European Statistical Meeting

Dose Selection in Late Phase Clinical Development

9:30am to 5:30pm
Thursday 12th November 2015
BMS, Brussels, Belgium

Adequately characterizing the risk/benefit of the selected dose and regimen of a new treatment in late phase 2 trials, or in phase 3, is essential for successfully navigating the regulatory submission and subsequent reimbursement processes. In this meeting we will hear from EU regulators and experts in the field of late phase dose selection and will present case studies of the evolving methodology in this area. There will be an opportunity for questions throughout the meeting and a panel discussion at the end. Interesting case studies will also be presented.

Agenda

Bjoern Bornkamp (Novartis, Switzerland)
Dose-Finding: MCP-Mod and Beyond

Flora Masuamba (UCL/Fed. Agency for Medicines and Health Products, Belgium).
Model informed benefit/risk assessment

Norbert Benda (BfARM, Germany)
Regulatory aspects of model based dose selection

Magnus Åstrand (AstraZeneca, Sweden)
Improve dose selection through Modelling and Simulation

Frank Miller (Stockholm University, Sweden)
Optimizing the design of a dose-finding trial: theoretical methods and practical aspects

Alun Bedding (Roche, UK)
The use of model based dose response in choosing doses in a lean clinical development plan for a rare disease

Panel Discussion

Venue

NV Bristol-Myers Squibb
Belgium SA
Parc de l'Alliance
Avenue de Finlande 4
B – 1420 Braine-l'Alleud
Belgium

Registration

Fee includes lunch & refreshments

On or before 1st Oct

Industry rate:	€170.00
Academic rate:	€110.00

After 1st Oct

Industry rate:	€200.00
Academic rate:	€130.00

To attend this meeting register your details at:

www.efspi.org

or contact

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For information regarding the scientific content contact:

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Agenda

9.00	**Arrival and Coffee**	
9.30	**Welcome and Introduction**	
9.45	**Dose-Finding: MCP-Mod and Beyond**	**Bjoern Bornkamp** **Novartis, Switzerland**
10.30	**Optimizing the design of a dose-finding trial: theoretical methods and practical aspects**	**Frank Miller** **Stockholm University, Sweden**
11.15	**Coffee Break**	
11.45	**Improve dose selection through Modelling and Simulation**	**Magnus Åstrand** **AstraZeneca, Sweden**
12.30	**Lunch**	
13.30	**The use of model based dose response in choosing doses in a lean clinical development plan for a rare disease**	**Alun Bedding** **Roche, UK**
14.15	**Model informed benefit/risk assessment**	**Flora Masuamba** **UCL/Fed. Agency for Medicines and Health Products, Belgium**
15.00	**Break**	
15.30	**Regulatory aspects of model based dose selection**	**Norbert Benda** **BfARM, Germany**
16.15	**Panel Discussion**	
17.15	**Final Remarks**	
17.30	**Meeting Close**	