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Opportunity Title: FDA Fellowship - External Controls in Rare Disease Clinical Trials
Opportunity Reference Code: FDA-CDER-2023-1248

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

Reference Code FDA-CDER-2023-1248

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 6/30/2023 3:00:00 PM Eastern Time Zone

Description One or two research opportunities are available in the Office of New Drugs (OND), Office of Immunology and Inflammation (OII), Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) located 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 research covers more than just medicines.

This is Part 2 of a farther-reaching project. Part 1 of this project was to characterize in detail original NDA/BLA approvals in non-oncological rare diseases in CDER between the passage of the Orphan Drug Act in 1983 and 2022 that relied primarily upon externally controlled clinical trials for their basis of approval by: (1) the type of external control, (2) the type of endpoints and (3) the types of confirmatory evidence that were used to establish substantial evidence of efficacy. Part 1 is near completion, and we are hoping to publish our findings. In Part 2, we plan to evaluate how safety is evaluated in externally controlled trials (considerably more challenging than evaluating safety in randomized controlled trials). We intend to characterize each approval by the safety concerns at time of approval, whether there were post-marketing requirements (PMRs) and why, and what the results of those PMRs were and how they influenced labeling. This project will help inform best practices for safety review in rare disease drugs when they are supported primarily by externally controlled trials.

Under the guidance of the mentor, the participant(s) will learn:

1. Regulatory, clinical trial, and drug development concepts and terminology to extract pertinent features of externally-controlled trials from review documents for non-oncological rare disease original NDA/BLA approvals.
2. Features of various rare diseases (pathophysiology, epidemiology, diagnostic methods, and current standard therapies)
3. Research methods to conduct descriptive analyses of the above data
4. Technical writing and presentation skills

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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(s) is/are full-time for a 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(s) is/are on location 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(s) should be currently pursuing or have received a bachelor's, master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

History of academic achievement, a broad skillset, and interest in rare diseases is preferred.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Physics** (1 👁)
  - **Social and Behavioral Sciences** (2 👁)

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.)