

**Center for the Biomedical Advanced Research and Development
Authority (BARDA)**

Rapid Response Partnership Vehicle (RRPV)



Draft Request for Project Proposals (RPP)

Solicitation Number: RRPV 26-08-PBD1

“Protection Before Day One”

Draft Issue Date: 30 September 2026

Center for the Biomedical Advanced Research and Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
400 7th Street, SW, Washington, DC 20024
[MedicalCountermeasures.gov](https://www.mediccountermeasures.gov)



1. Executive Summary

1.1 Rapid Response Partnership Vehicle Consortium

The Rapid Response Partnership Vehicle (RRPV) Consortium is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Center for the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services (HHS).

The RRPV will help fortify national health security by developing medical countermeasure products prior to and during a pandemic or public health emergency. The RRPV will focus on the acceleration of products and technology development, regulatory approval, commercialization, and sustainment to address pandemic influenza, emerging infectious diseases, and other biological threats.

Advanced Technology International (ATI) has been awarded an Other Transaction Agreement (OTA) by BARDA to serve as the Consortium Management Firm (CMF) for the RRPV.

RRPV is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from all organizations who work within stated technical focus areas. For more information on the RRPV mission, refer to the RRPV website at [RRPV.org](http://www.rrpv.org). For entities interested in joining the RRPV Consortium and responding to this solicitation, please visit <http://www.rrpv.org/how-to-join>.

1.2 Draft Solicitation Notice

BARDA, through the RRPV Consortium, is issuing this draft RPP to provide advance information regarding a potential future RPP for the effort described herein. The purpose of this notice is to improve industry awareness, support teaming and planning, and provide preliminary insight into the anticipated scope and acquisition approach before release of a formal RPP.

1.3 Background

Influenza viruses remain a persistent and evolving threat to public health in the United States and globally. Seasonal influenza causes substantial morbidity and mortality each year, while novel zoonotic influenza viruses retain the potential to cause 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.

BARDA has invested in improved influenza vaccines, advanced vaccine technologies, and domestic manufacturing capacity to strengthen pandemic preparedness and accelerate vaccine availability. Despite these advances, current approaches leave a critical protection gap during the earliest phase of a pandemic, when a strain-matched vaccine may not yet be available.

To address this gap, BARDA is advancing the Protection Before Day One initiative, focused on broadly protective influenza vaccines that could be routinely administered for seasonal influenza while also providing meaningful cross-protection against influenza viruses with pandemic potential. Protection Before Day One vaccines are intended to:

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

Modeling indicates that even partially effective protection available at the outset of a pandemic could reduce infections, decrease peak disease burden, and delay the epidemic peak, providing additional time

for development and deployment of strain-matched pandemic vaccines. Before Day One vaccines may also provide direct individual benefit by reducing the risk of severe disease and hospitalization.

Through this RPP, BARDA intends to advance promising Before Day One vaccine candidates from preclinical development through manufacturing and clinical evaluation, with emphasis on demonstrating breadth of protection, establishing IND readiness, developing scalable manufacturing processes, and generating clinical evidence supporting seasonal performance and potential pandemic benefit. The ultimate objective is to establish a sustainable seasonal vaccination capability that provides population-level protection before a pandemic begins, complementing subsequent deployment of strain-matched pandemic vaccines.

1.4 Purpose

The purpose of this RPP is to solicit proposals for the development and advancement of Before Day One influenza vaccine candidates. BARDA seeks to advance broadly protective influenza vaccines capable of providing routine seasonal protection while also providing meaningful cross-protection against influenza viruses with pandemic potential.

Proposed Before Day One vaccine candidates shall demonstrate, or provide a credible development pathway toward, the following characteristics:

- Capability for routine administration as a seasonal influenza vaccine;
- Non-inferior or improved seasonal protection compared with currently licensed seasonal influenza vaccines; and
- Inferred or demonstrated cross-protection against one or more influenza subtypes with pandemic potential, including, but not limited to, H2, H5, H7, H9 and H10.

Desired attributes of a Before 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	Provides background immunity reasonably likely to provide significant protection during the first wave of a pandemic	Provides background immunity that mitigates the risk of pandemic influenza
Target population	Adults, including tier 1* risk	All individuals ages 6 months and older
Safety and reactogenicity	Reactogenicity and related adverse events would not limit the use of the product. Minimal increase in reactogenicity may be acceptable	Similar to current FDA-licensed seasonal influenza vaccines
Preclinical data	Evidence in relevant animal model(s) of protection against pandemic viruses and equivalent seasonal protection compared with FDA-licensed seasonal influenza vaccines	Evidence in relevant animal model(s) of protection against pandemic viruses and superior seasonal protection

Clinical efficacy	Not inferior to FDA-licensed seasonal vaccine	Superior to FDA-licensed seasonal vaccine
Clinical immunogenicity	Establishes a biomarker/s 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, H9 and H10), 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	
*Tier 1 are critical healthcare and public health personnel, emergency medical services (EMS) and deployed and mission critical personnel.		

The Government intends to support candidates through defined stages of product development, including late-stage preclinical/nonclinical studies, IND-enabling activities, CMC and manufacturing development, and clinical evaluation, as applicable to the maturity of the proposed candidate.

1.3.1 Technology Areas of Interest

BARDA is interested in vaccine candidates and approaches capable of achieving the Protection Before Day One objectives. Technology areas may include, but are not limited to:

- Broadly protective vaccine designs targeting conserved influenza antigens or epitopes, including HA stem, NA, NP/M1, M2e, mosaic, or multivalent constructs; T-cell-based and multi-antigen vaccine approaches;
- Adjuvanted approaches designed to enhance breadth and/or durability of protection;
- Mucosal or alternative administration strategies with the potential to enhance protection and/or reduce transmission;
- Approaches incorporating broadly protective components into seasonal influenza vaccines;
- Co-formulated vaccine strategies;
- Novel correlates of protection, biomarkers, and immune-bridging strategies supporting assessment of pandemic benefit;
- Preclinical models or controlled human infection models capable of supporting assessment of breadth and cross-protection; and
- Vaccine approaches capable of supporting a regulatory pathway for both seasonal influenza protection and inferred or demonstrated pandemic benefit.

BARDA is not prescribing a specific vaccine platform or technological approach. Proposals will be evaluated based on their ability to achieve the required Protection Before Day One outcomes, scientific and technical merit, development maturity, manufacturing feasibility, and potential pathway toward regulatory approval and sustainable seasonal deployment.

1.3.2 Commercial Viability and Partnering

Offerors shall describe their strategy for transitioning the proposed vaccine from BARDA-supported development to sustainable commercial production and seasonal market deployment. Where the Offeror may not possess all capabilities required for development, manufacturing, licensure, or commercialization, the Offeror should identify existing or planned partnerships to address those gaps.

The proposed strategy should address, as applicable, manufacturing scale and capacity, cost considerations, integration into seasonal influenza vaccination programs, regulatory responsibilities, commercial manufacturing and distribution, and the roles of key partners. Preference may be given to approaches that demonstrate a credible path toward reducing long-term dependence on Government funding through successful integration into the commercial seasonal influenza vaccine market.

1.3.3 Out of Scope

The following approaches are outside the scope of this RPP and will not be considered for award:

- Pandemic-only, strain-matched influenza vaccines that do not provide a credible seasonal benefit;
- Heterologous prime-boost approaches
- Nucleic acid vaccine platforms
- Technologies focused solely on vaccine delivery devices without associated immunologic or vaccine-product innovation; and
- Vaccine candidates that lack a credible pathway for routine seasonal deployment.

Proposals primarily focused on enabling technologies without a defined relationship to the development, evaluation, or regulatory advancement of a Before Day One vaccine candidate is also outside the scope of this RPP.

2. Administrative Overview

2.1 RPP Approach

A multistage approach will be employed to streamline the process for preparation, submission, evaluation, and notification. A down selection will occur between Stage 1 (Abstract) and Stage 2 (full technical and cost proposal by invitation only).

Submission to Stage 1 does not guarantee the opportunity to submit a full technical and cost proposal under Stage 2. Submission of a Stage 2 full technical and cost proposal does not guarantee an award. Each stage of this RPP process is competitive. Offerors will be invited to submit a Stage 2 full technical and cost proposal via email from the RRPV Consortium Management Firm (CMF) following the results of the Stage 1 evaluation. Invitation to negotiations at any stage does not guarantee an award. Submissions that are not selected to proceed beyond Stage 1 or Stage 2, including the basket (see section 5.5/5.6 below) will receive notification, but may not receive feedback on their submission.

The solicitation stages are as follows:

Stage 1 – Abstract. In Stage 1 Offerors will submit an Abstract and quad chart that must follow the required templates and page limits (section 3.5 and Attachment 1). Abstracts that do not meet the mandatory eligibility criteria (section 2.6) will not be evaluated. Offerors invited for a Stage 2 full technical and cost proposal will be provided with feedback, particularly focusing on needed clarifications to be

addressed in the Stage 2 submission. Offerors not invited for Stage 2 will be notified via email but may not receive feedback.

Stage 2 – By invitation only – full technical and cost proposal. Successful Stage 1 Offerors will receive an invitation letter from the CMF to submit a full technical and cost proposal. Required documents for Stage 2 will be noted in the invitation, but are anticipated to include a technical proposal, a cost proposal narrative, a full cost proposal, and statement of work. Further instructions will be provided to successful Stage 1 Offerors in the invitation letter.

2.2 Order of Precedence

Each proposal selected for award under this RPP will be executed as a Project Award under the RRPV Base Agreement 75A50123D00005. The same provisions will govern this Base Agreement as the OTA between the U.S. Government (USG) and ATI (“RRPV Base”) unless otherwise noted in the Project Award.

2.3 Period of Performance and Funding

2.3.1 Period of Performance

The period of performance for Performers should be commensurate with the amount of work proposed. BARDA anticipates the full program Period of Performance, inclusive of the Planned and all Potentials, to be up to 5 years from the date of award. Specific dates will be negotiated prior to award of the project agreement.

2.3.2 Funding

The available funding for this project is approximately \$142 million. The funding estimated for this RPP is approximate and subject to realignment. The USG may apply additional dollars for follow-on efforts with appropriate modifications to an awarded Project Agreement.

The USG anticipates making up to approximately 14 awards.

Funding and estimated number of awards is subject to change and dependent on proposals received, BARDA priorities, and availability of Federal funds for this program.

2.4 Expected Award Date

Offerors should plan on the period of performance beginning August 2027. The government reserves the right to change the notional period of performance start date through negotiations via the RRPV CMF and prior to project award.

2.5 Proprietary Information

The RRPV CMF will oversee submission of abstracts, quad charts, proposals, and other materials submitted in response to this RPP. The RRPV CMF shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than proposal evaluation and agreement administration. Please mark all Confidential or Proprietary Information as such. An Offeror’s submission of a response under this RPP indicates concurrence with the aforementioned CMF responsibilities.

2.6 Mandatory Eligibility Criteria

To be eligible for consideration Offerors must be RRPV members when their Abstract is submitted. Prospective Offerors may join the consortium at www.rrpv.org/how-to-join.

Additionally, to be eligible for consideration under this RPP, the Offeror shall propose a defined Before Day One influenza vaccine candidate and provide supporting data demonstrating technical feasibility and sufficient maturity to execute the proposed Base Period activities. Offerors must meet all minimum eligibility criteria to proceed to technical evaluation.

Before Day One Vaccine Candidate

The Offeror shall propose a defined lead vaccine candidate and provide:

- Vaccine target(s)
- Vaccine platform
- Formulation, adjuvant, and/or carrier, as applicable
- Route of administration including any delivery device required
- Proposed dose and regimen, if established and
- Proposed mechanism of protection
- The candidate shall have a credible pathway for routine seasonal influenza vaccination while providing potential cross-protection against influenza viruses with pandemic potential.

2.6.1. Preclinical/Nonclinical Proof-of-Concept

The Offeror shall provide quantitative preclinical/nonclinical data demonstrating, at a minimum:

- **Seasonal immunogenicity:** Measurable immune responses against relevant seasonal influenza virus(es);
- **Pandemic breadth:** Measurable immune responses against at least one influenza subtype with pandemic potential (e.g., H2, H5, H7, H9 and H10), in addition to seasonal influenza viruses; and
- **Functional immune activity:** At least one functional or mechanistically relevant immune assessment appropriate to the vaccine candidate, such as neutralization, HAI, NI, ADCC, T-cell response, or another scientifically justified assay.

Supporting data shall identify the animal model(s), vaccine dose and regimen, virus/antigen panel, assay methodology, study timepoints, controls/comparators, and quantitative results.

2.6.2. Heterologous Protection and IND-Enabling Readiness

The Offeror shall provide available heterologous nonclinical challenge data demonstrating protection against relevant influenza viruses, including effects on viral load, disease severity, survival, or other scientifically justified endpoints.

Where heterologous challenge and/or IND-enabling studies have not been completed, the Offeror shall provide a detailed plan, schedule, milestones, and success criteria for completing these activities during the Base Period.

- The proposed IND-enabling strategy shall address, as applicable:
 - Heterologous challenge studies;
 - Safety and toxicology;
 - GLP toxicology;
 - Reactogenicity;
 - Adjuvant-specific assessments; and
 - Biodistribution.

2.6.3. CMC and Manufacturing Feasibility

The Offeror shall demonstrate an established or technically feasible manufacturing process for drug substance (DS) and final drug product (DP) capable of supporting continued development of the proposed Before Day One vaccine.

At a minimum, the proposal shall provide:

- DS and DP manufacturing process descriptions;
- Expression or production system, as applicable;
- Current demonstrated manufacturing scale;
- Available yield and throughput data;
- Formulation/adjuvant manufacturing process, as applicable;
- Available process controls and critical process parameters;
- Current cGMP status;
- Current manufacturing timelines, where available; and
- A plan for scale-up and manufacture of clinical trial material.

Offerors should clearly distinguish demonstrated manufacturing capabilities from projected capabilities or proposed process improvements.

2.6.4. Product Characterization and Analytical Readiness

The Offeror shall provide available product characterization data and describe the analytical strategy necessary to support continued development and release of the vaccine candidate.

The analytical strategy shall address, as applicable:

- Identity
- Purity and impurities
- Potency
- Sterility/endotoxin
- Bioburden
- Critical quality attributes and
- Stability

The Offeror shall identify the current status of each assay (e.g., development, qualified, or validated) and provide available real-time and/or accelerated stability data.

2.6.5. Clinical Manufacturing Capability

The Offeror shall demonstrate access to manufacturing capability, either internally or through a CDMO or other qualified partner, with a credible pathway to cGMP manufacture and release of clinical trial material.

The proposal shall identify:

- Manufacturing organization(s) and location(s);
- Current cGMP capability/status;
- Anticipated clinical manufacturing scale;
- Available fill/finish capability; and
- Roles and responsibilities of manufacturing partners.

2.6.6. Development and Regulatory Strategy

The Offeror shall provide an integrated product development and regulatory strategy describing progression from the candidate's current stage through IND submission and clinical development.

The strategy shall address:

- Remaining IND-enabling activities;
- Anticipated FDA interactions and submissions;
- Proposed regulatory pathway for a seasonal vaccine licensure
- proposed regulatory pathway for inferred pandemic benefit or protection; and
- Proposed correlate(s) of protection, biomarkers, immune-bridging strategies, or other scientifically justified approaches to support pandemic protection.

2.6.7. Commercial Viability and Partnering

The Offeror shall demonstrate a credible pathway to seasonal commercialization:

- Identify internal capabilities and key partners needed for clinical development, manufacturing, regulatory approval, and commercialization;
- Describe existing or planned partnerships and provide a strategy to address remaining capability gaps; and
- Demonstrate a credible pathway to scalable manufacturing, seasonal market integration, and sustainable commercial supply.

Candidates with critical capability gaps and no credible strategy to address those gaps will not meet the minimum eligibility requirement.

The Government will give extra considerations to proposals that exceed the minimum requirements by demonstrating broader protection across multiple pandemic-potential influenza subtypes, robust heterologous challenge protection, durable functional immune responses, advanced manufacturing readiness, and a credible pathway toward seasonal commercialization and regulatory support for pandemic benefit.

Proposals found to not meet these minimum eligibility criteria as detailed above may be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offeror(s).

2.7 Teaming Event

To enable teaming, RRPV may host a teaming event open to organizations that meet the minimum eligibility criteria. An online portal will be opened on the RRPV website where organizations can self-declare and provide a brief technology description. Organizations that align with criteria will be invited to participate in the teaming event. Participants do not need to be RRPV members at the time of the teaming event to participate. Additional information and details will be made available on RRPV.org.

2.8 Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). The extent of cost sharing is a consideration in the evaluation of proposals. While cost sharing is not required for early-stage studies, Phase 2b and later-stage studies will require cost sharing, as the Offeror may have a commercially viable product by that stage of development. If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g.,

vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-Performer collaboration.

2.9 Intellectual Property and Data Rights

Intellectual Property (IP) rights for RRPV Project Awards will be defined in the terms of a Project Awardee's Base Agreement. The RRPV CMF reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the Project Awardees during the entire award period.

The Offeror shall comply with the terms and conditions defined in the RRPV Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights as defined in the RRPV Base Agreement unless otherwise specified in Attachment 1, Abstract and Quad Chart, and agreed to by the Government. All proposed data rights are subject to Government review and approval. Rights in technical data agreed to by the Government will be incorporated into the Project Award.

3 Submissions

3.1 Question and Answer Period

Key dates related to this RPP are provided below. Please submit questions to Ms. Kathy Garee (rrpv-contracts@ati.org).

Approximate Date	Event	Method
30 September 2026	Draft RPP Released	RRPV Website
29 October 2026 12pm Eastern	Questions Due	Email to rrpv-contracts@ati.org
3 November 2026 (tentative)	Teaming Event	Zoom or equivalent
10 November 2026 (tentative)	Answers Released	RRPV Website
23 November 2026 (tentative)	Final RPP Released	RRPV Website
14 January 2027 by 1pm ET (tentative)	Abstracts Due	RRPV BDR Portal

*All dates are subject to change

3.2 General Instructions

The formats provided in this RRPV RPP are mandatory and shall reference this RPP number. **At the time of the submission, Offerors must certify on the cover page of their Abstract that, if selected for award, they will abide by the terms and conditions of the latest version of the RRPV Base Agreement.** Offerors may request a current copy of the RRPV Base Agreement terms and conditions by emailing RRPV-contracts@ati.org. Base Agreements are typically not executed until Offeror is selected for award.

Offerors are encouraged to contact the Point of Contact (see Section 6), identified herein up until the submission date/time to clarify requirements.

Abstracts shall reference this RPP number. The Abstract and Quad Chart is mandatory and shall remain valid for 180 days unless otherwise specified by the Offeror in the submission. Offerors are encouraged to contact the RRPV CMF with any questions so that all aspects are clearly understood by both parties.

All eligible Offerors shall submit Abstracts and Quad Chart for evaluation according to the criteria set forth in this RPP. Offerors are advised that only ATI, as the RRPV's CMF, with the approval of the Other Transaction Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

3.3 Abstract and Quad Chart Submission

Abstracts and Quad Charts shall be submitted by the date and time specified on the cover page to the BARDA Digital Resource (BDR) portal website at <https://rrpv.hhs.gov/>. Abstracts received after the date and time specified may not be evaluated.

Offerors will be required to register for a BDR portal account before a response can be submitted. A BDR account can be requested by contacting ATI at RRPV@ati.org. The account request process is simple but may take several days for approval and access. Upon confirmation of a BDR portal account, the Offeror will login using the prescribed two-factor authentication method.

Offerors are strongly encouraged to access the BDR Portal well in advance of the submission due date to verify their ability to log in, confirm account validity, and ensure full access to the submission system. Failure to submit on time for any reason (e.g., due to late registration in BDR portal) will result in the submission not being considered for award. Offerors will be provided an automated confirmation of successful submission.

Do not submit any classified information in the Abstract or Quad Chart submission.

3.4 Preparation Cost

The cost of preparing Abstracts, Quad Charts, and/or Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

3.5 Submission Format

Stage 1 submissions shall consist of a written Abstract of no more than twelve (12) pages, and 1-page Quad Chart, in accordance with the template and formatting instructions in Attachment 1. Submissions exceeding the page limits or not adhering to the prescribed format may be rejected without further review.

4 Technical Requirements

4.1 Introduction

The technical requirements focus on advancing PBD1 candidates through nonclinical development, manufacturing readiness, and early-stage clinical evaluation. Offerors must propose approaches that address the identified technical, regulatory, and manufacturing challenges, and that are capable of progressing through the defined decision gates toward potential seasonal use and pandemic preparedness. The Offeror shall clearly state how it intends to meet and, if possible, exceed the technical

requirements. Mere acknowledgement or restatement of the requirements is not acceptable, unless specifically stated otherwise.

4.2 Scope/Technical Requirements

This effort will support the development of Before Day One influenza vaccines, including activities spanning nonclinical development, manufacturing readiness, and early-stage clinical evaluation. The scope is structured to enable a phased approach, with a defined Planned effort and Potential expansions based on technical progress and program priorities.

4.2.1 Planned – Nonclinical Studies

The planned scope includes nonclinical activities necessary to establish the scientific and technical feasibility of Before Day One vaccine candidates. This includes generation of data to demonstrate breadth of protection across relevant influenza strains and completion of IND-enabling studies to support advancement into clinical development. This will also include feasibility of manufacturing approach and preliminary CMC studies to support the approach.

4.2.2 Potentials:

4.2.2.1 Potential 1 – Manufacturing of Clinical Trial Material

This includes activities required to produce vaccine material suitable for clinical evaluation, including process development and optimization, formulation development, and establishment of analytical methods to support product characterization, quality, and release.

4.2.2.2 Potential 2 – Clinical Trials for Before Day One Vaccine

This includes the design and execution of early-stage clinical studies to evaluate safety, immunogenicity, and breadth of response. Activities may include Phase 1 and Phase 2a clinical trials and controlled human infection studies to support further development and potential regulatory advancement.

4.2.2.3 Potential 3 – Manufacturing Process Enhancements

This will support manufacturing optimization, scale-up, and process improvements to enable advanced clinical development, commercialization, and sustainable seasonal use.

4.2.2.4 Potential 4 – Clinical Trials for Before Day One Vaccine: Phase 2b

Phase 2a/2b studies will evaluate safety, efficacy, dose optimization, immunogenicity, durability, and breadth, with advancement to late-stage development based on demonstrated seasonal performance, inferred pandemic benefit, manufacturing readiness, and FDA alignment toward licensure.

4.3 Performance Objectives

This effort supports the development of Before Day One influenza vaccines, spanning nonclinical development, manufacturing readiness, and early-stage clinical evaluation.

4.3.1 Planned – Nonclinical Studies

The planned scope includes nonclinical activities to establish feasibility and support advancement to clinical development. Key activities include generating data to demonstrate breadth of protection across relevant influenza strains and completing IND-enabling studies.

Decision Gate 1 (End of Planned):

- Advancement to Potential 1 will be based on demonstration of:
 - Evidence of cross-protective immune responses against relevant influenza subtypes
 - Favorable safety profile in nonclinical studies
 - Completion or readiness for IND-enabling studies including GLP-tox studies
 - Feasibility of manufacturing approach and preliminary CMC support

4.3.2 Potentials:**4.3.2.1 Potential 1 – Manufacturing of Clinical Trial Material**

This includes activities required to produce vaccine material for Phase 1 clinical evaluation, including process development and formulation, and development of analytical methods to support product characterization and release.

Decision Gate 2 (Post-Potential 1):

- Advancement to Potential 2 will be based on:
- Successful manufacture of clinical material suitable for a Phase 1 clinical trial
- Acceptable product quality and stability data
- IND submission and/or FDA authorization to proceed with clinical studies
- Demonstrated scalability and manufacturing feasibility

4.3.2.2 Potential 2 – Clinical Trials for Before Day One Vaccine

This includes the design and execution of early-stage clinical studies to evaluate safety, immunogenicity, and breadth of protection, including Phase 1/2a trials and controlled human infection studies.

Decision Gate 3 (Post-Potential 2):

Continuation of advanced development support will be based on:

- Acceptable safety and reactogenicity profile in humans
- Demonstration of immunogenicity, including evidence of breadth across antigenically distinct strains
- Preliminary evidence supporting potential for pandemic protection (e.g., cross-reactive responses and clinical outcome data)
- Alignment with regulatory pathway and commercial viability

4.3.2.3 Potential 3 – Manufacturing Process Enhancements

This will support manufacturing improvements necessary to enable advanced clinical development, commercialization, and sustainable seasonal use. Activities may include process optimization, yield and throughput improvements, formulation and stability enhancements, analytical method optimization and validation, scale-up, technology transfer, and improvements to product presentation, storage, or supply chain requirements.

Decision Gate 4: Advancement will be based on:

- Demonstrated process robustness and reproducibility;
- Improved or acceptable yield, throughput, and cost of goods;
- Adequate product stability and analytical control strategy;
- Demonstrated scalability and readiness to support later-stage clinical development; and

- A credible pathway to commercial-scale seasonal manufacturing.

4.3.2.4 Potential 4 – Clinical Trials for Before Day One Vaccine: Phase 2b

This includes Phase 2b clinical studies designed to further characterize safety, optimize dose and regimen, and evaluate efficacy, immunogenicity, durability, and breadth of protection. Studies should generate evidence supporting seasonal vaccine licensure and the proposed pathway for demonstrating or inferring protection against influenza viruses with pandemic potential.

Decision Gate 5: Advancement to late-stage development will be based on:

- Acceptable safety in the intended population;
- Demonstration of seasonal vaccine performance consistent with the target product profile;
- Clinically meaningful breadth and durability of immune responses;
- Evidence supporting the proposed correlate, biomarker/s or other basis for inferring pandemic benefit;
- Manufacturing readiness for Phase 3 and commercial scale; and
- FDA alignment on the regulatory pathway toward licensure.

Successful completion of the Planned and Potentials is intended to position promising Before Day One vaccine candidates for early to late-stage clinical development, licensure, seasonal commercialization, as appropriate. This milestone-driven approach allows BARDA to allocate resources to the most promising candidates while managing technical, regulatory, manufacturing, and programmatic risk.

Basis for Advancement

Selection for award of the Base Period does not obligate the Government to exercise any option. Advancement to subsequent manufacturing and clinical development options will be contingent upon successful achievement of negotiated technical milestones and Go/No-Go criteria, continued alignment with Protection Before Day One program objectives, availability of funding, and Government determination that continued development is in the Government's best interest.

5 Proposal Selection/Evaluation

5.1 Gain-of-Function Research

In accordance with Executive Order 14292 "Improving the Safety and Security of Biological Research," BARDA does not support gain-of-function research or research involving the manipulation of pathogens that may result in a gain of function.

For purposes of this RPP, gain-of-function research is defined as scientific research on an infectious agent or toxin that has the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility.

Covered research activities include those that could result in significant societal consequences and that seek or achieve one or more of the following outcomes:

- Enhancing the harmful consequences of an agent or toxin
- Disrupting beneficial immunological responses or reducing the effectiveness of immunizations
- Conferring resistance to clinically or agriculturally useful prophylactic or therapeutic interventions, or enabling evasion of detection methodologies
- Increasing the stability, transmissibility, or dissemination potential of an agent or toxin
- Altering the host range or tropism of an agent or toxin

- Enhancing the susceptibility of a human population to an agent or toxin
- Generating or reconstituting an eradicated or extinct agent or toxin

Abstracts and Proposals will be evaluated by BARDA for the appropriate use of strains in proposed studies, in addition to all other evaluation factors. Proposals that include gain-of-function research will be considered unacceptable and will not be eligible for award.

5.2 Compliance Screening

The RRPV CMF will conduct a preliminary screening of submitted Abstracts to ensure compliance with the RPP requirements. As part of the preliminary screening process, submissions that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the RRPV CMF. The Government reserves the right to request additional information, perform a pre-award audit, or eliminate from further consideration Abstracts that do not meet these requirements.

5.3 Evaluation Process

Following the preliminary screening, the Government sponsor will perform source selection using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified Proposals.

Qualified Proposals will be evaluated by a panel of subject matter experts (SMEs) who will make recommendations to a Source Selection Authority.

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP. An Offeror's submission of an Abstract and/or Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

5.4 Evaluation Factors

Evaluation of Stage 1 Abstracts and Stage 2 Proposals will be based on an independent, comprehensive review and assessment of the work proposed. The Government will evaluate each Abstract and Proposal against the evaluation factors detailed below and assign one of the following adjectival ratings in order to determine the best value to the Government.

- Outstanding
- Good
- Acceptable
- Marginal
- Unacceptable

Stage 1 Abstract and Stage 2 Proposal evaluation factors are as follows:

Evaluation Factor 1 - Technical Approach: This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach and the feasibility of proposed schedule.

5.4.1 Technical Evaluation Criteria

The Government will evaluate proposals based on the quality, strength, maturity, feasibility, and relevance of the proposed approach and supporting data.

The Government will evaluate:

- Scientific rationale and mechanism of protection;
- Magnitude and breadth of immune responses;
- Coverage of seasonal and pandemic-potential influenza viruses;

5.4.2 Nonclinical Proof-of-Concept

The Government will evaluate:

- Quality and relevance of animal models;
- Strength of immunogenicity and breadth data;
- Number and antigenic diversity of pandemic-potential subtypes evaluated;
- Functional immune responses;
- Durability of immune responses;
- Strength of evidence supporting both seasonal and pandemic protection.
- Heterologous challenge data;
- Reduction in viral load, disease severity, mortality, or other relevant outcomes;
- Appropriateness of controls and seasonal vaccine comparators;
- Available safety/toxicology data; and
- Readiness to complete IND-enabling development.

Greater consideration will be given to candidates demonstrating breadth against multiple influenza subtypes with pandemic potential and providing quantitative functional immune data.

5.4.3 CMC and Manufacturing Readiness

The Government will evaluate:

- Maturity and robustness of DS and FDP manufacturing processes;
- Demonstrated scale, yield, throughput, and reproducibility;
- Formulation and stability;
- Analytical and potency assay maturity;
- cGMP manufacturing readiness;
- Scale-up and technology-transfer feasibility; and
- Ability to support clinical development and future seasonal commercialization.

Greater consideration will be given to demonstrated manufacturing capabilities supported by data rather than projected or hypothetical capabilities.

5.4.4 Development and Regulatory Strategy

The Government will evaluate:

- Feasibility of the IND-enabling and clinical development strategy;
- Appropriateness of milestones and Go/No-Go decision criteria;
- Regulatory maturity and prior FDA interactions;
- Proposed pathway for demonstrating seasonal vaccine performance;
- Proposed pathway for demonstrating or inferring pandemic benefit; and
- Strategy for establishing correlates of protection, biomarkers, or immune-bridging approaches.

5.4.5 Team and Execution Capability

The Government will evaluate:

- Influenza vaccine development experience;
- Qualifications and experience of key personnel;
- Nonclinical, CMC, manufacturing, clinical, and regulatory capabilities;
- Capabilities of proposed CDMOs and development partners;
- Ability to execute within the proposed schedule; and
- Technical and programmatic risk-management strategy.

5.4.6 Commercial Sustainability

The Government will evaluate:

- Credibility of the seasonal deployment and commercialization strategy;
- Ability to integrate into the seasonal influenza vaccine market;
- Manufacturing scalability and projected annual dose capacity;
- Storage, handling, distribution, and supply-chain considerations; and
- Potential for sustainable commercial production.

Evaluation Factor 2 – Relevant Experience: This factor evaluates the offeror's demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems.

Evaluation Factor 3 – Cost Reasonableness: Assessment of the cost of the project to determine i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed.

5.4 Cost/Price Evaluation

Successful Stage 1 Offerors will be invited to submit full proposals. If a proposal is selected for award, the RRPV CMF will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP. Evaluation will include analysis of the proposed cost together with all supporting information. The RRPV CMF will request additional information or clarification as necessary. The RRPV CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the project value is fair and reasonable, subject to final Government negotiations.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

a) Realism. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each phase of the proposed project when compared to the total proposed cost.

The RRPV CMF will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down in the Cost Proposal Format. An optional template is located on the Members-Only RRPV website.

c) Completeness. The RRPV CMF will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The RRPV CMF will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The RRPV CMF will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal may not be selected for award.

5.5 Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Funding recommendations depend on various factors and programmatic relevance. Based on the evaluation of the Technical Approach, Relevant Experience, and Cost/Price, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offerors will have the opportunity to concur with the requested changes, propose further changes and revise cost proposals, as necessary.

5.6 Evaluation Results

Following the evaluation of the Stage 2 proposals, the Source Selection Authority may:

1. Select the proposal (or some portion of the proposal) for award;
2. Place the proposal in the Basket if funding currently is unavailable; or
3. Reject the proposal (will not be considered for award and will not be placed in the Basket)

The Government does not guarantee a minimum or maximum number of awards resulting from this solicitation.

5.7 Basket Provision

The electronic “Basket” is an innovative acquisition tool. Stage 2 Full Technical and Cost Proposals rated as Acceptable through Outstanding, but not immediately selected for award, may be placed in the Basket for 2 years following the close of the RPP and eligible for award during that time. Proposals rated as below Acceptable will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal best meets its needs.

6 Points of Contact

Questions related to this RPP should be directed to Ms. Kathy Garee (rrpv-contracts@ati.org).

All technical questions must be submitted by 12pm ET on 29 October 2026, to allow for Government response. The Government will respond to questions at its discretion. All questions and responses will be posted to the RRPV Solicitation webpage <https://www.rrpv.org/opportunities/>. Questions received after the stated deadline are not guaranteed a response.

Once an Offeror has submitted a submission under this RPP, the Government and the RRPV CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

ATTACHMENT 1 – ABSTRACT TEMPLATE

General Instructions

The Abstract must address the technical requirements described in the RPP in sufficient detail to permit evaluation from a technical perspective in accordance with the evaluation factors set forth in the RPP. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc.

The Abstract shall be limited to 12 pages and Quad Chart limited to 1 page; however, the Cover Page and the Data Rights Assertions are not included in the page count. Pages in excess of this limitation may not be considered. Offerors are advised that the number of pages should be commensurate with the degree of complexity of the proposed effort.

The following formatting requirements apply:

- 12-point font (or larger), single-spaced, single-sided, 8.5 by 11 inches
- Smaller type may be used in figures and tables, but must be 8-point font (or larger)
- Margins on all sides (top, bottom, left, and right) should be at least 1-inch
- Submit files in Microsoft Word, Adobe Acrobat (PDF – portable and searchable document format) formats. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension (.docx.pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters. Movie and sound file attachments or other additional files, will not be accepted.

To ensure Abstracts receive proper consideration, **the format shown below is mandatory**. If there are any items which are not applicable to a specific Abstract, include the section topic in the Abstract with a short explanation as to why it is not applicable.

- Cover page (not included in page count)
- Executive Summary
- Technical approach overview
- Teaming/subcontractors
- Facilities and personnel qualification
- Budget estimation
- Period of Performance/Schedule
- Data Rights Assertions (not included in page count)
- Quad Chart (not included in page count, 1-page limit)

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

Unique Entity Identifier (UEI) #: [UEI #]
CAGE code: [CAGE code]

RRPV 26-08-PBD1

[Title of Abstract]

[Offeror] certifies that, if selected for selected for an Award, the Offeror will abide by the terms and conditions of the RRPV Base Agreement.

[A proprietary data disclosure statement if proprietary data is included. Sample: This Abstract includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Abstract and negotiate any subsequent award. If, however, an award agreement is a result of, or in connection with, the submission of this data, the RRPV Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the RRPV Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

[Title of Abstract]

1. Executive Summary

- Provide the background and the Offeror's understanding of the problem.
- Provide a description of the technology/process.
- Emphasize how the proposed technology/process meets the overall objective specified in this RPP.

2. Technical Approach Overview

- Demonstrate how your proposed solution currently meets the Technical Requirements described in **Section 4**.
- Include any previous studies or preliminary data [non-clinical and/or clinical] that support the feasibility of the proposed technology solution as described in **section 2.6**

3. Teaming/Subcontractors

- Describe any current or potential partnerships or collaborations that may be of use when developing this process/technology.

4. Facilities and Personnel Qualification

- Describe the qualifications and expertise of the key personnel and organizations associated with the proposed solution.
- Detail any past performance(s) that demonstrate relevance to the program objective and solution requirements.
- Identify any key facilities, equipment, and other resources relevant for the solution being proposed.

5. Budget Estimation

- Provide rough order of magnitude (ROM) and any pertinent assumptions for the proposed work.

6. Period of Performance/Schedule

- Identify the proposed Period of Performance (PoP) in months and describe the overall schedule.

7. Data Rights Assertions

- It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights. If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the below table for any items to be furnished to the Government with restrictions. *An example is provided. This section is not part of the page count.*

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights	Name of Organization Asserting Restrictions	Deliverables Affected

DRAFT



Quad Chart Template

Your quad chart must contain the following information and be positioned in a landscape view.

Any quad chart submitted that exceeds the one-page limit will not be read or evaluated.

PROJECT TITLE, RPP#, TECHNICAL/ADMINISTRATIVE POC (NAME, EMAIL, PHONE), COMPANY NAME & ADDRESS

Abstract Information	Supporting Content and Project Planning Information
<u>Objective:</u> Clear, concise (two to three sentences) description of the objectives and methodologies of the effort. <u>Description of effort:</u> A bullet list (2-3) of the primary scientific challenges being addressed	Picture or Graphic that Illustrates the research or concept (e.g., data figures, molecule illustrations or processes)
<u>Benefits of Proposed Technology:</u> <u>Challenges:</u> <u>Maturity of Technology:</u>	<u>Bullet list of the major goals/milestones by:</u> <u>Project Year:</u> <u>Proposed Funding (required)</u> (Rough Order of Magnitude Estimate)