Opportunity Title: FDA Research Opportunity - Dose Selection of Products for Inflammatory Bowel Disease
Opportunity Reference Code: FDA-CDER-2026-0048

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

Reference Code FDA-CDER-2026-0048

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.

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 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. These efforts cover more than just medicines.

Research Project: This project will investigate strategies for optimizing pediatric dose selection to streamline pediatric drug development for inflammatory bowel disease (IBD). Since the approval of infliximab for Crohn's disease in 1998, multiple advanced therapies—including ten biologics and four small molecules—have been approved for ulcerative colitis (UC), Crohn's disease (CD), or both in adults. However, the approval of these products for pediatric patients has progressed more slowly due to the inherent challenges of conducting pediatric studies and the widespread off-label use of adult therapies. To date, only three products have been approved for pediatric IBD, including recently approved golimumab (October 2025), while additional products are currently under investigation for pediatric use.

The efficacy of approved products for IBD is relatively low -often described as a "therapeutic ceiling" - compared to other indications such as psoriasis

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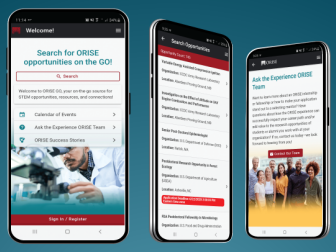

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or rheumatoid arthritis. In the meantime, the American Gastroenterological Association (AGA) has recommended therapeutic drug monitoring for certain TNF a-antagonists, though these recommendations are based on low-certainty evidence and clinical dose optimization for adults with IBD continues to be debated. On the other hand, given the limited number of eligible pediatric patients for clinical trials, the Agency recommends well-established dose-exposure-response relationship in adults to inform pediatric dosing, with pediatric efficacy evaluated in pediatric populations. Conversely, in the case of adalimumab, pediatric UC studies employing two dose levels have supported the approval of pediatric doses higher than the corresponding adult doses. These observations highlight the need for improved, evidence-based dose-selection strategies for both adult and pediatric IBD patients.

The overarching goal of this fellowship project is to identify and evaluate approaches that can better inform pediatric dose selection based on adult data and patient-specific factors. Specifically, the fellow will:

- Survey clinical development programs for IBD products, focusing on dose-selection strategies for adults and pediatric patients.
- Collect and analyze data from FDA reviews, internal databases (as available), and relevant published literature.
- Compare approved doses between adult and pediatric populations and across indications when products are approved for multiple diseases.
- Investigate how patient factors—such as age, body size, disease activity, and immunogenicity—affect pharmacokinetics (PK), pharmacodynamics (PD), and therapeutic dose selection for IBD.
- Identify best practices and gaps in dose-selection methodologies to support regulatory decision-making and future pediatric drug development strategies.

Learning Objectives:

- You will meet regularly with your FDA mentor and a project team to discuss progress, data interpretation, and methodological approaches. Additional learning opportunities will include participation in FDA seminars, workshops, and lectures open to fellows.
- You will develop a comprehensive understanding of IBD pathophysiology, therapeutic mechanisms, and clinical management, including therapeutic drug monitoring and dose optimization and understand the principles of pharmacokinetics and pharmacodynamics as applied to dose selection in adults and pediatric populations.
- You will gain practical experience at the intersection of regulatory science, pharmacology, and clinical drug development. Engagement with FDA professionals from diverse scientific backgrounds will promote interdisciplinary collaboration and broaden your professional perspective.
- The findings from this project will contribute to ongoing collaborative learning among reviewers and will support FDA’s mission to advance

model-informed drug development (MIDD) and regulatory science for pediatric therapeutics.

Mentor: The mentor for this opportunity is Insook Kim (Insook.Kim@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: Early May/June, 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, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 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 the one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Life Health and Medical Sciences** (2 👁)
  - **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.