Opportunity Title: FDA Fellowship in Drug Safety: Labeling of Drug Adverse Events
Opportunity Reference Code: FDA-CDER-2023-1261

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

Reference Code FDA-CDER-2023-1261

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 6/30/2023 3:00:00 PM Eastern Time Zone

Description

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

A research opportunity is available in the Office of New Drugs (OND)/ Immediate Office (IO), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located 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.

This project intends to better understand the threshold for inclusion of designated medical events in the labeling for novel drugs. It will determine whether there is an association between the rate for inclusion and the upgrading of the adverse events to a Boxed Warning or Warnings or Precautions within the first 3 years of marketing. This project involves computer modeling to assess safety adverse event data and graphical visualizations to aid in data interpretation.

Under the guidance of the mentor, the participant will learn to gather safety and clinical review information from the various databases in CDER. The participant will gain an understanding of the evaluation of safety data based on differences in clinical trials. The participant will also learn about various computer modeling techniques to evaluate safety data, and about tabulations and graphical visualizations that will be used to describe the model and aid in interpretation.

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**

Opportunity Title: FDA Fellowship in Drug Safety: Labeling of Drug Adverse Events
Opportunity Reference Code: FDA-CDER-2023-1261

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 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 or be currently pursuing a master's or doctoral degree in one of the relevant fields (pharmacy, epidemiology, or a related health science field -including PharmD, MPH, PhD) with completion by June 30, 2023. Degree must have been received within five years of the appointment start date.

Preferred skills/ knowledge:

- Familiarity with U.S. drug labeling and FDA drug review process
- Basic understanding of data analysis, including, interpreting, identifying patterns, and presenting data with clarity
- Knowledge of Microsoft Office, particularly Access and Excel

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2023 11:59:00 PM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (5 👁)

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.)