Opportunity Title: Anti-infective Fellowship: Pediatric Clinical Pharmacology
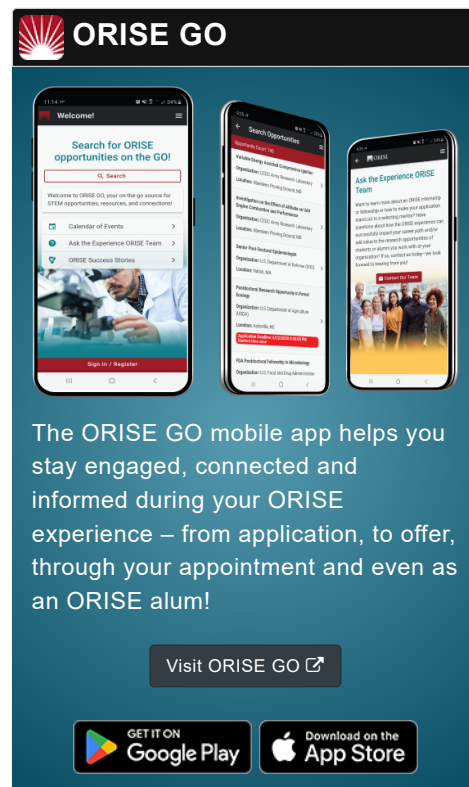**Opportunity Reference Code:** FDA-CDER-2024-1389

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2024-1389
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	6/28/2024 3:00:00 PM Eastern Time Zone
Description	***Applications will be reviewed on a rolling basis**

This project is located in the Office of Infectious Diseases (OID), Office of New Drugs (OND). The project seeks to address multiple challenges with the development of anti-infective drugs for pediatric use. Specifically, the results of the project are expected to provide best practices for designing and evaluating pediatric drug development programs, and to improve confidence in clinical pharmacology-based regulatory decisions for these programs.

Under the guidance of the mentor, the participant will gain a comprehensive understanding of pediatric drug development from a clinical pharmacology and regulatory perspective.
The participant's training will include learning:

- How clinical pharmacology principles contributed to the evaluation of efficacy and safety of anti-infective drug products currently approved for pediatric use.
- How to prepare a database capturing study design and PK results.
- Population PK and probability of target attainment (PTA) analyses.

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 work covers more than just medicines.

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 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.

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Qualifications

The qualified candidate should have a doctoral degree (PhD, PharmD, DPH, MD) in Pharmaceutical Science/Pharmacology. Degree must have been received within 60 months of the appointment starting date or anticipated to be received by 8/30/2024.

Preferred skills:

- Familiarity and experience with pharmacokinetics and pharmacodynamics modeling and data analyses, preferably in the anti-infective field
- Familiarity with data analysis tools (e.g., R, MATLAB, or SAS) and modeling tools (e.g., Phoenix NLME, Monolix, or NONMEM)

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 8/30/2024 12:00:00 AM.
- **Academic Level(s):** Postdoctoral or Post-Master's.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

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.)

I have read the FDA Ethics Requirements.