Schizophrenia Clinical Trial Design Optimization Fellowship
Division of Clinical Pharmacology IV
Office of Clinical Pharmacology
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Silver Spring, Maryland

FDA-CDER-2014-0040

Project Description:

A fellowship opportunity is currently available in the Division of Clinical Pharmacology IV within the Office of Clinical Pharmacology (OCP) at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA).

OCP's mission is to assure the safety and effectiveness of new drugs through the evaluation of clinical pharmacology 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 will be involved in building a patient-level database of schizophrenia efficacy trials submitted to FDA as part of NDAs. S/he will 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

The Research Participation Program for FDA is administered by the Oak Ridge Institute for Science and Education (ORISE). 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 depending on educational level and experience. The participant must show proof of health insurance. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications:

- A Doctoral degree in biostatistics received within the last five years.
- Experience with SAS is necessary.
- Experience in item response analysis and time to event analysis is preferred.

How to Apply:

To be considered, please send a current CV/resume to the attention of OTSORISE@fda.hhs.gov Please reference **FDA-CDER-2014-0040** in all communications.