Opportunity Title: Establish Novel Relational Database For Analysis of Postmarket Drug Safety Issues Fellowship – CDER
Opportunity Reference Code: FDA-CDER-2016-0082

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

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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 in the Office of New Drugs (OND) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).Within the FDA, CDER provides regulatory oversight for drugs during development and after approval for marketing. Postmarket oversight includes monitoring for and analysis of emerging drug safety issues.

Drug safety regulatory science includes the development of novel and/or improved tools and data sources to better manage safety issues that are identified for drug products. CDER is exploring and establishing additional scientific and analytic tools and data sources to systematically assess drug safety issues, data sources regulatory actions taken to address these issues, as well as the impact of the regulatory actions on risk mitigation and future drug development.

Within CDER, OND is seeking to progressively develop a new relational database that allows for detailed searching of comprehensively integrated information on postmarket drug safety issues. The database will be a core information source for improving CDER postmarket drug safety oversight.

The selected participant will establish the relational database by:

- Gathering data requirements from subject matter experts/reviewers at CDER
- Standardizing data elements and structures for the relational database.
- Retrieving information from source documents and entering source information into the database.
- Testing of the relational database
- Providing data analytic support for data derived from the database

This position provides the participant with the opportunity to acquire specialized skills in the public health informatics domain in the context of innovative IT implementations. This fellowship will emphasize developing and implementing IT as a tool for the evaluation of OND drug safety activities and enhancement of drug safety science. This fellowship will also

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provide the opportunity to join a dynamic, high-performing team that is engaged in forward-looking projects to address challenging problems. This position offers access to the outstanding facilities for computing and drug evaluation and regulation at CDER, with close collaborations between scientific reviewers and computational scientists.

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 24 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 Silver Spring, Maryland area. Prospective candidates who are still enrolled in school are eligible for a part-time position. Those who have completed their training are eligible for a full time role. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications

Currently pursuing a Bachelor’s or Master’s degree or have received a degree within the last five years.

A Masters degree or qualified Bachelor level degree in clinical informatics, bioinformatics, computer science, information science and technology, scientific computing and informatics, or related field. Experience in developing relational databases and analysis of data is desirable.

Eligibility Requirements

- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (4 👁)
  - **Life Health and Medical Sciences** (1 👁)