

Opportunity Title: FDA Clinical Trial Design for Viral Diseases Fellowship
Opportunity Reference Code: FDA-CDER-2022-0760

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

Reference Code FDA-CDER-2022-0760

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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 5/31/2022 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available in the Office of New Drugs (OND)/ Office of Infectious Diseases (OID) at the Center for Drug Evaluation and Research (CDER), 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. This work covers more than just medicines.

Viral infections cause significant illness across the lifespan and around the world. Despite years of drug development for common viruses (e.g., herpes simplex, influenza) and intense collaborative work for emerging viruses (e.g., SARS-CoV-2, ebola), there continue to be many challenges with study design, including selection of endpoints, defining patient populations, and off-label use of drugs considered standard-of-care. The project will analyze results from available clinical trial data and will enable the Division of Anti-Viral to gain new insights about viral diseases and identify clinical trial design elements that can be used to optimize the study of antiviral drugs.

Under the guidance of the mentor, the participant will learn to evaluate key issues that make antiviral drug clinical trials challenging and research that might provide a means to overcome these challenges. The participant will gain an understanding on how the Division of Antivirals leverages available data to address gaps in scientific knowledge. The participant will also gain an understanding of the process of receiving FDA Institutional Review Board approval when using data from various sources.




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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 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 the past five years.

Preferred Skills/ Knowledge:

- Skills with programming software (R Studio, Python, and/or SAS)
- Knowledge in basic statistics
- Knowledge in database development and validation, data mining, and data analyses

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** (17 )
 - **Engineering** (1 )
 - **Life Health and Medical Sciences** (48 )
 - **Mathematics and Statistics** (11 )
 - **Physics** (16 )

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Affirmation Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)