European Medicines Agency

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WORKSHOP ON MODELLING IN PAEDIATRIC MEDICINES
14-15 APRIL 2008
Room 2A, EMEA, 7 Westferry Circus, London, E14 4HB
Chairperson: Prof. Gérard Pons

AGENDA

Background

- New paediatric EU Regulation
- Advancement in modelling techniques

Objectives

The main objective of this workshop is to present the divergent approaches on M&S in the paediatric context and to enhance communication between the involved parties.

Monday 14 April 2008

Coffee and tea is available on the 2nd floor upon arrival.

Part 1 **Developmental PK/PD**		
09:00	Chairperson's Welcome and Introduction	Prof Gerard Pons PDCO Vice-Chair Hôpital Saint-Vincent de Paul
09:20	Current knowledge on developmental PK/PD	Prof Geoffrey Tucker Sheffield University
Part 2 **POP PK/PD Models**		
09:45	Introduction to population PK-PD modelling in paediatric clinical pharmacology	Dr Catherijne Knibbe University of Leiden / St. Antonius Hospital, Nieuwegein
10:15	Regulatory experience of paediatric applications - focusing on modelling aspects	Dr Anja Henningsson and Dr Siv Jönsson MPA
10:40 – 11:00	**Break**	

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	2.1) First in Children	
11:00	Dose selection in early paediatric development	Dr Oscar Della Pasqua GSK
11:20	Evaluating Study Design and Conduct Efficiency of Event-Driven Clinical Trials via Discrete Event Simulation: Applications in Paediatric Oncology	Dr Jeffrey S. Barrett University of Pennsylvania
11:40	Panel discussion (inclusion of guest panellists)	Anders Fuglsang, Daniel Brasseur, Neil John Parrott, Malcolm Rowland
12:10 – 13:10	**Lunch**	
	2.2) Exploratory trials	
13:10	Voriconazole paediatric dose: an example	Dr Peter Milligan Pfizer
13:30	K-PD Model Applications	Prof Pascal Girard Fac Medecine Lyon-Sud
13:50	Sparse sampling design in population PK/PD studies	Dr Sylvie Retout INSERM
14:10	Designing paediatric studies: scaling from adult populations	Prof Leon Aarons CAPKR University of Manchester
14:30	Regulatory experience in application of modelling in dose selection	Dr Elisabeth Rook Medicines Evaluation Board, The Netherlands
14:50-15:20	Panel Discussion (inclusion of guest panellists)	Bruno Flamion, John Warren, Nick Holford
15:20 – 15:40	**Break**	
	2.3) Confirmatory trials	
15:40	Statistical modelling issues arising from PK/PD bridging for paediatrics	Dr Jerry Nedelman Novartis Pharma
16:00	Clinical trial design optimization in paediatrics using prior knowledge combined with modelling and simulations	Dr Eric Snoeck Exprimo NV
16:20	Modelling and simulation in support of adaptive designs	Dr Alun Bedding GSK, London
16:40	Leveraging prior knowledge in guiding paediatric drug development	Dr Pravin Jadhav FDA
17:10 – 18:00	Panel discussion - Summary of first day (inclusion of guest panellist(s))	Bruno Flamion, Robert Hemmings, Carl Peck

Tuesday 15 April 2008

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Part 3 **PBPK- Mechanistic Models-Allometry**		
09:00	Introduction to PBPK	Dr Neil John Parrott Hoffmann La Roche
09:20	Using Size and Age to Predict Clearance and Volume	Prof Nick Holford University of Auckland
09:40	BBB in Paediatrics	Dr Rob Webster Pfizer
10:00	Using the Knowledge of Biology in Prediction of CL as the Main Determinant of Drug Exposure in Paediatric Population	Prof Amin Rostami SIMCYP University of Sheffield
10:20 – 10:40	**Break**	
10:40	Use of PBPK in simulating drug concentrations in paediatric populations: Case studies of Midazolam and Gabapentin	Dr Viera Lukacova Simulations Plus, Inc.
11:00	PBPK modeling with PK-Sim and MoBi in support of the PIP	Dr Jörg Lippert Bayer Technology Services GmbH
11:20	Alternative methods in risk assessment of potential toxicants vs kinetics in paediatric pharmacology: Similarities and role of PBPK modelling.	Dr Michel Bouvier d'Yvoire ECVAM, Institute for Health and Consumer protection
11:40	Advantages and challenges of a mechanism-based modelling approach to drug development and testing	Prof Erik Mosekilde Technical University of Denmark
12:00	Panel discussion -(inclusion of guest panellists)	Malcolm Rowland, Siri Wang, Geoffrey Tucker, Anders Fuglsang
12:40 – 13:40	**Lunch**	

Part 4 **Model based drug development in Paediatrics** Reality - Vision for the future.		
13:40	Modelling and simulation in paediatric drug development and regulation	Prof. Carl Peck Center for Drug Development Science, University of California
14:00	M&S and PIP	Dr Steven Kern Novartis Pharma AG
14:20	Population PK/PD in paediatrics: a perspective on the way forward	Dr Janet Wade Exprimo NV
14:40	Regulatory vision of paediatric applications	Dr Anja Henningsson and Dr Siv Jönsson MPA
15:00 – 15:10	**Break**	
15:10 – 16:10	Panel discussion -(inclusion of guest panellists)- Conclusions from the two days	Rob Hemmings, Pravin Jadhav, Daniel Brasseur, Anders.Fuglsang, Gérard Pons
16:10 – 16:30	Summary of the discussions	Prof Gérard Pons PDCO Vice-Chair Hôpital Saint-Vincent de Paul