

**EPPOSI Workshop on Clinical Trials**  
Shaping the future of European Clinical Research Legislation

Wednesday 22 April 2009  
Diamant Conference Centre – Brussels

**PROGRAMME**

- 09.00 Welcome Remarks**  
Nikos Dedes, EATG
- 09.10 Priorities for DG ENTR in Clinical Trials regulation in 2009**  
Stefan Fuehring, European Commission, DG Enterprise and Industry
- 09.20 The Voluntary Harmonisation Procedure (VHP); one step in the direction of harmonisation of clinical trial applications assessment by national competent authorities?**  
Hartmut Krafft, Heads of Medicines Agencies Clinical Trial Facilitation Group
- 09.40 Facts on the table: discussion of current trends and results**  
David H.-U. Haerry, European AIDS Treatment Group  
Ingrid Klingmann, European Forum for Good Clinical Practice  
Patricia Pellier, Merck-Serono
- 10.40 Coffee**
- 11.00 Break-out sessions**
- 1. How to measure quality in clinical trials?**  
**Chairs:** Gérard Nguyen, Rett Syndrome Europe  
Rosalind Smyth, Medicines for Children Research Network  
Patricia Pellier, Merck-Serono
- 2. How to better balance the level of required documentation and supervision - with the feasibility of clinical trials and the quality of collected data?**  
**Chairs:** David H.-U. Haerry, European AIDS Treatment Group  
Jocelyne Flament, European Organisation for Research and Treatment of Cancer  
Fabien Peuvrelle, Celgene
- 3. How to balance between intellectual property rights and patients' needs for information on clinical trials results?**  
**Chairs:** Nikos Dedes, European AIDS Treatment Group  
Christian Ohmann, European Clinical Research Infrastructures Network  
Andrew Freeman, GlaxoSmithKline
- 4. What are the requirements to ensure proper access to follow-on treatment?**  
**Chairs:** Jan Geissler, European Cancer Patients Coalition  
Kathy Pritchard-Jones, Institute of Cancer Research, SIOP Europe  
Dagmar Theis, Roche
- 13.00 Lunch**
- 14.00 Report of break-out sessions**
- 14.40 Discussion and preparation of final recommendations**  
**Moderator:** Ingrid Klingmann, European Forum for Good Clinical Practice
- 16.00 Conclusions**  
David H.-U. Haerry, European AIDS Treatment Group  
Patricia Pellier, Merck-Serono
- 17.00 End of the meeting**