

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

IMPACT-VIII (REVISED TO IMPACT-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 IMPACT update**
• Dennis Turk, PhD

8:20–8:30 AM **The IMPACT 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

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| 9:40–10:10 AM | Single-dose and short-term proof-of-concept trials in non-neuropathic pain <ul style="list-style-type: none"> • Nat Katz, MD <ul style="list-style-type: none"> ⇒ 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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Stephen Senn, PhD |
| 2:00–2:30 PM | Futility trials and other adaptive designs, including Bayesian approaches <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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

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| 7:00–8:00 AM | CONTINENTAL BREAKFAST |
| 8:00–8:30 AM | Dosage determination from preclinical to proof-of-concept trials, including toxicology considerations <ul style="list-style-type: none"> • Charles Taylor, PhD |
| 8:30–9:00 AM | PK-PD modeling and dosage determination for proof-of-concept trials <ul style="list-style-type: none"> • 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**
- IMPACT REPORT: progress report, continued**
- moderated by Bob Dworkin and Dennis Turk
- 4:30 PM** **ADJOURN**