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Comparative effectiveness research in pharma: A statistician's role in demonstrating the value of a new product

As part of the application process for the reimbursement of a new product, a manufacturer must demonstrate the clinical benefit of the product against standard of care (SoC) in a local market. SoC may include several treatment options or "comparators", most of which have not been directly compared to the new product in a head-to-head randomized controlled trial. There are several statistical approaches available to indirectly compare a new product to relevant comparators, including network meta-analysis. In a consultant role, it is important for a statistician to ensure valid indirect treatment comparisons (ITCs) are conducted in the manufacturer's target patient population. As such, a statistician must think outside the modelling box and develop a good understanding of the disease space and comparator evidence; this will help the statistician assess for potential violations of the assumptions underlying the models. This talk will introduce ITC methods and will discuss how a statistician plays a role in all stages leading up to a valid ITC, including the collection of evidence, ITC feasibility assessment, ITC methods selection, and dealing with uncertainty.