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

IMMPACT-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