Opportunity Title: FDA Pharmacovigilance Fellowship: Characterization of Newly Identified Safety Signals
Opportunity Reference Code: FDA-CDER-2024-1406

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

Reference Code FDA-CDER-2024-1406

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 6/28/2024 3:00:00 PM Eastern Time Zone

Description

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

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at Silver Spring, Maryland. This project is located in the Office of Pharmacovigilance & Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE).

Research Project: The project aims to better understand the landscape of newly identified safety signals (NISS) by evaluating aspects of NISS opened within CDER since the implementation of the Manual of Policies and Procedures (MAPP) for collaborative identification, evaluation, and resolution of NISS in 2020. The project will characterize operational and signal-specific attributes such as signal sources, evaluation time, and resulting regulatory actions. Results from these analyses will inform future pharmacovigilance practices and program enhancements.

Learning Objectives: Under the guidance of the mentor, the participant will learn best practices in drug and biological product postmarket safety surveillance and undergo hands-on training to retrieve data from relevant FDA databases and tools.

In collaboration with the mentor and research team, the participant will have the opportunity to

- Identify key characteristics for study from historical NISS.
- Collect and analyze data.

- Perform sub-analyses for areas of special interest (e.g., pediatric-specific and pregnancy/lactation-related NISS).
- Interpret and disseminate findings in the context of existing policies, procedures, and best practices for postmarketing safety surveillance.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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:

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- 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.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 6/1/2024 12:00:00 AM.
- **Academic Level(s):** Postdoctoral or Post-Master's.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (5 👁)
  - **Mathematics and Statistics** (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.)

I have read the FDA Ethics Requirements.