Program Title: Understanding Clinical Trials for Breast and Ovarian Cancer

Presented by: Support Connection, Inc.

Originally recorded on: February 7, 2013, 8pm – 9:30 pm (NY Time)

Guest Speakers:
Yelena Novik, M.D., Assistant Professor and the Medical Director for Clinical Trials Office at NYU Langone Medical Center. Dr. Novik's specialties and expertise include medical oncology, breast cancer and melanoma.
Gwen Harding-Peets, PhD, an ovarian cancer survivor and a patient advocate who shared the patient's perspective,. She has volunteered with Support Connection, Inc., SHARE, Survivors Teaching Students, and as a Peer Reviewer for the Dept. of Defense's Congressionally Directed Medical Research Program for Ovarian Cancer.

Moderator: Robin Perlmutter, Support Connection Peer Counselor

Topics:
- What are clinical trials?
- What are the phases of clinical trials?
- Why are clinical trials important?
- How is patient participation important to clinical trials?
- How is the patient safeguarded?
- What are the benefits and risks of participating in a clinical trial?
- What are the barriers to participation?
- As a patient, what is it like to participate in a clinical trial & how do you find them?

Robin Perlmutter: It is with my great pleasure that we have Dr. Yelena Novik, Assistant Professor and Medical Director for Clinical Trials at NYU Langone Medical Center, here tonight to tell you everything you wanted to know about clinical trials.

And we have Gwen Harding-Peets, PhD who will share the patient perspective. She's an ovarian cancer survivor, a patient advocate. She is also a Support Connection's volunteer facilitator for the ovarian cancer telephone support group.

I want to welcome you both tonight. We're going to begin with Dr. Novik, so Dr. Novik, thank you so much for sharing your time and expertise with us tonight.

Yelena Novik: Thank you so much, Robin, and it's a pleasure and a privilege to be able to speak to you. I'm a medical oncologist, and all my professional life and my training I've been involved in clinical trials, and mostly practice in breast cancer field and work with a lot of women with breast cancer and also with some who has ovarian cancer.

So I extend my gratitude to many, many women who come to us with questions, but also participate in many clinical trials. Because I think it's very important to understand that clinical trials bring us the knowledge that we possess today to be able to handle the treatments, the prevention, the diagnosis of many cancers. And also, progress that we've made up to today is really due to the courage of these women that participated in clinical trials.

Clinical trials are really research that involve people. And as I mentioned before, their goal is to improve the current status on prevention, diagnosis, and treatment of cancer. And the goal of this

trial was to bring the novelty from laboratory and animal research to treatment, prevention, and diagnosis of disease.

I think it's important to say a few words about the history. The clinical trials did not just appear out of the last couple of decades. They really existed throughout the history. And even going back to the Bible, in such old texts like Book of Daniel, there's description of some experiment going to two groups of people who either partook or did not partake the King's Meat over a period of 10 days.

And such a well-known and recognized Persian doctor is Avicenna. She's Canon of Medicine, one of the oldest medical textbooks which was published in 1025 AD, laid principles of what's called experimental medicine.

But one of the most known examples comes to really fight against scurvy, or really vitamin C deficiency, when the sailors on Her Majesty Salisbury in 18th century was found to have scurvy, and were randomly, by random assign, to take oranges and lemons. And those who were assigned to take lemons, up to six days of taking this were really cured of their symptoms. Just a note, resembling probably their atmosphere of today that the Royal Academy at this point decided not to introduce lemons into the diet of the sailors because they were deemed to be too expensive.

But moving on, especially in the 20th century, the clinical trials brought also a lot of controversy, especially when it came to ethics, and especially when it came to the World War II as the horrors of the concentration camps and some human experimentation that happened during that time. And after the Nuremberg Trials, the Nuremberg Code established some of the very basic rules that apply to human experimentation and clinical trial. And they are very important as they exist up to today. And this is voluntary consent; capacity to consent; freedom from coercion; and capacity to favor the patient, to bring some benefit to the patient.

And as we speak first, we'll talk about a little bit the Belmont Document and the Helsinki Declaration, which are very important documents stating the benefit to the patient, the protection of the patient against potential hazard of clinical experimentation, are also very important.

In the United States, this was taken very seriously. And as many of you probably know, there's a very important oversight created at the level of government, as well as the level of individual medical institutions, to oversee how the clinical research in medicine and in cancer happens.

And at the level of the government, you probably all heard the name of the FDA, which is Food and Drug Administration, and we'll say a few words about it. It is a level of separate hospitals and clinics, this is the Institutional Review Boards, which are really institutional organizations which are supposed to oversee and make sure that patients are never harmed by the research that's done to bring their results of laboratory investigation.

The FDA really exists since the beginning of 20th century. President Roosevelt introduced the Food and Drug Act in 1906. But more and more improvement came into review of legislation about clinical trials as the time ends.

Many of you may know that this year really brings the 50th anniversary of the Thalidomide tragedy. Thalidomide was a drug that was marketed for improvement of (inaudible) especially in pregnant women, and mostly was marketed and sold in Europe. And unfortunately, it caused a tremendous amount of tragic births of children without limbs and with other massive and quite tragic birth defect.

And that was one of very important reminders for all of us that safety in clinical trials is as important as positive result of developing new drugs. That the first important point in developing new treatments, new screenments (ph) , diagnosis is to make sure that this all safe.

And starting in the 1960s, the FDA and the government really improved significantly, and continued to improving the rules. How to make sure that all the investigators who work both with cancer and all the medical investigation do their job appropriately to maintain the safety. So all these rules are very well listed both in FDA website, and all institutions that conduct clinical research do have their rules on their website as well.

But let's come back a little bit to cancer research and is that something to close to you, and obviously close to me. And as we said before, everything that we are doing today in 2013 really came from our research in cancer. And we are very lucky that our predecessors and our colleagues in cancer really put a lot of years and a lot of effort to make research in cancer effective and very strongly regulated.

And some of the first things that many of our colleagues looked at was try to figure out how we all start speaking the same language. How we develop this new drugs, new diagnostic modalities, new surgeries so to prove to each other they work better. And we developed the outcome criteria so we can prove that our new treatments are better.

And they usually deal with the times that our patients can live, and that's called an overall survival. Or how long does our patient live without disease, and this is disease-free survival. Or a time our patient is free of progression of cancer, even when diseases, for example metastatic, time to progression.

And by being able to use the same points, we're able really to make progress saying that with this new drug, with this new type of surgery, this new schedule of radiation, we really can make our treatments and the outcome of our patient better.

I think as the time went on and we developed major strides in understanding cancer, understanding the molecular paradigms of how cancer does develop, we also developed what we call surrogate endpoint. So we not only can say that the patients lived longer, we also can say that this type of cancer does better with this particular drug. And again, as our knowledge improve and our understanding of the cancers and not just one disease, but probably a multitude of diseases that have different features, and we develop this specific surrogate, test for different diseases, we got better and better in understanding this.

So we start looking at tumor markers, molecular endpoints, genomic endpoints, and different type of novel imaging. Many of you definitely used probably different PET scanning, MRI PET imaging. There are now functional MRI imaging, trying to see how the tumor really function and breezes (ph) under condition of particular drugs. And this all brings new and novel results.

So their paradigm of how we do clinical trials also continues improving, but it's definitely, the war on cancer is still very far from being won. Why we cannot say that war on cancer is still not finished, because we still diagnosis quite many patients. Approximately one million people are diagnosed with cancer in the United States every year. And there are still probably quite a number, many hundreds of thousands of patients, die from cancer every year. In New York state, it's close to 800,000 to 900,000 patients living with cancer. And as a whole country, we know that there are more and more cancer survivors. Right now it's up to 13 million cancer survivors live in this country with cancer.

Why is it important to participate in clinical trials? Because the clinical trials lead to the answers that we are looking for. They are critical bridges that create the understanding between what we find in laboratory, what the brilliant scientists bring the understanding of cancer, to what we do in our clinics when we advise our patients on what their next best treatment when it comes to cancer.

So some of the rules that we've been using to develop of clinical trials is still very important. And in cancer especially, we divide our clinical trials in phases. The very early development of clinical trials are called Phase I trials, is when we get first the drug from the laboratory when we tried it in a petri dish and an animal, and we first start trying it in patients. We don't know yet whether the drug will be effective or not. We have all the reasons to believe it will be a very effective drug, but we first have to try whether it's safe, and we first have to establish whether the dose we think works, is it safe and correct dose? And this is called a Phase I trial.

And if we can get through this part and establish good dose that we think is safe, the next is so-called Phase II trials. And they really define if the dug, particular drug works in a particular type of cancer. Whether the cancer can shrink, whether we can find it by an x-ray or by a CAT scan, or by this all new novel technologies that I mentioned before, like a PET scan and MRI or this biomarker.

And if we can show well enough that the new drug seems to be working, it comes to so-called Phase III trials. Now we want to show if the new drug is any better than the old and established drugs, because then when we do so-called randomized, large clinical trials.

We frequently hear from our patient, why do you have to randomize or randomly assign us to one treatment or the other? And we do this really to avoid and reduce what they call bias. Because me as an investigator believe in the new drug, I can believe that the new drug is probably better, but if I knew it upfront, I would need to do this randomized trial. I also want to ensure that all patients are equal in this trial so I can really prove that one treatment is better than the other. And this is really our what we call evidenced-based.

How we do the clinical trial process? What do we need really to create this clinical trial? First I have, as an investigator, I have to put my thoughts on a paper. I have to write a detailed plan what I have to do. I have to figure out who are my patients are and what type of a treatment I have to design for them.

But I also have to very clearly define how I will protect my patients against harm. Not only I will have to look at it; multiple of my colleagues, as well as Institutional Review Board, frequently the FDA, and multiple data safety committees have to look at it to make sure that the research will not bring harm and potentially can bring good and potential positive result.

What is a benefit toward the participants to clinical trials? I think there's always a benefit to a patient facing a difficult disease, because not only they usually get a standard of treatment for their disease, they do get access to new and promising drugs.

They also bring something that enriches all of us, as well as new generation of patients that will come tomorrow that will be able to get the fruit of our knowledge, and you hopefully get better drugs.

But yes; there are risks in participating in clinical trials. There are sometimes unknown side effects, especially in what I called already early phase trials, like Phase I and II, when we did not learn yet a lot about this new agent.

It can turn out that the new drugs may not be as good as the existing drug. And this is something we can discover only in the Phase III trials when we randomly assign patient to drugs.

There is a potential for insurance issues, and there is a lot of legal battles happening everywhere, including the Congress, to make sure the insurance plans cover all the investigational drugs.

And there's always concern for patients that they lose their own decision making by somebody's assigning them to a treatment as it happen to randomized trial.

What's on the side of the patient? Who is safeguarding the patient? And first of all, their physician, as well as the investigators, are there safeguarding the patient. But there is a lot of other bodies that really there to support the patient and make sure they're protected against harm.

The FDA regulation really very strict to make sure that no harm is given. The Declaration of Helsinki and Belmont Report, they're baseline of our investigat-- Institutional Review Boards. And scientific and data safety review committees, which all look at how research is happening at all this institution to make sure no safety signal is being missed.

One of the issues we talk a lot among my colleagues who do clinical research that it's difficult to do clinical research. I think the numbers that are publicized in the United States, only 3% of adult patients in cancer participate in clinical research. This is quite a small number. For example, in pediatric oncology, in children oncology trials, up to 60% of patients participate in research.

And I think there is a lot of barriers that continue existing. And we as physicians and we as researchers want to make sure that we bring the message to our patients how important it is to overcome some of those barriers. And we want to make sure that patients A) are aware of ongoing research, that there is information. And we want to make sure we talk to about our patients about misconception about concerns that they're not protected enough, and they should develop trust to both their physicians, as well as investigators.

The physicians also have barriers. Some of them are not aware of the clinical trials. And they have their own biases and maybe concerns of their patients may be too sick, or may not understand because of some language barriers or some cultural barriers of developing research.

And there are some institutional barriers, because it is expensive to conduct research because we put so many measures to make sure that research is done well that it requires a lot of personnel to do a lot of things to make sure things are done well.

I think the main thing remains information, open communication, and transparency about the ongoing clinical trials, and open dialogue between patients, physicians, and investigators.

We especially concerned about some underrepresented groups, as we can call them in clinical trials -- elderly frequently do not participate adequately in clinical research; some representative of particular racial or ethnic group; women sometimes feel that they are more targeted; children and adolescent; patients who reside in rural areas where it's more difficult to get access to medical care, especially tertiary care; and people with special needs and co-morbidities as they have a lot of other medical conditions. But I think there are a lot of efforts happening nationally and internationally to make sure that all this group of patients have access to ongoing, exciting clinical trials that bring the new drugs to our patients.

I think as a breast cancer researcher, but also just as a medical oncologist, I think it's important for me to say that we live in quite an exciting time because we have a lot of new therapies coming

along. We call them targeted therapies. And they're especially exciting because they really represent a translation of all the advancement in laboratory research, all our understanding of how cancers happen and how they really develop and evolve. And attempts by chemists and laboratory scientists and doctors to create medications that specifically target this particular changes that create cancers, and to hopefully can bring good changes to cancer treatment. And I think with their advantage of having this number of new drugs, we also hope that we will accelerate or fasten the discovery of new drugs, but also incorporation them of clinical trials.

And especially I can be proud to say that in the area of breast cancer, there is a number of novel design of new trials. And we are able to bring new molecules, new drugs early in breast cancer treatment. And this trials really allow us to get results faster.

A good example will be something that we call, for example, locally advanced breast cancer. It's a breast cancer that we diagnose when we can feel them and not just find them on a mammogram. And this cancers we usually treat upfront with medication and not just with surgery. And this is very helpful that we can add new medication to transitional medication and find this novel medication, find better ways, defining better ways to treat this tumors, and if we can find this tumor shrunk or sometimes disappear at the time of surgery.

There are large national trials ongoing with a very interesting name which are called I-SPY 1 and I-SPY 2. It's like we are spying on this tumor,that introduce some of this novel drugs early in the treatment of the breast cancer. And we start collecting a lot of information on this drugs, and hopefully we'll come up with better, newer ways of treating breast cancer.

And many of these trials happen not only in very large hospitals, I'm sure they're happening around in many medical offices some of you go to to see your doctors. And I hope that after listening to me and after what Gwen has to say to you in her presentations, you will be more interested to speak to your physicians about available clinical trials, what's new happening in cancer medication and cancer clinical trials, and get access to this, as well as contribute to the novel development in cancer medication.

That's where I wanted to stop and would be happy to take question or have Gwen speak first.

Robin Perlmutter: Okay, I unmuted your lines, so if anyone has a question for Dr. Novik before we have Gwen speak about the patient's perspective?

Unidentified Participant: I have a question. Okay, so I follow the clinical trials for ovarian cancer. And I know that for one of the trials where they were testing Olaparib, they discontinued the path and canceled the Phase III trials because they didn't think that the results would translate to improved survival. But the results that they had showed that it did help with progression-free survival as compared to traditional statins (ph) or chemotherapy. And I was just wondering about the criteria for success and to continue, because I would think that for a cancer patient, being able to take a non-chemo drug and give them progression-free, improved progression-free survival would be a tremendous benefit. So could you comment about the criteria for success of a trial and what is forward?

Yelena Novik: It's a very good and a very complicated question. The ultimate goal for us as oncologists in our tumors is to make our patients live longer. And with this, we would like our patients to live longer without presence of the cancer. So yes, the way we design many of the trials is try to look at some of the drugs, bring improvement in the time, in the overall survival, and this is really the ultimate benefit.

I think some of the analysis, and we are going now into a lot of statistical difficulties, do show that time for the cancer to progress may be somewhat changed by adding one drug or another drug. But if it does not really affect the total time for patient to be alive and well may not be such an important drug.

This whole class of drug of PARP inhibitors, Olaparib and Veliparib, has been a very difficult discussion both in breast cancer and ovarian cancer, and it's probably still an ongoing dialogue in terms of ovarian cancer patient, and almost gone from the horizon of breast cancer trials.

There are many trials that were done before and done with some other biologic drugs. And progression-free survival on continuous look when a longer follow up was done on this patient did not appear still to continue to show progression-free survival with a longer follow up. Did not know the exact detail on a particular trials you are talking about. But the ultimate to really result that everybody wants to see is an improvement in overall survival. But also how is it-- studies are frequently being designed so that statistically they cannot prove the change in overall survival. They may not have proven their point.

I know it may sound disappointing, but they're, as you know, the Olaparib drug, as well as Veliparib, those drugs also do have some toxicity and some side effect profile. Some of them we are just discovering, because we've started using these drugs for a little longer period of time, that may not be as safe as we originally thought.

Gwen Harding-Peets: I can speak a little bit to that as well. You're talking about what are the endpoints for a particular trial. And in the ovarian cancer, that has been really hot topic for a number of reasons. Number one is most of us reoccur. And so when we reoccur, we get drug A. And in the end, by the time we get to the final end of our journey, we may have been to X, Y, Z. And so it's very difficult to determine how much did A actually contribute to our overall survival? And so that's where progression-free survival has been made as one of the surrogate endpoints for us.

But the other thing that you're starting to see more and more, especially in ovarian cancer, is the contribution of quality of life. That if it increases your progression-free survival such that you're spending less time in toxic environments, using toxic drugs and chemotherapy, there may be a benefit there. But there's been a lot of challenge right now over that. You saw that with Avastin. You're seeing that with the PARP inhibitors. That's one of the real controversial points about a lot of our trials right now.

Yelena Novik: Absolutely. And believe me, it's a very similar controversy in many diseases. Let's say if you take the example of breast cancer trial, and Avastin would be a good example, Avastin was originally approved for breast cancer based on progression-free survival. And then with later look at the same trials, the FDA rescinded their approval for the same drug, and there was definitely not change in overall survival. So there are some other trials and secondary and third line therapy that still show some improvement.

And it is true, let's say breast and ovarian cancer will be great example of what, that we still have a lot of good drugs that altogether allow us to keep our patients alive longer, but their quality of life really starts suffering. And even for novel drugs that we first are very enthusiastic about do have a negative impact on quality of life and do have some side effects that we originally did not see in early phase trial and discover later.

Unidentified Participant: Okay, thank you. And I just wanted to let you know that I am in a Veliparib trial and am doing well with no side effects.

Yelena Novik: Excellent, excellent.

Robin Perlmutter: Any other questions for Dr. Novik before Gwen speaks?

Unidentified Participant: Just one more thing, real quick question. What was the name of that drug that she's on?

Yelena Novik: Veliparib.

Yelena Novik: So we mentioned two PARP inhibitors. Both of them are only available in clinical trial. One is Olaparib and the other is Veliparib. I don't remember with my head right now which one is produced by which company. Veliparib I think is ABT and Olaparib--.

Gwen Harding-Peets: Actually, Veliparib, the company split, so it's now under company name "AbbVie." That's the new company for Veliparib. And Astra Zeneca is the one for Olaparib.

Yelena Novik: Yes. It used to be KuDOS and then it was AbbVie.

Unidentified Participant: Okay, thank you.

Robin Perlmutter: Any other questions for Dr. Novik?

Gwen Harding-Peets: I actually had two questions. One was do you see any changes in how clinical trials are going to be conducted in the future as we get more and more personalized and targeted therapies developed?

Yelena Novik: Excellent question. Yes, there is a lot of very interesting developments, and they are probably more done by statisticians but together with clinical investigators. There's a number of trial designs that people are trying to look at in their trial, of the number of surrogate endpoints.

There's so-called adaptive designs, for example. There's a lot of discussion and controversy. And the principle of them is also trying to, as you try to develop a trial for a particular group of patients or tumors with a particular feature, as you go, you increase the number with a particular feature if this drug works on the particular targeted design. So it's kind of a complicated statistical formula. But they may lead to improvement in time how much it may take to really develop this trial and prove that this drug or agent may be effective.

And the other feature is also developing things like functional imaging. For example, there is a lot of very interesting technology and novel. PET agents and PET MRI technology that allows also to combine, for example, vasoactive drugs in combination with some cytotoxic drugs. And to image them basically in vivo and see the drug distribution and also drug effect in a much shorter period of time to be able to assess some success, or lack of such, in a faster fashion.

So there is definitely a lot of effort trying to move this new drug into action at a faster pace. Because I think now we have a lot of drugs, but we're also trying to move them faster because it does take quite some time to really get a drug through the protocol design. Design it through clinical trials to get it anywhere closer to the market.

Gwen Harding-Peets: Thank you. The other question I had was when I was researching around on clinical trials a while back, I came across on NIH's website the concept of a research match for identifying potential participants; matching participants to researchers. Have you ever used that?

Yelena Novik: We use it somewhat. It's a wonderful instrument, though I think it still has limitations. I think the primary institution who really built the instrument is Vanderbilt. And it's trying to match patients with particular protocols. I know Vanderbilt had made some success, and I think it's an Oregon or Ohio State that has been really using it more.

We tried to use it through CTSI. I know non-oncology groups had done a lot of success using this instrument, pulmonary emphysema studies, etc. Our group has not used it that much. I just think it's a little harder, especially now with there are so many molecular testing and tumors that we all do that it's-- the future I think of matching all of this through some IT system, and I think it will be coming along, but there is a lot of also personal information that we'll have to figure out how to match it all. But it will be coming along. I think it will come along.

And I will tell you, NCI has been, it's already been working for a number of years, trying to put a number of databases together from different NCI-designated institution databases, because some of them work from different electronic platforms, to be able to make them universal. So let's say if you have a tumor which has this particular gene mutation, you theoretically can find a trial that, intended (ph) drug targeting this. But I don't think we are there quite yet.

Gwen Harding-Peets: Could you also maybe speak to, I know there's been some efforts to help start moving more clinical trials out to community hospitals.

Yelena Novik: I think there's a number of different initiatives. First of all, many large university-based and NCI-designated centers works, is through CCOP, which is Community Cancer Oncology Practices, or just affiliated through different hospitals and bring this, especially large, randomized Phase III trials into the community. But I think also some industry and some other trials are coming more and more into the community.

I think one of the things I spoke about is a very strict oversight, which is probably more difficult to do in smaller practices, just because they don't have the resources of larger academic institutions in terms of ROB and data safety committees. But I think it all comes also to resources and collaboration.

We, for example, I work at NYU. We work with large urban hospitals. Let's say if you go to Hopkins, they have multiple community hospitals all over Maryland and Virginia, working in the Hopkins kind of network surrounding. And I think many of their large institutions works through them. So I think there's more and more clinical trials coming through the community. It's a matter of educating I think a lot of physicians in the community to work with their peers in larger hospitals.

Robin Perlmutter: Okay. Anymore questions? Okay, folks. So now it's my pleasure to introduce to you Gwen Harding-Peets. As I mentioned, she's hear to speak tonight as an ovarian cancer survivor, a patient advocate, amongst many other things, about the patient perspective on clinical trials. Thank you so much, Gwen, for sharing your time tonight.

Gwen Harding-Peets: Basically what I wanted to do is just to kind of be the balance to the professional side and kind of talk a little bit about, well, what is it like from a patient's perspective to be participating in a clinical trial?

First of all, today is my eighth anniversary of being diagnosed with ovarian cancer, so I've got eight years' worth of experience here. And one of the things I want to point out is just in those eight years, there's been two advances in ovarian cancer that for some people have really meant a big-- have been very important improvements in terms of survival. And that's IP therapy and Avastin. And those wouldn't have been made available unless people had participated in clinical trials.

When did I start to consider participating in a clinical trial? And in my particular case, I started from day one. I made sure that when I first went in to see my gyn/ob, that they knew that I was interested in clinical trials. That if they had clinical trials that they felt were appropriate to me to please bring them to my attention. That didn't mean that I would necessarily buy into it, but that I wanted to at least know what was out there and seize an opportunity if I thought it was appropriate for me.

From day one, I did sign off on bio specimens in that everything that I give them, I give them free rights to any excess stuff that they need above and beyond whatever normal tests they do for me. I've also participated in a study where they wanted to do certain testing to see if certain blood samples correlated with certain other conditions.

But more importantly, at every stage, whenever I got to a decision point, that was always a discussion I had with my doctor. What's next? What are my options? And are there any clinical trials that are appropriate for my particular situation? And the one that I ultimately ended up taking advantage of was after I got to my second remission, I did participate in one of the vaccine trials. And I finished that up in the summer of '09, and have been off treatment ever since then.

One of the questions I'm at, whenever I talk with women about clinical trials, one of the questions that first comes up is how do you find out about clinical trials? And in fairness to doctors, it's not-- a doctor is really going to know what clinical trials are in their institution. That's what they're going to know best.

You're going to have to end up being your own best advocate in terms of finding clinical trials. And there's a couple of good places to look for it. One of them is clinicaltrials.gov. That's a huge database of clinical trials. And you can go in, put in your particular condition, and you can say I'm stage 3 ovarian cancer with papillary serous, and I'm currently in treatment, but I'm needing to move on. And you can see what other clinical trials are out there based on what you've currently been treated with and where you are, whether you're in remission or whether you're progressing.

Another place for those of you who are in ovarian cancer treatments, OCNA, or the Ovarian Cancer National Alliance, has a free clinical trial matching service. And one of the things that's really nice about that is not only can you do it online, but you can actually call an 800 number and have somebody walk you through it. I had one friend who used that, and as a result of that, for quite a while she got e-mails. As new trials were added to the database, then she would get an e-mail saying, hey, this one is opening up now or this one is now closed, or whatever.

And certainly one other place you can always find out about clinical trials is talking with other survivors. Survivors are in support groups in your local areas.

For me, one of the other places that I go when I look for clinical trials is I go to the ACOR list, or I go to OCNA's online support group, Inspire. And if I'm researching a particular clinical trial that I think might be good for me, I might put a call out saying, hey, does anybody on this clinical trial or does anybody know anything about this particular drug or have any experiences that can help me make a decision about it? Now, if you're on a Phase I trial, then you may or may not find

anybody else who has ever been on it, but that's certainly one way that you can at least put feelers out to see who else might know about some of those drugs.

There's two things that I want to make sure and point out. One is that all clinical trials are voluntary. That-- and I know that that was said earlier, but I really want to stress that. You have the right to choose whether or not you will participate in a clinical trial, and you also have the right to leave the clinical trial at any time for any reason. And ultimately, that shouldn't affect any of your long-term care.

The second thing that I wanted to point out is that very few clinical trials for cancer involve a placebo. One of the biggest things I hear from women is that they're afraid that they're going to get a placebo rather than treatment. If you are in a situation where you have progressive disease, and it's a choice of doing nothing or a drug, then you might get a placebo. But more often than not, you're going to get whatever the standard of a care is, plus whatever the other drug is. So it's not a case of where you're not going to get any kind of treatment.

I know earlier that there were some of the things said about why participate, what are some of the pros and cons. One of the pros is that you'll have access to new treatments that aren't necessarily available to other people outside the trial. For ovarian cancer patients, Avastin was a good example of that. Both Avastin and PARP inhibitors were very popular drugs that women wanted to try. And in early days especially, they were only available through clinical trials.

And in some cases, I have had friends who were on a clinical trial. It appeared that the drug was working for them. Even when the clinical trial ended, they were able to continue on with that drug, whereas if they had been part of the normal population that hadn't been on that trial, they wouldn't have had access to that drug long term.

Some other women do clinical trials because during the time that you're on the trial, often times you are watched much more closely than you would be if you weren't on the trial. There's some times more tests that are done to monitor your condition, more detailed bloodwork done, that kind of thing.

Now, that doesn't mean that there aren't risks. There are risks associated with anything we do in life, and this-- clinical trials are certainly no different. You, especially in the early trials, Phase I type trials, they don't always know much about what to expect about side effects. And so there may be some issues with side effects that may not be desirable. You may not be, in the later trials like a Phase III trial, if it's randomized, you may not be part of the treatment group that gets the experimental drug.

The other thing is that there-- it does-- clinical trials often times do require more time and attention on your part than just being treated standardly. There's, like I said, there's often times more bloodwork, more treatments and such, and so often times you end up having to spend more time dealing with treatments.

Another big issue for many of us, and this is actually one that I think I underrated when I first took-- when I participated in clinical trial, and that is who pays for the trial? When you think about a clinical trial, there's two kinds of costs associated with it. One is the patient care costs, and those are the normal kind of bloodwork and tests that would normally be run on you, regardless of whether you were in the trial or on other treatment. And the other are the research costs.

And for many people across the country, patient care costs, or those costs related to just treating your cancer, whether you're in a trial or not, things like paying for the doctors' visits, some of the lab tests, certain imaging tests, some of those are actually covered by health insurances, various health insurance and/or Medicare. Now the health insurance issue is a state-by-state situation. There are a lot of states that have laws in place now saying that health insurance must cover those patient care costs.

The other part of it is the research costs. And those are the costs that are associated in the trial that are not covered by health insurance, but that are often times covered by the trial sponsor, whether it be an institution, a pharmaceutical company, or whatever. And these are lab tests performed purely for research purposes, and additional tests, and of course the drug.

Now, when you take part in the trial, that's-- one of the things I would recommend that you do ahead of time is sit down and talk to your doctor about what are the costs associated with doing this trial, and how much of those costs am I going to end up having to bear. In my particular case, my health insurance did cover things, but the way my health insurance works, it only covers 75% of, like for example, imaging studies. And so in my trial, I had to have three imagings, CT scans, that I wouldn't have normally had. And so I ended up paying 25% of three scans that I wouldn't have necessarily normally had. And that, those costs are things that you need to think about upfront.

In addition to that, you're going to have extra, like if you're like me, I live two hours away from my institution, and so there's travel times and costs associated with that. And if you're a mother, then you also have to consider things like childcare.

Now, assuming that you found a trial that you're interested in, your next step is to sit down with the investigative team that's responsible for that clinical trial and talk through with them what the trial is about and so forth.

When you're sitting down with them you're going to want to know things like what are your options and how do they compare with what the clinical trial is offering. You're going to want to know what is known about this particular drug. In some cases, the drug may have already been used in other trials, and it'd be helpful to know what's been learned about it? How did people respond to it? What are the risks and benefits, both short and long term? How will I know whether or not I'm getting the investigated drug? How will I know whether or not the drug is working? If I benefit from the drug, will I be allowed to continue receiving it after the trial ends? Who will be in charge of my care? And who can I speak with about questions that I have during and after the trial? It's very important that while you're on the trial that you know, should you have any questions or any issues arise, you need to know who is the contact person that you can reach and get resolved whatever your issues are.

Whenever you do go for consultation for a clinical trial, or actually, a lot of these things would be applicable to almost any doctor's appointment you go to, consider taking a family member or friend along. One of the biggest issues for me was having that second pair of ears that could help decipher some of the things we were hearing. That if often times, you're at a decision point when you're going for a clinical trial, and you may not be able to absorb everything that's being said. And it's helpful to have somebody else who's a second pair of ears that can help you.

Plan ahead what to ask. Write down your questions the night before. I always write down my questions and I make two copies, one for me and one for my husband. And then on the way home, we compare what our answers were, or what we thought we heard as the answers.

You can also even consider bringing a tape recorder and asking the doctor or the nurse or whoever you're talking with if they'd be okay with you actually recording what was being said so that you don't miss something that may be critical to you down the line in terms of making your decision.

I guess what I want to do now is just open it for questions. If you have any questions about what's it like from a patient's perspective, that's really where I can answer questions, maybe.

Yelena Novik: Or I can take any questions, as well, if somebody came up with more ideas.

Robin Perlmutter: Okay, thank you, Gwen. Any questions for Gwen?

Unidentified Participant: I have a question. I was wondering, generally how long does it take to get into a clinical trial?

Gwen Harding-Peets: Really good question. In my particular case, it took me about seven months. In a lot of cases, it doesn't take nearly that long. I think in my mom's case, most of the time it took her maybe a week or two weeks. A lot of it depends on what trial you're trying to get into, what's available, what matches up with you, whether it's a case of you're looking for treatment, or are you looking for, in my case, I was looking for something to help prolong my remission. So a lot of it just depends on what it is and where it is.

Unidentified Participant: Okay, but sometimes the red tape can be pretty minimal and you can get into clinical trial as fast as a week?

Gwen Harding-Peets: Oh yes, yes. Oh yes.

Unidentified Participant: Neat. Okay, thank you.

Gwen Harding-Peets: In my case, it was a case of where I was trying to get into one clinical trial, and what happened was one of the manufacturers of part of the mix there quit making it, and so they had to find another supplier. But that meant that they had to go back through the FDA and stuff. So the red tape wasn't on my end; it was on their end trying to get the materials together.

Often times what will happen is you'll express an interest in it and they'll review your chart to see that, okay, is this even look like a good match? It may be that you need to have a scan or something that demonstrates something about where you are in your progression, if you're seeking a treatment drug. And then after that, it may be you're in.

A lot of it just depends on what's available. Is the clinical trial open? How many slots are there? And are you available to do what needs to be done?

Yelena Novik: And if I can add, sometimes let's say if it's some early phase trials, they do have some safety analysis happening periodically, so sometimes it's an additional wait to make sure that whatever level was happened already was analyzed and there is good safety to move forward.

And as Gwen said, if it's a regular-- if it's approved, it's open in an institution you're going to, and if all the tests and all the other things available, sometimes quite possible to get into a trial within a short period of time.

Robin Perlmutter: Okay, thank you. Any other questions for Gwen or Dr. Novik?

Unidentified Participant: For Dr. Novik, I was wondering, I'd like to keep up on the clinical trials. And at clinicaltrials.com, there's rarely any postings about the results of the trials. I was just wondering what's the best way to keep up on the results of trials and what solutions that comes out of it?

Yelena Novik: Clinicaltrials.gov now is, will start posting because the legislation covering the clinicaltrials.gov is really quite recent. So it will start posting the results both for efficacy as well as per toxicity for the trials that's ongoing. So it's kind of a tricky question.

Most results are really published in meetings. Let's say for American Society of Clinical Oncology will publicize results of most important meetings, let's say in breast cancer. Also San Antonio meetings, like as a GO, we'll have their Society of Gynecological Oncologists will have their meetings. They will publish results of most important trials.

But clinicaltrials.gov really gives you a lack, a lag of time before any results will appear there because it's kind of more individually looking for results. At this point there's no one repository that will, I think will publish everything together. So it's mostly ongoing and open trials in clinicaltrials.gov.

Gwen Harding-Peets: If I may interject there a little bit. One way that I kind of get a heads up about some results is I have a Google search on ovarian cancer that I get every day. It's an e-mail that comes back to me. And that is sometimes where I will find a heads up. For example, when the Farletuzumab just recently failed its second phase clinical trial, the press releases on that and the papers on that-- well, the press release is going to show up even before the papers do, and that's where you can kind of get a heads up on what the hot results are that are coming off trial.

Yelena Novik: Right. But the meetings, usually they'll give you a little more detail.

Gwen Harding-Peets: Yes, I understand that, but often times for us, we can't-- we get the abstracts, but at least we know a heads up what to look for.

Robin Perlmutter: Okay, terrific. Any other questions for Gwen or Dr. Novik?

Unidentified Participant: Yes, I have one question.

Robin Perlmutter: Okay, go ahead.

Unidentified Participant: She had mentioned with onsno, or something like that, at the very beginning about finding trials.

Gwen Harding-Peets: OCNA. Okay, if you're an ovarian cancer, somebody diagnosed with ovarian cancer, Ovarian Cancer National Alliance, or OCNA, O-C-N-A. Their website is ovariancancer.org, I think. They have a free clinical trial matching service on their website. If you go there, on the top bar there will be a place that says clinical trials. And if you drill down there, you'll find the information about the free matching service.

Unidentified Participant: Okay. Thank you.

Gwen Harding-Peets: I'm sorry, it's ovariancancer.org. Ovariancancer.org, clinical trials.

Robin Perlmutter: Do we have any other questions?

Unidentified Participant: Yes, I have one more. I was wondering if there are any advantages and disadvantages between trials that are sponsored by GOG (Gynecologic Oncology Group) or by the drug companies? And what pros and cons there might be between those two types of trials?

Robin Perlmutter: Dr. Novik, are you going to take that, or Gwen?

Yelena Novik: I think nowadays, I think you have to realize that all these types of trials do undergo a similar scrutiny, really, at the level of National Institute of Health and at the FDA, etc.

Yes, theoretically, any industry-sponsored trial will have some selfish intersts. It will be drugs that they developed and they're trying to push into the market. But the majority of trials, whether it will be GOG, or let's say if you take cooperative groups that work with other tumors like ECOG (Eastern Cooperative Oncology Group) or NSABP (National Surgical Adjuvant Breast and Bowel Project), they will work with some drugs that produce by industry.

So most cooperative groups, their largest trial as a randomized Phase III trials, so they will be this large trials comparing end of care to some novel drugs. So they rarely will do Phase I and not too many Phase II trials, and GOG may be better than some other cooperative groups. I think all of them are really good, well-designed, well-thought-of trials. So I think whatever really matches a particular clinical scenario I think can work.

Unidentified Participant: Okay, thank you.

Robin Perlmutter: We have time, guys, if anyone else would like to ask a question. Okay then. If there's no more questions, then I just want to take a minute to thank all of you for coming on the line tonight from all different time zones, and especially a big thank you to Dr. Novik and Gwen for sharing your time and expertise.

And we look forward to offering some more of these educational teleconferences as we go forward in 2013. And I wish you all a very good evening, and for anyone here on the East Coast, a safe travels tomorrow and enjoy the snow day.

Yelena Novik: And thank you everybody for joining. It's always a privilege for me to be able to speak to you.

Gwen Harding-Peets: Thank you.

Yelena Novik: Okay. Thank you, Gwen, a lot.

Gwen Harding-Peets: Well thank you, Dr. Novik, for your time.

Yelena Novik: Okay. Goodnight everybody. Be safe.