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A NEW FRONTIER IN DIGITAL HEALTH CARE:
Software As Medical Devices

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The digital revolution's impact on health care products and processes is already enormous, from data mining to telemedicine, wearables, remote monitoring, "smart" pills and artificial intelligence (AI). Digital tools are driving an increasingly interconnected health care environment geared to patient-centricity, cost-efficiency and appropriate self-management of diseases. This wave of innovation has brought new hybrid or unique products that leverage digital capabilities to complement or replace more conventional forms of health care intervention.

In the medical device sector, one outgrowth of the digital revolution is software as a medical device (SaMD). These are stand-alone computer programs – including apps – used in the prevention, diagnosis, treatment, monitoring or management of disease. They are distinct from software included in, or integral to, medical devices, and from software used in the manufacture or maintenance of devices. Digital therapeutics is one example of SaMD that is attracting a good deal of attention in this space.

Skye Hodson,
Asset Strategist,
Syneos Health

For agile, resourceful software developers, as well as mainstream device and pharmaceutical companies, SaMD offers significant opportunities for both commercial gain and health care transformation. It also presents a number of regulatory and market access challenges. These must be carefully negotiated to ensure the competitive velocity and ongoing health of the SaMD industry.

Unmet Needs

The main catalysts for the emergence of this new SaMD market over the last five years have been persistent unmet medical need and the limited access to effective treatments still faced by many patients, explains Skye Hodson, Asset Strategist at Syneos Health. These needs particularly arise in large populations with chronic conditions not adequately addressed by conventional pharmaceutical intervention: indications such as central nervous system diseases and disorders. The problem is compounded by the long life cycles and complexity characteristic of mainstream drug development.

SaMD products have moved increasingly from augmenting mainstream interventions in these areas toward providing the interventions themselves, Hodson points out. This shift from generic digital health and well-being toward a more explicitly therapeutic or diagnostic positioning has gone hand in hand with a surge in investor interest, in terms of the number and size of SaMD or digital therapeutics deals struck over the last five years, as well as the value of venture funding.

Around five years ago, there was a lot of clinical interest and research in the SaMD space, Hodson notes. By 2016–17, regulators were starting to take an "active interest in the field" and some SaMD products were being approved. That raised questions about robust definitions and pragmatic, innovation-friendly regulatory frameworks for SaMD, covering a whole range of issues from evidence generation and evaluation to quality assurance and data privacy.

These challenges are further complicated by the dynamism and fluidity of technology development in the SaMD and digital therapeutics space, whereby product functionality (and, by implication, positioning) may change quite quickly based on real-time product usage and data collection. Moreover, many product developers are not traditional medical device or pharmaceutical companies with experience of long-established regulatory pathways in these sectors.

As Hodson observes, the US has been a "hotbed" for SaMD development, and the Food and Drug Administration has taken a proactive stance on regulating the industry. The FDA published final guidance, *Software as a Medical Device: Clinical Evaluation*, in December 2017, providing what then-commissioner Scott Gottlieb described as "globally recognized principles for analyzing and assessing SaMD, based on the overall risk of the product."[1] The formation in 2017 of the global Digital Therapeutics Alliance (DTA) trade group was further evidence that the SaMD industry was gaining real momentum.

For all that, the SaMD phenomenon is still in its infancy. "Over the last two years we've seen a nascent market starting to grain traction, with a lot of interest from pharmaceutical companies and some significant investments," Hodson comments. "In terms of companies generating revenues, we're still at the bottom of the ladder. I think by 2022 we're going to start to see the market increasing significantly, as we continue the year-on-year growth into what will eventually become a multibillion-dollar sector."

One recent pointer was the $302m valuation of the Otsuka America partnership with Click Therapeutics to develop and commercialize prescription digital therapeutics for major depressive disorder. Just before that, in December 2018, medical equipment company ResMed bolstered its capabilities in managing chronic

obstructive pulmonary disease by acquiring digital therapeutics specialist Propeller Health for $225m.

Breakthrough Decade

"We have seen some encouraging developments these past years, which all point to a breakthrough decade for SaMDs and digital therapeutics, as this emerging market establishes itself and we start to see some of the roadblocks being resolved," Hodson predicts. There is also interest from insurance companies, which recognize in SaMD an opportunity to transition from a risk-based to a more outcomes-based model of health coverage.

This again reflects the rapid evolution of SaMD. It initially was focused on monitoring, observing or measuring disease, and now increasingly is geared to evidence-based claims that "target health outcomes very specifically," either independently or in combination with pharmaceuticals/medical devices, Hodson comments.

Stakeholder responses to the emergence of a viable SaMD market are generally very positive, Hodson says. Patients are particularly keen to embrace new technologies that give them a more central role in managing their health. With more people leveraging digital tools in their day-to-day lives, expectations of what health care can deliver have risen in parallel. "If anything, patients are frustrated by their limited ability to share or track their data and take more control of their health," Hodson remarks.

Health care professionals are "very interested" in understanding more about SaMD opportunities, although questions remain around securing reimbursement and determining how the products fit into long-established patterns of institutional practice. For example, physicians want to know how SaMD can be integrated effectively into their workflow, or how they can prescribe something virtual on a day-to-day basis. Moreover, they must be confident enough in SaMD not to take on the additional burden of constantly monitoring associated patient data for warnings of potential acute events.

Much of today's health care environment is framed by payer policies. The implications of SaMD for cost-efficiency and -effectiveness have not eluded the payer community. According to Hodson, the majority of US payers questioned during recent Syneos Health research aim to provide coverage for digital therapeutics under their medical benefit over the next five years, while half have already established coverage or intend to do so within the next two years.

From the regulatory perspective, digital therapeutics companies say agencies are engaging in early discussion and dialogue around marketing requirements for the new-generation products, with an emphasis on encouraging innovation while ensuring the safety of patients. The US is "very much pioneering" in this respect, whereas Europe is "getting there slowly," Hodson says. In addition, Asia is proving "very receptive" to SaMD, and could be a key growth driver in the future.

Access Challenges

The proactive approach taken by some regulators to evaluating SaMD is highly encouraging, as the "real challenge" comes in tackling market access barriers and adoption, Hodson believes. Some of this is down to whether the software is presented as a drug or a device (or something in-between), as a product or a service.

Although concerned bodies such as the DTA and the International Medical Device Regulators Forum have developed their own definitions and are pushing for global harmonization on this front, there remains an element of flux in the way SaMD is characterized. The gray areas, Hodson explains, typically relate to the claim being made, the associated risks of that claim, the evidence that substantiates it and how that evolves. Quite a lot of guidance now exists to inform those decisions.

One muddying factor is that many of these products incorporate sophisticated analytics, such as machine learning or AI. In market access terms, this can be "a double-edged sword," Hodson comments. "You're seeing products with one value proposition that will be enhanced or changed, based on data created and insights that can be gleamed from it." The question then is how much this process modifies the original product and the claims it could make.

Hodson sees "a little bit of nervousness" around this issue, with most of the responsibility resting with the manufacturer. Companies need to be very clear about the core functionality of their product, the data flow, how this is managed, what might constitute an update with potential impact on the core functionality and whether that affects the claims. If a company makes an explicitly medical claim for an SaMD, "it's still going to be a slower and more protracted process that requires robust demonstration of value and robust evidence," Hodson stresses.

"People want to know what the clinical efficacy is and how you are comparing it to current interventions," he adds. Where no such comparisons are available, companies have created "digital placebos" that mimic the effects of an SaMD product, but without the component designed to generate clinical outcomes, which is another area of complexity to navigate.

One more significant market-access challenge is how to achieve scale with SaMD. "Many companies are getting instances of reimbursement or local utilization," Hodson says. Translating that limited uptake into broad adoption is an essential component of the go-to-market strategy. This is where optionality is key. Partnerships with entities that can help to manage complexity, such as CRO/CSOs, industry consortia or medical device and pharmaceutical companies, may provide crucial leverage.

Data Management And Value Exchange

Positioning an SaMD product for sustained market impact is not just about functionality, scale and claims. The product also needs to be genuinely patient-centric and alert to the importance of user experience.

That might be the ability to use software at home or on the move, maintaining interest and adherence, maximizing patient interaction, creating opportunities for data integration, or ensuring the software is easily usable across different points of access (e.g., laptop, smartphone). Some companies are addressing these needs through engagement strategies more readily associated with the retail sector. "I think that patient-centric design and experience are absolutely critical for real-world use," Hodson comments.

For the patient and other stakeholders such as payers and health care professionals, the product should not only deal with a real-world problem but also provide sufficient incentive for regular use. In the initial phase, this might be structured as a direct-to-patient model with a focus on collecting evidence for reimbursement. Once coverage is established, payers and health care providers will want to be sure that usage is not going to tail off.

All of this calls for some form of value exchange between user and manufacturer. Data management is at the heart of this proposition. "Certain data collected will be very important to patients, and that will be part of an exchange of value that drives patient engagement," Hodson observes. It helps that at least some patients are eager to share their data. "They want to be part of the solution and to improve health care and outcomes, not only for themselves but also for others," Hodson adds.

Nonetheless, sensitivities around data security, integrity and access are an inevitable feature of the fast-expanding digital universe. For Hodson, the key is to gain trust early on and make sure patients understand precisely what their data will or will not be used for. Companies themselves must also be fully aware of the contexts in which explicit patient consent is needed.

Where it is required, SaMD platforms can draw on the already "very robust" mechanisms for obtaining patient consent in clinical trials, Hodson points out. Companies entering the SaMD arena may also think about following the lead of pharma in contracting out data collection, management and analysis to trusted expert intermediaries, while any insights gleaned from those data can be managed in-house.

Success Around The Corner

With the revenue-bearing market for SaMD still very much starting to bud, companies have plenty of opportunity to unlock value and carve out niches in the space. If anything, the differentiation challenges relate less to individual brands and more to the class as a whole, in particular how it can be distinguished from broader digital health offerings.

Although standardization will help to achieve that, there is "no one size fits all" for SaMD, Hodson emphasizes. Nonetheless, health-system engagement and "how you communicate your value stories" are crucial in laying the groundwork for commercial success. For Syneos Health, that success is already around the corner.

"We're starting to notice much interest from investors," Hodson comments. "We have mainstream companies entering the sector, to try and grow new capabilities or diversify. We have health-system confidence beginning to rise, and regulatory precedent set in the US. We have an increase in transactional activities. There's lots of traction, and we're really going to see the market explode over the coming years."

Reference

1 Statement from FDA commissioner Scott Gottlieb, MD, on advancing new digital health policies to encourage innovation, and bring efficiency and modernization to regulation. December 7, 2017. Retrieved from https://www.prnewswire.com/news-releases/statement-from-fda-commissioner-scott-gottlieb-md-on-advancing-new-digital-health-policies-to-encourage-innovation-bring-efficiency-and-modernization-to-regulation-300568421.html.

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