Opportunity Title: FDA Fellowship: Food Effect Evaluation for Oncology Drugs
Opportunity Reference Code: FDA-CDER-2026-0157

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

Reference Code FDA-CDER-2026-0157

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: The objective of this research project is to investigate and analyze food effect evaluation strategies used in approved and investigational oncology drugs to advance regulatory scientific understanding of food effect and to inform the relevant labeling recommendations for oncology drugs. You will have the opportunity to collaborate with FDA scientists and engage in comprehensive research initiatives that identify the factors impacting food effect, summarize the commonly used food effect study design, and investigate their impact on regulatory decision-making.

This research will contribute to advancing the agency's mission of ensuring safe and effective oncology therapeutics through evidence-based regulatory guidance. You will have the opportunity to contribute to advancing FDA's mission of protecting and promoting public health through evidence-based regulatory decision-making in oncology drug development. You will also have the opportunity to contribute to manuscript development and scientific presentations, enhancing your ability to communicate

complex regulatory science concepts and advancing the broader scientific understanding of food effect evaluation in oncology therapeutics.

Learning Objectives: This fellowship experience will significantly advance your academic and career development. You will engage in structured educational activities designed to develop expertise in clinical pharmacology and regulatory science. Under the guidance of a mentor, you will:

- Research and analyze comprehensive datasets from recently approved oncology New Drug Applications (NDAs) and active Investigational New Drug (IND) applications, focusing on food effect evaluation strategies and regulatory outcomes.
- Investigate factors that influence food effect outcomes in oncology drugs, including drug physicochemical properties, acid-reducing agent interactions, formulation characteristics, etc.
- Participate in collaborative discussions with clinical pharmacology reviewers to analyze how food effect study results inform labeling recommendations and regulatory guidance development.
- Contribute to the development of best practices for food effect evaluation in oncology drug development through systematic analysis of regulatory precedents and emerging scientific approaches.

Through this fellowship experience, you will develop specialized knowledge and competencies that directly support FDA's regulatory science mission:

- Advanced understanding of oncology-specific food effect considerations through systematic extraction and interpretation of relevant information from NDAs and INDs, with particular focus on US Prescription Information (USPI) food intake recommendations, clinical pharmacology review sections, and food effect study protocols and outcomes.
- Competency in regulatory labeling science including risk-benefit assessment for food intake guidance and translation of food effect study results into evidence-based labeling recommendations.

Mentor: The mentor for this opportunity is Yixuan Dong (yixuan.dong@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 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 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):**

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- **Computer, Information, and Data Sciences** (3 👁)
- **Life Health and Medical Sciences** (5 👁)
- **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.