



**INITIATIVE ON METHODS, MEASUREMENT, AND PAIN ASSESSMENT IN
CLINICAL TRIALS (IMPACT-XX)**

**RECOMMENDATIONS FOR THE ASSESSMENT OF PAIN OUTCOMES IN
CLINICAL TRIALS OF CHRONIC PELVIC PAIN AND IRRITABLE BOWEL SYNDROME**

**JULY 13-14, 2017
WESTIN CITY CENTER, WASHINGTON, DC**

AGENDA

THURSDAY, JULY 13, 2017

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| 7:45 – 8:15 AM | CONTINENTAL BREAKFAST |
| 8:15 – 8:30 AM | Introductions and Meeting Objectives <ul style="list-style-type: none">• <i>Dennis Turk, PhD</i> |
| 8:30 – 8:50 AM | Interstitial Cystitis: Overview and Assessment of Pain Outcomes and Implications for Inclusion Criteria <ul style="list-style-type: none">• <i>Henry Lai, MD</i> |
| 8:50 – 9:10 AM | Prostatitis: Overview and Assessment of Pain Outcomes and Implications for Inclusion Criteria <ul style="list-style-type: none">• <i>Michel Pontari, MD</i> |
| 9:10 – 9:40 AM | COFFEE BREAK |
| 9:40 – 10:00 AM | Vulvodynia: Overview and Assessment of Pain Outcomes and Implications for Inclusion Criteria <ul style="list-style-type: none">• <i>Andrea Rapkin, MD</i> |
| 10:00 – 10:20 AM | IBS: Overview and Assessment of Pain Outcomes and Implications for Inclusion Criteria <ul style="list-style-type: none">• <i>William Chey, MD</i> |



- 10:20 AM – 12:00 PM** **Q & A and Panel Discussion**
- *Moderators: Tony Lembo, MD and Ursula Wesselmann, MD, PhD*
 - *Panelists: William Chey, MD; Henry Lai, MD; Michel Pontari, MD; Andrea Rapkin, MD*
- 12:00 – 1:00 PM** **LUNCH**
- 1:00 – 1:20 PM** **FDA Approach to Clinical Outcome Assessments**
- *Sarrit Kovacs, PhD*
- 1:20 – 1:40 PM** **FDA Approach to Clinical Endpoint Development**
- *Laura Lee Johnson, PhD*
- 1:40 – 2:00 PM** **Clinical Trials of Interstitial Cystitis: Regulatory Perspective**
- *Roger Wiederhorn, MD*
- 2:00 – 2:30 PM** **COFFEE BREAK**
- 2:30 – 2:50 PM** **Clinical Trials of Prostatitis: Regulatory Perspective**
- *Jordan Dimitrakoff, MD, PhD*
- 2:50 – 3:20 PM** **Clinical Trials of IBS: Regulatory Perspective**
- *Lesley Hanes, MD, MSc*
- 3:20 – 5:00 PM** **Q & A and Panel Discussion**
- *Moderators: Robert Dworkin, PhD and Shannon Smith, PhD*
 - *Panelists: Jordan Dimitrakoff, MD, PhD; Lesley Hanes, MD, MSc; Laura Lee Johnson, PhD; Sarrit Kovacs, PhD; Roger Wiederhorn, MD*
- 7:00 – 9:00 PM** **DINNER**

FRIDAY, JULY 14, 2017

- 8:00 – 8:30 AM** **CONTINENTAL BREAKFAST**



- 8:30 – 9:00 AM** **Systematic Review of Chronic Pelvic Pain and IBS Clinical Trials: Pain Outcome Measures and Inclusion Criteria**
• *Jennifer Gewandter, PhD, MPH*
- 9:00 – 9:30 AM** **Lessons Learned from the Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Study**
• *Quentin Clemens, MD*
- 9:30 – 10:00 AM** **Lessons Learned Along the Path to Qualification of an IBS Outcome Measure**
• *Stephen Joel Coons, PhD*
- 10:00 – 10:45 AM** **COFFEE BREAK and HOTEL CHECK-OUT**
- 10:45 AM – 12:00 PM** **Q & A and Panel Discussion**
• *Moderators: Dennis Turk, PhD and Jennifer Gewandter, PhD, MPH*
• *Panelists: Quentin Clemens, MD; Stephen Joel Coons, PhD; John Farrar, MD, PhD; J. Richard Landis, MS, PhD*
- 12:00 – 1:00 PM** **LUNCH**
- 1:00 – 4:00 PM** **Group Discussion: Recommendations for the Assessment of Pain Outcomes in Chronic Pelvic Pain and IBS Clinical Trials**
• *With continuous coffee and refreshments*