Opportunity Title: FDA Drug Safety: Labeling of Drug Adverse Events Fellowship
Opportunity Reference Code: FDA-CDER-2022-0763

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

Reference Code FDA-CDER-2022-0763

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 5/31/2022 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 (OND)/ Immediate Office (IO), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located 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.

This project intends to better understand the threshold for inclusion of designated medical events in the labeling for novel drugs. It will determine whether there is an association between the rate for inclusion and the upgrading of the adverse events to a Boxed Warning or Warnings or Precautions within the first 3 years of marketing. This project involves computer modeling to assess safety adverse event data and graphical visualizations to aid in data interpretation.

Under the guidance of the mentor, the participant will learn to gather safety and clinical review information from the various databases in CDER. The participant will gain an understanding of the evaluation of safety data based on differences in clinical trials. The participant will also learn about various computer modeling techniques to evaluate safety data, and about tabulations and graphical visualizations that will be used to describe the model and aid in interpretation.

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

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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 doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills/ knowledge:

- Familiarity with U.S. drug labeling and FDA drug review process
- Basic understanding of data analysis, including, interpreting, identifying patterns, and presenting data with clarity
- Knowledge of Microsoft Office, particularly Access and Excel

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (5 👁)
  - **Mathematics and Statistics** (3 👁)

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.)

Opportunity Title: FDA Statistical Modeling for Drug AE Analysis Fellowship
Opportunity Reference Code: FDA-CDER-2022-0764

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

Reference Code FDA-CDER-2022-0764

How to Apply

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- One educational or professional recommendation

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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 available in the Office of New Drugs/ Immediate Office (IO), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located 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.

Drug-induced adverse events (AEs) are difficult to predict for early signal detection, and there is a need to develop new tools and methods to monitor the safety of marketed drugs, including novel approaches for evidence generation. This project will utilize natural language processing (NLP), data mining (DM), and statistical modeling increase our understanding of timing/early detection of AEs, which can be applied to targeted monitoring of novel drugs.

Under the guidance of the mentor, the participant will learn about drug safety labeling, AE detection, and signal identification. The participant will also gain knowledge on how OCR software can be used for AE data. The participant will also be trained on how NLP and statistical modeling can be used to retrieve and evaluate safety 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.

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Opportunity Title: FDA Statistical Modeling for Drug AE Analysis Fellowship
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- 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 doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred Skills/ Knowledge:

- Knowledge of various machine learning methods and applying them to real data
- Familiarity with a subfield of NLP (text mining), extracting information and mapping to standardized terms, and human language technologies
- Fluency in quantitative methods and modeling

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Life Health and Medical Sciences** (1 👁)
  - **Mathematics and Statistics** (11 👁)

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.)

A staff fellow position in DIDSR/OSEL/CDRH/FDA is open in the area of development of methods for the regulatory evaluation of home-use diagnostic devices including automated readers for OTC COVID and other screening and diagnostic tests. PhD students interested in the diagnostic review and research position who are finishing up soon and recommended can contact my division director Aldo Badano (aldo.badano@fda.hhs.gov), Director, Division of Imaging, Diagnostics, & Software Reliability.

Gene Pennello, Mathematical Statistician
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Science & Engineering Laboratories
Division of Imaging, Diagnostics, & Software Reliability
10903 New Hampshire Avenue, White Oak 64, Room 3020
Silver Spring MD 20993-0002
Tel: 301-796-6038, Fax 301-847-8123, gene.pennello@fda.hhs.gov

My name is Celene Moorer and I am the FDA Center for Drug Evaluation/Office of New Drugs ORISE Fellowship Program Lead. We have a research opportunity for an ORISE fellow in our office and wanted to reach out to find out if you could pass this information along to PhD candidates or recent graduates in your program who may be interested in this opportunity. I have included details below.

A research opportunity is currently available in the Office of New Drugs (OND)/ Office of Nonprescription Drugs (ONPD) 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. Interested candidates can apply here: https://www.zintellect.com/Opportunity/Details/FDA-CDER-2022-0757

This project will attempt to systematically analyze the Drug Facts Label (DFL) across all of the label comprehension studies by key label elements and by key demographic subgroups in order to inform evidence-based recommendations as to which aspects of the DFL most need to be addressed and potentially re-imagined. Under the guidance of the mentor, the participant will learn to perform data management/manipulation, meta-analysis modeling, data visualization and manuscript preparation. The participant will gain knowledge in working with consumer behavior studies and applying statistical methods involved in analyzing study data such as categorical data analysis, sample size estimation using confidence interval, and generating forest plots.

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 six months, 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.

Qualifications:
The qualified candidate should be currently pursuing or have received a doctoral degree in one of the relevant fields listed in the ad. Degree must have been received within the past five years.

Preferred skills:
Advanced classes in statistics
Knowledge in meta-analysis
Skills in using SAS programming and R programming

Regards,
Celene

Celene Moorer, MS (she/her/hers)
OND ORISE Fellow Program Lead, OND Research Program

Center for Drug Research and Evaluation (CDER)
Office of New Drugs, Office of Drug Evaluation Services (OND/ODES)
Division of Biomedical Informatics, Research, and Biomarker Development (BIRBD)
U.S. Food and Drug Administration (FDA)
Tel: +1 (240) 402-0556
10903 New Hampshire Ave, Bldg. 22, Rm. 4215
Silver Spring, MD 20903
Celene.Moorer@fda.hhs.gov