Biomedical Advanced Research and Development Authority (BARDA)

Administration for Strategic Preparedness & Response (ASPR)
U.S. Department of Health and Human Services (HHS)

Request for Information (RFI) for

"New Vaccine Platforms"

Issued: 26 November 2025

Responses Due: 1pm EST, 30 January 2026

Biomedical Advanced Research and Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
400 7th Street, SW, Washington, DC 20024

MedicalCountermeasures.gov

"New Vaccine Platforms"

Request for Information (RFI)

Background

The Rapid Response Partnership Vehicle (RRPV) is issuing this Request for Information (RFI) to assist in understanding the landscape of transformative vaccine platform technologies that are safe, broadly effective, and enable efficient development.

For the purposes of this RFI, the term vaccine platform technology refers to a well-understood, reliable technology that is incorporated into or used by an existing vaccine (e.g., ideally licensed vaccine or, at minimum, a candidate with an active IND) and is essential to its structure or function. It can be adapted to multiple candidate vaccines that share key features, enabling standardized methods for developing or manufacturing such vaccines. This streamlines the creation and production of more than one vaccine by using the same core technological process.

The goal of this RFI is to identify and understand the development maturity of vaccine platform technologies that (1) are safe and effective across a broad range of different known infectious disease threats and (2) can enable efficient development timelines in response to emerging infectious disease threats. There is a particular interest in understanding manufacturing capabilities, including demonstrated scale, yields, and development timelines through final drug product release. We are also interested in understanding the platform elements of a vaccine technology that can be leveraged when adapting to a newly emerged threat, including elements of the technology itself, data from prior development efforts, and any regulatory feedback on such elements.

Technology areas of interest

- Includes (non-exhaustive list):
    - Vaccine platform technologies (inclusive of expression system and formulation)
    - Expression systems / manufacturing platforms
    - Formulation / adjuvant technologies
- Excludes
    - Nucleic acid-based vaccine platforms
    - Technologies where the platform element is focused solely on delivery devices or physical administration methods

Request for Information

The objective of this RFI is to solicit feedback from industry, academia, and other stakeholders to assist BARDA in identifying, and understand the development maturity of, vaccine platform technologies that (1) are safe and effective across a broad range of different known infectious disease threats and (2) can enable efficient development timelines in response to emerging infectious disease threats.

Respondents do not have to be a member of the RRPV consortium to submit a response for this RFI; however, they must be a member of the consortium to respond to any future request for project proposals (RPP) for this requirement.

Please submit responses by email to rrpv@ati.org no later than

1pm EST January 30th, 2026.

Late responses will not be considered.

This RFI is for information gathering purposes only. It does not constitute a Request for Project Proposal (RPP) nor does it imply any obligation to issue a future solicitation, make any award, or pay any costs associated with responding to this RFI. Submission is voluntary and does not commit the responder to respond to any subsequent opportunities (if any) related to this topic. The RRPV will not return or provide feedback on any submissions, however, BARDA reserves the right to further engage with respondents in a Market Research Call to clarify understanding of submitted information. All responses to this RFI will be treated as sensitive information and confidentiality will be protected accordingly.

Requested Information:

Respondents are invited to provide a concise response addressing the following topics:

1. **Organizational Overview**
   - Brief description of your organization/team, core expertise, and primary focus areas
   - Summary of prior experience with vaccine development
   - Brief description of partner Contract Development and Manufacturing Organization (CDMO(s)) (if applicable), including name and location where manufacturing occurs
   - Indicate willingness to partner with other organizations to deliver an end-to-end vaccine platform solution (e.g., an expression system/manufacturing platform developer partnering with a formulation/adjuvant developer, or vice versa).

2. **Platform Technology**
   - Clear description of your proposed technical solution, including the type of vaccine platform (e.g., recombinant protein; etc.). Provide details for both the expression system and/or the formulation/adjuvant technology as applicable.
   - Projected timeline, and supporting rationale, for your platform technology to respond to a newly emerged threat, including FDA submissions and start of any clinical trial(s) (i.e., anticipated timeline from receipt of antigen sequence to platform deployment).
   - Provide a summary of candidates and licensed products that use your vaccine platform technology. Please use the provided table format in your response.
     - Development stage column. Entry should note
       - Development stage (e.g., Phase 1; Phase 2; etc.)
       - Associated regulatory status, e.g.,: IND filed; IND accepted; trial ongoing; trial completed; BLA filed; BLA accepted; FDA approved.
     - Dose regimen. Entry should indicate number of doses in the full vaccine regimen and administration timing. A vaccine platform that requires only 1-2 doses to achieve protection from disease is strongly preferred.

Disease target	Product name	Antigen target(s)	Formulation / adjuvant / carrier	Admin-istration Route	Dose Regimen	Development Stage	IND / BLA with US FDA?
Example disease target A	ABC	G, N	Oil-in-water squalene emulsion	IM	2-dose; D0 & D28	Ph2 IND accepted	Yes

3. **Platform Manufacturing**
   - Describe manufacturing details for both drug substance (DS) and final drug product (FDP):
     - Expression system details
     - Formulation/adjuvant manufacturing process
     - cGMP status
     - **Demonstrated** (i.e., known) DS scale, yield, and throughput.
     - End-to-end **demonstrated** (i.e., known) development timeline at your current yield and scale, including the timeline from:
       - Run start to DS produced (prior to release)
       - DS produced to DS released
       - DS produced to fill/finish completed
       - Fill/finish completed to FDP release
   - List assays and describe their current development status. Indicate whether each assay can be readily applied to a new target or candidate with minimal or no modification (i.e., platform-specific) or if it is candidate-specific and would require moderate to significant adaptation for a new target.
   - Responders may include projected or hypothetical yield, scale, and timelines with planned manufacturing process improvements. Clearly label this information as projected and present it separately from demonstrated (i.e., verified) manufacturing details requested above.

4. **Platform Nonclinical and Clinical Data**
   - Summarize nonclinical data for your platform technology, including but not limited to: safety data (toxicology; biodistribution; developmental/repro tox; etc.); immunogenicity; efficacy. Include nonclinical model used.
   - Summarize clinical data for your platform technology, including but not limited to: safety; immunogenicity; and efficacy. Include relevant clinical trial details (e.g., phase; study type; study population; etc.); database entry reference (e.g., NCT identifier for clinicaltrials.gov).

5. **Platform Regulatory Feedback**
   - Describe any FDA feedback on any platform elements, studies, etc. that support the utility of your technology as a platform. For example, but not limited to, FDA feedback/acceptance of leveraging nonclinical toxicology study from one candidate for a different candidate or platform technology designation.
   - Describe whether FDA has accepted the use of any special programs for any product using your platform. Examples include Fast Track, Breakthrough Status, rolling review, accelerated

approval, animal rule, etc.

Responses

Interested parties should respond to this RFI with a written response consisting of a cover page and a technical response (PDF; no smaller than 10-point font). The cover page should provide administrative and contact Information (contact name, title, email address, phone number) and organizational information of the responder (entity name, headquarters, mailing address). The technical response should be no longer than 10 pages, including a 1-page executive summary.

- Executive Summary (≤1 page)
- Organizational Overview (≤1 page)
- Platform technology (≤2 pages)
- Platform manufacturing (≤4 pages)
- Platform nonclinical and clinical summary (≤1 pages)
- Platform regulatory feedback (≤1 page)

Add references as necessary but be sure to include all relevant information in the response. Cited publications or attachments may not be read.

Respondents must clearly mark all copyrighted information, data, and materials with appropriate restrictive legends (e.g., confidential, privileged, proprietary, trade secret). To aid in protecting your information, please segregate proprietary information. DO NOT SUBMIT ANY CLASSIFIED 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 nondisclosure agreement prior to accessing the RFI responses.