DISITAL FUSION How smart collaborations will drive the healthcare revolution.

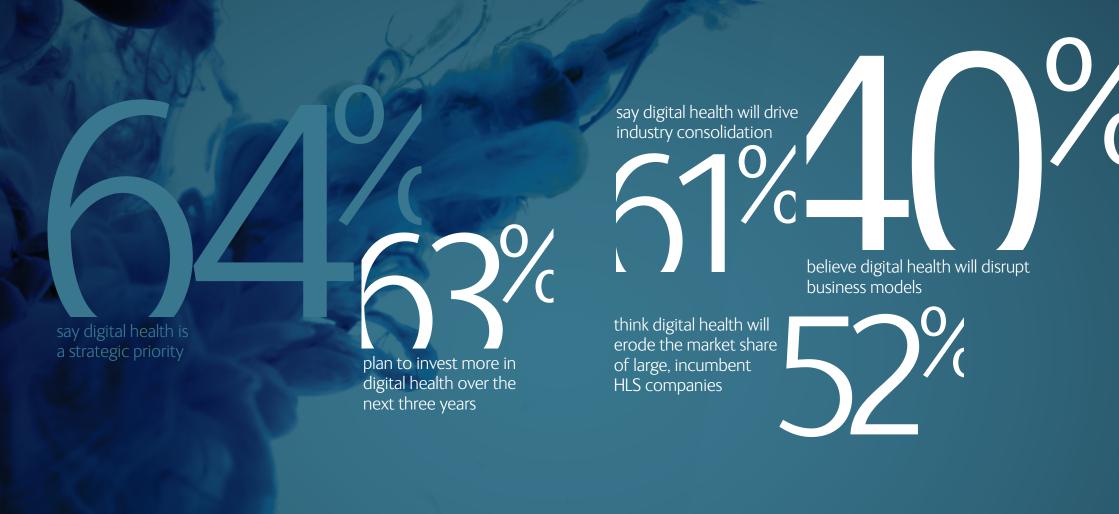
Simmons & Simmons

Healthcare is on the cusp of a digital revolution. The mass adoption of mobile devices and advances in robotics, artificial intelligence (AI), the Internet of Medical Things (IoMT) as well as other digital technologies are set to revolutionise healthcare and wellbeing. Together, they will transform every corner of the sector — from research and drug discovery to front-line care and business operations.

For payors, HLS businesses and TMT companies, digital health provides an opportunity to develop cost-effective, patient-centric products and services. For investors, digital health – and the disruption it brings – offers new opportunities to secure healthy returns. Estimates suggest the digital health market will hit a compound annual growth rate of 21% between 2018 and 2023, far outpacing many other asset classes.

"We cannot reverse the rise of digital technology. It's coming, and you're either part of it or you're not. We've already seen in other sectors what happens to those that are not ready to adapt."

- Salah Mostafa, Head of Legal, Novartis MENA



Digital health is now firmly on boardroom agendas. But seizing opportunities will lead to new risks. Management teams will need to steer their organisations through significant market disruption, while also making confident decisions about how to evolve their business models and how to protect their market share. The pace of change may seem overwhelming, but inertia is not an option.

Whether an organisation sinks or swims in this new era will largely depend on its willingness to adapt. Against this backdrop, we asked 441 decision makers and investors across the UK, Western Europe, North America, the Middle East and Asia-Pacific about how they plan to grasp the digital health imperative. We set out the strategies they will adopt in the year ahead, and the key barriers that will prevent many from realising their goals.

Drawing on our research and experience, we have developed an eight-point framework that we believe will give organisations the best chance of realising digital health opportunities and, in turn, of addressing the very real challenges faced by healthcare systems around the world.

Stronger together: seizing digital health opportunities

How will business leaders embrace the unprecedented opportunities created by digital health?

Our research shows they are exploring a range of options. Many are thinking about how to enhance internal capabilities — whether by attracting staff with the right digital expertise or changing company policies or cultures (Fig. 1). Ultimately, however, most believe they will need to look externally for answers.

Collaborations are the preferred approach, with 83% describing partnerships, JVs and alliances as important in the year ahead. A high proportion of respondents also say M&A activity and minority investments will be vital components of their digital health strategies over the next 12 months (Fig. 1).

"We live in a world where no single organisation has all the answers. We need to bring together the right teams to find solutions."

Andreas Haimböck-Tichy, Director, Healthcare and Life Sciences, IBM UK

Fig. 1 – How important will the following be to your organisation to unlock digital health opportunities in the next 12 months? % that say important / very important

Collaborations	39%	44%	83%
(partnerships, JVs alliances) Minority investments	31%	48%	79%
M&A	32%	46%	78%
Attracting staff with digital expertise	30%	40%	70%
Internal capability build	26%	39%	65%
Service contracts	25%	41%	66%
Changing company culture/policies	22%	44%	59%

☐ Very important ☐ Somewhat important

Base: NOT Investment institutions n= 370, Payors n=32, Healthcare n=199, Tech n=136

"To solve the systemic problems in healthcare, we'll need to work together. Organisations will need to look across the entire system to find solutions, not just one piece of the pie"

- Thomas Utech, Pharm.D., Vice President Strategic Innovation and Global Marketing – Medication Management Solutions

There are also clear signs that collaboration structures are becoming more complex. In our study, 71% of organisations say they will increase investment in multi-party deals over the next three years, and a further 64% will scan for cross-sector opportunities. In contrast, bilateral collaborations, despite remaining valuable, have started to fall out of favour (Fig. 2).

Collaborations that blend a wide range of skills, insights and expertise can offer some of the most interesting results. However, increased complexity often brings increased risk. Multi-party arrangements create a knot of contractual, intellectual property (IP),

regulatory, competition, governance and cultural issues that must be carefully unpicked. The more parties that are involved, the more difficult it is to resolve matters, and the higher the barriers to success.

It is critical that these challenges are overcome. Successful collaboration is now a key driver of competitive edge. Those that fail to forge the right relationships will become increasingly marginalised in a fast-moving, digitally led landscape.



Fig. 2 – How do you expect your level of investment in the following types of digital health collaborations to change in the next three years? % that say important / very important

Collaborations with multiple parties	19%	55%	71%
Open-science collaborations	18%	48%	66%
M&A	19%	46%	65%
Cross-sector/multi-industry collaborations	23%	41%	64%
Minority investments	15%	49%	64%
Bilateral collaborations	16%	39%	55%
Cross-border collaborations	17%	38%	55%
Consortia of competitors to tackle common industry-wide challenges	14%	38%	52%

☐ Significant increase ☐ Increase

The investment picture: digital health has become an important asset class, with investors moving to capitalise on buoyant opportunities.

In our survey, 51% say digital health is a strategic priority (only 24% say it is not). A further 41% plan to increase the amount they invest in digital health over the next three years. Unlike many other asset classes, digital health appears largely immune to wider market uncertainty. Just 30% of the investors we spoke to say the UK's exit from the EU will hinder their digital health strategy. Investors look first and foremost for leading technologies and products that have a clear path to market.

Collaboration: barriers to success

Collaborations are vital to seizing digital health opportunities, but we know they are difficult to pull off. Our research shows that only 11% of collaboration and investment proposals that cross organisations' desks ever enter detailed due diligence, and only 4% are executed.

Even when collaborations do go ahead, there is no guarantee of success. Respondents told us that only 34% of their collaborations achieved their stated objectives.

They not only prioritise organisations that are led by skilled management teams, but also those that have IP protection locked down. Interestingly, a further 51% consider an organisation's track record on collaborations when making investment decisions.



Fig. 3 – What is the greatest challenge to identifying and conducting due diligence for digital health collaborations/investments?

Determining the technology we want

Obtaining necessary quality of information

Establishing that the counterparty/target has good title to Ip and/or whether necessary third-party IP is available to license

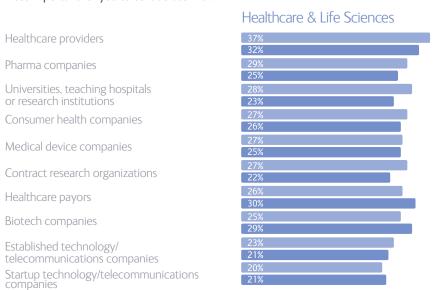
Identifying appropriate partners/targets

Working out who has contributed what to the counterparty's technology that will be

Base: n=440, Payors n=31, Healthcare n=199, Tech n=136, Investment institutions n=71

Fig. 4 – Which types of organisation are most important for you to collaborate with?

used in the collaboration



Why do collaborations struggle to realise their full potential?

Drawing on our experience and research, we identify eight barriers that prevent many from forging mutually beneficial relationships.

1. Lack of direction

Organisations are still unsure about their collaboration objectives. Many enter talks without having a clear view of what they are looking for or what they hope to achieve. In our study, respondents say the biggest challenge they face during due diligence is working out the technology they want (Fig. 3).

Our research also revealed that target companies are often ill-prepared to answer questions from potential collaboration partners or investors — respondents say obtaining the necessary quality of information is the second most common challenge when carrying out due diligence. Those unable to share the right information at the right time will find that doors to collaborations and investment soon close.

2. Siloed thinking

In our experience, the best digital health collaborations blend deep patient insights with cutting-edge technology. However, our research shows that HLS and TMT companies do not always want to work together. When



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to get any traction unless their encryption is appropriate and their security is compliant."

Amy Reddell, Vice President of Legal Services at Houston Methodist

TMT companies were asked which types of organisations they look to collaborate with, most mentioned established tech players or tech start-ups. Likewise, HLS companies seek to work with others in their sector, with most prioritising collaborations with healthcare providers or pharmaceutical companies.

This lack of cross-sector thinking will prevent many from realising their goals.

3. IP complexities

IP discussions are critical in digital health collaborations. Unfortunately, organisations can find it difficult to get the assurances they need. In our study, respondents say working out whether co-parties have good title to their IP is a top-three challenge when carrying out due diligence (Fig. 3). Foreground IP – IP that arises

from a collaboration — is another key sticking point. Our research shows that organisations struggle to resolve the ownership and licensing of rights to foreground IP. They also find it difficult to agree who should protect it and who is responsible for funding that protection. Those that do not have a firm handle on these key points may struggle to reach a fair agreement with their potential co-parties, or any agreement at all.

4. Data insecurity

High-profile cybersecurity breaches and a raft of new regulations have thrust data security and cybersecurity matters firmly into the spotlight. However, many organisations have still not embedded the right controls to keep sensitive data safe. Our research shows that 68% of organisations struggle to find partners

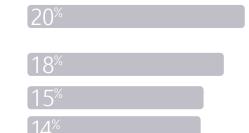
Fig. 5 – What is the greatest challenge of agreeing digital health collaborations with counterparties?

Resolving data protection/cybersecurity issues

Resolving regulatory/compliance issues

Incorporating flexibility into the contract

Resolving market access issues



Base: n=440, Payors n=31, Healthcare n=199, Tech n=136, Investment institutions n=71

with acceptable cybersecurity risk frameworks. Moreover, resolving data security and cybersecurity issues is the single greatest challenge faced when agreeing collaborations (Fig. 5).

5. Uncertain market access

Organisations continue to underestimate the hoops they need to jump through to bring products and services to market. Our research shows that resolving regulatory and compliance issues is the second greatest challenge when agreeing collaborations (Fig. 5). In part, problems arise because regulatory frameworks have struggled to keep pace with technology innovation. At the same time, some businesses do not realise their products qualify as medical devices, which are subject to stricter regulatory requirements that differ between countries. There are also indications that some actively try to avoid engaging with regulators altogether. This is a short-sighted strategy: co-parties, investors and regulators will always need confidence that organisations have properly understood their obligations.

6. Product liability issues

Product liability has become a critical battleground during digital health collaborations. All parties need to understand their accountability in the event that the innovation later causes harm to a patient. This can be challenging when creating products or services that link to a piece of software or operate within an IoMT ecosystem, as well as when developing personalised treatments or patient empowerment innovations. In these scenarios, all involved parties – including the medical device hardware manufacturer, software developers, physicians and even smartphone manufacturers – could potentially face costly and reputation-damaging product liability claims. As such, liabilities need to be clearly apportioned in contractual arrangements. Unfortunately, we know that many struggle to reach an agreement that all parties are happy with. In our study, respondents say product liability issues are the primary reason their collaborations did not deliver on their intended outcomes (Fig. 6).

Fig. 6 – Why digital health collaborations fail

Product liabilty issues

Misaligned/divergent objectives of the collaboration

Products/technology created by the collaboration did not add value or were not

A key individual or individuals left the collaboration

Cultural differences between collaborating parties

[36%]

30%

29%

Base: n=440, Payors n=31, Healthcare n=199, Tech n=136, Investment institutions n=71

7. Divergent objectives

Organisations often have different motivations when entering collaborations. Our research shows that payors and HLS companies keep patients front of mind: they look for partners that can help them build a better picture of patient needs, or help them improve patient outcomes and experiences. Conversely, our research shows that most TMT companies look for partners that either support the development of their technology or provide access to new products. Mismatched objectives do not always create problems; challenges only arise when organisations fail to understand or manage their co-parties' expectations. In our research, respondents say misaligned or divergent objectives have caused their collaborations to fail (Fig. 6).

8. Cultural clashes

Cultural differences can make or break a collaboration. While 63% of organisations believe successful collaborations are founded on diversity of all forms, 56% say cultural differences can hinder progress. Problems often arise because co-parties have different appetites for innovation and risk. The traditionally slower pace of innovation and rigour of scientific R&D may be perceived as stifling TMT players' creativity, while TMT players' failfast attitudes may not always gel in complex healthcare landscapes. The key is to manage potential conflicts from the start. Unfortunately, this does not always happen. In our study, cultural issues were cited as a key reason why collaborations fail (Fig. 6).

How to build a successful digital health collaboration

How can you make sure your digital health collaboration delivers?

In our experience, successful digital health collaborations and investments share common characteristics. Firstly, co-parties are not solely focused on their own motivations; they also spend time developing a shared vision and believe they will have a better chance of achieving their objectives if they work together. They are also well prepared, with a clear understanding of commercial, legal and regulatory risks. And finally, they create the right governance arrangements to ensure long-term success.

Drawing on these insights, Simmons & Simmons has developed a digital health collaboration framework, which sets out the eight areas you need to think about before diving in.

Discover this at www.simmons-simmons.com.

Product liability

Data

Preparation Technology Structuring & governance Culture Digital health: Smarter collaborations framework Regulatory ΙP



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