



// 15TH INTERNATIONAL
PAUL-EHRLICH-SEMINAR //



Allergen Products for
Diagnosis and Therapy:
Regulation and Science

September 6-9, 2017
Bad Homburg
Germany

PROGRAMME

>> www.pei.de/ipes2017
Email: PEI-Seminar@pei.de

COMMITTEE

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Vera Mahler Langen, German

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Stefan Vieths & Vera Mahler, Chair Persons;
Regina Gutberlet, Seminar Secretary;
Birgit Ahrens, Detlef Bartel, Andreas Bonertz,
Thomas Holzhauser, Susanne Kaul, Stephan Scheurer,
Frank Schuler, Lothar Vogel

SEMINAR SECRETARY

Regina Gutberlet
Paul-Ehrlich-Institut, Paul-Ehrlich-Straße 51-59
63225 Langen, Germany
Phone +49 6103 77 60 01 Mobile +49 177 266 39 25
Email PEI-Seminar@pei.de

// 15TH INTERNATIONAL PAUL-EHRLICH-SEMINAR //

WELCOME

to the 15th International Paul-Ehrlich-Seminar in
Bad Homburg, Germany, Maritim Hotel

Time flies when you are having fun! It has been already three years since the last IPES was held: three years during which exciting new developments have occurred in regulation and science concerning allergen products for diagnosis and therapy! We proudly present this year's programme and are very pleased that so many exquisite experts have followed our invitation to Bad Homburg to present and discuss these novel insights and trends in regulation, science, clinical research and manufacturing of allergen products.

The 15th IPES will proceed to serve as a forum for interdisciplinary exchange of thoughts, for taking the broader view and add new impetus to complex topics in the world of allergens and regulatory affairs.

At this point, we would like to thank our colleagues from the FDA, EAACI and DGAKI for their valuable support and ongoing sound cooperation.

On behalf of the Scientific Committee and the Local Organizing Committee of the 15th International Paul-Ehrlich-Seminar we wish you a fruitful and informative meeting and a pleasant stay in Bad Homburg.

With best regards,

Stefan Vieths

Vera Mahler

GENERAL INFORMATION

REGISTRATION AND INFORMATION DESK

OPENING HOURS

September 6, 2017 11:00 – 18:00

September 7, 2017 08:00 – 19:00

September 8, 2017 08:00 – 17:45

September 9, 2017 08:00 – 15:00

PRESENTATION MEDIA

Please bring your presentation files to the Conference Office before the morning or afternoon session, at latest. You may also send your data via e-mail to: PEI-Seminar@pei.de

SOCIAL PROGRAMME

WEDNESDAY SEPTEMBER 6, 2017

19:30

Opening and Welcome Reception with Dinner at Maritim Hotel, Bad Homburg

THURSDAY, SEPTEMBER 7, 2017

18.30 Leisure Time

Suggestions will be offered by our staff on request

FRIDAY, SEPTEMBER 8, 2017

18:45

Social Event at Alter Güterbahnhof, Bad Homburg

Throughout the conference and all contributions product neutrality is ensured. Potential conflicts of interest of the scientific committee, local organizers and speakers will be declared on the first slide of the speakers' presentations and a handout distributed on site.

Transferable CME credit will be assigned by the Hessian Regional Medical Board.



WEDNESDAY, SEPTEMBER 6, 2017

13:00 – 15:00

Expert Session on Regulatory Requirements for Mass Spectrometric Data (Pre-registration required)

Chairs: Andreas Reuter, Langen, Germany;
Ronald van Ree, Amsterdam, The Netherlands

- Andreas Reuter - Quality Control and Standardization of Allergen Products with Mass Spectrometry. Introductory lecture.
 - Jay Slater - Standardization of Allergen Products with Mass Spectrometry in the USA
 - Henrik Næsted - Quality Control of Complex Allergen Products
 - Martin Himly - Quality Control of Purified Allergens. Detailed Mass Spectrometric Characterization of Recombinant Allergens as Reference Preparations
-

parallel: 13:00 – 15:00

IUIS Allergen Standardization Subcommittee

Chairs: Stefan Vieths, Langen, Germany;
Martin Chapman, Charlottesville, USA

15:00 – 15:30 Coffee Break

ALLERGY DIAGNOSTICS

Chairs: Christoph Willers and Thomas Werfel

15:30 – 15:50

Opening Lecture:

In Vivo Diagnostics for Type I and Type IV Allergies – Current Status and Unmet Needs

Vera Mahler, Langen, Germany

15:50 – 16:10

State of the Art and New Developments of Haptens for Diagnosis of Type IV Allergies

Wolfgang Uter, Erlangen, Germany

16:10 – 16:30

Future Availability of Test Allergens – A Manufacturer's Perspective

Michael Bauer, Reinbek, Germany

16:30 – 16:50

How to Authorize New in Vivo Test Allergens?

Susanne Kaul, Langen, Germany

16:50 – 17:10

In Vivo Versus in Vitro Testing (EAACI Position)

Lars K. Poulsen, Copenhagen, Denmark

17:10 – 17:30

Relevance of Component Resolved Testing for AIT –
Current Evidence

Giovanni Passalacqua, Genova, Italy

17:30 – 17:45

General Discussion

17:45 – 18:15

Opening Lecture:

History and Future of Allergen Standardization

Thomas A. Platts-Mills, Charlottesville, USA

From 19:30 Opening and Welcome Reception with Dinner



THURSDAY, SEPTEMBER 7, 2017

**REGULATION OF ALLERGEN PRODUCTS –
STATE OF THE ART AND NEW DEVELOPMENTS**

Chairs: Thomas Bieber and Vera Mahler

09:00 – 09:10

Welcome Address

Stefan Vieths and Vera Mahler, Langen, Germany

09:10 – 09:30

Regulatory Tools for Accelerated Market Access
of Biomedicines

Hans-Georg Eichler, London, United Kingdom

09:30 – 09:50

Regulation of Allergen Products –
A Global Perspective

Andreas Bonertz, Langen, Germany

09:50 – 10:10

Regulation of Allergen Products in the US –
Current Status and Future Developments

Jay Slater, Silver Spring, USA

10:10 – 10:30

State of the Art and Recent Developments of
Allergen Regulation in France

Frédéric de Blay, Strasbourg, France

10:30 – 10:50

Update on the TAV Process in Germany

Stefan Vieths, Langen, Germany

10:50 – 11:10 Coffee Break

11:10 – 11:30

Recent Regulatory Developments at EMA
and HMA Level

Marcel Hoefnagel, Utrecht, The Netherlands

11:30 – 11:50

Experience of a European Allergen Manufacturer
in China

Anne Lützhøft, Hørsholm, Denmark

11:50 – 12:00

General Discussion

CHARACTERIZATION AND CONTROL OF ALLERGEN PRODUCTS

Chairs: Carlo Pini and Jay Slater

12:00 – 12:20

Process and Requirements for Revision of
Ph. Eur. Monographs

Karl-Heinz Buchheit, Strasbourg, France

12:20 – 12:40

Physicochemical and Immunological
Characterization of Grass Allergoids

Matthew Heath, Worthing, United Kingdom

12:60 – 13:00

The Use of Allergen-Specific Monoclonal
Antibodies for the Detection of Relevant Allergens
in Mite Allergoids

Gerald Reese, Reinbek, Germany

13:00 – 14:00 Lunch

14:00 – 14:20

Biological Standardization of Allergen Products –
An Outdated Requirement?

Jörg Kleine-Tebbe, Berlin, Germany

14:20 – 14:40

Allergenic Products Testing in the USA

Ronald Rabin, Silver Spring, USA

14:40 – 14:50

General Discussion

14:50 – 15:10

Mass Spectrometry vs ELISA in Allergen Product Quality Control

Julia Zimmer & Andreas Reuter, Langen, Germany

15:10 – 16:30

Pro and Con Discussion: Mass Spectrometry versus ELISA in Allergen Product Quality Control

Moderators: Jonas Lidholm and Jörg Kleine-Tebbe

- Martin Chapman, Charlottesville, USA
 - Julia Zimmer & Andreas Reuter, Langen, Germany
 - Philippe Moingeon, Paris, France
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16:30 – 16:50 Coffee Break

ENDPOINTS AND BIOMARKERS OF ALLERGEN IMMUNOTHERAPY

Chairs: Anthony Frew and Barbara Bohle

16:50 – 17:10

EAACI Task Force Paper on Biomarkers

Mohamed Shamji, London, United Kingdom

17:10 – 17:30

The Potential of Metabolomics for Developing AIT Biomarkers

Domingo Barber, Madrid, Spain

17:30 – 17:50

Validation of Endpoints of AIT Trials in Allergic Rhinitis

Moisés Calderón, London, United Kingdom

17:50 – 18:10

Endpoints of AIT Trials in Asthma

J. Christian Virchow, Rostock, Germany

18:10 – 18:20

General Discussion



FRIDAY, SEPTEMBER 8, 2017

RECENT DEVELOPMENTS OF ALLERGEN IMMUNOTHERAPY IN CHILDREN

Chairs: Kirsten Beyer and Graham Roberts

08:30 – 08:50

Current Status of Pediatric Studies According to the Standard PIP

Irmgard Eichler, London, United Kingdom

08:50 – 09:10

Allergen Exposure Chambers for the Development of AIT Products in Children?

Petra Ziegelmayer, Vienna, Austria

09:10 – 09:30

To what Extent is Extrapolation from Adult Results to Children Possible?

Hugo Tavares, Espinho, Portugal

09:30 – 09:50

Implications from the GAP Study for Future Pediatric Developments

Henrik Jacobi, Hørsholm, Denmark

09:50 – 10:10

Minimum Requirements for a limited Pediatric Development of AIT Products

Matthias Kopp, Lübeck, Germany

10:10 – 10:30

General Discussion

10:30 – 10:50 Coffee Break

IMMUNOTHERAPY OF FOOD ALLERGY

Chairs: Antonella Muraro and Clare Mills

10:50 – 11:10

Threshold Dose Determination in Food Allergy and its Relevance for Daily Life

Anthony Dubois, Groningen, The Netherlands

11:10 – 11:30

Epicutaneous AIT of Food Allergy

Hugh Sampson, New York, USA

11:30 – 11:50

OIT in Milk and Egg Allergy

Kirsten Beyer, Berlin, Germany

11:50 – 12:20

Hypoallergens for SCIT Treatment of Fish and Peanut Allergy

Ronald van Ree, Amsterdam, The Netherlands

12:20 – 12:40

Comparison of SLIT and OIT in Peanut Allergy

Kari Nadeau, Stanford, USA

12:40 – 12:50

General Discussion

12:50 – 14:00 Lunch

NOVEL FORMS OF ALLERGEN IMMUNOTHERAPY

Chairs: Stefan Vieths and Mark Larché

14:00 – 14:20

New Insights in AIT Mechanisms

Cezmi A. Akdis, Davos, Switzerland

14:20 – 14:40

Novel Vaccines Targeting Dendritic Cells by Coupling Allergoids to Mannan

Oscar Palomares, Madrid, Spain

14:40 – 15:00

Recombinant Allergens for the Treatment of Pollen-Related Food Allergy

Barbara Bohle, Vienna, Austria

15:00 – 15:20

Intralymphatic IMAT Approach in Veterinary Medicine

Horst Rose, Ingelheim, Germany

15:20 – 15:30

General Discussion

15:30 – 16:00 Coffee Break

CRITICAL FACTORS OF CLINICAL TRIALS IN ALLERGEN IMMUNOTHERAPY

Chairs: Marek Jutel and Moises Calderon

16:00 – 16:20

Placebo Effect in AIT Trials

Anthony Frew, Brighton, United Kingdom

16:20 – 16:40

Lessons Learned from the Peptide Approach

Mark Larché, Hamilton, Canada

16:40 – 17:00

Positive and Negative AIT Trials. What Makes the Difference?

Roy Gerth van Wijk, Rotterdam, The Netherlands

17:00 – 17:20

Defining Pollen Season including Pollen Concentrations for Clinical Trials of Allergen Immunotherapy

Oliver Pfaar, Wiesbaden, Germany

17:20 – 17:30

General Discussion

From 18:45

Social Event: Alter Güterbahnhof Bad Homburg





SATURDAY, SEPTEMBER 9, 2017

CHALLENGE TESTS FOR EFFICACY ASSESSMENT

Chairs: Lars Poulsen and Oliver Pfaar

09:00 – 09:20

Standardized Production and Characterization
of Food Challenge Meals

Clare Mills, Manchester, United Kingdom

09:20 – 09:40

Clinical Validation of AECs for Phase III AIT Trials

Torsten Sehlinger, Berlin, Germany

09:40 – 10:00

Nasal and Conjunctival Provocation Tests –
Suitable Tools in Dose Finding Studies

Tim Higenbottam, Worthing, United Kingdom

10:10 – 10:10

General Discussion

10:10 – 10:40 Coffee Break

BIOLOGICS FOR THE TREATMENT OF ALLERGY AND ASTHMA

Chairs: Kari Nadeau and Thilo Jakob

10:40 – 11:00

Monoclonal Antibodies for the Treatment of
Atopic Dermatitis

Thomas Werfel, Hannover, Germany

11:00 – 11:20

Biologics for Asthma Treatment and Corresponding
Biomarkers and Endotypes

Thomas B. Casale, Tampa, USA

11:20 – 11:30

General Discussion

PREVENTION OF ALLERGY BY IMMUNOMODULATION AND ALLERGEN IMMUNOTHERAPY

Chairs: Joachim Saloga and Philippe Moingeon

11:30 – 11:50

Lessons Learned from the Pilot Prophylactic SLIT
Study in High Risk Children

Graham Roberts, Southampton, United Kingdom

11:50 – 12:10

Interplay between a Microbiota and Immune
System: A Role for Probiotics?

Liam O'Mahony, Davos, Switzerland

12:10 – 12:30

EAACI Systematic Review on Allergy Prevention

Antonella Muraro, Padua, Italy

12:30 – 12:40

General Discussion

12:40 – 13:00

Farewell – Closing Remarks

Stefan Vieths, Susanne Kaul, Langen, Germany

13:00 – 14:30 Lunch

SEMINAR VENUE



MARITIM HOTEL BAD HOMBURG

Ludwigstraße 3

61348 Bad Homburg v. d. H., Germany

Telefon +49 (0) 6172 660-0

Fax +49 (0) 6172 660-100

TRAVEL INFORMATION

>> from Frankfurt International Airport

(25 km by taxi appr. € 50)

S-train S8/S9 to Frankfurt (Main) Central Station

>> from Frankfurt (Main) Central Station

S-train S5 to Bad Homburg leaves from track 104 every 15 minutes

SUPPORTED BY

BMG

Bundesministerium für Gesundheit

U.S. FDA

U.S. Food and Drug Administration

3 000 US Dollars

EAACI

European Academy of Allergy and
Clinical Immunology

3 000 Euros

DGAKI

Deutsche Gesellschaft für Allergologie
und klinische Immunologie

2 000 Euros

