Opportunity Title: Improving pattern discovery in the FDA Adverse Event Reporting System with Network Analysis
Opportunity Reference Code: FDA-CDER-2023-1252

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

Reference Code FDA-CDER-2023-1252

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 6/30/2023 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 Surveillance and Epidemiology (OSE), at the 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.
The current methods of statistical data mining are limited in their ability to facilitate the identification of patterns of potential clinical interest from spontaneous reporting systems of medical product adverse events. Network analysis (NA) allows for simultaneous representation of complex connections among the key elements of such a system and can facilitate pattern discovery.

Under the guidance of the mentor, the participant will learn how to apply NA to the FDA Adverse Event Reporting System (FAERS) to improve adverse event pattern discovery and safety signal identification. Through guided reading of published literature on methods of NA, especially as applied to document networks, the participant will gain general knowledge of NA techniques. The participant will also learn about the role of current methods of analysis of FAERS data, including statistical disproportionality methods, for drug safety assessment at FDA. The participant will also learn how to apply NA software tools to FAERS data.

Anticipated Start Date: 2023. The start date is flexible and will depend upon a variety of factors.

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

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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 doctoral degree in one of the relevant fields, or be currently pursuing the degree with completion before June 30, 2023. Degree must have been received within the past five years.

Preferred Qualifications:

- A strong background in programming for data analysis, using the R programming language
- Familiarity with medical terminology, pharmacology, and drug safety assessment
- Qualified Master's degree recipients will be considered

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2023 12:00:00 AM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Life Health and Medical Sciences** (3 👁)
  - **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 received my Master's Degree or I am currently pursuing or have received my Doctoral Degree.