

GRIP Roadshow

Training Course: Medicines in children – what you need to know?

Organised by Norwegian Society of Paediatricians, Medicines for Children Network, Norway and GRIP* (Global Research in Paediatrics)

Lecturers/Chairs

Kalle Hoppu, MD, PhD, Associate Professor of Paediatric Clinical Pharmacology, Hospital for Children and Adolescents and Dept. of Clinical Pharmacology, University of Helsinki, Helsinki, Finland

Evelyne Jacqz-Aigrain, MD PhD, Professeur, Pharmacologie Pédiatrique et Pharmacogénétique, et Réseau pédiatrique des CICs, Université Paris VII Diderot - Pres Sorbonne Paris Cité Hopital Robert Debré, Paris, France

PROGRAM

Wednesday 20 January 2016

Time	Topic	Teacher
08:30-9:00	Welcome and introduction to the course and to GRIP	Kalle Hoppu
09:00-09:30	General introduction to the theme of the course <ul style="list-style-type: none"> • The concept of children as “Therapeutic orphans” • Off-label and unlicensed use of medicines in children • The paediatric initiatives (US, EU, WHO) 	Kalle Hoppu
09:30-10:30	Basics of developmental/paediatric pharmacology <ul style="list-style-type: none"> • Birth to adulthood, pharmacodynamics and pharmacokinetics • Considerations of dose calculation • Routes of administration in children 	Evelyne Jacqz-Aigrain
10:30-11:00	Break	
11:00-11:30	Drug safety in children <ul style="list-style-type: none"> • Are adverse effects more common or more rare in children? • Adverse effects related to or affecting growth and development • Dosing errors 	Kalle Hoppu
11:30-12:00	When evidence is absent can we extrapolate data from adults to children or should we do clinical trials? <ul style="list-style-type: none"> • Off-label or off-knowledge use of medicines? • Experimental therapy vs. clinical trials 	Evelyne Jacqz-Aigrain
12:00-13:00	Lunch	
13:00-13:30	Pharmacological aspects in case of severe disease in children in relation to the pharmacodynamics and pharmacokinetics	Evelyne Jacqz-Aigrain
13.30-14:15	Paediatric formulations <ul style="list-style-type: none"> • Formulations most suitable for use in children 	Kalle Hoppu

	<ul style="list-style-type: none"> • Considerations of excipients used in paediatric formulations • Extemporaneous formulations Ethical aspects of drug research in children 	
14.15-14:45	<p>Understanding the basics of drug development in children</p> <ul style="list-style-type: none"> • Finding the right dose • Demonstrating efficacy • Demonstrating safety • Regulatory assessment and why it is important 	Kalle Hoppu
14:45-15:15	<p>What you need to know as an investigator of a paediatric clinical trial</p> <ul style="list-style-type: none"> • What is a good study and what is not • Good Clinical Practice (GCP) • Recruiting children for a study • Protocol deviations <p>Adverse Events</p>	Evelyne Jacqz-Aigrain
15.15-15:30	Summary & closing of the meeting (including evaluation)	Kalle Hoppu

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