HTA Meeting 2011 - Actual developments in European Regulatory and HTA Management - what does this mean for oncology in Europe

March 9, 2011
Bonn, Germany

08.30 Opening Address from the Chair on Behalf of BDA - Lothar Bergmann
Welcome Address on Behalf of BfArM - Karl Broich
Announcement and Introduction of Rapporteurs from Patient Advocacy Group Representatives - Alex Wyke and Jan Geissler

Session 1: Definition, Problems and Current Issues with the Model at Present
Chairs: Harald Enzmann, Wolfgang Wein, Heinz Zwierzina

08.40 An Academic Oncology Perspective on the Perceived Problem - Lothar Bergmann

08.55 An EMA Perspective on the Need for a Paradigm Change - Francesco Pignatti

09.20 Divergent Regulatory and HTA Assessments: Implications for Product Development Decisions - Gerhard Schlueter

09.35 The German Approach to Additional Benefits in Reimbursement Decisions - Maximilian Grüne

09.50 Open Forum Discussion

10.20 Coffee Break

Session 2: Coordination of Stakeholders Across Europe: Contributions and Benefits I
Chairs: Lothar Bergmann, Ansgar Hebborn, Francesco Pignatti

10.45 Current Approaches to European HTA: What are the Implications of Value-Based Pricing? - Stuart Carroll

11.05 Experiences with HTA Outcomes in Different Countries and Regions - Wolfgang Wein

11.25 A Pan-Industry Perspective: Implications for Novel Oncology Development, Licensing and Reimbursement - Ulf Staginnus

11.45 EU Coordination of HTA: A Perspective on the Current Challenges TBC

12.05 Open Forum Discussion

13.00 Buffet Lunch

Session 3: Coordination of Stakeholders Across Europe: Contributions and Benefits II
Chairs: Pierre Demolis, Leif Hakansson, Gerhard Schlüter

14.00 A Pan-European Regulatory View on Where Changes will Benefit all Stakeholders - Harald Enzmann

14.20 An Academic Oncology View on How the Changes will Impact Practising Oncologists - Silvia Marsoni

14.40 The Importance of Validated Biomarkers in the Regulatory and HTA Areas in Oncology: Can we Develop an Acceptable and Collaborative Approach? - Ilhan Celik

15.00 Can Pan-European Multidisciplinary Action Plans Work to Protect and Enhance Oncology R &D, Drug Development, Licensing and Reimbursement? - Christopher McCabe

15.20 First Experiences with a Multi-Stakeholder Consultation Process in Europe - Lindee Goh

15.30 Discussion

15.45 Coffee Break

Session 4: Action Points Based on Likely Agreements
Chairs: Christopher McCabe, John Smyth, Chris Teale

16.00 Feedback from the Patient Rapporteurs - Alex Wyke and Jan Geissler

16.15 Open Forum Discussion and Summary All

17.00 Closing Remarks on Behalf of BDA - John Smyth