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EMEA/EFPIA WORKSHOP ON ADAPTIVE DESIGNS IN CONFIRMATORY CLINICAL TRIALS
14th December 2007

AGENDA

08:30 – 08:40	Chairpersons opening statement, objectives, and background	Chairperson: Bruno Flamion (SAWP-Chair, CHMP Member) Co-chair: Solange Rohou (EFPIA efficacy adhoc group)
08:40 – 10:10	**Introduction and Overview**	
	Considerations behind the Reflection Paper on Confirmatory Trials with an Adaptive Design	Armin Koch (BfArM)
	Industry views on opportunities for adaptive designs to enhance clinical development	Judith Quinlan (GSK)
	Overview of regulator's experience: adaptive designs seen in Scientific Advice and by CHMP	Robert Hemmings (MHRA)
	Current FDA Thinking	Sue-Jane Wang (FDA)
	Panel Discussion [inclusion of guest panellist(s)] *Tomas Salmonson, Bertil Jonsson, Christy Chuang-Stein*	
10:10 – 10:30	*Coffee Break*	
10:30 - 12:00	**Phase II/III Studies**	
	Regulatory scene setting: benefits and risks of seamless trials	Robert Hemmings (MHRA)
	When is it appropriate to combine phases	Vlad Dragalin (Wyeth)
	An ongoing adaptive PII/III trial with dose selection - a pragmatic solution for a development programme	Andrew Stone (AZ)
	Phase II/III Adaptive Design with Treatment Selection: A case study	Frank Bretz (Novartis)
	Panel Discussion [inclusion of guest panellist(s)] *Eva Skovlund, Sue-Jane Wang, Michael Krams, Gérard Pons*	
12:00 - 13:00	*Lunch*	

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13:00 - 14:30	**Sponsor Involvement in Adaptive Trials**	
	DMC member experience: studies with an adaptive design / confidentiality	Peter Bauer (Univ. Vienna)
	EFPIA view: why is it important that the sponsor is involved in decision making about adaptations. How can it be handled	Michael Krams (Wyeth)
	Current Regulatory Recommendations in the Light of Adaptive Designs	Robert Hemmings (MHRA)
	Panel Discussion [inclusion of guest panellist(s)] *Daniel Brasseur, Armin Koch, Markku Toivonen, Brenda Gaydos*	
14:30 - 15:00	*Coffee Break*	
15:00 - 16:30	**Assessing Change / Establishing that the trial is reliable**	
	Considerations on guideline requirements in relation to homogeneity	Willi Maurer (Novartis)
	Exploring changes in treatment effects across design stages in adaptive trials	Tim Friede (Univ. Warwick)
	Homogeneity/heterogeneity over time in trials	Keaven Anderson (Merck & Co)
	How much is too much?	Armin Koch (BfArM)
	Panel Discussion [inclusion of guest panellist(s)] *Barbara van Zwieten-Boot, Eva Skovlund, Charles Benson*	
16:30-17:00	Harmonisation - Vision for the future	Christy Chuang-Stein (Pfizer)
	Summary of key positions from the discussion	Bruno Flamion (SAWP-Chair, CHMP Member)
17:00 - 17:30	Panel discussion : Overall discussion of the day (also opportunity to raise any additional points not covered/burning issues) *Gérard Pons, Robert Hemmings, Armin Koch, Sue-Jane Wang, Peter Bauer, Judith Quinlan, Michael Krams.*	
17:30	Chairman's closing remarks and future actions	Bruno Flamion (SAWP-Chair, CHMP Member)