

Opportunity Title: FDA Research Opportunity on Understanding Dose Selection for Oncology Drug Products

Opportunity Reference Code: FDA-CDER-2023-1276

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

Reference Code FDA-CDER-2023-1276

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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@oraui.org. Please include the reference code for this opportunity in your email.

Application Deadline 9/30/2023 3:00:00 PM Eastern Time Zone

Description *Applications will be reviewed on a rolling-basis.

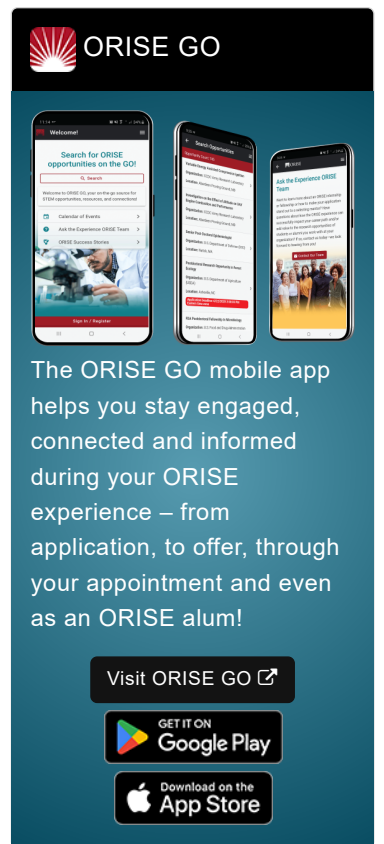
A research opportunity is available in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS) within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) located in Silver Spring, Maryland.

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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

This project will identify the dose-finding strategies employed during oncology drug products development over the past decade, analyze the data summarized in the marketing application used to justify the recommended dosage and the dose commonly used in clinical practice following approval, and identify the key limitations in past dose selection practices in order to refine and streamline regulatory recommendations that leverage all available data to better select doses for development.


Under the guidance of the mentor, the participant will learn to prepare a database describing information gathered from multidisciplinary regulatory reviews completed during clinical development and following submission of the marketing application and publicly available sources, including published literature and compendia. The participant will also learn the current approaches used to select the dosing regimen(s) incorporated into clinical trials designed to assess safety and effectiveness and support a marketing application.


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




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interagency agreement between DOE and FDA. **The initial appointment is for three months but may be renewed upon recommendation of FDA contingent on the availability of funds.** The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. 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 have received a bachelor's, master's, or doctoral degree in one of the relevant fields, or be currently pursuing one of the degrees with completion before May 21, 2023. Degree must have been received within five years of the appointment start date.

Preferred skills/ knowledge:

- Knowledge in Pharmaceutical Science, Clinical Pharmacology, Public Health, or related fields are preferred.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or anticipated to be received by 5/21/2023 12:00:00 AM.
- **Discipline(s):**
 - **Engineering** ([1](#))
 - **Life Health and Medical Sciences** ([48](#))
 - **Mathematics and Statistics** ([1](#))

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Affirmation 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.)

I have read the FDA Ethics Requirements.