

## GRIP Roadshow

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

Organised by Intresseföreningen för Barn och Läkemedel and GRIP\* (Global Research in Paediatrics)

### Lecturers/Chairs

**Anders Rane**, MD PhD, Senior Professor, Karolinska Institutet, Past Chair Div of Clinical Pharmacology, Karolinska University Hospital, Stockholm, Sweden

**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,

### PROGRAM

**Thursday 1 October 2015**

Time	Topic	Teacher
9:00-9:30	Welcome and introduction to the course and to GRIP	Kalle Hoppu
9:30-10:00	General introduction to the theme of the course <ul style="list-style-type: none"> <li>• The concept of children as “Therapeutic orphans”</li> <li>• Off-label and unlicensed use of medicines in children</li> <li>• The paediatric initiatives (US, EU, WHO)</li> </ul>	Kalle Hoppu
10:00-11:00	Basics of developmental/paediatric pharmacology <ul style="list-style-type: none"> <li>• Birth to adulthood, pharmacodynamics and pharmacokinetics</li> <li>• Considerations of dose calculation</li> <li>• Routes of administration in children</li> </ul>	Anders Rane
11:00-11:30	Break	
11:30-12:00	Drug safety in children <ul style="list-style-type: none"> <li>• Are adverse effects more common or more rare in children?</li> <li>• Adverse effects related to or affecting growth and development</li> <li>• Dosing errors</li> </ul>	Kalle Hoppu
12:00-12:30	Pharmacological aspects in case of severe disease in children in relation to the pharmacodynamics and pharmacokinetics?	Anders Rane
12:30-13:30	Lunch	
13:30-14:00	When evidence is absent can we extrapolate data from adults to children or should we do clinical trials? <ul style="list-style-type: none"> <li>• Off-label or off-knowledge use of medicines?</li> <li>• Experimental therapy vs. clinical trials</li> </ul>	Anders Rane
14:00-15:00	Paediatric formulations <ul style="list-style-type: none"> <li>• Formulations most suitable for use in children</li> <li>• Considerations of excipients used in paediatric formulations</li> <li>• Extemporaneous formulations</li> </ul>	Kalle Hoppu
15:00-15:30	Ethical aspects of drug research in children	Anders Rane
15:30-16:00	Break	

16:00-16:30	<p>Understanding the basics of drug development in children</p> <ul style="list-style-type: none"> <li>• Finding the right dose</li> <li>• Demonstrating efficacy</li> <li>• Demonstrating safety</li> <li>• Regulatory assessment and why it is important</li> </ul>	Kalle Hoppu
16:30-17:00	<p>What you need to know as an investigator of a paediatric clinical trial</p> <ul style="list-style-type: none"> <li>• What is a good study and what is not</li> <li>• Good Clinical Practice (GCP)</li> <li>• Recruiting children for a study</li> <li>• Protocol deviations</li> <li>• Adverse Events</li> </ul>	Anders Rane
17:00-17:30	Questions and General Discussion	Kalle Hoppu
17:30-18:00	Summary & closing of the meeting (including evaluation)	Kalle Hoppu

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