Office of Antimicrobial Products
Research Activities

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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&cview=0](https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=6a45bfcf5819c908ace491a6844faa5e&cview=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](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
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

• **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](http://www.fda.gov/aboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm536676.htm)

- Office of Antimicrobial Products Main Webpage:
  - [https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm275183.htm](https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm275183.htm)