Opportunity Title: FDA Research Fellowship - Characterizing Use of Real-World Evidence to Support Effectiveness for New Indications
Opportunity Reference Code: FDA-CDER-2026-0121

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

Reference Code FDA-CDER-2026-0121

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.

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Application Deadline 8/28/2026 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 within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at 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.

Research Project: You will join a project to conduct a systematic review of internal FDA approval documentation for new approvals, including clinical, epidemiological, and statistical reviews, advisory committee materials, and labeling. The project will extract key characteristics related to:

1. Approval context and regulatory pathway;
2. Intended versus actual use of real-world evidence (RWE) and rationale;
3. Role of RWE in the evidence base (substantial evidence of effectiveness/confirmatory evidence/other);
4. Real-world data (RWD) and RWE characteristics (data sources, study design, quality assessment, bias mitigation); and
5. FDA review findings (strengths, limitations, feedback, labeling).

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With the support of relevant subject matter experts, you will learn to develop at least 10 training-ready case studies across therapeutic areas focused on the use of RWE in demonstrations of effectiveness for newly approved drugs and biologics. Through this project you will create a standardized case study template and an internal data repository to enable access to and dissemination of findings.

Learning Objectives: Under the guidance of a mentor, you will have the following learning opportunities:

- **Regulatory science landscape:** You will become familiar with the role of RWE in regulatory science, gaining exposure to priority research areas and emerging methodological developments that shape FDA's approach to RWE.
- **Regulatory framework application:** You will learn how FDA evaluates the quality and reliability of RWE by studying how regulatory science principles and FDA frameworks have been applied in past new indication approvals for drugs and biologics.
- **Review and synthesis skills:** You will develop skills to conduct a comprehensive systematic review of internal FDA approval documentation — including clinical, epidemiological, and statistical reviews, advisory committee materials, and labeling — to assess the scope and frequency of RWE use in regulatory determinations across the Agency.
- **Thematic and methodological analysis:** You will build competency in identifying cross-cutting themes, methodological innovations, and recurring challenges across key characteristics such as approval context, regulatory pathway, data sources, study design, quality assessment, and bias mitigation strategies that inform the advancement of RWE in regulatory decision-making.
- **Translation of findings into practice:** You will practice translating synthesized findings into at least 10 training-ready case studies and actionable best practices that support the consistent and appropriate use of RWD and RWE across Divisions within CDER for new approvals.
- **Cross-Center collaboration:** You will have the opportunity to engage with subject matter experts and reviewers across other FDA Centers to explore how findings, case studies, and best practices developed through this project may be adapted or extended to support RWE use in regulatory decision-making across the Agency.
- **Scientific communication:** You will strengthen your ability to communicate key findings and recommendations through the development of standardized case study templates, an internal data repository, peer-reviewed publications, conference presentations, and strategic reports.

Mentor: The mentors for this opportunity are Silvia Perez-Vilar (silvia.perezvilar@fda.hhs.gov) and Marie Bradley (marie.bradley@fda.hhs.gov). If you have questions about the nature of the

research, please contact the mentors.

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 candidate should have received or currently be pursuing a doctoral degree (PhD or equivalent) in one of the relevant fields (epidemiology, data science, mathematics, statistics). Degree must have been received within the past five years or is anticipated to be completed by August 31, 2027. Candidates with a clinical doctorate (e.g., PharmD, MD) or equivalent and relevant experience will also be considered.

Point of Contact Ashley

Eligibility Requirements
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 8/31/2027 11:59:00 PM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (51 👁)

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.