[DIGITAL INTRO]

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GREG HORNE: Hello, welcome to *The Health Pulse,* a podcast exploring how analytics in the health and life sciences industry is growing and the convergence that is impacting all our lives. My name is Greg Horne, and I am your host for the series. And as always, I will be joined by my expert guests to discuss a topical subject.

And on this week's episode, we turn our attention to clinical trials with our very special guest, Javara CEO Jennifer Byrne. And she was included in the Women of Influence feature in the latest PHARMAVoice digital edition, and is an inspirational and influential leader in the industry. Before we get to speaking to Jennifer though, just one quick reminder that we still have our email address. And that is thehealthpulsepodcast@SAS.com. That's thehealthpulsepodcast@SAS.com.

Please keep those questions and suggestions coming through. We do find them very useful and very interesting. And they are helping us shape the series and episodes to come. So thank you very much for all those contributions.

So without further ado, please join me in welcoming this week's guest, Jennifer. Jennifer, good afternoon. Could you do a quick introduction please?

JENNIFER BYRNE: Good afternoon, Greg. Thank you so much for having me. Again, my name is Jennifer Byrne. And I have been, really, a career long clinical research fanatic is probably the best way to describe myself.

So I got lucky enough. I just kind of fell into this profession, coming right out of college. And I've had the great opportunity, over the past 30 years, to be involved in thousands of clinical trials, including hundreds of thousands of clinical trial participants. And I've had just the privilege of seeing the benefits of clinical research to real life people, every day.

GREG HORNE: Fantastic. And we always ask people at the start of the podcast about something they do when they're not researching or whatever else. So tell us about a hobby, Jennifer, that you do.

JENNIFER BYRNE: Well, I would say there are a lot of components to clinical research that I've taken on as hobbies, as far as a number of additional kind of extracurricular related clinical research activities. But probably apart from clinical research, in addition to just all the time that I can spend with my family, would be time on the road running miles after miles. And so, I'm in the process right now of actually training for what will be my 14th marathon.

GREG HORNE: Wow, that's fantastic. And when you're in that training mode, actually-- because I'm really interested in this idea-- does it help you to relax? Or does it help you think more about what you're doing in work? How does that kind of work for you when you run? What goes into your mind space?

JENNIFER BYRNE: I think it's really a mixed bag of relaxation and strategic thinking time. So I find myself using the time-- well, sometimes I'm running with a friend. And so, if I'm running with a friend it's probably a lot of storytelling.

If I'm running on my own, then it is an opportunity to relax, but also kind of replay conversations, replay scenarios, replay experiences, and just kind of take the time to go back to maybe a moment that I wasn't maybe quite so much in the moment, and really intentional about what was going on at that point in time. So it's always kind of a second chance.

GREG HORNE: Fantastic. That's interesting. I'm the same on my bike, to be honest. That's great. Jennifer, just tell us a little bit about Javara. What is it that you do? What's the company set up for?

JENNIFER BYRNE: So the company is really centered around building and providing a research clinical trial infrastructure that really supports larger health care organizations. And health care organizations can be pretty broadly defined, whether they're large mega-physician practices, practice management organizations, academic medical centers learning health systems.

We are really here to provide and to build a highly customized, again, clinical research infrastructure-- so the back office as far as pharma relationships, contract negotiations, budget negotiations-- all the regulatory framework that's necessary. And in addition to that, we are also providing a highly professionalized research staff. And that staff winds up really being embedded within our health care partners.

And the goal is always that we are integrating seamlessly so that at the end of the day, for a patient and for physicians involved with us in research, they really feel as though we are part of a unified team. So we're not here to create confusion or clunky hand-offs in the clinical research process.

GREG HORNE: Fantastic. Now, our podcast is aimed at health and life sciences. Let's jump back a step and think about some of this kind of traditional way that a clinical trial is done. Can you just explain a little bit about what is a CRO? And what is kind of the old way of doing the clinical trial?

JENNIFER BYRNE: Well, CROs-- Contract Research Organizations by definition-- really emerged I guess as an enterprise within the clinical research ecosystem, probably going back to the 1980s. And the genesis for CROs really was in response to pharma companies having a need to have another solution, rather than everything being in-sourced within the pharma company.

If you think about the clinical trials process, it is a finite process. While it's way too long and it costs too much it is, relatively speaking, a temporary state. And so, building a permanent workforce with highly customized professionals with therapeutic focus, and just many of the different elements that are required through the process, I think really drove the industry to innovate the clinical research organization, or the CRO.

So the CRO really is kind of an outsource partner for pharma. If you actually transition to Javara, Javara came to market as an integrated research organization. So the difference with the integrated research organization-- much like the CRO was built for purpose to serve the pharma industry to drive a more efficient kind of clinical trial partnership, so too is the integrated research organization to the health care system.

Health care systems can do research on their own. But oftentimes, the business problem around building a robust clinical research infrastructure from the system standpoint is that it's often very costly, can be very inefficient, and lead to some internal business challenges for the health care system.

GREG HORNE: Fantastic. And as you progress-- you've already mentioned it briefly there-- you're looking more at health learning environment-- learning health systems, sorry. And you mentioned it already, once. Just tell me a bit more by what you mean by a learning health system. What are the benefits of that kind of system?

JENNIFER BYRNE: Well, I think the concept behind the emerging learning health care systems across the United States is really a very symbiotic relationship, whereby that particular health care organization recognizes the opportunity to deliver improved health care through research. So research becomes care and care becomes research.

And from a Javara standpoint, our partnerships are very much centered around a strategic vision and partnership, so that we are bringing clinical research offerings to the health care system to really address the unmet needs of the patient population for the system. Simultaneously, we're still working with pharma companies in addressing the data needs and addressing all the scientific process that goes with clinical trials.

But we're actually stacking the impact-- as I would describe it-- of clinical research, and how can we actually leverage in particular phase II, phase III clinical trials across the again, the unmet needs of the patient population, for whom that health care system is serving.

GREG HORNE: Fantastic. And so, that must involve the introduction of new technologies. So can you just talk a little bit about your experience in that whole kind of new technology, and potentially new economic models that would come with that, too?

JENNIFER BYRNE: So the underpinning of addressing the unmet needs of the patient population obviously comes with the ability to be able to dive deeply into an electronic health record. But it's not the electronic health record alone, right, that answers those questions for us or directs us necessarily in a pinpointed direction. So I think data assets within the health care system-- a number of data assets-- very much can help us identify the right patient for the right trial at the right time.

So in addition from a technology standpoint, I think it would be again, claims data, troves, troves of health care data that health care systems have. We're finding, in addition to the data assets, technologies that really will allow us to further pinpoint within electronic health records.

So those technologies and those companies that are allowing actually protocol matching capability-- so taking the vast or a significant portion of the average of 50 to 60 inclusion exclusion criteria, and being able to take that data and driving that down using AI for example, and looking across the unstructured data within electronic health records and other data sources, so that's a key technology that really unlocks patient access in a pretty significant way.

GREG HORNE: In terms of our economic model then, what information have you-- do you find in that space, in terms of things like cutting costs or improving patient outcomes, in that sense?

JENNIFER BYRNE: Well, without that technology, again, identifying trial participants is extraordinarily cumbersome from a labor standpoint, and just from an outcome standpoint. So kind of back in the day, when I was earlier on in my career and we didn't have the benefit of the technology that we have today, it might well be that on average, it would be more likely that we would spend time and we would review paper charts or other sources.

And it was like a needle in a haystack finding a clinical trial participant. The manual labor that would go into that could be extraordinary. Whereas today, we can access across millions of patient records, and with the ability to really fine tune and lock in.

Like I said, especially in terms of some of the AI and the unstructured data, we can arrive to pointing us in the direction of a much smaller but very highly probable patient population. So I think the good thing for those of us who are very patient oriented and derive-- I'm going to say greater satisfaction and pleasure in directly connecting with patients-- from a research ecosystem standpoint, I think it allows the workforce to do the things that we really need for people to be doing.

And that's connecting with the participants, ensuring patient compliance, driving education, and then, leaving the technology to help us just much more efficiently target and identify the estimated 56 million patients that we need right now, participating in research.

GREG HORNE: Wow, that's a huge number of patients. And I think one of the things that's come out is a theme throughout making the podcast has been this idea of bias and perceived bias, as well. So when you're looking for these patients, now you have access to this information, do you find it easier to remove bias and get a more equitable view of populations? Or have you found bias is still just as prevalent as it has ever been?

JENNIFER BYRNE: Well Greg, I'm going to answer this. This might be taking this in a bit of a different direction than where you thought we were going to go with this. I'm actually going to say, in my experience, some of the greatest bias is physician and provider bias.

So a very common theme in my experience, and especially as we are starting to work with new health care systems and working with health care leaders, there tends to be a bias that number one, patients are not interested or not as interested in participating in research as they actually are. And number two, from an administrator standpoint within larger health care systems, oftentimes the bias of the leaders are that the physicians are not interested in research. And that is absolutely not the case.

GREG HORNE: Yeah, I see with this concept of decentralized clinical trials that we do need more physicians engaged. And there is often this feeling that physicians don't want to be involved in that. So can you talk a bit about how do we get more physicians engaged? And what does that mean in terms of access to new medicines for their patients?

JENNIFER BYRNE: Well, this is where I think technology can be a tremendous asset. I think we have to be thinking about using technology. And of course, the buzzword is all about patient engagement. But I think that we need to be more intentional about physician engagement.

Particularly, I believe strongly that the best way for a patient to come to a clinical trial is actually through and together with their trusted health care provider. Now, it might not be that trusted health care provider is walking hand in hand in the journey of their clinical trial participation as an investigator, for example. But I do think that as far as ultimately the outcome for the patient, their clinical trial participation and the insights that are gleaned through their participation, keeping that in sync with their overarching health care is absolutely fundamentally important.

So I think that using technology to ensure that the trusted physician or practitioner community-- whether that's one or that's 10-- surrounding that patient is well informed. I believe that is absolutely key. Now, the default is-- generally where the conversation goes in my experience is people will say, well, it's hard to get physicians involved and on board with advocating for trial participation, because they don't want to quote unquote, "lose their patient to another physician."

I think communication is key, and again, keeping those physicians in the know and informed. And if we can do that from a digital standpoint and on their terms, then all the better. I do think that there is an opportunity from a compensation standpoint.

I think we need to be thinking about a broader compensation model, so that perhaps those trusted physicians that are providing ongoing care for other ailments or concerns on an ongoing basis that a trial participant has as a patient, I think that there are professional services that physicians around a clinical trial participant can actually be involved-- and ensuring that the protocol and prohibited concomitant medications, for example, are not being breached in some way.

And so, in a way, you're really creating an economic model that is full support, thinking about the trial participant also as an ongoing health care consumer with ongoing patient needs.

GREG HORNE: And that raises an interesting question to me then, that one of the things we in health care in general is that people are very bad at things like adherence and being part of a process when it's not even a clinical trial. It's just they are sick. And they are being prescribed something.

And they have to keep taking it. And adherence is always a big issue. In this idea of a decentralized clinical trial, how do you keep the patient engaged, particularly if it's a trial that isn't necessarily something they're feeling direct benefit from? How do you keep adherence level high?

JENNIFER BYRNE: Well, inherent to the clinical trial process, I do believe that the construct of the clinical trial really can deliver what I'm going to describe to be probably a more optimal care delivery journey for a patient. So whether that's happening in a virtual environment or it's happening in a traditional environment, we know that to collect a complete set of data to answer those scientific questions that need to be answered, we do need ongoing feedback and data coming from the patient.

So I think that in the decentralized model or again, in the traditional model, technologies and communications, just in terms of keeping that ongoing contact, I do think that there are tremendous opportunities. And there are a number of change agents that are working on new solutions in a very active way.

But I do think the ideal state is when we get to that point where we allow the patient from the very beginning thinking about the phenotype. I mean, we fit into different phenotypes from a health care consumer standpoint-- how do we like to get our information, and the ability to be able to kind of customize based on phenotypes.

Do individuals prefer to be text? Do they want a text message? Do they want to be able to come into a clinic? Do they want to do video chat, and I think, kind of getting to the point where we can offer more customized approach without losing the scientific integrity around standardization and all of those principles that we know are so important that cannot be compromised.

GREG HORNE: So OK, here's a question for you then. We are currently arguably in the biggest phase III clinical trial that has ever been conducted with the rollout of vaccinations for the coronavirus, COVID-19. What impact do you think that's going to have on patients' willingness to be part of clinical trials? Do you think is going to help for the future? Or is it going to be something that hinders, maybe, the rollout of clinical trials?

JENNIFER BYRNE: Well, no doubt about it for me, it is helpful. And we're already seeing that in real time. This time last year, the vast majority of clinical trials and new clinical trials outside of COVID-19 were almost non-existent.

One year later, we're in a vastly different world. And while we're still living in the midst of the pandemic in a number of ways, life is resuming from an R&D standpoint. And overall, we are seeing tremendous-- I'm going to say, I don't know if it's a double.

I couldn't give you hard and fast statistics. But kind of anecdotally, I can tell you that what we're seeing across the clinics, in terms of patient receptivity to research, is tremendous. And as much if not maybe even more so, the level of interest from physicians.

There's not a week that goes by that I'm not having a conversation with somebody-- whether it's an administrator, it's a physician, or it's somebody on our team-- that they are relaying that a group of physicians or an individual physician who was not interested two years ago in research is very, very interested. And that's not just in participating COVID-19 related.

GREG HORNE: OK, so that's really interesting. So one last question before we wrap up. The future-- what do you hope or predict will the future bring in terms of clinical trials? Where do you think the next year or two years will bring us?

JENNIFER BYRNE: Well Greg, I mean, I think for me, I love that question. And thank you for asking that. So the hope and dream for me would be that we move to a place, together as a society, whereby clinical research is on the menu of options for all of us as health care consumers. We've got a long ways to go.

But I think that we are headed in the right direction. You don't know what you don't know. And the fact that 5% of oncology patients participate in clinical trials, no doubt this is evidence in and of itself that we must do better.

GREG HORNE: Yeah, fantastic. I couldn't agree with you more. I think that seeing more personalized medicine in that space is going to be a really big deal for a lot of patients. So thank you very much, Jennifer, for joining us today and for sharing your insights.

I think our audience are going to find that very interesting, because we certainly see a lot of tie through the series right now in terms of how data is shared, where clinical trials are happening, and how that is changing the research space in terms of pharmaceuticals. So again, thank you very much for joining us today, Jennifer. And we will be wrapping up today with just a reminder that we do have our email address, thehealthpulsepodcast@SAS.com.

Thank you very much for joining us today. My name's been Greg Horne. I have been your host. And I look forward to welcoming you to another episode in a couple of weeks. Thank you very much, and we'll speak to you soon.

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