BREAST CANCER CLINICAL TRIALS 201

Resource Guide

Patient Empowerment Network

Clinical Trial Phases

- **Phase I:** The goal is to test the safety of the drug, finding the appropriate dose that produces the fewest side effects.
- **Phase II:** Further assesses the safety of the drug and the effectiveness of the treatment.
- **Phase III:** Compares the efficacy of the new treatment to the standard-of-care treatment.
- **Phase IV:** Looks at drugs that have already been approved to get additional safety information and to learn more about long-term benefits and side effects.

Clinical Trial Questions

- Is this a two-arm study, and if so, what are the differences between the two arms of the study?
- What is the experimental drug in the study?
- What is the science and clinical data behind this treatment approach?
- Has the treatment been used in humans before?
- Why is it used in my cancer type?
- Why do you think it will work for me?
- What are the potential side effects?
- What is the patient commitment of time, etc.?

Glossary Terms

Informed Consent: Provides a thorough explanation of the purpose of the research, including the role of the patient and how the trial will work.

Institutional Review Board (IRB): Committees that ensure that the risks of trial participation are reduced and outweighed by potential benefits in order to protect the rights and safety of research participants. Most clinical trials, but not all, in the United States are approved and monitored by an IRB both before the research starts and as it proceeds.

Placebo: An inactive drug or treatment with no therapeutic benefit.

Protocol: The written description of a clinical study that includes the objectives, design, and methods. The protocol may also include scientific background and statistical information that pertains to the study.

Randomized Clinical Trial: Trial in which participants are randomly divided into separate groups that compare different treatments or other interventions. The randomization means that the groups will be similar so that treatment effectiveness they receive can be compared more fairly.

Standard of Care: An established guideline that is consensus among experts as the most appropriate and/or effective treatment for a specific type and stage of cancer.

Potential Clinical Trial Benefits

- Helping current and future patients.
- Learning more about a therapy and good practices for the future.
- Gaining access to a new therapy that might not be available otherwise.
- Personalized care and closer monitoring.

Barriers to Accessing Clinical Trials Include

- Access to a trial
- Lack of awareness
- Transportation and logistics
- Pre-existing health conditions and eligibility
- Geographic location
- Racial and ethnic disparities
- Lack of education

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