Program of EBF Focus Workshop “Today’s challenges and solutions in assessing immunogenicity in patients”

Lisbon, Portugal

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Session Title</th>
<th>Speaker(s)</th>
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<tr>
<td>19/sep/2018</td>
<td>08.45 – 09.00</td>
<td>Welcome and aim of the meeting</td>
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<td>09.00 – 12.30</td>
<td>Harmonized approaches for immunogenicity method validation</td>
<td>Jo Goodman, on behalf of the EBF</td>
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<td></td>
<td>09:00 – 09:25</td>
<td>Introduction to the session - Overview of current global regulations</td>
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<td>09:25 – 09:50</td>
<td>Harmonisation of immunogenicity testing : The EU perspective</td>
<td>Meenu Wadhwa (National Institute for Biological Standards and Control)</td>
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<td>09:50 - 10:10</td>
<td>Case Study: Request for a full tiered approach assay validation for a well-known drug used for a new indication – when clinical experience was not sufficient</td>
<td>Anna Laurén, Wieslab/Eurodiagnostics</td>
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<td>10:10 – 10:50</td>
<td>Coffee break &amp; networking</td>
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<td>10:50 – 11:10</td>
<td>Analytical scientists and the statisticians collaborate to make the right decision for cut-points</td>
<td>Alexandra Hawes, LGC</td>
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<td>11:10 – 11:30</td>
<td>Practical solutions to outlier decisions, pre-existing and treatment-boosted ADA and low biological variability</td>
<td>Viswanath Devanarayan, Charles River</td>
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<td>11:30 – 11:50</td>
<td>Experiences with different cut-point approaches in clinical immunogenicity testing</td>
<td>Szilard Kamondi, Roche</td>
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<td>12:30 – 13:40</td>
<td>Lunch</td>
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<td>13:40 – 15:00</td>
<td>Harmonized approaches for immunogenicity method validation - cndt</td>
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<td>13:40 – 14:00</td>
<td>Effect of different approaches on perceived assay sensitivity and drug tolerance – sense and nonsense of positive controls</td>
<td>David Egging, Synthon Biopharmaceuticals BV</td>
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<td>14:00 – 14:20</td>
<td>Feedback on EBF immunogenicity harmonisation activities</td>
<td>Jo Goodman, on behalf of EBF</td>
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<td>14:20 – 14:40</td>
<td>AAPS-sponsored ADA Validation Testing and Reporting Harmonization</td>
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14:40 – 15:00  Panel discussion

Moderator: Michaela Golob. Panel: Meina Liang, Shobha Purushothama, Jo Goodman, Robert Nelson

15:00 – 15:40  Tea break & Networking

15:40 – 17:30  Progress in Clinical nAb assays

15:40 – 15:50  Introduction to the session

James Munday, on behalf of the EBF

15:50 – 16:10  Integration of PK-PD-ADA data for assessment of immunogenicity impact

Robert Nelson, Novimmune

16:10 – 16:30  Developing neutralising assays – challenging molecules and challenging requirements

Carina de Lemos Rieper, Novo Nordisk

16:30 – 16:50  Inferring Neutralising Antibodies – When data integration is appropriate?

Shobha Purushothama, Biogen

16:50 – 17:30  Q&A

17:30  End of Day 1

20/sep/2018

08:45 – 09:00  Introduction to day 2

09:00 – 12:00  Clinical immunogenicity and the value for the patient and physician

09:00 – 09:20  Introduction to the session

Michaella Golob, on behalf of the EBF

09:20 – 09:40  Clinical relevance of unwanted drug-induced immune responses

Arno Kromminga, BioAgylitix

09:40 – 10:00  Considerations of immunogenicity assessment at different clinical phases

Kate Peng, Genentech

10:00 – 10:20  Evaluation of clinical impact of immunogenicity and its challenges

Veerle Snoeck, UCB

10:20 – 11:00  Coffee Break & networking

11:00 – 11:30  After 20 Years of immunogenicity testing, where do we stand today

Daniel Kramer, Sanofi

11:30 – 12:00  Taking the “false” out of ADA testing results: towards better interpretation of clinical relevance
Lorin Roskos, MedImmune

12:00 – 13:15  Lunch

13:15 – 14:30  Panel discussion – Clinical immunogenicity and the value for the patient and physician

13:15 – 13:30  Introduction to the closing panel discussion

Jo Goodman, on behalf of the EBF

13:30 – 14:30  Panel discussion


14:30 – 15:00  Summary, conclusion and next steps

15:00 – 16:00  Closing Tea break and adjourn