



14th OPEN SCIENTIFIC EIP SYMPOSIUM
ON
IMMUNOGENICITY OF BIOPHARMACEUTICALS

Program

April 26th – 28th 2023

Wednesday, April 26th 2023

Training Course

09:00 Coming together

In-Study Cut-Points

09:15 **Practical Advice When and How to Perform in-Study Cut-points**
Viswanath Devanarayan, Eisai
EIP Experts

10:30 **Coffee Break**

11:00 **Immunogenicity - Always a Concern?**
EIP Experts

12:00 **Lunch**

Assay validation and immunogenicity assessment

13:30 **Bring your own problems (break out sessions)**
Daniel Kramer, Sanofi
Arno Kromminga, BioNTech
Sebastian Spindeldreher, Integrated Biologix
Sofie Pattijn, ImmunXperts
Sophie Tourdot, Pfizer

15:00 **Coffee Break**

15:30 **Continue “Bring your own problems (break out sessions)”**

16:30 **Close of the training course**

17:00 – 18:30 **Meeting of the EIP Working Groups**
Members of EIP working groups

Thursday, April 27th 2023

09:00 **Welcome and introduction by the EIP chairman**
Daniel Kramer, Sanofi

09:15 **Keynote Speaker to be confirmed**

Session 1: Immunogenicity Assay Strategies

Chair: Veerle Snoeck

10:00 **EIP Immunogenicity Strategy Working Group Update**
Joanna Grudzinska-Goebel, Bayer on behalf of EIP

10:15 **EIP Immunogenicity Assays Working Group Update**
Linlin Luo, Merck Sharp & Dome on behalf of EIP

10:30 **S/N versus Titer to Quasi-Quantify Immunogenicity – Industry Perspective**
Daniel Baltrunkonis, Pfizer

11:00 **Coffee Break**

11:30 **S/N versus Titer to Quasi-Quantify Immunogenicity – Statistical Perspective**
Viswanath Devanarayan, Eisai

12:00 **S/N versus Titer to Quasi-Quantify Immunogenicity – Regulatory Perspective**
Joao Pedras-Vasconcelos, FDA

12:30 **Singlicate Analysis for Immunogenicity**
Johannes Stanta, Celerion

13:00 **Lunch Break**

Session 2: Prediction of Immunogenicity

Chair: Sebastian Spindeldreher on behalf of EIP

14:00 **EIP NCIRA Working Group update**
Sebastian Spindeldreher, Integrated Biologix

14:30 **Number of Donors Needed to Adequately Assess in-vitro Assays**
Sofie Denies, SD Analytics

15:00 **Coffee Break**

15:30 **Current FDA Thinking on Predicting Immunogenicity Risk for Biologics – title to be confirmed**
Daniela Verthelyi, FDA

16:00 **Opportunities and Challenges in Quantitative Systems Pharmacology: IG Simulator Evaluation**
Tim Hickling, Roche

16:30 **Standardization of in-vitro Assays”**
Laurent Malherbe, Eli Lilly & Sofie Pattijn, ImmuneXperts

Session 3: Social Event

Chair: Barbara Vercruyssen

17:30 Get Together
23:00 Good Night

Friday, April 28th 2022

Session 4: Immunogenicity of New Modalities

Chair: Arno Kromminga

- 09:00** **Role of the Innate and Adaptive Immune System to Immunogenicity in Gene Therapy**
Laura Salazar-Fontana, NDA
- 09:30** **Aspects of the Immunogenicity Assessment Against mRNA Based Products**
Arno Kromminga, BioNTech
- 10:00** **Immunogenicity risk assessments for Cellular and Gene Therapies – title to be confirmed**
Zuben Sauna, FDA
- 10:30** **Coffee Break**
- 11:15** **CAR-T Cell Therapy – Immunogenicity – title to be confirmed**
Lydia Michaut, Novartis
- 11:45** **Lunch Break**

Session 5: Clinical Relevance of Immunogenicity

Chair: Gregor Lotz

- 13:00** **Integrated PK/PD/ ADA Approach Instead of NAb Assays**
Karin Nana Weldingh, NovoNordisk
- 13:30** **Characterization of ADA Responses to Understand Impact of Immunogenicity on Bispecific Drug Exposure and Activity**
Gregor Lotz, Roche

Session 6: Regulatory

Chair: Daniel Kramer

- 14:00** **Current thinking on Immunogenicity Risk Assessment (IRA) and Integrated Summary of Immunogenicity (ISI) from EMA**
Speaker to be confirmed
- 14:30** **Current thinking on IRA and ISI from health Canada**
Speaker to be confirmed
- 15:00** **Conference Summary & Outlook by the EIP Chairman**
Daniel Kramer, Sanofi
- 15:15** **Close of the conference**