

Soft Endpoint

The endpoint in a clinical trial is an event such as occurrence of a disease, or symptom, or a particular laboratory result. Once someone reaches the endpoint, they are generally excluded from further research in the trial.

A soft endpoint is a subjective measure. For example, it is common to measure quality of life as an endpoint in Phase III trials, with patients asked specific questions about the impact of their disease and/or treatment.

In contrast, a hard endpoint is an endpoint that is well defined and can be measured objectively. For example in cancer research, the endpoint in a trial might be related to response to treatment (such as shrinkage of a tumour).

The endpoints used in a trial must be defined and documented as part of the trial design.