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Study 33: Analysing a cross-over study. Statistical work and challenges related to planning, conducting and analysing a clinical trial with cross-over design.

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Abstract

Conducting a trial according to Good Clinical practice requires input from a statistician (ICH, E9 http://www.ich.org/). The statistician plays an important role in the study throw the different stages of the study: Study planning, study conduction, study analysis and study reporting. This report will describe the author's statistical contribution during the conduction of a clinical trial named study 33. This study has been published, see section 7: Appendix 1, but the published paper have a clinical focus and will therefore not fully account of the statistical work in the study. Therefore the report also contains more general and more detailed sections describing relevant statistical aspects. Study 33 was carried out as a double blinded, randomized crossover study in healthy volunteers with the primary objective:"The primary objective for this study will be to compare sedation, one hour after first dose in each period, between qutiapine immediate release formulation (SEROQUEL®) and qutiapine extended release formulation (SEROQUEL XR®) during initial dose escalation."The crossover design, where all patients receive both treatment options, allows a within patient comparison. But it also introduces statistical challenges such as period effect and possible interaction between treatment and period. This report describes how these risks were handled in study 33. Furthermore this report includes the results from study 33 as presented in a publication of study 33 (section 7).

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