Common Terms Used in Abstracts and Research Articles for Clinical Trials

Below are the definitions of a list of terms commonly used in abstracts and research articles for cancer clinical trial results. These words build on terms used in ***How to Read an Abstract for a Clinical Trial Publication***. You can also ask your doctor or healthcare team to explain any words you don't know.

For additional definitions of clinical trial terms, refer to ***Understanding the Clinical Trial Process***.

ABSTRACT
A summary of the research and most relevant findings from a full *research article.* Within a *research article*, an abstract is generally presented at the beginning.

ADVERSE EVENTS
Any medical problem that happens to a participant while receiving treatment, whether or not it is expected or considered related to use of the treatment.

ADVERSE REACTION
An *adverse event* caused by a treatment. An *adverse reaction* is also known as a *side effect.*

CLINICAL BENEFIT
A positive, health-related effect from the treatment.

COHORT
A group of people who share a common trait (e.g., birth year). In the context of clinical trials, a *cohort* is a group that is part of the trial/study and is observed over a period of time. A particular outcome may be compared in multiple different cohorts.

COMPARATOR ARM
Made up of a group of participants in a clinical trial that receives a treatment that is used as the standard against the potential new treatment being measured. The *comparator arm* is also known as the control group. The *comparator arm* is different from the *experimental (or investigational) arm.*

CONFIDENCE INTERVAL
A result from a clinical trial only offers an estimate of how a treatment would work on the entire patient population with the same disease. The *confidence interval* offers a range that reflects the expected real effect of the treatment on the entire patient population, within a defined amount of certainty. For example, "median overall survival at 5 years was 77% (95% Confidence Interval: 0.62 to 0.96)" means that the median overall survival for the study group is 77% and there is a 95% chance that the result for the larger population (with the same disease as was studied), if they received the same treatment, would fall between 62% and 96%.

CROSSOVER STUDY

A type of clinical trial in which all participants receive the same two or more treatments, but the order in which they receive them depends on the groups to which they are randomly assigned. For example, Group 1 receives TreatmentA followed by TreatmentB, and Group 2 receives TreatmentB followed by TreatmentA; the participants "crossed over" to the other treatment. All participants receive TreatmentA and TreatmentB at some point during the trial but in a different order. This is different from a *parallel study.*

DISCONTINUATION

When a participant stops taking a treatment in a clinical trial. The participant may either continue to be evaluated in the trial or stop taking part in the trial altogether before the trial finishes.

DISEASE PROGRESSION

When a disease, such as cancer, worsens or spreads in the body.

DOUBLE-BLIND STUDY

A type of clinical trial in which both the participants and the researchers do not know which treatment in the study each participant receives until the trial ends. This design makes the results less likely to be influenced by factors that are not related to the treatment being studied (bias). Also called *double-masked,* this type of study is different from an *open-label study.*

EFFICACY

The ability of a treatment to produce a beneficial effect, for instance by shrinking a tumor or extending survival.

ENDPOINT

An event or outcome that will help determine whether the treatment being studied has a beneficial effect. A *primary endpoint* is the highest priority outcome for evaluating the effect of the treatment and plays a role in determining how many participants are needed in the trial. A *secondary endpoint* offers additional information for evaluating the effect of the treatment. Most clinical trials have more than one secondary endpoint. *Exploratory endpoints* are other outcomes (but not primary or secondary endpoints) that are included to explore new research questions.

EXPERIMENTAL (OR INVESTIGATIONAL) ARM

Made up of a group of participants in a clinical trial that receives the treatment that is under investigation in the trial. The *experimental (or investigational) arm* is different from the *comparator arm.*

HAZARD RATIO

A measure of how often a particular event, such as disease progression, happens over time in one group of a clinical trial compared with the other group. A *hazard ratio* of 1 means that there is no difference in the outcome between the two groups. If the hazard ratio is below 1, the experimental treatment has a larger effect than the comparator. If the hazard ratio is greater than 1, then the comparator treatment has a larger effect (e.g., disease progression).

INTERVENTIONAL STUDY

A type of clinical trial in which participants are divided into groups, or arms, that receive one or more treatments (or interventions) or no interventions, to determine the effects of the treatment(s) on the health outcomes being studied. An interventional study can be used to evaluate a medicine or other type of care that might benefit a patient like physical therapy or home healthcare.

MEAN

The average of a set of numbers.

MEDIAN

A statistics term representing the middle value, or midpoint, in a set of numbers.

MULTICENTER STUDY

A type of clinical trial that is carried out at more than one medical institution or medical practice.

NON-INTERVENTIONAL ARM

A group of participants in a clinical trial that does not receive any treatment during the clinical trial, unlike in an *interventional arm.*

OBSERVATIONAL STUDY

A type of study in which participants are not assigned a treatment or intervention as part of the research. One example is a patient registry, which collects information about people's medical conditions, personal characteristics, and/or treatments they have been prescribed to better understand how a condition or treatment affects outcomes in the real world. This type of study might also be known as a *non-interventional study* or a *real-world study.*

OPEN-LABEL STUDY

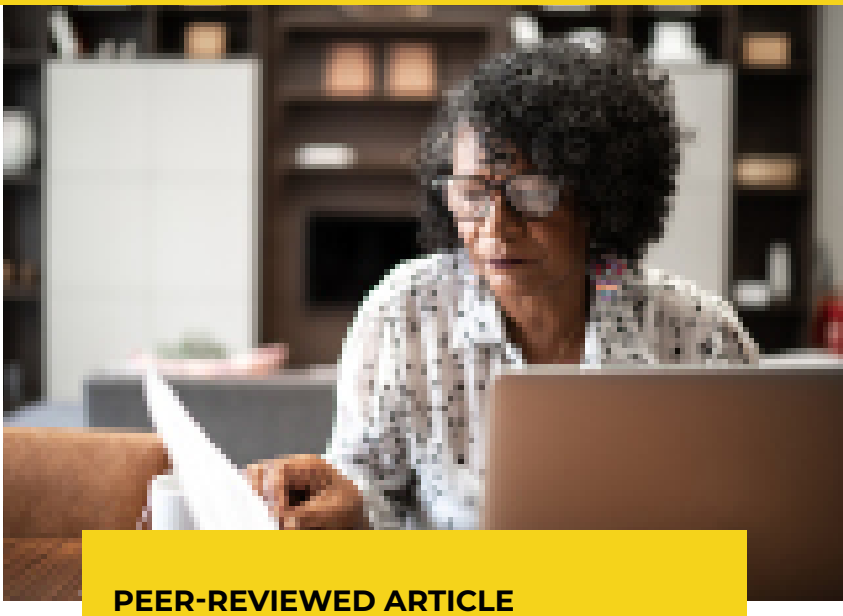
A type of clinical trial in which both the participants and the researchers are aware of which treatment each participant will receive during the study. This type of study is different than a *double-blind study*.

P-VALUE

A statistical measure used to understand whether the results of the study treatment are due to chance or to a real effect from the treatment. In most instances, to consider a result to be a real effect and not by chance, a *p-value* must typically be below 0.05, meaning there is less than a 5% possibility that the results occurred by chance. The lower the *p-value*, the more likely the result is due to a real effect from the study treatment and not due to chance.

PARALLEL STUDY

A type of clinical trial in which two or more treatments are examined at the same time in different groups of people (cohorts). Participants are divided into groups that are assigned different treatments; they remain on that treatment throughout the trial. For example, at the same time, or "in parallel," participants in Group 1 received TreatmentA while participants in Group 2 received TreatmentB. This type of study is different from a *crossover study.*



PEER-REVIEWED ARTICLE

A *research article* that has gone through an evaluation process in which the editors of the journal and other experts in the field assess the quality and scientific merit of the article and its research.

PLACEBO

An inactive substance that looks the same as, and is given in the same way as, the treatment being studied. In clinical trials, the effects of the treatment being studied may be compared with the effects of the *placebo*. A *placebo* is not used often in cancer clinical trials. *Placebos* are used when there is no *standard of care*, or they may be used in a clinical trial that compares standard of care plus a placebo with standard of care plus a new treatment.

RANDOMIZED STUDY

A type of clinical trial in which participants are assigned randomly, or by chance, to the different treatments being tested. This is done so that the researchers don't influence, or bias, the results.

RESEARCH ARTICLE

An article published in a journal that discusses data from a study, including clinical trials, and follows a certain format and structure. This format presents the data in a way that allows others to repeat the study. Most articles include background information, the researcher's methods, results, and the meaning of the findings, or conclusion.

SAFETY

In a clinical trial, safety information includes any *adverse events* or *adverse reactions (side effects)* the participants experienced during the trial.

SIDE EFFECT

A medical problem that occurs when treatment affects healthy tissues or organs.

STANDARD OF CARE

A treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called *standard therapy.*

STATISTICAL SIGNIFICANCE

A statistical term used to determine whether the difference in outcomes between the two studied groups is due to a real effect from the treatment being studied or is due to chance. Researchers typically require a *p-value* of 0.05 or less to determine that the results are *statistically significant* and likely due to the treatment itself.

TOLERABILITY

How well the *adverse effects* from a treatment can be tolerated by the participants.