BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

Proposers Conference

SOLICITATION Number: RRPV-24-06-DxR2

"Diagnostic Rapid Response Initiative (DxR2)"

April 4, 2024

Objectives

- What is the RRPV?
- What is an OTA?
- Highlight key aspects of the Request for Project Proposals
- Provide a deeper understanding of technical requirements
- Answer your questions

What is the RRPV?

The **Rapid Response Partnership Vehicle (RRPV)** supports BARDA in its object to accelerate Medical Countermeasure (MCM) product and technology development to address evolving needs including:

- Pandemic Influenza
- Emerging Infectious Diseases
- Other Biological threats

Focus Areas -

- **Medical Technology (MedTech)**: tools, equipment, and devices to diagnose and treat patients.
- **Vaccines (Vx):** Biological preparation that is used to stimulate the body's immune response against pathogens or diseases.
- **Therapeutics (Tx):** Medical interventions intended to treat a health issue, infection, or disease.

The consortium will advance health security, enhance preparedness, and enable a rapid response to the next pandemic or public health emergency.

What is an OTA?

- An "**Other Transaction Agreement" (OTA)** is a streamlined vehicle that brings innovative research findings and state-of-the-art technologies from industry to the federal government.
- OT-based collaborations are **not subject** to some of the regulations that apply to Federal Acquisition Regulation (FAR)-based acquisitions.
- OTs enable ***fast*** acquisition of critically-needed technologies.
- BARDA uses OTAs to further its advanced research and development goals, promote innovation, and support the mission of the HHS Public Health Emergency Medical Countermeasures Enterprise
- BARDA uses OTAs as a type of flexible, strategic partnership between the government and industry to foster innovation and promote collaboration

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Caution

The **RRPV-24-06-DxR2** Requests for Project Proposals (RPP) is the official source of information regarding the active solicitation.

If you act on information from any source other than these official sources, it is at your risk.

RRPV membership is required for the submission of a Proposal in response to this RPP.

To join RRPV, visit www.rrpv.org/how-to-join

Request for Project Proposals (**RPP**)

Biomedical Advanced Research and Development Authority (BARDA)

Rapid Response Partnership Vehicle (RRPV)

Request for Project Proposals (RPP)

Solicitation Number: 24-06-DxR2

"Biothreat Diagnostic Rapid Response"

Request Issue Date: March 27, 2024
Due Date: May 10, 2024 1PM ET

Issued by:

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

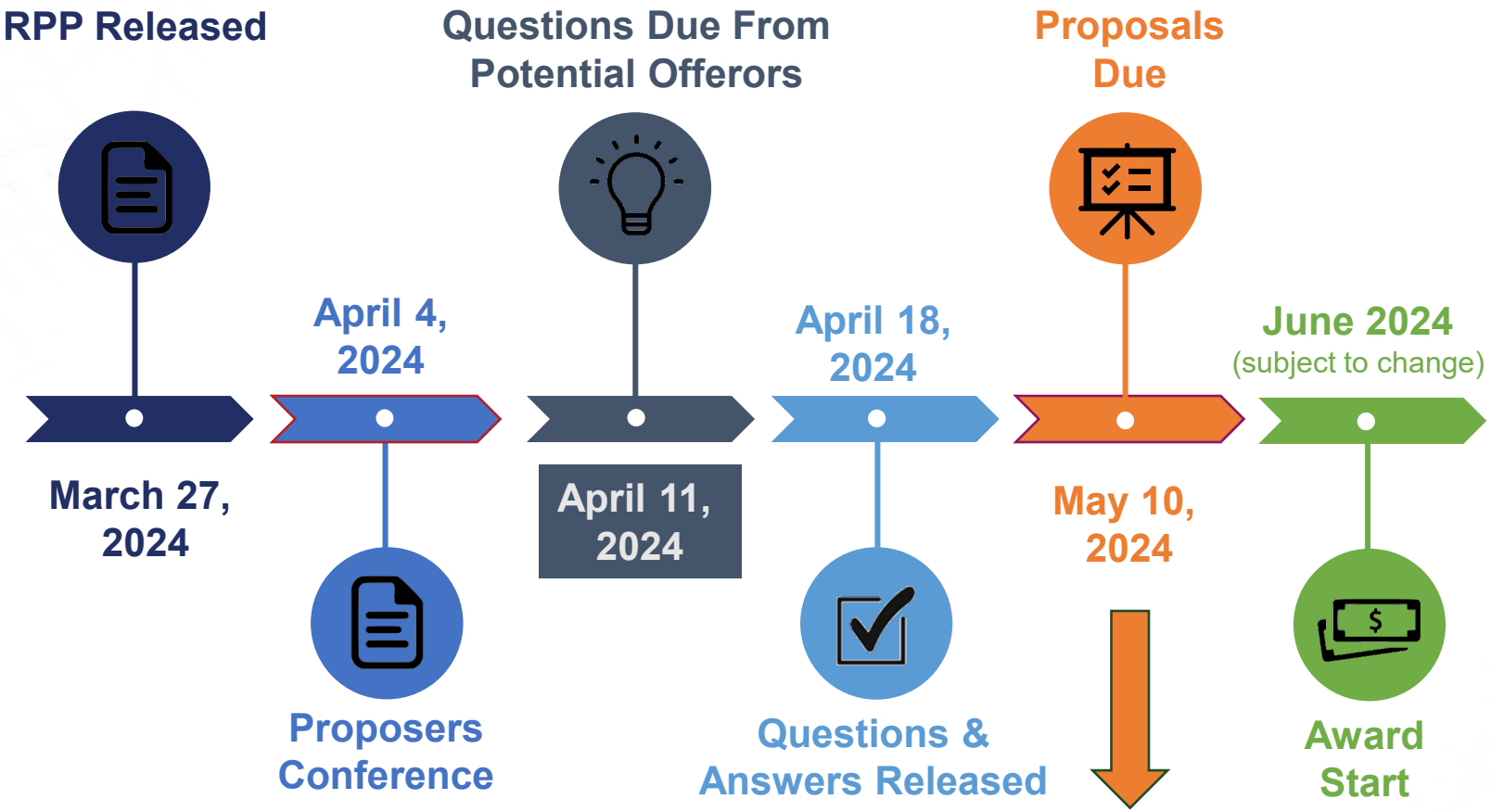
MedicalCountermeasures.gov

RPP can be found on the RRPV website:
https://www.rrpv.org/solicitation/rpp-24-06-dxr2/

Funding Plan and Period of Performance

- **Sponsor:** BARDA
- **Funding Available:** **Approximately $40 Million**
- **Anticipated Number of Awards:** **Four (4) awards**
- **Period of Performance (PoP):** **36 months**
- **Cost Sharing:** Cost sharing, including cash and in kind (e.g., personnel or product) contributions are encouraged but not required, have no limit, and are in addition to the Government funding to be provided under the resultant award(s).

Timeline



Proposals must be submitted:
https://secure.ati.org/RRPV/24-06-DxR

Required Submission Documents (3)

- **Technical Proposal** (see Attachment 1 of RPP for template)
  - includes cover page, information sheet, executive summary and minimum eligibility requirements, technical approach, current and pending support, Success Criteria, and key personnel resumes/CV
- **Cost Proposal:**
  - Section I: Cost Proposal Narrative (see Attachment 2 of RPP for template)
  - Section II: Cost Proposal Format (optional templates available on Members-only RRPV website)
- **Statement of Work/Milestone Payment Schedule** (see Attachment 3 of RPP for template)

Evaluation

- The Government will conduct an evaluation of all qualified Proposals after the preliminary screening.
- **Evaluation Factors**
    1. Technical Approach
    2. Relevant Experience
    3. Cost Reasonableness
- **Evaluation Outcome**
    1. Select the proposal (or some portion of the proposal) for award;
    2. Place the proposal in the Basket if funding currently is unavailable; or
    3. Reject the proposal (will not be considered for award and will not be placed in the Basket)

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Overall DxR2 Program Goal

- Build a biothreat diagnostic portfolio,
- Maintain domestic test manufacturing facilities, and
- Enable just-in-time manufacturing practices to be able to rapidly produce biothreat tests at scale, or other tests needed by the USG, along with the supplies needed, and to achieve aggressive test delivery schedules.

Phases of the Program
Phase I is required by this RPP

Phase I - Biothreat Test Development (Base Period):

- Development and regulatory clearance of biothreat tests, and
- Design transfer to manufacturing activities, such as limited production runs for validation, quality checks, stability studies, early adopter training, and manufacturing capacity studies.

Phase I work includes:

- Assay feasibility, verification, validation,
- Manufacturing capacity study

Phases of the Program
Phases II and III (optional follow-on work)

Phase II – Maintain Warm-Base Surge Capacity (Option Period): Establishing a domestic warm-base surge capacity via low-rate initial production to:

- Maintain the supplies needed to rapidly produce the biothreat test
- Conduct long-term storage and stability studies of tests and test components (i.e., primers, probes, consumable plastic components) for biothreat assays with potential agreements in place to rapidly manufacture tests from these components, if a public health emergency is declared
- Produce biothreat tests for use in a public health emergency or large-scale government exercises and public health laboratory competency and proficiency training

Phase III – Manufacturing Capacity Modifications (Option Period): Maintain domestic test manufacturing facilities and to enable just-in-time manufacturing practices to be able to rapidly produce biothreat tests, or other tests needed by the USG, along with the supplies needed and to achieve aggressive test delivery schedules.

Offeror Eligibility

Preferred eligibility criteria:

1. Have a minimum of 1 (one) FDA approved or CE Marked in vitro diagnostic product commercially available
2. Have a current production capacity of >1M tests/annually
3. Have US-based manufacturing (21 CFR 820 / ISO 13485)
4. Install base >300 domestic placements (applies only to instrument-based products)

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Questions and Answers

- Questions submitted prior to and during the call, will be answered now (to the maximum extent practical)
- A transcript of the Q&A will be posted along with answers to those questions submitted during the Q&A period as soon as possible
- Submit any other questions to:
  - Ms. Rebecca Harmon (Rebecca.harmon@ati.org and RRPV-contracts@ati.org)