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

IMMPACT-XIII

"RECOMMENDATIONS FOR IMPROVING ASSAY SENSITIVITY IN CHRONIC PAIN CLINICAL TRIALS"

JUNE 24-25, 2010
HYATT REGENCY
BETHESDA, MARYLAND

WEDNESDAY, JUNE 23

7:00 PM	**RECEPTION AND DINNER (at the Hyatt)**

THURSDAY, JUNE 24

7:30–8:00 AM	**CONTINENTAL BREAKFAST**
8:00–8:30 AM	**Welcome, introductions, and IMMPACT update** • *Dennis Turk, PhD*
8:30–9:00 AM	**Assay sensitivity: general issues and considerations** • *Michael Rowbotham, MD*
9:00–9:15 AM	**Q & A**
9:15–9:45 AM	**Increasing the reliability, validity, and responsiveness of pain intensity ratings** • *Mark Jensen, PhD*
9:45–10:00 AM	**Implications of new FDA patient-reported outcomes guidance for assessing pain intensity** • *Laurie Burke, PhD*
10:00–10:15 AM	**Q & A**
10:15–10:30 AM	**COFFEE BREAK**
10:30–10:45 PM	**Comments on Rowbotham, Jensen, and Burke presentations** • *Ian Gilron, MD*
10:45–12:15 PM	**Discussion: preliminary considerations for recommendations and research agenda**
12:15–1:15 PM	**LUNCH**
1:15–1:45 PM	**Improving assay sensitivity in proof-of-concept (i.e., Phase 2) trials: review of existing data and future directions** • *Nathaniel Katz, MD*

1:45–2:00 PM **Q & A**

2:00–2:30 PM **Improving assay sensitivity in confirmatory (i.e., Phase 3) trials: review of existing data and future directions**
- *Robert Dworkin, PhD*

2:30–2:45 PM **Q & A**

2:45–3:00 PM **Comments on Katz and Dworkin presentations**
- *Srinivasa Raja, MD*

3:00–3:15 PM **COFFEE BREAK**

3:15–4:45 PM **Discussion: preliminary considerations for recommendations and research agenda**

7:00–9:00 PM **DINNER**

FRIDAY, JUNE 25

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

8:00–8:45 AM **Discussion: should attempts be made to reduce placebo group responses and how could this be accomplished?**
- *moderated by Robert Dworkin and Michael Rowbotham*
  - factors known to influence the magnitude of the placebo group response and implications for assay sensitivity
  - approaches to decreasing responses in placebo groups and their advantages and disadvantages
  - placebo run-in periods

8:45–9:30 AM **Discussion: study staff and site characteristics and their impact on assay sensitivity**
- *moderated by Dennis Turk and John Farrar, MD, PhD*
  - investigator and staff training and standardization
  - frequency and structure of patient contacts
  - is the variability of pain scores higher in studies that use multiple sites, and is this because error variance is higher?
  - recruitment methods
  - use of international sites

9:30–9:45 AM **COFFEE BREAK**

9:45–10:15 AM **Regulatory perspective on improving assay sensitivity**
- *Bob Rappaport, MD*

10:15–12:15 PM **Consensus recommendations for improving assay sensitivity in chronic pain clinical trials**
- moderated by *Dennis Turk* and *Bob Dworkin*
  - study structure
  - patient characteristics

- pain measurement
- study conduct
- measures to address placebo group responses

12:15–1:15 PM **LUNCH**

1:15–2:15 PM **Consensus recommendations for improving assay sensitivity in chronic pain clinical trials, continued**

- moderated by *Dennis Turk* and *Bob Dworkin*

2:15–2:30 PM **COFFEE BREAK**

2:30–4:30 PM **Research agenda recommendations for improving assay sensitivity in chronic pain clinical trials**

- moderated by *Dennis Turk* and *Bob Dworkin*
  - critical research questions
  - how can these be addressed with existing data?
  - how can these be addressed with new collaborations?

4:30 **ADJOURN**