EURORDIS Summer School for patient advocates in clinical trials and drug development

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Background

EURORDIS' representatives (called patient advocates) are extensively involved in EU decision-making processes as well as in the European Medicines Agency (EMA) as members of its scientific committees and working parties. Their motivation is to i) promote drug development, ii) be involved in regulatory affairs, and to guarantee iii) information to patients and iv) access to treatments.

EURORDIS' representatives are supported by EURORDIS staff and volunteers from all over Europe and cover a wide range of diseases. They work together through Task Forces. These patient advocates are carefully selected based on calls for expression of interest and their experience. Their numbers are growing and they are increasingly involved in EURORDIS activities.

Prior to the EURORDIS Summer School, these patient advocates involved in drug development and clinical trials had not had the opportunity to meet each other and interact with regulators, academic partners and industry for in-depth exchange of information and experience.

Purpose

The aim of the EURORDIS Summer School is to assist these and future patient advocates to:
i) better promote drug development,
ii) be involved in regulatory affairs, and to
iii) guarantee access to treatments and
iv) improve the quality of orphan drug information to patients.

Selection criteria

Participants fill in an application form and are selected by an *ad hoc* committee based on the following criteria:
- level of English language skills,
- experience
- willingness to be involved in drug development and regulatory affairs at the European level.

Composition of the *ad hoc* evaluating committee:
- Fabrizia Bignami – Therapeutic Development Director
- Anja Helm - Manager of Relations with Patient Organisations and Members
- Maria Mavris – Drug Development Programme Manager

Programme

Day 1	Day 2	Day 3	Day 4
Clinical Research	Ethical aspects	Introduction to the European Medicines Agency	Presentation of EURORDIS volunteer activities
Methodology principles in clinical trials	Drug development in non-standard situations	COMP* SAWP PDCO CAT CHMP PCWP	Task Forces; Orphan Drug Paediatric Drug, Information and Transparency
Statistics in clinical trials	Regulatory Procedures	Training on Review of Product Information or Play-Decide Policy Scenarios	EURORDIS Charter on Clinical Trials

*COMP- Committee for Orphan Medicinal Products; SAWP – Scientific Advice Working Party; PDCO – Paediatric Committee; CAT – Committee for Advanced Therapies; CHMP – Committee for Medicinal Products for Human Use; PCWP – Patients' and Consumers' Working Party

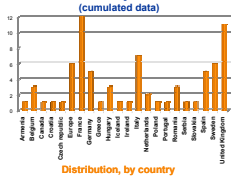
2008

2009

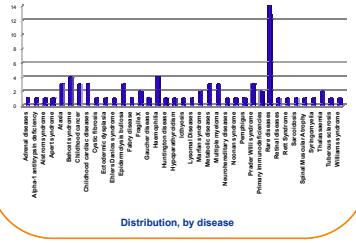
Small group sessions

Participants

(cumulated data)



Distribution, by country



Distribution, by disease

Informal discussions

Play Decide sessions

Patients' representatives, teachers and regulators - side by side

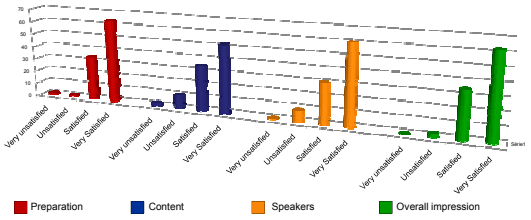
Its not all hard work….

The EURORDIS Summer School not only addresses the need to provide training and support to patient advocates but also provides the means for advocates to interact with each other as well as with regulators, academic partners and industry.

In addition to the learning experience, the Summer School provides an excellent forum for in-depth exchange of information and experiences, all in the beautiful city of Barcelona

Evaluation

(cumulated data)



Sponsorship and Support

Sponsored by:

Developed with the support of:

Summer School 2010

The objective of the 2010 Eurordis Summer School entitled ***'Regulatory Affairs and Health Technology Assessment (HTA) for Advanced Patient Advocates'*** is to extend the knowledge of advanced (previously-trained) patients' advocates using peer-based real case studies presented by members of the scientific committees and working parties at the European Medicines Agency as well as providing patient advocates with an initial introduction to Health Technology Assessment (HTA).

The aim is to build upon the previous Eurordis Summer Schools and to train patient advocates to a high-level in order for them to be prepared to be involved in regulatory affairs and to engage in discussions with national agencies regarding pricing and reimbursement of medicines.