

**Opportunity Title:** FDA Biomarker Qualification Fellowship

**Opportunity Reference Code:** FDA-CDER-2026-0024

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

**Reference Code** FDA-CDER-2026-0024

**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@oraui.org](mailto:ORISE.FDA.CDER@oraui.org). Please include the reference code for this opportunity in your email.

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**Application Deadline** 4/15/2026 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 (OND) / 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 (OND) 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. Through this opportunity, you will cooperate in research and training activities related to computer modeling and statistical analyses of liver injury cases using clinical trial data.

**Learning Objectives:** Under the guidance of a mentor, You will learn about regulatory science, clinical trial design, and safety analysis. You will collaborate with and gain skills from



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seasoned FDA statisticians and programmers who are already identified and ready to help you participate in research building a database and case prioritization model.

**Mentor:** The mentor for this opportunity is Paul Hayashi ([Paul.Hayashi@fda.hhs.gov](mailto:Paul.Hayashi@fda.hhs.gov)). If you have questions about the nature of the research, please contact the mentor.

**Anticipated Appointment Start Date: 2026.** 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.

**Participant Stipend:** The participant will receive a monthly stipend commensurate with educational level and experience.

**Citizenship Requirements:** This opportunity is available to U.S. citizens and Lawful Permanent Residents (LPR) only.

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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;

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

**Point of Contact** [Ashley](#).

- Eligibility Requirements**
- **Citizenship:** LPR or U.S. Citizen
  - **Degree:** Master's Degree received within the last 60 months or currently pursuing.
  - **Discipline(s):**
    - **Computer, Information, and Data Sciences** ([9](#) )
    - **Life Health and Medical Sciences** ([1](#) )
    - **Mathematics and Statistics** ([1](#) )
    - **Other Non-Science & Engineering** ([1](#) )

**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.