

Opportunity Title: FDA Postdoctoral Fellowship - Clinical Pharmacology and Immunogenicity Data Assessment

Opportunity Reference Code: FDA-CDER-2026-0010

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

Reference Code FDA-CDER-2026-0010

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@oraui.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 Clinical Pharmacology (OCP), Office of Translational Sciences (OTS), Center for Drug Research and Evaluation (CDER) within the Food and Drug Administration (FDA) located in Silver Spring, Maryland.

Research Project: This research project focuses on the systematic evaluation of immunogenicity effects on drug exposure and the investigation of anti-drug antibody (ADA) and neutralizing antibody (NAb) assay characteristics across approved biological products. If selected, you will collaborate with FDA scientists to compile immunogenicity assessment data from multiple regulatory sources, including Biologics License Applications (BLAs), validation reports, and clinical pharmacology review documents. You will analyze assay platforms, drug tolerance parameters, positive control concentrations, and validation practices. You will also research and analyze how immunogenicity information is communicated in FDA-approved product labeling, comparing review findings with final labeling language to identify alignment patterns and improvement opportunities.

Learning Objectives: Your educational training components and research activities will include:

- Structured learning sessions on FDA's immunogenicity guidance documents and regulatory framework
- Collaborating with experienced FDA reviewers to understand clinical pharmacology assessment methodologies
- Investigating current scientific literature and harmonization efforts in immunogenicity testing



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- Analyzing complex datasets using statistical software and FDA's analytical tools
- Learning research database design principles and data management best practices
- Contributing to development of evidence-based recommendations for regulatory policy enhancement
- Participating in preparation of scientific presentations and written reports
- Collaborating in drafting potential updates to regulatory guidance documents
- Contributing to peer-reviewed publications advancing regulatory science knowledge
- Experience in collaborative research within a regulatory environment
- Understanding of how regulatory science advances public health objectives

Mentor: The mentors for this opportunity are Jan-Shiang Taur (Jan-Shiang.Taur@fda.hhs.gov) and Yow-Ming Wang (Yowming.Wang@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

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, 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,

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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 have received a doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Point of Contact [Ashley](#)

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
 - **Communications and Graphics Design** ([1](#))
 - **Computer, Information, and Data Sciences** ([2](#))
 - **Life Health and Medical Sciences** ([1](#))
 - **Mathematics and Statistics** ([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.