The Biotherapy Development Association

The Biotherapy Development Association (BDA) is a not-for-profit organization. Our mission is to provide a unique platform to facilitate interactions between all stakeholders: academia, regulatory authorities, the pharmaceutical industry, patient advocates and policymakers in order to improve the efficiency of cancer drug development.

BDA organizes regular meetings and workshops where all stakeholders can meet and discuss the latest challenges in oncology drug development with the goal to create an “ideal” scientific, regulatory and commercial environment for the development of cancer drug.

For more information about BDA, please visit: www.bdaoncology.org

Meeting Objectives

The EMA published a concept paper in July 2013 with specific guidance concerning Minimal Residual Disease (MRD) in chronic lymphocytic leukaemia and other haematological malignancies, and the concept of pathological complete remission in breast cancer as endpoints for clinical trials. Following preliminary consultations a draft document will be issued early 2014 and it is the purpose of this workshop to discuss and give feedback to the expected draft guidance (Appendix 4 of the guideline on the evaluation of anticancer medicinal products in man).

Organising Committee

Workshop Chairs

- Axel Glasmacher (Celgene, Switzerland)
- Francesco Pignatti (EMA, UK)
- John Smyth (University of Edinburgh, UK)
Who should attend?

- Academics concerned with the design and evaluation of clinical trials
- Regulators from European and other regulatory bodies concerned with end-points in clinical trials
- Decision makers from the pharmaceutical industry
- Patient associations

Conference Venue

Novotel London Paddington

3 Kingdom St
London W2 6BD
United Kingdom
Phone: +44 20 7266 6000

www.novotel.com
or
www.novotel.com/gb/hotel-6455-novotel-london-paddington/index.shtml

How to get to the Novotel London Paddington

Take the Bakerloo, Circle, District or Hammersmith & City line to Paddington Station. At Paddington Station head towards the Hammersmith & City underground line running adjacent to platform 8. Once out of the station, bear left and follow the signs towards Sheldon Square and Kingdom Street. Follow the waterline until you reach Starbucks, at which point turn left. On the far side of Sheldon Square you will see Kingdom Street with the Novotel at the end (signage visible from this point).

- **Airport:** HEATHROW AIRPORT
- **Railway Station:** LONDON PADDINGTON
- **Underground station**

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<tr>
<td>4 Lines</td>
<td>PADDINGTON</td>
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- **Bus**

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<th>Line</th>
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<tr>
<td>7, 18, 23, 27, 159</td>
<td>Paddington or Bishops Bridge Rd</td>
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<tr>
<td>Time</td>
<td>Session</td>
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<tr>
<td>10:30</td>
<td>SESSION 1</td>
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<tr>
<td>11:00</td>
<td>Presentation of the EMA draft guidance</td>
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<td>12:00</td>
<td>KEY NOTE LECTURE:</td>
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<td>12:30</td>
<td>LUNCH (HOTEL RESTAURANT)</td>
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<tr>
<td>13:30</td>
<td>SESSION 2 – REVIEW OF MRD IN HEMATOLOGICAL MALIGNANCIES</td>
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<tr>
<td>13:30</td>
<td>Academic overview</td>
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<td>14:00</td>
<td>Industry presentation</td>
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<td>14:15</td>
<td>Joint discussion</td>
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<tr>
<td>14:30</td>
<td>Review of MRD in CML</td>
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<tr>
<td>14:30</td>
<td>Academic overview</td>
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<tr>
<td>15:00</td>
<td>Industry presentation</td>
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<td>15:15</td>
<td>Joint discussion</td>
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<tr>
<td>15:30</td>
<td>COFFEE BREAK</td>
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<tr>
<td>16:00</td>
<td>Review of MRD in MM</td>
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<tr>
<td>16:00</td>
<td>Academic overview</td>
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<td>16:30</td>
<td>Industry presentation</td>
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<td>16:45</td>
<td>Joint discussion</td>
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### SESSION 3 – REVIEW OF pCR IN EARLY BREAST CANCER

**Meeting Room:** Sheldon  

**Session Chairs:**  
- Rosa Giuliani (Hospital San Camillo-Forlanini /SAG-O, Italy)  
- Sybille Loibl (German Breast Group, GE)

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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| 17:00 | **pCR as an endpoint in the treatment of breast cancer and in the evaluation of new active therapeutics**  
Sybille Loibl, (German Breast Group, GE) |
| 17:30 | Neoadjuvant therapy in HER2 positive breast cancer  
Graham Ross (Roche Pharmaceuticals, UK) |
| 17:50 | Joint discussion |
| 18:00 | **END OF DAY 1** |

**DINNER**  

"THE TRUSCOTT ARMS" – 55 SHIRLAND ROAD, MAIDA VALE

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### SESSION 4 – PARALLEL WORKSHOPS

**Meeting Room:** Connaught  

**Session 4 – Parallel Workshops**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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| 8:30  | **PWS 1 – Breast Cancer**  
*Chairs:*  
- Rosa Giuliani (Hospital San Camillo-Forlanini /SAG-O, Italy)  
- Graham Ross (Roche Pharmaceuticals, UK) |
| 10:00 | COFFEE BREAK  
10:30 | PWS 1 – Breast Cancer, continued |

**Meeting Room:** Sheldon  

**Session 4 – Parallel Workshops (continued)**

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<th>Time</th>
<th>Session</th>
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| 8:30  | **PWS 2 – Hematological Malignancies**  
*Chairs:*  
- Francesco Pignatti (EMA)  
- Paul Sherrington (Celgene, Switzerland) |
| 10:00 | COFFEE BREAK  
10:30 | PWS 2 – Hematological Malignancies, continued |
| 12:00 | LUNCH (HOTEL RESTAURANT)  
| 13:00 | **SESSION 5 – CONCLUDING SESSION**  
*Session Chairs:*  
- Axel Glasmacher (Celgene, Switzerland)  
- Francesco Pignatti (EMA, UK)  
- John Smyth (University of Edinburgh, UK) |
| 13:00 | Concluding session  
| 15:30 | **END OF DAY 2** |
Programme Overview

Tuesday, 13 May 2014

10:00  Registration opens
10:30  SESSION 1
12:30  Lunch
13:30  SESSION 2
15:30  Coffee Break
16:00  SESSION 2 continued
17:00  SESSION 3
18:00  End of day 1 programme
19:30  Networking dinner at THE TRUSCOTT ARMS

Wednesday, 14 May 2014

8:30  SESSION 4
10:00  Coffee Break
10:30  SESSION 4 continued
12:00  Lunch
13:00  SESSION 5
13:30  CONCLUDING SESSION
15:30  Coffee Break
15:30  End of day 2 programme
16:00  SESSION 2 continued
17:00  SESSION 3
18:00  End of day 2 programme

Upcoming Meetings

It is a UNIQUE OPPORTUNITY to address hurdles and explore potential solutions together with experts from ACADEMIA, INDUSTRY, REGULATORY AUTHORITIES, PATIENT ADVOCATES and POLICYMAKERS.

BDA Society Session at the ESMO Congress: HOW TO IMPROVE EQUAL ACCESSS TO INNOVATIVE ONCOLOGY DRUGS IN EUROPE?
27 SEPTEMBER 2014 | MADRID, SPAIN

8TH ALPINE MEETING: CURRENT & FUTURE CHALLENGES OF ONCOLOGY DRUG DEVELOPMENT
29-31 OCTOBER 2014 | BUCHEN/INNSBRUCK, AUSTRIA

WORKSHOP ON COMPANION DiAGNOSTICS
11-12 DECEMBER 2014 | BRUSSELS, BELGIUM

For more information about BDA, please visit our website: WWW.BDAONCOLOGY.ORG
MINIMAL RESIDUAL DISEASE AND PATHOLOGICAL COMPLETE RESPONSE: ENDPOINTS IN CLINICAL TRIALS

13 & 14 MAY 2014 | LONDON, UK

WORKSHOP SECRETARIAT

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