

Welcome

2014 Autumn Conference

**International Society for CNS
Clinical Trials and Methodology**

6 - 8 October 2014

Boston, Massachusetts

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 February 2014 meeting)

- Working Groups:
 - Inaugural meeting of 2 new potential working groups
 - [Algorithms/Rules to Identify Clinical Inconsistency in the Use of Rating Scales in CNS RCTs](#) (Rabinowitz/Schooler)
 - [Identifying and Reducing the Effects of Non-Adherence in Clinical Trials](#) (Shiovitz/Bain)
 - Adaptive Design Group (Haynes)
 - [Adaptive Clinical Trials: Overview of Early-Phase Designs and Challenges](#) published in *Therapeutic Innovation and Regulatory Science*
 - Developing session for ISCTM 11th Annual Meeting
 - Suicidal Ideation and Behavior (Butler/Chappell)
 - **Prospective Assessment of Suicidal Ideation and Behavior: An Internet Survey of Pharmaceutical Sponsor Practices** accepted for publication in Sept/Oct issues of *Innovations in Clinical Neuroscience*
 - Assessing Abuse Liability Potential
 - Developing session for 11th Annual Meeting

Activities of the Society

(since February 2014 Annual Meeting)

- **Inaugural Consensus Group Meeting on *Challenges Issues and Perspectives in the Clinical Assessment of Response to Treatment of Cognition***
 - **Co-Chairs: Richard Keefe, George Haig**
 - **23 Panelists, 60 Observers**
 - **Publication due for release later this year**
 - **Rich Keefe will give an overview as part of the first session of this meeting**

Activities of the Society

(since February 2014 Annual Meeting)

- Upcoming Publications in ICNS Supplement
- NI Awardee Mercedes Perez-Rodrigues supporting Publication of Bipolar/Epilepsy session of this meeting
- Joint day with ASENT as part of 11th Annual Meeting 17-19 February 2015

11th Annual Scientific Meeting

17-19 February 2015 – Washington DC

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 Alphas, Ginger Haynes, Joanne Severe

Working Group Dinners

Wednesday 18 February 2015 – 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 Sokoloska, Michael
Klein

Wednesday (cont)

The European Federation of Pharmaceutical Industries Association's (EFPIA) Position on the European Medicines Agency/CHMP Depression Guideline Revision – Where do we go from here?

Chair: Heddy Martynowicz

Poster Session

11th Annual Scientific Meeting

Thursday 19 February 2015

Joint Day with ASENT

TBI Treatment Development

Chairs: ISCTM/ASENT Joint Scientific
Committee

Activities of the Society

Finalized plans for a European meeting

27-29 August 2015, Amsterdam

27 August 2015

Welcome Reception

28 August 2015

Joint Day with ECNP

Poster Session

29 August 2015

ISCTM Session

2015 “Autumn” Conference: Joint ECNP 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

2015 “Autumn” Conference: 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 Groeneweld



Spread the Word

- You will find mini-pamphlet with these upcoming meeting details on table – one to keep, one to give.
- NI Award Program Flyer on table – 4th year of program in 2015 – Deadline for submission is mid-November.

Involvement

- Ways to become involved
 - Submit topic ideas
 - Submit Working Group/Workshop topics
 - Submit Consensus Group topics(Request template for submission from Secretariat)
- 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)

Program Booklet

- QR code format
 - Direct links also available from “Welcome” email
 - Individual talk Abstracts included
 - Please provide feedback on the program book structure and content
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2014 Autumn Meeting Agenda

6 October

Workshops

- Report backs will be posted at this evenings Poster Session

7 October

Single focus meeting: *Targeting Cognitive Impairment Across CNS Disorders*

6:00 – 8:00 Poster session

8 October

Mid-day Adjournment

Scientific Program Committee

Nina Schooler – Chair	Thomas Laughren – Co-Chair
Munaf Ali	Amir Kalali
Larry Alphas	Richard Keefe
Charles Bowden	Atul Mahableshwarkar
Karl Broich	Stephen Marder
Adam Butler	John Messina
Carla Canuso	Steven Potkin
Michael Davidson	Jill Rasmussen
Larry Ereshefsky	Steven Romano
Douglas Feltner	Gary Sachs
Reuven Ferziger	Joanne Severe
Phil Harvey	Ira Shoulsen
Virginia Haynes	Michelle Stewart

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NeuroCog Trials, Novartis, PPD, ProPhase**

Contributor level Meeting Supporter

Covance
