Opportunity Title: FDA Fellowship: Evaluation of Novel Endpoints and Innovative Statistical Methodology in Oncology Clinical Trials
Opportunity Reference Code: FDA-CDER-2026-0158

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

Reference Code FDA-CDER-2026-0158

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 10/23/2026 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 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 research project aims to develop and evaluate innovative statistical methods and novel clinical trial endpoints in oncology, addressing key methodological gaps that have emerged as cancer therapies grow more complex and patient-centered outcomes become increasingly central to regulatory decision-making. Some topics for research as a part of this program could include:

Novel Endpoints Involving Repeated Measurements Over Time: Traditional time-to-event endpoints may not fully capture the longitudinal burden of disease or the dynamic trajectory of treatment benefit in oncology. This project will investigate endpoints that incorporate repeated measurements over time — such as tumor burden trajectories, patient-reported tolerability endpoints, or other endpoints of interest. Statistical approaches under evaluation could include joint models for longitudinal and time-to-event data, mixed-effects models for repeated measures (MMRM), non-parametric methods, and multistate models that characterize transitions

across clinically relevant health states throughout the disease course.

Intercurrent Events with Differential Prognostic Impact: Standard approaches to handling intercurrent events — such as avoidance of surgery in the perioperative treatment setting, transplant, treatment switching or use of subsequent therapies, or dose modifications — often fail to account for their heterogeneous prognostic implications. This project will evaluate principled estimand frameworks, consistent with ICH E9(R1), for defining and estimating treatment effects in the presence of intercurrent events whose occurrence may itself carry prognostic information. Methods of interest could include survivor average causal effect (SACE) estimators and principal stratification approaches that explicitly condition on patient subpopulations defined by intercurrent event status, with the goal of producing clinically interpretable estimates that reflect meaningful treatment contrasts.

Evaluation of Novel Endpoints in Rare Disease Settings: Many rare oncology disease settings have clinical trial design challenges due to a lack of available endpoints beyond overall survival. Other clinically relevant end points may exist, but without data from randomized clinical trials that capture both the novel endpoint of interest and overall survival, these endpoints cannot be formally validated. Innovative methods for evaluation of these endpoints could be explored to investigate the utility of their use in clinical trials for patients with rare tumors.

Collectively, these research areas address important methodological needs at the intersection of regulatory science, clinical trial design, and patient-centered outcomes in oncology.

Learning Objectives:

- Gain comprehensive education in oncology clinical trials through structured learning opportunities, available regulatory guidance, and fellowship-program resources.
- Develop applied analytics skills through mentored statistical analyses and simulations designed to evaluate research and project objectives.
- Participate in internal meetings and groups, receive mentorship, and engage in discussions of research methods, findings, and scientific priorities.
- Build scientific communication skills by presenting research findings at internal FDA meetings and, when appropriate, external scientific conferences.
- Gain experience preparing and submitting scientific manuscripts to disseminate research findings.

Mentor: The mentors for this opportunity are Pallavi Mishra-Kalyani (pallavi.mishra-kalyani@fda.hhs.gov) and Mallorie Fiero (mallorie.fiero@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

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

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;

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- 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

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Mathematics and Statistics** (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.