

**Opportunity Title:** FDA Review of Pediatric Extrapolation and Dosage Optimization  
**Opportunity Reference Code:** FDA-CDER-2026-0067

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

**Reference Code** FDA-CDER-2026-0067

**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](mailto:ORISE.FDA.CDER@orau.org). Please include the reference code for this opportunity in your email.

**Application Deadline** 5/31/2026 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 immediately with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in White Oak, 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:** Conducting adequate clinical studies and further determining the appropriate dosage of an oncology drug in pediatric patients is challenging. The objective of this project is to develop a pediatric oncology database by collecting data from pediatric study protocols, regulatory marketing applications and FDA review documents and to evaluate how dosing strategies are utilized for oncology drugs in pediatric patients. Findings from this project will inform the development of regulatory policy aimed at refining pediatric oncology drug development programs from a clinical pharmacology perspective. Project activities include reviewing Investigational New Drug (IND) submissions and New Drug Applications/Biologics License Applications (NDAs/BLAs) to collect data on pediatric clinical studies and to summarize drug development programs with respect to dose optimization and extrapolation of adult data to pediatric populations. Overall, this project will support the Agency's efforts to advance pediatric oncology drug development through enhanced clinical pharmacology evaluation.

**Learning Objectives:** During the appointment, you will gain hands-on experience with collecting and analyzing data from FDA submissions,



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written and oral scientific communication, and working within a collaborative team. You will also attend internal review meetings and training opportunities as applicable by FDA and Office of Clinical Pharmacology practices. The learning objectives are to learn to conduct a landscape analysis of pediatric oncology drug marketing applications received, summarize dosage optimization approaches used by the sponsors during pediatric drug development process, and summarize approaches used by the sponsors when extrapolating safety and efficacy data from adults to pediatrics.

**Mentor:** The mentor for this opportunity is Suryatheja Ananthula ([suryatheja.ananthula@fda.hhs.gov](mailto:suryatheja.ananthula@fda.hhs.gov)). If you have questions about the nature of the research, please contact the mentor.

**Anticipated Appointment Start Date: August 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 only.

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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

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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.

**Qualifications** The qualified candidate should be currently pursuing or have received a bachelor's, master's, or doctoral degree in the one of the relevant fields.

**Point of Contact** [Ashley](#)

**Eligibility** • **Citizenship:** U.S. Citizen Only

**Requirements** • **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.

- **Discipline(s):**
  - **Computer, Information, and Data Sciences** ([2](#))
  - **Life Health and Medical Sciences** ([5](#))
  - **Mathematics and Statistics** ([1](#))

**Affirmation** I am a U.S. citizen, or 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.