



17th OPEN SCIENTIFIC EIP SYMPOSIUM
ON
IMMUNOGENICITY OF BIOPHARMACEUTICALS

Program

March 16th – 19th 2026

Monday, March 16th 2026

09:00 **Welcome and Introduction by the EIP Chairman**
Daniel Kramer, Sanofi

09:15 **Keynote Presentation: Innate Immunity**
Bruno Lemaître, EPFL

10:15 **Coffee Break**

Trainings – Parallel Sessions

10:45	Immunogenicity Beginner Training: Mechanisms of Immunogenicity; Overview of Non-Clinical Risk Assessment Tools	Immunogenicity Advanced Training: Interactions With Health Agencies: Real Life Examples
	Chloé Ackaert, IQVIA Sofie Pattyn, IQVIA Noel Smith, Lonza Sophie Tourdot, Pfizer	Daniel Kramer, Sanofi Lydia Michaut, Novartis Sebastian Spindeldreher, Integrated Biologix

12:00 **Lunch Break**

13:00 **Bring Your Own Problems – Break Out Session:
Immunogenicity Assays, Assay Strategy, Immunogenicity Risk Assessment**

Daniel Kramer, Sanofi
Arno Kromminga, BioNTech
Lydia Michaut, Novartis
Denise Sickert, Roche
Veerle Snoeck, UCB
Christopher Tiedje, BioAgilytix

Main Program

Session 1: Immunogenicity of New Modalities

Session Chair: Lydia Michaut, Novartis

14:45 **Immunogenicity Risk Assessment for Nucleic Acid Therapeutics: A Comprehensive
Evaluation for ASOs, siRNAs, and non-vaccine mRNA/LNPs**
Joanna Grudzinska-Goebel, Bayer

15:15 **Imlifidase Treatment for Overcoming Pre-Formed Immunity**
Hitto Kaufmann, Hansa Biopharma

15:45 **Minimizing immunogenicity testing for development of oligonucleotide
therapeutics: A risk-based strategy**
An Zhao, Regeneron Pharmaceuticals

16:15 **Coffee Break**

16:45 **Transient blockade of the CD28/B7 costimulatory pathway with abatacept inhibits
immune responses to AAV vector and transgene product**

Rebecca Xicluna, Roche

17:15 **Advancing Immunogenicity Testing: Overcoming Drug Tolerance in a Neutralising Antibody Assay for a mRNA-Based Oncology Therapeutic**
Juliane Ober-Blöbaum, Moderna

17:45 **Immunogenicity Risk Assessment and Mitigation Strategy for AAV Gene Therapy**
Hélène Haegel, Roche

18:15 **End of Day 1**

Tuesday, March 17th 2026

Session 2: Regulatory

Chair: Daniel Kramer, Sanofi

- 9:00** **Immunogenicity, Where we Have Been and Where we are Going**
Susan Kirshner, Consultant (former 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**
- 11:00** **Rethinking Immunogenicity Testing Paradigm: Leveraging Risk Assessment Outputs to Support Clinical Development**
Vibha Jawa, EpiVax & Lauren Stevenson, Immunogix

Session 3: Immunogenicity of Therapeutic Peptides

Chair: Arno Kromminga, BioNTech

- 11:30** **Immunogenicity Risk in Peptide Therapeutics: Navigating Complexity, Prediction tools, and Bioanalytical Strategies**
Montserrat Puig, Merck Sharp & Dohme
- 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
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**
Yana Van Den Bossche, Sanofi
- 17:00** **Positive Controls in Immunogenicity Assays: Case Studies and Best Practices**
Esther 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 18th 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 Ebberts, 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 presentation; 5 minutes Q&A)

- 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 presentation; 5 minutes Q&A)

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 Move to lobby to take the bus

Session 8: Social Event (departure at 17:15)

Chair: Barbara Verduyssen

Thursday, March 19th 2026

Workshop – Parallel Sessions

09:00	Deep Dive 1: 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	Deep Dive 2: 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	In Depth Discussion Deep Dive 1 EIP Team	In Depth Discussion Deep Dive 2 EIP Team
12:30	Summary and Outlook of the EIP Chairman Daniel Kramer, Sanofi	
12:45	End of the conference	