

Opportunity Title: FDA Biomarker Qualification Fellowship

Opportunity Reference Code: FDA-CDER-2024-1443

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

Reference Code FDA-CDER-2024-1443

How to Apply

To submit your application, scroll to the bottom of this opportunity and click APPLY.

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.

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Application Deadline 8/30/2024 3:00:00 PM Eastern Time Zone

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

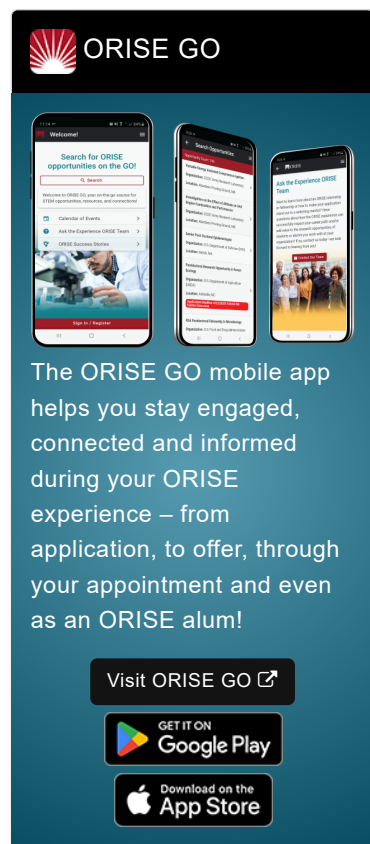
FDA Office and Location: A research opportunity is currently available in the Office of New Drugs / Office of Drug Evaluation Sciences (ODES), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

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.

Research Project: The Office of New Drugs is responsible for assessing safety and efficacy of new drug applications. The ability to accurately identify drugs that may cause drug-induced liver injury (DILI) has significant impact on the regulatory decision to approve or not approve a new drug. Historically, increases in liver enzymes (ALT and AST) has been used to identify subjects with potential DILI during drug development. However, local laboratory normal reference ranges can vary significantly (i.e., up to 2-fold) because they can be influenced by prevalent subclinical liver disease in the local population. Lack of uniform absolute values for ALT upper limit of normal (ULN) can result in miscategorization of subjects with potential DILI risk during regulatory review.


Learning Objectives: This project intends to review laboratory data clinical trials that enrolled adult populations without identifiable risk factors for liver disease submitted for evaluation of potential DILI. Training will be provided to the ORISE fellow in the following areas:


1. Scientific approach to evaluation of DILI to determine safety of new drug applications




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2. FDA's new drug review of DILI data requirements for regulatory submission
3. Data standards for regulatory submission

Anticipated Appointment Start Date: 2024. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the [Guidelines for Non-U.S. Citizens Details page](#) of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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 Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see [FDA Ethics for Nonemployee Scientists](#).

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 the past five years.




Preferred Skills/ Knowledge:

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- 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 or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Computer, Information, and Data Sciences** ([17](#) )
 - **Life Health and Medical Sciences** ([48](#) )
 - **Mathematics and Statistics** ([11](#) )

Affirmation I am a U.S. citizen, or I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)
and
I have read the FDA Ethics Requirements.