

Opportunity Title: FDA Drug Development for Pediatric Diseases Fellowship

Opportunity Reference Code: FDA-OPT-2022-01

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

Reference Code FDA-OPT-2022-01

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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.OC.other@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 2/28/2022 3:00:00 PM Eastern Time Zone

Description *Applications will be reviewed on a rolling-basis. Early submission of applications is strongly encouraged. A selection may be made at any time during the review process.

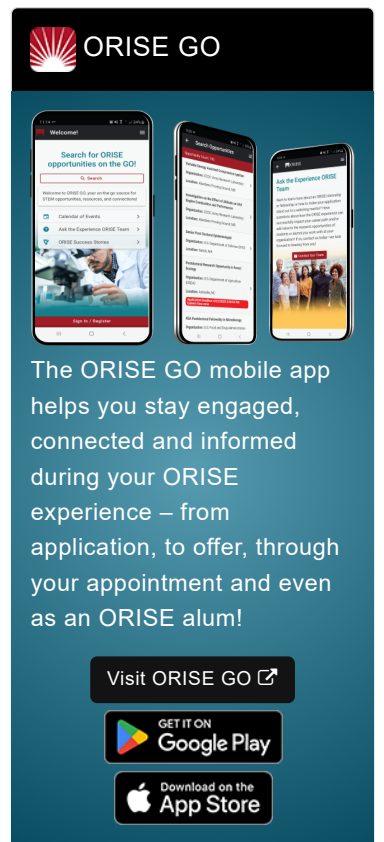
An opportunity is available at the U.S. Food and Drug Administration (FDA), Office of the Commissioner (OC), Office of Pediatric Therapeutics (OPT) located in Silver Spring, Maryland.

With mentors in the Office of Pediatric Therapeutics, the participant will participate in two research projects which aim to 1) review the Rare Pediatric Disease Priority Review Voucher (RPD PRV) program and 2) describe and analyze the landscape of neonatal randomized clinical drug trials.

RPD PRV: Using data from FDA databases, the participant will characterize the products and associated development programs for drugs granted rare pediatric disease designation and/or a rare pediatric disease voucher. To date, published data on the RPD PRV program are very limited. The aim of the scoping review is to provide a greater understanding of the impact of the RPD PRV program on access to treatments for rare pediatric diseases.


In advance of contributing to deliverables and under the guidance of a mentor, the fellow will participate in literature searches, data extraction and analyses from FDA databases, and drafting of a manuscript that summarizes the findings of the scoping review. This will include (1) performing a focused literature review to identify and understand any previously published analyses (2) participating in development of a comprehensive RPD PRV database that collates data from multiple FDA databases, 3) contributing to the development and implementation of a descriptive data analysis strategy.


Neonatology: Despite the many randomized controlled trials (RCTs) performed in newborns (both premature and term), very few drugs have been shown to be effective for neonate-specific conditions. The neonatology clinical trials project aims to collect the published interventional drug RCTs over the past 2 decades, characterize them by success or failure of the prespecified primary endpoint, and analyze design elements that may correlate with success or failure (e.g., whether dose finding studies were performed, use of correct incidence data for power calculations, endpoint selection). The Fellow will collaborate with a research team to build and populate the database,




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extract information from publications, perform descriptive analysis, and draft one or more publications.

Anticipated Appointment Start Date: As soon as a qualified candidate is identified; start date is flexible

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 have received a bachelor's degree in one of the relevant fields, or be currently pursuing a master's or doctoral degree. Degree must have been received within the past five years.

Preferred skills:

- Conducting comprehensive searches of the medical literature and organizing results
- Understanding principles of clinical study design, biostatistics, and epidemiology
- Creating spreadsheets and/or databases (e.g. Excel, Access) to collect extracted data
- Scientific writing

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
 - **Communications and Graphics Design** ([2](#))
 - **Life Health and Medical Sciences** ([9](#))

Affirmation I have received a bachelor's degree within the past 5 years, or am currently pursuing a master's or doctoral degree.

AND

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