
2013 Autumn Conference

International Society for CNS Clinical Trials and Methodology

30 Sept – 2 October 2013

Philadelphia, Pennsylvania

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

- Working Groups:
 - Inaugural meeting of 2 new working groups
 - Addressing Methodological Challenges in International CNS Clinical Trials (Kalali/Keefe)
 - Initiating Innovation in CNS Clinical Trials (Sachs)
 - Adaptive Design Group (Haynes)
 - Manuscript accepted for publication in *Therapeutic Innovation and Regulatory Science*
 - Suicidal Ideation and Behavior (Butler/Chappell)
 - Manuscript published in Inaugural ISCTM Supplement of *Innovations in Clinical Neuroscience*
 - Completed *Survey of Sponsor Practices in Conducting Prospective Assessments of Suicidal Ideation and Behavior in Clinical Trials* and presented initial data at last evening's workshop
 - Assessing Abuse Liability Potential
 - Many from this working group are unable to attend the Conference as they have been involved in organizing a meeting today with the FDA to discuss Guidance for Industry: Abuse-Deterrent Opioids-Evaluation and Labeling

- ISCTM comments on the following guidances:
 - FDA Guidance on Alzheimer’s Disease: Developing Drugs for the Treatment of Early Stage Disease (Submitted April 2013; Steve Romano, Chair)
 - World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects (Submitted June, 2013; Steve Potkin, Chair)
 - FDA Guidance on Availability of Masked and De-Identified Non Summary, Safety and Efficacy Data (Submitted August 2013; Joann Severe, Chair)
 - Currently meeting: 2 FDA Guidances on Major Depressive Disorder and Schizophrenia Draft Data Elements; Andrei Pikalov, Chair)
 - Just beginning; open to all members!

Activities of the Society

- Other Publications in Inaugural ISCTM supplement of ICNS
 - Large Registries Workshop Overview
 - Clinically Meaningful Effect from Feb 2012 Meeting
- NI Awardee David Roberts and runner up Taishiro Kishimoto supporting Publication of Comparative Effectiveness session from Autumn 2012.
- Jr Faculty supporting Publication of the main session of meeting
 - Jared Young, Steven Szabo and Rosie Curiel

Activities of the Society

- New Online Membership Management System that allows searching by role, profession, employment
 - Expanded Membership Demographic Survey on Renewal
- Continued outreach to academic leaders, neurologists, statisticians
- International outreach
 - *Acceptance of ISCTM-initiated symposium at ECNP in October 2014*
 - *Joint meeting of ISCTM and NEWMEDS on Negative Symptoms as a satellite to SIRS*
- Inaugural Consensus Group
 - Scientific Program Committee chose from 10 excellent suggestions from the membership. One-day meeting will focus on issues related the clinical assessment of cognition and negative symptom treatment response in patients with schizophrenia

New Investigator Award

- Flyer on table – 3rd year of program in 2014
- Also on tables will be Feb meeting mini-pamphlet

Committee Involvement

- Volunteers needed!
 - To become involved, advise Carlotta McKee and Rich Keefe of interest via email, attach CV
 - Open spots on the Publications Committee
 - These are actual ***working*** committees!
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Program Booklet

- QR code format
- Direct links also available from Welcome email
- Individual talk Abstracts included
- Please give feedback on the program book structure and content

Meeting Agenda

30 September

Workshops

- Report backs will be posted at this evenings Poster Session

1 October

Single focus meeting: *A Return to Rational CNS Drug Development: De-Risking Phase 3 Investments Through Rigorous Early Phase Evaluations*

6:00 – 8:00 Poster session

2 October

12:30 Adjournment

- Platinum: Janssen, Pfizer
- Gold: Shire, Bracket
- Silver: AbbVie, Lilly, Otsuka, Roche, Sunovion, Takeda
- Bronze: Envivo, InVentiv Health, Novartis, Parexel, ProPhase