

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

Special Instructions 003 Issuance for Easy Broad Agency
Announcement (EZ-BAA) BAA-20-100-SOL-0002

New Topic 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 003, BARDA is adding a new topics 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: Molecular Diagnostic Assay for SARS-CoV-2 virus on existing FDA-cleared platform

The development and Emergency Use Authorization (EUA) of an *in vitro* diagnostic assay for the detection of SARS-CoV-2 (2019-nCoV) RNA in clinical specimens, including upper (e.g, nasopharyngeal and oropharyngeal swabs, nasopharyngeal wash/aspirate, or nasal aspirate) and lower (e.g., bronchoalveolar lavage, tracheal aspirate, or sputum) respiratory tract specimens.

The assay must be developed for use with an existing FDA-cleared molecular platform that is currently widely placed in U.S. healthcare settings. Preference will be given to respondents who present a viable plan that achieves an EUA submission milestone within 12 weeks of award. As part of the abstract submission, respondents should describe the current development status of their SARS-CoV-2 (2019-nCoV) assay, including *in silico* analysis of targets, access to validation materials to support EUA submission, and contacts with the FDA. Priority will be given to products manufactured in the United States.

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 Assay for detection of COVID-19 disease

The development and Emergency Use Authorization (EUA) of an *in vitro* diagnostic test for COVID-19 disease that has a small footprint (e.g., hand-held) and is easy to use at the point of care (i.e., suitable for use in CLIA-waived settings). Assays should detect host or pathogen biomarkers specific for COVID-19 disease in 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 #4.2: Nonclinical Model Development and Screening for SARS-CoV-2 virus

The development of an *in vitro* assay and *in vivo* SARS-CoV-2 nonclinical model(s) for screening potential medical countermeasures for the treatment of SARS-CoV-2.

Respondents must possess a SARS-CoV-2 strain, hold a Select Agent Permit, and have access to a nonclinical BSL-3 laboratory capable of performing mouse therapeutic studies of SARS-CoV-2. As part of the abstract submission, respondents should describe the current development status of their SARS-CoV-2 assay, justify species to be used for *in vivo* screening, and demonstrate recent *in vivo* work with therapeutics for SARS-CoV and MERS-CoV.

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 003 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: Justin Yang, Ge.Yang@hhs.gov

AOI #4.1-B: Justin Yang, Ge.Yang@hhs.gov

AOI #4.1-C: Justin Yang, Ge.Yang@hhs.gov
AOI #4.2: Brian Tse, brian.tse@hhs.gov
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 003 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 003 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.