

CLINICAL TRIALS AND THE GENOMICS EVOLUTION: SOME STATISTICAL PERSPECTIVES

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Abstract:

The conventional randomized clinical placebo-controlled trials (PCT) have been critically appraised in the Helsinki (1997) Declaration by the World Medical Association (WMA). As a result, activity-controlled equivalence trials (ACET) have been recommended, thus calling for more nonstandard statistical modelling and analysis tools. During the past seven years, mainly inticated by the abundance of genomics evolution, the search for disease genes and gene-environment interaction have initiated a new research thrust in clinical trials (CT). The growth of statistical reasoning (modelling and analysis) in CT, at this juncture of time, calls for highly nonstandard, novel statistical methodology. Neither the genes are simple nor their association complex is totally understood biologically, clinically or statistically. Cost- benefit, ethics and affordability constraints in CT often lead to high-dimension (K) low sample size (n) environments ($K \gg n$), thus prompting a challenging statistical task to control errors of making incorrect decisions. Measures like the false discovery rate (FDR) are yet to be placed on a completely resolved platform. Some of these perspectives are appraised thoroughly.