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Opportunity Title: FDA Application of AI for Precision Medicine Fellowship
Opportunity Reference Code: FDA-CDER-2026-0026

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

Reference Code FDA-CDER-2026-0026

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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 12/31/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: Multiple research opportunities are available in the Office of Translational Sciences (OTS) / Office of Clinical Pharmacology (OCP), Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) located in Silver Spring, Maryland.

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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This effort covers more than just medicines.

Research Project: This project applies artificial intelligence (AI) and machine learning (ML) to advance precision medicine by analyzing data within the Center for Drug Evaluation and Research (CDER) drug submission database. The project will help modernize CDER's data analytics capabilities and support FDA's mission to protect public health through science-based drug evaluation.

You will collaborate with multidisciplinary FDA scientists in clinical pharmacology, clinical, data science, and regulatory review to investigate how AI/ML can uncover patterns across regulatory submission data to enhance understanding of drug response variability. Key training activities will include how to: 1) Curate and preprocess structured and unstructured submission data for model development; 2) Apply AI methods to identify key clinical and biomarker features that drive response to therapy; 3) Contribute to manuscripts, reports, and presentations that communicate findings to internal and external audiences; and 4) Support the development of reproducible analytic pipelines that can be reused for future regulatory science projects.

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Learning Objectives: Under the guidance of a mentor, you will receive structured learning and participate in various training activities, including: 1) Hands-on instruction in AI/ML methods; 2) Participation in scientific discussions and journal clubs on AI applications in drug development; and 3) training in science communication, including abstract, poster, and manuscript preparation.

By the end of the fellowship opportunity, you will be able to demonstrate proficiency in AI/ML applications to biomedical datasets, understand precision medicine principles and their use in regulatory decision-making, gain experience with FDA data infrastructures and submission standards (e.g., eCTD), and strengthen their competencies in scientific writing, visualization, and interdisciplinary teamwork.

Mentor: The mentor for this opportunity is Qi Liu (qi.liu@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(s) may be part-time or 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

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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 one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills/ knowledge:

- Skills in at least one programming language (e.g., Python, R)
- Analytical skills

Point of Contact

Ashley

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (29 👁)
  - **Life Health and Medical Sciences** (51 👁)
  - **Mathematics and Statistics** (11 👁)
  - **Physics** (1 👁)

Affirmation

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.

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