

Sometimes it takes an experiment to make you well

# Are Clinical Trials Safe?

by Dr. Jacqueline A. French

**J**UNE B. HAS A BIG DECISION TO make. She sits across from me, deep in thought. I've just offered her the chance to enroll in a clinical trial of a new epilepsy treatment. I know the decision will not be easy.

Five years ago, June was a healthy, active young woman with a great job as an executive. One day she found herself outside her apartment, without a clue how she got there. Several more terrifying episodes later, she was diagnosed with epileptic seizures. Some of the drugs approved by the Food and Drug Administration have either not controlled her seizures or they have made her feel sick. Now on disability and afraid even to leave the house, June is desperate for a treatment that will work.

But she's ambivalent about enrolling in the trial. If she does, she will be participating in a study that involves an "investigational" drug (one not yet approved by the FDA), and so there is no guarantee that it is safe or effective for her condition. Moreover, the trial will involve a "double-blind placebo control," which means that June has a 50/50 chance of either being placed on the drug being tested or getting a placebo (sugar pill). Neither she nor I will know what she is taking until the trial is complete. On the other hand, she's aware that if she doesn't take part, she'll be missing an opportunity to try a cutting-edge therapy to which she'd otherwise not have had access.

June is not alone in her dilemma. At any given time, according to *clinicaltrials.gov*, more than 70,000 trials are going on worldwide. There is an excellent chance that you will be faced with a decision about whether to participate in clinical research or a clinical trial at some point in your life. The decision you make may be for yourself or for a loved

one, such as your child or a parent who has lost decision-making capacity. The trial may involve a drug, surgery, or new device. Or it may be testing a new method of diagnosis. There may also be studies that compare available marketed drugs to see which is the most beneficial.

When making the choice about entering a trial, you need to consider the options available if you forgo

types of cancer may improve life expectancy by only six months. In this situation, a new option, even an unproven one, may offer more hope.

Sometimes, though, hope is all that can be offered. On paper, a drug might appear quite promising, but its benefits may as yet be unproven. Other trial drugs may be near FDA approval, and doctors may already know most of the risks and benefits.

If you enroll, you may need to undergo extra procedures, such as X-rays, diagnostic tests, and additional needle sticks for blood samples. These may be included so that the investigators can learn as much as possible or so they can keep trial subjects as safe as possible.

In the end, your decision comes down to a simple question: Is the uncertainty of the trial and treatment you'll undergo worth pursuing over established options? The answer will not always be clear. You should never feel like you are being pressured into a trial. Your doctor will not penalize you for saying no. But if you agree, you'll be helping not only yourself. Clinical trials provide doctors and patients with better information with which they can make more informed medical decisions.

If people did not participate in trials, no new therapies would be approved.

And what about June? She decided to enroll in the trial, and both of us are waiting to see how it turns out.

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## Questions to ask if you're offered a clinical trial

- How many people have been exposed to this drug or treatment and what is known about its safety?
- What makes the researchers think the therapy might work?
- What are my options if I do not participate in the trial?
- Will there be a group that only takes a placebo (sugar pill)?
- What happens when the trial ends?
- Will I be able to continue the treatment?

it, compared to the risks and benefits of the therapy being offered. In some cases, there may be no approved treatment for your condition, and the possibility of finding an effective treatment is through a trial. Even then, treatments might be risky, with a potential to make things worse instead of better. In other cases, choices may be available, but they may have substantial disadvantages, such as unwanted side effects, or they may not work for the majority of people. For example, approved treatments for certain

