

EPPOSI Workshop on Patients Registries for Rare Disorders

*Need for data collection to increase knowledge on rare disorders and
optimize disease management and care*

Wednesday 18 – Thursday 19 March 2009
Federal Public Service Employment, Labour and Social Dialogue
Rue Ernest Blérot, 1, Ernest Blerostraat – 1070 Brussels, Belgium

Programme

Wednesday 18 March 2009

13.30 - Registration

14.00 - Opening

- Alastair Kent, EPPOSI Chairman

Session 1: Current situation of registries in Europe

Chairs: Tsveta Schyns and Elisabeth Hernberg-Stahl

14.10 - Setting the scene: State of Art in Europe

- Ségolène Aymé, INSERM / Orphanet
- *Presentation and analysis of the current situation of patient databases in Europe*

14.30 - European Commission perspectives

- Antoni Montserrat, European Commission, Directorate General for Health and Consumers
- Catherine Berens, European Commission, Directorate General for Research

14.50 - Value of Registries from the point of view of stakeholders

- Christine Lavery, MPS
 - Charles Hay, Manchester Royal Infirmary
 - Danielle Dols, Genzyme
- *Presentation and analysis of established positive results obtained thanks to the existence of registries*

15.35 - Debate

16.05 - Coffee Break

Session 2 : Challenges for registries from the point of view of stakeholders in Europe

Chairs: Christel Nourissier and Samantha Parker

16.25 - Issues at stake from the point of view of stakeholders

- Tsveta Schyns, ENRAH
 - Stuart Tanner, EUROWILSON
 - Hartwig Gajek, Baxter
- *Presentation and analysis of the difficulty to establish and maintain registries*

17.10 - Debate

17.40 - End Day 1

20.00 – Dinner

Thursday 19 March 2009

Session 3 : Issues at stake with registries in Europe

Chairs: Cees Smit and Atul Mehta

9.00 - Partnerships: Success stories and Challenges

- Maryze Schoneveld van der Linde, International Pompe Association
 - Bodo Grimbacher, ESID, University Hospital Freiburg
 - Elizabeth Hernberg-Stahl, Shire HGT
- *Presentation of successes and difficulties faced when establishing partnerships, between countries and between stakeholders*

9.45 - Debate & identification of concrete recommendations

10.45 - Coffee Break

Session 4 : Registration of Patient Data: Legal and ethical issues

Chairs: Christine Lavery and Stuart Tanner

11.00 – Registration of Patient Data: Legal and ethical issues

- Simon Woods, Newcastle University

11.30 - Debate & identification of concrete recommendations

12.30 - Lunch

Session 5 : Data collection, management and analysis

Chairs: Christophe Beroud and Herwig Jansen

13.30 - Data collection, management and analysis: technical issues

- Paul Landais, CEMARA
 - Denis Costello, EURORDIS
 - Francesca Rancati, Novartis
- *What are the issues regarding technical platforms?*

14.30 - Debate & identification of concrete recommendations

Session 6: Governance of registries

Chairs: Antoni Montserrat and Kerstin Westermark

15.00 - Governance of registries from the point of view of stakeholders

- Atul Mehta, University College London
 - Linda Foley, Irish Cystic Fibrosis Registry
 - Samantha Parker, Orphan Europe
- *Governance rules: How to access and publish the data? What are the rules to protect the data and patient privacy? How to ensure sustainability?*

16.00 - Debate & identification of concrete recommendations

16.30 - Conclusions

Ségolène Aymé, INSERM / Orphanet

16.45 - End Day 2