Opportunity Title: Schizophrenia Clinical Trial Design Optimization Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2016-0081

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

Reference Code FDA-CDER-2016-0081

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 Translational Sciences /Office of Clinical Pharmacology at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

OCP's mission is to assure the safety and effectiveness of new drugs through the evaluation of clinical pharmacology and biopharmaceutics data in support of CDER's Investigational New Drug (IND), New Drug Application (NDA), and Biologics License Application (BLA) review programs. The selected participant will join OCP efforts in optimizing clinical trials for schizophrenia.

This project focuses on evaluating critical design elements of schizophrenia trials, in particular, trial endpoints and trial duration, in order to optimize trial design and increase the efficiency of schizophrenia drug development programs. The selected participant may be involved in building a patient-level database of schizophrenia efficacy trials submitted to FDA as part of NDAs. The participant may also be involved in data analysis that focuses on:

• Evaluating response of items in the positive and negative syndrome scale, which is typically used to evaluate the efficacy of schizophrenia medications in clinical trials using item response analysis
• Determining the optimal duration of schizophrenia efficacy trials
• Evaluating the feasibility of using time to dropout as an endpoint using time to event analysis

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, Maryland area. Participants do not become employees

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of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications Currently a doctoral student in the Life, Health, and Medical Science. Experience with SAS and item response analysis and time to event analysis is preferred.

Eligibility Requirements

- **Degree:** Currently pursuing a Doctoral Degree.
- **Discipline(s):**
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)