

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

IMPACT-XV

**RECOMMENDATIONS FOR THE ROLE OF BIOMARKERS AND RELATED MEASURES IN THE
DEVELOPMENT OF IMPROVED ANALGESIC TREATMENTS**

**JUNE 22-23, 2012
WESTIN GEORGETOWN
WASHINGTON, DC**

THURSDAY, JUNE 21

7:00 PM RECEPTION AND DINNER (at the Westin)

FRIDAY, JUNE 22

7:30–8:00 AM CONTINENTAL BREAKFAST

8:00–8:30 AM Welcome and introductions
• *Dennis Turk, PhD*

**8:30–9:15 AM What is the FDA perspective on biomarkers, surrogate
endpoints, and related measures in drug development and
approval?**
• *Marc Walton, MD*

**9:15–10:00 AM An academic perspective on the role of biomarkers and
surrogate endpoints in analgesic clinical trials and the
development of improved analgesic treatments**
• *Justin McArthur, MD*

10:00–10:30 AM COFFEE BREAK

10:30–11:00 AM Treatment benefit and outcome assessment
• *Laurie Burke, RPh, MPH*

11:00–12:00 PM Panel discussion and Q & A
• *moderator: Nathaniel Katz, MD*
• *Laurie Burke, RPh, MPH; Nathaniel Katz, MD
Justin McArthur; Marc Walton, MD*

12:00–1:30 PM LUNCH

**1:30–2:15 PM What is the role of imaging in analgesic clinical trials and
the development of improved analgesic treatments?**
• *Irene Tracey, PhD*

2:15–2:45 PM COFFEE BREAK

- 2:45–4:15 PM** **Panel discussion and Q & A on imaging**
- *moderator: John Farrar, MD, PhD*
 - *David Borsook, MD, PhD; Laurie Burke, RPh, MPH; John Farrar, MD, PhD; Irene Tracey, PhD; Tor Wager, PhD; Marc Walton, MD*

7:00–9:00 PM **DINNER**

SATURDAY, JUNE 23

7:30–8:00 AM **CONTINENTAL BREAKFAST**

- 8:00–8:45 AM** **What is the role of quantitative sensory testing (QST) in analgesic clinical trials and the development of improved analgesic treatments?**
- *Ralf Baron, MD*

- 8:45–10:15 AM** **Panel discussion and Q & A on QST**
- *moderator: Srinivasa Raja, MD*
 - *Lars Arendt-Nielsen, MD, PhD; Ralf Baron, MD; Sharon Hertz, MD; William Maixner, DDS, PhD; Srinivasa Raja, MD*

10:15–10:45 AM **COFFEE BREAK**

- 10:45–11:30 AM** **What is the role of punch skin biopsy in analgesic clinical trials and the development of improved analgesic treatments?**
- *Michael Polydefkis, MD*

11:30 AM–1:00 PM **LUNCH**

- 1:00–2:30 PM** **Panel discussion and Q & A on punch skin biopsy**
- *moderator: Michael Rowbotham, MD*
 - *Roy Freeman, MD; Justin McArthur, MD; Michael Polydefkis, MD; Bob Rappaport, MD; Michael Rowbotham, MD*

- 2:30–4:00 PM** **Group discussion: recommendations and research agenda**
- *with continuous coffee service*