# Clinical Trial Glossary

Common terms you may see in a clinical trial description:

## Study Protocol

### Randomization

This ensures that the trial is fair and the effects of the new drug candidate can be compared to what is currently prescribed, or if no treatment exists, a placebo. Participants are divided into two (or more) groups randomly where one group receives the new drug candidate and the other group is given the standard treatment or the placebo.

### Placebo

This is a treatment that does not contain the real drug. It will look and feel like the real treatment so that physicians administering it will not know whether it is actual drug or the not. This helps the clinical team to determine if the drug candidate has a real effect on individuals.

### Blinding

This term is used in a clinical trial to refer to whether a patient and/or their physician are told whether they are given the drug that is being tested or not. If the patient alone does not know it is called a single-blind study and if both patient and physician do not know, it is called a double-blind study. Blinding a clinical trial helps to prevent bias and expectations from study investigators and to make the study as accurate as possible.

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# Outcome Measures

### The primary endpoint

is the most important outcome of the study and is the main reason the trial is being conducted. This also determines how the clinical trial is designed and how many participants are required to adequately assess the impact of the drug candidate. In Phase 1 or Phase 2 clinical trials, there may be more than one primary endpoint. A typical primary endpoint to determine the impact of a treatment drug is survival. In serious and life-threatening diseases like cancer, evaluating treatment benefit/risk earlier allows us to accelerate the drug candidate's development and its approval, if it shows a beneficial impact on patients in the trial. This helps us provide our treatment drug other cancer patients faster.

### Secondary endpoints

are additional pre-specified measures used in a clinical trial and do not usually determine trial design and participant size. They are generally not sufficient to influence the efficacy of the treatment but can provide evidence of a particular mechanism by the drug that shows a clinical effect.

### Exploratory endpoints

may include clinically important effects that are expected to occur from drug treatment. These could be infrequent to show a treatment effect and may also be used to explore new hypotheses.

### Overall survival (OS)

The refers to how long a patient receiving our treatment lives, often from the start of the treatment in the trial. As cancer is often a life-threatening disease, this outcome measure gives an indication of how much longer a person may extend the time that they spend with loved ones when receiving the treatment.

### Progression-free survival (PFS)

This measure relates to how long an individual lives without the disease getting worse, which could include tumor progression, metastasis and/or death. An increase in PFS can have a positive psychological impact on the patient and can increase their quality of life.

### Disease- / Relapse-free survival (DFS/RFS)

This trial endpoint represents the time interval that a person lives without showing any symptoms associated with the disease or its recurrence following treatment completion. This early trial endpoint can give an estimate of the cure rate with the drug and is a faster measure than OS especially in an early-stage disease.

### Overall Response Rate (ORR)

This represents a portion of patients in the trial whose tumor completely shrunk or was significantly reduced following treatment. ORR is the sum of three responses over a specified period during the trial, including Complete Responses (CRs) – patients with no detectable presence of the tumor, and Partial Responses (PRs) – patients with a decrease in tumor size and no new tumors detected.

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### Duration of Response (DoR)

The duration of time that a tumor continues to respond to the treatment without it growing or the evidence of the cancer spreading.
The treatments of cancer are continuously evolving and there is a need for new or adapted clinical trial outcomes to measure treatment efficacy more accurately.

### Pathological Complete Response (pCR)

Following a drug treatment regimen, samples from the tissues where the tumor were are removed and checked under a microscope. If the cancer is in pCR, it implies that the anti-cancer treatment resulted in no detectable cancer cells. This is a faster assessment than OS and PFS and is an efficient predictor that the disease will not recur.

### Immune-related response criteria (iRECIST)

This is mainly used in cancer immunotherapy trials for solid tumors and considers responses not typically observed in traditional treatment criteria. Although it is not an endpoint, it accounts for the potential increase in the tumor size due to the entry of immune cells into the tumor.

### Minimal Residual Disease (MRD)

This refers to cancer cells that remain after treatment, which cannot be detected by traditional scans or tests, and can be an early predictor of PFS. The term is often used when treating patients with blood cancers.

**For more information on our trials, please visit clinicaltrials.gov and EudraCT.**

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