A consistency–adjusted strategy for testing an alternative endpoint or a subgroup of a clinical trial

Mohammad F. Huque[1] and Mohamed Alosh[2]

[1]Division of Biometrics IV, OB, OTS, CDER, FDA,
10903 New Hampshire Avenue, Silver Spring, Maryland 20993, USA
[2] Division of Biometrics III, Office of Biostatistics, OTS, CDER, FDA

A clinical trial might involve more than one clinically important endpoint or subgroup each of which can characterize the treatment effect of the experimental drug under investigation. There are several approaches which enable one to test for an alternative primary endpoint if the hypothesis for the designated first primary endpoint is not rejected. In recent literature, the alpha-level allocated to testing a subsequent hypothesis is taken to be dependent on the results of the first test. However, for alternative endpoints to be used interchangeably for establishing efficacy claim it is reasonable to expect certain degree of consistency in efficacy findings of these endpoints. In this presentation we consider a testing strategy which takes into account such consistency requirements for testing an alternative endpoint (subgroup). We investigate the properties of the proposed method and show that other approaches are special cases. In addition, we consider its application to actual clinical trial data.

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