Opportunity Title: FDA Fellowship - Digital Health Technology Review Support
Opportunity Reference Code: FDA-CBER-2026-0025

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

Reference Code FDA-CBER-2026-0025

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

Application Deadline 6/26/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is currently available at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). in White Oak, Maryland.

The Center for Biologics Evaluation and Research (CBER) is one Center within the Food and Drug Administration, an Agency within the United States Government's Department of Health and Human Services. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

The ORISE Research Participation Program at the U.S. Food and Drug Administration is an educational and training program designed to provide college students, recent graduates, and university faculty opportunities to connect with the unique resources of the FDA. With the support of an assigned mentor, participants have authentic hands-on research experience and allows them access to unique research opportunities, top scientists and engineers, and state-of the art facilities and equipment.

Research Project: The Digital Health Technology review team evaluates digital health technologies used in clinical trials for biologics development, including electronic clinical outcome assessments (eCOA), machine learning models, and wearable devices. Our research focuses on ensuring these technologies are fit-for-purpose and meet regulatory standards for safety and efficacy assessments. Under the guidance of a mentor, you will contribute to projects addressing critical challenges encountered during the regulatory review of biologics products. These research initiatives aim to

develop evidence-based frameworks, best practices, and guidance that enhance our ability to evaluate innovative digital health technologies in the biologics development context.

Throughout the course of the appointment, you will collaborate with multidisciplinary FDA scientists and learn how digital health technologies can advance biologics development and regulatory decision-making. Key training activities will include: 1) Conducting literature review, identifying research questions and relevant clinical datasets; 2) Applying scientific methods to advance and support the regulatory review of digital health technologies and AI/ML models; 3) Contributing to manuscripts, reports, and presentations that communicate findings to internal and external audiences; and 4) Supporting the development of reproducible frameworks and guidance documents that can be reused for future regulatory science projects.

Learning Objectives: Through this opportunity, you will: 1) learn to develop an understanding of the FDA's regulatory framework for Digital Health Technologies (DHTs) and their application in the development and oversight of biologics; 2) learn and apply the principles of verification, analytical validation, and clinical validation to determine if a DHT is fit-for-purpose in a specific context of use; 3) gain experience in evaluating the use of DHTs for remote data acquisition in clinical investigations, including assessing the suitability of novel endpoints, data management plans, and risk mitigation strategies; 4) analyze and discuss challenges related to the use of AI/ML in medical products, such as algorithmic bias, generalizability, and the importance of transparency for end-users and patients; and 5) enhance their ability to critically review scientific and technical information and effectively communicate regulatory science concepts to a variety of audiences.

Mentor: The mentor for this opportunity is Yun Lu (yun.lu@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 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 doctoral degree in the one of the relevant fields. Degree must have been received within the past five years, or be currently pursuing.

Point of Contact Ashley

Eligibility

- **Degree:** Doctoral Degree received within the last 60 months or currently

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Requirements

pursuing.

- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Life Health and Medical Sciences** (51 👁)
  - **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.