

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

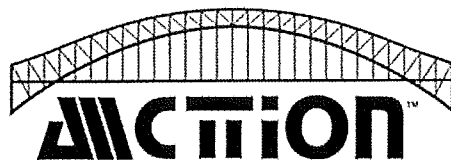
**IMPACT-XVII**

**ASSESSMENT OF PHYSICAL FUNCTION IN ANALGESIC CLINICAL TRIALS**

**APRIL 17-18, 2014  
WESTIN GEORGETOWN  
WASHINGTON, DC**

**THURSDAY, APRIL 17**

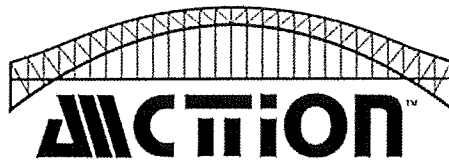
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|--------------------------|---|
| <b>7:30–8:00 AM</b>      | <b>CONTINENTAL BREAKFAST</b>  |
| <b>8:00–8:20 AM</b>      | <b>ACTION and OMERACT Welcome and Introductions</b> <ul style="list-style-type: none"><li>• <i>Dennis Turk, PhD, and Philip Mease, MD</i></li></ul>   |
| <b>8:20–9:00 AM</b>      | <b>FDA Recommendations for the Development or Selection of Outcome Measures</b> <ul style="list-style-type: none"><li>• <i>Ashley Slagle, MSc, PhD</i></li></ul>  |
| <b>9:00–9:20 AM</b>      | <b>FDA Approach to Review of Outcome Measures for Drug Approval and Labeling</b> <ul style="list-style-type: none"><li>• <i>Elektra Papadopoulos, MD, MPH</i></li></ul>   |
| <b>9:20–9:45 PM</b>      | <b>Q &amp; A and Panel Discussion on FDA Approach to Outcome Measures</b> <ul style="list-style-type: none"><li>• <i>Moderator: Robert H. Dworkin, PhD</i></li><li>• <i>Elektra Papadopoulos, MD, MPH; Bob Rappaport, MD; Ashley Slagle, MSc, PhD</i></li></ul> |
| <b>9:45–10:15 AM</b>     | <b>BREAK</b>  |
| <b>10:15–10:45 AM</b>    | <b>Conceptual Overview: What Exactly Do We Mean by Physical Function?</b> <ul style="list-style-type: none"><li>• <i>Dorcas Beaton, PhD, MSc</i></li></ul>  |
| <b>10:45–11:30 AM</b>    | <b>Patient-reported Outcome Measures of Physical Function</b> <ul style="list-style-type: none"><li>• <i>Ann Taylor, PhD</i></li></ul>  |
| <b>11:30 AM–12:30 PM</b> | <b>LUNCH</b>  |
| <b>12:30–1:15 PM</b>     | <b>Clinician, Observer, Laboratory, and Other Outcome Measures of Physical Function</b> <ul style="list-style-type: none"><li>• <i>Kristine Phillips, MD, PhD</i></li></ul>   |



- 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

+ Ann + Dorcas  
Laurie

12:15–1:30 PM

LUNCH

~~(+ Anrique)~~

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

+ Kristine + Dorcas

~~(+ Kushap)~~

Ashley  
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