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Proceedings of the University of Pennsylvania 6th annual conference on statistical issues in clinical trials: Dynamic Treatment Regimes

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This issue of *Clinical Trials* contains the proceedings of the sixth in a series of symposia held at the University of Pennsylvania on current statistical issues in clinical trials. This symposium, held in spring 2013, focused on dynamic treatment regimes, a topic highly relevant to the ever-increasing concerns about evaluation of treatment strategies in chronic diseases.

The concept of dynamic treatment regimes is an entirely new way of approaching trial design. Instead of focusing on a question that may address only a very small window of time in a patient's treatment, the dynamic treatment regime (or Sequential Multiple Assignment Randomization Trials (SMART)) considers long-term treatment strategies for individuals who may regularly require new treatment options over time. The goal is to optimize treatment for individual patients while allowing assessment of different strategies over time. Use of such designs in medical research is in its infancy; the most experience has been in the area of substance abuse, but it has potential applications in many areas of medicine, as discussed by the speakers. The presentations and panel discussions offer a very broad spectrum of viewpoints and emphases from both long-time and more recent researchers, and from methodologists as well as potential users of such study designs (see Table). Expert panels provided thoughtful commentary on the presentations, and there were provocative and insightful questions and comments from the floor; these discussions are included along with the papers.

The Penn conference series is aimed at facilitating advances in approaches to the statistical design, implementation and analysis of clinical trials. Earlier conferences in this series focused on proof-of-concept studies and 'go-no go' decision making [1], development of

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Conflict of Interest

None declared.

targeted therapies [2], comparative effectiveness studies [3], emerging statistical issues in the conduct and monitoring of clinical trials [4], and biomarker validation [5]

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5. Ellenberg, JH.; Ellenberg, SS. Clin Trials; Proceedings of the University of Pennsylvania 5th annual conference on statistical issues in clinical trials: emerging statistical issues in biomarker validation for clinical trials; 2013. p. 645-6.

Table

2014 Conference on Emerging Statistical Issues in Biomarker Validation for Clinical Trials

Faculty	Institution	Topic
Phil Lavori	Stanford University	Introduction to Dynamic Treatment Strategies and Sequential Multiple Assignment Randomization
Yingqi Zhao	University of Wisconsin-Madison	Estimation of optimal dynamic treatment regimes
Bibhas Chakraborty	Columbia University	Inference about the expected performance of a data- driven dynamic treatment regime
Discussion Panel	Keaven Anderson (Merck); Marshall Joffe (Penn); Michael Kosorok (UNC)	
Linda Collins	Pennsylvania State University	Optimization of behavioral dynamic treatment regimens based on the sequential multiple assignment randomized trial (SMART)
Erica Moodie	McGill University	Simulating Sequential Multiple Assignment Randomized Trials to Generate Optimal Personalized Warfarin Dosing Strategies
Kelley Kidwell	University of Michigan	SMART Designs in Cancer Research: Past, Present and Future
Discussion Panel	Christy Chuang-Stein (Pfizer); Dean Follman (NIAID); Estelle Russek- Cohen (FDA); Rick Chappell (Wisconsin)	
Closing Remarks	Susan Ellenberg (University of Pennsylvania)	