Opportunity Title: FDA Pediatric Extrapolation: Analysis Using FDA Clinical Trial Data
Opportunity Reference Code: FDA-CDER-2026-0190

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

Reference Code FDA-CDER-2026-0190

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click APPLY.***

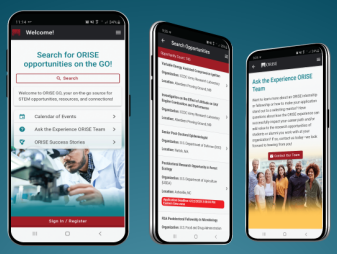
A complete application consists of:

- 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.

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

FDA Office and Location: A research opportunity is available at the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM), in the Division of Pediatrics and Maternal Health (DPMH) located in Silver Spring, Maryland. The participation is hybrid with some in-person at the FDA White Oak Campus 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. These efforts cover more than just medicines.

Research Project: Pediatric extrapolation relies on the use of inferences about efficacy in children often based on data in adults based on assumptions or evidence of similarity in disease, drug pharmacology and treatment response between adults and children. The need to systematically assess the assumptions underlying extrapolation is well recognized in pediatric drug development. The FDA has access to data from approximately 1,200 pediatric clinical trials, including data from 600 trials spanning more than 300 pediatric development programs, which enables a systematic, disease-focused review. The proposed project aims to analyze adult and pediatric clinical trial data to evaluate the assumptions underlying the extrapolation of pharmacokinetics (PK), efficacy, and safety for selected diseases/conditions.

Through this educational opportunity you will gain experience in research activities, including

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data collection from public and proprietary sources, data analysis and interpretation, and preparation and presentation of research findings for scientific dissemination and publication.

Learning Objectives: Under the guidance of the mentor(s), you will be involved in a systematic review of adult and pediatric clinical trial data. Through this process, you will learn to assess similarities in disease between adults and children, understand expected differences in treatment response (if any) in children, gain experience acessiing the possibility of leveraging information from previous studies (adult and pediatric), and contribute to a framework for optimizing trials.

Mentor: The mentor for this opportunity is Lily (Yeruk) Mulugeta (yeruk.mulugeta@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: January 2027. 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 participation is hybrid with some in-person at the FDA White Oak Campus in Silver Spring, Maryland.

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.

Qualifications The qualified candidate should be currently pursuing or have received a bachelor's, master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date, or be currently pursuing.

Point of Contact Ashley

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Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (3 👁)
  - **Life Health and Medical Sciences** (51 👁)
  - **Mathematics and Statistics** (11 👁)

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.)