Opportunity Title: FDA Antibacterial Drug Resistance (DOOR) Fellowship
Opportunity Reference Code: FDA-CDER-2023-1345

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2023-1345

How to Apply

Connect with ORISE...on the GO! Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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
- One educational or professional recommendation

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

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

Application Deadline 12/30/2023 3:00:00 PM Eastern Time Zone

Description

***Applications will be reviewed on a rolling-basis.**

A research opportunity is currently available in the Office of New Drugs/ Office of Infectious Diseases (OID) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

DOOR is an innovative approach in clinical trials that combines the global benefits and risks of an intervention into a composite endpoint. With DOOR methodologies, different strategies/treatments are compared according to the desirability of the composite outcome (e.g., from the most to the least desirable: (i) cure without major adverse events; (ii) cure with major adverse events; (iii) death). This project will explore the utility of a syndrome-specific desirability of outcome ranking (DOOR) approach for clinical trials for infections needing prolonged treatment such as tuberculosis, non-tuberculous mycobacterial (NTM) infections and invasive fungal infections including invasive aspergillosis. The project will build on previous research deriving and evaluating syndrome-specific ordinal endpoints using DOOR for anti-infective clinical trials for hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP) and complicated intra-abdominal infection (cIAI) indications.

Under the guidance of a mentor, the selected candidate will perform analyses of existing databases of recently completed antibacterial or antifungal drug trials to validate ordinal endpoints using the DOOR approach. The participant will gain an understanding of the multi-year Combating Antibiotic Resistant

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Bacteria Research Program that supports antimicrobial drug research as well as the development of new antimicrobial drugs and relevant aspects of drug regulation in the U.S. The participant will be trained in various tools, methods, and study designs used to evaluate antimicrobial drug products. In addition, the participant will learn about the different types of endpoints used in registrational trials specifically the ordinal endpoints using the desirability of outcome ranking (DOOR).

This program, administered by ORAU through its contract with the U.S. 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 one year 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, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The qualified candidate should be currently pursuing or have received a master's or doctoral degree in one of the relevant fields. Degree must have been received

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within five years of the appointment start date.

Knowledge in clinical microbiology, epidemiology, database development and validation, data mining, and data analyses is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Life Health and Medical Sciences** (46 👁)
  - **Mathematics and Statistics** (10 👁)

Affirmation

I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)

I have read the FDA Ethics Requirements.