Opportunity Title: Predicting Drug-Induced Liver Toxicity Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2019-0338

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

Reference Code FDA-CDER-2019-0338

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 for the first four months and then in Jefferson, Arkansas for the remainder of the appointment.

The overall goal of this project is to develop and evaluate a predictive model that can improve and support the assessment of Drug-Induced Liver Injury (DILI) risk at the early stage Investigational New Drug (IND) of drug review process. We will focus on the IND phase because of the Food and Drug Administration's (FDA)'s previous work evaluating New Drug Applications (NDAs), and because identifying DILI risk before a drug reaches the NDA stage of development is advantageous for public health. In this project, we aim to achieve two main objectives: (1) develop a better model for assessing DILI risk and (2) validate the new model for regulatory use.

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

- comprehensively annotating selected FDA approved drugs for their DILI risk, and using them as a reference database
- using the reference database to identify drug properties and mechanisms that will further enhance performance of published Rule-of-Two (RO2) model
- assessing the predictive performance of the revised model for its potential regulatory value
- preparing the analysis results for dissemination through presentations and publications

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 and the Jefferson, Arkansas 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 must have received a master's or doctoral level degree in computational

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biology/bioinformatics, chemical engineering, systems biology/pharmacology, biophysics or related fields with an emphasis on modeling, scientific computing. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Strong scientific computing and statistical analysis
- History of peer-reviewed publications
- Strong background in R or Matlab programming
- Knowledge in computational modeling to predict or enhance the understanding of disease or drug toxicity mechanisms
- Familiarity with the study of drug-induced liver injury

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (4 👁)