



Treatment by Trial

By Mia James

Patients considering clinical trials can benefit from expert insight, but, ultimately, the decision is entirely personal.



You have been delivered a cancer diagnosis. The next step? Creating a treatment plan that truly represents your unique needs and goals. As this process evolves, you may discover that participation in a clinical trial is right for you.

This decision, which should be made together with your health care team and take into account the specifics of your diagnosis and other factors (personal as well as treatment- and disease-related), is ultimately yours alone, but you'll be better able to make an appropriate decision with an understanding of the clinical trials process.

WHAT ARE CLINICAL TRIALS?

Clinical trials are medical research studies that test the safety and the effectiveness of new therapies for screening, prevention, diagnosis, or treatment of a disease in human participants. These trials, which test therapies that have already been evaluated for safety in pre-clinical trials, help determine the benefits as well as the side effects of potential new methods of cancer treatment and prevention.

WHY CHOOSE A CLINICAL TRIAL?

When it comes to patient participation in clinical trials, Maurie Markman, MD, senior vice president of clinical affairs and national

director of medical oncology at Cancer Treatment Centers of America® (CTCA), says that patient needs should always come before research findings. “Individuals who participate in trials are hopefully helping themselves and at the same time helping future patients,” he explains.

For this reason Dr. Markman supports patients’ decisions to enroll in trials only if participation truly serves their treatment needs and goals. The possibility of contributing to useful research findings is a secondary concern. “The only reason we would even consider offering a trial is if it’s in the patient’s best interest,” he explains.

To establish whether a specific trial is a good choice, Dr. Markman suggests that you ask yourself a basic question: *Why should I do this?* The question is critical, he says, to force you to weigh the risks and the benefits and because a trial may add more time and more tests to a treatment plan.

The potential benefit of participating in a trial is that the trial therapy will be effective—that it will shrink the tumor, improve symptoms, or extend survival. Risks, on the other hand, include possible side effects, the potential that the trial will extend treatment time and add to the number of tests to undergo, and, ultimately, the possibility that the therapy won’t be effective. Also important to add to the potential risk category, Dr. Markman says, is the fact that there may not yet be much information about the therapy. “With some of the experimental drugs, we actually don’t know a lot about the side effects,” he explains.

Learning as much as possible about a trial will help you decide whether participation is in your best interest. Depending on the product being investigated, there may be information available online about previous results and known side effects. At many treatment centers, Dr. Markman says, including CTCA, patients can also access

information about current trials in documents produced by an institutional review board (a group responsible for reviewing each trial before it is accepted by the treatment center) that explain in patient-friendly language the purpose of the trial, possible side effects, and time and effort required by participants. After reviewing all available information, you should discuss the trial with your nurses, doctors, and other members of your health care team, Dr. Markman says.

PAYING FOR CLINICAL TRIALS

An additional consideration in your decision will be the cost of the trial and how expenses will be covered. “If there’s an experimental drug—one that has not been approved by the US Food and Drug Administration—there will be no charge for that drug,” Dr. Markman says. In this case, the trial’s sponsor—the pharmaceutical company behind the drug—would cover those costs. The sponsor would also be responsible for any tests that would not be part of standard care for the disease in question (care that you would receive outside of the trial).

When it comes to tests or drugs that would be part of standard care, you or your insurer are responsible for those costs. This can get tricky, says Dr. Markman, because some insurers may consider this an opportunity not to pay.

In some cases, states have stepped in to create laws related to this scenario. “Some states have basically mandated that if an insurer is licensed and registered in that state and would otherwise have paid, they’re going to have to pay if the patient is on a trial,” Dr. Markman says. (State-by-state information is available through the National Cancer Institute website at cancer.gov/clinicaltrials/payingfor/laws).

To avoid complications and unexpected expenses, Dr. Markman suggests learning about

CLINICAL TRIALS AT CANCER TREATMENT CENTERS OF AMERICA

To view a list of clinical trials offered by CTCA, visit cancercenter.com/research/clinical-trials.cfm. Trials are listed by cancer type and by CTCA location. As of November 2011, studies are currently listed for bladder, breast, cervical, colon, liver, lung, ovarian, prostate, rectal, and vocal cord cancers.

A PATIENT PERSPECTIVE

A survivor and three-time clinical trial participant shares her insights.

As a three-time survivor of melanoma and a three-time clinical trial participant, Meg Monday of Hailey, Idaho, qualifies as an expert on the trials process from a patient's perspective. Though each diagnosis and subsequent clinical trial was unique, Meg's motivation to participate was similar each time around: she wanted the chance to receive a therapy that might be more effective than the current standard of care.

Meg found effective therapy for all three melanoma diagnoses in three separate trials. She entered the first trial (for early-stage disease) knowing that she'd receive the standard of care and also have the chance of getting a superior therapy. With the two subsequent later-stage diagnoses, Meg says that trials made sense because there was no effective treatment on the market at that time. "For the disease I had," she explains, "there really wasn't a standard of care." Fortunately, Meg found effective treatment in all three of the trials she entered.

Despite Meg's positive clinical trials experiences, she acknowledges that trials aren't for everyone. Anyone thinking about enrolling in a trial, she says, should consider carefully some key points and of course discuss these and all concerns with a doctor.

A clear understanding of potential risks and benefits is critical when you're deciding whether or not to enroll in a trial, Meg says. This entails knowing the effectiveness of the standard of care for your diagnosis and the potential benefits and risks of the trial.

"Really ask your doctor," Meg says, "What can I expect from this?" Ask also what the goals of this trial are for you, such as how much your outcomes might be improved with the trial therapy.

Meg also recommends asking yourself how comfortable you are with what you might experience in the trial. For example, if you're considering a placebo-controlled trial (where one group receives the therapy and the other receives a placebo), think about whether you're comfortable receiving a placebo instead of the therapy (even though participants receiving placebo are able to switch to therapy if it's proven effective).



the financial aspects of a trial before enrolling—then have the information evaluated before beginning the trials process and work with insurers to determine what will be covered.

QUESTIONS TO ASK

Before enrolling in a trial, Dr. Markman recommends asking your health care team the following questions:

- Why should I pursue this trial versus some other form of therapy? (What are my other choices?)
- What side effects are anticipated?
- What is known about the potential benefits?
- What extra time and effort will be required of me (and my family) compared with other available (nontrial) treatments?
- Are there any additional financial costs? What part will be covered by somebody other than my insurance company? What part will be covered by my insurance? What part am I expected to cover?

IT'S A PERSONAL DECISION

Though there are many important considerations in choosing whether to enroll in a clinical trial, the primary question remains constant: *Is the trial in your best interest?* Remaining focused on this critical question will help form a truly personal treatment plan based on your individual needs and goals. **cfThrive**