

Opportunity Title: FDA Characterizing the Trends and Opportunities for Streamlining Evidence Generation Involving Pharmacodynamic Biomarkers

Opportunity Reference Code: FDA-CDER-2026-0179

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

Reference Code FDA-CDER-2026-0179

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.

Application Deadline 11/20/2026 3:00:00 PM Eastern Time Zone

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

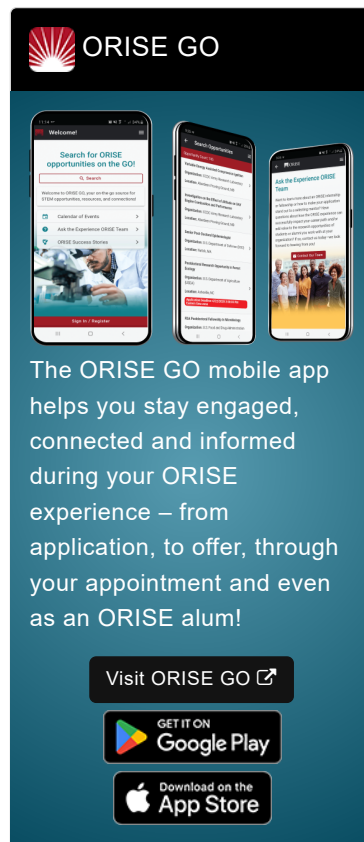
FDA Office and Location: A research opportunity is available immediately with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in Silver Spring, Maryland.

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. These efforts cover more than just medicines.

Research Project: Characterizing the Trends and Opportunities for Streamlining Evidence Generation Involving Pharmacodynamic Biomarkers - Pharmacodynamic biomarkers are increasingly central to drug development and regulatory decision-making. Their uses range from identifying target engagement, selecting doses to use in clinical trials, selecting patients, monitoring safety, performing exposure-response analysis, providing or confirming evidence as endpoints, etc. However, recurring limitations include unclear clinical relevance, variability, and bioanalytical challenges. This project will aim to identify trends in new drug approvals in the use of biomarkers in regulatory evaluation and identify the opportunities to inform and advance the development and application of biomarker-based information in drug development.

Learning Objectives: Under the guidance of a mentor, you will:

- Examine and understand how pharmacodynamic biomarkers are used in drug development and regulatory decision-making.



ORISE GO

The ORISE GO mobile app helps you stay engaged, connected and informed during your ORISE experience – from application, to offer, through your appointment and even as an ORISE alum!

Visit ORISE GO 

GET IT ON
 **Google Play**

Download on the
 **App Store**

Opportunity Title: FDA Characterizing the Trends and Opportunities for Streamlining Evidence Generation Involving Pharmacodynamic Biomarkers

Opportunity Reference Code: FDA-CDER-2026-0179

- Analyze trends in new drug approvals including use of biomarker for target engagement, dose selection, patient selection, safety monitoring, as endpoints and in exposure-response analysis.
- Develop an understanding of common challenges affecting pharmacodynamic biomarker use, such as uncertain biological variability, clinical relevance, and bioanalytical challenges.
- Identify opportunities to streamline, strengthen, and expand the development and application of pharmacodynamic biomarkers in drug development.
- Build skills in regulatory science, data review, and assessment of biomarker-based information.

Mentor: The mentor for this opportunity is Anuradha Ramamoorthy (Anuradha.Ramamoorthy@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: September 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, 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.

Qualifications The qualified candidate should be currently pursuing or have received a doctoral degree in the one of the relevant fields.

Opportunity Title: FDA Characterizing the Trends and Opportunities for Streamlining Evidence Generation involving Pharmacodynamic Biomarkers
Opportunity Reference Code: FDA-CDER-2026-0179

Point of Contact [Ashley](#)

Eligibility • **Degree:** Doctoral Degree.

- Requirements** • **Discipline(s):**
- **Computer, Information, and Data Sciences** ([1](#)👁)
 - **Life Health and Medical Sciences** ([7](#)👁)

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.)