INITIATIVE ON METHODS, MEASUREMENT, AND PAIN ASSESSMENT IN CLINICAL TRIALS
IMMPACT-V (revised to IMMPACT-VI)

June 2-4, 2005
Ritz Carlton Pentagon City
Arlington, Virginia

Thursday, June 2

7:00 PM  RECEPTION AND DINNER
at the Ritz Carlton

Friday, June 3

7:00–8:00 AM  CONTINENTAL BREAKFAST

8:00–8:30 AM  Welcome, introductions, objectives
Dennis Turk

8:30–8:50 AM  The IMMPACT web survey: patient perspectives on core domains
Dennis Revicki

8:50–9:50 AM  Multiple endpoints and multiple comparisons: introduction to conceptual and statistical issues
Thomas Permutt

9:50–10:20 AM  COFFEE BREAK

10:20–10:30 AM  Discussion
Lemuel Moyé

10:30–10:40  Discussion
Joseph Heyse

10:40–11:00  Q & A
Thomas Permutt, Lemuel Moyé, Joseph Heyse

11:00–11:30 AM  Responder and state-attainment criteria development in the rheumatic diseases
Nick Bellamy

11:30–12:00 AM  FDA perspective on multiple endpoints
Laurie Burke

12:00–1:00 PM  LUNCH
I. Primary, co-primary, and secondary endpoints  
(moderator: Dennis Turk)  
- correction for multiplicity for secondary endpoints  
- co-primaries—win on all; win on either  
- reverse multiplicity

COFFEE BREAK

II. Hierarchical and gate-keeping approaches  
(moderator: Thomas Permutt)  
- prospective allocation of alpha

Meet in hotel lobby for transport to dinner

RECEPTION AND DINNER  
- La Bergerie  
  218 N. Lee Street  
  Alexandria, VA

Saturday, June 4

CONTINENTAL BREAKFAST

III. Composite and responder endpoints  
(moderator: Bob Dworkin)  
- within and between domains  
- “low disease activity” models

COFFEE BREAK

Temporal factors, subgroups, and other complexities  
(moderator: Nat Katz)

Discussion and overview of issues for consensus recommendations

LUNCH

Consensus discussion

COFFEE BREAK

Consensus voting

ADJOURN