



16th OPEN SCIENTIFIC EIP SYMPOSIUM
ON
IMMUNOGENICITY OF BIOPHARMACEUTICALS

Program

February 24th – 26th 2025

Monday, February 24th 2025

Workshop Day

- 09:00** **Coming Together**
- 09:15** **Challenging the current paradigms for clinical immunogenicity testing – the pros and cons**
Daniel Kramer, Sanofi
Arno Kromminga, BioNTech
Sebastian Spindeldreher, Integrated Biologix
Christopher Tiedje, BioAgilytix
Lydia Michaut, Novartis
- 10:15** **Coffee Break**
- 10:45** **Continue “Challenging the current paradigms for clinical immunogenicity testing – the pros and cons”**
- 12:15** **Lunch**
- 13:30** **Bring Your own Problems (Break out Sessions)**
Daniel Kramer, Sanofi
Arno Kromminga, BioNTech
Sebastian Spindeldreher, Integrated Biologix
Sofie Pattijn, IQVIA
Noel Smith, Lonza
Sophie Tourdot, Pfizer
Tim Hickling, Roche
Lydia Michaut, Novartis
- 15:00** **Coffee Break**
- 15:30** **Continue “Bring Your own Problems (Break out Sessions)”**
- 16:30** **Closing of the Workshop Day**
- 17:00 – 18:30** **Meeting of the EIP Working Groups**
Members of EIP working groups

Tuesday, February 25th 2025

- 09:00** **Welcome and Introduction by the EIP Chairman**
Daniel Kramer, Sanofi
- 09:15** **Spotlight Presentations: Machine Learning and Immunogenicity: Perspectives on the use of AI in Risk Assessment and Mitigation**
Daniel Leventhal, Xaira Therapeutics

Session 2: Prediction of Immunogenicity

Chair: Sebastian Spindeldreher

- 10:15** **EIP NCIRA Working Group Update**
Sebastian Spindeldreher, Integrated Biologix on behalf of EIP
- 10:30** **Analyzing and decreasing the immunogenicity potential of biotherapeutics using in silico approaches**
Michael Gutknecht, Novartis -invited
- 11:00** **Coffee Break**
- 11:30** **Enhancing Large Molecule Design by Early Integration of MAPPs using Defined Allele Antigen Presenting Cells**
Andreas Hollenstein, Roche
- 12:00** **The localization of T-cell epitopes in biopharmaceuticals: from peptides to gene therapy vectors**
Bernard Maillere, University Paris-Saclay
- 12:30** **Lunch Break**
- 13:30** **Internalization of therapeutic antibodies into Dendritic cells as a risk factor for immunogenicity**
Michel Siegel, Roche
- 14:00** **Aggregation of therapeutic antibodies enhances dendritic cell uptake and T-cell responses**
Marc Pallardy, INSERM
- 14:30** **Suitable peptide controls for screening generic peptide products in adaptive immunogenicity assays**
Chloë Ackaert, IQVIA
- 15:00** **Coffee Break**

Session 3: Immunogenicity Assays

Chair: Arno Kromminga

- 15:30** **EIP Immunogenicity Assays Working Group Update**
Linlin Luo, Merck Sharp & Dome on behalf of EIP
- 15:45** **Current industry practices for in-study cut point setting for clinical immunogenicity assays**
Riejanne Bax-Seigers, ICON

16:15 **Comparing Signal-to-Noise with titer results – a retrospective analysis**
Karin Benstein, Sanofi

16:45 **Addressing Target Interference During the Development of a Neutralizing Anti-Drug Antibody Assay for the clinical support of a bispecific therapeutic antibody**
Saskia van der Lee, Genmab

Session 3: Social Event

Chair: Barbara Vercruyssen

18:00 Get Together

23:00 Good Night

Wednesday, February 26th 2024

Session 4: Immunogenicity Assays continued

Chair: Arno Kromminga

- 09:00** **Fit-for-purpose non-clinical immunogenicity assessment to support PK data interpretation – a case study**
Christopher Tiedje, BioAgilytix
- 09:30** **Evaluating and Mitigating Pre-existing Anti-Drug Antibodies of Bi-Specific Therapeutic Proteins in Early Drug Discovery: A Roche Case Study**
Janine Faigle, Roche
- Short Talks (15 min)**
- 10:00** **A retrospective analysis of clinical immunogenicity data – time for singlicate change?**
Sandra Ribes Miravet, Sandoz
- 10:15** **Is ADA-tiered approach suitable to therapeutics with pre-existing antibodies?**
Issa Jyamubandi, Intertek
- 10:30** **Coffee Break**
- 11:00** **Generation of anti-drug antibody (ADA) positive control and development of a bridging immunogenicity assay for RNA therapeutics in human serum**
Oli Gnana Rajaraman, AiCuris Anti-infective Cures AG
- 11:15** **Application of SPR technology for assessment of immunogenicity of a dual-peptide cancer vaccine**
Daniel Worms, BioAgilytix
- 11:30** **In-depth characterization and semi-quantification of ADAs using innovative hybrid LC-MS methods to support clinical development of biotherapeutics**
Stephane Muccio, Sanofi

Session 5: Clinical Relevance of Immunogenicity

Chair: Lydia Michaut

- 11:45** **Analysis of Clinical Immunogenicity Data for a Multi-Study Program**
Susan Irvin, Regeneron
- 12:15** **The effects of the immune modulator methotrexate on anti-drug antibody formation**
Karin Bloem, Sanquin
- 12:45** **Lunch Break**
- 13:45** **An American Association of Pharmaceutical Scientists (AAPS) Perspective on Clinical Relevance of Immunogenicity**
Mohsen Rajabi, Novartis (on behalf of AAPS)

Session 5: Immunogenicity of Novel Modalities

Chair: Noel Smith

- 14:15** **Success in treatment of cancer and autoimmunity with CAR T-cells: application to prevention and mitigation of immunogenicity of therapeutic proteins?**
Amy Rosenberg, Epivax
- 14:45** **Exploring alternatives to the 3-tiered immunogenicity testing paradigm for gene therapy programs**
Robert Nelson, BioAgilytix

Session 6: Regulatory

Chair: Daniel Kramer

- 15:15** **Applying Innate immune response modulating impurities testing for immunogenicity risk assessments: Statistical and regulatory considerations**
Daniela Verthelyi, FDA
- 15:45** **Future impact of immunogenicity data on Biosimilar developments.**
René Anour, Pfizer.
- 16:15** **Conference Summary & Outlook by the EIP Chairman**
Daniel Kramer, Sanofi
- 16:30** **Close of the conference**