

European Statistical Meeting on Subgroup Analyses

Friday 30th November 2012, Brussels

Subgroups analyses are important for a comprehensive assessment of confirmatory trials in marketing authorisation application. Indeed, the CHMP is currently preparing a guideline on this topic. This meeting aims to bring together statisticians from regulatory agencies, academia and the pharmaceutical industry, to gain an insight into current thinking with regards to methodology and guidelines. There will be an opportunity for questions throughout the meeting and a panel discussion at the end. Interesting case studies will also be presented.

9:00am to 5:30pm

Presenters include:

Rob Hemmings (MHRA)

Subgroup Analyses, Important, Infuriating and Intractable

and from industry and academia

Nigel Baker (Amgen)

Biomarker defined subgroups in gastric cancer, a case study

Frank Bretz (Novartis)

Multiplicity Considerations in Confirmatory Subgroup Analyses

Oliver Keene (GlaxoSmithKline)

Subgroup Analysis for Regulatory Purposes: A View from an Industry Statistician

Jean-Marie Ledeine (BMS)

*Geonomic Status in Optimizing Subgroup
Patient Selection: a case study*

Kit Roes (University Medical Center Utrecht)

Subgroups, clinical sense and statistical challenge

Gerd Rosenkranz (Novartis)

Case Studies of Confirmatory Subgroup Analysis

Nigel Stallard (University of Warwick)

Adaptive Clinical Trial Designs for Subgroup Selection



Venue

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

Registration Costs

Fee includes lunch & refreshments

Registration

on or before 19th October

Industry €160
Academic €100

Registration after 19th October

Industry €190
Academic €120

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