

**Opportunity Title:** FDA Fellowship in Quantitative Regulatory Science: Integrating Nonclinical and Clinical Data to Support Targeted Therapy Development  
**Opportunity Reference Code:** FDA-CDER-2026-0180

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

**Reference Code** FDA-CDER-2026-0180

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

**Application Deadline** 12/4/2026 3:00:00 PM Eastern Time Zone

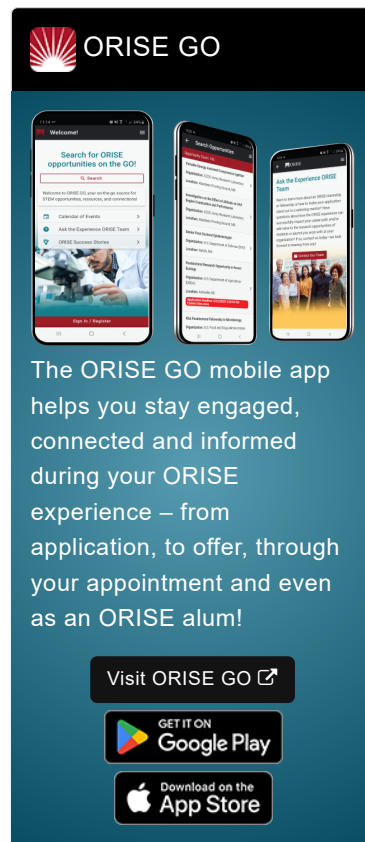
**Description** **\*Applications will be reviewed on a rolling-basis.**

**FDA Office and Location:** Office of Translational Sciences (OTS) Office of Clinical Pharmacology (OCP) Division of Applied Regulatory Science (DARS) at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA) 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:** This fellowship focuses on advancing the regulatory science of targeted therapies, including peptides and oligonucleotide therapeutics (ONTs), through the integration of nonclinical safety data evaluation and Model-Informed Drug Development (MIDD) approaches. Under the guidance of a mentor, you will investigate how available nonclinical and early clinical data can be leveraged more effectively to support key drug development decisions — including the characterization of safety profiles and the optimization of dosing strategies — in ways that complement or improve upon conventional development paradigms.

**Learning Objectives:** As a participant, you will have structured learning opportunities in regulatory science and computational modeling applications in drug development and use of artificial intelligence for data mining. You will gain experience in regulatory toxicology assessment, computational



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modeling methodologies, and FDA's drug evaluation processes. Additionally, you will develop competencies in data curation and analysis. The appointment will also allow opportunities to present research results at internal and external scientific conferences and participate in writing high-impact scientific manuscripts.

**Mentor:** The mentor for this opportunity is Lars Johannesen ([Lars.Johannesen@fda.hhs.gov](mailto:Lars.Johannesen@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, 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.

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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.

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

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

**Eligibility** • **Degree:** Master's Degree or Doctoral Degree.

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**Requirements** • **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.)