



# BARDA INDUSTRY DAY

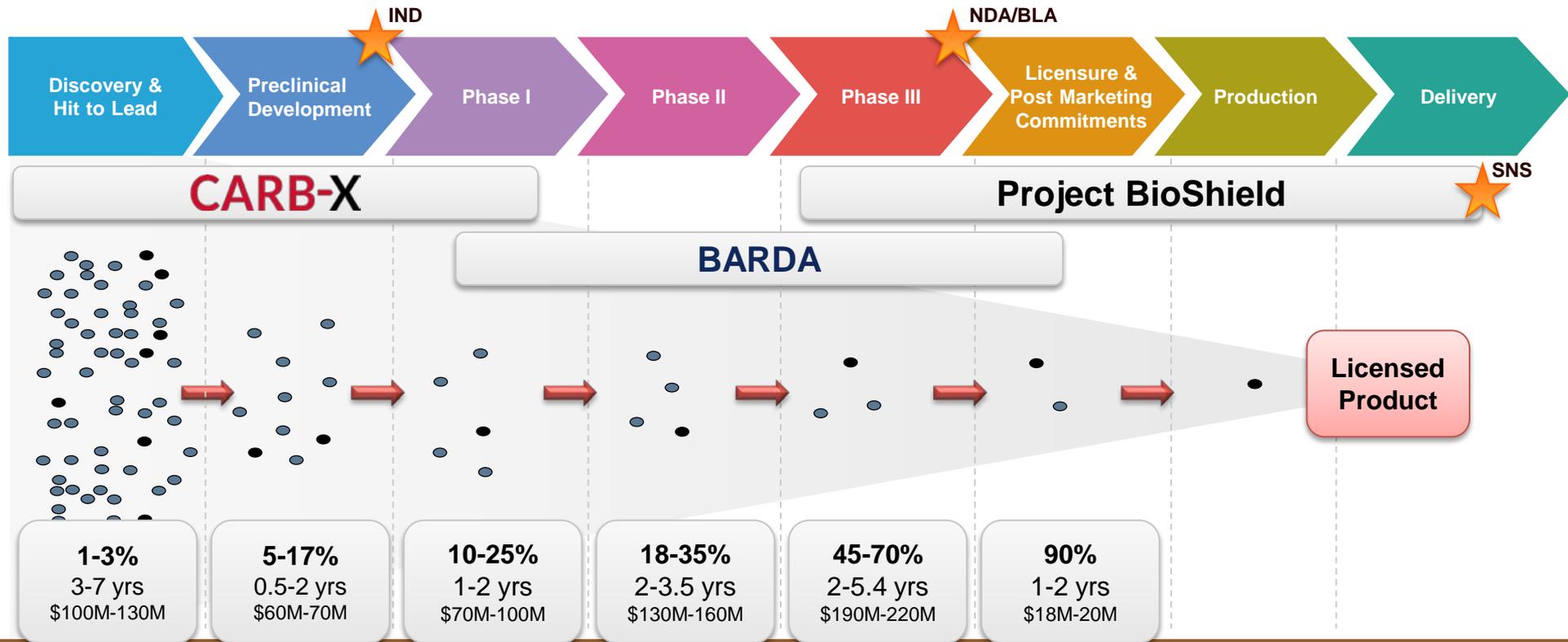
## Incentivizing Antibacterial Research and Development

Mark Albrecht, PhD  
Acting Branch Chief Antibacterial MCM  
Program  
October 29, 2018

October 29-30, 2018 | Grand Hyatt • Washington, D.C.



# BARDA Supports Advanced R&D



# BARDA's Innovation Partners

IND

NDA/BLA

Discovery & Hit to Lead

Preclinical Development

Phase I

Phase II

Phase III

Licensure & Post Marketing Commitments

Production

Delivery/ Access

CARB-X

Project BioShield

SNS

BARDA



NIH National Institute of Allergy and Infectious Diseases

Licensed Product



GARDP Global Allotopic Research & Development Partnership  
imi innovative medicines initiative



ASPR ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE



Saving Lives. Protecting Americans.

# Our Goal

***Reduce the morbidity and mortality caused by antimicrobial resistant bacterial infections following a CBRN incident, influenza pandemic, emerging infectious disease outbreak, or any other public health emergency***



Incentivizing industry efforts by providing financial support



Accelerating product development by providing partners with access to internal core services



Reducing technical risk during product development by providing SME support during all phases and in all areas of drug development



Facilitating interactions with interagency partners interested in providing additional support and R&D services to product sponsors



# Our Priorities

## Drug Class

- **Unprecedented**
  - Novel Target
  - Novel Chemistry
- **Precedented**
  - Reduced AR
- **Nontraditional Therapies**
  - mAbs, phage, host-based
- **Prevention/interdiction**
  - Vaccines
  - Microbiome

## Biothreat

- *B. pseudomallei*
- *B. mallei*
- *F. tularensis*
- *Y. pestis*
- *B. Anthracis*
- MDR *B. Anthracis*
- Genetically engineered biothreats

## Antibiotic Resistance

- CR *Enterobacteriaceae*
- MDR *A. baumannii*
- MDR *P. aeruginosa*
- ESBL *Enterobacteriaceae*
- *C. difficile*
- DR *N. gonorrhoea*
- VR *Enterococcus*
- MR *S. aureus*
- DR *S. pneumoniae*

## ConOps

- HABP/VABP
- CABP
- BSI
  
- Oral delivery

[www.fbo.gov](http://www.fbo.gov) BAA-18-100-SOL-00003



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# Our Partners



The Medicines Company  
SD LLC



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# BARDA's Antibacterial Pipeline

SPONSOR	COMPOUND	DEVELOPMENT STAGE				
		PRECLINICAL	PHASE I	PHASE II	PHASE III	APPROVED
Rempex/Melinta (formerly MDCO)	Vabomere	BL/BLI Combination cUTI/AP, CRE (Biothreat Relevance: melioidosis & glanders)				
Achaogen	Zemdri	Next-Generation Aminoglycoside cUTI/AP, CRE (Biothreat Relevance: plague & tularemia)				
CUBRC/Tetraphase	Xerava	Fully Synthetic Tetracycline cIAI, MDR (Biothreat Relevance: anthrax, plague, & tularemia)				
Melinta (formerly Cempra)	Solithromycin	Next-Generation Fluoroketolide CABP, GC (Biothreat Relevance: anthrax, & tularemia)				
AtoxBio	Reltecimod	Host-Directed Immune Modulator NSTI				
Basilea	Ceftobiprole	Cephalosporin ABSSSI, SAB, CABP (Biothreat Relevance: plague, & tularemia)				
GlaxoSmithKline	Gepotidacin	Topo II Inhibitor CABP, GC, uUTI (Biothreat Relevance: plague, tularemia, & anthrax)				
Pfizer	Aztreonam-Avibactam	BL/BLI Combination cIAI, HAP/VAP, MDR gram neg pathogens (Biothreat Relevance: plague)				
Hoffman-La Roche	Nacubactam	Broad Spectrum BLI				
Spero	Tebipenem	Oral BL cUTI (Biothreat Relevance: anthrax, melioidosis, & plague)				
Summit	Ridnilazole	Novel 1st in Class Oral Antibiotic C. Diff				
GlaxoSmithKline	GSK-680	Topo II Inhibitor cUTI, cIAI, HABP/VABP				
Achaogen	C-Scape	Oral BL/BLI Combination cUTI/AP (Biothreat Relevance: plague & tularemia)				
MDCO	ORlvance	Broad Spectrum BLI				
MDCO	OMNlvance	Broad Spectrum BLI				
MDCO	Novel Polymyxin	Polymyxin				



# Successes From the Past Year



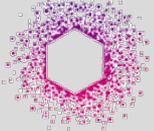
**VABOMERE™**  
meropenem and vaborbactam  
for injection (4 g)

*Treats complicated  
urinary tract infections  
and kidney infections*



**ZEMDRI™**  
(plazomicin) Injection

*Treats complicated  
urinary tract infections  
and kidney infections*



**XERAVA™**  
(eravacycline) for injection

*Treats complicated  
intra-abdominal  
infections*

# BARDA Broad Agency Announcement

**BAA-18-100-SOL-00003**

**Area of Interest #3: Antimicrobial Therapeutics**

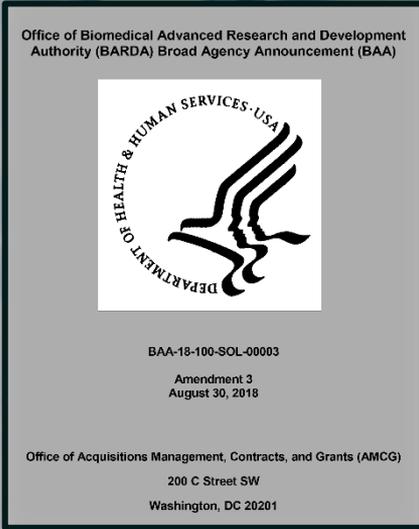
Develop and test antibacterial products that are in development for post-exposure prophylaxis (PEP) and treatment efficacy against one or more of the following biodefense threat agents: *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, *Burkholderia mallei*, and *Burkholderia pseudomallei*.

Develop new small molecule drugs that treat or prevent resistant bacterial infections either alone or in combination with other therapeutics

Develop non-traditional antibacterial therapeutics that treat or prevent resistant infections

Products should possess activity against one or more of the pathogens categorized as serious, urgent, or concerning threats in the September 2013 CDC Report

<https://www.fbo.gov/> (“FedBizOps”)



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# Qualities that Strengthen a Proposal

Candidates demonstrating substantial improvements over existing antimicrobial products are of greatest interest including novel first in class compounds with unprecedented mechanisms of action and candidates with in an existing class



Is the product differentiated from existing products?

Does product address an unmet medical need?

Does the product fill a portfolio gap? (Drug class, pathogen spectrum, indication, etc.)

Greater technological advancement of the candidate: the more advanced the more competitive

Regulatory feasibility: FDA correspondence regarding the development plan

Is the development approach sound?

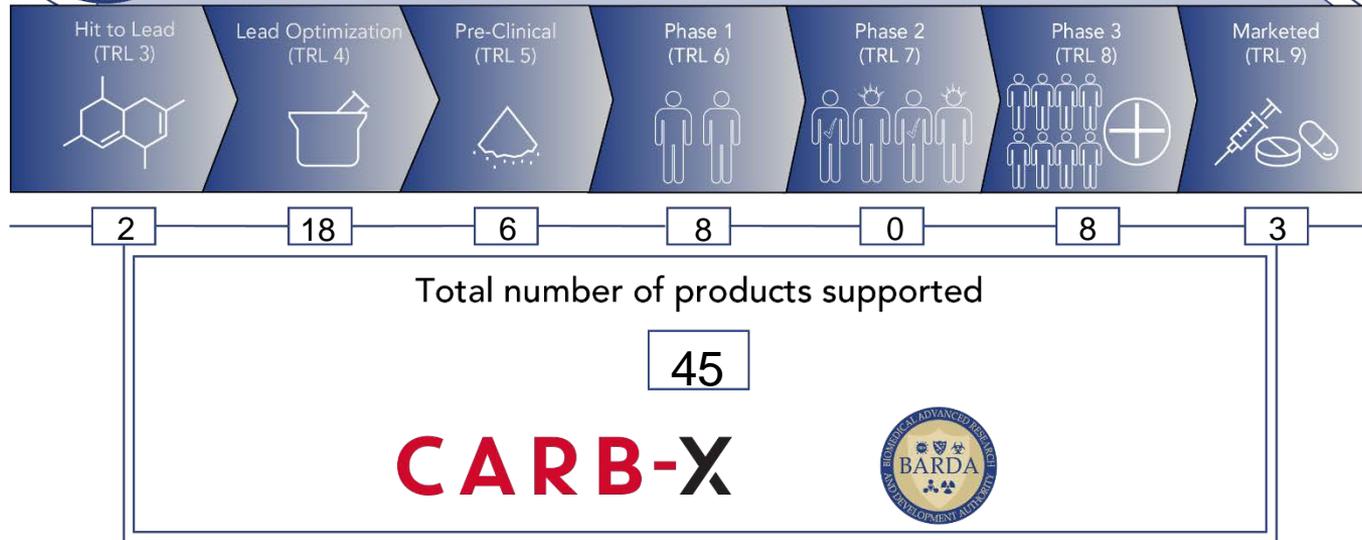
Special populations

Cost sharing

# CARB-X & BARDA's Antibacterial Pipeline



*Investing \$192 million in FY 2018 through Novel Public Private Partnerships to support a Portfolio of Antibacterial Products to repopulate the Antibacterial Pipeline*



Updated Sept 18, 2018 (Diagnostics product not shown)

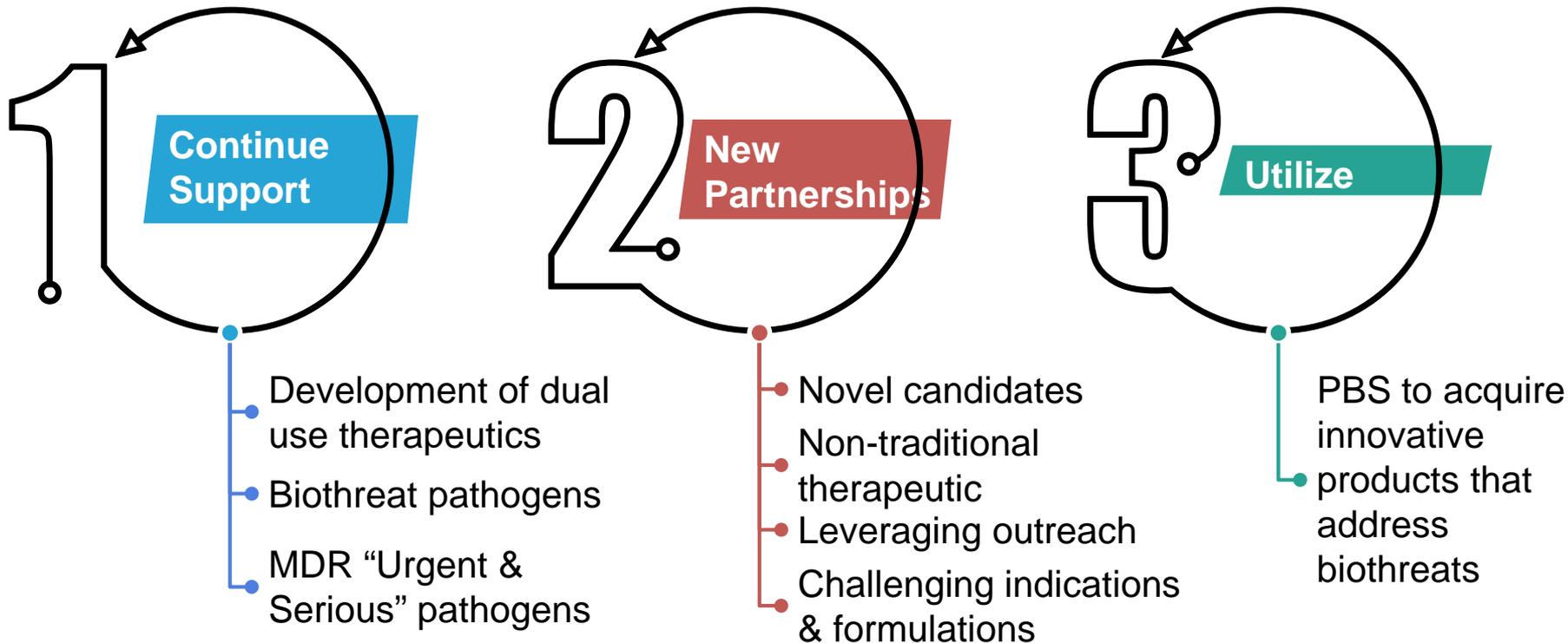


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# Continue our momentum



# How to contact BARDA



Medical  
Countermeasures.gov

[medicalcountermeasures.gov/home.aspx](https://www.mediccountermeasures.gov/home.aspx)

Portal to BARDA: **Register to request a TechWatch meeting!**



[www.fbo.gov/](http://www.fbo.gov/)  
("FedBizOpps")

Official announcements and info for all government contract solicitations



<https://www.phe.gov/about/BARDA/Pages/default.aspx>

Program description, information, news, announcements



[www.drive.hhs.gov](http://www.drive.hhs.gov)

*DRIVE questions*

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