McGill | Department of Epidemiology, Biostatistics and Occupational Health

Biostatistics Seminars

Winter 2017

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Current trends and open questions in dealing with treatment non-adherence and missing data in the clinical trials regulatory environment

Tuesday, 21 February 2017
3:30 pm – 4:30 pm - Purvis Hall, 1020 Pine Ave. West, Room 24

ALL ARE WELCOME

Abstract:
In recent years, members of the clinical research community have been promoting the use of estimands as a way to link high-level clinical trial objectives to analysis strategies, while providing a clear pre-specification of how non-adherence to randomized treatment, e.g., early discontinuation or initiation of rescue therapy, will be accounted for in the estimate of treatment effect. In practice, even with well-defined estimands and well-designed trials, some amount of missing data can be expected, or it may be impossible to obtain usable (non-confounded) data for a specific estimand for some subjects during the periods of non-adherence. This presentation will review missing data treatment in light of the current regulatory landscape. We will discuss the evolution of thinking regarding what constitutes a useful estimand for different decision makers, usability of data during treatment non-adherence, some common analysis strategies, and open questions.

Bio:
Dr. Bohdana Ratitch is a Scientific Advisor at QuintilesIMS Advisory Analytics group. Bohdana received a Ph.D. degree in computer science/machine learning from McGill University in Montreal, Canada in 2005. Bohdana has been working in biostatistics and clinical research for over 10 years. Missing data in clinical trials is one of her areas of special interest and she is working actively to advance and promote knowledge in this filed in the clinical research community. She is a member of the DIA Scientific Working Group on Missing Data and a co-author of the book "Clinical Trials with Missing Data: A Guide for Practitioners" (Wiley, 2014).