EIP
European Immunogenicity Platform

15th OPEN SCIENTIFIC EIP SYMPOSIUM

ON

IMMUNOGENICITY OF BIOPHARMACEUTICALS

Program

April 22nd – 24th 2024

Monday, April 22nd 2024

Workshop Day

09:00 **Coming Together**

Immunogenicity Risk Assessment

09:15 **Consolidated EIP Proposal for Immunogenicity Risk Assessment**
Veerle Snoeck, Joanna Grudzinska Goebel on behalf of EIP

10:15 **Coffee Break**

In-silico and in-vitro Assays as Part of the Immunogenicity Risk Assessment

10:45 **Immunogenicity potential assessment at Novartis**
Anette Karle, Novartis

11:15 **Immunogenicity potential assessment at Pfizer**
Sophie Tourdot, Pfizer

11:45 **Design and Implementation of a Risk-Based Strategy for Reducing Immunogenicity Risk of Protein Therapeutics**
Karen Heyninck, Sanofi

12:15 **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
Tim Hickling, Roche
Lydia Michaut, Novartis

15:00 **Coffee Break**

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

16:30 **Closing of the Workshop Day**

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

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Tuesday, April 23rd 2024

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

09:15 **Spotlight Presentations: MHC Class I and its Importance for the Immunogenicity of Novel Modalities**
Morten Nielsen, Technical University of Denmark
Zuben Sauna, FDA

Session 2: Prediction of Immunogenicity

Chair: Sebastian Spindeldreher

10:15 **EIP NCIRA Working Group Update**
Sebastian Spindeldreher, Integrated Biologix on behalf of EIP

10:30 **Immunogenicity: It's Personal**
Annie de Groot, EpiVax

11:00 **Coffee Break (and poster presentation)**

Short Talks (15 min)

11:30 **High-Sensitive MAPPS Analysis for High-Confident Immunogenicity Risk Assessment**
Elise Pepermans, ImmuneSpec

11:45 **Standardization of in-Vitro Assays - Update from the HESI Collaboration**
Sofie Pattyn, ImmuneXperts

12:00 **Immunogenicity of Therapeutic Antibodies: Role of Aggregation in T Lymphocyte Response**
Marc Pallardy, INSERM

12:15 **Lunch Break**

13:30 **Expanding the MAPPs Assay to MHC-II-DR, -DP and –DQ Receptors**
Axel Ducret, Roche

14:00 **Naive and Memory FVIII-Specific Regulatory and Conventional CD4 T Cells Share Common Epitopes in Healthy Individuals**
Bernard Maillere, CEA

Session 3: Immunogenicity Assays

Chair: Veerle Snoeck

14:30 **EIP Immunogenicity Assays Working Group Update**
Linlin Luo, Merck Sharp & Dome on behalf of EIP

14:45 **Coffee Break (and poster presentation)**

15:15 **Domain Characterizatin of Bi-specifics in the ADA and in the NAb Assay**
Issa Jyamubandi, Resolian Bioanalytics

15:45 **Case study: Developing an ADA assay with enhanced Free Drug Tolerance for Octreotide**
Rene Wuttke, Debiopharm

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16:15	**Phase-appropriate implementation of a domain specificity strategy** Matthias Reichel, Bioagilytix
16:45	**The IVDR and its Impact on Clinical Immunogenicity Assay Development** Robert Nelson, Bioagilytix

Session 3: Social Event

Chair: Barbara Vercruyssen

18:00	Get Together
23:00	Good Night

Wednesday, April 24th 2024

Session 4: Immunogenicity of New Modalities

Chair: Arno Kromminga

09:00 **Development of an ELIspot Assay for the Assessment of AAV Peptides to Examine Immune Safety**
Alison Johnson, Boehringer Ingelheim

09:30 **Immunogenicity Risk Assessment for mRNA/LNP Therapies**
Joanna Grudzinska Goebel, Bayer

10:00 **Total or Neutralizing Antibodies Against Adeno-Associated Virus, What is the Best**
Sabrina Lory, UCB

10:30 **Orthogonal Approach for AAV Immunogenicity Assessment: Evaluating Total and Neutralizing Antibodies**
Michael Tovey, SVAR

11:00 **Coffee Break (and poster presentation)**

Session 5: Clinical Relevance of Immunogenicity

Chair: Lydia Michaut

11:30 **Overcoming Magic Bullet Approaches for Immune Tolerance Induction for Complex Diseases: Application to Immunogenicity of Biological Therapeutics**
Amy Rosenberg, EpiVax

12:00 **ADA Monitoring Strategy for Repetitive High Doses of Biologics Therapies: Efficiently Integrating Scientific, Technical, and Regulatory Aspects**
Manisha Saxena, Novartis

12:30 **The Wonderful World of Immunogenicity; Scientific Understanding, Clinical Relevance, and Regulatory Necessity**
Floris Loeff, Sanquin

13:00 **Lunch Break**

Short Talks (15 min)

14:15 **Drug T Cell Reactivity in Delayed Type Hypersensitivity – Evaluation with Cyto-LTT**
Lester Thoo, ADR-AC

14:30 **Evaluating Immediate Type Drug Allergy and Immunostimulation in Vitro with the Basophil Activation Test (BAT)**
Daniel Yerli, ADR-AC

Session 6: Regulatory

Chair: Daniel Kramer

14:45 **How CDER Reviews Immunogenicity for Biologics- the Integrative Immunogenicity Assessment Paradigm**
Joao A. Pedras-Vasconcelos, FDA

15:30 **New approaches to assess immunogenicity risk: Regulatory considerations**
Daniela.Verthelyi, FDA

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16:00	**Conference Summary & Outlook by the EIP Chairman** Daniel Kramer, Sanofi
16:15	**Close of the conference**

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