zintellect
climb higher

Opportunity Title: FDA Fellowship - Strategies to Identify Cases of Prenatal Drug Exposure in FAERS
Opportunity Reference Code: FDA-CDER-2026-0008

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

Reference Code FDA-CDER-2026-0008

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 4/30/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available immediately within the Office of Surveillance and Epidemiology (OSE) within the Center for Drug Evaluation and Research (CDER) with the Food and Drug Administration (FDA), located in Silver Spring, Maryland.

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. These efforts cover more than just medicines.

Research Project: The Division of Pharmacovigilance I (DPV-I) in OSE will lead a project to determine the best approach for identifying cases of prenatal drug exposures in the FDA Adverse Event Reporting System (FAERS). The project aims to 1) assess the performance of existing Medical Dictionary for Regulatory Activities (MedDRA)-based search algorithms compared to a novel algorithm that leverages other features (e.g., patient age) for identification of cases of prenatal drug exposure; 2) characterize and compare the performance of different search strategies for identification of adverse events following prenatal drug exposures; and 3) compare and contrast the impact of drug product characteristics on the effectiveness of search strategies.

Learning Objectives: You will learn best practices in drug and biological product post-market safety surveillance and receive hands-on training to retrieve data from relevant FDA databases and tools. Under the guidance of mentors, you will learn about regulations, policies, and procedures pertinent to postmarketing drug safety surveillance. As a team with FDA staff, you will identify a list of products to be included in our study and explore methods to identify and

compare the performance characteristics of existing MedDRA search strategies and a novel search strategy. You will collaborate with the research team to interpret findings and develop materials to disseminate best practices to FDA staff. Through the appointment, you will gain 1) understanding of pharmacovigilance best practices; 2) hands-on experience retrieving information from internal FDA databases; 3) understanding of performance characteristics for different approaches for retrieving cases of prenatal drug exposure from FAERS data; and 4) understanding of the utility of different approaches in pharmacovigilance activities. You will also gain experience conducting regulatory research that contributes to pharmacovigilance science and informs FDA programs.

Mentor: The mentors for this opportunity are Ivone Kim (Ivone.kim@fda.hhs.gov) and Carmen Cheng (Carmen.Cheng@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

Anticipated Appointment Start Date: August 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full-time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens and Lawful Permanent Residents (LPR) only.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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;
- 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.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (4 👁)
  - **Mathematics and Statistics** (4 👁)

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 read the FDA Ethics Requirements.