Opportunity Title: FDA Evaluating Time-Course of Anti-Drug Antibodies for Therapeutic Proteins Fellowship
Opportunity Reference Code: FDA-CDER-2026-0025

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

Reference Code FDA-CDER-2026-0025

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 9/30/2026 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 in the Office of Combination Products (OCP) / Office of Translational Sciences (OTS), within the Center for Drug Evaluation and Research (CDER) at the 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. This effort covers more than just medicines.

Research Project: Immunogenicity assessment traditionally relies on a multi-tiered testing strategy to detect anti-drug antibodies (ADAs), involving sequential screening, confirmatory, and titer assays. Recently, the signal-to-noise ratio approach has emerged as a promising alternative for ADA evaluation. Compared to the conventional tiered methodology, the signal-to-noise approach offers greater precision than traditional titer assays and has the potential to streamline immunogenicity testing by consolidating the multi-tiered process into a single, more efficient method. While the signal-to-noise ratio approach demonstrates clear advantages, additional research is needed to establish its utility for quantitatively characterizing ADA time-course profiles compared to traditional tiered approaches. In our previous research, we developed a mathematical ADA model to provide quantitative immunogenicity assessment for therapeutic proteins. This model was constructed using antibody titer data from subjects across 10 clinical trials, with ADA time-course profiles characterized through a two-component semi-mechanistic model that captured the characteristic double-peak pattern of antibody responses. We also explored relationships between antibody titer levels and incidence rates. Although our research established a valuable framework for quantitative immunogenicity evaluation and impact

assessment, the model's utility remains constrained by its reliance on tiered assay data. Therefore, re-evaluation of the model using signal-to-noise ratio data represents a critical next step to enhance its clinical applicability and regulatory relevance.

The overarching goal of this project is to quantitatively assess the ADA response with a modeling and simulation approach and predict the time course of ADA incidence based on the model. Specifically, the project will:

- Survey the FDA-approved therapeutic proteins and identify those with immunogenicity assessments with titer and signal-to-noise ratio to further assessment
- Collect and summarize individual subject immunogenicity data from FDA internal databases
- Develop a population model with these data using a nonlinear mixed effect modeling approach and perform sensitivity analysis
- Evaluate the relationship between the change in individual level of immunogenicity over time and the change in population level internally and externally

Learning Objectives: Through participation in this research opportunities, the you will develop a comprehensive understanding of immunogenicity and its clinical impact from quantitative perspective, gain hands-on experience with data analysis and integration of internal database to inform regulatory assessments, and strengthen critical-thinking and scientific communication skills to support evidence-based decision-making in drug development. Under the guidance of a mentor, structured learning opportunities for you will include:

- Training in data extraction, interpretation of clinical pharmacology review documents, and literature synthesis
- Opportunities for manuscript or internal report preparation, presentation skills, and cross-disciplinary collaboration
- Applying modeling skill in helping regulatory decision making
- Participation in seminars on clinical pharmacology, pharmacometrics, and regulatory science
- Networking with experts across therapeutic areas, supporting career planning and professional growth

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

Anticipated Appointment Start Date: 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 full-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.

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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 or have received a master's or doctoral degree in one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**

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- **Computer, Information, and Data Sciences** (2 👁)
- **Life Health and Medical Sciences** (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.)

AND

I have read the FDA Ethics Requirements.