Opportunity Title: FDA Multiplicity Correction in Equivalence Testing Fellowship
Opportunity Reference Code: FDA-CDER-2022-0817

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

Reference Code FDA-CDER-2022-0817

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 11/30/2022 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 Translational Sciences/ Office of Biostatistics (OB) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), located in Silver Spring, Maryland. 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 work covers more than just medicines.

Multiplicity correction has been extensively researched for superiority/efficacy tests. However, for equivalence tests, there has not been much literature published, especially when there are multiple Test arms vs. one Reference arm in a crossover PK bioequivalence study. When the same Reference arm is used, Dunnet's method is usually preferred to the Hochberg, Holm, or Bonferroni method because it takes into consideration the correlation of test statistics when using the same control. However, Dunnet's method cannot be directly applied to a crossover study because all the Test arms and Reference arm are correlated (from the same subject) in a crossover study, which is different from a parallel setting where the Test arms are independent of each other. Furthermore, for equivalence testing, only the relevant two arms can be tested rather than including all treatment arms to get the pooled mean square error. Lastly, equivalence tests usually use the 90% CI rather than scaled P value. The project will involve researching an appropriate multiplicity correction for equivalence tests when multiple Test arms are compared to the same Reference arm in a crossover design.

Under the guidance of the mentor, the participant will:

- Review literature in multiplicity adjustment in efficacy and equivalence studies primary analysis.
- Propose a novel multiplicity adjustment method for equivalence.
- Conduct simulations to evaluate the performance of the proposed method and prepare the presentation and manuscript for publication.

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The participant will get in-depth knowledge in multiplicity and bioequivalence studies and get to apply the statistical theories learned in school to a real-world problem that impacts the health and life of the public.

Anticipated Start Date: August 8, 2022. Start date is flexible and will depend upon a variety of factors.

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 two 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 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/ Knowledge:

- Statistical background
- Microsoft Office Skills
- Knowledge of SAS and/or R

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or 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)