



EBF Cyberconnect Events:
Training Day: Practical Aspects of Immunogenicity
23-24 March 2021

Day 1: 23 March 2021

Times are in CET-zone (Brussels)

- 12:30 12:45** **Coming online**
- 12:45 13:00** **Getting started – Welcome**
Philip Timmerman – EBF
- 13:00 15:00** **Day 1 – Session 1**
Session chair: Jo Goodman, AstraZeneca
- 13:00 13:30 Joanne Goodman, on behalf of the EBF
Immunogenicity – an introduction
- 13:30 13:50 Robert Nelson, on behalf of the EBF
Immunogenicity and regulations
- 13:50 14:10 Anna Laurén, on behalf of the EBF
A strategic approach to nonclinical immunogenicity assessment: a Recommendation from the European Bioanalysis Forum
- 14:10 14:40 Roland Staack, on behalf of the EBF
Drug Tolerance target interference
- 14:40 15:00 Viswanath Devanarayan, GlaxoSmithKline
Cutpoint settings
- 15:30 18:00** **Day 1 – Session 2**
Session chair: Michaela Golob, Nuvisan
- 15:30 16:00 Viswanath Devanarayan, GlaxoSmithKline
Outlier exclusion, including Q&A on CP/Outlier exclusion
- 16:00 16:30 Mantas Malisauskas – Merck KGaA
Pre-existing ADA: why should we care?
- 16:30 16:50 James Lawrence – F-Star
Characterisation
- 16:50 17:10 Meina Liang – AstraZeneca
Case study on domain specificity
- 17:10 17:30 Ingeborg Dreher, on behalf of the EBF
Towards an EBF recommendation on nAb
- 17:30 18:00 Nicoline Videbaek – NovoNordisk
nAb assay case study – Much ado about nothing? including session Q&A
- 18:00 19:00 Zoom session stays open for post meeting interactions

Day 2: 24 March 2021

- 12:45 13:00** **Coming online**
- 13:00 15:30** **Day 2 – Session 3**
Session chair: Robert Nelson, Covance
- 13:00 13:30 Samuel Pine - Ablynx, a Sanofi Company
New Modalities – New Challenges or more of the same?
- 13:30 14:00 James Munday – on behalf of the EBF C> Team
CGT immunogenicity overview
Immunogenicity assessments against the transgene product
- 14:00 14:30 Manuela Braun – on behalf of the EBF C> team
Immunogenicity pre-screening in CGT development
- 14:30 15:00 Christian Joffroy – Novartis
Flow cytometry based immunogenicity assays for CART
- 15:00 15:30 Q&A
- 16:00 18:00** **Day 2 – Session 4**
Session chair: Kyra Cowan, Merck KGaA
- 16:00 16:30 Kyra Cowan – Merck KGaA
Clinical Immunogenicity: Case Studies in the Life Cycle of ADA Assays
- 16:30 16:50 Daniel Kramer – Sanofi
Risk Based Approaches to Immunogenicity
- 16:50 17:10 Jonas Blaes – AbbVie
Regulatory requirements translated into day-to-day practice
- 17:10 17:30 Michael Partridge – Regeneron
Immunogenicity Monitoring for Low-Risk Molecules: Are We Over Reporting ADA?
- 17:30 18:00 Close out discussion and Q&A
- 18:00** **Adjourn**
- 18:00 19:00 Zoom session stays open for post meeting interactions



Organising Committee:

Michaela Golob (Nuvisan), Joanne Goodman (AstraZeneca), Robert Nelson (Covance),
Kyra Cowan (Merck KGaA), Roland Staack (F. Hoffmann - La Roche) and Philip Timmerman (EBF)