

Welcome

International Society for CNS Clinical Trials and Methodology

2015 Autumn Conference, with ECNP Joint Day

27-29 August 2015

Amsterdam, The Netherlands

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

- Improving the lives of our patients through excellent science
- Many 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
 - Ample time for discussion, when problems can get solved collaboratively
 - 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 February meeting

Development of Consensus Meeting on Methodological Considerations for Suicide Assessment and CT Design

- **Objective of Meeting:** Convene stakeholders from governmental, pharmaceutical, academic, patient and CT settings to discuss and reach consensus on ways to resolve outstanding issues confronting the field
- **Prework:**
 - 5 Working groups
 - » Nomenclature and Classification
 - » Instrumentation and Special Populations
 - » Analysis of SIB Data
 - » Design and Methodology for SIB Treatment Studies
 - » Developing Policy and Education on SIB Assessment
 - Over 70 people involved in the pre-meeting work

Activities of the Society

since February meeting

Consensus Meeting 17-18 November 2015 Arlington, VA, USA

- Day 1
Five groups meet to discuss positions and finalize presentations for full attendance response on Day 2
- Day 2
Five groups present statements/viewpoints for voting by full attendance
- Steering committee:
 - Phillip Chappell, Michelle Stewart, Larry Alphas, Stephen Marder, Carlotta McKee, Mary Bea Harding

Activities of the Society

since February meeting

- Publications

- ISCTM Innovations in *Clinical Neuroscience* Supplement
April 2015

- Translational and Early Phase Strategies for Treatment Development: Report of ISCTM Autumn 2013 Autumn Symposium
J Young, W Potter, S Riley, G Groeneveld, B Kinon, M Egan, D Feltner
 - Lessons Learned and Potentials for Improvement in CNS Drug Development: Designing the Right Series of Experiments
S Szabo, B Kinon, S Brannan, A Krystal, J van Gerven, A Mahableshwarkar, G Sachs
 - Taking Personalized Medicine Seriously: Biomarker Approaches in Phase IIb/III Studies in Major Depression and Schizophrenia
H Murck, T Laughren, F Lamers, R Picard, S Walther, D Goff, S Sainati

- Accepted to *Schizophrenia Bulletin* (open access)

- Report on ISCTM Consensus Meeting on Clinical Assessment of Response to Treatment of Cognitive Impairment in Schizophrenia
R Keefe, G Haig, S Marder, P Harvey, E Dunayevich, A Medalia, M Davidson, I Lombardo, C Bowie, R Buchanan, D Bugarski-Kirola, W Carpenter, J Csernansky, P Dago, D Durand, F Frese, D Goff, J Gold, C Hooker, A Kopelowic, A Loebel, S McGurk, L Opler, A Pinkham, R Stern

Activities of the Society

(since February)

- **Active Working Groups**
 - Addressing Methodological Challenges in International Trials (Keefe, Kalali)
 - Algorithms/Flags (Schooler, Rabinowitz)
 - BPSD (Ereshefsky, Miller, Pani)
 - Cognitive Assessment in Alzheimer’s Disease (Posner, Harvey)
 - Non-Adherence (Shiovitz/Bain)
 - Suicidal Ideation and Behavior (Chappell, Stewart, Alphas)
- We are open to new topics for working groups. View Criteria for Working Groups on website. Submit to Executive Director, Carlotta McKee

16-18 February 2015 – Washington DC

- Improving Transparency of Clinical Trial Data (Weiser, Kalali)
- Drug Repositioning in CNS (Davidson, Canuso)
- Novel Developments to Address Methodological Issues in Autism Spectrum Disorder (Alphs, Gault, Pandina)
- Mitigating the Effects of Non-adherence in Clinical Trials (Shiovitz, Bain)
- Network Meta-analysis: Integrating Results of Direct and Indirect Treatment Comparisons (Schooler, Haynes, Stewart)
- Poster Session
- Working Group Dinners

Involvement

- Ways to become involved
 - Submit topic ideas
 - Submit Working Group/Workshop topics
 - Submit Consensus Group topics
- Advise of interest in serving on committees
 - Will be reconstituted in the spring
 - These are actual **working** committees!

(Submit interest to Carlotta McKee via email, attach CV)

Thanks to ISCTM Corporate Members

Platinum

Janssen

Pfizer

Gold

Bracket

Roche

Shire

Thanks to Corporate Members and Meeting Supporters

Silver

AbbVie, Otsuka, Sunovion, Takeda

Bronze

**Alkermes, Boehringer Ingelheim, Covance,
Forum, INC Research,
NeuroCog Trials, PPD, ProPhase,
Thievon-Wright Consulting**

AUTUMN 2015 MEETING *SUPPORTER*

CHDR

2015 Autumn Conference

28 August: Joint Day Sessions

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

Evening: ISCTM Poster Session

2015 Autumn Conference

29 August: ISCTM Session

*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

Thanks to those who have traveled from US to
Amsterdam

Welcome Guy Goodwin, ECNP President



