A term used to describe the situation when both the researcher and the participant in a research study know the treatment the participant is receiving. Open-label is the opposite of double-blind when neither the researcher nor the participant knows what treatment the participant is receiving.

An open-label study, also known as an open-label trial or open-label clinical trial, is a type of clinical research in which both the researchers and the participants are aware of the treatment or intervention being administered. In other words, there is no blinding or concealment of treatment allocation in an open-label study.

Key features of an open-label study include:

Transparency: In open-label studies, participants are informed about the treatment they are receiving, and researchers openly disclose the nature of the intervention. This transparency is in contrast to blinded or double-blind studies where treatment information is concealed from participants and sometimes researchers to minimize bias.

No Placebo: Open-label studies typically do not involve the use of placebos. Instead, participants receive the actual treatment or intervention being tested.

Treatment Evaluation: The primary purpose of an open-label study is to assess the safety, efficacy, and effects of the treatment or intervention. Researchers collect data on the outcomes and monitor participants to evaluate the treatment's impact.

Use in Early Phases: Open-label studies are often conducted in the early phases of clinical research, such as Phase 1 or Phase 2 trials, to gather initial data on a new drug, therapy, or medical procedure.

Safety Monitoring: Researchers closely monitor participants for any adverse effects or side effects related to the treatment. Safety is a primary concern in open-label studies.

Limited Control Group: While open-label studies do not have a traditional blinded control group, they may include comparator groups, such as historical controls or standard treatment groups, to provide some basis for comparison.

Preliminary Data: The data generated from open-label studies can provide preliminary insights into the potential benefits and risks associated with a treatment, helping guide the design of larger, controlled studies.

Open-label studies are valuable for obtaining initial safety and efficacy data for investigational treatments. However, they are considered less rigorous than double-blind, randomized controlled trials (RCTs) for establishing the true effectiveness of a treatment because the lack of blinding can introduce bias into the results. Open-label studies are often followed by larger, controlled trials to confirm and extend the findings observed in the open-label phase.