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Opportunity Title: FDA Postdoctoral Fellowship on Global Testing Methods for Rare Disease Trials
Opportunity Reference Code: FDA-CDER-2023-1325

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

Reference Code FDA-CDER-2023-1325

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

Application Deadline 12/29/2023 3:00:00 PM Eastern Time Zone

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

CDER Office/Lab and Location: A research opportunity is available in the Office of Biostatistics (OB), Office of Translational Science (OTS), Food and Drug Administration (FDA) located in Silver Spring, Maryland. This is a collaborative research project in the Center for Drug Evaluation and Research (CDER). 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This research covers more than just medicines.

Research Project: Multiple endpoints are often used to evaluate efficacy in clinical trials for rare diseases with heterogeneous clinical presentations. To address the resultant multiplicity issue, conventional methods may not be helpful because they do not have sufficient power to demonstrate effectiveness of a test product given the limited number of patients available for the trials. Thus, there is a great need for utilizing or developing alternative methods that can effectively evaluate multiple endpoints in rare disease clinical trials.

Under the guidance of the mentor, the participant will gain hands-on experience with regulatory research projects, learning about various statistical methods including global testing approaches for multiple endpoints, gain research and real-world problem-solving experience, and strengthen his/her programming skills. The participant will study some review examples of clinical trials to understand the research topic, conduct literature search on global testing methods including the newly proposed best-outcome-endpoint method, and evaluate the performance of commonly used methods/new methods via simulation studies and with applications to clinical trials data and draft a manuscript on the research outcomes.

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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 part-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 Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

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 the past five years.

Preferred skills/experience:

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- Strong skills in statistics
- Experience with SAS and/or R

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Mathematics and Statistics** (11 👁)

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.)

I have read the FDA Ethics Requirements.