Opportunity Title: FDA Real-World Evidence in Prescription Drug Use Fellowship
Opportunity Reference Code: FDA-CDER-2019-0409

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

Reference Code FDA-CDER-2019-0409

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. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

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 6/5/2019 3:00:00 PM Eastern Time Zone

Description

A research opportunity is available in the Office of Translational Sciences/Office of Biostatistics, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project in the Office of Translational Sciences/Office of Biostatistics seeks to develop dedicated software for generating real-world evidence (RWE) from the Agency's resources for monitoring prescription drug dispensing. The software will provide tools to augment the Agency's nationally representative database for prescription drug dispensing with other geographically referenced, publicly available, demographic, socioeconomic, or healthcare service data. The software will subsequently generate a comprehensive collection of RWE that will be of interest to the Agency, including simple descriptive statistics, spatio-temporal modeling for evaluating variability in the temporal or spatial domains, and machine learning for data mining factors associated with drug utilization.

Under the guidance of a mentor the participant will train on:

- developing a software for the analysis of the Agency's resources for monitoring prescription drug dispensing
- performing an analysis of Drug Utilization Database (DUD) investigating prescription dispensed for naloxone and Transmucosal Immediate Release Fentanyl (TIRF) medicines
- assisting with developing a data visualization module
- developing an extensive manual for the software and the data visualization module

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 eight months, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend

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commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment can be either full-time or part-time (10 hours per week), depending on the participant's availability, 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.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

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 a master's or doctoral degree in one of the relevant fields. Advanced doctoral students with completion of doctoral pre-qualifying exams are also encouraged to apply. Degree must have been received within five years of the appointment start date.

Strong problem solving and computational skills are desired.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (1 👁)

Affirmation

I have received a master's or doctoral degree within the past 5 years, OR I am currently pursuing a doctoral degree and have completed the doctoral pre-qualifying exams.