Opportunity Title: FDA Global Regulatory Research on Drug Companies Fellowship

Opportunity Reference Code: FDA-CDER-2020-0570

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2020-0570
How to Apply	*Connect with ORISE...on the GO!* Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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.

Application Deadline	3/31/2021 3:00:00 PM Eastern Time Zone
Description	***Applications will be reviewed on a rolling-basis.**

Three research opportunities are available in the Office of Pharmaceutical Quality/ Office of Quality Surveillance (OQS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.
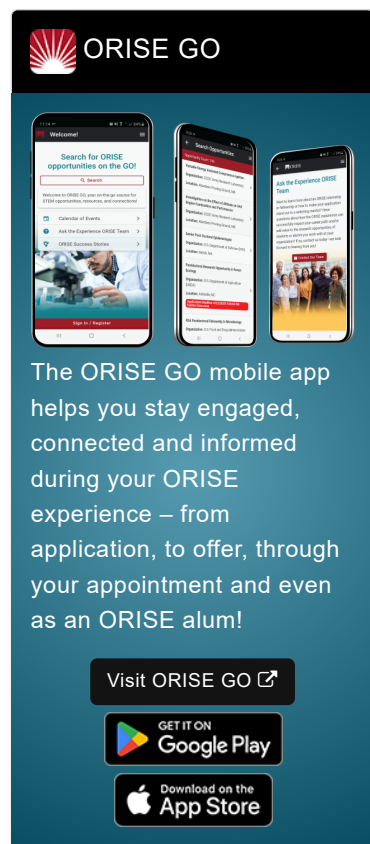
This project will research various modeling methodologies to determine potential models for scoring facilities based on FARs and other post approval incidents/signals. Specifically, the project will explore research methodologies to handle missing data (for example, imputation) as well as explore social media to assess if quality signals can be mined.

The participant will learn the most up-to-date and innovative techniques used to inform data-driven decision making. In addition, the participant will learn and research how to handle missing data and how to select appropriate models that deal with imputed data.

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 initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. 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 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 one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Knowledge in conducting web searches across various platforms with an emphasis on basic data extraction, manipulation, and aggregation
- Ability to surmise context of a given set of data/research and communicate to stakeholders

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** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (2 👁)
  - **Other Non-Science & Engineering** (1 👁)
  - **Social and Behavioral Sciences** (2 👁)