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Opportunity Title: FDA Pharmacovigilance Fellowship: Data Retrieval and Analysis Strategies
Opportunity Reference Code: FDA-CDER-2024-1393

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

Reference Code FDA-CDER-2024-1393

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 6/28/2024 3:00:00 PM Eastern Time Zone

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

This project is in the Office of Pharmacovigilance and Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE). This project will evaluate the utility and performance characteristics of different Medical Dictionary for Regulatory Activities (MedDRA) search strategies (e.g., individual Preferred Term(s), Standardized MedDRA Query (SMQ), custom MedDRA queries) to identify cases of anaphylaxis in the FDA Adverse Event Reporting System (FAERS). This project aims to:

- 1) characterize the performance characteristics (e.g., sensitivity, specificity) of the different search terms/strategies using a retrospective data set from prior DPV reviews of anaphylaxis and using a new prospective data set reviewed by an allergist,
- 2) compare and contrast the performance characteristics between the retrospective and prospective analyses, and
- 3) explore the feasibility of performing a similar analysis using cases of anaphylaxis from clinical trials. The anaphylaxis use-case will serve as a prototype for refining FAERS data retrieval and analysis strategies using data-driven approaches.

Under the guidance of the mentor, the participant will engage in a training program that will cover the best practices in drug and biological product post-market safety surveillance. The participant will be trained to retrieve information needed for the research project from FDA databases (e.g., FAERS cases, drug information, review documents, MedDRA desktop browser) with hands-on activities. Under the guidance of the mentor and in collaboration with the research team, the participant will:

- 1) identify a list of products to be included in the historical and new

prospective data set,
- 2) explore methods to identify and compare the performance characteristics of different MedDRA search strategies,
- 3) collect and analyze the data retrieved to understand the utility and performance characteristics of different MedDRA search strategies (e.g., individual PT(s), SMQ, custom MedDRA queries) to identify cases of anaphylaxis in FAERS, and
- 4) interpret findings in the context of DPV pharmacovigilance practices and develop materials to disseminate best practices to FDA staff.

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.

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 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;

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- 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 be currently pursuing or have received a master's or doctoral degree in the one of the relevant fields. Degree must have been received within the past five years, or expected to be received by August 30, 2024.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 8/30/2024 12:00:00 AM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (6 👁)
  - **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.)

I have read the FDA Ethics Requirements.