LEUKEMIA & LYMPHOMA SOCIETY®

THE BLOODLINE WITH LLS

A PODCAST FOR PATIENTS AND CAREGIVERS

Episode: 'Why You Should Consider a Clinical Trial'

Description:

Listen in as Alicia and Lizette from The Leukemia & Lymphoma Society (LLS) chat with John F. Gerecitano, MD, PhD, *Clinical Director of Lymphoma Outpatient Services* at Memorial Sloan Kettering Cancer Center and Margaret (Peg) McCormick, RN, BSN, MA, *Consultant*, Clinical Trials Support Center. Hear about the role clinical trials play in cancer treatment, who can participate in a clinical trial and how participants are protected, how LLS's Clinical Trial Support Center assists patients in finding a trial that is right for them, and why it is important to think of clinical trials as a possible treatment option instead of a last resort.

Transcript:

Alicia: So for clinical trials, I think a lot of people don't realize how much, you know, how much of a key research tool it is for advancing medical knowledge. For anybody who's just learning the term or just being introduced to them, doctor, how would you define a clinical trial for those who may be new to the concept?

Dr. Gerecitano: So, a clinical trial is done whenever we want to advance care or the patient experience for patients, in this case with cancer. And that can either mean finding drugs that are more effective in fighting the cancer or finding drugs that have better side effect profiles and will allow the patients to live a more complete, life while they're getting therapy to control or, hopefully, someday cure their cancer.

Lizette: And, Peg, I know that Dr. Gerecitano, mentioned that he was interested in Phase I, and had started with a lot of Phase I trials. Can you let people know what the different phases are for clinical trials? I know the patients do ask you all the time.

Peg McCormick: Oh, I sure can. Clinical trials start after a couple of steps have already been taken in investigating a drug. So, so drugs typically start in a laboratory setting, and then they move onto animal testing. When it's determined that that, uh, drug is ready for human testing, we have what's called a first-in-human trial, which is a very early Phase I trial, that'll then move on to a Phase I trial where we test the drug in a very small number of patients to determine whether it's safe to give to patients.

And in this case, we might start out with a very small dose of that drug in the first few patients, make certain that those patients do okay, and then increase the level of the drug in subsequent patients.

Once it's determined that that drug is safe, we can expand its use to a larger number of patients in a Phase II trial. The goal of a Phase II trial is to help us understand, how effective that drug is in the patient population with the disease.

Often Phase I and Phase II trials are combined, so, it's important to understand when we're looking for a trial how many patients have been treated in that trial so we have some sense of what phase it's in.

And then there's a Phase III trial where once we know the drug is safe and effective, we want to know whether it's more safe or, or more effective than the drugs or treatments that are currently on the market. So a patient population will be divided into two; half will get the experimental treatment and half will get this, what we call the standard-of-care treatment and we'll compare those two groups to see which one did better.

Alicia: Ah! And who can participate in clinical trials?

Peg McCormick: Honestly, anybody can participate in clinical trials. A, a common misunderstanding is that clinical trials are only for patients who've run out of all options. But actually, clinical trials (GAP) for, beginning treatment or induction therapy, for treatment for maintenance. Sometimes patients are, are initially treated and then we wait to see if they relapse, but we want to know how long we can prolong that remission. And then other trials are developed, especially for those who have relapsed or who have not responded to standard therapies. So, really anyone along the entire disease spectrum could be a potential candidate for a clinical trial.

Dr. Gerecitano: We have clinical trials for patients at all ends of the disease spectrum, so, in fact, some trials are even designed to detect cancer so patients without cancer may participate in clinical trials that are looking at new screening modalities say, that might detect cancer earlier in patients. Other patients may take part in trials that attempt to improve therapy in the first line during their very first line of treatment. Others may participate in trials to help them extend remissions after their first line of therapy. Others may participate in trials that look at the best treatment if the cancer comes back after the first line or the second line or the third line of therapy. And other patients may participate in trials that help us monitor the disease to, uh, potentially catch relapses sooner or in a less invasive way or in a way that doesn't involve s-, uh, for instance, radiation like PET scans or CAT scans. And other trials are designed to just look to improve comfort around the care that we give and all these other aspects that I talked about.

So really our goal is at least at a center like Memorial Sloan Kettering Cancer Center, to have trials that may benefit our patients, at all stages in their disease journey.

Alicia: And so for Peg, when you receive a phone call with somebody who wants information about a clinical trial that may be fitting for them, how do you help navigate clinical trials with that patient? What, what's the first thing that you do?

Peg McCormick: That is an excellent question. I, I'd like to start by comparing perhaps what we do to what patients might encounter in other situations when they, when they access a clinical trial database online, for example, uh, where they'll put in their name and perhaps their age and their disease and their ZIP code and they'll be presented with a list of clinical trials that they can bring into their physician. That list is frequently very long, and a great majority of those trials are not appropriate for them for one way or, for one reason or another.

LLS decided that it would be helpful to have a human interacting in between the database and the patient and the physician, so they began the Clinical Trial Support Center, as I said, about four years ago. We do use the comprehensive database, clinicaltrials.gov, as, as our baseline to help find trials, but we first talk to the patient. We really want to understand the patient situation. What is their understanding of clinical trials? Do they have a realistic view of what they might be in for or do they have an unrealistic view perhaps of what a trial could provide? What's the reason for entering a trial?

We want to understand what their physician has recommended. Often a physician says, "You need to find a clinical trial, but I can't help you," or the physician may have recommended standard of care; and in that case, we'll talk about the value of that standard-of-care treatment.

We need to understand if they're willing and able to travel to a distant site. They may not have a support person to travel with them. In that case, we're not going to give them trials that require them to travel across country.

We want to understand if their insurance covers clinical trials or if they need to maintain, remain within a network. Again, what we don't want to do is increase their level of hope that they can access a trial and have them be incredibly disappointed when in the end they find, for one reason or another, they can't enter that trial.

Then we'll understand, through questioning the patient, their diagnosis, their markers and mutations. If they don't know that, we'll help guide them back to their physician to get the information.

We want to understand their past treatments and their responses to those treatments. We, we'd like to know their current physical condition and we, we estimate what's called an ECOG score, which is a measure that researchers use to find if patients are healthy enough to enter their trial. And then we want to understand what medical conditions they're dealing with.

Then and only then do we use clinicaltrials.gov to conduct a search. We conduct the search, but we're not done yet. Instead of giving that list of 50 trials, we literally will open every trial that we, that comes back and we'll compare what we know about the patient to the inclusion and exclusion criteria listed on the listing. It's not perfect, but it is a lot closer to what patients are actually eligible for than just doing, providing a list based on the database.

We now have an actionable list of trials that that patient can carry into their physician for guidance about what their next step should be. If the physician is unable to take that step with the patient, then we will connect the patient directly to the clinical trial site so they can get more information about a particular trial.

Alicia: Oh, a lot of work!

Peg McCormick: It's a lot of work. It's incredibly rewarding.

Alicia: Yes.

Peg McCormick: The great majority of patients that come to us looking for a trial, end up enrolling in one or more trials throughout the course of their disease.

Alicia: Wow!

Lizette: And the patients that come to you, Peg, are, are already open to being part of a clinical trial. I know a lot of times that patients will contact us and they're asking, you know, "Are clinical trials safe? Am I going to get a placebo, a sugar pill? Am I not going to be treated?" There's a lot of questions that patients have and sometimes, patients as well as family members may not be as open to actually looking into clinical trials. And some patients don't even know that clinical trials are an option for treatment.

Doctor, have you seen this with patients and families, that they come to you and they talk to you, and they're really unsure of what a trial is or what a trial can do for them?

Dr. Gerecitano: Yeah, you've really hit on many of the, the most important aspects, of clinical trials and misperceptions about clinical trials. And there's a lot to unpack there, but let me just start by saying, that patients with leukemia and lymphoma are particularly advantaged by having a service such as the one that the LLS offers. I've seen many patients who have gone out and spent a lot of money hiring patient advocates or patient navigators that do that same service when they don't have access to things or they don't know that they have access to services like what the LLS is offering. It can be incredibly difficult for patients to navigate clinicaltrials.gov. And oftentimes, the, the choices are just too daunting, and they don't have the knowledgebase to make those important decisions.

But, one of the things that Peg said that resonated with me is that most of the patients who call her wind up on a clinical trial. And what that tells me is that when patients really educate themselves about the advantages of clinical trials, those are the patients who realize the real advantages.

You had mentioned "Are, are clinical trials safe?" Well, we have many, many safeguards in all clinical trials to make sure that patients are safe on clinical trials. And one frequent question that we get, a concern that many patients have is of being treated quote/unquote "like a guinea pig" on clinical trials. And, and what I take from that is that they're concerned that we're more worried about the science than we are about the patient. And that really couldn't be further from the truth. Even in Phase I clinical trials where we're testing brand new drugs that haven't been tried in humans before, we're already relatively certain that these are safe drugs based on preclinical testing that we've done. And patients are monitored so, so closely on these clinical trials to make sure that the drugs are as safe as we think they're going to be. And if they're not, we have no hesitation about stopping a clinical trial to make sure that we understand a specific side effect that may have come up that we didn't expect. And patients are monitored even more closely on clinical trials than they are during routine clinical care that they get.

You also mentioned patients being concerned that they're going to get a sugar pill. Placebos are rare in cancer clinical trials. When they are used, it's because, we don't think they'll do any harm. So let me give you an example of that.

In a randomized Phase III trial, which is pretty much the only place where you see placebos used in oncology clinical trials, the patient is typically randomized between a new treatment that you think and hope is going to be better than the standard of care or the old treatment or the best standard that we have to offer at the moment. And if that new treatment involves, for instance, treatment with the standard of care plus a new drug, well, it may be necessary to give the patients randomized to the standard of care arm a placebo in addition to the standard of care so that both the, the treating doctors and the patients can't tell whether they're getting the new treatment or the old treatment.

That's scientifically very important because that can introduce bias if you think you're on a new drug or you think you're not on the new drug. And by giving the placebo, we mask whether patients are on the standard of care or the new treatment, but they are always at least getting the standard of care, even if they're in the placebo arm. It's just the standard of care plus the placebo. So we're never leaving patients out to dry with no therapy at all unless there truly is no best standard of care for that disease.

Alicia: So then for those who are part of a trial, are they able to talk to other clinical trial participants about—

Dr. Gerecitano: So that's—

Alicia: -about the progress or about their own, you know, feelings about the trial?

Dr. Gerecitano: Right. So because of privacy rules, their, the ability to get patients in touch with other patients on clinical trials, is a somewhat complicated issue. We at Memorial and you at the LLS have programs that allow patients to connect to each other in ways that still protect their privacy or require them to volunteer to do so just to make sure that we don't reveal anything about a patient that they don't want other patients to know. But assuming that those are in place and we now have a program at Memorial where we particularly try to get patients, who want access to other patients in a clinical trial in touch with those patients, then it's always possible for patients to do so on their own and there are becoming ways that we can help facilitate that.

Peg McCormick: I'm glad that you mentioned that. The Leukemia & Lymphoma Society does have a peer-to-peer program where we can match newly diagnosed patients with patients or caregivers that have been through treatment, similar treatment, same diagnosis so people can talk to each other, that have gone through it. It's a different type of connection when you're talking to somebody that you know has gone through, what you're about to go through. So, I'm glad that you did mention that, and I'm glad that, at Memorial Sloan Kettering you also have programs that can connect patients because patients do want to talk to other patients as well as caregivers. Caregivers, we also have programs for you to talk to another caregiver.

Lizette: Now I know that patients, when they, look at clinical trials, some of the clinical trials, seem to be maybe a little bit long, and patients often wonder, well, what if this treatment doesn't work for me? Do I have to stay on this clinical trial until the end, or can somebody get off of a clinical trial?

Dr. Gerecitano: So, and this is, this is very important, a very important issue as well. One of the reasons, it's important, that you mention that is, that some patients are afraid of going on a clinical trial because they think that they're obligated to see it through to the end or do everything, that's required of the clinical trial in order to go on it.

Oftentimes, the Informed Consent process that we go through, which is designed to make sure that the patient has all the information they need to make an intelligent and informed decision about going on a clinical trial, involves a lot of paperwork. And some of the paperwork that we have to do at Memorial, for instance, involves signing a document in triplicate, that looks like you're closing on a house and makes the patient feel that they're, under legal obligation because they've signed this document in triplicate with the doctor in the room.

Really, what that Informed Consent document does is it's meant as a safeguard to the patient to show that the doctor has done due diligence in explaining all aspects of the

clinical trial to the patient, many of which may be optional so the patient doesn't have to participate in every aspect of the clinical trial in order to, to participate in, in any aspect of the clinical trial.

Even though those documents are signed in triplicate, the patient always has the option to come off a clinical trial at any time, even before they've started after they sign those documents and at any time during the clinical trial if they're concerned about their own safety or if their doctor is concerned about their care.

Clinical trials, as I said earlier, also involve very close follow-up. Sometimes this can be a little bit onerous, even on the patient if they have to make extra trips into the center to be evaluated, but it is all designed to make sure that patient safety comes first. And if at any point there's concern about a patient's disease growing through the clinical trial or an adverse side effect, that, that may make patient safety a concern, we will either evaluate that side effect using additional testing or maybe even move up the, studies that are required to see whether a patient's disease is responding, earlier than it's mandated in the trial.

Most trials will include regular restaging, what we call restaging studies, either CAT scans or PET scans or MRIs or other measurements of disease control to make sure that the patient is responding in a favorable way and that their disease is not growing. And if we detect disease growth that we don't expect, or if we detect any of these side effects that, we think are too onerous for the patient, we will recommend that the patient not continue on the trial. So, the patient always has the choice to come off of their own volition, and if we suspect anything in their care is suboptimal, we will recommend that the patient come off that trial and seek an alternative treatment.

Alicia: Right. And so you mentioned them, you know, patients fearing that they have to stay within a trial. What about if the treatment works? Can they continue using it even after the study?

Dr. Gerecitano: There are different trials that are set up different ways in terms of continuing to use the drug, after a study is completed. Most trials these days, or I should say many trials these days are looking at targeted agents that are given by mouth instead of intravenously. And this is particularly attractive in patients who are trying to run normal lives while they're getting care for their cancer. And many of these trials allow indefinite treatments. So as long as the drug is working you can continue to take it.

Places where patients have questions are what happens if the drug is FDA approved? Am I suddenly going to get a huge bill for taking the drug that I was getting for free as part of a clinical trial? Very frequently patients who are on clinical trials are, I don't want to say rewarded for being on the clinical trial, but it is a, a perk of being on a clinical trial that even after FDA approval many sponsors will allow the patient to continue on trial so that they can continue getting those drugs, for free as if they as if

the drug still wasn't FDA approved. And there are compassionate use programs in place where the patients can sometimes get discounted prices on the drugs if its FDA approved, or in the worst-case scenario, if it's FDA approved, they may need to submit for insurance reimbursement for the drug if the trial has ended. But that's only if the trial ends.

And oftentimes if a clinical trial ends and a drug is FDA approved, patients will be able to apply for, compassionate use programs that may allow them to have a discount on the drug that they were getting as part of a clinical trial once it is FDA approved. And in the worst-case scenarios, if a drug is FDA approved and a trial is stopped, then a patient may still be able to, petition, submit the same treatment to their insurance company for regular coverage of a routine cancer clinical care.

Peg McCormick: To the patients going off treatment within a clinical trial. So, the patients are, are very protected from, continuing on a therapy that is not, helping them or that is, in fact, harming them.

There is another layer of protection other than the treating physician, and that is the, and many trials have a data safety monitoring board that are looking at the general response to that treatment across a number of patients. And if this board feels there is a reason for the trial to be paused or even halted, they will, they will make that happen.

And then, lastly, there's actually a positive reason for a trial to be stopped. If, if this board or if it becomes known that the treatment group is doing incredibly better than the comparator group or the nontreatment group, that trial can be stopped and all the patients would have access to that new and highly effective therapy. That doesn't happen very often, but it's a wonderful reason for a trial to be stopped early.

Lizette: Sure. And, Peg, the doctor did mention, you know, financial reasons. So if if something is stopped, a trial is stopped and, people do need to go to their, their insurance, or they need compassionate use of a, of a medication, would you able, be able to help them and guide them in that process?

Peg McCormick: Yeah, patients often come to us with, financial concerns about medication. Sometimes they're asking or investigating, going onto a trial for financial reasons. They don't have access, to therapies and they're wondering if a clinical trial might be appropriate. So, in that case, we can help them directly.

In the case where they are attempting to pay for a drug, that they have access to within a clinical trial, and their insurance is perhaps not covering that drug, there are many options that the Leukemia & Lymphoma Society can help them with.

I typically send these patients immediately back to our Information Resource Center who are, honestly, have more information about resources for patients needing to

access drugs than any other organization or service that I've come across in my entire career. And I'm, I'm very confident that if there is anything available, it will be found by our IRC.

Dr. Gerecitano: Peg mentioned that, there are data safety monitoring committees that are made up of usually independent people or at least some independent people that can monitor a trial for safety concerns. There are also other layers of safety for patients who are on clinical trials. So, for instance, many clinical trials have either such large patient numbers or involve rare diseases where you'll need to include many, many different centers around the country, sometimes around the world, in order to, bring the trial to patients where they live and have enough participation to answer the questions of the clinical trial.

And in those cases, what usually happens is that there are investigator teleconferences on a regular basis so that all of the investigators who are seeing patients on that clinical trial get together once every week or two weeks or month and talk about their experience with patients on this particular clinical trial so that we can do some group think and come up with observations that we might not have been able to make if we were just dealing with a handful of patients in front of us or trends of toxicities or trends of side effects that we wouldn't have known if we weren't on these regular teleconferences.

And in addition to that, another layer of safety is that every significant or serious side effect that is seen by any one doctor is then sent to all of the other doctors who are participating so that we have a number of eyes on monitoring safety for all of the patients on a given clinical trial and can detect any patterns that we see as quickly as possible.

Alicia: How are patients in the trial told about the results of the trial?

Dr. Gerecitano: So, when patients are participating in clinical trials, if there are significant events that happen in that trial, then that's fed back to the patients in real time while they're on the clinical trial. So, for instance, if a safety signal comes up, if there's a side effect that we realize there's a trend that all patients on the trial need to know about, we'll tell them that in real time while they're on the trial. Or, as Peg said, if an independent review process shows that the trial arm is so much better than the standard of care that we're going to stop the trial early and change the standard of care, then we'll let the know, the patients know that at that time.

Unfortunately, many of the final results of clinical trials come back at some timepoint after the trial is completed and patients may or may not still be, uh, seen on a regular basis as part of that trial at the time those results come in. If results are being presented publicly, patients can always ask their treating doctors while they're on the trial, about that on a regular basis and just say, you know, "If, if you have any updated

information, please share it with me." And, and the treating doctors are usually very excited to share this data so there's, there's no problem with that.

And I've often had patients who are treated by me on clinical trials ask me to send them the final report of the trial after it's done. And some of those I send years later and, and patients are very, still very interested in, in seeing how their participation may have affected the standard of care for their disease.

Alicia: So when a, when a patient finds a clinical trial that's applicable to them, how long do they have to make up their mind about joining the trial?

Dr. Gerecitano: So there're a couple of different, stages or processes that patients go through when they've decided that they found a clinical trial that they're interested in. The first is the Informed Consent process. So sitting down with one of the investigators from the trial and discussing the risks and benefits for being on that trial, the purpose of the trial, what it entails, what are the expenses, are there any conflicts of interest? There is a whole script that the doctor needs to go through to discuss with that patient all aspects of the clinical trial.

If the patient, and then the patient has as long as they want to decide if they want to participate on that clinical trial. Depending on things like how long the trial will be running, when, slots open on the clinical trial, those may determine a different timeline, but in general patients have the luxury of time, as long as their disease allows and their doctor thinks it's safe to think about going on a clinical trial.

Once the patient has decided that they want to go on a clinical trial, the first step is usually in signing that Informed Consent document saying that they have been educated, uh, to their satisfaction, about the, pros and cons of going on the clinical trial. And that document usually has some sort of, expiration date, which is usually around a month or so. So once the document is signed, we have usually about a month to undergo the formal screening process to make sure that the patient meets all eligibility criteria for that clinical trial, and has all of the workup that needs to be done before they start on the clinical trial.

If it takes longer than a month, it sometimes may be necessary to repeat that Informed Consent process, sign those documents again, but in general, that's not usually an issue. Once a patient decides that they're interested in a clinical trial, things can usually move relatively rapidly to get them enrolled and started.

Lizette: Where are clinical trials held? Are they only held in major cities?

Dr. Gerecitano: Different clinical trials are handled different ways. Some are only available at major cancer centers. Some are rolled out to community practices as well as major cancer centers. Many are multi-institutional so, there are centers that can handle patients from different regions of the country.

At Memorial Sloan Kettering, one of the things that we're trying to do is open our clinical trials at our satellites that are closer to where our patients live or at our alliance sites that are in Miami and Pennsylvania and Connecticut and coming in other areas as well. Clinicaltrials.gov is, is the best tool I know of to find out everywhere where a specific clinical trial exists. And having people who can help you navigate through clinicaltrials.gov is a, is a huge asset.

One of the things to mention is that, one constant challenge of clinical trials is knowing what's available and when it's available. So at our own center, we have more than 100 clinical trials at any given time open for just our patients with lymphoma. Throughout the whole center, there are probably thousands of clinical trials that are available at any given time. And those trials are constantly opening and closing or, spots are becoming available or, or unavailable. And just keeping on top of what's available at our own center is often a daunting task, and we, unfortunately, can't keep patients abreast of what's available at all other centers that deal with lymphoma. So having navigators that can help them navigate through the clinicaltrials.gov, website or other resources is, is really incredibly valuable for patients.

Peg McCormick: I would, I would so agree with everything you said. It is challenging for clinicaltrials.gov, actually, to keep up on the openings and the closings of trials. And the research, coordinators change, very frequently. Their telephone numbers change very frequently. And patients who are looking for trials, they're, they're sick. They're not feeling well. It's very difficult for them to, to navigate this on their own.

So we have the benefit, I will say Memorial Sloan Kettering is one of the centers that immediately answers our call and will give us information about openings on their trials. And we so appreciate that information because that can help guide, help us guide patients to either Sloan Kettering or another setting that has a trial that is open for them.

We do keep track of all of our outreaches to different centers and different, and different sites. We don't have perfect information, but we probably have information that's a little more updated than clinicaltrials.gov. It, it's, I would say it's such a team effort with the sites and with LLS and patients feed us back information. It really works very well as a communication network.

Lizette: And, Peg, you've assisted patients in getting to a trial that's not physically close to them, correct? We've helped them.

Peg McCormick: Yes. We absolutely have. It's, it's often the, the- It's kind of a puzzle I would say to put together to say, to help a patient get from point A to point B starting with what support systems does that patient have to travel? Honestly, there are some patients that, that simply don't have that support system and we look very, diligently for trials that are around them.

But if they can travel and they don't have the finances to travel, we can often ask the sponsor of the trial, uh, if they have included that in their financial documents. Sometimes even the trial site isn't aware that that information or that help is available to patients. So we can access it through the sponsor. Often the site themselves have free housing or greatly reduced housing that they offer for patients entering trials in their sites. And then there's a, a number of organizations, including the Leukemia & Lymphoma Society, that offer travel assistance for patients accessing treatment, not only under clinical trials.

It's, it, we don't find resources 100% of the time, but we find resources for them a great percentage of the time.

Alicia: Who's on the clinical trial team?

Dr. Gerecitano: The clinical trial team is composed of different members and different centers run them differently. Different trials are run differently; but generally, there is a principal investigator that is appointed at each institution where the trial is run, sometimes several principal investigators and several sub-investigators, who participate in the trial. And those are usually the doctors who are caring for the patients.

At most centers, there are also research study assistants or research study coordinators that help keep track of the scheduling that needs to be done for patients, the data that's coming in about patients and reporting that data to the sponsor of the trial, whether that's the institution itself or whether it's a, a pharmaceutical company who is donating the drug for the clinical trial. And then oftentimes there's a clinical trial nurse who's assigned to a clinical trial that can also help with patient care and patient questions who are on those clinical trials.

Peg McCormick: And I would add to that that LLS Clinical Trial Support Center is a part of your team that you may not have even known existed. That we're supporting, practices and physicians and patients by educating patients about clinical trials in general and about specific trials that are open and available and guiding patients to those principal investigators or centers to get additional information about the trials.

Dr. Gerecitano: There is one thing I wanted to address. One concern that we sometimes get from patients is that they believe that clinical trials are a treatment of last resort and that they're only used when all other treatments have failed. And this is not true for most patients, and this is one of the things that I find myself most often or most frequently reeducating patients about.

Oftentimes patients will come to me and ask about clinical trials and say, "Well, you know, don't I really need to try all the chemotherapy that's out there before I go on a clinical trial, because I know there's a very effective chemotherapy for my, for my disease?" And what I'll often tell those patients is that, yes, there, there may be a very

effective chemotherapy; and we know the side effects of that chemotherapy, but there may be a clinical trial for you that could potentially carry less severe side effects or less risk for you. And if that clinical trial works, it may hold off on the need to undergo a, a chemotherapy whose toxicity we already know. So maybe, in your case, it would make sense to hold that chemotherapy or that approved therapy in our back pocket, and we can always use it if the clinical trial doesn't work. But the clinical trial may give you a treatment option that you might not have otherwise had and that may be in your interest to explore.

Peg McCormick: I'm so glad you added that. That, that question was actually something I had jotted down that I wanted to comment on. If I could waive a magic wand and eliminate the words, "There's nothing more I can do for you," from a provider's, uh, uh, lexicon I would. What patient, patients often come to us and say, "My doctor told me there's nothing more to do. I have to look at clinical trials." And it, it will take a while for us to turn that perception around to a level of actual excitement for them that now that they have tried a couple of treatments, they're eligible for clinical trials. There's a lot that can be done. There's rarely nothing to do.

Sometimes that is the case, and we help that with that phase of their treatment as well, but very frequently, and I would say most frequently, there is something to do. And clinical trials are not a treatment of last resort, so thank you, doctor, for, for pointing that out.

Dr. Gerecitano: One thing I just have a, a story that resonates with me from one of my patients who came from six hours away from our center for a Phase I clinical trial after his doctor had told him just that, that there were no other treatments. And he offered him a nice home hospice, but this guy was running marathons at the time and didn't want to go into hospice.

So he, he came to us and we had a clinical trial to offer him. And he would board a bus at 1:00 on the mornings that he had to be in the center, 1:00 in the morning, and, uh, be at our center promptly at 7:00 in the morning for his treatment on the days that he needed to come. And this clinical trial that he was on used an oral drug with minimal side effects, and he was on that drug for two years before his disease began to progress. He did, he ran I think three triathlons in those two years, spent some—

Lizette: Wow!

Dr. Gerecitano: -real quality time with his family. And at the end of the two years when the trial drug stopped working, he was now in better shape to be able to tolerate some of the approved therapies that he wasn't eligible before he started the trial, so he extended his life even beyond those two years and was just so grateful to have those extra years with his family and to do some of the things that he wanted to do.

Alicia: Wow! That's incredible. That is incredible.

Lizette: And I think that's what we have to start telling people because, patients aren't even starting the conversations with their physicians because they don't know that this is an option for them, and they don't know how hopeful an option it is for them.

Alicia: And there's so many facets to clinical trials. I mean on this podcast alone I learned so much. And I'm excited for those listening so that they can actually leave with confidence in the information that clinical trials have the potential to, you know, to give to them and the treatment that it can offer to them as well.

Dr. Gerecitano: Thank you to the LLS for having such an informative program available to your patients and for the support that you offer. We often refer patients to the LLS for, the many, many resources that you offer.

One thing to just remember about clinical trials is that every approved therapy that we have in the modern era of medicine started out as a clinical trial. This is the way that we advance the standard of care, but it's not just about advancing the care for other people. These are also often very effective tools for the individual patient to help them deal with their disease, give them more options for treatment for their disease, and often minimize the side effects, which is the focus of many of our clinical trials.

Peg McCormick: And I would like to tell patients that they're not alone. They do not have to navigate this very complex, world of clinical trials alone. They could certainly speak with their healthcare provider. They can attempt to find clinical trials on their own. And if, if they run into any difficulty or want support in navigation, they can call the Leukemia & Lymphoma Society Information Resource Center and they will direct them to our department.