Other Federal Funding Opportunities

Additional Funding Opportunities Not Discussed During the Session

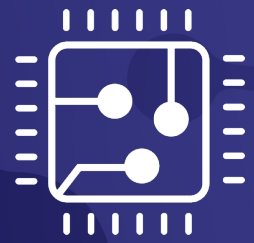
An interagency team building partnerships with U.S. industry and academia

Additional Funding Opportunities Not Discussed During the Session

- NIH – National Institute of Biomedical Imaging and Bioengineering
- Biomedical Advanced Research and Development Authority

DRIVe

ImmuneChip+ Program



MANUFACTURING

Ben Perman, Ph

ASPR
Administration for Strategic Preparedness and Response
BARDA

Microphysiological Systems

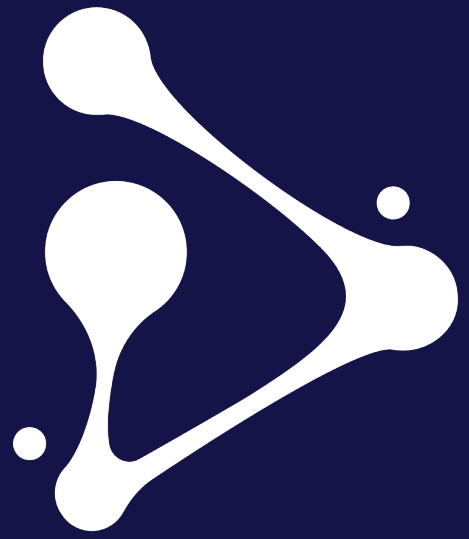
A NEW TECHNOLOGY FOR NON-CLINICAL RESEARCH

- The Biomedical Advanced Research and Development Authority (BARDA) supports national preparedness for and response to chemical, biological, radiological, and nuclear (CBRN) health security threats through the development and acquisition of medical countermeasures (MCMs).
- Development of MCMs for which human studies are not ethical or practical can benefit significantly from the use of physiologically relevant microphysiological systems (MPS), also called tissue chips.
- Microphysiological systems are platforms that support multiple integrated 3D tissues that faithfully replicate the histology and physiology of biological, including human, systems.
- The ImmuneChip+ Program is focused on developing MPS platform technologies that enable rapid, lower-cost, high-quality manufacturing of systems that can be shipped to third-party customers to increase the availability and use of validated systems.

ImmuneChip+ Program

FOCUS ON MANUFACTURING

- PROBLEM: Cells develop *in situ* and synchronously to form physiologically relevant tissues.
- SOLUTION: ImmuneChip+ supports research using multiple (more than 3) tissues including circulating immune cells to push the limits of current technologies.
- PROBLEM: Most developmental MPS platforms are composed of soft, elastomeric materials like Polydimethylsiloxane (PDMS).
- SOLUTION: ImmuneChip+ supports development of platforms constructed using tissue culture compatible plastics polyethylene terephthalate (PET), high- and low-density polyethylene (PE), polyvinyl chloride (PVC), and polypropylene (PP), but the most frequently used plastic in labs today is polystyrene (PS).
- PROBLEM: Individual, hand-fabricated components increase cost and introduce platform-to-platform variability
- SOLUTION: ImmuneChip+ supports development of automated manufacturing and assembly of platforms.



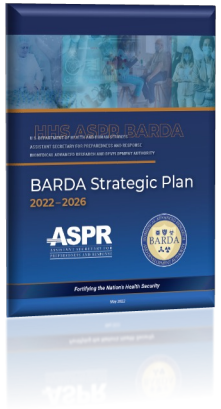
DRIVe

Transforming Health Security

Rapid Response Partnership Vehicle

Overview

Why do we need RRPV?



Findings and lessons learned from COVID-19:

"BARDA must be ready to rapidly establish or expand partnerships when a public health emergency occurs by having contracting vehicles pre-established. The first days of an emergency are critical, and delays in funding, resource availability, or contract awards costs lives."

– BARDA Strategic Plan 2022-2026

DOD OT MODEL WORKS

DOD saved BARDA/ASPR valuable time enabling us to make critical large-value awards throughout the pandemic when our acquisition system was clogged

ADDING A NEW PLATFORM

Leveraging our current OT authority, experience with DOD, and success with CARB-X and EZ BAA demonstrated that with the right partnership vehicle and staffing we can rapidly award innovative and essential projects to partners

EXPAND CONTRACTING CAPACITY

BARDA leveraged the other vehicles, designed for rapid awards, to make critical early and quick small-dollar awards

What is an OTA Consortium Model?

CUSTOM SOLUTION TO TRUSTED MODEL

RRPV borrows from Medical CBRN Defense Consortium model and incorporates COVID-19 lessons learned to evolve and support implementation of existing and new HHS and USG strategies

READY FROM DAY ONE

A new partnership vehicle built for the speed of response, leveraged for preparedness, and appropriately staffed to ensure it's tested and familiar to staff & partners for accelerated response time through *Pre-Negotiated Terms* to meet the speed necessary to respond to a Public Health Incident

Agile Execution

Rapid execution and partnering using an established model

Increased Competition

Integrates traditional, nontraditional, and university partners

New Partners

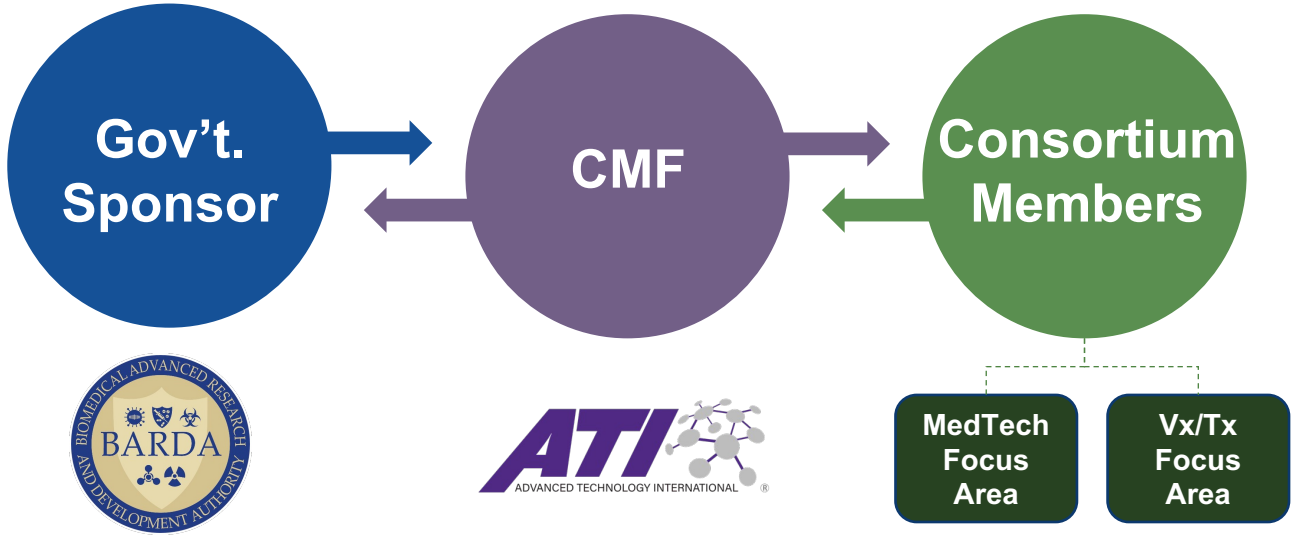
Ability to add partners to capture new and proven technologies

Single-Point Contracting

Consortium Management Firm (CMF) lessens burden on USG

RRPV Consortium Overview and Technical Focus Areas

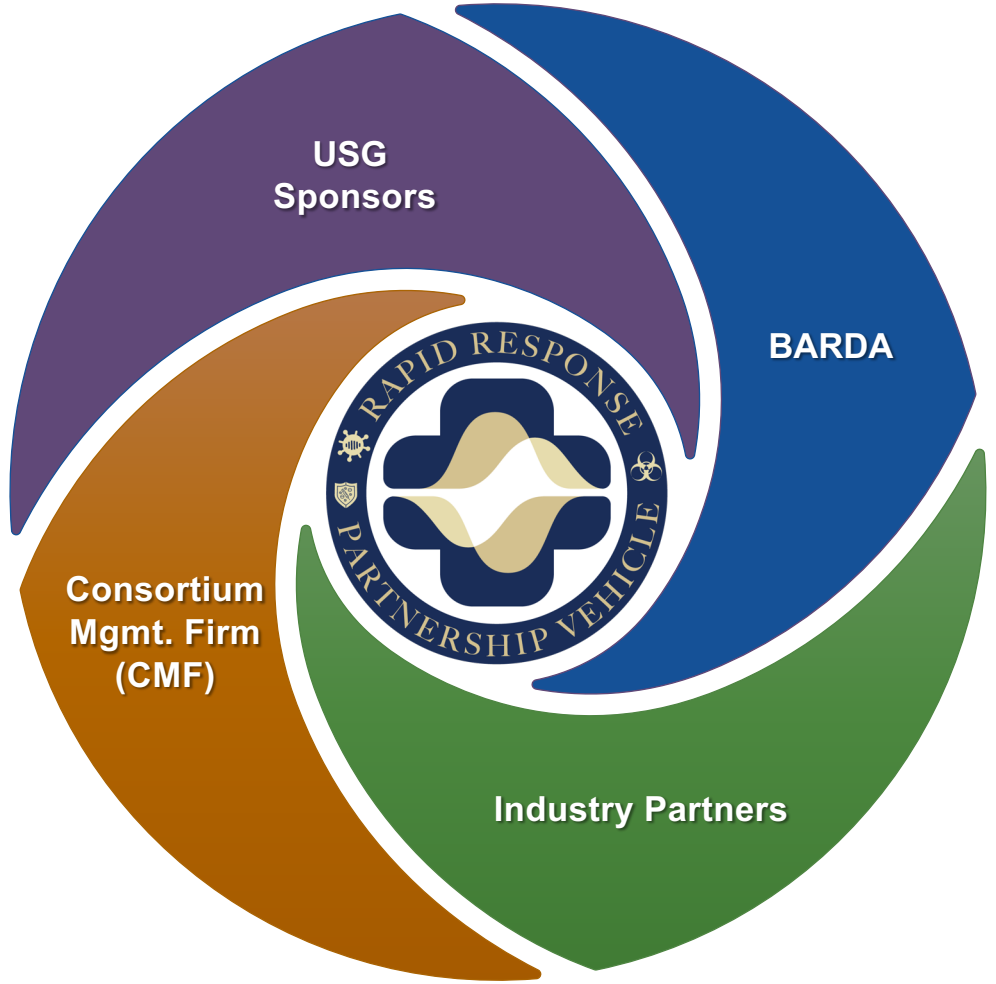
- RRPV Consortium is an **agile network** of technologists, innovators, traditional contractors, large and small business, academia, and nonprofit research institutions that can respond rapidly and effectively to future pandemic or high consequence biological threats.
- RRPV Consortium supports end-to-end MCM development across **two technical focus areas**: (1) MedTech including diagnostics and (2) Vaccines and Therapeutics (Vx/Tx).
  - Each has dedicated staff to ensure equitable allocation of resources during periods of increased MCM demand



RRPV Consortium Stakeholders

Drive requirements, create project documents, secure funding, and collaborate on managing efforts

Solicits proposals from consortium members; issues and manages project agreements with RRPV Consortium members



Houses the RRPV Consortium Program Office, streamlines interactions among groups, collaborates with CMF, offers contractual guidance (CMA), and performs all inherently governmental functions

Respond to solicitations, identify gaps, execute projects per USG requirements, and maintain dynamic collaboration with all stakeholder's post-award

RRPV Consortium – Driving Innovation Through Collaboration

"*Enterprise partnership*"

- Open communications, and a spirit of collaboration to learn about each other's requirements through the consortium for diverse industry engagement

Transparency

- All announcements cross-posted on SAM.gov and RRPV.org so non-members are aware of solicitation opportunities

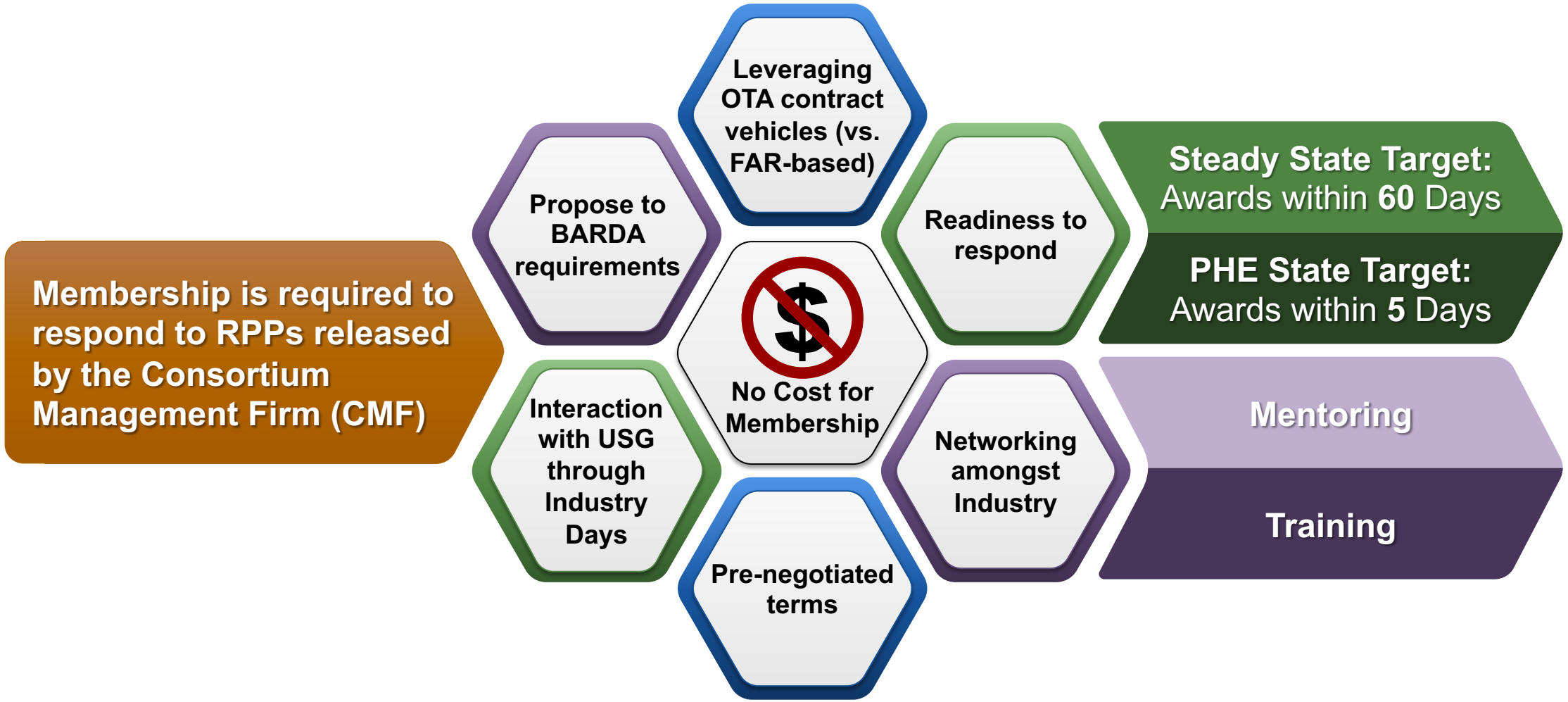
"Level the playing field"

- Proposers Conferences and webinars, where instructions and templates are explained in detail, as well as dedicated, on-call support for proposal development

Teambuilding

- Facilitate in-person collaboration events, networking webinars, and searchable databases to find teaming partners

Additional RRPV Consortium Membership Benefits



RRPV Vaccine Funding Opportunities

Vaccine R&D

- **RPP-24-04-NGVx** "NextGen Vaccinations: Phase 2B Clinical Trial Execution"
- **RPP-24-01-mRNA** "Accelerating Near-Term Availability of mRNA-based Pandemic Influenza Vaccine"
- **RFI** – "Oral Formulation Vaccines"
- **RFI** – "mRNA Vaccine Platform Production Capability for Rapid Pandemic and Priority Threat Response"

Vaccine Manufacturing

- **RFI** - "Project NextGen: On Demand Manufacturing"
- **RPP-24-05-NGClinMfg** "Project NextGen: Innovation in Clinical Manufacturing of COVID-19 Vaccines"
- **RPP** - "Project NextGen: On Demand Manufacturing"

Clinical Trial Innovation

- **RPP-24-02-HomeFocus** "Enabling Technology – Decentralized Clinical Trial – Home Focus"
- **RPP-24-02-Retail** "Enabling Technology – Decentralized Clinical Trial – Retail/Pharmacy Focus"

Immune Assay Development & Analytical Support

- **RPP-24-04-NGVxAssays** "NextGen Vaccines: Immune Assays"
- **RPP-24-04-NGVxStats** "NextGen Vaccines: Statistical Support, Correlates of Protection, and Meta-analysis"
- **RFI** – "Central Influenza and Emerging Infectious Diseases Vaccine Immunogenicity Laboratory"

◆ Closed ● Active ★ Upcoming

https://www.rrpv.org/opportunities/

RFI: Request for Information
RPP: Request for Project Proposal

RRPV
On-Demand Manufacturing Program

The Need for On-Demand Manufacturing

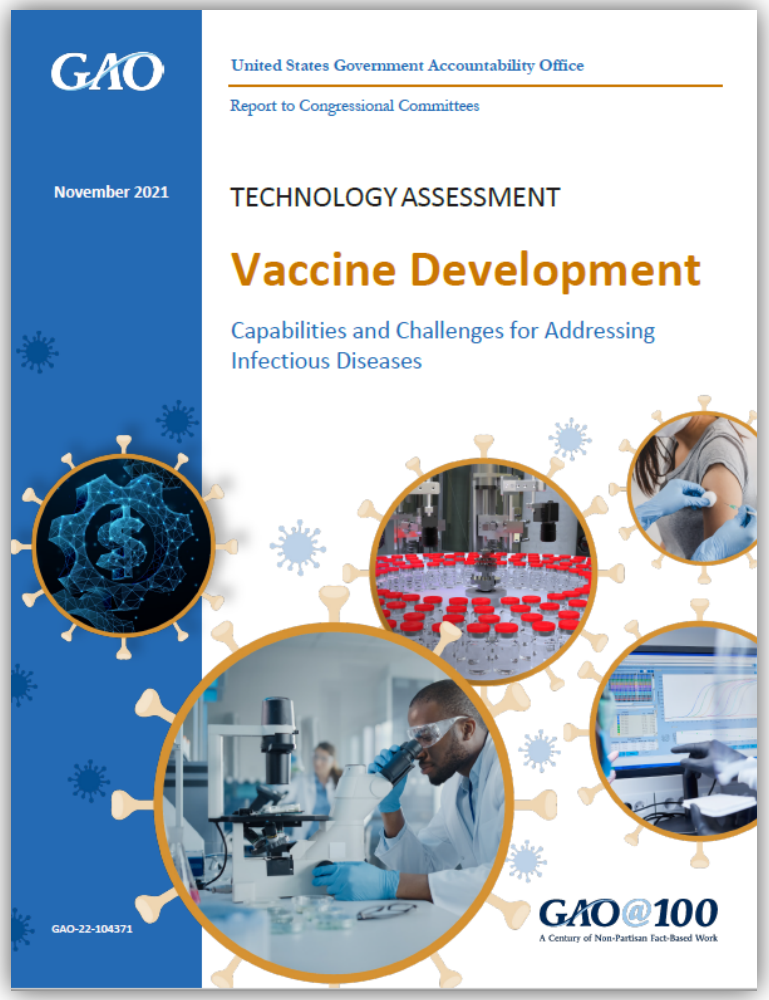
…BARDA will develop MCMs that enhance response capabilities and reduce burden on the health care system by promoting new engagements with end users to identify potential technologies at key inflection points along the continuum of care.

…expanding the geographic distribution of vaccine manufacturing capacity is critical to achieving vaccine equity.

...There remains a need to make vaccines better, faster, cheaper, easier to manufacture and closer to where they will be administered, especially in resource-poor settings.

…the COVID-19 pandemic has highlighted the extent to which the current model of vaccine manufacturing and distribution is highly concentrated geographically, making supply vulnerable to nationalism, export bans, and shortages.

Rationale



*"**Vaccine manufacturing is traditionally inflexible**, with many manufacturers producing single vaccines products in centrally located, dedicated facilities. As a result, **new vaccines cannot be easily incorporated into existing facilities**, and different vaccines cannot be manufactured simultaneously, in quick succession, or closer to the geographic point of need. Further, **centrally located, dedicated product manufacturing facilities can be a single point of failure**—a risk that can negatively impact vaccine supply."*

Government Accountability Office Technology Assessment, Vaccine Development: Capabilities and Challenges for Addressing Infectious Diseases, November 2021

Based on industry feedback, this program is envisioned to

- **Advance Diverse Manufacturing Platforms**: Goal is to not be restrictive if there are promising approaches that focus on small-molecules, viral vectors, or recombinant proteins
- **Multi-Staged**: Intended to have multiple stage and go/no-go gates to enable comprehensive development
- **Collaborative**: Interested companies may consider partnering with other organizations to achieve the best solution
- **Ambitious But Realistic:** The program team will strongly consider all responses provided via the RFI
- **R&D for Manufacturing Processes**: There is still a long way to go for generating vaccines on demand. Under this program, the work will focus on process development and optimization with less prioritization of preclinical studies

Coming Soon to the RRPV

After receiving industry feedback, BARDA is developing a program that meets both industry and the government's needs.

Solicitation is targeting a release of Q3 in FY2024.

Q3FY24 RPP	Project NextGen: On Demand Manufacturing	Under the Project NextGen Enablers Program, BARDA aims to advance technologies that decrease costs, speed production, and improve access for vaccines. The vision for on-demand manufacturing is to develop a portable, smaller footprint, end-to-end manufacturing system that can produce vaccines on-demand in GMP conditions. This program will make a meaningful step towards this envisioned end state by supporting the development of new manufacturing technologies that improve the speed, scale, cost, yield, and flexibility of on-demand capabilities, while maintaining high levels of product quality. The effort notionally plans to support a prototype and development phase and, if criteria for success are met, an optimization and final demonstration phase.

Contact the RRPV Consortium Team

- To learn more about the RRPV Consortium and to join:

www.rrpv.org

- To learn about BARDA's sister consortium, join us tomorrow:

Expansion of the Industrial Manufacturing Base for Medical Countermeasures

Speaker: Brooke Luck, BioMaP-Consortium Program Manager
April 4, 2024
10:10am ET
Room 209AB

ATI RRPV Consortium Team **RRPV@ati.org**
BARDA RRPV Consortium Team **RRPV@hhs.gov**

PATCH FORWARD PRIZE

Overview

April 18, 2024

This session is being recorded.
The recording will be published on **PatchForwardPrize.com**

PATCH FORWARD PRIZE

The Patch Forward Prize is a **$50 million Project NextGen competition** to advance microneedle patch-based RNA vaccines.

BARDA calls on **vaccine developers** and **patch makers** to partner and accelerate new vaccine technologies.

The need for vaccine innovation

The modern syringe has been the dominant vaccine administration method for 170 years. However…

- **Fear of needles** contributes to vaccine hesitancy.
- Prefilled syringes and vials require complex cold chain storage and transport, which can **limit access to vaccines**.
- Intramuscular vaccines need to be administered by **trained healthcare providers**.
- Intramuscular injection may be a **less efficient method** for eliciting protective and durable immunity.

The opportunity

Patch-based vaccines could address many of these limitations, and may elicit strong immune responses and durable protection.

- Developing compatible patch-based RNA vaccines presents technical challenges.
- Bringing these products to market will require partnerships between vaccine developers and patch makers.

The Patch Forward Prize will foster industry collaboration and support the advancement of patch-based RNA vaccine candidates toward the completion of Phase I clinical trials.

How will the Patch Forward Prize work

Prize competitions **complement** more traditional government funding mechanisms (e.g., grants and contracts) to **catalyze breakthrough innovation**.

The Patch Forward Prize:

- Encourages a variety of solution types and collaborations.
- Will evaluate how well submissions meet Concept, Preclinical and Clinical Stage evaluation criteria.
- Will award flexible, non-dilutive funds and non-monetary resources to support acceleration.

PATCH FORWARD PRIZE

Competition structure

Competition awards

$50 million total prize pool

Concept Stage
$8 million

Up to four Concept Stage winners will each receive a $2 million Concept Stage award.

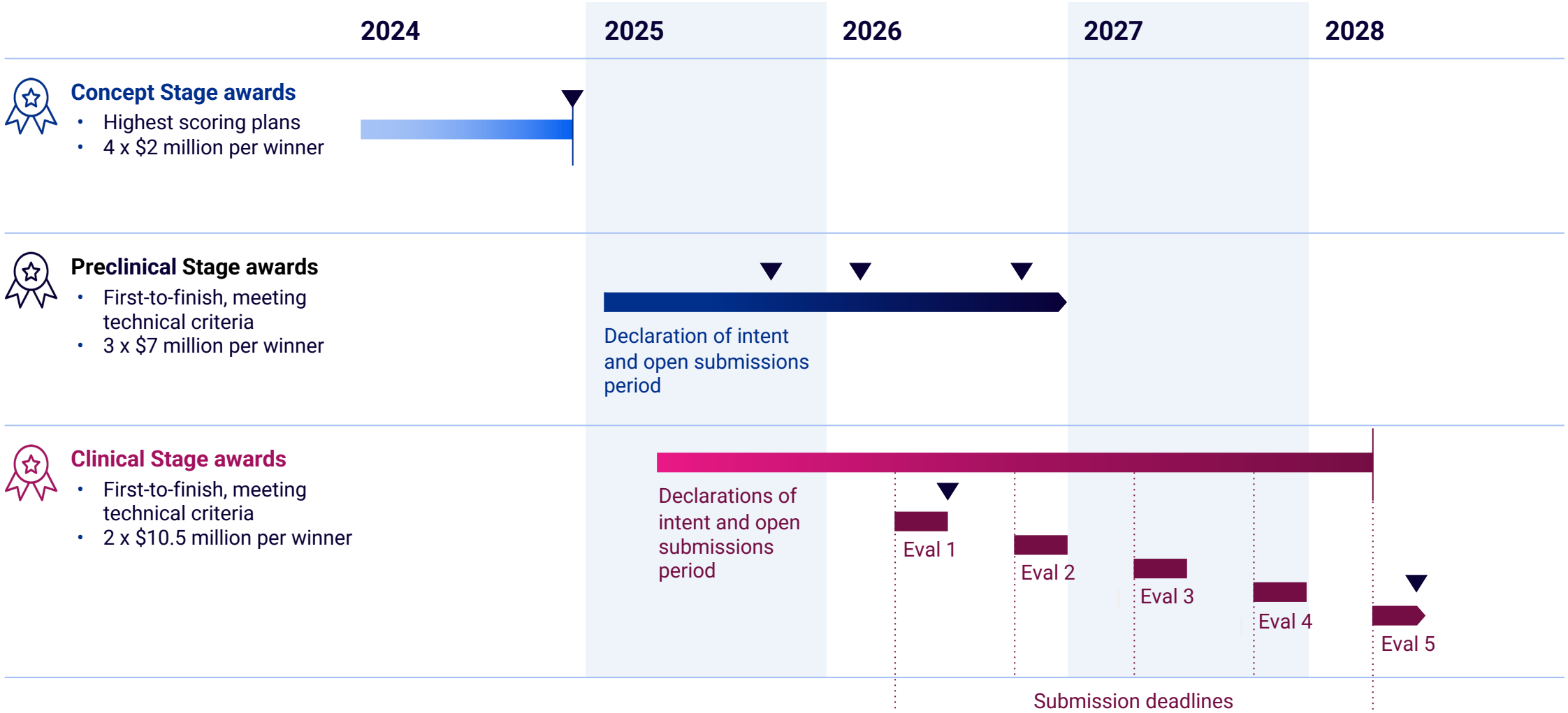
Preclinical Stage
$21 million

Up to three Preclinical Stage winners will each receive a $7 million Preclinical Stage award.

Clinical Stage
$21 million

Up to two Clinical Stage winners will each receive a $10.5 million Clinical Stage award.

Competition stages

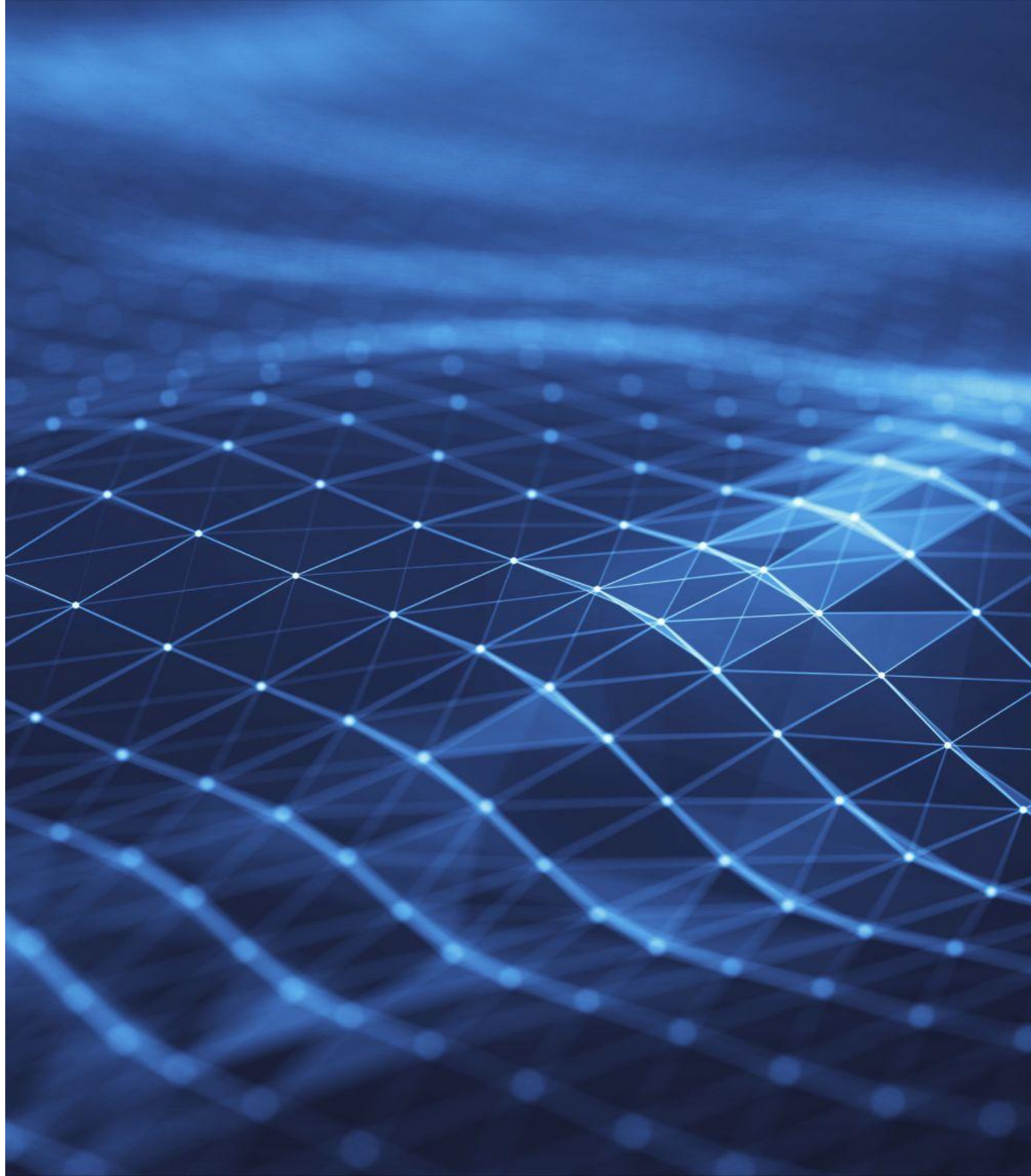


Stay up to date

Sign up for the challenge newsletter.

Visit **PatchForwardPrize.com** for:

- Complete challenge details
- Rules, terms, and conditions
- Curated resources
- Submission platform
- News and updates



Sign up to receive the
Patch Forward Prize newsletter

PATCH FORWARD PRIZE

Thank you!

Contact:

hello@PatchForwardPrize.com