Opportunity Title: In Silico Screening for Cardiovascular Safety - FDA CDER
Opportunity Reference Code: FDA-CDER-2018-0293

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

Reference Code FDA-CDER-2018-0293

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 U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of New Drugs/Office of Drug Evaluation (OND/ODE)

This project is part of a plan to develop cardiotoxicity assessments based on human cells and human proteins, with the expectations that this would improve the specificity of non-clinical cardiotoxicity assessment and reduce the use of animals for research. The project's efforts will inform efforts to define a non-clinical panel of cardiotoxicity assays for new drugs.

Under the guidance of a mentor the participant will have a hands-on learning experience in identifying, extracting and integrating in vitro, in vivo and genomic CV data into a structured format for efficient integration, evaluation and analysis. The participant will learn how to construct CV-specific QSAR models and apply principles of PBPK, TKTD and genomic pathway analyses to develop novel in silico tools to facilitate in vitro to in vivo extrapolation of human-relevant mechanistic bioactivity data.

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 Research Triangle Park, North Carolina area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

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 Applicant must have received a PhD in a relevant biomedical field and possess knowledge of and familiarity with phenotypic and genomic databases, from a U.S. accredited institution within the last

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5 years from the start date of the appointment. Experience with literature review, and the ability to extract, synthesize, and collate data in varying formats, are desired. Basic programming skills, ideally in R and/or Python, familiarity with in silico modeling, and the application of computational methods to high-throughput screening data are highly desirable.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (4 👁)
  - **Life Health and Medical Sciences** (5 👁)