

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

Special Instructions 010 Issuance for Easy Broad Agency  
Announcement (EZ-BAA) BAA-20-100-SOL-0002

**Adding Topic #4.1-E  
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 010, BARDA is adding topic #4.1-E under its temporary AOI #4: COVID-19 as part of its EZ-BAA (BAA-20-100-SOL-0002). We are only 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/Remote 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 empower the healthcare provider through remote monitoring or evaluation and 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 patient.

These technologies may include, but are not limited to, smartphone mobile applications, wearables, or non (or minimally) invasive sensors that can measure/monitor host-signature or diagnose response to infection, telehealth applications, EHR based tools, algorithms that can predict, identify or prognosticate risk trajectories, clinical decision support software, or continuous monitoring devices.

These technologies should be in advanced development and ready for clinical validation. 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. Pathogen-targeted and serology diagnostics, as well as bench-top diagnostics, are not of interest for this topic at this time.

To be considered relevant under this topic, respondents should have a need to assess clinical validation through conducting a pilot study that meets the following requirements:

- 1) Total period of performance should have impact for this current COVID-19 outbreak. After clinical validation, technology should have the ability to be rapidly scaled and deployed under an accelerated timeline of less than 90 days.

- 2) Software tools should be able to be integrated into EHRs or deployed in less than 30 days.
- 3) Significant preliminary COVID-19 data to support utility of technology for COVID-19.
- 4) Requires minimal infrastructure or training to deploy and support.
- 5) Achieved FDA regulatory clearance/approval or have identified a clear regulatory path for deployment, if applicable to technology.
- 6) Demonstrates a clear commercialization strategy to expand use.

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

#### **AOI #4.1-E: Pediatric Diagnostic Tools for Severe COVID-19 Disease and MIS-C**

The clinical presentation of COVID-19 in children is not fully understood and remains challenging to address. Many children infected with SARS-CoV-2 are asymptomatic or display mild symptoms, but the risk of severe COVID-19 disease that may lead to hospitalization and in some cases, sepsis, still exists. More recently, Multisystem Inflammatory Syndrome in Children (MIS-C) has been described as a condition where inflammation affects multiple organs causing a range of symptoms that may occur weeks after infection with, or exposure to, SARS-CoV-2. There is a need to develop solutions that recognize or predict severe COVID-19 disease in children and/or subsequent complications like MIS-C which may arise outside of apparent symptomatic infection.

Diagnostic technologies that can specifically identify and distinguish severe COVID-19 disease from mild illness in children and/or predict the onset of MIS-C are needed to aid in clinical management of these patients. These host-based or clinical technologies may include, but are not limited to:

- 1) In vitro diagnostics, EHR based tools, or algorithms that can collate data to predict, identify or prognosticate risk trajectories.
- 2) Clinical decision support software, or remote/continuous monitoring devices appropriately sized for children.

Technologies should be capable of capturing and quantifying a broad range of host biological, immunological, clinical, laboratory, and/or physiological data as appropriate to predict and identify severe pediatric COVID-19 and/or MIS-C. Pathogen-based approaches are not of interest at this time nor technologies that cannot distinguish these severe conditions from asymptomatic or mild COVID-19.

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

- 1) Completed initial studies with pediatric COVID-19 samples with sufficient performance metrics of the technology to identify severe outcomes.
- 2) Seeking FDA regulatory clearance/approval or EUA if applicable.
- 3) Have identified clinical study site partners, if needed, for larger scale or prospective studies.
- 4) Specifically focused on pediatric indication.
- 5) Focused on product development, not surveillance or epidemiological

research.

- 6) After seeking regulatory approvals, have ability to deploy in multiple US locations within the next 6-12 months in order to have impact during this COVID-19 pandemic.

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

**AOI #4.2: [CLOSED]**

**AOI #4.3: Alternative Routes of Administration (AROA) for Vaccines**

Vaccination saves millions of lives per year globally. It is the single most effective public health intervention for preventing infectious diseases. Traditional parenteral vaccinations using needles and syringes are the primary medical intervention for prevention of infections with these viruses. An identified risk during a pandemic response, including SARS-CoV-2, is the availability of needles and syringes used to administer vaccines.

One key risk impacting needle and syringe availability in the United States during a pandemic is limited domestic surge manufacturing. In an effort to reduce production costs, the medical supply industry has evolved to “just-in-time” supply chain models over the past two decades. Industry has also moved sourcing and production of raw materials outside the United States. As a result, domestic availability of needle and syringes would be limited during an infectious disease pandemic.

Another key risk is the limited number of qualified personnel needed to administer vaccine. Personnel trained in the administration of vaccine include physicians, nurses, physician assistants, emergency medical technicians, and pharmacists. In a pandemic where critical care personnel are likely to be in short supply, a successful alternative technology for vaccine administration would reduce the demand qualified personnel to administer vaccine. Enhancing the ease of vaccine administration would logically increase timeliness and vaccine coverage rates, reduce the number of infections, and mitigate mortality and morbidity rates during pandemics compared to current needle and syringe technologies.

Alternative technologies for vaccine administration (oral, transdermal (i.e. micro array patches), and aerosol/inhalation), have the potential to eliminate the need for using the currently available needles and syringes during a pandemic response and hopefully self-administration.

BARDA is seeking abstracts for the development of alternative routes of administration for vaccines (including oral, transdermal (i.e. micro array patches or aerosol/inhalation)) against CBRN threats, Influenza (seasonal/pandemic), SARS-CoV-1 / 2, or MERS-CoV.

Ideal attributes for vaccines delivered via alternative routes of administration would be single dose, room temperature stable, unadjuvanted and indicated for all populations. Vaccines delivered via alternate routes of administration would have similar or superior performance characteristics as traditional parenterally administered vaccines (i.e. safety and efficacy).

Although the technology for alternate routes of administration of vaccines are not expected to adhere to TRLs, it is expected that the respondent obtains and submits an Investigational New Drug (IND) application upon completion of BARDA DRIVE funding for this project or the respondent shall make the vaccine available for potential toxicology and efficacy assessments under separate USG mechanisms.

All submissions must include:

- 1) A vaccine candidate against CBRN threats, Influenza (seasonal/pandemic), SARS-CoV-1 / 2, MERS-CoV, or partnership with an antigen developer to be administered by an alternate route of administration.
- 2) Plans for IND enabling pre-clinical studies or provide existing data.
- 3) Product development plan.
- 4) Any regulatory communication with US FDA (pre-IND/IND).
- 5) Any pre-clinical or clinical data using this platform.

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

**AOI #4.4:** [CLOSED]

## **B. Eligible Respondents & Scope Parameters:**

These Special Instructions 010 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](mailto:COVID19DxEzBAA@hhs.gov)

AOI #4.1-E: [COVID19DxEzBAA@hhs.gov](mailto:COVID19DxEzBAA@hhs.gov)

AOI #4.2: [CLOSED]

AOI #4.3: Donna Boston, [donna.boston@hhs.gov](mailto:donna.boston@hhs.gov)

AOI #4.4: [CLOSED]

The open topics under AOI #4 will be open for abstract submissions through 31 October 2020, unless otherwise extended. Additionally, award(s) expected to be made under these Special Instructions 010 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](http://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](http://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 010 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.