

**Opportunity Title:** Clinical Outcome Assessments Fellowship - FDA CDER

**Opportunity Reference Code:** FDA-CDER-2018-0296



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

**Reference Code** FDA-CDER-2018-0296

**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](mailto: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.

This project seeks to produce an updated table in the Clinical Outcome Assessment (COA) Compendium of COAs from 2017-present in approved drug labeling. The updated table will assist COA staff on updating and communicating the repository of publicly available COAs and FDA public website of this information to provide external constituents with the opportunity to have a well-informed conversation with The Office of New Drugs (OND) review divisions on possible use of COAs to support clinical trial endpoints and assist in identifying areas of unmet needs of COAs to support clinical trial endpoints.

Under the guidance of a mentor the participant will be trained in compiling data from labels of new drugs approved from 2017 to present and completed DDTs from CDER Qualification Program; assisting COA staff to communicate with OND review divisions on the inclusion of new information in to the compendium; communicating effective information of the Compendium on FDA public website; and assisting in disseminating the updated COA Compendium information to CDER stakeholder.

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**

Master's or doctoral degree in life, health, medical, social, or behavioral sciences (e.g., PhD, PharmD, MD, MPH, MS, etc.) within five years of the desired starting date required.

Familiarity with health outcomes measurement or pharmaceutical health services research preferred.





**Eligibility Requirements**

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**

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- **Communications and Graphics Design** (1 )
- **Environmental and Marine Sciences** (1 )
- **Life Health and Medical Sciences** (45 )
- **Other Non-Science & Engineering** (2 )
- **Social and Behavioral Sciences** (28 )