

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

Special Instructions 006 Issuance for Easy Broad Agency
Announcement (EZ-BAA) BAA-20-100-SOL-0002

Adding Topic #4.1-D 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 006, BARDA is adding topic #4.1-D 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: Point-of-Care Diagnostic Assay for detection of SARS-CoV-2 virus

The development and Emergency Use Authorization (EUA) of an *in vitro* diagnostic test for the detection of SARS-CoV-2 (i.e., virus, viral RNA, or viral antigens) in respiratory specimens that has a small footprint (e.g., hand-held), is easy to use at the point of care (i.e., suitable for use in CLIA-waived settings) and produces results in less than 30 minutes (less than 15 minutes preferred). While there is no minimum Technology Readiness Level (TRL) required, Respondents should describe the platform, proposed detection targets, development status of the test, information to support clinical utility claims, and proposed plan to achieve EUA submission. Priority will be given to products manufactured in the United States.

AOI #4.1-C: Diagnostic Tests for detection of COVID-19 disease

The development and Emergency Use Authorization (EUA) of an *in vitro* diagnostic test for COVID-19 disease. Tests should detect host or pathogen biomarkers specific for COVID-19 disease. Both Laboratory and Point of Care tests are sought. Laboratory tests should be performed on instrument systems already in use in clinical laboratories with extensive US laboratory placements. Point of Care tests should analyze non-invasive specimens that can be easily collected in CLIA-waived settings, and provide results in less than 30 minutes (less than 15 minutes preferred). While there is no minimum Technology Readiness Level (TRL) required, Respondents should describe the platform, proposed detection targets, development status of the test, information to support clinical utility claims, and proposed plan to achieve EUA submission. Priority will be given to products manufactured in the United States.

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 of “ready to use”, rapid response platform technologies, alternative vaccine administration/delivery, and adjuvants for application to the production of COVID-19 vaccines on an accelerated timeline. Priority given to platforms that offer an integrated approach to the full spectrum of vaccine development; from creation of candidate vaccines through testing, selection and regulatory approval, to full-scale manufacturing capability with the fewest adjustments and refinements necessary for a vaccine for COVID-19. Priority will be given to products manufactured in the United States.

AOI #4.4: Advanced Manufacturing Technologies

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 006 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 AOI #4. The points of contact for each topic under AOI #4 are the following:

AOI #4.1-A: [CLOSED]

AOI #4.1-B: COVID19DxEzBAA@hhs.gov

AOI #4.1-C: COVID19DxEzBAA@hhs.gov

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

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 006 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.

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 006 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.