

SCT Pre-Meeting Conference Workshop Proposal (Sunday, May 18, 2014 in Philadelphia, 8a-12noon)

Title: Clinical Trials for Adaptive Intervention Designs: Workshop on the Design and Conduct of Sequential Multiple Assignment Randomized Trials

Background / Description: The effective treatment and management of a wide variety of health disorders often requires individualized, sequential decision making. To do this, each patient's treatment is dynamically adapted over time based on the patient's history and changing disease state. Adaptive Interventions operationalize individualized decision making using a sequence of decision rules that specify whether, how, for whom, or when to alter the dose, type, or delivery of pharmacological, behavioral, and/or psychosocial treatments.

Recently, there has been a surge of clinical and methodological interest in developing and evaluating adaptive interventions via clinical trials. Specifically, there is great interest in the use of sequential multiple assignment randomized trials (SMART, a multi-stage randomized trial design) to build adaptive interventions.

However, there is a dearth of guidance on how to design and conduct high-quality SMART studies. This gap is particularly important given that the key design considerations, including the rationale and choice of primary and secondary scientific aims in SMARTs differ (often to a great degree) from design considerations in standard randomized clinical trials. There is also much confusion about SMARTs, for example, with regard to the distinction between SMART and adaptive trial designs. In this workshop, we aim to fill these gaps by introducing SMART and discussing issues in the design and conduct of five real-world SMARTs currently in the field or completed. Presentations include discussion on the rationale for primary and secondary aims, pros and cons of different SMART designs considered, and specific challenges and obstacles encountered in the conduct of the SMART.

Target Audience: The target audience is clinical trialists and investigators with an interest in designing and learning how to use a multi-stage clinical trial design to build an effective adaptive intervention.

Goals: The specific educational goals of this workshop are to learn about

- Adaptive interventions, also known as dynamic treatment regimens or treatment policies.
- The use of sequential multiple assignment randomized trials (SMART), including study design principles, for the development of high-quality adaptive interventions.
- Real-world SMART design and conduct issues from five SMART case-studies.

Faculty, Main Affiliations, Topic & Timeline:

Topic	Faculty, Main Affiliation	Time(min)
Introductory Remarks by Daniel Almirall		5
An introduction to adaptive intervention designs and SMART	Inbal N-Shani, Univ of Michigan	30
Question and Answer (Q&A)		3
Design, implementation, and analysis of 2-stage SMARTs: Case studies in substance use	Jim McKay, Univ of Penn	40
Q&A		3
Improving mental health outcomes: Building an adaptive implementation strategy using a cluster-randomized SMART	Amy Kilbourne, Univ of Michigan	40
Q&A + Break		5 + 5
On the use of pilot studies to inform the design and conduct of a SMART for improving weight loss	Sylvie Naar-King, Wayne St Univ	40
Q&A		3
Rationale and design of two SMART studies to construct adaptive interventions for improving spoken communication in minimally verbal children with autism spectrum disorder	Daniel Almirall, Univ of Michigan	30
Q&A		3
Discussion	Peter Thall, MD Anderson	30
Final Q&A and wrap-up		3

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