

Inclusion Criteria

Inclusion criteria are the characteristics that potential participants must have in order to be considered for participation in a trial. They describe the patient population and patient selection criteria.

Inclusion criteria should specify the type of testing used to make the patients' diagnosis, as well as specific disease requirements (for example, how severe the disease is, failure or success with previous treatments, plus any other factors that might affect prognosis such as age, sex, or ethnicity).

The inclusion criteria (and exclusion criteria) are important parts of a trial protocol. If they are properly defined, inclusion and exclusion criteria will increase the chances that the trial produces reliable results. They also protect participants from harm and minimise the risks.