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
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