European Society for Developmental Perinatal & Paediatric Pharmacology
ESDPP

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UCL Université catholique de Louvain

Year 2005-2006

Module on drug evaluation in children

ORGANIZING COMMITTEE

- Chairperson : **- Gérard Pons (René Descartes University, Paris, France)**

- Coordination :
- Jean-Marc Husson (Eudipharm, Paris, France)
- Jean-Paul Langhendries (Clinique St Vincent, Liège, Belgium)
- Behrouz Kassaï (Eudipharm, Lyon, France)
- Jean-Marie Maloteaux (Catholic University, Louvain, Belgium)

- Organizing Committee members :

- **Elisabeth Autret-Leca (University of Tours, France)**
- **Maurizio Bonati (Mario Negri Instituto, Milan, Italy)**
- **Daniel Brasseur (EMEA, London, UK)**
- **Imti Choonara (University of Nottingham, UK)**
- **Tibor Ertl (Aok, Pecs, Hungary)**
- **Rafaël Gorodisher (Beer Sheva, ESDP, Israël)**
- **Kalle Hoppu (Helsinki University, Helsinki, Finland)**
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- **Catherine Lassale (LEEM, Paris, France)**
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- **Agnès Saint-Raymond (EMEA, London, UK)**
- **Anders Rane (Karolinska Institute, Stockholm, Sweden)**
- **Hannsjörg Seyberth (Philipps Universität, Marburg, Germany)**
- **Ekoe Tetanye (Yaoundé University, Cameroun)**
- **Josep Torrent-Farnell (Autonomous University Barcelona, EMEA, London, UK)**
- **John van den Anker (Sophia Children's Hosp., Rotterdam, NL)**

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OBJECTIVES

M 1 SPECIFIC ASPECTS OF PAEDIATRIC PHARMACOLOGY (7h30)

Understand differences between adults and children :
- growth, development and maturation of the child (1h30)
- impact of pharmacoeconomics on children therapies (1h00)
- drug kinetics and effects (PK/PD relationship in children) (1h00)
- pharmacogenomics during development (1h00)
- drug evaluation regarding main diseases unique to children (1h00)
- How to inform children & parents regarding medication (1h00)
- side effects in adults/children (1h00)

M 2 SPECIFIC ISSUES RELATED TO DRUG DEVELOPMENT AND DRUG USE IN CHILDREN (6h00)

- Define and be aware of the extent of unlicenced and off-label use of medicinal products in children (1h00)
- Determine the role of Medicine Agencies in drug evaluation and recommendations in drug use in children (1h00)
- Identify the needs for drug formulations adapted to children (1h00)
- Manage the specific aspects of pharmacovigilance in children (1h00)
- Identify the process used to develop a paediatric drug in the Pharmaceutical Industry (1h00)
- Understand the specific ethical issues in children including the use of placebo and obtention of consent form (1h00)
- How to investigate drug in children : Ethical Committee point of view (1h00)

M 3 SPECIFIC ASPECTS OF CLINICAL TRIALS AND POSTMARKETING SURVEILLANCE IN CHILDREN (6h00)

- Be aware of the forthcoming EU and existing US legislative incentives (1h30)
- How to develop Orphan drugs : Academic & EMEA viewpoints (1h00)
- Understand the specific requirements for investigator/centre to qualify for drug evaluation in children (1h00)
- Establish a quality assurance system and site management organization/SMO for investigational team and others (1h00)
- Understand the reasons why to initiate drug development in children at different phases of drug development in adults : the regulatory (EMEA/CPMP) view point (scientific advice…) (45 mn) and industry strategy including the CTD (45 mn)
- Explain and implement the methodological and technical specifications of clinical trials in children including placebo effect, choice and assessment of good endpoints (1h00)

M 4 PERINATAL DRUG EVALUATION AND USE (7h30)

- Explain drug evaluation by Regulatory Authorities and specific issues linked to their use during pregnancy : viewpoint of the toxicologist, writing product information/labelling, questioning clinical trials on medicinal products possible during pregnancy (2h00)
- Understand the principles and identify the methodological issues on the evaluation of placental drug transfer (1h00)
- Explain the treatment of pregnant women : Assess the risk of drug exposure at different stages of pregnancy. Evaluate the consequences for drug use in pregnant women (1h00)
- Review the risk of drug exposure during pregnancy (30mn)
- Understand the principles and identify the methodological issues on the evaluation of drug transfer into breast milk. Evaluate the consequences in lactating mothers (30mn)
- Review the different clinical situations related to foetal drug therapy. Elaborate on the methodological issues on drug evaluation in these situations (1h30)
- Reporting two specific foetal drug therapy (1h00)

M 5 DRUG EVALUATION IN VARIOUS SPECIFIC THERAPEUTIC AREAS (7h30)

- Describe specific aspects of epilepsia in children/adults (1h30)
- Describe specific aspects of pain in children/adults (1h30)
- Describe specific aspects of cystic fibrosis in children/adults, its symptomatic treatment and genetherapy (1h30)
- Describe specific aspects of evaluation in cancer diseases in children (1h30)
- Describe specific aspects of asthma in children/adults (1h30)

M 6 DRUG EVALUATION IN A SPECIFIC THERAPEUTIC AREA IN CHILDREN. STATE OF THE ART PROTOCOL DESIGN (WORKSHOP) to be continued … (6h00)

- Review the state of the art on drug evaluation in ductus arteriosus in neonates through evidence-based medicine (2h00)
- How to design a specific protocol & CRF in a therapeutic area in ductus arteriosus in neonates (4h00)

M 7 DRUG EVALUATION IN A SPECIFIC THERAPEUTIC AREA IN CHILDREN. STATE OF THE ART PROTOCOL DESIGN (WORKSHOP) … continued (3h30)

- How to write a protocol and the CRF (2h00).
- How to present each working group report (1h30)

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Modules on evaluation of medicinal products in children

TIME-SCHEDULE (2 periods)

- **M1 Thursday 9 February 2006**
- **M2 Friday 10 February 2006**
- **M3 Saturday 11 February 2006**

- **M4 Wednesday 29 March 2006**
- **M5 Thursday 30 March 2006**
- **M6 Friday 31 March 2006**
- **M7 Saturday 1 April 2006**

VALIDATION

- **5 modules required : M1, M2, M3, M4, M5 or M6**

VENUE

Catholic University of Louvain, Brussels, Belgium