CLINICAL TRIALS AS A PROSTATE CANCER TREATMENT OPTION: WHAT YOU SHOULD KNOW

Program 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**: Study that looks at drugs that have already been approved to get additional safety information and to learn more about long-term benefits and side effects.

Questions to Ask About Clinical Trials

- What is the treatment approach used in the study and the purpose of the trial?
- Why am I a good candidate for this approach?
- What is the science and clinical data behind this treatment approach?
- What are the potential risks and benefits?
- What are the financial costs, if any? Are there assistance programs to help?
- Where is the trial located? Is transportation available?

Glossary Terms

Health Insurance Portability and Accountability Act (HIPAA): A set of national rules that help protect the privacy of a patient's personal medical information, provide patients with access to their medical records, and help people get health insurance for themselves and their family members.

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.

Prostate Cancer Resources

- American Urological Association (AUA): auanet.org
- CancerGRACE: cancergrace.org
- Cure: curetoday.com
- Facing Our Risk of Cancer Empowered (FORCE): facingourrisk.org
- ZERO - The End of Prostate Cancer: zerocancer.org

Barriers to Accessing Clinical Trials

- Geographic location and logistics
- Racial and ethnic disparities
- Education/lack of awareness
- Financial and insurance barriers
- Prior health conditions

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