

Opportunity Title: FDA Statistical Modeling for Drug AE Analysis Fellowship

Opportunity Reference Code: FDA-CDER-2023-1247

Organization

U.S. Food and Drug Administration (FDA)

Reference Code

FDA-CDER-2023-1247

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.**

A research opportunity is available in the Office of New Drugs/ Immediate Office (IO), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) 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 work covers more than just medicines.

Drug-induced adverse events (AEs) are difficult to predict for early signal detection, and there is a need to develop new tools and methods to monitor the safety of marketed drugs, including novel approaches for evidence generation. This project will utilize natural language processing (NLP), data mining (DM), and statistical modeling to increase our understanding of timing/early detection of AEs, which can be applied to targeted monitoring of novel drugs.

Under the guidance of the mentor, the participant will learn about drug safety labeling, AE detection, and signal identification. The participant will also gain knowledge on how Optical Character Recognition (OCR) software can be used for AE data. The participant will also be trained on how NLP and statistical modeling can be used to retrieve and evaluate safety data.

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 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;

Opportunity Title: FDA Statistical Modeling for Drug AE Analysis Fellowship

Opportunity Reference Code: FDA-CDER-2023-1247

- 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. Degree must have been received within five years of the appointment start date.

Preferred Skills/ Knowledge:

- Pharmacology knowledge – PharmD or equivalent
- Experience with data management
- Proficient in MS Excel
- Experience with statistical analysis
- MD or equivalent will also be considered

Eligibility Requirements

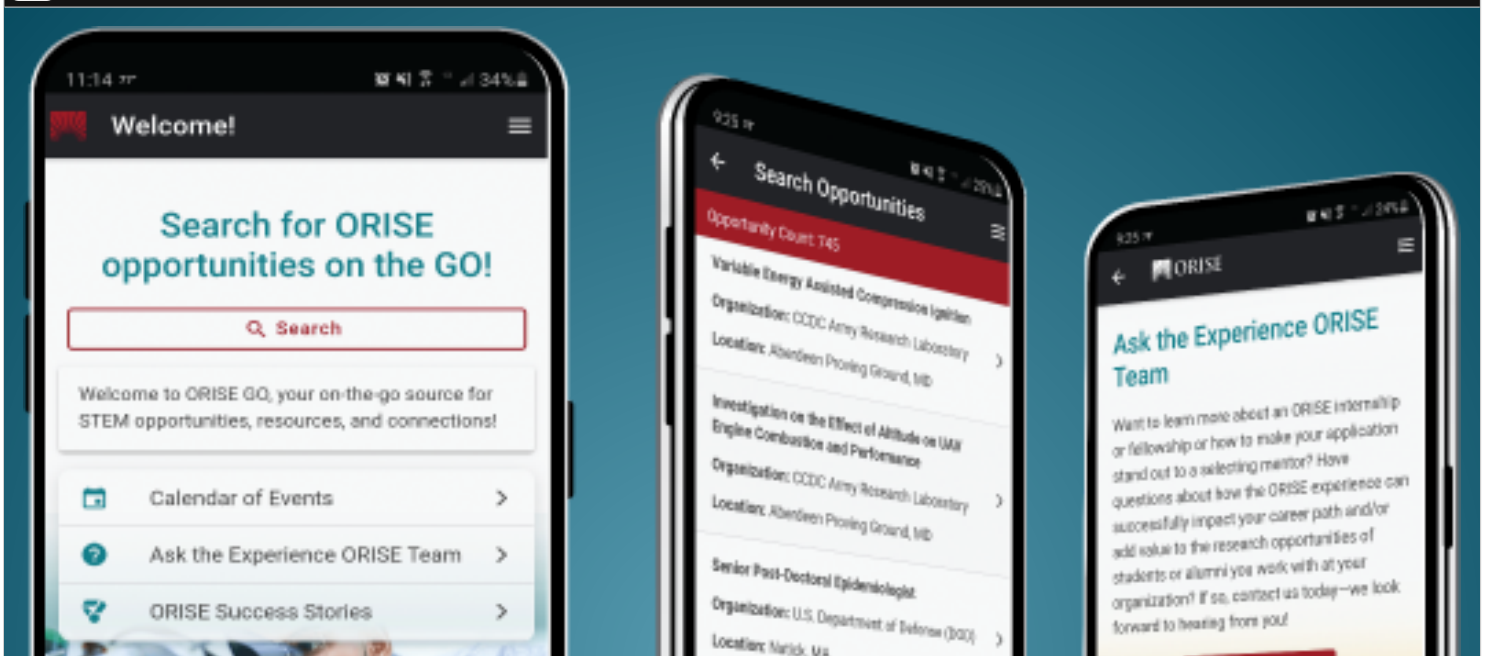
- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Academic Level(s):** Postdoctoral.
- **Discipline(s):**
 - Life Health and Medical Sciences (2 )

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.)

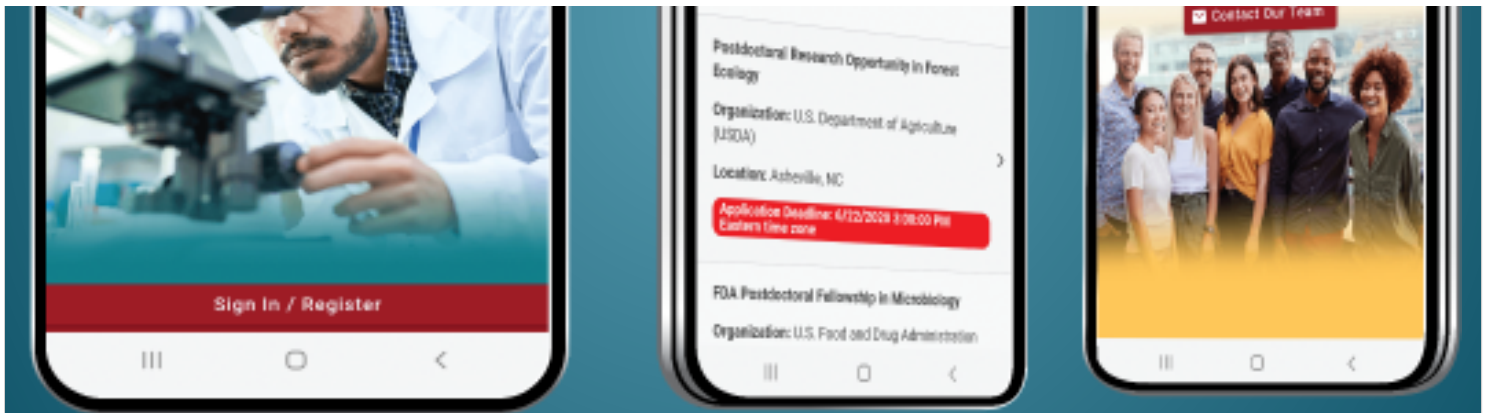


OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION



Opportunity Title: FDA Statistical Modeling for Drug AE Analysis Fellowship

Opportunity Reference Code: FDA-CDER-2023-1247



The ORISE GO mobile app helps you stay engaged, connected and informed during your ORISE experience – from application, to offer, through your appointment and even as an ORISE alum!

[Visit ORISE GO](#)

