Sample size

In a clinical trial, the sample size is the number of patients or observations made. There must be enough patients or observations so that differences between groups within the trial can be detected. An estimate of sample size is required and must be specified in the study protocol before recruitment starts. It is also necessary to control the probability with which a real effect can be identified as statistically significant. Too few patients or observations will mean that real effects might not be detected, or they will be detected but at a level that is statistically insignificant (a Type II error, which is directly proportional to sample size). It is just as true that it is unjustified for a medicine to be tested on too many patients.