Opportunity Title: Clinical Trial Data Standards Fellowship - FDA CDER
Opportunity Reference Code: FDA-CDER-2018-0300

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

Reference Code FDA-CDER-2018-0300

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

A project in the Office of New Drugs (OND) Immediate Office (IO) will evaluate clinical and non-clinical data submissions to the Agency between January 1, 2017, to present. This assessment will include a summary of whether a submission included one or more studies where the data standards should have been followed and a top-level assessment of if the appropriate data standards were used. Concurrently, we will reach out to reviewers to summarize their experiences using standardized data over this time frame. As part of this project, we aim to outline gaps in submitting information from newer technologies, such as wearable devices, and identify future submission strategies and standards for submitting such information.

Under the guidance of a mentor, the participant will be trained to: assess compliance with CDER guidance on electronic submission of study data, which will provide an opportunity to learn new regulations and its implementation; learn from clinical reviewers on the development of therapeutic area related data standards which is crucial in leveraging read world data; develop a set of frequently asked data standards related questions based on reviewer experience; and outline gaps in standards related to newer technologies, such as wearable devices.

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.

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Qualifications

Masters or doctoral degree earned within five years of the desired starting date is required.

Familiarity with clinical and nonclinical data standards (CDISC SDTM, ADaM, and SEND) desired.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (4 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (1 👁)
  - **Social and Behavioral Sciences** (1 👁)

Affirmation

I am currently enrolled in a master's or doctoral degree program or have earned a master's or doctoral degree in the past five years.