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Cancer Clinical Trials



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What Are Cancer Clinical Trials?

- Research studies involving people
- Try to answer scientific questions and find better ways to prevent, diagnose, or treat cancer



Why Are Cancer Clinical Trials Important?

- Cancer affects all of us
- Each year in the U.S:
 - More than half a million people are expected to die of cancer — more than 1,500 people a day
 - 1 of 4 deaths is from cancer
 - More than 1 million new cancer cases are expected to be diagnosed



Why Are Cancer Clinical Trials Important?

- Clinical trials translate results of basic scientific research into better ways to prevent, diagnose, or treat cancer
- The more people that take part, the faster we can:
 - Answer critical research questions
 - Find better treatments and ways to prevent cancer



Do Many People Participate in Cancer Clinical Trials?

- Only 3 percent of U.S. adults with cancer participate in clinical trials



Types of Cancer Clinical Trials

- Treatment trials
- Prevention trials
- Early-detection trials/screening trials
- Diagnostic trials
- Quality-of-life studies/supportive care studies

Clinical Trial Phases

Phase 1 trials

- How does the agent affect the human body?
- What dosage is safe?

Clinical Trial Phases

Phase 2 trials

- Does the agent or intervention have an effect on the cancer?

Clinical Trial Phases

Phase 3 trials

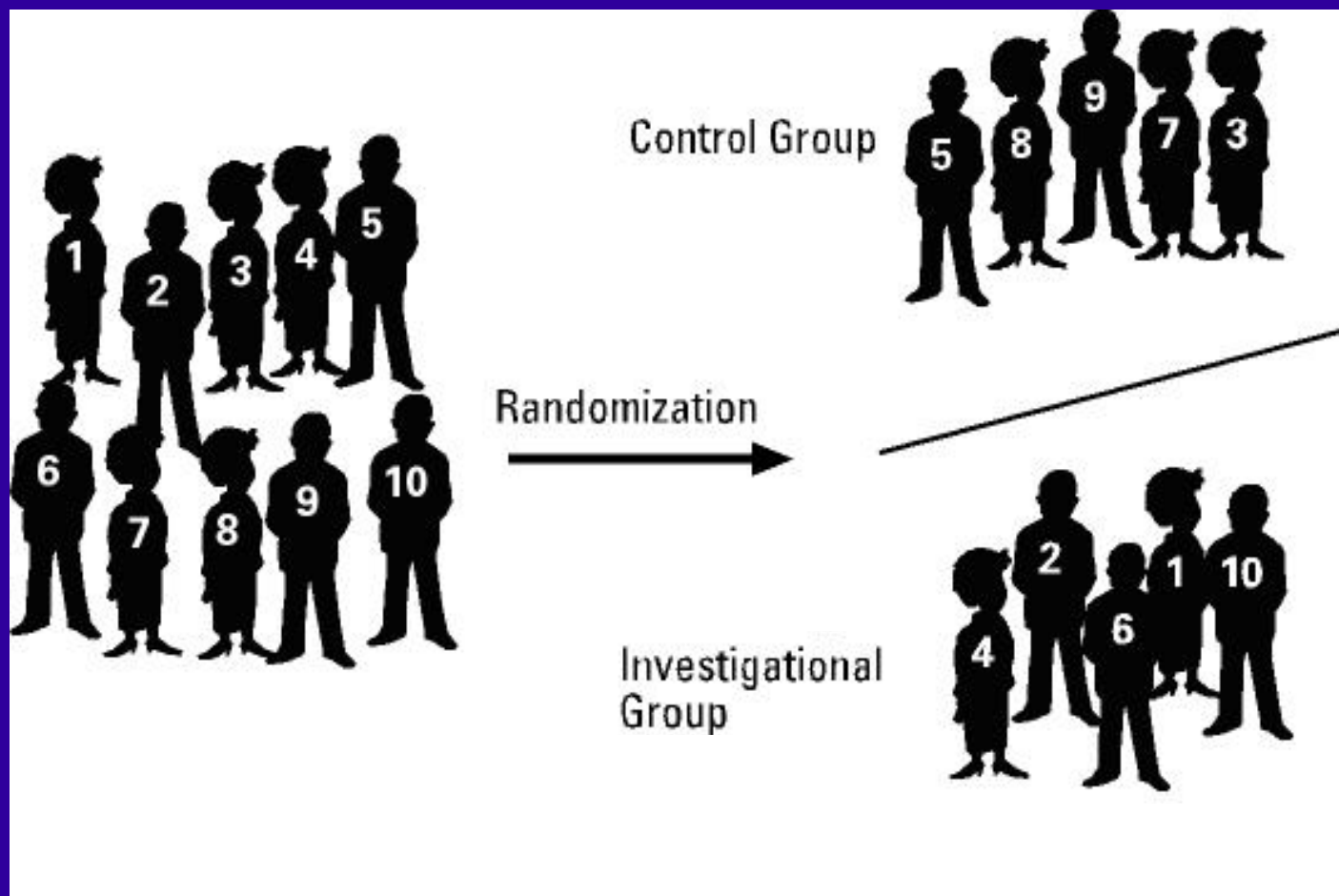
- Is the new agent or intervention (or new use of a treatment) better than the standard?
- Participants have an equal chance to be assigned to one of two or more groups

Randomized Trials

Participants have an equal chance to be assigned to one of two or more groups:

- One gets the most widely accepted treatment (standard treatment)
- The other gets the new treatment being tested, which researchers hope and have reason to believe will be better than standard treatment

Randomization



Why Is Randomization Important?

- So all groups are as alike as possible
- Provides the best way to prove the effectiveness of a new agent or intervention

Cancer Treatment Trials

- What new treatments can help people who have cancer?
- What is the most effective treatment for people who have cancer?



Cancer Treatment Trials

Placebos are almost never used:

- Placebos are used only when no standard treatment exists
- Patients are told of this possibility before deciding to take part

Cancer Prevention Trials

- Evaluate the effectiveness of ways to reduce the risk of cancer
- Enroll healthy people at high risk for developing cancer



Cancer Prevention Trials

- Action studies (“doing something”)
- Agent studies (“taking something”)—also called “chemoprevention studies”



Chemoprevention Trials

- Phase 3 chemoprevention trials compare a promising new agent with either a:
 - Standard agent
 - Placebo



Clinical Trial Protocol

- A recipe or blueprint
- Strict scientific guidelines:
 - Purpose of study
 - How many people will participate
 - Who is eligible to participate
 - How the study will be carried out
 - What information will be gathered about participants
 - Endpoints

Benefits of Participation

Possible benefits:

- Patients will receive, at a minimum, the best standard treatment
- If the new treatment or intervention is proven to work, patients may be among the first to benefit
- Patients have a chance to help others and improve cancer care

Risks of Participation

Possible risks:

- New treatments or interventions under study are not always better than, or even as good as, standard care
- Even if a new treatment has benefits, it may not work for every patient
- Health insurance and managed care providers do not always cover clinical trials

Patient Protection

- There have, unfortunately, been past abuses in patient protection
- Federal regulations ensure that people are told about the benefits, risks, and purpose of research before they agree to participate



How Are Patients' Rights Protected?

- Informed consent
- Scientific review
- Institutional review boards (IRBs)
- Data safety and monitoring boards

How Are Patients' Rights Protected?

Informed consent:

- Purpose
- Procedures
- Risks and potential benefits
- Individual rights



How Are Patients' Rights Protected?

- Scientific review
- Institutional review boards (IRBs) are required by Federal law for trials that are:
 - Federally funded
 - Subject to FDA regulation

How Are Patients' Rights Protected?

Data and safety monitoring boards:

- Ensure that risks are minimized
- Ensure data integrity
- Stop a trial if safety concerns arise or objectives have been met

Why Do So Few Cancer Patients Participate in Clinical Trials?

Sometimes patients:

- Don't know about clinical trials
- Don't have access to trials
- May be afraid or suspicious of research
- Can't afford to participate
- May not want to go against physician's wishes

Why Do So Few Cancer Patients Participate in Clinical Trials?

Doctors might:

- Lack awareness of appropriate clinical trials
- Be unwilling to “lose control” of a person’s care
- Believe that standard therapy is best
- Be concerned that clinical trials add administrative burdens

NCI Information Resources

- NCI Web site
www.cancer.gov
- Cancer Information Service
 - 1-800-4-CANCER
 - TTY- 1-800-332-8615
 - www.cancer.gov/cis