Putting Cancer On Trial

The Importance of Participating in Clinical Trials

BY DANIELLE TAYLOR

In the wake of a cancer diagnosis, and often for years post-treatment, many cancer survivors throw themselves completely into causes that raise funds and recognition for cancer research. Organizations such as Susan G. Komen for the Cure and the American Cancer Society promote education about early detection and gather critical funding to continue their missions of battling cancer in every way possible. Causes like these and the events they sponsor help get the entire community involved, and they're great because everyone can join in and lend a hand.

But as a cancer survivor, you have the unique opportunity to provide an even more vital contribution toward ending this terrible disease. By participating in a clinical trial, you can provide doctors and scientists with actual medical data that can help them diagnose future patients, create treatments and discover invaluable breakthroughs that may eventually lead to a cure.

"The progress in cancer research is always slower than you would like, and we've got a long way to go, but the only way to get there is through basic research, science and then clinical trials to apply what's being learned in the lab," says Dr. Neal Ready, a medical oncologist at Duke Cancer Institute who is active in multimodality treatments, clinical-trial development and translational research. In essence, all advancements in medicine come through clinical trials and research, which test the effectiveness of new therapies.

If your doctor mentions a clinical trial you might be eligible for, or if you learn of one on your own, it's greatly beneficial to the world of medicine and the prognoses of future cancer patients if you participate. But it's important to consider all the factors involved. In all likelihood, you will not receive much, if any, medical benefit, and many trials don't offer financial compensation, so your participation is largely a charitable act that will require sacrifices of your time.

Also, clinical trials, like most FDA-approved medicines and therapies, come with certain risks, from unpleasant side effects to, in extremely rare cases, life-threatening reactions. However, most drugs and therapies have been tested on animals before researchers test them on humans, so in the vast majority of cases, the risks are minimal. Ethical requirements are in place for every new therapy; in all trials, the risks must be justified by the importance of doing the study, and they must be minimized as much as possible.

Given their detriments, why would anyone want to voluntarily sign up for one of these trials? From a personal benefit standpoint, many patients greatly value the additional medical care and attention they receive from their participation. While regular doctor's appointments can sometimes be a little rushed and seemingly less thorough than a patient would like, researchers for clinical trials take a lot of time and care to examine their subjects and get to the bottom of their medical history, because the authenticity of their research depends on this accuracy. Also, many people who have already lived through a long medical ordeal recognize that they benefited from past medical studies and want to do their part to help future patients.

Dr. Leigh Ryan, a professor at the University of Maryland, has been involved in a clinical trial at the National Institutes of Health since 2009. After being diagnosed with breast cancer in 2004, she successfully underwent a lumpectomy and radiation therapy, after which her doctor put her on Arimidex for five years (a standard treatment for post-chemo breast cancer survivors). When she concluded that regimen, her oncologist approached her and asked if she would be interested in joining a follow-up study that would require her to take a pill each day for five more years. After considering the risks as well as the benefits she might receive and the contributions she could make to medical science, she agreed to sign up.

> "The U.S. has a very poor track record of enrolling people into oncology clinical trials. ... If we can't get patients to enroll in clinical trials, we will not bring new and effective therapies to the clinic."

"I figured I don't get anything for doing it, but I get to go see my oncologist every six months, so it's another five years of somebody closely watching me," she says. "And if somebody's going to benefit from this, I'm happy to contribute." At her trial check-ins, Dr. Ryan's doctor performs a very detailed assessment of her blood work and overall well-being, and she leaves feeling assured that medical professionals continue to keep a vigilant eye on her and that they would catch any negative developments before they progressed very far.

If you sign up for a clinical trial, one of the first steps will be an evaluation of your overall health, which may include blood work, an assessment of your vital signs, a stress test and/or a detailed questionnaire asking about your day-to-day health. This gives researchers a baseline they can use to compare any changes to your health over the course of the study. Following this initial assessment, the physicians and researchers conducting the study may ask you to take regimens of pills, undergo routine rounds of immunizations or blood tests or use a particular medical device. Your participation may range from a single visit to numerous visits over a number of years. Before you sign up for any clinical trial, talk with your doctor about the risks involved, the expected length of the study and how you will be expected to contribute.

Step By Step

Although a clinical trial can explore methods of prevention, screening or supportive care, most are pharmacological studies that evaluate new medications before they are released to the public. In general, there are four stages of trials a patient can participate in, and each tests a different parameter of a drug or treatment's safety, tolerability and effectiveness:

Searchable Resources

Cancer.net, a website with "oncologist-approved information" from the American Society of Clinical Oncology, says: "To find a clinical trial, a good first step is to talk with your doctor. Because new clinical trials are created constantly, many people also look in other places to find research studies that they may be interested in joining."

The organizations below offer free, searchable listings of cancer clinical trials:

The **National Cancer Institute** is the federal agency that provides funding for most U.S. cancer clinical trials. This comprehensive site provides information on both open and closed cancer clinical trials that are funded by the government, as well as many sponsored by pharmaceutical companies, medical centers and some international organizations. **www.cancer.gov/clinicaltrials**

CenterWatch is a publishing and information services company that offers a list of clinical trials approved by the institutional review board (IRB). **www.centerwatch.com**

EmergingMed Navigator offers a phone- and Internet-based service that identifies clinical trial options that match a patient's specific diagnosis, stage and treatment history. Clinical trial specialists provide telephone support upon request to help connect eligible patients with IRB-approved study sites that are enrolling new participants. **www.emergingmed.com**

TrialCheck is an online search engine where people can find tailored information about cancer clinical trials that are enrolling patients at hospitals, cancer centers and oncology practices in the U.S. and internationally. **www.cancertrialshelp.org**

The **World Health Organization (WHO)** coordinates health matters around the world. This database allows people to search clinical trial registration information from many countries' registries. **apps.who.int/trialsearch**

• A phase I trial evaluates how a drug should be administered (by pill, by intravenous or intramuscular injection, etc.), how frequently it should be taken and at what dosage. Although many medicines work more strongly at higher doses, side effects also tend to escalate, and a phase I trial studies the amount of a medication participants can tolerate given the increase in side effects. In most cases, the dosages given to humans are a fraction of what has been found to cause harm in animal testing. Phase I trials are generally conducted on a small group of healthy volunteers, though terminal patients without other treatment options are sometimes used as well. Trials in this early stage do not evaluate how well a drug works against the condition it is intended to treat.

• Phase II trials continue to study the safety of a drug but on a larger test group, and they begin to evaluate how well a treatment works. Depending on the treatment, a phase II trial might include both healthy volunteers and patients diagnosed with the disease the studied medication is intended to treat.

• In phase III trials, researchers expand their test parameters to include an increased number of subjects at multiple medical clinics in a randomized, controlled study. This means that participants may receive the treatment being analyzed, an existing form of treatment or a placebo. By studying the effectiveness of the new intervention against a standard control, researchers can better determine whether the new treatment is more effective than existing ones, and if so, how much better it works. In some cases, a medication that is already on the market might undergo a phase III trial to examine how well it might treat conditions beyond the diagnosis for which it was originally approved.

• Phase IV trials involve thousands of test subjects and continue studying any rare and long-term effects of a drug after it has been approved and released. Limitations of time and volunteers are no longer a concern in this phase of study, so researchers have the opportunity to observe how effective and tolerable a treatment is in a wider and more varied test population.

If the drug in question statistically fails to succeed or causes intolerable side effects in any phase of the trial, it will not be approved. In most cases, successfully bringing a drug through all the necessary phases of a clinical trial takes years of study, usually because researchers have difficulty getting enough participants to give their research statistical power.

"The U.S. has a very poor track record of enrolling people into oncology clinical trials. This is very unfortunate for a number of reasons," says Dr. Neil Spector, director of the translational research oncology program at Duke Cancer Institute. Because every drug only targets a specific subset of the population, and because many people who would be eligible to participate in a trial either don't know about it or are reluctant to join, many medications enter the market years after they could have otherwise been released. Says Dr. Spector, "If we can't get patients to enroll in clinical trials, we will not bring new and effective therapies to the clinic."

Fortunately for the patients of today and tomorrow, many people are happy to volunteer, and it is only due to their willingness to contribute that modern medicine has a chance of treating complex conditions and diseases.

"It's a common attitude of people after they had a cancer experience; the desire to give something back," says Col. Brooks Harris, a cancer survivor in the Triangle currently participating in a clinical trial. "People have given us so much to help us. The people who came before you helped you get through [the cancer journey]. It's only right we help those to come." *TBC*