Opportunity Title: FDA Oncology Drug Safety Assessment in HI Patients Fellowship
Opportunity Reference Code: FDA-CDER-2021-0719

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

Reference Code FDA-CDER-2021-0719

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 11/30/2021 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.

Hepatic impairment (HI) is a common co-morbidity for patients with cancer. This sub-population has a higher probability of experiencing toxicities (AEs) from oncology drugs, and biologics such as antibody drug conjugates (ADCs). This necessitates dose adjustments, which are complicated by the use of different HI classification systems (NCI-ODWG vs Child Pugh) and may lead to conflicting patient HI stratification and dose adjustments (DA). DAs for HI are further complicated for ADCs, because of the serious, potentially irreversible AEs they can mediate, and the difficulty in adjusting the effect of the payload without impacting efficacy. The fellowship will assess these issues and document guidance to better mitigate these issues and improve patient safety.

Under the guidance of a mentor, the participant will survey the currently approved oncology drugs and ADCs, for hepatic impairment studies and analyses from NDA/BLA submissions over the last 5 years. The participant will also learn to create a database consisting of nonclinical and clinical pharmacology data relevant to HI.

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 six months, but may

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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 part-time (20 hours per week) 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 in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Strong analytical experience
- Knowledge in Pharmaceutical Science, Clinical Pharmacology, Public Health, or related fields
- Interest in projects that advance regulatory science and public health

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** (1)
  - **Engineering** (1)
  - **Life Health and Medical Sciences** (46)
  - **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.)