



INITIATIVE ON METHODS, MEASUREMENT, AND PAIN ASSESSMENT IN CLINICAL TRIALS

IMPACT-XXIV

RESEARCH DESIGN CONSIDERATIONS FOR PRAGMATIC AND COMPARATIVE EFFECTIVENESS CLINICAL TRIALS OF PAIN TREATMENTS

THURSDAY, OCTOBER 22, 2020

12:00-4:30 Session I

- 12:00-12:15 Introductions and meeting objectives
- *Dennis Turk, PhD*
- 12:15-12:45 Definitions and general considerations for pragmatic and comparative effectiveness clinical trials
- *Lynn DeBar, PhD, MPH*
 - including an overview of objectives, designs; randomization; and blinding
- 12:50-1:20 Statistical considerations in the design and analysis of pragmatic and comparative effectiveness clinical trials
- *Scott Evans., PhD*
 - including estimands; inter-current events and missing data; and assay sensitivity
- 1:25-1:45 Lessons learned from psychiatry: CATIE and STAR-D
- *Ajay Wasan, MD*
- 1:50-2:10 Lessons learned from the NIH-DoD-VA Pain Management Collaboratory
- *Robert Kerns, PhD*
- 2:10-2:30 Break
- 2:30-2:55 Systematic review of methodologic aspects of pragmatic and comparative effectiveness clinical trials of pain treatments
- *David Hohenschurz-Schmidt, DO*
- 3:00-4:30 Session I panel discussion
- *Moderators: Daniel Cherkin, PhD, and Robert Edwards, PhD*
 - *Panelists: Lynn DeBar, PhD, MPH; Scott Evans, PhD; David Hohenschurz-Schmidt, DO; Robert Kerns, PhD; Ajay Wasan, MD*



FRIDAY, OCTOBER 23, 2020

12:00-4:30 Session II

- 12:00-12:05 Introductions and Session II meeting objectives
- *Dennis Turk, PhD*
- 12:05-12:25 Patient sources and eligibility criteria
- *John Markman, MD*
- 12:30-12:50 Choosing study sites and investigators
- *John Farrar, MD, PhD*
- 12:55-1:15 Concomitant and rescue treatments
- *Michael Rowbotham, MD*
- 1:20-1:50 Outcome domains, measures, and sources of data
- *Matthew Bair, MD*
 - including effectiveness, safety, and electronic health records
- 1:55-2:00 Break
- 2:00-3:00 Session II panel discussion
- *Moderators: Karen Sherman, PhD, MPH, and Dennis Turk, PhD*
 - *Panelists: Matthew Bair, MD; Penney Cowan; John Farrar, MD, PhD; John Markman, MD; Michael Rowbotham, MD*
- 3:00-4:30 Consensus discussion: what specific recommendations can be made for pragmatic and comparative effectiveness clinical trials of pain treatments?
- *Moderators: Robert Dworkin, PhD, David Hohenschurz-Schmidt, DO, and Andrew Rice, MD*

All times listed are Eastern time (New York).