

Agenda

9.00	<i>Attendees welcome</i>	
9.30	Clinical trials in the strategic perspective of the HMA European network	Jean Marimbert , Director General, Afssaps
9.45	Introductory remarks / Overview of CTFG (Clinical Trials Facilitation Group) activity report and action plan	Chantal Bélorgey , Afssaps
	Towards harmonisation of clinical trial applications and assessment <i>Moderators : Chris Parkinson (GSK) / Chantal Bélorgey</i>	
10.15	The VHP (Voluntary Harmonisation Procedure): experience and perspectives	Hartmut Krafft , PEI
10.45	<i>Questions and discussion</i>	
11.05	<i>Coffee break</i>	
11.20	Can we use a risk based approach for clinical trial applications and assessment ?	Martyn Ward , MHRA
11.35	The new CTA (Clinical Trial Application) guidance	Stefan Führung , European Commission
12.05	<i>Questions and discussion</i>	
12.45	<i>Lunch</i>	
	How to coordinate the assessment of clinical trials safety information? <i>Moderators : Nathalie Dubois (EORTC) / Chantal Bélorgey</i>	
14.15	Presentation of the DSUR (Development Safety Update Report)	Brian Davis , Member of ICH E2F Expert Working Group
14.45	<i>Questions and discussion</i>	
15.00	The CTFG perspectives on clinical trials safety assessment	Elke Stahl , BfArM
15.30	How Eudravigilance (EV-CTM) can facilitate work sharing ?	Gilles Touraille , EMA
16.00	<i>Questions and discussion</i>	
16.45	Closing remarks	Chantal Bélorgey , Afssaps Xavier de Cuyper , Director General, FAMHP (Belgium Federal Agency for Medicines and Health Products)

