

**Opportunity Title:** FDA Artificial Intelligence and Open-Source Data for Advanced Quality Surveillance

**Opportunity Reference Code:** FDA-CDER-2026-0085

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

**Reference Code** FDA-CDER-2026-0085

**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.

**Application Deadline** 5/31/2026 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.

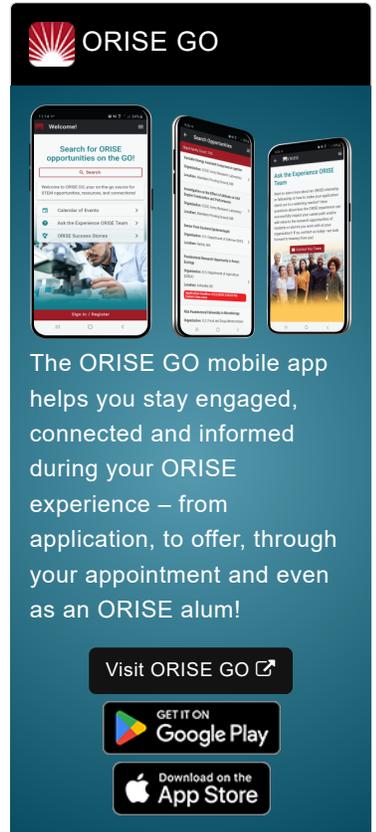
The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription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

**Research Project:** With the development of Artificial Intelligence and Open-Source Data for Advanced Quality Surveillance, the Office of Quality Surveillance (OQS) operates in an increasingly complex regulatory environment with exponential growth in data from regulated entities. Traditional manual data review and extraction processes are resource intensive and difficult to scale for establishment and product level intelligence assessments. The rapid development of new AI tools/models presents an opportunity to enhance facility assessments by leveraging Artificial Intelligence (AI) usage in open-source. This project aims to develop innovative assessment capabilities using techniques such as prompt engineering, data extraction, NLP, time series analysis, web-scraping, and traditional statistical methods. This will transform OQS surveillance operations while providing educational opportunities for staff to learn about the regulatory landscape and pharmaceutical industry.

**Learning Objectives:** This fellowship offers comprehensive training in the pharmaceutical regulatory space, OQS intelligence gathering methodologies, and cloud-based data science capabilities. During the appointment, you will gain hands on experience with various



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pharmaceutical data sources and practical exposure to model evaluation, open-source intelligence gathering, data engineering, and organizational change management. Through this, you will develop skills in translating experimental data analytics into practical pipelines for regulatory purposes and communicating complex findings to diverse stakeholders. This experience will prepare you for careers at the intersection of regulatory science, data science, and emerging technologies.

**Mentor:** The mentors for this opportunity are Stephen Cahill ([Stephen.Cahill@fda.hhs.gov](mailto:Stephen.Cahill@fda.hhs.gov)) and Neil Stiber ([Neil.Stiber@fda.hhs.gov](mailto:Neil.Stiber@fda.hhs.gov)). If you have questions about the nature of the research, please contact the mentors.

**Anticipated Appointment Start Date: June 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 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

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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 bachelor's, master's or doctoral degree in the one of the relevant fields. Degree must have been received within the past five years or is currently pursuing.

**Preferred Skills Include:**

- Knowledge and experience in developing artificial intelligence and predictive analytics using modern statistical or machine learning techniques.
- Previous experience with and mining complex and large data sets.
- A combined academic background in pharmaceuticals and data science is highly desired.

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

- Eligibility Requirements**
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
  - **Discipline(s):**
    - **Chemistry and Materials Sciences** (1👁)
    - **Computer, Information, and Data Sciences** (4👁)
    - **Engineering** (1👁)
    - **Life Health and Medical Sciences** (2👁)
    - **Mathematics and Statistics** (2👁)

**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.