Opportunity Title: FDA Fellowship on the Scientific Evaluation of the Use of Biomarkers in Neurology
Opportunity Reference Code: FDA-CDER-2022-1216

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

Reference Code FDA-CDER-2022-1216

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 3/31/2023 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 Translational Sciences (OTS), Office of Clinical Pharmacology (OCP), at the Center for Drug Evaluation and Research (CDER) within the Food and Drug Administration (FDA) in Silver Spring, Maryland.

The project will systematically evaluate and summarize available information on biomarkers for various neurological diseases including, but not limited to, Alzheimer's disease, Parkinson's disease, Amyotrophic Lateral Sclerosis (ALS) and Duchenne Muscular Dystrophy (DMD). The utility of these biomarkers in drug development and regulatory decisions, as well as their context of use, will be assessed using publicly available information. This comprehensive data on biomarkers and their potential applications can aid drug development for neurological diseases.

Under the guidance of the mentor, the participant will learn about the role of biomarkers in clinical drug development and in regulatory decision making for neurological diseases. The participant will also gain skills related to data gathering, database management and quantitative analyses.

CDER performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

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

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

Familiarity with basic statistical evaluation methodologies, and some experience with commonly used software tools such as R or SAS are preferred.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 3/31/2023 12:00:00 AM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (1 👁)

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.)