Opportunity Title: FDA Statistical Methodology for COVID-19 Fellowship
Opportunity Reference Code: FDA-CDER-2021-0620

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

Reference Code FDA-CDER-2021-0620

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 6/30/2021 3:00:00 PM Eastern Time Zone

Description

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

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

During the process of discussing the clinical development of drugs for the treatment or prevention of COVID-19, questions have arisen regarding appropriate statistical methodology to be used in the evaluation of data produced from such development programs. The answers to these questions can impact statistical analysis plans outlining the prespecified analytical methods to be utilized in the analyses of data from these COVID-19 development programs and study protocols describing the design and conduct of these studies. The project aims to address several of these statistical questions, which include selecting appropriate missing data imputation models and methods for analyzing time-to-event endpoints.

Under the guidance of the mentor the participant will gain insight regarding the regulatory process for evaluating the safety and efficacy of investigational drugs, as well as regulatory challenges that arise during the statistical evaluation of data collected for the purpose of addressing public health emergencies. Furthermore, the participant will gain experience conducting simulation studies and preparing reports/presentations summarizing the research results.

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 three months, 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

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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 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 doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred Skills:

- Knowledge with simulating data and analyzing time-to-event data
- Knowledge with medical practice

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Mathematics and Statistics** (2 👁)