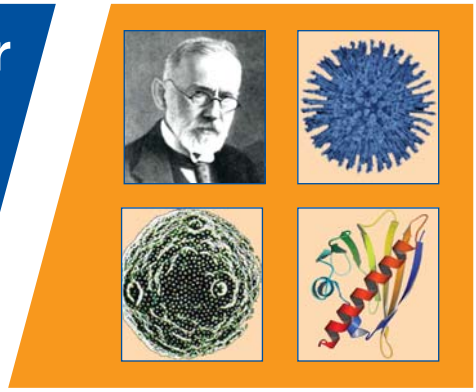
13th International Paul-Ehrlich-Seminar Allergen Products for Diagnosis and Therapy: Regulation and Science

September 14-17, 2011
Hyatt Regency Washington on Capitol Hill
Washington, DC, USA



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:

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PROGRAM CHAIRPERSONS

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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 affairs, 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

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(continued from previous page)

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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.

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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

9:40-9:55

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:

Fréderic 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

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

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

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

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 ❑
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❑ **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 I.D. # 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/capitol hill

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 cancelling 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.

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