

Stratification

In clinical trials, stratification is the separation of patients or the analysis of results based on something other than the treatment given.

Stratification has two different meanings. In its first meaning, it describes the natural distribution of patients into subgroups. For instance, patients may be stratified by age, disease severity, or biomarkers.

In its second meaning, stratification controls the random allocation of people to the different groups in a trial. Stratified randomisation is used to ensure that equal numbers of participants with a characteristic thought to affect response to the intervention will be allocated to each group in the trial.