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

IMMPACT-VII (REVISED TO IMMPACT-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, IMMPACT update
2. Definition of acute pain and meeting objectives
   • Dennis Turk, PhD

8:30–9:15 AM
What are the objectives and unmet needs in treating acute pain and enhancing patient recovery (including epidemiology of acute pain)?
   • Henrik Kehlet, MD, PhD

9:30–10:15 AM
What have we learned and what else do we need to know about assessing acute pain in clinical trials?
   • 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:
      o feasibility
      o responsiveness
      o generalizability
      o targets intended indication(s)
      o addresses unmet needs

   b. specific models, for example:
      o dental model
      o other post-operative models
      o 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:
      o feasibility
      o responsiveness
      o generalizability
      o targets intended indication(s)
      o addresses unmet needs

   b. specific models:
      o post-operative models, for example:
         ➢ bunionectomy, gynecologic surgery, orthopedic surgery, etc.
      o trauma, for example:
         ➢ fracture, myofascial inflammatory pain (e.g., sports injuries)
      o disease, for example:
         ➢ sickle-cell crisis, mucositis, herpes zoster, herpes simplex, dysmenorrhea
      o procedural, for example:
         ➢ debridement, bone marrow aspiration
      o 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;

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