Clinical Drug Trials

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What is a clinical drug trial?

A clinical drug trial is a *research activity* designed to learn if a new medication is effective and safe

- Three phases of testing
  - Phase 1: done in a small group to look at safety and side effects (DOES NOT LOOK AT EFFECTIVENESS)
  - Phase 2: larger group to look at effectiveness and safety
  - Phase 3: larger group to confirm effectiveness, look at side effects, compare with similar treatments, more on safety

Why or why not join?

- Why be in a trial?
  - Potential for treatment
  - Help others with a condition needing better treatments
- Why not to do it?
  - Don’t do it to please your doctor
  - *Don’t do it if you do not want to do it*

How do trials work?

- Trials have a sponsor
  - Have a principal investigator (PI)
  - Often multiple sites, each with a site PI
- Trials have a protocol
  - Defines the goal of the study
  - Defines who can participate (eligibility)
  - Gives details about tests, procedures, treatments
  - Describes protections against risks of the process
  - Describes duration of the trial
  - Establishes what information is to be gathered

Human Subject Protection (IRB)

Every trial is evaluated for human subject protection. The IRB considers

- Are risks minimized?
- What is the relationship of risks to benefits?
- Is selection equitable?
- How will consent be obtained and documented?
- How are privacy and confidentiality preserved
- How is safety monitored?

Children in research

- Children cannot consent to research (parent(s) must give permission)
- Children are asked to give assent (usually over age 8 or so)
- Assent must be obtained from your child unless:
  - your child is not capable of assenting
  - the treatment that may benefit your child is *only available* in clinical trials

Special protection for children

- Is what the child will experience more than “minimal risk”? (based on everyday life experience)
- If yes, is there potential for individual direct benefit?
- If not, will there be new generalizable knowledge learned about the condition being studied?
- If not, is this SO important to society that research should take place? (*very rarely invoked*)

Be aware – it's some work to do

- There may be unpleasant, serious, or even life-threatening effects of experimental treatment.
- May require more time and attention than standard treatment would
  - visits to the study site
  - more blood tests
  - more procedures or hospital stays
  - complex dosage schedules.

Tips for asking your doctor about trials

- Consider taking a family member or friend along for support and for help in asking questions or recording answers.
- Plan what to ask — but don't hesitate to ask any new questions.
- Write down questions in advance to remember them all.
- Write down the answers so that they’re available when needed.
- Ask about bringing a tape recorder to make a taped record of what's said (even if you write down answers)

https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics

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