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Clinical Trials

Frequently Asked Questions

What is a clinical trial?

Clinical trials test new therapies, new combinations of therapies, or medical technologies and devices on human volunteers. Federal laws require clinical trials for therapies before approval and availability to patients.

Why are clinical trials important for therapy development?

Clinical trials are the surest way for researchers to test the safety and effectiveness of therapies to improve the quality of care for affected individuals.

What do the different phases of clinical trials mean?

Phase I: New therapy tested in small group of volunteers (usually 10-50 people) to assess safety, side effects, and the safe dosage range.

Phase II: New therapy is given to a larger group of volunteers (up to a few hundred) to assess effectiveness, safety, and to determine appropriate dose levels. Effectiveness measures how successful the therapy is at producing the desired result.

Phase III: New therapy is given to large groups (several hundreds to thousands) of volunteers at the dose(s) intended for FDA approval to confirm the safety and effectiveness. In Phase III, researchers also look for side effects and safety issues that might only appear in large populations.

Phase IV: Sometimes called post-marketing studies, Phase IV studies are done after FDA approval. They may be intended to study the drug in a special population, to study a specific issue in a small population, or they may be large studies to determine whether the drug has the intended longer term beneficial effect, such as lowering the heart attack risk over a 10 year period.

Why is it important that more people volunteer for trials?

Finding volunteers is is one of the biggest challenges of clinical research and development. If clinical trials are not able to recruit enough volunteers, they will not be able to run the trials or the trial will be delayed. It is also important that trials include a diverse population.

How are the rights and safety of volunteers protected?

Clinical trial study protocols are subject to strict FDA regulations that aim to protect the safety of volunteers. A regulatory board must approve study protocols before volunteers can be recruited. The study protocol must be safe, appropriate, and ethical in order to be approved.

Clinical trials are completely voluntary.

Volunteers have to give consent before enrolling in a trial and may withdraw at any time. The consent process aims to inform the volunteer about the study protocol and plan, the benefits, the risks, and their rights.

I'd like to join a clinical trial, what can I do?

Search here for clinical trials that might interest you. Then talk to your doctor about whether you meet the trial criteria and what else you need to know about the trial. You can also find a contact for each clinical trial along with the information listed. You may want to discuss this decision with your family and other important people in your life.