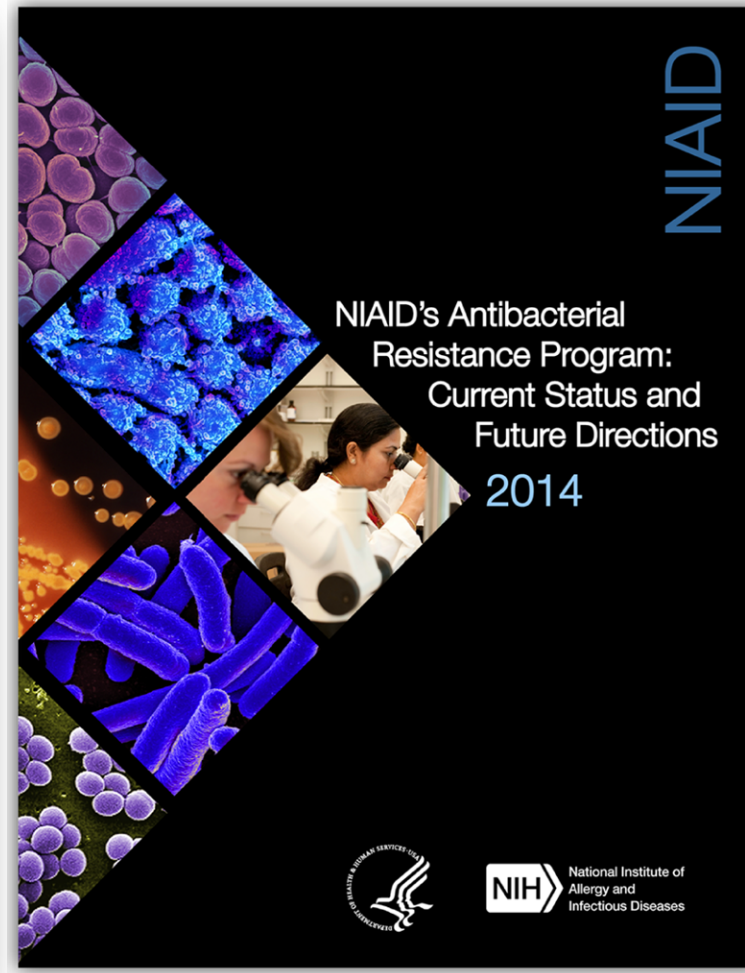
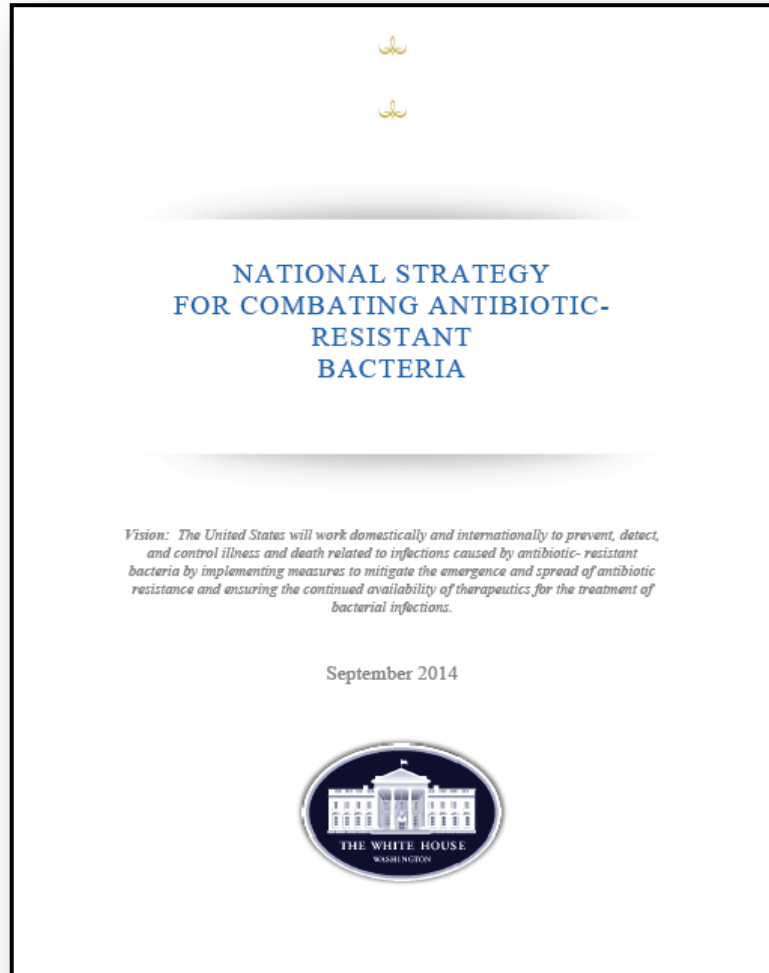


NIAID Resources for Research and Development of Therapeutics and Animal Models

Tina Guina, PhD
Program Officer, Drug Development
OBRRTR/DMID

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

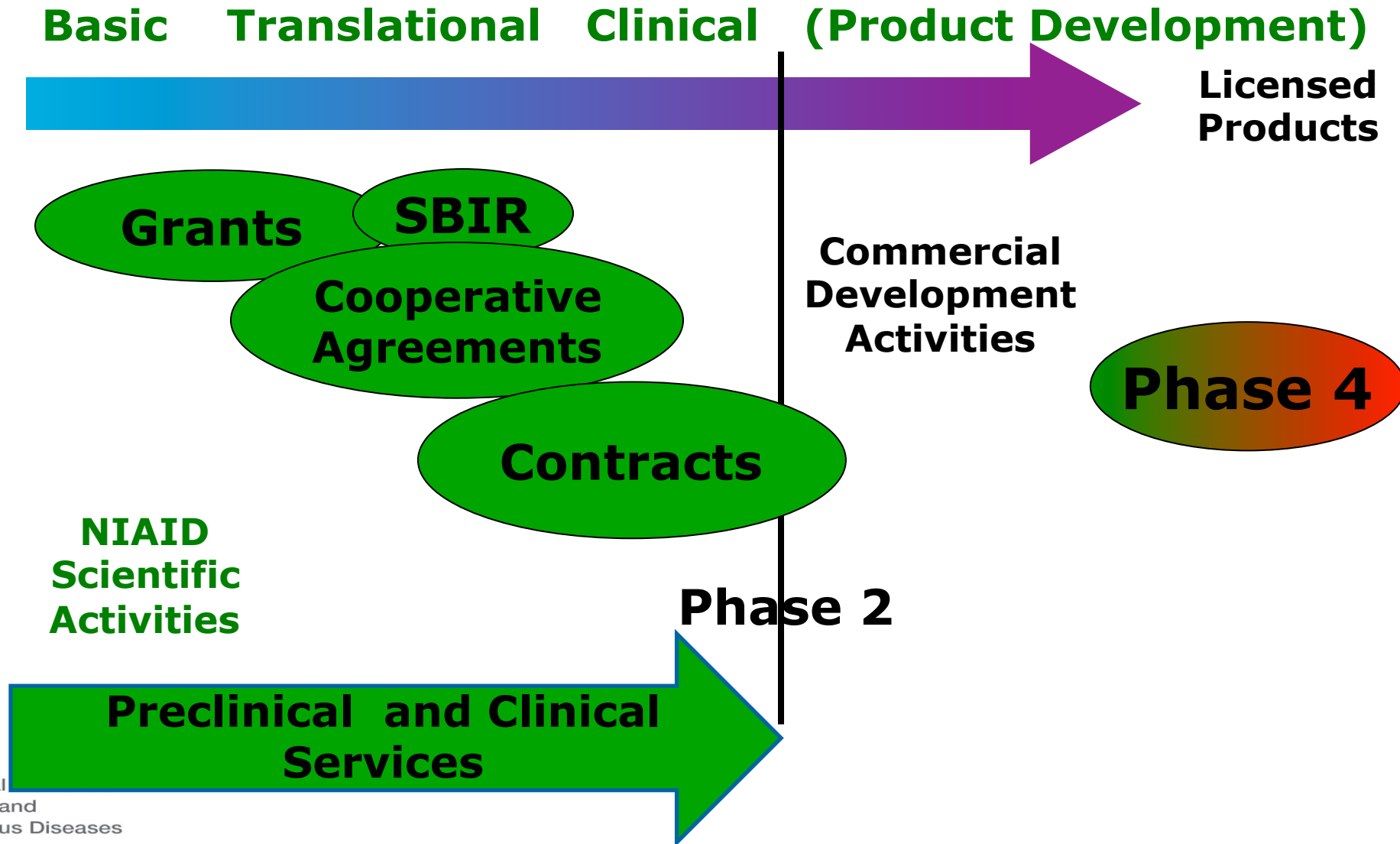


Basic Research
Translational Research
Clinical Research



Diagnosis
Prevention
Treatment

Overlapping Funding Mechanisms Lower Product Development Risk



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/>
 - 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>

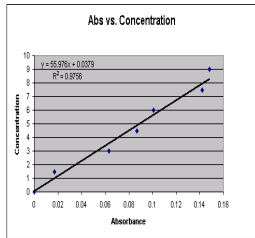
- **NIAID Council-cleared concepts** – information on upcoming potential opportunities

<https://www.niaid.nih.gov/grants-contracts/potential-opportunities>

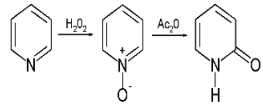
Product Development Services

Therapeutics

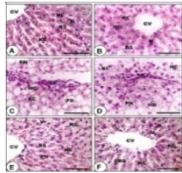
In Vitro Assessment of Antimicrobial Activity



Interventional Agent



ADME



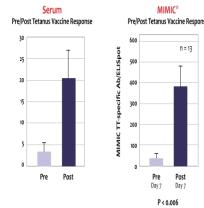
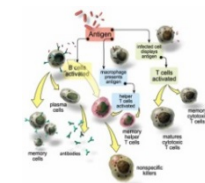
Biopharmaceutical Products



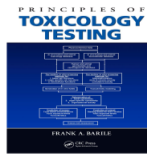
Chemistry,
Manufacturing, and
Controls (CMC)
Documentation for IND

Vaccines

Testing



Manufacturing



Clinical

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

Animal Models



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

Gap-filling Microbiology and Infectious Diseases Resources Contacts

<https://www.niaid.nih.gov/research/microbiology-and-infectious-diseases-resources>

NIH National Institute of Allergy and Infectious Diseases

Search NIAID Search

RESEARCH | DISEASES & CONDITIONS | GRANTS & CONTRACTS | CLINICAL TRIALS | NEWS & EVENTS | ABOUT NIAID

Research > For Researchers > [Tools, Datasets & Services](#)

For Researchers

- Tools, Datasets & Services**
 - Bioinformatics
 - Biological Materials
 - Translational Research
 - Technology Transfer & Intellectual Property
 - Partnering With NIAID
 - HIV/AIDS Research Resources
 - Allergy, Immunology, Transplantation Research Resources
- Microbiology and Infectious Diseases Resources**
- Research Rules & Policies

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.

Product Development Services

Basic Research → Preclinical Development → Clinical Evaluation → **Diagnostics, Vaccines, Therapeutics**

Research Tools and Biological Materials

Credit NIAID

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