

Office of Antimicrobial Products Research Activities

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Associate Director for Research
Animal Model Workshop
March 1, 2017



Regulatory Science Research

Background

- In 2011, FDA developed a [strategic plan for regulatory science](#).
- FDA's Strategic plan for regulatory science is critical to the agency in meeting its regulatory mission and to facilitate translation of breakthrough discoveries into innovative, safe, and effective products of tomorrow.

FY 2017 Research Focus

FDA issued a [Request for Information](#) (RFI) to develop animal models of infection in December, 2016

– **Purpose:**

- to solicit informal input from the public and private sectors to:
 1. evaluate the current state of animal models for different types of pneumonia due to *Acinetobacter baumannii* and *Pseudomonas aeruginosa*
 2. conduct studies of an animal model or models of serious infection caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa*

– **Deadline Extended Until:**

- 3/22/17

– **RFI Link:**

- <https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=6a45bfcf5819c908ace491a6844faa5e&cvview=0>



FY 2017 Research Focus

FDA has an ongoing [Broad Agency Announcement](#) (BAA)

– **Purpose:**

- Food and Drug Administration (FDA) solicitation for research and development to support regulatory science and innovation.

– **Deadline:**

- White paper (concept papers) submission by **March 31, 2017**
- Full proposals submission by June 26, 2017

– **BAA Link:**

- General BAA
 - <https://www.fbo.gov/index?tab=documents&tabmode=form&subtab=core&tabid=73eab5153e856dc3373dde7ed02a0584>
 - **Office of Antimicrobial Products (OAP) BAA**
 - » FDABAA-17-00123N; research area 2.4



Office of Antimicrobial Products Broad Agency Announcement

([FDABAA-17-00123N](#); research area 2.4.2)

FDA's roles in combatting antibacterial drug resistance are to:

1. facilitate the development of new antibacterial drugs to treat patients and
2. advance the science of clinical trial design

Specifically:

- 2.4.1 - Evaluate potential innovations in clinical trial design for new antibacterial drugs
 - such as enrollment strategies, data collection streamlining, drug development tools, clinical endpoints, and new statistical analytic approaches
- **2.4.2 - Advance the science of in-vitro, animal model, and/or pharmacokinetic studies to facilitate antibacterial drug development**
 - including studies focused on drug development for special populations such as patients with unmet need, children, and patients with renal or hepatic dysfunction
- 2.4.3 - Evaluate strategies to enrich enrollment in clinical trials for new antibacterial drugs
 - such as the use of rapid diagnostic tests
- 2.4.4 - Advance the science of antibacterial drug susceptibility testing

FY 2017 OAP Research Funding to Develop Animal Models:

- Approximately \$5,000,000

FY 17 OAP Research – Next Steps

- Review of Information Received from:
 - Today’s workshop
 - Responses from RFI
 - Deadline – 3/22/17
 - [BAA Process:](#)
 - Review white papers (on technical merit and contribution to FDA’s mission)
 - **Deadline for white paper submissions to FDA – 3/31/17**
 - FDA’s OAGS will send letter to offerors to submit full proposals
 - Deadline - 6/5/17
 - Offerors to submit full proposals
 - Deadline - 6/26/17
 - FDA Technical Evaluation Process
 - Award study through a BAA contract
- } summer
- **Initiate research study by 9/30/17**

Research Ideas/Questions

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Resources



- Office of Antimicrobial Products Research Webpage:

➤ <http://www.fda.gov/aboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm536676.htm>



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Antimicrobial Regulatory Science Research

Antibacterial drug resistance is a major threat to public health. In March 2015, The National Action Plan for Combating Antibiotic-resistant Bacteria was developed in response to Executive Order 13676: *Combating Antibiotic-Resistant Bacteria*, which was issued on September 18, 2014. The National Action Plan outlines steps for implementing the National Strategy for Combating Antibiotic-Resistant Bacteria to address urgent and serious drug-resistant threats that affect people in the U.S. and around the world. Implementation of the National Action Plan will also support World Health Assembly resolution 67.25 (Antimicrobial Resistance), which urges countries to take urgent action at the national, regional, and local levels to combat resistance. The FDA's roles in combatting antibacterial drug resistance include:

- Facilitating the development of new antibacterial drugs to treat patients; and
- Advancing the science of clinical trial design. The design and conduct of clinical trials to evaluate new antibacterial drugs in patients with serious bacterial infections is challenging and therefore of particular interest for FDA's regulatory science program.

What's New

- Request for Information (RFI) on the development of animal models of infection **still accepting late responses**
- Workshop on: Current State and Further Development of Animal Models of Serious Infections Caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa*

Background

- Office of Antimicrobial Products Main Webpage:

➤ <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm275183.htm>



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Mission

The Office of Antimicrobial Products is responsible for protecting the public health by assuring safe and effective drugs are available to the U.S. population for antimicrobials products (including antibacterial, antimycobacterial, antifungal, antiviral, and antiparasitic products), ophthalmology products, and products for the prevention of rejection in solid organ transplant recipients.

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