THE IMPORTANCE OF BASELINE DATA IN CLINICAL TRIALS

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Unilever has a long and rich history of performing food and nutrition research. Key objective of this research is to provide scientific evidence to support nutrition-health claims for Unilever products.

In the markets that Unilever operates positions have been established in the area of Heart Health and Weight Management. Recent innovations include the development and marketing of foods and beverages with health benefits for children, both in the developed and developing world.

Typically, nutrition health claims are based on evidence from nutrition intervention trials with healthy consumers that are done to understand mechanisms of action. Statistics play an essential role in designing and analysing these trials.

The presentation highlights the role of statistical consultation in setting up these trials and communicating the results. Topics that will be covered are the design of the study, power analysis and issues related to the analysis of these results, like selecting relevant covariates and how to use baseline information of key responses. Special attention will be paid on the selection of volunteers. Including in the trial only volunteers from specific interestgroups like individuals with elevated blood pressure can lead to misleading conclusions due to regression to the mean and measurement error. If random samples are drawn then an analysis of covariance is preferred over subgroup analysis and will be shown with illustrative examples.