Opportunity Title: FDA Fellowship - Enhancing Oncology Dose Optimization Through Patient-Reported Outcome Exposure-Response Analysis
Opportunity Reference Code: FDA-CDER-2026-0050

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

Reference Code FDA-CDER-2026-0050

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 4/30/2026 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: Current dose optimization strategies for oncology therapeutics rely primarily on clinician-reported adverse events (CTCAE) in exposure-response (ER) analyses, which may inadequately capture the patient tolerability experience that drives treatment discontinuation and real-world effectiveness. Patient-reported outcomes (PROs) represent the only quantitative tool available to assess tolerability of oncologic agents under development, providing unique insights into the patient experience of symptomatic adverse events that traditional clinical assessments may miss. Our published proof-of-concept study demonstrated that PRO-CTCAE-derived ER analysis may offer enhanced sensitivity, and to complement standard ER analysis, by detecting safety signals, particularly valuable in early-phase trials with limited sample sizes where critical dose optimization decisions must be made.

You will join a project to prospectively assess the use of novel PRO-based

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ER analyses of tolerability associated drug exposure related adverse events to inform standard ER analyses for safety and provide complementary tolerability data to improve dosage optimization strategies in oncology clinical trials.

Learning Objectives:

As an ORISE fellow you will have the opportunity to:

- Investigate the application of validated PRO instruments into exposure-response modeling to enhance sensitivity for detecting safety signals in early-phase oncology trials using in-house datasets.
- Collaborate with industry partners or academic institutions to establish standardized protocols for PRO data collection and analysis in clinical development programs
- Contribute to the development of regulatory guidance documents and manuscripts outlining best practices for PRO integration in dose optimization strategies into the clinical drug development timeline.
- Research advanced pharmacometric modeling techniques to compare traditional clinician-reported versus patient-reported safety endpoints in exposure-response analyses
- Participate in comprehensive training programs covering FDA's regulatory framework for oncology drug development, including current dose optimization paradigms and emerging patient-focused approaches
- Receive hands-on training in advanced statistical software platforms (R, SAS, NONMEM) for pharmacometric modeling and PRO data analysis
- Engage with leading experts in regulatory science, patient-centered drug development, and oncology clinical pharmacology at the FDA Office of Clinical Pharmacology, FDA Oncology Center of Excellence and academic collaborators.

Mentor: The mentor for this opportunity is Jeanne Fourie Zirkelbach, PhD (Jeanne.fouriezirkelbach@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.

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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):**
  - **Computer, Information, and Data Sciences** (4 👁)
  - **Engineering** (1 👁)

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- **Life Health and Medical 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.