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

Amendment 009 Issuance for Easy Broad Agency Announcement (EZ-BAA) BAA-22-100-SOL-00003

The purpose of this Amendment is the following:

1) Reopen the following Area of Interest (AOI):

AOI #21: Vaccines on Demand

INTRODUCTION AND OVERVIEWINFORMATION

A. Development Opportunity Objective:

Under this Amendment, DRIVe is doing the following:

1) Reopening the following research Area of Interest (AOI), which is reopened to support project Next Gen:

AOI #21: Vaccines on Demand

We are seeking abstract submissions for the following AOI:

AOI #21: Vaccines on Demand

Vaccines can be highly effective long-term medical countermeasures against biological attacks as well as emerging infectious diseases with pandemic potential. At current, vaccine-based preparedness and response strategies rely solely on centralized, commercial scale manufacturing processes followed by the stockpiling of vaccines, if needed. This strategy is operationally inefficient and financially burdensome when considering the resources needed to manufacture, distribute, and administer vaccines during public health emergencies.

The development and deployment of vaccines in response to the COVID-19 pandemic revealed a number of impediments to rapid response capability that are now critical areas for improvement. These include:

i) Bottlenecks in centralized large-scale manufacturing practices;
ii) Long lead times in raw material acquisition, release testing, and availability of manufacturing space;
iii) Geographic limitations of the stockpile and manufacturing facilities that compromise the timely distribution of vaccines; and
iv) Lengthy processes for clinical evaluation and regulatory approval.

Accordingly, BARDA is seeking technologies to enable the On Demand Manufacturing of next generation COVID-19 vaccines at or near the point-of-service. Technologies that will address one or more of the following key aspects of technology are of particular interest:

1. *Easily definable inputs:* The platform would utilize materials for vaccine manufacture that are easily sourced and handled within the device.
2. *Minimal to no release testing:* The platform would enable decentralized production by integrating in-line production testing and traceable documentation into the manufacturing process.
3. *In-line formulation capabilities:* The platform would enable formulation in a single, closed system.
4. *Logistically useful footprint:* The platform would possess a sufficiently small footprint to enable its use in facilities proximal to hospitals, pharmacies, or clinics.

5. *Small-scale validation:* The platform would be subject to validation of manufacturing for regulatory purposes.
6. *Plug and play capability:* The platform would utilize integrated precursor API materials, such as chemical or biological cartridges, for simple 'plug-and-play' operations.

Offerors are not expected to meet all the performance criteria outlined above. Rather, they can meet a few of the criteria with the expectation that improvement and optimization of the design will occur within the period of performance of a potential award.

Technology Product Profile

System Characteristics	**Goal**
Number of doses per batch	>1000
Number of days per batch	<7
Number of batches per resupply	1
Release Testing	Near real time/<24hour readouts
In-line Formulation	Fully automated, plug and play capability

To improve the United States' posture for pandemic preparedness, the development of novel strategies to accelerate vaccine production and deployment is warranted. In this solicitation, BARDA has a goal of demonstrating the proof-of-concept for technologies to produce next generation COVID-19 vaccines on demand, where "on demand" is defined as the rapidly responsive production of a vaccine following the receipt of a pathogen's genetic or antigen sequence, with an eventual goal of in-line formulation and release testing.

Next generation COVID-19 vaccine candidates utilizing any of the following platforms will be considered:

- mRNA
- Recombinant protein
- Virus-like particle
- Viral vector

Depending on the stage of product development, the final deliverables of this proof-of-concept effort might range from assessment of vaccine purity and stability to evaluation of safety, immunogenicity, and efficacy in a suitable animal model.

The end goal of this AOI is to generate proof-of-concept data from the proposed platforms that demonstrate *ON DEMAND* production of >1000 doses of vaccine within one week.

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 #21: Vaccines on Demand (ondemand@hhs.gov)

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

Area of Interest	Closing Date for Abstract Submissions
#21	12:00pm ET on September 28, 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.