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Challenges and Opportunities in MedTech, Innovation and Digital Health

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A recent McDermott roundtable on European health private equity generated key insights into the future of medtech, digital health, and data analytics, and identi?ed opportunities for companies and investors.

Digital health solutions are widely considered to be the next big growth market. Healthcare lags signi?cantly behind other industries when it comes to digitization, but the potential opportunities are driving developers, healthcare providers, and investors to ?nd solutions.

PATIENT CARE

A key point to bear in mind about healthcare technology is that success and adoption may often be measured by the quality of the users' experience, the resulting clinical outcomes, short and long term cost savings, and the resulting margin for both investors and the health care system at large. These multi-faceted goals are best illustrated by the demands for i) greater efficiency, and ii) better patient outcomes.

Efficiency is typi?ed by, for example, streamlined bookings and appointment reminders, algorithms that triage patients to ensure they are seen by the right person at the right time, and in-home patient monitoring after patients are discharged. Patient take-up is also an excellent gauge of efficiency, for example, a high tech product that measures and reports blood sugar is of no value if the interface is too complicated for an older population.

Better outcomes result from clinicians gathering and using data to determine the right treatment in the fastest possible time, and are demonstrated, for example, by permanent lifestyle changes, improvements in self-care or care outside hospital,accurate drug dosage and use of medicines, and, in direct contrast with other sectors, reduced, rather than increased, service usage.

PRIVACY AND REGULATORY HURDLES

One of the most obvious challenges inherent in digital health is data privacy and security. Stemming

from that are issues relating to control of the data, the right to use it, and ownership of the analysis. The most successful companies are those that, from the very beginning, understand the regulatory landscape in which they are operating; are transparent in terms of where their data comes from; make clear the type of data at issue, be that identi?able, pseudonymized, anonymized, or something in between; and identify who will control what data in what form. The ability to marry up these factors is a key part of any new entrant's value proposition.

The most effective way to address the regulatory hurdle is for companies and innovators to work with stakeholders, both consumers and regulators, rather than waiting for them to drive new and unnecessarily burdensome rules reactively.

In the United Kingdom, these collaborations have been enhanced by national support through the NHSX, which is a recently formed program team supported by the Department of Health and Social Care, NHS England and NHS Digital. NHSX was created partly in recognition of the developing technology and policy framework. It aims to set standards, and drive policy and implementation collaboratively.

Whilst the ambitions of NHSX are yet to be recognized in practice, it is useful that a collaborative approach is being adopted at a national level, which may bring cohesion to what may sometimes be seen as a fragmented market.

SCALE AND PAYMENT

US market for healthcare is vast, and growing quickly since the FDA signaled greater ?exibility relative to certain digital technologies evaluated on a risk continuum. Although states may have slightly different regulations and insurers don't always agree on what costs they will reimburse, the differences are small enough that a healthcare provider can hope to see a return on new technology and tools rolled out across this US$25 billion market.

This is particularly true if the technology doesn't involve any risk of physical harm, and can ultimately be used to facilitate greater patient access to care, produce better data that naturally funnels through to physicians' work ?ow, and reduces cost, or some combination of these goals. Managing technological development and building a roll-out strategy that works across jurisdictions, even in the United States, can be difficult, but the barriers to doing so are beginning to break down in a positive way.

In Europe, the market is slightly different. Although all digital health tools that fall within the meaning of a "medical device" are regulated by European medical device regulation, there are markedly different approaches taken by different European countries, particularly in terms of rules governing doctors, remote care, and reimbursement.

In practice, this means that any developer or investor in digital health technologies must both understand the Europe-wide standards and be sensitive to the local regulation and market approach in each country.

Some developers have spotted opportunities in developing countries, where there is signi?cant demand for technology that enables deprived populations to have access to care. This is particularly relevant in countries where capital investment in bricks and mortar health services is difficult to obtain, but where population groups may already have good access to mobile phones and digital technology. These markets are typically less regulated and governments may encourage investments

more openly than in other highly regulated environments.

Whilst there are clearly bene?ts for developers in terms of achieving scale and testing digital services, some commentators have raised questions about whether the rights of data subjects and patients are protected in the same way as they would be in developed countries.

One of the most exciting and accessible markets in Europe is now Germany, which is following the lead of the United States in allowing more ?exibility for health app use. The Digitale-Versorgung-Gesetz (Digital Care Act), will allow health insurance funds to reimburse patients for health apps prescribed by their doctors. To be approved for prescription, the app will be tested for data security, data protection, and functionality by the German Federal Institute for Drugs and Medical Devices (BfArM).

COMMON GROUND

Although international markets may have slightly different regulatory approaches, there are common factors that indicate the likelihood of success, regardless of the country in which the technology is deployed. These common factors include:

- Value to patients: as with all technology, the success and take-up will depend on users intuitively understanding the value that the solution brings to their care.
- Technology that is genuinely complementary and understands the clinical experience and pathway: there is a ?ne balance between technology that is helpful (real-time diagnostic reports), and technology that just adds to the clinician’s burden (endless pop-ups).
- Sensitivity and understanding of regulatory and policy developments: users and health systems want con?dence that developers and investments have built their tools in ways that actively anticipate the law and regulation, and respect constraints around patient privacy.
- A good cultural ?t with the organisation adopting and using the technology.

There is also a growing question of the extent to which health systems that provide valuable data for the development of health technology should share in the ?nancial bene?ts of any successful product. ?is topic is discussed internationally but is particularly relevant where health data has been generated in a publicly or non-pro?t funded system.

A MATURING MARKET

Digital health tools are maturing to meet the efficiency and patient outcome needs of the sector, but more work is needed and the market is still wide open for the right players with the right approach. The most successful companies will be those who work with advisors who know their way around the sector’s global regulatory landscape, can identify solutions to the challenges presented by data, and are deeply familiar with the needs and priorities of the health sector’s major players across the world.