

**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

1:00–2:30 PM	I. Primary, co-primary, and secondary endpoints (moderator: Dennis Turk) <ul style="list-style-type: none">• correction for multiplicity for secondary endpoints• co-primaries–win on all; win on either• reverse multiplicity
2:30–3:00 PM	COFFEE BREAK
3:00–4:30 PM	II. Hierarchical and gate-keeping approaches (moderator: Thomas Permutt) <ul style="list-style-type: none">• prospective allocation of alpha
6:40 PM	Meet in hotel lobby for transport to dinner
7:00–9:30 PM	RECEPTION AND DINNER <ul style="list-style-type: none">• La Bergerie 218 N. Lee Street Alexandria, VA

Saturday, June 4

7:00–8:00 AM	CONTINENTAL BREAKFAST
8:00–9:30 AM	III. Composite and responder endpoints (moderator: Bob Dworkin) <ul style="list-style-type: none">• within and between domains• “low disease activity” models
9:30–10:00 AM	COFFEE BREAK
10:00–11:00 PM	Temporal factors, subgroups, and other complexities (moderator: Nat Katz)
11:00–12:00 PM	Discussion and overview of issues for consensus recommendations
12:00–1:00 PM	LUNCH
1:00–3:00 PM	Consensus discussion
3:00–3:30 PM	COFFEE BREAK
3:30–4:30 PM	Consensus voting
4:30 PM	ADJOURN