How to develop and commercialise digital health solutions

Insights from our digital health leader survey

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Executive summary

After years of record investment and a major leap forward in digital healthcare sparked by the COVID-19 crisis, there are now some signs that enthusiasm for digital health is waning. This can be seen in tighter market conditions and falling adoption of telehealth. However, we believe that pessimism about the overall prospects for digital health would be premature. Behind the hype for telehealth, the pandemic has brought a fundamental change in both the technology infrastructure as well as the mindset of healthcare stakeholders. Both of these will enable the formation of true digital health ecosystems that bring value for patients and healthcare professionals and increase the efficiency of care workflows. To play a full part in the development of these ecosystems, pharma and MedTech leaders face the challenges of developing digital health solutions that meaningfully impact the lives of their users and then finding the right commercial approach that ensures adoption and sustainable business impact.

5 Strategy recommendations

Based on a survey of digital health professionals at leading companies, we derived five fundamental recommendations for digital health leaders developing their strategies as summarised below:

1 Solution development

Companies need to tackle the unmet needs of patients and go through the rigour of collecting evidence

Our survey records an increased focus on regulated solutions, with 65% of respondents saying they will concentrate on those in the future. In order to move rapidly along that path and create the solutions that will have the greatest impact, we recommend that companies involve regulatory teams at an early stage and take a strategic view of when best to involve the customer in solution development.

2 Commercial models

Reimbursement will become more important, but companies should not focus on one commercial model

Companies are increasingly building their business models around reimbursement, with 82% believing this will be the most promising source of revenue over the next 5-10 years. When designing a commercial model, we recommend pursuing a differentiated access strategy informed by a thorough understanding of the market and not focusing on only one business model.

3 Partnering

Connecting their solution to digital health ecosystems is essential but will require a robust data strategy

50% of survey respondents say they want to partner with providers and 48% with large tech companies in order to commercialise their digital health solutions. In order to forge strong partnerships, companies need to have a robust strategy for data and understand where to play in emerging digital health ecosystems.

4 Data

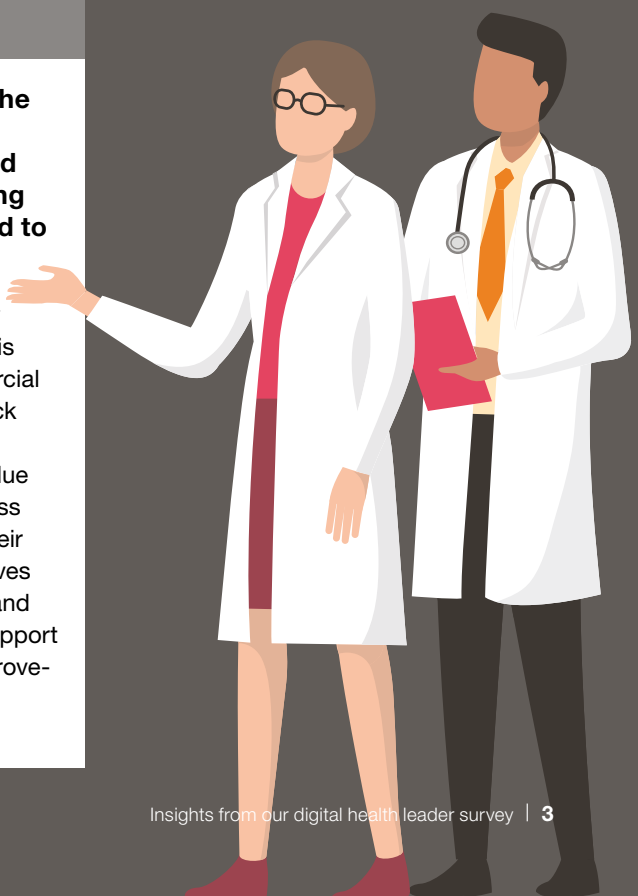
Companies are increasingly leveraging data from digital health solutions, but teams need to better demonstrate tangible use cases of how data is solving real problems

Only 41% of respondents say they use data to a significant extent. Teams often fail to convince their internal regulatory and cyber security colleagues that the value created with data outweighs the risk of collecting and owning it. As data becomes a key component of digital health success, companies should prepare their organisation for a data-driven future and strive to become a trusted steward of patients' data.

5 KPIs

Companies are seeing the importance of engagement KPIs, but they need to find ways of measuring outcomes that are linked to business objectives

While 80% of companies say that measuring engagement is their most important commercial KPI, fewer use metrics to track outcomes. However, the latter are critical for showing value to the organisation. To address this, companies should tie their solutions to business objectives and use KPIs for both short and long-term metrics that will support continuous iteration and improvement of their solution(s).



Introduction

After years of record funding, investors' enthusiasm for digital health solutions appears to be fading. In the first half of 2021, deal sizes decreased for the first time in many years.[1] Recently, many digital health start-ups have had to lay off a significant proportion of their workforce.[2] In the public market, digital health companies are underperforming other technology-driven indices such as the Nasdaq composite (see Figure 1). This is particularly the case for companies that focus on digital measurement, diagnostics and interventions.

However, we are convinced that this is a temporary headwind against what is set to be a longer-term and profound transformation. Likewise, we are equally confident that digital health solutions will play a substantial and critical role across the future healthcare system. Why?

In the public market, digital health companies are underperforming other technology-driven indices like the Nasdaq composite.

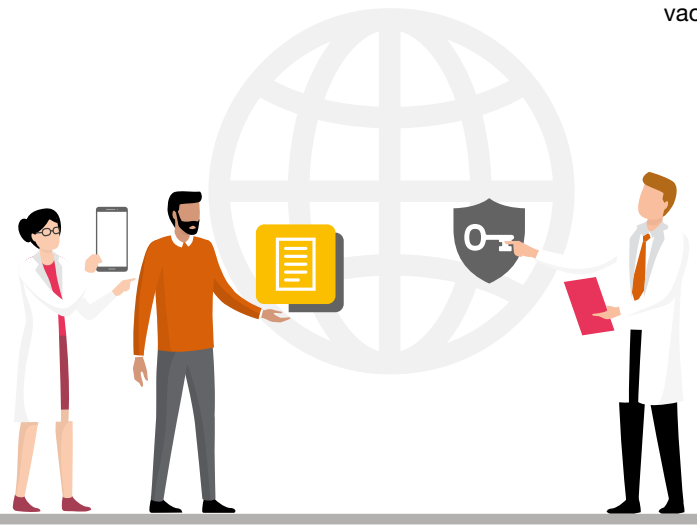
Four key reasons:

1) **Patients' needs and expectations:** Patients increasingly expect the same seamless experiences from their healthcare companies that they receive on a day-to-day basis as digital consumers. In addition, the evolution of advanced treatments such as personalised medicine relies on more patient data. A recent patient-centric analysis by PwC and Strategy& highlights how digital and data-driven technologies will be highly effective in addressing the changing needs, expectations and challenges that patients report.[3]

2) **The pipeline:** The number of clinical trials that include digital health solutions has been rising significantly.[4] These digitally enabled therapies and interventions will be available to patients in the coming years.

3) **The change in healthcare delivery:** Healthcare providers are transforming to become more connected networks, increase the efficiency of their workflows and implement value based and remote care models. This significant revenue shift towards new emerging models is underpinned by digital and analytics-driven offerings at the centre.[5]

4) **Early successes show value:** The influx of funding into this sector to date has created solutions that provide real value to patients and healthcare professionals (HCPs). An increasing body of evidence demonstrates both economic gains and patient benefits, including a reduced cost of monthly disease management[6] and improved outcomes for patients.[7] Companies on the other hand have demonstrated how digital solutions can improve their operations such as speeding up clinical trials for COVID vaccines.[8]



5 fundamental challenges of digital health leaders:

1. Which solutions should companies develop?
2. Which commercial models are sustainable?
3. Who should they partner with and how?
4. How should they leverage data from digital health solutions?
5. How can they learn fast to measure impact?

The recent headwind facing the sector makes it even more important for pharma and MedTech companies to prove that their solutions bring real value to patients, providers and other healthcare stakeholders. So, in order to understand which strategies companies pursue to ensure successful commercialisation of their digital health solutions and which challenges they face, we surveyed professionals across the leading pharmaceutical and medical device companies. In addition, we compared the views of those professionals with a selected group of digital health start-ups (Figure 2). From the outcome of this analysis and our interactions with digital health leaders we were able to derive five key takeaways, each of which addresses one fundamental question arising from the iterative processes of development and commercialisation (Figure 3).

Figure 1: Stock market performance of public companies in telehealth, digital measurement, intervention and diagnostics (21 companies) and broader digital health companies, including health IT, healthcare social networks (53 companies) compared to the S&P GLOBAL 1200 Health Care Index.[9] See Appendix for more details.

Stock market performance of **digital health** companies vs a leading **healthcare index benchmark**

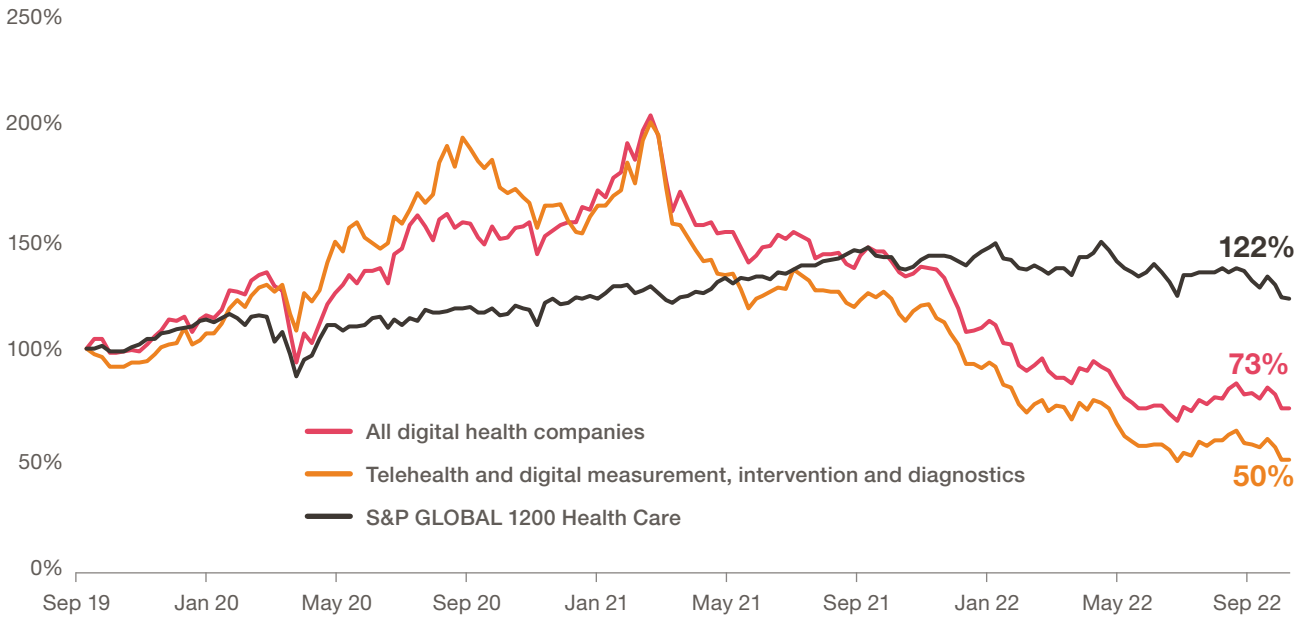


Figure 2: Surveyed digital health leaders across different company types

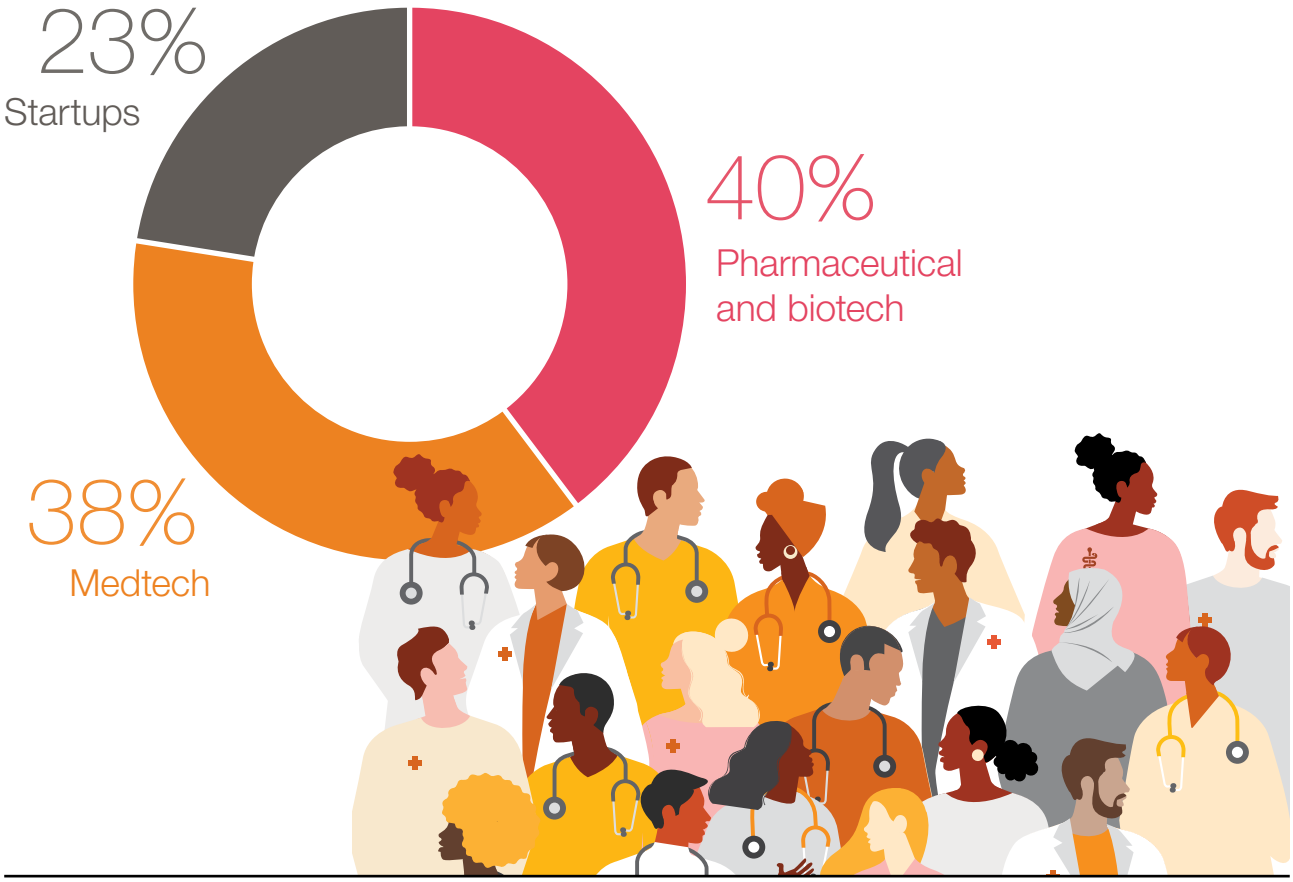
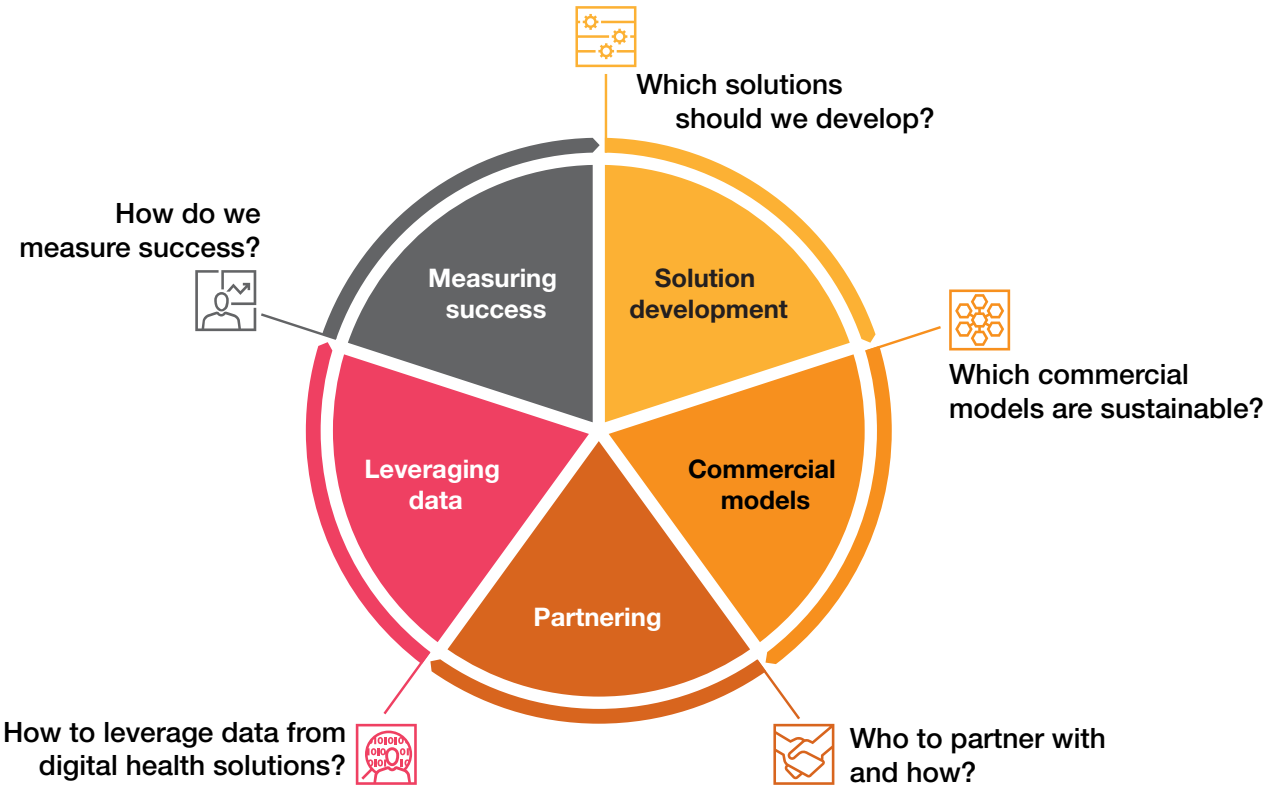


Figure 3: Key questions addressed



1 Which solutions to develop

The shift towards regulated digital health solutions

Companies develop digital health solutions to address the unmet needs of patients, healthcare professionals and/or other target users. Determining if these solutions will have regulated features is a vital stage of the development process. Our survey of digital health professionals from a diverse set of leading companies shows that the majority will shift their focus towards more regulated solutions in the near future (Figure 4).

This shift has significant implications for the development and commercialisation of new healthcare tools. Because regulated solutions claim to offer a medical benefit, they fall under the oversight of medical and public health agencies. These digital solutions, typically categorised as Software-as-a-Medical Device (SaMD) or Software-in-a-Medical-Device (SiMD), range from connected remote monitoring solutions to digital therapeutics. Regulated solutions must follow a more rigid development process, comply with more stringent documentation requirements and be able to prove their safety and efficacy. As a result, they tend to cost more to develop and take longer to bring to market than unregulated solutions.

Nevertheless, the shift towards regulated solutions follows a clear rationale and reflects a maturing market. Unregulated wellness solutions can help patients with education, adherence or connect them to their peers. However, they do not claim any significant improvement of medical outcomes. In contrast, by directly impacting the care pathway and providing previously unachievable insights, the next wave of digital health solutions aims to tackle areas of as yet unmet needs for patients and other stakeholders. Companies that want to effect real change need to be ready to collect evidence and potentially even undergo rigorous clinical trials to prove their devices are safe and effective and, most importantly, have a positive impact on health outcomes. The growing number of digital endpoints in conventional drug trials are also reflecting the opportunity of using validated digital health solutions to augment traditional diagnostic and treatment solutions.

65%

of companies will focus their digital health portfolio on more regulated solutions in the near future

To travel successfully along this path and develop regulated solutions that gain traction, **we recommend two key actions:**

Involve internal regulatory teams early:
During the development process, team members should understand the impact that intended features may have on regulatory classification. In-house regulatory teams can play a crucial role here. They can define a regulatory strategy that will serve as a roadmap for the coming years. In this context, we have seen successes with a staged approach, where companies launch their regulated product in multiple iterations. In some cases, companies start from a non-regulated solution that provides some value to patients and has a faster go-to-market. They then iterate that solution to become a fully-regulated SaMD. However, it is important that from the outset any solution is built in compliance with the documentation and quality management system (QMS) requirements for a regulated device. Having early engagement with regulatory experts can provide much-needed clarity about the impact on evidence requirements, time to market and regulatory scope. In Figure 5 we illustrate using a hypothetical example how features that address medication adherence can have different device classification (Figure 5).

Plan when to engage the customer:
It should always be the goal to co-create solutions with users and get feedback. Understanding the right time to engage the customer in the development process is critical for maximising the efficiency of the development while maintaining user-centricity. Solutions that are intended for widespread and well-researched disease areas such as Type II diabetes can rely heavily on secondary research and, in some cases, existing digital health solutions to understand the needs of a specific population. Desired end-users can be engaged in a more focused way and at a later stage for e.g. validation of a pilot or minimum viable product (MVP) solution.

Conversely, for rare and less well-understood disease areas, it is imperative to engage customers early in the development process to help shape and often co-create the solution. These stakeholders can include subject matter experts, patient advocacy groups and even primary caregivers depending on the disease in question and the targeted end-user of the solution.

Figure 4: Past and future strategic focus for developing digital health solutions

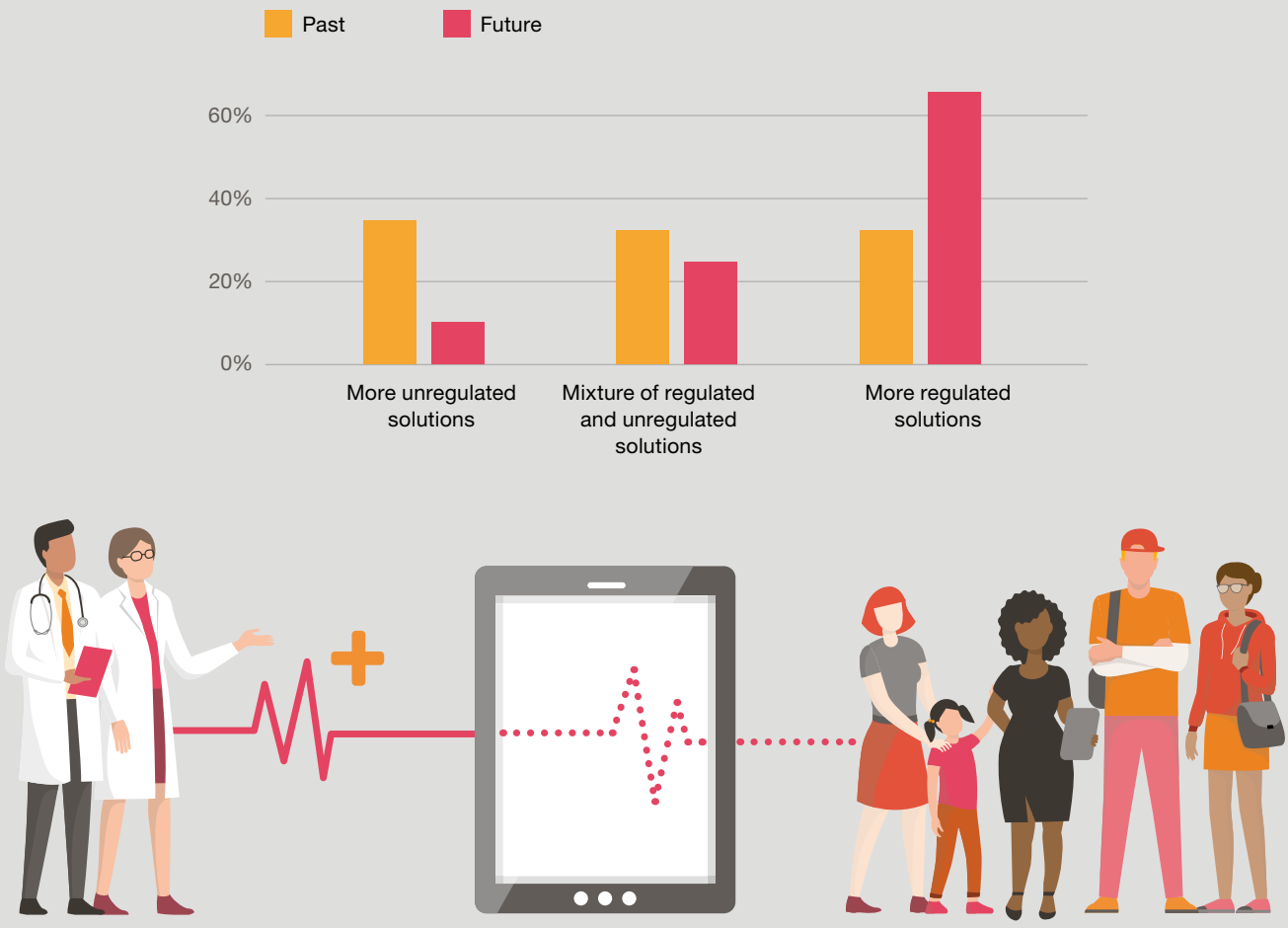
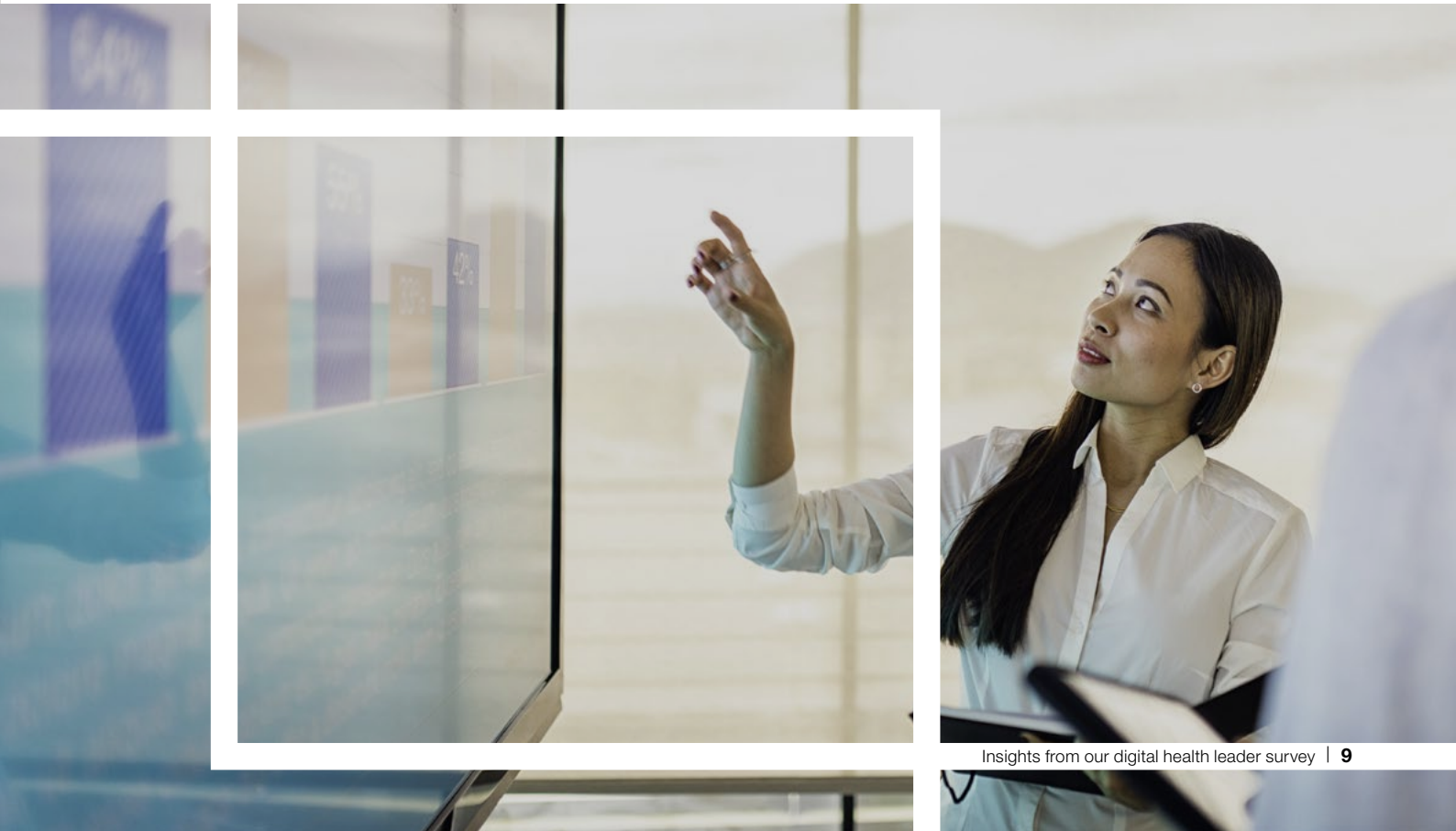


Figure 5: Illustrative example of how features that address an adherence problem impact a potential classification. As features become more invasive in the care pathways, the potential to create value increases. At the same time, the higher risk potential results in more stringent regulatory requirements. (Note: classification will always depend on medical claims and the intended use).

Example solution:	Self-set medication alarm	Automatic medication reminder with pre-determined medication dosing schedules	AI guided optimal medication recommendation to reduce side effects based on patient ePROs
Potential classification (not guiding): EU MDR*	Not regulated or potentially class I	Class I	Class II / III
Potential classification (not guiding): US FDA*	Not regulated or potentially under FDA enforcement discretion	Under FDA enforcement discretion	Class II / III
Rationale	May not be regulated, but if claims indicate patients can rely on app for self-management it may fall under FDA enforcement discretion	Likely to be low risk to patients if the condition is not critical and the app claims only to supplement and inform and not drive clinical management	Higher risk, especially if conditions are serious or critical; the solution appears to drive clinical management
Complexity	Low	Medium	High
Value potential	Low	Medium	High

* Potential classification depends on the individual solutions and related medical claims.



Case study

PwC recently worked with a global pharmaceutical company to improve the functionality and support with the regulatory submission and go-to-market approach for an AI-based decision support solution in oncology. Our approach included four steps.

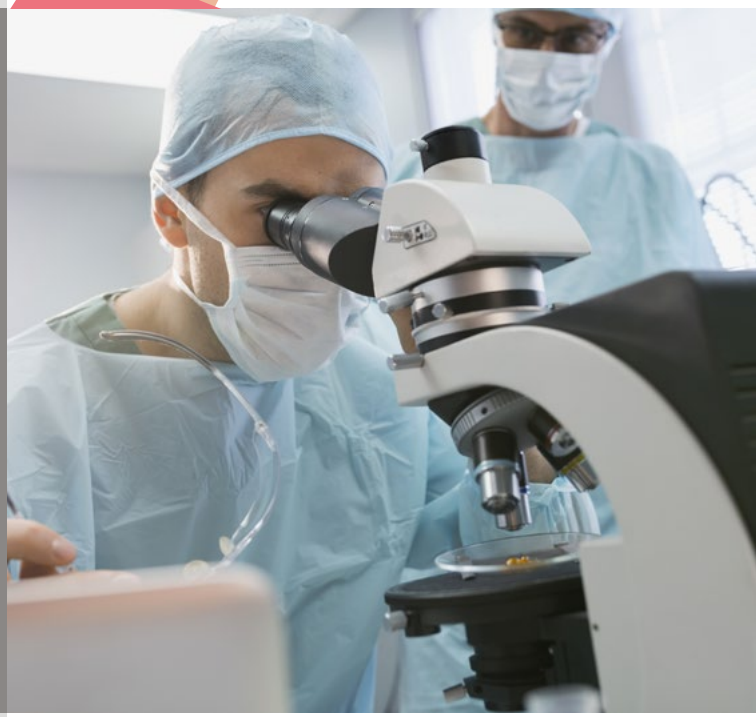
1. **Build a regulatory strategy:** Deep-dive into the regulatory requirements and analogues to develop a regulatory approach and an intended use statement.

2. **Get the voice of the customer:** Engage with a diverse set of customers including users, buyers and influencers to understand their needs and pain points.

3. **Develop the target product profile (TPP)** based on the voice of the customer analysis and regulatory strategy.

4. **Build a go-to-market roadmap:** Use our expertise and market understanding to develop a route to commercialisation for this new type of product.

A critical step in the process was to determine the key stakeholders to involve as the voice of the customer assessment. By engaging not only with the main users (radiologists) but also with Hema-oncologists, IT teams and procurement specialists, it was possible to map the needs and pain points across the key customers' workflows and build a consistent commercial strategy. Having a global PwC team with a diverse background and rich experiences in R&D, digital health and commercial strategy was critical in this project to work across silos and prepare the client for an international market entry.



2 How to build a sustainable business model

Payer reimbursement is seen as the most promising commercial model in the near future

A critical consideration for a digital health business model is to determine who will be the ultimate payer. Our survey shows that currently, most pharma and MedTech companies rely on internal sources of commercial value (see Table 1) where the solution helps to either increase revenues from traditional drug products or reduce internal costs. A typical example is when a digital solution helps to differentiate a traditional medical device or if the digital health solution helps to identify patients that may benefit from the company's drug treatment. In both examples, the digital solution generates commercial value by driving sales of traditional products.

In the future, however, we see a shift towards other sources of revenue. 82% of our survey respondents believe that reimbursement by payers will be promising or very promising in 5-10 years, making it one of the most attractive opportunities to generate commercial value (Figure 6). This optimism can be explained by **three main developments:**

- The shift towards regulated products with clinical evidence that demonstrates medical benefit to payers and providers.
- Regulatory changes that build a framework for the reimbursement of digital solutions. For example, the German DiGa law, now in its second year, has enabled more than 20 digital solutions to receive full coverage in Germany. Other European countries such as France and Belgium are pursuing similar measures. In addition, we see changes in reimbursement codes that allow physicians to cover the time they spend informing and applying digital health solutions.
- A growing number of successes using existing pathways: Regulators, payers and Health Technology Assessment (HTA) bodies are becoming more familiar with digital solutions and, as a result, opening up existing regulatory pathways. Examples include the decision to reimburse the remote monitoring and AI-driven alert solution Moovecare under the existing medical device pathway in France or the many successes with direct payer contracting, most notably in the US.

82%

of our survey respondents believe that reimbursement by payers will be promising or very promising in 5–10 years

Building a successful access strategy for reimbursement

Despite this promising outlook, it will remain difficult to build a sustainable commercial model based on reimbursement. First, a persistently fragmented reimbursement landscape across different countries makes it hard to achieve scale. Secondly, in addition to approvals, the price level of any reimbursed solution also needs to be negotiated. Experience from the German DiGa shows that negotiated prices can come in much lower than intended by manufacturers.[10] And, finally, reimbursement does not equal use. In Germany, relatively few physicians are prescribing DiGa solutions. Even once a digital treatment has been prescribed, it does not necessarily follow that patients will adopt it. The approximately 50% fulfilment rate of scripts for Pear Therapeutics's DTx addressing substance abuse shows how challenging it can be to ensure activation, even if HCPs prescribe the solution.[11]

In Germany, relatively few physicians are prescribing DiGa solutions thus far. Even once a digital treatment has been prescribed, it does not necessarily follow that patients will adopt it.

For companies that decide to fund their solution through payer reimbursement, we have **three recommendations** to inform their access strategy:

Understand the landscape and stakeholder needs:
It's critical to take into account different markets' level of maturity, trends as well as regulatory and HTA needs. For example, the US, Germany and the UK are more mature in terms of market access and have an attractive market size, while the Nordics have a high rate of digital literacy that favours adoption. Once priority markets are selected, it is important to engage with both payers and providers to understand what they need in terms of evidence and interoperability. Even if they do not pay, providers often want to see both economic and scientific evidence such as comparator studies to see how solutions impact their budgets and patients respectively.

Differentiate the offering:
Commercial models should be adapted in response to stakeholder input. For example, national payers are likely to opt for a flat rate to better predict and manage annual spending, while large private insurers' and risk-bearing Integrated delivery networks (IDN's) focus on healthcare provision and risks/outcomes management means they are more likely to be open to a value-based approach.

Build the market with prescribers:
It is crucial to ensure that prescribers are aware of the solution and its benefits. Selling to HCPs is traditionally supported by an extensive and well-resourced sales force. If these capabilities or relationships do not exist in the target market, it might be necessary to partner with others – e.g. a pharma or MedTech company or a software solutions supplier such as an Electronic health records (EHR) – in order to provide them.

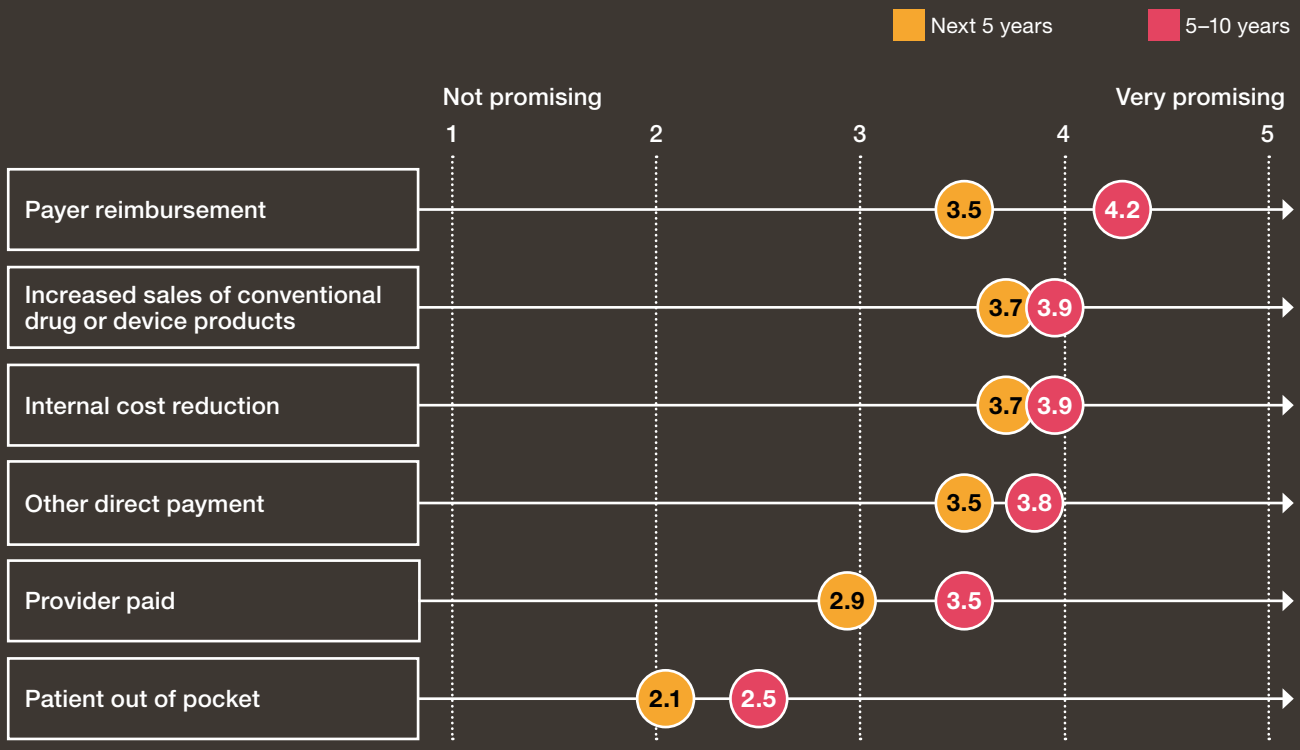
Think beyond a single model

It's important not to restrict the focus to one future commercial model. That's why we strongly advise our clients to work with scenarios rather than focusing on just a single revenue stream. The survey reflects this view, too. The respondents see several options becoming more promising in the future. For pharma and MedTech companies, linking a solution to a conventional product will remain a key source of revenue. This will be particularly attractive if they can tie a medical outcome to the combined product. The opportunity to co-label a digital solution with a drug has the potential to drive outcomes for patients and deliver higher value to the companies that are willing to go through the risk and combined effort of clinical development of such a combined approach. Another key growth area we see in the survey is in solutions that address provider challenges. More and more budgets at healthcare organisations are being opened up that address their workflow inefficiencies and help to coordinate care.

Table 1: Sources of commercial revenue from digital health solutions

Patient out of pocket	Patient pays a service fee or one time fee for the device	Mymee is an out-of-pocket solution for identifying environmental and dietary triggers for diagnosed autoimmune diseases. Patients pay per session.
Payer reimbursement	Selective: Contracts with individual payer groups (e.g. private health insurance, self-insured employers)	Livongo provides smart devices and support for patients with metabolic and cardiac diseases that are covered through specific private or employee-sponsored insurance partnership schemes.
	In-patient: Hospitals pay out of own budget for product or service	Tools like Jasper, a cancer care concierge service, are helping specialist treatment centres to differentiate their services and in return for a service or subscription fee.
Provider paid	Out-patient: HCPs or HCP networks buy product or service	Companies like Babylon Health and Klara provide primary care support and engagement directly with patients through digital solutions. These are delivered through service-based contracts with providers.
Other direct payment	B2B contracts with pharmaceutical companies, laboratories, CROs (often licensing contract or service fee)	Smart Patients and Sidekick health are examples of agnostic platforms with disease-specific education and adherence support, sponsored by pharma companies for their patients.
Internal commercial benefit	Increased sales of conventional assets, examples: • Differentiate assets with comparison products or functionalities • Collecting consumer data to improve product development and marketing activities	Smart pens for diabetes offer patients a simplified delivery method while also differentiating the product from its competitors, adding value to the patient and increasing sales.
	Cost reduction: • Reduce cost of clinical trial recruitment • Optimise internal workflows	Companies such as AbbVie, Novartis, Pfizer have partnered with a non-profit Digital Medicine Society to develop digital biomarkers e.g. for Alzheimer and Nocturnal Scratch for faster drug development and approval.

Figure 6: How respondents rate different opportunities to generate commercial revenue from their digital health solutions in the next 5 years and in 5-10 years.



3 Who to partner with and how

Partner for success

Companies also need to build a consistent partnering strategy that connects them to a digital health ecosystem and helps them to ensure a consistent experience across care delivery. As they seek to commercialise solutions, companies should think about **partnership drivers in four areas:**

- **Interoperability:** Interoperability between solutions (e.g. via APIs) and unified interfaces can complement solutions and drive a better experience for users (patients and HCPs).
- **Market reach:** Partners can provide access to a customer base. This can be the traditional healthcare customer (e.g. patients, HCPs) or non-traditional customers (e.g. wellness and fitness).
- **Acquire capabilities:** Partnering with companies for a go-to-market can bring a range of complementary expertise to the table, such as the ability to commercialise a digital asset or to bundle services with the solution in order to enhance the overall offering.
- **Enrich data:** Partners' data can enrich a company's own data sets to increase their value.

As they develop a partnering strategy, companies can map the different types of partners to the four categories above in order to understand the opportunity space (Figure 7). Our survey reveals that pharma and MedTech leaders see large provider networks and tech companies as the most promising partners to augment their commercialisation efforts (Figure 3). Provider networks are not only a key partner to unlock access to customers, but they may also provide the means to enrich existing data with valuable outcome data and offer a route to direct feedback from key user groups. Tech companies, on the other hand, offer access to consumers, strong technology capabilities and, most notably, help to build a seamless consumer experience.

Partnerships are only as strong as the foundations on which they are built. That includes a shared vision and expectations, transparency, legal and regulatory alignment and compliance. We believe that there are **two key considerations** that companies should bear in mind as they develop a partnering strategy:

Understand how to connect to the ecosystem:
Standalone solutions will find it difficult to drive adoption. We advise our clients to analyse the existing ecosystem of solutions they wish to move into in order to understand what role they want to play and who they need to connect with. In a recent article, we highlighted how the maturity of **digital health ecosystems** differs for various therapeutic areas. In less mature ecosystems companies often have more opportunity to shape the ecosystems, while in more advanced ecosystems they may have a lower degree of freedom.

Have a data partnering strategy:
Partners need to clarify the data roles of each company in the partnership, a process that often takes longer than anticipated. Key questions include:

- Who will act as Controller and Processor?
- Where data will be stored (physical location can have an impact on which laws are applicable)?
- Is one party gaining a controlling interest in the data?
- Does data sharing render any of the partners subject to other laws and regulation (here, for example, the new European Health Data Space needs to be closely watched, as it affects companies claiming interoperability with EHRs)?
- How data is shared between partners?
- How data is handled if the partnership ends?

Potentially technical solutions such as blockchain, homomorphic encryption and federated learning can limit data sharing and/or mask personal patient data wherever possible. For example, Roche and NHS Wales use blockchain technology to protect patient data collected for their innovative value-based contracting agreement.[12]

An example that highlights the challenges of sharing data in a partnership is when the NHS's data-sharing agreement with Google's DeepMind created a backlash after it was found to have no legal basis. The partnership was terminated in 2021 and Google deleted all related data.[13]

Figure 7: Most promising partners to commercialise digital health solutions (up to 3 answers were possible)

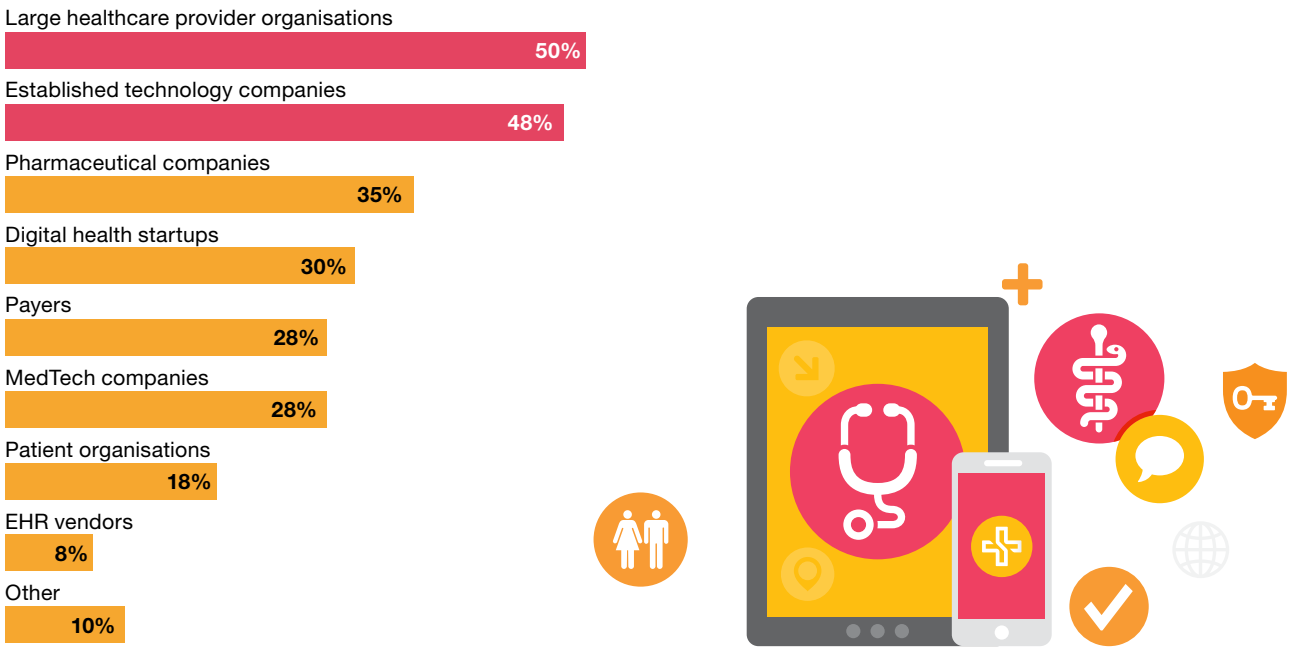


Figure 8: Illustrative example of the level of potential partners bring to commercialise a digital health solution from a pharma perspective

	Interoperability		Capabilities		Market reach		Data	
	Systems interoperability	Device interoperability	Healthcare	UX & Technology	Healthcare market	Consumer market	Healthcare data	Consumer data
Provider								
Tech companies								
Startups								
Payers								
MedTech								
Patient associations								
EHR vendor								

Strong | Medium | Case by case | Low

4 How to leverage data from digital health solutions

Turning healthcare data into value

Better health data is essential for driving future innovation, and digital health solutions are a promising source of precisely that data. However, in our survey we see that only 41% of companies say they are using data to a significant extent. This is reflected in the fact that many companies are struggling to turn data into actionable outcomes. Having a clear vision for how data will be used and turned into value and outcomes is essential for companies to ensure they collect the right data in the right quality and in a compliant and transparent way.

Only 41%
of companies say they are using data to a significant extent

At the moment, the majority of respondents are using data, at least to a moderate extent, to improve their own products (Figure 9). Our recent industry analysis of 45 leading digital health companies revealed that this use ranges from basic improvements such as personalising user interfaces to treatment alerts and recommendations. Using their proprietary data for their own projects or pipeline is often more straightforward for companies since the data remains inside the organisation.

The increasing importance of Real-World Evidence (RWE) and the challenge of selling data

Over half (62%) of respondents plan to leverage their digital health solutions to generate real-world evidence (RWE) for reimbursement and regulatory decisions. This highlights a clear expectation that RWE will become increasingly important for payers, regulators and HTA bodies in making their assessments. The US healthcare agency the FDA has already accepted data from mobile devices for their pre and post market decisions, such as for example the De Novo classification of a contraceptive solution.[14] However, our analysis shows that these examples are still rare. An important application for RWE is expected in the move towards outcome or value-based payment models. These require manufacturers to come up with data sources to measure the agreed outcomes.[15] Pharma and Medtech companies who can leverage digital health solutions to gather this kind of data will have a competitive edge in upcoming negotiations.

In contrast, a majority of companies remain reluctant to directly sell data to third parties. Patient data is highly sensitive and its use brings added complexity through the requirement to obtain patient consent and compliance with local regulations (for example GDPR). Most often, the risks involved far outweigh the proposed business case of selling this data.

Independently, if data is being used internally or externally, we recommend **three best practices for leveraging data from digital health solutions.**

Build a case that solves a problem with data:
This sounds obvious, but many product teams have no clear case on how the data collected from digital health solutions solves an important problem. As a result, they often fail to convince their internal regulatory, legal and cyber security teams why the company should take on the risk of collecting the patient data. Also, a clear purpose helps to identify the data quality and how data needs to be enriched in order to make it a valuable asset.

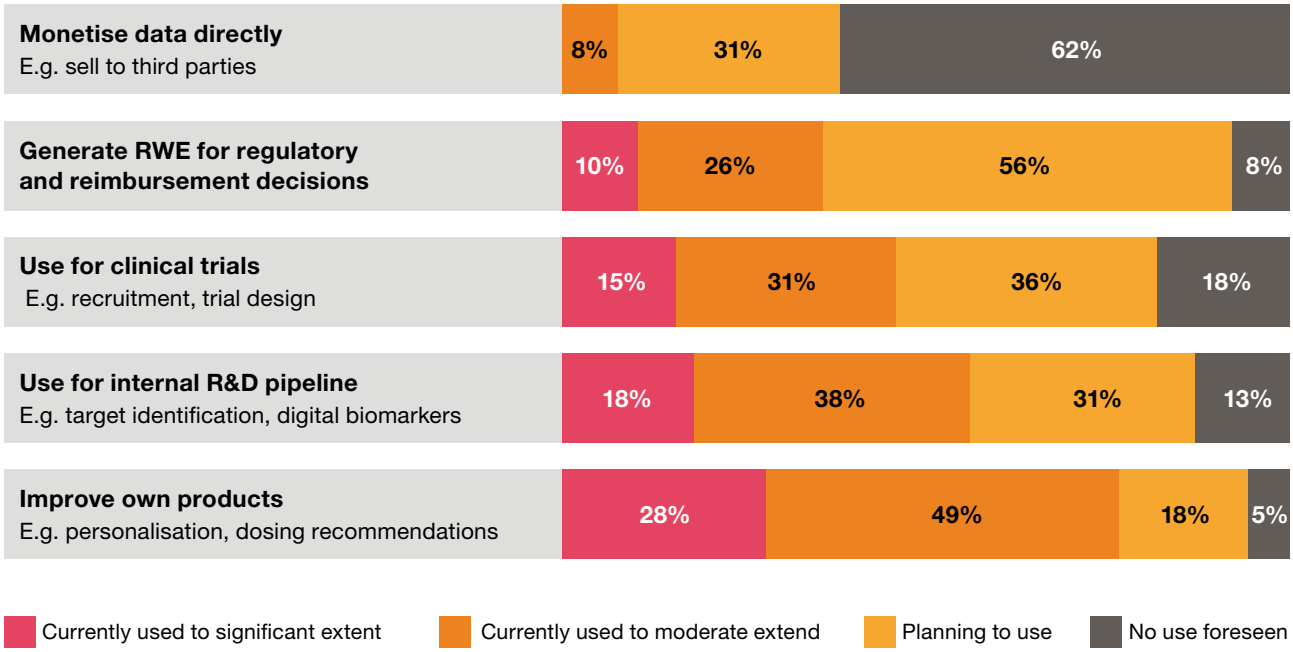
Put trust at the centre:
Health data is one of the most sensitive forms of personal information, and patients trust organisations to treat it as such. It is essential, therefore, that organisations understand and remain compliant with data privacy (e.g. GDPR, HIPAA, California Consumer Privacy Act) and data security regulations (e.g. FISMA). Beyond that, companies also need to ensure their partners are not a potential weak link (for example, connected devices are increasingly becoming an entry point for data breaches[16]) so requiring certifications such as the ISO/IEC 27000 series for information security management should be the norm for any agreement.

Set the organisation up for it:
Companies need to embed data into their operating model. This requires them to address a number of key steps:

- Establish a single source of truth and leverage a cloud-based infrastructure where possible
- Adopt business processes for a scalable "data analytics use case factory"
- Set up the corresponding global and local governance process
- Cultivate the right data citizenship mindset and culture
- Train their talent and empower them to take data-based decisions.

A recent **white paper** by PwC Switzerland outlines the importance of seeing data and analytics through an organisational lens, and sets out six building blocks to lay the foundation of a data and analytics operating model.

Figure 9: How companies are using or planning to use data generated from their digital health solutions



5 How to learn fast to measure impact

Measuring impact

"Measure, learn, improve" is the mantra for developing digital health solutions. However, companies often find it hard to define what to measure and what good looks like. Outcomes for patients and stakeholders should be a central measure for all digital health solutions. These types of KPIs are part of the evidence that is gathered for payers and regulators. Companies also need to establish ways of measuring the impact a solution has on their business. The majority of respondents believe that usage and engagement metrics are key to measuring success of their solutions (Figure 10). These metrics are important for learning and improving but they typically fall short of measuring the value to the business. 67% of digital health start-ups that completed the survey aim to measure financial KPIs that are directly related to their digital health solutions. This may not be possible if the digital health solution does not (yet) generate revenue directly. However, we argue that even in those cases, teams have to find relevant measurable outcomes which they can share with leadership in their annual budgeting cycle. In fact, our survey shows that the biggest internal challenge for pharma businesses is to demonstrate the value of a digital solution to internal stakeholders.

Starting to measure outcomes

The framework in Figure 11 (below) illustrates how different KPI categories tie into outcome measures that track the impact of digital health solutions. It is important to note that these do not necessarily need to be financial measures. However, it is essential that the outcome KPIs address a need of the organisation and are thus relevant to the leadership. Tracking the contribution made towards the ESG goals of a company can be a powerful opportunity to demonstrate the impact of digital health solutions. For example, tracking the inclusion of specific underrepresented communities in the treated patient groups can be a KPI to measure the contribution to a company's goal to promote health equity.

What does good look like?

With little historical experience to draw on and many variables to consider, defining realistic targets for KPIs is far from straightforward. Our recommended approach is to define both longer-term business objectives and shorter-term KPIs and to continue to iterate and improve them based on user feedback and learning as companies progress towards their business goals.

Define the bigger-picture business objectives:
Companies need to understand what role a digital health solution will play in their business. These objectives include increasing adherence for a newly-launched therapy, accessing usage data for the next generation of drug or devices, differentiating between products coming off-patent, improving brand perception among a target patient cohort or improving access to their device or drug for underrepresented communities. To define what *good* looks. A more pragmatic approach can be comparing the digital solution to other ways of achieving the business objective. For example, data can be purchased from vendors or adherence can be increased with a classical patient support programme. However, such a comparison must also take into account non-financial benefits, such as the acquisition of skills or platform synergies, if they are relevant to the long-term strategy.

Iterate and improve regularly:
Short-term KPIs can easily capture quantifiable metrics like downloads, engagement, improved adherence (anecdotal) or consistency with dosage timing. These can provide moment-in-time snapshots of how the digital health solution is performing. We recommend combining this quantitative data with qualitative data that assesses the features and functionality of the solution. This helps to identify where the highest impact for users is created. A possible setting to test new features can be a focus group or a pilot hospital. This combined approach allows companies to reach less tangible interim KPIs. If selected correctly, these interim KPIs will be a leading indicator for tangible outcomes such as better health outcomes for patients or lower cost of customer acquisition for the business respectively.

The objective should always be to maintain the focus on the desired longer term outcomes while using an iterative approach based on measurable data to work towards that goal.

Figure 10: Share of respondents who selected a commercial KPI type as most relevant (two answers possible)

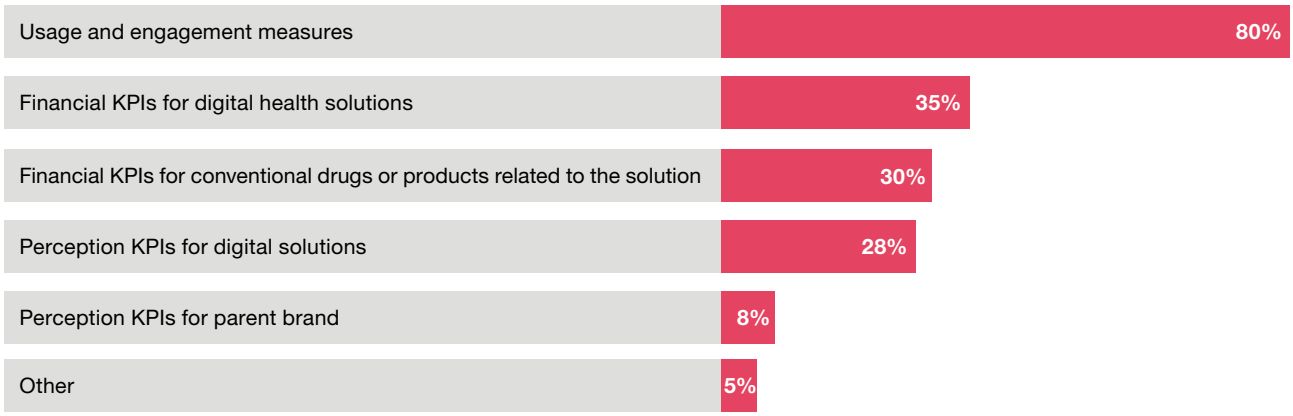
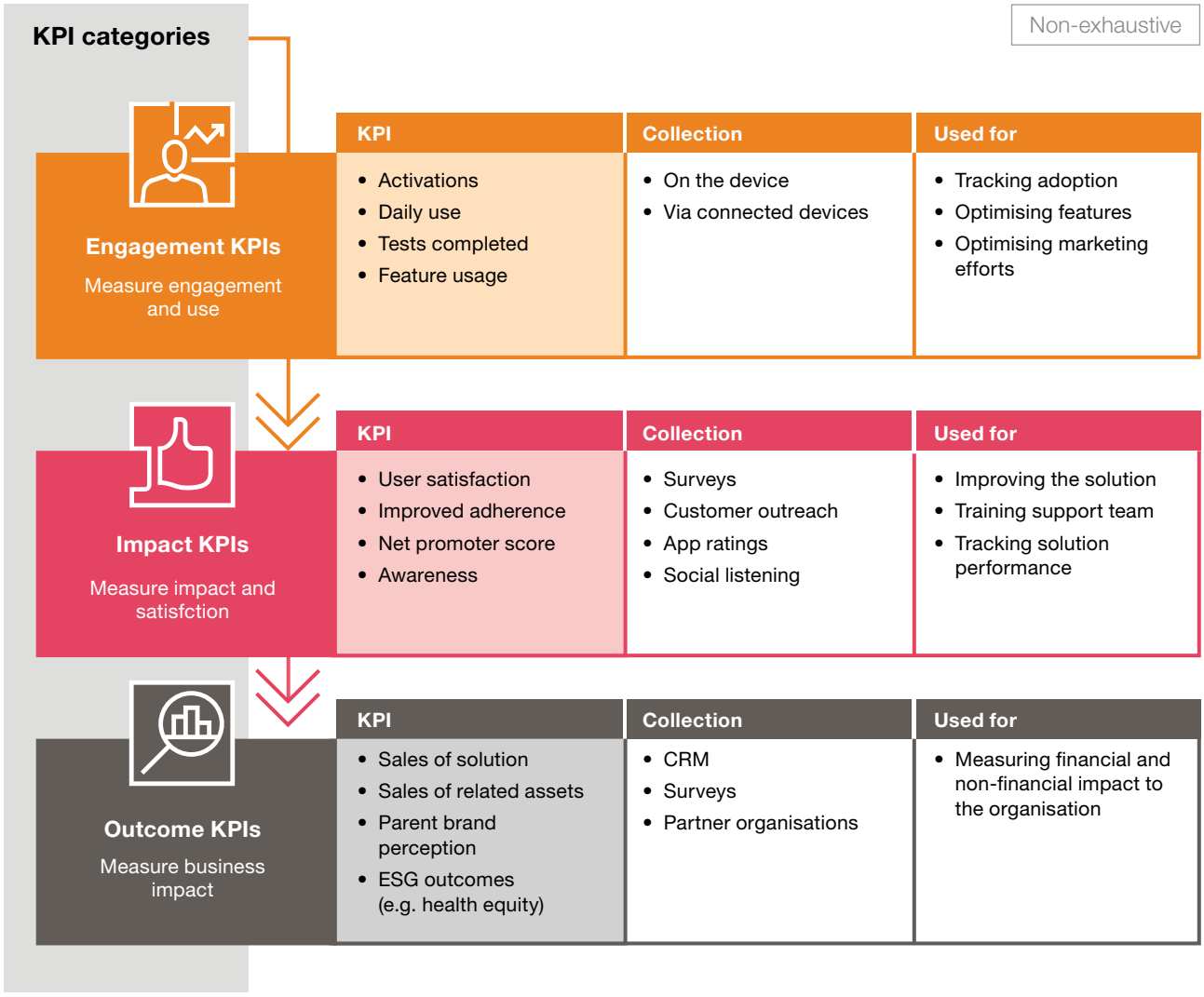


Figure 11: Framework to help with the selection of commercial KPI classes, starting from leading KPIs that measure engagement and satisfaction to give an early indication of success to outcome KPIs that measure the impact on the business. Outcome KPIs tend to be more lagging. Note: In addition to such commercial KPIs, there need to be patient outcome measures or outcome measures related to other users. These often form part of the medical evidence strategy.



Building an integrated digital health strategy

Digital health leaders that bring their solutions to market will likely face one or more of the questions that we address in this paper. As they work through these questions, they can learn from their peers who contributed to our survey. Here again are the five main takeaways from our engagement with those companies:

Companies are willing to undergo the rigours required to develop regulated solutions. The key to being successful here is to find ways to develop solutions rapidly and to ensure that they are built around clearly identified patient needs.

Companies are optimistic that sustainable commercial revenue streams will open up. While reimbursement seems the most promising avenue, companies should be careful not to focus on only one business model.

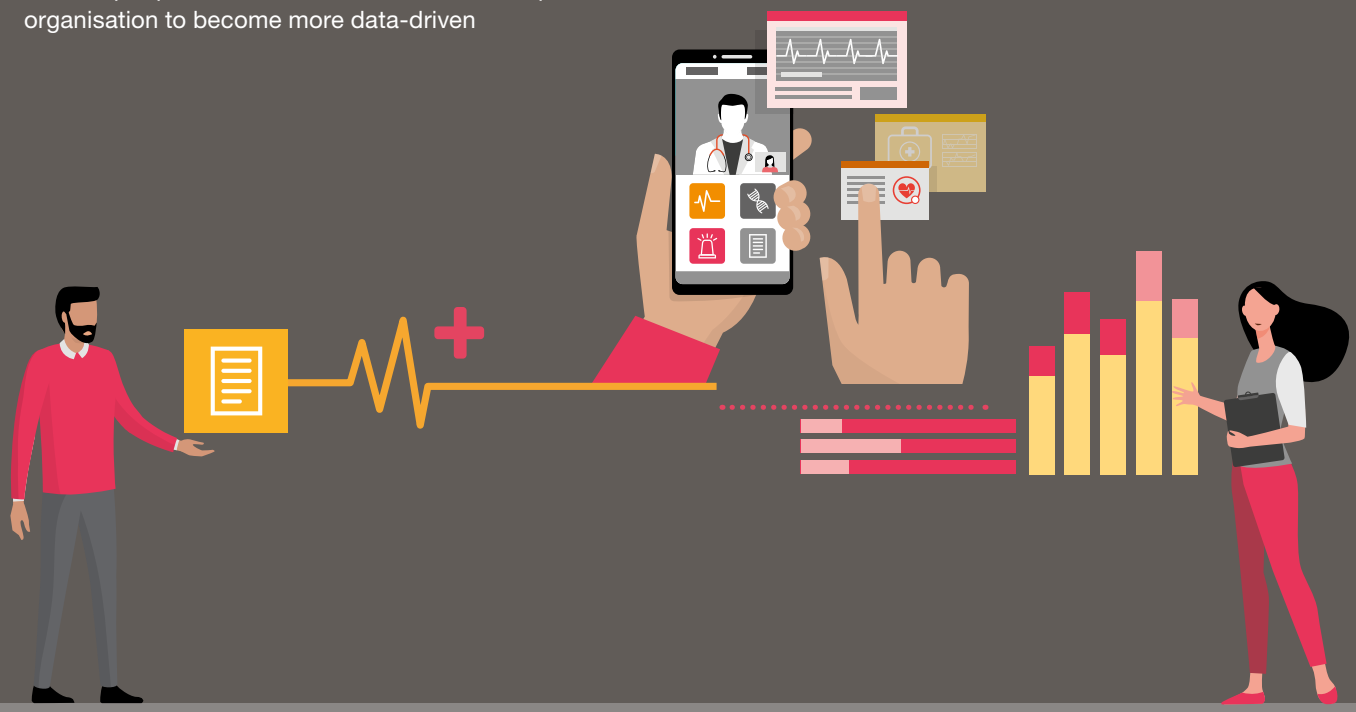
Large healthcare providers and tech companies appear to be the most attractive prospects for commercial partnerships. However, to make the most of these, a data strategy is crucial to protect patients and company interests in a connected health ecosystem.

Most companies are not yet making full use of data from digital solutions. Those that are tend to use it internally for their own product or company. To better leverage data, for example, to generate real world evidence, companies need to invest in measuring the real value of data, put patient trust at the centre and set up their organisation to become more data-driven

Engagement KPIs are seen as important by all, but there is less agreement about how to measure outcomes. Having measurable business objectives for any digital solution will enable teams to show the value of their solutions to the organisation.

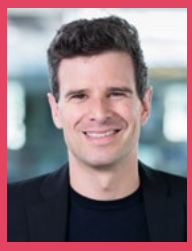
None of these findings should be viewed in isolation. Instead, they should inform an integrated digital health strategy that ensures digital health solutions deliver the intended benefits for patients, providers and other stakeholders of the healthcare ecosystem. PwC brings a diverse set of in-depth expertise from our global partner network to help our clients along that process.

For more insights into how to develop and commercialise digital health solutions and how to use digital technology to build meaningful engagement with healthcare stakeholders, please refer to **our website** or reach out to us directly.



Want to know how digital health is impacting your business? We have a broad and diverse team active in digital health, ranging from strategy to execution.

Authors



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Appendix

Stock market performance data: The digital health index was made up of companies with a strong focus on products that include digital health components.

Companies in telehealth, digital measurement, intervention and diagnostics

Letsgetchecked
Voluntis
Better therapeutics
Physitrack
Movano
DARIOHEALTH
Dialogue Health Technologies
Pear Therapeutics
Babylon health
Cue health
Outset Medical
Hims & Hers
23andME
GoodRx
PING AN HEALTHCA
IRHYTHM TECHNOLOGIES INC
Teladoc
Dexcom
SOC telemd
Uphealth and Cloudbreak Health
Carebook
ResMed

General digital health category

GoHealth
Augmedix
Computer programmes and systems
Health stream
Invitae
Accolade
Bright Health Group
Model N
Nextgen
Clover health
Phreesia inc
Care.com inc
Cerner
Convey Health
Inovalon
Schroedinger
Vocera
Tabula Rasa HealthCare
Benefitfocus
one medical
Evolent
Progyny
Privia health
Omnicell
Signify Health
Oak Street health
Doximity
Change healthcare
NathHealth
CloudMD
Instem PLC
Exscientia
Relaytx
Abcellera

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