

Opportunity Title: FDA Fellowship - Applied Regulatory Science in Bioinformatics and Omics Biomarker Discovery

Opportunity Reference Code: FDA-CDER-2026-0186

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

Reference Code FDA-CDER-2026-0186

How to Apply *To submit your application, scroll to the bottom of this opportunity and click 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.

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Application Deadline 12/11/2026 3:00:00 PM Eastern Time Zone

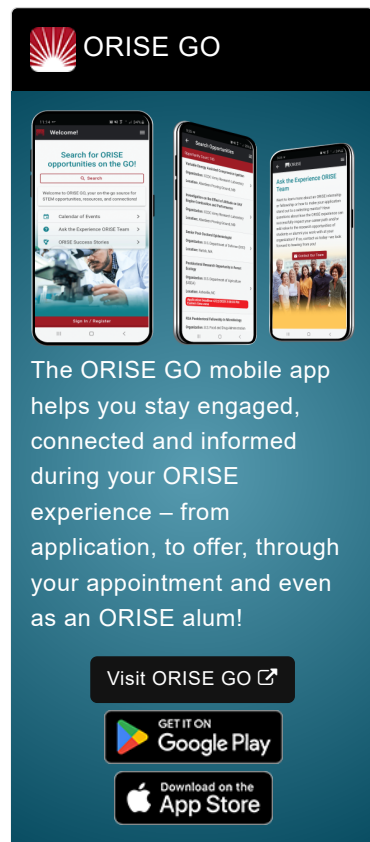
Description ***Applications will be reviewed on a rolling-basis.**

FDA Office and Location: A research opportunity is available within the Office of Translational Sciences (OTS) Office of Clinical Pharmacology (OCP) Division of Applied Regulatory Science (DARS) at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA) located in Silver Spring, Maryland.

The Center for Drug Evaluation and Research (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 U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. These efforts cover more than just medicines.

Research Project: The Food and Drug Administration is seeking a fellow for a Bioinformatics/Biostatistics research project in the Division of Applied Regulatory Science (DARS) located in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER). DARS seeks to move new science into the regulatory review process and close the gap between scientific innovation and medical product review.

Biomarker research has been revolutionized by the availability of technologies for assaying biological activity on a global basis by measuring features of the genome, transcriptome, and proteome (so-called "omics"). Large-scale proteomics data has the potential to identify clinically



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meaningful biomarkers for predicting disease progression, monitoring treatment efficacy, and stratifying patients in clinical trials. DARS is actively evaluating innovative omics technologies and analytical approaches to develop biomarkers that can serve as qualified regulatory tools, supporting standardized endpoints for drug development and informed regulatory decision-making.

This fellowship represents an excellent learning opportunity to research in a visible program area with the potential to substantively advance omics-based biomarker discovery and drug development. You will be directly involved in the statistical analysis of large-scale omics data to inform biomarker discovery for disease expression and severity and to support the development of biomarkers relevant to disease progression and therapeutic response.

You will contribute to the study design and statistical analysis of large-scale omics data generated from biospecimens from clinical trials or well-characterized cohorts. The fellowship will utilize differential expression analysis, systems-level analysis to identify molecular composites and organ-specific signatures, and correlation analyses between molecular markers and disease severity or treatment response. This will include quality control of omics data, statistical modeling, multivariate analysis, pathway and network analysis, data visualization, literature review, and manuscript preparation.

Learning Objectives:

- Learn to perform quality control and preprocessing of large-scale datasets relevant to regulatory biomarker development.
- Learn to design and conduct statistical analyses supporting biomarker discovery, including differential expression analysis, effect size estimation, and correction for multiple comparisons.
- Learn to apply advanced statistical and machine learning methods for identifying multi-protein biomarker panels and assess their correlation with clinical outcomes.
- Learn to conduct systems-level analyses to identify protein composites, organ-specific signatures, and potential pathways or networks associated with disease phenotypes or drug response.
- Learn to analyze and interpret omics data within the regulatory science framework to inform drug development and regulatory review.
- Learn to conduct literature reviews and prepare scientific manuscripts supporting regulatory research dissemination and potential biomarker qualification.

Mentor: The mentor for this opportunity is Paula Hyland (Paula.Hyland@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

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Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the [Guidelines for Non-U.S. Citizens Details page](#) of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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.

Qualifications The qualified candidate should be currently pursuing or have received a doctoral degree in one of the relevant fields (e.g. molecular biology, cell biology, genetics or genomics, biomedical sciences, pharmaceutical sciences, bioinformatics, biostatistics, or a closely related discipline.).

Preferred skills:

- Background in statistical analysis methods including differential expression analysis, multivariate statistics, and correction for multiple comparisons (e.g., Bonferroni, Benjamini-Hochberg, FDR).
- Experience with analysis of one or more omics data types (e.g., proteomics, genomics, transcriptomics, metabolomics, or epigenomics) and large-scale biological datasets.
- Working knowledge of statistical programming languages (R, Python) and data visualization tools.
- Familiarity with pathway analysis methods.
- Experience with quality control procedures for high-throughput biological data.
- Knowledge of data mining approaches for biomarker discovery, with the ability to interpret findings in a biological context.
- Excellent teamwork, organizational, communication, and time-management skills.
- Ability to multitask, prioritize efficiently, and work independently as well as part of a collaborative team.

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Point of Contact [Ashley](#)

Eligibility • **Degree:** Doctoral Degree.

Requirements • **Discipline(s):**
 ◦ **Life Health and Medical Sciences** ([51](#) 👁)

Affirmation I am a U.S. citizen, or 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.)