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

IMMPACT-XVIII

ENSURING DATA QUALITY IN CLINICAL TRIALS OF PAIN TREATMENTS: CONSIDERATIONS FOR STUDY EXECUTION AND CONDUCT

JUNE 4-5, 2015
WILLARD HOTEL, WASHINGTON, DC

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*