Opportunity Title: FDA Biostatistical Research Fellowship
Opportunity Reference Code: FDA-OC-OPT-2020-0002

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

Reference Code FDA-OC-OPT-2020-0002

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

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.OC.other@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 4/15/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is available with the Food and Drug Administration (FDA), as part of a multidisciplinary/multi-office collaboration between the Office of Pediatric Therapeutics within the Office of the Commissioner (OC), the Office of Translational Sciences/Office of Biostatistics, and the Office of New Drugs/Division of Bone, Reproductive, and Urological Products of the Center for Drug Evaluation and Research (CDER) located in Silver Spring, Maryland.

This project will involve evaluating and analyzing available data sources to determine whether gestational age (GA) at birth can be used as a primary clinical efficacy endpoint in studies of therapies to prolong pregnancy or prevent premature birth. With multidisciplinary mentorship, including statisticians and clinical review and regulatory staff, the research fellow will have the opportunity to understand how clinical trial endpoints are developed and considered in regulatory agencies and will participate in the development and execution of a statistical plan to apply existing datasets toward endpoint development. The primary aim is to better understand the ability of GA at birth to predict short-term and long-term outcomes in patients born prematurely, and to explore the utility of this endpoint for clinical trials of therapies to reduce premature birth.

With a team of mentor-collaborators, the research participant will perform a focused literature review to identify and understand any previously published analyses and specify covariates, clean the identified dataset(s), and participate in the development of the statistical analysis strategy. The research opportunity also includes data management, statistical analysis, and the chance to interact with a wide variety of FDA staff, attend and present at meetings, and contribute to manuscripts and reports. The participant will be encouraged to attend FDA trainings and seminars relevant to his/her project and interests.

Anticipated Appointment Start Date: as soon as a qualified candidate is identified

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 part-time (32 hours per

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week) 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 master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date. Completion of doctoral prequalifying exams is preferred.

Preferred skills:

- Experience conducting research with, cleaning, and manipulating large datasets
- Proficiency in programming with statistical software (e.g., SAS, R, SPSS, or Stata) and ability to create reproducible code
- Knowledge of applied statistical analyses, including coursework in regression, longitudinal analyses, and generalized linear models
- Strong problem-solving skills, creativity, and innovation
- Experience or interest in clinical trial design and/or drug development

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** (3 👁)