

**Opportunity Title:** FDA Statistical Analyses and Tool Development Fellowship  
**Opportunity Reference Code:** FDA-CDER-2023-1250

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

**Reference Code** FDA-CDER-2023-1250

**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](mailto:ORISE.FDA.CDER@orau.org). Please include the reference code for this opportunity in your email.

**Application Deadline** 6/30/2023 3:00:00 PM Eastern Time Zone

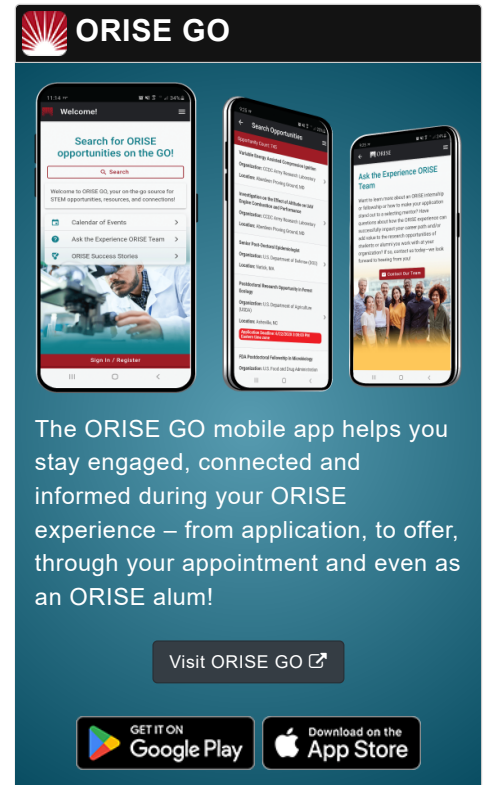
**Description** \*Applications will be reviewed on a rolling-basis.

**CDER Office/Lab and Location:** 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

**Research Project:** The Office of Pharmaceutical Quality (OPQ), Office of Quality Surveillance (OQS) performs research and statistical analyses of applicable product acceptance criteria including but not limited to parametric tolerance interval methods and Bayesian approaches. As applicable, we seek to standardize such analyses and program the methods and analyses in R and R Shiny.

Under the guidance of the mentor, the participant will review and analyze statistical tolerance interval and Bayesian methods in the context of product acceptance criteria. The participant will be able to perform statistical analyses of the applicable methods to assess characteristics and method performance and provide insights on the potential use of such methods in the pharmaceutical manufacturing landscape.

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 appointment is for 12 months. 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



**Opportunity Title:** FDA Statistical Analyses and Tool Development Fellowship

**Opportunity Reference Code:** FDA-CDER-2023-1250

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 have received a master's or doctoral degree in one of the relevant fields, or be currently pursuing one of the degrees with completion before June 30, 2023. Degree must have been received within five years of the appointment start date.

Preferred experience in applications of:

- Mathematics and Statistics
- Analysis
- Computational Mathematics
- Logic or Foundations of Mathematics
- Probability and Statistics

## Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2023 12:00:00 AM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 )
  - **Life Health and Medical Sciences** (1 )
  - **Mathematics and Statistics** (1 )

## 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.)