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Opportunity Title: FDA Fellowship - Integrated Clinical Trial Database Development for Drug Safety
Opportunity Reference Code: FDA-CDER-2026-0056

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

Reference Code FDA-CDER-2026-0056

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. 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 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. These efforts cover more than just medicines.

Research Project: Through an ORISE fellowship, you will engage in a regulatory science research initiative to create an integrated database from randomized and controlled clinical trials for drugs intended to treat diabetes, overweight, and lipid disorders, enhancing FDA's safety signal detection capabilities. You will collaborate with a multidisciplinary team to develop frameworks for standardizing and combining subject-level data from hundreds of clinical trials, including over 20 completed cardiovascular outcome trials.

You will investigate approaches to harmonize diverse clinical trial datasets, and analyze complex data across multiple studies. Through this, you contribute to developing analytical tools for rapid regulatory response and participate in meta-analyses of adverse events across drug classes to support both premarket and postmarket safety evaluation.

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Learning Objectives: The fellowship will provide you with learning in regulatory data science through weekly mentored meetings and monthly steering committee sessions with Office leadership. Educational components include hands-on experience with clinical trial data management, training in FDA regulatory processes, and instruction in clinical safety review.

You will receive training in advanced statistical methods for safety signal detection, machine learning applications in pharmacovigilance, and evidence synthesis techniques. You will collaborate with statistical team leaders and clinical reviewers to develop expertise in meta-analysis methodologies and regulatory decision-making processes.

This opportunity will provide you skills to enhance your future career in regulatory science, pharmaceutical research, or academic medicine by providing exposure to the largest controlled clinical database for diabetes therapeutics. The experience will allow you to develop a unique skill set combining regulatory science expertise with advanced data analytics, giving you great experience in regulatory data science.

Mentor: The mentor for this opportunity is Justin Penzenstadler (Justin.Penzenstadler@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 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,

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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 doctoral degree in the one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Life Health and Medical Sciences** (51 👁)
  - **Mathematics and Statistics** (11 👁)

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.