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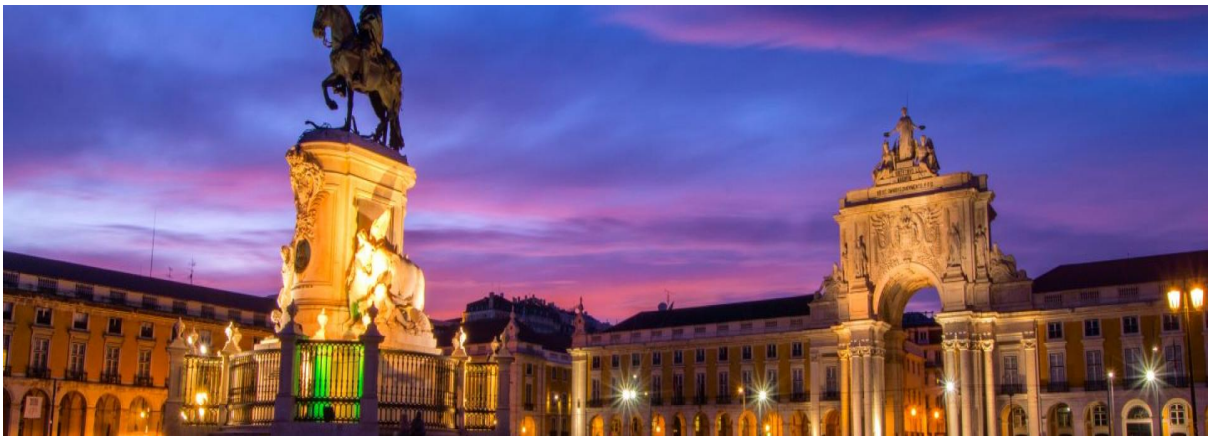
European Immunogenicity Platform



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**
Daniel Kramer, Sanofi
Viswanath Devanarayan, Eisai

10:30 **Coffee Break**

Assay Validation and Immunogenicity Assessment

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

12:00 **Lunch**

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
Veerle Snoeck, UCB
Gregor Lotz, Roche
Lydia Michaut, Novartis

15:00 **Coffee Break**

15:30 **Continue "Bring Your own Problems (Break out Sessions)"**

16:30 **Closing of the Training Course**

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

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Thursday, April 27th 2023

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

09:15 **Spotlight Presentation: Immunogenicity characterization - Anti-Brolucizumab Immune Response as one Prerequisite for Rare RV/RO Adverse Events**
Michael Gutknecht, Novartis

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 **Singlicate Analysis for Immunogenicity**
Johannes Stanta, Celerion

11:00 **Coffee Break**

11:30 **S/N versus Titer to Quasi-Quantify Immunogenicity – Industry Perspective**
Daniel Baltrunkonis, Pfizer

12:00 **S/N versus Titer to Quasi-Quantify Immunogenicity – Statistical Perspective**
Viswanath Devanarayan, Eisai

12:30 **S/N versus Titer to Quasi-Quantify Immunogenicity – Regulatory Perspective**
Joao Pedras-Vasconcelos, FDA

13:00 **Lunch Break**

Session 2: Prediction of Immunogenicity

Chair: Sebastian Spindeldreher

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

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 the use of Non-Clinical Tools in Immunogenicity Risk Assessments: Possibilities and Challenges**
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

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Session 3: Social Event
Chair: Barbara Vercruyssen

17:30	Get Together
23:00	Good Night

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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	**Understanding and Navigating Immune Responses to Cas Proteins Used in Gene Editing** Zuben Sauna, FDA
10:30	**Coffee Break**
11:15	**CAR-T Cell Therapy – Insights in Immunogenicity** 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	**Nonclinical Immunogenicity Risk Assessment from Regulatory Perspective** Tatjana Petkovic, Swissmedic
14:30	**Feedback of Health Agencies to EIP member companies: a survey analysis** Lydia Michaut, Novartis on behalf of the EIP assay working group
15:00	**Conference Summary & Outlook by the EIP Chairman** Daniel Kramer, Sanofi
15:15	**Close of the conference**

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