Postmarket Data Analysis Fellowship
Office of Computational Science
Office of Translational Sciences
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Silver Spring, MD

FDA-CDER-2014-0046

Project Description:

A fellowship opportunity is currently available in the Office of Computational Science (OCS) within the Office of Translational Sciences (OTS) at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA). OTS fosters novel drug development strategies through research and application of statistical and mathematical modeling and simulation techniques in the review and analysis of data in the areas of exposure-response, pharmacokinetics, pharmacodynamics, pharmacogenomics, bioequivalence assessment, clinical trials, quantitative risk assessment, toxicology, and product quality assessment.

Individualization of drug therapy is a goal for which subgroup analysis is performed in New Drug Application (NDA) review. Premarket prediction of safety and efficacy in patient subgroups could be limited, even when NDA data is pooled, because relevant subgroups may not be adequately represented in clinical trials and marketing approval is based on population means.

This project proposes to assess the feasibility of using postmarket data to assess subgroup differences in efficacy (reduction in HbA1c) and drug induced liver injury (DILI), using analytic approaches to limit confounding, and compare the premarket signals to those obtained postmarket. Under the guidance of clinical experts in OCS and FDA's Office of New Drugs, the selected participant will gain insight on clinically important outcome differences and variables that impact efficacy and safety of drugs for diabetes. Collaborating with the Office of Computational Science and Biostatistics, the participant will gain experience in the use of analytic methods to enable casual inference regarding differences in outcomes from observational data, and gain experience in deploying meta-analyses tools in the clinical trial repository environment.

The Research Participation Program for FDA is administered by the Oak Ridge Institute for Science and Education (ORISE). The initial appointment is for two years and is 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 Master's degree in statistics, mathematics or actuarial science received within the last five years.
- Experience working with large databases, using statistical analysis software, formulating hypotheses, pursuing scientific investigation and quantitative analyses is desired.

How to Apply:

To be considered, please send a current CV/resume to the attention of OTSORISE@fda.hhs.gov . Please reference **FDA-CDER-2014-0046** in all communications.