ASPR
ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE

BARDA
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

Project NextGen – On Demand Manufacturing

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Biomedical Advanced Research and Development Authority (BARDA),

Administration for Strategic Preparedness and Response (ASPR),

U.S. Department of Health and Human Services (HHS)

Rapid Response Partnership Vehicle (RRPV) – Request for Information (RFI) with Industry

January 16, 2024

Unclassified

Today's Agenda

Topic	Time
Opening Comments *Kumiko Lippold, PhD, DRIVe Alliance Office Branch Chief (Acting)*	5 min
Project NextGen Enablers *Kimberly Hofmeyer, PhD, BARDA Project NextGen Deputy Director*	10 min
BARDA's Rapid Response Partnership Vehicle (RRPV) *Chris White, PhD, BARDA RRPV Project Manager*	10 min
On Demand Manufacturing *Kumiko Lippold, PhD, DRIVe Alliance Office Branch Chief (Acting)*	30 min
Close Out *Kumiko Lippold, PhD, DRIVe Alliance Office Branch Chief (Acting)*	5 min

Request for Information (RFI) with Industry

- Continued market research for technologies that support on demand manufacturing of medical countermeasures
- Possible program under BARDA's Rapid Response Partnership Vehicle where BARDA would partner with organizations to work towards the goals of the Project NextGen Enablers Program
- RFI: https://www.rrpv.org/solicitation/rfi-on-demand-manufacturing/
  - Please respond!
  - Opportunity for quick-fire 1-on-1 with BARDA today
  - Sign up on RFI page

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

ASPR's mission:
Assist the country in **preparing for**, **responding to**, and **recovering from** public health emergencies and disasters.

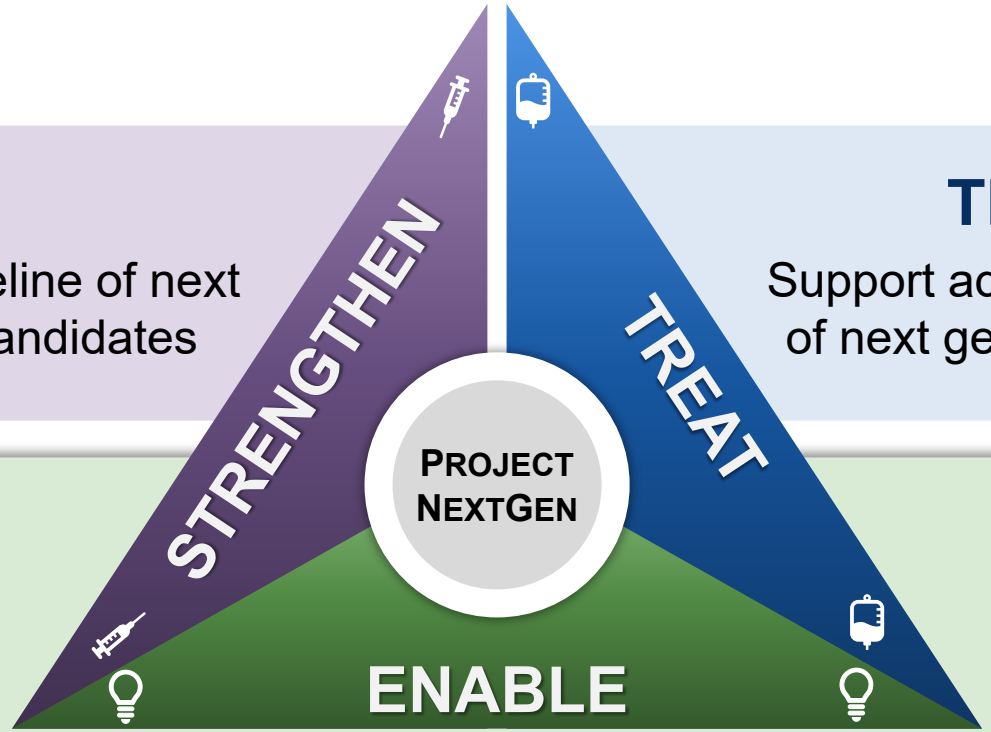
Strengthen. Treat. Enable.

VACCINES

Support a robust pipeline of next generation vaccine candidates

THERAPEUTICS

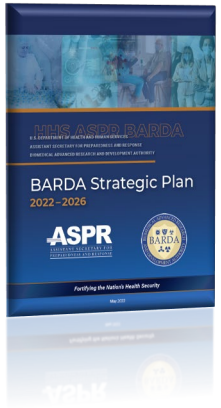
Support advanced development of next generation therapeutics



ENABLERS

Advance technologies that decrease costs, speed production, increase efficacy, and improve access

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

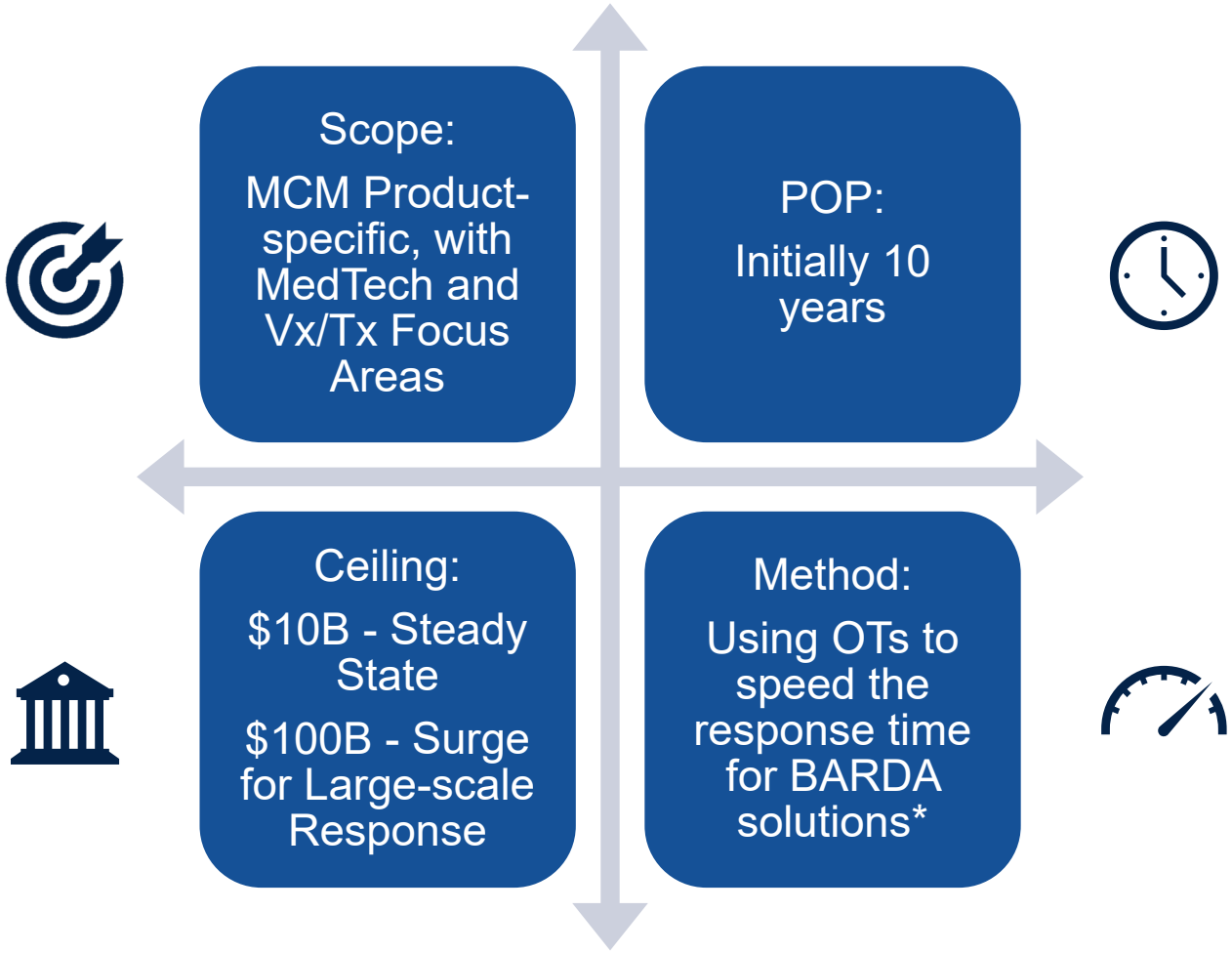
ADDING A NEW PLATFORM

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

RRPV High Level Overview



*To help meet the needs outlined in APPP and NBS

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

Disclaimers

- What this Industry Day is:
  - Continued market research for BARDA to learn from YOU about what is possible
  - An opportunity for industry to provide direct input and insights into future solicitations and program requirements
- What this Industry Day is NOT:
  - A Request for Proposals or an open solicitation
  - None of the information in the RFI is intended to suggest a particular approach or contract solution
  - None of the information provided signifies commitment by BARDA to issue any number of awards or funding amounts

We will not be answering questions live. We encourage you to put your questions in your RFI response by 5PM ET, January 19.

The Need for On-Demand Manufacturing

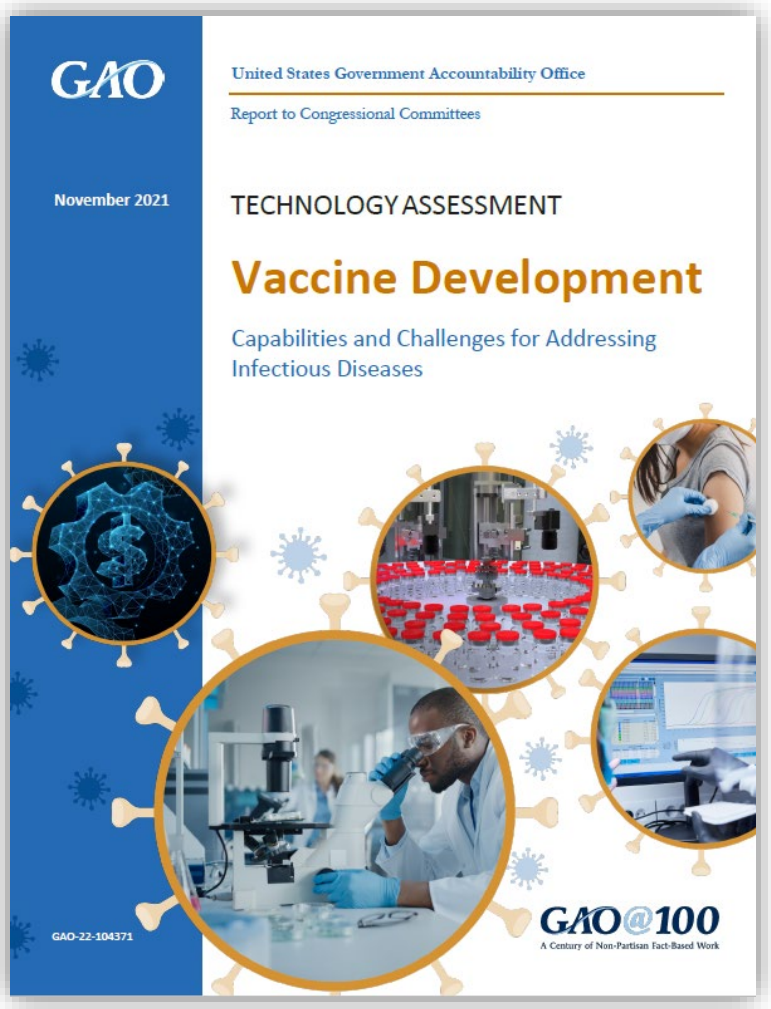
…BARDA will develop MCMs that enhance response capabilities and reduce burden on the health care system by promoting new engagements with end users to identify potential technologies at key inflection points along the continuum of care.

…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 vaccine 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."*

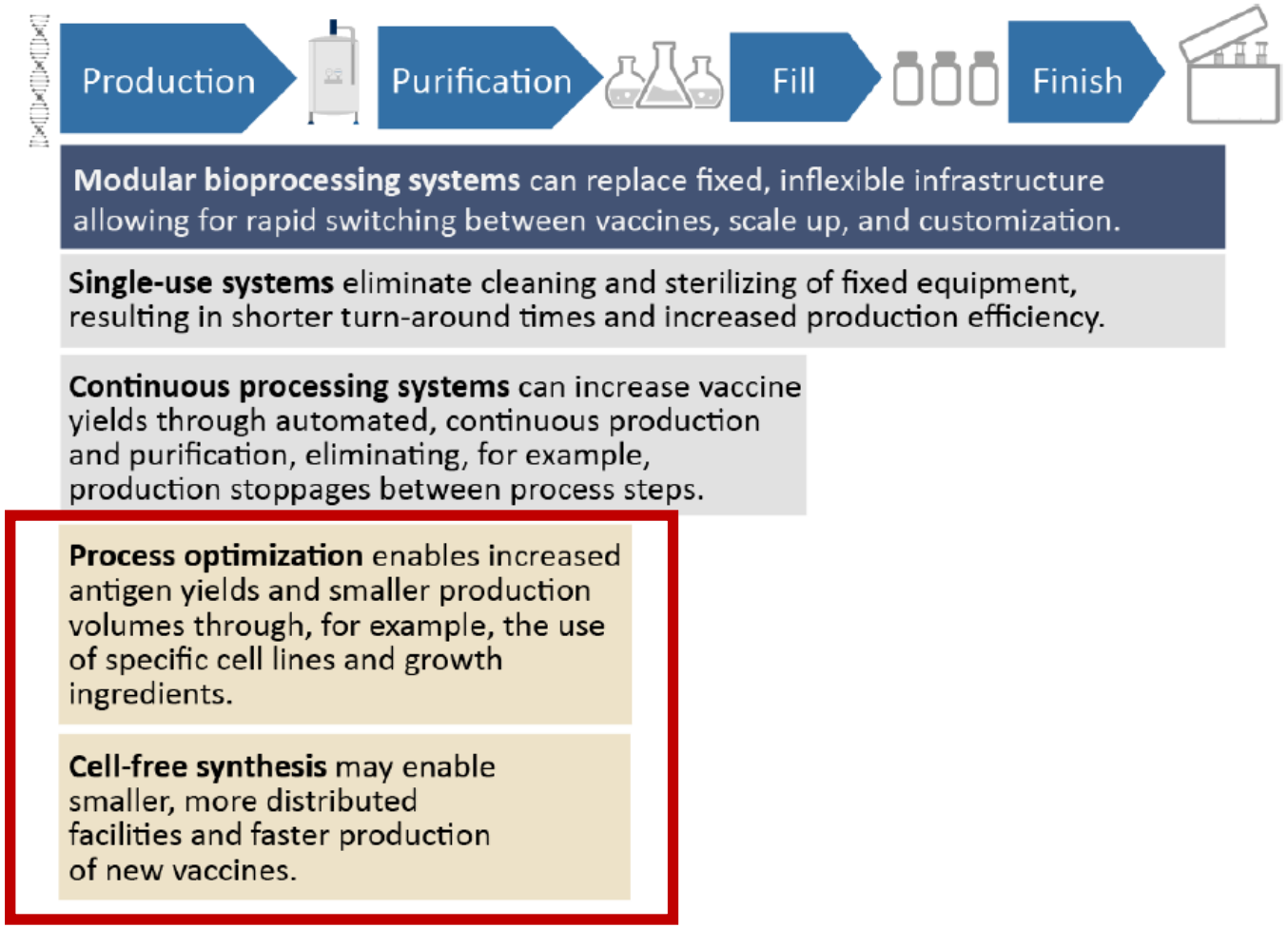
Government Accountability Office Technology Assessment, Vaccine Development: Capabilities and Challenges for Addressing Infectious Diseases, November 2021

ODM: Need for Bioprocess Intensification

Key Objectives

- Flexible, mobile facilities
- More productive equipment
- Improved technology

Smaller production volumes, **more distributed** facilities, **faster** production



Source: GAO analysis of scientific literature and rashadashurov/tutti_frutti/StockBURIN/divstock/stock.adobe.com. | GAO-22-104371

Vision for Vaccines on Demand

Vision for VoD: To build an end-to-end manufacturing capability that allows the production of vaccines when and where they are needed.

- Enable app-based download of vaccine instructions
- Manufacture rapidly on a small scale with in-line testing

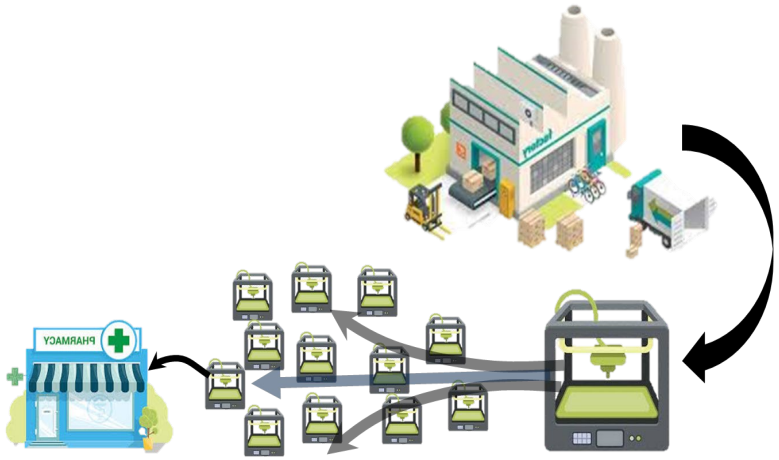
- Produce a range of vaccine types
- Utilize minimal, well-defined resource materials

- Fill/finish in-line for on-site production and administration
- Eliminate the need for long-term storage of product

- Promote calibration of printers in lieu of validation
- Push technology to hospital or primary care settings

Vision for Vaccines on Demand

- Invest in flexible technology to 1) enable rapid shifts to emerging threats, 2) improve sustainability, and 3) reduce downstream bottlenecks



Distribution and Administration
Production of vaccine onsite, as needed

Stockpiling and Sustainment
Eliminate or reduce the need to stockpile

Redesign and Reformulate
Enable rapid transition between products

Vaccines on Demand – DRIVe EZ-BAA

Technology Product Profile

System Characteristics	Goal
Number of doses per batch	>1000
Number of days per batch	<7
Number of batches per resupply	1
Release Testing	Near real time/<24hour readouts
In-line Formulation	Fully automated, plug and play capability

1. **Easily definable inputs:** The ideal platform would utilize materials for vaccine manufacturing that are easily sourced and handled within the device.
2. **Minimal to no release testing:** The ideal platform would enable decentralized production by integrating in-line monitoring and testing into the production process.
3. **In-line formulation capabilities:** The ideal platform would enable formulation in one closed system.
4. **Logistically useful footprint:** The ideal platform would possess a sufficiently small footprint to enable use in hospitals, pharmacies, or by primary care physicians.
5. **Small-scale validation:** The ideal platform would be subject to validation of manufacturing for regulatory purposes.
6. **Plug and play:** Integrated precursor API materials such as chemical or biological cartages for simple ‘plug-and-play’ operations.

Vaccines on Demand: Lessons Learned

- The AOI was open between October 2022 and September 2023
- During that time, the team conducted >25 market research calls, reviewed 18 abstracts, and granted three awards.
- From this program, we identified several critical gaps:
  - Companies addressed key components of the ODM process, but considerable gaps in product development and/or process optimization remained. Establishing collaborative partnerships in the manufacturing space is warranted
  - Companies seeking the EZ-BAA to leverage ongoing efforts in ODM proposed clearer deliverables and recognized limitations of their respective technologies.
  - Award ceiling of the EZ-BAA (<$750K) may be insufficient to support significant advancements in ODM technology

On Demand Manufacturing: Challenges

- Magnitude of Required Investment. Uncertainty of cost estimates (need to establish a pilot facility)
- Engineering a Flexible System. Limitations in the ability to rapidly pivot to new targets with new formulations
- Regulatory Guidance for ODM Unclear. Licensing and certification is needed, no current FDA guidance
- Personnel Knowledge and Expertise. Availability and ongoing training of skilled personnel
- Ensuring Product Consistency. Distributed manufacturing sites requires additional controls

RFI

We recognize that the development path for on-demand technologies may look different and require a unique partnership approach.

TECHNICAL CHALLENGES

REGULATORY HURDLES

INCENTIVES & MILESTONES

COMMERCIAL SUSTAINABILITY

TEAMING

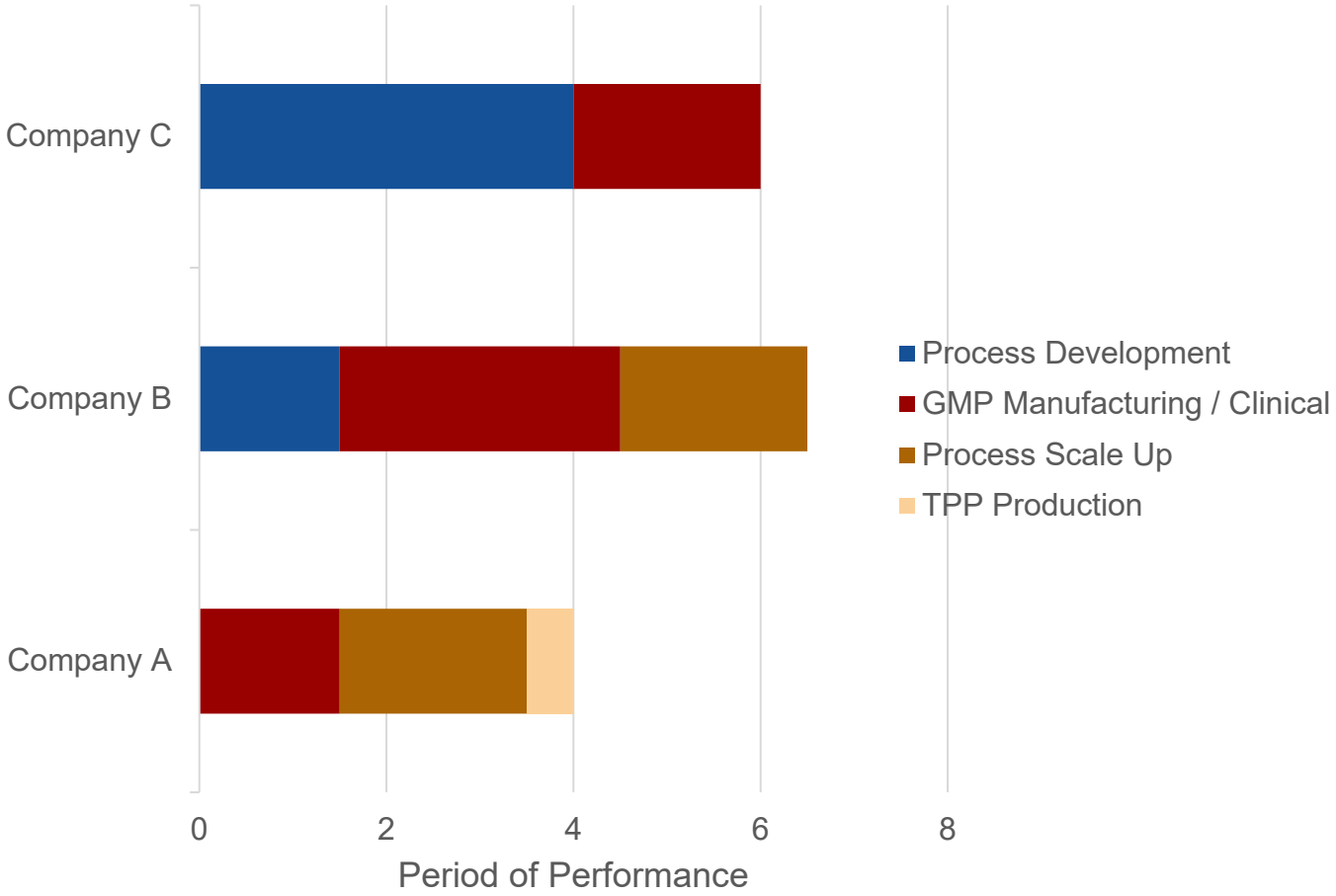
We want to know the realm of the possible is –

- What works and what doesn't
- If you don't think something is reasonable, tell us.

With your 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

Milestone Roadmap Example



Your development roadmap may look different depending on your company's TRL:

- Company A has completed their process development and is ready to optimize their GMP production processes
- Company B is nearly finished with process R&D and will be imminently ready to move towards GMP production
- Company C has recently found a new technology partner and is redesigning their process approach

Bottom line: Maturity, readiness, and milestones will differ between companies and that is okay.

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medicalcountermeasures.gov
Portal to BARDA: ***Register to request a TechWatch meeting!***

sam.gov/
Official announcements and info for all government contract solicitations

aspr.hhs.gov/BARDA/
Program description, information, news, announcements

drive.hhs.gov
Learn about DRIVe, including our Accelerator Network and EZ BAA

www.usajobs.gov
Join the team!

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