Opportunity Title: FDA Real World Evidence Fellowship
Opportunity Reference Code: FDA-CDER-2020-0528

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

Reference Code FDA-CDER-2020-0528

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 9/30/2020 3:00:00 PM Eastern Time Zone

Description

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

A research opportunity is available with the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project with the Office of Medical Policy seeks to support the agency's efforts to meet the mandates required by the 21st Century Cures Act and the Prescription Drug User Fee Act (PDUFA) VI Commitment Letter, by establishing a program to evaluate the potential use of real-world evidence (RWE) (1) to help support the approval of a new indication for a drug approved under section 505(c) and (2) to help to support or satisfy post approval study requirements. While the FDA has had some experience in the use of real-world data (RWD) to generate RWE, the landscape is large. As a result, stakeholders and regulatory authority are challenged to (1) understand the sources of real-world evidence, (2) identify all gaps in data collection, (3) describe standards, methods to analyze real-world evidence.

Under the guidance of a mentor, the participant will be trained to conduct relevant research, evaluations, and analyses, including but are not limited to: literature reviews of clinical studies that utilize RWD to generate RWE; collecting and analyzing data and studies relevant to understanding the potential use of RWE in regulatory decision-making; forecasting and anticipating potential policy opportunities and challenges related to RWD/RWE, and help identify potential solutions and approaches to address the challenges and to fill knowledge gaps. The learning objectives of this project include reports of reviewed clinical studies and analyzed data, presentations of findings, and concept papers to support the potential development of draft guidance documents.

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

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

Familiarity with analytics, clinical trials, and research is desired.

Eligibility Requirements

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

Affirmation

I have received a master's or doctoral degree within the past 5 years, or am currently pursuing a doctoral degree.