

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 #027 is the following:

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

AOI #20: DRIVE Forward

2) Removing two topic areas and adding one topic area to the following Area of Interest (AOI):

AOI #20: DRIVE Forward

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 #20: DRIVe Forward

- 2) Removing two topic areas and adding one topic area to the following research Area of Interest (AOI):

AOI #20: DRIVe Forward

Specifically, “Extremely mobile viral diagnostic platforms for use in extremely remote settings” and “Develop computational models to inform precision MCM and non-pharmaceutical intervention (NPI) rapid development and deployment during an outbreak” are removed as topic areas. “Next-generation tourniquets for civilian use” is added as a topic area.

We are now seeking abstract submissions for the following topic areas under the 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 **two** 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 existing vaccines. Examples include but not limited to 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, DRIVE is not interested in vaccine development; please check other DRIVE/BARDA funding programs for those opportunities. This topic is in alignment with BARDA's strategic plan goals for preparedness and response.

- **Topic #2: Next-generation tourniquets for civilian use:** Uncontrolled hemorrhage is a traumatic injury that can occur during mass casualty incidents such as nuclear detonation. Such penetrating and blunt traumatic injuries can cause death in 3-5 minutes, thereby increasing the reliance on bystanders to provide care. Use of standard tourniquets is a known countermeasure. The national "Stop the Bleed" (STB) campaign provides education for civilians on the proper use of Combat Application Tourniquets enabling them to provide immediate life-saving interventions. Research show skill retention for techniques not used regularly deteriorates over time, which poses a significant gap in the ability of civilian bystanders to provide immediate care. As such, there is a need for next-generation tourniquets that are easy for untrained civilians to use and that include guidance at the time of use. Development of such a device would bolster our national preparedness for mass casualty incidents. Under this topic, DRIVE seeks to develop new or modify existing products that are easy to use and customizable for untrained civilian users. Such solutions could include but are not limited to the capability to aid novice users through audiovisual prompts to ensure proper placement, eliminate errors, and to prevent ineffective application. The product solution should align with current STB training curricula. The solution should have demonstrable superiority in successful application rates when compared to the current standard of care. If already available, these data should be included in the application. This topic is in alignment with BARDA's strategic plan goals 1 and 2 for preparedness and response.

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.

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)

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

Area of Interest	Closing Date for Abstract Submissions
#20	12:00pm ET on May 31, 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.