Adaptive Design

The option to modify the design of an ongoing clinical trial is becoming increasingly common and is known as adaptive design. Data are evaluated before the trial is finished. This is known as interim analysis and might be carried out at several time points. Depending on the circumstances, this may lead to changes to the trial such as stopping one treatment arm or changing the number of participants in a group. The planned number of participants might be reduced if the interim analysis shows that a smaller sample size will still allow a valid result to be obtained. Alternatively, the sample size might be increased if that will allow a valid or reliable result to be obtained within a more acceptable period of time.

Adaptive designs can save time and resources, and can reduce the exposure of study participants to the inferior treatment.

Interim analyses and any anticipated changes to a trial should be described and justified in the study protocol.