Opportunity Title: FDA Fellowship in Biomarker Use in Rare Disease Drug Development
Opportunity Reference Code: FDA-CDER-2024-1403

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

Reference Code FDA-CDER-2024-1403

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 5/31/2024 3:00:00 PM Eastern Time Zone

Description

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

A research opportunity is currently available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in the Office of New Drugs/ Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM), 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.

Biomarker use in rare disease drug development is critical, particularly in slowly progressive, heterogenous rare diseases. This project will review rare disease medical product applications for previously approved products to characterize the use and key elements of biomarkers in addition to gathering data on disease characteristics, regulatory decision-making rationale, approval pathways, and relevant post-marketing outcome assessments. The review will explore key considerations related to the characteristics of biomarkers that were an important element in making a regulatory decision in rare diseases where natural history, size and length of development program, and trial design were challenging. This data review will focus on prior uses of biomarkers in development programs including as predictive, prognostic, pharmacodynamic, or surrogates.

Under the guidance of the mentor, the participant will gain a greater understanding and working knowledge in the design and conduct of clinical trials and expertise in the use and considerations of biomarkers and surrogate endpoints in rare disease drug development. The participant will gain experience mining large clinical trial databases, performing qualitative review of rare disease drug development data, and

analyzing datasets using statistical software such as SAS, R, and Excel. The participant will also gain experience in construction and presentation of an internal FDA white paper as well as the potential to externally publish and present on publicly available data from the analysis in a peer reviewed journal and/or scientific conference.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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 Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

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

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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 one. Degree must have been received within five years of the appointment start date or anticipated to be received by 5/31/2024.

Preferred skills/ knowledge:

- Knowledge and coursework in biology, clinical sciences, and pharmacology
- Knowledge in data analysis and familiarity with software/programming languages.
- Knowledge in critical thinking to identify trends and evaluate evidence.
- Knowledge in data interpretation, graphical representation of evidence, and critical analysis of associations is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 5/31/2024 12:00:00 AM.
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (2 👁)
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (12 👁)
  - **Mathematics and Statistics** (1 👁)
  - **Social and Behavioral 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.)

I have read the FDA Ethics Requirements.