Opportunity Title: FDA Optimization Modeling to Support Benefit-Risk Assessment Fellowship
Opportunity Reference Code: FDA-CBER-2026-0007

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

Reference Code FDA-CBER-2026-0007

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.CBER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 5/22/2026 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

FDA Office and Location: A research opportunity is currently available in the Office of Biostatistics and Pharmacovigilance (OBPV) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

The Center for Biologics Evaluation and Research (CBER) is one Center within the Food and Drug Administration, an Agency within the United States Government's Department of Health and Human Services. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

Research Project: You will participate in the development of novel quantitative approaches for benefit-risk analyses, which could include Bayesian methodologies and use of artificial intelligence to systematically integrate available information for evolving benefit-risk assessment. The goal is to tackle the major challenges inherent to biological products (such as vaccines, blood/transfusion medicine and gene therapies), including: limited clinical trial sample sizes that constrain traditional statistical inference; substantial variance in patient characteristics and clinical endpoints that complicate treatment effect estimation; uncertainty in estimating the duration of therapeutic benefit; the need for robust methods to assess emerging adverse events in post-market settings; and the critical comparison of real-world outcomes versus clinical trial outcomes to support regulatory decision-making.

Under the guidance of a mentor, you will apply novel technology to help develop a benefit-risk assessment modeling tool. The activities include literature reviews, data collection/curation, model development, presentation of research results, and preparation of scientific manuscripts.

Learning Objectives: Through this training, you will learn the challenges for benefit-risk

assessment of biological products, FDA framework, and how quantitative benefit-risk assessment can help inform regulatory decision.

Mentor: The mentor for this opportunity is Hong Yang (Hong.Yang@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, 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

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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 one of the relevant fields prior to the start of the appointment. The degree must have been received within 5 years of the appointment start date, or is anticipated to be received by 7/31/2026.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 7/31/2026 11:59:00 PM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (28 👁)
  - **Environmental and Marine Sciences** (14 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Mathematics and Statistics** (11 👁)
  - **Other Non-Science & Engineering** (2 👁)
  - **Physics** (16 👁)

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.