FRANKLY
SPEAKING
ABOUT CANCER

Clinical Trials

CANCER SUPPORT
COMMUNITY.

GILDA'S CLUB WORLDWIDE

WE NEED TO TALK: WHY CLINICAL TRIALS?

This is a book about clinical trials, but it is a story of people. The people featured in these stories have cancer. Like most people with cancer, they faced a moment in their treatment journey where they were asked to decide–what next? They needed to choose a treatment path. They chose a clinical trial.

The term "clinical trials" can raise a lot of questions. You may wonder what it means or how or why you would choose one. This book aims to answer those questions.

First, it is important to understand that there is seldom only one way to treat cancer. Patients work with their health care team to choose a treatment. The options depend on the type, subtype, and stage of cancer. One of those options may be a clinical trial. In some cases, it may be the best hope for recovery or better quality of life.

Second, cancer research moves at a fast pace. Every day, heath care providers learn more about how cancers start, grow, and spread. They turn what they learn in the lab into new drugs. Clinical trials make this possible. They are where science happens–where discoveries become cures. There are no new drugs or new cures without clinical trials. And clinical trials rely on people to join them.

Yet, for some of us, the term "clinical trials" evokes fear. It recalls a history of discrimination in medicine. We worry that, if we agree to be in a trial, we agree to put science over our own health. We do not want to be "experimented on."

For many Black Americans, this concern dates back to the 1930s, the start of the Tuskegee Syphilis Study. The study, which took place in Tuskegee, Alabama, in 1932-1972, enrolled 600 men. The researchers wanted to see how syphilis affects the body over time. All of the men were given free medical care. But they were not told if they had syphilis or why the study was being done. In the 1940s, penicillin was found to cure the disease. But the researchers never treated any of the men. (For more detailed information about the Tuskegee Syphilis Study visit www.cdc.gov/tuskegee/timeline.htm.)

The ethical abuses that took place in Tuskegee are upsetting. They should not be forgotten. What happened in Tuskegee would not happen today. Today, clinical trials are overseen by the U.S. Food and Drug Administration (FDA). The FDA has strict guidelines to keep patients safe. All people who take part in a study must go through a process called informed consent. The process teaches patients about the goals of the clinical trial, potential benefits, risks, side effects, and alternatives to participation.

Yet, patient recruitment to clinical trials continues to be a struggle. There is still distrust and lack of understanding. Too often, the people in the trial do not represent all the groups affected by the disease. This then raises the question of whether the results apply to everyone.

This publication is part of the Cancer Support Community's Frankly Speaking about Cancer Clinical Trials program. Our hope is that this book helps people who are thinking about being part of a trial. It is intended to answer questions and start conversations. Mostly, we hope that it encourages more people to enter clinical trials.

In order to produce this book, we turned to Gilda's Club Chicago. At Gilda's Club, we found a place of support, connection, and learning. We also found volunteers who shared their stories and helped make this book possible. We are profoundly grateful to them.

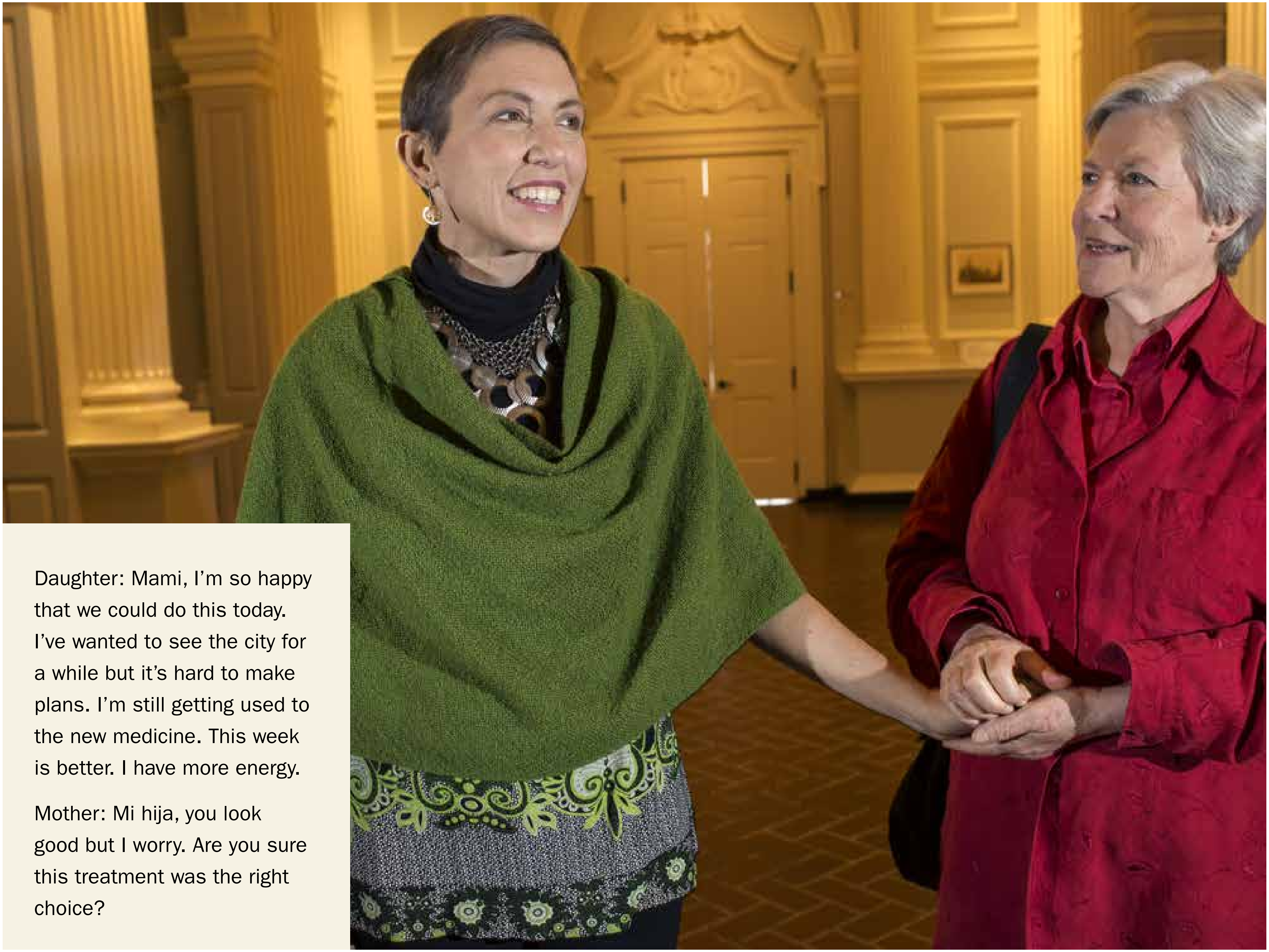
Our journey to create this book took us around the city of Chicago. We visited a 130-year old church, the Chicago History Museum, and Millennium Park. We took photos and drank coffee at the Chicago Hope Café and visited two medical centers that provide care for people with cancer. You may recognize these places in the photos.

The stories pictured are a blend of many stories we ran across in our research and not those of the volunteers pictured. For more information on clinical trials and to watch videos of people telling their own clinical trial stories, go to www.CancerSupportCommunity.org/ClinicalTrials.

Thank you for taking this step to learn more about clinical trials.

1

HOW CLINICAL TRIALS WORK



Daughter: Mami, I’m so happy that we could do this today. I’ve wanted to see the city for a while but it’s hard to make plans. I’m still getting used to the new medicine. This week is better. I have more energy.

Mother: Mi hija, you look good but I worry. Are you sure this treatment was the right choice?

There are many ways to treat cancer. Most patients have options. Some people with cancer choose to get treatment through a clinical trial.

Daughter: The drugs I was on in Chile stopped working. That happens sometimes. It was time to try something new. Coming here to join this clinical trial gave me hope.

Mother: But a clinical trial? So much unknown.

Daughter: When my doctor first suggested it, I was unsure too. But then I learned more about it. This drug might work better for the kind of cancer I have.

Patients who join trials hope for longer, better lives.

All drugs have to go through clinical trials before they are approved. The U.S. Food and Drug Administration oversees all clinical trials to make sure that patients are safe.

Mother: Are they sure it's safe?

Daughter: Doctors don't give drugs to people until they have studied them carefully. Clinical trials have different phases. The drug I'm taking was already tested in a smaller group of people. That's how they know the right dose to give. The drug I was on before this was only approved three years ago. Before that, it had been in clinical trials too. Every medicine we take was once part of a clinical trial.

A clinical trial compares the standard of care to a new treatment. In cancer, the standard of care is the treatment doctors have found works best for a certain type of cancer. It is also called standard care or best practice.

Mother: What if you're not getting a real cancer drug? What if it's a sugar pill?

Daughter: That's not how cancer treatment trials work. On a cancer clinical trial, everyone on the trial gets a real cancer treatment. They told me a lot about the new drug when I signed up for the trial. They explained how it works and what kind of side effects it might cause.

Mother: I'd feel more comfortable if your regular oncologist was taking care of you. I know she cares about you. We are so far from home, and these doctors are strangers.

Daughter: Everyone has been so nice to me. Being on a clinical trial means I have to get watched even more closely than if I were getting care from my regular oncologist. There is one person whose job is to check in with all the patients on the trial. He calls me to see how I'm doing and asks if I'm having any side effects from the treatment. He's the one who recommended the anti-nausea medicine that's been helping.

Placebos are rarely used by themselves as a treatment in cancer clinical trials. Most clinical trials compare adding a new treatment vs. adding a placebo to the standard of care.

If you're on a trial, you get excellent care. You, your health, the cancer, and any side effects will be monitored very closely.

Mother: Oh okay, so you know it will work? And you'll get better?

Daughter: I don't know yet. They test me regularly to see if the drug is working. They pay close attention to all the patients on the trial to make sure that we do not get sicker.

Mother: What if…if it doesn't work?

Daughter: Then, I guess we'll try something else, another treatment, maybe through a trial. We have to keep looking at the options. I feel good today, and it's nice to know that I may be helping future patients.

Mother: What do you mean?

Daughter: Doctors learn from every clinical trial. By participating, I get to be a part of science. It feels good to be able to contribute in this way. It's meaningful.

Mother: Mi vida, I love you more than anything. I just want the best for you.

Daughter: Right now, being on this clinical trial is the best hope for me.

Doctors learn from every clinical trial, even those that do not seem successful. For many people, helping future generations means a lot.

2

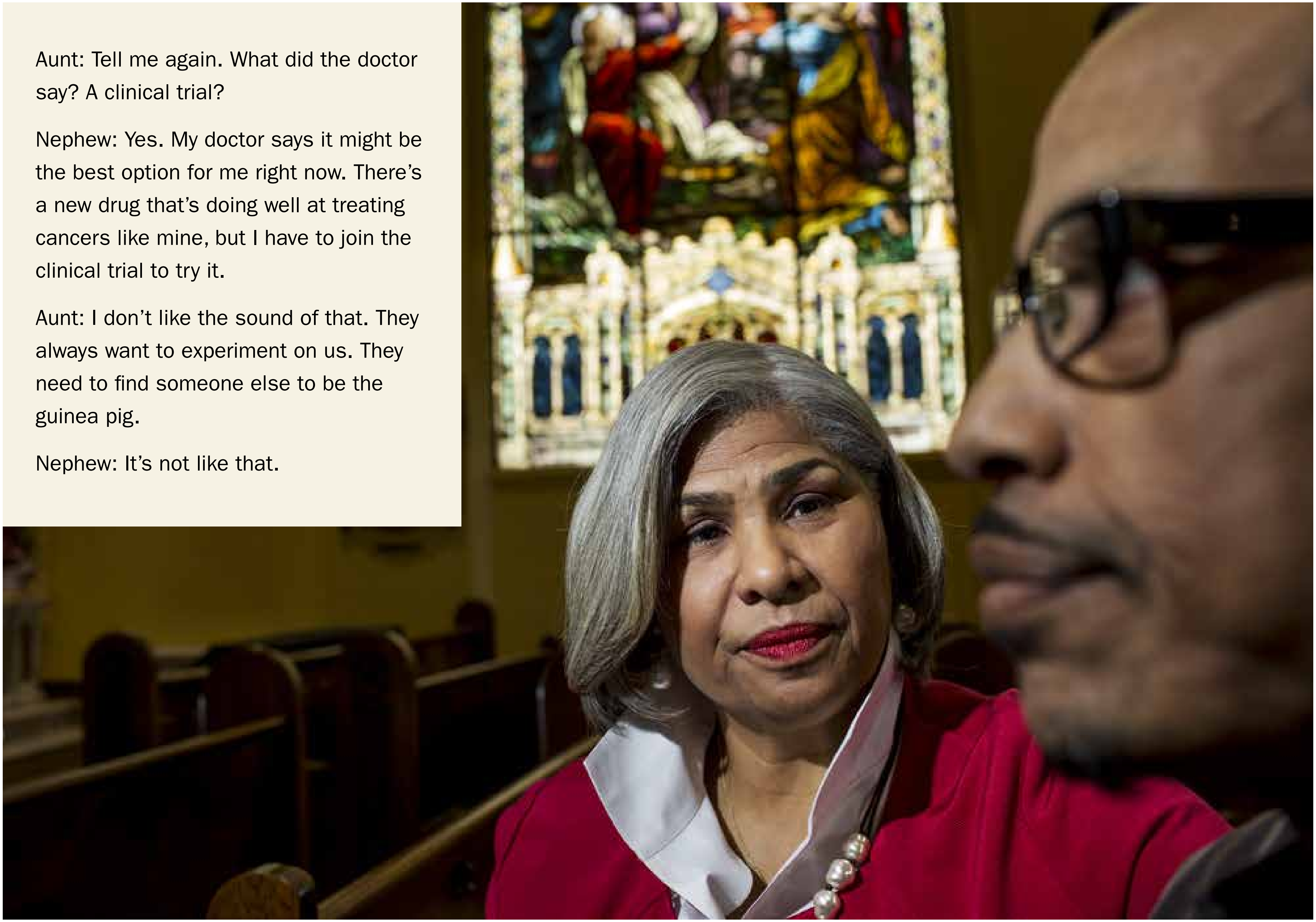
CLINICAL TRIALS ARE FOR ANYONE

Aunt: Tell me again. What did the doctor say? A clinical trial?

Nephew: Yes. My doctor says it might be the best option for me right now. There's a new drug that's doing well at treating cancers like mine, but I have to join the clinical trial to try it.

Aunt: I don't like the sound of that. They always want to experiment on us. They need to find someone else to be the guinea pig.

Nephew: It's not like that.

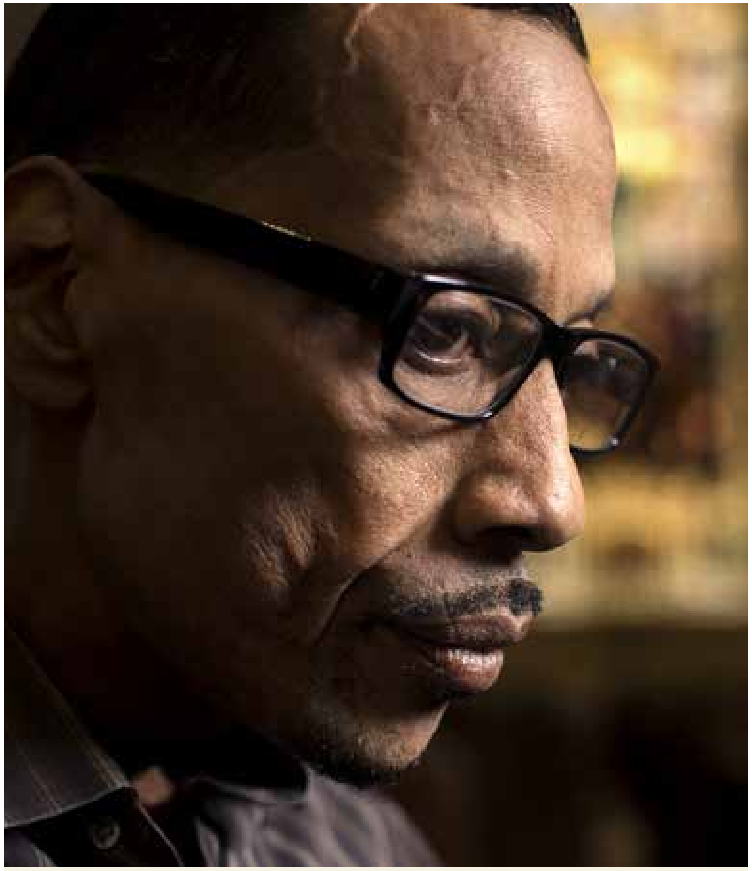


Clinical trials are done to find out if new treatments work better and are safer than existing treatments.

Aunt: You're too young to know. You don't remember Tuskegee.

Nephew: You mean the university? Of course I know about it. What does that have to do with clinical trials?

Aunt: The government ran tests on Black men in Tuskegee, Alabama for years, trying to learn more about syphilis. The men didn't know what they were getting into. They were promised medical care and all sorts of things, all lies. Even after there was a cure for syphilis, the men in the study didn't get treated. It was a tragedy.



Nephew: I've heard something about that. But things are different now.

Aunt: How do you know?

Some people do not trust clinical trials because of the past. Many years ago, doctors ran trials in ways that would never be allowed today. Today, there are better safeguards to protect patients.

Nephew: There are more safeguards in place. For one thing, there's something called informed consent. My doctor told me about it. They're going tell me exactly what will happen, including all the possible risks and benefits. Everything is in writing.

Aunt: That sounds like signing a contract. What if you change your mind after you sign?

Nephew: Informed consent isn't that kind of contract. I can leave the trial at any time. When I sign, I'm confirming that the doctor and nurse told me all about the clinical trial. I'm not promising to stay in it forever.

Informed consent describes the clinical trial. When you sign, you let your doctor know that you understand its risks and benefits, your other treatment options, and your rights as a patient.

Aunt: Did you talk to your nurse about this? I really liked the way she answered my questions when I went with you to your appointment.

Nephew: I did, in fact. She was great. She told me a lot about the study. She agrees that it is a good choice for me right now.

Nurses can answer your questions about clinical trials. If you consider a trial, make a list of all your questions. Ask questions until you get answers you understand.

Aunt: I still don't understand why you can't just get the regular treatment.

Nephew: Based on what they know about my tumor, they think this new drug might work better for me. They've done a lot of tests that show that this drug will work well for me. But it's not just that.

Aunt: What else?

Nephew: I did a little research on my own on clinical trials. It used to be that they only let white men in trials—no women and no people of color. Now, the medical community knows that's not right, but they have trouble finding people to participate.

Aunt: I've seen signs at the doctor's office but, otherwise, I don't hear much about clinical trials.

Nephew: Exactly. I feel lucky that my doctor is at a top cancer center. He is up on the latest research and took the time to find the best option for me.

Aunt: I hadn't thought of it that way. You're teaching me something new.

Every cancer patient should talk to his or her health care provider about clinical trials. If your provider doesn't bring it up, ask if clinical trials are an option for you.

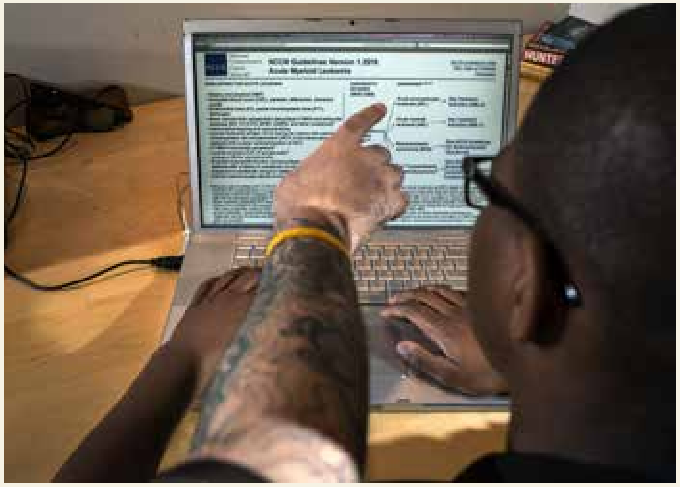
Nephew: It's extra important that people of color participate in trials. If we don't, we might miss out on getting the best care. Also, if we're not part of the research, how can we be sure that what they learn applies to us too? I want to get better, but I also want to help my community.

Aunt: That is true. We need a seat at the table, as they say. I'm proud of you.

By participating in clinical trials, you help provide important information on how treatments work for people like you.

3

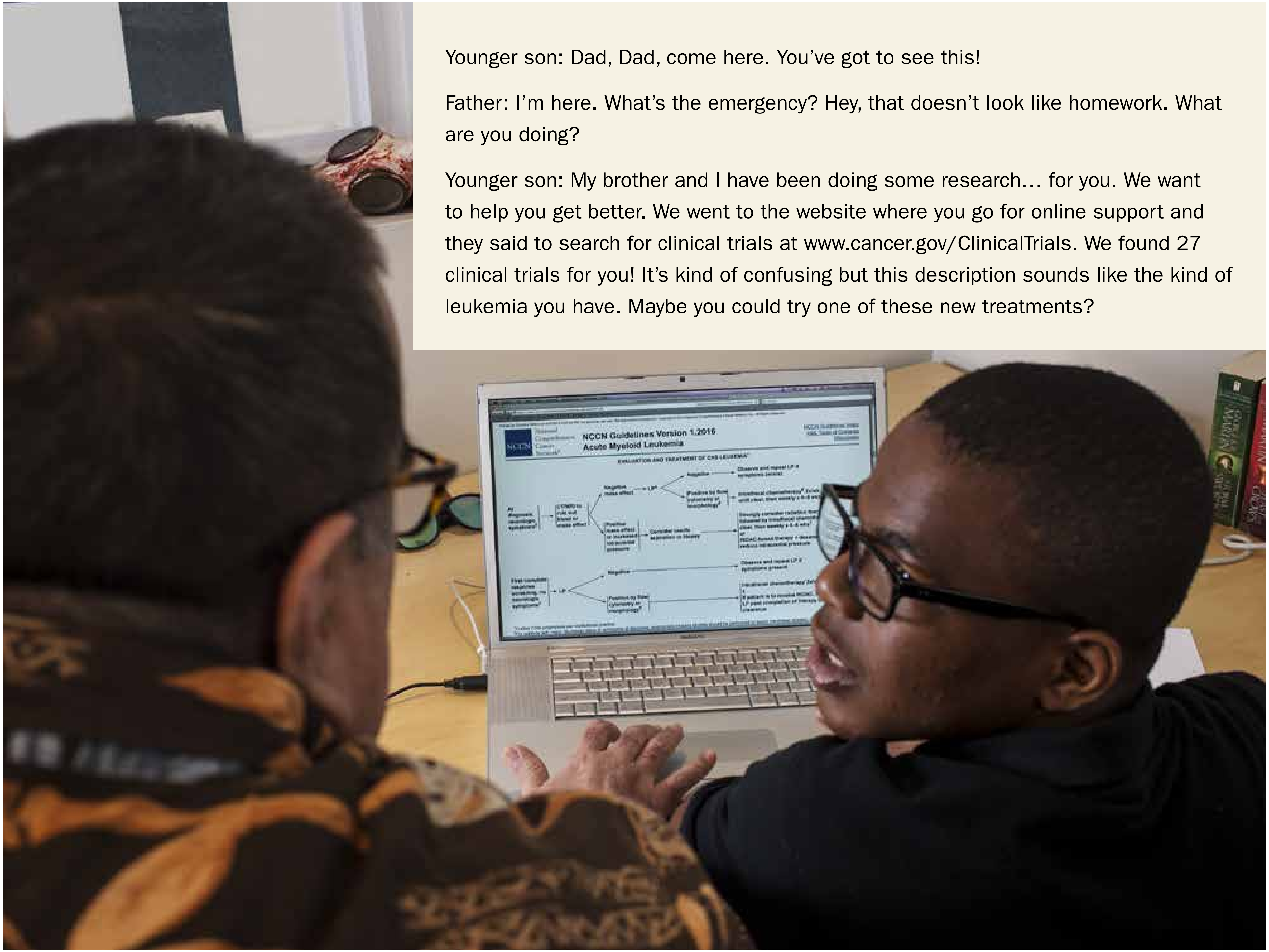
FINDING A CLINICAL TRIAL



Younger son: Dad, Dad, come here. You've got to see this!

Father: I'm here. What's the emergency? Hey, that doesn't look like homework. What are you doing?

Younger son: My brother and I have been doing some research… for you. We want to help you get better. We went to the website where you go for online support and they said to search for clinical trials at www.cancer.gov/ClinicalTrials. We found 27 clinical trials for you! It's kind of confusing but this description sounds like the kind of leukemia you have. Maybe you could try one of these new treatments?



Father: Oh, wow. A clinical trial. I hadn't thought about that. I don't understand some of what it says here. Let's wait and see what the doctor says. How did you even find these?

Younger son: Don't be mad but we wanted to help. We looked up cancer and saw an ad for clinical trials. It had a link where you could look them up yourself, so we did. Then we searched some more. It says here that sometimes the best drugs are only given to people on clinical trials.

Father: I'm not sure about that but I love that you're thinking of what's best for me. Your brother offered to come with me to the next appointment. Print this out and we'll ask the doctor about it.

The best way to find a trial that is right for you is to talk to your health care team. If you search the internet, take what you find and talk it over with them.

Doctor: How are you doing today? We're here to talk about your treatment options. Do you have any questions before we go over some possibilities?

Father: Yes, actually we do. My sons did some research on the internet. We want to know more about clinical trials. They found these. We don't really understand it though.

Doctor: I'm impressed with your sons' initiative. You must be very proud of them. In fact, clinical trials are one of the things I want to talk about today.

Father: I hope you can explain some of this. This part that says "eligibility criteria" has a lot of fine print.

Doctor: That's for sure. There are a lot of clinical trials out there. They all have very specific eligibility criteria. In other words, they look for certain kinds of patients.

Older son: So how do you decide who goes on what trial?

Doctor: We look at a number of factors. What kind of cancer do you have? What stage? Which therapies or treatments have you had and how did your cancer respond to them?

Older son: Is it better if the other treatment worked, or if it didn't? What if you haven't had any treatment?

Doctor: Some trials look for patients who responded well to other therapies. Others are looking for patients with cancers that could not be treated with other therapies. And some are for patients who have not already been treated for cancer. Let's see what you've got here.

Your previous treatments and your overall health may influence whether you go on a trial.

Father: Right here, this one has the same words you used to describe my cancer.

Doctor: OK, let's take a look. I have a matching service on my computer that makes it easier to find options that might be right for you. I can put in what we know about your type of cancer and see what comes up.

Father: So you really have to know exactly what you're dealing with when you look up trials online?

Doctor: That's right. It's one reason why we encourage people to get their medical records together and ask a lot of questions.

Keep a file on all your medical records and ask lots of questions when you see your health care provider.

Father: It sounds like a lot to figure out. How do you keep up with all this?

Doctor: We know which trials are here, and we talk to our colleagues at other centers. I read journals and go to meetings. Sometimes, I look online too, or people like you bring me what they have found.

Father: We didn't see this hospital listed for one of the trials. Does that mean I can't do that one?

Doctor: We offer a lot of trials here. But patients sometimes go to other hospitals or cancer centers to join a clinical trial. If you are interested in a trial, look at the study sites. Reach out to the site that is closest to you.

Father: How do I do that?

Doctor: The best way is to contact the trial team directly. You can use the contact information on their website. They will ask you some questions and look at your medical records. If you meet the trial criteria, the trial team will set up an in-person meeting. I can help you start a conversation.

Older son: We were having a hard time figuring out how to find a trial that might be right for my dad. Now I see that it wasn't just us. This is complicated.

Doctor: Yes, that's why we like to be involved. Connecting patients to clinical trials is a very important part of what we do.

Father: I’m still a little confused about what will happen during the trial. Will somebody explain it to us?

Doctor: The trial team will describe what will happen during the trial and answer all your questions. It is also their job to decide whether you are eligible to join the trial.

Father: Well, this is a lot to take in. Let’s go through the list that you found. It’s good to know that I have more options that I thought. For the first time in a while, it feels like there’s hope.

Ask questions. Communicating is key to getting good care whether you are enrolling in a trial or not.

4

DECIDING TO JOIN A CLINICAL TRIAL

Husband: Today’s appointment was a lot to take in.

Wife: Yes, I can’t stop thinking about it. I wasn’t expecting the doctor to suggest a clinical trial.

I’m so glad you were there, and you took notes. I don’t know how people do this on their own.

People with cancer find it helpful to bring a friend or loved one to appointments. This person can help listen, ask questions, and take notes. This is important when you are thinking about getting treatment through a clinical trial.

Husband: Of course. Where else would I be? There was a lot of information. I thought we were going to be talking about more of the same chemo. The trial idea surprised me too. How are you feeling about it?

Wife: The doctor says this is the most likely to work for me. I trust him, and I like the idea of fighting the cancer with all we've got. I'm tired of being in treatment. I want to get better, but I'm worried about being part of a study.

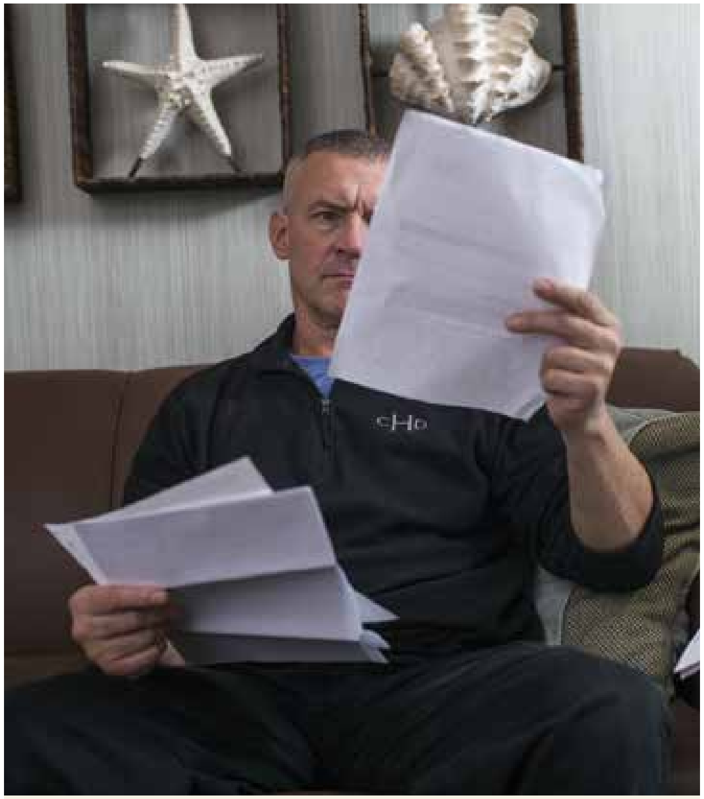
Husband: I hear you. I want you to get better but I'm not sure if it's worth the risk. What if it makes you sicker?

Wife: The nurse said they will watch me closely. If I'm not doing well, they'll take me off the trial. Also, remember, they said I can leave at any time.

Clinical trials are research studies. A cancer treatment trial compares a new treatment to the best treatment now used to treat the same type of cancer.

Wife: To be honest with you, that sounds reassuring, but I'm getting a little stressed just thinking about the costs. Watch closely sounds like more appointments. How can we afford this? We're already struggling with the bills from the last round of treatment.

You will probably need some additional appointments and procedures.



Husband: I don't think this is going to be a lot more expensive. Let's look at the paperwork. See, it says here that the trial covers most of the expenses, even the co-pays for our visits.

Wife: That's a relief. But what about parking and gas? That adds up.

Husband: I know those costs can add up. I'm not sure if they are included. But I remember something the nurse mentioned a while ago. She told us about an organization that helps with travel expenses for doctor visits. I didn't think we'd need it, but it's good to know that's an option.

Wife: Every little bit helps. I like what it says here about what they do to make sure that I will be safe. That makes me feel better. But I'm still concerned about the money.

Husband: Let's call our health insurance plan to ask.

Members of your health care team have a lot of helpful information. They are great resources when you are part of a trial. Talk with your doctor, nurse practitioner, or patient navigator about any concerns you have.

Most often, your health insurance plan will cover the medical costs not covered by the trial. Find out what is covered by the trial. Check with your health insurance plan to see what they will cover. Talk to your health care team about getting help with any other costs.

Husband: If you feel this is the right treatment for you, we will find a way to make it work. I love you, and only want you to get better.

Wife: I know. Let's learn more about the clinical trial.

You can take an active role in making decisions about your treatment. This is your life and your treatment.

5

A DIFFERENT APPROACH

Friend: It’s so good to see you. I’ve been thinking about you a lot. Is it okay to ask how the chemo is going?

Patient: It’s going pretty well, I guess. The day or two after are hard because of the nausea. But then I’m okay for a couple weeks until it’s time for another infusion.

Friend: Is there anything you can take to feel better? Does your doctor know how the chemo affects you?

Patient: Yes, the nurse is great. It was worse before I started talking with her about my symptoms. Now that she knows about the side effects I have, she’s on it. She even gives me medicine before the infusion that helps.

Always tell your health care team about any side effects you experience. They can help manage them if they know about them.

Friend: That's good to hear. I'm so glad that you could make it today.

Patient: Me too. I couldn't have done this a week ago.

Friend: I guess I still don't understand why you didn't have surgery first. I thought surgery usually came before chemo. That's how it went for other people I know who have had cancer.

Some trials are done to test treatments before the main treatment for a cancer—which is usually surgery. These trials are called "neoadjuvant therapy trials." They are done to reduce the amount of cancer before surgery. "Adjuvant therapy trials" are done right after surgery to reduce the chance the cancer will come back.

Patient: That is often how it works but I'm in a clinical trial. It's a study. They think that people like me might do better long term if we have chemo before surgery.

Friend: So it's a study? I don't know about that. If it were me, I think I'd rather have the usual treatment, just to be safe.

Patient: The usual treatment is what my doctors call the standard treatment. That was an option but my doctor thought this would be a better way to go.

Treating a cancer effectively the first time gives you the best chance for a good outcome.

Friend: My aunt was on a clinical trial, but it was a last resort. Your cancer hasn’t spread that much, has it?

Patient: No, they’ve caught it fairly early, but the doctor says that the risk of it coming back is high with the standard treatment. They could tell from looking at my blood work and other test results.

Doctors can often identify high risk features in a tumor that make it more likely to come back or spread.

Clinical trials are done for many reasons and for patients with many types and stages of cancer.

Friend: You’re brave. I think I’d be scared to be on a clinical trial. I like a sure thing.

Patient: Thanks for saying that. I am scared sometimes but having cancer is scary. Being on a clinical trial doesn’t make it feel any scarier. Doctors have learned a lot about cancer but there’s still so much they don’t know. By being on a trial, I’m helping them make discoveries. It feels like I’m making a difference.

Patient: Who knows, what they learn from this study may change the course of cancer treatment for future generations.

Friend: Wow, I hadn’t thought of it that way. I always said you were my most generous friend. This is the ultimate sacrifice.

Patient: I wouldn’t say that. My first priority is to get healthy and stay healthy. This trial is hopefully going to help me do that, and, if I can help others along the way, even better.

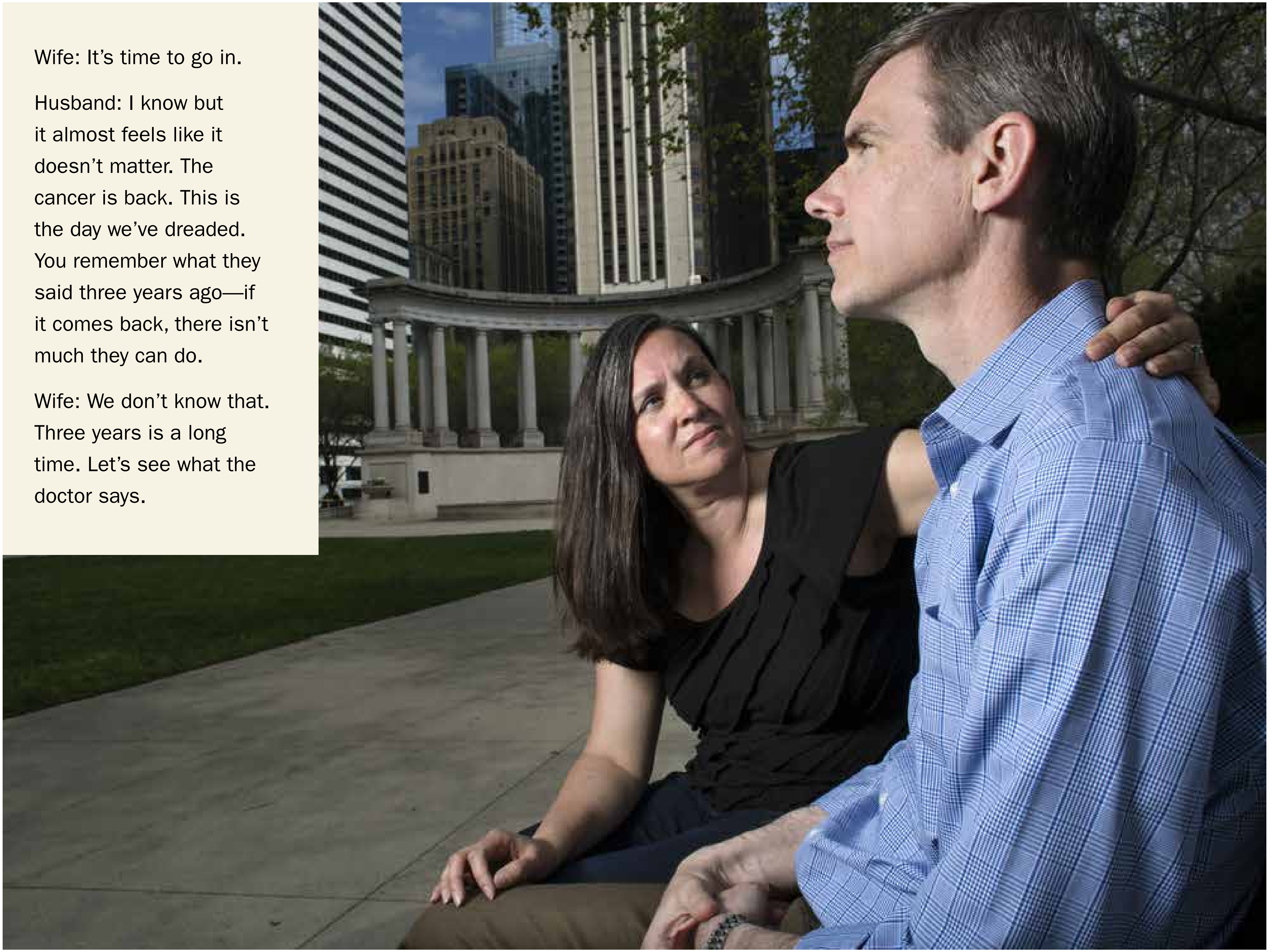
6

HOPE WHEN YOU ARE OUT OF OPTIONS

Wife: It's time to go in.

Husband: I know but it almost feels like it doesn't matter. The cancer is back. This is the day we've dreaded. You remember what they said three years ago—if it comes back, there isn't much they can do.

Wife: We don't know that. Three years is a long time. Let's see what the doctor says.



Doctor: Thanks for coming in today. As I mentioned on the phone, the results of the tests we ran show a recurrence of the cancer. This isn't what we hoped for it, but we knew it was a possibility. I know that things looked bleak a few years ago but a lot has changed. There's been some new research that is having good results. We have a couple options. One, which I think we should consider seriously, is a clinical trial.

Clinical trials find out whether new treatments are safe and effective.

Husband: A clinical trial? I've heard of clinical trials but, to be honest, I'm not really sure I know what they are.

Doctor: Clinical trials are a key part of medical research. It's how we discover new treatments, and find ways to use existing treatments more effectively. A trial is a study that compares a new approach to an established approach. The trial I'd like you to consider tests a new drug that is promising for cancers with your subtype. It's showing good results in people whose cancer has returned.

Wife: Is it risky?

Doctor: All trials are overseen by the Food and Drug Administration. There are a lot of steps taken before the trial even starts. Then, there are just as many safety measures in place during the trial to keep patients safe. We can go over all the possible risks and benefits.

If you participate in a trial, you will receive either the new drug or the best available treatment.

Husband: I'm not sure about being in a study. How will it work?

Doctor: This is a randomized trial, which has two groups. One will get the standard treatment which we know helps some people. The other will get the new drug. The computer makes the decision. It's called randomization.

Wife: Why not just give him whatever you think will work best?

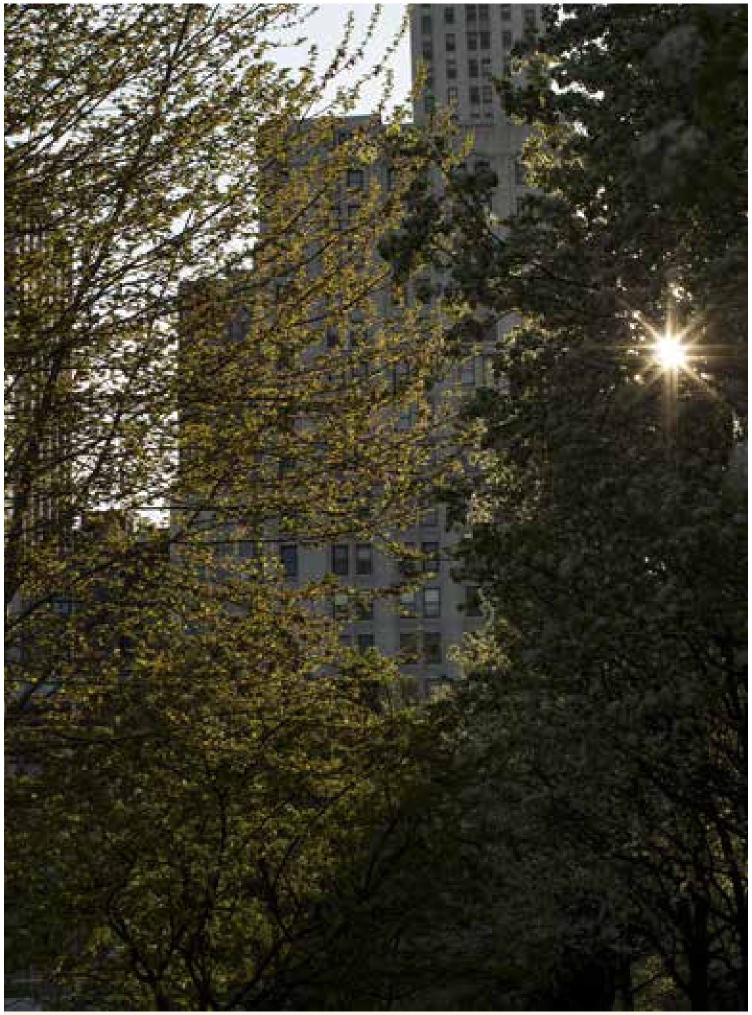
Doctor: When we develop new drugs, it's important to test them in an unbiased way. This is why we let the computer assign the treatments. Also, we don't know which drug will work best. The standard treatment has only been approved for a year. It's more effective than anything we had in the past. Either way, you will receive a more promising treatment.

Doctors compare what happens in the patients who get the different treatments.

If you are on a clinical trial, you may benefit from the new treatment. Only drugs that have shown promise are part of these research studies.

Wife: So clinical trials are always the way to go when cancer comes back?

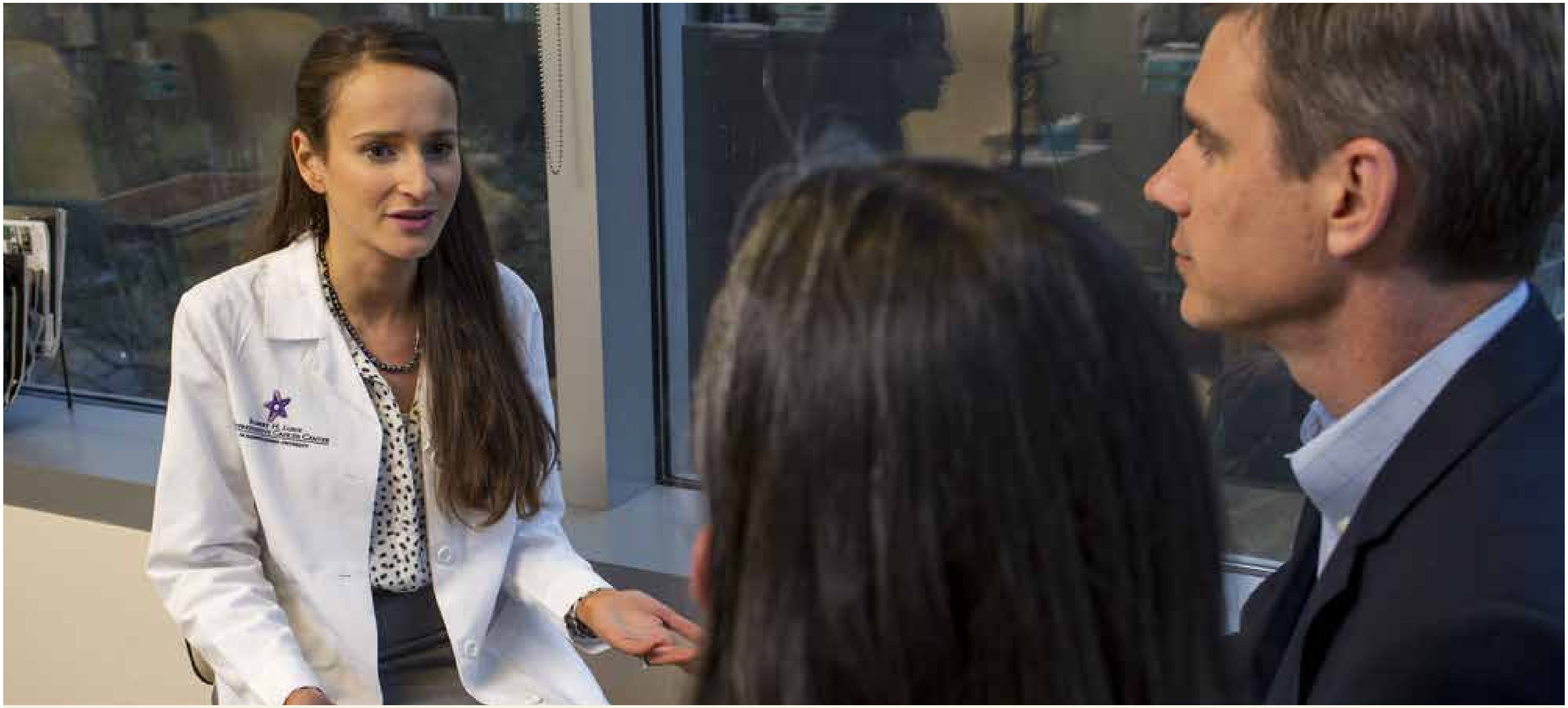
Doctor: Clinical trials are not just for a cancer that has returned. There are clinical trials for every type and stage of cancer. Some people choose a clinical trial as their first treatment. Cancer treatment is not one-size-fits-all. We encourage each patient to look at their options and choose the best one for them. I am here to discuss each option in detail and help you think through what feels right to you.



Husband: What if I don't respond well to the drug? Or the side effects are unbearable?

Clinical trials are available for every type and stage of cancer.

Health care teams keep careful track of everything that happens to people during a clinical trial. Patients on trials get a high level of care.



Doctor: We will monitor you closely to help manage any side effects. We will also be looking at how the cancer responds to the medication. Even though you are on a clinical trial, you are still my patient. Our goal is to manage the cancer and help you maintain as high a quality of life as possible. If you find it hard to participate for any reason, you can withdraw at any time. Or, if I see that the treatment is not working, I may pull you out of the trial and try something else. Your care is still our top priority.

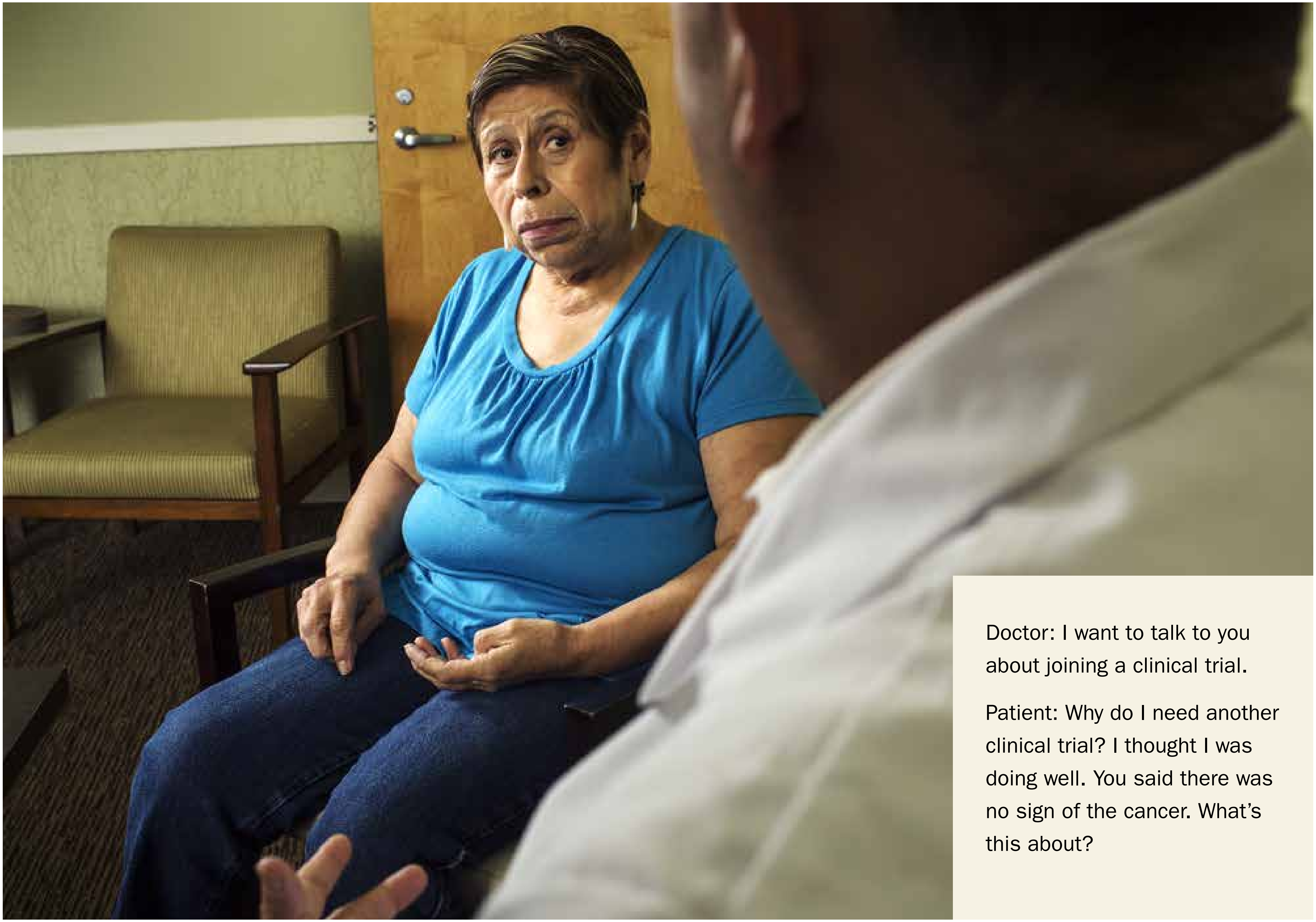
Husband: Thank you. This has been helpful. I'd like to look over the paperwork and talk with my family.

Doctor: Of course. I am here to answer any questions.

7

CLINICAL TRIALS TO MAKE LIFE BETTER

There are many reasons for having clinical trials—and for participating in one.



Doctor: I want to talk to you about joining a clinical trial.

Patient: Why do I need another clinical trial? I thought I was doing well. You said there was no sign of the cancer. What's this about?

Some trials are focused on improving mental and physical health.

Doctor: You are doing fine. This clinical trial doesn't involve any medicine. This study focuses on quality of life. They are conducting research to study whether exercise helps with your emotional and physical health.

Patient: Exercise? What does that have to do with clinical trials?

Doctor: This study focuses on the whole person, not just your cancer. We are trying to learn more about whether exercise can make you less tired, or feel less anxious.

Patient: That sounds interesting. I like to exercise, or at least I used to before I had cancer. Tell me more.

We have some ideas of how to help people with cancer live their best lives. But we don't really know what works until we study these ideas in people. That's where clinical trials come in. There are trials for counseling, support groups, meditation, symptom management, exercise, and more.

Doctor: It's sort of like the other trial you were on but there are no drugs involved. You'll be put into either a group that does supervised exercise, or one that doesn't. You have an equal chance of being in either group. We will check in with you and ask questions either way. It lasts for three months.

Patient: Okay.

Patient: Will this help make sure my cancer doesn't come back?

Doctor: No, it doesn't treat the cancer.

Researchers compare the results of the two groups in many ways. One way to do this is randomization. A computer or other method places people into groups. Both groups are part of the trial. One may receive something different—like extra phone calls or an exercise class. But they will both be followed.

There are many different kinds of clinical trials. Some study how to treat cancer better or find cancer earlier. Others look at other parts of the cancer experience. They help people live a better life.

Patient: Will I find out the results?

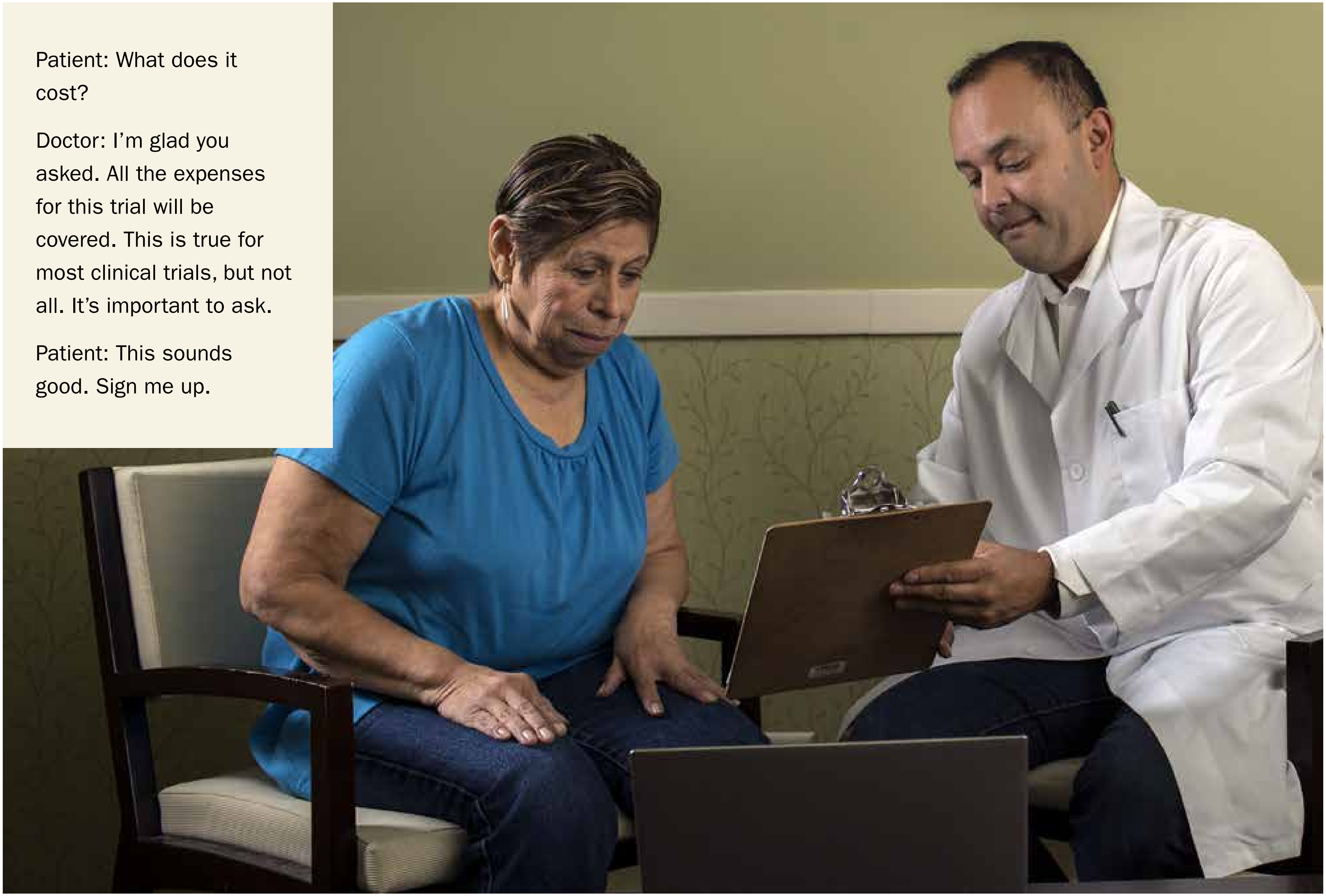
Doctor: Absolutely. You're a partner in this trial.

Patients are partners in clinical trials. Although it may take a long time to get answers, the trial should report its results back to you when it is done.

Patient: What does it cost?

Doctor: I’m glad you asked. All the expenses for this trial will be covered. This is true for most clinical trials, but not all. It’s important to ask.

Patient: This sounds good. Sign me up.



Many costs in a clinical trial are covered by the trial. Be sure to ask if there are any costs that the trial or your health plan won’t pay.

GLOSSARY

Medical terms are commonly used to talk about clinical trials. This is a list of some of the terms you may hear or read when you are thinking about being in a clinical trial.

A clinical trial or **clinical study** is a research study to test how well new medical treatments work in people.
Each clinical trial tests new ways of screening, preventing, diagnosing or treating cancer, or improving the quality of life for people with cancer.

Adjuvant trials: Research studies done after primary treatment for cancer, such as surgery or radiation therapy, to reduce the chance the cancer will recur or come back.

Adverse event: Any unfavorable change in a patient's health. This includes abnormal lab findings, side effects of the treatment and health problems that may not be caused by the trial but happen during or after a person participates. Doctors use adverse events to decide whether a treatment is safe and help set the dose.

Agent: In a clinical trial, a substance that produces or can produce an effect that treats cancer.

Arm: A group of participants in a study who are receiving the same treatment.

Bias: Any factors, such as human beliefs or choices that affect a clinical trial's result.

Blinding: Setting up a study so that neither the doctors nor the participants know who is getting which treatment.

Chemotherapy: The use of drugs to treat cancer.

Closed study: A trial that is no longer recruiting or open to new patients.

Combination therapies: Studies or treatments that use more than one drug or agent.

Complete pathological response (CPR): The total disappearance of a cancer following neoadjuvant therapy. CPR is an important way for researchers to measure the outcomes of a neoadjuvant clinical trial.

Controlled trial: This is a study in which the new treatment is compared to a control (usually the standard of care).

Data: Information from a study.

Disease-free survival: The time from when a person with no detectable cancer begins a treatment until the cancer appears or returns.

Eligibility requirements: Every clinical trial has certain standards that participants must meet in order to participate. These usually are related to the kind and stage of cancer, any previous treatment you have had and your overall health.

Endpoint: An outcome that researchers use to measure the results of a clinical trial.

Exclusion criteria: Factors that can make a person not eligible to participate in a clinical trial.

Experimental: Any research study that is designed to test whether a new drug or treatment is better than the available best treatments.

Food and Drug Administration (FDA): The federal agency responsible for assuring that all drugs and medical devices available in the United States are safe and effective. The FDA reviews–but does not conduct–clinical trials.

Human Subjects Review Board: See Institutional Review Board

Institutional Review Board (IRB): The group at a medical center that reviews all proposed clinical trials taking place in that center to make sure they are safe and effective for patients and that all patients' rights are protected.

Immunotherapy: Treatments that use the body's own natural immune system to fight cancer.

Inclusion criteria: The factors that allow a person to participate in a study.

Informed consent: The formal process researchers use to make sure patients understand a clinical trial and fully agree to participate in it. This is an important way of communicating with patients and caregivers about the goals of the study, possible results and side effects. It is also a time to ask questions.

Intervention: Any drug, agent, medical device or procedure that involves a patient. Surveys, interviews and education programs can also be interventions.

Investigational new drug: A drug or agent that is being used in a clinical trial but has not yet been approved by the FDA.

Investigator: The researcher who is conducting the clinical trial.

Neoadjuvant trials: Studies done to test treatments before the primary treatment for a cancer, such as surgery or radiation therapy. This is done to eliminate or reduce the amount of cancer.

Open study: One that is actively recruiting new participants.

Outcome measures: The ways that researchers decide if the new treatment is safe and effective. These are set before a study begins and can include measures of survival and quality of life.

Overall survival: The length of time a person lives from the beginning of treatment.

Phase: There are four basic stages of clinical trials:

> **Phase I** trials are the earliest. They are often small and are designed to establish the safety and effectiveness of a new treatment. They may involve people with many kinds of cancer.

Phase II are studies designed to see if a new treatment works in people with specific types of cancer. These trials are often larger and usually involve one group of patients who are all getting the new treatment at the same dose.

Phase III are the large studies that establish how a new treatment will be used. They compare the new treatment to the standard of care. These trials may involve hundreds or even thousands of patients and take place in many hospitals in this country and around the world.

Phase IV trials study the long-term side effects and results after a treatment is approved by the FDA.

Placebo: An inactive substance, sometimes called a “sugar pill.” Placebos are rarely used as a treatment in cancer clinical trials and only when there is no known treatment option. Most clinical trials compare a new treatment to the current standard of care.

Preclinical studies: Research done on new drugs and treatments before they are used in humans.

Progression-free survival: The time from when a patient begins taking a treatment until the cancer begins to grow or spread again.

Protocol: The written plan or design for a trial that tells doctors what treatments and doses patients get on a study. It is the doctor’s recipe for conducting the trial.

Quality of life: These are ways of measuring treatments and the patient experience that focus on a patient’s overall health, ability to live and enjoy life and sense of well-being.

Randomization: Many clinical trials involve assigning participants to treatment groups by letting a computer or other method choose who will get which treatment. This is done to make sure that there is no bias in the study and assures that every patient has an equal chance of getting either the standard of care or the new treatment being tested.

Single agent trials: Studies that test one drug.

Stage: The extent of the cancer.

Standard of care: This is the currently accepted and widely-used treatment for any specific type of cancer.
Clinical trials compare new treatments to the standard of care to learn if they work better and are safe for patients.

Targeted therapy: Treatments that target specific genetic mutations or changes in a cancer.

Toxicity: Harmful side effects that result from an agent being tested.

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