NIAID Resources for Research and Development of Therapeutics and Animal Models

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FDA Workshop ‘Current State and Further Development of Animal Models of Serious Infections Caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa*’
March 1, 2017
NIAID Antibacterial Resistance Program is Aligned with National Strategy for CARB
Overlapping Funding Mechanisms Lower Product Development Risk

- Basic
- Translational
- Clinical
- (Product Development)

Grants
SBIR
Cooperative Agreements
Contracts

NIAID Scientific Activities

Preclinical and Clinical Services

Commercial Development Activities

Licensed Products

Phase 4

Phase 2
NIAID Funding Opportunities

- **Grants**
  - NIH or NIAID Funding Opportunity Announcements
  - R01, R21, R03, partnerships, Small Business (SBRI/STTR) grants
- **Contracts**
  - Announced on FedBizOpps [https://www.fbo.gov/](https://www.fbo.gov/)
    - RFPs and BAAs
    - Up to 5-year contracts with milestone-based periods of performance
      - Preclinical lead optimization to clinical candidate
      - Preclinical candidate development, Phase 1 (Phase 2) trials
      - Preclinical and clinical development services
- For updates on Funding Opportunities, subscribe to [NIAID Funding News](https://www.niaid.nih.gov/grants-contracts/funding-news-2017)
- **NIAID Council-cleared concepts** – information on upcoming potential opportunities
  [https://www.niaid.nih.gov/grants-contracts/potential-opportunities](https://www.niaid.nih.gov/grants-contracts/potential-opportunities)
# Product Development Services

## Therapeutics

- **In Vitro Assessment of Antimicrobial Activity**
  - Interventional Agent
  - Biopharmaceutical Products

## Vaccines

- **Testing**
  - Chemistry, Manufacturing, and Controls (CMC) Documentation for IND
  - Manufacturing

## Clinical

- Phase I Units
- Vaccine Testing and Evaluation Units (VTEUs)

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**Animal Models**

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<th>Animal Models</th>
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<tr>
<td><img src="image1.png" alt="Animal Model 1" /></td>
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<td><img src="image2.png" alt="Animal Model 2" /></td>
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<td><img src="image3.png" alt="Animal Model 3" /></td>
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**NIH**

National Institute of Allergy and Infectious Diseases

**ARLG**

Antibacterial Resistance Leadership Group
Gap-filling Microbiology and Infectious Diseases Resources

• **Purpose**
  • To provide critical, gap-filling information needed to move a product forward. Not intended as the sole source of development funds.

• **Eligibility**
  • Open to academia, not-for-profit organizations, industry, and government
  • National/international sponsors
  • Don’t need to have current NIH funding

• **Assurances**
  • Confidentiality agreements, MTAs
Microbiology and Infectious Diseases Resources

The Division of Microbiology and Infectious Diseases supports a comprehensive set of resources for researchers. Their purpose is to facilitate the preclinical and clinical research needed to translate the ideas generated through basic research into safe and effective drugs, vaccines, and diagnostics to control and prevent infectious diseases.

Research Services

Generally, you may request services if you are an investigator in academia, a not-for-profit organization, industry, or government in the United States or worldwide. You need not be a grantee of NIAID or another National Institutes of Health Institute or Center. Look to each service for further eligibility information.
Thank You