

Opportunity Title: FDA Application of Quantitative Approaches to Streamline Drug Development and Enhance Patient Care

Opportunity Reference Code: FDA-CDER-2026-0043

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

Reference Code FDA-CDER-2026-0043

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 5/31/2026 3:00:00 PM Eastern Time Zone

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

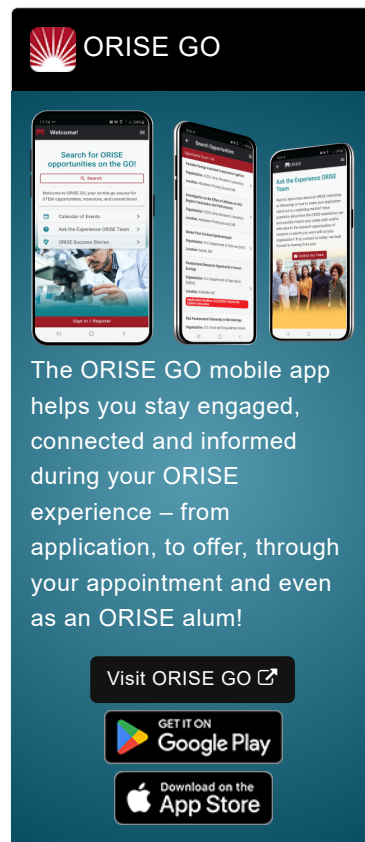
FDA Office and Location: A research opportunity is available immediately with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in White Oak, Maryland.

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 effort covers more than just medicines.

Research Project: The projects will focus on using quantitative analyses to support pediatric extrapolation in Ulcerative Colitis (UC) and Crohn's disease (CD), to identify appropriate selection criteria in Duchenne Muscular Dystrophy (DMD) patients, to fine tune exposure-response analysis in oncology, to improve dose selection in oncology and inflammatory & immune diseases, and to support risk and safety evaluation, to identify endpoints for Type 1 Diabetes.

During the appointment, you will use the clinical trial data under NDA and BLA submissions and published literature to cooperate in model building, covariate selection, and quantitative tool development. The findings are expected to be applied to innovate clinical trial design and streamline clinical development program, contributing to precision medicine.

Learning Objectives: The project provides training opportunities to



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 Application of Quantitative Approaches to Streamline Drug Development and Enhance Patient Care

Opportunity Reference Code: FDA-CDER-2026-0043

understand quantitative approaches that can be applied to support new drug development. During the appointment, you will learn basic skills in drug development, modeling and simulation skills for dose findings, endpoint selection, identification of confirmative evidence, and patient selection. You will also be able to participate in internal FDA scientific discussions, gain knowledges on drug development and learn quantitative skills on clinical trial data.

Mentor: If you have questions about the nature of the research, please contact the mentors at dpm-contact@fda.hhs.gov.

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 two years, 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.

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

Opportunity Title: FDA Application of Quantitative Approaches to Streamline Drug Development and Enhance Patient Care

Opportunity Reference Code: FDA-CDER-2026-0043

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 the one of the relevant fields.

Point of Contact [Ashley](#)

- Eligibility Requirements**
- **Degree:** Master's Degree or Doctoral Degree.
 - **Discipline(s):**
 - **Computer, Information, and Data Sciences** ([17](#) )
 - **Engineering** ([4](#) )
 - **Life Health and Medical Sciences** ([2](#) )
 - **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.