

**Opportunity Title:** FDA Bayesian Statistical Approaches to Address the Unique Challenges of Rare Disease Drug Development

**Opportunity Reference Code:** FDA-CDER-2026-0057

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

**Reference Code** FDA-CDER-2026-0057

**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. These efforts cover more than just medicines.

**Research Project:** The project is a comprehensive research initiative focused on advancing Bayesian statistical methodologies for rare disease drug development within FDA's regulatory framework. You and mentors will research Bayesian dynamic borrowing methods for augmenting small sample sizes through incorporation of historical data, external controls, and real-world evidence, while investigating techniques to assess the similarity between internal and external data sources to determine appropriate borrowing strength and borrow information from multiple endpoints. You will collaborate with FDA scientists to address multiplicity issues due to multiple looks and multiple endpoints and analyze adaptive trial designs using Bayesian frameworks and contribute to the development of Bayesian hierarchical models for basket trials targeting rare diseases with shared molecular etiologies. The research supports FDA's mission to facilitate innovative approaches for rare disease drug development while maintaining appropriate scientific rigor.



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 Bayesian Statistical Approaches to Address the Unique Challenges of Rare Disease Drug Development

**Opportunity Reference Code:** FDA-CDER-2026-0057

During the appointment you will develop skills in applying Bayesian statistical approaches to address the unique challenges of rare disease drug development. Educational activities will include mentorship from FDA biostatisticians, participation in cross-functional team meetings, and structured learning experiences in regulatory decision-making processes. You will also engage in professional development seminars on scientific writing for regulatory audiences and presentation skills for technical and policy-oriented stakeholders.

This fellowship experience will significantly advance your academic and career trajectory in biostatistics and regulatory science. You will contribute to peer-reviewed publications on methodological innovations in rare disease clinical trials, enhancing their research portfolio and establishing expertise in a rapidly evolving field. The experience will provide unique insights into FDA's regulatory processes, preparing you for leadership roles in drug development, regulatory affairs, or academic research focused on statistical methodology for medical product evaluation.

**Learning Objectives:** Building on the Bayesian framework demonstrated in the provided research, you will gain hands-on experience with Bayesian dynamic borrowing methods for augmenting small sample sizes through incorporation of historical data, external controls, and real-world evidence, while learning to assess the similarity between internal and external data sources to determine appropriate borrowing strength and borrow information from multiple endpoints and address multiplicity issues.

Training will include implementation of adaptive trial designs using Bayesian frameworks, development of informative priors based on natural history studies and mechanistic understanding, and application of Bayesian hierarchical models for basket trials targeting rare diseases with shared molecular etiologies. You will also learn to conduct sensitivity analyses to evaluate the robustness of Bayesian conclusions and communicate Bayesian results effectively to non-statistical stakeholders in regulatory settings.

Upon completion of the fellowship, you will be able to demonstrate advanced competency in applying Bayesian statistical methods to address multiplicity issues and optimize trial efficiency in resource-constrained rare disease settings. You will acquire expertise in evaluating and implementing dynamic borrowing strategies that appropriately balance the incorporation of external information with the risk of bias. You will gain comprehensive understanding of how to integrate patient preferences, disease burden considerations, and regulatory requirements into statistical decision-making frameworks.

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

**Anticipated Appointment Start Date: Spring, 2026.** Start date is flexible

**Opportunity Title:** FDA Bayesian Statistical Approaches to Address the Unique Challenges of Rare Disease Drug Development

**Opportunity Reference Code:** FDA-CDER-2026-0057

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 or part 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, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the [Guidelines for Non-U.S. Citizens Details page](#) of the program website for information about the valid immigration statuses that are acceptable for program participation.

---

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

**Opportunity Title:** FDA Bayesian Statistical Approaches to Address the Unique Challenges of Rare Disease Drug Development

**Opportunity Reference Code:** FDA-CDER-2026-0057

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 (biostatistics or statistics). Degree must have been received within the past two years or be currently pursuing.

Preference is given to:

- Master's degree received or;
- Pursuing doctoral

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

**Eligibility Requirements**

- **Degree:** Master's Degree or Doctoral Degree received within the last 24 months or currently pursuing.
- **Discipline(s):**
  - **Mathematics and Statistics** (2👁)
  - **Other Non-Science & Engineering** (1👁)

**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.