Biomedical Advanced Research and Development Authority (BARDA)

Rapid Response Partnership Vehicle (RRPV)

PRE-SOLICITATION NOTICE

"TACTIC: Threat-**A**gnostic **C**BRN Therapeut**IC**s**"**

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Biomedical Advanced Research and Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
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THIS IS A PRE-SOLICITATION NOTICE ONLY

This notice is for planning and informational purposes. It is not a Request for Project Proposals (RPP), does not solicit proposals, and does not constitute a commitment by the Government or ATI to issue an RPP or make an award.

1. Executive Summary

1.1 Rapid Response Partnership Vehicle Consortium

The Rapid Response Partnership Vehicle (RRPV) Consortium is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Center for the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services (HHS).

The RRPV will help fortify national health security by developing medical countermeasure products prior to and during a pandemic or public health emergency. The RRPV will focus on the acceleration of products and technology development, regulatory approval, commercialization, and sustainment to address pandemic influenza, emerging infectious diseases, and other biological threats.

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

RRPV is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from all organizations who work within stated technical focus areas. For more information on the RRPV mission, refer to the RRPV website at RRPV.org. For entities interested in joining the RRPV Consortium and responding to this solicitation, please visit http://www.rrpv.org/how-to-join.

1.2 Pre-Solicitation Notice

BARDA, through the RRPV Consortium, is issuing this pre-solicitation notice to provide advance information regarding a potential future RPP for the effort described herein. The purpose of this notice is to improve industry awareness, support teaming and planning, and provide preliminary insight into the anticipated scope and acquisition approach before release of a formal RPP.

1.3 Background

CBRN threats are associated with a range of downstream host-mediated pathophysiological effects, including but not limited to immune dysregulation, endothelial dysfunction coagulopathy, cellular injury, and progression to multi-organ dysfunction. Existing BARDA programs, including Antivirals and Antitoxins (AVAT), Chemical Medical Countermeasures (Chem MCM), and Radiation and Nuclear Countermeasures (RN MCM), have identified persistent gaps in interventions that address these shared drivers of morbidity and mortality.

For biological threats such as viral hemorrhagic fevers (VHFs), clinical outcomes are strongly influenced by the timing of antiviral administration, with diminished efficacy observed in later stages of disease where host-mediated pathology predominates. For chemical threats, the diversity and unpredictability of potential agents limit the feasibility of developing agent-specific countermeasures, necessitating approaches that target common injury pathways. Similarly, radiation exposure results in Acute Radiation Syndrome (ARS) and delayed effects driven by host responses, requiring therapeutics that remain effective beyond the initial exposure window.

Efforts to address these gaps have increasingly emphasized the development of therapeutics targeting conserved host pathways, including approaches such as drug repurposing, co-development for commercial and MCM indications, and label expansion of approved products. These strategies have the potential to reduce development timelines and risk while improving accessibility and operational feasibility across a range of CBRN scenarios.

1.4 Purpose

Medical countermeasures (MCMs) for chemical, biological, radiological, and nuclear (CBRN) threats have historically relied on agent-specific therapeutics that require rapid identification of the causative agent and early administration to achieve clinical benefit. While effective in defined scenarios, this approach presents a significant capability gap when diagnosis is delayed or infeasible, countermeasures are unavailable, or patients present during later stages of disease when direct-acting therapeutics are less effective.

To address this capability gap, BARDA seeks to support the development of therapeutics that treat host-dysregulation resulting from exposure to priority threats. Such therapeutics can be deployed independent of threat identification and retain clinical effectiveness in delayed treatment settings. Such therapeutics are intended to preserve or restore physiological function, mitigate systemic injury, and improve clinical outcomes by targeting host responses rather than specific threat agents. Products with the potential for broad applicability across multiple CBRN threat categories are of particular interest.

2. Administrative Overview

2.1 Anticipated RPP Approach

BARDA anticipates a multistage approach will be employed to streamline the process for preparation, submission, evaluation, and notification with a down selection between Stage 1 (Abstract) and Stage 2 (full technical and cost proposal by invitation only).

Submission to Stage 1 may not guarantee the opportunity to submit a full technical and cost proposal under Stage 2. Submission of a Stage 2 full technical and cost proposal may not guarantee an award. Each stage of this RPP process will be competitive.

The anticipated solicitation stages are as follows:

Stage 1 – Abstract – In Stage 1, Offerors will submit an Abstract and quad chart that must follow the required templates included with the final RPP. Abstracts that do not meet the mandatory eligibility criteria (section 2.6) will not be evaluated. A preliminary evaluation will be conducted to determine which proposed solutions best meet the evaluation criteria as well as BARDA's current technology priorities and program objectives. Following the preliminary screening, only selected offerors will move on to Stage 2. Offerors invited to submit a Stage 2 full technical and cost proposal may be provided feedback, particularly focusing on needed clarifications to be addressed in the Stage 2 submission. Offerors not invited for Stage 2 will be notified via email but may not receive feedback.

Stage 2 – By invitation only full technical and cost proposal – Successful Stage 1 Offerors will receive an invitation letter from the CMF to submit a full technical and cost proposal. Required documents and instructions for Stage 2 submissions will be noted in the invitation, but are anticipated to include a technical proposal, full cost proposal to include a cost narrative and cost spreadsheet, and statement of work.

Proposal(s) selected for award will be executed as a Project Award under the RRPV Base Agreement. The same provisions will govern this Base Agreement as the OTA between the U.S. Government (USG) and ATI ("RRPV Base") unless otherwise noted in the Project Award.

2.2 Period of Performance and Funding

2.2.1 Period of Performance

The anticipated Period of Performance for this effort is up to five (5) years from date of award for design, manufacturing, and nonclinical testing performed only in the U.S. Specific dates are to be negotiated. It is anticipated that the primary place of performance will be the contractors' facilities, however this aspect can be negotiated as part of each Offerors' submission.

2.2.2 Funding

The total USG funding amount anticipated to be available is approximately $15M. The USG anticipates making 2-3 awards. Additional funds in FY27 and FY28 are possible.

Funding and estimated number of awards is subject to change and dependent on proposal received, BARDA priorities, and availability of Federal funds for this program.

2.3 Proprietary Information

This notice does not request proposal submissions. Parties should not submit proprietary, confidential, classified, export-controlled, or other sensitive information in response to this notice unless specifically requested through an authorized mechanism. Any future RPP will include applicable instructions for protection and marking of proprietary information.

2.4 Mandatory Eligibility Criteria

To be eligible for consideration Offerors must be RRPV members when an Abstract is submitted. Prospective Offerors may join the consortium at www.rrpv.org/how-to-join.

2.5 Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-Performer collaboration.

2.6 Intellectual Property and Data Rights

Intellectual property and data rights for any resulting Project Award are expected to be addressed in accordance with the RRPV Base Agreement and the final RPP. Any effort-specific data delivery, licensing, Government-purpose, unlimited-rights, or other rights expectations will be identified in the final RPP, as applicable.

3 Questions and Submissions

3.1 Question and Answers

Questions or comments regarding this pre-solicitation notice may be submitted to Ms. Kathy Garee (rrpv-contracts@ati.org).

3.2 Abstract and Quad Chart Submission

The final RPP is anticipated to require submission through the BARDA Digital Resource (BDR) portal. Registration and access instructions will be provided in the final RPP.

No proposals, abstracts, white papers, or cost submissions are requested in response to this pre-solicitation notice.

3.3 Preparation Cost

The cost of preparing Abstracts, Quad Charts, and/or Proposals in response to any resulting RPP is not considered a direct charge to any resulting award or any other contract.

4 Anticipated Technical Requirements

4.1 Introduction

The information in this section reflects BARDA's current planning assumptions and is provided to help potential offerors assess technical alignment and prepare for a possible future RPP. Final technical requirements may differ. The Offeror shall clearly state how they intend to meet and, if possible, exceed the technical requirements.

4.2 Scope

BARDA seeks proposals for the development of therapeutics treating host-dysregulation caused by CBRN threats, with priority given to candidates demonstrating the potential for activity across more than one threat category (VHF, radiation exposure, and chemical injury).

Proposed efforts shall include:

- A clear description of the therapeutic's mechanism of action and supporting data demonstrating biological activity in relevant preclinical models.
- A description of the known or anticipated safety and toxicity profile of the proposed candidate, demonstrating that potential risks are justified by the expected therapeutic benefit.
- A feasible regulatory development strategy.
- A clearly defined commercial indication for the proposed product.

Given that therapeutics targeting host-dysregulation act on host factors, Offerors are encouraged to describe the extent to which the proposed pathophysiological target(s) are conserved across species relevant to preclinical development. Where such data are limited or unavailable, Offerors should identify this as a potential development gap and provide a plan to generate supporting data to evaluate cross-species activity and enable translational studies.

Multiple awards may be made under this RPP.

4.3 Initial Planned Timeframe

The Initial Planned Timeframe activities will be tailored to the candidate product's stage of development. Activities will focus on the evaluation and advancement of therapeutic candidates through early-stage development to establish proof of concept and translational feasibility. Efforts should generate the data needed to address key gaps in efficacy, safety, and/or product utility for BARDA priority threat indications (See "Performance Objectives"). Activities may include evaluation of the candidate therapeutic using relevant in vitro, ex vivo, in silico, and/or in vivo challenge models, as appropriate to the proposed indication and threat area. Proposals may also include enabling studies necessary to support efficacy testing and development decision-making, including but not limited to target confirmation, pharmacokinetics/pharmacodynamics (PK/PD), dose-ranging, product formulation or process development, and toxicity studies.

4.4 Possible Additional Work

At the discretion of the Government, additional work may be leveraged to expand the effort's scope of work/objectives to further advance the development and evaluation of the proposed therapeutic candidate. These additional periods may include, but are not limited to, expansion of efficacy studies across multiple CBRN threat categories to demonstrate broad-spectrum applicability and activities to include additional preclinical or nonclinical studies.

4.5 Performance Objectives

For submissions addressing biological threats, Offerors should describe a mechanism of action expected to improve disease outcomes by targeting host factors or pathways disrupted during filovirus infection. Relevant areas include, but are not limited to, endothelial injury, vascular leakage, coagulation abnormalities, and immune dysregulation. Combination studies evaluating a host-directed therapeutic alongside a direct-acting antiviral are also of interest, particularly when they demonstrate how the proposed MCM could complement existing or emerging therapies. Proposals must include a focus on filoviruses; additional work addressing injuries caused by other viruses associated with viral hemorrhagic fever (VHF) will also be considered.

For submissions addressing chemical threats, drug candidates or products must address at least one chemical threat(s) (listed below). These therapeutics should have a strong mechanistic justification for potential use as MCMs. Submissions must also consider the necessary attributes of effective MCMs against chemical threats including ease of administration during a mass-casualty situation and rapid efficacy as a post-exposure therapy. MCM candidates should have high potential for future approval of a commercial indication

- Pulmonary Agents: MCMs to prevent and treat lung damage (including pulmonary edema, pneumonitis, and fibrosis) resulting from exposure to agents such as chlorine, sulfur mustard and phosgene.

- Pharmaceutical Based Agents (PBAs): Development of MCMs to treat life-threatening respiratory depression caused by PBAs, including respiratory depressants and/or multi-drug toxicity. Ideally, these post-exposure treatments should be quick-acting and require a single dose. If targeting opioids, drug candidates or products should be effective against a variety of opioids, including synthetic opioids such as fentanyl, or ideally threat agnostic.

- Vesicants: Development of MCMs that limit harmful aspects of exposure to vesicating agents such as sulfur mustard and Lewisite. Preference will be given to drugs with potential to ameliorate the long-term effects of exposure including Mustard Gas Keratopathy.

- Knockdown/Metabolic Agents: Development of MCMs to treat acute poisoning from agents such as cyanides. Preference is given to those cyanide antidotes that also treat injuries stemming from smoke inhalation-related exposure.

- Nerve Agents and Organophosphorus (OP) Pesticides: Development of MCMs to treat the symptoms of nerve agents and OP pesticides.

For radiological/nuclear threats, therapeutic candidates may be novel, or FDA approved products and mechanistically target pathways associated with ARS, including but not limited to cell death, endotheliopathy and vascular leak, coagulation abnormalities, and immune dysregulation, and/or ischemia. MCMs to treat radiation injury should be effective when administered at least 24 hours or later

after exposure and should be easy to store, transport, and administer across a spectrum of response settings. The mechanism of action hypotheses for a candidate's efficacy should be well supported by a pharmacodynamic marker or similar correlate and available data described by the Offeror. MCM candidates should be approved for a commercial indication or have high potential for future approval of a commercial indication. Proposed studies may include evaluation of candidate products in relevant models of ARS.

4.6 Qualities That Strengthen Competitiveness

Broad applicability: Preference will be given to companies developing products that are potentially capable of addressing more than one of radiological, chemical, and VHF (with filovirus as a target) threats.

Regulatory status: An open Investigational New Drug (IND) application for any indication.

Product maturity and safety: Post-Phase 1 products with known and acceptable safety and toxicology profiles, or licensed products with the potential to undergo label expansion.

Preliminary Data: In vitro data supporting efficacy against one or more of the priority threat areas (biological, chemical, or radiation).

PK/PD Data: Exposure data that informs effective dose/dosing regimen and dose responsive marker that shows biological effect of the proposed candidate.

4.7 Out of Scope Topics

Proposals on the following topics will be considered out of scope:

a) Products that have a direct or indirect (host factor) anti-viral effect. Products anticipated to have a direct anti-viral effect as well as a role in mitigating injury caused by the virus will be considered.
b) Products with anticipated impact as prophylactic but not as a therapeutic
c) Vaccines

4.8 Deliverables

The Performer will be required to provide a number of deliverables throughout the course of this project which will be described in any resulting RPP.

5 Points of Contact

Questions related to this pre-solicitation notice should be directed to Ms. Kathy Garee (rrpv-contracts@ati.org).

6 Important Notice and Disclaimers

This pre-solicitation notice is issued solely for information and planning purposes and does not constitute an RPP, request for white papers, request for proposals, request for quotations, or promise to issue a future solicitation.

BARDA and ATI are not requesting proposals or binding offers through this notice and will not make an award based on this notice.

All information in this notice, including scope, requirements, funding, number of awards, acquisition approach, eligibility, evaluation criteria, and schedule, is preliminary and subject to change without notice.

Responses to this notice, if specifically requested, will not be considered proposals and will not create a preference, advantage, or guarantee of eligibility for any future RPP.

The Government and ATI will not reimburse any costs incurred in reviewing this notice, participating in related engagement activities, preparing for a potential solicitation, or submitting information requested for market research or planning.

Only the final RPP and any official amendments will establish binding solicitation requirements, submission instructions, evaluation criteria, and deadlines.

Any future award is subject to Government approval, availability of funds, successful negotiations, and execution under the applicable RRPV agreement framework.