Finding Clinical Trials for Patients

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Objectives

Understand the basic principles and phases of clinical trial research

Discuss the importance of dispelling common myths regarding clinical trials.
What is a Clinical Trial?

A clinical study that involves research using human volunteers that is intended to add to medical knowledge.

https://clinicaltrials.gov/ct2/about-studies/learn
Clinical trials explore a variety of areas including but not limited to:

- New drugs/devices not yet approved by the FDA
- New uses of drugs/devices already FDA approved
- New ways to administer drugs
- New testing used to diagnose and monitor disease states
- Drugs or procedures designed to provide symptom relief
Phases of Clinical Trials
Phase 0: Pre-Clinical Research

• Process by which researchers identify a potential compound/device and explore its mechanism of action, toxicities, and toxicity levels typically in animal models
• Overseen by the FDA
• Can take many years
Phase 1: Safety

• First in human administration of Investigational product
• Less participants due to potential risk
• Typically Divided into two parts:
  • Dose escalation
  • Dose expansion
Phase 2: Efficacy

- Around 70% of drugs pass Phase 1 and make it to Phase 2
- More patients are allowed to enroll—typically several hundred
- Safety continues to be reviewed but now **efficacy** of the drug becomes important
- Less than a third of all drugs continue to Phase 3
Phase 3: Better than the Standard

- Expands enrollment to thousands of participants
- Compares the safety and efficacy profile to standard of treatment
- Patients are often randomized
  - SOC vs. Experimental drug(s)
Phase 4: Post Approval

- Drug is now available to thousands of people.
- Adverse events are continuously collected and updated.
- Black box warnings may appear.
- Looks at long term side effects.
What are some common myths about clinical trials?
Myth #1: “I’m going to be a Guinea pig!”

Facts:

- Clinical trials are highly regulated by the FDA
- Follow a detailed FDA and IRB approved protocol
- Experimental products must undergo rigorous review
- Informed Consent
Myth #2: “I’m going to get Placebo!”

Facts:

• Early Phase clinical trials do **not** use placebos in the oncological setting.

• If placebos are used in later phases, it is **always** accompanied by a standard of care treatment.
Myth #3: “I can’t change my mind once I enroll in a clinical trial!”

Fact:

• Clinical trials are 100% voluntary!

• Patients can withdraw consent at any moment for any reason.
Myth #4: Clinic trials are only a last resort.

Facts:

• Clinical trials are available in every phase of the cancer journey.
• There are many clinical trials for first line and second line treatments.
Myth #5: Clinical trials don’t work.

• More and more patients are receiving benefit from enrolling in clinical trials.
• Provides access to drug(s) that are otherwise not available.
• All medications on the market today were once in a clinical trial.
Resources-Websites

- Sylvester Comprehensive Cancer Center: https://umiamihealth.org/sylvester-comprehensive-cancer-center/research

- National Cancer Institute: https://www.cancer.gov/about-cancer/treatment/clinical-trials

- Clinical Trial Registry: https://clinicaltrials.gov/

- Federal Drug Administration: https://www.fda.gov/