European Federation of Statisticians in the Pharmaceutical Industry
Promoting Professional Standards in Europe

European Statistical Meeting: Advances in the Treatment of Missing Data

On November 18th 2011 the SBS-BVS, PSDM, PSI and the EFSPI organized this one day meeting in Brussels with almost 100 delegates. The meeting was hosted by Bristol-Myers Squibb. After the opening by Nigel Howitt (PRA International and EFSPI) there were contributions by several experts in the field from various countries with different backgrounds.

Mike Kenward (London School of Hygiene and Tropical Medicine) gave a clear and conceptual presentation to set the scene for the day avoiding technicalities but introducing the important concepts of 'de jure' and 'de facto'.

Geert Molenberghs (University of Hasselt) gave an entertaining talk about the background of the report of the National Academy of Sciences. He also commented on the (in hindsight) confusing terminology (like MAR and MCAR) and the current roles of MCAR, MAR and MNAR analyses.

David Wright (MHRA) presented a regulatory view. He explained the regulators' conservative position and commented on the misconception by industry that regulators want certain techniques because of the past. He also stressed the importance of sensitivity analyses and 'de facto' approach for regulatory decision making.

James Roger (LiveData) illustrated in a clear and simple way a pattern mixture model using a nice example addressing the de jure question. The importance of correct software, both standard software and software in development, to implement MI was highlighted.

After the lunch Rolf Groenwold (University of Utrecht) showed that a Complete Case Analysis with covariate adjustment provided unbiased estimates and correct confidence interval coverage in a setting of an observational study with outcome data under a mix of MAR and MCAR.

Mouna Akacha (Novartis) explained the impact of the new regulatory guidelines in the different stages of a clinical study and the status of handling missing data within her company. She also presented the feedback received from different health authorities and the role of realistic sensitivity analyses.

Michael O'Kelly (Quintiles) discussed the handling of missing data when the objective is to render study results credible in the presence of missing data. By showing examples in various indications the impact of assumptions and sensitivity analyses was demonstrated.

Mark Donovan (Bristol-Meyers-Squibb) discussed how missing data was handled in a real case study in diabetes, including the role of post-rescue data in the analysis. In addition a simulation study assessing the behavior of different missing data approaches was shown.

The final presentation was made by Axel Krebs-Brown (Astellas) who discussed numerous practical situations to minimize missing data throughout all stages of a clinical trial rather than to deal with missing data in the analysis: "prevention is better than cure".

A panel discussion on various topics like the plea to avoid the misleading term MMRM completed this meeting.

The great venue in Brussels, the excellent organization of this meeting together with the lively presentations made it a very successful day.

The slides from the meeting can be found on the EFSPI Website under, "EFSPI International Events": http://www.efspi.org/index.php?p=EFSPI+activities&fid=19

Pierre Verweij (MSD and EFSPI) and Egbert Biesheuvel (MSD and PSDM)