THURSDAY, JUNE 4

8:00–8:45 AM Introduction and meeting objectives
• Dennis Turk, PhD, and Robert Dworkin, PhD

8:45–9:15 AM A regulatory perspective on threats to the integrity of analgesic clinical trial efficacy data
• Sharon Hertz, MD

9:15–9:45 AM Clinical trial quality: What is it, and what approaches can optimize it?
• Nathaniel Katz, MD

9:45–10:30 AM Q & A and panel discussion on clinical trial data quality
• Moderator: Robert Dworkin, PhD
  • Sharon Hertz, MD; Nathaniel Katz, MD; Michael Rowbotham, MD

10:30–11:00 AM BREAK

11:00–11:30 AM Pain reporting: patient training, compliance, and monitoring
• Mark Jensen, PhD

11:30–11:45 AM Fabrication and concealment by clinical trial participants
• Eric Devine, PhD

11:45–12:00 PM Combating participant misbehavior in analgesic clinical trials
• Robert Dworkin, PhD

12:00–1:00 PM BREAK

1:00–1:30 PM Evaluating and enhancing adherence to medications
• Bernard Vrijens, PhD

1:30–1:45 PM A regulatory perspective on electronic data capture
• Sarrit Kovacs, PhD
1:45–3:00 PM  Q & A and panel discussion: What can we do to ensure the quality and assay sensitivity of patient data?
   • Moderator: Kushang Patel, PhD
   • Eric Devine, PhD; Robert Dworkin, PhD; Mark Jensen, PhD; Bernard Vrijens, PhD

3:00–3:30 PM  BREAK

3:30–4:00 PM  Site selection, training, and surveillance
   • Richard Malamut, MD

4:00–4:30 PM  Central statistical monitoring
   • Amy Kirkwood, MSc

4:30–5:00 PM  Data quality issues in the design and analysis of clinical trials: an FDA perspective
   • Paul Schuette, PhD

FRIDAY, JUNE 5

8:00–9:30 AM  Q & A and panel discussion: What can we do to ensure site and data quality?
   • Moderator: Michael McDermott, PhD
   • Scott Evans, PhD; Amy Kirkwood, MSc; Richard Malamut, MD; Paul Schuette, PhD

9:30–10:00 AM  Discussant I: An academic perspective on clinical trial quality
   • John Markman, MD

10:00–10:30 AM  BREAK

10:30–11:00 AM  Discussant II: Industry and CRO perspectives on clinical trial quality
   • David Hewitt, MD

11:00 AM–12:30 PM  Q & A and panel discussion: Perspectives on clinical trial data and study quality
   • John Farrar, MD, PhD; Ian Gilron, MD; David Hewitt, MD; John Markman, MD

12:30–1:30 PM  BREAK

1:30–4:00 PM  Consensus discussion: Recommended considerations for ensuring study data quality in clinical trials of pain treatments
   • Moderators: Robert Dworkin, PhD, and Dennis Turk, PhD