



Federal Agency for Medicines and Health Products (FAMHP)

Strengthening of work sharing on clinical trials in Europe

Closing Remarks Next Steps

Xavier De Cuyper
CEO FAMHP

CFTG Paris, 11 June 2010



EU - Presidency : July - December 2010

- CTFG - mentor designated by HMA
- Optimisation of the coordination between National Competent Authorities (NCA) for clinical trials is a **priority**.
 - =>HMA - meeting 5-6 July, La Hulpe, Belgium
 - => Strategic paper II
 - => Enhancement of the efficiency of the NCA-network via "break-out sessions" .

EU - Presidency : July - December 2010



2010 – 2011 BELGIUM

CTFG

Clinical Trials Facilitation Group



EU - Presidency : July - December 2010

Belgian Presidency

CTFG workshop on early phase studies in oncology

18 and 19 November 2010

Day 1 : Thursday 18 November 2010

Meeting with Competent Authorities

Day 2 : Friday 19 November 2010

Clinical trials: from European perspective to National implementation CTFG/FAMHP/Pharma.be

Meeting with Competent Authorities, Industry representatives, Ethics Committees representatives and Investigators representatives

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Day 1 : Thursday 18 November 2010 Meeting with Competent Authorities

8.30 - 8.50	Registration and coffee	
8.50 – 9.00	Welcome and introduction	G.Musch (FAMHP)
9.00 – 10.30	Discussion of position paper by industry on studies with 2 new IMP	W. Janssens (FAMHP)
10.30 – 11.00	Coffee break	
11.00 - 12.30	Discussion of position paper by industry on seamless designs in early phase oncology trials	L. Kraváčková (SIDC) E. Stahl (BFARM)
12.30- 13.30	Lunch break	
13.30 -15.00	Discussion of position paper by industry on background therapies (IMP-NIMP) in oncology studies	E. Godfrey (MHRA)
15.00 – 15.30	Coffee break	
15.30 – 17.00	Finalization of common CTFG viewpoint on end of study procedures and continued treatment of patients that benefit in oncology trials ¹ And/or One-stop shop : definition and vision	K.Bonnarens (FAMHP) S. Fühling (EC DG SANCO) C. Belorgey (AFSSAPS) G.Musch (FAMHP)
	Other matters	

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Day 2 : Friday 19 November 2010

Clinical trials: from European perspective to National implementation CTFG/FAMHP/Pharma.be

8.30 - 9.00	Registration and coffee	
First part : chair : Leo Neels (Pharma.be) and Xavier De Cuyper (FAMHP)		
9.00 - 9.20	Introduction from an industry and an NCA point of view	L. Neels (Pharma.be) G. Musch (FAMHP)
9.20 -10.20	Feedback on topics from first day, reactions from industry and EC and proposals on how to proceed especially for (N)IMP issue	C. Belorgey (AFSSAPS) E. Godfrey (MHRA)
10.20 -10.40	Coffee	
10.40-11.40	“One-stop-shop” – Point of view EC – Point of view Industry:	S. Fühling (Repres. HST tba)
11.40 -12.40	Interventional and Non-Interventional trials	M. Ward (MHRA) F. Meunier (EORTC) C. Julou (EFPIA) M. Gobert (Pharma.be) G. Musch (FAMHP)
12.40-13.30	Lunch break	

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Second part : chair : Didier Malherbe (HST) and Greet Musch (FAMHP)

13.30 -15.30	Safety in clinical trials : from detection to decision (how safety events are captured and treated by promoters and NCA's)	E. Stahl (BFARM) tba (EFPIA) N. Dubois (EORTC)
15.30-15.50	Coffee	
15.50 -16.30	Wrap up : next steps Round table	C. Belorgey (AFSSAPS) G. Musch (FAMHP)
16.30 -16.40	Conclusion	D. Malherbe (HST) X. De Cuyper (FAMHP)

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Thursday 18 November 2010

Brussels



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hotelbloom!
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Thank you for your attention

**For more information
or registration :**

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