Office of Biomedical Advanced Research and Development Authority
Division of Research, Innovation & Ventures (DRIVe)
Easy Broad Agency Announcement EZBAA-22-100-SOL-00003

The purpose of Amendment #020 is the following:

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

   AOI #26: Agnostic Diagnostic

2) Add a topic to the following Area of Interest (AOI):

   AOI #20: DRIVe Forward

3) Update the closing date for the following Area of Interest (AOI):

   AOI #20: DRIVe Forward

INTRODUCTION AND OVERVIEWINFORMATION

A. Development Opportunity Objective:

Under this Amendment, DRIVe is doing the following:

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

AOI #26: Agnostic Diagnostic

2) Adding a topic for the following research Area of Interest (AOI):

AOI #20: DRIVe Forward

We are seeking abstract submissions for the following AOI:

AOI #20 DRIVe Forward

The continual threat of known and unknown emerging infectious diseases, pandemics, and other public health emergencies requires us to continually invest in products, capabilities, and technologies that have the potential to radically reshape and strengthen our ability to prevent, prepare for, and respond to those emergencies. Specifically, the Division of Research, Innovation, and Ventures (DRIVe) aims to develop products, capabilities, and technologies to rapidly and agnostically detect threats, improve patient care, including ancillary supplies and resources, as well as novel approaches to develop, clinically validate, and deploy/distribute medical countermeasures (MCMs). DRIVe and BARDA already have a variety of specific programs, each focused on specific problems or threat areas of interest, that address this broader aim. DRIVe recognizes, however, that many promising approaches don't fit into any current program areas but would nonetheless advance DRIVe's mission. Accordingly, submissions under this DRIVe Forward Area of Interest are designed to capture those blindspots either as a standalone proof of concepts or as a prelude to a potential future program. DRIVe Forward aims to support proposals that are not only outside the scope of other programs but also address high risk, high reward innovation which will promote the mission of BARDA to defend the nation against biomedical threats. We are interested in proposals that aim to address the following **four** topics. Note, these topics will be updated regularly.

- **Topic #1: Enhancing vaccine efficacy:** Vaccine efficacy can greatly vary amongst individuals and may be especially limited in those with compromised immune systems and elderly who face higher risk of severe disease outcomes to infectious diseases due to insufficient immune response. DRIVe is interested in innovative products and technologies to boost vaccine efficacy and duration to help individuals build a more robust and protective immune response to pathogen exposure. These technologies could be both pharmacologic products as well as non-pharmacologic interventions and would be used in conjunction with approved vaccines. Examples include but not limited to novel adjuvants, other pharmacological products including agonists and antagonists to relevant biological pathways, nutraceuticals, microbiome-based approaches, non-pharmacological approaches could include but are not limited to photo,

thermal, sonic, and electrical stimulations or treatments administered with the vaccine. For this topic, we are not interested in vaccine development; please check other DRIVe/BARDA funding programs for those opportunities.

- **Topic #2: Extremely mobile viral diagnostic platforms for use in extremely remote settings:** Light, portable, diagnostic platforms that can be carried by hand, can be self-powered (e.g., solar charged), for use in extremely remote settings. The platform would need to qualitatively assess known viral families, particularly filoviruses, and can accept multiple sample types and minimize user intervention (e.g., use of finger sticks and avoiding the need for complex sample preparation), as well as be ruggedized and environmentally stable for extended periods of time.

- **Topic #3: Develop computational models to inform precision MCM and non-pharmaceutical intervention (NPI) rapid development and deployment during an outbreak:** In the early COVID-19 pandemic response, it was often unclear what MCMs and NPIs were needed at what time and to what populations to optimally suppress community transmission and limit mortality and morbidity, under such complex, dynamic situations often with limited information and limited data and effectiveness. Further, the variability of healthcare delivery systems across the US has a significant impact on effective delivery and utilization. This greatly complicates decisions on prioritizing the development and deployment of interventions. DRIVe is seeking the development of computational models that can be used to optimally develop, deploy, and use a broad set of MCMs and NPIs against infectious disease outbreaks, under scarce conditions, whether time, money, or other resources, towards a variety of public health goals like suppression of community transmission or early containment. The model should be designed to support complex decision-making in real environments, including the ability for precision MCM deployment. Proposals that focus solely on logistical questions such as stockpile optimization and deployment will be non-responsive. Proposals should allow inputs on several parameters that contribute to impact of MCMs including public sentiment, Bayesian inference of a variety of already available diagnostic and surveillance testing, and synergistic effects among MCMs and NPIs (e.g., rapid testing and oral antivirals).

- **Topic #4: Novel Portable Diagnostics/Detection Methods for Prions as Protein-Based Agents of Disease:** BARDA's strategy is to develop threat-agnostic medical countermeasures, including point-of-need detection and diagnostics. BARDA is interested exploring whether point-of-need technologies can be used to detect and quantify misfolded proteins and diagnose diseases caused by protein pathogens, such as prions. Platform technologies with broad application to numerous protein-based agents of disease are ideal. In addition, the technologies should be deployable to point-of-care and field settings, utilize minimally invasive biological or environmental sampling, be applicable to a diversity of species and protein variants, and must not result in the amplification of infectious protein particles. Due to the widespread availability of samples and known etiology, we highly encourage utilizing CWD for demonstration of real-world functionality to address gaps in diagnosis and detection of prion-and similar protein-mediated diseases.

All interested parties should reach out to DRIVe with a description of the technology, its innovation, and its impact on a public health emergency via email to DRIVe_Forward@hhs.gov **with the topic number of**

interest. We will invite a select set of interested parties for a market research call. Abstracts will only be accepted from applicants who have completed a market research call prior to submission.

All eligible EZ BAA submissions must address the following attributes of the proposed technology:

- Scientific attributes: preliminary data, clear metrics of project success, performance goals and limits of the proposed solution, and comparison with the established technology standard.
- Impact attributes: innovation, impact on technology landscape, impact on public health landscape, equity, and commercialization timeline.

3) Updating the closing date for the following research Area of Interest (AOI):

AOI #20: DRIVe Forward

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 #20: DRIVe Forward (DRIVe_Forward@hhs.gov)
AOI #26: Agnostic Diagnostic (ngs@hhs.gov)

The closing date for abstract submissions for these AOIs is listed below.

Area of Interest	Closing Date for Abstract Submissions
#20	12:00pm ET on April 15, 2024
#26	12:00pm ET on January 15, 2024

Note: To streamline the EZ-BAA, all Areas of Interest will be open for a few months at a time following a staggered approach. This is being done to encourage high-quality submissions earlier in the fiscal year allowing adequate review time. Depending on programmatic need and funding availability, Areas of Interest may be reopened for another period of time.

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.