

Opportunity Title: FDA Generic Orphan Drug Products Fellowship

Opportunity Reference Code: FDA-CDER-2022-0821

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

Reference Code FDA-CDER-2022-0821

How to Apply **Connect with ORISE...on the GO!** Download the new ORISE GO mobile app in the [Apple App Store](#) or [Google Play Store](#) to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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

Application Deadline 8/31/2022 3:00:00 PM Eastern Time Zone

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

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

The aim of this project is to research model-informed approaches, including strategies for prioritizing product-specific guidance development, to facilitate the availability and accessibility of generic orphan drug products to patients with rare diseases. Under the guidance of the mentor, the participant will research and learn to develop a database regarding orphan drug products from multiple data resources. The participant will also learn to perform quantitative analysis to disclose generic availability for orphan drug products. The participant will utilize advanced modeling approaches to identify critical factors that impact the generic availability.

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 four months, 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



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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, master's or doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred skills:

- Strong data analysis experience
- R/Python programming skills

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Computer, Information, and Data Sciences** ([2](#) 👁)
 - **Engineering** ([1](#) 👁)
 - **Life Health and Medical Sciences** ([48](#) 👁)
 - **Mathematics and Statistics** ([10](#) 👁)

Affirmation I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)