Initiative on

METHODS, MEASUREMENT, AND PAIN ASSESSMENT IN CLINICAL TRIALS

(IMMPACT-II)

April 11-12, 2003 Washington, DC

AGENDA

THURSDAY, APRL 10

7:00 PM Reception and faculty dinner

FRIDAY, APRIL 11

8:00-8:20 AM Welcome, sponsorship, and faculty introductions

8:20-8:30 AM IMMPACT update

I. Status of manuscript from IMMPACT-I

II. IMMPACT website overview

- a. components of site
- b. content and timing issues

8:30-8:45

Objectives of IMMPACT-II

- I. Goals and scope of the meeting
 - a. The goal of this meeting is to develop consensus recommendations for specific measures of the six core outcome domains that should be considered in all chronic pain clinical trials identified at IMMPACT-I.
 - b. To be published as a jointly authored article (first choice: *Pain*)
 - c. Possibility of brief summary of recommendations accompanied by the 6 background literature reviews published separately as a special issue of a journal.
- II. Beyond the scope of this meeting
 - a. Considering which measures should be the "primary endpoint"
 - b. Acute pain clinical trials
 - c. Headache
- III. Format for the discussion of measures of all six core outcome domains during meeting:
 - a. Specific measures
 - b. Methods of assessment (e.g., paper, interview, etc)
 - c. Frequency of assessment
 - d. Other issues

| 8:45-9:00 AM | Reliability, validity, and responsiveness Robert Dworkin, PhD |
|--------------------|--|
| 9:00-9:15 AM | Pain assessment: overview Mark Jensen, PhD |
| 9:15-10:00 AM | Pain assessment: discussion |
| 10:00-10:30 AM | Coffee break |
| 10:30-11:00 AM | Pain assessment: discussion (continued) |
| 11:00-11:15 AM | Physical functioning: generic measures overview Gerold Stucki, MD |
| 11:15 AM-12:00 PM | Physical functioning: generic measures discussion |
| 12:00-1:00 PM | Luncheon |
| 1:00-1:30 PM | Physical functioning: generic measures discussion (continued) |
| 1:30-1:45 PM | Physical functioning: pain-specific measures overview Jennifer Haythornthwaite, PhD |
| 1:45-3:00 PM | Physical functioning: pain-specific measures discussion |
| 3:00-3:30 PM | Coffee break |
| 3:30-3:45 PM | Emotional functioning: overview Robert Kerns, PhD |
| 3:45-5:00 PM | Emotional functioning: discussion |
| 7:00-9:30 PM | Off-site Dinner (transportation provided) |
| SATURDAY, APRIL 12 | |
| 8:00-8:30 AM | Patient global ratings of improvement/satisfaction: overview John Farrar, MD |
| 8:30-9:30 AM | Patient global ratings of improvement/satisfaction: discussion |
| 9:30-10:00 AM | Negative health states and events: overview Nathaniel Katz, MD |
| 10:00-10:30 AM | Negative health states and events: discussion |
| 10:30-11:00 AM | Coffee break |
| 11:00 AM-11:30 PM | Negative health states and events: discussion (continued) |

11:30 AM-11:45 PM Patient disposition / CONSORT: overview

Dennis Turk, PhD

11:45-12:30 PM Patient disposition / CONSORT: discussion

12:30-1:30 PM Luncheon

1:30-3:30 PM Review and consensus on recommended measures

3:30-3:45 PM Coffee break

3:45-5:00 PM IMMPACT future directions

I. Publications and website content

II. Suggestions made at IMMPACT-I for focus of future meetings:

IMMPACT-II: Specific measures, methods of assessment, baseline characteristics, covariates, moderators, mediators, mechanisms.

IMMPACT-III: Clinically important differences, what is important to patients?, responder analyses, composite measures, what should be considered a positive trial?, ethical issues.

IMMPACT-IV: Research designs, primary vs. secondary endpoints, assessments of side-effects.

IMMPACT-V: Reporting of clinical trials, medical education.

IMMPACT-VI: Ethical and methodological aspects of placebo and no-treatment groups in pain research.