



**17<sup>th</sup> OPEN SCIENTIFIC EIP SYMPOSIUM**  
**ON**  
**IMMUNOGENICITY OF BIOPHARMACEUTICALS**

**Program**

**March 16<sup>th</sup> – 19<sup>th</sup> 2026**

**Monday, March 16<sup>th</sup> 2026**

## **Trainings**

- 09:00**                      **Welcome and Introduction by the EIP Chairman**  
Daniel Kramer, Sanofi
- 09:15**                      **Immunogenicity Training (one beginner and one advanced immunogenicity training in parallel sessions) – topics to be announced**  
EIP Team
- 10:15**                      **Coffee Break**
- 10:45**                      **Bring Your Own Problems – Break Out Sessions**  
EIP Team
- 12:15**                      **Lunch Break**

## **Main Program**

- 13:15**                      **Keynote Presentation: Innate Immunity**  
Bruno Lemaître, EPFL

### **Session 1: Immunogenicity of New Modalities**

Session Chair: Lydia Michaut, Novartis

- 14:15**                      **Immunogenicity Risk Assessment for Nucleic Acid Therapeutics: A Comprehensive Evaluation for ASOs, siRNAs, and non-vaccine mRNA/LNPs**  
Joanna Grudzinska-Goebel, Bayer
- 14:45**                      **Unraveling xRNA Immunogenicity: Insights and Future Horizons**  
Alessio Maiolica, Novartis
- 15:15**                      **Minimizing immunogenicity testing for development of oligonucleotide therapeutics: A risk-based strategy**  
An Zhao, Regeneron Pharmaceuticals
- 15:45**                      **Coffee Break**
- 16:15**                      **Transient blockade of the CD28/B7 costimulatory pathway with abatacept inhibits immune responses to AAV vector and transgene product**  
Rebecca Xicluna, Roche
- 16:45**                      **Advancing Immunogenicity Testing: Overcoming Drug Tolerance in a Neutralising Antibody Assay for an mRNA-Based Oncology Therapeutic**  
Juliane Ober-Blobaum, Moderna
- 17:15**                      **Immunogenicity Risk Assessment and Mitigation Strategy for AAV Gene Therapy**  
Hélène Haegel, Roche
- 17:45**                      **End of Day 1**

## **Tuesday, March 17<sup>th</sup> 2026**

### **Session 2: Regulatory**

Chair: Daniel Kramer, Sanofi

- 9:00**                      **New Version of the FDA Immunogenicity Guidance (title to be confirmed)**  
Joao Pedras-Vasconcelos, FDA
- 9:30**                      **Future Direction of Immunogenicity at FDA (title to be confirmed)**  
Susan Kirshner, FDA
- 10:00**                    **Harmonizing Adalimumab Anti-drug Antibody Assays through WHO International Standards**  
Meenu Wadhwa, Medicines and Healthcare Products Regulatory Agency
- 10:30**                    **Coffee Break**

### **Session 3: Immunogenicity of Therapeutic Peptides**

Chair: Arno Kromminga, BioNTech

- 11:00**                    **Immunogenicity Risk in Peptide Therapeutics: Navigating Complexity, Prediction tools, and Bioanalytical Strategies**  
Montserrat Puig, Merck Sharp & Dohme
- 11:30**                    **Clinical Pharmacology Perspectives on Immunogenicity of Peptide Drugs**  
Rajabi Mohsen, Novartis
- 12:00**                    **Aligning Regulatory Expectations on Immunogenicity to Support Peptide Drug Product Approvals**  
Laura Salazar-Fontana, Immunogenicity Integrated
- 12:30**                    **Lunch Break**

### **Session 4: Immunogenicity Assays**

Chair: Christopher Tiedje, BioAgilytix

- 13:30**                    **EIP Immunogenicity Assays and EIP Immunogenicity Risk Assessment Working Group Update**  
Linlin Luo, Merck Sharp & Dohme on behalf of EIP Assay Working Group  
Veerle Snoeck, UCB & Joanna Grudzinska-Goebel, Bayer on behalf of the EIP Immunogenicity Risk Assessment (IRA) Working Group
- 13:45**                    **Overcoming Unexpected Interference in a Highly Drug-Tolerant and Ultrasensitive ADA-SPEAD Assay**  
Florian Anlauff, BioAgilytix
- 14:15**                    **PABAD in Practice: Achieving High Drug Tolerance in NAb Assays**  
Lysie Champion, Celerion
- 14:45**                    **When Generic Assays Succeed (and Fail): Case Studies and a Fit-for-Purpose Strategy for Non-Clinical ADA Support**  
Noor Bodrul, Roche
- 15:15**                    **Coffee Break**

- 15:45**                    **The Immunogenicity Nexus: Investigating the Predictive Relationship Between Early-Onset ADA Kinetics in NHP and Human Immune Responses**  
Griet Conickx, Sanofi
- 16:15**                    **Positive Controls in Immunogenicity Assays: Case Studies and Best Practices**  
Ester Biemans, Ardena
- 16:45**                    **A Drug and Target-Tolerant Hybrid LBA-LC-MS Method for (Semi-)Quantification of ADA Isotopes, Using a Single-Tier Approach**  
Hendrik Folkerts, ICON Bioanalytical Laboratory
- 17:15**                    **End of Day 2**

## **Wednesday, March 18<sup>th</sup> 2026**

### **Session 5: Biosimilars**

Chair: Denise Sickert

- 09:00**                      **EIP Biosimilar Working Group Update**  
Martin Ullmann, Fesenius Kabi on behalf of EIP
- 09:15**                      **Establishing in-vitro assays for non-clinical immunogenicity assessment of biosimilars**  
Marc Rosenbaum, Hexal AG
- 09:45**                      **Title to be confirmed**  
Karsten Roth, Polpharma Biologics
- 10:15**                      **A Comparative Analysis of Antidrug Antibody Incidences of EU and US Approved Biosimilars and their Reference Products Reported in Single-Dose PK Studies in Healthy Volunteers and Multidose Studies in Patients**  
Hans Ebbers, Alvotech
- 10:45**                      **Coffee Break**

### **Session 6: Prediction of immunogenicity**

Chair: Sofie Pattyn

- 11:15**                      **EIP NCIRA Working Group Update**  
Sebastian Spindeldreher, Integrated Biologix
- 11:30**                      **Immunogenicity Risk Assessment: Enabling Quality by Design in Therapeutic Protein Discovery and Development**  
Tim Hickling, Quasor & Sophie Tourdot, Pfizer
- 12:00**                      **How to translate pre-clinical in silico immunogenicity profiling results to clinical immunogenicity rates?**  
Michael Gutknecht, Novartis
- 12:30**                      **Lunch Break**
- 13:30**                      **Unmasking Hidden Epitopes: Bridging In Silico Prediction and MAPPs Detection in Immunogenicity Assessment**  
Andreas Hollenstein, Roche
- 14:00**                      **Advancing Preclinical Immunogenicity Prediction: Machine Learning on Clinical Data and Pathogen Cross-Reactivity Integration**  
Olga Obrezanova, Astra Zeneca
- 14:30**                      **An Innovative Reductionist Antigen Presenting System to Rapidly Screen Protein Immunogenicity in Human Lysosomes**  
Sergio Gabriele Colangelo, RBM S.p.A., an affiliate of Merck KGaA
- 15:00**                      **Coffee Break**

### **Session 7: Clinical Relevance of Immunogenicity**

Chair: Noel Smith, Lonza

**15:30**                      **Assessment of Long-term Immunogenicity of Lonapegsomatropin in Children With Growth Hormone Deficiency**  
Per Holse Mygind, Ascendis

#### **Short Talk (10 minutes)**

**16:00**                      **Immunogenicity Assessment in Acromegaly Patients Treated with Ready-to-Use, Sustained-Release, Octreotide Subcutaneous Depot**  
K. Järås, Camurus

**16:15**                      **Immunogenicity Publication Bias and Its Consequences for Predictive Models: A Call for Transparent Reporting**  
Sophie Tascedda, RC2NB

**16:30**                      **End of Day 3**

### **Session 8: Social Event (reconvene at 17:00 in the Altis lobby)**

Chair: Barbara Vercruyssen

## **Thursday, March 19<sup>th</sup> 2026**

### **Workshop – Parallel Sessions**

- 09:00**                      **Deep Dive:**  
**Recent Publication “Immunogenicity Risk Assessment for Tailored Mitigation and Monitoring of Biotherapeutics and Biosimilars”**  
Veerle Snoeck, UCB and Joanna Grudzinska-Goebel, Bayer on behalf of the EIP Immunogenicity Risk Assessment (IRA) Working Group
- 9:00**                        **Deep Dive:**  
**Three Recent Publications of the NCIRA Working Group (EIP Recommendations for Dendritic Cell Maturation Assays, MAPPs and T-Cell Assays)**  
Sebastian Spindeldreher, Integrated Biologix on behalf of the EIP NCIRA Working Group
- 10:30**                      **Coffee Break**
- 11:00**                      **Bring Your Own Problems – Break Out Sessions**  
EIP Team
- 12:30**                      **Summary and Outlook of the EIP Chairman**  
Daniel Kramer, Sanofi
- 12:45**                      **End of the conference**