Solicitation # 24-06-DxR2

"Biothreat Diagnostic Rapid Response"

Questions and Answers

1. Do you have a list of biothreat targets for this Request for Project Proposals (RPP)?

The list of biothreat targets for this Request for Project Proposals can be found here: https://aspr.hhs.gov/PHEMCE/2022-SIP/Pages/Appendix-B-PHEMCE-High-Priority-Threats.aspx

All pathogens in the list are of interest EXCEPT influenza, COVID, and emerging infectious diseases.

TIP: If you don't know, which pathogen to target from the list, some advice is to try your best to identify a pathogen that takes advantages of the features and the benefits of your platform and gives you the greatest chances for success. For example, maybe your platform works best with a virus versus bacteria. Or maybe it works best for the detection in blood versus a respiratory sample. You can go through this kind of thought exercise which should help you develop an approach to this RPP.

2. Any Proposal Tips?

De-risk: Set yourself up to take as much risk out of the project as possible and achieve a biothreat test regulatory success. Get your first win under your belt. it is recommended to prove success to put yourself in the best position for a long-term partnership within the program team at BARDA.

How to scope out and budget work for bio-threat test development and regulatory validation:

1- Our preferred requirement is that Offerors have already been through the commercialization of an in vitro diagnostic test on their proposed platform which means you already have the experience and the quality system infrastructure in place for achieving design control V&V through regulatory clearance. If this is the case, scope out and budget your product development path as you would do for adding any new test menu onto your platform. It is likely that your quality system includes a typical new product development plan (NPD) for assay feasibility, verification, and validation. Continue that SOP for building out your statement of work and budget. BARDA has provided an outline of a suggested development plan in the RPP. However, you are not required to use this format especially if you already have your own Phase Gate Development process built into your quality system and your SOPs. We're not suggesting or requiring the offeror to change your development process; the outline is meant to be an example.

2- When building out the statement of work and budget, you may come across some difficult development tasks to address if you've not previously worked in the biothreat test space. For example, you may require a critical reagent like an antibody pair, or test specimen materials, or you may not be able to scope out the regulatory path for clinical validation because there is no FDA guidance. One option is that you leave those parts as TBD and if your product and proposal is selected, BARDA may work with you to fill in any gaps in your product development plan during the course of the project based on BARDA needs and proposed solution.' The program team has provided this level of support in the past and we have provided access to government furnished material (GFM) to provide reagents or test specimens, or contract research organizations (CROs) that can assist with materials, animal studies, logistics and facilities for working with BSL 3 and BSL 4 pathogens.

Versatile platform: We're looking across multiple technologies including protein, molecular, cellular, or others as well as both lab-based solutions in addition to field-based solutions for use in remote locations. If the proposed platform is for use in centralized labs, the proposal will be much more competitive should you already have a significant number of product placements in your install base. If the proposed product is for use in remote field-based locations, the proposal will be much more competitive should it prove to the reviewers that it can perform in an austere environment versus a controlled environment. It is preferred to see that the field-based product is portable, weighs less than 5 pounds, can operate in extreme outdoor temperature and humidity conditions, can operate with batteries or solar power, has wireless data transmission, is easily disposable and decontaminated and is easy to operate with PPE.

Manufacturing Capabilities: BARDA will evaluate your manufacturing capabilities during the course of the Phase One project. We refer to this in the RPP as design transfer to manufacturing activities and a manufacturing capacity study. This work will involve things like limited production runs for validation studies, stability studies, quality checks or line efficiency exercises. In addition, it will include limited post clearance production for performance monitoring and maybe early adopter training and testing. For the manufacturing capacity study, we want to verify the manufacturing capacity and we also want to understand the optimization required to ensure rapid response times and scaled production. The deliverable is a study report. The key elements of this study deliverable may include determination of production practices or modifications that will lead to long-term preservation of manufacturing capacity in terms of cost, performance, workforce and other factors. In addition, the report will include the determination of improvements to your existing production practices without implementing automation (such as batch size modifications, raw material inventory management, or replication of current lines). The study will also

- determine production capacity efficiencies and scaling with implementation of automation
- determination of processes and methods to improve supply chain resiliency. For example, under this program, we could evaluate design changes to critical components which could be sourced from US suppliers versus non-US
- determination of production practices or modifications that will increase the speed to pivot production from one test to another. For example, pivot production from your commercial influenza test to a USG biothreat test. The goal is to ship tests within one week of order placement

- determination of how any of the prior production practices or modifications may impact either positively or negatively on your workforce head count and the plans for redeploying, rehiring and retaining staff.

3. **There may be other BARDA funding opportunities unrelated to the RRPV that may have similar goals. Is this program related to those initiatives? Specifically, can you describe how this solicitation differs from AOI 7.1.2 under BAA-23-100-SOL-00004 Amendment 3? Will this supplant 7.1.2?**

The overall requirement to develop biothreat tests is related to other BARDA initiatives. This program is not in lieu of others. The other biothreat test development that is open in our Division does not have as strict of a maturity (TRL) requirement and manufacturing (ISO13485) requirement as this program. We are asking for more mature products and offerors in this program.

4. **Did I hear correctly that in order to apply, one has to have at least one product FDA cleared for clinical use?**

It's not a must have; it's a nice to have and is preferred. The closer you are to meeting our preferred requirements, the more competitive your proposal will be.

5. **Is this RPP more likely to focus on smaller and emerging innovators or established large manufacturers focused on innovative menu development?**

Yes, to all of the above. We are looking for some innovation and certainly open to new performers.

6. **Manufacturing is specified as being US based, what about product design and development?**

It is permissible to conduct product design and development outside of the United States as long as those developers are in nations with good standing. BARDA will evaluate whether those developers are in non-friendly nations, which will not be permissible. Should a policy come to fruition that alters this decision, that policy will supersede this answer.

7. **Do all sourced products need to be TAA-compliant?**

Trade Agreement Act (TAA) compliance does not apply to Other Transactions, however, there are often funding restrictions found in the appropriations language that may further restrict product and/or services sourcing.

8. **The proposal needs to focus on Phase One. Should the applicant also present plans for the option phases in the proposal?**

No.

9. **How about Teaming with various members of the RRPV?**

Although teaming is not required for award, BARDA's approach encourages partners to work together in a collaborative way to overcome roadblocks and provide a unique solution to this requirement. If you are

in search of a teaming partner, we encourage you to reach out to the point of contact listed in the RPP for ways to partner.

10. **If a company has a larger corporate partner that fits the 4 technical requirements would that be looked at as the same as initiating with all technical requirements covered? In other words, if the team overall can meet those Preferred Capabilities, is that sufficient?**

Yes, this is sufficient. This does not seem to be problematic based on just the information provided in the question.

11. **Can companies partner together in order to respond, i.e. separate companies for manufacturing and design/development?**

Yes.

12. **For eventual eligibility into Phase 2 or 3, does a manufacturer first have to successfully apply to Phase 1, or will there be direct access to Phase 2 or 3 if those phases are funded in the future.**

Typically, the awardees are the ones who have options for follow-on work and they're not re-solicited. The three phases outlined in this RPP are interdependent; the first step is to develop a biothreat test and get regulatory clearance.

13. **BARDA is seeking a portfolio. Does this mean applicants should propose multiple products? Are you looking for companies to pick one (or more?) of the biothreats noted or to create more of a generic plan that could cover a range of biothreat targets?**

This RPP is really focused on your first biothreat diagnostic product development and obtaining regulatory clearance or authorization. For your statement of work, you will need to pick one biothreat diagnostic product. After you obtain your first regulatory clearance or authorization, then it is an iterative process where you can move on to your next biothreat to build out your “menu.” It is suggested that you leave the other biothreats as general names of #2, #3, #4, etc. to build out the test menu as TBD.

TIP: A good way to position your proposal to be more competitive is to take advantage of the features and benefits of your diagnostic platform by emphasizing your ability to ultimately build a test menu. If you can detect across all of the different classes of biothreats, and/or detect across different types of clinical specimens (e.g., blood, urine, swabs, CSF, etc.), you can strengthen your proposal by describing your ability to build this full test menu and capability.

14. **Are the number of awarded proposals capped at 4?**

No.

TIP: Propose a budget that realistically reflects what you need to accomplish in your proposed scope of work. Create your budget based on your proposed statement of work with accurate levels of effort and metrics of success.

15. **Is specific test data related to one of the priority biothreats required prior to application?**

No. We are basing our evaluation of product maturity based on the performance of your commercially available tests, as described in your proposal.

16. **How should FDA costs be estimated when clinical samples are not available and the path will only be defined after a pre-sub? Or, if we were to want BARDA to supply us with human test samples would we need to budget that in somehow? Also since we wouldn't know exactly what samples we'd be using is it okay to put in that we'll be working with BARDA to get these samples without particulars? Will BARDA help on any resources for clinical verification? Are there any other government resources available for clinical validation on this RPP?**

This is where BARDA is going to work with you in partnership to get throughout this process. We will work with you to provide materials, whether it's analyte specific reagents or test specimens or facilities to perform work in (BSL 3 and 4). If needed, we are able to facilitate introductions with contract research organizations (CROs) that could offer assistance to the program. There is an expectation for the offeror to demonstrate an understand of the steps and goals required for success. If there are unknowns, for pricing purposes please start by providing your best estimate based on previous similar samples.

17. **Are host response-based tests (not looking for a specific pathogen but informing whether an infection is bacterial or viral) eligible?**

    No. The biothreat diagnostic tests of interest must identify a particular target pathogen from the list with specific sensitivity and specificity.

18. **There is a possibility that specific rapid diagnostic tests (Melioidosis, for example) designed for biothreat detection may be more effectively deployed in settings near-patient care rather than at the exact point of care (POC). This is because of the complexity of specimen types that must be tested to achieve superior PPA. Would BARDA consider such an application—tailored for near-patient settings rather than strictly at the POC acceptable for its intended use?**

    All ideal use-cases for specific pathogens are acceptable.

19. **The anticipated Period of Performance for Phase I is estimated to be 36 months [As per RPP, page 4, section 2.2. "Funding Availability and Period of Performance"]. As per Section 6. Table [RPP, page 23] under "Assay Validation" deliverables, the item "Receive 510(k) Clearance" would be included within the 36-month performance period. Please clarify that within 36 months, BARDA expects only the 510(k) package to be submitted and not 510(k) clearance, as the time to clearance is unknown until we start the process.**

    Submission is sufficient. 36 months is an estimate and depends on the biothreat target, the intended use, and access to clinical samples.

20. **Success Criteria on page 22 and 23: Could the USG please provide additional guidance or an example on the expectations for the success criteria listed on pages 22 and 23 of the RPP?**

    Examples include, successful delivery of XYZ report, document or data.

21. **Technical Reporting on page 43: On 4.3. Technical Reporting: Manufacturing (pages 43-51), are all these items applicable for the Phase I effort?**

    Unless stated directly otherwise, please assume all apply.

22. **International Organizations: Can international organizations be included in our bidding consortium?**

    You are not precluded from proposing international organizations as part of your team, so long as those entities are not from the Government's prohibited sources list of embargoed and sanctioned countries. See Section 18.10 of the Base Agreement for further details.

23. **Can you please further define the "emerging infectious disease" category within the biothreats listed on the PHEMCE list?**

    The emerging infectious diseases category of the PHEMCE list is out of scope for this RPP. Emerging infectious diseases, COVID and pandemic influenza are not of interest to BARDA for this solicitation. All other PHEMCE targets are of interest and will be responsive to this solicitation.

24. **How will responses related to the "emerging infectious disease" category be weighed against the other defined targets on the PHEMCE list? Can you please define the criteria that will be used to evaluate responses in the "emerging infectious disease" category? What information will need to be provided in order to quantify the need to prioritize a target within this category?**

    The emerging infectious diseases category of the PHEMCE list is out of scope for this RPP.

25. **Statement of Work & Payment Schedule: On page 7 of the RPP it references that Attachment 3 has to be provided in either a .docx or .doc format. Given that Attachments 1 and 2 are allowed as PDFs, would it be acceptable to the USG if Attachment 3 is provided in PDF format as well?**

    No. Please provide the Statement of Work/Milestone Payment Schedule in a.docx or .doc or.docx format as detailed in the RPP.

26. **SOW Clarification: Page 33 of the RPP states: "The SOW developed by the Lead RRPV member organization and included in the proposal (also submitted as a separate document)." Does the USG expect offers to submit the SOW as Attachment 3 only or as part of Attachment 1 as well?**

    The SOW (Attachment 3) and Technical Proposal (Attachment 1) should be submitted as two separate documents.

27. **Regarding the Preferred Capabilities of current production capacity of 1M tests - Could that be counted including current overseas (China) production with gradual transition onto our US facilities if selected by RRPV? -or do we need to transition prior to Proposal submission/start of implementation period?**

    It does not need to be transitioned prior to submission. In your submission, please describe your production capacity levels currently (US and non-US) and your timeline and capacity levels for transition phases.

28. **Regarding Preferred Capabilities of having a US-based manufacturing (21 CFR 820/ISO 13485)- Should all certifications be completed prior to submission/ start of the implementation period or do we have a grace period to finalize/update certification for our US-based facilities?**

    The manufacturing capability is preferred and not mandatory. In your submission, please describe the state of certifications and plans to update.

29. **Because RPP 24-06-DxR2 is an OTA, subcontractors would not usually be subject to FAR and FAR flow-down. Will the RRPV Base Agreement contain flow-down requirements to subcontracts and subcontractors, even though subcontractors do not need to be RRPV members [As per RPP, page 5, section 2.5. "Offeror Eligibility Criteria"]?**

    The RRPV Base Agreement includes the applicable flow downs from the RRPV Other Transaction Agreement (OTA). While some clauses within the RRPV Base Agreement do indicate flow down requirements, the prime organization will need to determine what is necessary to flow down to its subcontractors.

30. **Does the intent of the program have a connection to warm base?**

    Yes - should additional funding become available, BARDA may seek support for the two additional phases below, of which Phase II (Option) is focused on a Warm-base Surge Capacity: Maintain a warm-base surge capacity via low-rate initial production to produce biothreat tests for use in a public health emergency or large-scale government exercises, or for use in public health laboratory proficiency training, or for use in long-term storage and stability studies of tests and test components. Phase III focuses on capacity expansion. However, proposals are not required for the optional Phases II III (outlined in the RPP) at this time.

31. **Is there a TRL requirement?**

    Yes, maturity of your IVD product and maturity of your manufacturing are very important to your submission's competitiveness for award. Your technology should be at an appropriate maturity (commercial-ready) so that you are ready for the work requested in Phase I - Biothreat Test Development (Base Period): This phase focuses on the i) development and regulatory clearance of biothreat tests, and ii) design transfer to manufacturing activities, such as limited production runs for validation, quality checks, stability studies, early adopter training, and manufacturing capacity studies.

Offerors should show evidence in their proposal of the following “Preferred Capabilities”. Please note and expand on the “Preferred Capabilities” status. Proposals with “Preferred capabilities” will be reviewed more favorably:

1. Have a minimum of 1 (one) FDA approved or CE Marked in vitro diagnostic (IVD) 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)

32. Can existing projects benefit from this program?

This is a competitive program open to those eligible to apply. Existing projects can apply if they meet the intent of the RPP and compete, but must not propose a duplicated scope of an already existing award.