OPENING KEYNOTE ADDRESS: History of Specific Immunotherapy (SIT) and Allergen Standardization

Harold S. Nelson, MD
Professor, Department of Medicine,
National Jewish Medical and Research Center;
Professor of Medicine, University of Colorado Health Sciences Center

CLOSING KEYNOTE ADDRESS:
N. Franklin Adkinson, Jr., MD
Professor of Medicine and Program Director
Division of Allergy & Clinical Immunology
Johns Hopkins Medicine
The Johns Hopkins Hospital

PROGRAM CHAIRPERSONS
Stefan Vieths
Paul-Ehrlich-Institut, Langen, Germany
Jay E. Slater
US Food and Drug Administration, Rockville, MD, USA
Ronald L. Rabin
US Food and Drug Administration, Rockville, MD, USA

SCIENTIFIC COMMITTEE
Thomas Bieber
Bonn, Germany
Wesley Burks
Durham, North Carolina, USA
Fatima Ferreira
Salzburg, Austria
Anthony Frew
Brighton, United Kingdom
Marcel Hoefnagel
Bilthoven, The Netherlands
Henrik Jacobi
Hørsholm, Denmark

We are pleased to host the 13th IPES in Washington, DC.
This meeting will provide a forum to focus on the scientific and regulatory issues regarding the use of allergenic products to diagnosis and treat allergic diseases, as well as the impact of these issues on specialty practice and in the clinical setting. Key stakeholders including regulators, scientists and industry lead experts will join in this seminar continuum of discussion to: 1) provide an understanding of the modifications to immunotherapy which will decrease adverse events and still be efficacious; 2) address current changes in the use of oral immunotherapy and its impact on treatment of food allergies; and 3) focus on the new strategies to measure effectiveness of immunotherapy.

WHO SHOULD ATTEND
Professionals, researchers, academia, regulatory aff airs, contract research organizations, and clinicians focused in standardization, diagnosis and clinical immunology for allergen products.

Supported by
EAACI – European Academy of Allergy and Clinical Immunology
NIAID – National Institute of Allergy and Infectious Diseases

Co-sponsored by
Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA
Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China
CONTINUING EDUCATION CREDITS

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Postgraduate Institute for Medicine and Drug Information Association.

The Postgraduate Institute for Medicine is accredited by the ACCME to provide continuing medical education for physicians.

Postgraduate Institute for Medicine designates this educational activity for a maximum of 17.5 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

The Drug Information Association (DIA) has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102. (703) 506-3275.

DIA is authorized by IACET to offer 1.8 CEUs for this program.

If you would like to receive a statement of credit, you must attend the program and/or tutorial, scan your name badge at the DIA registration desk each day of the program/tutorial, and complete the on-line credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on October 3, 2011.

Disclosure Policy

It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

LEARNING OBJECTIVES

At the conclusion of this meeting, participants should be able to:

• Explain the basis for the standardization and characterization of natural allergen extracts used in allergen immunotherapy
• Discuss the potential for future use of recombinant allergens or modified natural allergens in allergen immunotherapy
• Describe the biological mechanisms of successful allergen immunotherapy
• Recognize the proper uses of subcutaneous allergen immunotherapy
• Discuss the potential for future use of alternative methods of allergen immunotherapy, such as sublingual immunotherapy and adjuvanted immunotherapy
DAY 1 | WEDNESDAY, SEPTEMBER 14, 2011

15:00-19:30  PRE-CONFERENCE REGISTRATION

19:30-20:30  OPENING KEYNOTE ADDRESS
History of Specific Immunotherapy (SIT) and Allergen Standardization
Harold Nelson

20:30-22:00  NETWORKING RECEPTION AND DINNER

DAY 2 | THURSDAY, SEPTEMBER 15, 2011

7:00-8:30  CONTINENTAL BREAKFAST AND REGISTRATION

8:30-9:55  SESSION 1
Legal Aspects of the Regulation of Allergen Products
Session Chair:
Stefan Vieths
Session Co-chair:
Harold Nelson

8:30-8:50  Legal Status and Regulation of Allergen Products in the US
Ronald L. Rabin

8:50-9:10  Regulation of Allergen Products in Europe (Including NPPs)
Carlo Pini

9:10-9:25  Current Status and Regulation of Allergen Products in China
Yin Jia

9:25-9:40  Current Status and Regulation of Allergen Products in Mexico
Desiree Larenas-Linnemann

9:40-9:55  Current Status and Regulation of Allergen Products in Canada
Nancy Green

9:55-9:55  Current and Future Challenges for Allergen Manufacturers
Lars Jacobsen

9:55-10:10  REFRESHMENT BREAK

10:10-11:50  SESSION 2
Standardization and Characterization of Natural Allergen Products
Session Chair:
Fatima Ferreira
Session Co-chair:
Marcel Hoefnagel

10:10-10:35  Update on the FDA/CBER Allergen Standardization Program
Jay Slater

10:35-11:00  Validation of Major Allergen References and ELISAs – Current State of the BSP 090 Project
Susanne Kaul

11:00-11:25  Molecular and Functional Characterization of Natural Allergen Extracts
Thierry Batard

11:25-11:50  The Potential of Mass Spectrometry as Novel Tool in Standardization of Natural Allergen Extracts
Andreas Reuter

11:50-13:00  LUNCHEON AND NETWORKING OPPORTUNITY

13:00-17:10  SESSION 3
Methods in Product and Study Design of Effective Allergen Products for Therapy
Session Chair:
Stephen Durham
Session Co-chair:
Frédéric de Blay

13:00-13:25  Quality by Design
Suzanne M. Sensabaugh

13:25-13:50  Primary Endpoints, Validation, Clinical Efficacy of SIT Trials
Peter Creticos

13:50-14:15  Specific Aspects of SIT Trials in Children
Robert Wood

14:15-14:40  Efficacy Testing of Allergen Mixtures
Jörg Kleine-Tebbe

14:40-15:05  Surrogates and Biomarkers for Determining Efficacy
Stephen Durham
15:05-15:30  
Multiplex IgE Testing as Tool to Define Study Populations  
Robert Hamilton

15:30-15:55  
REFRESHMENT BREAK

15:55-17:10  
SESSION 3 (Continued)

   15:55-16:20  
Pollen Count Variation Within and Among Regions of North America  
Michael Nelson

   16:20-16:45  
Environmental Exposure Chamber in SIT Clinical Trials  
Anne Ellis

   16:45-17:10  
Statistical Analysis for Demonstrating Efficacy in SIT Trials  
Tammy Massie

DAY 3 | FRIDAY, SEPTEMBER 16, 2011

7:00-8:15  
CONTINENTAL BREAKFAST

8:15-8:30  
HIGHLIGHTS FROM SEPTEMBER 15

8:30-9:45  
SESSION 4  
Standardization and Characterization of Modified and Recombinant Allergen Products  
SESSION CHAIR:  
Jay Slater  
SESSION CO-CHAIR:  
Geoffrey Mueller

   8:30-8:55  
Physicochemical Characterization of Allergoids and Adsorbed Allergoids  
Dion Luykx

   8:55-9:20  
Physicochemical Characterization of Recombinant Allergens and Hypoallergenic Variants  
Martin Himly

   9:20-9:45  
Antibody-based Techniques for Characterization of Allergoids and for Stability Studies of Alum Adsorbed Drug Product  
Erica Kerkvliet

9:45-10:00  
REFRESHMENT BREAK

10:00-12:15  
SESSION 5  
Immunological Mechanisms of Allergy Immunotherapy  
SESSION CHAIR:  
Rudolf Valenta  
SESSION CO-CHAIR:  
Calman Prussin

   10:00-10:35  
An Overview of Proposed Mechanisms of SIT  
Thomas Platts-Mills

   10:35-11:00  
Mechanisms of Immunotherapy Specific to the Sublingual or Oral Route  
Thomas Bieber

   11:00-11:25  
Oral Immunotherapy for Food Allergy  
Wesley Burks

   11:25-11:50  
Th2 Heterogeneity: Do Specific Th2 Subpopulations Alternatively Drive Allergy vs. Tolerance  
Calman Prussin

   11:50-12:15  
Use of Trichuris Suis Ova (TSO) Therapy for the Treatment of Allergy  
Peter Bager

12:15-13:15  
LUNCHEON AND NETWORKING OPPORTUNITY

13:15-15:20  
SESSION 6  
Immunotherapy with Purified Allergen Components  
SESSION CHAIR:  
Ronald van Ree  
SESSION CO-CHAIR:  
Barbara Bohle

   13:15-13:40  
Current Status of Subcutaneous and Sublingual Immunotherapy with Recombinant Allergens  
Marek Jutel

   13:40-14:05  
Recombinant Allergens for SIT of Mite Allergy  
Andreas Nandy

   14:05-14:30  
Recombinant Allergens for SIT of Cat Allergy  
Kare Meno
14:30-14:55  
Novel Approaches of Immunotherapy for Food Allergy  
Ronald van Ree

14:55-15:20  
Targeting Antibody Receptors as an Approach Towards Immunotherapy  
Judith Woodfolk

15:20-15:35  REFRESHMENT BREAK

15:35-16:50  SESSION 7  
Extrinsic Adjuvants in the Use of Allergen Immunotherapy  
SESSION CHAIR:  
Christopher Karp  
SESSION CO-CHAIR:  
Jörg Kleine-Tebbe

15:35-16:00  
Aluminium Hydroxide: Mechanism of Action and Safety Assessment  
Norman Baylor

16:00-16:25  
Toll-like Receptor Ligands as Adjuvants  
Barbara Bohle

16:25-16:50  
Adjuvants and Vector Systems for the Sublingual Route  
Philippe Moingeon

DAY 4 | SATURDAY, SEPTEMBER 17, 2011

7:30-8:30  CONTINENTAL BREAKFAST

8:45-9:00  HIGHLIGHTS FROM SEPTEMBER 16

9:00-9:50  SESSION 8  
Immunomodulatory Properties of Allergens  
SESSION CHAIR:  
Robert Esch  
SESSION CO-CHAIR:  
N. Franklin Adkinson

9:00-9:25  
Inherent Adjuvant Biological Properties of Natural Allergens  
Christopher Karp

9:25-9:50  
Inherent Adjuvant Structural Properties of Natural Allergens  
Geoffrey Mueller

9:50-10:05  REFRESHMENT BREAK

10:05-12:20  SESSION 9  
State-of-the-Art of Immunotherapy in Different Allergic Diseases  
SESSION CHAIR:  
Marek Jutel  
SESSION CO-CHAIR:  
Ronald L. Rabin

10:05-10:40  
SLIT—Overview of American Experience  
Paul Greenberger

10:40-11:05  
SLIT Clinical Trials for Allergic Rhinitis in the United States  
Robert Esch

11:05-11:30  
The Role of SCIT and SLIT in Rhinoconjunctivitis Across Europe  
Anthony Frew

11:30-11:55  
SIT for the Treatment of Atopic Dermatitis  
Thomas Werfel

11:55-12:20  
SIT for the Treatment of Asthma  
N. Franklin Adkinson

12:20-12:30  CLOSING REMARKS  
Stefan Vieths

12:30  CONFERENCE ADJOURNED

Receive Deep Discounts on ALL DIA Educational Offerings!  
For $140 you can take advantage of all the benefits of membership:
- Subscription to the Drug Information Journal, DIA’s peer-reviewed, scholarly journal
- Subscription to the Global Forum
- Subscription to ePublications, including timely FDA and regulatory updates delivered to your inbox
- Subscription to the Contract Service Organization Directory
- Member registration discounts on all conferences and Annual Meetings, training courses, and webinars
- Access to our comprehensive online career center
- Career development and networking opportunities through DIA Connex and as a member of Special Interest Area Communities (SIACs)
- Members-only searchable index of DIA articles
- Opportunities to join committees and to volunteer as a speaker, session chair, or author
- Discounts on industry products and services

For more information, visit www.diahome.org and click on Membership.
DIA is a financially independent nonprofit, global, multidisciplinary association that provides a neutral forum for sharing information that optimizes the development and lifecycle management of biopharmaceutical and related products.

13th International Paul-Ehrlich-Seminar
Allergen Products for Diagnosis and Therapy: Regulation and Science
Event #11018 • September 14-17, 2011
Hyatt Regency Washington on Capitol Hill, Washington, DC, USA

Contact Information
Contact Constance Burnett, Program Developer, at the DIA office by telephone 215.293.5800 fax 215.442.6199 or email ConstanceBurnett@diahome.org or JoAnn Boileau, Program Manager, telephone 215.442.6175 fax 215.442.6199 or email JoAnn.Boileau@diahome.org

Registration Fee — All Attendees
Registration fee includes refreshment breaks, luncheons, reception, dinner*, and will be accepted by mail, fax, or online.

Fee (includes dinner for all registered attendees) US $750 □
Companion Dinner Fee* TBD □

Join DIA now to save on future events and to receive all the benefits of membership www.diahome.org/Membership US $140 □


PAYMENT OPTIONS: Register online at www.diahome.org or check payment method.

☐ CREDIT CARD number may be faxed to: +1.215.442.6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX Exp Date

☐ CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

☐ BANK TRANSFER When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event ID # must be included on the transfer document to ensure payment to your account.

TRAVEL AND HOTEL The most convenient airport is Ronald Reagan National Airport and attendees should make airline reservations as early as possible. The Hyatt Regency Washington on Capitol Hill Hotel is holding a block of rooms at the reduced rate below until August 24, 2011, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $269 Double $269

Attendees must make their own hotel reservations. Contact the Hyatt Regency Washington on Capitol Hill Hotel by telephone at +1.800.243.2546 and mention the DIA event. The hotel is located at 400 New Jersey Avenue, NW, Washington, DC 20001, USA. http://www.washingtonregency.hyatt.com/capitolhill

CANCELLATION POLICY: On or before SEPTEMBER 7, 2011
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for canceling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

Please check the applicable category:
☐ Academia ☐ Government ☐ Industry ☐ CSO ☐ Student
Call for registration information

Last Name
First Name M.I.
Degrees ☐ Dr. ☐ Mr. ☐ Ms.
Job Title
Company
Address (As required for postal delivery to your location) Mail Stop
City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

Please check www.diahome.org for updated CE accreditation and program details.