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Opportunity Title: FDA Clinical Drug Development Fellowship
Opportunity Reference Code: FDA-CDER-2023-1249

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

Reference Code FDA-CDER-2023-1249

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.

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

A research opportunity is available in the Office of Translational Science (OTS)/ Office of Clinical Pharmacology (OCP)/ Division of Applied Regulatory Science (DARS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. CDER performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

DARS conducts integrated clinical research covering clinical pharmacology, experimental medicine and post market analyses. DARS has ongoing clinical studies in the areas of pharmacodynamic interactions between opioids and psychotropic drugs and cardiac electrophysiology biomarkers. It is important that the design, planning, conduct, data collection, and analyses of these and future studies is consistently performed.

Under the guidance of a mentor, the participant will learn about reviews of the literature, designing clinical studies and analysis plans as well as learn to perform analyses on clinical data available to the FDA. In addition, the participant will be given the opportunity to write and publish scientific manuscripts, and present findings internally and externally.

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

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only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

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 have received a master's or doctoral degree in one of the relevant fields, or be currently pursuing one of the degrees with completion by the end of August 2023. Degree must have been received within five years of the appointment start date.

Knowledge in clinical pharmacology, clinical study design, clinical study analysis, literature review, and epidemiology is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 8/31/2023 11:59:00 PM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (46 👁)

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.)