Opportunity Title: FDA Fellowship - Evaluating Approaches for Synthetic Data Generation and Evaluation in Regulatory Submissions
Opportunity Reference Code: FDA-CDER-2026-0115

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

Reference Code FDA-CDER-2026-0115

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 8/14/2026 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 within the Center for Drug Evaluation and Research (CDER) with the Food and Drug Administration (FDA), 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. These efforts cover more than just medicines.

Research Project: The primary goals of this research fellowship project include:

- Conducting a systematic literature and tools review on synthetic data generation models and their published applications in clinical research, including their context of use.
- Identifying, operationalizing, and empirically applying quantitative metrics for evaluating synthetic data quality across three dimensions: fidelity, utility, and privacy preservation.
- Synthesizing and communicating research findings through internal technical reports, including technical memos, annotated bibliographies, and presentations for FDA staff.

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

- Acquire foundational knowledge of the regulatory scientific landscape surrounding synthetic data by exploring emerging computational

challenges and methodological gaps relevant to the development of FDA regulated products.
- Develop proficiency in systematically reviewing and comparing state-of-the-art synthetic clinical data generation approaches across fidelity, utility, and privacy dimensions, with a focus on their published applications in clinical research contexts.
- Gain hands-on experience designing and applying a reproducible evaluation framework using quantitative metrics — such as Jensen-Shannon divergence, Wasserstein distance — to assess synthetic clinical data quality using publicly available datasets.
- Build scientific communication and knowledge translation skills through translating complex computational and methodological findings into accessible findings — including technical memos, annotated bibliographies, and staff presentations — to support awareness and readiness around synthetic data evaluation in regulatory contexts.

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

Anticipated Appointment Start Date: October 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 and Lawful Permanent Residents (LPR) only.

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

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (3 👁)
  - **Life Health and Medical Sciences** (2 👁)
  - **Mathematics and Statistics** (3 👁)

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.