Opportunity Title: CURE Real World Evidence in Infectious Diseases Fellowship - FDA CDER

Opportunity Reference Code: FDA-CDER-2019-0307

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2019-0307

How to Apply

A complete application consists of:

- An application
- Transcripts – <u>Click here for detailed information about acceptable transcripts</u>
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional references

All documents must be in English or include an official English translation.

If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Description

A research opportunity is available at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Medical Policy/Immediate Office.

The Collaborative Use Repurposing Engine (CURE) pilot tests whether collecting real-world experience in a systematic, accurate, and detailed manner could be valuable to the medical and scientific community. For example by promoting drug development, better information regarding positive and negative health outcomes related to the use of existing products may help drug developers narrow potential drug candidates for study. This project will contribute to efforts to improve drug development for infectious diseases lacking adequate approved therapy and will contribute to an understanding of how to utilize real world evidence in the drug approval process.
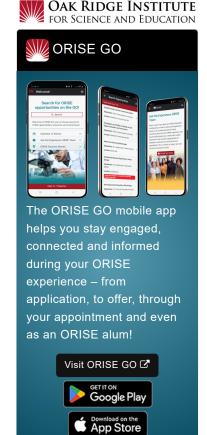
Under the guidance of a mentor the participant may be involved in:

- contributing to design and generation of a newsfeed on the CURE application including content generation and curation
- conducting literature review of all infectious diseases that are in the CURE app
- reaching out to clinicians and engaging stakeholders to generate users and partners
- further developing the Anti-Microbial Resistant organisms and emerging threats sections

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 and/or Rockville, Maryland area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

Qualifications

An individual with a medical degree (MD, MBBS, etc.) having completed training in a residency program and is within 5 years of graduation of that program. Clinicians with training in the treatment of infectious diseases are strongly desired.

Opportunity Title: CURE Real World Evidence in Infectious Diseases Fellowship - FDA CDER

Opportunity Reference Code: FDA-CDER-2019-0307

Preferred skills:

- Familiarity with use of technology and mobile apps among clinicians today
- Demonstrable knowledge of the concept of off-label use and the difference between how drugs are labeled by FDA versus how they are employed in clinical practice

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)

Affirmation I have a medical degree (MD, MBBS, etc.) having completed training in a residency program and is within 5 years of graduation of that program.