**Opportunity Title:** FDA Research Fellowship in Large Language Models for Clinical Pharmacology
**Opportunity Reference Code:** FDA-CDER-2023-1326

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| **Organization** | U.S. Food and Drug Administration (FDA) |
| **Reference Code** | FDA-CDER-2023-1326 |
| **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.

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| **Application Deadline** | 12/29/2023 3:00:00 PM Eastern Time Zone |
| **Description** | **\*Applications will be reviewed on a rolling-basis.** |

**CDER Office/Lab and Location**: A research opportunity is available in the the Office of Clinical Pharmacology (OCP), Office of Translational Science (OTS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

**Research Project:** The project will consist of developing prototype of large language models (LLMs) for internal use, collaborate to design, develop, and refine large language models and generative models for various applications.

Under the guidance of the mentor, the participant will collaborate closely with scientists at the FDA to conduct research that will advance new drug development and promote public health. During participation in this program, the fellow will engage in various activities that include but are not limited to the applications of LLMs for precision medicine, drug development and regulatory science.

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 research covers more than just medicines.

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 initial appointment is for one year but may be renewed

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upon recommendation of FDA contingent on the availability of funds. The
participant will receive a monthly stipend commensurate with educational
level and experience. Proof of health insurance is required for participation
in this program. The appointment is full-time at FDA in the Silver Spring,
Maryland, area. 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**  A doctoral degree in in Applied Mathematics, Statistics, Electrical
Engineering, Computer Science or a related STEM field is preferred.

Qualified master's and bachelor's level candidates may also be considered
provided that the candidate demonstrates large language model
experience.

**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** ([27 👁])
- **Life Health and Medical Sciences** ([48 👁])
- **Mathematics and Statistics** ([11 👁])

**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.