Office of Biomedical Advanced Research and Development Authority (BARDA)

Special Instructions Issuance
for
Broad Agency Announcement 18-100-SOL-00003
(BAA-18-100-SOL-00003)

Title: Special Instructions – Area of Interest #3.4
Antibacterial Accelerator

Biomedical Advanced Research Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
200 C Street SW
Washington, DC 20201

1. INTRODUCTION AND OVERVIEW

1.1. Overview of Opportunity

These Special Instructions under BARDA BAA-18-100-SOL-00003 Area of Interest #3.4 *Antibacterial Accelerator* aim to identify and support an accelerator capable of managing a portfolio of antibacterial candidates and overseeing the development of these candidates. From 2016-2021, BARDA funded Boston University's (BU) Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) program to build a diverse early-stage development portfolio of innovative antibiotics, non-traditional therapeutics, vaccines, diagnostics, and other products to treat, prevent, and diagnose antibiotic-resistant infections. The period of performance for BARDA's existing Cooperative Agreement supporting BU ends in 2022. In an effort to continue driving innovation, BARDA intends to award an Other Transaction (OT) to support an accelerator responsible for managing the preclinical and early clinical development of a pipeline of antibacterial candidates. The accelerator will provide non-dilutive financing and wrap-around research and development (R&D) support in the form of subject matter expertise and business mentoring to companies worldwide. This accelerator will support the early-stage development of antibacterial candidates with the ability to counter the threat of multidrug-resistant organisms (MDROs). The accelerator will advance the development of these candidates through Investigational New Drug (IND) filing and Phase 1 clinical trials, such that they are poised for further clinical development outside the accelerator.

1.2. Background

In 2014, the United States Government (USG) released the National Strategy for Combating Antibiotic-Resistant Bacteria, which led to the development of the National Action Plan for Combating Antibiotic-Resistant Bacteria. One objective of the National Action Plan was to establish an accelerator for combating antibiotic-resistant bacteria to repopulate the preclinical pipeline and catalyze investment in early-stage innovative candidates of companies focused on preclinical and IND-enabling R&D. The accelerator was designed to provide wrap-around services and funding for early development activities that would help progress antibacterial candidates from the hit-to-lead stage through Phase 1 development.

In 2016, BARDA partnered with the National Institute of Allergy and Infectious Diseases (NIAID) and the Wellcome Trust to fund the CARB-X program, whose mission was to "accelerate a diverse portfolio of innovative antibacterial products towards clinical development and regulatory approval with funding, expert support, and cross-project initiatives." Administered by BU, CARB-X supports an early-stage (preclinical and Phase 1) portfolio of antibacterial diagnostics, vaccines, prophylactics, and therapeutics for the detection, prevention, and treatment of infections due to drug-resistant bacteria. Through CARB-X, BARDA has established global partnerships to revitalize the early-stage pipeline and decrease the risks and barriers that impede further R&D investment by pharmaceutical companies, private investors, and government partners.

The USG's National Action Plan for Combating Antibiotic-Resistant Bacteria 2020-2025 directs BARDA to continue supporting the discovery and preclinical development of new therapeutics, diagnostics, and preventatives.

1.3. The Antibacterial Accelerator

These Special Instructions solicit Offerors to propose an antibacterial accelerator program that will create systems and processes to administer and manage a portfolio of investments. The accelerator will assemble an international coalition of funders and life science partners to accelerate the pace of development of a focused portfolio of advantageous antibacterial candidates from preclinical development through Phase 1 clinical trials to combat antibiotic-resistant bacteria.

By leveraging an industry accelerator model, the award recipient will operate based on a strategy and provide financial and technical support to companies that will facilitate the development of their antibacterial candidate(s). BARDA defines the "accelerator" as an entity that provides a unique and highly flexible combination of: non-dilutive funding, technical support, business development processes, infrastructure, and subject matter expertise designed to support companies through the challenging early stages of product development.

BARDA expects that the accelerator will utilize BARDA funds to provide non-dilutive funding to companies for R&D activities. Non-dilutive funding is financing that does not require an equity stake in the company. BARDA does not intend to limit the accelerator from exploring additional financing models that include both non-dilutive and dilutive funding, but funds used to take an equity stake in companies would need to be provided by other sources.

The terms of these Special Instructions supplement BAA-18-100-SOL-00003 (“BAA”). Any apparent conflict of terms of the original BAA, the terms of these Special Instructions will control. Proposals that do not conform to the requirements outlined in these Special Instructions or the BAA may be considered non-responsive and not considered for review.

1.4. The Accelerator Portfolio

The accelerator’s enterprise will be strategy-driven focusing only on supporting antibacterial candidates defined as those that support the treatment, prevention, or detection of bacterial infections. The accelerator’s portfolio will prioritize new classes of antibiotics, products for novel targets or those with novel mechanisms of action, and non-traditional approaches. Through sub-awards, antibacterial candidates may enter the portfolio as early as the hit-to-lead stage of development; devices may enter the portfolio as early as the feasibility stage of development. The accelerator will advance/accelerate the development of these candidates through IND filing and Phase 1 clinical trials (single ascending dose/multiple ascending dose), such that they are poised for further clinical development outside the accelerator. The accelerator may elect to provide technical and financial support to companies to support additional early clinical studies or Phase 2 clinical trials if approved by the Joint Oversight Committee (JOC).

The scope of the portfolio will be established by the JOC and will likely include projects that target drug-resistant bacteria highlighted in the ‘Antibiotic Resistant Threats in the United States’ report published by the Centers for Disease Control and Prevention (CDC) in 2019 and the ‘Priority Bacterial Pathogens List’ published by the World Health Organization (WHO) in 2017 – with a priority on those pathogens deemed Serious or Urgent on the CDC list or Critical or High on the WHO list. The JOC will have the discretion to revise the scope of the accelerator’s portfolio to include MDROs beyond bacterial pathogens if warranted.

Individual candidates will be selected by the JOC for inclusion in the portfolio based on the strategic goals and needs identified by the accelerator’s strategy.

2. KEY FUNCTIONS

Independently and not as an agent of the USG, the Offeror shall furnish all the necessary services, qualified personnel, materials, supplies, equipment, and facilities not otherwise provided by the USG as needed to perform the work described below. In addition to points stated above, Offerors shall address the following in their proposed statement of work:

2.1. Develop and Refine Strategy

The accelerator will establish a portfolio strategy that weighs risks and rewards, prioritizing investments that have a high chance of success and strong clinical value. Working within the bounds

of the portfolio's scope and budget parameters, the strategy will be developed using data gathered by landscape analyses with clinicians, subject matter experts, funders, and other stakeholders, and it should be updated on a regular basis. Priority pathogens, clinical indications, and product types should be evaluated within the strategy to position the accelerator to make investments that are balanced and based on identified gaps within the antibacterial development pipeline. The JOC will have the responsibility for approving the strategy and all subsequent updates.

In addition to a strategy, the accelerator will generate systems and tools to allow the accelerator's funders to evaluate potential investments and track progress against the program's goals and objectives.

In their proposal, Offerors should outline the basic tenants of the strategy that they envision, how they plan to execute its development and refinement, and the systems/tools that will accompany its implementation. Strategic objectives should be based on the landscape, life-cycle of antibacterial candidates, and clinical need. Offerors who already have an investment strategy should include that document with their proposal.

2.2. Consortium Members

Fostering collaboration between BARDA and the consortium of accelerator partners is a key function of the accelerator. It is paramount that the accelerator supporters are provided the flexibility to maximize the collective potential of a portfolio approach in the complex and uncertain environment of antibacterial development. It is anticipated that coordination of consortium members may be needed in two ways: 1) convening a JOC, and 2) managing any additional funders; however, Offerors may propose alternative models for consortium member management.

Offerors must outline their proposed model for consortium configuration and its management in detail. Offerors may consider proposing a mechanism for consortium member management that could allow funders to contribute to a collective pool of funds used to support the majority of the portfolio's projects. Potential options for targeted investments that meet individual funders' needs outside of the collective could also be considered.

Offerors must additionally propose basic tenants of a JOC charter outlining responsibilities of approving governance policies, portfolio scope, and strategic direction, and including options for the addition of new JOC members. In consideration of the JOC charter, note that the Chair of the JOC must be an independent antibacterial subject matter expert, elected by the JOC voting members. Accelerator staff will not be eligible for JOC Chair. Preparation of all presentations, files, agendas, and subsequent minutes for JOC meetings and any necessary sub-committee meetings will be the responsibility of the accelerator and will be done in coordination with the JOC Chair.

2.3. Managing Conflicts of Interest

The Offeror shall propose a plan to identify and manage any actual or perceived organizational or individual conflicts of interest (COI) associated with managing the accelerator. The COI plan should also extend to include intellectual property and necessary policies and procedures to ensure companies maintain all intellectual property associated with their candidates for work supported under the accelerator. The COI plan will be reviewed annually for updates and will require BARDA concurrence.

The accelerator will also be responsible for enacting necessary internal policies and procedures to ensure their role in leading the portfolio does not result in unequal access of information or impaired objectivity. The accelerator shall identify an independent third -party entity to conduct an annual COI review of their plan, implementation of that plan, and the ability to identify and avoid or mitigate any actual or perceived organizational COI.

It is expected that the accelerator will also appropriately solicit and retain non-disclosure agreements for individuals with access to confidential materials.

2.4. Sub-Award Application Process

The accelerator shall manage the process for companies to apply for accelerator sub-award funding. The accelerator shall convene independent scientific advisory boards comprised of external experts to provide recommendations on portfolio inclusion based on level of scientific rigor and innovation, alignment with accelerator strategy, and other requirements.

Offerors should articulate how sub-award application opportunities will be managed. The application process should allow for objectivity, alignment with the accelerator strategy, and flexibility. Offerors should outline a resourcing plan that anticipates staffing needs based on portfolio size. Offerors should also propose a mechanism that could allow technical direction and feedback from non-voting advisory board observers to refine the quality and utility of the scientific advisory boards as needed.

2.5. Sub-Award Issuance and Management

After projects are approved for funding, the accelerator will be responsible for all aspects of sub-award issuance and management. Sub-awards should be negotiated and issued in a timely fashion and include all necessary USG provisions, including USG regulatory requirements for animal and human subjects research, where applicable. Offerors should propose a mechanism for managing the sub-award process across multiple international funders and articulate their process flow for management of such provisions.

To best leverage all the resources of the USG, Offerors should outline how NIAID's Pre-Clinical Services and other partners will be involved during sub-award negotiations to create realistic milestones, budgets, and timelines. Offerors should also propose how funding and sub-award milestones can remain nimble to accommodate challenges often associated with early-stage antibacterial development.

The accelerator must have financial and programmatic systems in place to document accountability and performance. The accelerator must also establish a document management system that ensures information security of program data.

2.6. Wrap-Around Support

In addition to financial support, a major component of the accelerator is to provide wrap-around support (technical, regulatory, and business) to companies for their candidates. The accelerator will provide a host of tailored support in a number of areas, including: nonclinical development; pharmacokinetics/pharmacodynamics; toxicology; clinical planning; chemistry, manufacturing, and controls; and regulatory, business, and strategic planning. Specific company needs should be assessed and properly matched to wrap-around services required for the best development progression for their candidate. Offerors will also be required to develop and implement a stewardship and access plan and describe how companies will utilize and track individual plans through the life of their projects and beyond.

Offerors should propose their operating model for providing wrap-around support to companies including identifying needs within the antibacterial development space and how a full suite of expertise will be provided.

The accelerator should leverage in-house expertise from a well-developed, diverse, and highly experienced R&D team, complimented by a pool of consultant subject matter experts, to provide wrap-around services. The accelerator should also plan to augment their support by creating a network of global accelerator partners with complimentary capabilities and connections within expanded global regions, as well as utilizing funder subject matter expertise where available. It is

anticipated that the global accelerator partners will provide technical support to the companies throughout the implementation of their programs.

The accelerator should also propose engagements with other USG and non-USG partners to leverage support, expertise, and in-kind services. These engagements are key to ensure that candidates are adequately poised to meet BARDA's advanced research and development portfolio needs. Examples may include preclinical services, candidate evaluation of activity against biothreat pathogens, or targeting special populations.

2.7. Options Post-Accelerator Funding

Given the scope of the accelerator program, candidates will have the opportunity for funding and support through IND-filing and Phase 1 studies. A key responsibility of the accelerator will be to coordinate with other ventures, funders, and accelerators to identify opportunities to continue candidates' progression, where appropriate, after funding from the accelerator has concluded. The accelerator will also be expected to track the progression of candidates' development post-accelerator funding for reporting purposes.

On an annual basis, the accelerator will develop a plan that outlines realistic opportunities for post-accelerator progression for candidates within the accelerator's portfolio. The plan should show alignment with the M&E plan and larger accelerator strategy. Offerors should outline their vision for this plan in their proposal.

2.8. External Learning Opportunities

Lessons learned shall be shared across the portfolio of companies and with the wider antibacterial community, as appropriate. The accelerator shall produce peer-reviewed publications relevant to the field and contribute to relevant platforms with publicly available datasets. Information dissemination via a user-friendly and regularly updated web site will be required. The accelerator shall also effectively communicate the accelerator's successes and lessons learned with external audiences.

In their proposal, Offerors should outline their plans for fostering external learning opportunities for companies within the portfolio.

2.9. Monitoring and Evaluation

The accelerator shall be able to clearly demonstrate the value of its acceleration model in comparison with programs that provide financing only. Offerors should describe how they will develop, implement, and maintain a robust M&E plan that is rooted in best practices, drives portfolio management to allow for down-selection, and creates a mechanism for funders to gauge the success of the portfolio. At a minimum, the M&E plan should include a theory of change, an M&E framework aligned with the portfolio strategy, key performance parameters, and a system for real-time reporting on key data.

2.10. Meetings and Reporting

The accelerator shall plan and participate in collaborative meetings with BARDA. Outside of routine program management meetings, Offerors should outline a model for instituting a process by which BARDA is notified of and participates as an observer during pre-IND and other meetings with the U.S. Food and Drug Administration (FDA).

The accelerator shall regularly compile program results from sub-recipients and other partners into consolidated reports and convey programmatic and operational status updates quarterly or in appropriate intervals. All reports (e.g. technical, progress, programmatic, financial, etc.) and deliverables outlined within the award shall be provided to BARDA at agreed upon intervals.

2.11. Sustainability Planning

Within three years of award, the accelerator will be required to present a sustainability plan to the JOC. As a component of their proposal, Offerors should propose actions they would take to inform the sustainability plan's development by year three and outline potential sustainability options that the accelerator could seek.

3. AWARD STRUCTURE AND COSTS

3.1. Award Overview

BARDA anticipates making one award under these Special Instructions using an Other Transaction (OT). BARDA anticipates the Base Period of the OT will have a targeted ceiling of up to $20 million of USG funding (based on the availability of funds) with a period of performance up to five years.

Multiple Option Periods, each with a period of performance of up to five years, may be exercised under the OTA to support continued activities, based on the availability of funds. Base and Option Periods may perform concurrently. Option Periods cannot extend beyond the total OT period of performance. It is anticipated that the total OT period of performance, inclusive of the Base plus any Option Periods, will be up to 10 years with a total targeted ceiling of up to $175 million exclusive of cost sharing.

Each Base and Option Period(s) will be a firm-fixed-price (FFP) contract line item number (CLIN) to support:

- Administration of the program, including core operations;
- Transition of projects from the concluding CARB-X-BU Cooperative Agreement into the accelerator portfolio;
- Existing projects within the accelerator portfolio;
- New projects to enter the accelerator portfolio;
- External learning opportunities and other BARDA-requested support activities.

BARDA anticipates that administration and core operational costs for the accelerator should be shared across multiple global funders contributing to the program.

The final OT will contain the price/cost provisions agreed upon by the Government and the Offeror.

3.2. Cost Sharing

Cost sharing is required for this award. BARDA envisions that all USG funding will be matched by additional funding or in-kind services from other sources.

The accelerator will be responsible for tracking and reporting on cost sharing expenditures.

4. MANDATORY CRITERIA AND APPLICATION GUIDANCE

4.1. Mandatory Criteria

It is mandatory that Offerors possess and clearly demonstrate experience in the criteria below.

1. Offerors must have experience in establishing and managing a portfolio of at least 20 antibacterial candidate projects including therapeutics, diagnostics, and preventatives.

2. Offerors must have experience in administering USG agreements or contracts comprised of sub-awards with companies and established financial and management systems in place to execute sub-awards.
3. Offerors must organize a Core Management Team that includes, at a minimum, personnel with the following expertise:
    a. Principal Investigator with experience in advancing anti-infective portfolios from discovery/preclinical through clinical development;
    b. Chief Operating Officer with experience running operations and implementing USG agreements/contracts in the biotechnology or pharmaceutical industries;
    c. Chief of Research and Development, or equivalent position, with a PhD degree in life sciences or medicine and industry experience in advancing anti-infective portfolios from discovery/preclinical through clinical development;
    d. Chief Medical Officer, or equivalent position, with an MD degree and experience in clinical development of anti-infectives.

4.2. Application Guidance

Offerors must submit Full Proposals in accordance with the instructions provided in Part VI Full Proposal Instructions of the BARDA BAA-18-100-SOL-00003. Proposals that do not conform to the requirements outlined in the BAA will not be considered for further action. Note that an initial Quad Chart/White Paper will not be sought for these Special Instructions; Offerors should only submit Full Proposals.

In addition to the instructions provided in Part VI of the BARDA BAA-18-100-SOL-00003, the Offeror shall provide a dedicated section that addresses the mandatory criteria for eligibility. Offerors must clearly crosswalk the mandatory criteria elements as described in SECTION 4.1. to the documentation provided to support criteria compliance. **There is no page limit for Mandatory Evaluation Criteria.**

A well-conceived Full Proposal should summarize key concepts to demonstrate the accelerator's knowledge and understanding of the aforementioned key functions.

The Full Proposal should also provide sufficient detail to establish the experience and expertise of the entity operating as an accelerator and its ability to establish and manage a global portfolio of investments specific to the advancement of antibacterial candidates from preclinical through Phase 1 development, including new antibiotics, non-traditional therapeutics, vaccines, and diagnostics.

In their mandatory criteria proposals, Offerors must clearly describe their ability to:

Meet the mandatory criteria elements:

1. Offerors must provide a list of at least 20 antibacterial candidate projects including therapeutics, diagnostics, and preventatives that the Offeror has managed in their portfolio.
2. Offerors must provide a narrative demonstrating experience in administering USG agreements or contracts comprised of sub-awards with companies and established financial and management systems in place to execute sub-awards.
3. Offerors must include a list of proposed key personnel for the Offeror's Core Management Team with degrees, titles, and roles within the program to meet the mandatory criteria.

In their technical proposals, Offerors must clearly describe their ability to:

1. Establish a portfolio strategy that weighs risks and rewards, prioritizing investments with a high chance of success and strong clinical value. Conduct landscape analyses with clinicians, subject matter experts, funders, and other stakeholders to form the basis of portfolio investment strategies, and develop strategic objectives based on the landscape, life-cycle of antibacterial candidates, and clinical need.
2. Develop approaches for planning, identifying, selecting, and advancing the development of multiple antibacterial candidates across a portfolio.
3. Organize scientific advisory boards comprised of subject matter experts with experience in the development of antibacterial candidates including diagnostics, preventatives, vaccines, and therapeutics.
4. Offer a suite of industry-leading technical, regulatory, and business services and capabilities commensurate with the developmental stage of the candidates to enable their accelerated development.
5. Establish partnerships with existing life science accelerators to progress antibacterial candidates and aid companies in overcoming common business hurdles.
6. Organize a team of personnel with scientific and technical expertise in all areas of antibacterial research and development including but not limited to medicinal chemistry, preclinical testing, pharmacokinetics, toxicology, manufacturing, and regulatory and quality affairs. Maintain a robust and extensive network of partners and subject matter experts to support in antibacterial candidate development and preparation of regulatory submissions.
7. Develop partnerships with late-stage development funding partners, such as large pharmaceutical companies, venture capital firms, private investors, government partners, etc. to increase the likelihood of candidates' successful continued development.
8. Establish a document management system that ensures information security of program data. Manage both organizational and individual conflicts of interest. Fully adhere to the terms and conditions of a USG award, including but not limited to, developing and implementing program plans, coordinating approved activities, and adhering to budget, monitoring and evaluation, and reporting requirements.

In their cost proposals, Offerors must:

1. Provide proposed cost sharing to at least match USG funding as a demonstrated commitment of resources in the form of sharing the cost of the overall program.

4.3. Evaluation Criteria and Other Evaluation Factors and Considerations

4.3.1. Mandatory Evaluation Criteria

Each mandatory evaluation criteria response will be reviewed for eligibility. The documentation provided must support criteria compliance. Any Offeror(s) who submit proposals that do not meet the Mandatory Evaluation Criteria for eligibility at the time of proposal submission will not be considered for further evaluation. All proposals that satisfy the mandatory criteria for eligibility will be considered for further evaluation.

4.3.2. Evaluation Criteria

The selection of one source for award will be based on an evaluation of each Full Proposal. Full Proposals will be evaluated by a Peer or Scientific Review process and will be evaluated based on the following criteria that are listed in descending order of importance. The sub-criteria listed under

a particular criterion are of equal importance to each other. Pursuant to FAR 35.016(e), the primary basis for selecting proposals for acceptance shall be technical (criteria 2 and 3), importance to agency programs (criterion 1), and funds availability (cost-related factor). Cost realism and reasonableness shall also be considered. When together, non-cost related evaluation criteria significantly outweigh cost-related evaluation criteria.

1. Program Relevance
    a. The extent to which the proposed effort fills the programmatic needs of these Special Instructions.
2. Overall Scientific and Technical Merits of the Proposal
    a. The degree of innovation and potential to offer a revolutionary increase in capability commensurate with the potential risks of the innovative approach;
    b. The soundness, feasibility, and validity of the proposed plans, methods, techniques, and procedures of the technical proposal;
    c. The Offeror's understanding of the scope of the proposed work and the technical effort needed to complete it;
    d. The reasonableness of the proposed schedule; and
    e. The Offeror's understanding of the statutory and regulatory requirements for FDA approval of IND applications to enable Phase 1 clinical trials and conduct Phase 1 clinical trials.
3. Offeror's Capabilities and Related Experience, including Qualifications, Capabilities, and Experiences of the Proposed Key Personnel
    a. The expertise of technical personnel proposed;
    b. The Offeror's experience in relevant efforts with similar resources;
    c. The reasonableness of the proposed project management approach and expertise of the project management personnel proposed;
    d. The necessary facilities and infrastructure to carry out the proposed effort. (The Offeror may identify specific subcontractors and other partners); and
    e. An organization chart of the Offeror's personnel that demonstrates the Offeror has relevant infrastructure to support the project.

4.3.3. Cost/Price

Each price / cost response will be reviewed for price / cost realism, reasonableness, and overall best value to the Government. Proposals will be reviewed to determine if the costs proposed are based on realistic assumptions, reflect a sufficient understanding of the technical goals and the objectives of the BAA, and are consistent with the Offeror's technical approach. Proposed cost sharing will also be considered. Preference will be given to Offerors whose proposed cost sharing at least matches USG funding.

The final evaluation will be based on an assessment of the overall best value to the Government based on these criteria. An award, if any, will be made based on proposal evaluation and funds availability.

4.4. Evaluation Rating

Evaluators will assign one merit rating to each evaluation criterion listed above. The individual merit ratings per Technical Evaluation Panel member will be consolidated into one overall merit rating for each evaluation criterion. The Full Proposal will be evaluated and categorized as follows:

- Excellent: Greatly exceeds the minimum performance or capability requirements in a very beneficial way to the USG. The proposal has no significant weaknesses or deficiencies and contains several significant strengths. Based on the information provided, the Offeror demonstrates an excellent understanding of the OT requirements. The highest level of OT performance is anticipated with very low degree of risk.

- Good: Exceeds the minimum performance or capability requirements in a beneficial way to the USG. The proposal contains some significant strengths. There may be weaknesses that are correctable during discussions, but no significant weaknesses or deficiencies exist. Based on the information provided, the Offeror demonstrates the capability of providing the services required to meet and exceed OT requirements above a minimum level of performance.

- Acceptable: Meets the minimum performance or capability requirements. The proposal may contain some strengths. There are several weaknesses identified in the proposal that are considered to be potentially correctable during discussions. The proposal contains no significant weaknesses or deficiencies. Based on the information provided, the Offeror demonstrates the capability of providing the services required to meet OT requirements at a minimum level of performance.

- Unacceptable: Fails to meet the performance or capability requirements. There are unacceptable significant weaknesses or deficiencies that would require a major revision of the proposal. An Offeror who receives a consolidated overall merit rating of Unacceptable for any criterion will not be eligible for award.

4.5. Deadlines and USG Response Time

Deadline for Submission	Government Response
The Full Proposal submission deadline is no later than 4:30 PM Eastern Time on June 28, 2021. A Full Proposal may be submitted on any day during the open period of the BAA Special Instruction.	A receipt confirmation will be sent within 1 week. A response will be provided on or around 120 days of the submission deadline.

4.6. Inquiries

BARDA will extend an open inquiry period from May 12, 2021 to May 19, 2021 for respondents to seek clarification of these Special Instructions. Inquiries submitted no later than 4:30 PM Eastern Time on May 19, 2021 may be considered for written response.

Written responses to collected inquiries from respondents will be provided after the open inquiry period has concluded. Responses will be posted as a subsequent amendment to the BARDA BAA-18-100-SOL-00003.

4.7. Eligibility

These Special Instructions are open to all responsible sources.

4.8. Contact Information

All inquiries and submissions regarding this BAA must be sent to: BARDA-BAA@hhs.gov with copy to Jill.Johnson@hhs.gov and Sabrina.McIntyre@hhs.gov.