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Opportunity Title: FDA Pharmacovigilance Fellowship
Opportunity Reference Code: FDA-CDER-2020-0546

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

Reference Code FDA-CDER-2020-0546

How to 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 12/31/2020 3:00:00 PM Eastern Time Zone

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

An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland.

This project in the Office of Surveillance and Epidemiology (OSE)/Office of Pharmacovigilance and Epidemiology (OPE) will perform an analysis of the Divisions of Pharmacovigilance (DPV) practices for surveillance of post marketing data. Findings from the project will inform the practices utilized by DPV to identify and evaluate safety signals in the FDA Adverse Event Reporting System (FAERS) database for all marketed drug and therapeutic biological products.

Under the guidance of FDA staff, the participant may be involved in:

- Characterizing various pharmacovigilance practices
- Evaluating efficiency, consistency, and effectiveness of current pharmacovigilance practices
- Evaluating the impact of enhanced pharmacovigilance and industry sponsored programs on the FAERS database
- Assisting in developing internal guidance aimed at improving surveillance practices

The participant will learn about regulatory practices for surveillance of post-marketing data which is used to identify safety signals and inform Agency actions.

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 six to twelve months, 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.

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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 be currently pursuing or have received a master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Strong data analysis skills, familiarity with computer programming (e.g., SAS, R), and an interest in drug safety is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (46 👁)