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Opportunity Title: FDA Fellowship in Analysis of Rare Disease Submissions and Reviews
Opportunity Reference Code: FDA-CDER-2022-1202

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

Reference Code FDA-CDER-2022-1202

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 12/31/2022 3:00:00 PM Eastern Time Zone

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

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

Innovative approaches to drug development in rare disease is critical, particularly in slowly progressive, heterogenous rare diseases. Rare diseases without reliable or well-developed direct measures of clinical benefit or clinical outcome assessments rely on biomarkers and other evidence to support or serve as surrogate endpoints or confirmatory evidence of effectiveness for drug products. Approval decisions need to be made on novel drug products without the benefit of lengthy or multiple development programs to inform regulatory decision-making. This project reviews rare disease drug product applications to characterize the use and key elements of biomarkers against disease characteristics, regulatory decisions, approval pathways, and relevant post-marketing outcomes. The review will inform and help create a framework for key considerations related to the strength of biomarkers in making regulatory decisions in rare diseases where natural history, size and length of development program, and trial design are challenging.

The project will review rare disease drug product applications to characterize the use and key elements of biomarkers against disease characteristics, regulatory decision, approval pathway, and relevant post-marketing outcomes.

Under the guidance of the mentor, the participant will gain working knowledge in the following:

- Design and conduct of clinical trials in rare diseases.
- Use and considerations of biomarker/surrogate endpoints in rare disease.
- Ability to generate analysis datasets from clinical trial databases.

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- Construction/presentation of an internal white paper for a regulatory agency as well as potential to externally publish/present on publicly available data from the analysis in a peer reviewed journal/meeting.

Anticipated Start Date: The start date is flexible and will depend upon a variety of factors.

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 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 master's degree or a PhD/Medical degree in biological science with coursework and/or experience in clinical sciences or pharmacology, programming, and basic statistics. Degree must have been received within the past five years. The ideal candidate will have demonstrated experience in the completion of an independent research project.

Preferred skills:

- Knowledge of statistics and familiarity with pharmacology and/or health sciences.
- Ability to exercise critical thinking and systematic approaches to identify trends and evaluate the evidences from a large set of clinical studies.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (2 👁)
  - **Life Health and Medical Sciences** (12 👁)
  - **Mathematics and Statistics** (3 👁)

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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.)