

Opportunity Title: Pulmonary Drug Efficacy in the Sentinel Database

Fellowship - FDA CDER

Opportunity Reference Code: FDA-CDER-2019-0339

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

Reference Code FDA-CDER-2019-0339

How to 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
- 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 An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland.

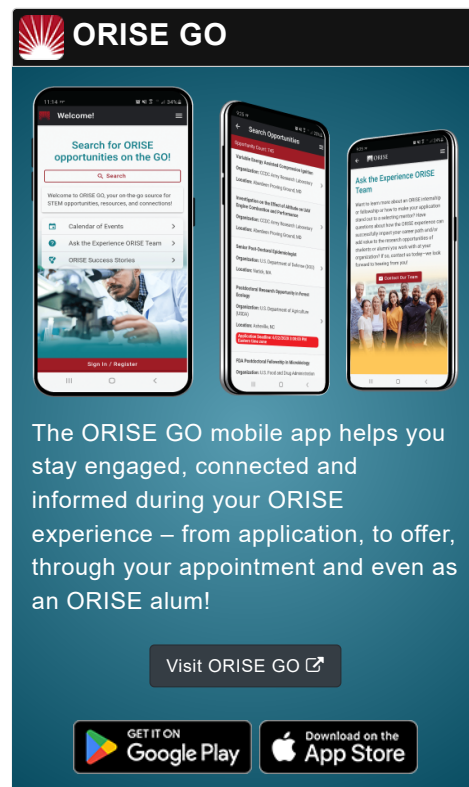
CARE Sentinel, a project in the Office of New Drugs (OND)/Office of Drug Evaluation II (ODE II), will examine clinical questions about Chronic Obstructive Pulmonary Disease (COPD) using the Sentinel Distributed Database system, a large distributed healthcare claims database. The project will focus on creating precise and robust programmatic definitions of obstructive lung disease cases, clinical endpoints, and medication use, for purposes of COPD queries in the Sentinel database. The project will examine access to Sentinel and the applicability of available tools for querying the database for medication efficacy trial designs. The outcome of interest will be descriptive statistics that define and characterize the sample space for COPD in Sentinel including rates of exacerbations, hospitalizations, medication use, and disease-specific covariates to facilitate answering clinical questions.

Under the guidance of a mentor the participant may be involved in:

- researching and learning about prior healthcare claims data analyses
- understanding strengths and limitations and how they apply to Sentinel data
- exploring respiratory disease definitions, associated clinical endpoints, and medication use in Sentinel
- providing statistical models to answer clinically impactful questions in respiratory disease using Sentinel 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.

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



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for FDA to be able to complete a background check.

Qualifications

The qualified candidate should be currently pursuing a master's or doctoral degree, or have received a master's or doctoral level degree in the relevant fields. Degree must have been received within the last 5 years before the appointment start date.

Familiarity with biostatistics or bioinformatics including scientific computing (programming in SAS or other languages) and healthcare data analysis is desired. A familiarity with data analysis of healthcare claims databases including developing statistical models of prospective and retrospective clinical studies is also desired.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
 - **Communications and Graphics Design** (1 )
 - **Computer, Information, and Data Sciences** (3 )
 - **Life Health and Medical Sciences** (2 )
 - **Mathematics and Statistics** (1 )

Affirmation

I have received a master's or doctoral level degree within the past five years, or are currently pursuing a master's or doctoral level degree.