



Implementing BARDA's Pandemic Preparedness and Response Capability

Gary Disbrow, Ph.D

Director, Biomedical Advanced Research and Development Authority
Deputy Assistant Secretary for Preparedness and Response
Department of Health and Human Services

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

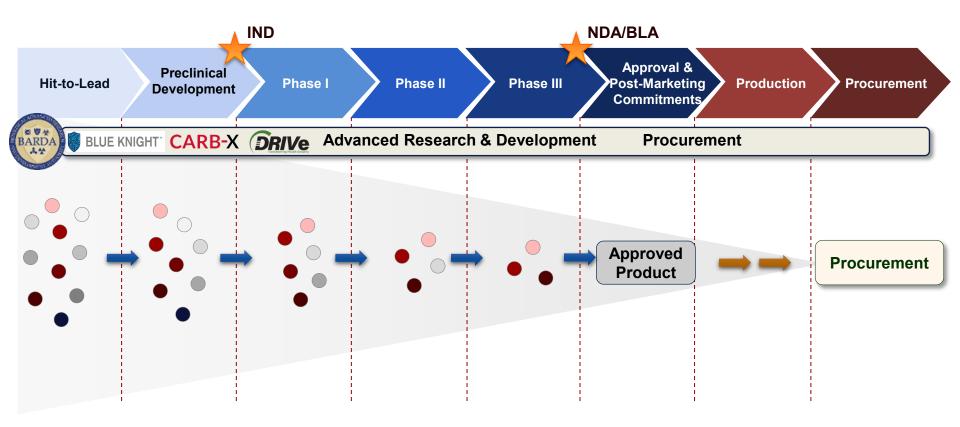
Cutting edge expertise

Facilitate partnerships

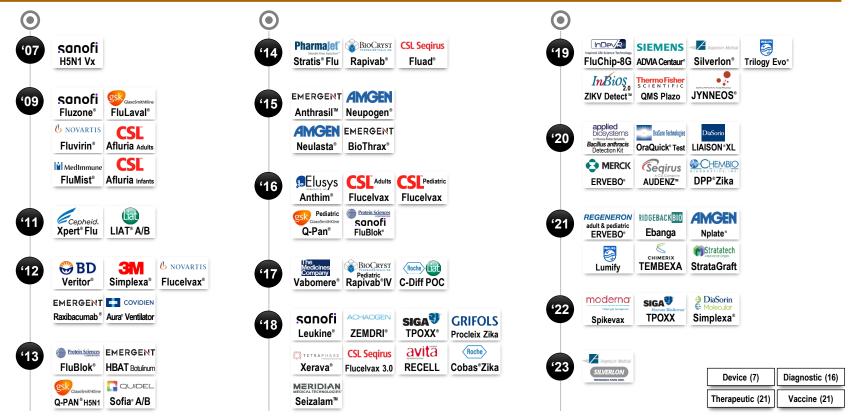
Promote innovation



BARDA's Medical Countermeasure Development Pipeline



65 FDA Approvals, Licensures, and Clearances





COVID-19 Response

146 COVID-19 Partnerships

4724

Market Research Submissions

789

CoronaWatch Meetings

FDA Approvals, Licensures, and Clearances

29

Diagnostic Test EUAs

286MDiagnostic
Test Kits
Shipped

Emergency Use
Authorizations Supported
by the USG

4 Vaccines

8 Therapeutics

105 Products Supported

COVID-19

Vaccine

Doses

918M

Delivered

653M

Administered

\$80 billion

\$47.5B \$31.4B \$.81B

vaccines therapeutics diagnostics

As of 12/01/2022



BARDA's Role in Future Pandemic Preparedness



American Pandemic Preparedness: Transforming Our Capabilities

September 2021

I. Transforming our Medical Defenses

Goal: Have the ability to rapidly make effective vaccines against any virus family.

Goal: Have a range of therapeutics suitable for any virus family, available before a pandemic or readily created during a pandemic.

Goal: Have simple, inexpensive, high-performance diagnostic tests available at large scale within weeks after the recognition of an emerging pandemic threat.

https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/03/fact-sheet-biden-administration-to-transform-capabilities-for-pandemic-preparedness/



The Challenge and Opportunity

1.2 Vaccine R&D

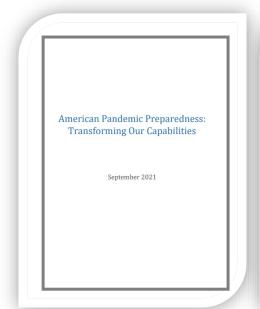
"Enable design, testing, and review of a safe and effective vaccine against any human virus within 100 days after the recognition of a potential emerging pandemic threat"

1.2 Vaccine Production

"Enable production of enough vaccine for the entire United States population within 130 days and for the global population within 200 days after its recognition as a potential emerging pandemic threat"

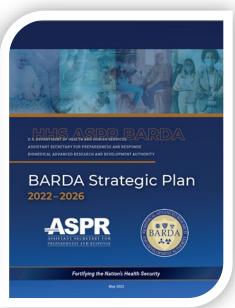
3.0 Diagnostics

"Simple, inexpensive, accurate tests for any virus available within weeks"



A Bold Vision

What is BARDA's model to implement rapid partnering and manufacturing?



Objective 2.1

"Enhance BARDA's response posture by leveraging a diverse MCM portfolio of proven technologies"



Benefits of Regulatory Approval to Response and Access



» Licensed monoclonal antibody, vaccines and diagnostics for Ebola and licensed vaccine for monkeypox, shipment occurs immediately

62 days
 62 days to update prototype COVID vaccine to bivalent formulation to include variant strain

5 months

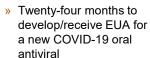
» Five months to repurpose a therapeutic that was in Phase 3 for another indication to receive EUA to treat COVID-19

10 months

» Ten months to develop/receive EUA for a new COVID-19 monoclonal antibody

11 months

» Eleven months to develop/receive EUA for a mRNA COVID-19 vaccine









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/MCM/

Program description, information, news, announcements



drive.hhs.gov

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