

**Opportunity Title:** FDA Pharmacovigilance Fellowship

**Opportunity Reference Code:** FDA-CDER-2021-0685

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

**Reference Code** FDA-CDER-2021-0685

**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](mailto:ORISE.FDA.CDER@orau.org). Please include the reference code for this opportunity in your email.

**Application Deadline** 10/29/2021 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)/Office of Pharmacovigilance and Epidemiology (OPE), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

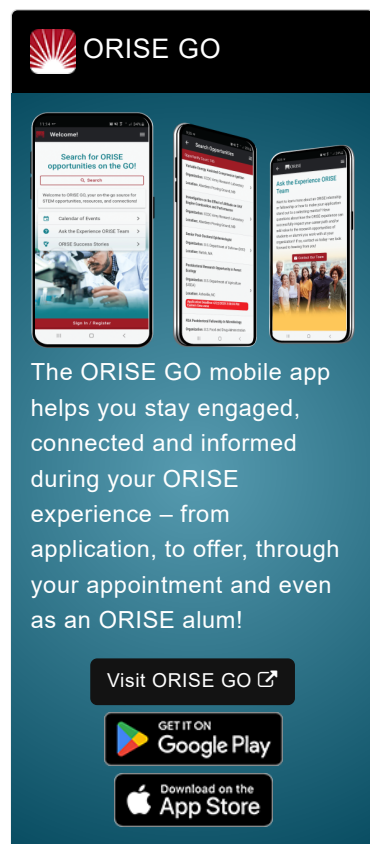
This project will perform an analysis of the Divisions of Pharmacovigilance (DPV) practices for surveillance of post marketing data. Findings from the project will inform the practices utilized by DPV to identify and evaluate safety signals in the FDA Adverse Event Reporting System (FAERS) database for 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 for 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.



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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 be currently pursuing or have received a master's or doctoral degree in epidemiology, public health, bioinformatics, or related field. Degree must have been received within the past five years.

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](#) )

**Affirmation** Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)