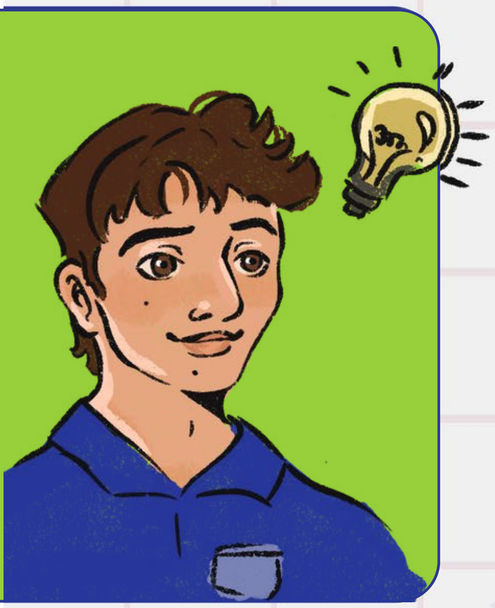
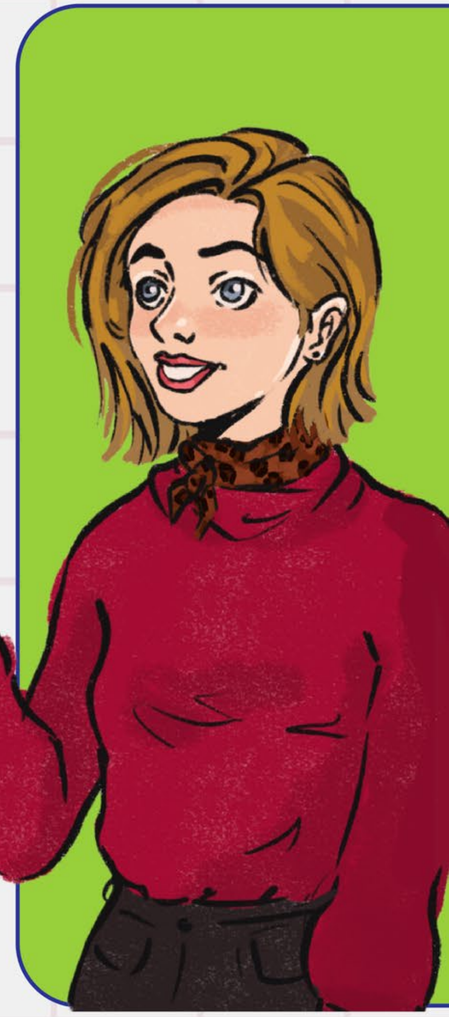
ICAN x MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Understanding Clinical Trials

LESSON TWO





Acknowledgements

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- Creator of Curriculum

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- Designer and Illustrator of Curriculum

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Special thanks to the KIDS Curriculum Steering Committee:
- Anvita, KIDS CHOC; Joey, KIDS Rainbow; Meghan, KIDS Virtual

Month Two

Objectives

- Explain Phases 1–4
- Describe trial flow
- Identify roles
- Use glossary terms
- Reflect on impact

Understanding Clinical Trials and Team Roles

How new medicines are tested—and who makes it happen

Warm-Up

Why can't new medicines or devices be used right away?

Ok

Created with the MRCT Center, iCAN Leadership, and iCAN Youth Members: Meghan, Anvita, and Joey

What We Learned Last Month:

What Is a Clinical Trial?

1

We learned last month that:

- Clinical trials help us learn what works and what's safe.
- We get to choose whether we want to be in a study or not.
- Kids and families get to ask questions and have their voices heard.
- Using plain language is important so we can all make informed decisions (glossary: MRCT Center).
- Clinical trials are about learning, not experimenting on people.

2

Big Idea to Remember:

- Clinical trials are about helping people, and kids have something important to say.
- We now know what clinical trials are and why kids have something important to say about them. Today, we get to learn how they work and who does what.

Today's Lesson Overview

At the end of the lesson kids will be able to:

1. Explain the purpose of Clinical Trial Phases 1-4.
2. Explain how a clinical trial begins and ends.
3. Identify people who run a clinical trial.
4. Define basic terms from the Clinical Research Glossary: Phase, monitor.
5. Think about which part of the Clinical Trial feels most impactful and why.

Video on overview of phases and the importance of kids' voices in research

Lisa Koppelman, (Team & Program Director MRCT Center of Brigham and Women's Hospital and Harvard)

Warm Up:

- **Why can't new medicines or devices be used right away?**

Learning Objectives:

- Explain Phases 1–4
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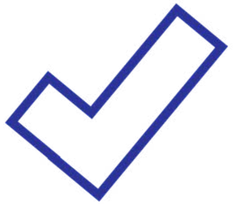
Clinical Trial Phases for Drug Development

Phase 1:

Safety

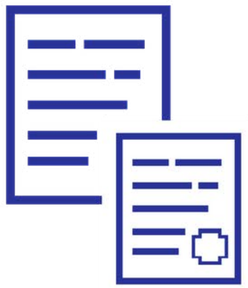
Phase 2:

Efficacy



Phase 3:

Comparison



Phase 4:

Long-term safety

A Note About Device Clinical Trials

Medical Device Clinical Trial Phases

- The phases of clinical trials of medical devices are different from those of clinical trials of drugs.
- Device clinical trials generally go through the following stages:
  - Pilot studies: Also known as feasibility studies, these trials evaluate basic safety and whether the device performs as intended;
  - Pivotal studies: Larger trials designed to demonstrate effectiveness and safety compared with other devices or treatments; and
  - Post-market studies: Ongoing monitoring after the device is approved to determine long-term performance, reliability, and safety.
- The stages of medical device clinical trials vary depending on the type of device, its risk level, and regulatory requirements.
- Source: https://www.cancertherapyadvisor.com/factsheets/clinical-trial-phases/

Please note that this curriculum will focus on drug trials!

Analogy to Recipe: Thumbs Up/Down

Clinical trials are like testing the recipe, starting small, checking safety, testing on more people, comparing, and keeping an eye on it even after it's approved. That's how we protect study participants.

1. "You should serve a brand-new recipe to the entire restaurant the first time you cook it."

2. "If a recipe tastes good for one person, everyone will like it."

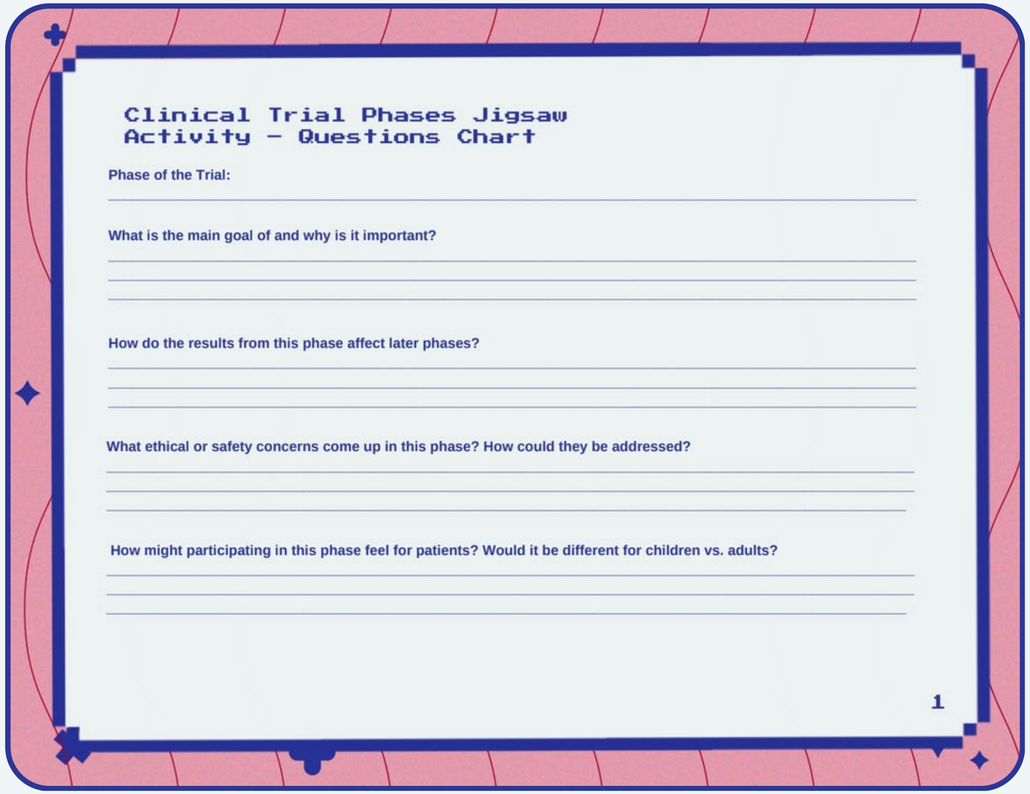
3. "You only need to test a recipe once before putting it on a menu forever."

4. "After a recipe is on the menu, you can stop paying attention to it."

Jigsaw Activity:

The Full Life Cycle of a Clinical Trial

- The students are divided into different groups and given a phase of a clinical trial. Each group will become “experts” on the phase of the clinical trial they are given. Then, the students will work in a group and attempt to put the phases together in the correct order, creating the entire life cycle of a clinical trial.


Clinical Trial Phases Jigsaw Activity – Questions Chart

Phase of the Trial:

What is the main goal of and why is it important?

How do the results from this phase affect later phases?

What ethical or safety concerns come up in this phase? How could they be addressed?

How might participating in this phase feel for patients? Would it be different for children vs. adults?

1

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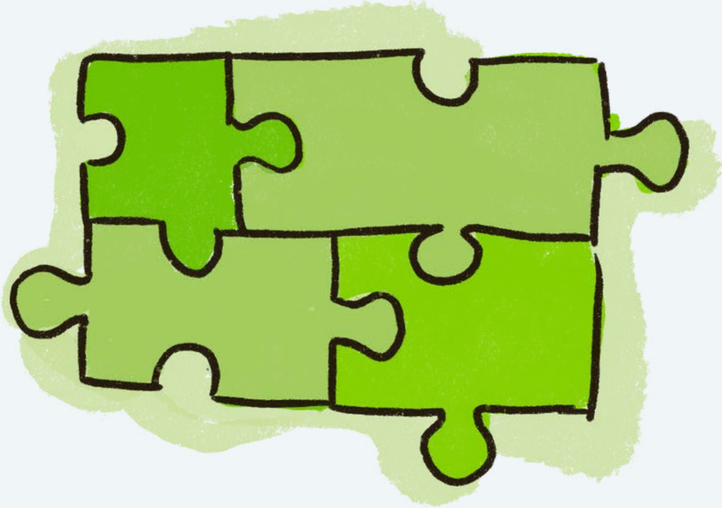
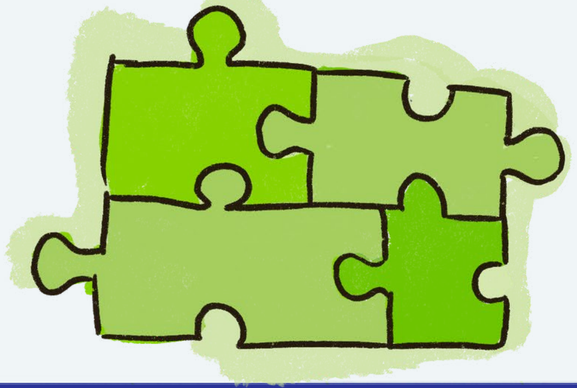
Example Here...

Fill in the Process As Groups Share



Phase One:	Phase Two:	Phase Three:	Phase Four:



Check For Understanding:

Instructions:

- Each scenario below describes a moment in a clinical trial. Match the scenario to the correct Clinical Trial Phase (1–4). Some clues are subtle—read carefully.

Whodunnit Cards PDF

Clinical Trial Phases:

- A. Phase 1
- B. Phase 2
- C. Phase 3
- D. Phase 4

Check For Understanding Cont.

Scenarios:

1) A new medication is given to a small group of volunteers to determine how the body processes it, what dose is safe, and what adverse events appear first.
2) Researchers study whether the treatment improves symptoms in people with the condition, while continuing to track short-term side effects.
3) Thousands of patients across multiple hospitals receive either the new treatment or the current standard of care to determine which works better.
4) After FDA approval, researchers continue collecting data on rare side effects that may only appear after long-term use.
5) The main goal of this stage is to find the answer (while also keeping participants safe).
6) This phase often involves randomization and comparison groups to support regulatory approval decisions.

Some of the Roles of Who Runs a Trial

- **Principal Investigator:**
  - Leads the trial, makes medical decisions, ensures participant safety.
- **Research Nurse / Clinical Coordinator:**
  - Educates patients, schedules visits, collects data, supports families.
- **Monitor:**
  - Reviews trial conduct, checks data accuracy, ensures rules are followed.
- **Data Manager:**
  - Works closely with the Research Nurse/Coordinator to ensure that all data is collected and entered directly.
- **Sponsor:**
  - Provides oversight, prepares regulatory submissions, and sometimes funds the research.

Whodunnit Activity

The Case of the Missing Data Point:

"The Setup"

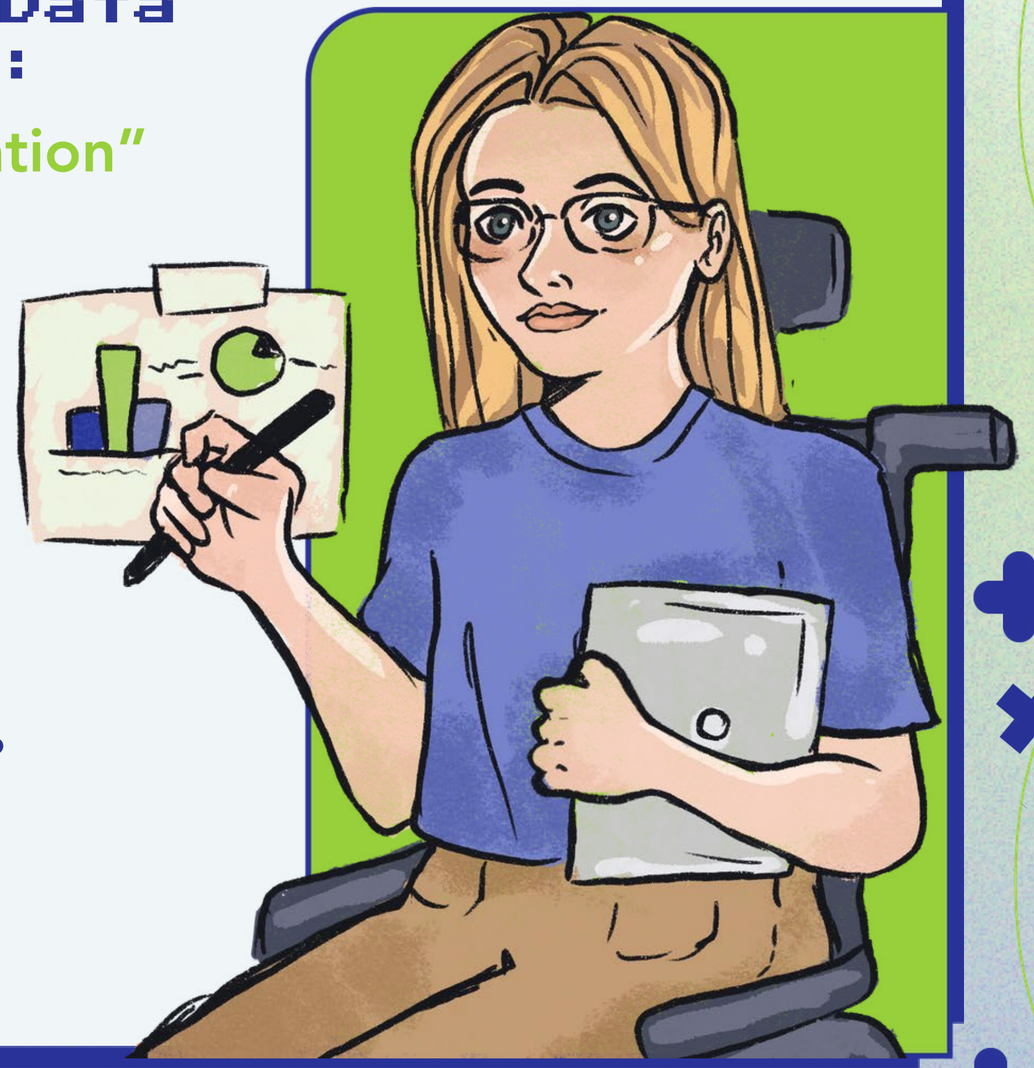
- **Setting up the Story:**
  - A pediatric clinical trial is running smoothly… until suddenly:
    - One important data point is missing from the final trial report.
    - The trial cannot move forward until the team figures out:
      - What happened
      - When it happened
      - Who is responsible for fixing it
  - Everyone insists they did their job correctly…
    - Roles Introduced (Assign One per Group or Person)
    - Each participant (or small group) gets a Role Card with:
      - What their job is
      - What they *do not* do
      - A clue they can share

Whodunnit Activity Cont.

The Case of the Missing Data Point:

"The Investigation"

- **Investigation Phase (15–20 minutes):**
  - Have the students:
    - Share their clues
    - Ask each other questions
  - Decide:
    - Where the breakdown occurred
    - How the breakdown could have been prevented
  - Questions to prompt discussion:
    - Who do you think first touched the data?
    - Who do you think was responsible for checking the data?
    - Who do you think noticed the problem?
    - Who do you think has the power to make the fix?



Whodunnit Activity Cont.

The Case of the Missing Data Point:

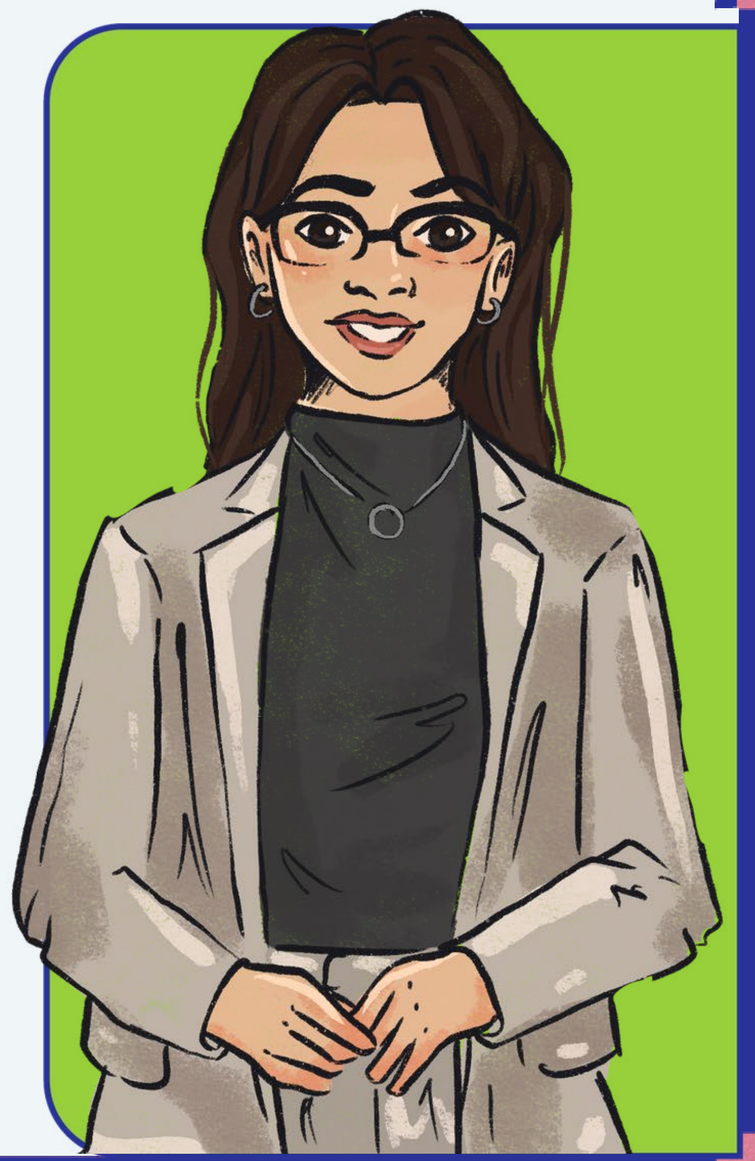
"The Reveal"

- **Concluding the Tale:**
  - The main point is that clinical research is a team effort, and problems are solved through communication and checking, rather than fault-finding.
    - The Research Nurse handled the data collection
    - The Data Manager worked closely with the Research Nurse/Coordinator
    - The Monitor did the right thing in raising the issue
    - The PI is in charge of the solution
    - The Sponsor wants the solution
  - Everyone did their jobs properly; the system just needs better communication.

Key Takeaway

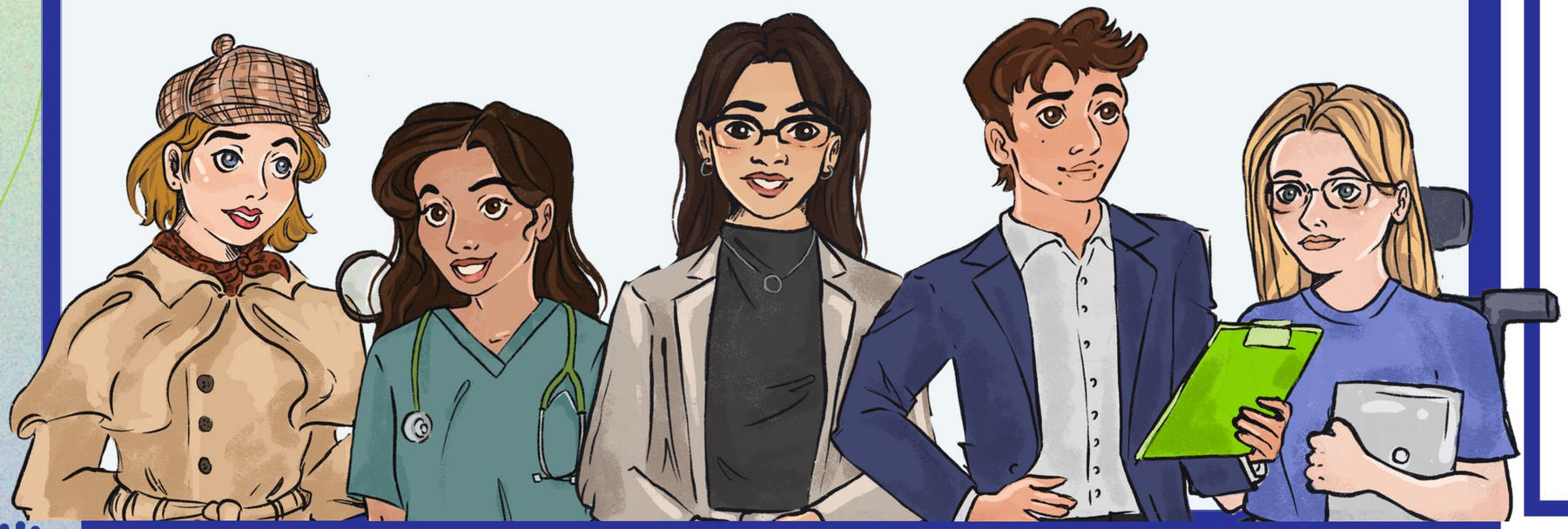
Successful clinical trials rely on...

- Teamwork
- Communication
- Following the protocol
- Attention to detail!



Guest Speaker (Recorded) (10-15 minutes)

- **Guest Speakers:**
  - **Phyllis Kennel,** (Associate Director, Government and Network Trials Duke Clinical Research Institute)
  - **Sarah Hunt, (**Associate Director, Clinical Research Operations, Dana-Farber/Boston Children's Cancer and Blood Disorders Center)



Focus Questions:

- **What does your job require you to do daily?**
- **What do you do during a clinical trial?**
- **Which phase do you work in most?**
- **How do you help patients understand the trial?**

- Phyllis' Video
- Sarah's Video

Design Activity

"Creating a Play-Based Clinical Trial"

Objectives:

- Students will be able to apply everything they learned about phases, roles, communication, and pediatric safety in this activity.
- Example: A trial for a medication that helps kids not be on their phone so much!

Step 1: Formation of Small Teams

- Same teams from the Whodunnit activity or mix the teams up.
- Each group will design their own mini clinical trial for a brand new medicine for children.

Step 2: Trial Design Challenge

- Each group will discuss and decide:
  - Name of the Medicine / Treatment – Let's make it fun!
  - Age Group – Who will participate
  - Phase Activities – Briefly explain the activities involved in each phase (1 to 4).
  - Roles Needed – Who from the group is needed, and what is their role?
  - Safety Measures – How will you ensure the safety of the participants?

Step 3: Creative Presentation

- The group is given the freedom to creatively present their mock trial in any of the following ways:
- Poster, Comic strip, Short skit, News report" from the mock trial, Computer slide/storyboard

Example Here...

Download Template Here...