Hard Endpoint

The endpoint of a clinical trial is a pre-defined event: for instance, the occurrence of a disease, the occurrence of a symptom, or a particular laboratory result. Once someone reaches the endpoint, they are generally excluded from further research in the trial.

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). Endpoints related to a response are typical in Phase II clinical trials for cancer treatments. Endpoints relating to the survival of patients are common in Phase III cancer trials. 'Progress free survival' and 'disease free survival' measure the length of time patients are alive without their disease worsening.

In contrast to hard endpoints, soft endpoints are subjective measures. Quality of life measures, for example, are soft endpoints. It is common to use quality of life measures as endpoints in Phase III trials. In this case, patients are asked specific questions about the impact of their disease and/or treatment.

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