Office of Biomedical Advanced Research and Development Authority

Division of Research, Innovation & Ventures (DRIVe)

Easy Broad Agency Announcement EZBAA-22-100-SOL-00003

<u>The purpose of Amendment #035 is the following:</u>

1) Reopen the following Area of Interest (AOI):

   AOI #16: Lab at Home

2) Open the following Area of Interest (AOI):

   AOI #29: Type to Treat

INTRODUCTION AND OVERVIEW INFORMATION

A. Development Opportunity Objective:

Under this Amendment, DRIVe is doing the following:

1) Reopening the following research Area of Interest (AOI):

AOI #16: Lab at Home

2) Open the following research Area of Interest (AOI):

AOI #29: Type to Treat

We are now seeking abstract submissions for the following AOI:

DRIVe Type to Treat EZ-BAA AOI # 29

Type to Treat: Patient Stratification for Improved Therapeutic Efficacy

The development of efficacious therapeutics for PHE preparedness and response is hampered by heterogeneity of treatment effect, as there is an inability to identify and treat patient populations most likely to respond to particular interventions. BARDA DRIVe has launched the "Type to Treat" program focused on development and validation of platform technologies for endotyping or patient stratification to enhance the efficacy of therapeutic intervention for injuries, insults, infection, or severe disease relevant to BARDA's mission space. "Type to Treat" aims to transform the "Test to Treat" paradigm, by now discerning via a test, not just who is positively infected, but also determining what treatment options would most benefit an individual.

The program goal is to advance development of commercially sustainable platform technologies that could be used to improve therapeutic efficacy in specific populations. This AOI is seeking development and validation of stratification technologies for either a FDA-approved (in BARDA's mission space) or BARDA-supported therapeutic. BARDA is primarily interested in partnering with the stratification tool developer versus the therapeutic developer, to enable primary focus on the platform capability and not the therapeutic investigational product, thereby enabling the potential to expand development of the stratification approach to other therapeutic use cases (beyond the scope of this AOI). The goal is to advance the technology towards FDA approval (e.g., as a complementary or companion diagnostic). Selection of the therapeutic use case should take into consideration what clinical trial and retrospective real-world datasets from patients treated with the therapeutic are available to support development of the stratification technology. Through this AOI, BARDA DRIVe seeks to support therapeutic innovation by enabling identification of the right treatment, at the right time for patients.

To be responsive to this AOI, offerors must:

- Define and justify the selection of the FDA-approved or BARDA-supported therapeutic that will be used for the first use case to develop the stratification platform.

  - Please describe the relevance of the therapeutic's, or candidate's proposed label indication to BARDA's mission space. It is suggested that offerors review the FDA-approved products on medical countermeasures.gov as well as consider the threat space that BARDA addresses (CBRN, pandemic influenza, and emerging infectious diseases) and associated interventions that may demonstrate value in patient management. Some examples may include but are not limited to steroids, nonsteroidal anti-inflammatory drugs (NSAIDs), COVID-19 therapeutics, antibiotics that address antimicrobial resistance, therapeutics for Acute Radiation Syndrome, traumatic brain injury, Acute Respiratory Distress Syndrome (ARDS), sepsis, etc. Therapeutics may be pathogen-targeted or host-directed and may include a range of therapeutic and clinical management approaches including biologics, small molecules, and devices.
- Explain how the proposed stratification and endotyping technology could improve the clinical efficacy of the FDA-approved or BARDA-supported Therapeutic within a defined population.
- Include in the proposal a plan to clinically validate the stratification or endotyping technology through retrospective clinical data or leveraging access to prospective clinical testing of patients treated with the therapeutic product. Preclinical data alone is acceptable for indications subject to the animal rule.
- Propose future development plans to prospectively evaluate the endotyping platform with the FDA-approved or BARDA-supported therapeutic (Fig. 1). It is desired to conduct the prospective evaluation under this proposal, but if not feasible, then please describe the future approach and timeline.
- Describe the intended use and clinical setting for the endotyping platform with the proposed therapeutic, as well as the commercialization plan.
- Provide a regulatory plan/strategy, including FDA engagement for the development of the endotyping platform that would ultimately lead to regulatory approval. FDA engagement is expected within the project period, although it is understood if FDA approval cannot be achieved within the scope of the proposed work. It is desired that offerors already have had initial engagement with the FDA to better inform the proposed development plan.
  - Provide an overview of past regulatory interactions related to the platform
  - Describe a regulatory plan for ultimately achieving regulatory approval for the endotyping product and specify what part of the work would be completed under the proposed scope of work.
- Provide a description of the endotyping technology in terms of form factor, sample type used (if analyzing samples) or other required data and inputs, and how the inputs will be collected and analyzed. Describe the stage of development of the technology. At a minimum a prototype should be available to evaluate under this proposal.
- Describe the evidence (e.g., preliminary data generated by the offeror, scientific publications) to link the endotyping features associated with treatment effect and the therapeutic mechanism(s) of action.
- Describe how the endotyping platform could pivot to inform other therapeutic indications or threat spaces and the work and time that would be required to do so.
- As part of the proposal submission, respondents must also:
  - Provide evidence of intellectual property rights for the endotyping platform

- Provide evidence of established or letters of intent for partner agreements necessary to conduct the proposed work and gain access to the necessary samples, data, etc (e.g., data rights, data access agreements, CROs, clinical study sites)
    - Provide evidence for the right to proceed with commercial development of the product based on access to any shared data, samples, etc. (i.e. support that access to such data is not just for research and development).
- Propose and describe capabilities of individuals that will perform and manage the project, (include CVs for key personnel) necessary for all aspects of the project.
- Describe the plans supporting the commercial viability of the endotyping platform

The following are considered out-of-scope at this time:

- Proposals focused only on early development of endotyping platform technology, prior to readiness for validation with retrospective or prospective clinical data (or preclinical data if the indication is subject to the animal rule)
    - This includes focus only on exploratory biomarker data generation (e.g., exploratory RNA data generation) without further development and validation of endotyping platform technology
- Proposed use cases of therapeutics that are not marketed/FDA-approved or not relevant to BARDA's mission space. (e.g., oncology)
- Technologies that only identify patients at risk of severe outcomes and do not further delineate patient risk subgroups based on underlying pathomechanisms or do not further inform on therapeutic interventions.
- Technologies that solely leverage pathogen-based biomarkers to inform on pathogen-directed therapeutics (e.g., antibiotic resistance and antibiotic administration)

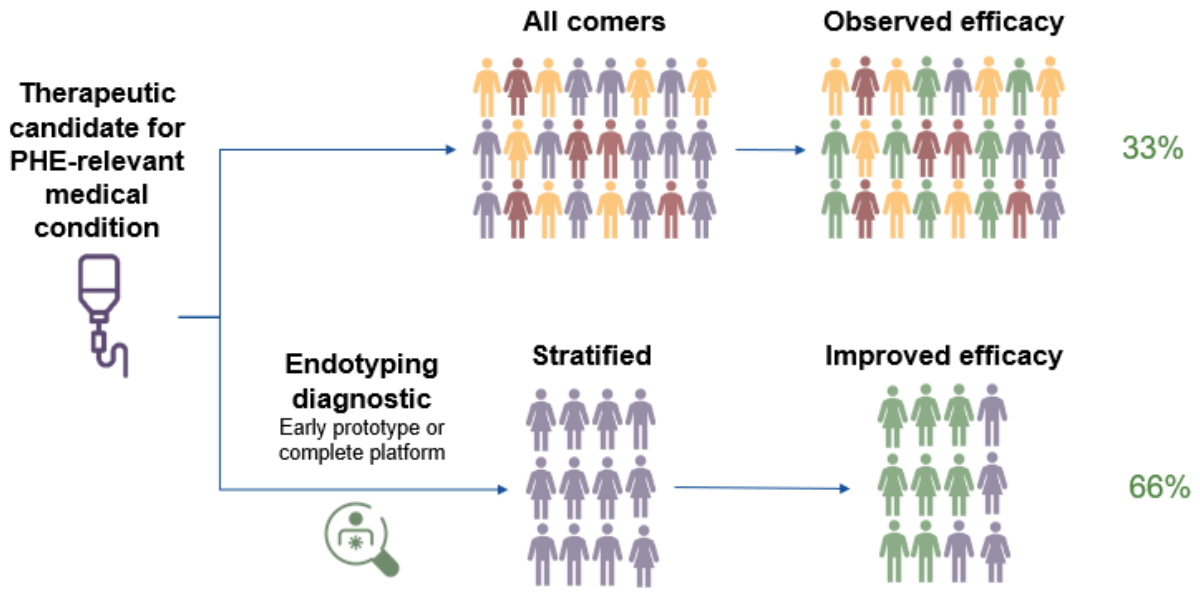

Figure 1. The proposed project must generate evidence demonstrating improved therapeutic efficacy based on use of endotyping technology

B. Eligible Respondents & Scope Parameters:

This Amendment is open to all responsible sources as described in the EZ-BAA. Abstract submissions that do not conform to the requirements outlined in the EZ-BAA may be considered non-responsive and will not be reviewed. An entity must have an active registration with https://sam.gov at the time of submission to be reviewed. If not, the abstract submission will not be reviewed and will be rejected. Please do not attempt to submit an abstract if your registration is not active in https://sam.gov.

IMPORTANT NOTE: Interested vendors are strongly encouraged to request and schedule a pre-submission call before submitting an abstract. This request should include the project title, key project staff, and a brief description of the proposed project. Please submit the requests to the following:

AOI #16: Lab at Home (homediagnostics@hhs.gov)
AOI #29: Type to Treat (TyPE@hhs.gov)

The closing date for abstract submissions for the AOI is listed below.

Area of Interest	Closing Date for Abstract Submissions
#16	12:00pm ET on February 14, 2025
#29	12:00pm ET on May 12, 2025

C. Number of Awards:

Multiple awards are anticipated and are dependent upon the program priorities, scientific/technical merit of abstract submissions, how well the abstract submissions fit within the goals of the AOI, and the availability of funding. The program funding is subject to change based on the Government's discretion.

Funding is limited, so we encourage any interested vendors to reach out to the respective program as soon as possible before submitting an abstract.

D. Amendment Application Process:

This Amendment will follow the same submission process and review procedures as those established under this EZ-BAA, unless otherwise noted. For complete details, please read the EZ-BAA in its entirety along with all amendments.

IMPORTANT NOTE: Respondents who are awarded a contract under each of these AOIs will be required to share any collected, de-identified data to advance the field and knowledge. Interested Respondents are strongly encouraged to commercialize their technology and algorithms, however, note that consistent with BARDA's mission and federal standards, data collected through the use of government funding will be delivered to BARDA for government usage pursuant to applicable regulations and law.