Opportunity Title: FDA Synthetic Control Arm (SCA) Approach to Advance Extrapolation of Data Fellowship
Opportunity Reference Code: FDA-CDER-2020-0556

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

Reference Code FDA-CDER-2020-0556

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.CDER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 3/31/2021 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 New Drugs / Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

Single arm, uncontrolled studies are used in approximately 25% of pediatric drug development programs and 63% of rare disease trials. Single arm trials are often difficult to interpret. This project proposes that patient-level matching approaches like propensity scores can be used with historical clinical trial data to create a synthetic control arm to improve context for the interpretation of single arm trials.

The participant will gain extensive knowledge on methodological approaches used with historical clinical trial data to create a synthetic control arm. In addition, the participant will gain experience in review of methodological features of studies, data curation and database building, data analysis, dissemination of results (presentations, publications), etc.

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.

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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.

Familiarity with manipulating data using statistical software (such as R, SAS, etc.) with knowledge of generalized linear models is preferred.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (1 👁)
  - **Mathematics and Statistics** (2 👁)