EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

efpia
European Federation of Pharmaceutical Industries and Associations

28 November 2011
EMA/455573/2011

Agenda – EMA-EFPIA Modelling and Simulation Workshop

30 November – 01 December 2011

7, Westferry Circus, Canary Wharf, London E14 4HB

Workshop's objectives:

The objective of the workshop (WS) is to discuss the role and scope of modelling and simulation (M&S) in drug-development both from the developer's and the regulator's perspectives.

The WS should lead to a joint understanding of how M&S can be better integrated into the drug development process. It should also provide an opportunity for industry, academia and regulators to learn about and from each other, create greater awareness, share experiences, identify gaps and future opportunities.

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Day 1: 30 November 2011

Room 2A

~ Registration and Coffee ~

11.30 - 13.00

1. Introduction	13.00 – 13.10
Chairpersons opening statement, objectives, and background *Chairperson: Rob Hemmings (SAWP chair, CHMP member, MHRA)* *Co-chair: Solange Rohou* *(EFPIA Clinical Development Committee)*	

2. Current position and expectation for use of M&S in drug development and regulatory decision making	13.10 – 15.00
The EFPIA view point	Peter Milligan (Pfizer)
The EMA view point	Terry Shepard (MHRA)
The FDA view point	Pravin Jadhav (FDA)
The PMDA view point	Yuki Ando (PMDA)
Discussion	Workshop Participants

~ Coffee Break ~

15.00 -15.30

3. M&S examples that failed or succeeded to meet regulators' expectations	15.30 – 17.45
A M&S example that succeeded meeting expectations	Valerie Cosson (Roche)
A M&S example that failed meeting expectations	Monica Edholm (MPA)
A M&S example that failed meeting expectations	Oscar Della Pasqua (GSK)
Discussion	Workshop Participants

4. End of Day 1	17.45 – 18.00
Closing remarks	Rob Hemmings Solange Rohou

Day 2: 1 December 2011

5. Identifying advantages and challenges of using M&S to support decision making during drug development and in regulatory assessment, through case studies *Four parallel Breakout sessions*	08.30 – 12.30
Break out session 1 (BOS1) - Room 4C **M&S in early development** - M&S in preclinical studies - Translational Modelling and Simulation - M&S to support design of First-in-Man studies – the MABEL approach - Leveraging prior information (*in-vitro*, pre-clinical and literature information) - M&S in early PK and safety studies - Methodology and good practices	Refer to BOS1 Agenda
Break out session 2 (BOS2) - Room 4B **M&S in clinical pharmacology and dose finding** - Dose finding (Model-finding vs dose finding) - PK/PD - Pharmacogenetics - Renal/hepatic impairment - DDI - Methodology and good practices	Refer to BOS2 Agenda
Break out session 3 (BOS3) - Room 2G **M&S as a tool to bridge efficacy and safety data in some special populations** - In support of PIP (choice of dose to be studied, data analysis and interpretation, and inferences) - Between ethnic groups – support of global clinical trials - Geriatrics - Methodology and good practices	Refer to BOS3 Agenda
Break out session 4 (BOS4) - Room 2A **M&S to optimise the design of confirmatory trials, to analyse Ph3 data** - M&S to bridge gap between learning and confirmatory phase - Optimal design of Phase IIB/III (based on previous knowledge, comparator information etc) – comparison of model-based methods with empirical methods - Incorporating disease models for planning and analysis of data - Methodology and good practices	Refer to BOS4 Agenda

~ Lunch Break ~

12.30 -13.30

6. Plenary session - Room: 2A	13.30 – 15.30
Debriefing from breakout sessions - Define the role of M&S in internal decision making - Define the current regulatory acceptance of M&S - Identify opportunities and gaps in M&S - How M&S can be further integrated into drug development and regulatory decision-making?	BOS presenters
Discussion: Overall discussion of the break out sessions (also opportunity to raise any additional points not covered/burning issues)	Workshop Participants

~ Coffee Break ~

15.30 -15.45

7. M&S good practices and next steps	15.45 – 17.00
- How to avoid bias and check assumptions in a model? - How to report and review the results of M&S exercise? - Future steps. - How could a pragmatic interaction between industry and regulatory authorities regarding decision based on M&S look like?	
Approaching the Agency	Spiros Vamvakas (EMA)
The EFPIA view point	Donald Stanski (Novartis)
The EMA view point	Rob Hemmings
The EMA view point	Tomas Salmonson (CHMP vice Chair, MPA)
Discussion	Workshop Participants

8. Closing remarks and future actions	17.00 – 17.30
Rob Hemmings Solange Rohou	