Opportunity Title: Real-World Evidence Simulation of Long-term Drug Safety & Efficacy
Opportunity Reference Code: FDA-CDER-2024-1435

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

Reference Code FDA-CDER-2024-1435

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.

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!

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 8/31/2024 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at 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: This project is located in The Office of New Drugs (OND), Immediate Office (IO). This methods study aims to understand if real-world evidence (RWE) can accurately estimate long-term medication safety and effectiveness in a simulated dataset where the "true" estimates are known. Knowledge of long-term medication safety and effectiveness from randomized controlled trials (RCTs) is often limited at the time of drug approval--especially in typically underrepresented populations--but may be evaluated with postmarket real-world data (RWD) by emulating an RCT that compares treatment durations. However, confounding is still possible with RWD. We aim to understand if positive control outcomes (i.e., adverse drug reaction) and negative control outcomes (i.e., with expected null association) can identify unconfounded comparisons for valid estimation of real-world long-term medication safety and effectiveness by using plasmode simulations developed from RWD.

Learning Objectives: Under the guidance of a mentor, the participant will learn about using administrative health claims data for RWE, including how treatment duration is measured from prescription claims data. The participant will also learn how to apply plasmode simulations with RWD to

estimate hypothetical “true” unconfounded treatment effects. The participant will also be trained on how to apply marginal structural models to RWD in order to emulate RCTs, as well as how positive and negative control outcomes can be used to assess assumptions of no unmeasured confounding.

Anticipated Appointment Start Date: Start date is flexible and will depend on a variety of factors.

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.

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

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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 candidate should have received or currently be pursuing a doctoral degree (PhD or equivalent) in one of the relevant fields (epidemiology, data science, mathematics, statistics) with anticipated completion by December 31, 2024. Candidates with a clinical doctorate (e.g., PharmD, MD) and relevant experience will also be considered. Degree must have been received within five years of the appointment start date.

Preferred Skills/ Knowledge:

- Proficient in programming with R or Python
- Experience creating research datasets from administrative health claims data or other complex relational databases
- Experience simulating research datasets

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 12/31/2024 11:59:00 PM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Life Health and Medical Sciences** (5 👁)
  - **Mathematics and Statistics** (3 👁)

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.