Opportunity Title: FDA Clinical Pharmacology / Model Informed Drug Development
Opportunity Reference Code: FDA-CDER-2026-0063

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

Reference Code FDA-CDER-2026-0063

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 work covers more than just medicines.

Research Project: This fellowship will focus on a regulatory science project examining how dose selection and optimization decisions are made for nucleotide-based therapeutics—such as antisense oligonucleotides, siRNA, and mRNA—intended for neurological diseases. The you will help investigate how safety margins, nonclinical data, biomarkers, and model-informed drug development (MIDD) approaches inform final dose selection. Key activities will include reviewing FDA regulatory documents such as Pre-IND communications, End-of-Phase 2 and MIDD meeting summaries, and Clinical Pharmacology review memoranda. The you will help systematically extract and analyze information on dose rationale, optimization strategies, and supporting evidence. Acting collaboratively with Clinical Pharmacology, OND Neurology, and the MIDD program, you help will identify trends and gaps in regulatory practices and synthesize findings into a regulatory science report with recommendations for best practices in dose optimization. This will contribute to the FDA's mission to advance regulatory

science that supports the development of safe, effective, and optimally dosed therapies for neurological disorders. This fellowship promotes evidence-based dose optimization that improves efficacy and minimizes risk, being a part of FDA's mission to foster innovative regulatory science and prepare the next generation of regulatory scientists.

Learning Objectives: The fellowship combines structured learning with applied regulatory research. You will attend seminars on pharmacometrics, exposure–response modeling, and MIDD approaches, and collaborate with experts in neurology, pharmacology, and toxicology. Under FDA mentorship, you will learn to evaluate regulatory documents, integrate nonclinical and clinical data, present findings, and contribute to a manuscript or FDA white paper.

You will collaborate with FDA reviewers and MIDD leaders, participate in workshops and symposia, and engage in research dissemination. These experiences will enhance expertise in quantitative clinical pharmacology and expand professional networks within FDA and the regulatory science community.

By the end of the program, you will understand principles of dose selection and optimization across drug development stages and gain insight into FDA decision-making for complex modalities. Skills developed will include data abstraction, evidence synthesis, and integration of nonclinical, biomarker, and PK/PD data. The fellowship will also strengthen communication, writing, and presentation skills essential for regulatory science.

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

Anticipated Appointment Start Date: Summer 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

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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 bachelor's, master's, or doctoral degree in the one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17)
  - **Engineering** (29)
  - **Life Health and Medical Sciences** (51)
  - **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.