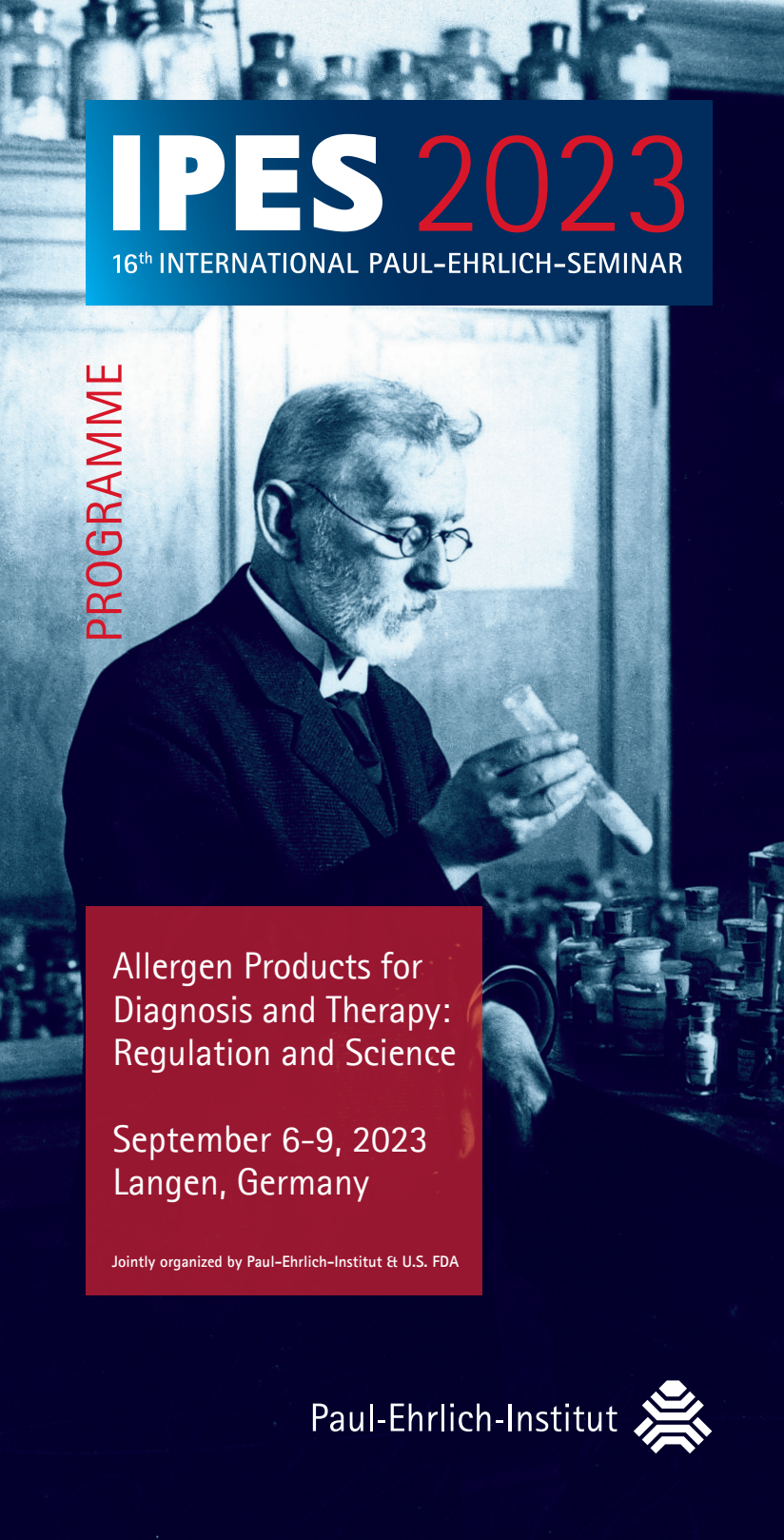

IPES 2023

16th INTERNATIONAL PAUL-EHRLICH-SEMINAR

PROGRAMME

Allergen Products for Diagnosis and Therapy: Regulation and Science

September 6-9, 2023
Langen, Germany

Jointly organized by Paul-Ehrlich-Institut & U.S. FDA

Paul-Ehrlich-Institut

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Vera Mahler	Langen, Germany

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Birgit Ahrens / Anja Hampe
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PEI 2023

IPES 2023

16th INTERNATIONAL PAUL-EHRLICH-SEMINAR

Welcome

To the 16th International Paul-Ehrlich-Seminar in Langen (Hesse), Germany, Stadthalle

After three long years which have been overshadowed by the pandemic we are now looking forward very much to the renewed opportunity to meet with you to exchange information and opinions on regulation and science concerning allergen products for diagnosis and therapy!

We are delighted that so many outstanding experts have accepted our invitation to Langen to present and discuss current hot topics and emerging developments in the field.

The 16th IPES is for the first time organized as a hybrid meeting, however, will proceed to serve as a forum for interdisciplinary exchange of ideas, for taking the broader view and give new perspectives to the complex issues in the global field of allergens and regulatory affairs.

On behalf of the Organizing Committee and the Programme Committee of the 16th International Paul-Ehrlich-Seminar we wish you a stimulating meeting and a very pleasant stay in Langen.

With best regards,

Stefan Vieths *Vera Mahler*

General Information

Registration an Information Desk

OPENING HOURS
September 6, 2023 12:00 – 18:00
September 7, 2023 08:30 – 19:00
September 8, 2023 08:30 – 17:45
September 9, 2023 09:00 – 14:00

Social Programme

WEDNESDAY SEPTEMBER 6, 2023
19:00 – 23:00
Opening and Welcome Reception with Networking Dinner Buffet at Neue Stadthalle Langen

THURSDAY, SEPTEMBER 7, 2023
18:30 – Leisure Time
Suggestions will be offered by our staff on request

FRIDAY, SEPTEMBER 8, 2023
19:00 – approx. 23:00 River Cruise in Frankfurt with Networking Dinner

Wednesday, September 6, 2023

from 12:00 **REGISTRATION**

13:00 – 15:00
Premeeting (Working Group)
IUIS Allergen Standardization Subcommittee
Chair: Stefan Vieths, Paul-Ehrlich-Institut, Langen, Germany

15:00 – 15:30 **COFFEE BREAK**

15:30 – 16:00
Welcome and Opening Address
(Start of Hybrid Meeting)
Stefan Vieths, Vera Mahler, Paul-Ehrlich-Institut, Langen, Germany

Key Note Lecture – Recent evidence on epithelial barriers and allergic disease
Cezmi Akdis, Swiss Institute of Allergy and Asthma Research, Davos, Switzerland

1. Allergy Diagnostics

Chairs:
Susanne Kaul, Paul-Ehrlich-Institut, Langen, Germany
Ludger Klimek, Center of Rhinology and Allergology, Wiesbaden, Germany

16:00 – 16:20
Legal Framework Conditions for the Development and Approval of new Patch Test Preparations – Manufacturers' View
Curt Hamann, SmartPractice, Phoenix, AZ, USA

16:20 – 16:40
Legal Framework Conditions for the Development and Approval of new Patch Test Preparations – Regulators' View
Vera Mahler, Paul-Ehrlich-Institut, Langen, Germany

16:40 – 17:00
The Contribution of Data from Clinical Epidemiology to Quality Assessment of Patch Test Preparations
Wolfgang Uter, Friedrich-Alexander-University Erlangen, Germany

17:00 – 17:20
New Regulatory Guidance for Authorization of Test Allergens
Andreas Bonertz, Paul-Ehrlich-Institut, Langen, Germany

17:20 – 17:40
Diagnostic Need for rare Occupational Type I Allergies
Monika Raulf, IPA Bochum, Germany

17:40 – 18:00
Implementation of the New Regulation of In-vitro-Diagnostics in the EU
Micha Nübling, Paul-Ehrlich-Institut, Langen, Germany

18:00 – 18:20 **GENERAL DISCUSSION**

18:20 – 18:40
Opening Lecture –
The role of HMA and EMA in the EU Regulatory Network
Karl Broich, Federal Institute for drugs and medical devices, Bonn, Germany

18:40 – 19:00
Opening Lecture –
Parallel Distribution and Counterfeit of Biomedicines in the EU
Stefan Vieths, Paul-Ehrlich-Institut, Langen, Germany

19:00 – 23:00 **GET TOGETHER**

Opening and Welcome Reception with Networking Dinner Buffet at Neue Stadthalle Langen

2. Regulation of Allergen Products – State of the Art and New Developments

Chairs:
Andreas Bonertz, Paul-Ehrlich-Institut, Langen, Germany
Milica Mitrevski, Italian Medicines Agency, Rome, Italy
Joachim Saloga, Johannes Gutenberg-Universität, Mainz, Germany

09:00 – 09:10
Introduction
Stefan Vieths, Vera Mahler, Paul-Ehrlich-Institut, Langen, Germany

09:10 – 09:30
Regulation of Named Patient Products in Spain – State of the Art
Marcos Timón Jimenez, Spanish Agency of Medicines and Medical Device Products, Madrid, Spain

09:30 – 09:50
Post Launch Approval Process for Allergens in Italy
Milica Mitrevski, Italian Medicines Agency, Rome, Italy

09:50 – 10:10
CMDH and CHMP Activities on the Harmonization of regulatory Approaches for Allergens
Marcel Hoefnagel, MEB, Utrecht, The Netherlands

10:10 – 10:30
Developing Products to meet Global Allergy Patient Needs: Product Development and Regulatory Considerations
Pieter-Jan De Kam, Clinical Director, ATL, Worthing, UK

10:30 – 11:00 COFFEE BREAK

11:00 – 11:20
Risk Evaluation and Mitigation Strategy (REMS) – Process, Procedure and Management
Taruna Khurana, FDA, Silver Spring, USA

11:20 – 11:40 Veterinary Allergy and Immunotherapy
Rosario Bullido, Medicines and Medical Devices Spanish Agency, Madrid, Spain

11:40 – 12:00 GENERAL DISCUSSION

3. Quality of Allergen Products

Chairs:
Marcel Hoefnagel, MEB, Utrecht, The Netherlands
Andreas Reuter, Paul-Ehrlich-Institut, Langen, Germany

12:00 – 12:20
Molecular Characterization of Allergoids
Jerónimo Carnés, Laboratorios LETI S.L.U., Spain

12:20 – 12:40
Antibody Based Techniques for Testing of Allergoids
Simon Hewings, Allergy Therapeutics, Worthing, UK

12:40 – 13:00
The Role of the European Pharmacopeia in the European Regulatory System
Michael Wierer, EDQM, Strasbourg, France

13:00 – 14:00 LUNCH

14:00 – 14:20
Current State of the BSP 090 Project on Allergen Standardization
Julia Zimmer, Paul-Ehrlich-Institut, Langen, Germany

14:20 – 14:40
Mass Spectrometric Analysis of Allergen Therapeutics, Vaccines and Diagnostics – a Relationship between Antigen Content and Potency?
Jelena Spiric, Paul-Ehrlich-Institut, Langen, Germany

14:40 – 15:00
Molecular Requirements for innovative AIT Approaches in Food Allergy
Ronald van Ree, Amsterdam University Medical Centers, The Netherlands

15:20 – 15:30 **GENERAL DISCUSSION**

15:30 – 15:50 **COFFEE BREAK**

4. Biomarkers and Outcome Measures

Chairs: Barbara Bohle, Medical University of Vienna, Vienna, Austria
Thilo Jakob, Universitätsklinikum Gießen und Marburg, UKGM, Gießen, Germany

15:50 – 16:10
Update EAACI TF on Biomarkers
Mohamed Shamji, National Heart & Lung Institute, Imperial College, London, UK

16:10 – 16:30
New Biomarker Candidates in Allergic Asthma
Marek Jutel, Wrocław Medical University, Wrocław, Poland

16.30 – 16.50
Development and Implementation of Core Outcome Measures sets for Severe Asthma in Paediatric Patients
Graham Roberts, University Hospital Southampton, UK

16:50 – 17:10
Requirements for Regulatory Acceptance of Biomarkers
Hilke Zander, Paul-Ehrlich-Institut, Langen, Germany

17:10 – 17:20 **GENERAL DISCUSSION**

5. Allergen Immunotherapy in Children – Round-Table Discussion

Chairs/Moderators:
Tobias Ankermann, Städtisches Krankenhaus Kiel GmbH, Germany
Dirk Mentzer, Paul-Ehrlich-Institut, Langen, Germany
Eike Wüstenberg, ALK-Abelló Arzneimittel GmbH, Hamburg, Germany

17.20 – 17.30
Fourteen years of standard PIP for Allergen Products for Specific Immunotherapy – Ways forward from a Clinician's Point of View
Susanne Halken, Hans Christian Andersen Children's Hospital, Odense University Hospital, Denmark

17:30 – 17:40
Fourteen years of standard PIP for Allergen Products for Specific Immunotherapy – Ways forward from a Manufacturer's Point of View
Angelika Sager, Leti Pharma, Witten, Germany

17:40 – 17:50
Fourteen years of standard PIP for Allergen Products for Specific Immunotherapy – Ways forward from a Regulator's Point of View
Dobromir Penkov, European Medicines Agency, The Netherlands

17:50 – 18:30 ROUND-TABLE DISCUSSION

6. Novel Developments in Food Allergy Treatments

Chairs:
Jay Slater, CBER, FDA, Silver Spring, USA
Birgit Ahrens, Paul-Ehrlich-Institut, Langen, Germany

09:00 – 09:20
Challenges in evaluating the long-term Efficacy of Food Immunotherapy
Kari Nadeau, Harvard T.H. Chan School of Public Health, Boston, MA, USA

09:20 – 09:40
Regulation of Food Allergy Immunotherapy in the US
Anubha Tripathi, CBER, FDA, Silver Spring, USA

09:40 – 10:00
Epicutaneous Immunotherapy of Food Allergy: What's cooking?
Pharis Mohideen, DBV Technologies, Montrouge, France

10:00 – 10:20
Food AIT: Impact of different Clinical Outcome Definitions on the perceived Effect
Pablo Rodriguez del Rio, Hospital Infantil Universitario Niño Jesús, Madrid, Spain

10:20 – 10:40
Subcutaneous Immunotherapy of Food Allergy
Lars K. Poulsen, Copenhagen University Hospital Gentofte, Copenhagen, Denmark

10:40 – 10:50 **GENERAL DISCUSSION**

10:50 – 11:20 **COFFEE BREAK**

7. Novel Developments in Allergen Immunotherapy

Chairs:
Ioana Agache, Transylvania University, Brasov, Romania
Stefan Vieths, Paul-Ehrlich-Institut, Langen, Germany

11:20 – 11:40
AIT guidelines in 2023 – from evidence to clinical recommendations
Oliver Pfaar, University Clinic Marburg, Marburg, Germany

11:40 – 12:00
The role of IgG1 and IgG4 as dominant IgE-blocking antibodies shifts during allergen-specific immunotherapy
Barbara Bohle Medical University of Vienna, Vienna, Austria

12:00 – 12:20
Toxicokinetics of Aluminium – Novel Insights in an old Adjuvant
Karin Weißer, Paul-Ehrlich-Institut, Langen, Germany

12:20 – 12:40
Novel Adjuvants in Allergen Immunotherapy
Stefan Schülke, Paul-Ehrlich-Institut, Langen, Germany

12:40 – 12:50 **GENERAL DISCUSSION**

12:50 – 13:50 **LUNCH**

8. Critical Factors and Recent Results of Clinical Trials in Allergen Immunotherapy

Chairs:
Ronald Rabin, CBER, FDA, Silver Spring, USA
Vera Mahler, Paul-Ehrlich-Institut, Langen, Germany

13:50 – 14:10
Key Factors for Success or Failure in AIT Trials
Roy Gerth van Wijk, Erasmus Medical Center, Rotterdam, The Netherlands

14:10 – 14:30
How to deal with the Placebo Effect in AIT Trials?
Christoph Willers, Allergopharma GmbH, Reinbek, Germany

14:30 – 14:50
Novel Insights from the Post Marketing PV System in the USA
David Bernstein, University of Cincinnati College of Medicine, Cincinnati, Ohio USA

14:50 – 15:10
The Use of EEC in AIT Trials for Asthma
Frederic de Blay, Nouvel Hôpital Civil, Strasbourg, France

15:10 – 15:30
FDA Position on EECs
JooHee Lee, CBER, FDA, Silver Spring, USA

15:30 – 15:50
Allergen Immunotherapy in Patients with House Dust Mite driven allergic Asthma – a specific Challenge
Ioana Agache, Transylvania University, Brasov, Romania

15:50 – 16:00 **GENERAL DISCUSSION**

16:00 – 16:30 **COFFEE BREAK**

9. Impact of Omics and Big Data on Allergen Immunotherapy

Chairs:
Harald Renz, Universitätsklinikum Gießen und Marburg, UKGM, Marburg, Germany
Ronald van Ree, Amsterdam University Medical Centers, The Netherlands

16:30 – 16:50
Introduction to Big Data Approaches in the Field of Medicine and Potential Application in Clinical Trials
Amke Caliebe, Christian Albrechts University, Kiel, Germany

16:50 – 17:10
Big Data and Omics in the Regulation of Medicines
Renate König, Paul-Ehrlich-Institut, Langen, Germany

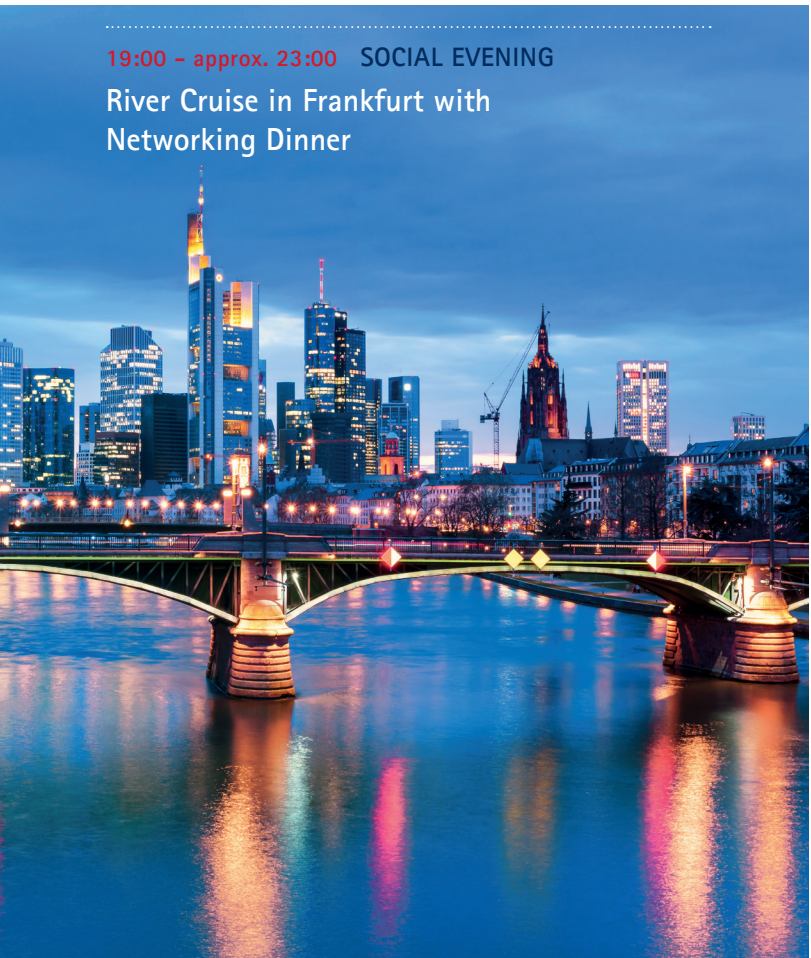
17:10 – 17:30
Lessons learned from system biology approaches in AIT
Domingo Barber, University CEU San Pablo, Spain

17:30 – 17:50
Benefit and limitations of Apps and eHealth Wearables in Allergen Immunotherapy
Jean Bousquet, Charité, University Medicine Berlin, Berlin, Germany

17:50 – 18:00 **GENERAL DISCUSSION**

19:00 – approx. 23:00 **SOCIAL EVENING**

River Cruise in Frankfurt with Networking Dinner



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10. Immunomodulation for Prevention of Allergy

Chairs:
Susanne Halken, Hans Christian Andersen Children's Hospital, Odense University Hospital, Denmark
Katharina Blümchen, University Hospital Frankfurt, Frankfurt, Germany

09:30 – 09:50
Microbiota and Allergy Prevention
Harald Renz, University Clinic Marburg, Marburg, Germany

09:50 – 10:10
Modulation of Microbiota by Dietary Fiber and Effect on Allergies
Masako Toda, Tohoku University, Sendai, Japan

10:10 – 10:30
Bright Future for AIT in Allergy Prevention?
Anna Maria Dittrich, Hannover Medical School, Hannover, Germany

10:30-10:50
Patient Needs in further development of AIT
Marcia Podestà, EFA - European Federation of Allergy and Airways Diseases Patients' Associations, Brussels, Belgium

10:50 – 11:00 **GENERAL DISCUSSION**

11:00 – 11:10 **COFFEE BREAK**

11. Marketing Authorization and Health Technology Assessment – Unequal Siblings?

Chairs:
Mark Aagren, ALK-Abelló, Hørsholm, Denmark
Wolfgang Pfützner, Universitätsklinikum Gießen und Marburg, UKGM, Marburg, Germany

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11:10 – 11:30
Optimizing the Integration of randomized and non-randomized Studies of Interventions in Evidence Syntheses
Holger Schünemann, Cochrane Canada & McMaster GRADE Centre, Hamilton, Canada

11:30 – 11:50
Real World Studies, Strengths and Weaknesses - Options to overcome Limitations
Silvia Scurati, Stallergenes, Antony Cedex, France

11:50 – 12:10
Health Technology Assessment of Allergens in Germany
Antje Behring, Federal Joint Committee (G-BA), Berlin, Germany

12:10 – 12:30
Health Technology Assessment and its Implementation in the Authorization of Medicines in the EU
Joan O'Callaghan, National Centre for Pharmacoeconomics, Dublin, Ireland

12:30 – 12:40 **GENERAL DISCUSSION**

12:40 – 13:00
Farewell – Closing Remarks
Stefan Vieths, Vera Mahler, Paul-Ehrlich-Institut, Langen, Germany

from 13:00 **LUNCH**

Seminar Venue

Neue Stadthalle Langen

Südliche Ringstraße 77
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neue-stadthalle@langen.de
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Travel Information

>> from Frankfurt International Airport
S-Train S8/S9 to Frankfurt Main Station
>> from Frankfurt Main Station
S-Train S3/S4 to Langen, leaving from Platform 101
every 15 Minutes
>> by Taxi, 25 km, appr. € 50
>> Mercure Hotel Shuttle Service

All parties commit to unbiased and product-neutral presentation and will disclose potential conflicts of interest on their first slide.

The conference is organized without sponsorship from pharmaceutical companies and or companies dealing with medical devices.

Total expenses of the conference are calculated with 180.000 EUR.

The Paul-Ehrlich-Institut, the Federal Institute for Vaccines and Biomedicines, is a senior federal authority reporting to the German Federal Ministry of Health.

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