

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

Amendment 006 Issuance for Easy Broad Agency Announcement  
(EZ-BAA) BAA-22-100-SOL-00003



**The purpose of this Amendment is the following:**

- 1) Update the closing date for the following Area of Interest (AOI):

**AOI #19:** Healing Lungs

- 2) Update the closing date for the following Area of Interest (AOI):

**AOI #17:** Digital MCMs

- 3) Update the closing date for the following Area of Interest (AOI):

**AOI #16:** Lab at Home

- 4) Revise the following Area of Interest (AOI):

**AOI #16:** Lab at Home

## INTRODUCTION AND OVERVIEW INFORMATION

### A. Development Opportunity Objective:

Under this Amendment, DRIVE is doing the following:

- 1) Updating the closing date for the following research Area of Interest (AOI):

**AOI #19:** Healing Lungs

- 2) Updating the closing date for the following research Area of Interest (AOI):

**AOI #17:** Digital MCMs

- 3) Updating the closing date for the following research Area of Interest (AOI):

**AOI #16:** Lab at Home

- 4) Revising the following research Area of Interest (AOI):

**AOI#16:** Lab at Home

We are seeking abstract submissions for the following revised AOI:

#### **AOI #16: Lab at Home**

DRIVE is seeking proposals to develop novel platform technologies and instrumentation for on-demand detection of multiple biochemical health markers at the point of need. The goal is to obtain (quantitative) information about patients' health status at the point of need without going through traditional central laboratory testing, which requires laboratory skills, long turn-around times, and can lead to delays in receiving care. Such platforms could enhance the capabilities of point-of-care medicine by enabling data-driven diagnoses by physicians without requiring sample shipping or travel to a sample collection site. Enabling such testing could greatly enhance infection detection, chronic disease management, clinical trial management etc., leading to a healthier population with reduced healthcare costs. The instrumentation / platform technologies developed through this program are primarily intended for settings such as the home, but could also be useful in doctor's offices, nursing homes, or immediate care facilities, where access to analytical results at the point of need is vital.

While DRIVE does not specify a particular platform form factor or sensing modality and will consider both desktop (portable) and wearable platforms, a successful platform technology will provide single time point quantitative measurements comparable to a central laboratory or continuous or near-continuous quantitative measurements from a wearable device.

**The goal of projects funded through this AOI is feasibility demonstration of enabling technologies that allow for simultaneous detection and quantification of several different biochemical markers in a multiplexed manner.**

Applicants should address the following in their proposals:

- The technological innovation.
- The scientific premise for interrogating a specific set of biomarkers using the proposed sample and method, as well as the clinical relevancy of those biomarkers.
- The desired limit of detection and accuracy of the proposed sensing modality.
- A plan for comparison between the proposed solution and the laboratory standard in function and clinical value, including how the novel technology could replicate the central laboratory function and/or outcome.
- A plan to address critical feasibility issues that need to be demonstrated as a prerequisite to advancing the platform to a specific product application.
- A plan to demonstrate detection of several patient biochemical markers – preferably at least four – from a clinical sample in a multiplex assay.
- Preliminary data that supports key assumptions of the proposal.

Examples of desired use cases include detection of host biochemical markers relevant to infectious diseases, radiological injury, rapid results of critical cardiac function, among others. Biochemical markers of interest include, but are not limited to: host lipids, proteins, nucleic acids, and small molecules; examples include bilirubin, creatinine, CRP, uric acid, triglycerides, hemoglobin, iron, calcium, potassium, IP-10, TRAIL, cortisol, etc.

**Responsiveness criteria:**

- Novel platform technologies should ideally provide quantitative biomarker data/detection of biomarkers when used by untrained personnel in the home or other CLIA-waived environment. Both desktop/portable and wearable form factors will be considered. Among wearable form factors, microneedle patches, smart tattoos and other innovations are particularly desired.
- The proposed platform technology should ideally produce quantitative test results and be readily adaptable to a broad menu of test panels (e.g., proteins, large molecules, lipids, etc.) to cover a wide range of disease states as well as standard health assessments.
- Proposals do not need to include interpretation of the biomarker levels for diagnostic purposes.
- Sample specimens should preferably be collected non-invasively at home by an untrained individual 18 years of age or older. Acceptable samples include saliva, urine, sweat, breath, nasal swabs, or minimally invasive samples such as finger stick blood or interstitial fluid. However, analytes measured from novel sample types should demonstrate comparability to values from samples used for analogous laboratory testing (i.e. venous blood samples).
- The entire testing process including sample collection, sample application to test, and test readout should preferably take no more than 2 hours. Alternatively, devices in wearable form factors producing multiple quantitative measurements per day will be considered. The test (or quantitative measurement) must be designed to be performed in point-of-need settings listed above by untrained personnel 18 years of age or older.
- Any visual readouts confirming proper use of the system should be easy to interpret by lay individuals.
- The analytical performance (i.e., limit of detection, accuracy) of the proposed sensing modality should be clinically relevant and commensurate with up-to-date regulatory and public health guidance. Ideally, performance of the platform would be similar to the FDA-approved gold standard.
- Priority will be given to platforms being developed in the United States.

**Other characteristics:**

- The system may include a smartphone, mobile device, portable desktop device, or instrument for collection and transfer of data to a medical care provider, however, projects focusing chiefly on data transfer mechanisms will not be prioritized.

- The collection and transfer of data by the device or a mobile device should follow accepted data standards to allow connectivity with medical professionals, as well as comply with current privacy laws and guidelines.
- Plans for product commercialization, including a regulatory pathway, are desired but not required.

**Non-responsive / out-of-scope topics:**

- Technologies requiring venous blood draws or invasive samples.
- Proposals combining at-home sample collection with testing at another location.
- Proposals focusing on clinical validation or clinical utility of existing technologies; infection severity/sepsis; or interpretation of quantitative biochemical results for diagnostic or triage purposes are not responsive. Interested applicants may consider AOI #23 instead.

**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. In particular, 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 #16:** Lab at Home ([homediagnostics@hhs.gov](mailto:homediagnostics@hhs.gov))

**AOI #19:** Healing Lungs ([HealingLungs@hhs.gov](mailto:HealingLungs@hhs.gov))

The closing date for abstract submissions for this AOI, unless otherwise extended will be:

Area of Interest	Closing Date for Abstract Submissions
#16, #17	12:00pm ET on February 6, 2024
#19	12:00pm ET on June 30, 2023

**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 in an effort 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.