not limited to addressing all elements that will accomplish the program's goals and milestones. The Awardee shall propose a workforce management plan, e.g., how workforce will train, maintain,	Initial submission within (30) days after project award, updated as necessary. Report format: Microsoft Word and PDF

	etc., that reflects the ability to meet the requirements.	