Allergen Products for Diagnosis and Therapy: Regulation and Science

Oct 29 – Nov 1, 2014
Bad Nauheim, Germany
Hotel Dolce

PROGRAMME

>> www.pei.de/ipes2014
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WELCOME

to the 14th International Paul-Ehrlich-Seminar in Bad Nauheim, Germany, Hotel Dolce

It is with great pleasure that I welcome you to Bad Nauheim. We put together a programme with contributions from regulators, scientists and representatives from industry. As usual, the upcoming 14th International Paul-Ehrlich-Seminar will serve as a forum to discuss recent developments and improvements of control methods and standardization procedures for current and novel forms of allergen products as well as regulatory aspects of allergen products.

On behalf of the Organizing Committee and the Programme Committee of the 14th International Paul-Ehrlich-Seminar I wish all of you a wonderful stay in Bad Nauheim.

Stefan Vieths
GENERAL INFORMATION

REGISTRATION AND INFORMATION DESK

OPENING HOURS
October 29, 2014  11:00 – 18:00
October 30, 2014  08:00 – 19:00
October 31, 2014  08:00 – 17:45
November 1, 2014  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: ipes2014@pei.de.

SOCIAL PROGRAMME

WEDNESDAY OCTOBER 29, 2014
19:00
Opening Lecture (Klaus Cichutek) and Welcome Reception at Hotel Dolce, Bad Nauheim

THURSDAY, OCTOBER 30, 2014
18.30 Leisure Time
Suggestions will be offered by our staff on request

FRIDAY, OCTOBER 31, 2014
18:45
Social Event at Burg Ronneburg, Ronneburg
WEDNESDAY, OCTOBER 29, 2014

13:00 – 15:00
IUIS Allergen Standardization Sub-Committee
Chair: Stefan Vieths, Paul-Ehrlich-Institut, Langen, DE

13:00 – 15:00
Workshop on regulatory requirements for mass spectrometric data
Closed Session – invited participants only
Chair: Andreas Reuter, Paul-Ehrlich-Institut, Langen, DE

15:00 – 15:30  Coffee Break

1. ALLERGY DIAGNOSTICS
Chairs: Jörg Kleine-Tebbe and Martin Chapman

15:30 – 15:50
Regulation of in vitro diagnostics: U.S. versus Europe
Robert Hamilton, Johns Hopkins, Baltimore, US

15:50 – 16:10
Future availability of allergens for in vivo diagnosis in the view of the European Allergen Manufacturers Group
Lars Jacobsen, European Allergen Manufacturers Group, Smørum, DK

16:10 – 16:30
Regulatory requirements and status of test allergens in different EU Member States
Susanne Kaul, Paul-Ehrlich-Institut, Langen, DE

16:30 – 16:50
Quality of allergens for in vitro diagnostics
Åse Borgå, Thermo Fisher Scientific, Uppsala, SE

16:50 – 17:10
Is component-resolved diagnosis relevant for allergen immunotherapy?
Joaquin Sastre, Clinica de Nuestra Senora de la Concepcion, Madrid, ES

17:10 – 17:20  General Discussion
19:00 – 19:30
Opening Lecture -
Personalized approaches in biomedicine
Klaus Cichutek, President of the Paul-Ehrlich-Institut

19:30
Welcome Reception, Hotel Dolce
All participants
2. REGULATION OF ALLERGEN PRODUCTS IN DIFFERENT COUNTRIES
Chairs: Ronald Rabin and Stefan Vieths

09:00 – 09:10
Welcome Address
Stefan Vieths, Paul-Ehrlich-Institut, Langen, DE

09:10 – 09:30
Update of the FDA reclassification of allergens for diagnosis and treatment
Jay Slater, Food and Drug Administration (CBER), Rockville, US

09:30 – 09:50
Harmonization of allergen regulation in different countries
Sergio Bonini, University of Naples, Naples, IT

09:50 – 10:10
Status of allergen products regulation in The Netherlands
Marcel Hoefnagel, Medicines Evaluation Board, Utrecht, NL

10:10 – 10:30
Status of allergen products regulation in Spain
Marcos Timon Jimenez, Spanish Medicines Agency, Madrid, ES

10:30 – 10:40 General Discussion

10:40 – 11:10 Coffee Break

11:10 – 11:30
Status of allergen products regulation in Italy
Lorenzo Montrasio, Sandra Petraglia, Agenzia Italiana del Farmaco, Rome, IT

11:30 – 11:50
Regulation and clinical use of allergen products in Japan
Motohiro Ebisawa, Sagamihara National Hospital, Yokosuka, JP
### 11:50 – 12:10
Therapy allergen ordinance: current status and lessons learned
Andreas Bonertz, Paul-Ehrlich-Institut, Langen, DE

### 12:10 – 12:35
The EAMG White Paper on Regulation of allergen products
Lars Jacobsen, European Allergen Manufacturers Group, Smørum, DK

### 12:35 – 12:45  General Discussion

### 12:45 – 14:00  Lunch

### 3. CHARACTERIZATION AND CONTROL OF ALLERGEN PRODUCTS
Chairs: Karl-Heinz Buchheit and Ronald van Ree

### 14:00 – 14:20
Quality requirements for allergen source materials
Carlo Pini, Istituto Superiore di Sanità, Rome, IT

### 14:20 – 14:40
Official batch control of allergens by
Paul-Ehrlich-Institut
Detlef Bartel, Paul-Ehrlich-Institut, Langen, DE

### 14:40 – 15:00
Update on BSP090 – recombinant allergens as reference materials
Martin Chapman, Indoor Biotechnologies, Charlottesville, US

### 15:00 – 15:20
Control of allergoids – possibilities and limitations
Enrique Fernandez-Caldas, Inmunotek, San Sebástian, ES

### 15:20 – 15:40
Biological standardization of allergens using in vitro and in vivo assays
Ronald van Ree, Academic Medical Center, Amsterdam, NL

### 15:40 – 15:50  General Discussion

### 15:50 – 16:20  Coffee Break
# 4. NEW METHODS IN ALLERGEN PRODUCT TESTING

Chairs: Alberto Martinez and Jay Slater

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker</th>
<th>Location</th>
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<tbody>
<tr>
<td>16:20 – 16:40</td>
<td>Alternatives to the use of human sera in control of allergens - needs and prospects</td>
<td>Jerónimo Carnés, Leti, Madrid, ES</td>
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<td>16:40 – 17:00</td>
<td>Summary – Workshop on regulatory requirements for mass spectrometric data</td>
<td>Andreas Reuter, Paul-Ehrlich-Institut, Langen, DE</td>
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<td>17:00 – 17:20</td>
<td>Mass spectrometry for the characterization and control of allergen extracts – grass pollen and mite allergens</td>
<td>Emmanuel Nony, Stallergenes, Anthony, FR</td>
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<tr>
<td>17:20 – 17:40</td>
<td>Mass spectrometry for the characterization and control of allergen extracts – birch pollen</td>
<td>Jelena Spiric, Paul-Ehrlich-Institut, Langen, DE</td>
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<td>17:40 – 18:00</td>
<td>Mass spectrometry – allergoids</td>
<td>Peter Briza, University of Salzburg, Salzburg, AU</td>
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<td>18:00 – 18:10</td>
<td>General Discussion</td>
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FRIDAY, OCTOBER 31, 2014

5. ENDPOINTS OF IMMUNOTHERAPY – CLINICAL TRIALS IN RESPIRATORY ALLERGIES
Chairs: Henrik Jacobi and Anthony Frew

08:30 – 08:50
Presentation of the forthcoming EAACI task force document “Clinical outcomes in allergen immunotherapy trials”
G. Walter Canonica, University of Genoa, Genoa, IT

08:50 – 09:10
Design of immunotherapy studies in children
Irmgard Eichler, European Medicines Agency, London, UK

09:10 – 09:30
Technical validation of environmental exposure chambers
Anne Marie Salapatek, Inflamax Research, CA

09:30 – 09:50
Validation of pollen chambers for clinical trials
Oliver Pfaar, Zentrum für Rhinologie und Allergologie, Wiesbaden, DE

09:50 – 10:00  General Discussion

10:00 – 10:30  Coffee Break

10:30 – 10:50
Lessons learned from dose-finding trials
Pascal Demoly, University Hospital of Montpellier, Montpellier, FR

10:50 – 11:10
How to define a clinically relevant effect
Randolf Brehler, Universitätsklinikum Münster, Münster, DE

11:10 – 11:30
Validation and suitability of the Allergy-Control-Score (ACS™)
Annemie Narkus, Allergopharma, Reinbek, DE
11:30 – 11:50  
Presentation of the EAACI task force document “Allergen Immunotherapy Contraindications”  
Moises Calderon, Imperial College, Royal Brompton Hospital, London, UK

11:50 – 12:00  
General Discussion

12:00 – 13:20  
Lunch

6. NEW INSIGHTS IN IMMUNOTHERAPY MECHANISMS  
Chairs: Pascal Demoly and Stephen Durham

13:20 – 13:40  
State-of-the-art knowledge on immunotherapy mechanisms  
Stephen Durham, Imperial College, Royal Brompton Hospital, London, UK

13:40 – 14:00  
When to initiate immunotherapy?  
Roy Gerth van Wijk, Erasmus Medical Center, Rotterdam, NL

14:00 – 14:20  
Mechanisms in immunotherapy – asthma and rhinitis/grass and mites: what is in common?  
Harald Renz, Universitätsklinikum Gießen und Marburg, Marburg, DE

14:20 – 14:40  
Prognostic markers for allergen immunotherapy  
Philippe Moingeon, Stallergenes, Antony, FR

14:40 – 15:00  
Are there any different mechanisms: allergoids versus allergens in specific immunotherapy  
Barbara Bohle, Medical University, Vienna, AT

15:00 – 15:20  
The role of innate lymphoid cells in allergy and asthma  
Jillian Barlow, Medical Research Council, Cambridge, UK

15:20 – 15:30  
General Discussion
7. ADJUVANTS AND IMMUNOMODULATION
Chairs: Barbara Bohle and Irmgard Eichler

16:00 – 16:20
Mechanism of aluminium hydroxide as adjuvant
Erik B. Lindblad, Brenntag Biosector, Frederikssund, DK

16:20 – 16:40
Safety of aluminium hydroxide as adjuvant
Karin Weißer, Paul-Ehrlich-Institut, Langen, DE

16:40 – 17:00
Safety assessment of adjuvants
Jan Willem van der Laan, Medicines Evaluation Board, Utrecht, NL

17:00 – 17:20
New aspects of adjuvants
(for allergen immunotherapy)
Oscar Palomares, Universidad Complutense de Madrid, Madrid, ES

17:20 – 17:30 General Discussion

Social Event
Departure to Ronneburg: 18:45
8. ROUND TABLE DISCUSSION

08:45 – 10:00
Clinical trials in children/pediatric investigation plans
Moderator: Jörg Kleine-Tebbe

Discussants
- Dirk Mentzer, Paul-Ehrlich-Institut (EMA/PDCO Chair)
- Ronald Rabin, FDA/CBER (Chief, Laboratory of Immunobiochemistry)
- Angelika Sager, Leti Pharma (Medical Director)
- Henrik Jacobi, ALK Abellò (Executive Vice President, Research and Development)

9. CRITICAL FACTORS OF CLINICAL TRIALS IN IMMUNOTHERAPY
Chairs: Lars Jacobsen and Oliver Pfaar

10:00 – 10:20
Why can clinical trials be successful/unsuccessful?
Anthony Frew, Brighton and Sussex Medical School, Brighton, UK

10:20 – 10:40
How can safety and efficacy be addressed in immunotherapy trials?
Jörg Kleine-Tebbe, Allergy and Asthma Center, Berlin, DE

10:40 – 11:00
Power calculation revisited: how many subjects are enough?
Peter Volkers, Paul-Ehrlich-Institut, Langen, DE

11:00 – 11:10 General Discussion

11:10 – 11:40 Coffee Break
10. INNOVATIVE APPROACHES IN IMMUNOTHERAPY

Chairs: Harald Renz and Stephan Scheurer

11:40 – 12:00
Viaskin peanut: epicutaneous immunotherapy
Pierre-Henri Benhamou, DBV Technologies, Bagneux, FR

12:00 – 12:20
BM32, a hypoallergenic vaccine containing a PreS carrier protein for allergen immunotherapy of grass pollen allergy
Rudolf Valenta, Medical University, Vienna, AT

12:20 – 12:40
Applying the ToleroMune® technology for treatment of allergies (Cat-PAD)
Rod Hafner, Circassia, Oxford, UK

12:40 – 13:00
A novel allergen-adjuvant conjugate for allergen immunotherapy of respiratory allergy
Alessandra Vultaggio, University of Florence, Florence, IT

13:00 – 13:20
Hydrolyzed grass pollen proteins for allergen immunotherapy
Ralph Mösges, Universitätsklinikum Köln, Cologne, DE

13:20 – 13:30 General Discussion

13:30 – 13:40
Farewell – Closing Remarks
Stefan Wieths, Paul-Ehrlich-Institut, Langen, DE

13:40 Lunch
FAREWELL

The Organizing Committee would like to thank speakers, chairs, and attendants for their contributions to the 14th International Paul-Ehrlich-Seminar. See you in 2017 for the 15th International Paul-Ehrlich-Seminar. Have a safe trip home!

On behalf of the Organizing Committee and the Paul-Ehrlich-Institut,

Prof. Dr. Stefan Vieths  
Vice President  
Paul-Ehrlich-Institut  
Conference Chairman

Prof. Dr. Klaus Cichutek  
President  
Paul-Ehrlich-Institut

SUPPORTED BY

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BMG – Bundesministerium für Gesundheit  
DGAKI – Deutsche Gesellschaft für Allergologie und Klinische Immunologie  
EAACI – European Academy of Allergology and Clinical Immunology  
FDA – U.S. Food and Drug Administration