Opportunity Title: FDA CDER Regulatory Science Fellowship
Opportunity Reference Code: FDA-CDER-2026-0097

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

Reference Code FDA-CDER-2026-0097

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 6/19/2026 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 within the Immediate Office of the Office of Translational Sciences (OTS), 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: You will join a project to analyze data for CDER drug premarketing applications housed in internal regulatory science databases. This data analysis may be performed using various programming languages such as, SAS, R, or Python. As part of this opportunity, you will be able to engage with a multi-disciplinary team and may help in designing and developing visualizations and dashboards. Results of the research may inform updates to data considerations for internal regulatory science databases. Additionally, you will have the opportunity to disseminate research findings to internal and external data stakeholders (e.g. publication)

Learning Objectives: Under the guidance of a mentor, you will:

- Develop useful knowledge of data fields related to CDER drug premarketing applications
- Gain an understanding of fundamentals of data analysis utilizing best practices in ensuring data quality and traceability
- Learn the structure and content of internal regulatory science databases

- Gain familiarity with accepted regulatory science data management and governance procedures
- Help develop tools to visualize trends and analyses for novel drug applications
- Gain understanding of data pipelines used for dashboard development.

Mentor: The mentor for this opportunity is Mary Doi (mary.doi@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: October 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 have received or be currently pursuing a bachelor's, master's, or doctoral degree in one of the relevant fields.

Degree preference:

- Applicants who have both obtained a bachelor's degree and a master's or doctoral degree.

Point of Contact

Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (5 👁)
  - **Life Health and Medical Sciences** (5 👁)
  - **Mathematics and Statistics** (3 👁)

Affirmation

I am a U.S. citizen; or I have resided within the U.S. for 36 out of the 60 months (do not need to be consecutive).

AND

I have read the FDA Ethics Requirements.