Welcome

11th Annual Scientific Meeting
International Society for CNS Clinical Trials and Methodology

17-19 February 2015
Washington, DC
Mission Statement

The International Society for CNS Clinical Trials and Methodology (ISCTM) is a multi-disciplinary independent organization, devoted to promoting advances that address strategic clinical, regulatory, methodological and policy challenges that arise in the development and use of CNS therapeutic agents. This work is accomplished through partnership with persons in academia, industry, government, policy-making, and the public.
Principles

• Improve the lives of our patients through excellent science
• Acknowledge breadth of stakeholders
  – Patients, Clinicians, Investigators, Statisticians, Regulators, Policy-makers, Public
• International
• Non-commercial, non-promotional
• Mutually critical
• Mutually respectful
• Pre-competitive and/or collaborative
Principles

- Active participation is strongly encouraged
  - Questions and solutions provided by audience are key to promotion of better methodologies
  - Provide ample time for discussion, so problems can get solved collaboratively
  - Do not debate for its own sake—we have serious work to do, problems to solve and patients who suffer

- Approaches utilized at this meeting
  - Plenary sessions
  - Workshops/Working Groups
  - Poster Session
  - Efforts to increase publications resulting from meeting (*Innovations in Clinical Neuroscience*)
Activities of the Society
(since Autumn 2014 Meeting)

• ECNP 2014, Berlin: Romano, Van Gerven, Potter
  – presented ISCTM session *Refining Designs of Early Drug Trials to Speed Decisions and Registration*

• Working Groups: 11 ISCTM working groups/9 holding sessions at 11th Annual meeting

• Two working groups have developed sessions for this meeting
  – Assessing Abuse Liability (Setnik, Sokolowska, Klein)
  – Adaptive Design Group (Marcus/Kando)

• Two groups working toward potential Consensus Group Meeting
  – Suicidal Ideation and Behavior Assessment (Stewart/Chappell/Alphs)
  – Behavioral and Psychiatric Symptoms in Dementia (Ereshefsky, Miller, Pani)

• Full list found with descriptions just past the agenda section of the program book (if you haven’t signed up for a WG dinner see Mary Bea at registration).
Publications
(since Autumn 2014 Meeting)

Innovations in Clinical Neuroscience Vol 11, 9-10

• Prospective Assessment of Suicidal Ideation and Behavior: An Internet Survey of Pharmaceutical Sponsor Practices


Innovations in Clinical Neuroscience (ISCTM Supplement)

• Taking Personalized Medicine Seriously: Biomarker Approaches in Phase 2b/3 Studies in Major Depression and Schizophrenia

ICNS Supplement cont:

- Translational and Early Phase Strategies for Treatment Development: Report of ISCTM Autumn 2013 Symposium
  
  Young JW, Potter W, Riley S, Groeneveld G, Kinon B, Egan M, Feltner D

- Lessons Learned and Potentials for Improvement in CNS Drug Development: ISCTM Section on Designing the Right Series of Experiments
  
“Autumn” 2015

27-29 August 2015, Amsterdam

27 August 2015
Welcome Reception

28 August 2015
Joint Day with ECNP
ISCTM Poster Session

29 August 2015
ISCTM Session
Challenges in Utilizing Outcome Measures Across Regions and Cultures
Chairs: Richard Keefe, Stefan Leucht

Cognitive Impairment in Major Depressive Disorder as a Target for Drug Development
Chairs: Thomas Laughren, Catherine Harmer

An Update on Critical Issues for Alzheimer’s and Other Dementias
Chairs: Ravi Anand, Gitte Knudsen
Continued Challenges with Placebo Response in CNS Trials: What Has Changed and What Have We Learned in Mood Disorders, Schizophrenia and Pain

Chairs: Steven Romano, Geert Groeneveld

Poster Session

Registration will launch March 2015
11th Annual Scientific Meeting

Tuesday 17 February 2015

Forming and Utilizing Integrated Clinical Trials Databases to Advance Insights in Treatments for Cognition in Schizophrenia and Alzheimer’s Disease

Chairs: Larry Alphs, Ginger Haynes, Joanne Severe

Evening: Working Group Dinners
11th Annual Scientific Meeting

Wednesday 18 February AM
Parallel Sessions

Adaptive Design in the Real World
Chairs: Ron Marcus, Judy Kando

Regulatory Guidelines and Methodological Approaches to Assess Prescription Drug Abuse and Misuse During CNS Drug Development
Chairs: Beatrice Setnik, Marta Sokolowska, Michael Klein
Wednesday 18 February PM

Challenges in Developing Therapeutics in Partially Responsive and Treatment Resistant Depression – Where Do We Go from Here?

Chair: Heddie Martynowicz

Poster Session
Thursday 19 February 2015
Joint Day with ASENT
TBI Treatment Development
Chairs:
Geoffrey Ling
Alan Faden
Reuven Ferziger
Involvement

• Ways to become involved
  – Submit topic ideas
  – Submit Working Group/Workshop topics
  – Submit Consensus Group topics
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<th>Thomas Laughren – Co-Chair</th>
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