Opportunity Title: FDA Diversity in Drug Development Fellowship
Opportunity Reference Code: FDA-CDER-2023-1226

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

Reference Code FDA-CDER-2023-1226

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.**

CDER Office/Lab and Location: The project is in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS) in collaboration with the Office of Minority Health and Health Equity (OMHHE). OMHHE serves to promote and protect the health of diverse populations through research and communication of science that addresses health disparities.

Research Project: The project is to characterize the extent of demographic subgroup enrollment in phase I–III clinical trials for drugs approved to treat diseases with known racial or ethnic differences in morbidity and/or mortality. Additionally, as race and ethnicity can contribute to differences in drug exposure and/or response, the goal of the project is to understand how exposure differences are characterized. The methods used in this project can be refined for future use and the results may be used to support best practices for enhancing demographic diversity of clinical trials.

Under the guidance of a mentor, the participant will learn how race and ethnicity data is collected during clinical trials and utilized to evaluate exposure and response differences, and how some of this information is conveyed in the labeling. The participant will have the opportunity to gain additional training in regulatory science research via systematic synthesis of data and literature, database development and analysis, learning how this can be applied for policy development and assessment. The participant will gain an educational experience in the regulatory science research project and professional development through didactic training leveraging FDA's seminars and lecture series, as well as participating in research and communication projects with the Office of Minority Health and Health Equity.

This program, administered by ORAU through its contract with the U.S. Department

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of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The appointment is for 12 months. 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 part-time or full-time at FDA in the Silver Spring, Maryland or St. Louis, Missouri areas. 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 doctoral degree in one of the relevant fields, or be currently pursuing a doctoral degree with completion before June 15, 2023. Degree must have been received within five years of the appointment start date.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 6/15/2023 12:00:00 AM.
- **Discipline(s):**
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (9 👁)

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.)