Opportunity Title: FDA Bayesian Inference for Safety Signal Detection
Opportunity Reference Code: FDA-CDER-2026-0094

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

Reference Code FDA-CDER-2026-0094

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 5/29/2026 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: Safety signal detection presents challenges for regulatory decision making when dealing with rare adverse events or adverse events in rare disease populations due to limited data and low event frequencies. Frequentist methods often lack sufficient power to detect safety signals in these scenarios. Bayesian methods offer a promising framework for addressing these challenges by incorporating prior knowledge to enhance detection and evaluation capabilities.

This project focuses on advancing Bayesian inference methods for low frequency events. You will research and develop Bayesian inference methods for detecting safety signals in rare adverse events. Activities include creating prior distributions for low-frequency adverse events, testing Bayesian inference methods at various frequencies, and developing disease-specific prior distributions.

Learning Objectives: Under the guidance of mentors from the Clinical

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Data Science (CDS) staff, you will develop comprehensive expertise in Bayesian statistical methods for safety signal detection. Training will include structured learning through selected reading, guided coding in R, collaborative discussions with Clinical Data Science staff, and regular one-on-one mentoring sessions. You will acquire advanced skills in applying Bayesian inference, data cleaning and preprocessing, data modeling, and clinical interpretation. You will also learn to apply statistical concepts to regulatory decisions and gain experience in communicating complex analytical concepts and techniques to other review disciplines in cross-functional review teams. You will present research at CDS meetings and gain hands-on review experience of NDA and BLA application reviews.

Mentor: The mentor for this opportunity is William Quarles (william.quarles@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

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, 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

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

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** (4 👁)
  - **Life Health and Medical Sciences** (3 👁)
  - **Mathematics and Statistics** (2 👁)

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.