Proposers Conference

Solicitation Number: RPP-26-09-AgDx

“Agnostic Diagnostics”

November 6, 2025

Objectives

- What is the RRPV?
- What is an OTA?
- Highlight key aspects of the Request for Project Proposals
- Provide a deeper understanding of technical requirements
- Answer your questions
- Teaming Connect

What is the RRPV?

The **Rapid Response Partnership Vehicle (RRPV)** supports BARDA in its objective to accelerate Medical Countermeasure (MCM) product and technology development to address evolving needs including:

- Pandemic Influenza
- Emerging Infectious Diseases
- Other Biological threats

Focus Areas -

- **Medical Technology (MedTech)**: tools, equipment, and devices to diagnose and treat patients.
- **Vx/Tx:** Vaccines (Vx): Biological preparation that is used to stimulate the body's immune response against pathogens or diseases. Therapeutics (Tx): Medical interventions intended to treat a health issue, infection, or disease.
- **Medical Countermeasure Clinical Research Centers (MCCRC):** Clinical development services and infrastructure

The consortium will advance health security, enhance preparedness, and enable a rapid response to the next pandemic or public health emergency.

What is an OTA?

- An "**Other Transaction Agreement" (OTA)** is a streamlined vehicle that brings innovative research findings and state-of-the-art technologies from industry to the federal government.
- OT-based collaborations are **not subject** to some of the regulations that apply to Federal Acquisition Regulation (FAR)-based acquisitions.
- BARDA uses OTAs to further its advanced research and development goals, promote innovation, and support the mission of the HHS Public Health Emergency Medical Countermeasures Enterprise
- BARDA uses OTAs as a type of flexible, strategic partnership between the government and industry to foster innovation and promote collaboration

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Caution

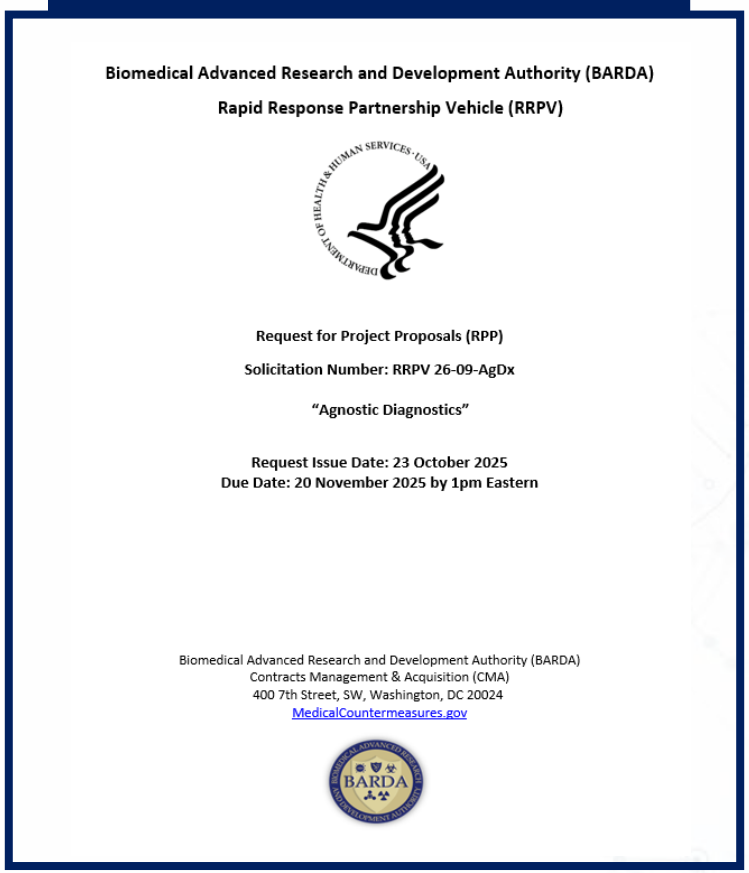
The **RRPV-26-09-AgDx** Request for Project Proposals (RPP) is the official source of information regarding the active solicitation.

If you act on information from any source other than these official sources, it is at your risk.

RRPV membership is required for the submission of an abstract in response to this RPP.

To join RRPV, visit www.rrpv.org/how-to-join

Request for Project Proposals (**RPP**)



Biomedical Advanced Research and Development Authority (BARDA)

Rapid Response Partnership Vehicle (RRPV)

Request for Project Proposals (RPP)

Solicitation Number: RRPV 26-09-AgDx

"Agnostic Diagnostics"

Request Issue Date: 23 October 2025
Due Date: 20 November 2025 by 1pm Eastern

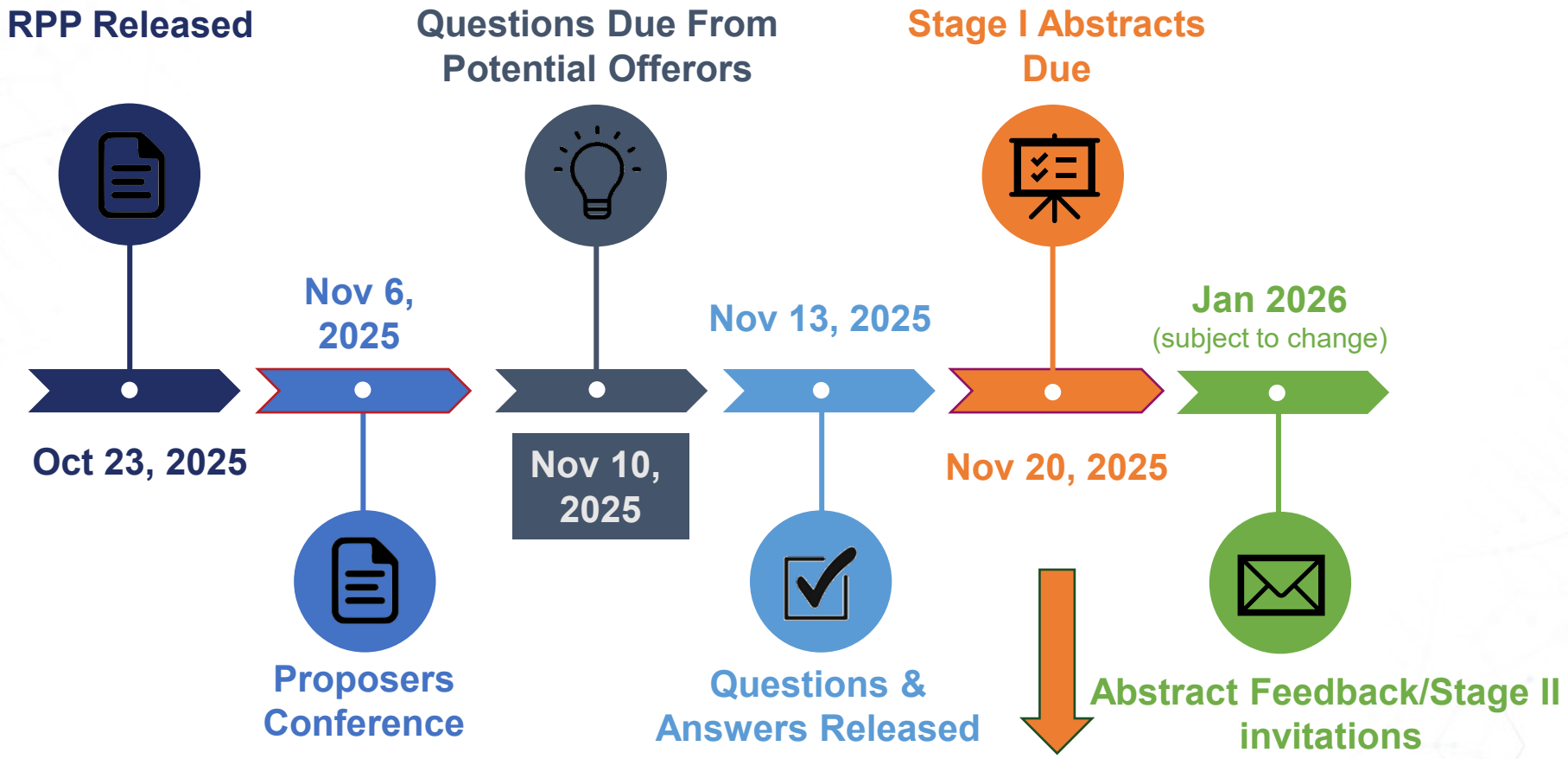
Biomedical Advanced Research and Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
400 7th Street, SW, Washington, DC 20024
MedicalCountermeasures.gov

RPP can be found on the RRPV website:
https://www.rrpv.org/solicitation/agnostic-diagnostics/

Funding Plan and Period of Performance

- **Sponsor:** BARDA
- **Funding Available:** **Approximately $20M-40M**
- **Anticipated Number of Awards:** **Three (3) awards**
- **Period of Performance (PoP):** **36 months anticipated, may extend beyond**
- **Cost Sharing:** Cost sharing is defined as the resources expended by the Project Awardee on the proposed Statement of Work (SOW). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-Performer collaboration.

Timeline



Abstracts must be submitted to the RRPV BDR Portal at: rrpv.hhs.gov

Required Submission Documents (2)

- **Abstract** (see Attachment 1 of RPP for template)
  - includes cover page, 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** (see Attachment 1 of RPP for template)
  - 1 page limit
  - Includes objective, description of effort, benefits of proposed technology, challenges, maturity of technology, picture/graphic that illustrates research/concept, bullet list of major/goals milestones

Evaluation

- The Government will conduct an evaluation of all qualified Abstracts after the preliminary screening.
- **Evaluation Factors**
    1. Technical Approach
    2. Relevant Experience
    3. Cost Reasonableness
- **Evaluation Outcome**
    1. Feedback and invitation to proceed to Stage 2 provided
    2. Notification that not selected to proceed to Stage 2

Request a BDR RRPV Portal Account

In order to submit an abstract, an account is REQUIRED. ATI is not able to accept submissions by any other method.

Request Access to the BDR RRPV Portal by filling out the BDR RRPV Portal Access Request form linked on the RRPV.org site.

https://atisc.formstack.com/forms/bdr_rrpv_portal_access_request

Request a BDR RRPV Portal Account

BDR Portal Information

***IMPORTANT* - Accounts with no activity for 60 days are automatically deactivated.**

- If you have an account, log in and make sure it is still active a few days before you intend to submit.
  - *If deactivated, send an email to RRPV @ati.org to reactivate.*
- If you do not have a BDR account, submit your request several days before the close of the RPP.

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The BARDA Model

BARDA develops and makes available medical countermeasures (MCMs) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.

- Flexible, nimble authorities
- Multi-year funding
- Cutting edge expertise
- Facilitate partnerships
- Promote innovation

DDDI Strategy

VISION

Develop diagnostics and devices across BARDA's threat portfolio and improve diagnostic capabilities for faster emerging disease response.

STRATEGY

Partner with private & public sectors to develop MCMs

Leverage and improve testing platforms and technologies

Support rapid diagnostic response capabilities

DDDI Threats and Use-cases

THREAT SPACE

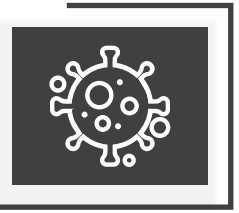
CBRN
Antimicrobial Resistance (AMR)
Biothreats – w/ MTD's

Annual Funding

EMERGING INFECTIOUS DISEASE
(Zika, COVID-19)

Supplemental Funding Only – Outbreak Specific

PANDEMIC INFLUENZA



Annual Funding

USE-CASES

HOME-USE/ REMOTE

POINT-OF-CARE/ PHARMACY

LABORATORY

BARDA Diagnostics Key Initiatives

QUICKLY AVAILABLE

- THREAT AGNOSTIC TESTING
- PATHOGEN FAMILY TESTING
- HOME/PORTABLE MOLECULAR
- RAPIDLY AVAILABLE A_B/A_G'S

TESTING CLOSER TO PATIENT

- HOME/PORTABLE MOLECULAR
- HIGH PERFORMANCE RAPID ANTIGEN TESTING
- POC/PHARMACY TESTING

RAPID RESPONSE CAPABILITY

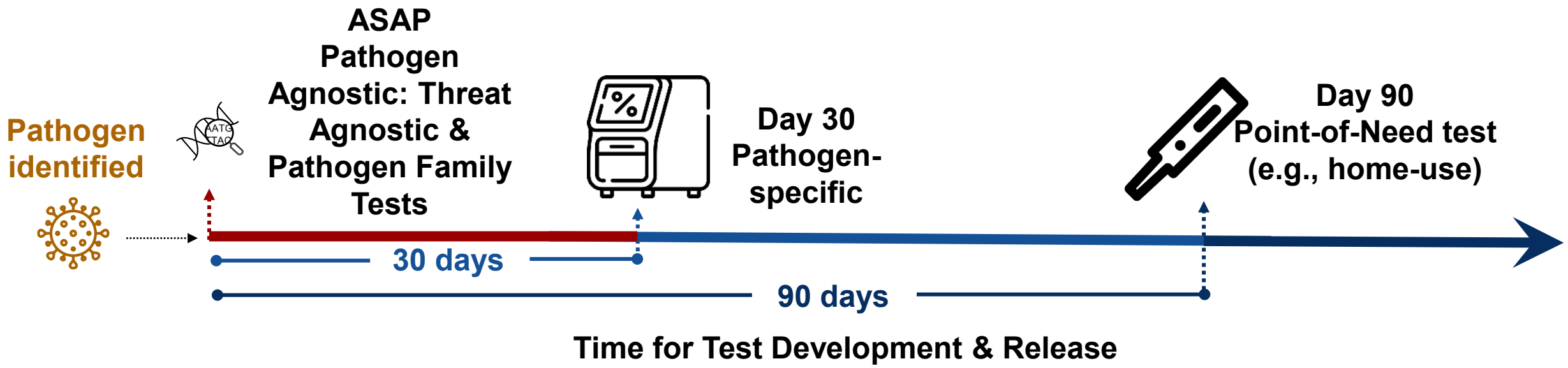
- HOME/PORTABLE MOLECULAR
- HIGH PERFORMANCE RAPID ANTIGEN TESTING
- BROAD PANEL MOLECULAR TESTS
- EID EXERCISE AND RESPONSE

AMR TESTING

- PHENOTYPIC TESTING
- VIRAL VS. BACTERIAL
- BROAD PANEL MOLECULAR TESTS
- THREAT AGNOSTIC TESTING

Early Outbreak Response

Goals:
1) FDA cleared database and mNGS diagnostic
2) Multiple FDA Cleared Pathogen Family Tests



Test Settings

Laboratory	Laboratory & POC	Laboratory, POC, & PON

Threat Agnostic Tests: mNGS IVD Testing for Newly Identified Pathogen

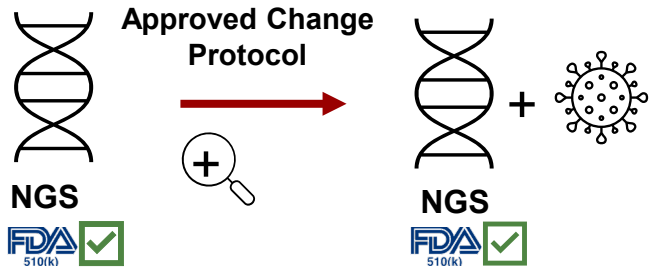
Threat agnostic test = no pathogen specific reagents.

The FDA cleared mNGS test for known pathogens

- Same technologies(s) as mNGS surveillance tests
  - Configuration controlled & validated: Equipment, Reagents, & Protocols
- Bioinformatics package - included
  - Calls pathogen from known sequences
  - Validated **controlled reference database**
  - Viruses first (e.g., respiratory)

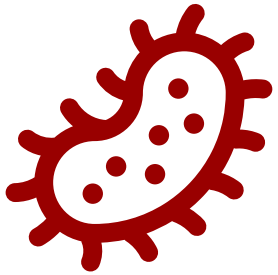
Update for newly identified pathogen

- Update **controlled reference database**
- Validate system performance – contrived samples
  - Hope to utilize a “preapproved change protocol”
- Controls/specimens needed for CLIA lab proficiency testing

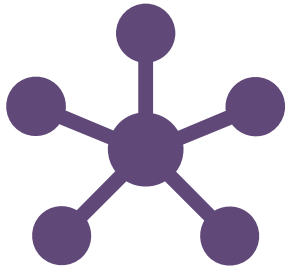


New RRPV Agnostic Diagnostics Request for Proposals

Program Goals



Pathogen Agnostic tests (viral & bacterial)



Widely distributed for rapid response during a disease outbreak

Ready on day 1 of any future pandemic threats

Why are we doing this?

BARDA must respond rapidly (days 1-30) in a PHE with diagnostics to emerging threats

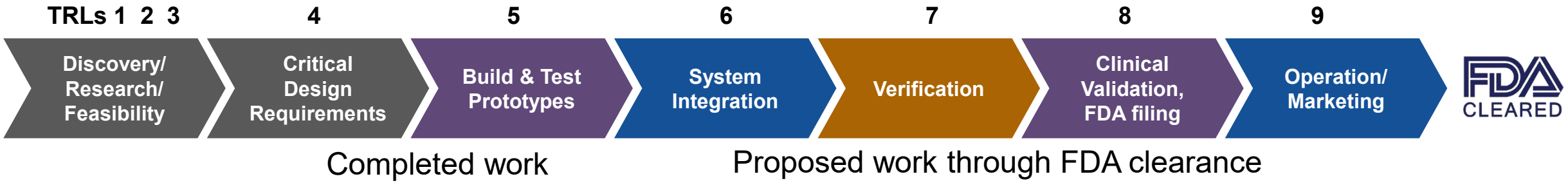
Problem: Gap between pathogen identification and pathogen-specific tests

- Traditional antigen and molecular tests take weeks to months to develop
- Issues with drop-out mutations
- Access to samples is extremely limited in early stages of an outbreak

BARDA's need:

- Metagenomic Next Generation Sequencing based tests
- Sample-to-answer solution
- Achieve 510(k) clearance/de novo approval

mNGS IVD Test for Newly Identified Pathogens



- Platform at Technology Readiness Level (**TRL**) **5** or greater
- Sample to Answer Solution that includes:
  - Automated sample processing
  - Library preparation
  - Enrichment/depletion if needed
  - Metagenomic sequencing
  - Process controls
  - Bioinformatics/data analysis
- Medium to High-throughput random access

mNGS IVD Test Development (1 of 2)

Feasibility Data for both viral and bacterial from at least **One Sample Type**

Plan for creating **Contrived Specimens** for Verification & Validation

Plan for **Analytical and Clinical Validation**

Collaborate with FDA to determine requirements for **Acceptable Database**.

mNGS IVD Test Development (2 of 2)

Methods for **Determining a Positive** – Depth of coverage, Percentage of Genome, …

Strategy for **Rapid Modification** of the database to **Add** newly identified viruses and bacteria

Strategy to achieve **FDA 510(k) Clearance/de novo Approval** for targeted pathogens

Clinically Actionable data reports

Results in less than 12 hours are preferred

Out of Scope

- Laboratory Developed Test (**LDT**) or Research Use Only (**RUO**) mNGS development without FDA clearance/approval
- Development of **New sequencing platforms**
- **Surveillance** and environmental testing
- Development of **Targeted** NGS assays

Our Industry Partners

ASPR Website:
aspr.hhs.gov/BARDA
Check out ASPR's programs, news, and announcements

BARDA Website:
medicalcountermeasures.gov
Learn about BARDA's programs, our annual industry day, and funding opportunities!

Solicitations:
sam.gov
See official announcements and info for government contract solicitations

DRIVe Website:
drive.hhs.gov
Learn about DRIVe, including open EZ-BAA solicitations

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bardagov.bsky.socal

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Questions and Answers

- Questions submitted prior to the call will be answered now
- A transcript of the Q&A will be posted along with answers to those questions submitted during the Q&A period as soon as possible
- Submit any other questions to:
  - Ms. Rebecca Harmon (RRPV-contracts@ati.org)