Clinical Trials:

New Options and Opportunities

National Webinar Transcript

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Melissa Rosen:

I want to thank everybody for joining us at Sharsheret today for an important conversation about clinical trials. My name is Melissa Rosen, I'm the director of training and education. I want to again, thank you. Before we begin, we have just a few housekeeping items to share. First, I want to thank our sponsors for today's webinar. Our sponsors enable us to continue to offer meaningful programs. Thank you to Daiichi-Sankyo, GlaxoSmithKline, ImmunoGen, Merck and the Siegmund and Edith Blumenthal Memorial Fund. And of course we are proud to partner on this webinar with Cancer Support Community's Frankly Speaking program. This webinar is being recorded and will be posted on Sharsheret's website, along with a transcript for you to use as a resource. Participants' faces and names of course will not be in the recording and you do have the option to remain anonymous during today's live webinar. You can turn off your camera and even change your name in your Zoom square and there are instructions in the chat box as to how to do those now.

Melissa Rosen:

We've received many really interesting questions through the registration process but as questions arise during the presentation, please use the chat box and we will address them during the Q and A session at the end of the webinar. As a reminder, Sharsheret has been providing telehealth services to the breast and ovarian cancer communities for more than 20 years because cancer is both a physical and a psychosocial experience. If you're interested in finding out about Sharsheret's free, confidential and personalized services, please email us or visit our website and those are both going into the chat box right now.

Melissa Rosen:

Before we welcome our main speaker, Dr. Brian Slomovitz, we are so very fortunate to welcome Janet, who is a Sharsheret program participant from Sherman Oaks, California and she credits Ibrance clinical trial with saving her life. Janet, thank you so much for being with us today and we're so glad you could be here to share your story.

Janet Klein:

I am as well. Thank you for inviting me. My name is Janet Klein and I'm a stage 4 breast cancer survivor. I was diagnosed with stage 4 breast cancer in 2009 and was cancer free in 2010. I wasn't totally surprised by the diagnosis as my mother had been diagnosed twice and my sister once. My cancer was found on a routine mammogram, which I did according to my doctor's recommendations. At the time of my diagnosis, annual screenings were recommended. Things have changed quite a bit since my experience. Today, my daughters go to a high risk gynecologist at UCLA and either receive an MRI or a mammogram every six months. 12 years later, I'm still cancer free. The biggest reason I am alive and cancer free is because some wonderful doctors saw a drug on a shelf in a laboratory which was designated for another illness entirely and asked the question, "Why not?"

Janet Klein:

I was offered a space in the phase I of the clinical trial of the drug now known as Ibrance. It worked. Just in case you're not familiar with Ibrance, it is the most revolutionary discovery in breast cancer treatment since Herceptin in the 1970s. It treats the most common type of breast cancer, which accounts for 65% of all women diagnosed. One thing I learned on my cancer journey that I like to share with other patients and families is that clinical trials for cancer patients do not give placebos. I was given the same standard of care as any other woman diagnosed but not in the clinical trial, as well as exceptional monitoring. It is very important to be

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a part of your team. Don't just sit on the sidelines and listen. It's ultimately your life being discussed and you should assemble a team that you can work with.

Janet Klein:

Today, I am a happy, healthy wife, mother, grandmother, who leads a crazy busy life. Pilates, needlepoint, cooking and playing with our beautiful grandson, just to name a few. I appreciate the opportunity to share my story of survival and joy through the wonderful Sharsheret organization, which can guide and support women on their journey, just like mine.

Melissa Rosen:

Thank you so much for sharing your story. Your experience really does fill us with hope and it's good to hear such a positive outcome. Thank you.

Janet Klein:

Thank you.

Melissa Rosen:

As we move into the webinar itself, I also want to remind you that Sharsheret is a national not for profit cancer support and education organization that does not provide any medical advice or perform any medical procedures. The information provided by Sharsheret is not a substitute for medical advice or treatment for a specific medical condition. You should not use tonight's advice to diagnose or treat a health problem. Always seek the advice of your physician or qualified healthcare provider with any questions you might have regarding your specific medical condition.

Melissa Rosen:

We are so very fortunate to have our speaker with us today. A specialist in clinical trial development, robotic surgery, sentinel lymph node evaluation and immunotherapy, Dr. Brian Slomovitz is director of gynecologic oncology and co-chair of the cancer research committee at Mount Sinai Medical Center in Miami Beach, Florida. He is also a professor of obstetrics and gynecology of Florida International University. Dr. Slomovitz is a member of the board of directors of the GOG Foundation and uterine cancer lead for GOG Partners. GOG stands for gynecology oncology group, which is a nonprofit organization funded by the National Cancer Institute. He is also the national global principal investigator on a number of GOG partners, NCI and Alliance Foundation clinical trials. He authored more than 100 peer reviewed articles and lectured extensively. Dr. Slomovitz has been recognized as a top doctor by Castle Connolly Medical for the past several years.

Melissa Rosen:

Dr. Slomovitz graduated from Rutgers University New Jersey Medical School and completed his residency at New York Presbyterian Cornell Medical Center. At MD Anderson Cancer Center, he completed a fellowship in gynecologic oncology and he's board certified in both obstetrics and gynecology and gynecologic oncology. Wow. Welcome and thank you so much for being with us today. This topic is such an important one.

Dr. Brian Slomovitz:

Well Melissa, thank you so much for the introduction and it's really a pleasure for me to be here today and to talk to your group. I know we have a bunch of people on, I think so far 69

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participants, which is always exciting. Real quick, I just want to highlight what was said about Ibrance. Ibrance is a CDK 4/6 inhibitor that's used in breast cancer. It goes after the machinery, the cell, which is pretty neat so there's less toxicity. A lot of what we do in GYN, we borrow from what we learn in breast cancer. And actually right now I'm running two trials looking at CDK 4/6 inhibitors, not the Pfizer product but I have one from Lilly that we're working on endometrial cancer actually and one from Novartis that we have going on in low grade ovarian cancer. It is a great drug and I'm so happy to hear positive stories from it.

Dr. Brian Slomovitz:

Tonight, we're going to talk about cancer clinical trials, the importance of trials and how they really set the pace for beating cancer and how we come up with new discoveries. Until a treatment has a 100% chance of cure, we're not satisfied, I'm not satisfied with not doing more, not doing more research in order to make it better for all the patients. I want to thank Sharsheret and the folks involved for inviting me to speak tonight. And it's my pleasure to speak to this group. This program is Frankly Speaking about Cancer, a program of community support and I'm going to advance my own slides.

Dr. Brian Slomovitz:

Here's the disclosure statement about the presentation and just as a quick point, there's a ton, not a ton, a bunch of slides here. I want to get through them, I'm going to sort of break some things down into layman's terms because I think that whenever we do a session like this, not only is it important to give you the information that we have here but the question and answer session is really crucial. And I just want to remind people sort of what was already mentioned. I'm not going to answer specific medical questions. I'm happy to answer general type questions but a lot of personal questions, people have a tendency to ask appropriately but I'd have to defer them to their own doctor.

Dr. Brian Slomovitz:

Thanks you for the introduction. Here's who I am. I'm at Mount Sinai Medical Center. The GOG Foundation, we lead all of the large clinical trials, if not most if not all the large clinical trials in gynecologic cancer. I'm on the board there. And my portfolio is the uterine cancer clinical trials for our industry sponsored arm. I have a financial relationship as an advisor, a consultant with Novartis and I also failed to list here Merck, I think was mentioned as one of the sponsors. I'm running two of their trials, one global trial, one for the US and I'm a paid advisor from them as well but I'm happy to disclose that.

Dr. Brian Slomovitz:

This is an overview of what we're going to go through tonight of this workshop. Basically, just to define a clinical trial, why they're important, how trials work, how to participate, some of the barriers to participation, rethinking what we're doing in the future and then best ways to communicate with your doctor about trials. And as mentioned, then we're going to go through a question and answer session, which is always a top part of the program.

Dr. Brian Slomovitz:

Tips for living in the strange new land, cancer's the scariest word. I diagnosed a woman this morning, 9:00 o'clock this morning with a new ovarian cancer and it's scary. The reality of it, the truth of it is scary but we could focus on the fear and the anxiety of it only so long and then we have to turn the negative into, I don't want to say a positive, but we have to turn it constructively. Look at the glass half full or three quarters full and come up with best ways to treat patients so

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they could live a long, happy, productive life, which even when the advanced cancers that we treat ovarian cancer and others we're getting better and better at treating them.

Dr. Brian Slomovitz:

It's important with a new diagnosis for a friend or family member or yourself, it's to get educated, to get support and as mentioned, glass half full, to have hope, courage. Get out of bed in the morning. Don't roll over and go back to bed, get out of bed, have lunch with your friends, go play mahjong, go to work, do what you need to do but it's so important to do that.

Dr. Brian Slomovitz:

This presentation is tumor agnostic, so we're not focusing on any one clinical site of origin. This is clearly not the gynecologic clinic, it's a male patient. What is a clinical trial? A clinical trial's a research study that compares a new treatment or approach to the existing standard of care in order to come up with new standards, new best practices, in order to treat patients in a better fashion.

Dr. Brian Slomovitz:

They could be prevention trials, early detection trials, adjuvant trials, meaning early stage or tumors that are gone to help keep them away longer. They could evaluate the reduction of risk of recurrence. Obviously, a lot of trials are looking at advanced stage disease. We're focusing on rare tumors too. It's not only important to study the breast cancer and the prostate cancer, the lung cancer but some of the rare cancers as well. One little secret in GYN, we're jealous of pink. We are so jealous of pink because we have teal in September and I'm saying this jokingly, so don't take me so seriously but it is great to make awareness and to study some of the rare cancers as well. I like to say teal and pink are my favorite two colors.

Dr. Brian Slomovitz:

Some studies look to reduce the side effects of treatment. And we're learning, it's not only the efficacy that's important but it's also quality of life. Making sure that patients could again, get up and do what they want to do and have a productive life. And also patient reported outcomes. It's important to look at the outcomes that we evaluate but surveying patients to see how they feel and how they're doing are important part of studies now.

Dr. Brian Slomovitz:

Two out of three patients in the US live at least five years after a cancer diagnosis. This is now compared to one out of two in the 70s. The cancer death rate has dropped 18% since the early 90s, which reverses decades of increasing and individuals with cancer are increasingly able to live active, productive lives.

Dr. Brian Slomovitz:

Why are they important? Here's a couple of disease sites we could see why they're so important. Melanoma and even lung cancer, non-small cell lung cancer, as you know, if you watched the Super Bowl, Keytruda, immunotherapies, checkpoint inhibitors, they really change the standard of care and I mentioned Keytruda, there's also several other companies so it's not just that one that have a checkpoint inhibitor. Immunotherapy changes standard of care. The winner of one of the last Nobel prizes in medicine helped develop checkpoint therapy, for out of Dr. Allison out of MD Anderson. New T-cell therapies in blood cancers have a 90% remission. Pediatric cancers, 80% of children with cancer are cured of their disease. One of the nice things

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about pediatric cancers too, is there's such a high accrual rate of patients with cancer who get accrued to clinical trials. Something that we're sort of need to model in our other disease sites. And we already spoke briefly about breast cancer but adjuvant therapies have really worked and focused on keeping the disease away, have really significantly increased survival rates.

Dr. Brian Slomovitz:

Now there's a lot of words on this slide and I'm really not going to read all the words but what I want to say here is that we're learning more and more that we need to, it's not should we, it's we have to include minorities in studies. We need to do it for a couple of reasons. One, is we need to make sure there's an appropriate access to care, that we're providing equal care across all different populations and socioeconomic groups but we've learned that's not really the most important issue. What we're learning is that cancers amongst different diverse populations actually have different prognoses and have different responses to therapy. If we're doing a study that is for example, a cervical cancer trial, which cervical cancer affects a large number of Black women, Hispanic women, Asians in addition to White patients, we need to sure that the clinical trials that are being done in cervical cancer have this diversity. It's becoming much, much more important.

Dr. Brian Slomovitz:

The other thing that I want to add here is that we've been doing okay in making it better. The FDA released a broad statement back in April of this year, basically saying, a statement towards drug companies, pharmaceutical companies, if you want to get FDA approval, you really need to focus on minority accrual, which was really a phenomenal step. But a lot of the studies that I'm dealing with were actually having as a standing agenda item, the role of accruing minorities and making sure there's diverse populations into all of our clinical trials. And we know that, and to get FDA approval, they're going to have to play a larger role in the makeup of the trial.

Dr. Brian Slomovitz:

We know that Black women may stay out of trials. There's a lot a history for some of these is that there was Tuskegee experiments back many, many years ago, which didn't provide standard of care to patients who were injected with syphilis. There's a lot of fear from previous trials. We need to better educate our patients, particularly those of diverse backgrounds, that research now is well regulated. It's ethical. It's monitored by several oversight committees and institutional review boards, data safety monitoring boards. It's a safer environment, where most of our informed consents not only are in English now but they're in Spanish.

Dr. Brian Slomovitz:

In Miami, we have a large Creole Haitian population so we have them in Creole. In other regions of the country where there's other large representation of ethnic groups of different languages, we have those as well, which is very important. It's difficult when someone is English as a second language or not a language at all, to give them an English consent form to try to convince them that joining the trial is the best thing to do. It's not a very successful way of doing it. Other reasons listed here why minorities are important and where it's difficult to get them enrolled, that group enrolled in clinical trials.

Dr. Brian Slomovitz:

Also, a lot of times clinical trials do offer the best care for our patients. And remember, and I'll talk about this in the beginning, the placebo effect does, everyone's afraid that if they get on a clinical trial, they're going to get a drug that doesn't have activity. That's only the case if no

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activity is the standard of care. If the standard of care is a Tylenol, for example, the clinical trial will look at Tylenol plus something else or something else to see if it could be Tylenol. It's not ethical to give no treatment to patients. I'll focus on that again but we really have to teach that to all of our patients, not only those of diverse backgrounds. Being on a clinical trial is the best way to treat cancer. It's offering the latest and greatest treatments in order to help beat the disease and we really need to emphasize this across different populations.

Dr. Brian Slomovitz:

Why clinical trials are important for treatment, every new treatment was tested in a clinical trial. It can't be FDA approved without going through a clinical trial. The faster that trials find participants, the faster they accrue, the faster they can get to patients off of protocol. We're seeing dramatic changes. The FDA is becoming more user friendly when it comes to FDA approvals. There's something called an accelerated approval pathway, which we've had several gynecologic drugs approved in the last couple of years. Newer therapies are more precision based, based on a better understanding of how cancers arise and grow and being more unique, individualized towards the patients. And as mentioned earlier, emphasis on quality of life.

Dr. Brian Slomovitz:

The problem is even with all the benefits that we talked about and a slew of more benefits, only 4% of adult cancer patients ever participate in a clinical trial. And we haven't been successful in increasing them. Patients who could potentially benefit them are unaware. Minorities as mentioned, are underrepresented and progress is slowed when trials are unable to recruit patients they need to evaluate. This is a problem that we have to change and really, frankly, this is one of the reasons why we're having this webinar is to increase the awareness of clinical trials and to encourage when you are talking to your family member or their friends or the patients themselves, to encourage them to consider trials.

Dr. Brian Slomovitz:

Let's go through the different type of trials very quickly. A lot of this is information that some of us may know. Preclinical research or we'll call these phase zero trials, before human lab work, test tube work, pre-animal safety studies, looking for activity in cells to predict that there may be some activity in humans.

Dr. Brian Slomovitz:

Phase I or safety trials, first in human trials, these couldn't just not only side effects or toxicity, some of these trials can also look for efficacy. We found a new treatment with cervical cancer that I'm a co-author of that we reported out in the phase I data, first in human, which showed effectiveness in the few people who had cervical cancer that eventually a couple years later led to an FDA approval of the drug. The goal of phase I is to get those to look at safety in this population of patients. And this is what I was discussing with efficacy. If there's an early effective signal, the next stage isn't to say we approve something in a phase I trial, the next stage is to say, "All right, there's an early signal. Let's move to a phase II study."

Dr. Brian Slomovitz:

Phase II trials are looking more at efficacy and they also look at safety but efficacy is the looking for the effectiveness of a drug. These usually could take two years to involve a larger number of patients. Some studies are open labeled phase II studies, meaning everyone knows what the patients get. Some are randomized to different treatment arms in order to get sort of a baseline, given the standard treatment versus a newer treatment. This is not a head to head trial but we

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just want to make sure when we come up with benchmarks for the new treatment, that it's comparable to that as soon as the older treatment. These are sort of contemporary arms of the trial.

Dr. Brian Slomovitz:

Then the trials that really change the standard of care. As mentioned, this is changing a little bit. Phase II trials can lead to an accelerated approval, which is sort of like a temporary approval pending a phase III confirmatory trial. We see some FDA accelerated approvals but eventually it's the phase III trials that lock in a new drug into becoming standard of care. Again, these are studying the current treatments versus a new treatment or adding something to the current treatments. They are not giving placebo unless no treatment is the current standard of care. Here it says very specific measures of success. The statistical design in these trials is crucial to make sure that a positive study is positive, a negative study is negative. A lot of smart statisticians get together to put these trials together and these are the ones that lead to newer FDA approvals. We're doing a lot of these within the US. And again, just like anything else we need to get more patients involved.

Dr. Brian Slomovitz:

You may have heard of phase IV trials. These are after FDA approval, looking more real world evidence of once a drug's approved. Sometimes it's quality of life or patient reported outcomes, looking at side effects in the real world. But these are ongoing. Not as much as of a priority because the drug is already approved.

Dr. Brian Slomovitz:

Later phase trials are pretty much looking at either overall survival or progression free survival. If it's in an adjuvant setting, meaning if it's in patients that don't have disease but they want to see how long the disease could stay away, then they look at disease free survival and phase II studies often look at response rates or complete remission is when the disease goes away completely.

Dr. Brian Slomovitz:

Every person facing cancer should talk to his or her doctor about a clinical trial. Here's one of the problems, doctors and so there's so many good doctors out there and it has nothing to do with their knowledge. Doctors oftentimes if they don't have clinical trials in their practice, there may be an inherent resistance or reluctance to send the patient for a clinical trial because doctors like their patients, doctors love their patients oftentimes, and to send them away means they're not caring for the patient. We need to overcome this burden or this hurdle. We need to have patients become more educated to challenge their doctors about clinical trials. To be able to tell their doctor, "You are my doctor but I'm going to go to this university or this center to get on a trial and I'll continue to see you." But that has to stop being a barrier as far as to resistance and accrual.

Dr. Brian Slomovitz:

Informed consent trials are ethically run. They're managed by ethic review boards. Everyone has to give informed consent. It's a process. A trial is a cookbook. A large part of the beginning of the cookbook is to explain the trial to the patient in order that they're giving the informed consent to make sure they really understand what they're signing up for. One of the important things about informed consent is once you sign up for a trial, you always have the right to drop out of the trial. There's no coercion. There's no forcing. There's no, well, you got dose one. You

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need to get doses two to six. A patient can withdraw informed consent at any time. If it's a surgical trial, they can't wake up in the middle of the surgery and say, "Stop," but I'm joking a little bit there, but you guys know what I mean.

Dr. Brian Slomovitz:

One other important point, if a clinical trial gets an endpoint sooner than expected, meaning it's a trial of drug A versus drug B and sooner they expected they find out that drug A is better by a statistical endpoint, the people who run that trial, whether it be a pharmaceutical sponsor, the local investigators or the government are responsible for making sure people know the results and they're responsible for making sure that those patients who received drug B, the lesser effective one, are offered drug A in order to give them the best treatment. We just don't leave patients hanging if they're sort of randomized to the quote unquote, wrong arm. They eventually will be offered the best treatments available.

Dr. Brian Slomovitz:

How do you find a trial? Talking to your doctor, getting a second opinion, look for a cancer center in your area that does a lot of clinical research. Patient advocacy groups, the Gilda's Club, Sharsheret, other advocacy type groups. Patients really need to go out and get the resources necessary and to do their own search to find the trials. Personally, in my practice, I have any time about 10 or 12 gynecologic trials ongoing but I never ever tell a patient not to get a second opinion if they want one. For a couple reasons, one, I could always learn something. I've said that more and more earlier in my career but still I could always learn something. I could learn what trials are going on if I'm not aware of them and help me better take care of my patients. Which is important thing to do. Another reason to get a second opinion is sometimes the centers that we send them to have trials open that I may not have in my practice but patients really need to be their own best advocate.

Dr. Brian Slomovitz:

Some tips, clinicaltrials.gov is an online resource for clinical trials. All prospective clinical trials that go on in the United States are required to be listed on clinicaltrials.gov, they're required. If it's being done in the US, it's on clinicaltrials.gov so it's a good place to look. Cancer center websites and advocacy groups, as mentioned. In order to find a trial, you need to know what type of cancer you have, the stage, if it's new or recurrent, if you have a certain mutation. It is hard to find, complicated language, very specific eligibility criteria. You really sometimes need to partner with your doctor, even if it's the doctor who doesn't necessarily offer you trials in the beginning, you can talk with him or her and use them as a resource to potentially find the trials that are either in your area or if it's such a unique trial with a great promise, to go to a different area of the country, to get onto the trial.

Dr. Brian Slomovitz:

Here's the guinea pig myth. I taught this is the placebo effect or part of it's a placebo effect, part of it is treating patients like guinea pigs. We talked about this, there's preclinical data to see some of the effects, including toxicity, there's phase I studies, which are very limited population, small, small studies given in sequentially, not necessarily at the same time to see if a drug is safe because we don't want to treat patients like guinea pigs. One of the other things about clinical trials is there's not only a team of clinicians from the office helping out but there's also a whole research team looking, which is sort of nice. And patients in my experience tend to like that in order to get more attention. All trials in the US require that the clinical team truly believes that the therapy being tested might be better than the standard of care in order to move forward.

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Dr. Brian Slomovitz:

I talked about this at length, the placebo issues. Again, patients have to get an active treatment if one exists.

Dr. Brian Slomovitz:

Why don't people participate? Changing doctors or centers. I touched on this. Not only do doctors want to keep their patients, patients want to keep their doctors. Patients have established a long relationship with their doctors. They trust them. They know them. They know their family. They know their friends. I always tell my patients who feel sometimes they question, oh Dr. Slomovitz, are you going to be upset if or I was afraid to tell you but. Patients worry too much about what their doctors think.

Dr. Brian Slomovitz:

I'd like to say, "Oh, I go home every night and before bed I think about every single patient I saw that day." It's not true. Patients need to do what's best for themselves. Their family needs to guide them and if a patient comes to me and say, "Hey doc, I want to go somewhere else for second opinion," please do. I'm happy to call up the doctor they want to see, let them get a second opinion. Truthfully, that approach most patients come back because they don't feel like there's an intimidation factor or a secret factor. And again, I just want to make sure that patients get the best care. And if there's a study at another center, able to go on that trial.

Dr. Brian Slomovitz:

Cost, clinical trials, people don't participate because they're worried about the cost of a clinical trial. Here's the bottom line, Real simple, if the cost is not standard of care covered by your insurance, the clinical trial's costs need to be covered by the sponsor of the trial. Again, whether that be pharma, whether that be the NCI or the local institution, you cannot charge someone. It's unethical to charge someone to reap the benefits of a newer drug in a clinical trial. It's either covered by their standard of care or the pharmaceutical company covers it. People then say, "Well, I came in, I got all this therapy and I was charged my deductible of 1,500." You're going to have to pay your deductibles. That doesn't change that aspect. But your health coverage is covered. If it's covered by your insurance, then it's covered, otherwise the trial will pay for it.

Dr. Brian Slomovitz:

Why people don't participate. We talked about this, suspicion or distrust in the medical profession. Talked about some historical events that's led to this. There was an old Jewish home in Brooklyn, I forget the story. Years and years ago, they used to inject melanoma into patients to see what happens when you inject melanoma into skin. Totally unethical, totally advanced the disease. This is a Jewish old age home. I think it was in Brooklyn, back in the 30s or 40s. Clearly we don't do that anymore, obviously.

Dr. Brian Slomovitz:

Other reasons why people don't participate, they need a good nurse navigator who's a research nurse navigator to direct patients, to educate them, not to force them but to educate them by clinical trials. It could help facilitate a conversation between the patients and their doctors. Conversations could lead to more relevant questions, which could help convince a patient that a trial is best for them. And as I mentioned, I talked about second opinions as being an option.

Dr. Brian Slomovitz:

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Other reasons why people don't participate, they think that being on a clinical trial is that's their last treatment and they're going to die if it doesn't work. That's not the case. As I mentioned earlier, we have clinical trials for early detection, screening, prevention, adjuvant therapy. Yes, some trials are being done to see if there could be a save at the end or towards the end of one's treatment period. But for the most part that these are not last ditch efforts. These are trials that are being done again to improve the efficacy, the side effect profile or the quality of life.

Dr. Brian Slomovitz:

Trials bring hope. I'm getting something new, maybe it's going to work. The most innovative therapies. Trials bring excellent care and monitoring. Again, not one team but two teams. Trials, your voice gets to be heard and you could really contribute to the greater good. You could be part of a trial as mentioned earlier, being a part of a trial that leads to a new indication of breast cancer. It's for the greater good of all patients and you feel good about yourself being a part of a trial that really helped change the standard of care. And obviously could provide a better care for yourself.

Dr. Brian Slomovitz:

Talk to your doctors about clinical trials. Bring it up if they don't bring it up with you. Make a list of questions. I always tell patients, a new diagnosis, go out to the Walgreens or CVS, buy one of those composition notebooks, the ones that you can't rip the pages out so you don't miss anything. And every doctor's visit, go with your notebook and write down your answers to your questions and between doctor's visits have the notebook around and write down the questions. All the time for me, I think of questions, that's a great question, I'm going to ask my doctor or ask someone, whatever. When I go and I have the opportunity to ask clearly, I forget what the question was. Write it down. Patients ask me all the time if they could record the interaction. I'm always willing for them to do that. But you have to ask your doctor, just don't do that without permission but most doctors will allow you to do that.

Dr. Brian Slomovitz:

If you're offered a trial, take time, think about it. A lot of patients are given an informed consent. They don't need to sign it that day. You can take the informed consent home, read it over with your family, show it to your other doctor if you have one to see what's best for you. No coercion. And if you look for trials on your own, discuss what you find with your doctor. It's good to have open communication.

Dr. Brian Slomovitz:

Newer models of clinical trials are looking at targets, looking at mutations, not necessarily organs. Trials focus on specific genetic mutations rather than cancer types. We're doing more and more flexibility in trial designs to allow more accrual, to allow smaller studies, in order to get the same answers. More effective therapies are being investigated. With the newer, more effective therapies, there's better patient participation. And finally, there's more input from patients and advocates in designing and evaluating trials. These are some of the newer models that we're using.

Dr. Brian Slomovitz:

We're getting to the end here. Here's one helpline, cancersupporthelpline.com. The Gilda's Club is a good resource. There's plenty of good resources out there, clinicaltrials.gov. Talk to your doctor. A lot of hospitals and cancer centers have their own support groups. It's important to not feel that you're alone. It's important to talk to people that are maybe going through the same

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thing as you. As a patient, no one could put themselves in your shoes. As a loved one, no one could put themselves in your shoes so it's important to really openly communicate and get as much help and support as you can.

Dr. Brian Slomovitz:

That's what I have. You guys have been great as far as hopefully listening. We have 74 people and I'm happy to start answering questions because I know this group is going to have a lot of questions for us.

Melissa Rosen:

We do. We do have a lot of questions, not only the ones that came in earlier but a lot that have come through the chat box now. Dr. Slomovitz, I'm going to ask you to unshare. There you go. Unshare your slides. Perfect. Perfect. I'm just going to get started because we've got a lot and you've given us a wonderful overview of all the things we need to be thinking about and how clinical trials work. Now I would like to ask some more specific, not specific to a particular patient, but more specific about clinical trials in general. A couple of them, a couple of people have asked just very quickly because we have a lot of questions and not a lot of time. As an example, could you give one or two, just explain one or two very quickly of the trials you're currently conducting.

Dr. Brian Slomovitz:

Sure. That's a great question. There's a drug called Tivdak is the commercial name, it's made by Seagen. I was involved with trials through the phase II setting that got an accelerated approval, as mentioned by the FDA, a quicker approval. And then now there's a confirmatory trial, an international confirmatory trial, looking at this drug Tivdak versus chemotherapy to confirm whether the Tivdak is better in second line or third line cervical cancer. I'm the national principal investigator for the Gynecologic Oncology Group of that trial. It's an international trial. We're doing it here throughout Europe with our colleagues. There's a group in Europe and ENGOT it's called, it's our partner group, GOG and ENGOT, we partner. We do a little trials together and the results of this trial will be confirmatory if they're positive, then Tivdak will remain FDA approved. If not, then it will not remain FDA approved but most drugs that have an accelerated approval clearly there's activity there so we're optimistic that'll be.

Dr. Brian Slomovitz:

I have another trial I'm doing an endometrial just to mention another one, endometrial cancer, immunotherapy versus chemotherapy, newly diagnosed patients with a particular mutation. How cool would it be if this is a positive trial, we're going to eliminate chemotherapy for advanced endometrial cancer in some patients. That's remarkable. That's something I've been fighting for my whole career.

Melissa Rosen:

Incredible thought. Wow. Thank you for that. Let ask you a couple of other questions. One of them is one that I bet everybody's wondering. Can or will a doctor connect a patient to trials outside of their own hospital affiliations?

Dr. Brian Slomovitz:

Yeah, that's a great question. The answer number one, is they should but unfortunately that's not always the case. And it's not done in a malicious way. Sometimes doctors aren't aware of

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the trials that are available. Sometimes it's, I don't want to say malicious, but sometimes doctors don't want to give up patients for a variety of reasons but this is why we're having conferences like this. This is why patients and their families need to be the best advocate for themselves in order to seek out areas or facilities that have clinical trials available. The other thing is sometimes clinical trials, some clinical trials are better than others so it's not only finding the clinical trial but finding the best one for yourself.

Melissa Rosen:

For this next question, I think you mentioned this during your presentation but I think it's worth confirming. Somebody asked, "If I'm not doing well in a trial, can I return to the standard of care?" You did say you could leave a trial at any time but does being part of a trial make the standard of care not available for some medical reason?

Dr. Brian Slomovitz:

No. If they want to withdraw from the trial and they decide not to get the current experimental drug, if that's what they're getting, they could definitely. I can't think of any exceptions. But they could definitely go and get onto the standard of care. Definitely.

Melissa Rosen:

Great. What goes into a decision where the patient is about to embark on a highly successful treatment protocol but was offered a clinical trial with less treatment. In other words, the patient was diagnosed, the treatment is very, very effective but they're given an option to have less treatment. How does one decide something like that?

Dr. Brian Slomovitz:

That's a great question. And first of all, this is where a lot of thought and energy's put into this statistical design. The higher the effectiveness of the current treatment makes some of these trials very, very, very difficult to design because they have to beat that benchmark. That's one thing. And then so a lot of times it requires larger numbers or sort of a well thought out statistical approach in order to prove that it's better is one way of doing it. And your ultimate question was, how do you decide? And that's easy, the patient decides. Not without getting proper information, not without having the resources available to them.

Dr. Brian Slomovitz:

But oftentimes for example, I'm running immunotherapy trials on endometrial cancer. Sometimes the drugs that we're studying are similar to drugs that are already approved. There may be the hope that the ones we're studying work better than the ones that are approved but maybe they'll be the same. Patients need to know what the current drug that is approved the effectiveness and that'll be a response rate amongst patients or some sort of activity and they need to know what we're studying in the protocol and then they could decide which way to go.

Melissa Rosen:

Somebody asked about out of the box treatments used for other cancers. This particular caller happens to be dealing with triple negative breast cancer but this would be for any type of diagnosis. How do you find out about specifically treatments that have already been approved for other diagnoses that are being tested for?

Dr. Brian Slomovitz:

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Oh, so I think you're saying if they have breast cancer, if they want to see if a drug that worked for pancreatic cancer may work for them. I think that's what you're alluding to. It's about talking to their doctors. It's about getting second opinions. It's about doing a little bit of homework for themselves. And making sure they're comfortable with the doctor and the doctor's opinions. Again, oftentimes I'm using breast regimens on some of my women with endometrial cancer or low grade ovarian cancer because they're fairly similar diseases. Similar, something called a mucinous ovarian cancer, oftentimes I'll use a GI regimen, a colon regimen because they're very similar, even though it's different disease sites. It's important to have that outside the box ability. The problem there is on some of these examples I'm giving, you also have to get insurance authorization, which sometimes isn't the easiest. That's another reason if you're outside the box on a clinical trial, as mentioned, the costs are covered.

Melissa Rosen:

Let me ask you another question to follow up with that. I'm thinking finances, and while the treatment protocols for the trial are covered, I know one of the reasons you mentioned people don't participate is additional expenses. Additional expenses including travel and lodging or if you have to travel to get to that, are those included in any? Are those expenses included in any clinical trials?

Dr. Brian Slomovitz:

That's a great point. More and more we're doing it. Not necessarily and not for a reason of our role for diversity, which one would think but it's really for our role to get patients in who don't necessarily live near a cancer center and it could be of any ethnicity or any population. We don't entice patients with monetary rewards for participating in a trial but paying for parking or paying for lunch if they're there all day or if they come in from hundreds of miles away and they need a hotel room, that's not monetary enticement, that's fair market value, assistance that patients need. That is being covered more and more.

Melissa Rosen:

That's good to hear. This next question is something we hear all the time, trials about the benefits of aromatase inhibitors or tamoxifen five years, seven years, 10 years, 15 years, what's going on there? What's the latest research?

Dr. Brian Slomovitz:

That's a great question. Just for disclosure, I'm not a breast cancer expert. I have plenty of trials, I have a trial in sarcoma with aromatase inhibitors. I have a trial in endometrial cancer. Actually, we did a trial endometrial cancer with an mTOR inhibitor and an aromatase inhibitor that we changed the standard of care. I use aromatase inhibitors but as someone somewhat knowledgeable in breast cancer, tamoxifen was a great drug. It really changed just the way we treat patients with breast cancer. As time went on with breast cancer, aromatase inhibitors were discovered and that's good for one, patients who don't tolerate tamoxifen or two, some patients who fail tamoxifen, they can get an aromatase inhibitor.

Dr. Brian Slomovitz:

And as far as the timing of it, the studies that are being done, the longer time goes on, the more we're learning about how long some of these drugs should stay on patients. I think in the chat I saw, well, what about the osteoporosis associated with aromatase inhibitors? Any effective drug has side effects. It does. And I'm not saying to ignore the side effects and to go on but I'm

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saying that we have to look at the side effects, see if there's any quick remedies or easier remedies or relatively easy remedies for the side effects and then go from there.

Melissa Rosen:

Somebody just put in the chat box, "If a drug that can be potentially effective," I'm just reading this question. I want to make sure it's right. It's a question about compassionate care. If someone needs a drug immediately or knows they might be given standard of care versus the new drug or they don't qualify for a particular clinical trial, is there a possibility that oncologists could get a compassionate care usage that's outside of the clinical trial?

Dr. Brian Slomovitz:

Yeah. The keyword in that question is potentially. If there's studies that have shown that it's effective in a certain disease site, then it's easier to appeal to an insurance company, say. What we do is we print out the study and we send it to them. Here, this study's been done and it's demonstrated activity. There's no better options for the patient so can you give approval? And even with some of the reluctance of insurance companies to give approval, oftentimes in my experiences, we've gotten those approved. Now, if there's a drug that hasn't been used in certain disease sites and there's no report in literature, then it requires a compassionate use and that's actually even treating one patient is a whole research protocol. It's timely. It's very difficult to do. And it doesn't mean we can't prescribe it as doctors but we can't necessarily pay for it.

Dr. Brian Slomovitz:

For example, a lot of times there used to be some evidence that metformin prevents endometrial cancer. Not so much anymore but I'd provide metformin to those patients who came in and asked about it because there's no harm. It could help prevent diabetes. And the cost off of insurance is 57 cents a day. That's not a big deal there. But on these expensive drugs, it's more difficult.

Dr. Brian Slomovitz:

And then I see Mimi asked about compassionate care versus expanded care. Compassionate care is what I sort of just described to see if in a drug that hasn't been studied in a certain disease site, if we could try to do it as an N of one, where one patient's studied and things like that. That's compassionate care. Expanded access is when insurance doesn't cover a drug or the patient doesn't have the resources to pay for it and it's sort of a financial assistance program that a lot of companies have in order to help get the drugs to patients.

Melissa Rosen:

We only have time for a couple more questions. There have been people who have asked some somewhat specific questions but not necessarily medical advice. Somebody asked if you were familiar with any current studies that deal with HER2-negative breast cancer.

Dr. Brian Slomovitz:

Yeah. No, I'm not a breast cancer expert. I'm sorry.

Melissa Rosen:

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I just wanted to make sure. Another person asked about and I don't know if I'm pronouncing this one, correct, ivermectin. Is that currently still in clinical trials or has it been approved? And if it is still in trials, how can one access that?

Dr. Brian Slomovitz:

Is that for COVID? Ivermectin, is that what they're talking about?

Melissa Rosen:

No, it was not. No, they were asking about cancer. You're not familiar.

Dr. Brian Slomovitz:

Not familiar. Just another example of a trial I'm doing just to give you guys a sense. In endometrial cancer, we have a biomarker driven trial. Before we treat patients with a drug, it's actually a six arm trial, we test the tumor for a specific marker and then we assign the patients to a particular group based on that marker's positivity. I like to call that sort of a patient specific or sort of a smart trial, looking at the mutations in a certain cell and it's the same trial but they can get one of six arms. Not in a randomized fashion but predicted by the markers on our cells. This is another way. I know there's I-SPY 2 in breast cancer's doing the same thing. This is sort of the new next generation of studies that are again, smart studies looking at particular mutations and assigning the treatment arm based on that. It's another example I wanted to mention.

Melissa Rosen:

That takes it to a whole different level. That's amazing.

Dr. Brian Slomovitz:

It's really neat.

Melissa Rosen:

I'm going to ask, it's not really a question but I'm hoping you can address it. A couple of people have shared that they've tried to engage in a clinical study or they have engaged in a clinical study and their experiences weren't positive. For instance, one woman noted actually I should say one person noted that she was on clinicaltrials.gov and every time she connected with something that was listed there, the trials weren't happening or weren't available. Another person shared that she was in a clinical trial. They weren't readily given the results. She did find out she was in the group that was not the new approach but the standard of care and it was somewhat devastating and there was no support for that. She felt they were dismissive. I'm hoping these examples are from a little bit ago but I wondered if you could just speak to that for a moment.

Dr. Brian Slomovitz:

We mentioned earlier, the last ditch effort, that's not the case. But when patients are seeking out a clinical trial, oftentimes in their mind, they're really focusing on that trial. They need to be on that trial. Clinical trials are designed in order to get FDA approval and to provide a better treatment for patients. They're designed very carefully and very meticulously with inclusion and exclusion criteria and performance status, how healthy is a patient? In order to standardize the arms as best of ability. And in order to say, well, the patient didn't do well because the disease. Not well, something else was going on. Patients sometimes get frustrated when they're not, this

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is one point, when they're not eligible for a trial because they don't meet the eligibility criteria specifically. And we can't make exceptions because hundreds and hundreds of millions of dollars are poured into one trial in order to come up with an answer.

Dr. Brian Slomovitz:

We're compassionate. We're passionate about what we do but if the FDA doesn't accept those trials if we have what's called deviations, then we need to do what's best practices and not include those patients. COVID was a horrible time for clinical research. Clinical research staff at many large university based facilities who are either underfunded, the staffing was redirected towards COVID trials or the staffing was really redirected towards other areas of the hospital. A lot of them are nurses, they needed help. That was a tough time to really focus on that.

Dr. Brian Slomovitz:

I understand people's frustrations. People's frustrations in order to wanting to be on a trial and then not being accepted but it's actually, believe it or not a thoughtful, purposeful process in order to see who's eligible or not. And it's done in a way in order to do what's best for the patient. I'm looking at this about ivermectin. And I heard about this in the past, back in May of 2020, there was a study that showed in a test tube, ivermectin, which is an anti-parasitic drug, thanks to Andrea for forwarding it, can prevent ovarian cancer from growing. This study that she referred to was published in June of 2020, two authors from China, where it basically showed that proteomics expression levels looked at different proteins. I'll say in the most polite way, this thing's not ready for primetime.

Melissa Rosen:

Great. Well, you know what? Everything starts somewhere but right now it's not something that looks particularly hopeful. Maybe in the future.

Dr. Brian Slomovitz:

And one of my mentors once said, when we had some ideas that we said, "Well, I thought about that five years ago." And it said, "Well, you were ahead of your time." And sometimes it takes years to mature an idea.

Melissa Rosen:

That's right. That's right. I wish we had time for more questions. But I'm cognizant of the time. I want to thank you, Dr. Slomovitz for sharing your expertise with us today. I learned so much and I hope all of you did too. I want to thank once more, our generous sponsors, Daiichi-Sankyo, GSK, ImmunoGen, Merck and the Siegmund and Edith Blumenthal Memorial Fund. Thank you to Cancer Support Community for their partnership on today's program. Please take a moment to fill out a brief evaluation study that is going into the chat box now. You can click that and still listen to the last couple of notes here. During the next few days, you will receive a follow up email with a link to the recording, a transcript and access to some of the resources noted today, as well as some additional Sharsheret resources on clinical trials. Please be on the lookout for that.

Melissa Rosen:

And please remember that Sharsheret is here for you and your loved ones during this time. We provide emotional support, mental health counseling and other programs designed to help you navigate through your cancer experience. And as always, all are free, completely private, one

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on one. Our contact information is in the chat box but our number is (866) 474-2774 or you can email clinicalstaff@sharsheretr.org.

Melissa Rosen:

Finally, we'd love to stay connected with you. Remember that we are on social media. We post about events like these, program updates, fun ways to get involved. The links are in the chat and we've several exciting webinars on a wide range of topics planned over the next few weeks, including a music and movement webinar this Thursday and evening, meant as a therapeutic evening for anyone at any point, whether they are in bed, sitting down, actively moving. And a webinar on hormone usage and cancer next week. Check out our website regularly to see what topics are coming up and that is in the chat box right now. Thank you again, Dr. Slomovitz, thank you all for joining us and have a wonderful evening. Good night.

Dr. Brian Slomovitz:

Bye bye.

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About Sharsheret

Sharsheret, Hebrew for “chain”, is a national non-profit organization, improves the lives of Jewish women and families living with or at increased genetic risk for breast or ovarian cancer through personalized support and saves lives through educational outreach.

With four offices (California, Florida, Illinois, and New Jersey), Sharsheret serves 150,000 women, families, health care professionals, community leaders, and students, in all 50 states. Sharsheret creates a safe community for women facing breast cancer and ovarian cancer and their families at every stage of life and at every stage of cancer - from before diagnosis, during treatment and into the survivorship years. While our expertise is focused on young women and Jewish families, more than 15% of those we serve are not Jewish. All Sharsheret programs serve all women and men.

As a premier organization for psychosocial support, Sharsheret’s Executive Director chairs the Federal Advisory Committee on Breast Cancer in Young Women, Sharsheret works closely with the Centers for Disease Control and Prevention (CDC), and participates in psychosocial research studies and evaluations with major cancer centers, including Georgetown University Lombardi Comprehensive Cancer Center. Sharsheret is accredited by the Better Business Bureau and has earned a 4-star rating from Charity Navigator for four consecutive years.

Sharsheret offers the following national programs:

The Link Program

- Peer Support Network, connecting women newly diagnosed or at high risk of developing breast cancer one-on-one with others who share similar diagnoses and experiences
- Embrace™, supporting women living with advanced breast cancer • Genetics for Life®, addressing hereditary breast and ovarian cancer
- Thriving Again®, providing individualized support, education, and survivorship plans for young breast cancer survivors
- Busy Box®, for young parents facing breast cancer
- Best Face Forward®, addressing the cosmetic side effects of treatment
- Family Focus®, providing resources and support for caregivers and family members
- Ovarian Cancer Program, tailored resources and support for young Jewish women and families facing ovarian cancer
- Sharsheret Supports™, developing local support groups and programs

Education and Outreach Programs

- Health Care Symposia, on issues unique to younger women facing breast cancer
- Sharsheret on Campus, outreach and education to students on campus
- Sharsheret Educational Resource Booklet Series, culturally-relevant publications for Jewish women and their families and healthcare Professionals

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