Exploring the potential of digital therapeutics

Three European digital health CEOs share their perspective on digital therapeutics

**McKinsey:** What is your definition of digital therapeutics, and why is it important to define the space?

**Peter Hames, CEO, Big Health:** The terminology I tend to use is digital medicine. I would consider digital medicine as something that mimics the same fundamental qualities of drugs, and therefore has the ability to be an industry that can scale to challenge large sections of the pharma industry. For me, the exciting thing is being able to deliver these interventions without any human interactions.

**Jörg Land, CEO, Sonormed:** A digital therapeutic is an intervention based on software as the key ingredient, which has direct impact on a disease. This is what distinguishes this category from the broader term digital health. We will see digital therapeutics and digital diagnostics integrated
into the health system and, in many cases, also reimbursed – providing a kind of guidance for the patient and also the physicians. A solution reimbursed by insurance signifies it complies with the rules of market access and that someone has had an in-depth look at the solution's quality.

**McKinsey:** What is the role of regulatory approval and clinical trials to differentiate digital therapeutics from digital health and wellness more broadly?

**Edouard Gasser, CEO, Tilak Healthcare:** Clinical validation in trials and regulatory approval like CE marks and FDA approval are key for digital therapeutics because it is what doctors will trust, and it helps them regard a product as an actual digital medicine that is going to help the patient and that they can prescribe.

**Peter Hames:** I think there is a strong ethical duty for anyone producing any intervention that is intended to help someone with their health to demonstrate effectiveness and safety to the highest standards – whether it’s a molecule or an algorithm, the same principles should apply. We are in what I would consider the “quack medicine” era of digital medicine and digital therapeutics, where there’s a huge morass of solutions with incredible variance in quality – and there isn’t yet an established set of criteria. For Sleepio, we have assembled significant levels of clinical evidence, including five randomized control trials and 20 peer-reviewed clinical papers, but only few digital interventions have that level of evidence.

**Jörg Land:** You need some sort of proof for digital therapeutics; therefore, clinical trials are important, in particular for regulatory approval. However, I would expect products to be treated according to their potential risk, with low-risk products requiring less evidence up front, in favor of data generation once employed. In digital health you can track and analyze vast amounts of data constantly and at very low cost, which makes digital health ideally suited to the collection of real-world evidence.

**McKinsey:** From your point of view, which therapeutic areas are most ready for digital health or digital therapeutics, and why?

**Peter Hames:** Any health problem that has an evidence-based behavioral or psychological solution. Around 80 percent of healthcare budgets are accounted for by chronic health issues, and a very significant proportion of those can be directly or indirectly addressed with cognitive behavioral therapy. Our focus is on mental health, a domain that I am particularly passionate about. Given the cost burden both directly and indirectly associated with those issues, combined with the fact that they are massively undertreated, this is a domain that could benefit hugely from a more private, self-driven, in-the-palm-of-your-hand solution.

**Jörg Land:** The most interesting areas are those in which value can be demonstrated and solutions can be found that are more effective than established treatments. Any chronic disease related to habits is interesting in terms of digital therapeutics. Areas where demand will outgrow treatment capacity are also promising. For example, if you look at Germany, the population is aging, and we only have 4,500 neurologists in Germany. Unless that number
increases significantly, we won’t be able to treat the rising number of patients. Some companies are focusing on early detection, but I think diagnostics only makes sense if it leads to a therapeutic solution. Otherwise the patient could be affected in a negative way – imagine you know that in 20 years’ time you might get Alzheimer’s, but there is no cure for it currently. I think the market will favor solutions that offer a mixture of therapeutic and preventative value.

**Edouard Gasser:** In my opinion, areas where digital can play an active role in the treatment itself and where treatment capacity in a health system is restrained are likely to take off first. Ophthalmology, neurology or psychiatry are amongst those. Psychiatry, for example, is a big subject because of the importance of patient monitoring. A therapist cannot be with a patient 24 hours a day, and for people who have bipolarity or depression, having an app that accompanies them is extremely important. In Tilak, we’re really trying to find areas where mobile games and applications can help follow a patient’s disease. We started with ophthalmology, where an aging population and a low number of healthcare professionals – 8.8 ophthalmologists for 100,000 inhabitants – are causing obstacles and dysfunction in the healthcare process. The use of digital therapeutics will be inevitable in the future.

**McKinsey:** What is the right business model for digital therapeutics? Is it direct to consumer or direct to patient? Should payors or providers be convinced to finance it? Is it employer backed?

**Peter Hames:** I’m a huge believer that, if we retain value for patients and we’re incented to deliver that, we stand to correct one of the foundational issues with healthcare: the, in general, misaligned incentives between the providers of care and those receiving it and those paying for it. For me, outcome-linked payments and anchored payments are inevitable and also desirable in terms of incenting everyone to go in the right direction and do things that work. Where we’re incented to help the user get well and back to their life as cheaply and quickly as possible, the payor is saving money and getting a significant ROI per outcome versus what they’re currently paying through the inefficient traditional methods of delivering health. But we also get reimbursed properly at a significant level, such that we can grow an industry to a scale that can help millions and hundreds of millions of people.

You can, of course, deliver a wellness product directly to the consumer. Given that consumers’ willingness to pay out of pocket for healthcare is incredibly low – at least in the US and UK – the only viable way you could make that work is a subscription model. But then you’re in the trap where you’re incented to addict people to your service; you’re back to that kind of world where you no longer want your users to be cured and to go away, which diverges you from that mission.

**Edouard Gasser:** We believe in a B2B2C approach, where physicians are the key actors. As with nondigital medicine, you need to gain the trust of doctors who have the power to prescribe a digital therapeutic to their patients. For Odysight, in our first game the ophthalmologist prescribes the application and then has access to an online dashboard to follow the medical data sent in.

When it comes to payment, we see more acceptance of self-pay in the US, but we are also working towards reimbursement in all regions by conducting post-market analyses of the social and economic benefits of our application.
**Jörg Land:** It all depends on the specific use case and medical area. In my view, unlike a wellness solution, a digital therapeutic solution should be reimbursed. Even though this takes much longer, it is paramount to gain access to the physician (which also leads to quality assurance) and the patient. The business models of digital therapeutics can be very different from those used for drugs. A digital intervention can be tracked, so why not take advantage of this and get payors to choose your solution when applying performance-based models that help payors manage risk. For example, the payor would reimburse more if the patient used the therapeutic as intended (compliance) and especially if the digital therapeutic prevented readmission or repeat intervention in a given amount of time. This is also different from the wellness area. Wellness apps are B2C focused and optimize for KPIs, such as number of users, usage, and direct turnover – a formula like the above would not be applicable.

**McKinsey:** How would you describe the pharmaceutical industry’s relationship with digital therapeutics? And why hasn’t pharma invested in this as much as one would expect given the opportunities and potential disruption?

**Peter Hames:** I think there’s one answer, which is generic to any incumbent industry: why did it take Tesla to really spark the electric car revolution? Incumbents do not radically change their approach. I think that time will tell the degree to which they are able to foster and incubate their own digital therapeutics and digital medicine units and to what extent they need to work with other new companies in the space. I think it’s a little bit too early today, to be honest.

**Edouard Gasser:** I don’t think that they have the culture and agility right now for proper digital deployment. From what I see, it’s a very different mindset and they are partnering more with digital start-ups instead of doing it themselves because it’s not in their nature. Of course, they have extensive expertise, especially when it comes to commercial deployment of medicine. And they see the potential of digital, such as inserting digital applications in their clinical developments. I definitely hope we see them as partners. I think they have a key role to play.

**Jörg Land:** I think we are in a very early phase. The pharma industry still enjoys healthy margins, which cannot be compared to the revenue potential of digital health solutions. So, there isn’t huge pressure. Also, most new digital players still need to find out how to make revenue with their tools. Once added value can be demonstrated, pharmaceutical companies will take a much closer look at these solutions.

Innovation will likely be driven by start-ups, since pharma companies are highly regulated and structured around the concept of developing one pill, producing it, and selling it a million to a billion times. This structure needs to be adapted for digital innovation, where solutions are evolving continuously.

**McKinsey:** What’s your relationship with existing large players in the digital sector? Are they your competitors or channel partners, and how do you see your place in existing networks?
**Jörg Land:** So far, to be honest, we haven’t seen much of the big technology players in health. I think the main reason is the complexity of market access and regulation in healthcare. Healthcare is very fragmented; it is not a global market. In healthcare, you need to act differently in every single market. I think tech companies depend on partners in order to make use of their core competencies to sell their hardware. I don’t think that these players want to establish digital therapeutics, but they might want to provide the technology to do so.

**Edouard Gasser:** Large tech companies are potential partners because they provide the network for us to thrive when it comes to the app store and the technology. Social media companies are similar; they contact digital healthcare start-ups because they want the data to understand how diseases work. I don’t see them as a threat. However, it’s true that to me they are more of a threat than the pharmaceutical companies because they have knowledge of digital development and obviously have the money to develop what they want. They can also be tremendous partners, and the way they are entering the healthcare industry right now is mainly through partnering.

**McKinsey:** There is potentially huge value in digital therapeutics, and, in some cases at least, this has been proven. So, if there are therapies that are proven to have a great clinical effect, what is holding digital therapeutics back?

**Peter Hames:** I think this is largely due to the culture of payors. Healthcare in general has a culture of moving slowly and being very careful. From my own experience, the vast majority of payors have a real interest in these solutions. Payors can understand that these digital solutions appeal to the way that people solve problems today. But they also all have very valid practical questions: for example, do we want to tie payment to outcomes. Or, what if everybody uses it; what will that mean for our costs? What’s the risk profile when we actually deliver this at population scale? How do we handle clinical governance at scale? There needs to be a stepwise process, demonstration projects, and the like. In the main, this is an industry that works on precedence and practices that spread from flagship projects. I think we’re at the stage where we need a handful of those to tip the balance. I think we’ll see what happens very rarely in healthcare: sudden and very, very rapid change. All health systems throughout the world are under incredible cost pressure, and digital medicine and digital therapeutics are perfectly placed to meet that seemingly impossible task of increasing quality of care while reducing costs and handling a population’s health.

**Edouard Gasser:** Right now it’s in the early stages. It’s not the technology that is the problem; I wouldn’t even say that it’s clinical trials that are the problem; it’s more consumer habits. Consumers haven’t yet adopted the habit of considering an application as medicine, per se. The tech is here, but the habits of the consumers are not – so you need to build products that are going to change those habits.

**Jörg Land:** It’s a very young market, it takes a lot to become successful, and you need luck and good timing to make it to the top. Getting your digital therapeutic through the approval process of health insurance companies takes a long time and requires them to not only trust in a young unknown player, but also in the technology’s capability to ensure data privacy.
and IT security. In addition, striking a reimbursement deal with insurance companies doesn’t automatically mean that you will generate any revenue. You also need to have the physician as the gatekeeper on your side as well as the patient who is asking for your solution. So, reimbursement is the first condition to generating revenue, but it’s not a guarantee. That is why companies such as Clue or MySugr – built around patient experience – do not spend much of their resources on the reimbursement track. I think therapeutics and diagnostics definitely have the best chance to make big money within the system. The reason is simple: they are tackling existing budgets within the healthcare system. That makes it much easier to convince payors to reallocate their money to digital healthcare.

About the author(s)

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