



Catalyzing Product Development to Respond to the Threat of Antimicrobial Resistance

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ASM/ESCMID Joint Conference on Drug Development to Meet the Challenge of AMR

Boston, Massachusetts; September 22, 2023

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



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

Our Government Partners



Biomedical Advanced Research and Development Authority (BARDA) Office of the Director

MEDICAL COUNTERMEASURES (MCM) PROGRAM

Chemical, Biological, Radiological and Nuclear (CBRN) MCMs



Influenza & Emerging Infectious Diseases (IEID)



Detection, Diagnostics, & Devices Infrastructure (DDDI)



Division of Research, Innovation, and Ventures (DRIVE)



Pharmaceutical Countermeasures Infrastructure (PCI)



MEDICAL COUNTERMEASURES SUPPORT SERVICES PROGRAM

Regulatory and Quality Affairs (RQA)



Clinical Development (DCD)



Nonclinical Development (DNCD)



CONTRACT MANAGEMENT & ACQUISITIONS AND BUSINESS PLANNING AND STRATEGY

Medical Countermeasures Development Services



Medical Countermeasures Support Services



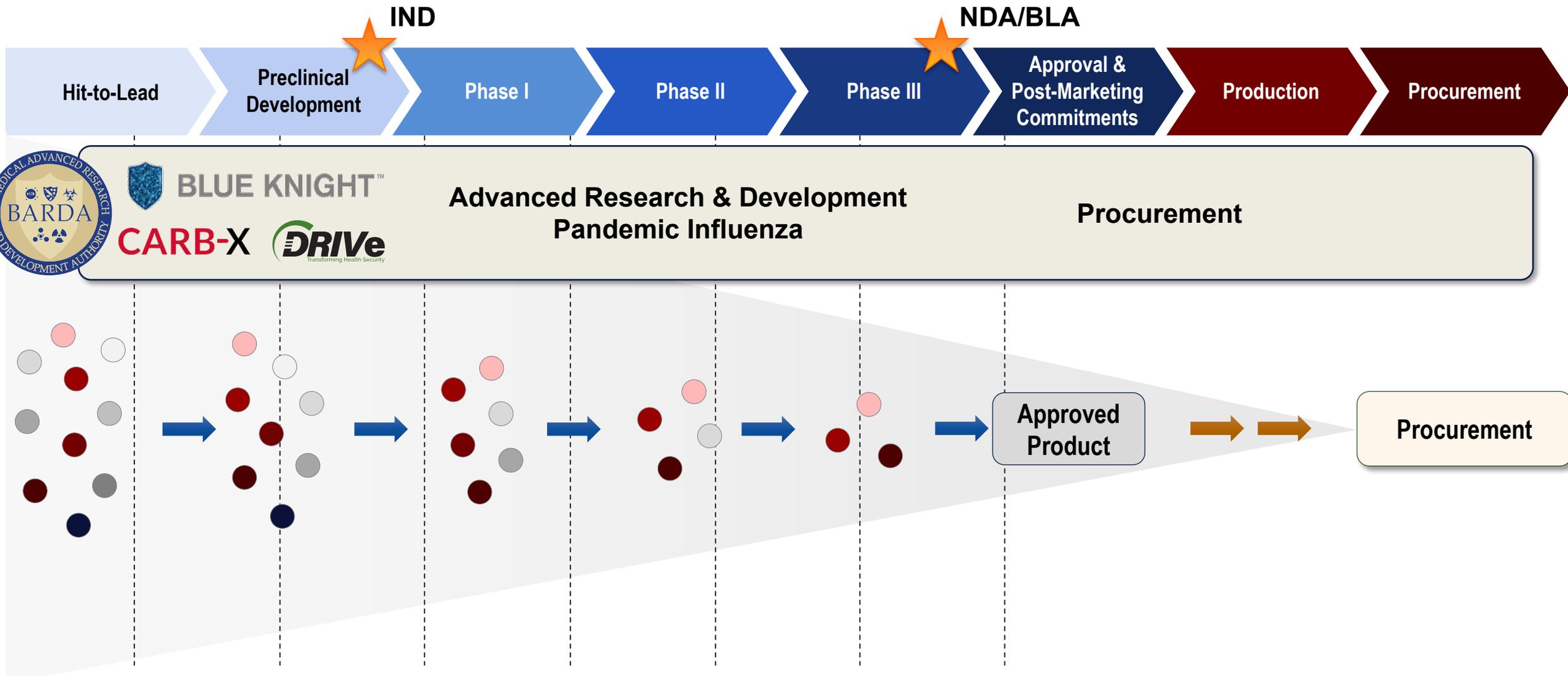
Business Operations and Compliance



DRIVE Acquisitions and Partnerships

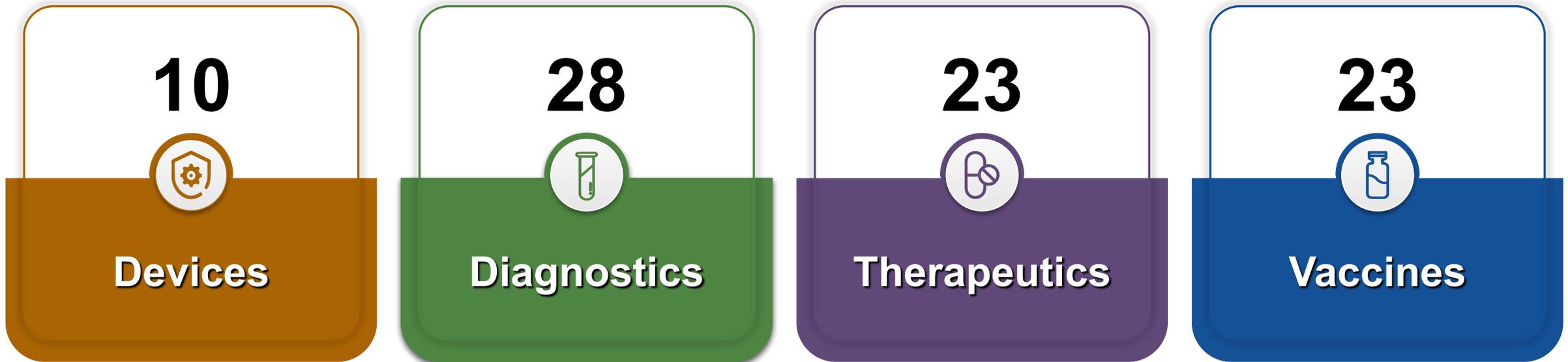


BARDA's Medical Countermeasure Development Pipeline



84 FDA Approvals, Licensures, and Clearances

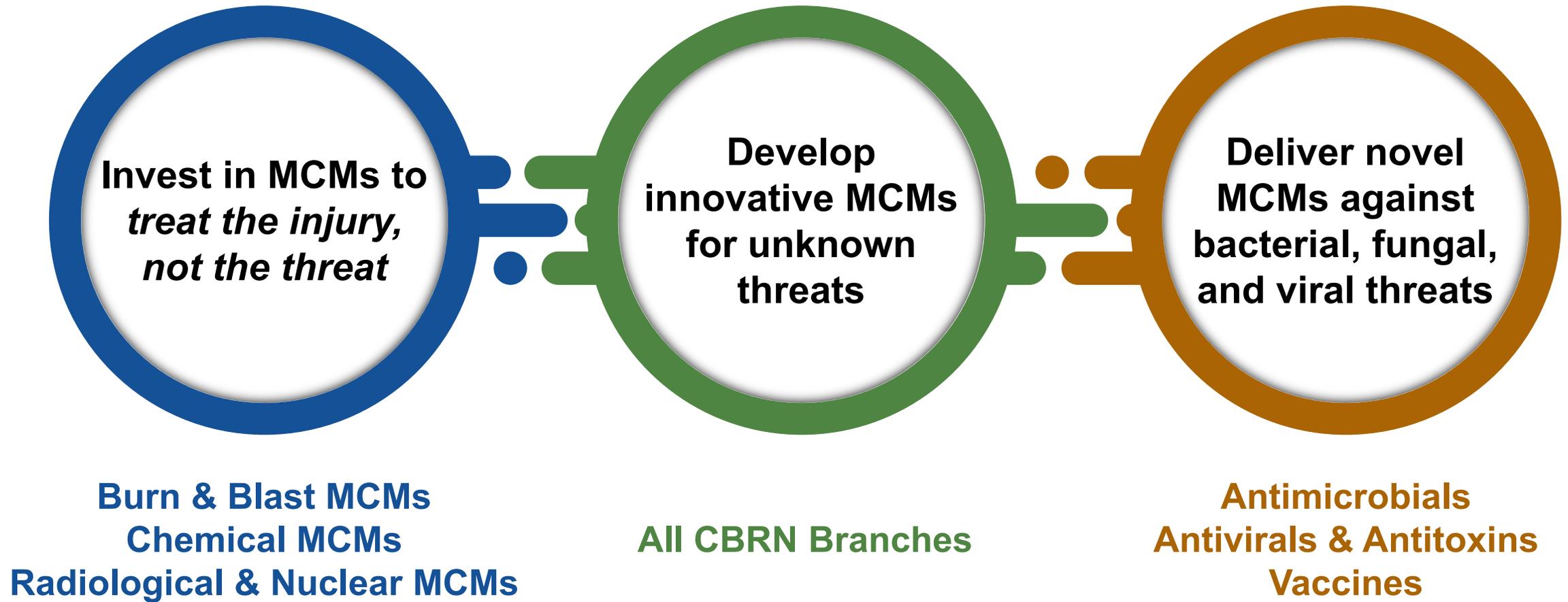
BARDA supports a diverse [portfolio](#) of medical countermeasures and these products have received a total of 84 FDA approvals, licensures, or clearances.



AND WE HAVE MORE IN THE PIPELINE

These products cut across our threat space and have been supported with annual and supplemental appropriations. Explore more about BARDA's expanding medical countermeasure portfolio by visiting our [website](#).

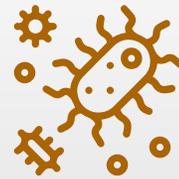
CBRN Mission: Make Available **at Least One** Medical Countermeasure (MCM) for **ALL** CBRN Material Threats



Secondary Infections during Public Health Emergencies

PUBLIC HEALTH EMERGENCY

- CBRN Incident
- Pandemic Influenza
- Emerging Infectious Disease



HOSPITALIZED PATIENTS

- More hospitalized patients
- Patients with prolonged hospital stays
- Additional patients requiring outpatient care

SECONDARY INFECTIONS

- Drug-resistant bacteria and fungi present in healthcare settings
- Increased likelihood of patients developing secondary infections that cannot be treated with available antimicrobials

EFFECTIVE ANTIMICROBIALS

- Therapeutics needed to effectively treat patients
- Diagnostic tools needed to appropriate prescribing
- Allows patients to fully recover from the emergency

The Need for Next Generation Antimicrobials



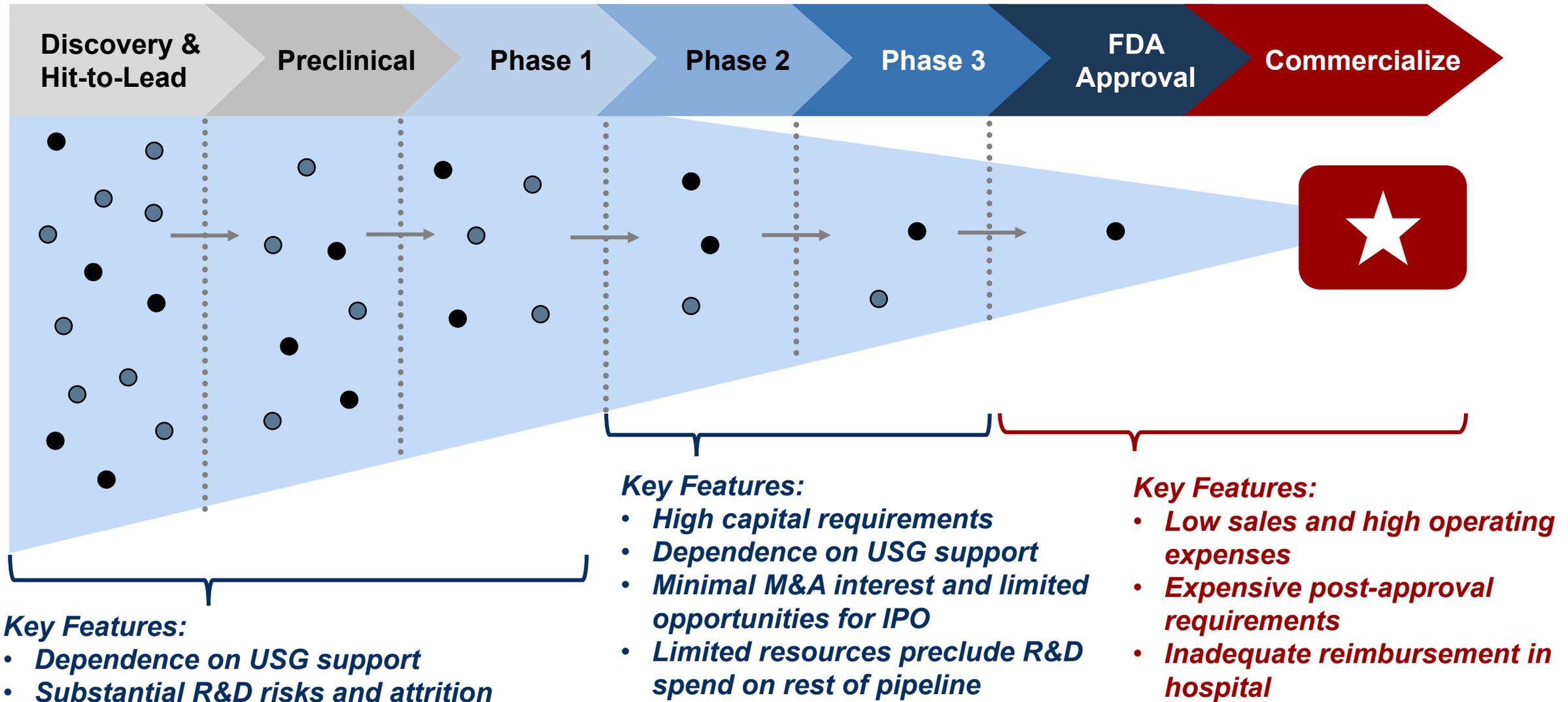
Next generation antimicrobials are critical for the treatment of increasingly common multidrug-resistant secondary infections

<https://www.bmj.com/content/379/bmj.o2731.long>

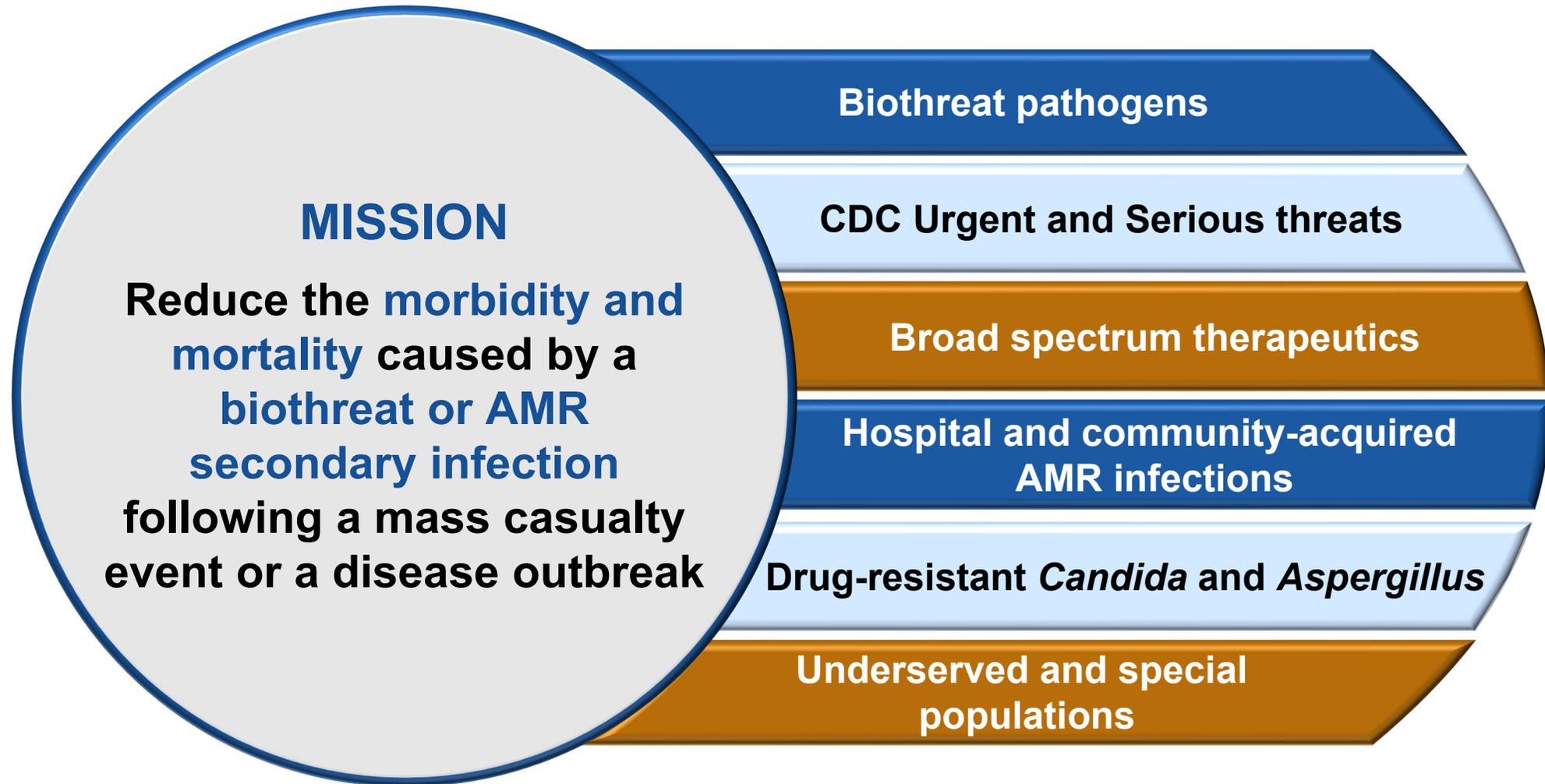
https://wwwnc.cdc.gov/eid/article/29/8/23-0567_article

[https://www.ijidonline.com/article/S1201-9712\(23\)00523-4/fulltext](https://www.ijidonline.com/article/S1201-9712(23)00523-4/fulltext)

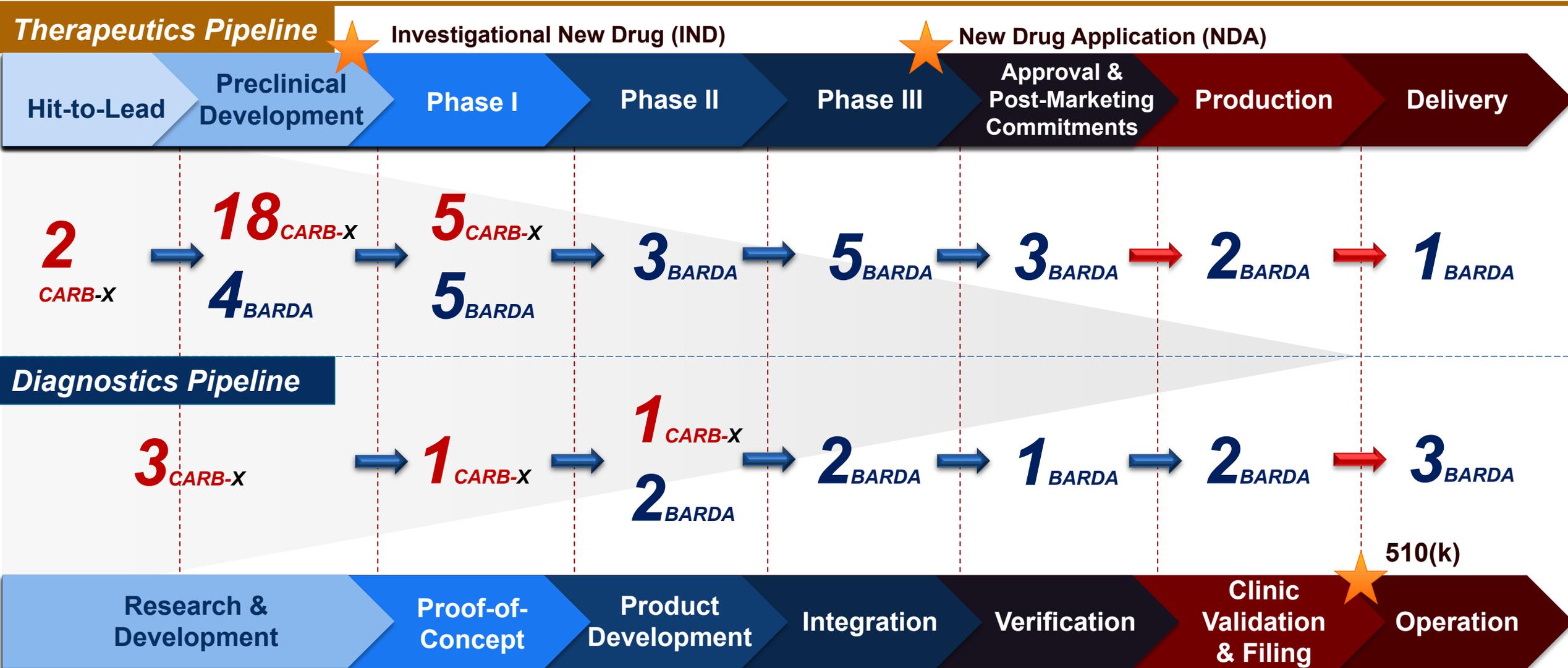
The Business Landscape for Antimicrobials



Antimicrobials Mission and Priorities



BARDA's Antimicrobial Continuum of Support



CARB-X

An Engine to Accelerate Preclinical Products into Clinical Development

29

Active Projects

4 in Phase I Trials



INDIRECT-ACTING LARGE MOLECULE ANTIBACTERIAL



CRISPR-ENGINEERED PRECISION PREVENTATIVE



NOVEL CLASS OF DIRECT-ACTING ENGINEERED PEPTIDES



GYRASE-TOPOISOMERASE INHIBITOR

14

Candidates Graduated

5

In clinical development outside CARB-X



SERES THERAPEUTICS



VEDANTA BIOSCIENCES



ITERUM Therapeutics

92

Projects

61

Therapeutics

16

Preventatives

15

Diagnostics

1 in 5 Supported Candidates Initiate Phase 1 Trials

THERAPEUTICS

14

Active

7

Graduated

PREVENTATIVES

10

Active

2

Graduated

DIAGNOSTICS

5

Active

5

Graduated

PARTNERS



Bundesministerium für Bildung und Forschung



Canada



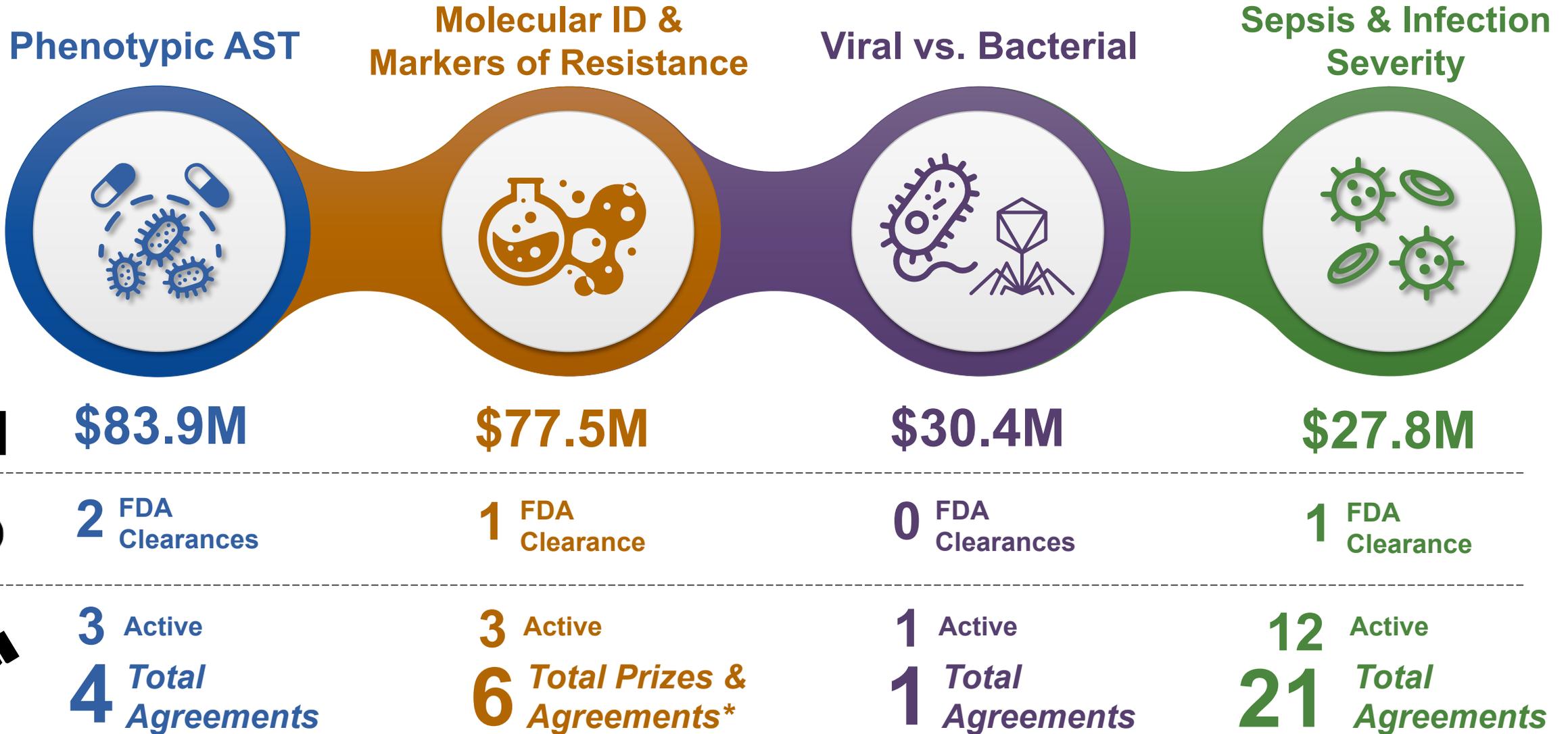
National Institute of Allergy and Infectious Diseases



BILL & MELINDA GATES foundation



BARDA AMR Diagnostics Portfolio



Therapeutics Advanced Research & Development Portfolio

as of 08/23/2023

12 Companies Actively Supported

More than **5** novel classes

Invested over **\$2B**

In Antimicrobial Product Development

3 FDA APPROVALS
2 NON-TRADITIONAL CANDIDATES

18

ARD candidates in active development

6

in Phase 3

5

in Phase 1

3

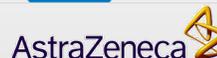
in Phase 2

4

in Preclinical development



The Medicines Company SD LLC



Majority of the CDC Urgent and Serious Priority Threats

- » Carbapenem resistant *Acinetobacter*
- » *Clostridioides difficile*
- » Carbapenem resistant *Enterobacteriaceae*
- » Drug resistant *Neisseria gonorrhoeae*
- » ESBL producing *Enterobacteriaceae*
- » Multidrug resistant *Pseudomonas aeruginosa*
- » Methicillin-resistant *Staphylococcus aureus*
- » Drug-resistant *Streptococcus pneumoniae*

New Priority: Advanced Development of Antifungals

Estimated number of US hospitalizations due to fungal infections is **~75,000/year**

Resistance to existing antifungal drugs has risen two-fold in the last two years

Secondary & opportunistic invasive fungal infections pose a significant health threat following a mass casualty incident (e.g., Rad/Nuc emergency, respiratory pandemic)



Prioritize investment towards **new classes, broad spectrum, oral/IV**

DR *Candida* species, including ***Candida auris***, & **DR *Aspergillus* species**

Requirement for MCM targeting opportunistic secondary **fungal infections following Rad/Nuc incident**

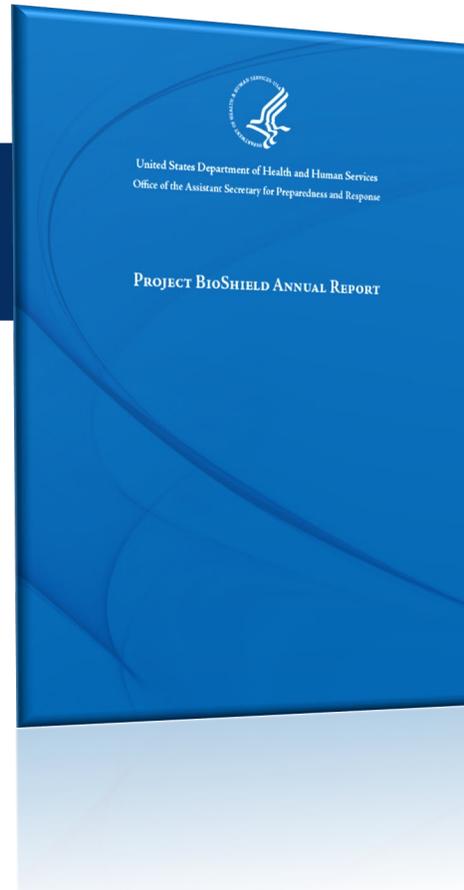
PBS: the Push that Pulls



PUSH TACTICS

Contract designed to support necessary late-stage development activities

- » Notably a Phase 3 study in a pulmonary indication to both support a biodefense indication as well as increase the commercial potential of the product



PULL TACTICS



Potential procurement of successful products

- » Provides a critical element of commercial demand for the antibiotics of interest to a market where stakeholders are concerned about the future

Expanding Health Security using Project BioShield

GOAL

Procure additional antimicrobial products to address **Biothreats and AMR infections**

- » **Biothreats** include *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, and *Burkholderia spp*
- » **AMR** secondary bacterial infections

PREPAREDNESS

Current preparedness posture does not account for new forms of drug resistance that have emerged in the **healthcare setting**

- » **Next-generation antibiotics** are needed to overcome hospital-acquired, community-acquired, or engineered drug-resistant pathogens

STRATEGY

Establish **public-private partnerships** for at least 4 new antibiotics using PBS authorities

- » Continued R&D to **expand access** to new antibiotics
- » **Bridges** capital intensive launch period & provides revenue
- » Supports **domestic manufacturing** capability
- » **Mitigates the threat of MDR secondary bacterial infections** and biothreats

Expanding Health Security using Project BioShield

NUZYRA (omadacycline)

- » FDA approved (10/2018) as once-daily IV and oral antibiotic for the treatment of adults with CABP
- » Supported activities:
 - Studies needed for a pulmonary anthrax indication
 - Post-marketing commitments, including activities needed for a pediatric indication
 - First procurement in June 2021



Cefepime-taniborbactam

- » IV antibiotic successfully completed Phase 3 cUTI under ARD, in development for HABP/VABP
- » Supported activities:
 - Studies needed for a melioidosis indication
 - Post-marketing commitments including surveillance

CABP – community-acquired bacterial pneumonia • cUTI – complicated urinary tract infection
HABP – hospital-acquired bacterial pneumonia • VABP – ventilator-associated bacterial pneumonia

Funding Priorities

Therapeutics

Diagnostics

Pathogens & Compounds

- DR *Candida* & *Aspergillus*
- First-in-class compounds
- Broad spectrum compounds

Indications

- Pneumonia
- Bloodstream infections
- Skin and wounds

Routes of Administration

- Oral & IV products

Post-Approval Support

- Onshoring manufacturing
- Pediatrics

Phenotypic AST

Decrease TTR <<24hrs, from current >4 days

Molecular Assays for AMR

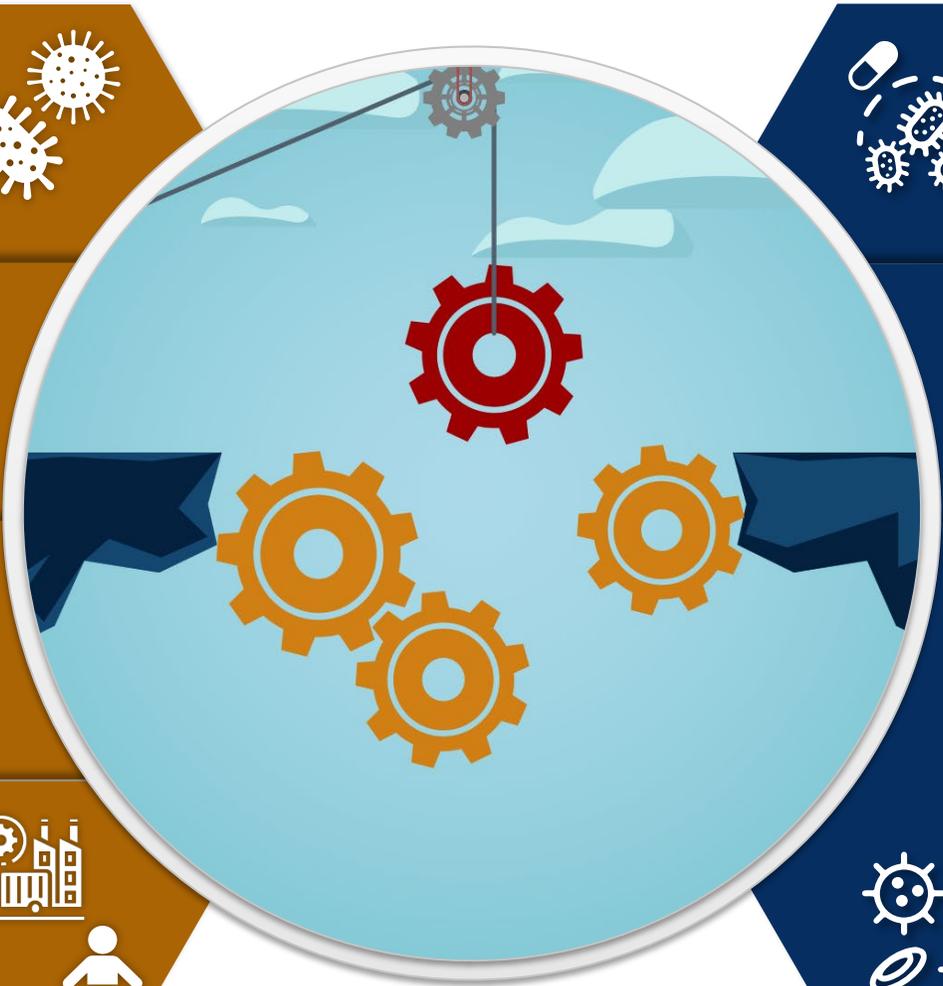
Assay development for diagnosis of AMR infection

Viral vs. Bacterial

Test at POC

Sepsis Tests

Develop first-in-class diagnostic assay for sepsis



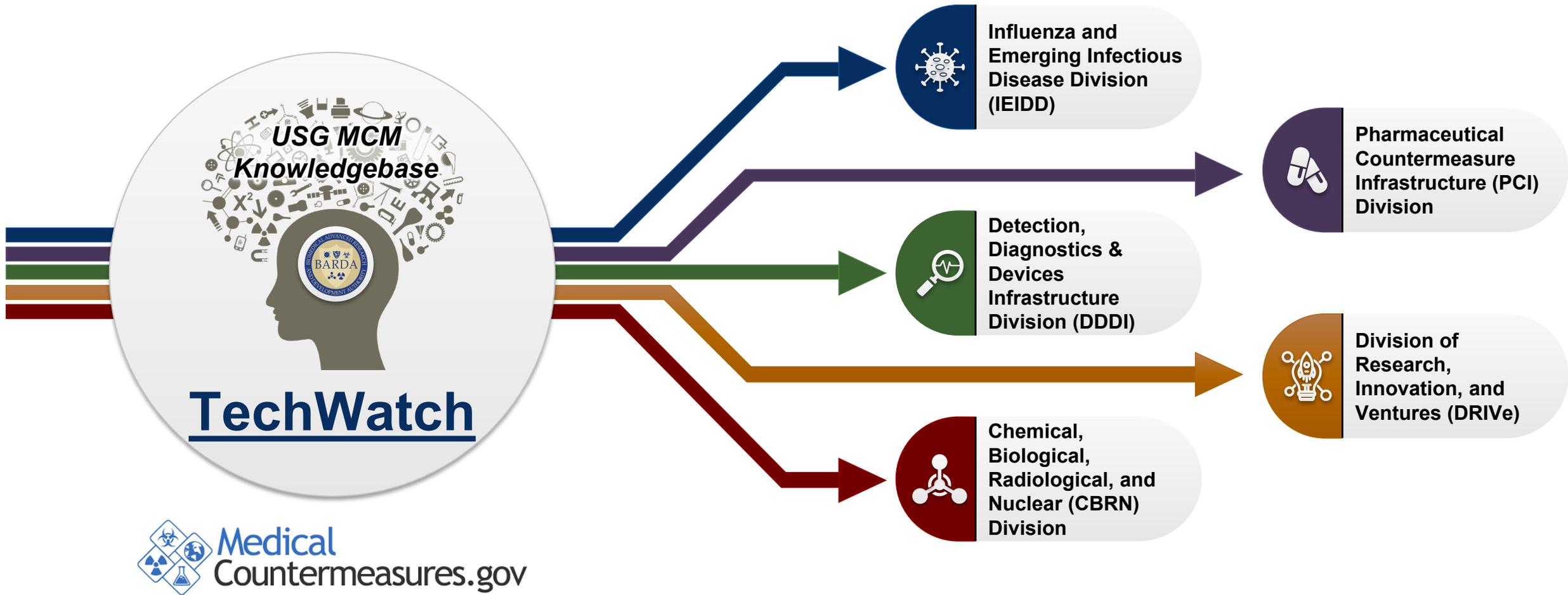
BARDA AMR: A Decade of Investment and Partnership

	<p>Invested over \$2 billion</p>		<p>3 FDA approvals 4 FDA 510(k) Clearances</p>		<p>Incentivized antimicrobial and diagnostic innovation & clinical development</p>	
<p>Established partnerships for 10+ years</p>	<p>\$</p>	<p>Supported over 150 AMR therapeutics and diagnostics</p>		<p>Emphasized unmet medical needs & CDC priority multidrug resistant organisms</p>		<p>Facilitated FDA approval to ensure availability</p>

**Partners in
Development:**



TechWatch





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



[sam.gov/](https://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



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