Opportunity Title: Physiologically Based PK Modeling in Pregnancy Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2019-0378

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

Reference Code FDA-CDER-2019-0378

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
- Two educational or professional references

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 An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of New Drugs (OND), Office of Drug Evaluation III (ODEIII) in Silver Spring, Maryland and the University of California, San Diego (UCSD).

The goal of this research program is to leverage the unique and extensive Pharmacokinetics (PK) database generated in pregnant women with HIV treated with antiretroviral drugs to improve our understanding of the PK changes and safety issues associated with pregnancy. This PK database will be used to develop a physiologically based pharmacokinetic (PBPK) model applied to pregnancy in pregnant women with HIV. The results of this research will allow us to optimize the design and conduct of PK studies in pregnant women treated with antiretroviral drugs (e.g., more precise selection of periods of gestation to be studied, more informed decisions about necessary sample sizes and initial doses to study in pregnant women).

Under the guidance of a mentor the participant will gain specific scientific training on: PBPK analysis; analyzing databases to build PBPK model based on necessary compartmental PK analysis from candidate drugs and published literature; verifying physiology model during pregnancy; and discussing recommendations for optimal pregnancy (and potentially postpartum) PK sampling times to inform future clinical trials.

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 for the first 3 months, and then at the University of California, San Diego for the remainder of the appointment. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

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

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

Familiarity with PBPK modeling software is preferred.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students or Postdoctoral.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (5 👁)
  - **Mathematics and Statistics** (2 👁)