Opportunity Title: FDA Utilizing Artificial Intelligence to Enhance Pharmacovigilance and Inspection Fellowship
Opportunity Reference Code: FDA-CDER-2026-0028

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

Reference Code FDA-CDER-2026-0028

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

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

FDA Office and Location: Two research opportunities are available immediately within the Office of Translational Science (OTS) in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA), located in Silver Spring, Maryland.

Research Project: The focus of the project will be on developing an artificial intelligence-enabled opioid pharmacovigilance and inspection software application that advances drug safety surveillance by integrating real-world data and regulatory data. The new comprehensive multi-resource artificial intelligence-enabled opioid pharmacovigilance and inspection software application will facilitate harnessing automated safety signal detection and inspection management, previously manual time-consuming tasks are replaced by streamlined computerized processing that enhances surveillance for timely detection of new emerging issues for drug and inspection related activities.

Under the guidance of a mentor, you will engage in cutting-edge research activities to learn how to develop and implement artificial intelligence-enabled systems for surveillance and inspection. Key activities will include:

- Researching and analyzing biomedical data integration methodologies by investigating how disparate data sources can be unified through knowledge graph and Artificial Intelligence (AI) technologies.
- Training in the development of innovative AI architectures that graphically interconnect disparate biomedical information sources to

address public health needs.
- Collaborating with interdisciplinary teams to investigate automated safety signal and inspection detection mechanisms, contributing to the transformation of manual, time-consuming pharmacovigilance and inspection tasks into streamlined computerized processes.
- Contributing to FDA inspection software development by exploring how artificial intelligence can enhance inspection data analysis, risk-based inspection planning, and integration of inspection findings with pharmacovigilance signals.

Learning Objectives: Upon completion of this fellowship, the participant will have developed skills in:

- Advanced competencies in AI-enabled systems specifically designed to support regulatory review teams during public health emergencies.
- Comprehensive understanding of how knowledge graphs facilitate the uncovering of new information about serious safety concerns and augment early detection of emerging safety issues critical to regulatory decision-making.
- Practical expertise in integrating multiple biomedical data sources to create unified platforms that streamline access to relevant publications informing regulatory actions.
- Research proficiency in user acceptance testing methodologies, including bug documentation, tracking, and management of technical issues encountered during software validation processes.

Mentor: The mentor for this opportunity is Rashedul Hasan (mdrashedul.hasan@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 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

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 have received a master's or doctoral degree in one of the related fields. Degree must have been received within the past five years.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (5 👁)
  - **Mathematics and Statistics** (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.)

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AND

I have read the FDA Ethics Requirements.