

Opportunity Title: FDA Postdoctoral Fellowship in Biostatistics

Opportunity Reference Code: FDA-CBER-2020-0031

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

Reference Code FDA-CBER-2020-0031

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

Application Deadline 9/21/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available with the Office of Biostatistics and Epidemiology (OBE), at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

Under the guidance of a mentor, the selected participant will participate in the development of innovative design and analysis strategies for immune-oncology (IO) trials. Specifically, the goal of this project is two-fold: first, to develop innovative approaches to ensure adequate study power for IO trials and reduce the risk of false-negative finding; second, to enhance IO trial efficiency and mitigate the occurrence of non-proportional hazards (NPH) patterns. The participant will be involved in the development and application of novel techniques to develop strategies for trial design and data analysis, as well as perform literature reviews, presentation of research results, and preparation of scientific manuscripts.

Anticipated Appointment Start Date: September 1, 2020

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 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:



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- 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 have received a doctoral degree in one of the relevant fields, or be currently pursuing the degree and will reach completion by the appointment start date. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Knowledge of biostatistics
- Modeling and programming skills
- Prior experience with clinical trials especially oncology trials
- Excellent written and oral communication skills

- Eligibility Requirements**
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 9/1/2020 11:59:00 PM.
 - **Discipline(s):**
 - **Communications and Graphics Design** ([1](#) )
 - **Computer, Information, and Data Sciences** ([16](#) )
 - **Environmental and Marine Sciences** ([1](#) )
 - **Life Health and Medical Sciences** ([45](#) )
 - **Mathematics and Statistics** ([10](#) )