Opportunity Title: FDA Fellowship - Statistical Methods for Three-Arm Clinical Trials with Multiple Testing Procedure
Opportunity Reference Code: FDA-CDER-2026-0040

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

Reference Code FDA-CDER-2026-0040

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 3/31/2026 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: In-vivo, in-vitro and therapeutical bioequivalence studies often involve comparing multiple test groups with a common control group. The conventional Dunnett's type I error rate adjustment proposed in 1955 is for superiority tests with normally distributed data. There are statistical concerns about generalizing the procedure to equivalence testing and with other variables such as lognormal and binary variable.

The participant will investigate statistical methodologies for three-arm bioequivalence studies, with particular focus on evaluating the applicability of the conventional Dunnett's procedure to equivalence testing frameworks. The participant will research the theoretical foundations of multiple comparison procedures originally developed for superiority testing and analyze their performance when applied to bioequivalence assessments involving multiple test formulations compared against a common reference product.

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Participants will engage exclusively in educational and research activities that support FDA's regulatory science mission while being prohibited from performing inherently governmental functions, including but not limited to conducting reviews of drug safety or efficacy and from participating in employee staff meetings to ensure compliance with fellowship guidelines. The participants are encouraged to contribute to educational seminars such as Departmental Rounds and may participate in meetings with industry when all parties provide consent. All research activities are mentored by FDA-OB staff to ensure compliance. All research outcomes will enhance the scientific rational for FDA reviewers in evaluating future application submissions, directly advancing the agency's public health mission through improved statistical methodologies for bioequivalence assessment.

Learning Objectives: Upon completion of the fellowship, you will have learned;

- Proficiency in evaluating whether Dunnett's procedure is applicable to equivalence test setting.
- Advanced understanding of publications of statistical procedures proposed since 1955 with objectives such as tests for nonnormal data, such as sign test, rank sum test, binary test and sequential test.
- Skills in statistical simulation and method validation techniques.

This is an educational and developmental program in mathematics and statistics, including biometrics and biostatistics, in which you will receive related training and opportunities to:

- Continue your education and research training in advanced biostatistical methodologies
- Enhance your professional development
- Become familiar with research areas conducted at CDER
- Become interested in future careers related to CDER and/or the FDA's public health mission

Mentor: The mentors for this opportunity are Tengfei Li (tengfei.li@fda.hhs.gov) and Meiyu Shen (Meiyu.Shen@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

Anticipated Appointment Start Date: June 1, 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for three months (until August 31, 2026), 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.

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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 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

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Mathematics and Statistics** (2 👁)

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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.