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SCALING DIGITAL HEALTH

AN ACTIONABLE GUIDE FOR INNOVATORS & BUSINESS LEADERS

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EXECUTIVE SUMMARY

Innovation is becoming increasingly essential in tackling growing healthcare challenges, from ageing populations with a high chronic disease burden to staffing shortages and funding squeezes. There's incredible scope for improving patient outcomes and experiences while reducing healthcare costs through the adoption of digital health solutions across the value chain. In this paper, we first look at the key challenges around successfully implementing and scaling innovation within the healthcare system. We then propose a series of recommendations for startups, corporates and health providers to help overcome these challenges and drive forward digital health innovation.

The insights and anecdotes presented in this paper have been distilled from conversations with key stakeholders across the healthcare ecosystem. From digital health founders to corporate innovators, and even clinicians, we've sought to tap into the experiences and guidance of those at the forefront of global healthcare innovation. Our geographic focus has been Europe and the USA, with our deepest insights predominantly from the UK. However, the innovation challenges faced within each health system are broadly applicable on a global scale.

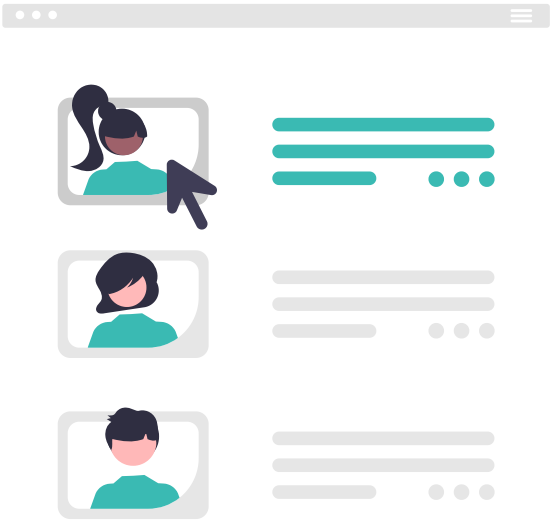
Many of the key enablers to innovation in all industries, such as access to funding, knowledge, talent and customer insights, are areas that represent enormous bottlenecks in the healthcare space too. Additional value is being lost because the necessary infrastructure and vehicles to deliver innovation are underdeveloped, largely a reflection of the added complexity that the healthcare space brings. Fragmented delivery systems, regulatory hurdles and a cultural fear towards innovation within healthcare institutions all contribute towards this complexity. The challenges that we've identified fall into six broad themes, each telling a chapter in the story around how scale and adoption of digital health solutions are stifled.

Beyond the overarching challenges, we evaluate some of the entrepreneurial initiatives that are already being implemented and suggest new ways in which different stakeholders can boost innovation. In particular, we explore the role of pharmaceutical companies in the emerging digital health ecosystem, which we see as one of a centrifugal connector. There remains untapped potential in partnering with digital health startups to develop and commercialise new solutions, whilst also working with healthcare providers and payers to integrate digital health solutions into patient care. Pharma companies that are able to develop their innovation functions to harness, commercialise and scale digital health will ultimately benefit the most and spearhead the evolution of the digital health space into a more mature position.

What do we mean by digital health?

The use of digital technology within the healthcare industry, including both software and medical devices, to deliver either:

1. New data-driven products, services and treatments that enable greater precision and personalisation
2. Fundamental technology-led operational transformation that unlocks greater efficiency and improves interventional outcomes



INTRODUCTION

Many healthcare systems around the world are experiencing a state of significant strain, stretched to their limits as they wrestle with ongoing challenges such as staffing shortages, increased wait times, and growing inequalities. The need for innovative solutions to play a role in addressing these complexities has become clearer than ever.

But where do we start? It's clear that we are at a reckoning point across the US, UK and Europe where healthcare systems need to evolve. Transforming legacy healthcare systems through a digital-first approach is essential.

Unfortunately that is a very simple answer to a highly complex and nuanced problem. It's no secret that scaling innovation is hard, and that in the healthcare industry it is even harder still.

Some of the reasons for this are more obvious than others. For instance, healthcare is a highly regulated space with enormous geographical variation. A significant barrier, but not insurmountable - look at the rate of change in other highly controlled industries such as financial services.

Other problems are hidden beneath the surface, such as the cultural engineering that has placed physicians at the centre of decision-making. Not to mention the layers and layers of gradual evolution in healthcare delivery have created an opaque system that is almost impossible to fully comprehend.

At present, the scope of cutting innovation within healthcare exists mainly within R&D. How can this focus be expanded to also accelerate digital and business model innovation that drive the system?

The trillion-dollar question:

"How do we successfully scale innovation in healthcare?"

At Founders Intelligence, part of Accenture, we help large corporates to solve their biggest challenges by looking to the startup world for inspiration.

With the above question a recurring theme, we set ourselves the task of answering it, speaking to 30+ founders, investors, experts and corporate leaders for insights.

This white paper is our answer to that question: an actionable guide with our recommendations for how the barriers to scaling innovation can be overcome.

We will provide our perspective through six overarching problems, bringing these to life with case studies. We will also deliver targeted advice to startups, corporates and healthcare providers.

We chose to apply a focused lens on **digital health** because:

1) It intersects multiple facets of the healthcare industry and is a focus area for innovation efforts amongst virtually all players in the medical arena

2) It is highly complex to navigate from a commercial & regulatory perspective

3) Despite significant investment and high expectations, digital health remains a relatively nascent space with enormous growth potential

We have also thought about 'scale' in a broad sense - defining it as the ability to grow through increased user adoption, revenue and market expansion.

With the scene set, let's dive in!

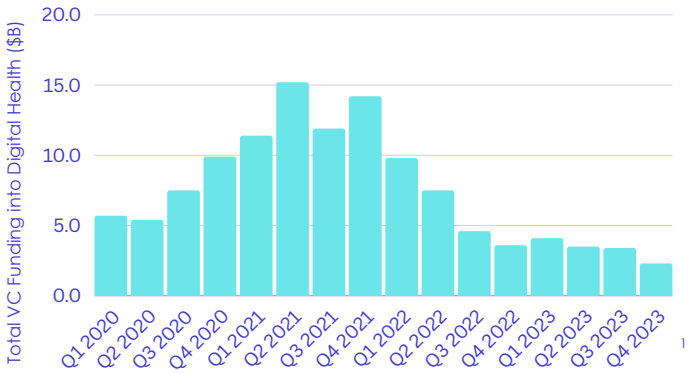
PROBLEM SNAPSHOT

Digital Health Through a Venture Lens

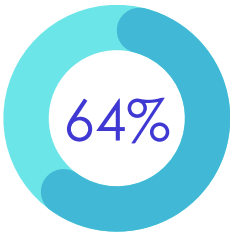
Early-stage digital health startups have continued to attract venture funding, despite the challenging economic climate. However, investors are becoming more selective following notable high-profile failures, a lack of exit opportunities, and macro-economic uncertainty.

01. Investors are placing smaller bets, with a greater emphasis on the path to profitability

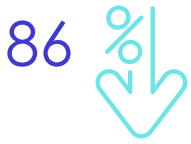
- Global VC funding into digital health halved for 2 consecutive years, falling from $52.7B in 2021 to $13.2B in 2023 [1]
- While the median early-stage deal size increased from $2.1M to $2.5M between 2021 & 2023, the median late-stage deal fell from $75M to $28M [2]
- Mega rounds ($100M+) represented 62% of total digital health funding in Q1 2021, but just 17% in Q4 2023 [3]
- Only 3 mega round investments took place in Q4 2023 (Devoted Health, Headway and Iambic Therapeutics) [4]



[1]



Digital health funding is seed or early stage [5]



Decline in mega-round deal count from 2021-23 [6]

02. The pipeline remains strong but exits are proving challenging

- There were only 4 digital health IPOs in 2023, plunging from 19 in 2022 [7]
- M&A activity nearly doubled in Q4 2023, driven by poor public market performance, sparse VC funding and economic headwinds [8]
- High-profile failures due to a lack of profitability, a problem exacerbated by limited long-term commitment from pharma, who often view digital health as a marketing exercise
- The digital health unicorn herd shrunk from 97 to 94 during 2023 [9]

2x

M&A exits quarter-over-quarter from Q3-4 2023 [8]

- Pear Therapeutics
- Babylon
- Truepill

03. Europe remains a challenging market for startups to scale

- The median deal size in Europe has risen to $3.2M, but remains significantly lower than the US and Asia, at $4.6M and $3.7M respectively [10]
- Despite significant funding, less than 10% of digital health unicorns are in Europe, a low percentage when compared with other sectors [11]

Median deal size for digital health startups in the US is the highest of all global regions [10]

Digital health unicorns emerging from Europe despite housing 25% of unicorns across all sectors [11]

JOURNEY TO SCALE

The problems that startups encounter vary depending on their stage of maturity. We've identified six key challenges faced by all new solutions in digital health, each emerging at different points along journey to scale: Ideation, Building, Funding and Adoption.

In the following chapters, we'll deep dive into how the challenges present themselves, suggest how hurdles can be overcome and explore the roles that different stakeholders within the ecosystem can play to support the progression of innovation.

LACK OF EVIDENCE

UNREALISTIC GROWTH TARGETS

CONSTRAINED COMMERCIAL MODELS

GEOGRAPHIC FRAGMENTATION

KNOWLEDGE GAP

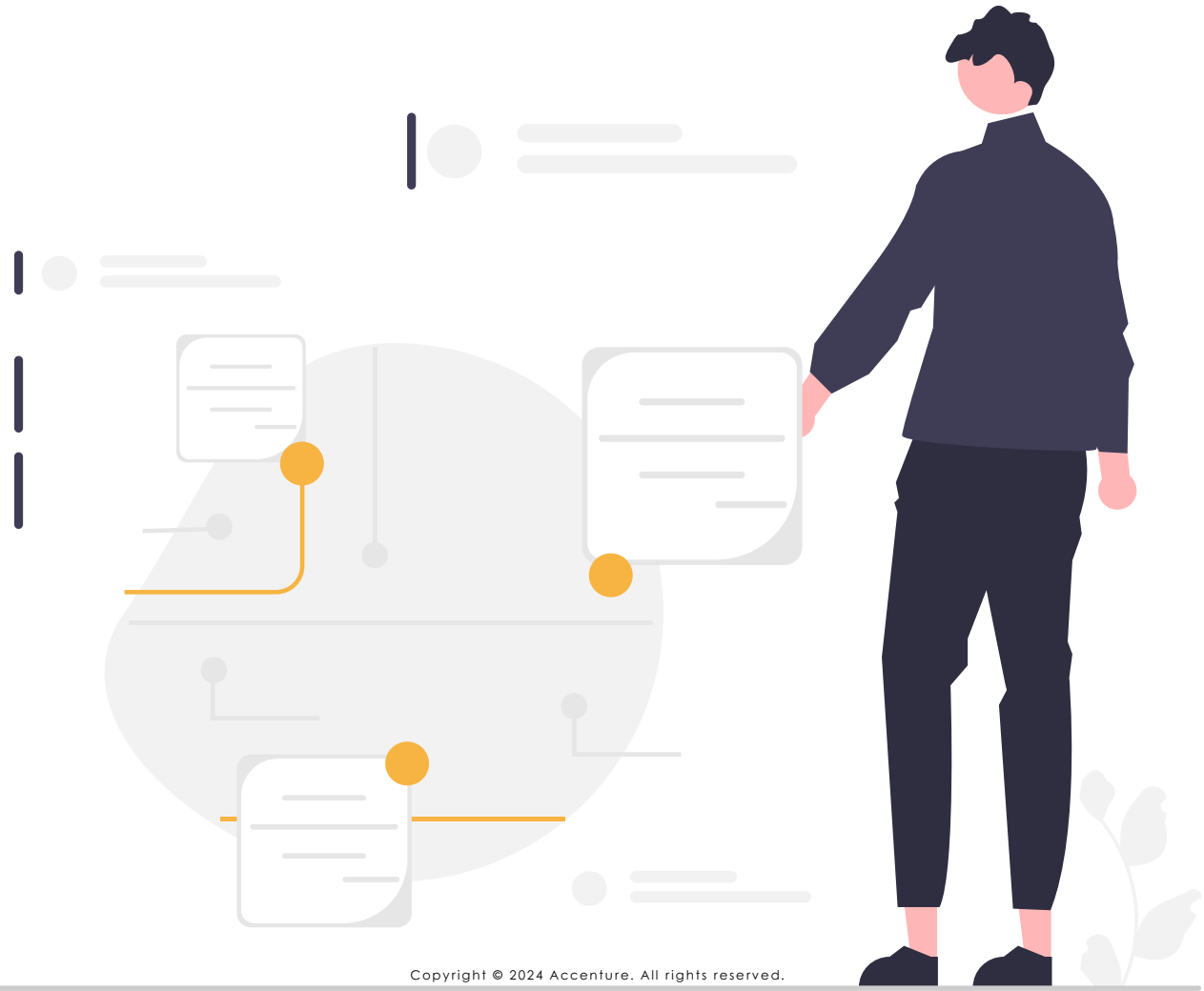
CULTURAL FEAR OF INNOVATION

IDEATION BUILDING FUNDING ADOPTION

Chapter 1

CULTURAL FEAR OF INNOVATION

The high stakes nature of healthcare has understandably cultivated risk aversion, meaning resulting mindsets and incentive structures are incompatible with disruptive digital innovation



PROBLEM SNAPSHOT

According to a survey from the Academic Health Science Networks (AHSN), 55% of local health stakeholders feel confident in their ability to **access innovation**, but around 70% do not feel confident in their ability to **implement it**.[1]

IDEATION BUILDING FUNDING ADOPTION

Healthcare is hyperfocused on core business

Healthcare providers and pharma alike are focused on delivering their current offerings and driving R&D-focused innovation. The strategy, operations, and culture built by these organisations has evolved to reflect this. As a result, there is typically little bandwidth or incentive for innovation efforts around digital health solutions that are more distant from day-to-day activities.

Practitioners deliver care, not innovation

The primary role of healthcare professionals is service provision. The immense strain on resources, particularly staff, prevents doctors and allied healthcare professionals from having the necessary time and space to think about how the system can be improved.

This barrier is compounded by the need for greater caution when innovating in healthcare. The startup mantra of "move fast and break things" doesn't really work when people's lives are at stake! Ultimately, the incentive structure in healthcare institutions does not reward innovation - it rewards clinical outcomes.

Operating in a pressurised environment with high stakes means that the time investment, combined with the repercussions of failure, discourages practitioners from implementing new ideas if it makes their already difficult job even harder.

This situation is often worsened by procurement, with Dr Leslie Dickson-Tetteh, founder of digital health startup Cherub, explaining that the buyers who purchase new solutions for clinical settings often do not understand the needs of those who will ultimately use it. Change management is therefore another key element for startups to consider to alleviate the consequences of innovation in healthcare.

The end result is healthcare systems seem to push back innovation before it has even had the chance to begin. Dr Chris Ross, founder of cervical screening startup Thyia, pointed out that we need to show the cost of business-as-usual. Providers seem to be oblivious to the consequences of failing to innovate, adopt new ideas, and evolve.

"The NHS is a traditional organisation, so it's difficult for entrepreneurs to break the system. There is a good reason for the regulations in place, but the end result is a healthcare ecosystem that struggles to embrace innovation. Get under the layers of bureaucracy and there is a tremendous opportunity to change the fortunes of every patient."

DR AMIR HANNAN MBE - NHS GENERAL PRACTITIONER

The green shoots of a healthier innovation ecosystem are beginning to grow

The challenges that we are witnessing have not gone unnoticed, with healthcare providers and policymakers looking for ways to promote innovation in the broader healthcare ecosystem. While these are only the first steps, top-down initiatives that encourage and endorse innovation are a vital part of changing the wider culture within healthcare, building an ecosystem in which startups and corporates can succeed.

In the UK alone, there are a growing number of initiatives promoting both intrapreneurship and entrepreneurship.

The NHS Accelerated Access Collaborative (NHS AAC) commissioned a number of initiatives to support innovation across each stage of product development, including:

- Clinical Entrepreneur training programme
- NHS Innovation Accelerator
- Pathway Transformation Fund

Germany's "DiGA" aims to make digital health prescribing easier for doctors

In 2019, Germany introduced DiGA, a national directory of digital health apps. The DiGA law allows doctors to prescribe 12-week courses of app and web-based therapy to any of the 73m people using public health insurance, circumventing the need for solutions to be sold to each of the 100+ public insurers separately.

Digital health applications are rapidly evaluated by the Federal Institute for Drugs & Medical Devices (BfArM). Those meeting stringent regulatory and efficacy standards are permanently listed, whilst provisional approval grants 12 months to demonstrate clinical efficacy.

The law is a clear attempt to address the cultural aversion to innovation by making it easier for digital health solutions to be trialled by doctors and patients alike. Similar frameworks have since been introduced or evolved in other European countries, including the PECAN program in France and mHealth in Belgium.

> **"Pharma companies are still product oriented organisations. They still haven't learnt to create new business models for anything outside of actual products."**
>
> SARA ADAMS - ?WHATIF! INNOVATION

Pharma companies need to be more agile and less clunky

The commercial model in the pharma industry has been built around long R&D cycles with a high failure rate, leading to a small number of highly profitable revenue lines. In principle, this doesn't sound dissimilar to the school of thought in the startup world. However, the focus on short-term commercial priorities and typically conservative cultures prevent deviation from the status quo.

During our conversation with Series D digital health startup Biofourmis, it was discussed that pharma needs to shift their thinking from drug development towards product delivery. Closer collaboration with startups and other key stakeholders across the healthcare ecosystem is vital for pharma to ensure their business model is future-proofed and that they can capture the growth opportunities that digital health presents.

Pharma often fails to seize the opportunity that digital health startups present

Innovation teams are typically the bridge between pharma and the venture world, responsible for establishing mutually beneficial partnerships. However, all too often we see from our work with pharma companies that they do not have a sense of the vendor landscape, and how they can plug into startup innovation. Operational accountability for fostering a strong ecosystem network is imperative.

Catalina Cernica, Founder of the Health & Happiness Lab, highlighted the importance of positioning where an innovation team should sit within a large organisation. Too close to the core, innovation can be stifled and adjacent opportunities missed. Too distant and it can be hard to secure buy-in and connect to existing business functions.

CASE STUDY

NHS Innovation Accelerator

The NHS Innovation Accelerator (NIA) is one of the many initiatives in play attempting to support the scaling of innovation within the NHS. The program aims to support fellows on their product maturity journey.

Driving innovation in public healthcare

Konrad Dobschuetz, National Director of the NIA & Chief Enterprise Officer at UCLPartners, explained that the programme has been built around three key pillars: mentoring, learning and market access. The NIA provides collaboration opportunities for innovators with key bodies such as NICE, NHRA, DHSC and market facing stakeholders such as pharma companies. The credibility and network access provided through the programme is of great value to ambitious digital health companies. Accelerators have proved to be an effective mechanism to catalyse growth for healthcare startups. According to a report by CB Insights, the top 10 healthcare accelerators have helped startups to raise a combined total of over $10bn in funding and includes the likes of Rock Health, StartUp Health and Techstars Healthcare accelerators.[2]

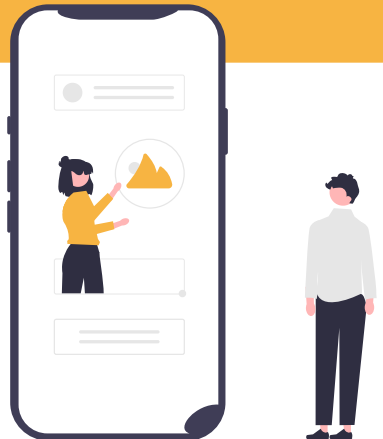
However, the effectiveness of the NIA program and the wider Accelerated Access Collaborative (AAC) initiatives have been debated by former programme participants. Founders have cited that the route to nationwide adoption was not expedited to a significant extent, with individual bodies reluctant to deploy digital solutions without conducting their own internal regulatory processes.

A national scale and adoption fund?

Konrad is spearheading a proposal to create a national adoption and scale fund, fed by industry and government alike, allocating £500m per year to support the implementation and scaling of proven health tech solutions. One of the problem areas he identified within the NHS is a tendency to launch multiple small scale pilots without converting any to scaled solutions.

Additionally, there is currently no national, centralised delivery infrastructure to adequately connect healthcare providers with digital health companies. The lack of a unified approach in solution adoption across various NHS Trusts runs the risk of creating too many varied tech stacks in the future. In his proposed approach, the fund would have a rigorous selection process and support only a few companies across each of the targeted focus areas. NHS Trusts would only be able to procure one of these vetted and approved solutions.

The proposal has shades of the DiGA regulation launched in Germany, however DiGA does not restrict the directory of viable startups to a curated list. Balancing competition with fragmentation will be key to maximising success.



CASE STUDY

FOUNDERS INTELLIGENCE
Part of Accenture

Founders Intelligence was born as the advisory arm of Founders Forum, Europe's leading tech founder and investor community, and is now part of Accenture Strategy. FI helps large corporates to identify and deliver new growth by leveraging insights and connections into the startup world.

Culture is king

Through working with some of the global leading companies in the health and life sciences space, we have learned that often the biggest barrier to innovation is the culture. People often exhibit fixed ways of thinking and offer very little mindset malleability. Within corporates, the definition of success is predominantly tied to traditional ROI metrics which only paint a partial picture of the performance of innovative ventures and create a skewed perception of failure. If corporates intend to encourage innovation instead of stifle it, the cultural transformation must be reflected in how success is measured. Switching to a more innovative mindset and culture will also be vital in attracting the best young talent to drive future prosperity.

Exec buy-in is vital

Innovation teams need advocates in senior positions who are happy to take a long-term view without being constrained by immediate business pressures. Innovation teams must be positioned far enough away from the core business that they're able to establish a culture and ways of working akin to startups, but not so far that stakeholders within the core business have no vested interest in the team's output. Dr Alexander Finlayson, founder of startup Nye (partnered with Roche UK), feels that it is important that buy-in, and ultimately success, is not tied to a single product. Otherwise the fate of an initiative can be sealed by a failed clinical trial.

Innovation teams are at home in R&D business lines

Innovation is often aligned with marketing or commercial functions, despite the cultural fit aligning better with R&D. The nature of R&D activities mean they have a greater resilience to failure, expectations of longer timeframes to achieve ROI, and crucially, experience at the forefront of new product development. Aligning innovation efforts with the existing R&D value chain can bring success in the short-term too, as transformational ideas have a clearer route to scale. This also makes it easier to provide the commercial rationale to convince stakeholders of the value in these pursuits.

RECOMMENDATIONS

TO PROMOTE & NURTURE INNOVATION

DIGITAL HEALTH STARTUPS

01 Factor in ease of integration and change management support into your solution

Digital health startups need to understand that any innovation that is adopted should be accompanied by an internal change management process. By providing this service as part of the offering, digital health companies are likely to find greater success and adoption. Craig Oates, MD of Doctrin UK shared that they usually provide an allowance of "change management consultancy days to optimise the adoption of [their] products".

CORPORATES

02 Redefine metrics of success and ROI

Demonstrating ROI can be a challenge, particularly if it's viewed from a traditional revenue-based lens. Innovation lends itself to an R&D culture, and therefore similar metrics should be set to incentivise innovation. In doing so, teams can set realistic milestones, helping to manage the expectations of seniors, and allocate the necessary resources to achieve scale.

HEALTHCARE PROVIDERS

03 Support to build innovation into the day job

Healthcare professionals experience a lack of bandwidth to allocate time to activities and initiatives beyond their core responsibilities. Providers can look to the startup ecosystem for examples of the benefits of management sponsorship to focus on innovation. Google's famous “20% time” policy has allowed employees to spend 20% of their work time on projects that they are passionate about, even if not directly related to their job duties. Successes such as Gmail, Maps and AdSense have been attributed to this. Adopting a similar policy within healthcare institutions can help to spur on innovation and ensure that it is incentivised appropriately.

EVERYONE

04 Create a mass learning initiative

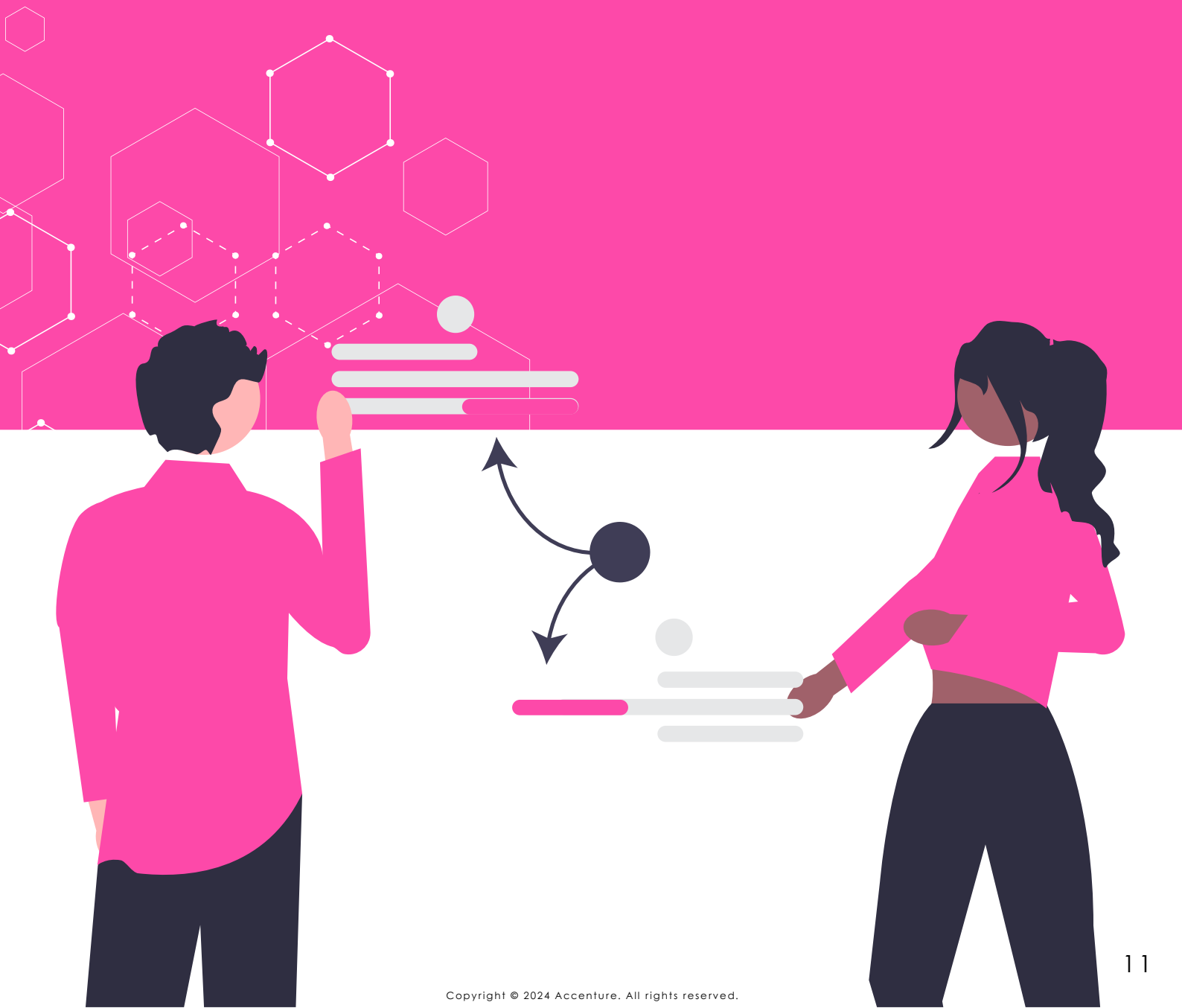
Across the ecosystem from investors, to regulatory bodies, corporates and especially HCPs, there is a lack of knowledge and understanding around the innovation process, particularly in relation to digital health products. Hakim Yadi, CEO of Closed Loop Medicine, suggests that a mass healthcare system education initiative is needed across the board - a centralised initiative with the aim of ensuring stakeholders are well informed and subsequently able to make clearer decisions.

A Senior Innovation Lead from a global Pharma organisation echoed this point, suggesting that organisations need to heavily invest in proactively transforming employee's understanding of innovation and its significance, to be able minimise the risk of external disruption.

Chapter 2

KNOWLEDGE GAP

It is hard for founders to know if they are building the right solution, or if they're even solving the right problem in the first place



PROBLEM SNAPSHOT

The Digital Leadership Report found that **67% of health executives** believe that their companies **lack the right skills and knowledge** to keep up with the pace of change in the digital healthcare ecosystem.[1]

IDEATION BUILDING FUNDING ADOPTION

Knowledge decentralisation

Knowledge and its dissemination are key enablers of innovation across all industries, empowering companies to understand problem areas within a space as well as devise the most effective approaches to tackle them.

As such, the centralisation of knowledge within clusters of experts creates a major barrier both to entry and scaling digital health offerings within the healthcare space. Through our conversations with founders, investors, corporate leaders and practitioners, we identified the following areas as critical knowledge gaps that exist within many digital health companies:

- Patient, customer & user needs
- Optimal routes to market
- Key advocates & stakeholders to engage
- Commercial viability & business model
- Regulatory complications
- Clinical robustness

Product-market fit

Many digital health companies fall into the trap of creating patient-centric solutions that can improve medical outcomes, while failing to factor in that healthcare providers are ultimately the paying customers in the majority of clinical scenarios and have additional unmet needs.

Marc Serra Bartra, co-founder of Barcelona-based healthcare accelerator Axial Biotech, sees a lack of product-market fit as a key reason why many startups fail. Understanding who wants to use your product or service, who would pay for it and acquiring buy-in from these parties is imperative in obtaining product-market fit.

Healthcare customers are often immature buyers, whose core focus is to deliver care to patients, not to innovate. This mindset, combined with the difficulties of integrating new solutions into existing workflows, sometimes makes innovative solutions a hard sell. Innovation bolted onto existing workflows often fails to meet expectations, whilst re-engineering pathways across specialties can be extremely challenging.

"There is not enough collaboration between founders, healthcare providers, policymakers and regulators to understand the biggest pain points that need solving and achieving product-market fit with new solutions."

MARIA CARUANA - FOUNDERS FACTORY

Constructing your product strategy

A key decision digital health companies must address is to whether to cast their net wide and attempt to solve a number of problems, before doubling down on the most promising opportunities, or whether to concentrate on solving a highly specific problem.

Companies such as Avegen and Biofourmis have found success through their platformised product approaches that allow customers to leverage the modular nature of their platforms to solve a wide array of their different needs.

On the other end of the spectrum, companies with a niche focus have also experienced success. Ultromics is one such company, utilising AI capabilities to drastically improve the detection of complex heart failure and improve outcomes through early intervention. This narrow focus on solving an unmet need has seen them establish partnerships with an array of large payers, providers and collaborators including Mayo Clinic, the NHS and Northwestern Medicine.[2]

Clearly, there isn't one fixed route to success. However in order to make the best decisions when determining product strategy, digital health companies must ask themselves:

- Is one product enough to generate sustainable revenue?
- Will spreading resources across multiple use cases limit our ability to execute to a high standard?
- How competitive is this space in the market and is our offering differentiated?

"Knowing the right people who are going to be advocates for your solution is key if you want to get traction in a clinical setting, particularly within the digital health space."

MARC SERRA BARTRA - AXIAL BIOTECH

Building the right relationships

Many of the aforementioned challenges that are born from lack of knowledge sharing arise when companies fail to identify, establish and nurture relationships with key people and institutions. This results in difficulty gaining traction further down the line. A failure to appreciate the motivations of potential partners can also lead digital health companies to build the wrong solutions, or take products to market through the wrong route.

Academic expertise is highly valued within the healthcare ecosystem, making research institutes powerful partners for digital health companies to acquire. Relationships with key decision makers within healthcare providers has also been a key commonality amongst successful digital health companies. Trade associations provide a great environment to learn and connect with industry participants.

The most crucial aspect of relationship development is identifying potential partners that are mission aligned. When collaborators care about your solution, you gain engaged allies who proactively want you to succeed.

Drawing a map of the healthcare landscape

The healthcare industry is complex, meaning that an appreciation of the nuances within the space, and how these vary between different locations, therapeutic areas and product types is critical. Large corporates such as pharma often have an advantage given the wealth of experience brought by people within the business, but in a new space such as digital health, this knowledge may still need to be sourced externally.

Regulatory complexity is one of the biggest barriers to entry in healthcare as it is almost impossible to access the necessary knowledge online. Laura Vidal Borrell, founder of digital women's health startup Happy Sneeze, spoke of her experiences navigating regulatory frameworks, describing healthcare as an opaque industry. Knowledge is centralised among experts and insiders who can be difficult to access. She explained that this problem is compounded by investors, who often disregard "unsexy" lower-tech solutions regardless of them having the best product-market fit in the first place!

CASE STUDY

ULTROMICS™

Ultromics is a digital health company leveraging AI to build solutions that set new standards for world-class cardiovascular diagnostic tools.

Find key industry advocates

Ultromics struck early partnerships with key players (such as Mayo Clinic and the NHS) in its mission to improve cardiovascular disease detection. Founder Ross Upton emphasised the importance of establishing 1 or 2 key partnerships early on, and how building a successful partnership can be a catalyst for attracting future customers.

Ross highlighted the American Society of Echocardiography, along with Academic and Health Science Networks (AHSNs) as great resources to navigate the system. Reputation is an invaluable asset in building and utilising networks - many of Ross' connections were made through research work during and after his PhD in the field.

Partnerships bring both knowledge & commercial value

Ross explained that strategic partnerships were vital in giving Ultromics access to real world data for their first product, EchoGo Core, which applies AI and automates the diagnosis of echocardiograms. Meanwhile, he discussed how close collaboration with health systems enabled the validation of Ultromics' AI-powered software for the diagnosis of heart failure in a prospective clinical setting. Ross highlighted the immense value gained from working with the provider, to better understand clinicians needs, and the support they provided around navigating reimbursement and billing challenges. The time invested in nurturing individual partnerships creates a domino effect, opening the doors for successful partnerships with other providers in the future.

Build an ecosystem around your product

Ultromics understands that their innovation only plays a partial role in improving health outcomes of patients. While earlier and more accurate diagnosis is supremely beneficial for patients, earlier treatment intervention is also a crucial piece of the jigsaw. This creates ample scope for partnerships to collectively improve patients' lives.

Ultromics and Janssen Biotech announced a collaboration agreement in November 2021 to develop an AI-powered tool to identify patients with amyloidosis with cardiac involvement from routine echocardiograms. Janssen manufactures daratumumab, a drug that can be used to treat amyloidosis with cardiac involvement, thus the partnership greatly benefits both parties. Ultromics is also one of the 10 industry partners in the Accelerating Medicines Partnership Heart Failure (AMP HF), a public-private partnership that was launched with the goal of accelerating the development of new treatments for heart failure.

CASE STUDY

FOUNDERS FACTORY.

Founders Factory is a venture studio and early-stage investor, backing founders across the world with capital, dedicated support from a team of 70+ operators, and access to a coalition of market leading coroprate partners.

Brainy Breakfasts

Founders Factory organises regular breakfasts and networking sessions to bring together founders, investors and healthcare providers around a particular theme. The ambition is to drive forward the thinking and culture around the topic as they believe that product-market fit is the biggest challenge they observe around healthcare innovation; knowledge is not properly shared across the ecosystem.

NHS CLINICAL ENTREPRENEUR PROGRAMME

The NHS Clinical Entrepeneur programme is a free development programme with the aim of empowering healthcare professionals to engage in entrepreneurial pursuits whilst continuing to work in clinical roles.

Curated Community

The NHS Clinical Entrepreneur Programme is a competitive scheme, meaning that only successful applicants are invited to join each cohort and access the mentoring, networking and training on offer. While the programme is effective in helping applicants to develop ideas and build their personal network, it remains less impactful when it comes to tackling the challenge of building a product that can be scaled.

RECOMMENDATIONS

FOR ACQUIRING KNOWLEDGE TO BUILD RESILIENT OFFERINGS

DIGITAL HEALTH STARTUPS

01 Hire healthcare professionals

One of the most effective ways to fill knowledge gaps is to hire healthcare professionals, or those who have developed a robust network within the ecosystem. Livi, a leading provider of online healthcare was founded in the Nordics and is now established in the UK. The company appointed Juliet Bauer as their UK MD, who joined with almost two decades of experience in the healthcare system. Her experience from roles including Chief Digital Officer of NHS England undoubtedly helped Livi to navigate the intricacies of the UK healthcare landscape and gain traction.

02 Seek out advocates and community

Building the right professional network is essential for digital health startups to connect with potential customers, partners, and investors. Below are a few examples of great starting points for companies to build out their network:

- Tech UK - Health and social care team
- AHSN networks
- Medical Futures Awards
- Health Professional Network
- Global Digital Health Network

CORPORATES

03 Develop an ecosystem strategy

The knowledge gap that digital startups face presents an opportunity for corporates to engage in partnerships that offer ample value exchange. Beyond a revenue stream, corporates have extensive and established channels to market, along with teams that are experienced in navigating areas such as regulation. This value add can attract collaboration with digital health companies that can enhance core products and key business processes as well as help expand into adjacent markets.

04 Narrow focus to the biggest long-term opportunities

Focusing time, money and attention on the most pressing issues that you can solve will allow corporates to identify knowledge gaps and understand how to address them. For example, shifting towards preventative health and early diagnosis can be strategic for pharma companies, capturing new revenue and protecting the core from future disruption.

Chapter 3

GEOGRAPHIC FRAGMENTATION

Local differences in healthcare delivery have spawned operational inefficiencies and regulatory discrepancies, making it difficult to navigate and plan accordingly

PROBLEM SNAPSHOT

In the UK, the NHS is often seen as a single entity, when in reality it is comprised of **42 integrated care boards (ICBs)**, beneath which sit **229 trusts, 515 hospitals, 826 community health providers and 6,925 GP practices.**[1]

IDEATION **BUILDING** **FUNDING** **ADOPTION**

Geographic fragmentation inhibits rapid growth across geographies

Language, culture, operational models, regulation, tech stacks and data privacy - just some of the regional differences that can make it challenging to enter a new geography. This vast complexity means that a digital health solution, or even an entire business model that works in one setting may be a complete not-starter in another environment. This largely explains why we've not seen any rapidly scaling disruptors (such as Uber or Airbnb) in healthcare to date.

Regulatory complexities are one of the biggest barriers to scale

Healthcare is understandably a highly regulated space, a barrier that is only exacerbated by each country, and even individual hospital, having its own set of processes governing the development and adoption of digital health products.

Marc at Axial Biotech asserts that in his experience "regulatory compliance is the area that is least understood by founders - navigating this space is one of the key values that accelerators can provide".

Marc explained that the approval process is saturated too - "it can take 12-24 months to get CE marked for a Class 2a device". Repeating this across multiple geographies is expensive and time-consuming.

Cultural differences between countries should not be underestimated

Different nations not only have individual healthcare systems, but also contrasting attitudes towards health more broadly, and how care should be delivered.

UK MD at Doctrin, Craig Oates, has observed that founders are often naive to the impact of cultural differences. "Many innovators and startups have a bright idea, but assume every health service is the same. Differences in language and mindset create tension or misunderstanding, meaning deep knowledge of the system is vital when entering a new market".

"Healthcare is the least disrupted industry by technology due to issues with interoperability - entering new markets is only really feasible when you have scale due to the huge resource requirement"

DR LESLIE DICKSON-TETTEH - CHERUB

Deploying a one-size-fits-all solution is rarely a viable option

Geographical fragmentation is even a problem at a country level. Regional variation manifests in the form of disjointed data, inconsistent infrastructure and operational discrepancies from provider to provider. This often makes it incredibly difficult to scale a single solution as it is expensive and arduous to individually integrate with providers. There is both a lack of know-how and technological capabilities to scale efficiently in this way.

Dr Leslie Dickson-Tetteh, founder of Cherub, a platform to help physicians optimise patient medications, described his experience building a new digital health solution from scratch. He commented that "geographical fragmentation means products must be tailored to the market and use case", meaning that multiple variants of Cherub's solution will need to be created to achieve scale.

Legacy infrastructure is the primary cause of operational variability - meaning greenfield opportunities in developing countries can be more appealing for innovators. Consolidating operational and clinical processes can encourage innovation and ultimately lower the cost of care delivery.

The US is seen as more commercially attractive than Europe, but is not without its challenges

Digital health companies often assess the viability of expanding in the US or in Europe. The greater operational and cultural fragmentation across European markets, combined with factors such as lower reimbursement rates and less maturity across investment and adoption, makes the US appear a more attractive market for digital health companies to attempt to grow and expand in. However, substantial variation also exists across different states in the US, in a manner that is not too dissimilar from Europe.

Despite the fragmentation challenges, Chris Ross, founder of oncology startup Thyia, tipped the US as a more favourable region to expand given the shared language and growing tendency to share legal frameworks between different states.

Chris also pointed to differences in the funding model compared to European counterparts. Privatised systems like the US with healthcare insurers are incentivised to drive innovation, while in the UK there isn't the same infrastructure or motivation to adopt new solutions, especially if changing will drive health inequities.

CASE STUDY

Min Doktor

Docly (a spin-off from Min Doktor) is a Swedish telehealth platform that enables patients to book appointments, order prescriptions and reach healthcare professionals via video consultations.

Geographic expansion is expensive

Min Doktor spin-out Docly embarked on a mission to rapidly expand into new geographies, discovering just how difficult it is to build a pan-European healthcare business when piloting services in the UK, France and the Netherlands.

Docly underestimated the capital and resources required to successful expand into a new market. This led to an initial focus on the UK market, with insights suggesting that regulation and reimbursement would pose greater difficulties in France and the Netherlands. However, without the financial muscle to deliver they had to retreat from the UK market too, struggling in comparison to better funded doctor-on-demand startups such as Babylon and Kry. It is worth noting that Babylon declared bankruptcy in 2023, whilst Kry has faced strong headwinds, reflecting the capital-intensive nature of rapid, cross-geography scaling amidst profitability challenges.

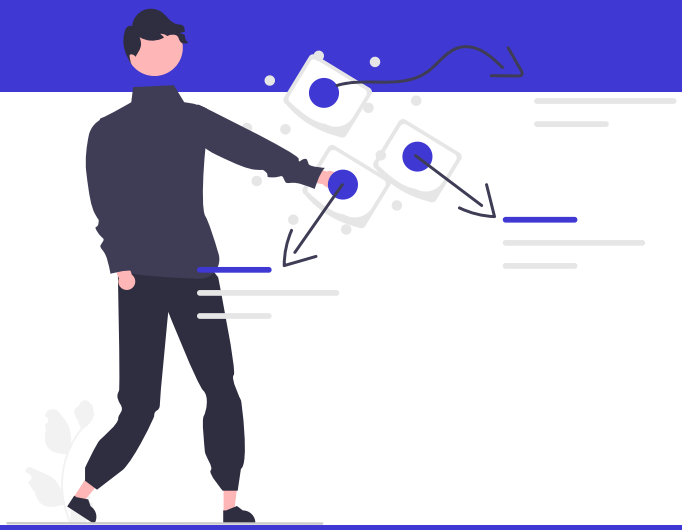
Doctolib

Doctolib is a French telehealth platform that helps doctors manage appointments, refer patients to colleagues and exchange patient information online.

Acquisition can simplify geographical expansion

Doctolib, another telehealth provider, pursued a different course for their expansion. In 2021, they were operating in France and Germany, and wanted to expand into Italy. However, rather than expanding organically, they decided to acquire Dottori, a competitor with established operations in the Italian market, enabling Doctolib to leverage Dottori's existing infrastructure, knowledge and local relationships.

While M&A isn't a viable option for all companies, particularly early-stage startups, it can be a sensible route to pursue for high-growth startups and large corporates looking to expand into new markets. Depending on strategic priorities, conviction in the opportunity and available finances, the optimal approach could range from startup partnership or joint venture, to acquisition or investment in organic growth.



CASE STUDY

Lumeon orchestrates care delivery through their AI-powered platform which uses machine learning to automate tasks such as appointment scheduling and care plan management.

Lumeon orchestrates healthcare systems

Healthcare delivery today is wildly inconsistent with enormous clinical and operational variation, meaning that quality can be unpredictable. Lumeon helps to automate best practices and scale these across care teams through a digital platform, bringing both personalisation and standardisation to delivery pathways.

We need a common operating model

Lumeon founder, Robbie Hughes, explained that physicians have been culturally engineered to sit at the centre of decision-making, meaning that clinical pathways, operational models and reimbursement pathways are all built around individual ways of working. Solutions that can be scaled effectively are those that narrow the parameters of variation such that they are inconsequential.

Combatting fragmentation requires long-term planning

With governments changing every few years, there is limited opportunity or incentive to plan healthcare delivery over a longer time horizon. This problem is compounded in the US by annual insurance enrolment which disincentivises taking a long-term view on care. Service providers should take inspiration from "franchised" services such as national screening programmes that have a standard operating model.

RECOMMENDATIONS

FOR SUCCESFUL GEOGRAPHIC EXPANSION

DIGITAL HEALTH STARTUPS

01 **Do your homework early**

Thorough due diligence is a requirement, and it takes time. Given the stakes, it is essential to make informed decisions about where are the most promising places to invest time and resources. This extends beyond identification of the market size and opportunity; rather it should consider areas such as regulation, reimbursement rates and existing competition.

02 **Strike a balance between market size and strategic partnerships**

Given the number of complexities and barriers to launching and securing market share, digital health companies can benefit from careful curation of strategic partners who can bring credibility and accelerate adoption when looking to expand in competitive markets.

CORPORATES

03 **Support digital health companies in their expansion plans**

Corporates have an opportunity to become key expansion partners by leveraging their network, know-how, and existing operations, particularly around regulation. Piloting digital products or services with startups can be a mutually beneficial exercise, allowing corporates to derive new learnings in an agile way, whilst unlocking revenue and growth opportunities for startups.

04 **Invest in critical technology**

Procuring or developing technology that supports hyper-customisation can be a key enabler to delivering at scale by creating a backbone from which digital health products can be adapted to varied geographies.

EVERYONE

05 **Consider alternative routes for expansion**

As with any major decision, there are both financial & commercial options to consider. Based on your due diligence, strategic priorities and resources, different expansion options, such as M&A or partnerships, may be better suited to short-term and long-term goals than organic growth.

Chapter 4

CONSTRAINED COMMERCIAL MODELS

Existing reimbursement structures within healthcare are rigid, often making innovative solutions commercially unviable

PROBLEM SNAPSHOT

63% of surveyed digital health companies view **limited reimbursement options** as the biggest barrier to monetising their solutions.[1]

IDEATION BUILDING **FUNDING** **ADOPTION**

Integrating with core healthcare systems is the leading approach to monetising digital health

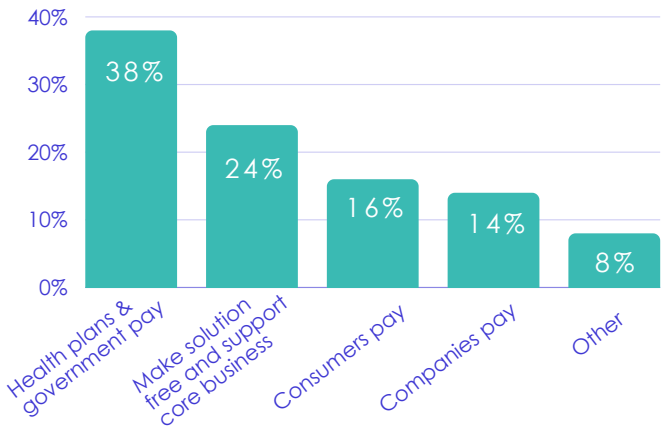
Survey data indicates that 38% of digital health companies view payers and providers as the best approach to monetising their solutions, ahead of alternatives such as seeking revenue from companies or directly from consumers.[2]

Investors at firstminute capital have noted that many startups naively enter the industry with business models too heavily focused on D2C. Instead, leveraging D2C pathways to attract customers and gather data on clinical efficacy, with the goal of accessing healthcare provider reimbursement in the longer-term, represents a better business strategy in most cases.

However, archaic reimbursement models, which are typically saddled with procedural complexities, low rates and suboptimal incentive mechanisms, can make this a challenging route to commercial viability. This may at least partially explain why only 2% of global healthcare spending is going towards digital health companies.[3]

Laura Vidal Borrell, Founder of Happy Sneeze, highlighted how reimbursement models in the US are at odds with digital health solutions. Fee-for-service payment models and billing codes force many startups to add unnecessary complexity to their core product as digital services alone generally do not qualify for reimbursement. Similar issues can be seen in funding pathways across the globe.

WHAT IS THE BEST APPROACH TO MONETISE DIGITAL HEALTH SOLUTIONS?



Source: Research2Guidance - Monetizing Digital Health Solutions (2023)

"Across global healthcare systems, there are a lack of payment models that match the delivery system and innovation that you're providing."

LAURA VIDAL BORRELL - HAPPY SNEEZE

Qualification for reimbursement tends to be a lengthy and rigorous process

Understanding the requirements to obtain reimbursement from healthcare providers is an extensive process due to the lack of standardisation at a country level and amongst different payers. Nonetheless, digital health reimbursement pathways often have key steps in common:

- Assessments to ensure compliance with data policies and interoperability standards
- Rigorous review of clinical evidence and socio-economic benefits
- Negotiation of reimbursement pathway, pricing and contract duration

Alternatives to the standard reimbursement pathway are more attractive

Payers are not oblivious to the challenges presented by traditional modes of reimbursement, which has spawned new pathways. However, specific digital health codes and contracts remain nascent.

52% of digital health companies cited digital health codes and selective contracts as a more promising monetisation route than the standard pathway, both seen as favourable to standard reimbursement pathways. [4] Reimbursement code engineering, where solutions are built around existing codes, is generally seen as a less favourable approach as it can compromise the solution itself.

Countries are recognising the challenge posed by rigid reimbursement

Based on survey findings, the USA is seen as the country with the most reimbursement potential for digital health, followed by Germany and the UK. While there are indeed complexities and flaws in the US reimbursement pathway, the size of the addressable market remains highly appealing for digital health providers. In addition, the availability of codes for telehealth, remote monitoring and virtual care are the most comprehensive and lucrative of all countries.

TOP RANKED COUNTRIES FOR DIGITAL HEALTH REIMBURSEMENT POTENTIAL

1ST 2ND 3RD

Source: Research2Guidance - Monetizing Digital Health Solutions (2023)

Germany was the first country to launch a purpose-built digital health app reimbursement pathway, known as DiGA, which includes a fast-track process for apps to be provisionally listed for up to 12 months without robust clinical evidence on efficacy.

Several European countries have since followed suit in implementing standardised reimbursement pathways for digital health apps and medical devices. In the UK, applicants must navigate NICE guidance to receive recommendation and reimbursement, although there is now a fast-track process called Early Value Assessment. France launched a fast-track process called PECAN in 2023 to accelerate market access for digital health products too.

DiGA is a step in the right direction, but is not a perfect pathway for reimbursement

One of the emerging problems with DiGA is the negotiation of prices between digital health companies and insurers. DiGA companies tend to initially charge higher prices for their products, reflecting both the cost of ensuring commercial viability and perceived patient value of their solution. Yet insurers demand far lower prices after 12 months, when statutory insurance ceases to pay the price set by the developer.

The negotiation of prices between digital health companies and insurers is a complex process which currently lacks transparency. However, what is clear is that the final price set for approved DiGA's tends to be within the range of 170€ to 250€. The lack of variance in this final price has raised questions over the process, as it seems unlikely the true value of diverse digital health solutions falls within such a narrow range. [5]

PRICING OF DIGITAL HEALTH PRODUCTS THROUGH THE DIGA PATHWAY

Source: Flying Health DiGA watchlist (2023)

CASE STUDY

aidhere x DiGA

Aidhere is a German healthcare technology company that aims to sustainably improve the health and quality of patient's lives by developing holistic digital therapeutics based on nutrition, behaviour, and exercise.

DiGA: Germany's innovative legislation

The Digital Healthcare Act is a German law that came into place in 2019, enabling doctors to prescribe digital health applications (DiGAs) to patients. This law created a direct route for digital health companies to receive reimbursement from the 110 public health insurers in Germany.

Huge potential for change

The potential benefits of Germany's proactive legislation are numerous:

- Patients have access to a wider range of digital health technologies that can help them manage their health
- DiGAs can help to improve patient outcomes and therefore reduce costs, whilst simultaneously alleviating some of the burden on doctors and nurses
- Digital health companies have a standardised reimbursement pathway to navigate, incentivising innovation by removing major barriers

Aidhere bankruptcy shows DiGA imperfections

DiGA allows companies to set their own prices for their digital health products, however, after 12 months, the price is negotiated with the insurers' representative body. This has led to startups being compelled to lower their prices by as much as 60%. One such example is Aidhere, who were forced to lower the price of their obesity treatment app, Zanadio, from €500 to €218, resulting in an €8m hole in the startup's finances. [6]

The problem emerged after protracted price negotiations with health insurers left the company with a product that was no longer financially viable. Aidhere's founder, Henrik Emmert, believes that current negotiation system is suboptimal and there should be a stronger connection between price and benefit of the DiGAs. As it stands, regardless of their medical benefit, all DiGAs are priced similarly. Insurers are unwilling to pay high prices for DiGA products, arguing that they are new, unproven, and should be priced lower than traditional medical treatments. Ensuring that companies are reimbursed through a fair and transparent process, that reflects not just the immediate patient benefit, but the long-term cost savings too, is crucial to future success.

CASE STUDY

Little Journey is a digital health company that supports children to better health by providing engaging, interactive content designed to psychologically prepare and support families throughout healthcare treatments.

NHS reimbursement provides limited revenue

Little Journey has been transformative for children and their families - their solution has delivered a 32% reduction in pre-operative anxiety levels for children with autism and ADHD and a 42% reduction in on-the-day surgery cancellations. A cost-benefit analysis showed that for every £1 spent on Little Journey there was a £3.50 saving for healthcare organisations. Founder Chris Evans explained that this health economic data was vital to their successful integration across 50 NHS Trusts.[7]

Despite the clear benefit for care providers, Chris explained that only 5% of Little Journey's revenue is generated through this avenue. While the NHS is great for building traction, accumulating data and proving the use case, it isn't a commercially attractive partner. The margins are incredibly low, meaning that it's difficult to achieve profitability without substantial scale. This stems back to the broader issue around the funding of healthcare delivery - NHS Trusts have limited spending capacity to reimburse digital health companies, even when the long-term benefits are clear.

Little Journey is currently preparing to expand its offering into the US healthcare system, which provides superior reimbursement rates to the UK. Much of this is driven by better product-market fit - patient experience is more important to providers in the US due to the competition between private providers. This means that solutions such as Little Journey that positively impact patients can increase customer retention.

Pharma pays the bills

The remaining 95% of Little Journey's revenue is largely derived from pharmaceutical companies, whom they assist in both clinical trials and the post-market authorisation of drugs and medical devices to monitor the safety and efficacy of the drug in the real-world setting. Their age-appropriate content reduces patient drop-out rates by supporting children and families, which is of huge financial benefit to pharma companies given the expense associated with bringing new products to market.

Chris has found that pharma offers faster sales cycles, larger contract values and swifter integration compared with NHS partnerships. Additionally, each project helps Little Journey to build out modular components that make their offering more comprehensive and cheaper to deploy.

RECOMMENDATIONS

FOR NAVIGATING THE PATH TO PROFITABILITY

DIGITAL HEALTH STARTUPS

01 **Consider routes to profitability that circumvent complex reimbursement pathways**

Provider reimbursement pathways often offer suboptimal monetisation opportunities for many digital health companies in the beginning. Startups such as Little Journey and Avegen have demonstrated success by turning to pharma companies as their primary revenue source. Targeting privatised sectors such as mental health & fertility, where payment falls on corporates or consumers, can be another way to optimise reimbursement.

02 **Invest in advisory support prior to reimbursement approvals**

Reimbursement is undoubtedly one of the most important areas to source external expertise for growing digital health companies - understanding the process helps to inform how you build your business. Ultromics founder, Ross Upton, noted that "it's very easy to shoot yourself in the foot before you even apply for reimbursement". Within the UK there are organisations such as ORCHA and Hardian Health who offer services to support digital health propositions in navigating the reimbursement space.

03 **Be strategic in managing your burn rate**

Mohammad Al-Ubaydli, founder of digital data platform Patients Know Best, placed a huge emphasis on the fact that the company has been able to conserve their spending as a critical component to their success. When developing a digital health offering that is reliant on close collaboration with public healthcare bodies, slow progress and low reimbursement are inevitable. Operating with a low burn rate provides an edge over competitors by increasing endurance and building trust through longevity.

CORPORATES

04 **Identify emerging digital health companies and ecosystem partners aligned with your objectives**

Through our past work with global pharma companies, we've seen the key role that innovation teams play in bridging the gap between digital technology and the company's strategic objectives. Through continuous market scanning, corporates can identify solutions to improve core business activities such as drug discovery and product commercialisation. Janssen's partnership with digital health company Ultromics to co-develop an AI tool to screen for heart failure, perfectly illustrates how these relationships can be symbiotic, helping Janssen to increase revenues from cutting-edge heart failure treatments. Exploring B2B commercial approaches can augment existing care delivery, diversify revenue streams, and unlock new growth.

Chapter 5

UNREALISTIC GROWTH TARGETS

The traditional VC model is built around rapid growth, clashing with the longer product development cycles required to bring a digital health solution to market

Problem Snapshot

The top performing healthcare SaaS businesses take roughly 5.5 years to reach $10 million ARR, & 8.5 years to reach $100 million ARR, **much longer than tech-enabled services**, which scale to $10 million ARR in under 2 years & $100 million ARR after roughly 5 years. [1]

IDEATION BUILDING **FUNDING** **ADOPTION**

VC growth targets and return expectations can be unrealistic for digital health startups

The VC model is anchored around the prevailing assumption that the majority of startups in a portfolio will fail, with returns on a small number of highly successful businesses more than covering the losses. This mindset places an emphasis on rapid growth, with many successful venture-backed startups unlocking success through aggressive scaling.

As a result, VC expectations around the pace of growth are often at odds with what digital health startups can realistically achieve, driven by arduous compliance requirements, long sales cycles and market fragmentation. This can lead to overly ambitious milestones, creating tension at best, or failure at worst, when startups spread themselves too thin or burn through cash too quickly.

From a recent survey of 87 early-stage digital health startups run by Rock Health, there is evidence that is a current underestimation of CAC and overestimation of LTV.[2] These numbers are typically educated guesses that are overly optimistic, therefore creating unrealistic targets for these startups. Clearly, investors cannot apply the same principles to healthcare as they do to retail or even finance. Growth rate and commercial metrics need to be contextualised with revenue harder to capture.

Investors who understand the healthcare space generally make the best partners

Through our conversations with founders, a common thread has been the crucial nature of finding investors who understand the unique challenges within healthcare.

Many VCs are put off the UK market due to low reimbursement rates for digital health from the NHS, whilst others neglect low-tech or human-centric solutions that are viewed as less innovative.

Finding an investor who is aligned with your vision is critical - avoid narrow-minded VCs who are hellbent on fancy technology and only interested in the US market!

> **"Healthcare is a different beast and only those VCs with domain-specific expertise in the industry will have realistic expectations around growth targets"**
>
> JACKIE ROEPERS - BIRDIE

CASE STUDY

avegen

Avegen is a purpose-led health company with a unique approach to creating digital health solutions that deliver value for partners.

Strap up your boots!

Avegen struggled to attract investment from VCs in their early days, with founder Nayan Kalnad telling us that they "couldn't raise funding from VCs because of their dismissive approach to the platform". This led them to bootstrap the company (build a business without the injection of external capital), a pathway that they would recommend for the early phases.

Upfront customer payment can cover building costs

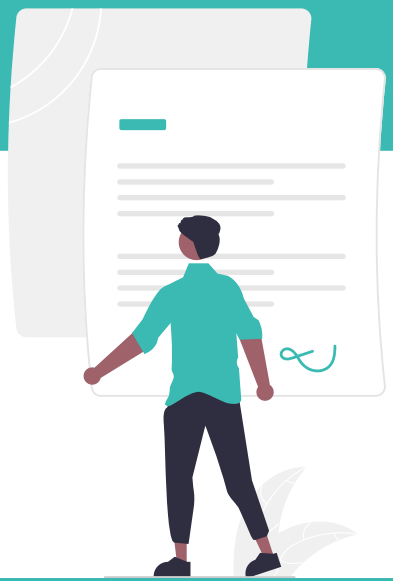
There's a general tendency within VC-backed tech companies to focus on building the product first, then looking to sell to customers once the solution is mature. However, securing customers before investing in the product is a great alternative avenue for companies that are bootstrapping. Nayan used funds from Avegen's first customers to cover build costs, mitigating the need for VC investment while generating organic revenue streams.

Pharma partnerships can trump VC funding

Having spent over a decade working in the pharmaceutical industry, Nayan's network in the space made it a natural place to build connections, a decision that would prove very effective. Avegen have since partnered with multiple pharma giants to produce a suite of digital health products across their key focus areas: Mental Health, Maternal Health, Infectious Disease, Cardiovascular and Metabolics. Nayan cited the benefits of earning credibility and trust through executing for one partner at first, rather than spreading yourself too thin early on.

Stay as lean as possible for as long as possible

Nayan described how Avegen was able maintain strategic autonomy in the absence of external investors. This agility enabled Avegen to rapidly test propositions and find product-market fit before turning their attention to scaling further down the line. While investors can undoubtedly provide invaluable strategic guidance, they must be aligned with the company vision to avoid conflict when pivoting or iterating the solution.



CASE STUDY

firstminute capital

firstminute capital is a leading venture capital firm that is committed to backing seed-stage founders with magnetic ambition.

Lesson 1: Temper expectations around ARR

As an investor in healthcare, it is vital to have a different mindset due to the long sales cycles needed to integrate across clunky systems and opacity around regulations. It is important to avoid comparisons to other industries in which rapid growth is more feasible.

Lesson 2: Focus on meaningful metrics

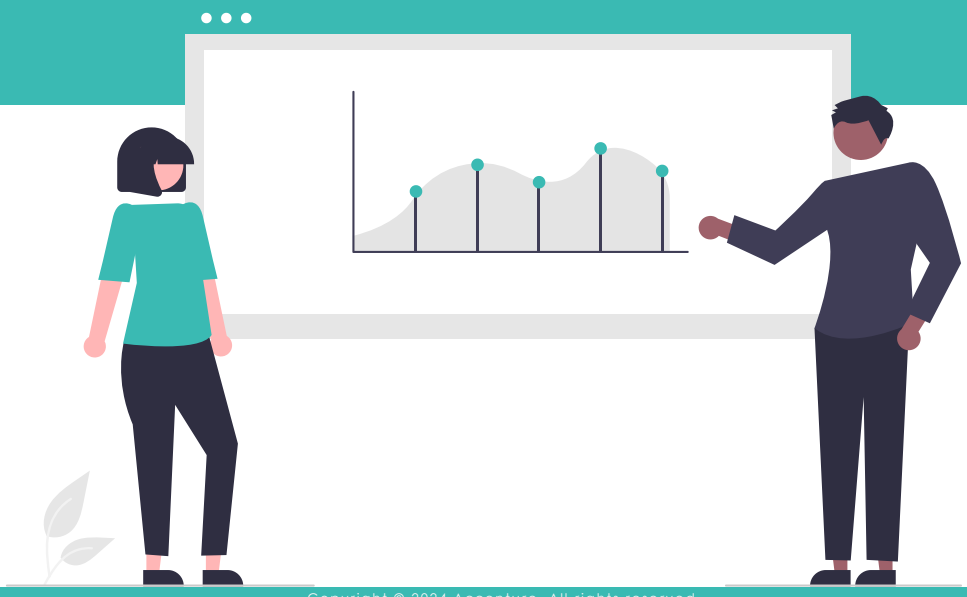
Given the recent high-profile failures in the healthcare space, particularly at later stages, startups need evidence of traction and meaningful metrics as investors are now more cautious and set the bar higher. However, this can be difficult as data on healthcare outcomes in particular can be very time-consuming to obtain. Focusing on self-reported data or commercial metrics can be an effective approach to demonstrating efficacy.

Lesson 3: Maximise runway

At early-stage, venture investment has been impacted to a lesser extent by current macroeconomic uncertainty, with VC spreading their bets. A key contributing factor to the resilience of early-stage investment is talent leaving corporate roles to build something new. For founders to stand out from the crowd, they need to think sensibly about how they can maximise their runway in a slow-moving space.

Lesson 4: Target privatised industries

One way to circumvent clunky reimbursement pathways is by targeting underfunded therapeutic areas that are typically paid for by patients themselves, such as fertility and mental health. The combination of patient demand and lack of established reimbursement pathways can make it easier to scale in these spaces.



RECOMMENDATIONS

FOR FINDING THE PERFECT INVESTOR FIT

DIGITAL HEALTH STARTUPS

01 Seek investment from those who understand the healthcare industry

By doing your research and finding the right investors, you can increase your chances of success. There are a number of VCs that have more realistic expectations of revenue targets and deeper understanding of the regulatory landscape. Focusing on core competencies, rather than trying to be a one stop shop for healthcare, will resonate with investors who know the space.

For instance, digital health solutions classified as Software as a Medical Device (SaMD) bring higher cost and time requirements to deploy. Hakim Yadi, founder of SaMD startup Closed Loop Medicine, explained that having investors on-board who understand the complexity of their solution is enabling them to build a sustainable business.

02 Explore non-conventional funding routes

There are a number of non-conventional funding routes that offer unique benefits to healthcare startups. These include bootstrapping at early-stage, seeking angel investors, joining an accelerator, or collaborating with a large corporate (e.g. pharma). Exploring partnership approaches with existing market players, including revenue and risk sharing models, can often lead to faster growth. Grants can also provide funding for research and proposition development, some of which are listed below:

- NIH Director's New Innovator Award
- Medtech Innovator Global Challenge
- Wellcome - Research Funding

CORPORATES

03 Create or enhance a CVC offering for startups

Corporates can capitalise on the friction between traditional VCs and digital health companies, by offering an alternative avenue for funding through CVC propositions. Pharma companies are well-placed to address many of the challenges that traditional VC cannot, such as navigating complex regulatory pathways and building relationships with healthcare payers

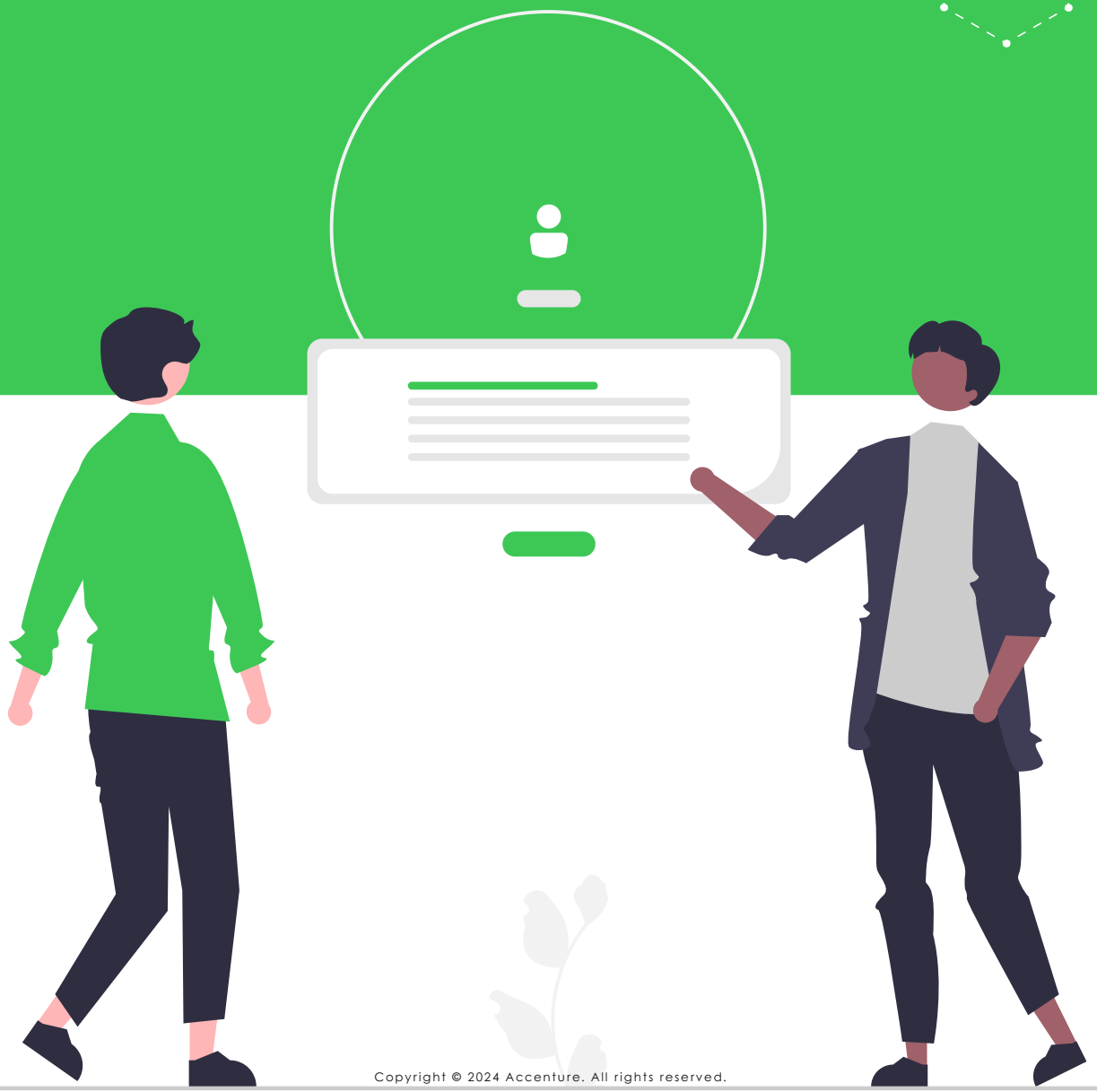
Multiple pharma companies have developed venture arms to invest in early stage companies and build relationships with startups. By gaining access to new technologies & therapies, new revenue lines can be unlocked. Successful CVCs tend to exhibit the following characteristics:

- Clear investment thesis
- Long-term horizon
- Channels to leverage expertise and networks within the core business

Chapter 6

LACK OF EVIDENCE

Digital health solutions struggle to gain widespread traction unless impact is clearly evidenced and proven



PROBLEM SNAPSHOT

44% of venture-backed digital health companies were found to have a **clinical robustness score of 0**, while only 20% had a clinical robustness score of more than 5/10.[1]

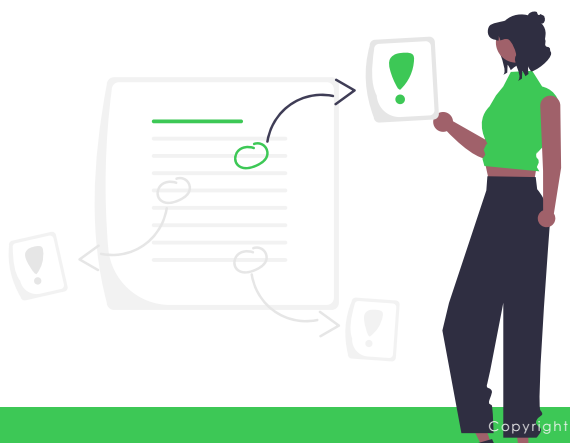
IDEATION BUILDING **FUNDING** **ADOPTION**

Gathering the necessary evidence to build trust is highly challenging

Medicine is an evidence-based industry, with current care pathways informed by critical evaluation of the safety and efficacy of diagnostics and interventions. Data is therefore fundamental for the approval of any digital health solution, needing to meet rigorous standards to be trusted by healthcare professionals.

Obtaining the requisite evidence can be an uphill struggle for startups. Randomised-controlled trials (RCTs), generally seen as the gold-standard for clinical research, are time-consuming and expensive to run. This leads many early-stage digital health companies to turn to self-reported data, which lacks the same degree of clinical robustness.

Given the interwoven nature of data and trust, this has created skepticism around digital therapeutics amongst clinicians. In fact, 47% of German doctors did not intend to prescribe DiGA when surveyed in 2022, with lack of scientifically proven efficacy cited as the most important reason for this.[2]



Choosing the right end-point to prove efficacy is key to adoption

General skepticism around the impact of digital health solutions has led many startups to focus on non-clinical metrics - cost savings are easier to prove than life-saving efficacy!

Prova Health is an innovative startup trying to help digital health solutions generate robust clinical evidence in a pragmatic manner. RCTs are generally not appropriate or feasible at MVP stage, with alternatives such as clinical simulations hugely valuable in enabling early-stage companies to validate and optimise their solution with real-world users.

Given that the digital health space is still relatively nascent in terms of clinical integration, long-term benefits are not yet conclusive. Creating standardised metrics to prove clinical impact & efficacy will be essential, along with educating doctors around the evaluation of digital solutions.

"It's much easier to show that a new solution saves money compared with saving lives - it can be too time consuming and expensive for early-stage startups to build robust evidence on clinical efficacy"

LESLIE DICKSON-TETTEH - CHERUB

CASE STUDY

Closed Loop Medicine

Closed Loop Medicine is integrating pharmaceuticals and digital therapeutics into a single prescription to unlock precision medicine through optimised drug dosing and personalised digital experiences.

Digital Health doesn't exist - it is just healthcare!

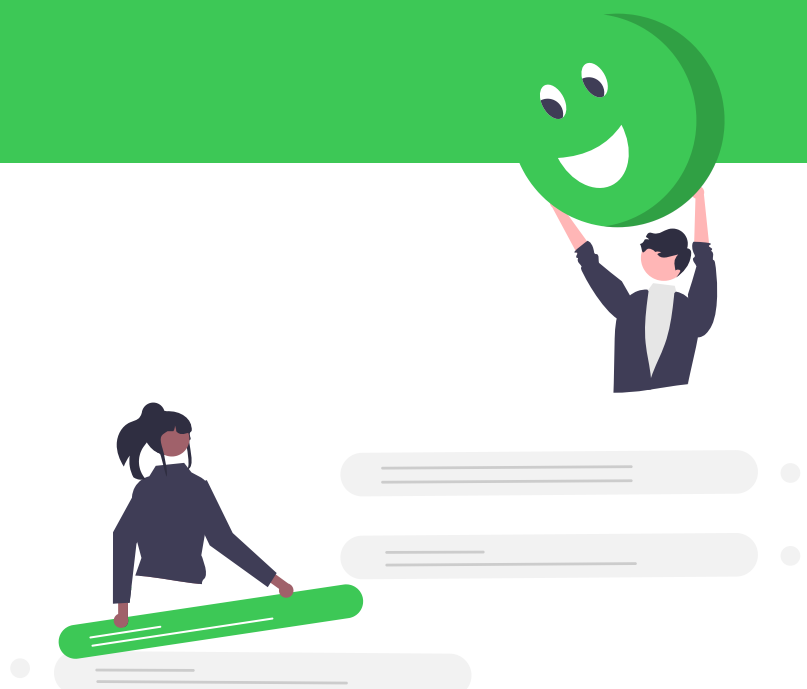
We spoke with the co-founder of Closed Loop Medicine, Hakim Yadi, who feels that the language around digital health is currently dangerous in its lack of specificity. Wellness apps and software-as-a-medical-device are worlds apart - it's like comparing a DTC fitness app with a pharma company! Closed Loop Medicine is constructing a highly complex and specialised device, so formalised nomenclature is necessary to build understanding and trust around their product.

Medical students should learn how to prescribe apps

Every clinician knows how to write a prescription for a drug, but very few understand how to do the same for an app. Until digital health becomes a cornerstone of the medical school curriculum, it is inevitable that a lack of understanding, and ultimately trust, will mean most doctors are not inclined to become advocates. Hakim believes that the 100,000 Genomes Project sets an example for how we should tackle the lack of trust around novel technologies such as digital health, where a proportion of the 100,000 Genomes Project budget was allocated for the education of clinicians.

Citizens Juries are an effective tool for building trust

Hakim previously worked on Connected Health Cities, a four-year pilot program funded by the UK government to improve data sharing practices within healthcare. He felt that Citizens Juries, where a diverse group of people are educated on a topic and asked to reach a verdict on the most appropriate policy decisions, are the most effective tool he has seen in action for overcoming a lack of trust. The opinions of real patients are needed to convince the wider public that new and innovative solutions should be embraced within healthcare.



CASE STUDY

PATIENTS KNOW BEST®
MANAGE YOUR HEALTH

Patients Know Best creates a secure personal health record that gives patients control of their own medical data, facilitating sharing with health and social care providers.

Covid-19 as a catalyst

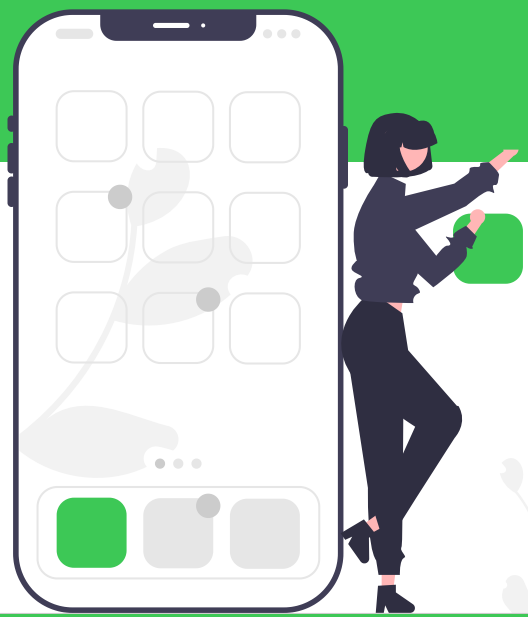
Mohammad Al-Ubaydli founded Patients Know Best in 2008 to solve the problem that patient records cannot be shared between different healthcare providers. Wider adoption took more than a decade, with the global COVID-19 pandemic providing the urgency for decision-makers to better share health information. Building trust with key stakeholders was a vital unlock for Patients Know Best - Mohammad's advice to startups is to forge strong relationships with potential customers and demonstrate how you can be an asset to them.

Open Banking for healthcare

Open Banking has been a revelation in the finance space, enabling customers to grant permission for their financial data to be shared between banks. Patients Know Best view this as a great analogy for their vision within healthcare, pitching to governments around the globe as a provider of open banking infrastructure for medical data. This can accelerate innovation by making it easier for startups and corporates to access patient data, whilst building trust through greater transparency and by giving patients more control.

Better Data, Better Evidence

3.6 million patients manage their records through PKB, a figure that is forecasted to exceed 5 million before the end of 2024. PKB receives 15-20 million NHS test results every month along with SNOMED and DM+D codes, vital data for qualifying patients for clinical trials. Patients can share the data in their PKB record whenever they want, for as long as they want. The patient can choose researchers, health care providers, family members and technology companies they trust. This can be a key enabler in generating robust evidence for future digital health products.



RECOMMENDATIONS

FOR BRIDGING THE EVIDENCE GAP

DIGITAL HEALTH STARTUPS

01 Forge relationships with key institutions

Ultimately, the ability to build trust with healthcare providers and payers will determine the adoption of digital health solutions. Startups can receive feedback on their solutions, educate the ecosystem on the benefits of their product and foster a deeper understanding of the evidence needed to secure reimbursement. Academic institutions can also be invaluable partners access data and collaborate with academic researchers. Their endorsement can help persuade healthcare providers to adopt digital health solutions.

02 Establish a dedicated path to evidence generation

Startups should frame their growth strategy around data generation, acquisition and monetisation. In addition to providing evidence around efficacy, a clear data strategy will incentivise investors and provide rationale for any pivoting in the underlying product or business model.

03 Generate trust amongst doctors and patients

Beyond the need to provide robust evidence, digital health startups face the challenge of influencing existing opinions of clinicians and patients. Citizens Juries are one such way to overcome this problem - by immersing a diverse group of patients in a specific policy area, informed decisions can be reached that reflect the sentiment of the general public. A similar approach could be highly impactful in building trust in digital health.

CORPORATES

04 Engage with HCPs around digital health

Pharma companies can tap into their existing relationships with healthcare professionals to educate clinicians on the value of digital solutions. Focusing energy on product launches that connect new drugs with a digital service can remove some of the friction around the adoption of these products.

HEALTH CARE PROVIDERS

05 Validation-as-a-service

In the UK, the NHS currently offers a limited service called the Test Beds Programme which is aiming to bring NHS organisations and industry partners together to test and validate combinations of digital technologies with pathway redesign in real-world settings. Initiatives to expedite validation with transferability between different clinical settings can be transformative in building trust with healthcare providers and helping digital health to scale.

CONCLUSION

Through the challenges laid out in this white paper, it is clear that scaling innovation in digital health faces a plethora of obstacles, many of which are unique to the healthcare space. However, the success stories that we have seen and the solutions that we propose provide us with optimism that we can create an ecosystem that incentivises innovative ideas and enables them to benefit patients. To achieve this, it is clear that individual and collective strategies are needed by all stakeholders within the space to carve more effective routes to adoption.

Strategy can be stripped down to three core principles:

1. Identifying the key changes that need to be made
2. Motivating people to build a better ecosystem
3. Developing an innovation mindset that is backed by core technology

Digital Health Companies

Product adoption in the healthcare space rarely hinges on the potential value that the solution can bring to patients, but rather on the company's ability to convince providers, payers and corporates that it is the right thing to be building.

Digital health companies should begin by articulating a clear vision, seeking first to understand the motivations and focus areas of decision-makers, and feeding these insights into their product development and strategy. It is easier to gain traction by identifying stakeholders who align with your vision, and collaborating with them to refine your product-market fit. Ultimately, building a strong network within the digital health space is the key unlock for achieving scale.

Investors

Investors who have limited knowledge of the healthcare ecosystem can sometimes hinder rather than enable innovation, backing startups that are not best placed to succeed in the complex healthcare space, or bringing unrealistic expectations around growth targets. VCs need to ensure they understand the nuances of the healthcare landscape before investing, rather than treating the space like any other. Meanwhile, founders need transparent relationships with their investors to ensure alignment around vision and scale.

Corporates

There is huge untapped opportunity for large corporates in collaborating with digital health startups and forging strong partnerships. The value and resources that pharma companies in particular can offer, through funding, expertise and network access, is highly desirable given the barriers to scale facing startups.

The value exchange is mutually beneficial, with digital health not only offering new growth opportunities, but arguably being a strategically vital area for pharma companies to explore to avoid future disruption. Strong relationships with the startup ecosystem can allow corporates to rapidly experiment in the digital health space, with long-term partnerships or acquisition representing potential delivery pathways when conviction in an opportunity is high.

Corporates that are able to undertake a cultural re-alignment to promote innovation are far more likely to succeed, with buy-in from senior executives key. Establishing innovation teams is just the beginning - they need alignment with the core business but also a mandate to pursue opportunities in adjacent spaces that can become important future revenue streams.

Healthcare Providers

Within the innovation ecosystem, healthcare providers are positioned as gatekeepers and decision makers who have the power to accelerate and ultimately unlock widespread adoption. The effects of inaction are costly for patient well-being and to the providers themselves whose resources are becoming increasingly stretched. Without integrating startup and corporate innovation into existing care pathways, it risks creating a largely private consumer digital health ecosystem that does not bring the necessary benefits to the entire population.

A clear and effective delivery infrastructure needs to be built to enable the most impactful digital health products to reach patients. Empowering healthcare professionals to partake in the advancement and adoption of innovation requires education to create a culture of innovation that will robustly challenge health systems worldwide.

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GLOSSARY

AHSN
ACADEMIC HEALTH SCIENCE NETWORK

ARR
ANNUAL RECURRING REVENUE

CE MARKED
CONFORMITÉ EUROPÉENE MARK

CVC
CORPORATE VENTURE CAPITAL

DHSC
DEPARTMENT OF HEALTH AND SOCIAL CARE

DIGA
DIGITALE GESUNDHEITSANWENDUNGEN (DIGITAL HEALTH APPLICATIONS IN ENGLISH)

DM+D
DICTIONARY OF MEDICINES AND DEVICES

DTC
DIRECT TO CONSUMER

HCP
HEALTHCARE PROFESSIONAL

IPO
INITIAL PUBLIC OFFERING

LTV: CAC
LIFETIME VALUE: CUSTOMER ACQUISITION COST

M&A
MERGERS AND ACQUISITIONS

NIA
NHS INNOVATION ACCELERATOR

NICE
NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NHRA
NATIONAL HEALTH REGULATORY AUTHORITY

PECAN
PRISE EN CHARGE ANTICIPÉE NUMERQIUE DES DISPOSITIFS MÉDICAUX (EARLY ACCESS TO REIMBURSEMENT FOR DIGITAL MEDICAL DEVICES)

ROI
RETURN ON INVESTMENT

SAAS
SOFTWARE AS A SERVICE

SAMD
SOFTWARE AS A MEDICAL DEVICE

SNOMED
SYSTEMATIZED NOMENCLATURE OF MEDICINE CLINICAL TERMS

VC
VENTURE CAPITAL

WANT TO KNOW MORE?

LET'S TALK

Of course, there's no one-size-fits-all solution. If you want to learn more about building win-win models, let's talk.

At Founders Intelligence, part of Accenture, we work with corporate leaders to identify and deliver ambitious growth. We bring strategic rigor to the innovation process, helping our clients map out what to do, where to play and how to win, both today and tomorrow.

We believe the next chapter of growth will be entrepreneurial. We look to the startup world to accelerate innovation through partnership, investment, and acceleration programs.

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