
NIH/NIAID's Ongoing Role in AMR Initiatives

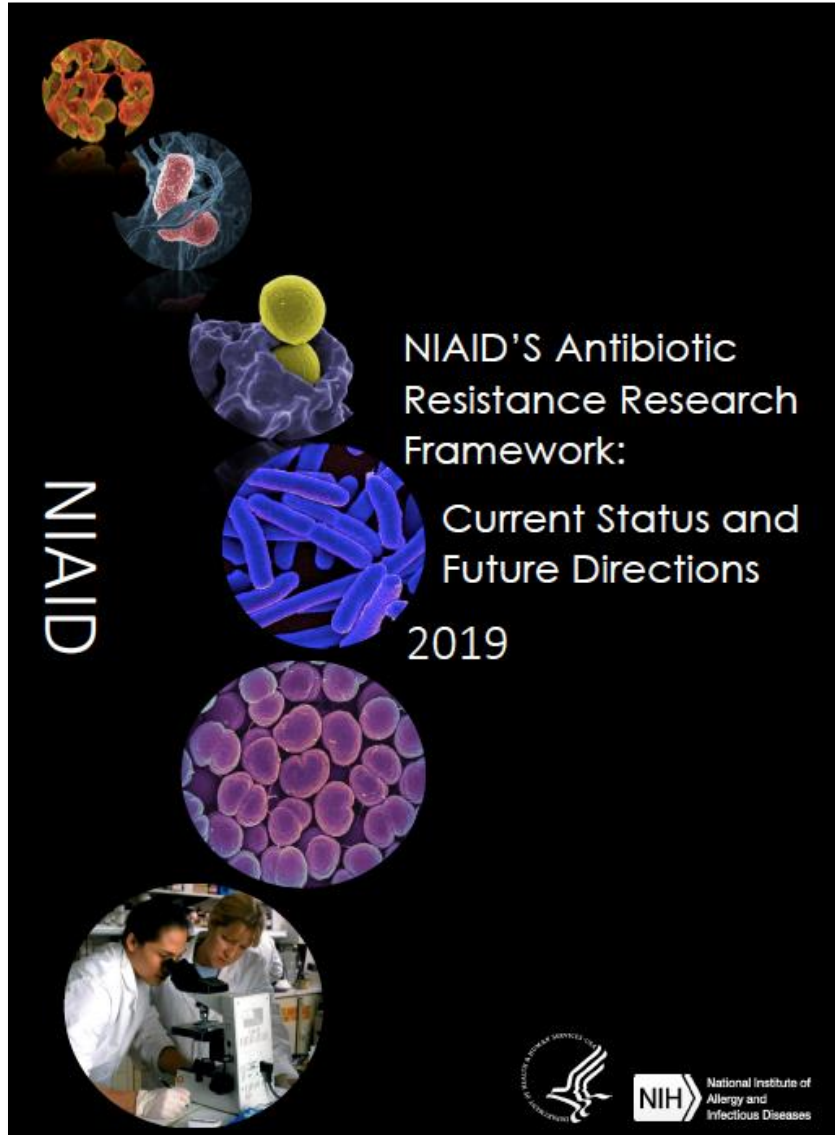
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December 1, 2021 (USA)
PAC CARB Virtual



NIAID Antibiotic Resistance Program



- **Basic Research**
- **Translational Research/ Product Development**
- **Clinical Research**



Diagnosis, Prevention and Treatment

<https://www.niaid.nih.gov/sites/default/files/AR2019.pdf>

NIAID Mechanisms to Support Antimicrobial Development

Investigator-initiated grants

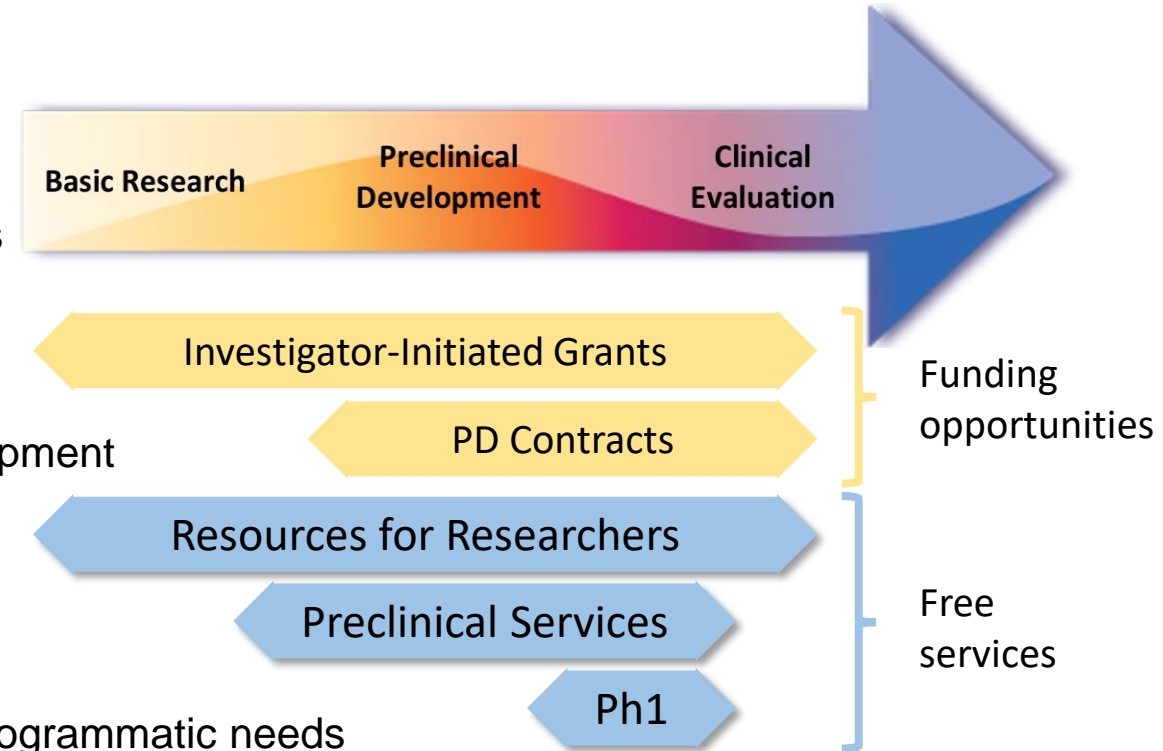
- Investigator proposed research topics within the scope of a general or specific program area
 - Program Announcements (PAs)
 - R01: 5 yrs of funding, up to \$500,000/yr direct costs
 - R21: Up to \$275,000 direct costs over 2 yrs

NIAID preclinical services (PCS)

- Suite of free services intended to support product development

Targeted initiatives

- Requests for Applications (RFAs)
- R&D contracts that require programmatic oversight
 - Requests for Proposals (RFPs): address specific programmatic needs
 - Broad Agency Announcements (BAAs): government-defined research areas of interest intended to advance the state of the art or increase knowledge



Open Funding Opportunities & Support (includes Dx and Rx)

Type	FOA	Scope
R01	Parent Announcement	Investigator-initiated, Academia and Industry, 5 yr Mid-Stage
R21	Parent Announcement	Investigator-initiated, Academia and Industry, 2 yr Early-Stage
K	Parent Announcement	Clinical Study projects by early-career Investigators
SBIR	Parent Announcement	Investigator-initiated, Phase I (early), Phase II (Mid), CRP (Late)

NIAID supports diagnostic and therapeutic product development, as well as basic and clinical study grants, on an ongoing basis yearly from open funding announcements that have 3 receipt dates per year.

Targeted Solicitations. Special Needs, RFA, RFP, Etc. (Dx)

Date	RFA Number	Title of RFA	Awards
2012	RFA-AI-12-017	Partnerships for Development of Therapeutics and Diagnostics for Biodefense (R01)	1
2014	RFA-AI-14-019	Partnerships for Diagnostics to Address Antimicrobial Resistance of Select Bacterial Pathogens (R01)	9
2017	RFA-AI-17-014	Partnerships for Development of Clinically Useful Diagnostics for Antimicrobial-Resistant Bacteria (R01)	5
2023		Partnerships for Rapid Diagnostics and Phenotypic Antibacterial Susceptibility Testing for Bacteremia or Hospital Acquired Pneumonia (R01)	TBD
Grand Total			?

Targeted Solicitations. Special Needs, RFA, RFP, Etc. (Rx)

Date	RFA/RFP Number	Title of RFA	Awards
2017	RFA-AI-16-034	Partnerships for Countermeasures Against Select Pathogens (R01)	6
2018	RFA-AI-16-081	Partnerships for the Development of Tools to Advance Therapeutic Discovery for Select Antimicrobial-Resistant Gram-Negative Bacteria (R01)	7
2018	RFA-17-017	Partnerships for the Development of Vaccines and Immunoprophylactics Targeting Multiple Antimicrobial-Resistant Bacteria (R01)	3
2019	RFA-AI-17-026	Partnerships for Countermeasures Against Select Pathogens (R01)	5
2021	RFA-AI-19-065	Understanding Phage Biology to Support the Development of Bacteriophage Therapy (R21)	10
2021	NIHAI75N9301 9R00024	Chemistry Center for Combatting Antibiotic-Resistant Bacteria (N01)	1
Grand Total			32

<https://www.niaid.nih.gov/research/recent-initiatives-antimicrobial-resistance>

INSPIRE-ASP Abdominal and Skin and Soft Tissue Infections

- Builds on prior cluster randomized clinical trials (RCTs) of adults admitted with pneumonia and urinary tract infections (UTIs)
 - If prescribed extended spectrum antibiotic, prompt provides patient-specific risk for MDRO disease based on patient EHR data
 - Prompts one-button exchange for standard antibiotic if <10% risk
- Impact
 - **28% reduction in broad spectrum use for inpatient pneumonia**
 - **17% reduction in broad spectrum use for inpatient UTI**
 - **No change in length-of-stay, ICU transfer, antibiotic escalation**

Testing Algorithms to Improve Antibiotic Prescribing

- INSPIRE-ASP (INtelligent **Stewardship** Prompts to Improve Real-time Empiric Antibiotic Selection for Patients): The INSPIRE-ASP Trial for Intra-Abdominal and Skin and Soft Tissue Infections
- PIs Susan Huang, MD, and Richard Platt, MD
- UC Irvine, Harvard Pilgrim, HCA Healthcare
- NIAID IICT: Investigator-Initiated Clinical Trial
 - U01 Peer reviewed grant
- **Goal:** to improve physician antibiotic prescribing by reducing unnecessary use of broad-spectrum antibiotics

INSPIRE-ASP Abdominal and Skin and Soft Tissue Infections

- Cluster RCT of Smart Prompt vs Routine Care to Improve Antibiotic Use
 - Targets empiric prescribing before cultures return
 - Creates risk algorithm based on >150K patients with each disease
 - If extended spectrum antibiotic prescribed, prompts for standard spectrum antibiotic if real-time patient risk of MDRO is <10%
 - Prescriber free to override prompt and prescribe at will with reason
 - Prescriber feedback given for reasons for overriding prompt
- INSPIRE-ASP has 97 participating hospitals. Sites are randomized and functionality of risk algorithms is in beta testing.

Thank you

... For your interest

NIAID Preclinical Services

Suite of service contracts that provide a broad range of assays and capabilities to the extramural research community free-of-charge

- Innovators from academia, non-profit organizations, industry, and government
- Domestic or foreign institutions
- Do not need to have NIH funding
- Simplified request process – available year-round

Preclinical Services Offered

***In Vitro*
Antimicrobial
Activity**



**ADME &
Toxicity Profiling**



**Animal Models
of Infection**



**Chemical and Biopharmaceutical
Synthesis & Manufacturing**

