

**BDA Executive Workshop - Oncology Biomarker Based
Drug Development**
9th February 2010, Brussels

[Summary of meeting](#)

[Session 1 - 9.00 - Updating the current paradigm – Setting the scene](#)

Moderators: Leif Hakansson, Eric Abadie, Anne deBock, Lothar Bergmann

9.00 Coffee and refreshments

9.30 Welcome and Introduction - Leif Hakansson

9.35 An academic perspective on oncology biomarkers - Heinz Zwierzina

10.00 An industry view on the current and future perspectives - Anne De Bock

10.20 A European Regulators View - Eric Abadie

10.40 Questions and Discussion

[Session 2 - 11.15 Key Elements which would improve biomarker based drug Development](#)

Scenario setting – practical examples one hour each plus 15 minutes discussion

1. Clinical challenges including endpoints – 1 hour led by academia

12.30 Buffet lunch

13.00 Scenario setting – practical examples continued

2. Statistical design challenges – 1 hour led by industry

3. What is needed to achieve a positive benefit/ risk outcome – 1 hour led by CHMP

[Session 3 - 15.45 - Conclusion and possible next steps?](#)

15.45 Moderators draw together a "Summary of Conclusions" and "Recommendations for Next Steps"

16.00 Close