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