



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

IMPACT-XXI

RESEARCH DESIGN RECOMMENDATIONS FOR CLINICAL TRIALS OF
OPIOID SPARING IN PATIENTS WITH ACUTE AND CHRONIC PAIN

JULY 25-27, 2018
WASHINGTON, DC

Wednesday, July 25, 2018

7:00 – 9:00 PM

WELCOME RECEPTION/DINNER
Monticello East (Lower Level)

Thursday, July 26, 2018

7:15 - 8:00 AM

CONTINENTAL BREAKFAST
Monticello East

8:00 - 8:30 AM

Welcome and introductions
Monticello West

- Dennis Turk, PhD

8:30 - 9:00 AM

What do we mean by opioid sparing and what are its
potential individual and societal benefits?

- Eric Strain, MD

9:00 - 9:30 AM

Opioid-sparing clinical trial objectives and outcomes:
Acute pain

- Tong Joo Gan, MD

9:30 - 10:00 AM

Opioid-sparing clinical trial objectives and outcomes:
Chronic pain

- Nathaniel Katz, MD

10:00 - 10:30 AM

BREAK

10:30 - 11:00 AM

A regulatory perspective on opioid sparing clinical trial
objectives and outcomes: Drugs

- Sharon Hertz, MD



11:00 - 11:30 AM	<p>A regulatory perspective on opioid sparing clinical trial objectives and outcomes: Devices</p> <ul style="list-style-type: none">• Carlos Peña, PhD
11:30 AM - 1:30 PM	<p>WORKING LUNCH</p> <p>Group discussion: Study objectives and outcomes</p> <ul style="list-style-type: none">• Moderators: John Farrar, MD, PhD, and Kurt Kroenke, MD• Panelists: all morning speakers
1:30 - 2:00 PM	<p>Scoping review of methodologic characteristics of acute and chronic pain clinical trials of opioid sparing</p> <ul style="list-style-type: none">• Shannon Smith, PhD
2:00 - 2:30 PM	<p>Assessing opioid use and opioid outcomes (e.g., dosage, time to event, duration of use)</p> <ul style="list-style-type: none">• Brett Stacey, MD
2:30 - 3:00 PM	<p>Sparing of opioid-related patient-reported side effects and symptoms: assessment and analysis</p> <ul style="list-style-type: none">• Srinivasa Raja, MD
3:00 - 3:30 PM	<p>BREAK</p>
3:30 - 4 :00 PM	<p>Sparing of opioid-related respiratory depression: assessment and analysis</p> <ul style="list-style-type: none">• Denham Ward, MD, PhD
4:00 - 4:30 PM	<p>Opioid sparing outcomes: What patient improvements and group differences would be clinically meaningful?</p> <ul style="list-style-type: none">• John Markman, MD
4:30 - 5:30 PM	<p>Group discussion: opioid-sparing clinical trial outcomes</p> <ul style="list-style-type: none">• Moderators: James Rathmell, MD and Dennis Turk, PhD• Panelists: all afternoon speakers
7:00 – 9:00 PM	<p>DINNER</p> <p>Monticello East</p>



Friday, July 27, 2018

- | | |
|---------------------|--|
| 7:15 - 8:00 AM | CONTINENTAL BREAKFAST
Monticello East |
| 8:00 - 8:45 AM | Measuring opioid sparing in acute pain trials: research designs, methods, and study execution
Monticello West <ul style="list-style-type: none">• Ian Gilron, MD |
| 8:45 - 10:00 AM | Group discussion: Recommendations for acute pain opioid sparing trial research designs, methods, and study execution <ul style="list-style-type: none">• Moderators: Jennifer Gewandter, PhD, Ian Gilron, MD, and Richard Rauck, MD |
| 10:00 - 10:30 AM | BREAK |
| 10:30 - 11:45 AM | Group discussion, continued: Recommendations for acute pain opioid sparing trial research designs, methods, and study execution <ul style="list-style-type: none">• Moderators: Jennifer Gewandter, PhD, Ian Gilron, MD, and Richard Rauck, MD |
| 11:45 AM - 12:45 PM | LUNCH |
| 12:45 - 1:30 PM | Chronic pain opioid sparing trials: Research designs, methods, and study execution <ul style="list-style-type: none">• Michael Rowbotham, MD |
| 1:30 - 4:00 PM | Group discussion: Recommendations for chronic pain opioid sparing trial research designs, methods, and study execution <ul style="list-style-type: none">• Moderators: Robert Dworkin, PhD, Jennifer Gewandter, PhD, and Michael Rowbotham, MD |