Protocol

The protocol of a clinical trial is a document that contains:

- The objectives (aims) of the trial
- The trial design, including:
    - How participants will be selected;
    - How many participants are needed;
    - What measurements and endpoints will be used; **and**
    - How bias will be minimised
- How the safety of people taking part, and the privacy of their data, will be ensured
- How the data will be analysed
- How the study will be reported

The protocol is of critical importance to the conduct of a clinical trial; it is referred to frequently throughout the trial and the medicines development process as a whole.