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Opportunity Title: FDA Large Language Models (LLM) for Case Definition Classification Fellowship
Opportunity Reference Code: FDA-CDER-2026-0009

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

Reference Code FDA-CDER-2026-0009

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.

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!

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 within the Office of Surveillance and Epidemiology (OSE) within the Center for Drug Evaluation and Research (CDER) with the 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. This effort covers more than just medicines.

Research Project: The objective of this research is to apply large language models (LLMs) to enhance case definition processes by developing a prototype that demonstrates the capability of LLMs to accurately categorize and classify case definitions. The selected fellow will contribute to projects that are mandated under the 21st Century Cures Act (2016) Section 3022 (Drug Safety) to evaluate real-world evidence data on drug's use or risks from sources other than clinical trials.

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

- Gain foundational knowledge of pharmacovigilance and AI application: you will learn the key elements of adverse event case definition and

how it is applied to Individual Case Safety Reports (ICSRs). They will support the development and refinement of the AI prototype, providing a practical introduction to how AI can be applied to a regulatory safety context.
- Contribute to the usability testing of the AI-assisted review tool: you will interact with the prototype's user interface to perform assigned tasks, document any issues or challenges, and provide feedback on the user experience. This objective will help you understand the importance of human-centered design and how to provide constructive feedback for software development.
- Support the evaluation of the AI prototype by assisting with basic data tasks: you will help organize test data and run pre-written Python scripts to generate performance metrics. This will provide you with introductory, hands-on experience in data handling and the steps involved in assessing an AI model's performance.

Mentor: The mentors for this opportunity are Rashedul Hasan (MdRashedul.Hasan@fda.hhs.gov) and Oanh Dang (Oanh.Dang@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

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.

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 be currently pursuing or have received a master's or doctoral degree in the one of the relevant field. Degree must have been received within the past five years.

Preferred Skills:

- Experience with database design and knowledge of Oracle, PostgreSQL
- Proficiency in Python for both quantitative analysis and data engineering
- Background in LLM, natural language processing, machine learning, and Deep Learning frameworks

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)

Affirmation I have lived in the United States for at least 36 out of the past 60 months.

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(36 months do not have to be consecutive.)
and
I have read the FDA Ethics Requirements.