Request for Information (RFI) 24-PRIZE-RFI-001: Strategies to develop a single-dose vaccine for pandemic influenza

Date: July 8, 2024

Agency:
Biomedical Advanced Research and Development Authority (BARDA)
Administration for Strategic Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, S.W., Washington, D.C. 20201

1.0 Description

The Division of Research, Innovation and Ventures (DRIVe) of the Biomedical Advanced Research and Development Authority (BARDA), the Administration for Strategic Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS) is issuing this Request for Information (RFI) to solicit feedback from biopharmaceutical stakeholders and other vaccine development experts. Responses should address strategies to develop a pandemic influenza vaccine that elicits robust and durable immunity following a single dose in humans. Information collected in this RFI may serve as market research that supports the design of a Project NextGen prize competition.

This RFI is not a solicitation, nor does it commit HHS to issue a solicitation, make any award, or pay any costs associated with responding to this RFI. This RFI is issued solely for information-gathering and program-planning purposes and does not constitute a Request for Proposal (RFP) or a promise to issue an RFP. This RFI also does not commit the United States Government to contract for any supply or service whatsoever. Submission is voluntary and is not required to submit to any subsequent opportunities (if any) on this topic. Information collected from this RFI may serve as continued market research for the development of a prize competition in which BARDA would partner with a third-party entity, Luminary Labs LLC ("Luminary Labs"), to strategically address gaps in single-dose pandemic influenza vaccine development. A response to this RFI indicates the respondent's concurrence with the United States Government sharing the submission with Luminary Labs. BARDA will not return or provide feedback on any submissions. However, BARDA will reserve the right for BARDA or Luminary Labs to further engage with respondents to clarify understanding of submitted comments. BARDA and Luminary Labs will treat any response to this RFI as sensitive information and will protect confidentiality accordingly.

2.0 Background

BARDA is tasked with improving preparedness and response through public-private partnerships that advance research and development of medical countermeasures against health security threats.

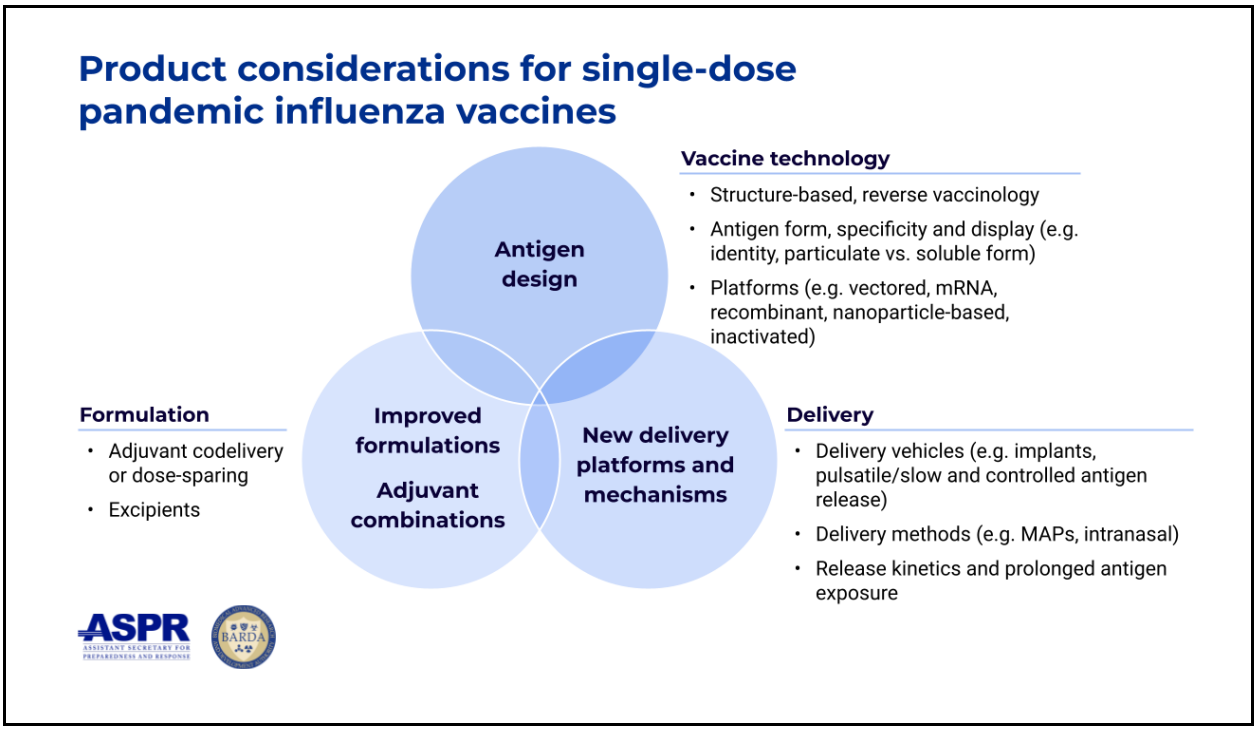
Treatment and prevention of new health security threats requires breakthrough solutions. The mission of DRIVe is to accelerate innovations and improve the availability of transformative technologies and medical countermeasures to protect Americans from health security threats. To that effect, DRIVe is using new funding mechanisms, such as prize competitions, to identify and promote the advanced development of novel strategies against infectious disease threats, including pandemic influenza and SARS-CoV-2.

Through this RFI, DRIVe seeks information on current research efforts in vaccines and vaccination strategies to enhance preparedness against pandemic influenza and other emerging pathogens. In the event of a pandemic caused by a new strain of influenza or another pathogen, achieving protective immunity typically requires two doses of a vaccine, spaced at least 21 days apart, similar to the original COVID-19 vaccination schedule. Reliance on a two-dose immunization regimen as a pandemic response strategy presents several challenges and vulnerabilities. These challenges include logistical issues in vaccine manufacturing, distribution, and administration; delays in achieving widespread immunization coverage; and an increased risk of incomplete immunization. The availability of single-dose vaccine technologies that could be applied against pandemic influenza or other pathogens would significantly simplify vaccination campaigns, reduce the burden on healthcare systems, and help prevent morbidity, mortality, and societal disruption. These technologies may include (1) antigen design, (2) novel or improved formulations (including adjuvants), and (3) novel vaccine-delivery platforms (Figure 1).

The development of single-dose vaccines for pandemic influenza and other pathogens, such as SARS-CoV-2, presents multifaceted challenges across several critical domains. In general, BARDA recognizes several key considerations that limit the development of single-dose vaccine technologies.

Successful navigation of these obstacles demands interdisciplinary collaboration, technological innovation, and strategic planning. Therefore, this RFI seeks information on technologies and strategies to address these challenges with diligence and innovation, aiming to advance the development of a single-dose vaccine for pandemic influenza and other emerging threats.

Figure 1



3.0 Requested Information

Respondents should provide a brief synopsis of the technology or technologies under development that may align with the goal of developing a single-dose vaccine for pandemic influenza (either H5N1 or H7N1). Respondents should also describe the critical barriers they foresee to vaccine development, evaluation, licensure, and manufacturing. Respondents may consider and respond to some or all of the following prompts.

1) What are your organization's opinions and perspectives regarding the feasibility of a single-dose vaccine formulation?

2) How do existing developers, manufacturers, and suppliers perceive the potential of a single-dose vaccine for clinical use?

3) What new or innovative technologies or approaches to product design does your organization see as showing the greatest potential to develop single-dose vaccines?

4) What investments, resources, and manufacturing infrastructure would be necessary to support the development of single-dose vaccines?

5) How would a transition to single-dose pandemic influenza vaccines change clinical pathways, including any potential impacts on vaccine procurement and reimbursement?

6) What specific product and/or device design performance challenges would a single-dose pandemic influenza vaccine have to overcome when compared with the currently available influenza vaccines?

7) What animal models should be used for single-dose pandemic influenza vaccine development?

8) How long do you anticipate the research and development, clinical evaluation, and regulatory approval processes would take to bring a single-dose pandemic influenza vaccine to licensure?

9) If needed, how would your organization access pandemic influenza (H5N1 or H7N1) vaccine for formulation efforts? Is access an issue that may negatively impact your participation?

10) Would your organization participate in a $41 million prize competition that is focused on advancing single-dose formulations using H5N1 or H7N1 as a target pathogen?

4.0 Responses

4.1 Interested parties should respond to this RFI with a written response.

4.2 Written responses should adhere to the following:

- Format must be compatible with either the Microsoft Office software package or word-searchable Adobe Acrobat;
- Font must be no smaller than 10-point size;
- Pages must be numbered;
- Responses must be no longer than 10 pages;
- Responses must be submitted via email only to the individual(s) identified in **Section 5.0 Submission** below.

Respondents **must clearly mark** all copyrighted information, data, and materials with appropriate restrictive legends (e.g., confidential, privileged, proprietary, trade secret). To aid BARDA in protecting your information, please segregate proprietary information.

Please note that non-federal employees performing advisory and assistance services will have access to any submission under this RFI. All non-federal employees are required to sign a non-disclosure agreement prior to accessing the RFI responses.

4.3 The first part of the written response should provide administrative and contact information (contact name, title, email address, phone number) and organizational information of the responder (entity name, entity headquarters, mailing address).

4.4 The second part of the written response should answer the question(s) posed in **Section 3.0 Requested information** of this RFI and must be limited to 10 pages.

5.0 Submission

Please include RFI No. 24-PRIZE-RFI-001 on all correspondence concerning this RFI.

Electronic responses to this RFI are due no later than:

4:59 p.m. EDT on Monday, August 5, 2024

Your electronic response should be submitted to the following individual(s):

DRIVeComments@hhs.gov

All submissions will become BARDA and United States Government property and will not be returned.