Opportunity Title: FDA Fellowship - Endpoint Strategy Selection and Statistical Analysis Plan for Non-Malignant Hematologic Disease
Opportunity Reference Code: FDA-CDER-2026-0099

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

Reference Code FDA-CDER-2026-0099

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.

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), Center for Drug Evaluation and Research (CDER), located in White Oak, 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 participant will collaborate with statistical and clinical reviewers to research and develop a practical framework for selecting (primary) endpoint strategies and determining the corresponding statistical analysis plan for non-malignant hematologic diseases in confirmatory trials, starting with the use of historical clinical trials from NDA/BLAs and selected ongoing trials from INDs in myelofibrosis, with the intent to apply the framework to other rare, non-malignant hematologic diseases including PNH, SCD, Anemia of CKD, WAHI, ITP, Hemophilia and others). The participant will:

- Survey and synthesize endpoint strategies (e.g., co-primary, composite, Hochberg, win ratio, etc.) as well as the statistical analyses from recent submissions/literature with emphasis on clinical interpretability, multiplicity control, estimands, and alignment with common regulatory expectations.
- Analyze operating characteristics under realistic data-generating scenarios (endpoint correlation, effect assumptions, alpha

requirements), compare study power and other metrics (e.g., probability that endpoints are individually significant given declared success of the study by a strategy) to understand the pros/cons of different strategies.
- Investigate regulatory flexibility relevant to rare diseases (e.g., alpha relaxation, smaller study power, no requirement for nominal significance for each endpoint, etc.) and balance statistical rigor with clinical feasibility.
- Explore whether the real-world evidence (RWE) approaches as well as Bayesian borrowing can help address sample size and ethical concerns for rare diseases.
- Collaboration between the statistician at DB9 and the clinical team at the Division of non-malignant hematology to map endpoints to disease biology and patient-meaningful benefit; develop annotated case studies highlighting the trial operational characteristics
- Compare and justify endpoint strategies with respect to FWER control, power, and interpretability in the context of FDA's regulatory mission;
- Conduct and explain simulation-based operating characteristic assessments, including power, type I error, and other metrics of interest, and communicate their implications for protocol design;
- Translate clinical objectives into estimand definitions and aligned statistical strategies;
- Contribute to regulatory science by documenting case studies and best practices for non-malignant hematologic diseases that generalize to other areas to improve consistency.

Learning Objectives: Under the guidance of a mentor, you will learn from the following:

- Methods curriculum: You will be provided guided readings in familiar issues for many non-malignant diseases and also on rare diseases via available guidance and also some statistical guidance (e.g., ICH E9, multiple endpoints, estimands).
- Applied analytics training: You will learn to conduct simulations using R or other programming languages to compare study power and other metrics for different endpoint strategies over different settings and scenarios.
- Participate in weekly internal meetings/groups, receive guidance from mentors, and discuss research. Communicate with mentors as needed during the weekday.
- Participant will have an opportunity to attend clinical or statistical conferences for presentation and publication of the project findings.
- Learn practical hands-on experiences in terms of statistical programming for clinical trial design and implementation of different endpoint strategies for a new and rare disease areas.
- Present findings at internal FDA seminars and (as appropriate) external scientific meetings.
- Pursue the opportunity to co-author a manuscript presenting the finding from this program.
- Obtain a comprehensive understanding of clinical trial design in non-malignant

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hematological diseases

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

Anticipated Appointment Start Date: June 1, 2026. 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.

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.

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.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Life Health and Medical Sciences** (2 👁)
  - **Mathematics and Statistics** (2 👁)

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.