

EURORDIS SUMMER SCHOOL FOR PATIENT ADVOCATES IN CLINICAL TRIALS AND DRUG DEVELOPMENT



Programme June 2-6, 2014

A capacity building programme for patient representatives involved in the development, information and access to orphan, paediatric, advanced therapies, and health technology assessment

Co-funded by:



Developed with the support of:



Organisers:

Dr. Maria Mavris
Therapeutic Development Director
maria.mavris@eurordis.org

Nancy Hamilton
Training Manager
nancy.hamilton@eurordis.org

Fundació Dr. Robert
Iolanda Arbiol
Helena Garrigos

www.eurordis.org

EURORDIS SUMMER SCHOOL FOR PATIENT ADVOCATES IN CLINICAL TRIALS AND DRUG DEVELOPMENT



June 17- 21, 2013
BARCELONA, SPAIN

Welcome Dinner
2 June

Day 1
June 3rd

Life-cycle of Drug
Development

Principles of clinical trials

Day 2
June 4th

Ethics

Post-marketing phases

Health Technology
Assessment

Day 3
June 5th

Regulatory committees and
working parties at the
European Medicines
Agency

Day 4
June 6th

Regulatory committees
cont...

EURORDIS activities

EURORDIS SUMMER SCHOOL FOR PATIENT ADVOCATES IN CLINICAL TRIALS AND DRUG DEVELOPMENT



PROGRAMME

Tuesday June 3, 2014

Day 1

08:45-09:45	EURORDIS & Fundacio Dr. Robert	Welcome Address and Introduction to Summer School (Participants present themselves)
09:45-10:45	Small group discussions using <u>session 1</u> material provided	
10:15-11:15	Dr. Markku Toivonen	Clinical Research <ul style="list-style-type: none"> • Need for evidence-based medicine • Life cycle of drug development from pre-clinical (specificity of orphan medicinal products) • Diagram demonstrating stages of drug development.
11:15-11:30	Coffee break	
11:30-12:30	Small group discussions using <u>session 2</u> material provided	
12:30-13:30	Dr. Markku Toivonen	Methodology principle in clinical trials <ul style="list-style-type: none"> • The 'Gold Standards' <ul style="list-style-type: none"> ➤ Controlled ➤ Blind ➤ Randomised ➤ Small populations
13:30-14:30	Lunch	
14:30-16:00	Prof. John Norrie	Methodological principles <ul style="list-style-type: none"> • Statistical significance • Clinical significance • <i>p</i> value • Statistical power • Statistical risks

EURORDIS SUMMER SCHOOL FOR PATIENT ADVOCATES IN CLINICAL TRIALS AND DRUG DEVELOPMENT

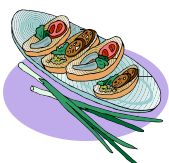


PROGRAMME

Wednesday June 4, 2014

Day 2

09:00-10:00	Group discussions using <u>session 4</u> material provided	
10:00-11:00	ds Eric Koster MA	Ethical aspects <ul style="list-style-type: none"> • Therapeutic v Experimental situation • Consent for participation
11:00-11:30	Mr. Rob Camp	Ethical Aspects from a US perspective
11:30-11:45	Coffee Break	
11:45-12:45	Group discussions using <u>session 5</u> material provided	
12:45-13:45	Dr. Patrick Salmon	Regulatory procedures <ul style="list-style-type: none"> • Importance of Post-Marketing phases • Compassionate use • Accelerated review • Conditional Approval • Marketing Authorisation under exceptional circumstances • Risk management plans
13:45-15:00	Lunch	
15:00-16:30	Dr Edmond Jessop	<ul style="list-style-type: none"> • Introductory HTA workshop



Cocktail evening at Hotel Alimara



EURORDIS SUMMER SCHOOL FOR PATIENT ADVOCATES IN CLINICAL TRIALS AND DRUG DEVELOPMENT



PROGRAMME

Thursday June 5, 2014

Day 3

09:00-09:30	Dr. Juan Garcia Burgos	General Introduction to the European Medicines Agency
09:30-10:15	Dr. Jordi Llinares Garcia	Committee for Orphan Medicinal Products (COMP)
10:15-11:15	Mini-COMP session	
11:15-11:30	Coffee Break	
11:30-12:00	Prof. Josep Torrent i Farnell	Scientific Advice Working Party (SAWP)
12:00-12:30	Mini-SAWP session	
12:30-13:30	Lunch	
13:30-14:00	Dr. Patrick Salmon	Committee for Medicinal Products for Human Use (CHMP)
14:00-16:00 (Includes 5 minute break)	Dr. Juan Garcia Burgos	Training on Review of Product Information - workshop

Tour of the Cosmo Caixa Museum



EURORDIS SUMMER SCHOOL FOR PATIENT ADVOCATES IN CLINICAL TRIALS AND DRUG DEVELOPMENT



PROGRAMME

Friday June 6, 2014

Day 4

09:00-09:30	Dr. Fernando de Andres-Trelles	Paediatric Committee (PDCO)
09:30-10:30	Mini-PDCO session	
10:30-11:00	Dr. Michele Lipucci di Paola	Committee for Advanced Therapies (CAT)
11:00-11:15	Coffee break	
11:15-12:00	Mr. François Houÿez	Patients' and Consumers' Working Party (PCWP)
12:00-12:30	To be announced (need a speaker) Albert.	Pharmaceutical Risk Assessment Committee (PRAC)
12:30-13:30	Lunch	
13:30-14:00	Dr. Christine Kubiak	Presentation of ECRIN project
14:00-14:45	Mr. Rob Camp and Mr. François Houÿez	EURORDIS Clinical Trials Best Practice and demonstration of EUCTR – Clinical Trials Register
14:45-15:30	Open discussion and Closing of Summer School	