Clinical Trials: A Guide for Patients & Caregivers
Webinar – October 12, 2023

Kevin Radelet:

At this time, I'd like to introduce you to our expert speaker today, Dr. Karen Carlson. Dr. Carlson is an associate professor of medicine at the Medical College of Wisconsin in the division of Hematology and Oncology, where she is the section head and medical director for acute care oncology. She specializes in acute and chronic myeloid leukemias, MDS, and MPNs. And in addition to her clinical roles, Dr. Carlson is passionate about both patient and trainee education.

She serves as a associate program director for the medical residents at MCW, and has also been a member of the Leukemia Research Foundation's Medical Advisory Board. Dr. Carlson, welcome and thank you for joining us today.

Dr. Karen Carlson:

Kevin, thanks so much for the invitation. I love talking with patients and families, and trying to teach people as much as I can about their disease and opportunities for treatment.

So my goal is to make it through a slide deck about clinical trials. They're a really important component of the clinical care of people with a diagnosis of leukemia. And then, I'll work our way through some of the submitted questions as best as I can. And so with that, I'm going to steal the screen and put my slides up and get started. Let's see. All right. How does this look to everyone?

Kevin Radelet:

Looks good.

Dr. Karen Carlson:

And my closed captions are back on again. Sorry about that. Let me find where to turn that off. Sorry, one more moment. There we go. All right. So thanks again for inviting me to talk about what it's like to participate in a clinical trial.

So the first question is, what are clinical trials? Why do we do them? What do we gain from participating in them? Essentially, they are research. The goals of the research can be to learn about the disease itself. So these are very mechanistic trials, trying to understand the biology or the science behind the disease. What is potential outcomes of the disease? How does it impact people's lives? How can we intervene and stop a specific disease or circumstance?

We may have pilot or feasibility endpoints, or even exploratory or developmental endpoint. So we may be very early in testing a potential treatment, and we may be in later stages.

The NIH or the National Institutes of Health says or defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to a treatment intervention in order to evaluate the effects of that intervention on health related biomedical or behavioral outcomes. It's kind of a mouthful. But essentially, at the root of it means it's research that involves people.

Just briefly, do I have any conflicts of interest? No, no formal conflicts of interest to disclose. But I will share that I do regularly offer clinical trial participation to my personal patients. I'm at an academic institution, and I strongly believe, as do all my colleagues, that if we can't offer a low side effect, 100% efficacious treatment to every person we take care of... And frankly, we can't really do that for any disease at this point, that really we owe it to our patients to try to advance treatments so that we get to the outcomes that we want for all of our patients and that our patients want.

In thinking about this talk, I try to think about what are some of the terms that us on the physician and treating side maybe take for granted, but can be a little bit confusing if you're not living within this world? And one of those sets of terminology involves the phase of a clinical trial. If a treating physician, or physician assistant or nurse offers a clinical trial to someone, you may see in the title it says it's a phase 1, phase 2, or phase 3 clinical trial.

And the question is, what does that mean? And each of those phases encodes very specific information that's useful, as you start thinking about whether a trial is right for you.

So a phase 1 clinical trial really means that it's being tested. It's very early in its testing. So it may be the first step in testing the medication or the intervention, whatever it is, in people. It's often designed to test safety and side effects while reaching the best dose. It may also test timing in which a treatment is given.

Phase 1 clinical trials, the number of participants is usually quite limited, and often they're done in a very slow step of both dose. The goal is to not cause harm to anyone. The goal is to find what is the dose at which we can safely deliver a medication, and perhaps learn what are some of the actual potential side effects that we need to share as we develop further, a clinical medication or intervention.

The next phase is a phase 2 clinical trial, and that's really designed to test whether a treatment works for a specific disease. So these are really the tests where perhaps, we found what seems to be the maximum safe dose of a medicine. And now, we're going to make it available to more clinical trial participants.

And there's a lot of data that will be collected about people in really every phase of a clinical trial, but the goal is to find out how common or uncommon are side effects, and then to start getting some information about whether or not we see response of a specific disease to its treatment.

Phase 3 clinical trials are typically the last phase before a medication or an intervention is evaluated by the FDA for formal approval. Often, these trials involve a large number of participants. And often, these are the trials you see where there is some sort of randomization between the study intervention, or the new medicine or new treatment that's being tested, and whatever the other standard of care might be. Most trials move to phase 3 only after they've gone through phases 1 and 2. And these trials also often include a large number of participants.

So since clinical trials are trials or research that involve people, as you can imagine, there's a lot of regulations and safety checks involved to do this research as safely as possible for the people participating in it.

There's really three main bodies that I want you to be aware of, that really are watching out for participant safety, in pretty much every clinical trial to some degree. And these are the FDA, something called an IRB, and something called a DSMB. And the goal of these is a clinical trial that's done with good clinical practice. And in the next couple slides, we're going to talk a little bit about each of these, so you know what the abbreviations stand for and how they're looking out for participants in clinical trials.

So the FDA is a body that's a little bit more familiar to most people. It's the Food and Drug Administration. It's an agency of the US federal government, and its mission is to protect public health by making sure that medicines, medical devices, and equipment are safe and effective. So it has to be safe and it has to do what the company providing that treatment says it does. It's also the group that ensures food, cosmetics, and attritional supplements are labeled safely and truthfully. So the FDA does have a role in approving early clinical trials of non already FDA approved medications.

The next group that will be involved in oversight to a clinical trial is an Institutional Review Board. And this is a group that probably has a little bit more day-to-day oversight. And it's a group of scientists. Typically, scientists, doctors, there may be clergy, and there's patient advocates as well, so non-medical individuals, that review and ultimately approve or not a detailed plan for a clinical trial.

IRBs are meant to protect the people who take part in a clinical trial. That is their goal. And every single trial that involves human subjects or people is reviewed by an IRB before it begins. And once a clinical trial is underway, there are regular periods at which a trial is reviewed, and any safety events or things that happened that might've been surprising are required to be reported back to the Institutional Review Board for ongoing review.

And then finally, there's a Data and Safety Monitoring Board, and this is a third group of individuals, and they oversee a clinical trial and review the results to see if they're acceptable. This group really is there to help determine whether a trial should continue, should be changed, or is closed. So they along with the investigators, are continually reviewing the results, any unexpected side effects or toxicities, and making a plan for what to do moving forward with this clinical trial.

And as I alluded to, the goal is good clinical practice. And this kind of makes intuitive sense, but it's actually a phrase that has a very specific meaning when we're talking

about clinical trials. And this good clinical practice is actually a formalized set of guidelines, international guidelines, that all clinical trials adhere to make sure that the results are reliable and that patients are protected. And it's really wide-ranging. Covers how they're designed, conducted, performed, monitored, audited, recorded, and analyzed.

So there's a lot of layers of oversight. And again, they're really designed to make sure that participants are protected, and that participants' effort in participating in a clinical trial, it's done well. And what we learn from the trial is then broadly applicable.

As you can imagine, there's been a lot of work to try and understand what is the right way to hold a clinical trial, what is the right way to have people participate in clinical research. And really, the best and guiding principles for this are contained in something called the Belmont Report. It was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, actually back in 1976. So you can imagine a lot has evolved and developed in the field of ethics and clinical trials since then.

But its main principles really remain in place today. And this is really respect of person, so respect of the people who are considering or actually participating in a clinical trial, beneficence, and justice. So doing the right thing, and giving people autonomy and the ability to make their own decisions about participating in the trial.

It's the basis for what is called the Common Rule and the revisions of the Common Rule. And this is the federal policy that protects participants in clinical research.

So why go through all of this? It seems like a lot of oversight and regulation, and a lot of concern about safety and how to do things the right way. Do we really need this?

Well, just taking a quick look at how the treatment of acute myeloid leukemia has changed in the last we'll say 50 plus years, through clinical trials, we've really gone from what some of you may have heard of as 7+3 induction, which is a combination of cytarabine and daunorubicin, which was first administered back in the 1970s, all the way through the first bone marrow transplant, and then to approval and actually withdraw of an AML drug that was subsequently returned. All of this based on safety data and clinical trial data, and then the approval of several other new treatments.

To where we are now, where frankly many of you will be aware that 7+3 remains a backbone of very intensive AML therapy. But now, we have a lot of very targeted, molecularly targeted treatments that we can use, and even a highly efficacious doublet that is a little bit lower intensity treatment as well for AML.

And all of this is because of clinical trials. And obviously, there's a lot going on in clinical trials for AML currently, and it's exciting to see what options we'll have available because of clinical trials in the future.

So what is the process for enrolling in a clinical trial? So first off, the disease that is being treated needs to be diagnosed. If there are available clinical trials at the institution at which a person is being treated or within an area that a person can reasonably gain treatment access, the trial needs to be identified. Often, there's a preliminary screening that happens, and it's really based on available clinical information. There are typically a list of inclusion and exclusion criteria that have to do with a potential participant's general overall health and potential specific risks individualized to the patient.

If a patient or a potential participant is someone who could consider a specific clinical trial, then there's a discussion between the patient and their treating physician about whether the clinical trial is the right option for them, and then something that we call a discussion of informed consent, which really is explaining what to expect during the clinical trial. And what are the risks and benefits of participating.

In general terms, what's involved in participating in a clinical trial? So before the treatment of the trial actually starts, there's likely to be some additional studies that have to happen before a person is officially enrolled in a clinical trial.

This means sometimes, people may consent to participate in a clinical trial. But after these post-enrollment studies are done, it may be that your doctor identifies something in them that makes it clear that this clinical trial isn't the right thing for you. And so some people may consent, but may ultimately not be eligible for a particular clinical trial.

Afterwards, a clinical research coordinator and a clinical research nurse will end up working with the participant and their doctor, and make sure that all the safety protocols are followed, and then work through the process of the clinical trial with the team. Continued participation in the trial will be reviewed regularly by the participant and by their doctor.

What may participants in a clinical trial need to do? It's very specific to the clinical trial, but things to be aware of, you may need to have a complete history and physical exam, completed by someone who is considered a study doctor. You may need to have additional blood or bone marrow tests done, additional heart function tests. Some trials ask about patient experience, so you may need to fill out a journal or a symptom diary as you move through the trial, so that the people overseeing the trial know what your experience was.

And then a big one to be aware of. You may need to spend some additional time at the treating hospital or clinic, for visits specifically associated with the study. And that really plays into the factors that someone should consider when they're trying to decide whether to participate in a clinical trial.

So what we talked about at the very beginning, what phase is the trial, and what is the goal of the clinical trial? Where is the clinical trial being offered? It seems wonderful to say, "Hey, there's this great clinical trial and it's being offered in a city six hours away from me. I'll go and I'll be in that trial."

So that's wonderful, and it may be the right thing for a participant. But it may also mean that that participant is away from their family and a social support system for many weeks, if not months, or would require regular travel back and forth to the trial site. And so this is something you really want to think about as you're considering a clinical trial.

Also think about personal goals and motivation for participating in a trial. Some people will participate in a clinical trial for very altruistic reasons. "I want to help support research." If this clinical trial is asking for an extra sample of my bone marrow and it will help future researchers design all new treatments, great, this is wonderful. Some people are participating in clinical trials because they are looking for additional treatment options for their disease. Wonderful. These are all valid reasons, and sometimes they overlap.

And so you just want to be really clear about what your motivation is, and that'll help you decide whether a specific trial is right for you. And then obviously, time available and necessary to participate in the trial.

What I just alluded to, some trials will ask about the ability to collect, and retain, and then study blood and bone marrow or clinical data as part of a bank for future research. And you just need to start thinking about whether that's something that you're comfortable with.

A lot of people find it very satisfying. They're contributing to research, and development in the treatment of future people with their disease. But there's certain risks and benefits as well that comes from that.

Something else you may hear about as you work through the trial consent with your treating doctor is something called the Genetic Non-Discrimination Act. And for some clinical trials, they will ask to do very specific genetic research on your blood or bone marrow samples. It's often to help them understand why a specific treatment worked or didn't work. Was there something in your DNA or genetic material that made that highly likely? But then there's risks to having your DNA sequenced and studies as well. And so this federal rule covers those risks. And so, something to ask your treating physician about.

What other questions should you ask? Well, the biggie, what are the risks to participation? What are the potential side effects of treatment or study related procedures? Are there any potential risks to privacy or any financial risks to participating?

And then the flip side, what are the benefits? Is it personal benefit, is it altruistic, or is it a little bit of both? And then what are the time commitments, and what should you expect to experience by participation? Will you need to be hospitalized? Is this something that can be done in clinic as an outpatient? And for how long are you in the trial? And what if you want to leave the trial? How does that work?

So how do you find out information about clinical trials? So the biggest registration of clinical trials in the US is through clinicaltrials.gov. This is the website. I'll say it's an exhaustive list of clinical trials, and you can find out a lot of information in terms, you can search by disease. Sometimes you can add in some additional text characterizations of the clinical trial that you're looking for, and you can pull out completed trials, current trials, about to be activated trials, you name it. I'll say it's a pretty dense website, but there is a lot of information there.

And then you'll see in a little bit, this wonderful website that the Leukemia Research Foundation has open, Clinical Trials Leukemia Research Foundation. And this is the website, and it's a very user-friendly interface for clinical trials specifically related to leukemia.

Just a brief overview of how patient care and treatment for AML or other leukemias can be improved by participating in clinical trials. So obviously, addition of general knowledge about AML. Remember, some of what was experimental years ago is now part of our standard of care. That timeline I showed you.

Although not specific to a clinical trial, you may find that you're a participant in a patient advocacy group. I know we have several of them in our area. And you may find that you've participated in a clinical trial, and you may be sitting next to someone who's considering doing the same, and you may be able to give some advice about what your experience was. So you may become a peer resource for other individuals.

Something else I'd encourage you to consider, every institution that has clinical trials in some way has an Institutional Review Board overseeing the trial. And as you move through your health journey, you may find that you're in a position to consider taking on one of those patient advocate roles on a local IRB. And I encourage you to do that. It's really actually quite empowering and reassuring to see how hard the IRBs work to make sure that they're advocating for patients and safe care of patients within the context of clinical trials. So something else to consider.

As we're nearing the end of this, before we start taking questions, just a few other topics. If you have gone through a clinical trial or a group is performing a clinical trial, obviously the goal is to improve healthcare for people who maybe aren't in the clinical trial but could benefit from the knowledge that's gained from one of these trials.

How do we share knowledge? That's a really big part of a clinical trial. You'd sure hate to have people continuing to repeat the same clinical trial over and over, doing research to which we already know the answers.

So first off, in cancer, there's actually these clinical trial collaboration groups. They're cooperative groups. They include US, and actually international clinicians, that basically get together to try to decide what do we think might be the next best thing to improve treatment of people with a certain disease. And then these large groups of experts get

together to design a clinical trial, and then revise and review until it's ready to go. And then obviously as these trials are completed, these groups share the information amongst themselves, and by other meetings and publications.

There are multi-institutional trials. So several institutions may get together to ask a certain experimental question or treatment question. And then there are also company sponsored trials that may also be offered through multiple institutions.

I'm part of an academic institution, and so we certainly do our own research. But at some point, we really do rely on companies to help invest in a treatment and to help make it through the final hurdles of clinical trials, to see if it's the right thing to really offer people as a new standard of care treatment.

Data sharing is a big deal. So clinical trial results are shared at our national meetings. We have the American Society of Hematology coming up in December, and a large number of us attend. And we attend so that we can actually learn what the latest results of clinical trials are. What were the things that worked, what are the things that didn't work, and how should we be changing our clinical practice based on the results? And then a lot of results are published in peer reviewed manuscripts, and this data becomes publicly accessible.

All right, with that, I'll wrap up. I'd first and foremost like to thank my patients and their families. They're incredibly important to me, and I know to everyone I work with. I'd like to thank the Leukemia Research Foundation, and then my home institution, the Medical College of Wisconsin in Milwaukee.

And with that, we'll move on to questions, and I'm going to stop sharing, and I'll refer to the file of questions that I have. And then I'll try and keep a tab on the, I guess webinar chat and maybe Q&A. And Kevin, if you want to speak up, if I'm missing something that comes through, that would be great too.

Kevin Radelet:

Okay, great.

Dr. Karen Carlson:

So the first set of questions were kind of general questions, kind of about leukemias in general and cancer treatment in general. How do I make sure my hematologist is highly knowledgeable in my cancer type? And that question in several versions was actually asked throughout the questions that were submitted.

So I would say first off, ask them. I think you would be pleasantly surprised how transparent most of us are willing to be. None of us want to be acting outside of the scope in which we're comfortable practicing. And if someone were to ask me to treat their heart disease, I certainly would be very comfortable saying, "Well that's not my expertise, but I have a colleague who I'd like to refer you to."

And within the world of hematology and oncology, it's the same thing. You'll find a lot of oncologists, we talk together as a group, even amongst leukemia experts. And general oncologists will often refer people to a specialty group, so they have specialty in leukemia or whatever the malignancy is, for second opinion, sometimes for treatment management. And often, we share care of patients based on our level of expertise.

I see some questions about, how do I discuss clinical participation with my oncologist? Hopefully I gave you some tools in this talk. But I would say to begin with, just be really transparent that you're interested in clinical trial options, and are there any at the moment? Be prepared to hear whether there's clinical trial options at the place where you're being treated, or clinical opportunities at nearby treatment areas or treatment institutions. But just ask your doctor.

Also, you can use the Leukemia Research Foundation website or clinicaltrials.gov and see what's available. I'm sure your treating oncologists will also be using these resources, or their local intra institutional clinical trial management resources to make sure they're continuously looking for options for you.

Another question that I really liked was, when participating in clinical trials, can you request that the results of a clinical trial be sent to you? It really depends on the clinical trial. So for a lot of trials, actually, if new information arises that would change someone's decision, or could potentially change someone's decision about participating in a clinical trial, we're actually required to revise the consent form and discuss those results with patients who are currently involved. The IRBs are often quite involved in making these

recommendations to the clinical trial groups. So there's probably someone behind the scenes deciding whether there's something you have to know about.

In terms of results, again, there's national meetings and things where their data is presented. And you can ask your treating provider what information they have as updates that they've gathered from some of these meetings.

In terms of genetic data, if your trial involves DNA testing, genetic screening, it'll often specify whether that data will be passed back to you or not. It's a little specific to each clinical trial, and I'd urge you to ask that as part of the consent process as you're looking at a clinical trial option.

Another general question I saw, "At what point does someone consider a clinical trial?" I would say you can consider a clinical trial at any point in your treatment. Again, some clinical trials really involve collection of an extra tube of blood or an extra teaspoon or tablespoon of bone marrow sample. And that's appropriate at any point in treatment, if that's something that you feel is meaningful to you and something that you're comfortable providing.

I'll say, clinical trials that are set for initial treatment often are ones that we're looking at at later stages, or later phases of clinical trials. And I would say just talk to your doctor to see if a certain clinical trial makes sense.

And then another question, if I'm doing well and my disease is stable, but a clinical trial becomes available where the drug or the dose could be changed, should I do that?

I think that's a very individualized question and answer. I can envision circumstances where that might be the right choice, and I can envision circumstances where it may not be the right choice.

For instance, in CML, some of the recent clinical trials have involved potentially stopping CML treatment for people who are doing incredibly well and have been doing incredibly well on their treatment for several years. In that instance, you may say, "Wow, I sure would really like to not be on my CML drug anymore, but I'd like to know that I'm off of this drug safely. And if my information can help other people decide if they can safely stop drug, I'd be happy to participate in that."

And so that's an instance where you may be doing well and have stable disease, and you may want to be in a clinical trial where the drug or dose might be changed. But obviously, I can think of some instances where that might not be your personal choice as well. Again, I urge you to discuss it with your treating cancer doctor. They have your best interest at heart, and bring your family into the discussion as well. They'll know you well, and kind of be a good sounding board as you're thinking your way through this, family and friends.

I did see a group of questions specific to CMML, including a comment that maybe we haven't addressed CMML as much in some of our Q&A sessions that we had earlier last winter.

So are there CMML trials and research going on? Absolutely. It's a very important area of research, especially since it's such a relatively uncommon disease. Something that is a little unique to CMML and maybe a little confusing is that it used to be classified as a type of myelodysplastic syndrome. And so people with CMML have been involved in clinical trials and research for decades honestly, but they were often included in clinical trials for a disease with a different name.

So there are clinical trials, there is a lot of clinical research going on for CMML. Again, I'm going to sound like a broken record, but ask your doctor. But definitely, there is a lot of research ongoing. And at several institutions, there are very specific targeted trials directed towards CMML, just like there are for other leukemias.

Lots of questions about CLL clinical trials, some asking about very specific treatment options. Some asking, well, I think a lot of people with CLL find that they're in this watch and wait period where they know they have CLL, but their doctor has told them... And I've had this conversation with many of my own patients, "Right now, your disease doesn't need to be treated. And we have some older data that treating early isn't beneficial, so we're going to wait for these very specific criteria before we start treatment." Some people asked, "Well, if I'm in this watch and wait mode, are there clinical trials for me?"

So actually, there are. Again, the location varies, but there is a very large trial going on right now actually looking at whether or not the watch and wait approach is the right thing, now that we have a wealth of new treatment options that come with a different set

of side effects and risks to them than the older treatments that were included in some of the original data that led to the watch and wait approach.

So we don't know the answer to what the right thing is, but you may find that you're nearby one of these clinical trial places. And if so, you might want to consider that.

And then other questions. Trying to kind of wade through, and also see if there's any coming in from our participants right now. Feel free to add in, if you'd like, to the chat.

I think I saw a few questions maybe alluding to the risk of Evusheld trial, or treatment, or preventative strategies for Covid for people with CLL or other blood cancers. And I would say what's hard about that and why you may find your treating institutions saying to follow FDA guidance, as the virus has evolved, some of the monoclonal antibodies or things like Evusheld, their efficacy has changed. They're really targeted at specific strains, and so the availability of these monoclonal antibodies may change.

So back when Evusheld was the thing we were recommending, there was some benefit for people with leukemias, and keep tabs on that with your treating facility. It's a changing landscape. And then a few other questions. I don't know, Kevin, are there some that you want to make sure we highlight as well?

Kevin Radelet:

One question that we saw a couple times was the role that age might play in it.

Dr. Karen Carlson:

Yes. So age can be a factor. It's a factor in how we select treatments. And with age comes a lot of different potential comorbidities. Comorbidities meaning other medical issues that may make a specific treatment higher risk for you than others. And often, clinical trials will set age limits for who can participate.

Now where we see this most often is actually in the younger age limit. There are very specific and additional safety requirements for enrolling children and infants. And so you will more often see age limits. And actually, the consent process is different for people who are not considered adults as well. It's something we call assent or we have a parent providing consent on behalf of their child. And obviously, whether someone's a baby versus a teenager has a big difference on how that consent process is included. Some trials will have an upper age limit, some won't.

Kevin Radelet:

Okay. There is one that was just shared through Zoom. As a patient, where can you go to see the results of clinical trials? And tips in navigating this process before making a treatment decision after participation in a trial.

Dr. Karen Carlson:

I love this question. So the hard answer is that if it's a clinical trial, we truly don't know the answer. It's unethical to perform a clinical trial in which we know the answer.

So the hard answer is you probably can't find out what the efficacy of a treatment is in a clinical trial, because no one probably knows at that moment. If we knew, it would either be standard of care, or would be something that we knew we shouldn't offer as a treatment.

Kevin Radelet:

Interesting.

Dr. Karen Carlson:

That being said, maybe you're looking at a phase 2 clinical trial. So one where maybe we've found what we think is the best dose, the highest, safest dose. You can ask, "Hey, do you know in the earlier phases of the trial, so in the phase 1 aspect of the trial, did anyone have a good disease response to the medication? What were the side effects participants experienced?" And actually, the person who's providing consent will probably have something we call an investigator brochure that has a lot of that data compiled for them. So they may have some early inkling in terms of what other people experienced from a side effect perspective.

Asking efficacy, which is of course what I want to know as someone's doctor and what you all want to know as a potential participant, you're welcome to ask. It's just something we're probably not going to know. And it's even hard to know looking back to earlier phases, because the phase 1's tend to be ones where we're slowly escalating the treatment dose in a safe way as possible. Some people may have been at a very low

dose, and saying that their disease did or didn't respond is really hard to interpret, just based on that upwards titration of doses.

Yeah. So tips for navigating. Just really have a frank discussion with the person doing the consent discussion with you. They're equipped with that information. And if they're not equipped, they know how to find the people that have that information to share it with you.

Kevin Radelet:

Okay. The Q&A is still open.

Dr. Karen Carlson:

All right.

Kevin Radelet:

But your presentation was phenomenal I thought, Dr. Carlson. You gave a great guide to clinical trials with an overview and summary that touched on the phases, the regulations, the ethical report, which I was not aware of myself. Why they're important, participation factors to consider, questions to ask. And one of the other things you touched on is to find out about clinical trials, and where to go to find out. And you mentioned clinicaltrials.gov. And what I would like to do is to show on my screen if I can figure it out... Is that up there?

Dr. Karen Carlson:

It looks great.

Kevin Radelet:

When you go to the **Leukemia Research Foundation website (**www.leukemiarf.org) , you'll see up top here that there are dropdowns, and we're just rolling out today the Clinical Trials hub that we're very proud to offer. And you can navigate through this, and it tells you how do they work, the myths, is a trial right for you, diversity. I just lost it. Finding clinical trials.

And then we have an online search tool that we're very proud to introduce. And you can go through this, and it'll ask you step-by-step questions so that you can find where there might be a clinical trial near you.

As Dr. Carlson mentioned, clinicaltrials.gov is wonderful, and it is very dense. It's enormous. These are specific to leukemia. We're not sure if there's anything else like this quite honestly. We don't really care. But we do care in hoping to provide this service for the patients and their families so that they can learn more. There's things that you can print out, PDFs and that type of thing, that you can take with you when you are talking with your doctor. And we're just very excited about that. So please just go to leukemiarf.org, and all that information will be available to you there.

Now we did record today's session with Dr. Carlson, and that's going to be sent out to everybody who registered. And then it's also going to be posted on our website here within the next couple of days. So you'll be getting that.

And again, we just urge you to come back and to check out and spend some time on this Clinical Trials hub, and you'll find out all kinds of information that'll prove very helpful. We do have one last question here, doctor, if you can see it. But there is, is there any clinical trials going on for RUNX1 mutation?

Dr. Karen Carlson:

Yeah, for RUNX1 mutation. So I have to say, as I saw that pop in, I went over to... And I'll have to say just because I'm not yet as familiar with the Leukemia Research Foundation site, I popped over to clinicaltrials.gov and searched RUNX1. And it looks like there is a clinical trial recruiting out of Houston, Texas for a combination treatment for relapsed or refractory AML or MDS harboring mutant RUNX1.

So there are clinical trials available for a lot of different specific subtypes of leukemias, a lot of points in people's disease process. Really, if you work within either the Leukemia Research Foundation's website or clinicaltrials.gov, but I suspect the Leukemia Research Foundation's is going to be a lot more user-friendly. So I'd encourage you to go there first. And type in key disease characteristics like RUNX1 as your target thing to start with, and you'll be able to find what is actively available. And you want to make sure it says actively recruiting, not completed, or on pause, or on hold.

And then obviously the things we talked about already this afternoon. Is it in the right location? Is it at the right point of treatment for you? Do the goals of the trial really make sense for you? And where you are in the process of your disease.

Kevin Radelet:

Looks like another one might've come in.

Dr. Karen Carlson:

"I'm in [inaudible 00:50:27] clinical trial and was not able to reach remission due to CLL complex genetics. Is there a clinical trial who can see more deeply into my genetics and obtain better responses?" So there's actually a lot of clinical trial work going on in CLL. And you hit upon a really important topic, which is this idea of residual disease or minimal residual disease after initial treatment.

So there definitely are clinical trials looking at these sorts of things. And the CLL clinical area is really... There's quite a few options there, either clinical trial or even standard of care. So absolutely, and I'd encourage you to work with your hematologist to see what might be the next right thing for you.

In terms of deletion 5q and 7. So some of the complex DNA changes that often I think of associated with MDS and AML. There are definitely clinical trials. Whether you find something that is specific to your particular disease's cytogenetics, or DNA, or more to your disease and status of disease. Absolutely, there are a lot of options out there. Again, it really depends on your disease status, other factors about your health. And you can certainly work within the Leukemia Research Foundation and clinicaltrials.gov to see what's available to you.

But I'd also say don't underestimate your treating oncologist or hematologist as a resource. They will often have a lot of information about what is available locally to you, and be able to guide you in some pretty good directions. And then a great question, I guess this one's for Kevin.

Kevin Radelet:

Yes. When we follow up, we're going to send you the PowerPoint, the recording, and also a link to the Clinical Trials hub that we're so excited about. We're kind of giddy about it. We're so excited to be able to offer that starting today. So you'll get that all within the next couple days.

Dr. Karen Carlson:

Awesome. One of the participants asked, are the clinical trials updated on the LRF website?

Kevin Radelet:

Yes. It's real time, through the tool that I showed earlier. When you get down to the search tool, it's live. Once you get into it and you fill out the initial information, what you'll get back is real time information, once you fill out all the initial questions here.

So again, we will send out the PowerPoint, the recording, and also a link to that site. You can go to leukemiarf.org. It's right there on the dropdown if you want to look at it later on today.

For now, Dr. Carlson, we can't thank you enough for volunteering your time and taking out so much time in the middle of your day. So thank you again. I thought it was a great presentation, a primer for those interested to learn more about clinical trials, and to go back to their specialist, and ask some really good questions. So we appreciate everything that you do for our foundation, doctor. And thank you to everybody else for tuning in today. Again, we'll be sending these things out shortly. And everybody enjoy their October, and we wish good health and happiness to everybody. So thank you all for participating.

Dr. Karen Carlson:

Thanks, bye-bye.