Tuesday, May 13, 2008

09:00 Welcome and Introduction

Daan JA Crommelin, EUFEPS President, Top Institute Pharma, Leiden NL
Malcolm Rowland, Conference Co-Chair, University of Manchester, Manchester UK

Session I: Perspectives on variability in drug response

09:20-10:50
Co-chairs: *Malcolm Rowland, University of Manchester, Manchester UK, Roberto A Gomeni, GlaxoSmithKline, Verona IT*

09:20 Quantifying variability: A basic introduction
Mats O Karlsson, University of Uppsala, Uppsala SE
09:50 How do clinicians perceive and act on variability in drug response?
Jeffrey K Aronson, University of Oxford, Oxford UK
10:20 How does an industrialist perceive variability in drug response and product performance?
David A Tainsh, GlaxoSmithKline, Harlow Essex UK

10:50 Coffee/Tea

Session II: Sources of variability in drug response

11:20-12:50
Co-chairs: *Dionigio Franchi, GlaxoSmithKline, Verona IT, Mats O Karlsson, University of Uppsala, Uppsala SE*

11:20 How much does pharmacogenetics explain?
Michel Eichelbaum, Institute of Clinical Pharmacy, Stuttgart DE
11:50 What influence of the GI transit on sources of variability?
Werner Weitschies, Ernst Mortiz Arndt University of Greifswald, Greifswald DE
12:20 How to put together a 'systems approach' to integrate sources of variability?
Geoffrey T Tucker, University of Sheffield, Sheffield UK

12:50 Lunch & Posters

Session III: Judging variability in clinical drug development

14:20-17:10
Co-chairs: *Jeffrey K Aronson, University of Oxford, Oxford UK, David Tainsh, GlaxoSmithKline, Harlow Essex UK*

14:20 Is it possible to predict variability?
Amin Rostami-Hodjegan, University of Sheffield and Simcyp Ltd, Sheffield UK
14:50 Impact of pharmacokinetic and pharmacodynamic variability on clinical study design and program decision making
Don Nichols, Pfizer, Sandwich UK
15:20 Managing variability: How to use a model-based approach to improve clinical trial design?
Roberto A Gomeni, GlaxoSmithKline, Verona IT

15:50 Coffee/Tea

16:20 Electronic monitoring of dosing histories usefully explains residual variability in PK/PD and delivers novel insight for therapeutic decision making
Bernard Vrijens, University of Liège, Liège BE
16:40 How can biomarker and co-variates be used in understanding and managing variability?
E Niclas Jonsson, Exprimo NV, Mechelen BE

Session IV: Variability in the regulatory review process

17:10-18:45
Co-chairs: *Hendrik de Jong, I.R.I.S. Servier International Research Institute, Courbevoie FR*
Michel Eichelbaum, Institute of Clincial Pharmacy, Stuttgart DE

17:10 Variability in drug response: A European regulator's view
Bruno Flamion, University of Namur, Namur BE

17:40-18:45 Panel Discussion
Co-chairs: *Douwe D Breimer, Leiden University, Leiden NL, Franck Leveiller, Novartis Pharma AG, Basel CH*

19:00 Bus shuttle from Conference Center (Dinner 19:30)

Wednesday, May 14, 2008

08:45 Welcome to the Second-Day Programme
Daan JA Crommelin, EUFEPS President, Top Institute Pharma, Leiden NL
Malcolm Rowland, Conference Co-Chair, University of Manchester, Manchester UK

Session IV – continued: Variability in the regulatory review process
09:00-09:30
Co-chairs: *Hendrik de Jong, I.R.I.S. Servier International Research Institute, Courbevoie FR*
Michel Eichelbaum, Institute of Clincial Pharmacy, Stuttgart DE

09:00 How do EU regulators view personalised medicines?
Gunnar Alvan, Medical Products Agency, Uppsala SE

09:30 Coffee/Tea

10:00 Variability in oral administration: A formulator's perspective
Oskar Kalb, Novartis Pharma AG, Basel CH
10:30 How to reduce variability in gastro-intestinal absorption of poorly water soluble compounds through self-emulsifying formulations?
Jan Vertommen, Capsugel, Bornem BE
11:00 How to select physical form of a drug candidate to reduce variability?
Erik Söderlind, AstraZeneca, Mölndal SE
11:30 Performance of biopharmaceuticals: Sources of variability
Daan JA Crommelin, Top Institute Pharma, Leiden NL

12:00 Lunch & Posters

Session VI: Case studies & Panel Discussion
13:15-16:45
Co-chairs: *Malcolm Rowland, University of Manchester, Manchester UK, Sven Stegemann, Capsugel, Bornem BE*
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13:15 **Case 1:**
Is changing the administration route an option for reducing variability? A case study on a HIV-drug
Lieven Bart, Tibotec, Mechelen BE
13:55 **Case 2:**
Overcoming PK variability of poorly soluble compounds: Two case studies
Marcel Schmid, F Hoffmann – La Roche, Basel CH

14:35 Coffee/Tea

15:00 **Case 3:**
Wondering about dosage form impact on variability: Case studies for discussion and identification of a way to get through
Patrizia Ghiotti, GlaxoSmithKline, Verona IT

15:40 – 16:45 Panel Discussion, Outcomes
Co-chairs: *Sven Stegemann, Capsugel, Bornem BE, Clive G Wilson, Strathclyde Institute for Biomedical Science, Glasgow UK*

16:45 Closing of the Conference
Dionigio Franchi, GlaxoSmithKline, Verona IT