

**Opportunity Title:** FDA Fellowship - Characterizing Use of Artificial Intelligence to Substantiate Evidence of Effectiveness and Safety Information for Approved CDER Products

**Opportunity Reference Code:** FDA-CDER-2026-0105

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

**Reference Code** FDA-CDER-2026-0105

**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.

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**Application Deadline** 9/1/2026 3:00:00 PM Eastern Time Zone

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

**FDA Office and Location:** Multiple research opportunities are available in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA) located in White Oak, Maryland.

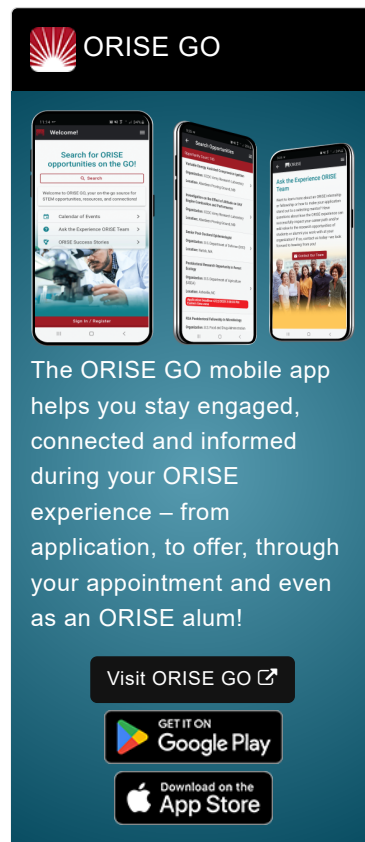
The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. These efforts cover more than just medicines.

**Research Project:**

- **Systematic Review:** Analyze CDER approval packages (NDAs/BLAs) from 2016–2026 to characterize how AI has been used to substantiate evidence of effectiveness and safety information in drug and biologic approvals.
- **Database Development:** Build an interactive, queryable dashboard (e.g., Power BI) to track and monitor historical and incoming AI use cases, prioritizing those with the highest regulatory impact.
- **Training & Dissemination:** Translate findings into draft training materials, seminars, and capacity-building resources to standardize FDA reviewer feedback and upskill CDER staff on AI in drug





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development.

- **Scientific Output:** Learn to disseminate findings to the broader scientific and regulatory community via peer-reviewed manuscript, white papers, and conference presentations, etc.

**Learning Objectives:** Under the guidance of a mentor, you will have the opportunity to learn;

- **Regulatory Review of AI Evidence:** Develop proficiency in systematically reviewing and evaluating AI model characteristics, outputs, and their evidentiary role in CDER drug and biologic approval decisions.
- **Data Infrastructure & Visualization:** Gain hands-on experience designing and deploying an operational database or interactive dashboard to track, query, and analyze AI use cases in regulatory submissions.
- **Scientific Communication & Knowledge Translation:** Build experience in translating complex regulatory and scientific findings into accessible training materials, peer-reviewed manuscripts, and conference presentations for both internal FDA audiences and the broader scientific community.

**Mentor:** The mentor for this opportunity is Gabriel Innes ([gabriel.innes@fda.hhs.gov](mailto:gabriel.innes@fda.hhs.gov)). If you have questions about the nature of the research, please contact the mentor.

**Anticipated Appointment Start Date: September 1, 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.

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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

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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 degree in one of the relevant fields. Degree must have been received within five years of the appointment start date or be currently pursuing.

#### **Preferred skills/ knowledge:**

- Skills in at least one programming language (e.g., Python, R)
- Analytical skills

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

**Eligibility Requirements**

- **Degree:** Master's Degree received within the last 60 months or currently pursuing.
- **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

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the past 60 months. (36 months do not have to be consecutive.)

AND

I have read the FDA Ethics Requirements.