

Opportunity Title: Physiologically-Based PK Modeling in Pregnancy Fellowship - FDA CDER

Opportunity Reference Code: FDA-CDER-2017-0066

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

Reference Code FDA-CDER-2017-0066

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

Description A research opportunity is available at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER).

The physiologic, anatomic and biochemical changes associated with pregnancy may have a major impact on drug disposition, however, pregnant women are generally excluded from drug development programs. As a result, while medication use in pregnancy is common, pregnant women frequently receive drugs in the absence of the pregnancy specific safety and PK data needed to inform dosing, posing potential risks to the health and wellbeing of both mother and fetus. Bridging this knowledge gap is critically important in HIV-infected pregnant women receiving antiretroviral medications given the critical need to effectively treat HIV infection in these women in order to suppress HIV replication to maintain the health of the mother and reduce the risk of HIV transmission to the fetus.

The goal of the program is to leverage the unique and extensive PK database available from the ongoing NIH funded IMPAACT network study (P1026s) to improve our understanding of the PK changes associated with pregnancy in order to optimize design and conduct of PK studies in pregnant women, including prioritization of drugs to be studied and selection of periods of gestation to be studied, necessary sample sizes and initial doses.

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 12 months, 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 San Diego, CA area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION

<complex-block>

The ORISE GO mobile app helps you stay engaged, connected and informed during your ORISE experience – from application, to offer, through your appointment and even as an ORISE alum!





Opportunity Title: Physiologically-Based PK Modeling in Pregnancy Fellowship - FDA CDER

Opportunity Reference Code: FDA-CDER-2017-0066

Qualifications This opportunity will be based at the University of California, San Diego via a Memorandum of Understanding (MOU) with FDA/CDER. The opportunity is for a recent graduate (within the past 5 years) from an accredited university or equivalent, with a strong emphasis/knowledge on Pharmacokinetics (PK), and Physiologically-Based Pharmacokinetics (PBPK).

Eligibility Requirements

- Degree: Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 month(s).
 - Discipline(s):
 - Computer, Information, and Data Sciences (2.)
 - Engineering (<u>1</u>
 - Life Health and Medical Sciences (5.)
 - Mathematics and Statistics (2_)