**Opportunity Title:** FDA Biostatistics and Epidemiology Fellowship
**Opportunity Reference Code:** FDA-CDRH-2024-0017

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

**Reference Code** FDA-CDRH-2024-0017

**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. Your application will be considered incomplete and will not be reviewed until one recommendation is submitted.

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDRH@orau.org. Please include the reference code for this opportunity in your email.

**Application Deadline** 9/30/2024 3:00:00 PM Eastern Time Zone

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

**FDA Office and Location:** A research opportunity is available in the Office of Science and Engineering Laboratories (OSEL), within the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA). **This opportunity is remote.**

**Research Project:**

- During this research appointment, ORISE Fellow will learn about Real-World Data (RWD) based research on medical devices with clinical, regulatory, and public health aspects.
- This opportunity uses knowledge and skills in using Biostatistics/ Bioinformatics methods such as relative risk analysis, multivariate and logistic LASSO regression, Kaplan-Meier (time-to-event) analysis, network and heatmap analyses.
- ORISE Fellow will be shown how to create the study cohorts using Electronic Health Records (EHR) with ICD10- identifiable device procedures and how to apply a methodological framework for EHR-based RWD analysis pertaining to patients with implants.
- ORISE Fellow will also observe and learn how to keep the records with study results and technical information on datasets, data analysis/ visualization methods, and other details needed for preparation of manuscripts and presentations.

**Learning Objectives:** This experience will allow him/her to:

- Gain knowledge on implant-related procedures and clinical conditions.
- Acquire methodological skills for identifying adverse post-implant sequelae and their potential risk factors and demographic modifiers.

As a result, ORISE Fellow will gain exposure to research leveraging RWD and Real-World Evidence (RWE) to support regulatory decision making.

**Appointment Length:** The appointment will initially be for nine months, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

**Level of Participation:** The appointment is part time.

**Citizenship Requirements:** This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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 a doctoral degree in the one of the relevant fields.

**Preferred skills:**

Preferred candidate will have background in Biostatistics and/or Data Sciences (Computer Science, Scientific Computing and Informatics) and hands on experience performing statistical analyses to include multivariable modeling, statistical programming, data cleaning/ preparation.

**Eligibility Requirements**

- **Degree:** Currently pursuing a Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Life Health and Medical Sciences** (1 👁)
  - **Mathematics and Statistics** (3 👁)

**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.)
and
I have read the FDA Ethics Requirements.