# INITIATIVE ON OUTCOMES MEASUREMENT AND PAIN ASSESSMENT IN CLINICAL TRIALS (IMPACT)

November 1-2, 2002 Annapolis, Maryland

#### AGENDA

#### **THURSDAY, OCTOBER 31**

7:00 PM

#### **Reception and faculty dinner**

#### **FRIDAY, NOVEMBER 1**

8:00-8:30 AM Welcome, sponsorship, and faculty introductions (with continental breakfast)

#### 8:30-9:15 AM Objectives, goals, and scope

- I. Why IMPACT and its objectives
  - a. variability in pain outcomes assessment provides impetus for consistency
  - b. overall objectives of IMPACT involve the development of standardized approaches to the assessment of treatment outcomes in pain clinical trials
  - c. IMPACT will be an ongoing process
- II. Goals and scope of this meeting
  - a. the goal of this first meeting is to develop consensus guidelines
  - b. these guidelines will consist of recommendations for core outcome domains that should be assessed in all *chronic pain* clinical trials
  - c. guidelines will also include recommendations for supplemental domains that can be assessed depending on the particular trial
  - d. published as a jointly authored article (first choice: *Pain*)
- III. Beyond the scope of this meeting
  - a. deciding which variable (or variables) should be the "primary endpoint"
  - b. acute pain clinical trials
  - c. specific measures
  - d. headache

# 9:15-9:45 AM Current assessment practices

IV. Recent clinical trials and their approach to pain outcomes: illustrations

- a. Eisenach et al. (*Pain*, 1995) epidural clonidine cancer pain trial
- b. Backonja et al. (JAMA, 1998) gabapentin diabetic neuropathy trial
- c. Geba et al. (JAMA, 2002) coxib/APAP osteoarthritis trial
- d. Raja et al. (Neurology, 2002) opioid/tricyclic postherpetic neuralgia trial

#### 9:45-10:15 AM

# **Coffee break**

# 10:15 AM-12:00 PM Outcome domains

- V. Pain, the pivotal outcome domain a. intensity, location, duration, quality
- VI. Identification and discussion of "core domains," for example
  - a. physical function/daily activities
  - b. emotional well-being/distress
  - c. interpersonal functioning
  - d. patient-rated improvement/satisfaction/global judgments
  - e. side effects and adverse events
  - f. others

12:00-1:00 PM Luncheon

#### 1:00-2:45 PM Outcome domains, continued

VI. Identification and discussion of "core domains," continued

- VII. Consideration of supplemental domains, for example
  - a. rescue medication use
  - b. pharmacoeconomic variables
  - c. pharmacokinetic variables
  - d. quantitative sensory testing
  - e. treatment adherence
  - f. coping
  - g. provider global judgments
  - h. others

# 2:45-3:15 PM Coffee break

# 3:15-3:45 PM Populations/samples of chronic pain patient

- VIII. Patient groups that may require somewhat different assessments
  - a. inflammatory (nociceptive) pain
  - b. neuropathic pain
  - c. cancer pain

3:45-5:00 PM

- d. children and adolescents
- e. geriatric patients
- f. patients unable to communicate (e.g., stroke)

# Introduction to the population x domain x variable "grid"

- IX. Identify specific variables (within grid of core domains by patient groups)
  - a. variables, *not* measures (e.g., pain intensity, pain quality, pain duration, location)
  - b. consider methods of assessment (e.g., self-report, behavioral observation, lab

tests)

c. identify variables/methods for which there are measures with demonstrated (or likely) reliability, validity, responsiveness, and feasibility

# **7:00-9:30 PM Off-site Dinner** (transportation provided)

# **SATURDAY, NOVEMBER 2**

8:00-9:45 AM	The grid, continued
	(with continental breakfast)

IX. Identify specific variables (within grid of core domains by patient groups), continued

- a. variables, *not* measures (e.g., pain intensity, pain quality, pain duration, location)
- b. consider methods of assessment (e.g., self-report, behavioral observation, lab tests)
- c. identify variables/methods for which there are measures with demonstrated (or likely) reliability, validity, responsiveness, and feasibility

#### 9:45-10:15 AM Coffee break

#### **10:15 AM-12:00 PM** Implementing the grid: exercise

X. Design a Phase III trial of an opioid analgesic in patients with fibromyalgia syndrome

- a. research design (e.g., duration of trial)
- b. specific variables and methods of assessment, as in above grid
- c. identify questions where we need to review the literature (e.g., daily vs. weekly pain ratings)

#### 12:00-1:00 PM Luncheon

# 1:00-2:00 PM Grid redux

XI. Revisions of the grid in view of the exercise

# 2:00-2:45 PM Younger and older patients

- XII. Discussion of specific pediatric design and assessment issues
- XIII. Discussion of specific geriatric design and assessment issues

# 2:45-3:15 PM Coffee break

#### 3:15-5:00 PM Future directions

- XIV. Proposed objectives for IMPACT II
  - a. specific measures
  - b. determining clinically important differences
  - c. what constitutes a positive trial?
  - d. others