MEDICAL UNIVERSITY OF VIENNA

Wiener Biometrische Sektion
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A CLASS OF TWO-SAMPLE BINARY AND SURVIVAL STATISTICS WITH APPLICATION TO IMMUNOTHERAPY TRIALS

30. September 2020, 9:15h

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ABSTRACT:

Cancer immunotherapies have emerged as alternative treatments to fight cancer. The response pattern in Immuno-Oncology (IO) therapy differs from previous cancer treatment regimes and is mainly characterized by a delay in the clinical effect. As a consequence, traditional endpoints such as objective response and overall survival might not capture the benefits of IO. Moreover, the assumption of proportional hazards seldom holds because of the delayed separation of the survival curves. Hence, novel endpoints and alternative statistical approaches accounting for the non – proportionality of the hazards are needed.

Aiming to capture both tumor and survival responses of the immuno-response, we propose a two-arm trial design where the efficacy is evaluated using a short-term binary endpoint and a survival endpoint. We propose a class of two-sample statistics for testing the equality of proportions and the equality of survival functions. We build our proposal on a weighted combination of a score test for the difference in proportions and a Weighted Kaplan-Meier statistic-based test for the difference of survival functions. The proposed statistics are fully non-parametric and do not rely on the proportional hazards assumption for the survival outcome.

We discuss different choices of weights including those that control the relative relevance of each outcome and emphasize the type of difference to be detected in the survival outcome. We illustrate our proposal through an IO trial dataset.