Opportunity Title: FDA Serum Creatinine Elevation Due to Renal Transporter Inhibition
Opportunity Reference Code: FDA-CDER-2026-0034

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

Reference Code FDA-CDER-2026-0034

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 5/14/2026 12:00:00 AM 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. This effort covers more than just medicines.

Research Project: At least five oncology drugs have increased serum creatinine described in their approved labeling secondary to a drug interaction. The objective of this to project is to evaluate the pharmacokinetic interactions and risk mitigation strategies relating to increased serum creatinine caused by inhibition of renal transporters for currently approved oncology drugs. The specific aims are to enhance our understanding of drug-induced creatinine increases that do not reflect true nephrotoxicity, distinguish these effects from actual kidney injury, and inform regulatory decision-making regarding appropriate monitoring and labeling strategies for drugs that inhibit renal transporters.

During the research project and under the guidance of the mentor, you will contribute with:

- Collecting comprehensive data on oncology drugs known to inhibit renal

transporters (particularly OCT2, MATE1, and MATE2-K), including their mechanisms of action, transporter selectivity, clinical pharmacokinetics, and documented effects on serum creatinine levels from approved drug labeling, in vitro and clinical study reports, and regulatory submissions.
- Analyzing clinical datasets to characterize the time course, magnitude, and reversibility of creatinine elevations, identifying patterns across different drug classes and patient populations while distinguishing transporter-mediated effects from true nephrotoxicity.
- Evaluating exposure-response relationships between drug concentrations and creatinine elevation, including assessment of dose-dependency, time to onset, plateau effects, and recovery patterns following drug discontinuation or dose reduction.
- Reviewing regulatory precedents and current FDA guidance documents to understand how transporter-mediated creatinine increases have been addressed in drug labeling and postmarketing surveillance.
- Participating in cross-divisional discussions with clinical pharmacology reviewers, medical officers, and safety evaluators to discuss findings and their implications for regulatory policy development and review practices.
- Presenting research findings to the Division of Clinical Pharmacology and other audiences, including recommendations for standardized approaches to evaluate and communicate transporter-mediated creatinine effects.
- Contributing to regulatory guidance development or scientific publications that provide clarity on distinguishing transporter-mediated creatinine elevation from true nephrotoxicity in drug development and regulatory review.

Learning Objectives: Educational activities will at least include:

- Understanding renal transporter physiology including the roles of OCT2, MATE1, and MATE2-K in creatinine secretion, and how inhibition of these transporters affects serum creatinine without impairing glomerular filtration rate.
- Developing expertise in nephrotoxicity assessment including differentiation between functional creatinine elevation and structural kidney damage, interpretation of complementary biomarkers, and understanding of appropriate monitoring strategies.
- Gaining proficiency in pharmacokinetic-pharmacodynamic modeling of transporter-mediated drug interactions, including prediction of creatinine effects based on drug exposure and transporter inhibition potency.
- Acquiring regulatory review skills for evaluating safety, in vitro and pharmacokinetic data in drug applications, including determinizing the adequacy of the study design and data to inform the proposed risk mitigation strategies.
- Understanding policy implications of transporter-mediated effects on drug development timelines, labeling requirements, and postmarketing surveillance.

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Expected Learning Outcomes:

The participant will gain specialized expertise in clinical pharmacology and drug interaction evaluation that supports career advancement in clinical pharmacology and regulatory science. This experience provides valuable insight into complex pharmacokinetic interactions and their regulatory implications, preparing the fellow for scientific and regulatory leadership.

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

Anticipated Appointment Start Date: May/June 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.

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

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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 bachelor's, master's, or doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Life Health and Medical Sciences** (6 👁)
  - **Mathematics and Statistics** (1 👁)
  - **Other Non-Science & Engineering** (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.