



Challenging the Current Paradigm for ADA testing

21-22 September 2023

NH Malaga, Malaga, Spain

Thursday 21-Sep-2023

9:00 9:10 **Welcome**

9:10 9:30 **Session 0: Why this meeting? & introduction to the round tables**

A prepared mind: introduction to and intended deliverable of the themes the afternoon round table questions

9:30 11:00 **Session 1: Setting the Scene - the current landscape**

9:30 9:50 *presenter on behalf of the EBF, tbd*

Increasing the value of science in ADA testing

9:50 10:15 *Lauren Stevenson, Immunogix Laboratories*

A 21st century paradigm: Immunogenicity assays are biomarker assays

10:15 10:40 *Daniel Baltrukonis, Pfizer*

All We Need Is Screen; When Confirmatory and Titer Tiers Are Not Necessary in Clinical ADA Assays

10:40 11:00 Q&A

11:00 11:30 **Coffee break**

11:30 12:30 **Session 2: Alternative approaches for titer - Case studies (20 min + 5 min discussion)**

11:30 11:55 *Carsten Krantz, Novartis*

Considerations and opportunities on the lean approach of anti-drug antibodies based on the several cases.

11:55 12:20 *Desislava Galeva, Labcorp*

An alternative approach to the classic anti-drug antibody (ADA) titer assay used in a clinical trial

12:20 12:45 *Davide Guerrieri, Sandoz*

Signal-to-Noise for a more accurate determination of immunogenicity response

12:45 13:45 **Lunch break**

13:45 15:25 **Session 3: Clinically relevant detection - Case studies (20 min + 5 min discussion)**

13:45 14:10 *Hanna Widmaier, Nuvisan*

Cut-Point Limbo - low cut-points and their challenges

14:10 14:35 *Karien Bloem, Sanquin*

Clinically relevant ADA testing for monoclonal antibody biologics

14:35 15:00 *Foka Venema, Ardena*

Key publications for cut point calculations - CRO perspective: choosing between multiple implemented experimental and statistical approaches

15:00 15:25 *Brendy Van Butsel, Sanofi*

Challenging the classical tiered approach in clinical ADA testing

15:25 15:50 *John Cook, Charles River Laboratories*

Title under revision: Does the confirmatory tier always add value?

15:50 16:20 Coffee break

16:20 18:20 Session 4: round table discussion

The delegates will be grouped into tables of maximum 10 (including moderator and note taker). The outcome of the discussion will serve as the basis for the recommendation for an alternative approach for clinically relevant ADA testing to be presented and discussed in plenary on day 2

18:20 Day 1 close out

Friday 22-Sep-2023

9:00 10:15 Session 5: Rethinking assay - Case studies (20 min + 5 min discussion)

9:00 9:25 *Adriano Luis Soares de Souza, Fresenius Kabi Swiss*

Demonstrating the feasibility ADA titer determination by singlicate analysis: Case study based on a Tocilizumab biosimilar

9:25 9:50 *Luis C. Perez Tosar, Novo Nordisk*

Re-thinking Radioimmunoassay for the detection of anti-drug antibodies against peptide drugs

9:50 10:15 *Toralf Roch, CheckImmune*

Detection of anti-PEG antibodies in clinical studies

10:15 10:40 *Gregor Jordan, Roche Diagnostics*

Model informed assay development (MIAD). How can we confirm with an orthogonal method the "Signal/Noise" immunogenicity reporting strategy?

10:40 11:20 Coffee break

11:20 11:55 Session 6: Multidomain specificity characterisation - Case studies (20 min + 5 min discussion)

11:20 11:55 *Lysie Champion, Celerion*

Alternative approach to refine validation of immunogenicity assays with domain specificity characterization

11:55 12:20 *Christopher Tiedje, BioAgilytix*

Title tbc

12:20 12:45 *Open slot: as we further prepare the case studies additional relevant contributions are being identified*

Presentation fitting the focus of session 6

12:45 13:45 Lunch

13:45 14:30 *Joao Pedras-Vasconcelos, CDER (online contribution)*

Regulatory feedback, incl. discussions on S/N as an alternative to titer assessment and the use of integrated PK/PD and titer as an alternative to formal NAb assay assessment, under what conditions that is possible?

Incl. Q&A "live - on line"

14:30 16:30 Session 7: The fruit of our labour...

14:30 15:00 *Feedback from round tables - draft Workshop recommendations (incl. Q&A and refinement suggestions)*

15:00 16:00 *(selection from) Case studies presenters to come on stage again to share their learnings, take home message and impact on the project if/when using workshop ideas/recommendations in their project/strategy*

example: <https://e-b-f.eu/wp-content/uploads/2022/12/30.-Take-home-for-case-studies-presented.pdf>

16:00 16:00 Close out & networking coffee break



Organising Committee: Jo Goodman (AstraZeneca), Michaela Golob (Nuvisan), Kyra Cowan (Merck KGaA), Robert Nelson (BioAgilytix) and Philip Timmerman (EBF) - We are planning to expand the Organising committee.

EBF Focus workshops are organised by the EBF vzw as non-sponsored non-profit events and are independent from EBF member companies.