Opportunity Title: FDA Inter-study Anomalies of PK and PD Fellowship
Opportunity Reference Code: FDA-CDER-2021-0714

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

Reference Code FDA-CDER-2021-0714

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 1/31/2022 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.

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. This work covers more than just medicines.

Atypical pharmacokinetic or pharmacodynamic characteristics of a clinical pharmacology study compared to the overall patient population often indicate underlying factors that are unique to the study, such as study design, assay methodology, formulation, patient population. Or they are attributed to pharmacological mechanism of the drug, for example: dose nonlinearity, immunogenicity, and receptor mediated metabolism. Meta-analysis methods will be developed and implemented to investigate anomalies in pharmacokinetics or pharmacodynamics of clinical pharmacology studies by comparing multiple study outcomes in a drug application submission. The root causes of the anomalies will be determined and summarized by drug class or therapeutic area.

Under the guidance of the mentor, the participant will learn to develop meta-analysis methodology and perform analyses to identify anomalies in pharmacokinetic or pharmacodynamic characteristics of clinical pharmacology studies in NDA/BLA submissions. The participant will also obtain knowledge and key concepts related to the FDA NDA/BLA review process.

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

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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 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 pharmacokinetic analysis skill
- Knowledge in pharmacokinetic analysis and modelling

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Life Health and Medical Sciences** (46 👁)