CDDF WORKSHOP
NEW FRONTIERS IN THE USE AND DEVELOPMENT OF COMPANION DIAGNOSTICS

ADVANCE PROGRAMME
BRUSSELS, BELGIUM
11-12 DECEMBER 2014
Workshop Objectives
The goal of the workshop is to discuss new frontiers of biomarkers and companion diagnostics together with experts from academia, regulatory authorities, pharmaceutical industry and payers.

Conference Chairs
- Leif Hakansson (Sweden)
- Silvia Marsoni (Italy)
- Terri Ozegovich (USA)
- Joachim Reischl (Germany)

Detailed Advance Programme

**DAY 1 | 11 DECEMBER 2014**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>13:00</td>
<td>Welcome and Introduction</td>
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<tr>
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<td><strong>SESSION 1: INNOVATIVE TRIAL DESIGNS FOR PRECISION MEDICINE</strong></td>
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<td>13:15</td>
<td>Focus 4 Trial</td>
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<td>13:35</td>
<td>FUNNEL Embedded POC trials</td>
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<td>13:55</td>
<td>Match trial</td>
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<td>14:15</td>
<td>Lung Master trial</td>
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<td>14:35</td>
<td>Regulatory considerations</td>
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<td>14:55</td>
<td>Interaction with industry</td>
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<td>15:15</td>
<td>Discussion</td>
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<td>16:00</td>
<td>Break</td>
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<td><strong>SESSION 2: DEVELOPMENT OF BIOMARKER SIGNATURES</strong></td>
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<tr>
<td>16:30</td>
<td>Introduction: From bench to clinic: the validation and practical issues of developing tumor signature</td>
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<td>16:50</td>
<td>Case study 1 - Mammaprint (established) and Coloprint (experimental)</td>
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<td>17:05</td>
<td>Academic view</td>
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<td>17:40</td>
<td>Case study 2 - Oncotype available for Breast (established) / experimental for CRca dfn prostate</td>
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<td>17:20</td>
<td>Industry perspective</td>
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<td>17:55</td>
<td>Case study 3 - Prosigna / Nanostring PAM50</td>
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<td>18:10</td>
<td>Academic view</td>
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<td>18:25</td>
<td>Discussion</td>
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<td>19:00</td>
<td>End of Day 1</td>
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<td>19:30</td>
<td>Dinner</td>
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DAY 2  12 DECEMBER 2014

SESSION 3: BIOMARKERS IN IMMUNOTHERAPY

08:30  Introduction - Which are the hurdles
08:50  Impact of tumour infiltrating lymphocytes for immunotherapeutic efficacy
09:10  Predictive value of regulatory T-cells and MDSC for response to immunotherapy
09:30  Monitoring of MAGE-3 vaccination
09:50  Monitoring checkpoint blockers
10:10  Discussion
10:45  Break

SESSION 4: COMMERCIAL STRATEGIES FOR CDX

11:15  Centralization of diagnostic testing in France
11:35  LDT model (Labcorp etc.) vs IVD model
11:55  Provision of biomarker panels
12:15  Discussion
12:45  Wrap up and next steps
13:00  End of the workshop

Target audience
- Representatives from Academia
- Pharmaceutical Companies, Mature Diagnostic Companies, Diagnostic Start-Up-Companies
- Representatives from Regulatory Authorities (EMA, FDA)
- Investors
- Payers

Workshop venue
Hotel Dolce La Hulpe - Brussels
135, Chaussée de Bruxelles
1310 La Hulpe
Belgium
www.dolcelahulpe.com

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The Cancer Drug Development Forum (CDDF)

The Cancer Drug Development Forum (CDDF), previously known as the Biotherapy Development Association (BDA), is a not-for-profit association whose mission is to provide a unique platform to facilitate interactions between all stakeholders (academia, regulatory authorities, policymakers, the pharmaceutical industry and patient advocates) to improve the efficiency of cancer drug development.

For the past 14 years, CDDF has strived to leverage the discussion on the most promising advances in oncology drug development, uniting experts from academia, the pharmaceutical industry and regulatory authorities in the quest of overcoming the main challenges in cancer treatment.

For more information please visit:

www.cddf.org