



**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