

ASENT

16TH ANNUAL MEETING

**American Society *for* Experimental
NeuroTherapeutics**

February 20 – 22, 2014

Bethesda North Marriott Hotel
& Conference Center

Bethesda, Maryland



- **Preliminary Program**
- **Call for Abstracts**
- **Call for Pipeline Submissions**
- **Registration Form**

AMERICAN SOCIETY FOR EXPERIMENTAL NEUROTHERAPEUTICS

Bethesda North Marriott Hotel & Conference Center ■ Bethesda, Maryland

Join us for the premier meeting in experimental neurotherapeutics – The ASENT 16th Annual Meeting – Improving Patient Involvement and Care

Make your plans now to attend the only meeting that advances neurotherapeutics by bringing together academia, advocacy, government and industry.



Start this year's 16th Annual Meeting with a new welcome and networking reception on Wednesday evening. Meet old friends and welcome new as we arrive for three days of intensive and informative sessions. Clinical trials in neurology take center stage at this year's annual meeting. The commonalities that exist in clinical trial measures will be covered in detail Thursday morning, followed by a new luncheon session that will allow attendees to discuss particular issues and report back to the group afterward. Exploring treatments that may have been considered science fiction in the past are discussed in the afternoon. Stay late on Thursday evening for the Information Exchange and Poster Presentation Reception, followed by the dinner session discussing conflict of interest from a lawyer's perspective. Friday morning brings another new session – a breakfast workshop on cognition. This is followed by an informative session on psychiatric pharmacogenomics. Saturday wraps up the meeting with concurrent sessions on gene therapy, and a new course on the nuts, bolts and best practices in the conduct of clinical trials. Make your plans now to join us for this expanded annual meeting program designed to keep you informed on today's efforts in experimental neurotherapeutics.

Call for Abstracts



Submit a new poster and attend the Annual Meeting for free!

The Call for Abstracts online submission system at www.asent.org is open and ready to accept your poster presentation for the Information Exchange and Poster Presentation Reception on Thursday, February 20, 2014, 5:00 p.m. – 6:30 p.m. All posters will be peer reviewed and new, previously unpublished data from investigators in any field of neurotherapeutics will be published in ASENT's journal, *Neurotherapeutics*®. Previously published posters are eligible for presentation, but will not be published.

Anyone who submits an accepted new or previously unpublished poster will receive a complimentary registration to the 16th Annual Meeting. **The submission deadline is Monday, January 13, 2014.** Acceptance notifications will go out by email the week of January 20, 2014.

Pipeline Session

The popular Pipeline Session will take place on Friday, February 21, 2014, from 2:15 p.m. – 6:00 p.m. This session enables investigators in academia, government, industry and advocacy to present an update on research and/or developments in a specific project related to neurotherapeutics. Projects may address potential or actual treatments for neurological disorders, psychiatric disorders, pain, neuro-oncology, neurological infections or any other disorder affecting the central or peripheral nervous systems. Clinical and preclinical stage projects will be considered.

You are encouraged to submit one or more Pipeline abstracts for consideration. The online Pipeline submission system at www.asent.org is open and ready to accept your presentation.

The deadline for submissions is Monday, January 27, 2014, and acceptance notifications will go out by email on **Friday, January 31, 2014.**

Pipeline presenters are offered a special discounted annual meeting registration fee of \$150 for the full meeting!



Special Interest Topics Roundtables and Luncheon

On **Thursday, February 20**, the morning session will continue with a new feature – the Clinical Trial Measures Working Groups Luncheon. Choose from one of eleven topics to discuss in greater detail with fellow attendees. Results of these roundtable luncheon discussions will be presented directly after lunch. See the registration form for the topics and register early to get the topic of your choice. This special event is covered by your registration fee.

Returning for the fourth time is the popular **Friday** (February 21) luncheon with special interest topic roundtable discussions. Join your colleagues for a casual, yet informative lunch by selecting one of the eleven challenging topics to investigate while enjoying a buffet lunch. See the registration form for this year's topics and register early to get the topic of your choice. This special event is also covered by your registration fee.

ASENT Meeting Program

Wednesday, February 19, 2014

6:00 p.m. – 8:00 p.m.

Welcome Reception

NEW

Thursday, February 20, 2014

Commonalities in the Development of Clinical Trial Measures in Neurology

Co-Chairs: Jesse Cedarbaum, MD, consultant; Robin Elliott, MA, Parkinson's Disease Foundation; Karl Kieburtz, MD, University of Rochester; Marc Walton, MD, FDA

8:00 a.m. – 8:05 a.m.	Presidential Welcome	Michael Rogawski, MD, University of California Davis
8:05 a.m. – 8:25 a.m.	Introduction	Marc Walton, MD, FDA
8:25 a.m. – 8:45 a.m.	CAMD and C-Path Introduction	Diane Stephenson, PhD, Critical Path Institute
8:45 a.m. – 9:00 a.m.	C-Path Progressive Multiple Sclerosis Initiative	Richard Rudick, MD, Cleveland Clinic
9:00 a.m. – 9:15 a.m.	CAMD Alzheimer's Disease Initiative	Maria Carrillo, PhD, Alzheimer's Association
9:15 a.m. – 9:30 a.m.	Parkinson's Disease: Updating the UPDRS	Glenn Stebbins, PhD, Rush University Medical Center
9:30 a.m. – 9:45 a.m.	Motor Neuron Diseases	Douglas Kerr, MD, PhD, Biogen Idec
9:45 a.m. – 10:00 a.m.	Panel Discussion	
10:00 a.m. – 10:20 a.m.	Break and Lunch Table Sign-Up	
10:20 a.m. – 10:40 a.m.	The Concept of Functional Domains in the Assessment of Psychiatric Disorders – RDOC	Jill Heemskerk, PhD, NIH/NIMH
10:40 a.m. – 11:00 a.m.	NINDS-CDE	Wendy Galpern, MD, PhD, NIH/NINDS
11:00 a.m. – 11:20 a.m.	NIH Toolbox	Petra Kaufman, MD, MSc, NIH/NINDS
11:20 a.m. – 11:40 a.m.	Including the Patient Voice in the Development of Rating Scales	David Cella, PhD, Northwestern University
11:40 a.m. – 12:00 p.m.	Wrap-Up Discussion	Laurie Burke, RPh, MPH, FDA and Maria Issac, MD, European Medical Agency
12:00 p.m. – 1:15 p.m.	Clinical Trial Measures Working Groups Luncheon	
1:15 p.m. – 1:45 p.m.	Reports and Wrap-Up	NEW

Science Non-Fiction in Neurotherapeutics

Chair: Martha Morrell, MD, NeuroPace

2:05 p.m. – 2:35 p.m.	Applications of Nanotechnology for Treatment of Diseases of the Nervous System Gabriel Silva, PhD, UCSD Jacobs Retina Center
2:35 p.m. – 3:05 p.m.	Optogenetics: Tools for Analyzing and Repairing the Nervous System Anthony Zoros, PhD, MIT Media Lab
3:05 p.m. – 3:20 p.m.	Break
3:20 p.m. – 3:50 p.m.	Application of Neural Interfaces to Treatment of Amputation and Spinal Cord Injury Jack Judy, MD, PhD, UCLA
3:50 p.m. – 4:20 p.m.	Brain Machine Interfaces for Language Prostheses Brian Pasley, PhD, University of California, Berkeley
4:20 p.m. – 4:30 p.m.	CDRH Office of Science and Engineering Laboratories Victor Krauthamer, PhD, FDA, CDRH and OSEL
4:30 p.m. – 5:00 p.m.	Panel Discussion

Animal Research and Brain Diseases **NEW**

3:30 p.m. – 5:00 p.m.

Hosted by the American Brain Coalition and the Society for Neuroscience, with support from the Esther A. & Joseph Klingenstein Fund, Inc.

Humane and well-regulated animal research is an essential component in the development of treatments for brain diseases. Hear perspectives from a scientist, a clinician, and a patient, and engage in a thoughtful conversation on the importance of animal research. The panel will be moderated by Mark Rasenick, distinguished University of Chicago professor and American Brain Coalition Advocacy Chair, who studies the neuroscience of depression and antidepressants.

Information Exchange and Poster Presentation Reception

6:30 p.m. – 8:30 p.m.	Dinner Session: Conflict of Interest Josephine Torrente, JD, Hyman, Phelps & McNamara; Sheila Walcoff, JD, Goldbug Strategies LLC
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Co-Chairs: Mitchell Brin, MD, Allergan, Inc.; Kathleen Clarence-Smith, MD, PhD, KM Pharmaceutical Consulting

Friday, February 21, 2014

Cognition Workshop

Co-Chairs: Amy Chappell, MD, Eli Lilly & Company; Jill Rasmussen, MD, Psi-Napse

7:30 a.m. – 8:10 a.m.	Designing a Battery for Clinical Trials: The MATRICS Project for Schizophrenia	Richard Keefe, PhD, Duke University Medical Center
8:10 a.m. – 8:40 a.m.	The Problem of Cognitive Dysfunction/Decline in Epilepsy	Kimford Meador, MD, Stanford University School of Medicine
8:40 a.m. – 9:00 a.m.	Panel Discussion	

Psychiatric Pharmacogenomics: From Single DNA Nucleotides to Improved Patient Care

Chair: C. Anthony Altar, PhD, AssureRx Health, Inc.

9:15 a.m. – 9:55 a.m.	Gene Polymorphisms: How They Alter Enzymes, Transporters and CNS Response Proteins	Andrea Gaedigk, PhD, Children's Mercy Hospitals and Clinics
9:55 a.m. – 10:25 a.m.	Associations of DNA Polymorphisms with Psychiatric Drug Responses	Roy Perlis, MD, Massachusetts General Hospital

Annual Meeting Program *(subject to change)*

February 20 – 22, 2014 • Bethesda, Maryland

Friday, February 21, 2014 *continued*

10:25 a.m. – 11:00 a.m.	Using Combinatorial Pharmacogenomics to Predict and Improve Antidepressant Outcomes	C. Anthony Altar, PhD, AssuRex Health, Inc.
11:00 a.m. – 11:10 a.m.	Break	
11:10 a.m. – 11:45 a.m.	Next-Generation Sequencing Pharmacogenomics for Psychiatry and CNS Therapeutics	Richard Weinshilboum, MD, Mayo Clinic
11:45 a.m. – 12:30 p.m.	Panel Discussion/Q&A	
12:45 p.m. – 2:15 p.m.	Special Interest Topics and Luncheon	

Pipeline Session

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

2:15 p.m. – 6:00 p.m. 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, neuro-oncology, neurological infections or any other disorder affecting the central or peripheral nervous systems.

Saturday, February 22, 2014

8:30 a.m. – 9:00 a.m. ASENT Annual Business Meeting

Gene Therapy – Concurrent Session

Chair: Howard Federoff, MD, PhD, Georgetown University

9:15 a.m. – 9:35 a.m.	Overview of CNS Gene Transfer as an Evolving Neurotherapeutic Modality Howard Federoff, MD, PhD, Georgetown University
9:35 a.m. – 9:55 a.m.	AADC Gene Transfer for Movement Disorders Krystof Bankiewicz, MD, PhD, University of California, San Francisco
9:55 a.m. – 10:15 a.m.	Prosavin Gene Transfer to Parkinson's Disease Stephane Palfi, MD, Henri Mondor Hospital
10:15 a.m. – 10:35 a.m.	Using Functional Imaging to Measure Gene Transfer Function David Eidelberg, MD, Feinstein Institute for Medical Research
10:35 a.m. – 10:55 a.m.	Break
10:55 a.m. – 11:45 a.m.	Panel Discussion

9:00 am – 1:00 pm

Nuts, Bolts and Best Practices in the Conduct of Clinical Trials *(separate registration and fee required)*

Chair: Jesse Cedarbaum, MD

Course Outline

- Negotiating, and managing a site budget/contract IRBs – submitting protocols, follow-up docs, correspondence, privacy considerations, etc.
- The regulatory framework for drug development
- Managing clinical trials in your practice
- Site management logistics
- Interfacing with the Operations Team (CRO)
- Data entry and queries
- Safety reporting and SAE management
- Patient Recruitment and relations
- Interpreting clinical trial data and discussing new outcomes with patients

Faculty will include ASENT membership, CROs engaged in neurological clinical trials, NeuroNEXT clinical and data coordinating center personnel, and other clinical trial consortia (Muscle, Parkinson and Huntington Study Groups, ADCS, etc.)

Goals:

- Attendees will develop an operational understanding of clinical trial conduct from the perspective of how the pharmaceutical industry conducts clinical studies in order to enable them to conduct high-quality work as independent clinical research sites in the community.
- The organizational and regulatory frameworks for clinical drug development will be discussed. An emphasis will be placed on best practices in clinical research.

If you are a:

- Neurologist in private practice who would like to participate in multicenter trials or who would like to develop your own clinical research programs and staff
- University-based clinician interested in increasing their participation in clinical trial programs
- Graduating resident and fellow who anticipates participating in multicenter trials in your practices or would like to develop your own clinical research program
- Investigator and site personnel in the NeuroNEXT network
- Member of an advocacy group who would like to better understand the “inner workings” of the clinical drug development

Attendees completing the course will receive a Certificate of Attendance.

ASENT Registration Information (please print or type below)

Early registration deadline: Monday, January 27, 2014 ■ Pre-registration deadline: Monday, February 10, 2014

Online registration: www.asent.org

First Name: _____ Last Name: _____ Degree(s): _____

Nickname for Badge: _____

Institution/Company: _____

Address: (Please check) ☐ Home ☐ Business_____

City: _____ State: _____ Zip/Postal Code: _____ Country: _____

Business Telephone: _____ Cell Phone: _____ Email: _____

Emergency Contact Name: _____ Contact Phone: _____

Check boxes if applicable:

☐ I require special ADA accommodation. Please describe: _____

ASENT fully complies with the legal requirements of the Americans with Disabilities Act (ADA) and the rules and regulations thereof.

☐ Special dietary needs (deadline to order 2/3/14): _____

Registration Fees for Annual Meeting (includes all General and Special Sessions)	By 1/27/14	By 2/10/14	Amount
Members:			
☐ Academic/Medical Center/Consultant/Government	\$350	\$425	\$
☐ Industry	\$475	\$550	\$
Non-Members:			
☐ Academic/Medical Center/Consultant/Government	\$450	\$475	\$
☐ Industry	\$600	\$700	\$
☐ Non-Profit/Advocacy	\$175	\$195	\$
☐ Pipeline Presenter	\$150	\$150	\$
☐ Attendee with Accepted Poster Abstract	\$0	\$0	\$0
CME Certificate:			
☐ Member	\$100	\$100	\$
☐ Non-Member	\$150	\$150	\$
Nuts, Bolts and Best Practices in the Conduct of Clinical Trials:			
☐ Member	\$50	\$60	\$
☐ Non-Member	\$75	\$85	\$
☐ 2014 ASENT Membership Dues (see reverse side for more information)			\$

Note: If you register onsite, fees are \$50 higher per category

Total Fees **\$****PLEASE COMPLETE THE REVERSE SIDE OF THIS REGISTRATION FORM****Method of Payment**☐ Check enclosed: make payable to ASENT. Checks must be payable in U.S. dollars and issued by a U.S. Correspondent Bank. Each registrant is responsible for any and all bank charges. Check with your local bank before processing.☐ MasterCard ☐ Visa ☐ AMEX

Card #: _____ Expiration Date: _____

Signature: _____ Date: _____

Cancellation/Refund Policy

Refund and cancellation requests must be received in writing by Monday, February 10, 2014, to be eligible for a refund, less a \$50 administrative charge. No refunds will be issued after February 10, 2014.

Complete this form and return to:

ASENT, 342 North Main Street, Suite 301, West Hartford, CT 06117-2507 • Fax: (860) 586-7550

Questions? Email info@asent.org • Telephone (860) 586-7570

ASENT 16th Annual Meeting Registration Form, *continued*

Please tell us which sessions you plan to attend. This is particularly important for the Thursday and Friday luncheon roundtables, the Thursday night dinner session, and the Nuts and Bolts session where tickets will be required.

Wednesday, February 19, 2014

- ☐ **Welcome Reception – 6:00 p.m. – 8:00 p.m.** 

Thursday, February 20, 2014

- ☐ **Clinical Trial Measures Working Groups Luncheon – 12:00 p.m. – 1:15 p.m.** 

Select one topic:

- ☐ Incorporating the patient voice in the presence of cognitive limitation (including pediatrics)
- ☐ Assessing ADLs across indications
- ☐ Developing new instruments: starting from scratch vs. composites of existing items
- ☐ Assessment of motor function across neurological diseases
- ☐ Assessing cognition across neurological diseases (to continue with breakfast session Friday)
- ☐ Assessment of sensory function across diseases
- ☐ Assessing mood and anxiety in neurological disorders
- ☐ Issues in AD
- ☐ Issues in PD
- ☐ Issues in MS
- ☐ Issues in ALS

- ☐ **Dinner Session: Conflict of Interest – 6:30 p.m. – 8:30 p.m.**

Friday, February 21, 2014

Special Interest Topics Roundtables and Luncheon – 12:45 p.m. – 2:00 p.m.

- ☐ 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 Development
- ☐ Drug Development and Health Care Reform
- ☐ 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)

Saturday, February 22, 2014

- ☐ **Nuts, Bolts and Best Practices in the Conduct of Clinical Trials Course – 9:00 a.m. – 1:00 p.m.**
(separate registration and fee required)

JOIN NOW OR RENEW YOUR ASENT MEMBERSHIP AND TAKE ADVANTAGE OF THE DISCOUNTED REGISTRATION FEE FOR MEMBERS

Save time and money by adding your 2014 ASENT dues to your payment. ASENT's membership year runs from January to December so renew or join now and get a full year of benefits, including your subscription to ASENT's premiere quarterly journal, *Neurotherapeutics*®.

Select the right membership level for you:

- REGULAR Member:** Open to professionals with an interest in the field of neurotherapeutics research and development. \$250
- TRAINEE Member:** Open to physicians in training, doctoral candidates and postdoctoral fellows who are receiving training and experience, or competence in, neurological therapeutics. \$100
- GOVERNMENT Member:** Open to professionals who are employed full-time by a U.S. government agency or office who demonstrate an interest in the field of neurotherapeutics. \$50
- ADVOCACY Member:** Open to professionals who are employed full-time by a patient advocacy organization. \$125

See our website, www.asent.org, for more information on ASENT activities, or call 860-586-7570 for more information.

ASENT Registration Instructions

Online Registration

Enjoy the convenience and efficiency of registering on the secure ASENT website. Go to the 16th Annual Meeting page at www.asent.org for online instructions.

Mailed Registration

Complete the attached registration form (copies are acceptable) and mail to the ASENT office with payment. Completed forms and payment must be received by Monday, February 10, 2014. Please make a copy of your completed form for your records prior to mailing to:

ASENT
342 North Main Street, Suite 301
West Hartford, CT 06117-2507

Faxed Registration

Fax the completed registration form with credit card information to (860) 586-7550. Use MasterCard, Visa or American Express only. ASENT is not responsible for faxes not received due to mechanical failure or circumstances beyond our control.

Registration Deadlines

Monday, January 27, 2014 – Early-bird registration ends.

Monday, February 10, 2014 – Pre-registration ends. Please plan to register on-site after this date. No refunds will be made after this date.

Cancellation/Refund Policy

Refund and cancellation requests must be received in writing by Monday, February 10, 2014 to be eligible for a refund, less a \$50 administrative charge. No refunds will be issued after February 10, 2014.

Meeting Hotel

Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Road
North Bethesda, Maryland 20852
www.marriott.com

The Bethesda North Marriott Hotel & Conference Center is a premier hotel offering easy access to downtown Bethesda and Washington, DC. Close to many major corporations and biomedical facilities, the Marriott is within a short Metro ride to the National Institutes of Health, the Bethesda Naval Medical Center and the Food and Drug Administration. The Metro Red Line White Flint Station (www.metroopensdoors.com) is located next door to the hotel. The Marriott is 23 miles from Ronald Reagan National Airport, 25 miles from Washington Dulles International Airport, and 36 miles from Baltimore/Washington International Thurgood Marshall Airport. The hotel is also convenient to Union Station in Washington, DC, with an easy transfer to the Metro. The hotel offers a Fitness Center with pool and in-house dining.

Hotel Reservations

You are encouraged to make your reservations early as rooms may sell out prior to the deadline of Tuesday, January 28, 2014. A one-night, NON-refundable deposit representing the first night of your reservation will be charged by the hotel on Monday, February 10, 2014. ASENT's annual meeting room rates are \$144 single/double. Reserve a room online at www.asent.org or to confirm a reservation by phone, please call Marriott Central Reservations at 1.877.212.5752 and identify yourself as part of the ASENT group.

Special Needs

ASENT fully complies with the legal requirements of the Americans with Disabilities Act (ADA) and the rules and regulations thereof. Please check the box provided on the registration form and describe the needs that require special accommodation (hearing, mobility, dietary, etc.) to attend the Annual Meeting.

Registration Categories

Member

This year, ASENT is offering different categories under the Regular Member Rate. All members must be in good standing, with dues paid through December 31, 2014, at the time of registration to receive the member rate. You may renew or join ASENT with your registration to qualify for the member rate. A completed application with payment must be received with the registration.

Non-Member

Anyone who is not a member of ASENT must pay the non-member rate.

Trainee Member

This is a reduced annual meeting registration fee for ASENT Trainee Members only, with dues paid through December 31, 2014. You may join ASENT with your registration to qualify for the member rate. A completed application with payment must be received with the registration. Trainee membership is open to physicians in training, doctoral candidates and postdoctoral fellows who are receiving training and experience in neurological therapeutics.

Non-Profit/Advocacy/Government

Any employee and/or representative of a non-profit, advocacy or government agency may register in this category. Your organization must be a publicly recognized agency.

Pipeline Presenter

Anyone who has a Pipeline Session presentation accepted by the Program Committee for Friday, February 21, 2014 may register in this category for \$150.00. This is a full-meeting registration. Pipeline abstracts can be submitted on the ASENT website at <http://www.asent.org/pipeline/submitabstract.cfm>. The call for pipeline abstracts deadline is Monday, January 27, 2014 and you will be notified shortly after this date.

Attendee with New Accepted Poster Abstract

Any attendee who has a new poster presentation accepted by the Program Committee may register in this category. This is a full-meeting registration. Please see the Call of Abstracts for more information.

CME Credits

ASENT will be offering CME credits provided by The University of Vermont. The program has been approved for 12.5 Category 1 credits. Those attendees wishing to take advantage of CME credits will pay an extra fee. Certificates will be from the university.

ASENT

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ASENT 16TH ANNUAL MEETING

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& Conference Center
Bethesda, Maryland**



www.ASENT.org

- Clinical Investigators – Junior and Senior
- Investigators in Neurology and Psychiatry
- Pharmaceutical Directors in CNS
- Officials from Drug Regulatory Agencies
- Academic Investigators
- Voluntary Health Organizations

Who Should Attend?

**The ASENT 16th Annual Meeting –
Improving Patient Involvement and Care**

ASENT

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