**Opportunity Title:** Medical Dictionary of Regulatory Activities (MedDRA) Queries Fellowship - FDA CDER
**Opportunity Reference Code:** FDA-CDER-2019-0369

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

**Reference Code** FDA-CDER-2019-0369

**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 develop standardized groupings of The Medical Dictionary of Regulatory Activities (MedDRA) Preferred Terms (PT)s to accurately and consistently identify clinically meaningful adverse drug reactions. The project will integrate the queries into analytic tools that will allow clinical reviewers to use standard groupings and also customize the terms to include as needed for the analysis, as well as develop additional analytic tools or features in existing tools for more advanced assessments of the adverse event data, e.g., algorithm-based for adverse event (AE) database-assessments or developing tools that evaluate other New Drug Application (NDA)/Biologic License Application (BLA) safety datasets (laboratory, VS, ECG) to identify or confirm potential safety signals from application safety databases.

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

- how to examine existing customized MedDRA queries or grouping strategies
- compile a proposed list of PTs for each single-concept query based on a thoughtful curation of existing groupings/queries
- disseminate the queries with OND divisions and obtain feedback on the lists and if there are any additional queries that are needed
- provide feedback regarding integration of FDA Medical Queries (FMQ)s into existing data analysis tools and possible training gaps

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

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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.

Preferred skills:

- Familiarity with MedDRA, clinical study data
- Experience evaluating program and processes using quality metrics

**Eligibility Requirements**

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Communications and Graphics Design** (1 👁)
  - **Computer, Information, and Data Sciences** (3 👁)
  - **Life Health and Medical Sciences** (4 👁)
  - **Mathematics and Statistics** (2 👁)