



**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 Break**
- 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

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, University Paris Saclay

14:30 **Suitable peptide controls for screening generic peptide products in adaptive immunogenicity assays**
Chloë Ackaert, IQVIA Laboratories In Vitro Immunology (FKA ImmunXperts)

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**

Floris Loeff, 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
- 15:15** **Cell-Based Assays for Neutralizing Antibodies: From Gene Therapy to Immune Effector Functions**
Michael Tovey, Svar Life Science

Session 6: Regulatory

Chair: Daniel Kramer

- 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**