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Using pattern mixture models in sensitivity analysis

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Missing data is a concern in most clinical trials, especially in those with a longitudinal structure. Sensitivity analyses are often used to assess the robustness of statistical inference made under conditions of missing data. There has been an increasing trend to use Pattern Mixture Models (PMMs) to impute missing data in sensitivity analyses. The key to proper implementation of PMMs is to make valid assumptions about the link between observed values and missing values. By applying different assumptions to the data from a phase II trial, we have demonstrated that conclusions drawn from such sensitivity analysis fluctuate depending on what assumptions underlie the missing data imputation. Therefore, PMMs should be used with caution and the plausibility of model assumptions should be evaluated first by the clinical study team, taking into consideration past experience with the study drug and the patient population.

Biography

Wei Zhong is Senior Program Manager in the Biostatistics Department at ICON Clinical Research. She received her doctoral degree at the University of Cincinnati and has 15+ years of experience in the pharma industry.

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