INITIATIVE ON METHODS, MEASUREMENT, AND PAIN ASSESSMENT IN CLINICAL TRIALS

IMMPACT-VIII (REVISED TO IMMPACT-IX)

“EARLY CLINICAL STUDY DESIGNS, EMPHASIZING PROOF-OF-CONCEPT TRIALS”

JUNE 12–14, 2008
RITZ CARLTON PENTAGON CITY
ARLINGTON, VIRGINIA

THURSDAY, JUNE 12

7:00 PM RECEPTION AND DINNER
at the Ritz Carlton

FRIDAY, JUNE 13

7:00–8:00 AM CONTINENTAL BREAKFAST

8:00–8:20 AM Welcome, introductions, and IMMPACT update
• Dennis Turk, PhD

8:20–8:30 AM The IMMPACT Resource for Evaluating Procedures and Outcomes of Randomized Trials (REPORT): progress report
• Robert Dworkin, PhD

8:30–9:10 AM Proof-of-concept trials: overview (including brief mention of human experimental studies, imaging, etc.)
• 8:30–8:50 AM: Industry perspective
  ⇒ Christine Rauschkolb, MD, PhD
• 8:50–9:10 AM: Academic perspective
  ⇒ Ian Gilron, MD

9:10–9:40 AM Single-dose and short-term proof-of-concept trials in neuropathic pain
• Srinivasa Raja, MD

⇒ criteria for evaluating approaches, for example, feasibility and targeted conditions
⇒ differences in assay sensitivity, generalizability, risks of false positive vs. false negative conclusions
⇒ use of positive controls
9:40–10:10 AM  Single-dose and short-term proof-of-concept trials in non-neuropathic pain
  •  Nat Katz, MD

  ⇒ criteria for evaluating approaches, for example, feasibility and targeted conditions
  ⇒ differences in assay sensitivity, generalizability, risks of false positive vs. false negative conclusions
  ⇒ use of positive controls

10:10–10:30 AM  COFFEE BREAK

10:30–12:30 PM  Proof-of-concept trials: discussion and preliminary recommendations
  •  moderated by Dennis Turk and Bob Dworkin

12:30–1:30 PM  LUNCH

1:30–2:00 PM  Statistical considerations in small proof-of-concept trials, including crossover designs
  •  Stephen Senn, PhD

2:00–2:30 PM  Futility trials and other adaptive designs, including Bayesian approaches
  •  Cyrus Mehta, PhD

2:30–3:00 PM  COFFEE BREAK

3:00–5:00 PM  Approaches for increasing efficiency and assay sensitivity of proof-of-concept trials
  •  moderated by Bob Dworkin and Dennis Turk

6:45 PM  Meet in hotel lobby for transport to dinner

7:00–9:30 PM  RECEPTION AND DINNER

Saturday, June 14

7:00–8:00 AM  CONTINENTAL BREAKFAST

8:00–8:30 AM  Dosage determination from preclinical to proof-of-concept trials, including toxicology considerations
  •  Charles Taylor, PhD

8:30–9:00 AM  PK-PD modeling and dosage determination for proof-of-concept trials
  •  Marc Gastonguay, PhD
9:00–10:30 AM  Dose determination for proof-of-concept trials: discussion and preliminary recommendations
• moderated by Dennis Turk and Bob Dworkin

10:30–11:00 AM  COFFEE BREAK

11:00–11:30 AM  Phenotyping chronic pain patients for proof-of-concept trials
• Ralf Baron, MD

11:30–12:30 PM  Phenotyping patients for proof-of-concept trials: discussion and preliminary recommendations
• moderated by Bob Dworkin and Dennis Turk

12:30–1:30 PM  LUNCH

1:30–3:30 PM  Consensus recommendations: proof-of-concept trials
• moderated by Dennis Turk and Bob Dworkin

3:30–3:45 PM  COFFEE BREAK

3:45–4:30 PM  Consensus recommendations: proof-of-concept trials, continued
IMMPACT REPORT: progress report, continued
• moderated by Bob Dworkin and Dennis Turk

4:30 PM  ADJOURN