Opportunity Title: FDA Real World Evidence Fellowship
Opportunity Reference Code: FDA-CDER-2021-0606

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

Reference Code FDA-CDER-2021-0606

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 6/30/2021 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 Surveillance and Epidemiology/ Office of Pharmacovigilance and Epidemiology, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

The 21st Century Cures Act is designed to accelerate medical product development and bring new innovations and advances faster and more efficiently to the patients who need them. Under this Act, FDA must evaluate the use of real-world evidence (RWE) to support regulatory decision making, including approval of new indications for approved drugs or to support or satisfy postapproval study requirements. FDA initiated a RWE Program to address key issues in the use of RWE for regulatory purposes. This project aims to describe the nature of the RWE submissions, summarize recommendations, and analyze the lessons learned in regulatory implications, which would inform future RWE reviews and regulatory decision making.

Under the guidance of a mentor the participant will gain skills in quantitative and qualitative analyses of RWE submissions. In addition, the participant will gain knowledge in regulatory science, clinical trials and pharmacoepidemiology research, and real world evidence use for regulatory decision making.

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 can be full-time or part-time (20 hours per week) 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 be currently pursuing or have received a doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Pharmacoepidemiology or clinical research knowledge
- Qualitative and quantitative analytical skills

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (46 👁)
  - **Social and Behavioral Sciences** (1 👁)