Opportunity Title: FDA Pediatric Extrapolation: Analysis Using FDA Clinical Trial Data
Opportunity Reference Code: FDA-CDER-2026-0038

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

Reference Code FDA-CDER-2026-0038

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 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 at the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Office of New Drugs (OND) Office of Immunology and Inflammation (OII), 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. These efforts cover more than just medicines.

Research Project: Extrapolation relies on the use of inferences about efficacy in children often based on data in adults based on assumptions or evidence of disease and response similarity between adults and children. The critical need to systematically assess extrapolation assumptions is well recognized in pediatric drug development. The FDA has access to data from approximately 1,200 pediatric clinical trials of which data from 600 trials spanning over 300 pediatric development programs will allow disease-focused systematic review. These data can provide the basis for an extrapolation framework of adult clinical trial information in pediatric drug evaluation. The proposed project is aimed at analyzing adult and pediatric clinical trials to verify assumptions underlying extrapolation of efficacy.

Educational and Training Components: The fellow will be involved in the following activities related to the research project: participate in data collection from public and proprietary sources, analyze research data, and contribute to presentation/publication of research findings.

Learning Objectives: Under the guidance of the mentor(s), you will be

involved in a systematic review of adult and pediatric hypertension trials with a focus on patients less than 6 years of age. You will learn to study similarities of disease between adults and children; understand expected treatment response differences in children, if any; you will assess possibility of borrowing information from previous studies (adult and pediatric) and provide 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: July 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, 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 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 be currently pursuing or have received a Master's or Doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 5/31/2026 11:59:00 PM.
- **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.)

and

I have read the FDA Ethics Requirements.