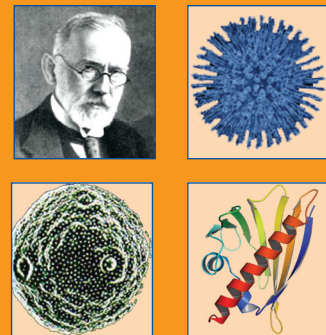


# 13<sup>th</sup> International Paul-Ehrlich-Seminar Allergen Products for Diagnosis and Therapy: Regulation and Science

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:



**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

### **Wesley Burks**

Durham, North Carolina, USA

### **Fatima Ferreira**

Salzburg, Austria

### **Anthony Frew**

Brighton, United Kingdom

### **Marcel Hoefnagel**

Bilthoven, The Netherlands

### **Henrik Jacobi**

Hørsholm, Denmark

*continued on next page*

## 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

## DRUG INFORMATION ASSOCIATION

800 Enterprise Road, Suite 200  
Horsham, PA 19044-3595 USA

## 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

## Co-sponsored by



Paul-Ehrlich-Institut



**SCIENTIFIC COMMITTEE***(continued from previous page)***Jörg Kleine-Tebbe**

Berlin, Germany

**Philippe Moingeon**

Antony-Cedex, France

**Carlo Pini**

Rome, Italy

**Calman Prussin**

Bethesda, MD, USA

**Rudolf Valenta**

Vienna, Austria

**Ronald van Ree**

Amsterdam, The Netherlands

**LOCAL ORGANIZATION COMMITTEE****Judith Badoo**

US Food and Drug Administration, Rockville, MD, USA

**JoAnn Boileau**

DIA, Horsham, PA, USA

**Constance Burnett**

DIA, Horsham, PA, USA

**Regina Gutberlet**

Paul-Ehrlich-Institut, Langen, Germany

**Leslie Haynes**

US Food and Drug Administration, Rockville, MD, USA

**Sandra Menzies**

US Food and Drug Administration, Rockville, MD, USA

**Ronald L. Rabin**

US Food and Drug Administration, Rockville MD, USA

**Jay E. Slater**

US Food and Drug Administration, Rockville MD, USA

**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)*<sup>™</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.

To receive a certificate of credit you must complete both of the evaluation forms, both DIA and PIM.



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](http://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

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice.

Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

## DAY 1 | WEDNESDAY, SEPTEMBER 14, 2011

16:30-19:30 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

---

## DAY 2 | THURSDAY, SEPTEMBER 15, 2011

7:30-8:30 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  
**Peter Briza**

11:50-13:05 SESSION 3 - PART ONE

**Methods in Product and Study Design of Effective Allergen Products for Therapy**

SESSION CHAIR:

**Stephen Durham**

SESSION CO-CHAIR:

**Frédéric de Blay**

11:50-12:15

Quality by Design  
**Suzanne M. Sensabaugh**

12:15-12:40

Primary Endpoints, Validation, Clinical Efficacy of SIT Trials  
**Peter Creticos**

12:40-13:05

Specific Aspects of SIT Trials in Children  
**Robert Wood**

13:05-14:15 LUNCHEON AND NETWORKING OPPORTUNITY

---

14:15-15:30 SESSION 3 - PART TWO

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 CO-CHAIR:

**Phillippe Moingeon**

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

**Jean Pierre Allam**

11:00-11:25

Oral Immunotherapy for Food Allergy

**Wesley Burks**

11:25-11:50

Th2 Heterogeneity: Do Distinct Th2 Subpopulations Drive Different Allergic Disease Processes?

**Calman Prussin**

11:50-12:15

Use of Trichuris Suis Ova (TSO) Therapy for the Treatment of Allergy

**Peter Bager**

12:15-13:05 SESSION 6 - PART ONE

**Immunotherapy with Purified Allergen Components**

SESSION CHAIR:

**Ronald van Ree**

SESSION CO-CHAIR:

**Barbara Bohle**

12:15-12:40

Current Status of Subcutaneous and Sublingual Immunotherapy with Recombinant Allergens

**Marek Jutel**

12:40-13:05

Recombinant Allergens for SIT of Mite Allergy

**Andreas Nandy**

13:05-14:05 LUNCHEON AND NETWORKING OPPORTUNITY

14:05-15:20 SESSION 6 - PART TWO

14:05-14:30

Recombinant Allergens for SIT of Cat Allergy

**Kåre 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**

19:00-22:00 DINNER

## 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

Structural Characterization of Allergens Suggest Hypotheses for Immune System Interactions  
**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  
**Jean Pierre Allam**

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](http://www.diahome.org) and click on Membership.

**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](mailto:ConstanceBurnett@diahome.org) or JoAnn Boileau, Program Manager, telephone 215.442.6175 fax 215.442.6199 or email [JoAnn.Boileau@diahome.org](mailto: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** US \$80

Join DIA now to save on future events and to receive all the benefits of membership **MEMBERSHIP** US \$140   
[www.diahome.org/Membership](http://www.diahome.org/Membership)

**PAYMENT OPTIONS:** Register online at [www.diahome.org](http://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 \_\_\_\_\_

Card # \_\_\_\_\_

Name (printed) \_\_\_\_\_

Signature \_\_\_\_\_

**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 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 no longer has sleeping rooms available. Two possible alternatives are:

Washington Court Hotel  
 525 New Jersey Avenue NW  
 Washington DC 20001  
 1-800-763-0487

The Liaison Capitol Hill  
 415 New Jersey Avenue NW  
 Washington DC 20001  
 1-866-246-2203

Attendees must make their own hotel reservations. Please feel free to contact one of the above mentioned hotels for availability

**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.

**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](http://www.diahome.org) for updated CE accreditation and program details.**