Exploratory and confirmatory subgroup analyses in clinical trials

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The identification of subgroups of patients responding particularly well to a treatment has become of increased interest in a move to personalized or stratified medicine. We start by reviewing methods for exploration of subgroups within a single trial (Ondra et al, 2015) with a particular focus on a modification of the Adaptive Refinement by Directed Peeling algorithm by LeBlanc et al (2005). Then we extend these ideas to the setting of several trials using a meta-analytic framework highlighting the importance to model between-trial heterogeneity (Friede et al, 2015). Finally, we consider how subgroup identification and confirmation can be integrated in clinical development plans and discuss the role of adaptive enrichment designs (Friede et al, 2012).

References

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