Opportunity Title: General Antibacterial Drug Database Development Fellowship -
FDA CDER

Opportunity Reference Code: FDA-CDER-2018-0208

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2018-0208
How to Apply	A complete application consists of:

- An application
- Transcripts – **Click here for detailed information about acceptable transcripts**
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional references

All documents must be in English or include an official English translation.

If you have questions, send an email to *FDArpp@orau.org*. Please include the reference code for this opportunity in your email.

Description	A research opportunity is available at the Food and Drug Administration (FDA), The Center for Drug Evaluation and Research (CDER), Office of New Drugs/Office of Antimicrobial Products.

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* (CARB), 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.

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.

As part of ongoing efforts to harmonize and facilitate the global development of antibacterial drugs, a research project will focus on development and analysis of a database of antimicrobial drugs in development. Elements of the database will include the class of drug, mechanism of action, ability to maintain activity in the presence of various resistance mechanisms, and stage of development. Analyses will include periodic pipeline reports focused on addressing antibacterial drug resistance and projections including the timing of meeting key milestones in drug development.

The selected candidates will perform research analysis to learn how to develop and analyze antimicrobial drug development pipeline database to provide real-time reports and projections.

This program, administered by ORAU through its contract with the U.S.

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Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for 12 months, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications A doctoral degree (or PhD candidate), medical degree, post masters, or PharmD received within the last 5 years with a course of study in infectious diseases, microbiology, pharmacology, and computational biology/bioinformatics or related fields.

Qualified Masters level degrees may also be considered if the candidate demonstrates strong understanding and has experience in database development and pharmacokinetic modeling or clinical microbiology or epidemiology.

It is desired that the candidates be able to evaluate complex information relating to the safety and efficacy of drugs, e.g. understanding the mechanism of action of drugs and antimicrobial activity and clinical outcomes.

Specialized training in data base development and validation, data mining, and data analyses is preferred. Training in clinical microbiology or drug development is also desired.

Eligibility Requirements
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)