16th Workshop
Eurordis Round Table of Companies (ERTC)

The value of partnering in RD therapies:
Benefits of working with patients along the treatment lifecycle in the areas of clinical trials, regulatory affairs and health technology assessment

Thursday 1st March 2012
Brussels, Belgium

Hotel Le Plaza Brussels, Boulevard Adolphe Max 118 -126

Agenda

Morning session

Chairpersons:
Kerstin Westermark (Chairperson, Committee for Orphan Medicinal Products, EMA)
Marlene Haffner (former Director of OOPD-FDA)

9:00 – 9:15: *Welcome address:* ***Yann Le Cam (CEO, EURORDIS)***

9:15 – 9:30: "Industry experience of working with patients on clinical trial protocols" – Andras Fehervary (Novartis) *(including 5' for Q&A)*

9:30 – 9:45: "Patient perspective of working with industry on clinical trial protocols" – Bo Karlberg (Tuberous sclerosis complex association, Sweden) *(including 5' for Q&A)*

9:45 – 10:15: "Benefits of early dialogue with patients": Cancer/RD experience – Mark Krueger (Mark Krueger & Associates, Inc.) and **HIV/RD experience** Rob Camp (AIDS Treatment Activist Coalition, US; EURORDIS) *(including 10' for Q&A for both presentations)*

10:15 – 10:30: "Regulatory benefits of early dialogue with patients –Protocol Assistance" – Josep Torrent-Farnell (EMA - COMP, SAWP) *(including 5' for Q&A)*

10:30 – 11:00 - COFFEE BREAK

11:00 – 11:30: "Overview of EMA experience in working with patients" – Juan Garcia Burgos (EMA, Medical Information Sector) and Pauline Evers (COMP member, Federation of Cancer Patients Organisations, Netherlands) *(including 10' for Q&A)*

11:30 – 12:00: "Patient involvement in EMA reporting for adverse drug reactions and Benefit/Risk" – François Houÿez (EURORDIS) *(including 10' for Q&A)*

12:00-12:30: Training programmes for patients representatives – Maria Mavris (EURORDIS) and Jan Geissler (EUPATI) *(including 10' for Q&A for both presentations)*

12:30 – 14:00 - LUNCH

Afternoon session

Chairpersons:
Alicia Granados (Global HTA Strategy/Genzyme)
Yann Le Cam (Chief Executive Officer, EURORDIS)

14:00-14:30: HTA agency experience of working with patients – Javier Gracia (Consejeria de Sanidad de la Comunidad de Madrid, Spain) *(including 10' for Q&A)*

14:30-15:00: Patient perspective of working with HTA agencies – Christos Sotirelis (United-Kingdom Thalassaemia Society) *(including 10' for Q&A)*

15:00-15:30: Health Technology Assessment and Rare Diseases – Alicia Granados (Global HTA Strategy/Genzyme) *(including 10' for Q&A)*

15:30 End of the workshop