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

Amendment 012 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 #16:** Lab at Home

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 #19:** Healing Lungs

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

   **AOI #16:** Lab at Home

5) Add the following Area of Interest (AOI):

**AOI #26:** Agnostic Diagnostic

## 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 #16:** Lab at Home

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 #19:** Healing Lungs

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

   **AOI #16:** Lab at Home

   We are seeking abstract submissions for the following AOI:

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

DRIVe is seeking proposals to develop novel instrumentation-based platform technologies for on-demand, simultaneous 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, avoiding the long sample-to-answer times and personnel training requirements of traditional central laboratory testing that can lead to delays in receiving care. Such platforms could remove existing complications patients face in seeking remote diagnoses by physicians, including sample shipping or travel to sample collection sites. Enabling testing at the point of need could greatly improve the efficiency and accessibility of tools for infection detection, chronic disease management, clinical trial management etc., leading to a healthier population with reduced healthcare costs.

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

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, urgent care facilities, pharmacy clinics or anywhere access to analytical results at the point of need is vital. DRIVe does not specify a particular platform form factor or sensing modality and will consider devices ranging from portable benchtop formats to handheld or wearable platforms. Both single time point and continuous (or near-continuous) quantitative measurements will be accepted. Platform technologies will ideally provide results comparable to those from a central laboratory, when applicable, or to a relevant control assay.

Applicants should address the following in their proposals:

- The technological innovation, potentially including, but not limited to:
  - how the technology addresses gaps in the capabilities of existing platforms,
  - how the technology improves upon or differs from similar platforms,
  - how the technology uniquely addresses barriers to access such as cost, ease of use or time to result.
- The scientific premise for interrogating a specific set of host biomarkers using the proposed sample and method, as well as the clinical relevancy of those biomarkers in the BARDA context.
- 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 simultaneous detection of host biochemical markers from a single clinical sample in a multiplex assay.
- Preliminary data that supports the key assumptions of the proposal.

The respondent should explain how the choice of host biomarkers addresses BARDA's mission. Examples of desired use cases include detection of host biochemical markers relevant to infectious diseases, chemical/radiological injury, or rapid results of critical cardiac function, among others. Biochemical markers of interest include, but are not limited to lipids, proteins, nucleic acids, and small molecules; examples include cytokines, bilirubin, creatinine, CRP, uric acid, triglycerides, hemoglobin, iron, calcium, potassium, IP-10, TRAIL, cortisol, etc.

<u>Responsiveness criteria:</u>

- Innovative platform technologies should ideally provide quantitative data/detection of biomarkers that is compatible with use by untrained personnel in the home or other CLIA-waived environment.
- The proposed platform technology should 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.
- Both desktop/portable and wearable form factors will be considered. Among wearable form factors, microneedle patches, smart tattoos, eye lenses and other innovations are desired.
- Proposals do not need to include interpretation of the biomarker levels for diagnostic purposes. The interpretation of the results will be performed by healthcare professionals.

- Sample specimens should preferably be compatible with collection non-invasively or minimally invasively at home by an untrained individual 18 years of age or older. Acceptable sample types include saliva, urine, sweat, breath, exhaled breath condensate, nasal swabs, finger stick blood, capillary blood, and interstitial fluid. However, analytes measured from novel sample types should demonstrate comparability to values from venous blood samples used for analogous laboratory testing.
- 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.
- Any visual readouts confirming proper use of the system should be easy to interpret by lay individuals and those with visual impairment.
- 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 or those whose target markets include the US.

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.
- Projects focused on interpreting qualitative data will not be prioritized.
- While projects may include the development or implementation of machine learning algorithms, proposals whose primary innovation combines ML or AI with existing technologies will not be considered.
- The collection and transfer of data by the device or a mobile device should follow accepted data standards to allow connectivity with medical systems, 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.
- Technologies focusing on biophysical health markers (e.g. blood pressure, respiratory rate).
- 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.

5) Adding the following research Area of Interest (AOI):

**AOI #26:** Agnostic Diagnostic

We are seeking abstract submissions for the following AOI:

**EZ-BAA AOI #26: Advancing Metagenomic Next-Generation Sequencing-Based Agnostic Diagnostics for Viral Pathogens**

Metagenomic next-generation sequencing (mNGS) is a powerful technology that has been well-established in research, surveillance, and biomarker discovery communities. It has the potential to improve diagnostics, especially in cases of unknown or emerging pathogens. An agnostic test based on mNGS that can detect any and every virus, known or unknown, and can be implemented in routine clinical labs and point-of-care settings, could help reshape the public health response to a pandemic. It could also aid in tailoring interventions to improve patient outcomes.

The translation of mNGS as a clinical diagnostic for agnostic detection has not yet occurred due to multiple challenges associated with higher cost, turn-around time, standardization of sample preparation, the complexity of sequencing methods, and bioinformatics analysis.

To address this, DRIVe is interested in advancing approaches that could enable agnostic mNGS-based diagnostics for viral infection in routine clinical labs and point-of-care settings. DRIVe is seeking proposals for innovation in **one or more** of the following areas:

1) **Sequencing Hardware:** Novel, accurate, and efficient sequencing technology featuring one or more of the following:
    a. Reduced size and portability. Platform hardware with a desktop-sized footprint or smaller, that could be moved by a human without assistance with minimal and easy calibration requirements.
    b. Novel scalable sequencing chemistry and flow cells intended for eventual point-of-care use in clinical settings.
2) **Sample preparation, mNGS assays, and reagents:** Faster, more efficient methods and reagents for sample and library preparation that are automated and portable for clinical use.
    a. Novel sample preparation methods with fast turnaround time from sample to library (Less than 3 hours), minimal hands-on time (Less than 45 minutes), and fewer liquid-handling steps.
    b. Protocols that work for all types of viruses (including both DNA and RNA) and for more than one sample type (e.g., saliva, NPS, urine, whole blood, serum) with the ability to adapt to any other pathogen (e.g., bacteria, virus, fungi, or protozoa) are preferred.
3) **Bioinformatics:** Software for mNGS data analysis and clinical interpretation
    a. Fully automated analysis software with the ability to ingest data from any sequencing platform for clinical applications using existing/new viral databases.
    b. Novel AI/ML-based algorithms to inform on signal to background and spurious reads, real-time analysis, clinical interpretation and to predict pathogenicity and/or pandemic potential of discovered sequences.

NOTE: All awarded partners will be required to share any collected de-identified data in an effort to advance the field and knowledge. Interested partners are encouraged to commercialize their technology and algorithms but data collected through the use of Government funding will be made available through full Government purpose rights.

## 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)
**AOI #17:** Digital MCMs (digitalhealth@hhs.gov)
**AOI #19:** Healing Lungs: (HealingLungs@hhs.gov)
**AOI #26:** Agnostic Diagnostic (ngs@hhs.gov)

The closing date for abstract submissions for these AOIs, unless otherwise extended will be:

| Area of Interest | Closing Date for Abstract Submissions |
|---|---|
| #16, #17, #19 | 12:00pm ET on December 15, 2023 |
| #26 | 12:00pm ET on January 15, 2024 |

## 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.