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Welcome to the PharmaVOICE Webcast Network.

In this episode, I meet with Maya Desai, Director, Life Sciences, Guidehouse. We talk about digital therapeutics and the many hurdles and challenges associated with pharma companies and tech companies collaborating from development to commercialization.

I'm Dan Limbach, your host and producer of the PharmaVOICE Webcast Network.

Dan: Welcome to the podcast program Maya.

Maya: Hi Dan. It is a pleasure to be here. Thank you for having me on your podcast today.

Dan: It's my pleasure. We're here to talk about digital therapeutics and in the recent years we've heard a lot about this topic. Could you define digital therapeutics for us?

Maya: Absolutely. A commonly used definition for digital therapeutics comes from the Digital Therapeutics Alliance, and that defines digital therapeutics as products that deliver evidence-based therapeutic interventions to patients that are driven by high quality software programs to prevent, manage and treat a medical disorder or disease. And these diverge from broader digital health market that we commonly hear about, as well in that digital therapeutics must be approved by regulatory bodies and displaying proof of concept is at the core of their models.

Dan: Excellent. Thanks for that definition. So that being said, are digital therapeutics becoming increasingly popular now and could you elaborate on that?

Maya: Digital therapeutics are certainly getting a lot of attention lately. The value of the global market was estimated to reach 9 billion USD by 2025, but new forecasts are suggesting an estimated 56 billion USD market opportunity for digital therapeutics in the next five years. And as you can imagine, this is not surprising. We've all experienced virtual healthcare at this point. With the healthcare ecosystem, we've seen innovation coming to fruition faster than ever before in the past year and a half. We're collecting massive data and in turn, have the ability to provide tailored solutions to meet individual patient needs.

With the emergence of social media, smartphones, wearables, cloud-based data platforms, real-world evidence, we're now able to utilize digital therapeutics to treat, monitor and prevent various health conditions beyond restricted spaces such as hospitals and clinics.

Now, if we put this in perspective and we look we at the benefit of digital therapeutics in chronic conditions, which does make the lion's share of our healthcare spending, it is massive. This is further being fueled by the anticipated long-term pandemic effects on mental, emotional and physical health conditions. And with this, companies they recognize the value of digital therapeutics and have had a

renewed interest in accelerating activities to tap into this market, and this is what is contributing to its popularity.

Dan: Well given this Maya, are digital therapeutics mainly being developed by pharma companies now?

Maya: No. It is a combination of pharma companies and technology companies. Historically, the development of digital therapeutics was predominantly an academic endeavor or one undertaken by technology companies. In my previous life as an academic as well Dan, I myself had a strong interest in developing digital therapeutics for different forms of dementia. But it was unheard of pharma playing a role in digital therapeutics at that time. Since then, the landscape has considerably evolved.

In the more recent years while technology companies continue to invest in digital therapeutics, we're also seeing pharma companies venture into this space. Pharma companies are doing so through investments and strategic partnerships with tech companies. And we are definitely going to see a further uptick in MNA activity over the next five years. And with this, pharma companies will likely continue to be active acquirers of technology-heavy companies.

I believe we'll see a lot of more unified collaboration between the two – pharma and tech companies – in bringing digital therapeutics to market, ultimately to the benefit of the patients.

Dan: Outstanding. So with pharma and tech companies joining forces to bring digital therapeutics to market, do you anticipate that there will be any challenges? Ad if so, what are the primary challenges?

Maya: Absolutely. When we have two or more disciplines coming together to work towards a common cause we often see positive results and innovation. However, it is equally common to see accompanying challenges that the disciplines face. It is no different in this case.

If you look at their expertise individually, pharma companies know how to develop drugs and all the steps to bring these to market, but they're not as experienced with software development.

On the flip side, technology companies are of course experts at developing the software and bringing the software app to market, but they usually don't have the regulatory expertise and know how necessarily on how to bring a therapeutic software to market. While these individual expertise can be viewed as complementary, it also poses operational and cultural challenges that can have an impact on different aspects of development and commercialization of their products. To make it a truly successful endeavor, these challenges need to be recognized and addressed while accounting for interdependencies and implications for both sides.

Dan: Very good. Maya, could you give us an example of a challenge these companies might be facing?

Maya: Definitely. One such area is technology development and adaptation when it comes to digital therapeutics. Let's look at the pharma side. The companies focus on developing drugs requiring a rigorous research and development process, followed by carefully orchestrated clinical trials and highly detailed pre-market and post-market regulatory submissions. So while speed to market is extremely important for pharma companies, safety and efficacy come first. However, most software developers are not used to this. The barrier to entry is generally much easier for softwares that do not classify as a medical device or digital therapeutic. Software companies are accustomed to sprinting to the finish line with a minimum viable product comfortable knowing it can be refined later if and as needed. For pharma companies less experienced in the ways of software, a major hurdle comes from not fully understanding best practices and implications related to technology development and adaptation by developing and commercializing the digital therapeutic products.

Dan: So how can companies address this gap and knowledge when it comes to technology development and adaptation?

Maya: To address this, the company should develop the next generation of digital therapeutics commercialization playbooks. So what I'm talking about here is a unified comprehensive commercial playbook that both pharma and the technology partners can refer to. Pharma continues to rely on its traditional product commercialization playbooks for digital therapeutics. And while this maxed out a list of functional activities, timelines, interdependencies, ownership and responsibilities, it lacks considerations and allowances for the technical development and adaptation. And the pharma company often sees this as the technology partner's responsibility.

As I mentioned earlier, we're talking about high quality software programs with digital therapeutics. Given this, it is absolutely crucial that the launched playbooks include technology development and adaptation as an integral part of it. The playbook should also connect here further regulatory compliance and legal interdependencies and implications, especially as we look at global markets.

Dan: Let's talk more about the playbook. What are some technology development and adaptation-related considerations that pharma companies should be including as part of this next generation digital therapeutics commercialization playbook?

Maya: Of course, Dan. So they should be considering regulatory compliance and legal as key functions as I just mentioned. Additionally, user research and testing, technology adaptation, data security and privacy, infrastructure, operational model are amongst others. Again, there are cross-functional interdependencies and implications across all these.

Let's talk about some of it. Like one area that I mentioned is user research and testing. This allows technology companies to understand how real users will use the software, and it is critical to inform adjustments to ensure the best user experience which is a step pharma companies do not have to worry about with traditional drugs because there is no UX interface. This is particularly important given majority of digital therapeutics rely on cognitive behavioral therapy.

Pear Therapeutics that has launched multiple prescription digital therapeutics in the past years has also indicated that they continue to grapple with design question about process, patient feedback and user diversity. This goes to show how crucial this aspect is. Now execution on this requires market scans, competitive, analysis, prototyping, qualitative testing, cultural research, etc., which the pharma counterparts are not involved in. However, communication between the two teams here would be beneficial. As you can imagine, the pharma side has an in-depth understanding of competitors, target patients and physician segments and demographics which the two can iteratively build on to enhance product development and their market focus.

Next is technology development. Now, this aspect is also important because it informs modifications to the software to reflect learnings not only from the user research and testing that we just spoke about. In addition, this also has medical affairs and evidence generation elements that are associated with it, as well as region-specific regulatory and data security requirements while adapting the softwares. Now, this is another critical step, but can be a particular challenge due to the agile nature of software developers who do not have knowledge of therapeutics and the requirements and regulations associated with it.

I'll give you an example. In a recent case scenario, there was friction around defect management for digital therapeutic in mental illness that arose between the pharma company and its software development partner. Now, the pharmaceutical company pushed for fully finalized and bug-free product while the developer pushed for a minimum viable product. Now this negatively impacted the entire team's product design and development process which had an impact on both the pharma partners as well as the software developers. Yet another consideration is data security and privacy demands as these companies set up the infrastructure across various regions.

Health data breaches are rising globally creating new challenges as organizations are holding more sensitive data today than ever before. This puts at stake product advancements as well as the company reputations. So this is another area where companies need to consider building safe and scalable strategies and carry it throughout the playbook, thus minimizing adaptation hurdles that they may face in the future.

As with many emerging industries, regional state and national governments globally are developing new and sometimes conflicting privacy policies, which also need to be thoroughly understood and addressed as these products are developed as well as commercialized.

So this again are just a few examples that should be considered, but there are several more, Dan, that need to be included to create a comprehensive understanding of what goes into developing and commercializing a digital therapeutic.

Dan: Excellent. Well, Maya to sum up our conversation today, what would your advice be to companies venturing into digital therapeutics for the first time?

Maya: So digital technologies and data science have incredible potential to unlock the next chapter of medical innovation today and in turn, help individuals finally take control of their own health in a meaningful way. We're going to continue seeing an uptick in pharma and technology companies coming together to make this happen. So with that, each party, Dan, must commit to advancing the alliance and demonstrate commitment through investment and strategy, structure and culture.

One way that the critical gaps in style and approach between pharma companies and software developers can be bridged is through literal alignment and appreciation of the critical roles and interdependencies, some of which we talked about today from both disciplines that are being brought together through a next generation digital therapeutics commercialization playbook.

These companies will require creating a new script with a genuine commitment to return on collaboration and mutual success, thus enhancing the position of each partner as they commercialize these digital therapeutics products.

Dan: That's excellent advice. This has been a great conversation Maya. I want to thank you for sharing you thought leadership and expertise with us today.

Maya: My pleasure. Again, thank you for having me today, Dan.

And that does it for this episode. For more information about Guidehouse, visit guidehouse.com. And don't forget to check out our other podcasts, white papers, webinars, virtual panels, case studies, videos and more at pharmavoice.com.

Until next time, I'm Dan Limbach.