

National Institute of Allergy and Infectious Diseases

FDA Workshop: Advancing Animal Models for
Antibacterial Drug Development

Preclinical Services at NIAID

March 5, 2020

NIAID



National Institute of
Allergy and
Infectious Diseases

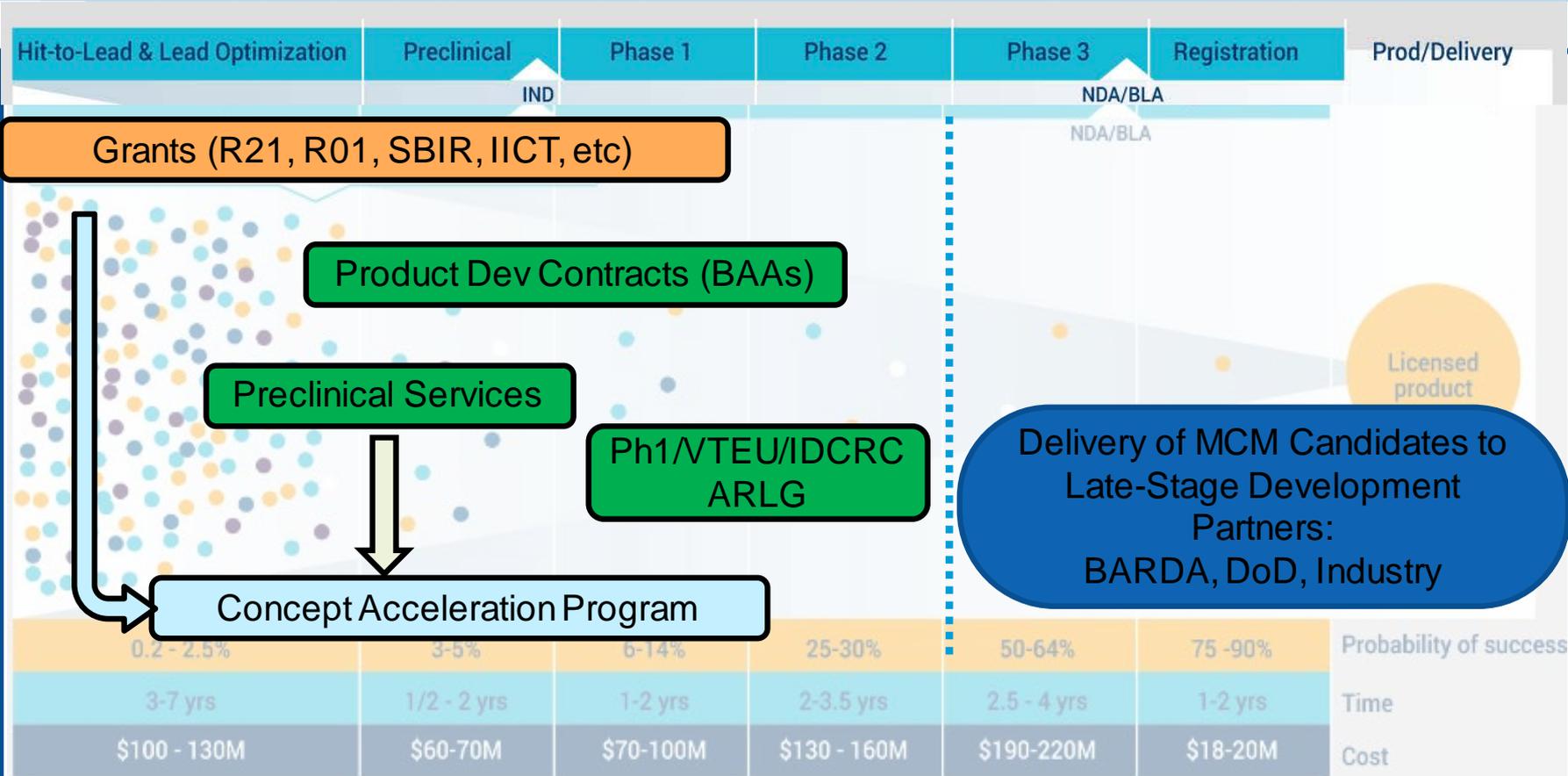
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Translational Research, Division of Microbiology & Infectious Diseases

NIAID Mission:

Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases

DMID Provides Support to Reduce Product Development Risk

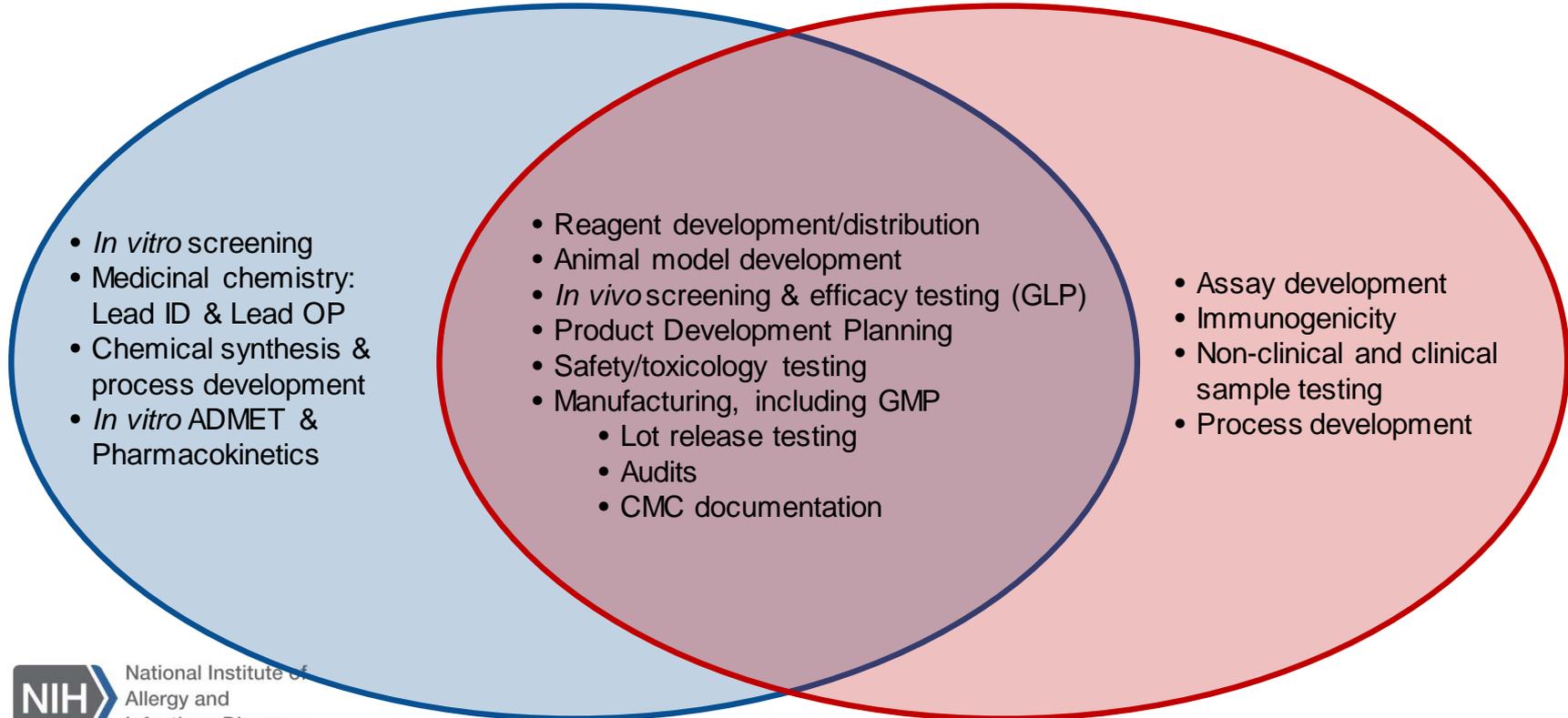


What do Preclinical Services Provide?



- Lower the risk for developers/encourage scientists to develop products that can be used to reduce the burden of infectious diseases
- Expertise/capability in product development
- Help move promising discoveries along the product development pathway
- Gap-filling, not intended as full development program
- Agreements assure confidentiality and maintain intellectual property (IP) of product developer

Therapeutic and Vaccine Preclinical Services are available to product developers



Animal models of bacterial infections that are available for testing candidate therapeutics



■ ESKAPE Pathogens

- 24 hour thigh or lung infection (all ESKAPEs including FDA/CDC strains)
 - PK/PD baselining in thigh infection with ceftazidime, levofloxacin and colistin
- Peritonitis (ESKPE)
- Ascending UTI (*K. pneumoniae* & *E. coli*)
- 120 hour lung infection (*P. aeruginosa*)
- Chronic lung infection representing CF (*P. aeruginosa* & *S. aureus*)
- Chronic infection in CF



■ *N. gonorrhoeae* infection



■ *C. difficile* infection

BEI resources is available to help investigators share strains and access reagents

www.beiresources.org

be i RESOURCES

SUPPORTING INFECTIOUS DISEASE RESEARCH

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Catalog Search Choose a Resource Choose an Organism

Catalog » Antimicrobial Search

Antimicrobial Search

Search Filters

Acinetobacter baumannii Cefepime Drug Resistance Clear All Filters

Enter Keywords or Item Number: Search within Results

Results

Showing 1 to 12 of 12 Results

NR-9667 <i>Acinetobacter baumannii</i> H72721 Bacteria	In Stock	BEI Level 2			
Drug Information					
NR-13374 <i>Acinetobacter baumannii</i> Isolate 1 Bacteria	In Stock	BEI Level 2			
Drug Information					

NIAID is a funder of CARB-X, a global public-private partnership supporting great science to fight drug-resistant bacteria

CARB-X FUNDING >\$550 million 2016-2021

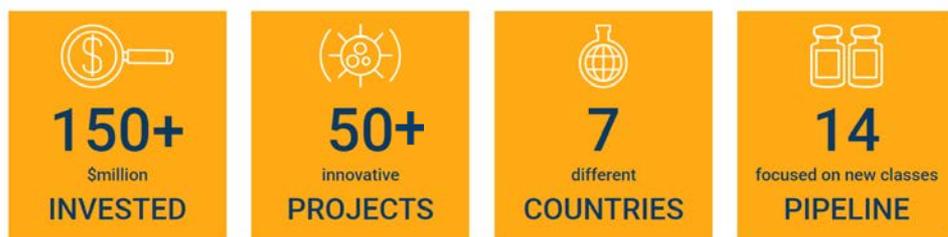
Combating Antibiotic Resistant Bacteria



BILL & MELINDA GATES foundation

PORTFOLIO of Drugs, Vaccines, and Diagnostics Projects (Hit-to-Lead through Ph1):

Since July 2016



NIAID provides up to \$50M in in-kind support through **preclinical services (PCS)** and **technical expertise** to assist product developers in the CARB-X program



DMID has provided substantial support for many CARB-X projects

59
CARB-X
projects
(including 6
graduates)

Pre-award NIAID
support, in the form of
grants, PCS, or
PD contracts:

32 CARB-X projects

Post-award PCS
Support:

36 CARB-X projects
>180 studies

Please Contact Us!

- Your Program Officer
 - OR -
- In Vitro Assessment of Antimicrobial Activity, invitro@mail.nih.gov
- Preclinical Models of Infectious Diseases, pcmid@mail.nih.gov
- Interventional Agents, pcs.ia@mail.nih.gov
- Biopharmaceutical Products, pcs.bp@mail.nih.gov
- Vaccine Manufacturing, pcs.vm@mail.nih.gov
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