THRIVER

Clinical Trial Guide

What You Need to Know Before You Say Yes

"You don't have to do this alone."

Written by a nurse who has also been a cancer patient for nearly six years. One perspective. Both sides of the bed.

STRAIGHT TALK. PLAIN LANGUAGE. LIVED EXPERIENCE.

Why This Guide Exists

When you hear the words *"clinical trial,"* it can feel like a heavy decision. You might wonder if it is a last resort, if you will be treated like a guinea pig, or if it is your best shot at a longer, healthier life.

I have been on both sides of the bed — and I mean that literally. I am a nurse by profession. I understand the science, the strict protocols, and the terminology that doctors use. I have read the research, I know what the data says, and I know how to ask the right clinical questions.

But for nearly six years, I have also been a cancer patient. I have sat in the chemo chair. I have heard words that changed everything. I have made decisions that felt bigger than I was prepared for — not as a clinician reviewing a chart, but as a person whose life was on the line. Both of those things are true at the same time, and that is exactly the perspective I bring to this guide.

At Thriver, we believe in honest conversations — no hype, no false promises. This guide is not here to convince you to join a trial, nor is it here to scare you away. It is here to give you **clarity and steadiness** so you can make a decision that feels right for *you*.

> *Every standard cancer treatment available today exists because patients before us participated in clinical trials. That is not a small thing. That is everything.*

What Is a Clinical Trial?

A clinical trial is a carefully designed research study that tests how well a new medical treatment works in people. Before any drug or therapy reaches your oncologist's prescription pad, it must pass through a rigorous series of trials to prove it is safe and effective. The process is slow by design — because the stakes are your life.

Trials are run by research teams at hospitals, cancer centers, and universities, and they are overseen by an **Institutional Review Board (IRB)** — an independent committee whose entire job is to protect you. Every protocol is reviewed. Every risk is documented. You are never just a number in a study.

The Benefits — For You and For Everyone

For You, the Individual

Access to new treatments. You may receive a therapy that is not yet available to the general public — one that could be more effective than what currently exists.

Closer monitoring. Patients in trials are watched with extraordinary care. More frequent check-ins, scans, and bloodwork mean your team has eyes on you at all times.

An active role in your care. Many patients describe feeling empowered by choosing to participate. You are not just receiving care — you are shaping it.

For the Whole Community

Advancing science. Even if a trial does not cure your cancer, the data gathered helps researchers understand the disease in ways that will save future lives.

A lasting legacy. The patients who came before us gave us the treatments we have today. Participating in a trial is one of the most profound ways to pay that forward.

Faster access for others. Your participation helps move promising drugs through the approval process so that other patients can benefit sooner.

The Honest Reality — The Risks

I am a nurse. I will not sugarcoat this. There are real risks in clinical trials, and you deserve to know them before you agree to anything.

- **Unknown or unexpected side effects.** Because the drug is new, not every side effect is known yet. Some may be mild; some may be serious. The research team will monitor you closely, but surprises can happen.
- **It might not work for you.** A drug that shows promise in a lab or in early trials may not respond the same way in your body. That is not a failure on your part — it is the nature of cancer biology, and I say that as someone who has lived it.
- **More time and logistics.** Trials often require additional clinic visits, extra blood draws, and more paperwork. This is real, and it matters for your quality of life. Factor it in.

Choosing to join a trial — or choosing not to — is a deeply personal decision. Both choices can be the right one. What matters is that you make it with full information and without pressure.

Understanding the Phases of a Clinical Trial

Clinical trials happen in phases. Each phase has a very specific purpose, and knowing the phase of a trial tells you how much is already known about the drug. Think of it as a ladder — each rung must be climbed before the next one can begin. As a nurse, I have seen patients confused by this. As a patient, I have been confused by it myself. Here is what each phase actually means.

Phase 0

Exploratory — Is This Worth Studying Further?

Phase 0 is a small, early-stage study involving fewer than 15 people. Researchers give tiny doses of a new drug to see how it behaves in the human body — does it reach the tumor? How do cancer cells respond? There is almost no chance of direct personal benefit in Phase 0. Its purpose is to gather early data quickly so that promising drugs can move forward faster. It is not a required step, and not all drugs go through it.

Phase I

Safety — What Is the Right Dose?

This is the first time a drug is tested in a meaningful way in humans, typically in a group of 10 to 30 people. The research team starts with a very low dose and gradually increases it, watching closely for side effects. They are looking for the highest dose that can be given safely — what clinicians call the **maximum tolerated dose (MTD)**. Phase I trials carry the most uncertainty. Placebos are never used. This phase is often considered when standard treatments have stopped working.

Phase II

Effectiveness — Does It Work Against This Cancer?

Now that a safe dose has been established, the drug is given to a larger group of 25 to 100 patients who all share the same cancer type. The team is watching for tumor response: Does the cancer shrink? Does it stop growing? Do patients live longer? Placebos are rarely used here. If enough patients respond well and side effects are manageable, the trial advances to Phase III.

Phase III

Comparison — Is It Better Than What We Already Have?

This is the gold standard of clinical research. Hundreds or thousands of patients are randomly assigned to receive either the new treatment or the current standard of care. When possible, neither the patient nor the doctor knows which treatment is being given — this is called a **double-blind study**, and it exists to eliminate bias. You will never be left without treatment. If a placebo is used, it is always given alongside the standard treatment, never instead of it. A successful Phase III trial can lead to FDA approval.

Phase IV

Post-Approval Monitoring — What Else Do We Need to Know?

The drug is already FDA-approved and available to the public. Phase IV trials track it over years in thousands of patients to find rare side effects, long-term outcomes, and quality-of-life data that earlier trials couldn't capture. This is the safest phase. You can receive the drug outside of the trial — but by participating, you are helping researchers understand it more deeply for everyone who comes after you.

What Happens If the Trial Ends Early?

This is a conversation that doesn't happen often enough — and as both a nurse and a patient, I can tell you it should happen before you ever sign the consent form.

Clinical trials can end earlier than planned for several reasons. Sometimes the drug is working so well that it would be unethical to keep it from the patients in the control group, so the trial is stopped and the drug is fast-tracked. Sometimes the drug turns out to be unsafe and the trial is halted to protect everyone. And sometimes — and this is the hard one — a trial ends because of funding problems, manufacturing issues, or business decisions made by the company sponsoring the research. None of those reasons have anything to do with whether the drug is working for you.

> ***Here is what I want you to know:*** *If a trial ends and that drug has been working for you — shrinking your tumor, keeping your cancer stable, giving you more time — you are not automatically cut off. You have options, and you have the right to ask about them before you ever agree to participate.*

Expanded Access (Compassionate Use)

The FDA has a formal pathway called **Expanded Access**, sometimes referred to as **Compassionate Use**. It allows patients with serious or life-threatening conditions to continue receiving an investigational drug outside of a clinical trial when no comparable alternative exists. Your oncologist can submit a request to the drug's sponsor — the company making it — and to the FDA to allow you to keep receiving the medication.

The sponsor has to agree to provide the drug, and the FDA has to approve the request. It is not automatic, and it is not guaranteed. But it is a real pathway, and it is one you deserve to know about before you commit to a trial. I have seen patients not know to ask this question. Do not be one of them.

⚠ Ask This Before You Sign

Before agreeing to any clinical trial, ask your doctor directly: *"If this trial is discontinued for any reason, but the treatment is working for me, will the sponsor continue to make it available through Expanded Access or Compassionate Use?"*

Get the answer in writing if you can. This question is included in the printable checklist on the next page.

Other Options If a Trial Ends

If Expanded Access is not available, there may be other paths forward. Your care team may be able to identify a different clinical trial studying the same drug or a similar mechanism. There may also be a waiting period before joining a second trial after the first one ends — ask your team about this timeline so you can plan accordingly.

The most important thing is this: do not wait until a trial ends to ask these questions. Ask them now, while you still have leverage and time to make a clear-headed decision.

A Final Note Before Your Appointment

I hope this guide sits well with you and helps to enable you to be your own advocate. When you are sitting in that clinic room, it is so easy to get overwhelmed. It is easy to just nod along because the person in the white coat is talking fast and you are scared. But this is your body. This is your life. You have the right to slow the conversation down.

If anything ever seems confusing — in this guide, or along any part of your path during this journey — and you need more guidance, there are people out there to help at every step of the way. You are not in this alone.

You can always feel free to email us at Thriver. But even better, reach out to the **Nurse Navigator or Social Worker** at your cancer center. That is exactly what they are there for. They know the system, they know your doctors, and they know how to help you find the clarity you need to make the right choice for yourself.

> *Do with this guide what you will. Bring the checklist on the next page to your appointment. Take notes. Ask them to repeat themselves. And remember: you don't have to do this alone.*

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10 Questions to Ask Before Joining a Clinical Trial

Print this page. Bring it to your appointment. Take notes. Ask them to slow down if you need them to.

- [ ] 1 **What is the main purpose of this trial, and what phase is it in?**

- [ ] 2 **Why do you believe this trial is a good option for my specific type of cancer right now?**

- [ ] 3 **What are the known short-term and long-term side effects of the treatment being studied?**

- [ ] 4 **How will this trial affect my daily life? How many extra visits, scans, or blood draws are required?**

- [ ] 5 **Will I have to pay for any part of the trial, or will my insurance be billed for standard care costs?**

- [ ] 6 **Is there a chance I will receive a placebo? If so, will I still receive the standard of care treatment alongside it?**

- [ ] 7 **How will we know if the treatment is working, and how often will I be updated on my progress?**

- [ ] 8 **What happens if my cancer grows while I am on the trial? What is the backup plan?**

- [ ] 9 **If this trial ends early or is discontinued — but the treatment is working for me — will the sponsor continue to provide the drug through Expanded Access (Compassionate Use)?**

- [ ] 10 **Who can I contact 24/7 if I have a severe side effect or an emergency while on this trial?**

You are allowed to take your time. You are allowed to say no. You are allowed to ask every question on this list twice.

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