Opportunity Title: Software Engineer for Cardiac Safety Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2016-0055

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

Reference Code FDA-CDER-2016-0055

How to Apply 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 Since 2005, FDA has required most new drugs to undergo Thorough QT/QTc Studies to assess the effect of drugs on the QT interval, a marker of potential drug-induced risk for potentially fatal ventricular arrhythmia torsade de pointes. Digital electrocardiograms (ECGs) are submitted and stored in the FDA digital ECG Warehouse which contains more than eight million ECGs from more than 400 drug studies. While drug-induced QT prolongation is a relatively sensitive marker of drug-induced torsade risk, it is not a specific marker because drugs can prolong the QT interval with little-to-no risk of torsade. Promising ECG biomarkers have been developed that have the potential to improve assessment of risk for torsade de pointes, but so far they have only been evaluated for a limited number of drugs.

The overall aim of this research project is to extend that analysis and improve our understanding of the relationship between advanced ECG biomarkers and arrhythmic risk. To accomplish this aim it is necessary to develop software that can run in the High-performance Integrated Virtual Environment (HIVE) super computer efficiently and allow for massive parallel analysis of the >8 million available ECGs. Analysis of these ECGs will improve our understanding of the relationship between drug-induced changes in the heart and electrocardiographic patterns and help inform risk of new drugs.

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, MD area. Participants do not become employees of FDA or the program

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administrator, and there are no fringe benefits paid.

Qualifications

A Bachelor's, Master's , or Doctoral degree in computer science, software engineering or a degree such as biomedical engineering or bioinformatics with a strong emphasis on programming within the last five years is desirable. In lieu of an M.S., a B.S. with 3+ years of directly related experience will be considered. Graduate students currently pursuing a degree in bioinformatics or computer science are also eligible to apply.

A highly qualified candidate will have:

- Strong experience in C++ programming
- Experience with Doxygen, Boost and Armadillo is not required but desirable
- Previous experience with highly parallelizable problems and developing in high performance computing environments is a plus

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Engineering** (27 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)