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

IMMPACT-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  A regulatory perspective on opioid sparing clinical trial objectives and outcomes: Devices
   • Carlos Peña, PhD

11:30 AM - 1:30 PM  WORKING LUNCH
Group discussion: Study objectives and outcomes
   • Moderators: John Farrar, MD, PhD, and Kurt Kroenke, MD
   • Panelists: all morning speakers

1:30 - 2:00 PM  Scoping review of methodologic characteristics of acute and chronic pain clinical trials of opioid sparing
   • Shannon Smith, PhD

2:00 - 2:30 PM  Assessing opioid use and opioid outcomes (e.g., dosage, time to event, duration of use)
   • Brett Stacey, MD

2:30 - 3:00 PM  Sparing of opioid-related patient-reported side effects and symptoms: assessment and analysis
   • Srinivasa Raja, MD

3:00 - 3:30 PM  BREAK

3:30 - 4:00 PM  Sparing of opioid-related respiratory depression: assessment and analysis
   • Denham Ward, MD, PhD

4:00 - 4:30 PM  Opioid sparing outcomes: What patient improvements and group differences would be clinically meaningful?
   • John Markman, MD

4:30 - 5:30 PM  Group discussion: opioid-sparing clinical trial outcomes
   • Moderators: James Rathmell, MD and Dennis Turk, PhD
   • Panelists: all afternoon speakers

7:00 – 9:00 PM  DINNER
  Monticello East
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<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>7:15 - 8:00 AM</td>
<td>CONTINENTAL BREAKFAST</td>
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<td>Monticello East</td>
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<tr>
<td>8:00 - 8:45 AM</td>
<td>Measuring opioid sparing in acute pain trials: research designs, methods, and study execution Monticello West</td>
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<td>• Ian Gilron, MD</td>
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<td>8:45 - 10:00 AM</td>
<td>Group discussion: Recommendations for acute pain opioid sparing trial research designs, methods, and study execution</td>
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<td>• Moderators: Jennifer Gewandter, PhD, Ian Gilron, MD, and Richard Rauck, MD</td>
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<td>10:00 - 10:30 AM</td>
<td>BREAK</td>
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<td>10:30 - 11:45 AM</td>
<td>Group discussion, continued: Recommendations for acute pain opioid sparing trial research designs, methods, and study execution</td>
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<td>• Moderators: Jennifer Gewandter, PhD, Ian Gilron, MD, and Richard Rauck, MD</td>
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<td>11:45 AM - 12:45 PM</td>
<td>LUNCH</td>
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<tr>
<td>12:45 - 1:30 PM</td>
<td>Chronic pain opioid sparing trials: Research designs, methods, and study execution</td>
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<td>• Michael Rowbotham, MD</td>
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<td>1:30 - 4:00 PM</td>
<td>Group discussion: Recommendations for chronic pain opioid sparing trial research designs, methods, and study execution</td>
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<td>• Moderators: Robert Dworkin, PhD, Jennifer Gewandter, PhD, and Michael Rowbotham, MD</td>
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