Opportunity Title: Pharmacometrics Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2019-0334

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2019-0334
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   An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland.

This project in the Office of Translational Sciences (OTS) Office of Clinical Pharmacology (OCP) Division of Pharmacometrics (DPM) seeks to evaluate the effect of multiple patient factors on the drug Pharmacokinetic (PK) / Pharmacodynamic (PD) by examining how multiple patient factors, both intrinsic and extrinsic, can affect the drug PK, PD and thereby drug response. Utilization of modeling and simulation to predict effects of combined patient factors on PK study results will have an impact on the Food and Drug Administration (FDA) recommendations on policy related to the evaluation of multiple factors on PK.

Under the guidance of a mentor the participant may be involved in:

- collecting data from the FDA database and literature related to single intrinsic and extrinsic factors (age, drug-drug interactions, renal impairment, etc) affecting PK
- utilizing modeling and simulation (e.g., physiologically based pharmacokinetic modeling) to evaluate the effect of combined patient factor on the PK

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 part-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.

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.

Qualifications	The qualified candidate should be currently pursuing a doctoral degree or have received a doctoral degree in the relevant fields. Degree must have been received within the last 5 years of the appointment start date.
	Familiarity with modeling and simulation software (e.g., SAS, Splus/R, NONMEM, Trial simulator, WinBUG, Phenix, Monolix, GastroPlus, PKSIM, SimCYP, etc), and good knowledge of epidemiology, statistics, and PKPD modeling principles are desired.
Eligibility Requirements	**Degree:** Doctoral Degree. **Discipline(s):** **Life Health and Medical Sciences** (2 👁) **Mathematics and Statistics** (10 👁)
Affirmation	I have received a doctoral degree within the past five years, or are currently pursuing a doctoral degree.