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Opportunity Title: FDA Oncology Real World Evidence (RWE) Fellowship
Opportunity Reference Code: FDA-CDER-2022-0742

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

Reference Code FDA-CDER-2022-0742

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 2/28/2022 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Office of New Drugs/ Office of Oncologic Diseases (OOD) Center for Drug Evaluation and Research (CDER), in collaboration with the Oncology Center of Excellence (OCE) at the Food and Drug Administration (FDA) in Silver Spring, Maryland. 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

The 21st Century Cures Act is designed to accelerate medical product development and bring new innovations and advances faster and more efficiently to the patients who need them. Under this Act, the FDA must evaluate the use of real-world evidence (RWE), generated from real-world data (RWD) to modernize trial design and evidence development. Within the Oncology Center of Excellence (OCE), the newly established RWE Program has active opportunities to advance the use of RWD in OCE Scientific Priority Areas through collaborations with ongoing projects in Health Equity (specifically in understanding underrepresented groups), Special Populations (pediatric, older adults, rare cancers), Immunotherapy, Patient-Focused Drug Development, and Precision Oncology.

Under the guidance of a mentor the participant will gain knowledge in scientific project management, research collaborations, methodologic approaches, patient focused drug development, genomics, regulatory science, clinical trials and pharmacoepidemiology research, and RWE use for regulatory decision making.

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

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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 have received a master's or doctoral degree in a medical or scientific field relevant to real-world date (RWD), including but not limited to, pharmacoepidemiology, biostatistics, health services research, and health outcomes, or be currently pursuing one of the degrees with completion by May 31, 2022. Degree must have been received within the past five years.

Preferred skills:

- Knowledge in Pharmacoepidemiology, Data Science, Biostatistical or Clinical Research
- Moderate level of quantitative programming (e.g. SAS, R)
- Scientific organizational skills

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 5/31/2022 11:59:00 PM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (3 👁)
  - **Mathematics and Statistics** (1 👁)