Opportunity Title: FDA SAS Programming and Machine Learning Fellowship
Opportunity Reference Code: FDA-CDER-2019-0399

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

Reference Code FDA-CDER-2019-0399

How to 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. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

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 12/31/2019 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Office of Translational Sciences/Office of Clinical Pharmacology, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

The Office of Clinical Pharmacology (OCP) Immediate Office's (IO) goal in this project is to develop Machine Learning (ML) algorithms for gaining new insights from the integrated summary of safety (ISS) data in conjunction with pharmacokinetic (PK), demographic (DM), and laboratory (LAB) information. The evaluation of the big safety datasets for new molecular entity (NME) submissions and post marketing safety reporting can benefit from automated machine learning methods to gain more insights into drug safety profiles.

Under the guidance of a mentor the participant will train on the ISS data analyses NME submissions, learn to develop machine learning algorithm for adverse event data, and develop ML tool for analyzing the integrated summary of safety (ISS) data. This educational experience provides the participant with knowledge in key concepts related to the Food and Drug Administration (FDA) regulatory process, and the Integrated Summary of Safety review.

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 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 requires ORISE participants to read and sign their FDA Education and Training Agreement

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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 biostatistics. Degree must have been received within five years of the appointment start date.

A strong background in clinical data analyses is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (1 👁)
  - **Mathematics and Statistics** (1 👁)