EBF - Focus Workshop – agenda

Current Analysis of Immunogenicity: Best Practices and Regulatory Hurdles

27-28 September 2016 , Lisbon

The Altis Grand Hotel, Lisbon, Portugal

26-Sep-16

17:00 – 19:00	Registration desk opens

27-Sep-16

07:30	Registration desk opens
08.45 – 09.00	**Welcome and aim of the meeting**
09:00 – 10.10	**The current landscape and future challenges on immunogenicity**
09:00 - 09:30	The current regulatory landscape on immunogenicity *Michaela Golob, on behalf of the EBF*
09:30 - 09:50	EMA view on immunogenicity regulations *Venke Skibeli, Avd. for legemiddelutredning, Norway*
09:50 - 10:10	FDA Regulatory perspectives on therapeutic protein immunogenicity- an update *João A. Pedras-Vasconcelos, FDA/CDER/OBP/DRR3, US*
10:10 – 10:40	**Coffee break & networking**
10:40– 12:30	**A rapidly changing regulatory environment**
10:40 - 11:00	EBF's feedback to the EMA and FDA draft guidance *Jo Goodman,* on behalf of the EBF
11:00 - 12:30	*Panel discussion*
12:30 – 13:30	**Lunch**
13:30 – 15:00	**Challenges of drug tolerance and interferences**
13:30 - 13:45	Case study 1 – Strategies for improving ADA assay sensitivity, when high drug or target concentrations cause interference *James Munday, Covance*
13:45 - 14:00	Case study 2 – Overcoming drug & target interference in ADA and NAb assays *Robert Nelson, Novimmune*
14:00 - 14:15	Case study 3: Reflections on the use of acid treatment for improving drug tolerance in ADA assays *Nicoline Videbæk, NovoNordisk*
14:15 - 14:30	Case study 4 – Pitfalls in ADA Analysis - Workarounds for Clinical Meaningful Immunogenicity Assessment *Thomas Emrich, F. Hoffmann - La Roche*
14:30 - 15:30	*Panel discussion*

15:30 – 16:00	**Tea break**
16:00 – 18:00	**Alternatives for NAb assessment**
16:00 - 16:30	Strategies to assess the neutralizing capacity of Biopharmaceuticals *Daniel Kramer, Sanofi*
16:30 - 17:00	Strategies to determine assay format for the assessment of neutralizing Antibody responses to biotherapeutics *Jim McNally, Merck Serono*, on behalf of the AAPS Immunogenicity DG
17:00 - 18:00	*Panel discussion*
18:00	**End of day 1**

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09:00 – 13:00	**Cut-point setting in ADA and NAb assays**
09:00 - 09:30	Setting cut points – a statistician's perspective *Simon Cowen, LGC*
09:30 - 10:30	Simplified strategy for immunogenicity cut point evaluations & some practical considerations *Viswanath Devanarayan, Abbvie*
10:30 - 11:00	**Coffee break & networking**
11:00 - 11:20	Pitfalls in cut-point setting *Timo Piironen, Syrinx Bioanalytics*
11:20 - 11:40	Challenges with pre-existing anti-drug antibodies *Denise Sickert, Novartis*
11:40 - 13:00	*Panel discussion*
13:00 – 14:00	**Lunch**
14:00 – 15:00	**Closing Focus Workshop panel discussion**
15:00 – 15:30	**Tea break**
15:30 – 16:00	**Summary, conclusion and next steps**
16:00	**Adjourn**

MEETING ORGANISATION

Jo Goodman (MedImmune) – Michaela Golob (Merck) – Marianne Scheel Fjording (NovoNordisk) – Robert Nelson (NovImmune) – David Egging (Synthon) – Timo Piironen (Syrinx Bioanalytics) – James Munday (Covance) - Philip Timmerman (Janssen R&D)

The conference is organised as a non-sponsored non-profit event by European Bioanalysis Forum VZW