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  10:40 - 11:00 EBF’s feedback to the EMA and FDA draft guidance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
<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>15:30 – 16:00</td>
<td>Tea break</td>
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<tr>
<td>16:00 – 18:00</td>
<td><strong>Alternatives for NAb assessment</strong></td>
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<td>16:00 - 16:30</td>
<td>Strategies to assess the neutralizing capacity of Biopharmaceuticals</td>
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<td><em>Daniel Kramer, Sanofi</em></td>
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<td>16:30 - 17:00</td>
<td>Strategies to determine assay format for the assessment of neutralizing</td>
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<td>Antibody responses to biotherapeutics</td>
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<td><em>Jim McNally, Merck Serono</em>, on behalf of the AAPS Immunogenicity DG</td>
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<td>17:00 - 18:00</td>
<td>Panel discussion</td>
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<td>18:00</td>
<td>End of day 1</td>
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**28-Sep-16**

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