Challenging the Current Paradigm for ADA testing

21-22 September 2023

NH Málaga, Málaga Spain

Thursday 21-Sep-2023

9:00 9:10 Welcome

9:10 11:00 Session 1: Setting the Scene - the Current Landscape

9:10 9:35 *Jo Goodman, on behalf of the EBF*
Why this meeting? & Increasing the value of science in ADA testing

9:35 10:00 *Lauren Stevenson, Immunologix Laboratories*
A 21st century paradigm: Immunogenicity assays are biomarker assays

10:00 10:25 *Daniel Baltrukonis, Pfizer (not released for publication)*
All We Need Is Screen; When Confirmatory and Titer Tiers Are Not Necessary in Clinical ADA Assays

10:25 10:45 Q&A

10:45 11:00 Prepare for Session 4: Introduction to the Round Tables
A prepared mind: introduction to and intended deliverable of the themes the afternoon round table questions

11:00 11:30 Coffee break

11:30 12:30 Session 2: Challenging the Current Paradigm - 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 *Ching-Ha Lai (Vickie), Regeneron*
Clinical Case Studies of Different ADA Testing Strategies – What Do We Gain With 3 Tiers of Assessment?

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: Rethinking Assay I - Case studies (20 min + 5 min discussion)

13:45 14:10 *John Cook, Charles River Laboratories*
Leaner Approaches to Clinical Analysis: Does the Confirmatory Assay Always Add Value?

14:10 14:35 *Adriano Luis Soares de Souza, Fresenius Kabi Swiss*
Demonstrating the feasibility ADA titer determination by singlicate analysis: Case study based on a Tocilizumab biosimilar

14:35 15:00 *Toralf Roch, CheckImmune*
Detection of anti-PEG antibodies in clinical studies

15:00 15:25 *Gregor Jordan, Roche Diagnostics*
Model informed assay development (MIAD). How can we confirm with an orthogonal method the "Signal/Noise" immunogenicity reporting strategy?

15:25 15:50 *Luis C. Perez Tosar, Novo Nordisk*
Re-thinking Radioimmunoassay for the detection of anti-drug antibodies against peptide drugs

15:50 16:30 **Coffee break (reorganising the meeting room towards the round tables) (+ rebuild meeting room for round tables - TAKE YOUR PERSONAL BELONGINGS)**

16:30 18:30 **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

18:30 **Day 1 close out**

Friday 22-Sep-2023

9:00 10:40 **Session 5: Clinically Relevant Detection - Case studies (20 min + 5 min discussion)**

9:00 9:25 *Hanna Widmaier, Nuvisan*
Cut-Point Limbo - low cut-points and their challenges

9:25 9:50 *Karien Bloem, Sanquin*
Clinically relevant ADA testing for monoclonal antibody biologics

9:50 10:15 *Foka Venema, Ardena*
Key publications for cut point calculations - CRO perspective: choosing between multiple implemented experimental and statistical approaches

10:15 10:40 *Brendy Van Butsel, Sanofi*
Challenging the classical tiered approach in clinical ADA testing

10:40 11:20 **Coffee break**

11:20 12:45 **Session 6: Rethinking Assays II, incl. 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 *Minh Dang, BioAgilytix*
Pros and Cons of Different Approaches to ADA Domain Specificity Characterization

12:20 12:45 *Desislava Galeva, Labcorp Drug Development*
An alternative approach to the classic anti-drug antibody (ADA) titer assay used in a clinical trial

12:45 13:45 **Lunch**

13:45 14:45 *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?
Includes Q&A "live - on line"

14:45 0:00 **Session 7: The Fruit of our Labour…**

14:45 15:30 *Feedback from the Round Tables*
(incl. Q&A and refinement suggestions)

15:30 16:00 *Drafting the Workshop Recommendations*

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), adding round table moderators: John Cook (CRL) and Salvatore Calogero (Swiss BioQuant)