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
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Vera Mahler Langen, German

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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
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: Chistoph 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

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
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