Global BC Advocacy Webinar Series

Webinar 1: Introduction to Medicine Development and Research

PATTI JEWELL, *Pfizer*: Good morning, good afternoon, good evening, everyone, depending on where you're joining from, we are so happy that you are here with us today. Thank you for joining. On behalf of the Pfizer team, I am very pleased to welcome you here today

My name is Patti Jewell. I am Senior Director of patient advocacy for Pfizer. And again, on behalf of the entire Pfizer team, thank you for taking the time to be with us here today. This webinar is the first in a series that Pfizer is planning. We are hosting this to support you as breast cancer advocates to learn more from experts in the field about specific topics and to learn from each other about programs that other advocates have developed on particular topics. And many of these are going to give you some ideas of some different activities and programs that you can be doing in your communities.

For our session today, we hope to improve understanding of how medicines are developed and to discuss key steps and data gathering and analysis. We're also looking forward to sharing two best practices of how advocates can educate and reach patients about clinical trials and breast cancer.

Next slide, please. So this webinar series was inspired by a meeting that we hosted last October to learn from leaders in the advocacy community about ideas that they had to improve breast cancer care and the categories of research, policy and patient support.

Participants in the summit came up with a list of 81 action items, the report from this meeting and these 81 actionable solutions can be found on breastcancervision.com. I encourage you to go check that out. We have the materials available in eight languages: English, German, Spanish, French, Hindi, Malay, Portuguese and Chinese. We hope these materials are helpful to you and the communities that you serve and encourage you to visit and share.

A key theme that we heard throughout the summit is that advocates really like to learn from each other, and they wanted to learn more about specific topics. We have put together this webinar series to do just that.

If you go to the next slide, please. We're working with a planning committee of six advocacy leaders from around the world who have provided input on the specific topics and specific programs to be able to highlight in these webinars. So many thanks to Conchi Biurrun, Bertha Aguilar, Renate Haidinger, Stacy Lewis, Shirley Mertz and Ranjit Kaur for taking the time to share your ideas and insights that are informing this and future webinars. I'd like to turn over now to Conchi Biurrun a volunteer with FECMA in Spain to lead today's session Conchi over to you.

CONCHI BIURRUN, *Federación Española de Cáncer de Mama (FECMA):*
Thank you, Patti, and nice to meet you here for our first webinar. And good afternoon from Spain, good morning to all of you. I'm really honored to be here today and thank you very much Patti for having me on this project. It was our discussion with you and your advocacy colleagues last year that led us to create this webinar, which is the first in a four-part series and is the direct result of the feedback received during the summit of last year. During the series, we will explore different aspects of breast cancer research, including today's introductory session on medicine development and research, a focus on real-world data generation, how to infuse the patient voice into medical research and how to generate and utilize advocacy-led research.

Next slide, please. We are looking forward to a great session today. To give you a brief overview of the agenda that we will spend the next 15 minutes hearing from Dr. Elizabeth Comen about how doctors collect it and why it is important in breast cancer research. From there will be real case studies from Cancer Support Community and BreastCancerTrials.org of how our fellow patient advocacy organizations are engaging with patients on clinical trials, and then we're going to spend the last portion of our time together answering any questions you may have of the speakers.

Questions can be submitted throughout our session using the chat function. Now, let me introduce today's presenters.

Next slide, please. Dr Comen is a medical oncologist specializing in treating breast cancer patients at Memorial Sloan Kettering Cancer Center in New York. She will take us through the important aspect of breast cancer research. Claire Saxton is the Vice President of Cancer Support Community, the largest professionally led nonprofit network of cancer support worldwide. Claire serves as an external ambassador and internal adviser on the cancer patient caregiver experience, utilizing the full breadth of CSC psychosocial and patient experience research. Finally, we will have Elly Cohen, who is Co-Founder of and Senior Adviser to BreastCancerTrials.org as program director until 2020 she led BCT to its development, pilot evaluation and successful launch as a nationwide nonprofit service in 2008. Dr. Cohen is frequently invited to talk about clinical trials to patient groups and is a breast cancer survivor. I kindly request presenters to beware that part of the audience is non-native English, so please speak slowly. Thank you. And now we coming forward to Dr. Comen please.

HOW WE COLLECT DATA AND WHY IS IT IMPORTANT FOR BREAST CANCER RESEARCH?

DR. ELIZABETH COMEN, *Memorial Sloane Kettering Cancer Center*: Hi Everybody. It's my absolute pleasure to be here. I've worked with a number of advocates over the years, and one of the things this really makes me think about is how important breast cancer advocates are in really infusing academic medicine and pharmaceutical approaches with a sense of what it's like to be part of a breast cancer community, what it's like to be a breast cancer patient. And in many instances, we're so caught up in the academics and biology of it that we really need to make sure that we are infusing our work with the with the voice of the advocate. So I really appreciate your being

here. As I speak quickly, I also am reminded that many of you do not speak English as your first language. I really don't speak any other languages very well, so I admire you for being here and taking the time, especially if English is not your first language.

I'm here really to talk about how we collect data in the academic setting, in the research setting and why it's so important for breast cancer research. My background is as an oncologist. I treat exclusively breast cancer patients only, but I'm also a physician scientist as well. And what I love so much about the work that I do is that I collaborate with not only different pharmaceutical companies, but really, at my hospital and other academic centers, I work with different laboratories to help understand what they're doing in a little Petri dish and trying to, or potentially in the mouse experiments that they're doing, trying to really understand what they're doing in the laboratory and how we can bridge that into the clinic to make clinically meaningful advances for patients.

One of the things that you may hear a lot is that the latest news may say that we've cured cancer in mice. Well, obviously patients are not mice. We're not made out of plastic. We're not Petri dishes. We're not laboratory test tubes. And it becomes so important to understand how we actually bring these seemingly exciting laboratory advancements and make them clinically relevant for people. So, what I'll talk about today briefly in our time together is how we do that.

If you could go to the next slide, please? So, understanding the research process. Well, first, as you can imagine, it's very complicated. On the left here, you can see the concept of an observation or hypothesis, and one of the challenges and in research is it takes a lot of infrastructure, it takes a lot of coordination, and it frankly takes a lot of money. So, people can have a good idea. But if they don't have the background, if they don't have the support, if they don't have the collaboration, it's very hard to execute an idea and actually have it even pass the first step here. So you know, an observation or hypothesis could come from a laboratory investigator or a scientist. It could come from someone in clinic saying, I saw this patient and they responded differently or unusually to a treatment and I wonder if trying a different approach might work. Or maybe they work at a big institution, and they've seen a drug or another medical concept work in another type of cancer, or maybe even another type of medical problem, and that's what inspired their idea.

The next step is how do you really pull this together in in terms of discovery? And again, that almost always involves laboratory analysis and people working who may be PhDs or scientists and not have any idea of what it's like to be a patient. Which is why when you think about how we do research, it's so important to have breast cancer advocates. I'll give you a little example, which is that I am working on a project that is trying to develop a blood test to detect breast cancer in patients before they even know they have it. Before they have an abnormality on a mammogram. And one of the ways some of the patients that are participating in this are women who have an abnormal finding on a routine mammogram, and it's not clear before it's biopsied, whether it's cancer or not. And one of the brilliant scientists that I work with was very confused about why it was so hard to consent women for a blood test when they were coming in for their mammogram. He literally didn't understand why a mammogram in that setting would be stressful to a woman. And we really had to educate him that it's not just an X-ray of the breast, but it can be really scary to have to go get a mammogram, let alone get a biopsy.

So good research really involves scientific collaboration, clinical collaboration and, of course, understanding what it means to be a patient and what it means to participate in a clinical trial. And then you can see on the next line here, potentially you're developing something that can be a preventative intervention or preventative test.

Go back to the other slide. Are you advancing me because I'm talking too much? And then obviously the most important point is, are we changing clinical practice? Research is the reason why we have made all of the medical advances and why breast cancer outcomes have improved dramatically in the last several decades. And so what we're all moving toward is seeing how we can change clinical practice. Although, in reality that is much harder to do even if you have a great idea.

And now next slide, please. And so here's just an overview of some of the clinical trials that we might do. We might think about doing a prevention trial, whether a certain diet or exercise, or potentially even a medication might work to prevent a future breast cancer. Then we think about screening. Are there better ways that we can image potential breast cancers? And, as the study that I'm working on, trying to refine the type of imaging that we do and who and how we image patients so that we catch the most important breast cancers, but also don't subject women to unnecessary biopsies, for example.

Then there's also diagnostic. How do we improve the diagnosis of breast cancer? Of course, we all want to focus on treatment. How do we improve treatment for all stages of breast cancer? And then another really important area of clinical trials is that, particularly when it comes to cancer, we don't want women just to live longer, but we want them to live better. And that could mean if it's early-stage breast cancer, whether we're not just curing patients but also thinking about their other quality of life functions. How well are they able to exercise? What is their sexual function like? How happy are they in their lives?

And then, of course, our metastatic patients, patients who have more advanced disease, we're not just looking to extend their life by months and years, but how do we give them a good quality of life? And these studies have become increasingly important, particularly as our outcomes for breast cancer are better.

And then there's the natural history of our observational studies. So these are ones where we're not necessarily intervening on somebody, but we're observing how they do over time. And those can be a little bit trickier because you're often relying on patients reporting their own findings or as part of a survey. And it's a little bit different than if you are actually giving them a drug and seeing how they do over time.

Next slide. So the drug development process. The thing to know here is it takes a long, long time to develop a drug. The most important thing is in the very beginning you want to be able to try out medications based on the science that you've been investigating, but you don't want to do that in people right away. So as you can see on the left here, some of the first things that we do are test toxicity and the safety. We can do that looking at cancer cells, but we also use that or test that with animal models such as mouse models. And we use mice very often in breast cancer research.

And then before you can ever test anything in a human, you have to apply for a special application called an Investigational New Drug Application. And that's an application to the FDA where you discuss what you want to use this drug for and the plans for how you're going to test it safely in humans.

A Phase 1 trial is where you're testing how safe a drug is in humans. You're not necessarily testing how well it's going to work for a given disease, but really just whether it's safe or not. And what is the appropriate dosing for that. Then when you move on to a Phase 2 and you can see a lot of drugs don't work once they get to this Phase 2,

when you actually start saying, how safe is this in people? But also, how well does it work, what's the efficacy of the drug or the drugs?

And then this is where we really want to see benefits. In a Phase 3 trial, you're looking at a large number of patients to see whether, let's say you're trying a different drug, does it actually improve outcomes for patients? And that's where you have the larger numbers and the ability to have more statistical power to really assess whether the drug is going to work.

And then based on the Phase 3 trials, you can apply for what's called a new drug application or biologic license application with the various regulatory authorities in a given country and, provided that that is approved, that's when you can launch a new drug. And so if you see on the next slide, it can take years and years, and that's a frustrating process for everybody involved.

So next slide, please. So, what are the stages then of the data analysis, or how we actually get going with a trial? As someone who's been part of trials? Yes, it involves a lot of collaboration, which is a good thing. But the collaboration and coordination again takes a lot, a lot of work and coordination. So first, you have to figure out the design of the trial and who's going to participate. One of the most important things with the clinical trial is to figure out, is this going to be launched at one hospital? Is it going to be launched among many different hospitals or practices in a given country? Or is it going to be an international study where you think about including people from all over the world? And so to execute and coordinate all of that, you can imagine with many different hospitals, thousands of patients potentially and maybe even a hundred different hospitals, it's a lot of coordination.

And then of course, there's the data analysis that happens all the time. And the data analysis isn't something that just happens at the end of a given trial. It happens throughout the everyday. The data is being analyzed in terms of side effect profiles that patients could be experiencing or any other concerns, including how well people are responding, how often are they coming in, how are we coordinating their imaging, their blood tests, all of that. It's a major, major process every single day, both for the larger collaborative groups, but also for the individual doctors that are helping to participate in these trials.

And then, of course, it all comes together, often in a publication or a presentation at a at a big conference. And most importantly, the hope is that the data is robust and shows some benefit to patients. And in that setting, a drug can then be approved for a larger use.

Next slide, please. This is what I've sort of been alluding to all along, which is that to actually develop a drug is a lengthy and very expensive effort. And unfortunately, most drugs fail. And there's a lot of thought about why that may happen. But the complicated part of statistics is that in order to see a benefit and to prove that something actually works, you often need to try it on a lot of people. And one of the things that we're learning is it may be that when you try a drug on a large number of people that there may be still some people that have benefit and we don't know why. There's a lot of interest right now in trying to figure out how do we find unique responders to medications that might not necessarily show up if you're just looking at big numbers. But in terms of how long it takes to have one FDA approved drug, you can see from this trial it could take up to 10 to 15 years, depending on what stage of disease that you are trying to look at. For example, if you're looking at metastatic breast cancer patients, unfortunately, as we know, some of those patients may not do well over time. And so you can see more quickly how well a drug may work or not work, because if they're not going to do well a metastatic patient might

get sicker sooner. If you're looking at a drug, let's say, at preventing breast cancer or treating early breast cancer patients where most patients do really well, it can take a long time – years and years to really figure out who are the patients that did well, who are the patients did that did not do well and did our intervention, or our drug, perchance make any difference in their lives at all?

So again, you can see drug discovery and pre-clinical studies can take a long time. Just developing the drug and coordinating a trial can take a long time. And FDA approval, of course, can take a long time as well. One of the things I think that's my last slide, but one of the things I wanted to really address, as well as something that I hear from patients a lot, which is, are you talking to me about a clinical trial because I'm a guinea pig or there's nothing left? Or are there no other options for me? Are you just experimenting on me? And I think it's so important for doctors to be able to communicate why we do clinical trials. What they mean for patients. And for patients to really express what their concerns are. One of the most important things to know again is clinical trials, and the benefit of them, is why we have been able to improve outcomes for breast cancer patients with all stages of disease. If you come to my hospital Memorial Sloan Kettering and let's say you're just at increased risk for breast cancer, but you don't have it, you can still participate in a clinical trial. Maybe that's looking at prevention. Maybe that's looking at how we screen for breast cancers. And in terms of whether people are going to just be given a placebo – for patients who have cancer, we are almost never giving anybody a placebo unless not treating it would be standard of care. We always have to give patients what's called standard of care. Meaning that we're giving them either the option of standard of care or if they're going to participate in a clinical trial that we're very, very clear about what the different options are. There's never any experimentation without patients giving what's called informed consent where they understand what their options are and why they're doing them. But we are very much aligned with our patients. We want to do what is best for them. And it's very important that if patients have concerns about why they're participating or being offered a clinical trial, that they express them to their doctor. I'll just end again with really an emphasis on, I want everybody here who's a breast cancer advocate to know how important you are in the breast cancer community internationally. And we thank you for all the work that you do to communicate with physicians, to advocate for patients and to help be a part of improving outcomes for patients. Thank you so much.

CONCHI: Thank you very much, Dr. Comen, for such an interesting speech. I want to remind you that you can use a chat function at the, in the bottom right corner of your screen to ask questions while the session is on. Next slide please. I turn it over Claire Saxton. Please go ahead. Thank you.

RESOURCES TO KNOW

PATIENT-CENTERED CLINICAL TRIAL EDUCATION PROGRAM – CANCER SUPPORT COMMUNITY

CLAIRE SAXTON, *Cancer Support Community*: Hello, I'm Claire Saxton, Vice President of Patient Experience at Cancer Support Community, also known as CSC. Today, I'm going to talk to you about how CSC co-created a clinical trial education program with input and feedback from patients and caregivers. And when I say caregivers, I mean friends and family with the primary support of their loved ones. You may call them carers.

Next slide. First, let me quickly introduce Cancer Support Community. Our mission is to ensure that all people impacted by cancer are empowered by knowledge, strengthened by action and sustained by community. CSC has local cancer support communities and Gilda's Clubs in about 50 U.S. markets, and we also have five international affiliates in Canada, Israel and Japan. These in-person service centers, combined with healthcare and hospital

partnerships and satellite locations, means CSC's support and navigation services are available at about 175 locations nationwide and provide about $50 million of practical support, emotional support and education to cancer patients and their loved ones at no charge each year. In order to accomplish our mission, CSC relies on three pillars: Our Research and Training Institute conducts psychosocial research into the cancer patient and caregiver experience. We then use the insights from that research to inform the direct patient services that we offer, such as those offered by our local affiliates, our helpline, our online community and our educational programs, as well as to help us focus our policy and advocacy efforts.

Next Slide. CSC has a commitment to increasing enrollment in clinical trials. In fact, we embed messages about asking your healthcare team if clinical trials are right for you in all of our educational materials that talk about treatment. When we looked to completely revamp our clinical trial education program in 2015, we started at the very beginning with a needs assessment and worked with cancer survivors and caregivers to co-create a brand new program with materials that met specific communication gaps that we had identified.

Next Slide. When creating educational materials our best practice is to first do a needs assessment, then create prototypes, test those prototypes with cancer survivors and caregivers, incorporate those changes and then retest them to ensure we addressed concerns well. When we have the resources, we do both qualitative research to gain insights and do a survey or other quantitative research to validate those insights and findings. So, the first two steps in the timeline of our best practices is the needs assessment.
For Frankly Speaking About Cancer Clinical Trials, we did 27 interviews with healthcare providers and other stakeholders involved in running and recruiting for clinical trials. And then in order to validate the communication gaps and the insights that we gathered through our healthcare providers, we did an online national survey of 506 cancer survivors and 81 cancer caregivers.

Next slide. You can see some of the insights from our research here. We heard from clinicians that in their experience, extended family members very often influence patients' decisions of whether to participate in a trial. And these extended family members often are not part of the conversation the clinical trial team has with the patients about the trial. In our survey, we found about half of the survivors said that family and significant others have strong positive feelings about them participating, and was moderately or very important regarding making the decision to participate in a clinical trial.

Secondly, in our survey, 94 percent of cancer survivors reported that a one-on-one conversation with another patient who had participated in a clinical trial would be helpful in making their own decision on whether to participate in a trial. Yet this was only offered to patients by their healthcare team to about 10 percent of survivors who were considering joining a trial.

Our third big insight was that language matters when talking about clinical trials. Most of the words in clinical trial educational materials reflect the fact that information surrounding clinical trials has been through medical and legal review often and often the words used in a lot of the official documents about the clinical trial don't reflect how patients and caregivers actually talk about the clinical trial themselves. We set about refreshing the dialogue on clinical trials by using patient's own words. And of course, we set the reading level at sixth grade reading level because at least in the U.S., you can reach about 85 percent of the audience, the adult audience you're trying to reach, with sixth grade reading level materials.

Next slide. I talked about number one and number two on this timeline of how we develop materials and for a signature piece in this, Frankly Speaking About Cancer clinical trials program, we thought a photo narrative booklet would be a good solution. Kind of like a comic book or graphic novel where the images help tell the story. The idea was that we would depict discussions that cancer survivors, their loved ones and healthcare providers had when trying to decide whether to participate in clinical trials. So, we took photos of actual cancer survivors reenacting discussions that they and others had.

If you flip to the next slide, you can see what the first prototype of this booklet looked like. It was a full letter-sized book with eight chapters telling eight different survivors' stories. These stories also had information in it to help debunk many of the myths of clinical trials that Dr. Comen alluded to. Things like, am I going to be a lab rat? What is a placebo? Those kinds of things. But the idea is that the piece would be aimed at both people considering clinical trials and their loved ones so that they had something to share with their extended family, who might not be part of the initial discussions with the healthcare provider about clinical trials and who might be skeptical of clinical trial participation.

If you flip back to slide six in the testing of the materials, so in in step number five, testing it with patients and caregivers, we tested that version, incorporated changes and then retested to make sure that our changes address the issues that were pointed out by focus group participation or participants, and that gave us the basic photo narrative in English that I just showed you. We then went on to culturally adapt that English piece for three specific audiences that are underrepresented in clinical trials, black and African American cancer patients, cancer patients who are age 65 and older. And then we also translated the piece into Spanish and tested it culturally adapted for Spanish speakers in the US so that it wasn't just a straight translation.

And then if you flip forward to the next slide. As part of that testing and cultural adaptation, you can see that the photo narrative changed quite a bit with that feedback. Patients thought the book was too big. We needed to condense things down from a two-page photo spread to one page photo spread. But they didn't want to lose most of the stories, and so most of the stories were still kept. But in making sure that we were using patient's own words and hearing feedback from patients on what that would look like, we cut the text even more so that you can see in that third version less words, more pictures and a clear delineation between the words that were the narrative and the words that were the discussion.

So ultimately, that feedback allowed patients and caregivers to give us information that not only did we use in that photo narrative, but then we also, because of talking to patients and caregivers, created the Importance of Diversity in Clinical Trials materials because we got a lot of feedback about patients and caregivers needing that information. And we also created a discussion tool that patients and caregivers can go through to talk with their healthcare team about – Are cancer clinical trials right for them?

And carrying through the finding that patients wanted to hear from others who had been part of clinical trials, we also created videos of clinical trial participants telling their story of what it was like in those in English and Spanish.

The last piece that I want to tell everybody about from this cancer clinical trials education program, if you go to the next slide, is that we offer a workshop toolkit about clinical trials. It's available at no charge. We create these toolkits to help our local cancer support communities and Gilda's Clubs and other patient advocacy groups, provide in-person or virtual workshops using local experts to give the talk. And ideally, that local expert would be a doctor

or clinical trial nurse, plus a support group leader. The toolkit includes a workshop, slide deck, sample marketing materials, and the toolkits are available in English and Spanish. If anybody wants to learn more about the Frankly Speaking about Cancer Clinical Trials program or to talk about using our Workshop Toolkit, please contact me at CSaxton@cancersupportcommunity.org.

CONCHI: Thank you Claire for this interesting presentation. I remind the audience that you can still use the chat function to ask questions. Now I had it over to Elly, please Elly.

HOW ADVOCATES CAN HELP PATIENTS LEARN ABOUT CLINICAL TRIALS – LESSONS LEARNED FROM BREASTCANCERTRIALS.ORG

ELLY COHEN, *BreastCancerTrials.org*: Hi Conchi and Patti, thank you so much for inviting me to participate and talk to my fellow advocates across the world. I'm delighted to talk to you about BreastCancerTrials.org,which we affectionately refer to as BCT. Our main reason for being is really to empower patients to consider clinical trials as a routine option for care by providing clinical trial education that dispels misinformation and to provide easy access to trials so that patients can find trials that are right for them.

Next slide. We were born and are deeply rooted in the patient experience in 1998. Joan Schreiner and Joan Tyler, who were recently diagnosed with breast cancer, wanted to participate in clinical trials but were not supported by their providers, and they recognized that there was a need for patients to be able to find trials on their own and bring that information back to their providers for discussion in treatment decision making. Their idea was to create a clinical trial matching service that would be accessible over the internet, and at that time, the internet was really in its infancy. So this was kind of a radical and crazy idea. But it gained traction at the UCSF Breast Care Center and then, with the collaboration of National Cancer Institute, BCT was born and launched as a nonprofit clinical trial matching service and is now a program of Quantum Leap Healthcare Collaborative. I just want to stress that we are a nonprofit service. Our mission is to provide patients with information about clinical trials to aid them in their decision making. We don't recruit patients to trials.

Next slide. Fast forward now to 2021. We operate two clinical trial matching services. The first is our grand dame BreastCancerTrials.org BCT. If you go to the BCT website, there's clinical trial education and we support patients across the entire breast cancer journey, including those who are newly diagnosed, those who are managing metastatic disease and post-treatment survivors as well.

In 2014, we saw a need to really focus on the needs of metastatic patients. And then, in collaboration with five breast cancer advocacy organizations, we created Metastatic Trials Search, affectionately known as MTS, to help metastatic patients really find trials that were appropriate for them. I'm very proud that in 2021, MTS is either embedded on or linked to from over 25 advocacy websites.

Next Slide. BCT and MTS share the same patient-friendlyfeatures. All of our applications really try to be very patient centered, and we use patients focus groups in developing them. On both MTS and BCT patients can use the service as a guest or if they want to have the ability to update their profile, they can register. We do provide deep matching and by that, I mean, we match to trials based on both the diagnostic and the treatment history. And if you don't want a match, you can actually browse our listings, and we provide a number of filters to help you hone in on what

you're looking for – whether you want to look at all trials across the United States, whether you want to look at those that are nearest you, or to look at a specific trial type, such as immunotherapy or a trial that's focusing on a specific mutation. We provide lots of ways for you to find trials. When you look at your results we show you the results on a map with a pin representing the nearest site to where you live, and we create patient trial summaries and very patient friendly language. We rewrite. We write each summary. We just don't link to ClinicalTrials.gov. And we tested our summaries in focus groups. At the very top level we provide you with our own title, the purpose, who is this for, and convenience factors such as how many visits I might need to make at a research site. For those who want to go deeper, we provide more information in detail about the tests that are involved in the trial or what are the study drugs.

Next slide, please. Now, when we were developing Metastatic Trials Search, we heard from patients that it was very difficult for them to really find the latest information about breast cancer research that they were completely overwhelmed by searching in Google. So of course, we saw the need to create a consumer-friendly alternative to Dr. Google, which became Metastatic Trial Talk. In Metastatic Trial Talk, our staff selects topics every month. MTT is published monthly, and we search the Internet for news and features related to that topic and present them in an easy-to-read format. It's published monthly, so the topics change monthly, and we focus on unbiased, relevant and accurate content that we collate from trusted sites.

Next Slide. Even though the topics change monthly, the template for MTT is static and is organized by eight content areas as shown on this slide. So just to give you an example for Conference Talk, this month we provided an update on presentations from the European Society of Medical Oncology in Inside Clinical Trials we had collated a number of articles related how advocacy organizations and institutions were working hard to diversify the number of patients that were participating in clinical trials. And then in From the Experts, we created a topic or provided topical theragnostics, which was something that was new to me as well. And it's really the development of agents that both provide imaging to detect the tumor and also treat the tumor at the same time. Our staff just loves creating Metastatic Trial Talk. It's fun for us and a learning experience for us as well. It's free and anybody can subscribe to it to get it delivered to your email box.

Next slide. I just want to conclude with some information. We are asked by other advocates who may be interested in creating a clinical trial matching service. How did you get started? How can we consider bringing trial matching to our communities? And what I always advise is first thing is to really define your goal. What are the diseases you are looking at? Who are your users? What is the geographic reach you're focusing on? And are you looking to be a nonprofit or for-profit model? There's pros and cons to both. But the most important step in this is before you embark on building anything, really do a landscape analysis. What is already available? And then with that information under your belt, explore your options. The easiest option is to link to embed the existing service on your site. You don't need to reinvent the wheel. If there is a matching service that already meets your needs, and if the one doesn't, then consider the option of working with a matching service to customize its platform to help you. It would be less costly and entail less resources than starting from scratch to build your own. And we really love to collaborate and make our tools accessible to various matching services. And if you decide to build your own, just remember that it's not just the cost of development if you've just secured that money, it's really to sustain an ongoing operation over the years.

Next slide. I'm happy to answer questions, either during the presentation, offline or offer advice on how we work on BCT or how you might approach creating your own matching service. My contact information is

Elly.Cohen@quantumleaphealth.org, and I've also included links to all of our various services. Thank you for your attention.

QUESTION & ANSWER SESSION

CONCHI: Thank you Elly. I want to thank you, the three of you Dr. Comen, Clair and Dr. Cohen for your insightful presentation. Now, I asked you to come back with us, Dr. Comen please, because we are starting the question and answer session. If you have any questions that haven't been answered yet, you can use the chat function at the bottom part of the screen. The first question is the to Dr. Comen, at what phase of trials do most drugs fail?

DR. COMEN: At what phase do most drugs fail? I think the, I think it was on one of my slides, but mostly it's around Phase 2 in terms of when you start to look at safety and efficacy before you get to a Phase 3. That's the time point where most drugs, if they're not going to continue on to a Phase 3 trial, that's the most likely point that they're going to fail, unfortunately.

CONCHI: OK, thank you. Next question to Claire or Elly. How can we help patients feel more comfortable to ask about a clinical trial?

ELLY: I think the most important thing, and I think Claire would agree with me, is providing them information that is easy for them to absorb, that's in patient-friendly language. That's why we rewrite all of our trial summaries. We just don't extract the information from clinical trials. It's probably one of the most labor-intensive parts of our work because we want patients to have the confidence when they're going back to their providers and talking about a trial that they understand the trial and they understand what questions they might want to ask from their providers.

CONCHI: How can we help them gain access to a clinical trial, or treatments, and that is not involved in the trial?

CLAIRE: And I'm sorry, who is that question aimed at?

CONCHI: How can we help patients gain access to a clinical trial, especially if they're doctor or treatment center isn't involved with the trial?

ELLY: I think your understanding if the center that a patient is seeking their care doesn't host that clinical trial, how can the patient participate? Is that the question you kind of broke up? Yeah. So I think this gets to again, patient empowerment sometimes, but not always, when patients are at a center, they're told about the trials that are at that center or with patients are being seen in the community, some of the community practices really don't host clinical trials. And that's one of the reasons that BreastCancerTrials.org was founded to be able to empower patients to see trials that are available near their home or if the participation was not difficult in terms of visits to consider trials some distance from their home, but there are other barriers. You have to consider the patient's insurance. And so I think if you're looking at trials outside of your home hospital, you really need to explore the financial implications of participating in that trial. Finding the trial is a start and then really looking at, talking to the research sites and just really finding out what are the requirements for trial participation there.

CLAIRE: OK. Some of that is some things that some clinical trials are trying to address. Looking at things like offering reimbursement for transportation. In the U.S., you can't pay somebody to be in a clinical trial like this, but you can, and in just in the last few years the FDA made it abundantly clear, that you can make them not have additional costs over what it would cost to participate in, or to have their care done closer to home. Things like transportation, lodging, if they actually have to stay on-site overnight, and parking and other kinds of out-of-pocket expenses can be reimbursed, but that really depends on a trial by trial basis if that's offered.

ELLY: So just one other thing I'd like to add, which is very exciting, and you know, sadly it took COVID to bring this out, is the emergence of telemedicine. And I think one thing you might ask at a trial, if you find one, is do you have the opportunity to participate to a certain extent by telemedicine that will cut down the number of visits. And I suspect this is going to become more and more a presence in clinical trials because it's really so important.

CONCHI: Thank you. Next question to Dr. Comen. Can a patient leave a trial or stop taking the drug while the trial is ongoing? What happens then?

DR. COMEN: Absolutely, I mean, I think the most important thing to remember is that this is your body and your life and your choice, so this is not like you go to jail for not being part of a clinical trial or stopping at any point. It's your choice. You can sign up. You can sign a consent and then decide, I don't want to participate. You can be part of a clinical trial, be taking some medication or be part of some study, and at any point, it is your choice to say, I no longer want to do this anymore. There are different options at that point. Sometimes they might ask you to just follow up with them to see how you're doing, or you could disappear into the wilderness and decide, I want nothing to do with any of these doctors anymore. It's all up to you.

CONCHI: Right. And next question to Claire please. In addition to Frankly Speaking About Cancer Clinical Trials, does your organization provide any other information or assistance to patients regarding clinical trials?

CLAIRE: Absolutely, like I said, our organization is committed to increasing the number of patients who have clinical trials as an option to receive their treatment through. On our helpline we have a specialty navigator who's a clinical trial navigator, so for folks who the first person that they talk to, if the conversation really is aiming towards clinical trials, we can make an appointment for them to talk to our specialty clinical trials navigator. We also promote clinical trials matching services like metastatic breast cancer trials search and BreastCancerTrials.org. Right now, we're actually putting together a pilot program because we heard so much from patients that they wanted to hear from others like them who had been in a clinical trial. And we know that the participation of blacks and African Americans in the U.S. is well below their percentage of the population in clinical trials. We're actually putting together a peer-to-peer clinical trial support program for blacks and African American cancer patients, where they can actually talk to black or African American cancer patients who've been part of a clinical trial, hear what that experience was like and hear it from somebody who's been there and somebody who looks like them. We have other programs like Open to Options, which helps people make treatment decisions by coming up with a list of questions to ask their healthcare provider so that they really understand all the pieces that they need to understand when making those kinds of treatment decisions, especially for clinical trials.

CONCHI: And Dr. Comen you mentioned that it can take at 10 to 15 years to find a new treatment. During the COVID epidemic, we saw drugs created very quickly. What of the COVID experience can be applied to developing new treatments for metastatic breast cancer patients?

DR. COMEN: What a fabulous question. So I think I share in whoever asked that question, I share in the sentiment of the world coming together to find a COVID vaccine. The world has, I mean, unfortunately, not everybody's vaccinated, but for the most part, the scientific community has collaborated. And while I'm not an infectious disease expert, I think one of the important take-home lessons is that collaboration is essential and ego is not, and this may not be the most inspiring comment, but I think it's important to recognize, which is that a lot of times, unfortunately, the incentives in academic medicine are to be the first author on a paper, to be the first person to speak about it, to have a national award for it. And the reality is that we should be moving toward a much more collaborative reward system in medicine where if you play nice on the playground, that's what you're rewarded for. And if you do good work as opposed to being the first author on a paper. And when you think about the COVID vaccine, there was a lot of collaboration that went on there from a number of different companies and organizations and scientific communities, and we need that same energy. Now, I know that was a little bit of a negative twist. The complicated part of cancer is that we're not just dealing with one virus and one vaccine for one virus we're dealing with, as we know, a very different type of cancer, depending on who the individual is in the subtype of breast cancer. And so it's not as simple. Even though COVID is complicated. It's not as simple as one virus, even a virus that mutates so a little bit more complicated or a lot more complicated with breast cancer. But also, we need people to play more collaboratively in the scientific community.

CONCHI: And the last question for Dr. Comen too. The participation of black women in trials is a mere3%. So we think that the tactics currently in place are not working for black women. How well are you reaching these important population as our mortality rates are significantly higher than white women in the U.S?

DR. COMEN: Right. So we know that breast cancer patients who are black are 40 percent more likely to die, unfortunately, from disease. And I think what you're picking up on is really a broader conversation that we could have many hours of discussion about. But I'll say briefly, as someone who's interested in the history of medicine, is that it really sparks the importance of understanding how doctors develop trust with their patients and how doctors develop trust with the public at large. Because when you meet with the doctor to consent for a clinical trial, you may not meet with that doctor for that long. So how is it that doctors and the community build that sense of trust that the person that I'm going to has my best interest? I think it is on many different levels that the medical community needs to be more representative of the diverse populations that we treat. If you look at the percentage of oncologists that are black, it certainly does not mirror the percentage of black people in the community or the percentage of black people that have breast cancer. We need much better efforts to engage the black community very early on about considering the field of oncology as a field to go into and supporting minority physicians in pursuing those paths.

We also need to understand that when we have black patients that they may have special questions and considerations about how do they know and trust you? How do they know that they have your best interest? And of course, we rely also on patient advocates to be diverse and to engage in diverse populations so that we are all representative and all represented and all taken care of, both from an advocate standpoint, from a patient standpoint and from a doctor's standpoint. Lastly, I'll say it's really important that academic institutions are available to a diverse population. One of the things we know is that, in part, the reason why black women may not do as well is because they may not have access to the same quality of doctors. We saw from COVID, which really highlighted the health care in inequalities in our system, that we need to have affordable healthcare, thoughtful healthcare and trusting healthcare for all members of our population.

CONCHI: Thank you very much. I turn it over to Patti please.

PATTI: Thank you so much, Conchi, Dr. Comen, Claire and Elly. Such an interesting and informative discussion. We had other questions in the chat. I'm sorry, we didn't have time to get to them all. But I do appreciate everybody's engagement, and we're very much looking forward to our next webinar and continuing this conversation with you. Our next webinar is on Tuesday, November 16th. We will focus on real-world evidence and how advocacy leaders communicate complex research information to patients. Stay tuned for a proper invitation for that webinar. And in the meantime, we would love your feedback. What was helpful for you today? Where can we do better? We will send out a survey link and encourage you to take it as we do take your feedback seriously and we read every comment. Thank you so much on behalf of the planning committee and my colleagues at Pfizer around the world. Thank you for signing on today, and we look forward to seeing you soon. Take good care. Bye, bye.

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