

Opportunity Title: FDA Comparative Gaps Analysis in Sickle Cell Disease

Fellowship

Opportunity Reference Code: FDA-CDER-2022-0755

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

Reference Code FDA-CDER-2022-0755

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 5/31/2022 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 (OND)/ Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) at the 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.

Conducting clinical trials and developing new therapies meeting unmet needs of patients with Sickel Cell Disease (SCD) have been challenging due to large gaps in our current understanding of the natural course of the disease and its variable manifestations from one patient to the next. There is also a lack of consistent scientific data to facilitate informed regulatory decision-making that may lead to significant health improvements in the SCD community. The project is designed to address these gaps through strategic analysis between the clinical trial data that supported FDA approved for SCD therapeutic products and real world data at CDC SCD.

Under the guidance of the mentor, the participant will learn to create a SCD clinical trial database with available data, compare and define critical gaps between clinical trial data and the real world data, and develop strategies/tools to predict outcomes in SCD.

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



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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 a master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills/knowledge:

- Sickle Cell Disease, Clinical trial, Clinical and epidemiological data analysis
- Software, such as SAS, R and JMP, to design and perform analyses and simulation, as well as result interpretation

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
 - **Life Health and Medical Sciences** (48 👁)

Affirmation

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)