

WORKSHOP
ADAPTIVE DESIGNS FOR CLINICAL TRIALS
OPPORTUNITIES FOR TRANSLATIONAL RESEARCH

JUNE 10, 2013

Conference Room C, Neuroscience Center
6001 Executive Blvd, North Bethesda, MD

AIMS

1. To describe and demonstrate the potential for flexible adaptive clinical trials to accelerate discovery of effective treatments that improve health.
2. To consider mechanisms to incorporate carefully planned adaptations in the planning and conduct of NIH organized clinical trials.

DRAFT AGENDA

9:30 – 9:45 am	Introduction to ADAPT-IT and Overview of Agenda <i>William Barsan, MD</i>
9:45 – 10:30 am	An Introduction to Flexible Adaptive Designs <i>Roger Lewis, MD, PhD</i>
10:30 – 10:55 am	ICECAP: a duration finding trial of hypothermia after cardiac arrest <i>Scott Berry, PhD</i>
10:55 – 11:20 am	ESETT: a three drug trial to determine optimal treatment of established status epilepticus <i>Jason Connor, PhD</i>
11:20–11:45 am	ProSPECT: Progesterone and Stroke – learning the dose and schedule in Phase II <i>Will Meurer, MD</i>
11:45–12:00 pm	Break to obtain lunch
12:00–1:00 pm	Insights from ADAPT-IT and DESIGN-IT <i>Will Meurer, MD, and William Barsan, MD</i>
1:00–2:00 pm	Concurrent Sessions: (Expected products—summary action points for further discussion) A. Training issues (intra and extra-mural) and Public/Private Partnerships <i>Roger Lewis, MD, PhD</i> B. Communication of Simulations and Peer Review <i>Will Meurer, MD, and Scott Berry, PhD</i> C. Enhancing clinician / biostatistician interactions <i>William Barsan, MD, and Jason Connor, PhD</i>
2:00 – 2:30 pm	Return to Plenary Session: Review action points from Breakouts <i>Roger Lewis, MD, PhD</i>
2:30 – 3:15 pm	Questions, Answers and Next Steps <i>Roger Lewis, MD, PhD</i>