

**Opportunity Title:** FDA Regulatory Science Research Project Related to Safety of Medications in Pregnancy in the Post Approval Setting  
**Opportunity Reference Code:** FDA-CDER-2026-0058

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

**Reference Code** FDA-CDER-2026-0058

**How to Apply** *To submit your application, scroll to the bottom of this opportunity and click 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](mailto:ORISE.FDA.CDER@orau.org). Please include the reference code for this opportunity in your email.

**Application Deadline** 5/31/2026 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 with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in White Oak, 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. This effort covers more than just medicines.

**Research Project:** This research proposal aims to assess and compare the FDA and European Medicines Agency (EMA) regulatory approaches to post approval Pregnancy and Lactation Studies. Specifically, the focus is on evaluating the pregnancy and lactation postmarketing requirement studies issued between 2007 and the present to identify differences and similarities, with the goal of identifying opportunities for global alignment. Additionally, the research will assess the rationale or criteria used in each region to support issuance of pregnancy and lactation postmarketing requirement studies.

Pregnant and lactating women have historically been excluded from drug development trials. Therefore, at the time of new drug/biologic approval, there are only animal data to inform the safety in pregnant and lactating women. Pregnancy safety and lactation data are collected predominantly in the post approval setting. The 2007 FDA Amendments Act gave FDA the



OAK RIDGE INSTITUTE  
FOR SCIENCE AND EDUCATION



**ORISE GO**

The ORISE GO mobile app helps you stay engaged, connected and informed during your ORISE experience – from application, to offer, through your appointment and even as an ORISE alum!

Visit ORISE GO 

GET IT ON  
 Google Play

Download on the  
 App Store

**Opportunity Title:** FDA Regulatory Science Research Project Related to Safety of Medications in Pregnancy in the Post Approval Setting

**Opportunity Reference Code:** FDA-CDER-2026-0058

authority to require postmarketing requirement (PMR) safety studies in pregnant and lactating women. Stakeholders including the HHS Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) have been calling for more comprehensive data collection in pregnant and lactating women and the need for improved collaboration. Recently, the FDA, EMA, and the United Kingdom Medicines and Healthcare Regulatory Agency (MHRA) formed a pregnancy and lactation cluster to discuss scientific and regulatory issues relevant to these populations. Discussions at this cluster have highlighted the need for greater collaboration and alignment in advice given to sponsors. One such need identified is in the area of aligning study protocols with the purpose of expanding the study population to facilitate more timely conduct of studies. Pregnancy registries face challenges with regard to enrollment and take over ten years to complete. Aligning protocols in both regions would facilitate faster accrual of the needed sample size.

Activities of the project:

- Identify FDA and EMA Pregnancy and Lactation PMRs issued from 2007 through 2025.
- Compare which drugs received a PMR/PASS by both agencies, vs which ones did not. Identify trends over time and potential relationship with milestone events (e.g. guidance publication, rule making, public workshops, etc.).
- Identify the therapeutic areas where there is alignment in issuance of PMRs/PMRs.
- Verify the status of the studies: (ongoing, completed, released (if so, why?).
- Retrieve and review the study protocols and identify where there is alignment in the protocol (i.e. same study protocol for both regions). Define the characteristics of the study: e.g.
  - study method (pregnancy registry, claims database study, descriptive pregnancy safety study)
  - is the intent to expand the study population? Is there planned pooling of the data?
- Review the study protocols and identify where there are differences based on region, in methodology (e.g. exposure definition, outcome definitions, duration of infant follow-up, etc.)
- Review the Pregnancy and Lactation labeling in each region for each drug issued a PMR to assess if the study contributed to labeling changes.

The research addresses the need to improve data collection in pregnant and lactating women.

**Learning Objectives:** This appointment provides structured learning through FDA courses and training on drug development topics, teaching by mentor and colleagues. The fellowship will provide experience in a regulatory environment to enhance career opportunities at FDA, industry,

**Opportunity Title:** FDA Regulatory Science Research Project Related to Safety of Medications in Pregnancy in the Post Approval Setting

**Opportunity Reference Code:** FDA-CDER-2026-0058

and academia. You are expected to gain knowledge on drug development and regulatory review. Skills related to collaborating in a multidisciplinary environment will be gained.

**Mentor:** The mentor for this opportunity is Leyla Sahin ([Leyla.Sahin@fda.hhs.gov](mailto:Leyla.Sahin@fda.hhs.gov)). If you have questions about the nature of the research, please contact the mentor.

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

**Appointment Length:** The appointment will initially be for two years, 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 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:

**Opportunity Title:** FDA Regulatory Science Research Project Related to Safety of Medications in Pregnancy in the Post Approval Setting

**Opportunity Reference Code:** FDA-CDER-2026-0058

- 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 bachelor's, master's, or doctoral degree in the one of the relevant fields.

**Point of Contact** [Ashley](#)

**Eligibility** • **Citizenship:** U.S. Citizen Only

**Requirements** • **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.

• **Discipline(s):**

- **Computer, Information, and Data Sciences** ([2](#))
- **Life Health and Medical Sciences** ([51](#))

**Affirmation** I am a U.S. citizen, or 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.