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Digital Health: Transformation and Innovation within the US

How MedTech and Big Tech are disrupting the status quo

A report by The Economist Intelligence Unit

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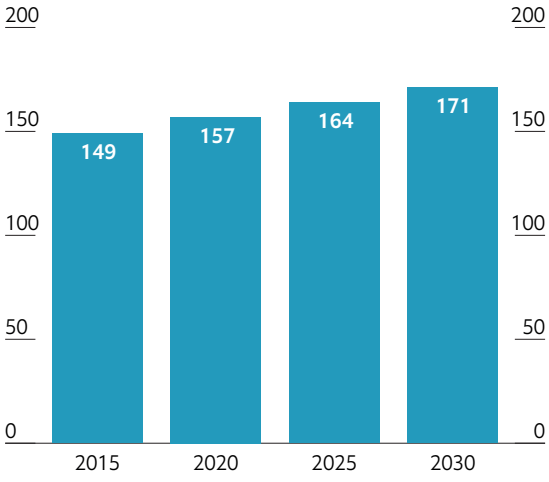
Introduction: Challenges within the US healthcare system and the need for disruptive innovation

A fundamental question surrounding the US healthcare system is "How do we improve overall health while reducing costs?" Health care spending in the US greatly exceeds that in other wealthy countries, but does not achieve better health outcomes. By 2030, an estimated 171m people in the US will suffer from a chronic disease.[1] This fact, coupled with an aging population in need of greater health services signals the need for change.

Figure 1: Leading chronic diseases in the US

Source: Centers for Disease Control and Prevention

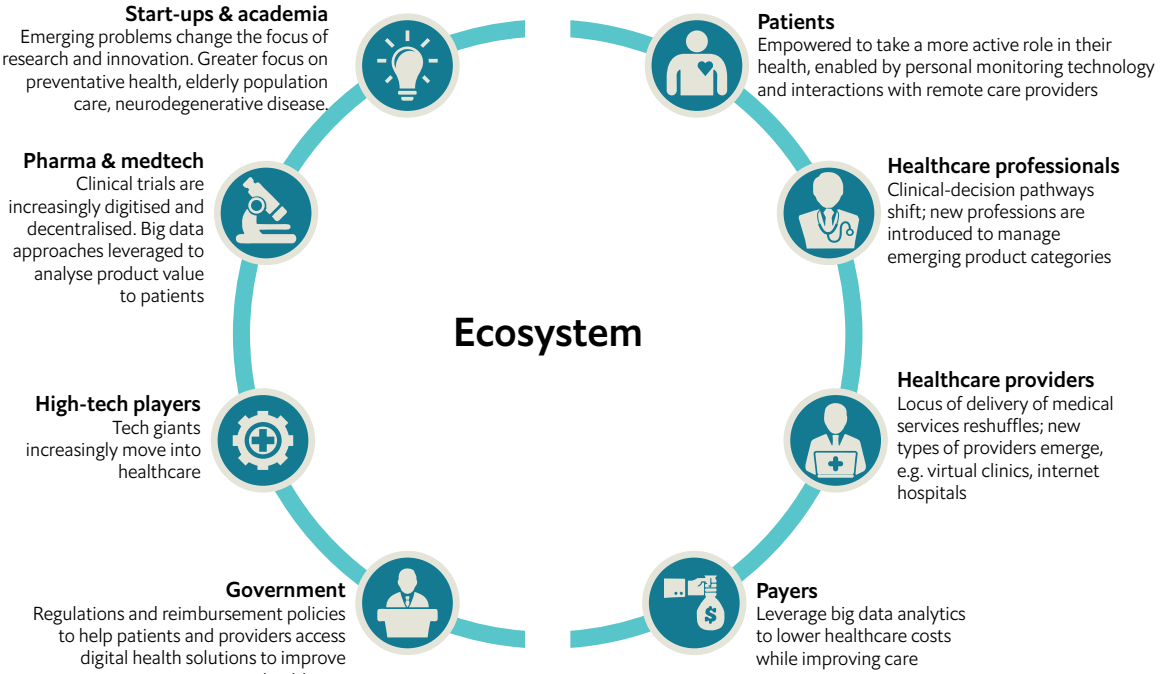
Figure 2: Growing number of people in the US with a chronic disease
(millions)



A promising response to this question has come in the form of the digital health transformation. The internet of things, artificial intelligence (AI), and wearable technology are a few examples of digital transformations that have great opportunities in healthcare, and they have already begun to disrupt the healthcare landscape. In addition to 'pure' medical innovators, big tech firms such as Google, Apple, and IBM are now lending their capabilities to the healthcare industry.

Digital innovation, though an overwhelming space and daunting to adopt, has the potential to drive significant positive changes through streamlined workflows, optimised systems, improved patient outcomes, reduced human error, increased transparency, and, of course, lowered costs. Medical technology (medtech) companies should be prepared with the knowledge of how digital transformation may impact their business environment and the understanding of how to successfully bring new innovations to the market.

Figure 3: Who is impacted: Stakeholders in healthcare innovation



Source: EIU Healthcare

Modes of digital disruption: The technologies reshaping healthcare

Companies are innovating through digital transformation. This section looks at how trending digital health technologies are impacting healthcare, and the outlook on the adoption of these technologies.

Medical Internet of Things (mIoT)

Applications to watch:

- Medical facility infrastructure and security
- Workflow tracking and optimisation
- Medication compliance tracking
- Data recording (EHRs)
- Chronic condition management

Impacted populations: Healthcare facilities and device manufacturers are already benefiting from the medical internet of things. Organisations can analyse processes at scale with mIoT to determine trends and improve efficiencies. Doctors are increasingly using mIoT to monitor patients with chronic diseases.

Adoption trends: In order for mass adoption to take place, the cost of sensors and other integral components of these technologies will need to decline further and become cost effective. The predictive analytics engines interpreting data collected by the mIoT will also need to improve, so that healthcare professionals can learn about issues and respond quickly.

AI

Applications to watch:

- Patient diagnosis based on pattern recognition from large databases (genomic and symptom information)
- Early prediction of conditions likely to develop
- Assistance in image analysis for scans and slides (e.g. X-ray interpretation for radiologists, slide interpretation for pathologists)

Impacted populations: AI stands to improve on how well physicians can predict health risk, come to diagnoses, and draw insights from large sets of data. Workflow optimisation centred around AI is already being used to reduce inefficiencies, and the technology's predictive power may be able to speed up R&D for medtech manufacturers. AI will be a key way to analyse the massive amounts of clinical data generated by increasing use of wearable sensors. This analysis will enable deeper understanding of patients' disease states, and support physician's decision-making process when providing care. Improved outcomes for patients and reduced costs for providers will be among the largest benefits of this technology.

Adoption trends: The application of AI is being rapidly adopted across major medical sectors including radiology, cardiology, oncology, and endocrinology. There are over a hundred companies that are applying AI technology to solve healthcare challenges. The majority of companies are startups, but larger players like Medtronic, IBM and Google are also investing heavily in the space. Among over 40 surveyed healthcare executives, AI applications in precision medicine was anticipated to have the strongest impact on the industry in coming years.[2]

Wearable technology/Remote patient monitoring

Applications to watch:

- Activity monitors for sports and fitness
- Heart rate and diabetes monitoring
- Neurological disease monitoring to conduct large studies and track disease progression
- Post-discharge patient monitoring for treatment response
- Chronic condition management
- Patient health risk assessment from activity and biometrics monitoring
- Ingestible sensors for biomarker tracking and smart drug delivery

Impacted populations: A component of the mIoT, wearable devices are capable of collecting and transmitting health data about the individuals wearing them. The growing elderly population will benefit heavily from this technology's adoption because physicians will be able to draw health insights from larger amounts of data than previously possible, and without the need for constant in-person visits. The same is true for people with chronic diseases. Their symptoms can vary immensely from day to day, making it difficult for doctors to make treatment decisions based off infrequent visits.

Adoption trends: Among healthcare leaders surveyed by the EIU in 2015, remote health monitoring devices were seen to be an inevitable next step in the evolution of care delivery. 50% saw wearable devices as a way to reduce the cost of care delivery, and another 50% of respondents saw a benefit in wearable devices giving patients the ability to participate proactively in their care.[3] One of the most widely adopted health monitoring wearables is the Apple Watch, which has been predicted to make up 50% of global smartwatch sales with 20 million sold in 2017.[4]

Telemedicine

Applications to watch:

- Medical specialties well-suited for telemedicine, e.g. radiology, psychiatry, dermatology, ophthalmology
- Follow-up doctor's visits
- Healthcare access for rural populations
- Remote chronic disease management
- Assisted living center support
- Preventative care support

Impacted populations: Widespread adoption of telemedicine will be especially impactful for those unable to easily access a medical centre. Major groups affected are those living in rural areas with a shortage of doctors, and the elderly who may be unable to travel for a clinician visit. The ease of visiting with a doctor via a phone or tablet may also lead to fewer appointments cancelled at the last minute.

Adoption trends: When surveyed, over 40 healthcare executives unanimously expect the use of telehealth to increase at their health facility over the 2019-2021 period.[5] The number of doctors who list telemedicine as a skill has grown from 15% to 25% from 2016 to 2019.[6]

Augmented reality (AR), virtual reality (VR) and mixed reality (MR)

Applications to watch:

- Medical practitioner training
- Remote surgery
- Diagnosis support
- Mental health support tools for patients
- 3D patient rendering for improved surgery planning

Impacted populations: VR and AR technologies will have the greatest impact on clinicians in the coming years. VR is already being used in some settings to train doctors by allowing them to practice operations in a realistic environment. AR gives doctors faster access to real-time information, aiding in diagnosis and treatment decisions. The technology can also be used to visualise patient organs and systems in 3D, a feature that will significantly improve the quality of surgery planning.

Adoption trends: AR devices are used by some healthcare organisations, though the technology is still in its early stages of adoption. One currently used device is produced by the company, AccuVein. The device visualises veins under a patient's skin and allows doctors to easily and quickly locate areas to draw blood from. Microsoft has also developed an AR system which allows doctors to render the organs and systems of their patients, reducing the need for highly invasive surgery in some cases. The system is currently being used to augment surgery training at Case Western Reserve University.

Several challenges lie ahead for digital technology driven medtech innovation.

- **Security**: As innovations in medtech generate greater amounts of patient data it will become increasingly important for companies to invest heavily in protecting said data. Digitised health records represent new targets for cyber-attacks, and many healthcare organisations use outdated hardware and software. Small medtech startups may not have the resources or expertise to adequately secure patient data, and there is a lack of proper cybersecurity education drawing attention to this issue.
- **Communication** between devices is a necessity for mIoT to function properly. There are two major challenges in achieving this.
  - Hardware – Connected devices need to be able to communicate with each other or a central data hub very quickly, and at varying distances, to be as useful as possible. Increased adoption of 5G networks may support this issue.
  - Software – For healthcare providers and device manufacturers to take full advantage of all the data that will be available, it will need to be possible to integrate data points coming from different sources. Proprietary devices and software kits will come from multiple manufacturers, which can result in compatibility issues. The resulting data silos restricts the ability of providers to analyse health data and draw insight.
- **Regulation** will need to adapt as quickly as new technology does, to ensure that innovative health services maintain quality and some level of standardisation. At the same time, the Food and Drug Administration (FDA) approval process is expensive and arduous, and many companies fail to gain approval.

  - The FDA is currently in the pilot stages of a Digital Health Precertification Program "to make sure that patients continue to have access to new treatments that meet [the FDA's] gold standard for safety and effectiveness."

- **Funding**: It has become increasingly difficult for small, innovative startups to procure early-stage funding. Venture capital (VC) firms prefer low-risk investments when it comes to the healthcare space, meaning that many choose to invest only after FDA approval has been secured. Because it costs US$75m on average to bring a premarket approval (PMA) product through clinical trials,[7] this represents a major issue for small medtech companies.

Access to innovation: Routes of alternative commercialisation

As demand grows and new technologies emerge, medtech companies are racing to commercialise new products. The challenge of funding these innovations has expanded and evolved. The traditional path for a medtech startup has been to raise funds from VC, develop their technology with this money, then either get acquired by a bigger player or raise additional VC financing to move through clinical trials and begin generating revenue. This is no longer possible in every case. According to analysis from EIU Healthcare, there was a 14% decrease in the number of investments VC made in medtech in the US from 2014 to 2018. Over the same time period there was a 37% decrease in the number of medtech acquisitions. Both VC investors and potential acquirers in the industry are becoming hesitant to take on risky investments that have not been clinically validated.

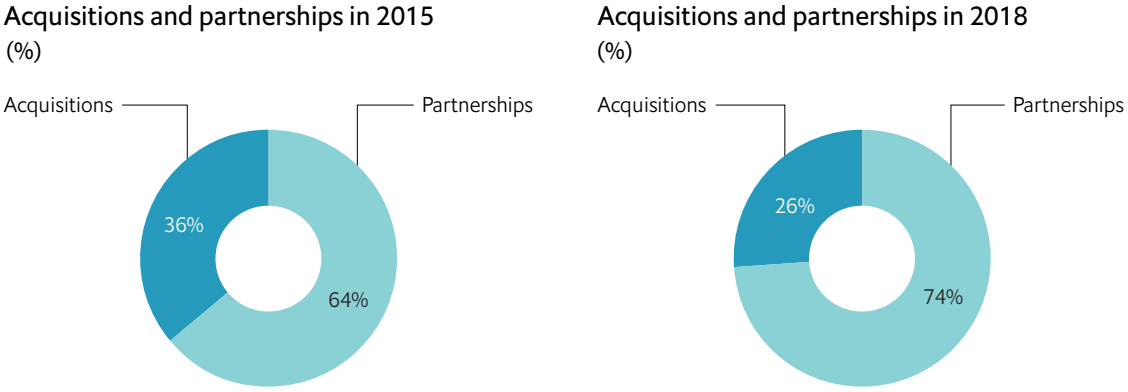
In response, companies have increasingly commercialised their technology through different means, and received support from established players. This section focuses on how medtech players big and small are adapting to secure investment and reach commercial success.

Strategic partnerships

As the number of acquisitions in medtech falls, the number of strategic partnerships being formed has increased.

As the number of acquisitions in medtech falls, the number of strategic partnerships being formed has increased. The ratio of partnerships to acquisitions announced in a given year by medtech companies has grown from 1.79 in 2015 to 2.78 in 2018,[8] a strong indication of their growing popularity.

Figure 4: Growing number of strategic partnerships in medtech

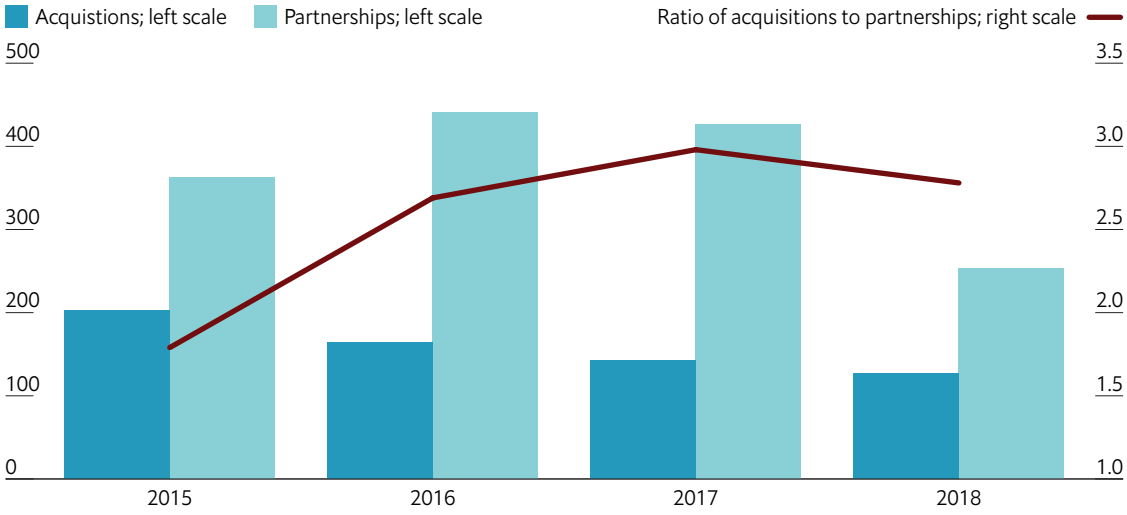


Sources: GlobalData, EIU Healthcare analysis .

A popular form of strategic partnerships among medtech companies is co-development. Small companies gain access to important capital and expertise by engaging in these deals, while established players foster the development of innovative technologies that may be acquired after further de-risking their offering. Through this partnership they are able to mitigate the financial risks of acquiring a pre-revenue company, which might not provide a return on investment depending on trial results. Co-development agreements made up 45% of all announced medtech partnerships in 2018, having grown from 34% in 2015.[9]

Co-marketing deals, joint ventures, and licensing agreements make up smaller portions of the total partnerships formed in medtech in recent years. Co-marketing agreements, in which companies jointly

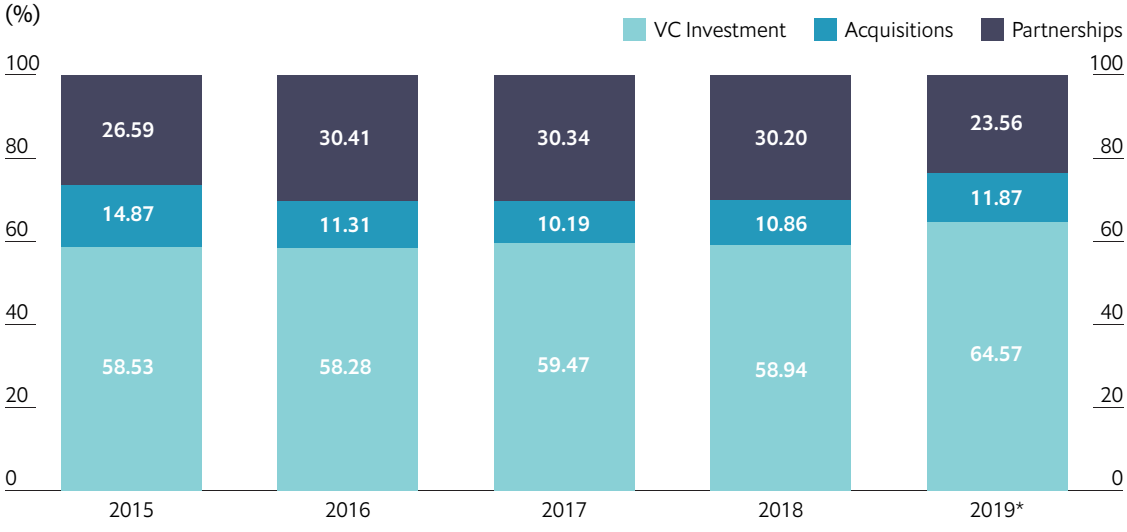
Figure 5: Acquisitions are becoming less attractive



Sources: GlobalData, EIU Healthcare analysis.

market each other's products, are useful for small companies in that they do not need to invest the capital in growing a mature salesforce. Large companies with co-marketing deals can leverage their large salesforces to test innovative solutions in the market, supplementing their product offerings and sharing in the profits. Joint ventures involve two or more parties forming a separate legal entity to undertake economic activity together. Though joint ventures are an opportunity to develop projects that require more resources from each company than a licensing deal might cover, they represent a declining percentage of the total partnerships being created in medtech. This is potentially because they offer many of the same benefits as co-development, while requiring greater investment from both parties.

Figure 6: Trends in deal types



* Year to date.
Sources: GlobalData, EIU Healthcare analysis.

An investment model commonly seen in biopharma is the "build-to-buy" agreement, where a large company invests in a smaller one with the option to make an acquisition at a later stage if certain development or regulatory milestones are met. The investment can come in the form of equity purchase by a corporate capital (CVC) division or through a co-development deal. Large biopharma companies may do this by investing in a portfolio of startups at once, leaving room for some of the projects to fail. This strategy may prove to be worthwhile for large medtech companies to implement as another opportunity to mitigate the risks involved in acquiring a company without a commercially validated product.

Alternative funding sources

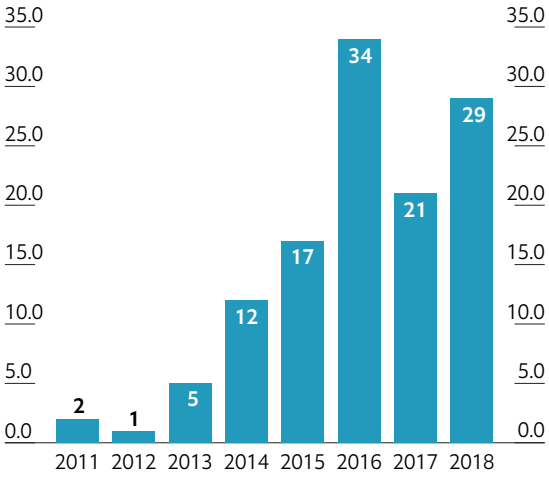
As useful as strategic partnerships may be, emerging companies must still reach a certain stage of maturity before being able to engage in them. Growing a team and developing an understanding of the commercial landscape takes time and capital, so it is very often necessary to take advantage of alternative funding sources.

Corporate venture capital groups are most commonly deployed to help other established companies achieve regulatory, reimbursement, and commercialisation goals. That being said, CVC groups at large medtech companies can make equity investments in pre-revenue companies, through a "build-to-buy" or other deal structure. Given a lower cost of capital and the ability to broadly diversify, CVC groups can typically shoulder riskier individual investments than VC firms in the same space. CVC groups represent a good way for large companies to make equity investments because a profit can be made off successful companies without needing to make a full acquisition in every case. It is also important to note that the CVC groups investing in medtech are not solely medtech companies. Consumer technology companies, health systems, and a health plan provider are among the top 15 CVC investors in digital health.[10]

Government programmes can serve as critical funding sources in the transition from the academic lab (or garage) to the realm of available institutional capital. An increasingly popular funding source for early-stage medtech is the Small Business Innovation Research, or SBIR, grant. Any federal agency with an extramural R&D budget of more than US$100m is required to allocate 3.2% of that budget to SBIR grants, the medically interested National Institute of Health (NIH) and National Science Foundation (NSF) included among those agencies. The number of SBIR grants awarded each year to digital medtech innovators has increased from 1 in 2012 to an average of 28 from 2016 to 2018.[11] These grants are popular because where venture capital firms or corporate investors look for low-risk, FDA approved investments, the agencies awarding grants look only for commercial and technical feasibility. This enables small companies to fund R&D in the early stages without giving up equity. The National Science Foundation has granted SBIRs to nearly 3,000 companies since 2012, 87 of which have had successful exits.[12]

In addition to federal grants, medtech innovators can look to state and local government programmes for assistance. The states of New York, Massachusetts, Texas, and others are investing heavily in fostering medtech innovation, because new companies in the space bring lucrative jobs and attract larger industry players to the area. The Massachusetts Life Sciences Center (MLSC) is one such economic development agency born out of a public-private partnership. The MLSC describes its purpose as accelerating "the commercialisation of promising treatments, therapies, and cures that will

Figure 7: SBIR grants awarded in digital medtech
(number)



Source: seedfund.nsf.gov.

improve patient care". Through 2017, the MLSC contributed more than US$650m to accelerators, tax incentive programmes, and loans to small businesses. At the city level, LifeSci NYC is a newer economic development initiative which began in 2017. The New York City government has developed a 10 point plan and invested $500 million under the LifeSci name, with the goal of attracting 16,000 new jobs in the industry. These programmes typically support life science innovation as a whole, but they are nonetheless critical opportunities for digital innovators in medtech to grow and connect with established members of the industry.

Some accelerators for medtech companies are state-funded, like the SUNY Downstate Biotechnology Incubator in Brooklyn, New York. Others, like the ATT&T Foundry in the Texas Medical Center, are run by corporate investors or health systems themselves. Companies must typically apply to be a part of these programmes and access the valuable funding, lab space, and networking opportunities they offer. By having access to industry veterans, medtech entrepreneurs in accelerators report being able to pressure-test their ideas and learn how to navigate the difficult regulatory process much faster than otherwise possible. All of these alternative avenues to funding and experience are becoming commonplace in medtech. A new ecosystem of collaboration between corporations, governments, startups, and end users is becoming better defined, and innovators will need to learn to navigate it in order to be successful.

Partnerships in practice: Big tech in healthcare

Amazon - Haven

Amazon is exceedingly good at standardising back-office processes and establishing itself as the leading platform in industries it targets. The company enters most markets with the same goals – facilitate transparent competition between offerings with the majority of said competitors outsourcing their processes to Amazon. The company's large e-commerce marketplace allows countless product manufacturers to reach new audiences, and Fulfillment By Amazon (FBA) allows them to send their products to Amazon warehouses. By doing this they avoid the extensive logistics necessary to manage inventories and shipping.

The healthcare industry in the US is full of process inefficiency and fragmentation issues, coupled with skyrocketing demand. All of this makes healthcare extremely attractive for Amazon, and the company has already begun making inroads. Amazon, JP Morgan, and Berkshire Hathaway announced a joint venture in 2018,

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now named Haven, which seeks to "create better outcomes, greater satisfaction, and lower costs" for the employees of the three companies. Based on the leadership team that Haven has hired, it has been speculated that Haven will build a curated clinical network. It will likely guide patients to providers which fit cost-effectiveness and care outcome criteria, while incentivising clinicians' participation in said platform. To create these incentives Amazon could improve the experience of participating physicians by standardising tedious digital processes, such as EMR documentation or insurance claims management. It could also offer a platform for providers to participate in bulk purchasing or supplies, or integrate the recently acquired PillPack for easy prescription handling. Haven is a not-for-profit, and considers one of the key issues in healthcare to be "profit-making incentives and constraints". If the venture is capable of operating with low margins or even at a loss for some time (which is likely given the success of its contributing companies), it stands to put immense pressure on established health systems.

Google Healthcare

Google's major strength is its ability to manage and draw insights from massive sets of data. In recent years the company has increasingly worked to present itself as a leader in AI and machine learning technology, as can be seen in its increasing mentions of the technology in its annual reports. Google's parent company, Alphabet Inc., has also been actively acquiring firms in the space, including a research firm called DeepMind in 2014 for US$500m. DeepMind's technologies have since been applied to predict protein folding more accurately than trained scientists, optimise cooling for Google's data centers, and consistently defeat professional players at a real-time strategy game called StarCraft II.

Google is now applying its proficiency with data to the healthcare industry. As patient data is generated from new sources every day, there is more to parse than ever, and interventions stand to become increasingly personalised and complex. Alphabet believes that it is up to the task of managing this, and in 2015 spun out a subsidiary named Verily to do it. Supported by DeepMind research, Verily is forming collaborations with established healthcare companies to develop sensors, interventions, and precision medicines in multiple disease areas, including diabetes, heart disease, and Parkinson's disease. For patients with diabetes, Verily is developing a disposable, continuous glucose monitor (CGM) the size of a penny in collaboration with Dexcom. By using AI to analyse the information generated by this monitor, Verily can detect small anomalies in disease progression and transmit important information to physicians.

To work along the full disease progression, Verily has also begun a joint venture with Sanofi called Onduo, which is creating an integrated type II diabetes management programme. Onduo's programme combines health coaching, various sensors, and AI data analysis to develop a personalised health support system, and began its commercial launch in early 2018.

Outside of Verily, Google is building a new data infrastructure for healthcare. The industry is shifting towards a new data standard called Faster Healthcare Interoperability Resources, or FHIR. By adopting FHIR standards, data from wearable sensors, doctor's notes, MRIs, and more can be used all at once to draw insights from. Google acquired the API management company Apigee in 2016 for US$625m, with the goal of building APIs that integrate FHIR health data from multiple sources to be used by developers (and DeepMind). An API (short for "Application Program Interface") is a standard way for programmers to work with code written by others. By applying its AI capabilities to multiple parts of the patient and provider journeys, Google is creating invaluable resources for the healthcare industry. If the patient-centred projects based on this novel approach are successful, it may be able to disrupt the fragmented industries concerned with disease detection, treatment, and management. If the new data infrastructure is as useful as Google believes, it will become an industry standard.

Apple Healthcare

There are more than 900 million iPhones in use around the world right now. Apple revealed as much during its 2019 Q1 earnings call, noting an increase of 75 million iPhones over the preceding 12 months. Roughly 100 million of these active iPhones are in the US, and this number is not likely to drop. In addition to selling hardware that many consumers love, Apple makes money by offering a suite of services, such as Apple Music, iCloud storage, and its App Store marketplace. The high level of interoperability between Apple's products - the ability to read text messages on an Apple Watch, for example - creates a tightly defined ecosystem for Apple users.

When the company introduces a new software offering to this ecosystem, it is placed in the hands of every iPhone owner. This is one of the key advantages that the company is leveraging as it enters the healthcare space. Apple launched ResearchKit in 2015, an open source software framework which allowed researchers to build applications for remote patient health studies. Anyone conducting a study can recruit candidates more easily than otherwise possible, and patients can sign up to participate in studies using their phones. Patients can also be easily recruited at high scale and across geographies, two consistent barriers to conducting population health studies. ResearchKit has been highly successful, with one heart health study recruiting more than 400,000 people in a year. The company will face competition as Google develops mobile health applications for the same purpose, but extensive adoption of either company's solution will set a new standard for the way clinical trials are conducted.

Following ResearchKit's performance, Apple released CareKit in 2016, which allows patients and provider organisations to develop apps that monitor patients in real-time using sensors in the Apple Watch, third-party bluetooth-enabled devices, and the iPhone itself. Patients can use these new additions to the Apple ecosystem to monitor their chronic conditions in real time and send information to their doctors without needing to go in for check-ups each time they have something to share. The Geisinger Health System in Danville, PA has adopted the CareKit for extensive use in its facilities, giving iPads to both patients and providers throughout the hospital. Care providers are able to quickly access patient records on iPads running the Canto app, and receive notifications about test results or adverse events on Apple watches. Patients are able to access their own records on the iPads they are given in bed, and children on their way to surgery can play games on the iPads to reduce stress. Both the patients and providers have reported feeling more in-touch with their data, and empowered to make decisions more quickly. Apple will likely attempt to repeat this model in other medical institutions around the country, and the success of the Geisinger Health System pilot indicates that this might work very well. By leveraging its strong brand and the extensive ecosystem which already exists for users, Apple has moved into healthcare more easily than others. Startups and more traditional medtech companies need to work hard for early adopters of their digital health solutions. Apple, by contrast, will find itself with a large user base on release day for each new offering, software and hardware alike.

Opportunities from innovation: Fuelled by competition

Although we are in the midst of a transformative time for healthcare, it remains a challenge for emerging and established medtech players to keep up with increased competition and innovation from big tech organisations. The overlap amongst the different modes of digital disruption signals the importance of integration-friendly solutions. As the industry shifts into a more patient-centric and patient-owned environment it will be increasingly important for suppliers, providers, payers, and patients to embrace an end-to-end digital mindset. Key questions to consider along the way are:

- As digital healthcare evolves, what innovations give medtech a lasting edge?
- Is your company focused on the core areas for value creation?
- How scalable is your innovation?
- What organisations should you partner with to access the technologies and talent required for business model transformation?

Emerging impact outside the US

It is important to mention this transformation extends to well beyond the US – not just in developed markets, but also emerging ones. This raises key questions for medtech MNCs, such as:

- Are your company's innovations aligned with the needs of emerging markets?
- How much adaptation of your product to address the pockets and preferences of emerging markets is needed to successfully enter and capture the market?
- What are the key drivers and barriers of adoption of innovations in emerging markets?
- What does competition from innovative local players look like?

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