



22 May 2016
Pullman Hotel, Berlin

**A PSI Pre-Conference Training Course
on**

**Subgroup Analysis
Presented by**

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It is common to conduct subgroup analyses in clinical trials at all phases of drug development. Consistency of treatment effect across subgroups indicates that the conclusions made regarding treatment benefit are applicable across various baseline characteristics and associated subpopulations, whilst substantial heterogeneity in treatment effect may suggest clinically relevant differential treatment effects across relevant subpopulations. At the extreme, the presence of substantial heterogeneity may imply that the conclusion of beneficial treatment effect is only relevant for a subset of the population. Interpretation of subgroup analyses is challenging as subgroup findings can be due to chance. This is particularly likely when a large number of subgroup analyses are undertaken. Further, clinical trials are generally not powered for detecting heterogeneity, so statistical tests may also miss important interactions due to low power.

EMA issued draft guidance on approaches to subgroup analysis and convened a workshop to discuss this guidance in 2014, with further work ongoing within PSI to explore approaches to analysis that may be acceptable in regulatory submissions, with the aim of having further interactions with regulatory agencies regarding their use.

This course will address the importance of pre-specification, how this can help inform interpretation of apparent subgroup findings, will outline the key concepts from the EMA draft guidance and will introduce approaches to subgroup analysis which account for some of the issues described. The course will consist of lectures. There will not be any computer exercises.

The following key topics will be covered:

- The documents from US and European regulators.
- The role of subgroup pre-specification and how this can inform the analysis and interpretation process.
- The use of graphical methods to understand subgroup effects in the context of the number of analyses performed.
- The use of bias-adjusted analyses to account for the over-selection inherent when conducting a number of subgroup analyses.
- Presentation of results from Bayesian analyses looking to borrow information across subgroups, or to incorporate prior data and belief into the analysis.

Course runs from: 13:00 – 17:00 on the first day (Sunday) of the conference

Registration

Register online via the conference portal at:
<https://b-com.mci-group.com/Registration/16PSIBER.aspx>

Costs: 240 Euros (Early Bird rate – up to 29 Feb 2016)
285 Euros (Standard rate – 1 Mar 2016 onwards)
Includes refreshments during course only (no accommodation or dinner)

PSI aims to be fully inclusive and endeavours to accommodate delegates with disabilities wherever possible. Please help us to help you by letting us know if you require additional facilities or have any special requirements. Please contact us on +44 (0) 1730 715 235 or at PSI@mci-group.com for further information.

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