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

3:45-5:00 PM 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