



**ASPR**

# **Catalyzing Antibiotic Development**

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**PACCARB Public Meeting**

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**UNCLASSIFIED//For Public Distribution**

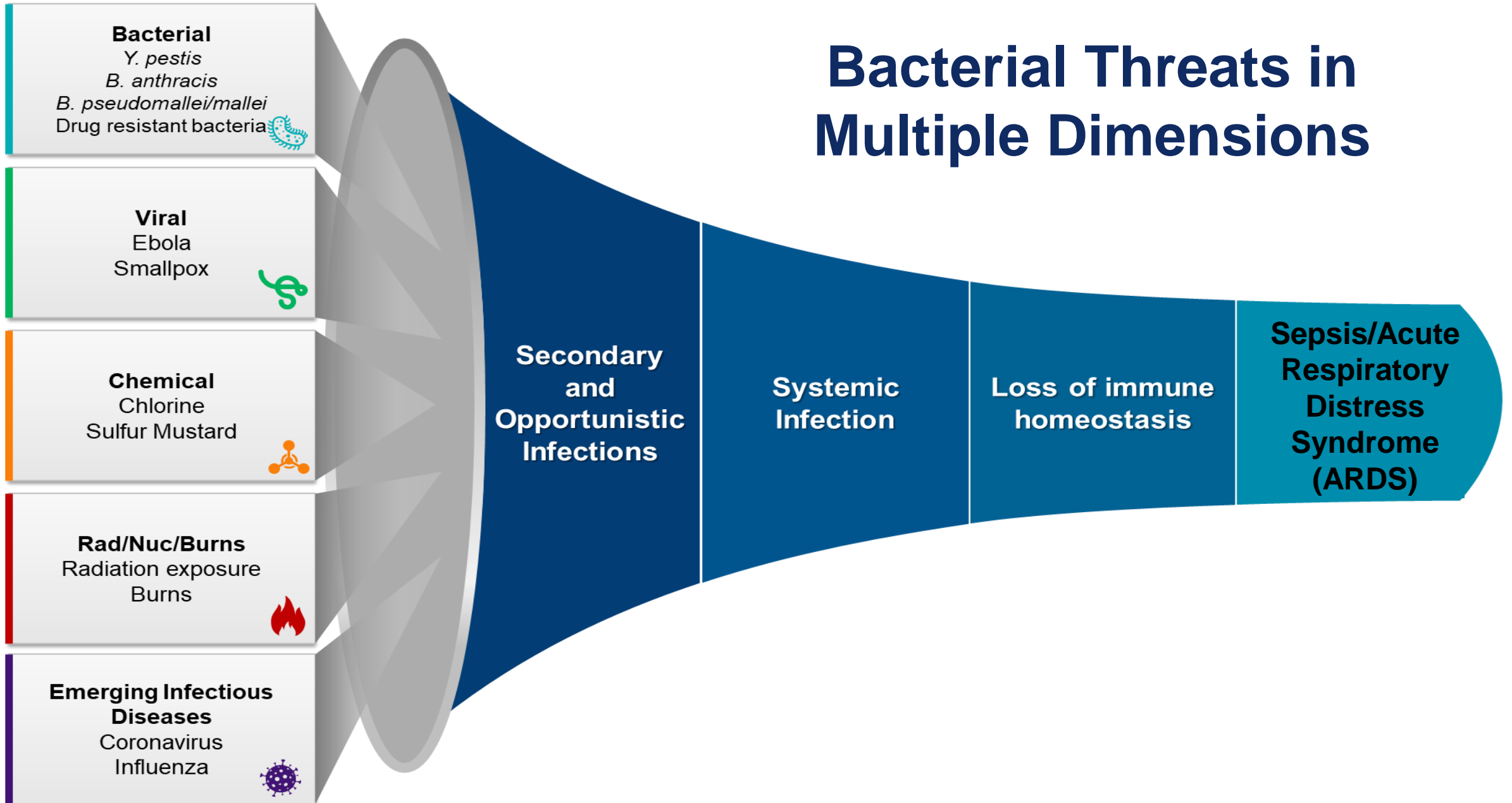


# ASPR Mission

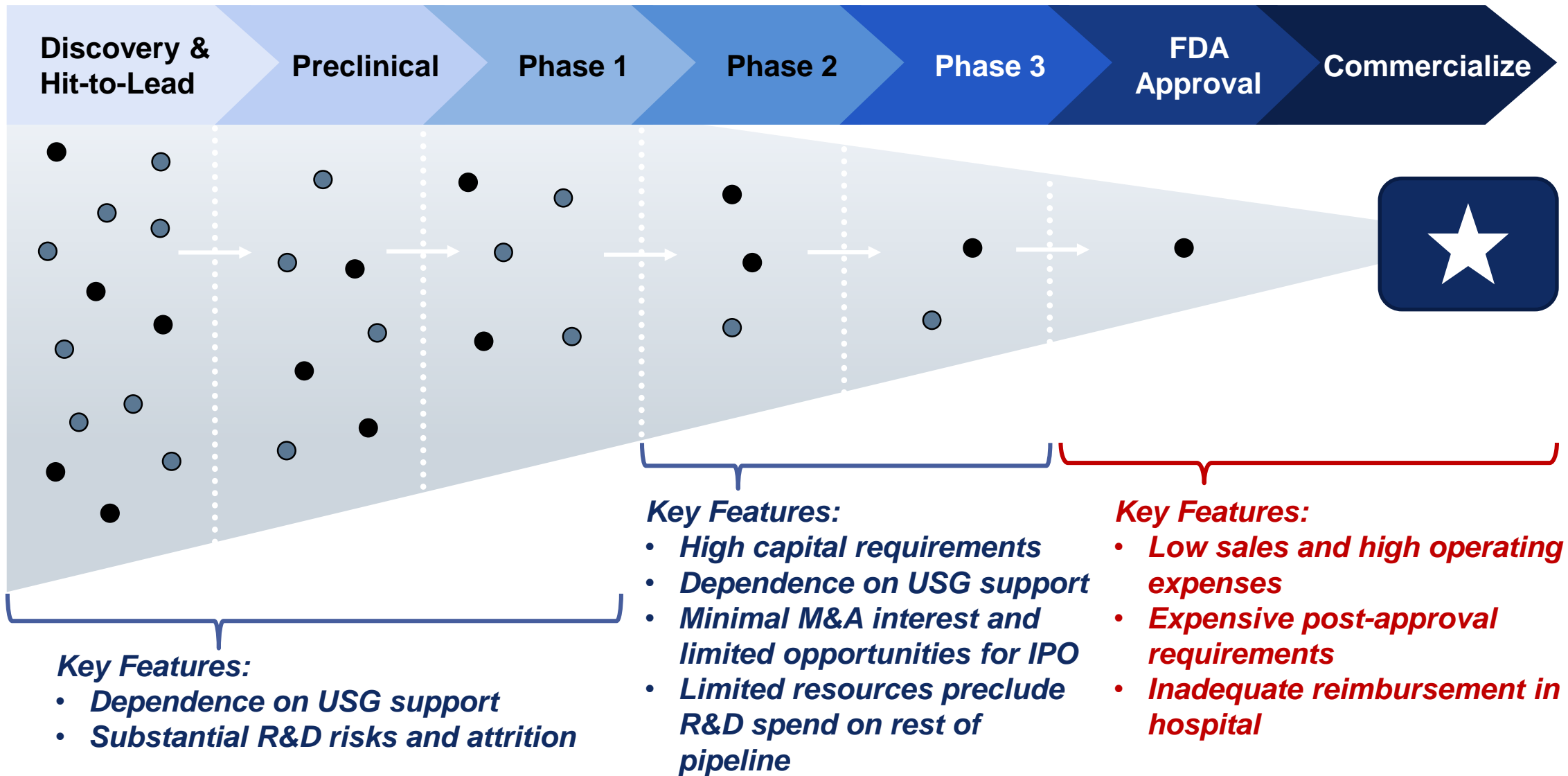




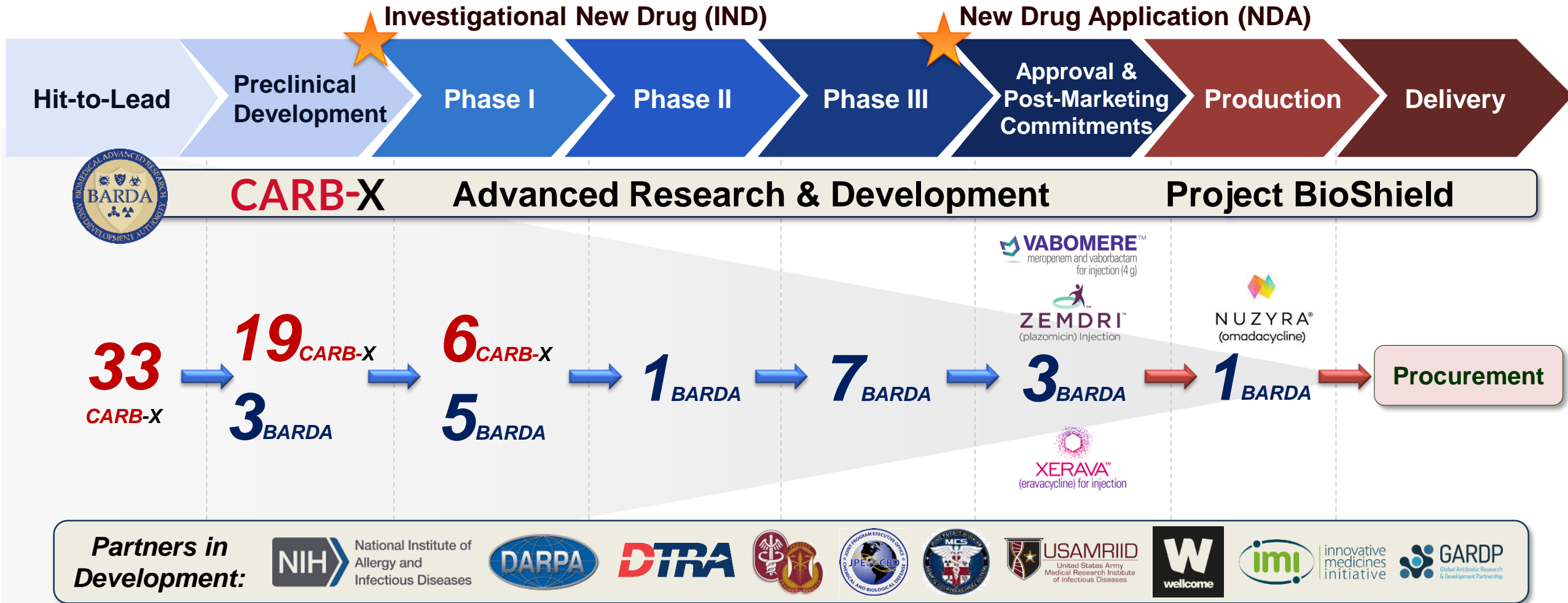
# Bacterial Threats in Multiple Dimensions



# The Business Landscape for Antibiotics

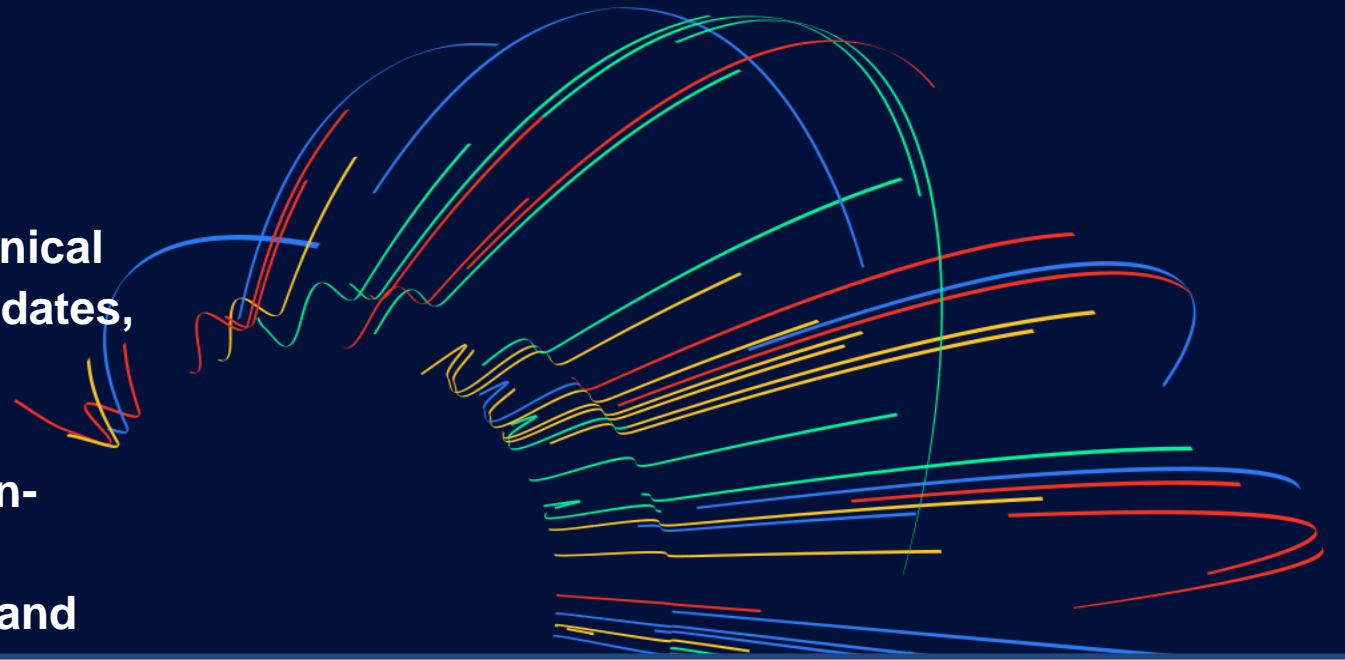


# A Continuum of Support



# NEXT-X

- **BARDA is committed to preclinical and early clinical development of a pipeline of antibacterial candidates, therapeutics, and diagnostics with the ability to counter the threat of MDROs.**
- **The next generation accelerator will provide non-dilutive financing as well as wrap-around R&D support in the form of subject matter expertise and business mentoring.**



## Highlights

- **Other Transactional Agreement**
- **10-year period of performance**
- **Targeting a funding ceiling greater than previous award with 1:1 matching funds**
- **Sustainability planning**

## Improvements Under NEXT-X

- + **Accelerator will develop a strategy that is the basis for all investments**
- + **Wrap-around support (technical, regulatory, and business) will be provided to product developers**
- + **A collective pool of funds can be used to support the majority of the portfolio's projects, with options for targeted investments that meet individual funders' needs**
- + **Requirement for annual plan that outlines realistic opportunities for post-accelerator funding**

# Top AR&D Priorities for the Future

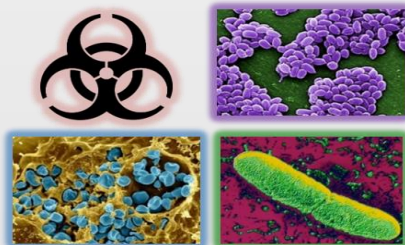
## AMR

- Hospital Acquired and Community Acquired drug-resistant infections
- Secondary/opportunistic infections
- CDC urgent and serious threats
- Unmet medical needs



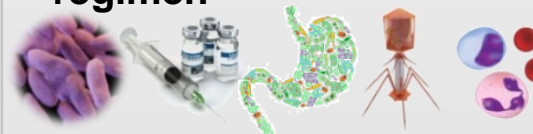
## BIOTHREATS

- (MDR) *Bacillus anthracis*
- *Burkholderia pseudomallei*
- *Burkholderia mallei*
- *Francisella tularensis*
- *Yersinia pestis*



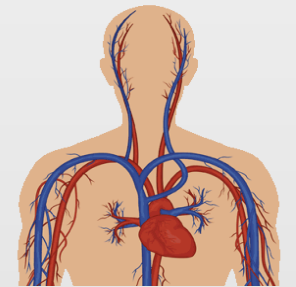
## INNOVATION

- First-in-class compounds
- Novel mechanisms of action
- Non-traditional modalities and compounds
- Significant improvement over other similarly marketed products
- Improved formulation or alternate delivery regimen



## INDICATIONS

- Clinically differentiated from approved antimicrobials
  - HABP/VABP
  - CABP
  - BSI
- Underserved/special populations (e.g., pediatrics)



# Expanding Health Security using Project BioShield

## 4 by 30 Initiative

Augment the makeup of the antibacterial cache to address **AMR and Biothreats**

- **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 **4** new antibiotics using PBS authorities

- **Bridges** capital intensive launch period & provides revenue
- **Maintains** access to new antibiotics
- **Sustains** and **expands** U.S. industrial base
- **Mitigates** the threat of MDR secondary bacterial infections and biothreats





# Nuzyra: Expanding Our Preparedness Posture

## Nuzyra (Omadacycline)

- FDA approved (10/2018) as once-daily IV and oral antibiotic for the treatment of adults with CABP
- PBS supports:
  - Studies needed for a pulmonary anthrax indication
  - Post-marketing commitments that include development and approval for a pediatric indication
- Procurement supports our preparedness posture and maintains access to omadacycline



NUZYRA®  
(omadacycline)



**PBS funding is just one tool to support late-stage development,  
market challenges still exist**



[medicalcountermeasures.gov](https://www.medicalcountermeasures.gov)  
*Portal to BARDA: Register to request a TechWatch meeting!*



[beta.sam.gov/](https://beta.sam.gov/)  
*Official announcements and info for all government contract solicitations*



[phe.gov/BARDA](https://phe.gov/BARDA)  
*Program description, information, news, announcements*



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