Opportunity Title: FDA Rare Diseases Fellowship
Opportunity Reference Code: FDA-CDER-2020-0521

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

Reference Code FDA-CDER-2020-0521

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 9/30/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Office of New Drugs, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

Under the Prescription Drug User Fee Act (PDUFA), the CDER Rare Diseases Program (RDP) is tasked with several commitments regarding rare disease clinical development programs. In order to make adequate assessments of RDP methods, a knowledge management platform was developed to allow tracking/analysis of RDP activities. Based on this platform and supplementary data, analyses can be performed to aid RDP in identifying (1) emerging disease areas where patient-focused drug development enhancements are needed, (2) review issues that support improved clinical development, or (3) international issues in clinical development programs in rare disease.

This project will train the participant on basic concepts in rare disease development and review, rare disease concepts (e.g. small clinical trials, expanded access, flexibility approaches), guidances and PDUFA VI commitments. The participant will gain understanding of the fundamentals of rare disease drug development as well as concepts/approaches utilized to accelerate development, gain knowledge of the activities of the CDER Rare Diseases Program and the deliverables to Congress, and gain experience in analysis methods to identify emerging areas, review issues, and/or international issues in the rare disease space.

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

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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 bachelor's or master's degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Familiarity in programming and computing within MS Access and other computing environments
- Basic knowledge of rare disease drug development

Eligibility Requirements

- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)