Opportunity Title: Clinical Trial Data Transformation & Integration Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2016-0129

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

Reference Code FDA-CDER-2016-0129

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 at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

The Office of New Drugs has established a new Biomedical Informatics program to incorporate new technologies into the drug review process. We have several new regulatory review research projects under development that span across multiple therapeutic areas. FDA has a large and growing repository of clinical trial data from regulatory submissions on new drugs. Pooling data across multiple studies is an important component to answer regulatory questions. However, there are several issues to consider, to ensure the validity of the pooled data such as harmonizing different data definitions and formats, converting laboratory parameters to standardized central units, time trends affecting clinical testing, diagnosis, etc. This project will identify challenges, research frequently encountered issues, and provide potential solutions to combine data across multiple studies/sources. Knowledge gained from this project will be very important to multiple stakeholders, in light of upcoming implementation of the binding guidance for standardized study data submission.

The participant will be involved in:

- Reviewing the existing experience with data transformation for regulatory review science projects in CDER, and combine these examples with review of literature to identify challenges and prospective solutions to data integration
- Developing a knowledge base that will be used to create a data transformation tool, with the goal of facilitating the combination of data from multiple studies and applications (e.g., INDs/NDAs/BLAs) efficiently and in a cost effective manner to support regulatory research and decision-making
- Developing case studies where data integration across multiple studies/sources was successfully accomplished and identify the key elements that made the case successful

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The objectives of the project are to review the existing experience with data transformation for regulatory review science projects in CDER; combine these examples with review of literature to identify challenges, research frequently encountered issues and provide solutions to combine data across multiple studies. The participant will engage with clinical reviewers and computer scientists to develop knowledge base that will be used to create a data transformation tool. The goal for the tool is to accomplish the data transformation to combine data from multiple studies/NDAs efficiently in a cost effective manner to support regulatory research.

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 Silver Spring, MD area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Qualifications

Applicants must have received a bachelors degree in health and medical sciences, biomedical informatics, clinical trial management, computer science, population medicine, public health, or epidemiology within five years of the desired starting date, or completion of all requirements for the degree should be expected prior to the start date. A masters, or doctoral degree is preferred.

Experience working with clinical trial data and a familiarity with data standards, especially as they relate to clinical trials and health records, data standards and data analyses is preferred. A working knowledge of coding, programming, developing algorithms in addition to computer software used for data analyses (such as JMP, J-review, Empirica, SAS, R, etc.) is also desired.

Eligibility Requirements

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