

Opportunity Title: FDA Biomarker Discovery Fellowship

Opportunity Reference Code: FDA-CDER-2022-0815



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

Reference Code FDA-CDER-2022-0815

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
- 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 9/30/2022 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in Silver Spring, Maryland. This project in the Office of Translational Sciences / Office of Clinical Pharmacology / Division of Applied Regulatory Science will explore the utility of -omic technologies to characterize biomarkers of drug response and resistance. This is a high priority project that has the potential to alter in a substantive way the direction of genomic- and transcriptomic-based biomarkers of drug-target interactions and biomarker discovery as well as drug development at the national level.

Under the guidance of a mentor, the participant will be trained in next-generation sequencing technologies, genomics and molecular genetics in cell-based systems, small RNA transcriptomics of clinical samples, and bioinformatic and statistical analyses of data resulting from these experiments. This will inform biomarker discovery of drug response and resistance as well as drug-target interactions and downstream effects in tissues. This training will prepare the participant for a successful career transition into regulatory science research.

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,

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

Preferred skills:

- Exposure and familiarity with next-generation sequencing
- RNA/DNA/protein extraction and quantification
- Genome editing, molecular cloning, and reporter gene assays
- PCR- and array-based technology
- Prokaryotic and eukaryotic DNA and/or RNA next-generation sequencing
- Biostatistics and bioinformatics

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Environmental and Marine Sciences** (1 )
 - **Life Health and Medical Sciences** (45 )

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.)