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Welcome to WoW, the Woman of the Week podcast series from PharmaVOICE.

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In this episode, Taren Grom, Editor-in-Chief of PharmaVOICE magazine, meets with Kellie Malloy Foerter, chief clinical development officer at OncoSec Medical.

Taren: Kellie, welcome to the WoW podcast program.

Kellie: Thank you, Taren. I am honored to be part of this great series and just thrilled with all that PharmaVOICE does for women in the healthcare industry.

Taren: Well, you were very kind and very generous. Let's delve into your career journey if you will. I know you worked for more than two decades working in the CRO industry, and now you're applying your considerable knowledge and expertise to guide OncoSec Medical clinical development programs.

So, tell me, what was that transition like for you?

Kellie: For me, transitioning from the CRO side of the business to the pharma or biotech side of the business really wasn't a big leap. I had been engaged in leading clinical operations, activities in departments for a number of years and had been working very closely with many different pharma partners from small biotech to many of the larger pharma organizations.

And in doing so, really got a good appreciation for the perspective coming from the pharma side of the business, as well as the passion driving those in this industry to really find solutions for patients. I have to say it was pretty easy transition to this role with OncoSec Medical. I felt like I could bring the years of experience and expertise that came from the CRO side of the business to delivery of our oncology portfolio.

Taren: That's wonderful. Well, we can get you into that portfolio in just a minute, but what initially drew you to the clinical space?

Kellie: My undergraduate degree was actually in sociology. When I started in this industry, I did not even really appreciate the field. I was brought in in an entry level position, where I was supporting studies and study teams, and I sort of grew and evolved within the field and continued to learn more as I went, took on new roles and new responsibilities, and looked for

kind of a next challenge and an ability to really grow in my career within the industry because I was enjoying the work I was doing and the people that I was working with. I had tremendous mentors throughout my career.

Taren: That's wonderful. Now that you are in this position of chief clinical development officer, tell me about what's your typical day look like?

Kellie: My typical day is really focused on bringing our studies forward, making sure that the investigative sites that we're working with have all that they need to manage their trials, and we're supporting them and the trial participants that are part of our studies. I think it's been a little bit more challenging right now with the COVID outbreak. We're really focused on finding ways that we can lessen the burden for patients and ensure that we maintain safety of the site staff and all of the trial participants.

Taren: Fantastic. Let's talk about some of those development programs. I know that you have one trial going on in metastatic melanoma and triple-negative breast cancers, really cancers without a lot of options right now, how's the research going?

Kellie: Well, we are extremely encouraged by the results that we're seeing so far in these trials. We have done a number of studies across a few other solid tumors, which led to these two programs. And when we look at triple-negative breast cancer, there really are not a lot of options.

We were able to present some early preliminary data at the San Antonio Breast Cancer Symposium in December. And that was actually picked up by the ASCO Post to highlight the early results that we have. So we are very excited and encouraged. We saw responses in patients who were PD-L1 negative, which were again extremely encouraged by these early results and this proof of concept study.

And then on the metastatic melanoma, that is a registration enabled trial, which is in a setting where patients have tried all other therapies and their cancer is still advancing. So that study is one that we are now at a point where we have very significant data collected with assessments from about half of the patients were continuing to enroll in that study. But what we're seeing is that the results we've originally published, which were some early views to that data are holding, that responses are deepening, and that the duration of response is holding as well.

We're looking to complete that study this year and hopefully be filing with the FDA very shortly after. So again, we're really just excited and encouraged by the results that we're seeing, and we're hoping that we have an effective treatment that can come forward. The overall safety profile that we're seeing is consistent with our earlier studies because it's an intratumoral therapy.

We see very limited systemic effects for patients, which means it can be easily combined with other products which is what's happening with our two studies that I just talked about. They're in combination with checkpoint inhibitors in this case. These are two keynote studies working with Merck and their pembrolizumab checkpoint.

Taren: Well, that is exciting. And I know in your role, you get to interact with patients on a more intimate level than perhaps you did previously, is that true?

Kellie: It is true. We work quite a bit with patients. We have expanded access for compassionate use programs, where patients or their physicians may reach out to myself or our regulatory head directly, exploring if there's an opportunity. So those are ones where we work with their physicians and we have been supplying individual patient studies, where the patients have no other options. That's something that the federal government brought forward and we're thrilled to be able to participate in it.

We also work with a number of patient advocacy groups to make sure that we're bringing the patient perspective into the trials that we're running. Our unique platform with IL-12 includes an electroporation device. So there's often additional conversations around the intratumoral delivery and the follow-up with the electroporation device.

That is the way that the DNA plasmid is delivered into the tumor cell. It enables it to be taken up within the tumor cell. It's not an ablative procedure. It is just an electrical charge that passes over about three seconds to enable the cell wall membrane to open and allow the IL-12 to be taken up within the tumor to cause an immune reaction within the patient, so that the patient's own body is fighting the tumor cells.

Taren: Interesting. You've been a lot involved in the clinical trial space now for quite some time. I'd love to know, what are some of the biggest clinical trends you are currently tracking?

Kellie: So I think especially with the COVID outbreak, we are looking more and more at electronic medical records and being able to leverage those where possible, including some remote monitoring, but I see that as a trend that will come forward in a more meaningful way over the next few years where patient data goes directly into a study database from the EMR and there's not an interim need to have sites entering data separately.

We've also seen a lot of technology and focus on personalized medicine. And one of the things that I've seen at a recent conference was leveraging technology from astronomy and galaxy mapping that Dr. Janis Taube and Andres Szalay had developed for the micro tumor environment. I think that will significantly change our understanding of solid tumor cancers as the data begins to build within that database that they've established.

And it's an open access. It follows a lot of the same things that have been established within the galaxy mapping system that it was built on. So I think there's a lot of exciting new data that's going to be coming from initiatives like that, that will help us battle cancer in a more personalized way to fight the type of cancer that each patient has.

Taren: That's totally cool. I can't wait to see how that plays out.

Kellie: Every time I see it, I get excited about just the advances that are being made.

Taren: Exponentially, right. There we're just seeing advance after advance after advance.

Kellie: It's so true.

Taren: It's exciting. You're one of the few women in a chief clinical development officer role. Do you consider yourself to be a role model?

Kellie: Taren, I don't specifically look at myself as a role model, but I do focus on mentoring individuals within the industry. I think that's one of the most rewarding aspects of my role and something that I felt I received along my career path. And so it's an opportunity for me to give back. So I think that's important sharing your knowledge and expertise and helping people develop on their own career trajectories based on their interests, based on their focus.

Within our organization, we have someone who began in an entry level position and is looking to become a CRA. And so we have her engaged with some training focused on CRA specific skills. We also have someone within our lab, we have a very in-depth clinical science team led by Dr. Christopher Twitty, who is developing new plasmids as well as managing the immunohistochemistry reviews that we're doing of the patients that are participating in our trials, so that we can identify the patients that are more likely to respond to our treatment.

And within that team, he has someone that's interested in expanding her knowledge in statistics. So we have her actually helping with our study reports and review of tables and listings for some of our earlier trials, so constantly looking at ways that we can continue to help that next generation who's going to further science, really develop their skills and their skill sets to bring more effective treatments to patients.

Taren: That's wonderful. And thank you for doing that because I think we do need more women sitting in seats of influence and in the C-suite to bring along that next generation of leaders. So kudos to you.

Along that same vein, what do you think are some of the skills that women need to develop, to navigate to reach that executive level?

Kellie: I think in many cases, it is a continued focus on communication and striving to further enhance and develop communication skills. I think the level of communication at one part of your career will change and evolve over time. And I do believe that a focus on enhancing those skills as you move up the ladder, watching presentations from others who may be a step or two ahead of you within your career ladder, I think can certainly help.

I think paying attention to the trends in the industry overall is also important. But I think oftentimes, there are some softer skills that may not have been valued previously within the C-suite that I think are gaining recognition that women in general bring to the table. And so I think it's important that the approach to gaining or establishing a C-suite leadership position is not necessarily the same skill set that was looked at 10 or 15 years ago.

And I think there are different opportunities today where some of the skills that I think women bring to the table, in general, are more highly valued now than they may have been in the past.

Taren: And what are some of those skills? Let's get into it a little bit.

Kellie: So I think there is an approach to strong team building. And it's not to say that women are the only ones that can build a strong and effective team, but I think there's a level of sensitivity that women may bring to the table that may not have been present previously and an ability to really build consensus within team structures. Now there are times where decisions have to be made that are not going to be valued within the overall structure, but they're hard decisions that have to be taken. I think sometimes there's room for consensus and really that consensus building, and I think that's where women can really enhance the activity within teams.

Taren: And those are some excellent examples. So thank you for bringing that to the forefront.

Kellie, one of my favorite questions to ask is if there's something you know now that you wish you knew back in the days.

Kellie: I think one of the things that I wish I knew then, was that there are times that you don't have to have all the answers and that you have experts in the field that are out there and willing to help and not to be afraid to ask the questions. I think within my career, I had opportunities to take on new and bigger challenging roles and positions.

And going into those roles, the expectation is not that you're an expert immediately on day one, but that you build the skill set so that you are able to deliver fully in that role, and to understand and acknowledge where you may have a weakness and be ready to reach out for that support so that you can strengthen that and so that you're delivering the role holistically and really helping your team, your team members, and building on the knowledge base that you have.

Taren: Fantastic, and you've had a really successful career. Would you be able to identify one wow moment that either shaped your career or has left it a lasting impression on you?

Kellie: So when I think about this, I think there have been a lot of small wow moments where I had opportunities to learn something significant, either through working with individuals within my career or in locations. I had an opportunity to work in Singapore and live in Singapore for four months as one of my prior employers was expanding their operations within Singapore.

And within that, I had a chance to really understand some of the differences in the way medical practice is carried out within Southeast Asia as compared to the US or Europe or Latin America. And so I think that was one of the things that opened my eyes a bit about some of the differences and different expectations we may have culturally. I think it was a fantastic opportunity.

I would recommend that if individuals get an opportunity to work in an expat position that they take that. I think it definitely opens your eyes to our world in general, both within industry and on a personal level. So I think it's a very enriching opportunity.

But I think one of the other things that I have had as a wow moment is the support and that passion that individuals bring to this industry. Folks are in this because they want to make a difference. They want to impact lives in a very meaningful way and bring a greater level of health to our global population.

One of the trials that I had was a large outcome-based study that for safety reasons needed to come to a close very quickly. And within that circumstance, we were notified on a Saturday morning. We had a study team established. That team started working to notify the sites before 5 p.m. that evening.

We had 25 other people who weren't part of the study team who came into our offices on Saturday and Sunday. They work till midnight. They were back 7 a.m. the next morning, making sure that we got notifications out to every single site.

We called, we emailed, we faxed, we FedExed to make sure that everyone got the information as quickly as possible and that they could take actions. That's something that collaboration, that ownership even be on what they were immediately working on, has stuck with me. And that's the environment that I've seen time and time again within this industry, where people pull together because it's the right thing to do.

Taren: That's an amazing story of community and putting the patient first. So kudos to your leadership and to your team for taking on that mantle because it wasn't easy. They sacrificed their personal time. And so that's really a very inspired story. Thank you.

Tell me a little bit too about some of the skills that you've developed. Obviously, you are a tremendous leader, but what are some of those skills that you personally developed to get to the C-suite?

Kellie: I think as I started my career, my ultimate goal did not envision where I am today. I think I started really working on and trying to do the best that I could do within the roles that I was in at the time and trying to learn as I was with working within those roles more and more about what I was doing get better at what I was doing.

I think because I brought that focus, there were opportunities that I was given. I had a number of excellent, excellent mentors who really did work to develop their team who was reporting into them. And I think I was very fortunate. One of my key mentors was Dalvir Gill who now heads up TransCelerate.

He always gave me plenty of opportunity to take on new and different challenges. And even when it was something that I didn't think I could really take on, he would encourage me to go forward and raise my hand when I needed help and having that and having someone there to back you along the way, I think is something that I've learned is important not just for individuals personally, but for your whole team that's working with you.

And if you have that type of empowerment within the team, you're really going to be able to get very good outcomes. I've also had a number of large projects with pharmaceutical partners on the CRO side of the business and the ones that worked the best, we're aware it was a true partnership. There was a very open and honest dialogue when there were issues.

And in this industry, you are going to run into the unexpected and being able to have a frank discussion about what that is, and how we can address those issues together is absolutely critical. So I think those are a couple of the big things that I have learned in my career.

Taren: That's excellent. I think all that is great advice. I think being open, being transparent are key, as you said, to that CRO/pharma partnership, which is really the engine that drives clinical development. So thank you for sharing those insights.

And thank you for being part of our WoW podcast program. I love getting to know you, and thank you so much for sharing your insights.

Kellie: Thank you, Taren, for including me in this podcast and all that you and PharmaVOICE are doing to raise awareness of women in healthcare and the contributions that we're making to this industry.

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