Opportunity Title: FDA Fellowship in Physiologically Based Pharmacokinetic (PBPK) Modeling
Opportunity Reference Code: FDA-CDER-2022-0810

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

Reference Code FDA-CDER-2022-0810

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 10/31/2022 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available in the Office of Translational Sciences/Office of Clinical Pharmacology (OCP) at the Center for Drug Evaluation and Research (CDER) of 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 research project will utilize physiologically-based pharmacokinetic (PBPK) modeling to aid selection of safe and appropriate dosages of oncology drugs for pregnant women with cancers such as melanoma, breast cancer, cervical cancer, lymphomas, leukemias, and thyroid cancer. The project will improve understanding of the PK changes associated with pregnancy in patients with cancer, facilitate the design of PK studies of oncology drugs in pregnant women to support dosing recommendations, and provide model-informed PK data to support regulatory decision-making and possibly labeling changes for oncology drugs.

Under the guidance of a mentor, the participant will learn the application of physiologically based pharmacokinetic (PBPK) modeling in maternal clinical pharmacology. In addition, the participant will learn maternal physiology and clinical pharmacology principles and the impact on drug disposition in the specific population of pregnant women with cancer.

Anticipated Appointment Start Date: June 1, 2022. Start date is flexible and will depend upon a variety of factors.

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 appointment is for one year, 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

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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 (preferred) degree in one of the relevant fields. Degree must have been received within the past five years. Qualified candidates who are currently pursuing or have received bachelor's or master's degrees will be considered provided that the candidate demonstrates strong knowledge in mechanistic modeling.

Preferred Skills:

- Statistical and clinical pharmacology principles to perform and interpret PBPK modeling and simulation
- Knowledge of oncology
- Knowledge of maternal-fetal medicine and physiology of pregnancy

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)
  - **Computer, Information, and Data Sciences** (17)
  - **Engineering** (2)
  - **Life Health and Medical Sciences** (48)
  - **Mathematics and Statistics** (11)
  - **Physics** (16)

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)