



Sleep
Research
Society®

**THE DEVELOPMENT OF
NEW WAKE
ENHANCING
DRUGS**

APRIL 11-12, 2012

BETHESDA MARRIOTT • MARYLAND

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THE DEVELOPMENT OF NEW WAKE ENHANCING DRUGS

The Sleep Research Society's course, *The Development of New Wake Enhancing Drugs*, will be held April 11-12, 2012 at the Bethesda Marriott in Bethesda, Maryland.

COURSE OVERVIEW

This day and a half course is intended for individuals involved in any aspect of the development of wake-enhancing agents. Presentations will cover topics ranging from the neural basis of sleep and wakefulness, causes and consequences of sleepiness, current medications used to treat insomnia and the identification of potential targets for future drug development. All aspects of drug development will be presented including clinical trial designs, polysomnography, patient-reported outcomes, safety outcomes, statistical considerations and regulatory affairs. Presenters will represent all aspects of the development process including industry, academia, clinical trial sites and regulatory bodies.

TARGET AUDIENCE

- Pharmaceutical industry, including those involved in drug discovery, drug development, medical affairs and regulatory affairs
- Academics involved in research on understanding the nature of sleepiness, wake-enhancing therapeutics and clinical trial design
- Clinical trial sites involved in laboratory or non-laboratory trials
- Clinical research organizations involved in the management of wake enhancing therapeutic trials

COURSE OBJECTIVES

Upon completion of the course, participants should be able to:

- Describe the nature of sleep-wake control
- Describe the nature, epidemiology and morbidity of sleepiness
- Discuss the nature of efficacy endpoints, current and future, in wake enhancing therapies
- Discuss the nature of safety endpoints in the development of wake enhancing agents
- Define issues involved in the design and analysis of stimulant trials
- Define the regulatory requirements for the development of wake-enhancing agents

Continuing Medical Education (CME) Credit for Physicians: The Development of New Wake Enhancing Drugs course has been planned and implemented in accordance with the guidelines of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the American Academy of Sleep Medicine and the Sleep Research Society. The AASM is accredited by the ACCME to provide continuing medical education for physicians.

The AASM designates this course as a live activity for 11.25 *AMA PRA Category 1 Credit(s)*[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.

GENERAL INFORMATION

LOCATION & ROOM RESERVATIONS

The Development of New Wake Enhancing Drugs course presented by the Sleep Research Society will be held at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD, 20814.

A block of guest rooms has been reserved at the Bethesda Marriot. Space is limited, so please make reservations well in advance. The room rate at the hotel is \$199.00 per night plus tax and is only valid until March 12, 2012, or until the room block sells out.

Reservations must be made by individual attendees directly with the hotel's reservation department via phone at (800) 266-9432 or online at www.sleepresearchsociety.org/course2012. To receive the special group rate, you must identify yourself as a member of the Sleep Research Society group block.

CHECK-IN TIME: 4:00 PM

CHECK-OUT TIME: 12:00 PM

HOTEL POLICIES

The Bethesda Marriott is smoke-free in all areas of the hotel. For more information about the hotel and its amenities, visit <http://www.marriott.com> or call (301) 897-9400.

MEALS

Breakfast will be served daily during the course. Lunch will be served on the first day of the course. Meal functions are available for registered attendees only. Guests of attendees will not be accommodated during meal functions. All other meals are the responsibility of attendees.

TRANSPORTATION

Book your airfare with our official travel agent: Corporate Travel Solutions/American Express. Call toll-free (800) 526-4540, Monday-Friday from 8:00 am to 5:00 pm Central Time, or e-mail res@ctsinc.com and reference the Sleep Research Society.

The Bethesda Marriott is 21 miles from Ronald Reagan Washington National Airport (DCA), 25 miles from Dulles International Airport (IAD) and 35 miles from Baltimore/Washington International Thurgood Marshall Airport (BWI). Taxi and bus service is available from all three airports. Taxi service (one way) averages as follows: DCA \$45; IAD \$50; BWI \$60. Subway service is available from Ronald Reagan Washington National Airport (DCA) with the closest stop 1.5 miles from the hotel.

Hotel shuttle service is available to downtown Bethesda, the subway and other nearby points of interest but is not available to/from the airport.

RECORDING

Photographing and/or recording of any kind of sessions and speakers is strictly prohibited. Violation of this policy could result in the confiscation of film, memory card, and/or recording device. Repeated violations of the policy will result in removal from the course without refund.

PRELIMINARY SCHEDULE AND TOPICS

Wednesday, April 11, 2012

SESSION 1: BASIC SCIENCE

- 8:00 a.m. Registration and Continental Breakfast
- 9:00 a.m. **Neural Control of Sleep and Wakefulness**
Thomas Scammell, MD, Harvard Medical School
- 9:45 a.m. **Classic Mechanisms: Dopamine**
George Uhl, MD, PhD, Johns Hopkins University
- 10:30 a.m. **Break**
- 10:45 a.m. **Classic Mechanisms: Norepinephrine**
Gary Aston-Jones, PhD, Medical University of South Carolina
- 11:30 a.m. **New Mechanisms: Histamine and Orexin**
John Renger, PhD, Merck Pharmaceuticals
- 12:15 p.m. **Lunch**

SESSION 2: CLINICAL SCIENCE

- 1:15 p.m. **Prevalence and Consequences of Sleepiness**
Thomas Roth, PhD Henry Ford Hospital
- 2:00 p.m. **Sleepiness due to Sleep and Circadian Disorders**
Phyllis Zee, MD, PhD, Northwestern University
- 2:45 p.m. **Break**
- 3:00 p.m. **Sleepiness due to Psychiatric Disorders**
Andrew Krystal, MD, Duke University Medical School
- 3:45 p.m. **Sleepiness due to Medical Disorders**
Meir Kryger, MD, University of Connecticut
- 4:30 p.m. **Panel Discussion**

Thursday, April 12, 2012

SESSION 3: DEVELOPMENT OF WAKE ENHANCING DRUGS

- 7:00 a.m. Continental Breakfast
- 8:00 a.m. **Broad Indication vs. Disease Specific Approaches**
Russell Katz, MD, Director, Division of Neurology Product, Food & Drug Administration, Center for Drug Evaluation and Research
- 8:45 a.m. **Critical Elements of Sleepiness in Clinical Trials**
Ronald Farkas, MD, PhD, Clinical Team Leader, Division of Neurology Products, Food and Drug Administration
- 9:30 a.m. **Outcome Measures**
Thomas Roth, PhD, Henry Ford Hospital
- 10:15 a.m. **Break**
- 10:30 a.m. **Evaluation of Abuse Liability of Wake Enhancing Drugs**
Chris-Ellyn Johanson, PhD, Department of Psychiatry, Wayne State University School of Medicine
- 11:15 a.m. **Evaluation of Cardiovascular Effects**
Victoria Vetter, MD, MPH, Children's Hospital of Philadelphia
- 12:00 p.m. **Panel Discussion**
- 12:45 p.m. **Adjourn**

REGISTRATION FORM

The Development of Wake Enhancing Drugs • April 11-12, 2012

REGISTRATION INFORMATION: Please type or print clearly

Last Name: _____

First Name: _____ Degree: _____

Company: _____

Address 1: _____

Address 2: _____

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

Country: _____ Phone: (____) _____ – _____

Fax: (____) _____ – _____ E-mail: _____
(e-mail required to receive confirmation)

Special Needs/Accommodations: _____

SPECIALTY:

- | | | |
|---|--|---|
| <input type="checkbox"/> Aging | <input type="checkbox"/> Alcoholism and Drug Abuse | <input type="checkbox"/> Biological Rhythms |
| <input type="checkbox"/> Endocrinology | <input type="checkbox"/> Epidemiology | <input type="checkbox"/> Excessive Daytime Sleepiness |
| <input type="checkbox"/> General Physiology | <input type="checkbox"/> Genetics | <input type="checkbox"/> Molecular Biology |
| <input type="checkbox"/> Neurophysiology | <input type="checkbox"/> Pharmacology | <input type="checkbox"/> Phylogeny |

Please Check One:

- Yes, I give my permission to include my contact information on an attendee list to be distributed to course attendees.
- No, I do not give my permission to include my contact information on an attendee list to be distributed to course attendees.

MEMBERSHIP CLASSIFICATION:

Receive immediate membership savings by joining the SRS today! Please visit <http://www.sleepresearchsociety.org/Benefits.aspx> for more information regarding membership.

- | | |
|---|---|
| <input type="checkbox"/> Regular Members – \$180 | <input type="checkbox"/> Postdoctoral Fellow Members – \$90 |
| <input type="checkbox"/> Associate Members – \$90 | <input type="checkbox"/> Predoctoral Student – \$45 |
| | <input type="checkbox"/> Undergraduate Student – \$45 |

REGISTRATION CATEGORY: Please Check One

Pre-registration (on or before March 12, 2012)	Registration (after March 12, 2012)
<input type="checkbox"/> SRS or AASM Member \$1,900	<input type="checkbox"/> SRS or AASM Member \$2,100
<input type="checkbox"/> Nonmember \$2,000	<input type="checkbox"/> Nonmember \$2,200

MEMBERS:

To register as a member, the registrant must currently be an individual member of the Sleep Research Society (SRS) or American Academy of Sleep Medicine (AASM). If the SRS is unable to confirm that the individual is a member, the SRS will register the individual as a nonmember at the prevailing fees.

NONMEMBERS:

If you are not a member of the SRS and would like to become a member, please complete the membership classification information above. For more information regarding SRS membership, call the SRS Membership Department at (630) 737-9702.

REGISTRATION FORM *Continued*

REGISTRATION DISCLAIMER:

Registration is limited. Please register early. Confirmation letters will be sent via e-mail within one week of receipt of registration form and payment. All attendees must pre-register; on-site registration will not be accepted.

The SRS will not be held liable if an individual purchases an airline ticket before receiving confirmation of registration for this course.

METHOD OF PAYMENT: *Please Check One:*

- Please make checks payable to the SRS (U.S. funds drawn on a U.S. bank)
- For payment by credit card (Visa/Master Card/American Express):

Card#: _____

Exp. Date: _____ / _____ Validation Code*: _____

Card Holders Name: _____

Mailing Address: _____

Signature: _____

Date: ____ / ____ / ____

**For a Visa or Master Card, the validation code is the last 3 numbers in the signature box. For an American Express, the validation code is the 4 numbers above the credit card number.*

3 WAYS TO REGISTER



ONLINE *(credit card only)*
www.sleepresearchsociety.org



FAX *(credit card only)*
630.737.9789



MAIL *(check or credit card)*
Sleep Research Society
Attn: Meeting Department
2510 North Frontage Road
Darien, IL 60561

EXPERIENCE THE BEAUTIFUL BETHESDA!



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NATIONAL PARKS ATTRACTIONS SHOPPING RESTAURANTS

Bethesda, Maryland is a short trip to our Nation's Capitol where course attendees can visit numerous National Monuments, National Parks, the White House and U.S. Capitol building. In 2012, Washington, D.C. will be celebrating the Centennial of its world-renowned Cherry Blossom Festival. This is a once in a lifetime side trip course attendees won't want to miss.

Downtown Bethesda is home to numerous fashion boutiques, home design shops, art galleries, salons, and community services. With nearly 700 retailers and businesses in the downtown, Bethesda is a destination for any shopping need.

Downtown Bethesda's restaurant community showcases diverse cuisine from around the world. Whether you're looking for a deli, bakery, sushi or fine American cuisine, Bethesda's nearly 200 restaurants are sure to deliver a delectable dining experience.

For more information on Bethesda attractions visit: www.bethesda.org

QUESTIONS?

For more information or questions regarding the course, please contact:

Sleep Research Society at 2510 North Frontage Road, Darien, IL 60561

Phone: (630) 737-9702 • Fax: (630) 737-9789

E-mail: ncekosh@srsnet.org • Website: www.sleepresearchsociety.org

**Photos used are from the Maryland Office of Tourism -www.visitmaryland.org*



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