Opportunity Title: FDA Oncology Bioinformatics Fellowship
Opportunity Reference Code: FDA-CDER-2023-1233

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

Reference Code FDA-CDER-2023-1233

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.

Description

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

CDER Office/Lab and Location: A bioinformatics research opportunity is currently available with the Office of New Drugs/Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

Research Project: This project is a collaborative effort between multiple CDER offices and will provide critical information to FDA/CDER regarding the practical application of Next Generation Sequencing (NGS) from tissue acquisition to patient outcome. Through multiple collaborations (including with Johns Hopkins University and the National Cancer Institute), we will assess the use of NGS technology to answer critical research questions in cancer such as drug-induced adverse events and patient-specific indicators of disease or outcome. The main objective of this program is to assess critical parameters involved in the adoption of NGS technology for cancer care. These parameters include, but are not limited to, tissue processing, laboratory protocols, bioinformatics and variant calling, data processing and related statistical analyses.

Under the guidance of a mentor, the participant will be involved in the following:

- analyzing various bioinformatics approaches to understand best-in-practice NGS analytics and novel methodologies
- examining current SOPs and protocols and emerging tools to understand best-in-practice approaches for NGS analysis and downstream bioinformatics
- collaborating with a multi-disciplinary team including clinicians, sequencing biologists, programmers, and regulators, and engaging with multiple investigators for individual projects

This project is critical to our public health mission and will prepare the participant for a successful career transition into regulatory science research.

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

Preferred skills:

- Familiarity with next generation sequencing analysis, including development and application of algorithms to perform data analysis of DNA and RNA sequencing outputs
- Knowledge of scripting and development languages
- Outstanding communication skills to translate bioinformatic findings for non-experts and implement feedback from investigators into bioinformatic tools

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (2 👁)

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