EURORDIS SUMMER SCHOOL 2010
Programme outline

Sunday Sept 26	Monday Sept 27	Tuesday Sept 28	Wednesday Sept 29	Thursday Sept 30
	COMP update and workshop on orphan designation	PCWP update Workshop/ Panel discussion on Protocol Assistance	Introduction to Health Technology Assessment (HTA)	Panel discussion on HTA experiences from all stakeholders
Welcome dinner for speakers and participants	PDCO update and discussion on paediatric investigation plans	Training on Review of Product Information	Workshop on HTA assessment tools	

Days 1 and 2 – European Medicines Agency activities

	Monday 27 September		Tuesday 28 September
9.00 – 9.15 9.15-9.30	Welcome by **Professor Josep Torrent i Farnell (UAB)** Purpose of Summer School by **Fabrizia Bignami and Maria Mavris (EURORDIS)**	9.00-10.30	Update of PCWP - Safety communication - Benefit/Risk - Scientific Advisory Groups (SAG)
9.30-10.30	Update of COMP activities emphasis on new aspects **Dr. Jordi Llinares Garcia (EMA)**		**Mr. Francois Houyez (EURORDIS)**
10.30-11.00	Coffee break	10.30-11.00	Coffee Break
11.00-12.30	Components of Summary Report by **Mrs. Lesley Greene (COMP member)** Division in to small groups for mini-COMP sessions (Tutors: **Mrs. Lesley Greene, Dr. Patrick Salmon, Dr. Jordi Llinares Garcia, Dr. Fabrizia Bignami, Professor Josep Torrent i Farnell**) Regroup for debriefing on group sessions	11.00-12.30	Scientific Advice/Protocol Assistance **Dr. Markku Toivonen (NDA)** Open discussion with Summer School members who have participated Experiences and expectations (**Dr. Rainald von Gyzicki** – ProRetina, Germany **Mr. Guenter Eibel** – Gaucher, Germany)
12.30-13.30	Lunch	12.30-13.30	Lunch
13:30-14:15 14:30-15:30	PDCO activities: assessing Paediatric Investigation Plans mini-PDCO: waiver debate (group activity and feedback) **Dr. Julia Saperia (EMA)**	13.30-15.30	Training on Review of Product Information **Dr. Juan Garcia Burgos (EMA)** + debriefing

Days 3 and 4 – Health Technology Assessment

	Wednesday 29 September		Thursday 30 September
9.00 – 10.30	Introduction to Health Technology Assessment (HTA) by **Dr. Edmund Jessop (NHS)**	9.00 – 10.30	Panel discussion between (chaired by **Dr. Edmund Jessop**) -Industry (**Dr. Vanessa Stevens**, Merck, **Dr. Geraint Thomas**, GSK) -Patients (**Mr. Bernd Quadder** – Deutsche Sarkoidosis, **Chris Sotirelis**, UK Thalassaemia) -HTA agency representatives (**Professor Finn Kristensen, EUnetHTA; Dr. Javier Gracia, Consejería de Sanidad de la Comunidad de Madrid**) On their experience with HTA
10.30-11.00	Coffee break	10.30-11.00	Coffee break
11.00-12.30	Introduction to HTA continued… **Professor Mandy Ryan (University of Aberdeen)**	11.00-12.00	Continuation of panel discussion and debriefing
12.30-13.30	Lunch	12.00-1.00	Concluding comments and open discussion (**Mr. Yann Le Cam, EURORDIS**) Closing of Summer School – certificates
13.30-16.00	Ethical aspects of Health Technology Assessments Workshop on practical aspects of HTA – Understanding the QALY and HTA decisions. (**Dr. Iñaki Gutiérrez Ibarluzea – Basque HTA agency**)	1.00	Lunch

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Training Resources

Eurordis's training programmes and resources are designed to strengthen the capacity of rare disease patient representatives to take part in clinical trials, and become involved in the drug development and regulatory process in Europe. Training empowers patient representatives to advocate effectively for rare diseases.

Clinical Research

Markku Toivonen Toivonen, MD, PhD Scientific Director NDA Regulatory Science Ltd gives a presentation entiled Clinical trials: When and why? ...

View

Ethical Aspects of Research

Rob Camp introduces Ethical Aspects of Medical Research from a US perspective...

View

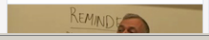
Statistics

Dr Ferran Torres Statistics and Methodology Support Unit, Hospital Clinic, Barcelona on the Analysis and Interpretation of Clinical Trials...

View

Regulatory Procedures

Patrick Salmon Irish Medicines Board introduces the EURORDIS Summer School attendees to the Regulatory Procedures at the EMEA...

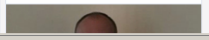


Ethics

Dr. Eric Koster speaks gives a presentation entitles ETHICAL ASPECTS OF MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS...

Clinical Trials in Non-Standard Situations

Markku Toivonen Toivonen, MD, PhD Scientific Director NDA Regulatory Science Ltd gives a presentation entiled Clinical Trials in Non-Standard Situations...



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A National Conference on Rare Disorders in Cyprus

Mon, 21 Feb 2011 - The Cyprus Alliance for Rare Disorders (C.A.R.D.) is a non-governmental, non-profit

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