Opportunity Title: FDA Postmarket Drug Safety Fellowship
Opportunity Reference Code: FDA-CDER-2020-0537

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

Reference Code FDA-CDER-2020-0537

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
- 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 3/31/2021 3:00:00 PM Eastern Time Zone

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

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

FDA/CDER drug review divisions evaluate results from postmarket studies required by FDA to assess specific safety concerns with marketed drug products. A number of these studies are drug-product based registries established to evaluate safety outcomes such as malignancies, major adverse cardiovascular events, or neuropsychiatric events. While FDA reviews the results of individual studies to make decisions on drug products, a comprehensive, scientific analysis of multiple postmarket safety studies is needed.

The participant will gain a scientific and regulatory understanding of the fundamentals of how FDA uses postmarket clinical safety studies to assure safe drug product use. Many drugs and biologics are being approved with the requirement to conduct post-marketing epidemiologic studies and/or clinical trials to gain a better understanding about the product safety profile (PMR, post-marketing requirement). The goal is to review data (to include registries) to allow the Agency to update the label of a product with safety information; however, the results are often insufficient and the studies do not produce valuable data.

Under the guidance of a mentor, the participant will collect and analyze data from completed PMR studies to see how many of them resulted in sufficient data to provide updated safety profiles. If the study concludes that many provide insufficient data, the participant and mentor will determine what changes need to be made to fulfill the need for acquiring additional safety data post-marketing.

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

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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 be currently pursuing or have received a master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Familiarity with clinical and medical terminology is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (3 👁)
  - **Mathematics and Statistics** (1 👁)