

Group sequential design

Group sequential design is an example of a statistical approach in clinical trial design. It means that the sample size of the trial is not fixed in advance, and data is sequentially evaluated as it is collected. This is known as interim analysis, and might be carried out at several points in time. The trial can be stopped when significant results are seen, or if the interim analysis shows that there are safety concerns, or that the trial will not in fact be able to give a significant result. In this case no more recruitment of patients or further sampling from the patients involved will occur.

Before the trial starts, the 'stopping rule' (i.e. the reason for stopping) must be documented and explained. The stopping rule is a description of exactly what the interim analysis must show to cause the trial to be stopped.

Group sequential analysis can lead to a conclusion much earlier than would be possible with a classical design. It can therefore save time and resources, and reduces the exposure of patients to inferior treatments.