

SURROGATE ENDPOINT VALIDATION: STATISTICAL ELEGANCE VERSUS CLINICAL RELEVANCE

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A variety of approaches have been proposed to provide formal and informal validation of proposed surrogate markers. To achieve true clinical impact, the validation must convince both the statistical and clinical communities. In this talk I argue, through actual data examples, that the best approach is not a single method but a multi-faceted exploration, using two types of approaches (1) those that directly appeal to clinicians but with less statistical foundation and (2) those arising from statistical considerations but are harder to interpret clinically.