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

IMMPACT-XVII

ASSESSMENT OF PHYSICAL FUNCTION IN ANALGESIC CLINICAL TRIALS

APRIL 17-18, 2014
WESTIN GEORGETOWN
WASHINGTON, DC

THURSDAY, APRIL 17

7:30–8:00 AM  CONTINENTAL BREAKFAST

8:00–8:20 AM  ACTTION and OMERACT Welcome and Introductions
   •  Dennis Turk, PhD, and Philip Mease, MD

8:20–9:00 AM  FDA Recommendations for the Development or Selection of Outcome Measures
   •  Ashley Slagle, MSc, PhD

9:00–9:20 AM  FDA Approach to Review of Outcome Measures for Drug Approval and Labeling
   •  Elektra Papadopoulos, MD, MPH

9:20–9:45 PM  Q & A and Panel Discussion on FDA Approach to Outcome Measures
   •  Moderator: Robert H. Dworkin, PhD
   •  Elektra Papadopoulos, MD, MPH; Bob Rappaport, MD; Ashley Slagle, MSc, PhD

9:45–10:15 AM  BREAK

10:15–10:45 AM  Conceptual Overview: What Exactly Do We Mean by Physical Function?
   •  Dorcas Beaton, PhD, MSc

10:45–11:30 AM  Patient-reported Outcome Measures of Physical Function
   •  Ann Taylor, PhD

11:30 AM–12:30 PM  LUNCH

12:30–1:15 PM  Clinician, Observer, Laboratory, and Other Outcome Measures of Physical Function
   •  Kristine Phillips, MD, PhD
1:15–1:45 PM  Actigraphy
   • Kushang Patel, PhD, MPH

1:45–3:00 PM  Q & A and Panel Discussion: Patient-reported and Other Outcome Measures of Physical Function
   • Moderator: Dennis Turk, PhD
   • Dorcas Beaton, PhD, MSc; Sharon Hertz, MD; Elektra Papadopoulos, MD, Kushang Patel, PhD, MPH; Kristine Phillips, MD, PhD; Ann Taylor, PhD

3:00–3:30 PM  BREAK

3:30–4:00 PM  Social Participation Outcome Measures
   • David Williams, PhD

4:00–4:30 PM  Work Participation Outcome Measures
   • Monique Gignac, PhD

4:30–5:00 PM  Outcome Measures Involving Caregiver Burden
   • John Markman, MD

7:00–9:00 PM  BUFFET DINNER

FRIDAY, APRIL 18

7:30–8:00 AM  CONTINENTAL BREAKFAST

8:00–9:00 AM  Q & A and Panel Discussion: Social Participation, Work Participation, and Caregiver Burden Outcome Measures
   • Moderator: Philip Mease, MD
   • Laurie Burke, RPh, MPH; Monique Gignac, PhD; John Markman, MD; Ashley Slagle, MSc, PhD; Shannon Smith, PhD; David Williams, PhD

9:00–9:30 AM  Interpreting the Clinical Importance of Improvements in Patient-reported and “Objective” Assessments of Physical Function
   • Daniel Clauw, MD

9:30–10:00 AM  Q & A and Group Discussion: Patient-reported vs. “Objective” Assessments of Physical Function
   • Moderators: Daniel Clauw, MD, Lee Simon, MD, and David Williams, PhD
10:00–10:30 AM  BREAK

10:30 AM–12:15 PM  Group Discussion I: Considerations for the Assessment of Physical Function in Analgesic Clinical Trials Using Patient-reported Outcome Measures
  • Moderators: Bob Dworkin, PhD, Philip Mease, MD, and Dennis Turk, PhD

12:15–1:30 PM  LUNCH

1:30–4:00 PM  Group Discussion II: Considerations for the Assessment of Physical Function in Analgesic Clinical Trials Using Clinician, Observer, and Laboratory Outcome Measures
  • Moderators: Bob Dworkin, PhD, Philip Mease, MD, and Dennis Turk, PhD

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(Heather)