EURORDIS
European Organisation for Rare Diseases

3rd Workshop
Eurordis Round Table of Companies

"Rare Disease Clinical Trials: Ensuring Fruitful Collaborations between Sponsors & Patient Organisations"

November 21st 2005
9.00 am-5.40 pm
Fundació Doctor Robert- UAB Casa Convalescència
Barcelona- Spain

8.30 am Welcome-Coffee

Morning Session co-chaired by: *Prof. Bruno Flamion (chair of the CHMP- SAWP)-Prof. Josep Torrent-Farnell (Fundació Doctor Robert-Chairperson of the COMP)*			
	Topic	Speaker	Institution / Position
9.00 am	**Welcome & Introduction**	Prof. Lluis Ferrer i Caubet Mr Yann Le Cam	*-President of the Universitat Autònoma de Barcelona (UAB)* *-Chief Executive Officer of Eurordis*
9.05 am	**Sponsors & Patients' Groups: an Uncommon Collaboration. Expectations and Fears of Industry**	Mr Kennet Rooth	*Country Manager, Swedish Orphan AB. (SE)*
9.20 am	**Sponsors & Patients' Groups: an Uncommon Collaboration. Expectations and Fears of Academic Clinical Research**	Prof. Christian Gluud	*Head of the Copenhagen Trial Unit, Copenhagen University Hospital- ECRIN (European Clinical Research Infrastructures Network) (DK)*
9.35 am	**PO Commitment vs. Sponsors' Responsibility: Shared Rules or Regulation ?**	Dr Phillipe Vella	*Head of the Trial Unit, AFSSAPS (French Agency for the Safety of Health Products) (FR)*
9.50 am	**NORD's Role in Clinical Development for Rare Diseases in the USA**	Mrs Mary Dunkle	*Vice President of Communications, NORD (National Organization for Rare Disorders) (USA)*
10.05-10.30	*Coffee break*		
10.30 pm	**Individual vs. Collective "Interest": the Respective Roles of Ethics Committees and Patient Organisations in Clinical Development.**	Mr Francis P.Crawley	*Director General, Good Clinical Practice Alliance (BE)*
10.50 am	**The Need of a European Framework for Collaboration: the Eurordis Charter**	Mrs Flaminia Macchia	*European Public Affairs Officer, Eurordis (BE)*
11.20 am	**Debate** *With panellists*		
1.00 pm	**Lunch**		

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Afternoon Session chaired by: *Dr Marlene E. Haffner* **(Director, Office of Orphan Products Development, FDA)-Dr Fernando de Andrés Trelles (Spanish Medicines Agency, COMP member, EMEA)**			
	Topic	**Speaker**	**Position /Institution**
2.30 am	**Patient Organisations' Expertise in "Document" Rewriting (content and/or form)**	Dr Jean Genève	*Head of the BECT/FNCLCC (Clinical Research Department, National Comprehensive Cancer Center Federation) (FR)*
2.50 am	**Patient Organisations' Role in Clinical Trials Development (case stories, lessons)**	Mr Nikos Dedes	*Chair of the EATG (European Aids Treatment Group) (GR)*
3.10 pm	**Role of Patients in Clinical Trials. From Participation to Collaboration: the Need for Training**	Mrs Dominique Donnet-Kamel and Dr Marga Pla	*-Manager Inserm Office for Patient Organisations, INSERM (National Institute for Public Health and Medical Research) (FR)* *-Director of the Master of Qualitative and Participative Research, UAB (SP)*
3.30 pm	**The FDA's Experience with Patient Organisations in Clinical Trials**	Mr Richard Klein	*Public Health Specialist, Office of Special Health Issues, FDA (Food and Drug Administration) (USA)*
3.45 pm	*Coffee break*		
4.00 pm	**Keys for Ensuring Fruitful Collaborations between Sponsors and Patient Organisations.**	Panel of representatives from Patient Organisations and Industry	*-Mrs Christine Lavery, Chief Executive, MPS Society (UK)* *-Dr Andreas Reimann, CEO Mukoviszidose.eV.(GE)* *-Dr René Goedkoop, VP Clinical Development, Apoxis S.A.(CH)* *-Mrs Claudia Hirawat, VP Corporate Development, PTC Therapeutics (USA)*
4.20 pm	**Debate** *With panellists*		
5.30 pm	**Closing speech** *Dr Maria Teresa Pagés, General Director of Pharmacy, Ministry of Health and Consumer Affairs (SP)*		
5.40 pm	**Adjourned**		

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