Opportunity Title: FDA Rescue Therapy in Real-World Evidence (RWE) Studies
Opportunity Reference Code: FDA-CDER-2026-0189

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

Reference Code FDA-CDER-2026-0189

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click APPLY.***

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

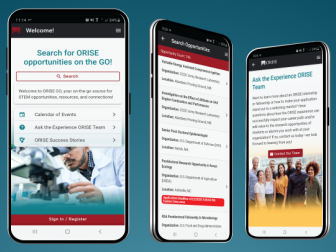
All documents must be in English or include an official English translation.

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

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Application Deadline 12/18/2026 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 within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at Silver Spring, Maryland. You are expected to based at the duty station in Silver Spring with the possibility of 1-2 days of hybrid participation.

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. These efforts cover more than just medicines.

Research Project: This study aims at evaluating and comparing estimand strategies for handling treatment discontinuation/switching and additional/alternative therapy use in randomized controlled trials (RCTs) and real-world evidence (RWE) studies. We propose to study the consequences of the use of different strategies for handling intercurrent events mentioned above under a variety of clinical scenarios of interest. Simulation studies will be conducted with realistic switching mechanisms and confounding structures. We propose to implement statistical methods such as IPCW, G-estimation, and other commonly used methods to evaluate bias, precision, and robustness trade-offs across clinical scenarios

and strategy choices.

Learning Objectives: Under the guidance of a mentor, you will:

- Learn to review the estimand framework as proposed in the ICH E(9) R1 guideline.
- Gain experience recognizing how the estimand framework is used to define treatment effects in RCTs and RWE studies.
- Compare strategies for handling treatment switching and rescue therapy across a range of clinical-study scenarios in RCTs and RWE studies under mentor direction.
- Gain experience designing and conducting simulation studies under scenarios of interest.
- Build skills in implementing causal-inference methods, including inverse probability of censoring weighting (IPCW) and G-estimation.
- Learn to compare alternative statistical approaches for addressing treatment changes during follow-up.
- Assess methods based on bias, precision, robustness, and their trade-offs under different clinical scenarios.
- Strengthen skills in statistical programming, evaluating study designs, and interpretation of RCT and RWE analyses.

Mentor: The mentors for this opportunity are Shanti Gomatam (shanti.gomatam@fda,hhs.gov) and Yueqin Zhao (yueqin.zhao@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

Anticipated Appointment Start Date: End of 2026 or early 2027. Start date is flexible and will depend on a variety of factors.

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

Level of Participation: The appointment is full-time or part-time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens and Lawful Permanent Residents (LPR) only.

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

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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.

Qualifications The qualified candidate should be currently pursuing or have received a doctoral degree in statistics, biostatistics, mathematics or related field.

Preferred skills:

- Strong foundation in statistics
- Good programming skills (preferably in R)
- Candidates with courses/experience in causal inference and/or observational data may be preferred (but lack of such experience should not deter strong candidates from applying)

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Mathematics and Statistics** (5 👁)

Affirmation I am a U.S. citizen, or 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.)