

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

## IMPACT-VII (REVISED TO IMPACT-VIII)

### “ACUTE PAIN”

**May 31 – June 2, 2007**  
Ritz Carlton Pentagon City  
Arlington, Virginia

#### Thursday, May 31

**7:00 PM**

**RECEPTION AND DINNER**  
at the Ritz Carlton

#### Friday, June 1

**7:00–8:00 AM**

**CONTINENTAL BREAKFAST**

**8:00–8:30 AM**

**1. Welcome, introductions, IMPACT update**  
**2. Definition of acute pain and meeting objectives**

- Dennis Turk, PhD

**8:30–9:15 AM**

(including

**What are the objectives and unmet needs in treating acute pain and enhancing patient recovery epidemiology of acute pain)?**

- Henrik Kehlet, MD, PhD

**9:30–10:15 AM**

trials?

**What have we learned and what else do we need to know about assessing acute pain in clinical**

- Henry McQuay, MD

**10:30–11:00 AM**

**COFFEE BREAK**

**11:00–11:45 PM**

**Models and methods for acute pain clinical trials (including generalizability of results)**

- Paul Desjardins, DMD, PhD

**12:00–12:30 PM**

**Discussion: What are the gaps between acute pain unmet needs and existing clinical trial models?**

- moderators: Bob Dworkin and Dennis Turk

**12:30–1:30 PM**

**LUNCH**

**1:30–2:30 PM**

**Single-dose acute pain trials**

- moderators: Bob Dworkin and Paul Desjardins

**1. Models**

a. criteria for evaluating models:

- feasibility
- responsiveness
- generalizability
- targets intended indication(s)
- addresses unmet needs

b. specific models, for example:

- dental model
- other post-operative models
- tension headache

**2:30–3:00 PM**

**COFFEE BREAK**

**3:00–5:00 PM**

**Single-dose acute pain trials, continued**

moderators: Bob Dworkin and Paul Desjardins

**2. Pain and other outcomes**

- a. pain intensity
- b. pain relief
- c. rescue medication
- d. satisfaction and other global measures
- e. side effects
- f. opioid sparing
- g. composite measures
- h. clinical importance of changes

**3. Methods, measurement, data analysis**

- a. onset of effect
- b. duration of effect
- c. rescue dosing
- d. safety evaluations
- e. baseline characteristics and covariates
- f. missing data

**6:45 PM**

**Meet in hotel lobby for transport to dinner**

**7:00–9:30 PM**

**RECEPTION AND DINNER**

**Saturday, June 2****7:00–8:00 AM****CONTINENTAL BREAKFAST****8:00–8:30 AM****Models and methods for multiple-dose acute pain clinical trials**

- Nathaniel Katz, MD

**8:30–9:30 AM****Multiple-dose acute pain trials**

- moderators: Dennis Turk and Nat Katz

**1. Models****a. criteria for evaluating models:**

- feasibility
- responsiveness
- generalizability
- targets intended indication(s)
- addresses unmet needs

**b. specific models:**

- post-operative models, for example:
  - bunionectomy, gynecologic surgery, orthopedic surgery, etc.
- trauma, for example:
  - fracture, myofascial inflammatory pain (e.g., sports injuries)
- disease, for example:
  - sickle-cell crisis, mucositis, herpes zoster, herpes simplex, dysmenorrhea
- procedural, for example:
  - debridement, bone marrow aspiration
- acute recurrent pain, for example:
  - acute low back pain, OA flares

**9:30–10:00 AM****COFFEE BREAK****10:00–12:00 PM****Multiple-dose acute pain trials, continued**

- moderators: Dennis Turk and Nat Katz

**2. Pain and other outcomes**

- a. pain intensity
- b. pain relief
- c. rescue medication
- d. physical activities and physical functioning
- e. sleep

- f. satisfaction and other global measures
- g. side effects
- h. opioid sparing
- i. opioid side effect sparing
- j. composite measures
- k. clinical importance of changes

### **3. Methods, measurement, data analysis**

- a. duration of treatment
- b. dosing intervals
- c. flexible- vs. fixed dosing
- d. rescue dosing
- e. onset of effect
- f. duration of effect
- g. safety evaluations
- h. baseline characteristics and covariates
- i. missing data

**12:00–1:00 PM**

**LUNCH**

**1:00–3:00 PM**

**Consensus recommendations: Filling the gaps between acute pain unmet needs and existing clinical trial models and methods**

- moderators: Dennis Turk and Bob Dworkin

- 1. Models**
- 2. Pain and other outcomes**
- 3. Methods, measurement, data analysis**
- 4. Pre-emptive treatments to reduce postoperative pain and enhance patient recovery;**

recovery;

**3:00–3:30 PM**

**COFFEE BREAK**

**3:30–4:30 PM**

**Discussion of topics for IMMPACT 2008 and 2009**

- moderators: Bob Dworkin and Dennis Turk

- 1. Subacute pain; prevention of chronic pain**
- 2. Proof-of-concept studies**
- 3. Other topics...**

**4:30 PM**

**ADJOURN**