Opportunity Title: Clinical Trial Data Transformation and Integration Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2019-0370

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

Reference Code FDA-CDER-2019-0370

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.

A Project in the Office of New Drugs (OND), Immediate Office (IO) seeks to identify challenges, research frequently encountered issues and provide solutions to combine data across multiple studies for adverse event and safety data; pooling data across multiple studies to answer regulatory questions and incorporate new technologies into the drug review process.

Under the guidance of a mentor the participant will receive training on:

- general FDA regulatory application and data standards
- identifying datasets from multiple applications and evaluating metadata related to clinical studies to identify challenges and find a way forward to solve those challenges in order to combine data across multiple studies
- creating a pooled dataset combining data from multiple studies as a resource to answer regulatory questions, as well as assessing quality of coding of adverse events
- developing and submitting a manuscript publication summarizing results

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, 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 should be currently pursuing or have received a master's or doctoral degree in the relevant fields. Degree must have been received within five years of the appointment start date.

Opportunity Title: Clinical Trial Data Transformation and Integration Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2019-0370

Preferred skills:

- Familiarity with clinical trial data and data standards, especially as they relate to health records and data analyses
- Knowledge of coding, programming, developing algorithms in addition to computer software used for data analyses (such as JMP, J-review, Empirica, SAS, R, etc.)

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (3 👁)
  - **Life Health and Medical Sciences** (4 👁)
  - **Mathematics and Statistics** (1 👁)
  - **Social and Behavioral Sciences** (1 👁)