PRACTICAL EXPERIENCE WITH META-ANALYSIS TO EVALUATE SURROGATE ENDPOINTS

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Statistical approaches for evaluating potential surrogate endpoints using a meta-analysis of data from randomized clinical trials have received extensive attention in the past decade. These approaches have also been applied in a number of disease areas and have contributed to regulatory policymaking. There are many practical issues that have arisen in this work. Examples, among many, include: the use of summary data versus individual patient data; the need to identify a "control" treatment in the randomized comparison; the approach for determining whether a potential surrogate endpoint is good or bad; the use of subpopulations in a single trial rather than multiple trials as the basis for the meta-analysis; censoring or missingness of the potential surrogate endpoint after patients develop the clinical endpoint of interest. This talk will illustrate and discuss some of these practical issues drawing on applied experience from the past few years.