

Opportunity Title: FDA Research Fellowship: Biologic Products and the Regulatory Evaluation of Biosimilars

Opportunity Reference Code: FDA-CDER-2026-0035

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

Reference Code FDA-CDER-2026-0035

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 4/30/2026 3:00:00 PM Eastern Time Zone

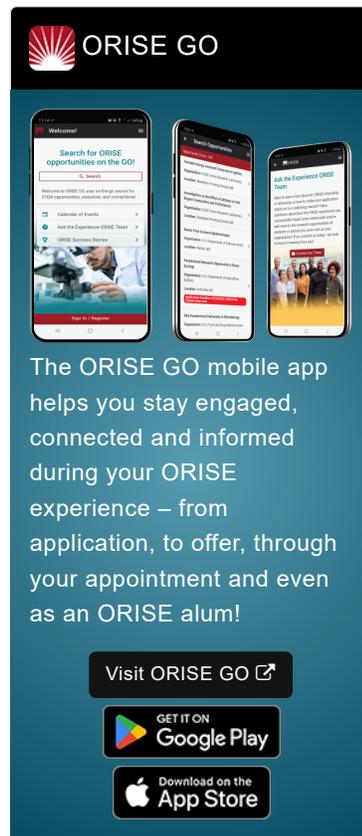
Description *Applications will be reviewed on a rolling-basis.

FDA Office and Location: A research opportunity is available in the Office of Translational Sciences (OTS) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), located in Silver Spring, 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: Biosimilars are complex biologic medicines designed to be highly similar to reference products, with no clinically meaningful differences in safety, purity, or potency. Despite advances in analytical and functional characterization, establishing a robust quantitative link between analytical quality attributes (AQAs) and clinical outcomes—such as pharmacokinetics (PK), immunogenicity, and safety—remains a key challenge.

Traditional approaches rely on expert-driven statistical comparisons or limited multivariate analysis. However, the increasing dimensionality and complexity of analytical data demand AI/ML-based frameworks capable of learning nonlinear, high-dimensional relationships between molecular attributes and biological responses.



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This project proposes to develop an AI/ML-integrated translational framework that associates analytical quality parameters to PK, immunogenicity, and safety endpoints—thereby supporting data-driven biosimilarity assessments and potentially enabling predictive modeling for clinical performance.

Learning Objectives: Under the guidance of the mentor(s), you will 1) learn about biologic products and the regulatory evaluation of biosimilars; 2) use AI/ML to model relationships between molecular structures, biological responses, and clinical outcomes; 3) assess the performance of translational statistical approaches under a range of simulated scenarios based on available data.

Mentor: The mentor for this opportunity is Wanjie Sun (wanjie.sun@fda.hhs.gov). If you have questions about the nature of the research please contact the mentor(s).

Anticipated Appointment Start Date: May 15, 2026. 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 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 have received or be currently pursuing a doctoral degree in one of the related fields. Degree must have been received within the past five years, or is anticipated to be completed by June 30, 2028.

Point of Contact [Ashley](#)

- Eligibility Requirements**
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2028 12:00:00 AM.
 - **Discipline(s):**
 - **Computer, Information, and Data Sciences** (2 )
 - **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.