**Opportunity Title:** FDA Regulatory Analysis of Dose-Finding and Optimization Approaches in Targeted Oncology Therapeutics
**Opportunity Reference Code:** FDA-CDER-2026-0066

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

**Reference Code** FDA-CDER-2026-0066

**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** 5/31/2026 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. This effort covers more than just medicines.

**Research Project:** The objective of this research project is to collect and analyze the dosage selection and optimization strategies used in recently approved and investigational targeted oncology drugs (e.g., tyrosine kinase inhibitors). The project aims to characterize trends in oncology dose-finding and selection methodologies and analyze the impact of these changes on regulatory decision-making. During the project, you will help:

- Collect comprehensive data on dosage optimization strategies from recently approved oncology New Drug Applications (NDAs), Biologics License Applications (BLAs), and active Investigational New Drug (IND) applications for targeted oncology drugs, focusing on dose-finding study designs, dose-limiting toxicities (DLTs), recommended Phase 2 doses (RP2D), maximum tolerated/administrated doses (MTD/MAD), randomized dosage optimization, relevant pharmacokinetic and pharmacodynamic characteristics and exposure-response (E-R)

relationships.
- Analyze large datasets to identify patterns, trends, and challenges in dose selection of targeted oncology drugs.
- Participate in discussions with the Division of Cancer Pharmacology (DCP) leadership, clinical pharmacology reviewers, and team leads regarding how the results of the project may impact regulatory decisions and/or guidance that protect public health.
- Present the results of the project and their conclusions to the DCP and/or a broader clinical pharmacology audience.
- Contribute to a manuscript regarding the results of the project.

**Learning Objectives:** During the project you will learn about:

- Understanding oncology-specific dosage considerations including the transition from MTD to optimized dosing paradigms, the role of totality evidence in dosage selection, and unique challenges in oncology dose optimization.
- Understanding dose-finding methodologies, including dose escalation and expansion strategies, randomized dosage optimization approaches, and the determination of key dosing parameters (RP2D, MTD, MAD, DLTs).
- Proficiency in navigating and extracting relevant data from NDAs, BLAs and INDs, including US prescription information (USPI), multi-disciplinary review clinical pharmacology section, clinical protocols and reports, pharmacology sections, and dose-finding study results.
- Competency in systematically collecting and organizing complex regulatory and clinical data from multiple sources within FDA's information systems.

You will gain regulatory science experience and policy development insight that supports advancement in clinical pharmacology, drug development, and regulatory affairs across multiple sectors.

**Mentor:** The mentor for this opportunity is Siyan Zhu (siyan.zhu@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

**Anticipated Appointment Start Date: Early May/June, 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.

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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 or doctoral degree in the one of the relevant fields.

**Point of Contact** Ashley

**Eligibility Requirements**

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Life Health and Medical Sciences** (6 👁)
  - **Mathematics and Statistics** (1 👁)

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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.