Opportunity Title: FDA Biomarker Qualification Fellowship
Opportunity Reference Code: FDA-CDER-2022-0773

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

Reference Code FDA-CDER-2022-0773

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 6/30/2022 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 New Drugs / Office of Drug Evaluation Sciences (ODES), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) 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 gather evidence to qualify serum alanine aminotransferase (ALT) as a safety biomarker for the context of use (COU) of detecting potentially serious drug-induced liver injury (DILI) with superior performance to the current practice of applying different upper limit of normal (ULN) which have increased over time and vary from study to study.

Under the guidance of the mentor, the participant will gain knowledge in regulatory data standards and how they pertains to the evaluation of DILI. The participant will also gain valuable experience in FDA safety evaluation and how safety analytics can be used to identify potential subjects at risk for DILI. The participant will also have opportunities to present the findings of the study to the scientific community internally and externally as well as to publish the findings in a peer reviewed journal.

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

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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 master's degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred Skills/ Knowledge:

- Knowledge in clinical trial research.
- Background in statistics and data analysis.
- Programming skills in R, Python, or SAS.
- Knowledge with Microsoft Access, Office 365 (Power Apps, SharePoint, Power Automate etc.)

Eligibility Requirements

- **Degree:** Master's Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Mathematics and Statistics** (11 👁)

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.)