5th Workshop
Eurordis Round Table of Companies

"Rare Disease Patient Registries: an Essential Tool in the Development of Therapies?"

November 20th, 2006
Hôtel Lutetia
45, boulevard Raspail - 75006 Paris- France

Programme

8:30 Registration & coffee

MORNING 9:00 - 13:00
Chairpersons:
Dr. Marlene E. Haffner, Director, Office of Orphan Products Development, FDA, USA;
Dr. Domenica Taruscio, National Centre Rare Diseases, Italian Public Health Institute, COMP member, Italy

9:00 - 9:15 Welcome address

9:15 - 9:50 “Discovering registries” (35’ including discussion)
(Dr. Maurizio Clementi, University of Padova, North East Italy Congenital Malformation Registry, member of EUROCAT)

9:50 -10:25 “Role of registries as major tools for medicinal product development in the pre and post-marketing phases”(35’)
(Dr. Per Nilsson, Actelion)

10:25 -11:00 Discussion (35’)

11.00 - 11.20 – COFFEE BREAK

11:20 – 11:55 “Legal and ethical issues related to registries in Europe”
(Dr. Stella Blackburn, EMEA, UK) (35’)

11:55 – 13:00 Discussion (1h05’)

13:00-14:15 – LUNCH
14:15 -15:30  “Rare Disease registries: real-life experiences” (1h 15’)

- EuroWilson project database
  (Prof. Stuart Tanner, University of Sheffield, UK)

- European Paediatric Cancer Registry
  (Dr Jacqueline Clavel, National Registry of Childhood Blood Malignancies, INSERM U754, France)

- PTC Therapeutics and the Cystic Fibrosis Foundation’s registry
  (Mrs Cláudia Hirawat, PTC Therapeutics, USA and Dr Hanne Vebert Olesen, CF Centre Aarhus, Denmark)

15:30 -16:30  Panel discussion (1h)
Registries for Rare Diseases: legitimacy of all interested parties in the creation, management access and ownership of patient registries. Respective responsibilities, best practices, etc.

16:30       End of Workshop