



EMA/EFPIA 2nd WORKSHOP ON ADAPTIVE DESIGN IN CONFIRMATORY TRIALS

2nd April 2009
EMA Headquarters, Canary Wharf, London, UK
Meeting room 2A

Final AGENDA

07:30-08:30	Registration and welcome coffee	
08:30-08:45	Chairpersons opening statement background and objectives: Discuss scope of seamless adaptive phase II/III trials as confirmatory clinical trials through examination of case studies; Review Bruno Flamion summary slides on open questions from Dec 2007 workshop	Co-Chair: Bruno Flamion (SAWP-Chair, CHMP Member) Co-chair: Solange Rohou (EFPIA/AstraZeneca)
08:45-10:35	Case Study 1: The Lilly case study Objective: Illustrate how to implement “Good Adaptive Practices” Focusing on the following questions from the 07 workshop	
08:45-09:15	Case study 1: the Company view point <ul style="list-style-type: none">- Overview of the design- DMC- Dose selection- Simulation used to establish the robustness of the design- Missing data.	Brenda Gaydos & Charles Benson (Eli Lilly)
09:15-09:45	Case study 1: The academic view point	Peter Bauer & Andy Grieve
9:45-10:15	Case study 1: The regulators’ view point <ul style="list-style-type: none">- Regulatory agency’s views on Design- Information provided to agency- Areas of regulatory concerns	Armin Koch, Rob Hemmings and Sue-Jane Wang
10:15-10:35	Round table discussion on critical issues	Speakers and panelists (Rick Sax, Michael Krams, John Warren) and questions and comments from the floor
10:35-10:50	Coffee break	

10:50-11:45	Case Study 2: The Novartis case study Objective: Illustrate how to implement “Good Adaptive Practices”	
10:50-11:15	Case study 2: Phase II/III adaptive design with treatment selection: A completed case study <ul style="list-style-type: none"> - Trial design of a confirmatory study with pre-planned adaption at interim - Interim decision making - The role of the Sponsor - Recommendations for ADs in this setting 	Frank Bretz & David Lawrence (Novartis)
11:15-11:30	Case study 2: The regulators’ view point <ul style="list-style-type: none"> - Regulatory agency’s views on Design - Information provided to agency - Areas of regulatory concerns 	Armin Koch, Rob Hemmings and Sue-Jane Wang
11:30-11:50	Round table discussion on critical issues	Speakers and panelists (Rick Sax, Michael Krams) and questions and comments from the floor
11:50-12:05	Considerations of US FDA Draft Guidance on Adaptive Design Clinical Trials	Sue-Jane Wang (FDA)
12:05-13:05	Lunch break	
13:05 -15:05	The value of Adaptive Dose Ranging Objective: lessons learnt	
13:05-13:35	Case Study 3: Failing efficiently and succeeding efficiently	Michael Krams (Wyeth)
13:35 -14:05	Case Study 4: Adaptive dose-finding in the development of an anti-migraine compound	Frank Fan (Merck & Co)
14:05-14:35	The Regulator’s view point	Armin Koch, Rob Hemmings and Sue-Jane Wang
14:35-15:05	Round table discussion	Speakers and panelists (Eric Abadie, John Warren, Rick Sax, Andy Grieve, Peter Bauer) and questions and comments from the floor
15:05-15:20	Coffee break	

15:20-16:50	Adaptive Designs : A users guide to implementation	
15:20-15:35	How to identify opportunities for adaptive designs	Keaven Anderson (Merck & Co)
15:35-15:50	How agencies will assess adaptive designs	Armin Koch
15:50-16:05	How industry views boundaries between learn and confirm	Michael Krams (Wyeth)
16:05-16:20	How to implement best practices for adaptive designs	Judith Quinlan (Cytel)
16:20-16:40	How agencies view the changes in submitted adaptive designs since 2007	Rob Hemmings, Franz Koenig and Sue-Jane Wang
16:40:17:15	Discussion/Roundtable to recap on day, and any questions still unanswered	
17:15-17:30	Chairs' closing remarks and future actions	Bruno Flamion and Solange Rohou