

AMERICAN SOCIETY FOR EXPERIMENTAL NEUROThERAPEUTICS

ASENT

15th Annual Meeting

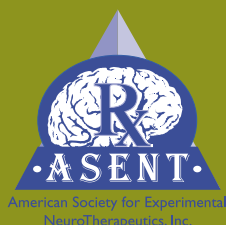
February 28 – March 2, 2013

Hyatt Regency Bethesda
Bethesda, Maryland

Vision Statement

To advance the science of neurotherapeutics and
to improve and accelerate the development
of new treatments.

PROGRAM BOOK



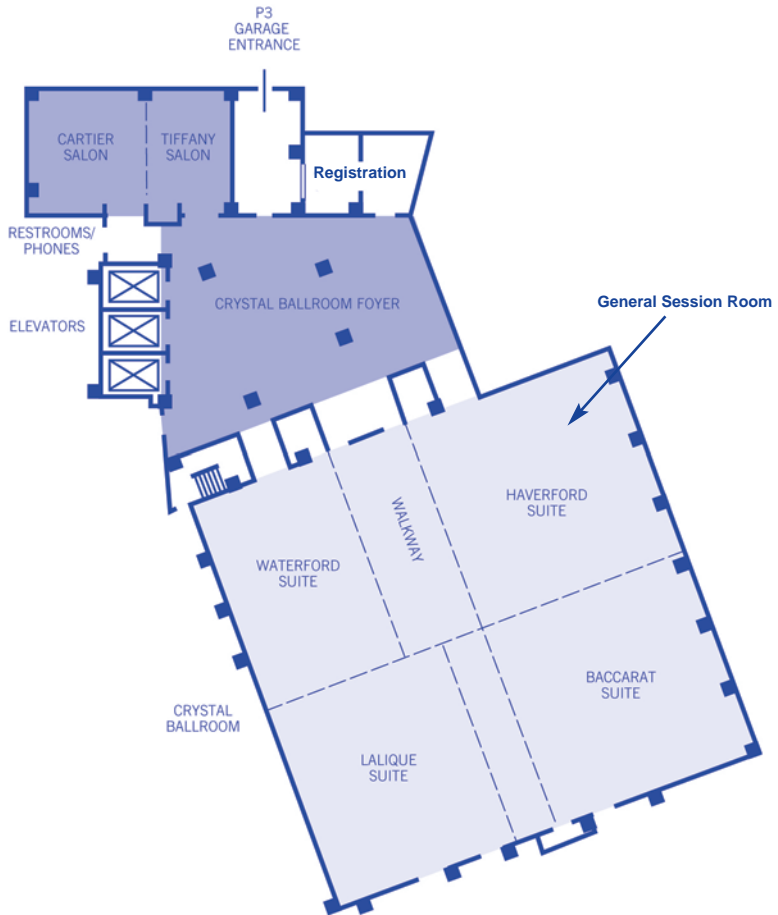
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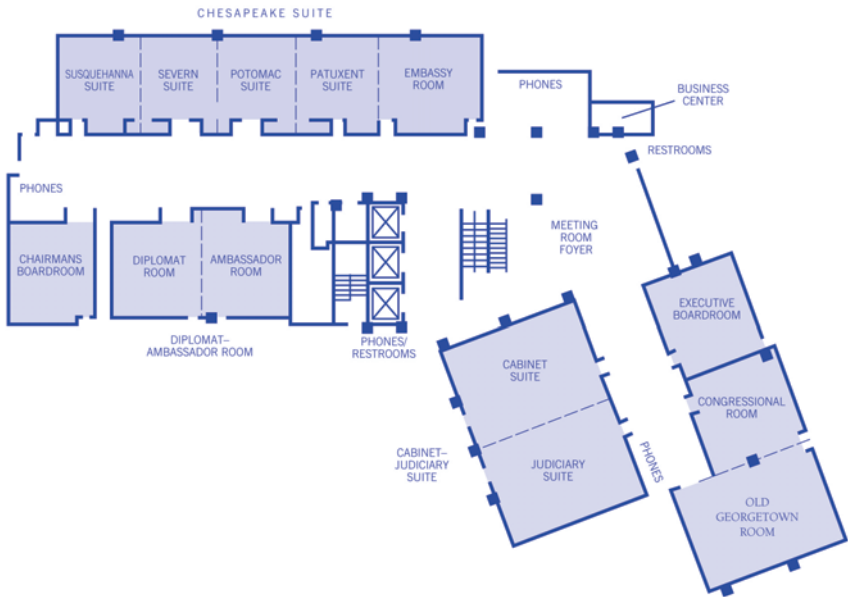
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American Society for Experimental NeuroTherapeutics



Ballroom Level

American Society for Experimental NeuroTherapeutics



Conference Level

**American Society for
Experimental NeuroTherapeutics**

Program Schedule

THURSDAY, FEBRUARY 28, 2013

8:00 a.m. – 12:00 p.m.
***Crystal Ballroom –
Haverford Suite***

**Clinical Neurostimulation for CNS
Diseases: From Basic Mechanisms
to Current Therapeutics**

Program

Co-Chairs: Shaun Comfort, MD, MBA, Adaptix Clinical Solutions, LLC;
Martha Morrell, MD, NeuroPace, Inc.

8:00 a.m. – 8:05 a.m.	Presidential Welcome Michael Rogawski, MD, PhD, University of California, Davis
8:05 a.m. – 8:15 a.m.	Introduction to Neurostimulation Shaun Comfort, MD, Adaptix Clinical Solutions, LLC
8:15 a.m. – 9:05 a.m.	Basic Mechanisms of Neurostimulation Cameron McIntyre, PhD, Cleveland Clinic
9:05 a.m. – 9:30 a.m.	Neurostimulation for the Treatment of Neurological Disease Jaimie Henderson, MD, Stanford University
9:30 a.m. – 10:00 a.m.	Intracortical Neural Interfaces for the Restoration of Function Leigh Hochberg, MD, PhD, Massachusetts General Hospital
10:00 a.m. – 10:20 a.m.	Break
10:20 a.m. – 10:40 a.m.	The Emergence of Therapeutic Neurostimulation John Reppas, MD, PhD, Neurotechnology Industry Organization
10:40 a.m. – 11:00 a.m.	Neurostimulation Devices: A Regulatory Perspective Victor Krauthamer, PhD, U.S. Food and Drug Administration
11:00 a.m. – 12:00 p.m.	Moderated Panel Discussion
12:00 p.m. – 1:30 p.m.	Lunch On Your Own

American Society for Experimental NeuroTherapeutics

Program Schedule (Continued)

THURSDAY, FEBRUARY 28, 2013

1:30 p.m. – 4:30 p.m.
***Crystal Ballroom –
Haverford Suite***

**Brave New World: Use of the Internet
and Social Media to Conduct Clinical
Trials**

Program

Chair: Nancy Santilli, BSN, MSN, Endo Pharmaceuticals, Inc.

1:30 p.m. – 1:40 p.m.

**Introduction to the Session and the Power of Social
Media**

Nancy Santilli, BSN, MSN, Endo Pharmaceuticals, Inc.

1:40 a.m. – 2:00 p.m.

Social Media and Clinical Trial Recruitment

Eileen O'Brien, Siren Interactive

2:00 p.m. – 2:15 p.m.

**Clinical Trial Enrollment through the New Social
Media – Mobil Health Applications**

Joseph Kim, BS, MBA, Shire Pharmaceuticals

2:15 p.m. – 2:30 p.m.

**Digital Tools for Clinical Development – Virtual
Clinical Trials and Beyond**

Craig Lipset, MPH, Pfizer Inc.

2:30 p.m. – 2:45 p.m.

The FDA Perspective

Russell Katz, MD, U.S. Food and Drug Administration

2:45 p.m. – 3:00 p.m.

Security and Privacy Pitfalls

Joanna Napp, Esq., HealthTronics, Inc.

3:00 p.m. – 3:15 p.m.

Break

3:15 p.m. – 3:30 p.m.

**From Ground Zero to PreIND in 3.5 Years:
How Social Media Helped Us Get Here**

Lori Sames, Hannah's Hope Fund, Giant Axonal
Neuropathy

3:30 p.m. – 4:30 p.m.

Panel Discussion: Putting It Together

4:30 p.m. – 6:30 p.m.
***Crystal Ballroom –
Waterford Suite***

**Information Exchange and Poster
Presentation Reception**

American Society for Experimental NeuroTherapeutics

Information Exchange and Poster Presentations

Thursday, February 28, 2013

4:30 p.m. – 6:30 p.m. (Opening Reception)

Crystal Ballroom – Waterford Suite
Authors Present

Friday, March 1, 2013

7:30 a.m. – 8:30 a.m.

Crystal Ballroom – Waterford Suite
Posters available for viewing

Since 1999, ASENT has sponsored a poster session of new and previously unpublished data from physicians, researchers and industry leaders in the field of neurotherapeutics. All posters are peer-reviewed and accepted posters will also be published in ASENT's journal, *Neurotherapeutics*[®]. These abstracts are also printed in this program book.

In addition, previously published data, preliminary data and/or previously reviewed posters are also welcome. These posters will not be found in the program book and will not be published in the journal.

The poster session is an opportune time for academicians to showcase potential therapeutic opportunities to the industry and for the industry to provide review data on the progress of their approved or unapproved therapies. Join us in the poster session, and meet the presenters and discuss their projects.

(See the abstract descriptions handout available at the Information Exchange.)

Information Tables

While in the poster session, please take a few minutes to meet with our exhibitors:

American Brain Coalition
American Neurological Association
INC Research
International Essential Tremor Foundation
Parkinson's Action Network
Springer Science

**American Society for
Experimental NeuroTherapeutics**

Program Schedule (Continued)

THURSDAY, FEBRUARY 28, 2013

6:30 p.m. – 8:30 p.m.
Crystal Ballroom –
Haverford Suite

**Dinner Session: Assessment of Benefits
and Risks: Deciding Whether to Use a
New Medication – Patient and Physician
Viewpoints**

Program

Co-Chairs: Mitchell Brin, MD, Allergan, Inc.; Kathleen Clarence-Smith, MD, PhD,
KM Pharmaceutical Consulting LLC

Speakers: James Simsarian, MD, The Neurology Center of Fairfax, Ltd.
Robin Elliott, MA, Parkinson's Disease Foundation



American Society for Experimental
NeuroTherapeutics, Inc.

**See You at
Next Year's Meeting**

ASENT 16th Annual Meeting
February 20 – 22, 2014
Bethesda North Marriott Hotel & Conference Center
Bethesda, Maryland

Abstract submissions begin June 1, 2013

American Society for Experimental NeuroTherapeutics

Program Schedule (Continued)

FRIDAY, MARCH 1, 2013

8:00 a.m. – 11:45 a.m.
***Crystal Ballroom –
Haverford Suite***

**Barriers in Early Drug Development:
Lessons Learned**

Program

Co-Chairs: Jesse Cedarbaum, MD, Bristol-Meyers Squibb R&D; Amy Chappell, MD, Eli Lilly & Company; Jill Rasmussen, MD, Psi-Napse

- 8:00 a.m. – 8:30 a.m. **Of Mice and Men: How Temporal and Other Biological Factors Affect Interpretability of Animal Models**
Gene Kinney, PhD, Prothena Biosciences
- 8:30 a.m. – 9:00 a.m. **Using Toxicology and Toxicokinetics to Better Predict Therapeutic Index**
Steve White, PhD, University of Utah
- 9:00 a.m. – 9:30 a.m. **Phase 1 Trials: More than Feed and Bleed**
Ajay Verma, MD, PhD, Biogen Idec
- 9:30 a.m. – 10:00 a.m. **Phase 2 Trials: What Can Go Wrong When You Think You've Get it Right**
Amy Chappell, MD, Eli Lilly & Company
- 10:00 a.m. – 10:15 a.m. Break
- 10:15 a.m. – 10:45 a.m. **A National IRB for Neurodegeneration Studies**
Ara Khachaturian, PhD, Khachaturian, Radebaugh & Associates
- 10:45 a.m. – 11:15 a.m. **The Evolving Mission of NINDS Office of Translation**
Rajesh Ranganathan, PhD, NIH/NINDS
- 11:15 a.m. – 11:45 a.m. **Panel Discussion**

American Society for Experimental NeuroTherapeutics

Program Schedule (Continued)

FRIDAY, MARCH 1, 2013

12:00 p.m. – 2:00 p.m.
***Crystal Ballroom –
Waterford Suite***

Special Interest Topics Tables and Luncheon

- Health Information Technology (HIT) as a Tool to Enable Comparative Effectiveness Research
- How Can Phase I Inform Efficacy?
- What are Appropriate Expectations for Animal Models?
- How to Most Efficiently Find the Right Dose?
- How to Use Social Media to Engage Patients in Clinical Research
- Innovation in Clinical Patient Data Collection: Use of Smart Phones and Other Remote Monitoring Techniques
- Challenges to Young Researchers Entering the Field of Neurotherapeutics
- Challenges to International Drug Development
- How Much Safety Must We Have to Support Marketing Authorization and to Get to Phase III Trials?
- Challenges for Start-Up Companies to Achieve POC (proof of concept)

2:15 p.m. – 6:00 p.m.
***Crystal Ballroom –
Haverford Suite***

Pipeline Session

Co-Chairs: Philip Perera, MD, Dart Neuroscience LLC; Michael Rogawski, MD, PhD, University of California, Davis

Investigators in academia, government, industry and advocacy present an update on research and development progress on a specific project in the broad area of neurotherapeutics. Such projects may address neurological disorders, psychiatric disorders, pain, neurooncology, neurological infections or any other disorder affecting the central or peripheral nervous systems.

American Society for Experimental NeuroTherapeutics

Program Schedule (Continued)

SATURDAY, MARCH 2, 2013

8:30 a.m. – 9:00 a.m.
*Crystal Ballroom –
Haverford Suite*

ASENT Annual Business Meeting

9:15 a.m. – 11:45 a.m.
*Crystal Ballroom –
Haverford Suite*

**New Models for Collaboration: Patients
as Drivers and Partners in Neurological
Research**

Program

Co-Chairs: C. Anthony Altar, PhD, AssureRx Health, Inc.; Robin Elliott, MA,
Parkinson's Disease Foundation

9:15 a.m. – 9:30 a.m.	Session Introduction and the Patient Perspective Linda Morgan, MBA, RPh
9:30 a.m. – 9:45 a.m.	How Patient Collaborations Can Drive Innovation Bray Patrick-Lane, BS, MFS, PFO Foundation
9:45 a.m. – 10:00 a.m.	Partnering with Patients in Study Protocol Development Kimberly Moran, PhD, UCB, Inc.
10:00 a.m. – 10:15 a.m.	Rethinking Recruitment and Retention Through Patients Engagement Petra Kaufmann, MD, NIH/NINDS
10:15 a.m. – 10:30 a.m.	Break
10:30 a.m. – 10:45 a.m.	Integrating Patient Input Within the Drug Approval Process Russell Katz, MD, U.S. Food and Drug Administration
10:45 a.m. – 11:00 a.m.	Patients as Drivers in Research Prioritization and Funding Robert Pacifici, PhD, CHDI
11:00 a.m. – 11:45 a.m.	Panel Discussion
11:45 a.m.	Annual Meeting Adjourns

Annual Business Meeting

Saturday, March 2, 2013

Hyatt Regency Bethesda

Crystal Ballroom – Haverford Suite

8:30 a.m. – 9:00 a.m.

Preliminary Agenda

- I. Call to Order
- II. Financial Report
- III. *Neurotherapeutics*[®] Journal Report
- IV. Membership Report
- V. 16th Annual Meeting, February 20 – 22, 2014
- VI. Recognition of Outgoing Board Members
- VII. Introduction of Incoming Board Members
- VIII. Old Business
- IX. New Business
- X. Adjournment

Meeting Evaluation/ How Do I Obtain CME Credits?

To obtain a CME certificate for the ASENT 15th Annual Meeting, please access the online evaluation on our website, www.asent.org. A link to the evaluation is on the homepage. Evaluations must be completed by March 29, 2013 in order to receive credit.

ASENT's 15th Annual Meeting has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the University of Vermont and the American Society for Experimental NeuroTherapeutics. The University of Vermont is accredited by the ACCME to provide continuing medical education for physicians.

The University of Vermont designates this live activity for a maximum of 13.75 *AMA PRA Category 1 Credits*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Your number of credits will be determined based on the questions you answer in the online evaluation.

Continuing Medical Education Statement and Session Objectives

Session Objectives: At the completion of the meeting, participants will be able to:

- Recognize that neurostimulation is being actively developed as a treatment for many neurological disorders and is a treatment option for some;
- Understand how social media is being used by patients to communicate their medical concerns and to gather medical information, and will be aware of how social media can be utilized to facilitate the enrollment and conduct of clinical trials.

Meeting Disclaimer: Regarding written materials and information received, written or otherwise, during this activity: The scientific views, statements and recommendations expressed during this CME activity represent those of the authors, and speakers and do not necessarily represent the views of the University of Vermont.

Interest Disclosures: As an organization accredited by the ACCME to sponsor continuing medical education activities, The University of Vermont is required to disclose any real or apparent conflicts of interest (COI) that any speakers may have related to the content of their presentations.

The University of Vermont requires that each speaker participating in a program designated for AMA Physician's Recognition Award Category 1 credit disclose any financial interest/arrangement or affiliation with a corporate organization that may impact on his/her presentation (i.e. grants, research support, honoraria, member of speakers' bureau, consultant, major stock shareholder, etc.)

No Interests to Disclose:

C. Anthony Alter, PhD**
Mitchell Brin, MD**
Amy Chappell, MD**
C. Anthony Alter, PhD**
Mitchell Brin, MD**
Amy Chappell, MD**
Robert Hamill, MD**
Leigh Hochberg, MD, PhD
Russell Katz, MD
Petra Kaufmann, MD, MSc
Ara Khachatryan, PhD
Joseph Kim
Gene Kinney, PhD
Victor Krauthamer, PhD
Bennett Lavenstein, MD**
Craig Lipset, MPH
Linda Morgan

Martha Morrell, MD**
Eileen O'Brien
Robert Pacifici, PhD
Bray Patrick-Lake, MFS
Philip Perera, MD**
Rajesh Ranganathan, PhD
Jill Rasmussen, MD**
John Reppas, MD, PhD
Michael Rogawski, MD, PhD**
Lori Sames
Nancy Santilli, MSN**
James Simsarian, MD
Barbara Slusher, PhD**
William Theodore, MD**
Ajay Verma, MD, PhD
Marc Walton, MD, PhD**

**Continuing Medical Education
Statement and Session Objectives**

(Continued)

Interests to Disclose/COI/Bias Resolved*:

Jesse Cedarbaum, MD**

Elan Pharmaceuticals

Kathleen Clarence-Smith, MD, PhD**

Chase Pharmaceuticals; Kurma Bofnd; Key Neuroscience

Shaun Comfort, MD**

KAI-Amgen; Incline Therapeutics; Medivation; Cyberonics; RHI

Jacqueline French, MD**

Grant funding from several sources

Jaimie Henderson, MD

Nevro Corp.; Proteus Biomedical

Cameron McIntyre, PhD

IntElect Medical Inc.; Boston Scientific Neuromodulation Corp.

Joanna Napp, JD, MPH

Endo Pharmaceutical

Roger Porter, MD**

GSK; Lilly; NeruoPace; Upsher-Smith; Valent; Zalicus

H. Steve White, PhD

SynapCell; Upsher-Smith Laboratories; Janssen Pharmaceuticals;
NeuroAdjuvants, Inc.; UCB Pharma

*Having a financial interest or other relationship with a corporate organization may not prevent a speaker from making a presentation; however, the existence of the relationship must be made known to the Program Committee prior to the conference so that any possible conflict of interest may be resolved prior to the talk.

**ASENT Program Committee

**15th Annual Meeting
Program Committee**

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Children's Hospital Medical Center

Martha Morrell, MD, Co-Chair
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AssureRx Health Inc.

Mitchell Brin, MD
Allergan, Inc.

Jesse Cedarbaum, MD
Bristol-Myers Squibb

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Parkinson's Disease Foundation

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Schedule-At-A-Glance

Thursday, February 28, 2013

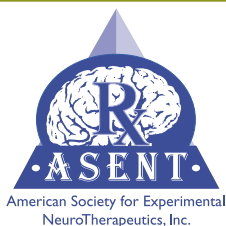
7:30 a.m. – 6:00 p.m. <i>Crystal Ballroom Foyer</i>	Registration (Continental Breakfast 7:30 a.m. – 8:30 a.m.)
8:00 a.m. – 12:00 p.m. <i>Crystal Ballroom – Haverford Suite</i>	Clinical Neurostimulation for CNS Diseases: From Basic Mechanisms to Current Therapeutics
12:00 p.m. – 1:30 p.m.	Lunch – On Your Own
1:30 p.m. – 4:30 p.m. <i>Crystal Ballroom – Haverford Suite</i>	Brave New World: Use of the Internet and Social Media to Conduct Clinical Trials
4:30 p.m. – 6:30 p.m. <i>Crystal Ballroom – Waterford Suite</i>	Information Exchange and Poster Presentation Reception
6:30 p.m. – 8:30 p.m. <i>Crystal Ballroom – Haverford Suite</i>	Dinner Session: Assessment of Benefits and Risks: Deciding Whether to Use a New Medication – Patient and Physician Viewpoints

Friday, March 1, 2013

7:30 a.m. – 6:00 p.m. <i>Crystal Ballroom Foyer</i>	Registration
7:30 a.m. – 8:30 a.m. <i>Crystal Ballroom – Waterford Suite</i>	Continental Breakfast
8:00 a.m. – 11:45 a.m. <i>Crystal Ballroom – Haverford Suite</i>	Barriers in Early Drug Development: Lessons Learned
12:00 p.m. – 2:00 p.m. <i>Crystal Ballroom – Waterford Suite</i>	Special Interest Topics Tables and Luncheon
2:15 p.m. – 6:00 p.m. <i>Crystal Ballroom – Haverford Suite</i>	Pipeline Session

SATURDAY, MARCH 2, 2013

8:00 a.m. – 12:00 p.m. <i>Crystal Ballroom Foyer</i>	Registration (Continental Breakfast 8:15 a.m. – 9:15 a.m.)
8:30 a.m. – 9:00 a.m. <i>Crystal Ballroom – Haverford Suite</i>	Annual Business Meeting All members are welcome!
9:15 a.m. – 11:45 a.m. <i>Crystal Ballroom – Haverford Suite</i>	New Models for Collaboration: Patients as Drivers and Partners in Neurological Research



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