Opportunity Title: FDA Clinical Pharmacology of Therapeutic Biologics Fellowship
Opportunity Reference Code: FDA-CDER-2021-0644

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

Reference Code FDA-CDER-2021-0644

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 7/31/2021 3:00:00 PM Eastern Time Zone

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

Multiple research opportunities are available in the Office Translational Sciences/ Office of Clinical Pharmacology (OCP), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) 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.

The FDA's published guidance documents outline general principles regarding how to use clinical pharmacology data to support a demonstration of biosimilarity. The implementation of clinical pharmacology programs for biosimilar development depends on the characteristics of PK (and PD when appropriate). Given the diversity of therapeutic proteins in structural features and in the PK properties, the study design characteristics for the PK (or PK and PD) similarity study are determined on a product-by-product basis. This project aims to ultimately improve the efficiency in regulatory review and enhance consistency across programs by developing recommendations for clinical pharmacology study design delineated by product groups which will be more advantageous when compared to the current product-by-product approach.

The participants will gain in-depth knowledge on (1) clinical pharmacology of therapeutic proteins by reviewing the PK characteristics of approved products (CDER BLAs) and PD properties based on treatment responses measured using various biomarkers, (2) regulation and regulatory considerations for biosimilar drug development, (3) current practice of study design for clinical pharmacology studies in biosimilar programs, (4) information needed to support study design, and (5) similarities/dis-similarities in PK and PD among protein products.

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 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 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 have received a PhD, Pharm D, or MD in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Computer skills for data manipulation and analysis, experience with pharmacokinetic modeling tools is preferred.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (46 👁)