

Opportunity Title: FDA Pediatric Pharmacometrics/ Clinical Pharmacology

Fellowship

Opportunity Reference Code: FDA-CDER-2023-1236

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

Reference Code FDA-CDER-2023-1236

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 3/31/2023 12:59:59 PM Eastern Time Zone

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

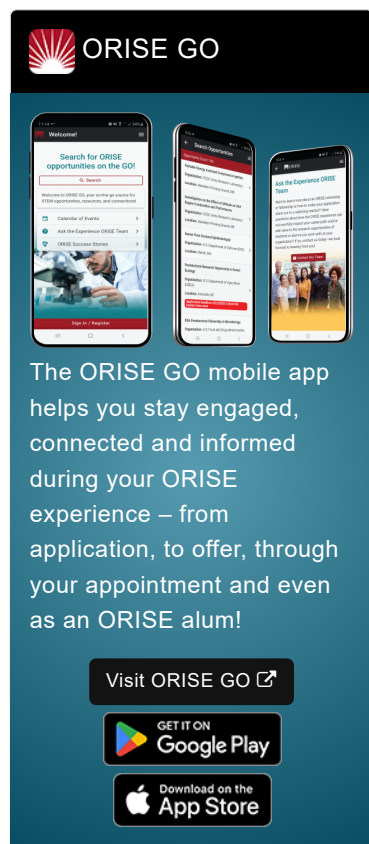
A postdoctoral research opportunity is currently available in the Office of Specialty Medicine, Office of New Drugs at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA) located in Silver Spring, Maryland. We are interested in applying modeling and simulation to address specific questions in specific populations, e.g. in pediatrics and pregnancy. For example, we propose developing data-driven and scientifically-based regulatory recommendations to assess: pediatric renal function, exposure-response and Bayesian methods, and physiologically-based pharmacokinetic modeling to predict drug disposition in pregnant women. Under the guidance of a mentor, the participant will be learning modeling and simulation techniques, and regulatory and clinical knowledge in drug development.

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 initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. 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 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;



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- 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 one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Familiarity with modeling and simulation software
- Knowledge of PK/PD modeling principles and statistics

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Life Health and Medical Sciences** ([48](#) 👁)
 - **Mathematics and Statistics** ([2](#) 👁)

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.)