

# Welcome

## **12<sup>TH</sup> Annual Scientific Meeting International Society for CNS Clinical Trials and Methodology**

16-18 February 2016  
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 meetings and consensus activities (*Innovations in Clinical Neuroscience*)

# Activities of the Society

(since Autumn 2015 Meeting)

- Working Groups: 9 ISCTM working groups
  - Biomarkers Working Group (Potkin/Goff)
    - Publication accepted - *European Neuropsychopharmacology*
  - Cognitive Assessment Group (Harvey/Posner)
    - Pair of publications in review *Innovations in Clinical Neuroscience*
  - Nonadherence Group (Shiovitz/Bain)
    - Developed session for 12th Annual Scientific Meeting
    - Publication accepted *Journal of Clinical Pharmacology*
  - Suicidal Ideation and Behavior Assessment (Stewart/Chappell/Alphs)
    - Held Consensus meeting this past November 2015; publications pending

# Activities of the Society

(since Autumn 2015 Meeting)

- Other Publications
  - **Sleep Disturbance Associated with TBI**  
Accepted *Neurotherapeutics*
  - **Report on ISCTM Consensus Meeting on Clinical Assessment of Response to Treatment of Cognitive Impairment in Schizophrenia**  
Published *Schizophrenia Bulletin*
- [Comment on HL7 V3 Domain Analysis Model for Bipolar Disorder](#)  
(January 2016) Chair: Gary Sachs, MD

# 2016 Autumn Conference

26-27 September 2016 - Philadelphia

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- ***Missing Data in Neuroscience Clinical Trials: Truth or Consequences***  
Chairs: Pilar Lim / George Haig
  - ***Methodological Challenges in the Development of Brain Therapeutics***  
Chairs: Jill Rasmussen / Dawn Velligan
  - ***Should the Randomized Withdrawal Design for Relapse Prevention Studies in Mood Disorders be Updated?***  
Chairs: Atul Mahableshwarkar / Gary Sachs
  - ***Update from IOM meeting “Neuroscience Trials of the Future”***  
Chairs: Richard Keefe / Atul Pande
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# 2016 Autumn Conference

**Note: Shorter duration (1.5 days), same content**

## Monday 26 September

1:00 Welcome/Session 1

5:30 Welcome reception / dinner

6:45 Workshop Sessions

## Tuesday 27 September

8:00 Parallel Sessions 2a, 2b

11:45 Poster Session / Luncheon

1:45 Session 3

5:30 Meeting Adjourns

Registration will launch April 2015



# 12<sup>th</sup> Annual Scientific Meeting

## Tuesday 16 February 2016

Session 1:

*Improving Transparency of Clinical Trial Data*

Chairs: Mark Weiser, Amir Kalali

### Working Group Dinners

**Abuse Liability**

Chairs: Setnik, Sokolowska, Klein

**BPSD**

Chairs: Ereshefsky, Miller, Pani

**Adaptive Design**

Chairs: Marcus, Kando

**Cognitive Assessment**

Chairs: Posner, Harvey

**Algorithms/Flags**

Chairs: Schooler/Rabinowitz

**International**

Chairs: Keefe, Kalali

**Biomarkers**

Chairs: Potkin/Goff

# 12<sup>th</sup> Annual Scientific Meeting

## Wednesday 17 February 2016

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### Session 2:

*Drug Repositioning in CNS: Can We Give a Hand to Serendipity and Promiscuity?*

Chairs: Michael Davidson, Carla Canuso

### Session 3: Parallel Sessions

*A) Novel Developments to Address Methodological Issues in Autism Spectrum Disorder*

Chairs: Laura Gault, Gahan Pandina, Larry Alphs

*B) Mitigating the Effects of Nonadherence in Clinical Trials*

Chairs: Thomas Shiovitz, Earle Bain

### Poster Session/Reception

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# 12<sup>th</sup> Annual Scientific Meeting

## Thursday 18 February 2016

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Session 4:

*Network Meta-Analysis: Integrating Results of Direct and Indirect Treatment Comparisons*

Chairs: Nina R Schooler, Michelle Stewart, Ginger Haynes



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# Involvement

- Ways to become involved
  - Submit topic ideas
  - Submit Working Group/Workshop topics
  - Submit Consensus Group topics

# Scientific Program Committee

<b>Thomas Laughren– Chair</b>	<b>George Haig– Co-Chair</b>
Munaf Ali	Richard Keefe
Larry Alphs	Atul Mahableshwarkar
Alan Breier	Stephen Marder
Karl Broich	John Messina
Adam Butler	Steven Potkin
Carla Canuso	Jill Rasmussen
Michael Davidson	Steven Romano
Larry Ereshefsky	Gary Sachs
Reuven Ferziger	Nina Schooler
Phil Harvey	Joanne Severe
Virginia Haynes	Michelle Stewart
Amir Kalali	Daniel Umbricht

# Thanks to Corporate Members

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Platinum

**Janssen**

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Gold

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# Thanks to Corporate Members

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