Opportunity Title: FDA Evaluate the Impact of Regulatory Activities Fellowship
Opportunity Reference Code: FDA-CDER-2022-1183

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

Reference Code FDA-CDER-2022-1183

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple 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 12/31/2022 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- Immediate Office, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project will explore trends in nonprescription drug cases captured in the National Poison Data System during COVID-19. We are using the American Association of Poison Control Centers' (AAPCC) National Poison Data System (NPDS) for this project. We aim to evaluate the impact of FDA's regulatory activities, which may include labeling changes, Risk Evaluation and Mitigation Strategies (REMS), or Drug Safety Communication (DSC). The project may provide insight on whether FDA should develop guidance on how to communicate/manage marketed drugs during unprecedented times like the COVID pandemic; and will help improve evidence-based regulatory decisions. Under the guidance of a mentor, the participant will learn how to handle and use the real-world data (RWD) such as patient-level longitudinal data or large cross-sectional data sets. In addition, the participant will learn how to design and propose regulatory research; then conduct and summarize the study results.

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

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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.

Preferred skills:

- Knowledge in statistics and analytical skills
- Skills in SAS

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** (10 👁)

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.)