

**December 19, 2019**

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*In this episode, Taren Grom, Editor-in-Chief of PharmaVOICE magazine meets with Kathy Vandebelt, Global Head of Clinical Innovation, Oracle.*

**Taren:** Kathy, welcome to the PharmaVOICE WoW podcast program.

**Kathy:** Thank you very much. I really appreciate the opportunity to chat with you today.

**Taren:** It's my pleasure, and it was so great to get to meet you in person last week at the CNS Summit. What a treat.

**Kathy:** It was wonderful to catch up with you in person. I know we get to hear about each other over web, over email and so forth, and yes, it was a treat to actually see you in face-to-face. It was lovely to catch up.

**Taren:** And we got to enjoy a little bit of Florida sunshine too. I've done some research on you, and I would love for you to share your career journey. I know you were at Lilly for almost 30 years – a little bit more than 30 years. Let's talk about your Lilly years and then what ultimately led you to be named global head of clinical innovation at Oracle. That's quite a leap.

**Kathy:** Sure. Actually though not planned, I actually was at Lilly 30 years to the nose. I actually joined Lilly in Canada at a pivotal time when the patent laws actually changed for the pharmaceutical industry. There was a new law passed known as Bill 22. I had just graduated with my pharmacology degree from the University of Toronto. And what this new law meant was is that the patent protection was extended to be inline with other countries, like the United States and other industries that existed in Canada, and what that meant was is that in order for that patent protection to be afforded to pharmaceutical products in Canada they needed to invest 10% of their sales back in research and development. So I actually ended up joining Lilly as their first CRA in the Canadian affiliate. So my career grew as the portfolio grew and the team grew in Canada. And I was actually quite fortunate because the Chief Medical Officer that was there, Dr. Subandek actually placed me in the regulatory area to start, even though I was a CRA, and he felt it was really important to instill the importance of GCP and regulations.



He felt it was so important for me to understand that as a starting point and I was very grateful for that and I really sort of taken that as something to be important with anybody that I worked with as we move forward. And he also created an environment where we could be creative and grow and did the most of what we can. When you work in an affiliate environment you don't necessarily have always a lot of money. We definitely didn't have a lot of people and we also were a young organization both in like we were new too – because of this new bill that was passed but also in age, and so we also had a lot of fun.

My career grew and as well as I personally grew up with the affiliate. Every about 18 months and two years I got more and more responsibility and went into middle management. And I actually was confronted with a male supervisor during that tenure, and that male supervisor was kindhearted and he actually was trying to help, but he fundamentally said if I was going to be successful in the pharmaceutical industry I should change my characteristics and I should maybe stop laughing and perhaps maybe dress more like a man. I really listened to him, but I thought I really needed to be my authentic self, believe in who I am and I thought that's how I could be the best employee I possibly could be for Lilly. So I sort of just continued on and I got the reputation of being a builder, is probably the best way, somebody who built organizations and built new ways of working.

So they approached and asked me to move out to Asia Pacific and build a new organization out there. And then all roads eventually lead – for those of you that don't know the head office for Lilly is in Indianapolis, Indiana – and so all roads eventually lead there, and then I got responsibility for global statistical operations and then global head of data science and solutions and then my last tenure was the global head of clinical innovation. And then that made sense because I had these diverse cross portfolio, global clinical experiences and sort of all that learning, all that experience really helps put together this very dynamic group and we really started to focus on coming up with newer and better ways to conduct clinical research and try and do that to benefit the industry and so that really was sort of an awesome opportunity to round out my career at Lilly.

And obviously when you're working on these new and better ways to possibly look at research, technology and digitization and working with different members in the health industry and ecosystem became part of that and obviously throughout my entire career technology had been a part of it. And so even from the beginning like when I was back in Canada we were working on fluoxetine which is known as Prozac and we found that it was cheaper to work with a local company and build a remote data capture system to fund the work to do that fluoxetine work rather than the CRO, never envisioning it would go anywhere.

So technology has sort of always been a part of it and I guess then from that, I had always wanted to see clinical research being done better, being done faster, being easier for the



humans that were engaged in it and really feel that technology is an enabler to make that happen. And so eventually – though I never thought I would actually be at a large company like Oracle – I had developed relationships with the leaders at this company and so it ultimately led for me to be here.

One of the reasons I am here is that they actually have developed a new platform that I think could unlock some new ways of thinking, and I'm really intrigued by that. I think the pharmaceutical industry could – we really need to change the way we are thinking, and I'd really like to be part of that and I'd really like to still see us do things in a very different way than we have done in the past. And if I can be part of that, I'd really like to do that. So that's what sort of brought me here.

**Taren:** That's fascinating. From being one of the first CROs to now changing how drug development does at a technology company and then with all that global experience. What is one of the biggest learnings from having that global perspective because when you talk to women and they're plotting out their career, so many times one of the biggest pieces of advice is to take a global job if you can, if it's offered to you. Do you think that really was part of your career make-up that really helped accelerate you?

**Kathy:** I do. I have family with children, and so I think it's an important decision to consider that as well. It's not easy, because it is a big change for everybody involved, and it is also a great experience for everybody involved. I went to all English speaking countries and locations and so that is something that helps with the transition. However, the cultures are very different and so even though I worked at Lilly for those 30 years, I really feel I did work at very different companies. I felt that Canada was extremely different than – I actually was located when I was in Asia Pacific I was located in Sydney, Australia. It couldn't be a more beautiful location to be in, and then also then being in Indianapolis, Indiana. I feel in each of those instances I actually felt I was working at a very different company.

The reason for that is that the culture is different. The work ethic is influenced by the culture. The talents that's located in the area they are motivated by different things based on their culture and their environment. And then when you travel around the area, you really need to learn and listen and I believe sort of behave and really understand what's going on there. And so I feel when I actually came to Indianapolis, the head office and we would talk about what is needed on the global stage, I felt I was more equipped and actually could offer real life examples having worked in Asia Pacific and actually hadn't worked in Canada even though a lot of people think it's very similar to United States. It is different because the healthcare systems are different and the way people make decisions are different and the population is different, but I could actually talk about when you think about going global or you think about interacting with these markets or you think about what's important to them, we need to think about getting this



type of data or this type of information or perhaps think about sequencing and these things in this way and I could speak about that in a very practical way, where others just didn't know what they didn't know.

And so I think it helped accelerate things. I think it brought more credibility to the table and I guess from a family side, what it helped my children with is they knew that when a significant change happened that they would get through it and they will be okay. And so I really didn't realize at the time I was giving them a skill and a confidence that now in their later life that they really value and they also – it's given them more confidence as they now going to their working career that some of – that I was unaware that I was actually going to provide them by giving them on these excursions and so forth and so that was actually an unintended consequence that came out of this as well.

Though it's hard and though you need to be mindful of it and I realized it's a different experience for everyone else, it ended up being a fabulous experience for my career and it actually also gave sort of a foundation to my children as they started their career because it gave them confidence in knowing that they could take on more challenging opportunities and they know that they can actually go through significant change and know that that's okay because there are ups and downs and there's hard things and that they'll be okay on the end of it.

**Taren:** Yeah. They got their passports stamped like that kids don't get to do today, so that's amazing. It's like you gave them an amazing journey so that's wonderful.

**Kathy:** Absolutely. Absolutely.

**Taren:** Let's talk a little bit about innovation now. Your title as global head of clinical innovations. Now innovation means different things to different people, so how do you define innovation in your current role?

**Kathy:** This is interesting because when I was global head of innovation in Lilly actually the team we talked about this a lot and so we sort of think of – I guess I really was influenced by us as a group talking about that and simplistically I brought that to this role and probably need to test it as we move forward. But I think of it as being a new way that's – and that new way needs to be better. It just can't be different. So when you think of it as the new way, a new way and what's that new way for. Well, that new way needs to meet a customer or a user's need and just can't be just a new way.

So again, a new way that is better to actually meet a customer need and I guess what you get into is sometimes a customer doesn't know what that need is but they sure as heck know when



something is wrong or they sure as heck know that they have a problem or they sure as heck know that there is an issue.

Sometimes they articulate the solution and I think what we have to sort of separate is when they articulate the solution they could be dead on and they could be right, but sometimes when they articulate that solution the need and the problem is going better than new. So I think that requires us to be really less mean and try and walk in their shoes and it would be in their environment, be empathetic and really try to understand them and really try and figure out what that need, real need is. But if I take away all that extra stuff, it's just really to find a new and better way to meet that customer's need. To me, that's what innovation is.

**Taren:** Fantastic. And speaking of innovation, you lead the global – as we said the global innovation at Oracle in terms of the healthcare practice and life sciences business and this is a new business unit within Oracle, correct?

**Kathy:** Absolutely.

**Taren:** Your global team consists of how many people?

**Kathy:** Well, as of today two, but also when I started in February it was one, just me. The leader of our business unit Steve Rosenberg had this vision of bringing this new capability to the health sciences global business unit and he tasked me to take on the leadership role for this. So I was honored to do that, and really what he was looking for is for me to take a global view, so bringing that global experience I had which I'm happy to do and to really try and influence the broader health sciences global business unit and as well as outside the organization and so do some of the things that I had done in previous work, in previous activities.

So don't be constraint by the fact that we're just Oracle. Try and look at the broader ecosystem and then also understand what Oracle has and has to offer and then determine what it is that is needed in order to try and achieve the mission and vision that I believe in collaboration with the lead team that needs to be fulfilled in order to help make the clinical research or health business better so for everybody based on the work that we're doing. And right now I guess I brought someone on board that has a different set of – more scientifically focused and more clinical research focused than in looking for someone that is understand healthcare a little bit better, way better than I do. So really trying to bring people on board that has a way different experience and different skill set and knowledge that then what I have so that we can start expanding our knowledge base and having innovation in different areas that can help benefit the broader ecosystem.



But right now we're – to go back to your question, yes trying to cover. So I've been focusing most of my attention on clinical research initially because that's the space I know best and then broadening it out to other sectors as we bring more and more people on board.

**Taren:** Fantastic. Can you identify maybe your top two, three priorities as you go forward over the next six months now that you have what, 10 months behind you?

**Kathy:** Yeah. So basically I think – so let's give a little bit of background in the first part. So I sent the first really trying to validate what the problems are and how I did that was actually going to people in their own backyard, so talking to pharma, biotech, CROs, healthcare providers. I'm now trying to figure out how to take to patients, but getting to them in their own backyard in their own environment and actually saying these brought problems and so forth. And so having, trying to gather that information and getting, confirming that these are really, really important problems in them, now what I'm focusing on is working with individuals to actually run experiments on what it might take to solve those problems short term and long term and then determining what we should to actually then once we've confirmed how we would solve those problems do we actually build those internally here within Oracle and add that to our product suite.

Do we partner with people that are out there in the ecosystem and develop partnerships because Oracle is quite comfortable and very familiar with doing those types of partnerships or in many cases like we've done with the other things is we might do some acquisitions. And so really work with the lead team and come with recommendations on what we should do short term and long term and then prioritize how we should do that, what areas we should go after first, what areas we should go after second and I have my eye on the healthcare provider, healthcare professional that looks at the research facility, so that group of humans that are actively involved in clinical research right now. I feel they're very heavily burdened. I feel that it's really important to start and lighten that burden.

I feel I was part of that working at pharma. I didn't mean to do that. I apologized to them. That was not my intent. So I'd like to help to lighten that load and I'd like to prevent a kind of that moving on to the patient. I think through patient-centricity I think that's the right thing to do. I think that there is a chance that technology will be part of that patient-centricity. I don't want to see that burden laying on the patient as well and I think we want to get in front that and we want to help that experience with the patient to be really good and not repeat what we did with the investigators and see us some more outcome. And so try and get in front of that and so we look at how do we manage both of those things as well as do the right by them.

So really having conversations about what's manageable, how do we support that in the clinical research space while in parallel starting kicking off some other activities in healthcare so that we





then can manage that. So hopefully that sounds clear. So ask me questions if I'm maybe a little bit jumbled, so ask me if I wasn't there.

**Taren:** No. It's great. No, it's totally clear. I'd love to really talk about, dig a little bit deeper in terms of where you think those areas within the clinical research paradigm, ecosystem, whatever you want to call it along that chain need the biggest piece of innovative like change. Is it in the patient recruitment? Is it in the patient retention? Is it recruiting patients? I know the focus to you right now is on decentralized trials and I'd love to talk about that because I think there's a lot of chat now between a sightless and virtual and the term that you introduced me to was decentralized trials. So tell me about that area.

**Kathy:** Yeah. Before we jump into decentralized trials, I guess one of the areas I am trying to work on is more of a mind shift change, which I know is hard and it links to the decentralized trials is that what I feel we've done in pharma and I experienced this and I had experienced this with a lot of my colleagues as well is that I think we've done a really great job implementing point solutions and I would really love to see us to get to more of thinking digitally which is a mindset of change where technology really could be leveraged to help us support compound development plans, designing protocols, executing trials, doing enrollment, doing decentralized trials like you said. So that we actually think digitally and we really empower staff to get access to information to making decisions and we actually have information, data, tools, things that are more readily available rather than getting together as a bunch of individuals and talking and making decisions together or through conversation, we really have analytical tools and simulations and things to help us actually pull large quantities of data together rather than large quantities of people together to actually make decisions. So that's one thing I'd like us to see, and then I think that would help us actually do things like decentralized trials.

What decentralized trials means to me is that you would actually have a scientific question that you're trying to answer in a protocol and you would really know what data is absolutely essential to support the label that you would like to have for that particular compound and the patient population that you're looking to validate the safety and efficacy to support that label.

And you would actually design the experiment through the protocol that you would like to run it and you would make it as easy as possible for those healthcare providers and those participants in that protocol to participate in that particular trial to get that data to answer those scientific questions. And so you would take an account where those healthcare providers would be and where those participants or those patients would be and then you would marry it up to what that data would be. And so you would then – that's how you would actually do it. And so if that means that it should be done in rural areas or in people's homes or it should be in local medical facilities or it should perhaps maybe should be a combination of research facilities as well as maybe closer to people's homes then all of that would be factored in to how you actually should

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run it because that would produce the best way to actually generate the information you need to and for the scientific questions.

And so what you're doing is rather than having all the participants come to one location which is sort of centralized and gather the information, you're actually allowing it for it to be decentralized and actually you're going to where the information could be collected and making it easier for that information to be collected because hopefully that will increase the speed once you collect it, a quality that you can collect it and be easier for everyone to collect it. And by doing that then that you probably need good control systems and technology and you make sure everyone is properly supported and they have the knowledge to do that and you need to be able to monitor the safety of the patients appropriately and people need to be well-informed about what they're doing and everything exists to allow that to happen.

But the mindset of the individuals to actually approach research that way and then the knowledge of the individuals to know that everything – the risk so that they actually put all that in place. Lots of people don't even know that exists and so like how do they even begin to even be aware that they can actually put that in place and all that type of stuff. So it's kind of like that chicken and the egg. Like what you often see is that people have this protocol and then they know that some of these technologies exists and then they try and apply them after the protocol has been written and so then you get this point solution effect.

**Taren:** No which is the opposite of what you're trying to change which is to think more digitally from the outset. So you can't apply a digital strategy on top of something that's already done. It has to be done in conjunction. Correct?

**Kathy:** That's right. And I think right now the pharmaceutical industry just isn't wired that way. They're very people-focused. Like they still are very much, they get a large group of people together, key opinion leaders to get advice. They get a large group of people internally within the company to discuss the protocol. And there's nothing wrong – like I'm not trying to be critical of that. I think all that's good. It's just that somehow we need to figure out a way to help bring more of the digital mindset and digital culture, digital processing. Otherwise, it's really hard to make that transition to this type of way of working and to really get the value out of them. It's really challenging.

And I think right now we're feeling the pain of the point solution approach. That's what I think is really painful right now. So we're trying things. We're putting stuff in. We're piling things, but we really haven't taken that larger leap of – some are actually so I wouldn't say it's mainstream, but I would say some are and they're really actually starting to see the value of it where I still think – I really want to try and help people see the value kind of just going just a little bit further like taking maybe three or four more steps and then they can really see just how





unlocking that and how more benefit can come out of just helping, releasing that and unlocking the ability to think more digitally and how more advantageous and free and helpful that can be for everyone involved.

**Taren:** Perfect. And so the people don't freak out, it doesn't mean go into a decentralized kind of approach meaning taking the HTP out of the equation because that's not the case.

**Kathy:** No, no. It's actually if anything it's humans they're still all involved. The study team is still involved and the healthcare provider is still involved and the patient is still involved, but it's like what I said when you said when it's innovation it's doing something in a – hopefully, in a new and better way than using technology to enable it versus doing it the same way and just putting technology in place of this and I think that's the key is we have to start thinking about how to do it. You have to almost reengineer some of this stuff and then realize now technology can enable you to do it this way.

So it is different when you take, you do data collection outside of a research facility rather than just assume oh we're now going to just collect this data outside of a research facility, you have the technology to do that. I think we just need to realize that you almost need to reengineer that, just not assume it's the same while we just taking out of the research facility, now we're just going to collect it this way. I think that's what gets people a little bit in trouble. You have to reengineer it a bit and you need to think about that more holistically and we do, I'd love to help people with that. That's kind of part of my journey of what I've done with innovation over the last many years is let's just help with that kind of mindset, that kind of cultural change, that process change and what that means for everyone involved everyone feels really comfortable with that type of change.

**Taren:** That was a great explanation in terms of defining how the decentralized trials are really going to provide I think you're right, a new pathway forward in terms looking at how trials are conducted in the future and I couldn't agree with you more in terms of the digital aspect. I think that technology is going to be the piece of the puzzle that is going to solve so many of the challenges that plague clinical trials right now in drug development. So it does require a change in the mindset, and I think that leaders of today really need to get comfortable with that because they're going to be pushed because patients are going to be demanding more value from the drugs and companies need to derive more value from their pipelines and that's the thing to do it.

**Kathy:** I agree. I agree with you.

**Taren:** So earlier on, you had said that you had been identified as a builder as one of your leadership skill sets, how else do you define your leadership style?



**Kathy:** I believe my leadership style is actually situational. So I really like to get to know the people I'm working with and I like to find out if what they're doing is this something new or is this something they've done before. Are they really highly motivated to do it or is this the last thing they wanted to do on earth? And so like because yeah, jobs right. There are stuff we love to do and there's stuff we have to do and it's life. Wouldn't it be awesome if everything we did in our job we just always wanted to do? There's stuff in my job like you have to do it. It's just the way it has to go.

So I really try and get to know that from the team members and if it's possible and you could do everything you love to do and we have other member teams that picks up every time, that'd be great, but unfortunately like it doesn't always believe that deck of cards. And then what I do is there's actually a course I took called situational leadership and it was actually one of my favorite courses and a huge light bulb went on and I thought wow, this is like really insightful and I combined that with I also learned how people like to communicate. So certain people who like they're actually really chatty. Other people like to get right to the point. Some people like to incorporate their feelings. Some people just not just talk and so we sort of learned that about how people like to communicate and so I tried to combine sort of those three things together and so with the – and you don't do this like you don't do this holistically.

You actually try and do this when you're actually doing some key things within your job and even though you might have the most experienced person from your team that you've worked with for multiple years, I always found it was really good to even say hey, have you ever done this before and is it something you're excited then do it. And you'd be surprised what you hear. And so you'd always sort of have a conversation about so how can I help you with this. Do you need me to bump you because it's probably going to be the bottom of your to do list and do you want to get it done or do want to use some advice from training with my folks.

We can actually get it better or do you want to run things – let's check in like at the beginning of the week and so you can run by how you're going and they can give you some coaching on it. So I always found situational leadership was really good and I think really understanding how your people and your team want to communicate with you is so important because there's nothing worth than having somebody who's really chatty really wanting to work with somebody who just want the facts, like if you want to really irritate your employees really, really quickly that take home advice it doesn't work. Yeah. So that's what I found work really for me and those are probably the two things in my – over my development and all that I felt has worked really, really well for me and that helped me build a lot of things and I couldn't have done it without my team.



**Taren:** Fantastic. Speaking of teams, you are a role model to so many women out there because there are just so few women sitting in those global lead positions. So do you feel that weight of responsibility?

**Kathy:** Oh gosh I don't, but it's interesting because I get reminded of it by my son, and he has this group of women that he hangs out with and he reminds me that I have a fan club with them. People that they look up to me and he introduces me to them and I talk to them sometimes which was eye-opening one time, so thank you to them and I'm honored that that's the case. They're in their early 20s. There is a group of women in my neighborhood that I recently has started to get to know and I've also started to help them if they need anything and so I was – I'm happy to do that anytime. So I guess I wasn't aware of it initially.

Probably over the last five years I've become more and more probably aware of it and I am always eager to help support, mentor, provide guidance and so that is probably a little more eye-opening to me than I had thought. So in the past I guess I just felt like I was doing my job and I continually wanted to take on more responsibility because I wanted to see drugs get to market. I wanted to see drug development change. I was really passionate about the cause. I really wanted to help and in fairness, this may sound really bizarre, it was really my children that brought it to my attention that I was probably more of a role model to other women than anybody else.

**Taren:** Oh, I'm glad that they brought it to your attention. Let's talk about is there a piece of advice you would give to your younger self, something you wish you knew then that you know now.

**Kathy:** Yes. I give this advice when someone asks me what advice I would give them. You hire your direct opposite as soon as you possibly can, so because then when you and you're new teammate are a direct whole, are a whole. So yes, that would be the best advice and if you guys don't know what I'm talking about give me a call and I can explain it to you, but there are things that you're really good at and there's things that you're really strong at and that's just your natural tendency. So it comes out in stress. It comes out when you're really motivated and so forth, but there's another individual out there that is really good at other things.

No matter what, you're probably just not good at. I'm not good at certain things and I probably can do them, but I'm not – they're not the best things I can do. And so you have to hire – I strongly encourage you to hire direct opposite. The challenge to that is they're not naturally the person you're going to gravitate to.

**Taren:** That makes sense because they're not exactly like you.



**Kathy:** Right.

**Taren:** And so that's great advice. I appreciate that. Finally, is there one wow moment of your career that you can pick out?

**Kathy:** Yes. So close your eyes and I'm going to take you to Sydney, Australia and it's going to be beautiful. I was the chief operation officer of this newly envisioned clinical outcomes and research in there too that hasn't been built and there were leaders at Lilly that had this bright idea that they were going to sign this proposal with the government and sign up to a yearly commitment for the next four years to invest, to deliver a research commitment that was like outrageous. And when I got there and I arrived and they showed me what this yearly commitment and research was, I was actually speechless. I actually didn't say anything. I just sort of said, "Oh."

And so if this achievement around this investment in research and development across Asia Pacific was met, what that meant for Lilly was is that the Australian government would actually pay Lilly money, revenue for the cost of pharmaceutical products because what happens is the cost of pharmaceutical products is different around the world and so Australia's prices are traditionally a lot lower than what they called the global price. And so what would happen is the Australian government would make up – if we pick certain products, they would make up the difference between the Australian price and the global price and they would actually pay us Lilly the money for the difference provided we met our commitment that were put into this agreement that someone signed. So big rough because I went okay, whoa.

And so this is the only kind of my career that I would actually bring revenue into the company because R&D spends money. Some portion spends money. So this is the only time in my career I'd actually be a revenue generator, but again I'll say this again, I can't really disclose, but the goals were outrageous. I was like are you guys crazy?

Anyway, I pulled an initial team together. They were all Australian born. Some of them are recruited from outside of Australia so they're in the UK or whatever, so we brought the brain drain back. So everyone was Australian born. We worked together. We worked really hard. I was impressed by the global awareness of the employee base and the ingenuity comes from being a steward of environment, a lot of the affiliate and all that.

I'm proud to say that the team grew, but the core team stayed intact the entire four years that we were together, that they exceeded the goal. We had lots of calibrations around all that because I can't even – like we did it. They exceeded the goal and the experience that this core team acquired was very diverse and all of them had senior leadership positions across the industry today. I still keep in touch with them. So now my Oracle role, I've actually crossed –



because I'm traveling quite a bit to do some of these validations sort of popped in on some of these companies.

I've already touched base with at least three of them like in their senior VP of this and senior executive of this and it's been so lovely to actually see them, being able to give them a hug and after all these years and stuff like that they're all doing great and it's just wonderful to see them leading in the ecosystem and it was just a pleasure to work with them and learn from them and be with them in Australia and to actually achieve this goal. They were great.

**Taren:** It was really a wonderful conversation. Thank you so much.

**Kathy:** Thank you so much for the time. I really appreciate you asking the questions and I love the conversation and really appreciate the opportunity. Thank you.

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