FDA Workshop: Advancing Animal Models for Antibacterial Drug Development

Preclinical Services at NIAID

March 5, 2020
NIAID Mission:

Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases
DMID Provides Support to Reduce Product Development Risk

Grants (R21, R01, SBIR, IICT, etc)

Product Dev Contracts (BAAs)

Preclinical Services

Ph1/VTEU/IDCRC ARLG

Concept Acceleration Program

Delivery of MCM Candidates to Late-Stage Development Partners: BARDA, DoD, Industry
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

- **In vitro** screening
- Medicinal chemistry: Lead ID & Lead OP
- Chemical synthesis & process development
- **In vitro** ADMET & Pharmacokinetics

- Reagent development/distribution
- Animal model development
- **In vivo** screening & efficacy testing (GLP)
- Product Development Planning
- Safety/toxicology testing
- Manufacturing, including GMP
  - Lot release testing
  - Audits
  - CMC documentation

- Assay development
- Immunogenicity
- Non-clinical and clinical sample testing
- Process development
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
NIAID is a funder of CARB-X, a global public-private partnership supporting great science to fight drug-resistant bacteria.

**FUNDING**  >$550 million 2016-2021

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.

**PORTFOLIO** of Drugs, Vaccines, and Diagnostics Projects (Hit-to-Lead through Ph1):
Since July 2016

- **150+** Smillion INVESTED
- **50+** Innovative PROJECTS
- **7** different COUNTRIES
- **14** focused on new classes PIPELINE
DMID has provided substantial support for many CARB-X projects

- **59** CARB-X projects (including 6 graduates)
- **32** CARB-X projects with pre-award NIAID support, in the form of grants, PCS, or PD contracts
- **36** CARB-X projects with post-award PCS support
- **>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
- Vaccine Testing, pcs.vt@mail.nih.gov