



**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

#### Trainings – Parallel Sessions

09:15	<b>Immunogenicity Beginner Training – Topic to be Announced</b> EIP Team	<b>Immunogenicity Advanced Training – Topic to be Announced</b> EIP Team
10:15	<b>Coffee Break</b>	
10:45	<b>Bring Your Own Problems – Break Out Session 1</b> EIP Team	<b>Bring Your Own Problems – Break Out Session 2</b> EIP Team
12:15	<b>Lunch Break</b>	

### Main Program

13:45 **Keynote Presentation: Innate Immunity**  
Bruno Lemaître, EPFL

#### Session 1: Immunogenicity of New Modalities

Session Chair: Lydia Michaut, Novartis

14:45	<b>Immunogenicity Risk Assessment for Nucleic Acid Therapeutics: A Comprehensive Evaluation for ASOs, siRNAs, and non-vaccine mRNA/LNPs</b> Joanna Grudzinska-Goebel, Bayer
15:15	<b>Imlifidase Treatment for Overcoming Pre-Formed Immunity</b> Hitto Kaufmann, Hansa Biopharma
15:45	<b>Minimizing immunogenicity testing for development of oligonucleotide therapeutics: A risk-based strategy</b> An Zhao, Regeneron Pharmaceuticals
16:15	<b>Coffee Break</b>
16:45	<b>Transient blockade of the CD28/B7 costimulatory pathway with abatacept inhibits immune responses to AAV vector and transgene product</b> Rebecca Xicluna, Roche
17:15	<b>Advancing Immunogenicity Testing: Overcoming Drug Tolerance in a Neutralising Antibody Assay for an mRNA-Based Oncology Therapeutic</b> Juliane Ober-Blobaum, Moderna
17:45	<b>Immunogenicity Risk Assessment and Mitigation Strategy for AAV Gene Therapy</b> Hélène Haegel, Roche
18:15	<b>End of Day 1</b>

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

### **Session 2: Regulatory**

Chair: Daniel Kramer, Sanofi

9:00 **Immunogenicity, Where we Have Been and Where we are Going**  
Susan Kirshner, FDA

9:30 **The Slings and Arrows of Outrageous Product Quality Fortune- Current Immunogenicity Risk Perspectives from CDER's Office of Pharmaceutical Quality**  
Joao Pedras-Vasconcelos, 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

14:00 **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

14:30 **Overcoming Unexpected Interference in a Highly Drug-Tolerant and Ultrasensitive ADA-SPEAD Assay**  
Florian Anlauff, BioAgilytix

15:00 **PABAD in Practice: Achieving High Drug Tolerance in NAb Assays**  
Lysie Champion, Celerion

15:30 **When Generic Assays Succeed (and Fail): Case Studies and a Fit-for-Purpose Strategy for Non-Clinical ADA Support**  
Noor Bodrul, Roche

16:00 **Coffee Break**



16:30 **The Immunogenicity Nexus: Investigating the Predictive Relationship Between Early-Onset ADA Kinetics in NHP and Human Immune Responses**  
Griet Conickx, Sanofi

17:00 **Positive Controls in Immunogenicity Assays: Case Studies and Best Practices**  
Ester Biemans, Ardena

17:30 **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

18:00 **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, Fresenius Kabi on behalf of EIP

09:15 **Establishing In-Vitro Assays for Non-Clinical Immunogenicity Assessment of Biosimilars**  
Marc Rosenbaum, Hexal AG

09:45 **Biosimilar Medicines: The Story of European Pioneering Success in Advancing Patient Access to Lifesaving Biologic Treatment**  
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 **Poster/Exhibition Lunch**

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

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

15:00 **Improving TCR-pMHC Structure Prediction with TCR-Specific Spatial Restraint Features**  
Joakim Nøddeskov, Technical University of Denmark



15:15

**Coffee Break**

**Session 7: Clinical Relevance of Immunogenicity**

Chair: Noel Smith, Lonza

15:45

**Assessment of Long-term Immunogenicity of Lonapegsomatropin in Children With Growth Hormone Deficiency**

Per Holse Mygind, Ascendis

**Short Talk (10 minutes)**

16:15

**Immunogenicity Assessment in Acromegaly Patients Treated with Ready-to-Use, Sustained-Release, Octreotide Subcutaneous Depot**

K. Järås, Camurus

16:30

**Immunogenicity Publication Bias and Its Consequences for Predictive Models: A Call for Transparent Reporting**

Sophie Tascedda, RC2NB

16:45

**End of Day 3**

**Session 8: Social Event (reconvene at 17:15 in the Altis lobby)**

Chair: Barbara Vercruyssen



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

### Workshop – Parallel Sessions

09:00	<b>Deep Dive 1:</b> <b>Recent Publication “Immunogenicity Risk Assessment for Tailored Mitigation and Monitoring of Biotherapeutics and Biosimilars”</b> Veerle Snoeck, UCB and Joanna Grudzinska-Goebel, Bayer on behalf of the EIP Immunogenicity Risk Assessment (IRA) Working Group	<b>Deep Dive 2:</b> <b>Three Recent Publications of the NCIRA Working Group (EIP Recommendations for Dendritic Cell Maturation Assays, MAPPs and T-Cell Assays)</b> Sebastian Spindeldreher, Integrated Biologix on behalf of the EIP NCIRA Working Group
10:30	<b>Coffee Break</b>	
11:00	<b>In Depth Discussion Deep Dive 1</b> EIP Team	<b>In Depth Discussion Deep Dive 2</b> EIP Team
12:30	<b>Summary and Outlook of the EIP Chairman</b> Daniel Kramer, Sanofi	
12:45	<b>End of the conference</b>	