

Wednesday, December 5, 2007

08:15 Welcome to the Conference and Introduction to the Programme

Conference Co-Chairs

Hartmut Derendorf, University of Florida, Gainesville FL USA
Erik Mosekilde, Technical University of Denmark, Lyngby DK
Christian R Noe, University of Vienna, Vienna AT

Session I: Approaching biosystems: How and why

08:30-10:15

Co-Chairs

Erik Mosekilde, Technical University of Denmark, Lyngby DK, *Christian R Noe*, University of Vienna, Vienna AT

08:30 Identification and reverse engineering of biological systems: What can mathematics contribute?

Heinz W Engl, University of Vienna and Austrian Academy of Sciences, Vienna AT

09:00 Biosimulation: The link between theory and experiment

Morten Colding-Jørgensen, Novo Nordisk A/S, Bagsvaerd DK

09:30 Molecular correlation networks in systems biology and biomarker discovery

Robert N McBurney, BG Medicine Inc, Waltham MS USA

10:00 Discussion

10:15 Coffee/Tea

Session II: Biosimulation and virtual organs: Contributions and challenges

10:45-12:30

Co-Chairs

Blanca Rodriguez, University of Oxford, Oxford UK
Hans V Westerhoff, Free University of Amsterdam, Amsterdam NL

10:45 Multiscale modelling of drug-induced effects on cardiac activity
Blanca Rodriguez, University of Oxford, Oxford UK

11:15 Long-lasting therapeutic effects of desynchronizing brain stimulation
Peter A Tass, Research Centre Jülich, Jülich DE

11:45 The virtual patient: Biosimulation in anaesthesia
Samsun Lampotang, University of Florida, Gainesville FL USA

12:15 Discussion

12:30 Lunch

Session III: Model building: The disease component

13:45-15:30

Co-Chairs

Fritz R Bühler, ECPM, Basel CH, *Igor Goryanin*, Edinburgh Centre for Bioinformatics, Edinburgh UK

13:45 Pathway-based strategy for discovering oncology therapeutics: Integrating text mining, modelling and high content assay development

Carolyn Cho, Pfizer, Cambridge MA USA

14:15 Human metabolic network reconstruction and drug R&D
Igor Goryanin, Edinburgh Centre for Bioinformatics, Edinburgh UK

14:45 Patient stratification in CV disease: Virtual populations and biomarker patterns in the CV PhysioLab
Thomas Paterson, Entelos, PaloAlto CA USA

15:15 Discussion

15:30 Coffee/Tea

Session IV: Model building: The patient population component

16:00-17:45

Co-Chairs

Amin Rostami-Hodjegan, University of Sheffield and Simcyp Ltd, Sheffield UK,
Steffen Thirstrup, Danish Medicines Agency, Copenhagen DK

16:00 Individualised chronotherapy of cancer patients

Francis A Lévi, INSERM, Paris FR

16:30 Designing antidepressant clinical trials: The role of placebo response models and imaging biomarkers

Roberto A Gomeni, GlaxoSmithKline, Verona IT

17:00 Co-morbidity affecting PK: Regulators request and what's available from modelling

Amin Rostami-Hodjegan, University of Sheffield and Simcyp Ltd, Sheffield UK,
Steffen Thirstrup, Danish Medicines Agency, Copenhagen DK

17:30 Discussion

17:45 Introduction to Breakout Sessions

18:00 Breakout Sessions A-B-C-D

A Education and training

Ole J Bjerrum, University of Copenhagen, Faculty of Pharmaceutical Sciences, Copenhagen DK & *Daan JA Crommelin*, Top Institute Pharma, Leiden NL

B Harmonising and sharing quality data management

Igor Goryanin, The Edinburgh Centre for Bioinformatics, Edinburgh UK & *Malcolm Rowland*, University of Manchester, Manchester UK

C Software/libraries/systems for models and simulations

Norbert Haider, University of Vienna, Vienna AT & *Ursula Kummer*, EML Research, Heidelberg DE

D Modelling and simulation as a risk mitigation tool

Joga Gobburu, Food and Drug Administration, Silver Spring MD USA & *Thomas Senderovitz*, UCB Pharma, Braine-l'Alleud BE

19:30 Reception Buffet

Thursday, December 6, 2007

08:30 Welcome to the Second-day programme

Conference Co-Chairs

Hartmut Derendorf, University of Florida, Gainesville FL USA

Erik Mosekilde, Technical University of Denmark, Lyngby DK

Christian R Noe, University of Vienna, Vienna AT

Session V: Model building: The exposure response component (PK/PD)

08:45-10:30

Co-Chairs

Meindert Danhof, Leiden University, Leiden NL
Hans Günter Schaefer, Boehringer-Ingelheim, Biberach an der Riss DE

08:45 State-of-the-art PK/PD modelling: Theory and concepts

Meindert Danhof, Leiden University, Leiden NL

09:15 Using system models in characterising exposure response

Mats Karlsson, University of Uppsala, Uppsala SE

09:45 The industry perspective on pharmacometrics: Past, present and future

Thorsten Lehr, Boehringer-Ingelheim Pharmaceuticals Inc, Ridgefield CT USA

10:15 Discussion

10:30 Coffee/Tea

Session VI: The full clinical trial simulation incl the drop-out issue

11:00-12:45

Co-Chairs

Hartmut Derendorf, University of Florida, Gainesville FL USA

Carl Peck, Center for Drug Development Science, Washington DC USA

11:00 Clinical trials simulation in drug approval

Joga Gobburu, Food and Drug Administration, Silver Spring MD USA

11:30 Trial simulation to facilitate decision making in drug development

Marc Pfister, Bristol Myers Squibb Research Institute, Princeton NJ USA

12:00 Clinical trial simulations for anti-infective agents

Johan W Mouton, Canisius-Wilhelmina Hospital, Nijmegen NL

12:30 Discussion

12:45 Lunch

Extra Session: Contribution of microdose studies (to be continued in the afternoon of the third day)

13:30-14:15

Co-Chairs

R Colin Garner, Xceleron, York UK

Malcolm Rowland, University of Manchester, Manchester UK

13:30 Physiologically based pharmacokinetic modelling as a tool to support interpretation of microdose studies

Simon Thomas, Cyprotex, Macclesfield UK

Session VII: Integration for exploratory development including simulating drug development plans: The helicopter view

14:15-15:45

Co-Chairs

Tim Goggin, F. Hoffmann-La Roche, Basel CH

Colin Pillai, Novartis Pharma AG, Basel CH

Thomas Senderovitz, UCB Pharma, Braine-l'Alleud BE

14:15 Panel with short contributions and discussion

15:45 Coffee/Tea

16:15 Breakout Sessions E-F-G-H

E How to arrive at a global regulatory strategy for model based drug development
Carl Peck, Center for Drug Development Science, Washington DC USA

F Translational pharmaceutical sciences
Erik Mosekilde, Technical University of Denmark, Lyngby DK &
C Ian Ragan, BioSim Advisory Board, London UK

G Integration of company research: What and When

Hans Günter Schaefer, Boehringer-Ingelheim, Biberach An Der Riss DE &
Igor Goryanin, Edinburgh Centre for Bioinformatics, Edinburgh UK

H R&D Organisation: How and when

Adriano M Henney, AstraZeneca, Macclesfield UK &
Michael Zuehlsdorf, Novartis Pharma, Basel CH

17:30 Poster Session Drinks & Snacks

‘Speakers corner’ and guided tour

Anne Marie Clemensen, Technical University of Denmark, Lyngby DK &
David Rand, Warwick University, Coventry UK

Friday, December 7, 2007

08:00 Welcome to the Third-day programme

Co-Chair

Hartmut Derendorf, University of Florida,
Gainesville FL USA

Erik Mosekilde, Technical University of Denmark,
Lyngby DK

Christian R Noe, University of Vienna, Vienna
AT

Session VIII: Relevant R&D Stimulating Initiatives

08:15-10:25

Co-Chairs

Ole J Bjerrum, University of Copenhagen,
Copenhagen DK

Hartmut Derendorf, University of Florida,
Gainesville FL USA

08:15 InnoMed/IMI JU: Contributions to date and to come

Arnd Hoeveler, European Commission,
Brussels BE

08:35 TI Pharma: The Dutch Top Institute
Pharma, a PPP: A public private partnership
bridging the gap

Daan JA Crommelin, TI Pharma, Leiden
NL

08:55 Visionary thinking about systems biology
contributions

Adriano M Henney, AstraZeneca,
Macclesfield UK

09:15 Seeking first to understand and then to be
understood: A regulatory policy initiative
for a better agency interaction in China

Zili Li, Merck & Co, Rahway NJ USA

09:35 The US critical path initiative and utilisation
of all initiatives for better drug development

Carl Peck, Center for Drug Development
Science, Washington DC USA

10:05 Coffee/Tea

10:35 EMEA initiatives to stimulate and
facilitate drug developments
Hans-Georg Eichler, EMEA, London
UK

11:00 Discussion

Breakout Session Reports & Conclusions and Recommendations

11:20-12:35

Co-Chairs

Christian R Noe, University of Vienna, Vienna AT

Erik Mosekilde, Technical University of
Denmark, Lyngby DK

12:35 Wrap-up and farewell to those not staying for the Extra Session

Hans V Westerhoff, Free University,
Amsterdam NL

13:05 Lunch

Extra Session: Microdosing to learn and confirm quicker

14:00-16:10

Co-Chairs

R Colin Garner, Xceleron, York UK

Rokus de Zeeuw, BEBO Foundation, Assen NL

14:00 Molecular dosing. NOAEL versus MABEL
Colin T Dollery, GlaxoSmithKline, Harlow UK

14:25 Microdosing: What have we learnt so far?
R Colin Garner, Xceleron, York UK

14:50 Key safety issues in microdosing: Call for harmonisation to the regulatory authorities
Rokus de Zeeuw, BEBO Foundation, Assen NL

15:15 Regulatory aspects on microdosing
Carolyn Belcher, Constella Group Ltd, Cambridge UK

15:40 Discussion (with above panel) and wrap up
R Colin Garner, Xceleron, York UK
Rokus de Zeeuw, BEBO Foundation, Assen NL

16:10 Closing of the Extra Session