

Welcome

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

2018 Autumn Conference

***Advances in Clinical Trial Technology: Impact on
Methodology and Signal Detection***

15-16 October 2018

Marina del Rey, California

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.

- Many stakeholders
 - Drug Developers, Academic Investigators, Statisticians, Regulators, Clinicians, Policy-makers, Public
- Non-commercial, non-promotional
- Pre-competitive and/or collaborative
- Ample time for discussions
- Active participation is encouraged

- Please complete evaluations – value feedback

Meetings Development

- **February 2018 – included joint day with Michael J Fox Foundation**
- **Autumn 2018**
- **February 2019* 19-21 February, Washington DC**
- **Autumn 2019* 5-7 September, Copenhagen**
-- Includes Joint Day with ECNP

** QR code in program book will link to Preliminary Agenda and Poster Submission information*

- 11 Active Working Groups, some with multiple subgroups
- Activities have included: Webinars; Manuscript development; Collaboration with other organizations (e.g. Alzheimer's Association, ECNP); Consensus building; Session development
- Many ISCTM members involved in leading and participating
- Detailed information on these groups, their deliverables and how to join or submit a topic found in Program book

Current Working Groups

- **Adaptive Design (Kando/Marcus)**
- **Algorithms/Flags (Rabinowitz/Schooler)**
- **Autism Spectrum Disease (Mantua/Farchione/Arango)**
- **BPSD – Chair: Larry Ereshefsky**
- ❖ **Agitation Subgroup (O’Gorman/Rosenberg)**
- ❖ **Apathy Subgroup (Lanctôt/Miller)**
- **Cognitive Trajectories (Harvey/Sand)**
- **Estimands (Lim/Polverejan)**
- **Late Onset Depression (Cappacione/DeBoer)**
- **Negative Symptoms (Marder/Daniel)**
- **Orphan Disease (Busner)**
- **Prevention Trials in Alzheimer’s Disease (Posner/Schneider)**
- **Suicidal Ideation and Behavior – Policy Subgroup (Ratcliffe/Alphs)**

- ***FDA Early Alzheimer's Disease Developing Drugs for Treatment*** Chairs: Brannan, Butler, Potkin
- ***FDA Major Depressive Disorder: Developing Drugs for Treatment*** Chairs: Canuso, Kalali, Rabinowitz

Ariana Anderson PhD - Semel Institute / UCLA

2018 Autumn Conference session speaker; Membership Committee member; New Investigator Committee member

Walter Dunn MD, PhD – Semel Institute / UCLA

2018 Autumn Conference session co-chair; Scientific Committee member

Dawn Ionescu MD – Janssen Pharmaceuticals

New Investigator Award Committee member; Late Onset Depression Working Group member

Manish Jha, MBBS – UT Southwestern

FDA MDD Draft Guidance for Industry Comment Group member

Tim Mariano MD, PhD, MSc– Harvard Medical School

**FDA MDD Draft Guidance for Industry Comment Group member;
15th Annual Scientific Meeting session co-chair**

 **2019 NI Award Applications due 1 November 2018**

 **Access Submission form**

ISCTM website

QR code on back page of program book

ASCP

- **Develop a 2.0 course on drug development in CNS**
- **Submitting workshop on precision medicine for ASCP 2019**

ECNP

- **2019 Autumn Conference 5-7 September, Joint Day**
- **Joint Working Group on Autism Spectrum Disorder**
- **Submitting abstract for ECNP 2020**

Emory Center for Ethics/Neuroethics Program

- **Consensus Conference on Preclinical Research Guidelines**

Executive Committee

Carla Canuso, President
Ramy Mahmoud, President Elect

Larry Alphas

Amir Kalali

Adam Butler

Antony Loebel

Phillip Chappell

Stephen Marder

George Haig

Luca Pani

Philip Harvey

Jonathan Rabinowitz

Judith Jaeger

Carlotta McKee

Scientific Program Committee

George Haig, Chair
Philip Harvey, Co-Chair

Munaf Ali	Reuven Ferziger	Steven Potkin
Larry Alphs	Robert Goldman	Jill Rasmussen
Stephen Brannan	Amir Kalali	Steven Romano
Adam Butler	Richard Keefe	Gary Sachs
Carla Canuso	Atul Mahableshwarkar	Nina R. Schooler
David Daniel	Ron Marcus	Michelle Stewart
Walter Dunn	Stephen Marder	Daniel Umbricht
Larry Ereshefsky	Heddie Martynowicz	Mark Weiser

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Otsuka

Sunovion

Takeda

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And thanks to all of you who join as individual members!