Opportunity Title: FDA Oncology Drug Product Dose Selection Fellowship
Opportunity Reference Code: FDA-CDER-2022-0772

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

Reference Code FDA-CDER-2022-0772

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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 9/30/2022 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 Translational Sciences/ Office of Clinical Pharmacology (OCP), Center for Drug Evaluation and Research (CDER), 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.

The project will identify the dose-finding strategies employed during oncology drug product 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 a 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 interagency agreement between DOE and FDA. The initial

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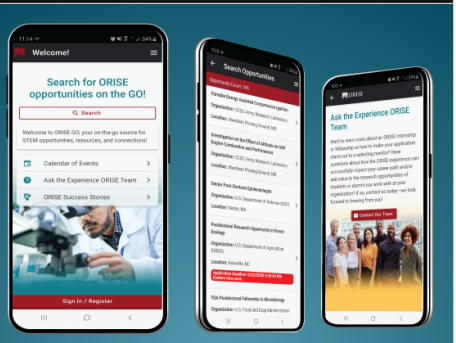

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appointment is for three months, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is 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 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 bachelor's, master's or doctoral degree (PhD, DPH, PharmD, MD) in one of the relevant fields. Degree must have been received within the past five years.

Preferred skills/ knowledge:

- Knowledge in Pharmaceutical Science, Clinical Pharmacology, Public Health, or related fields
- Strong analytical experience

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Mathematics and Statistics** (1 👁)

Affirmation

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)