

## 16th International Paul-Ehrlich-Seminar "Allergen Products for Diagnosis and Therapy: Regulation and Science", Bad Homburg, September 2 – 5, 2020

### Draft Programme

#### Wednesday, September 2, 2020

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| From 12:00 | Registration                               |   |
| Afternoon  | IUIS Allergen Standardization Subcommittee | Chair: Stefan Vieths<br><i>Paul-Ehrlich-Institut, Langen, Germany</i>       |
|            | <b>Welcome Address</b>                     | Stefan Vieths, Vera Mahler<br><i>Paul-Ehrlich-Institut, Langen, Germany</i> |

#### 1. Allergy Diagnostics

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|-----------|---|--|
| Afternoon | Legal Framework Conditions for the Development and Approval of new Patch Test Preparations – Manufacturers' View (Hamann) | Curt Hamann<br><i>SmartPractice, Phoenix, AZ, USA</i>        |
|           | Legal Framework Conditions for the Development and Approval of new Patch Test Preparations – Regulators' View (Mahler)    | Vera Mahler<br><i>Paul-Ehrlich-Institut, Langen, Germany</i> |

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|                     | The Contribution of Data from Clinical Epidemiology to Quality Assessment of Patch Test Preparations | Johannes Geier<br><i>Information Network of Departments of Dermatology (IVDK), Göttingen, Germany</i> |
|                     | New Regulatory Guidance for Authorization of Test Allergens  | Andreas Bonertz<br><i>Paul-Ehrlich-Institut, Langen, Germany</i>                                      |
|                     | Diagnostic Need for rare occupational Type I Allergies   | Kristiina Aalto-Korte<br><i>Finnish Institute of Occupational Health, Helsinki, Finland</i>           |
|                     | Implementation of the New Regulation of In-vitro-Diagnostics in the EU                               | Michael Chudy<br><i>Paul-Ehrlich-Institut, Langen, Germany</i>  |
|                     | <b>General Discussion</b>  |   |
|                     | <b>Opening Lecture – The role of HMA and EMA in the EU Regulatory Network</b>                        | Christa Wirthumer-Hoche   |
|                     | <b>Opening Lecture – Parallel Distribution and Counterfeit of Biomedicines in the EU</b>             | Stefan Vieths   |
| <b>Get together</b> |  |   |

**Thursday, September 3, 2020**

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

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| Morning | Introduction   | Stefan Vieths, Vera Mahler<br><i>Paul-Ehrlich-Institut, Langen, Germany</i>                    |
|         | Regulation of Named Patient Products in Spain – State of the Art                     | Sol Ruiz<br><i>Spanish Agency of Medicines and Medicinal Products (AEMPS), Madrid, Spain</i>   |
|         | Post Launch Approval Process for Allergens in Italy                                  | tbd  |
|         | CMDH and CHMP Activities on the Harmonization of regulatory Approaches for Allergens | Marcel Hoefnagel<br><i>Medicines Evaluation Board (MEB), Utrecht, The Netherlands</i>          |
|         | Regulatory Challenges after Brexit   | Anne Cook<br><i>Medicines and Healthcare Products Regulatory Agency, London, UK</i>            |
|         | Risk Evaluation and Mitigation Strategy (REMS) – Process, Procedure and Management   | Taruna Khurana<br><i>U.S. Food and Drug Administration (FDA), Silver Spring, Maryland, USA</i> |
|         | Veterinary Allergy and Immunotherapy   | Ralf Müller<br><i>Ludwig Maximilians University, Munich, Germany</i>                           |
|         | <b>General Discussion</b>  |  |

### 3. Quality of Allergen Products

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| Afternoon | Molecular Characterization of Allergoids                                | Jerónimo Carnés,<br><i>LETI S. L. U, Madrid, Spain</i>   |
|           | Antibody Based Techniques for Testing of Allergoids                     | Murray Skinner<br><i>Allergy Therapeutics, Worthing, UK</i>  |
|           | The Role of the European Pharmacopeia in the European Regulatory System | Michael Wierer<br><i>European Directorate for the Quality of Medicines and HealthCare (EDQM), Strasbourg, France</i> |
|           | Current State of the BSP 090 Project on Allergen Standardization        | Julia Zimmer<br><i>Paul-Ehrlich-Institut, Langen, Germany</i>  |
|           | Quantification of Allergens in Insect Venoms by Mass Spectrometry       | Jelena Spiric<br><i>Paul-Ehrlich-Institut, Langen, Germany</i>   |
|           | Molecular Requirements for innovative AIT Approaches in Food Allergy    | tbd  |
|           | <b>General Discussion</b>   |  |

#### 4. Biomarkers of Allergen Immunotherapy

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| Afternoon | Update EAACI TF on Biomarkers                        | Mohamed Shamji<br><i>National Heart &amp; Lung Institute, Imperial College London, UK</i>             |
|           | New Biomarker Candidates in Allergic Asthma          | Marek Jutel<br><i>Wroclaw Medical University, ALL-MED Medical Research Institute, Wroclaw, Poland</i> |
|           | Requirements for Regulatory Acceptance of Biomarkers | Jan Müller-Berghaus<br><i>Paul-Ehrlich-Institut, Langen, Germany</i>                                  |
|           | <b>General Discussion</b>                            |   |

#### 5. Allergen Immunotherapy in Children

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| Afternoon | <b>Pro-Con-Session:</b><br>Ten years of standard PIP for Allergen Products for Specific Immunotherapy – Ways forward from a Regulator’s Point of View | Dirk Mentzer<br><i>European Medicines Agency, The Netherlands</i> |
|           | Ten years of standard PIP for Allergen Products for Specific Immunotherapy – Ways forward from a Manufacturer’s Point of View                         | Angelika Sager<br><i>Leti Pharma, Witten, Germany</i>             |
|           | Innovative Clinical Trial Designs for Allergen Immunotherapy in Children  | tbd   |

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|  | Status of (paediatric) Network of Sites with the Capacity to conduct large AIT Studies | tbd |
|  | Panel Discussion   | tbd |
|  | <b>General Discussion</b>  |     |

## Friday, September 4, 2020

### 6. Novel Developments in Allergy Treatments

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| Morning | Challenges in evaluating the long-term Efficacy of Food Immunotherapy | Meng Chen<br><i>Stanford University School of Medicine<br/>Sean N. Parker Center for Allergy and Asthma Research<br/>Stanford, CA, USA</i> |
|         | Regulation of Food Allergy Immunotherapy in the US and Europe         | Jay Slater<br><i>Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA), Silver Spring, MD, USA</i>  |
|         | Epicutaneous and oral Immunotherapy of Food Allergy: What's cooking?  | Kirsten Beyer<br><i>Charité Universitätsmedizin Berlin<br/>Paediatric Allergology Study Center, Berlin, Germany</i>                        |
|         | Subcutaneous Immunotherapy of Food Allergy                            | Carsten Bindslev-Jensen<br><i>Allergy Center Odense University Hospital, Odense, Denmark</i>   |

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|  | Experiences from the German, Austrian and Swiss AIT Guideline Development | Oliver Pfaar<br><i>University Clinic Marburg, Section of Rhinology and Allergology, Marburg, Germany</i>         |
|  | Innovative Approaches on Allergen Immunotherapy – Where do we stand?      | Alberto Martinez<br><i>ROXALL Medicines, Zamudio/Bizkaia, Spain</i>  |
|  | Update on SLIT with recombinant Mal d 1 and Bet v 1 in Apple Allergy      | Barbara Bohle<br><i>Institute of Pathophysiology and Allergy Research, Medical University of Vienna, Austria</i> |
|  | Toxicokinetics of Aluminium – Novel Insights in an old Adjuvant           | Karin Weisser<br><i>Paul-Ehrlich-Institut, Germany</i>   |
|  | Novel Adjuvants in Allergen Immunotherapy                                 | Stefan Schülke<br><i>Paul-Ehrlich-Institut, Germany</i>  |
|  | <b>General Discussion</b>   |  |

## 7. Critical Factors and recent Results of Clinical Trials in Allergen Immunotherapy

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| Afternoon | Key Factors for Success or Failure in AIT Trials   | Moisés Calderón<br><i>Imperial College, Section of Allergy and Clinical Immunology, London, UK</i> |
|           | How to deal with the Placebo Effect in AIT Trials? | Christoph Willers  |

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|  |   | <i>Allergopharma GmbH, Reinbek, Germany</i>   |
|  | Food AIT: Impact of different Clinical Outcome Definitions on the perceived Effect                    | Pablo Rodriguez del Rio<br><i>Hospital Infantil Universitario Niño Jesús, Madrid, Spain</i>   |
|  | Novel Insights from the Post Marketing PV System in the USA   | David Bernstein<br><i>Division of Immunology, Allergy and Rheumatology, University of Cincinnati College of Medicine, Cincinnati, OH, USA</i> |
|  | The Use of EEC in AIT Trials for Asthma   | Frederic de Blay<br><i>Nouvel Hôpital Civil, Strasbourg, France</i>   |
|  | Allergen Immunotherapy in Patients with House Dust Mite driven allergic Asthma – a specific Challenge | tbd   |
|  | <b>General Discussion</b>   |   |

## 8. Impact of Omics and Big Data in Allergen Immunotherapy

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| Afternoon | Introduction to Big Data Approaches in the Field of Medicine and Potential Application in Clinical Trials | Amke Caliebe<br><i>Christian Albrechts University, Institute of Medical Informatics and Statistics, Kiel, Germany</i> |
|           | Big Data and Omics in the Regulation of Medicines   | tbd   |
|           | Metabolomics in AIT   | Domingo Barber  |



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|                     |                           | <i>University CEU San Pablo, Faculty of Medicine, Boadilla del Monte, Spain</i> |
|                     | <b>General Discussion</b> |   |
| <b>Social Event</b> |                           |   |

## Saturday, September 5, 2020

### 9. Immunomodulation for Prevention of Allergy

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|---------|---|---|
| Morning | Microbiota and Allergy Prevention                                 | Harald Renz<br><i>Institute for Laboratory Medicine and Pathobiochemistry, University Clinic Marburg, Germany</i>   |
|         | Modulation of Microbiota by Dietary Fiber and Effect on Allergies | Masako Toda<br><i>Laboratory of Food and Biomolecular Science, Graduate School of Agricultural Science, Tohoku University, Sendai, Japan</i>  |
|         | Skincare for Prevention of Allergy?                               | Thomas Werfel<br><i>Clinic of Dermatology, Allergology and Venerology, Research Division Immunodermatology and experimental Allergology, Hannover Medical School, Hannover, Germany</i> |
|         | Bright Future for AIT in Allergy Prevention?                      | Jörg Kleine-Tebbe<br><i>Allergy and Asthma Center Westend, Outpatient &amp; Clinical</i>  |

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|  |                           | <i>Research Center, Berlin, Germany</i> |
|  | <b>General Discussion</b> |   |

### 10. Marketing Authorization and Health Technology Assessment - Unequal Siblings?

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|-----------------------------------|---|---|
| Morning                           | The Role of Mobile Health Technologies in Allergy Care  | Paolo Matricardi<br><i>Charité Universitätsmedizin Berlin, Germany</i>            |
|                                   | Real Life Studies, Strengths and Weaknesses - Options to overcome Limitations                   | Martine Le Gall<br><i>Stallergenes, Antony, France</i>                            |
|                                   | Health Technology Assessment of Allergens in Germany  | Antje Behring<br><i>Federal Joint Committee (G-BA), Berlin, Germany</i>           |
|                                   | Health Technology Assessment and its Implementation in the Authorization of Medicines in the EU | Giovanni Tafuri<br><i>National Health Care Institute, Diemen, The Netherlands</i> |
|                                   | <b>General Discussion</b>   |   |
| <b>Farewell – Closing Remarks</b> |   | Stefan Vieths, Vera Mahler<br><i>Paul-Ehrlich-Institut, Langen, Germany</i>       |
| <b>Lunch</b>                      |   |   |