Opportunity Title: FDA Fellowship in Statistical Methods for New Approach Methodologies (NAMs)
Opportunity Reference Code: FDA-CDER-2026-0144

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

Reference Code FDA-CDER-2026-0144

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 8/31/2027 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 Silver Spring, 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: This fellowship encompasses interrelated research projects addressing methodological challenges at the intersection of statistical science, in vitro pharmacology, and regulatory decision-making under the New Approach Methodologies (NAMs) framework. Potential project topics may include but are not limit to:

- Investigating statistical methods for evaluating parallelism of dose-response curves between test and reference standards through simulation studies.
- Evaluation of multiple statistical approaches — including logistic regression, principal component analysis, and artificial neural networks — to determine optimal modeling frameworks for high-dimensional in vitro data generated by platforms such as organ-on-a-chip systems and MEA-based stem cell models.
- Contribute to a robust statistical framework to support the regulatory use of NAMs in proarrhythmia risk assessment, with a focus on

characterizing cardiac safety signals such as delayed repolarization and QT interval prolongation using in vitro assay data from CiPA reference compounds, ultimately informing regulatory decision-making under ICH S7B/E14 guidelines.

Learning Objectives: Upon completion of this fellowship, you will have gained the following competencies and practical experiences:

- Develop proficiency in statistical methods for evaluating parallelism of dose-response curves with direct application to regulatory bioassay development and drug product quality control.
- Gain experience in building, selecting, validating, and calibrating predictive models appropriate for small preclinical drug safety datasets, with attention to overfitting, uncertainty quantification, and regulatory defensibility across varying sample sizes and data variabilities.
- Develop applied artificial intelligence (AI) and statistical programming skills in R and/or SAS by implementing end-to-end machine learning pipelines, including data preprocessing, model training, cross-validation, simulation automation, and regulatory-standard reporting.
- Master quantitative risk assessment principles, including the statistical and scientific basis for safety margins, and design simulation studies to evaluate statistical methodologies for establishing safety bounds in regulatory pharmacology applications.
- Acquire practical experience analyzing in vitro assay data characterized by significant inter-laboratory variability, and develop strategies for identifying, quantifying, and mitigating its impact on statistical inference and regulatory decision-making.
- Gain skills in how to create reproducible, audit-ready analytical outputs, communicate findings effectively to multidisciplinary scientific and regulatory audiences, and co-author a manuscript for publication in a peer-reviewed statistical or regulatory science journal.

Mentor: The mentor for this opportunity is Meiyu Shen (meiyu.shen@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: October 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. citizen and Lawful Permanent Residents (LPR) only.

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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 master's degree in the one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree.
- **Discipline(s):**

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- **Mathematics and Statistics** (11 👁)

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.