



17th OPEN SCIENTIFIC EIP SYMPOSIUM
ON
IMMUNOGENICITY OF BIOPHARMACEUTICALS

Program

March 16th – 19th 2026

Monday, March 16th 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 17th 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 18th 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 bio-similars**
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 19th 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**