Bias

In clinical trails, bias is the systematic deviation from true values of treatment effect through the intentional or unintentional adjustment of results. Bias can result from aspects of trial design, the way a trial is carried, or the way the results are analysed or evaluated.

Bias can be ‘operational’ – when it arises because of the way a trial is carried out; or ‘statistical’ – when it arises because of trial design or the way results are analysed or evaluated

For example, poor trial design might mean that participants at lower risk of experiencing a symptom are placed in one treatment arm as opposed to another treatment arm. Excluding data from certain participants because of knowledge of their outcomes would also cause bias in a trial.

The most important design techniques for avoiding bias in clinical trials are blinding and randomisation. The potential effect of bias should also be taken into account during statistical analysis of trial data.