Finding Clinical Trials for Patients

Lucia Carranza, MSN, APRN, AOCNP

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

Objectives

Understand the basic principles and phases of clinical trial research

Discuss the importance of dispelling common myths regarding clinical trials.

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

Clinical Trials…

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

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

Phases of Clinical Trials

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

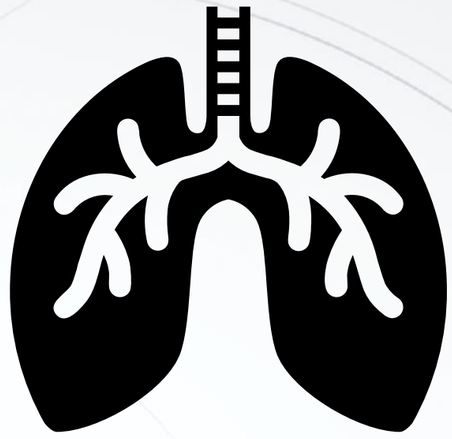
Phase 1: Safety

- First in human administration of Investigational product
- Less participants due to potential risk
- Typically Divided into two parts:
- **Dose escalation**
- **Dose expansion**

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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



UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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)

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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?

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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.

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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.

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

Myth #4: Clinic trials are only a last resort.

Facts:

- Clincal trials are available in *every* phase of the cancer journey.
- There are many clinical trials for first line and second line treatments.

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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.

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

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/

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM