



## Autumn Focus Workshop

### Biomarker Assay Validation

#### Bringing *Context of Use* into practice

NH Málaga Centro - Málaga, Spain  
18-19 September 2019

#### Preliminary Agenda Outline v.07MAY2019

Abstracts can be submitted into sessions session 2 - 5

#### Wednesday 18-Sep-2019

|       |       |  |
|-------|-------|--|
| 08:45 | 09:00 | Welcome and aim of the meeting   |
| 09:00 | 10:30 | <b>Session 1: Setting the Scene - presentations managed by the Organising Committee,</b><br>The EBF Biomarker Recommendation from 2012 revisited<br>Context of Use<br>Integrating Biomarker data into projects: an end user or stakeholders' perspective<br>The value of open communication between stakeholders and the bioanalytical lab |
| 10:30 | 11:00 | Coffee break   |
| 11:00 | 12:15 | <b>Session 2: Limitations of the current analytical paradigm for Biomarker assays (we will</b><br>Creating awareness of our current limitations as BA expert<br>The Bioanalyst / Stakeholder interface: is there value in submersing the stakeholder in the<br>Breaking down the silos: The value of a new paradigm of analysis            |
| 12:15 | 13:30 | Lunch  |
| 13:30 | 15:30 | <b>Session 3: Context of Use (we will host 5 or 6 presentations) on case studies:</b><br>Examples of where it went wrong<br>Examples of where it worked out fine   |
| 15:30 | 16:15 | Coffee break   |
| 16:15 | 18:00 | <b>Session 4: Starting from a white page...preparation for Day-2 round tables (we will host 3</b><br>Why reinvent the wheel - What can we learn from clinical labs?<br>What does success look like? Including:<br>- Introducing "The Certified Biomarker Analytical Scientist"<br>- A sustainable Bioanalyst / Stakeholder relationship    |

#### Thursday 19-Sep-2019

|       |       |  |
|-------|-------|--|
| 08:30 | 09:00 | <b>Summary of day 1 &amp; Introduction of round tables</b>   |
| 09:00 | 10:30 | <b>Session 5: Bioanalytical lab challenges (Plenary or Breakout) (we will host 4 or 5</b><br>Scientific presentations on challenges for Biomarker assays - (scientific/regulatory) strategic |
| 10:30 | 11:00 | Coffee break   |
| 11:00 | 12:30 | <b>Session 6: Focus Workshop Round tables</b><br>Workshop delegates will be assigned to discuss in a round tables format. Each (group of)  |
| 13:00 | 14:15 | Lunch  |
| 14:15 | 15:30 | <b>Summary from round tables - Closing Panel discussion - agree on next steps</b>  |
|       | 15:30 | <b>Adjourn</b>   |
| 15:30 | 16:30 | Closing Coffee break   |

#### MEETING ORGANISATION

From the EBF: Ulrich Kunz (Boehringer-Ingelheim), Linda Terry (GlaxoSmithKline), Kyra Cowan (Merck KGaA), Robert Nelson (Novimmune) and Philip Timmerman (EBF)

Meeting is organised in collaboration with industry stakeholders:  
Jani Darshana (Pfizer), Steven Piccoli (GlaxoSmithKline), Lars Karlsson (Ferring), Hans Ulrichts (UCB Biopharma) and Lauren Stevenson