Opportunity Title: Modeling and Simulation of Development of Anti-drug Antibody - FDA CBER

Opportunity Reference Code: FDA-CBER-2019-0023

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CBER-2019-0023
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.CBER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 12/2/2019 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**
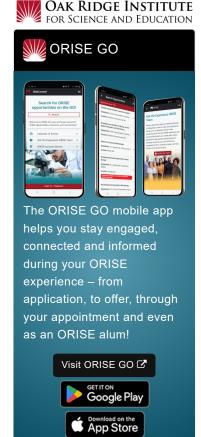
A research opportunity is available with the Office of Biostatistics and Epidemiology (OBE) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

The successful candidate will participate in the development of an immune response model to predict immunogenicity and simulate anti-drug antibody development among hemophilia patients treated with recombinant factor products. The goal of this project is the development of a computational tool to enhance efficacy and safety evaluation of current and next-generation engineered therapeutic products, leading to personalized, optimal treatment regimens for hemophilia patients. Under the guidance of a mentor, the participant will help to develop and apply novel techniques to model and simulate interactive components of the human immune system, as well as perform literature reviews, data collection, model development, presentation of research results, and preparation of scientific manuscripts.

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, MD, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

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 June 1, 2019. Degree must have been received within five years of the appointment start date.

Preferred skills/experience:

- Knowledge of immunology, modeling and programming skills
- Experience with differential equations
- Excellent written and oral communication skills
- Solid background and skills in both biology and computing science

Eligibility Requirements
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 6/1/2019 12:00:00 AM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Engineering** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)