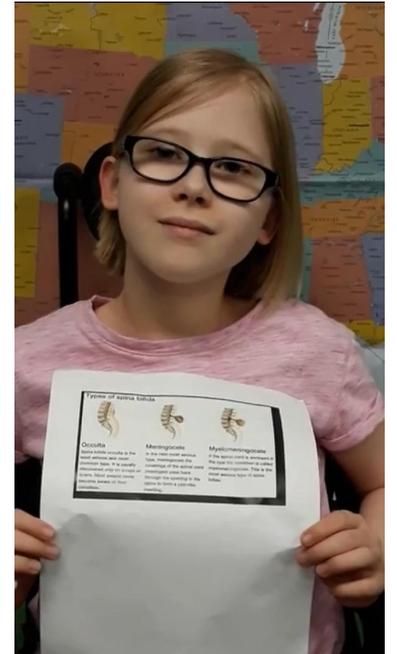


Learn About Clinical Drug Development



How are new drugs studied and approved?

- In this iCAN module, you will learn about:
 - **Who** approves drugs? Regulatory authorities
 - **How** drugs are researched? Phases of drug research
 - **When** are children typically involved in drug research?



Why are research studies done for new medicines?



- Sometimes, researchers want to better understand more about the medicine, as not all medicines work or are safe for all people.
- Sometimes, researchers want to see if a new medicine can make you healthy or feel better.
- Sometimes, to help patients, medicines can be made into new forms like:
 - Tablet or capsule (pill)
 - Intravenous (parenteral)-given through a vein
 - Suspension/liquid
 - Topicals (creams or ointments)-placed on the skin

What does it mean when a medication is approved?

Medication is approved when these three things happen:

- **Safe**- can be used without harm
- **Effective**-has shown that the medication works
- **Regulatory Approval** -government review ensures that a medicine is BOTH SAFE and EFFECTIVE



What are regulatory agencies?

- **Who?** The government has a group of people that help decide if a medicine is safe and works. Those people are in a regulatory agency.
- **Why?** Their role is very important to make sure patients have medicines that can make people better



What are regulatory agencies?

- Each country or region has their own regulatory agency
- Here are a few examples
 - **Food and Drug Administration (FDA)** <https://www.fda.gov/>
 - **European Medicines Agency (EMA)**
<https://www.ema.europa.eu/en>
 - **Medicines and Healthcare Products Regulatory Agency (MHRA)**
<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>



How is new medication studied?

There are two ways that a new medication is studied:

- **Laboratory research**

This type of research does not involve humans.

- **Phases of Research**

This type of research does involve volunteers or patients

- Phase 1
- Phase 2
- Phase 3
- Phase 4



Laboratory Research

- When is Laboratory Research conducted? **It occurs before a medicine is studied in people**
- It is done to see how a drug works or how safe it is by using lab tests and animals
- Laboratory Research is important to understand before giving the new medicine to people



Clinical Research Phases

Clinical studies have different phases

- Phases of research involve more and different types of people with and without a disease
- The goal of each phase is to answer a question about how safe or how well a medicine works



When are pediatric patients enrolled in clinical trials?

- Children may be involved in any phase of research
- Children are usually involved after adult studies are done
- Sometimes older children are involved in studies for adults if they have the same disease
- Children may be in a study earlier if the disease only happens in children



When is a new drug approved?

- After all the studies are done, the regulatory authority sees if the drug works and it is safe
- If it is safe, the new drug is approved and your doctor can give it to you to use outside of a study
- Sometimes the regulatory authority will want to see if the new drug is safe and works for a long time, so they ask for a study to test that the long term outcomes
- When that happens, you can still get the new drug from your doctor, but the doctor collects data to give to the company making the medicine and the regulatory authority

Thank you!

- Regulatory Agencies help decide if a new drug is safe and it works
- Phases of research are different based on:
 - **What** is studied?
 - **Who** is studied?
 - **How** many people are studied?
 - **How** long the study is?
- Children may be involved in any phase of research

