

Opportunity Title: FDA Fellowship - Statistical Considerations in the Design and Analysis of Oncology Clinical Trials

Opportunity Reference Code: FDA-CDER-2026-0055

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

Reference Code FDA-CDER-2026-0055

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.

Application Deadline 7/30/2026 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 immediately with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in White Oak, Maryland.

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.

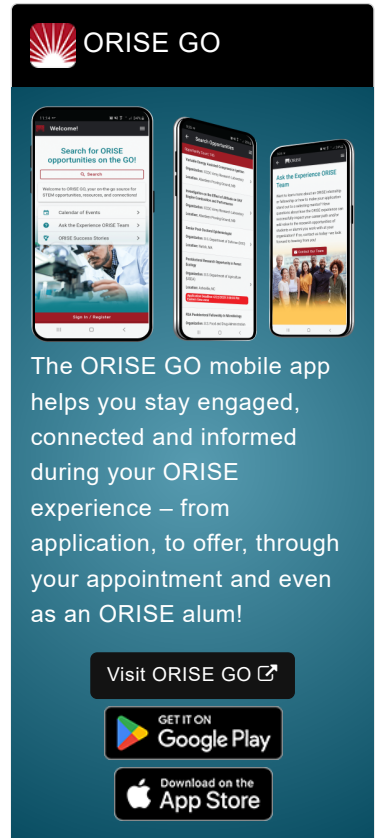
Research Project: Drug development in oncology is becoming more complex, with more agents being explored in combination with other products. Such programs need to provide evidence of the contribution of each product to the efficacy of the combination. A recent topic of debate has been the use of products in multiple phases of therapy, yielding a similar question about contribution of phase of therapy to the overall efficacy of a product. This question is particularly critical in disease areas in which the new phase of therapy would define a new indication on its own (e.g., adjuvant therapy in breast cancer, maintenance therapy in AML). However, generating such evidence may be prohibitive, as it typically would involve randomization to more than two arms.

A number of different design and analysis strategies have been proposed to address contribution of phase of therapy. The goal of this project is to investigate the impact of some of these options and to determine their impact on the drug approval process. Such design and analysis features include but are not limited to:

- Re-randomization
- 2:2:1 or 2:1:2 randomization to the multiple phase, single-phase, and control arms
- Estimation of impact of later phase via propensity score methods





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- Use of a less stringent criterion to claim the additional phase is necessary (e.g., superiority vs single-phase therapy at a one-sided Type I error of 0.10)
- This project includes simulation of survival data in multiple phases (e.g., piecewise modeling).
- Evaluation of potential design features using clinical trial data to guide designs of similar future trials.

Learning Objectives: Under the guidance of a mentor, you will learn, among other ideas:

- Research methods in this space by reviewing the scientific literature
- How to determine which design features are most efficient in determining contribution of phase
- Additional programming and modeling skills through generating simulations for the proposed designs
- How to communicate with statistical and clinical experts in oncology to understand the unique challenges in this space
- This program will aid your professional development through engagement in projects which will likely lead to peer-reviewed publications. Furthermore, you will learn from experts in the field, which is essential for future opportunities such as presentations at conferences, involvement in other fellowships, and future careers.
- **Evaluation of clinical trial data**

Mentor: The mentor for this opportunity is Xin Wang (Xin.Wang@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: As early as May 18, 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for eight months to 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, 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.

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.

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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 the one of the relevant fields.

Point of Contact [Ashley](#).

Eligibility • **Degree:** Doctoral Degree.

Requirements • **Discipline(s):**

- **Computer, Information, and Data Sciences** ([1](#) )
- **Life Health and Medical Sciences** ([1](#) )
- **Mathematics and Statistics** ([1](#) )

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.)
and
I have read the FDA Ethics Requirements.