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Opportunity Title: FDA Fellowship in Comparative Gap Analysis in Sickle Cell Disease
Opportunity Reference Code: FDA-CDER-2025-1471

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

Reference Code FDA-CDER-2025-1471

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click APPLY.***

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 1/31/2025 3:00:00 PM Eastern Time Zone

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

CDER Office and Location: A research opportunity is available within the Food and Drug Administration (FDA), Office of New Drugs (OND)/ Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) in The Center for Drug Evaluation and Research (CDER), located in Silver Spring, Maryland.

The Center for Drug Evaluation and Research (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 U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

Research Project: Conducting clinical trials and developing new therapies to address unmet needs of patients with Sickle 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 SCDC.

Learning Objectives: 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.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

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Level of Participation: The appointment is full-time.

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

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Preferred skills/knowledge:

- Knowledge in Sickle Cell Disease and clinical trial
- Experience in clinical data mining/analysis, Python programing, ML/AI, SAS, JMP and R

Point of Contact Sara Beth Hensley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Mathematics and Statistics** (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.)
and
I have read the FDA Ethics Requirements.