Office of Biomedical Advanced Research and Development Authority (BARDA) Division of Research, Innovation & Ventures (DRIVe)

Special Instructions 008 Issuance for Easy Broad Agency Announcement (EZ-BAA) BAA-20-100-SOL-0002

Revising Topic #4.3 and Closing Topic #4.4 under Area of Interest (AOI) #4: COVID-19

DRIVe Contracting Office
200 C Street SW
Washington, DC 20201

I. INTRODUCTION AND OVERVIEW INFORMATION

A. Development Opportunity Objective:

Under these Special Instructions 008, BARDA is revising topic #4.3 immediately, and closing topic #4.4 at 1700 HRS ET on 04 June 2020 under its temporary AOI #4: COVID-19 as part of its EZ-BAA (BAA-20-100-SOL-0002). We are now seeking abstract submissions for the following:

AOI #4.1-A: [CLOSED]

AOI #4.1-B: [CLOSED]

AOI #4.1-C: [CLOSED]

AOI #4.1-D: Remote Patient Monitoring and Diagnostic Tools

The development of adjunctive diagnostic technologies with near-term impact that are critical to improving the efficiency and effectiveness of our health infrastructure during the COVID-19 outbreak. These technologies may empower the patient through providing a means of self-monitoring or diagnosis, or empower the healthcare provider through enabling remote monitoring or diagnostic capability throughout the care continuum of the patient – i.e. pre-hospital, inpatient, and post-discharge. There is also a need to rapidly assess and diagnose severity of illness in order to triage patients for care or to aid in early recognition of decompensation for improved clinical management of patients.

Current technology emphasis includes telehealth applications, wearables, non-invasive (or minimally invasive) sensors or algorithm-based tools. These technologies should be capable of capturing and quantifying a broad range of host biological, immunological, biometric, clinical, laboratory, and/or physiological data. In addition, technologies that incorporate novel informatics approaches to data collection, reporting, and analysis are of interest.

To be considered relevant under this topic, technologies should meet the following requirements:

1) Ability to be rapidly scaled and deployed under an accelerated timeline of less than 90 days. Software tools should be able to be deployed in less than 30 days.
2) Ability to demonstrate potential utility for COVID-19.
3) Require minimal infrastructure or training to deploy and support.
4) Achieved FDA regulatory clearance/approval or have identified a clear regulatory path for deployment, if applicable to technology.
5) An innovative approach to addressing COVID-19 is preferred.
6) Manufactured components in the United States are desired.

AOI #4.2: [CLOSED]

AOI #4.3: COVID-19 Vaccine

The development and broad delivery of effective vaccines are critical to combat the COVID-19 and other pandemic viruses such as avian influenza (H5N1/H7N9). Conventional vaccine delivery systems pose a supply-chain risk, require the use of adjuvants, biosafety and disposable concerns, and create barriers to self-administration and other ways modes of delivery to the broad public, nationally and globally.

BARDA is seeking abstracts for the development of an alternative vaccine delivery platform to be used to administer vaccines on an accelerated timeline. Specifically, BARDA DRIVe is seeking to develop alternative routes of administration including self-administration (via the oral route and skin patches) that can deliver vaccines quickly, easily, and at a lower cost to large numbers of people. This combined with any novel formulation such as the use of single-dose, thermostable, and the unadjuvanted vaccine would be preferred. The novel formulation and alternative delivery could more effectively address national and global demand for vaccines in upcoming years while eliminating the potential need for adjuvants, minimize or reduce cold chain shipping and storage requirements, reduce or eliminate the need for vials, needles, and syringes and reduce medical waste. Additional benefits could include improvements to protection due to an enhanced immune response, improves ease of use, and improved deployment of vaccines to remote areas in both domestic and international settings.

Ideally, preference will be given to technologies that have demonstrated the feasibility and/or immunogenicity either in humans or in animal models against Influenza (Seasonal/Pandemic), SARS-CoV-1 / 2, or MERS-CoV. Although the novel alternate delivery methods of vaccines are not expected to adhere to TRLs, it is expected that the offeror obtains and submits an Investigational New Drug (IND) application upon completion of BARDA DRIVe funding for this project including qualification of all release assays necessary to demonstrate the safety of candidate product as well as any associated toxicology studies necessary for the IND filing.

- All responsive submissions must have demonstrated, ideally prior to submission, sufficient proof of concept, technology transfer, and IND-enabling studies completed including demonstration of a robust upstream development process and scalable downstream purification process.
- All submissions must bring forth a vaccine candidate against SARS-CoV-2 or Influenza viruses with pandemic potential along with a new method or route of administration other than traditional administration and delivery vehicles for these vaccines. The alternative delivery vehicle should provide clear integration into the fill/finish component of vaccines and studies in support of this should ideally be completed prior to submission.
- Abstracts will be evaluated based upon the demonstration of scalability of process, antigen-sparing effects, dosing, ease of use, long term thermostability, and cost as compared to traditional vaccination routes.
- The manufacturing technology for the proposed vaccine should be suitable for commercial-scale production and product delivery.

- Priority will be given to products manufactured in the United States.

AOI #4.4: Advanced Manufacturing Technologies [CLOSING on 04 June 2020]

The development and demonstration of innovations and enhancements to manufacturing platforms to support the development of necessary medical countermeasures including vaccines and therapeutics in prevention, preparation, and response to COVID-19. The purpose of the innovations and enhancement to advanced manufacturing technologies may include, but are not limited to, improving pharmaceutical quality, rapidly scaling manufacturing capabilities, shortening supply chains, increasing manufacturing resilience to disruption, accelerating availability of emerging therapies/vaccines, or reducing the risk of pharmaceutical shortages. Advanced manufacturing technologies may include, but are not limited to, continuous manufacturing and additive manufacturing (including 3D printing). Priority will be given to products manufactured in the United States.

B. Eligible Respondents & Scope Parameters:

These Special Instructions 008 are open to all responsible sources as described in the EZ-BAA. Preliminarily, a call with the relevant Program Manager is strongly encouraged prior to any submission to better understand the program objectives for each topic under AOI #4. The points of contact for each topic under AOI #4 are the following:

AOI #4.1-A: [CLOSED]
AOI #4.1-B: [CLOSED]
AOI #4.1-C: [CLOSED]
AOI #4.1-D: COVID19DxEzBAA@hhs.gov
AOI #4.2: [CLOSED]
AOI #4.3: Armen Donabedian, armen.donabedian@hhs.gov
AOI #4.4: Timothy Belski, timothy.belski@hhs.gov [CLOSING on 04 June 2020]

The open topics under AOI #4 will be open for abstract submissions until 1700 HRS ET on 30 June 2020, unless otherwise extended. Additionally, award(s) expected to be made under these Special Instructions 008 will be less than $750,000 in total government funding.

Abstract submissions that do not conform to the requirements outlined in the EZ-BAA may be considered non-responsive and will not be reviewed. To clarify, an entity must have an active registration with www.SAM.gov at the time of submission to be reviewed. If not, submissions will not be reviewed and will be rejected. Please do not attempt to submit an abstract if your registration is not active in www.SAM.gov.

NOTE: Funding is limited, so we encourage any interested vendors to reach out to the appropriate Program Manager listed above before submitting an abstract as soon as possible.

C. Number of Awards:

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

D. Special Instructions Application Process:

These Special Instructions 008 will follow the same submission process and review procedures as those established under the EZ-BAA. For complete details, please read the EZ-BAA solicitation in its entirety.