Office of Biomedical Advanced Research and Development Authority
Division of Research, Innovation & Ventures (DRIVe)
Easy Broad Agency Announcement EZBAA-22-100-SOL-00003

The purpose of Amendment #030 is the following:

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

AOI #28: Influenza Vaccine Innovation

2) Pause the following Area of Interest (AOI):

AOI #26: Agnostic Diagnostic

INTRODUCTION AND OVERVIEW INFORMATION

A. Development Opportunity Objective:

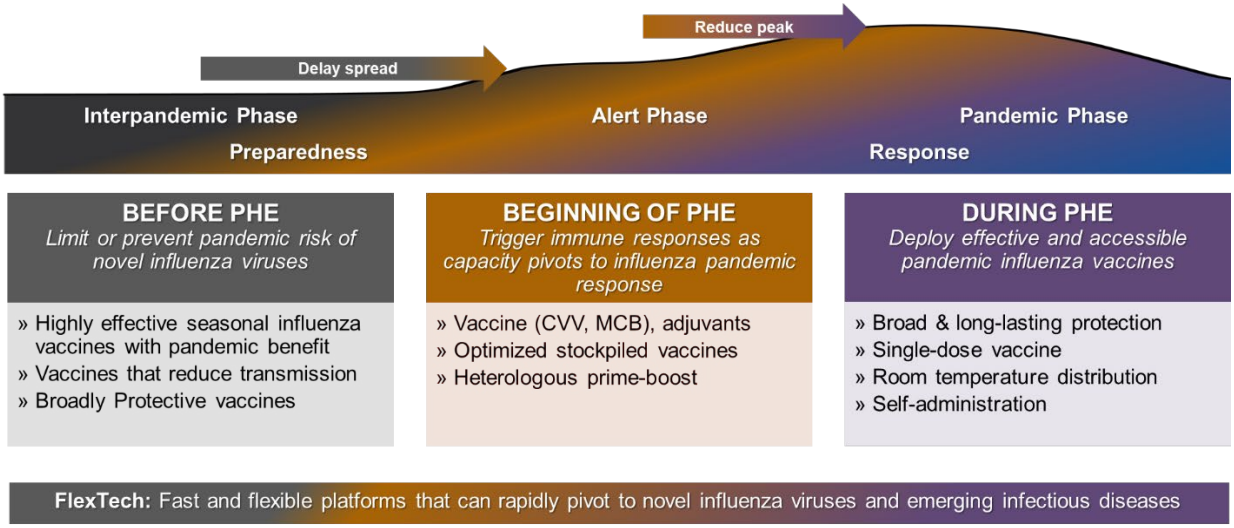
Under this Amendment, DRIVe is doing the following:

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

AOI #28: Influenza Vaccine Innovation

AOI #28: Influenza Vaccine Innovation

Influenza remains a serious health concern in the U.S. and globally, both as an annual disease (seasonal influenza) and as a threat for periodic outbreaks of widespread disease with higher rates of morbidity and mortality (pandemic influenza). There are three opportunities for vaccine intervention for pandemic influenza: during a public health emergency (PHE) in response to the emergence of a novel influenza virus, around the beginning of an influenza pandemic, and before a PHE has begun. Influenza vaccines are most effective when they induce neutralizing antibodies to the influenza virus strain causing disease. Less effective but still highly impactful to public health are pandemic influenza vaccines designed to be stockpiled and deployed at the beginning of a public health emergency. Since most of the U.S. population is vaccinated against seasonal influenza every year, an opportunity exists to confer partial immunity to influenza viruses with pandemic potential that could delay spread or potentially even prevent an influenza virus with pandemic potential from becoming a public health emergency.



The Influenza and Emerging Infectious Diseases Division (IEIDD) seeks innovations in influenza vaccines that could be deployed either before, around the beginning of, or during a PHE that are faster, more easily deployed, and/or more effective than currently available influenza vaccines. Currently there are two open sub-areas of focus for this topic, which may change over time.

Respondents may propose to any of the sub-areas individually or in combination, if appropriate. Sub-areas of focus include:

X.1 Before a PHE Vaccine Innovations

X.1.1 Pandemic Protection on Day 1

Regardless of how much emergency vaccine capacity is established and sustained and how fast pandemic influenza vaccines are developed, manufactured, and deployed, a gap of a few months will always exist between the start of an influenza public health emergency and the start of vaccinations. Developing influenza vaccines that can take advantage of earlier intervention opportunities are needed. IEIDD seeks vaccine products that can be deployed during the interpandemic phase, likely through incorporation into or replacement of seasonal influenza vaccines, to elicit robust and durable immunity and thereby reduce disease severity and/or incidence in advance of the next influenza pandemic. These vaccines would provide improvements for seasonal influenza protection but would critically have the additional benefit of conferring some levels of immunity that would protect against severe disease in the event of a novel influenza pandemic. Such a vaccine may also prime an individual and allow for a single dose of a matched pandemic vaccine to be sufficient for protection in event of the emergence of a new influenza virus.

Solutions of interest include, but are not limited to:

- Incorporation of additional antigens into existing seasonal vaccines ("supra-seasonal" vaccines[1])
- Development of next-generation influenza vaccines that utilize a different strategy than currently licensed seasonal vaccines to elicit protective immune responses against seasonal and pandemic influenza strains ("broadly protective" or "universal" vaccines[2])
- Vaccines that could elicit immunity to a broad range of potentially pandemic strains with a priming dose, such that a subsequent boost with a vaccine matched to the pandemic strain would confer protective immunity.
- Multivalent vaccines that elicit immunity against a wide range of seasonal and potentially pandemic influenza viruses

X.1.2 Transmission-reducing vaccines

A vaccine that reduces transmission, even if it does not fully prevent infection, could reduce the size of influenza outbreaks and slow the rate of viral evolution[3]. Preclinical studies of influenza vaccines in ferrets have demonstrated the ability of vaccines developed against conserved viral proteins to reduce transmission of highly pathogenic influenza strains[4]. Vaccines that reduce transmission of a broad range of influenza strains would fill a critical time gap in the period before a public health emergency and have the potential to prevent or delay a public health emergency until a matched vaccine is available.

X.2 Beginning of a Pandemic Vaccine Innovations:

There are no open topics in this sub-area at this time.

[1] Kanekiyo M and Graham BS. https://perspectivesinmedicine.cshlp.org/content/11/8/a038448.long
[2] Erbelding, EJ et. al. https://academic.oup.com/jid/article/218/3/347/4904047
[3] Arinaminpathy, N. et. al. https://pubmed.ncbi.nlm.nih.gov/19729082/
[4] Price, GE et. al. https://www.pnas.org/doi/10.1073/pnas.1113342109

X.3 During a Pandemic Vaccine Innovations:

X.3.1 Alternative Delivery:

Whether in pandemic or non-pandemic settings, mass immunization campaigns contribute to disease prevention strategies by rapidly increasing rates of vaccine coverage in the population. While administration of vaccines by syringe and needle is commonplace, supply chain disruptions and shortages of ancillary supplies remains a major vulnerability for immunization programs worldwide. Enabling new methods of vaccine delivery may have numerous long-term benefits, including: ease of administration, addressing vaccine hesitancy, reducing the requirement for trained healthcare personnel, and reducing hazardous waste (sharps) from vaccination campaigns. BARDA seeks the development of influenza vaccines with oral, nasal, or inhaled routes of administration. Solutions of interest include, but are not limited to:

- Vaccine delivery strategies that enable self-administration or administration by non-health care personnel
- Vaccine formulations that obviate the need for cold-chain storage
- Vaccine formulations that facilitate improved effectiveness (e.g., protection of immunologically naïve recipients with a single dose of vaccine, enhanced immunogenicity and durability, mucosal delivery).

X.4 Flexible Technology Innovations:

There are no open topics in this sub-area at this time.

Scope of Funding and Selection Criteria

The EZ-BAA is meant to fund gap-filling studies. BARDA seeks to support preclinical and nonclinical studies as well as potency and immune assay development and testing that enables the advancement of vaccines that are responsive to the four sub-aims described above. For X.3.1, formulation optimization and stability studies will also be considered.

To be considered responsive under this AOI, respondents should have a vaccine that are seeking to advance that demonstrates:

- Protection in a lethal influenza virus challenge in an established influenza animal model (.e.g., mice or ferrets)
- Data demonstrating equivalent or superior immune responses (i.e., breadth, durability) to current seasonal vaccines *in vivo* or *in vitro*
- A scalable and reproducible manufacturing process amenable to GMP.

Priority will be given to proposals that:

- Demonstrate protection in animal models for multiple seasonal and pre-pandemic influenza strains
- Provide a detailed Product Development Plan that includes a feasible vaccine commercialization strategy.

The following topics will be considered out of scope and will be found unacceptable.

- Development of monoclonal antibodies or other pharmacologic products (e.g., immunomodulatory agents, stimulators of innate immunity) for disease prevention
- Proposals that exclusively focus on safety/toxicity and/or in vitro work
- Proposals that exclusively propose novel adjuvants without a novel vaccine component

- Involve alternative delivery methods besides oral, inhaled, or intranasal (e.g., patches, intradermal delivery)
- Do not already have data that demonstrates protection in a lethal influenza virus challenge in an established influenza animal model (.e.g., mice or ferrets)
- Do not contain data demonstrating equivalent or superior immune responses (i.e., breadth, durability) to current seasonal vaccines *in vivo* or *in vitro*
- Do not already have in place a scalable and reproducible manufacturing process amenable to GMP

Email Inbox for this effort will be: IEIDD_Vx@hhs.gov

2) Pausing the following research Area of Interest (AOI):

AOI #26: Agnostic Diagnostic

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. 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 #28: Influenza Vaccine Innovation (IEIDD_Vx@hhs.gov)
AOI #26: Agnostic Diagnostic (ngs@hhs.gov)

The closing dates for abstract submissions for these AOIs are listed below.

Area of Interest	Closing Date for Abstract Submissions
#28	12:00pm ET on January 20, 2025
#26	12:00pm ET on September 30, 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 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.