Center for the 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 for

"Protection Before Day One Vaccine: Advancing Broadly Protective Seasonal Influenza Vaccines with Pandemic Coverage"

Issued: June 3, 2026

Responses Due: 1pm EDT, July 15, 2026

Center for the Biomedical Advanced Research and Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
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MedicalCountermeasures.gov

"Protection Before Day One Vaccine: Seasonal Influenza Vaccines with Pandemic Coverage"

Request for Information (RFI)

1.0 Background

Influenza viruses remain a persistent and evolving threat to public health in the United States and globally. Seasonal influenza epidemics cause significant morbidity and mortality each year, while novel zoonotic influenza subtypes retain the potential to trigger pandemics. A critical vulnerability in current pandemic preparedness is the time required—typically at least three months—between identification of a novel pandemic strain and deployment of strain-matched vaccines at scale.

The Center for the Biomedical Advanced Research and Development Authority (BARDA) has led efforts to develop improved influenza vaccines and expand domestic manufacturing capacity, including initiatives to accelerate vaccine development timelines. However, limitations in current vaccine technologies result in a protection gap during the earliest phase of a pandemic.

In a pandemic setting, early intervention is crucial to dampening the spread and impact of a novel virus. Prior modeling studies have demonstrated that a modestly effective but rapidly distributed vaccine can provide a greater benefit than a highly efficacious but delayed vaccine. Similarly, bolstering population immunity before a pandemic would lessen the damage caused by emergent influenza strains, even if the vaccine is only partially protective. BARDA refers to these vaccines as offering "Protection Before Day One", with "Day One vaccines" providing some degree of protection at the outset of a pandemic. Day One vaccines, would:

1. Deliver seasonal influenza protection; and
2. Provide partial protection against emerging pandemic influenza viruses at the onset of a Public Health Emergency.

Modeling suggests that Day One vaccines can not only reduce the total number of infections and peak infection rate but also delay the peak to allow more time for strain-matched pandemic vaccines to become available. In addition to the population-level benefits, Day One vaccines would also benefit individual vaccine recipients by reducing the risk of severe disease. Even with modest effectiveness, receiving a Day One vaccine could reduce an individual's hospitalization risk by 35%.

Through this RFI, BARDA seeks to understand the availability of candidate Day One vaccines, including their development maturity, technical feasibility, manufacturing readiness, and regulatory considerations associated with vaccine candidates intended to meet this dual-benefit profile.

2.0 Purpose

The objective of this RFI is to solicit feedback from industry, academia, and other stakeholders to assist BARDA in identifying and understanding the development maturity of Day One influenza vaccine candidates and associated enabling technologies.

This RFI seeks information on vaccine candidates and enabling approaches intended to function as Day One influenza vaccines, defined as:

- Potential to be routinely administered as a seasonal influenza vaccine
- Demonstrating non-inferior or improved seasonal protection compared to currently licensed seasonal vaccines
- Providing inferred or demonstrated cross-protection against one or more potential pandemic influenza subtypes; e.g., H2, H5, H7, H9.

2.1 Technology Areas of Interest (Non-Exhaustive)

- Broadly protective vaccine designs (e.g., conserved HA stem, NA-focused, NP/M1, M2e, mosaic or multivalent constructs)
- T-cell–based or multi-antigen approaches
- Adjuvants that enhance breadth and durability
- Mucosal or alternative delivery strategies that may reduce transmission
- Combination strategies incorporating broadly protective components into licensed seasonal vaccines
- Novel correlates of protection and immune-bridging strategies
- Enabling preclinical models or controlled human infection models supporting breadth of protection claims
- Can support regulatory pathways for dual seasonal-pandemic benefit
- Co-formulated vaccine strategies

Technology platform is not prescriptive; outcomes are prioritized over mechanism.

2.2 Out of Scope

- Pandemic-only strain-matched vaccines
- Technologies focused solely on delivery devices without immunologic innovation
- Products lacking a credible seasonal deployment strategy

3.0 Request for Information

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 visit RRPV.org to learn more about the RRPV consortium and how to apply to become a member.

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

1pm EDT July 15th, 2026

Late responses will not be considered.

This RFI is for information gathering purposes only. It does not constitute a 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 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.

At the discretion of the U.S. Government (USG), selected companies may be invited to attend a one-on-one meeting in conjunction with the RRPV Annual General Membership Meeting, to be held on August 26–27, 2026 in Arlington, Va.

4.0 Requested Information:

4.1 Technical Questions:

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

1. **Organizational Overview**
   - Brief description of organization/team, core expertise, and influenza vaccine development experience
   - Summary of prior experience with vaccine development
   - Brief description of partner Contract Development and Manufacturing Organization (CDMO(s)) (if applicable), including manufacturing location(s)
   - (If applicable) A plan to partner for end-to-end development (e.g., vaccine developer + adjuvant partner + manufacturer)

2. **Vaccine Candidate Overview**
   - Clear description of the vaccine construct (antigen targets, platform, adjuvant, formulation).
   - Intended seasonal deployment strategy (stand-alone or adjunct to licensed vaccine)
   - Proposed mechanism of protection (e.g., stem neutralization, NA inhibition, T-cell–mediated protection)
   - Proposed correlate(s) of protection and supporting rationale
   - Describe how your candidate aligns with the following attributes:

Desired attributes of a Day One Vaccine (Target Product Profile)		
Attribute	**Minimal**	**Ideal**
Indication and usage	Indicated for prevention of seasonal influenza and inferred protection against pandemic influenza	
Public health impact	Reduces infection by at least 10% and/or hospitalization by at least 30% during the first wave of a pandemic	Eliminates the risk of pandemic influenza
Target population	Adults, including tier 1 risk	All individuals ages 6 months and older
Safety and reactogenicity	No Adverse Events of Special Interest (AESI), Serious Adverse Event (SAEs), or long-term Adverse events (AEs) identified from clinical trials	Similar to current seasonal vaccine

	Minimal increase in reactogenicity may be acceptable	
Preclinical data	Evidence in relevant animal model(s) of protection against pandemic viruses and equivalent seasonal protection	Evidence in relevant animal model(s) of protection against pandemic viruses and superior seasonal protection
Clinical efficacy	Not inferior to seasonal vaccine	Superior to seasonal vaccine
Clinical immunogenicity	Demonstration of immune responses against multiple, antigenically distinct influenza viruses	Establishes a biosignature that is reasonably predictive against viruses with pandemic potential
Breadth of protection	Covers one or more of highest priority avian viruses (e.g., H2, H5, H7, and H9), in addition to seasonal viruses	Covers all known influenza A subtypes, in addition to all seasonal influenza viruses
Duration of protection	6 months to 1 year, administered annually	Multiyear coverage, administered intermittently
Storage/handling	Stable at -20°C	Stable at 4°C or room temperature
Sustainability and commercial viability	Capable of competing in seasonal vaccine market Manufacturing can support commercialization and rapid expansion	

- Projected Pandemic Response Utility
    - Describe how your candidate would provide Day One protection in a pandemic.
    - Provide modeling assumptions or data supporting expected impact.
    - Describe whether vaccine is intended to prime for rapid boost with strain-matched vaccine.
- Development Status Table
    - Entry should note development stage (e.g., Preclinical, CMC-ready, Phase 1; Phase 2; etc.) and associated regulatory status, e.g.: IND filed; IND accepted; trial ongoing; trial completed; BLA filed; BLA accepted; FDA approved.

Product name(s)	Antigen target(s)	Formulation / adjuvant / carrier	Administration Route	Dose Regimen	Development Stage	IND / BLA with US FDA?

- Projected development timeline and supporting rationale, including (if applicable) FDA submissions and start of any clinical trial(s)
    - Indicate the next anticipated area of development that will be targeted (e.g., generation of additional preclinical data; CMC; initiation of a clinical trial)

3. Nonclinical Data

Summarize available and planned data addressing:

A. Product Characterization

- Target identity and structural validation

B. Immunogenicity and Breadth

- Animal model(s) used
- Breadth panel (including pre-pandemic strains)
- Immune assays (neutralization, NI, ADCC, T-cell assays, etc.)
- Durability timepoints

C. Heterologous Challenge Data

- Animal model(s) used
- Reduction in viral load and/or severe disease
- Comparator arms (seasonal vaccine vs placebo)

D. Safety/Toxicology

- GLP tox status
- Reactogenicity
- Adjuvant-specific package (if applicable)
- Biodistribution (if applicable)

4. Manufacturing and CMC Readiness

A. Manufacturing Process

Describe manufacturing details for both drug substance (DS) and final drug product (FDP):

- Expression system details
- Formulation/adjuvant manufacturing process
- Process flow diagram with in-process controls
- Seed lot / cell substrate characterization
- Viral safety strategy
- cGMP status
- Demonstrated (i.e., known) DS scale, yield, and throughput.
- End-to-end demonstrated (i.e., known) manufacturing timeline at the 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

B. Release and Testing

- Identity
- Purity/impurities
- Potency assay status
- Sterility/endotoxin
- Stability data (real-time and accelerated)

C. Product characteristics

Parameter	***Value***	***Other Information***
Product concentration(s)		
Product form	(liquid, lyo)	
Container	(vial type/size/syringe)	
Closure	(elastomeric stopper, seal)	
Administration volume/dose		

Fill volume	(single or multi-dose)	
Storage temperature		
Shelf-life/expiry dating		
Excipients	(adjuvant type/concentration)	
Administration route/device		
Dose Prep	(single/multiple vials, diluent required, adjuvant/mixing)	

Changes from a typical or established process and characteristics of a seasonal influenza vaccine should be highlighted (e.g., different form, administration, preparation).

D. Scale and Commercial Feasibility

- Demonstrated manufacturing scale
- Estimated annual dose capacity
- Time from lot start to release
- Ability to support seasonal commercialization
- List assays and describe their current development status.
- Responders may include projected or hypothetical yield, scale, and timelines with planned manufacturing process improvements. Responses should clearly distinguish demonstrated capabilities from projected improvements.

5. Clinical Data and Planned Development Strategy

- Summarize any available clinical data for your candidate vaccine, 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).
- Summarize planned clinical trial designs for the proposed pathway for inferring pandemic benefit
    - **Trial Design**
        - Population
        - Safety endpoints
        - Immunogenicity battery (seasonal + breadth panel)
        - Durability timepoints
    - **Seasonal Non-Inferiority / Superiority Strategy**
        - Comparator
        - Proposed endpoints
        - Development pathway (non-inferiority → post-licensure superiority vs pre-licensure superiority)
    - **Co-administration or Incorporation Strategy**
        - Plan for co-administration with licensed seasonal vaccine (if applicable) including CMC aspects- specifically, the feasibility of co-formulation with current seasonal vaccines.

6. Regulatory Considerations

- Describe the proposed pathway for inferring pandemic benefit
- Plans for establishing correlate of protection
- Regulatory interactions to date
- Special program eligibility (Fast Track, Breakthrough, etc.)

4.2 General Questions:

7. Does your organization prefer an Other Transaction Agreement (OTA) over a traditional Federal Acquisition Regulation (FAR) contract for this effort? Please explain.

8. Does your organization provide this service competitively in substantial quantities in the common marketplace based on established catalog or market prices for specific tasks performed or specific outcomes to be achieved and under commercial terms and conditions?

9. Is your organization an "Other than Small Business" under NAICS 541714?

10. When the solicitation opens, how many days will your organization require to provide a thorough response?

11. Would a requirement to join the RRPV consortium prevent your organization from competing for this requirement?

12. BARDA may, at its discretion, invite RFI respondents to a 1:1 session either in-person at the 2026 RRPV General Membership Meeting taking place Aug 26-27 at the Hyatt Regency Crystal City in Arlington, VA or virtually as time allows. Is your organization interested in participating in a 1:1 meeting with BARDA? If so, in-person or virtually?

5.0 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)
- Vaccine Candidate Overview (≤2 pages)
- Nonclinical Data (≤2 pages)
- Manufacturing and CMC Readiness (≤2 pages)
- Clinical Data and Planned Development Strategy (≤1 page)
- Regulatory Considerations (≤1 page)

BARDA is seeking information on the type of product development work for which respondents would seek funding (e.g., preclinical, CMC, and/or Phase 1). Respondents may propose work across one or multiple categories and should clearly specify all applicable categories explicitly rather than relying on it to be inferred from other details. If feasibility data is not yet available for any of the proposed categories, respondents should still provide a detailed plan outlining how they intend to generate such data.

Add references as necessary but please 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 non-disclosure agreement prior to accessing the RFI responses.

DISCLAIMER: THE GOVERNMENT DOES NOT INTEND TO AWARD A CONTRACT ON THE BASIS OF THIS RFI OR OTHERWISE PAY FOR INFORMATION RECEIVED IN ANY RESPONSE TO THIS RFI.

(End of Request for Information)