Opportunity Title: FDA Methodological Evaluation of Validation Approaches for AI/ML-Based Predictive Medical Devices for Regulatory Settings
Opportunity Reference Code: FDA-CDRH-2026-0022

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

Reference Code FDA-CDRH-2026-0022

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.CDRH@orau.org. Please include the reference code for this opportunity in your email.

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Application Deadline 9/30/2027 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 Devices and Radiological Health (CDRH).

The mission of CDRH is to protect and promote public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, caregivers, and providers with understandable and accessible science-based information about products. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Research Project: This research fellowship will allow you to conduct structured landscape analysis of AI/ML device submissions (510(k), De Novo, PMA SSEDs) to characterize predictive/prognostic claims, clinical study designs, performance metrics and validation strategies, and statistical methodologies. The project will also involve designing and executing simulation studies to evaluate alternative validation approaches under varying data, model, and clinical scenarios, identifying methodological gaps and assessing robustness considerations.

Learning Objectives: Guided by multidisciplinary mentors and collaborators with experience in regulatory science, statistics, epidemiology, and AI/ML, you will gain in-depth knowledge of the regulatory

landscape for AI/ML-based medical devices and the methodological frameworks used to evaluate their safety and effectiveness. Specifically, you will:

- Develop proficiency in conducting structured landscape analyses of FDA device submissions (510(k), De Novo, PMA SSEDs), with a focus on characterizing predictive and prognostic claims, clinical study designs, performance metrics, and statistical validation strategies.
- Build skills in simulation study design and execution, learning to evaluate alternative validation approaches across varying data, model, and clinical scenarios in collaboration with statisticians and epidemiologists.
- Gain hands-on experience identifying methodological gaps in AI/ML device validation and assessing the robustness of statistical approaches used to support regulatory decision-making.
- Acquire firsthand exposure to CDRH's regulatory processes and the evolving standards for AI/ML device oversight, positioning you to contribute to evidence-based regulatory science in this rapidly advancing field.

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

Anticipated Appointment Start Date: 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 part 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.

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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 doctoral degree in the one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (1 👁)
  - **Mathematics and Statistics** (11 👁)

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.