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Opportunity Title: FDA Fellowship in Regulatory Science Advancement for Continuous Glucose Monitoring (CGM) Endpoints
Opportunity Reference Code: FDA-CDER-2026-0148

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

Reference Code FDA-CDER-2026-0148

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 11/6/2026 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 immediately with the 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. This effort covers more than just medicines.

Research Project: Under the guidance of a mentor, you will implement two-stage meta-analytic models and weighted least squares correlation methods to estimate the surrogacy strength of CGM-derived metrics (e.g., Time in Range (TIR)) relative to hemoglobin A1c (A1C) across multiple clinical trials, calculating and interpreting trial-level correlations across diverse study populations including adults with Type 1 and Type 2 diabetes and children with congenital hyperinsulinism, while integrating FDA-accumulated marketing application datasets with publicly available RCT data to conduct comprehensive, reproducible surrogacy analyses that identify and articulate discrepancies between CGM endpoints commonly used in clinical trials and the evidentiary standards required for regulatory marketing approval, and constructing simulation datasets grounded in real data characteristics to assess surrogacy under scenarios not fully represented in existing data.

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You will also have the opportunity to distinguish and formally model missing data mechanisms as they apply to CGM-specific intermittent and informative missingness patterns, design simulation studies to evaluate and benchmark existing and novel statistical approaches for handling complex, hierarchical CGM data under combined missingness and censoring scenarios, extend these methodologies beyond TIR to metrics with distinct distributional characteristics such as time above/below glycemic target ranges and glycemic variability measures, develop or adapt missing data methods for count-based or overdispersed discrete endpoints such as hypoglycemia event rates, and incorporate hierarchical and temporal dependencies introduced by CGM device characteristics and within-patient physiological variability into statistical models.

Additionally, you will participate in the creation, testing, and refining structured prompts using FDA's AI tool to automate routine CGM data cleaning, merging, and processing tasks, assess the impact of these standardized prompts on the speed, reproducibility, and consistency of regulatory data handling, demonstrate adherence to FDA data governance policies and applicable privacy regulations, and translate AI-assisted analytical outputs into clear, auditable documentation suitable for inclusion in regulatory review workflows.

Learning Objectives: By the end of this appointment, you will have developed the skillsets to:

- Articulate the regulatory framework governing the use of surrogate endpoints in drug development, including FDA standards for clinical meaningfulness and reliability.
- Integrate statistical, clinical, and regulatory perspectives to evaluate continuous glucose monitoring (CGM)-derived endpoints within the context of diabetes drug approval.

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

Anticipated Appointment Start Date: Early 2027. 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 for a second year upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

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 and Lawful Permanent Residents (LPR) only.

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.

FDA Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

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 the one of the relevant fields.

Preferred Skills:

- Experience with surrogacy analyses using regression model and/or meta-analytic model including Bayesian methods and knowledge of continuous glucose monitoring data (or any digitally derived endpoint data)
- Programming experience using SAS and R for dealing with large amount of data and knowledge how to construct and execute simulation datasets grounded in real data
- Strong communication, presentation, and critical thinking skills with a mindset of enthusiastically learning new analyses and engaging effectively in a multidisciplinary team

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree.

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- **Discipline(s):**
  - **Mathematics and Statistics** (11 👁)

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.)
and
I have read the FDA Ethics Requirements.