Opportunity Title: FDA Fellowship - Evaluation of Non-Inferiority Margin for Drug Products
Opportunity Reference Code: FDA-CDER-2026-0002

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

Reference Code FDA-CDER-2026-0002

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 4/30/2026 1:19:37 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available in the Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. The Center for Drug Evaluation and Research 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, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. These efforts cover more than just medicines.

Research Project: The increasing number of approved ophthalmology products over the past two decades has created new challenges for non-inferiority trial design, as placebo-controlled studies are often no longer ethical and patient populations have become more heterogeneous with varying treatment histories. Current non-inferiority studies must account for evolved reference standards, mixed treatment-naive and treatment-experienced populations, and updated clinical practice patterns that differ substantially from historical superiority trial settings. This project will systematically evaluate the scientific basis for non-inferiority margin selection in wet age-related macular degeneration (wAMD) and diabetic macular edema (DME), with potential expansion to other retinal indications, through network meta-analysis and patient matching methodologies applied to historical and recent clinical data. The participant will contribute to developing internal FDA guidance and supporting peer-reviewed publications on appropriate non-inferiority study design and margin

justification in modern ophthalmic drug development.

Learning Objectives: Under the guidance of the mentor, you will gain comprehensive experience in regulatory biostatistics through hands-on analysis of clinical trial data from FDA submissions in ophthalmology, focusing on wAMD and DME indications. You will collaborate with experienced FDA statisticians to learn advanced statistical methods including network meta-analysis techniques, patient matching algorithms, and non-inferiority margin derivation methodologies. You will develop proficiency in regulatory database management, systematic data extraction from NDA submissions, and implementation of network meta-analysis software packages for indirect treatment comparisons. Specific technical skills will include patient-level data matching techniques and statistical methods for addressing treatment effect heterogeneity across studies from different clinical practice eras.

Through this mentored, intensive summer experience, you will also contribute to internal FDA guidance development and manuscript preparation for peer-reviewed publication, bridging academic statistical methodology with practical regulatory application in a focused 10-12 week timeframe.

Mentor: The mentor for this opportunity is Abel Eshete (abel.eshete@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: May 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for 12 weeks, 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.

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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 be currently pursuing or have received a Master's or Doctoral degree in one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Mathematics and Statistics** (8 👁)

Affirmation Have you 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.