

The Resilience of Early-Stage European Healthtech

//// July 2023

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About the Octopus Ventures health team

Octopus Ventures is one of the largest and most active venture capital investors in Europe.¹ The specialist health investment team benefits from a wealth of experience in operational healthcare, sector investment and medical practice, bringing serious depth of thought to their analysis. At the forefront of what has become one of the leading investment sectors in the world, the team's mission is to invest in the people and ideas that will fuel the healthtech revolution, supporting European start-ups to impact 1 billion lives.



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Introduction

01

Driven by a perfect storm of Brexit, the COVID-19 pandemic and an unprecedented surge in venture capital (VC) investment, the past five years have seen European healthtech undergo a profound transformation, leaving the landscape of today virtually unrecognisable from its 2019 form.

The surge in demand for healthtech has extended beyond the individual to touch the level of health systems, insurers and employers. The effect has been revolutionary. Health systems have been forced to adapt and embrace new technology, founders are finding radically new ways of scaling their ventures, individuals are developing new relationships with healthtech and the nature of investments in the sector has shifted for good.



Despite tough market conditions, early-stage (Seed to Series A) European healthtech founders and investors have remained resilient. Total funding for Pre-seed to Series B healthtech companies **increased 49% year-on-year (YoY) from 2020 to 2021, keeping resilient in 2022 with an 8% YoY growth, reaching \$4.4 billion.²**

With this report, we hope to offer a comprehensive analysis of Europe's rapidly evolving healthtech landscape. Combining expert opinions from founders, investors and health system experts, it provides a one-stop guide for founders and investors alike.

We begin by providing a VC funding overview of 2022 and early 2023, with analysis of the UK, France and Germany. Taking a deep dive into their respective health systems, we address the three primary challenges facing European health systems: ballooning healthcare costs, the transition from treatment to prevention of disease, and the need to meet population health demands. The challenges are explored in-depth, with a focus on the opportunities they present, particularly to those entrepreneurs building ventures that demonstrate efficiency, productivity and automation plays.

The report goes on to highlight the role of start-ups in bridging the gap between treatment and prevention through direct-to-consumer routes, before reviewing consumer, go-to-market and regulatory trends. Finally, we offer our predictions on the ripest opportunities for 2023 and beyond. With a focus on the latest trends, best practices and emerging technologies, we hope this report will offer invaluable insights and clarity at a time of unprecedented change.

The European healthtech landscape

02

Headlines have been largely negative about the post-pandemic phase, with inflationary pressures, tough macro-trends and regulatory changes having a major impact on both the current market and investor appetite.

But on closer inspection, the fundamentals are healthy and the outlook is positive.

Early-stage European healthtech founders have been resilient throughout the pandemic and 2022. Pre-seed to Series A investment increased steadily from 2020 through 2021 and 2022, proving that the partnership between entrepreneurs and investors continues its disruption of the healthcare industry despite strong headwinds. This year began optimistically with an investment upswing, only to be interrupted by the collapse of Silicon Valley Bank, adding to investor and public-market nervousness around the instability of early-stage investing.

The global IPO market remains closed, with no IPOs recorded in the first quarter of 2023.³ Digital health exits dwell at a five-year low.⁴ But in febrile public markets and in a sector that many equity investors continue to find complex and difficult to navigate, an IPO is often the least favoured exit route for many healthtech founders. Specifically in Europe, the total number of digital health M&A exits has increased 1.7x year-on-year to deliver a record-breaking 50 deals⁵ in 2022, and there are good reasons for us to look forward to the continued growth of this figure.

The unsettled economy of the past 12 months has left founders reluctant to raise and certain venture capitalists hesitant to invest. Southern and Central Eastern Europe have seen the largest gains in dry powder, possibly due to economic and political uncertainties. Dry powder for European VC as a whole reached an all-time

high of \$44 billion at the end of 2021.⁶ This is reason for optimism, with stockpiled capital ready to be poured into healthtech start-ups when the time is right.

The founders building VC-backed start-ups don't just need funding – they need time if they're going to be as creative and innovative as the market demands. Public markets will always be fickle, and start-ups are remaining private for longer, which means venture capitalists need to offer long-term conviction (as well as capital and support) if they are going to play their role in a start-up's success.

With healthtech in Europe exhibiting great resilience, and offering good reason for optimism, it presents a wealth of opportunities for founders and investors alike.



2.1 The continent at a glance

Funding overview in 2023:

Total funding and investment types²

- VC investment in European healthtech in the first half of 2023 is approaching \$3 billion, sitting at \$2.8 billion at the time of writing this report. This is the fifth highest half-year period in the last five years.
 - Investment was slower in the first quarter of 2023 (\$1.5 billion) when compared to the first quarter of 2022 (\$2.4 billion), but reached similar levels of investment to the first quarter of 2021 (\$1.4 billion).
 - Total investment in healthtech in 2023 is unlikely to reach 2022 figures, unless growth stage rounds pick up in the second half of 2023.
- So far in 2023, mega-rounds have been scarce, relative to the amount of early and mid-stage investment activity (Seed to Series C). This is likely due to well-capitalised companies choosing not to fundraise given unfavourable market conditions and growth investors making fewer, safer bets this year.
 - The proportion of early-stage investment in 2023 has remained constant from 2021 and 2022, hovering at around 35% of total capital invested.

Biggest funding rounds of 2023 so far²

So far in 2023, the largest rounds in European healthtech comprise a mixture of a growth equity VC round for DistalMotion, a Series C for Patient21 and Medwing, and a Series B for Peppy.



Based in Switzerland, DistalMotion is a medical device company that provides on-demand robotics for complex and minimally invasive procedures. DistalMotion raised a growth equity VC round led by Revival Healthcare Capital of \$150 million.



Based in London, Peppy is a B2B health platform supporting underserved areas of healthcare for employees including fertility, pregnancy and menopause. Peppy raised a €45 million Series B in January 2023 from Seedcamp, Felix Capital, Hambro Perks, Sony Innovation Fund, MTech Capital, AlbionVC, Outward VC, Kathaka and Simplyhealth.

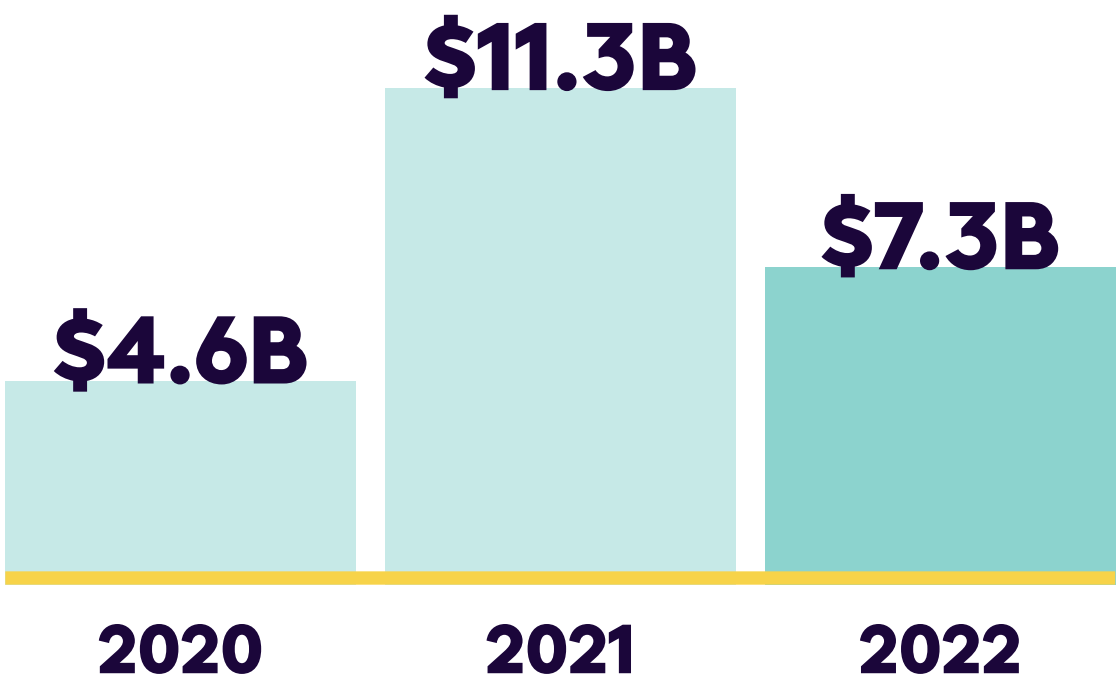


Based in Berlin, Patient21 is a healthtech company that aims to empower patients and doctors to make better decisions by leveraging data. In May 2023, they raised a \$108 million Series C in a funding round led by VC firm Pitango.

Funding overview in 2022:²

- VC investment dropped from its record high in 2021, but 2022 was still the second highest VC investment year on record.
- European healthtech investment dropped to \$7.3 billion in 2022 from its 2021 peak of \$11.3 billion, likely reflecting wider macroeconomic trends, inflationary pressures, rising interest rates and fears of a recession. This drop in investment is largely due to a low number of mega-rounds (growth rounds greater than \$100 million) in 2022 (\$1.4 billion) in comparison to 2021 (\$4.7 billion), but earlier stage investment has proven more resilient.
- Mega-rounds aside, early-stage resilience was on display from 2021 to 2022. Europe saw an increase in early-stage investment, which grew from \$2.3 billion to \$2.5 billion.
- Putting 2021 aside (an outlier year with many mega-rounds), Europe saw a jump from \$4.7 billion in investment in 2020 to \$7.3 billion in 2022, a 57% growth between those two years. This is higher than the US and Asia at 29% and 23% growth, respectively. Still, total VC investment in the US in 2022 (\$35 billion) remained significantly higher than Europe and Asia combined.

2022 saw European healthtech investment drop from its 2021 peak of \$11.3 billion to \$7.3 billion. But 2022 was still a strong uplift when compared to the 2020 figure (\$4.6 billion).²



Largest funding rounds 2022²

Software-as-a-service (SaaS) and health insurance platforms dominated European healthtech VC investment in 2022. The three biggest funding rounds were for Doctorlib, Alan and Cera.

Doctorlib

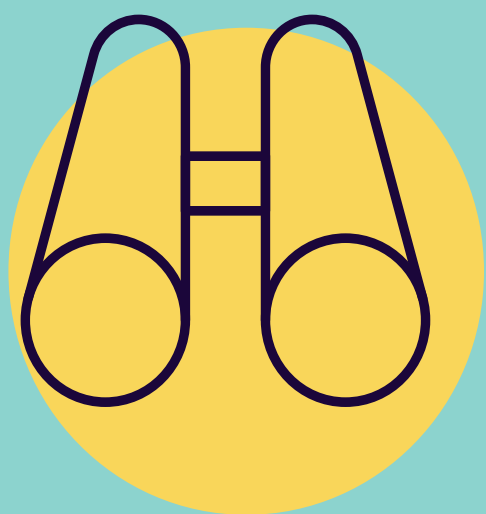
Founded in Paris in 2013, Doctorlib is a SaaS and booking platform, connecting patients with doctors for health consultations. With over 60 million users across France, Germany and Italy, Doctorlib is the highest-valued French start-up at \$6.4 billion. It received the highest funding round in 2022 with €250 million in late VC funding from General Atlantic, Bpifrance and Eurazeo.

Cera⁺

Founded in London in 2015, Cera is a care provider service, which removes unnecessary administrative work for carers and patients. Cera provides digital monitoring, which enables prediction and helps to prevent changes in a patient’s condition. It raised £130 million in late VC backing by Robin Klein, Yabeo Capital, Oltre Impact, Vanderbilt University, Guinness Ventures, Kairos, Squarepoint Capital, Jane Street Capital, 8090 Partners and Schroders Capital.

alan

Founded in Paris in 2016, Alan is France’s first digital health insurance company. Alan revolutionized health insurance as a SaaS platform, offering insurance for companies ranging in size from start-up to enterprise. Alan combines an insurance offering with access to personalised healthcare advice, preventative care and payment. The company raised €183 million in Series E funding to reach a valuation of \$3.0 billion.



Opportunity spotter: digital therapeutics

Digital therapeutics (DTx)

Delivering medical interventions directly to patients using evidence-based, clinically evaluated software to treat, manage and prevent a broad spectrum of diseases and disorders.

DTx is now the fastest-growing segment in European healthtech, increasing fourfold since 2017.⁷ Over the same period, VC investment in the space has grown by 4.3x, from \$0.3 billion to \$1.3 billion in 2022. Other fast-growing sectors include AI-enabled drug discovery and development (4.0x since 2017) and remote monitoring and wearables (2.4x since 2017).⁸

Big Health has now become the first-ever DTx business to receive guidance from the National Institute for Health and Care Excellence (NICE), which recommends Big Health's digital insomnia therapy, Sleepio, as an effective alternative to sleeping pills.⁹ Seeing DTx services being approved is the first step, with getting more clinicians to prescribe them being the next.

| | 2017 | 2022E | VC funding growth 2022E vs. 2017 |
|-----------------------------------|---------|---------|----------------------------------|
| Digital therapeutics | \$0.3bn | \$1.3bn | 4.3x |
| AI-Drug discovery & development | \$0.7bn | \$2.9bn | 4.0x |
| Remote monitoring & wearables | \$0.7bn | \$1.6bn | 2.4x |
| Mental health | \$0.9bn | \$2.0bn | 2.2x |
| Digital care (incl. telemedicine) | \$1.4bn | \$2.7bn | 1.9x |
| Femtech | \$0.5bn | \$1.0bn | 1.9x |
| Digital health insurance | \$0.8bn | \$1.3bn | 1.7x |
| Clinical trials | \$1.0bn | \$1.6bn | 1.6x |
| Online Pharmacies | \$0.5bn | \$0.7bn | 1.3x |
| Home tests | \$1.6bn | \$1.2bn | 0.8x |

Healthtech sector growth 2017–2022 estimate for the third quarter, Source: Dealroom Digital Therapeutics Report.⁸

Early-stage investment into digital therapeutics start-ups



Hopefully, the next two years is spent ironing out bottlenecks and challenges on getting DTx into the prescription flow. We're not seeing proactive scepticism from clinicians, which is positive, it's purely just bandwidth. To get around that, we need healthtech to become part of undergraduate education and clinical training.

– Will Gibbs, investor at Octopus Ventures

Growth in European early-stage VC investment in digital therapeutics has outpaced the US. In Europe, VC investment into early-stage digital therapeutics has grown by 9x since 2016, compared to 3.6x in the U.S.⁷

2016
\$220million

3.6x

2021
\$795million

US-based digital therapeutics



We're at a stage where people, clinicians, providers and insurers are all understanding the clinical and economic benefits of moving beyond the pill. We expect major distribution agreements to materialise into national and European-wide scale.

– Matthieu Vallin, investor at Octopus Ventures

2016
\$37million

9.0x

2021
\$333million

Europe-based digital therapeutics

2.2 The UK in depth

In 2022, investment into UK healthtech start-ups reached \$1.9 billion, the most of any European country. Still, that figure represented a sharp drop from the \$5 billion figure in 2021. The drop was largely down to a lack of mega-rounds in 2022 (\$292 million, compared to \$3.9 billion in 2021). Early-stage funding has remained more resilient and the UK holds major opportunities for the start-ups able to engage with the country's unique context.²

Context and opportunities

A look at the NHS

Demographic and epidemiological transitions present a threat to the UK health system, at the same time as political, legal and regulatory factors create an increasingly enabling context for UK-based healthtech start-ups.

The demographic transition stage of a country has significant implications for the economic landscape and potential investment opportunities. The UK is in stage four of the demographic transition; the health needs of the UK are in line with the demographic stage, and like other high-income countries, the UK's health system, the National Health Service (NHS), is threatened by a confluence of factors including an ageing population living with multiple chronic

health conditions¹⁰ (non-communicable diseases or NCDs), a shrinking working age (15–64 years) population and a threatening economic context.

Relative to Europe's other high-income countries, the UK is lagging on outcomes including life expectancy and infant mortality. The burden of mental illness is increasing.⁷ Nine out of the top ten causes of death in the UK are due to NCDs, a burden that is also increasing (Figure 3).¹⁰ In this, the UK is congruent with global trends, the number one killer being cardiovascular disease (CVD), which carries a profound global economic cost (estimated to rise to \$1 trillion by 2025¹¹) associated with the loss in productivity and human capital.



In an ageing population, NCD multimorbidity is a burden, and an opportunity.

Rising healthcare costs present an opportunity for start-ups to provide cost-effective preventative solutions at scale, using innovative financing arrangements with the NHS, such as strategic public-private partnerships.

Last year introduced uncharacteristic levels of political instability to the UK, but the current Prime Minister, Rishi Sunak, is committed to generating an enabling context for UK start-ups. As Chancellor of the Exchequer, he launched the Future Fund, a support package for high-growth start-ups affected by the pandemic. As Prime Minister, he has frequently outlined his support for innovative start-ups, promising

Healthtech start-ups have a major part to play in relieving the stresses facing the NHS.

*All references to NHS refer to NHS England.

to expand seed enterprise investment schemes and tax relief for angel investors, making the UK attractive for early-stage start-ups.

The UK’s NHS is both a source of national pride and a strong dictator of political popularity. With healthcare workers striking, healthcare costs rising and flagging population health, there’s a strong opportunity for founders to address the many pain points facing actors within the health system (such as health care workers, NHS managers and patients) at a cost-effective level using a systems-based approach.

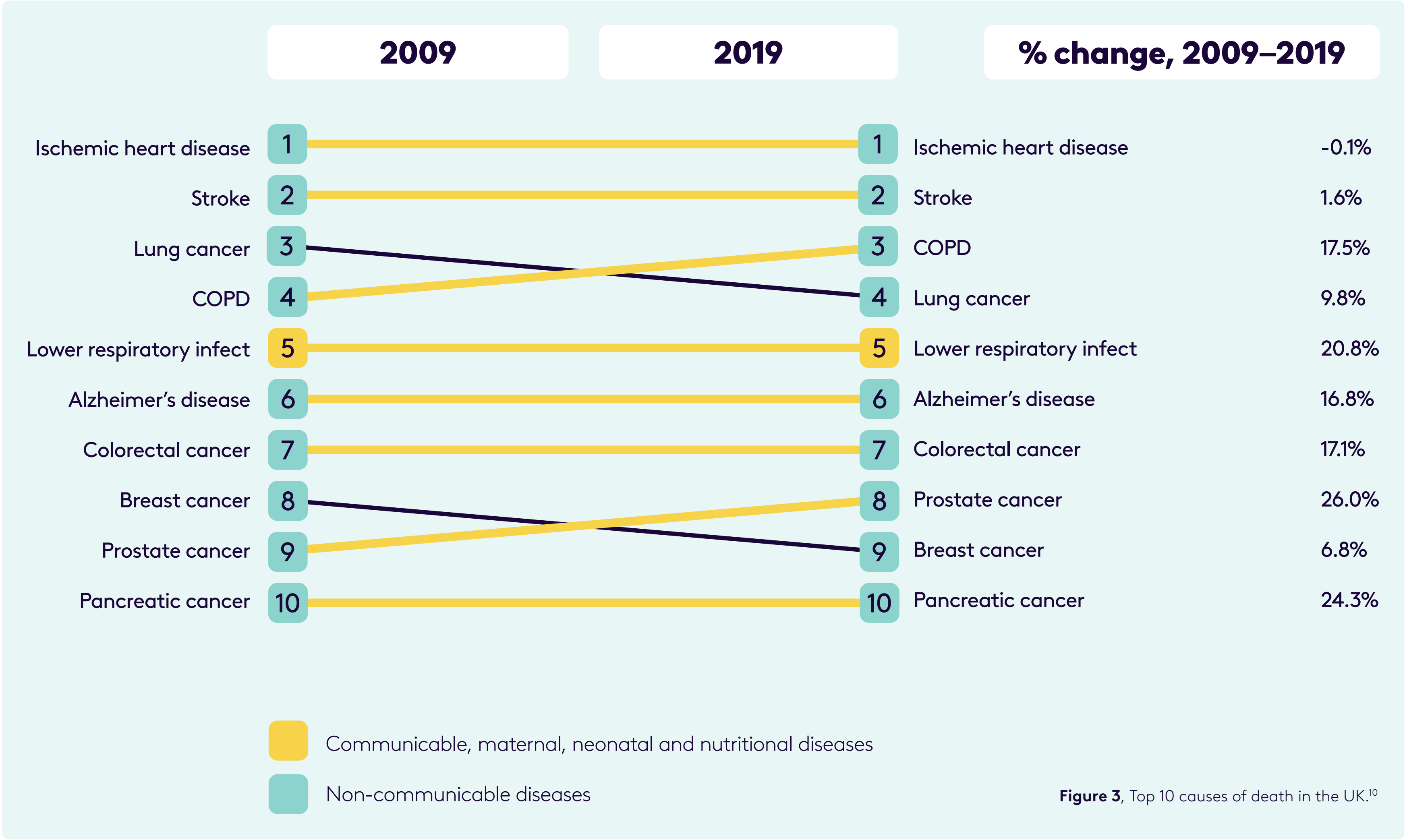


Figure 3, Top 10 causes of death in the UK.¹⁰



We have challenges across workforce, productivity, safety and quality of care for our patients, and just the sheer demand to be able to deliver for every patient, wherever they are in our community. We have to reimagine how we deliver healthcare, and at scale, in a way that goes beyond the typical bricks and mortar.

– Dr Nadine Hachach-Haram FRCS (Plast), BEM, founder and CEO of Proximie

The NHS Long Term Plan has emphasised the need of healthtech to create a more effective, efficient, equitable and responsive health system¹², but previous political will has struggled to translate into an enabling legal and regulatory environment for healthtech commercialisation and scale up. While this is partly due to issues regarding digitisation and interoperability, the main obstacle has been the challenge of proving cost-effectiveness and safety to the National Institute for Health and Care Excellence (NICE) standards.¹³ The pandemic accelerated digital innovation within the NHS and now larger organisations, such as Palantir Foundry, have seen success at creating healthtech solutions for the NHS backlog, which offers an encouraging precedent for healthtech start-ups.

Traditionally, the NHS has been geographically decentralised, with local providers and purchasers spread across numerous disparate NHS bodies. In combination with internal markets, inspection, regulation and performance management systems, this has previously resulted in England being one of the most centralised healthcare systems in the developed world. The new governance and organisation has sought to strike a new balance. However, there is a long way for this newfound equilibrium to go before the potential economic and outcome improvements can be realised.

The movement towards an integrated NHS provides an opportunity for diffusion and scale up for the healthtech innovations offering efficiency and productivity savings.

The NHS Confederation 2022 Report,¹⁴ which outlines the governance conditions for success, called for closer alignment between the Department for Health and Social Care with NHS England and NHS Improvement in the process of merging. The implementation of integrated care systems (ICSs) has led to further decentralised responsibility and greater integration at the same time. This has major implications for start-ups. The ICSs are responsible for delivering on a small number of national and local priorities and receive a population-based budget accordingly. With ICSs now working more collaboratively — focusing on integration, efficiency and productivity — there's an opportunity for healthtech start-ups to enter the NHS market at the local provider/purchaser level, evidence population-based outcomes and benefit from a tried and tested go-to-market strategy with rapid scale up through these ICSs – creating around 42 large customers rather than 300 smaller ones.

Because this organisational setup creates an impetus for greater integration across primary, secondary and social care — in addition to efficiency and productivity gains for the respected ICSs — the start-ups that stand to benefit most are the ones actively focused on providing greater coordination of services across those service areas. While ICSs have gained greater autonomy, they are strategically coordinated and still bound by centralised independent bodies, such as NICE, NHS England and the Department for Health and Social Care. While we have discussed the overall growth of DTx across Europe, a combination of strict NICE requirements and variable motivation of ICS leaders creates a challenging environment for novel drugs or DTx, which means start-ups operating in these areas are less likely to win in the UK setting. In summary, the organisation of the health system relates to the motives of those governing the system and, as a knock-on effect, the start-ups most likely to succeed in that context.

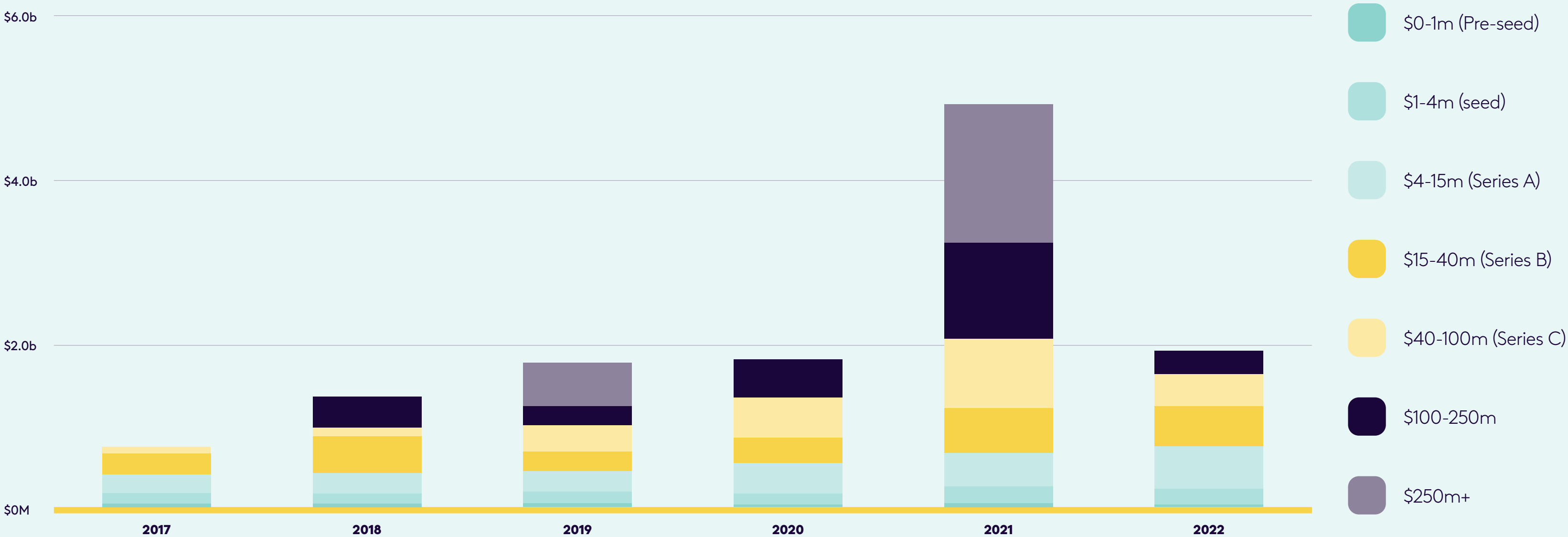
Pharmaceutical precedent provides a playbook for healthtech start-ups.

The NHS aims to be an efficient, equitable, effective and responsive health system that provides cost-effective, population-based prevention. In pursuit of this, recent years have seen a shift from individual to population-level solutions, from treatment to prevention, and from geographic decentralisation to functional decentralisation. Companies such as Palantir and Novartis have seized upon the opportunities this has afforded. Palantir entered the NHS market to address the vaccine supply chain and has subsequently moved on to tackle the elective backlog. Novartis entered a strategic public-private partnership with the NHS to deliver a novel, injectable, cholesterol-lowering agent in primary care, to treat adult patients within its licenced indication who also have persistently elevated low-density lipoprotein-cholesterol (LDL-C) levels and a history of certain cardiovascular events.¹¹ Healthtech start-ups able to align themselves with the priorities of the NHS can utilise the approaches deployed by Palantir and Novartis to rapidly scale up through the healthcare system.

The UK healthcare start-up landscape in numbers²

- Excluding Pre-seed deals, 2022 saw 187 deals in UK healthtech, a small drop from 194 in 2021 and an increase from 134 in 2020. 2023 has yet to catch up to these levels, with a total of 68 to date.
- 2022 saw total investment reach \$1.9 billion, the most of any European country.
- The UK was aligned with gross European healthtech investment trends in early-stage funding. Pre-seed to Series A deals represented 38% of deals and reached \$754 million, growing from \$670 million in 2021.
- Series B and Series C rounds took a hit, falling from \$1.4 billion in 2021 to \$874 million in 2022.

VC investment in UK healthtech



UK health funding.²

UK summary: losing its magic? Not quite...

Promise for start-ups

Historically, the UK has faced barriers to healthtech innovation. However, the COVID-19 pandemic heralded a change in attitude towards tech-based solutions and initiated a restructuring of the NHS through ICSs, two developments that offer real promise for healthtech start-ups. Still, the impact of Brexit, alongside other regulatory challenges such as Medical Device Regulation (MDR), is making itself felt.

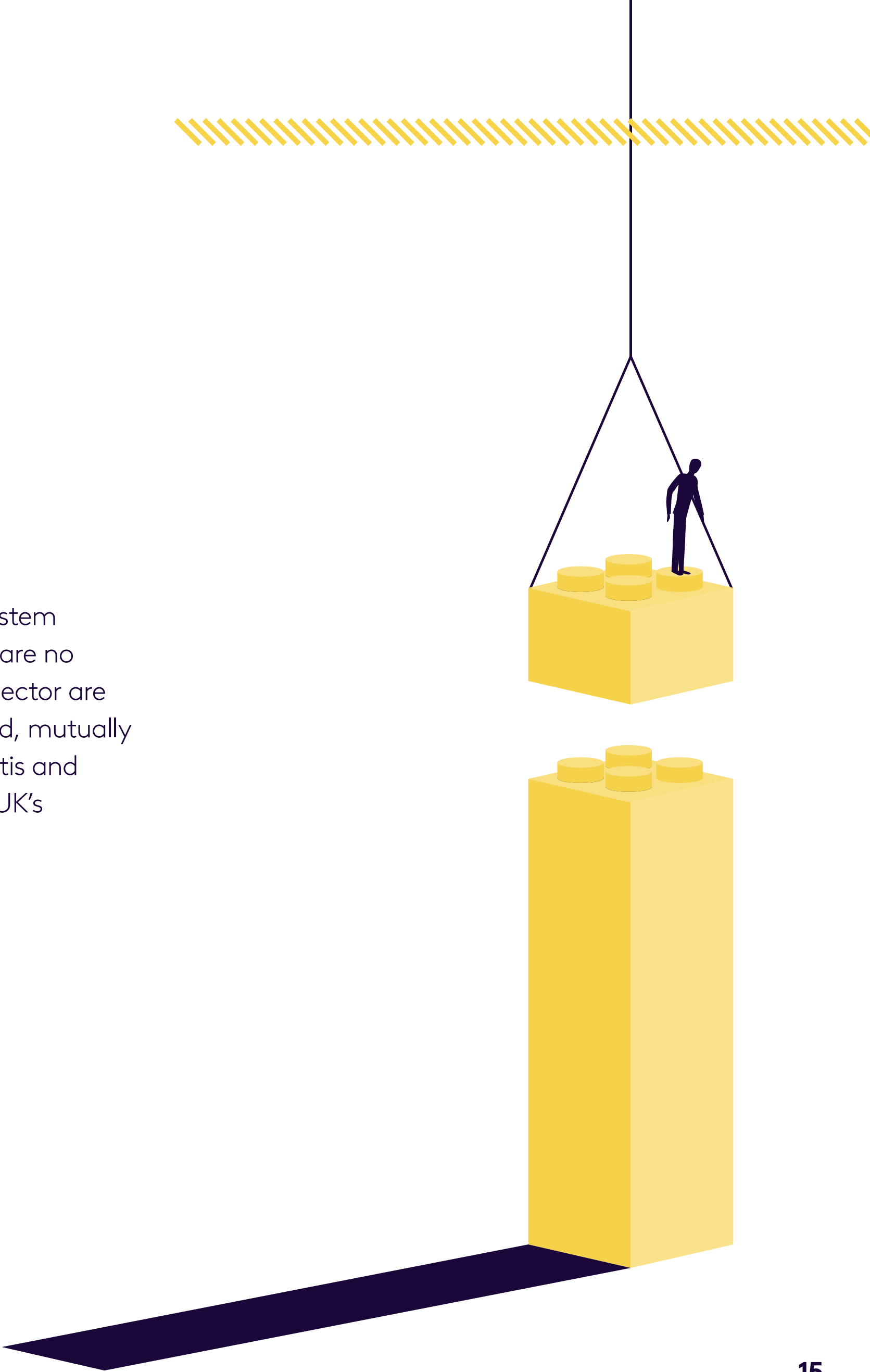
These challenges aside, healthtech start-ups in the UK enjoy access to a multitude of funding opportunities. The country boasts a vibrant VC industry, while the government is active in supporting start-ups through public funding initiatives including Innovate UK, UK Research and Innovation Funding, Biomedical Catalyst Programme, Innovation Loans and London’s Digital Health Accelerator Programme. A broad range of grants is also available to start-ups, such as those from the National Institute for Health Research (NIHR), Medical Research Council (MRC), Healthy Ageing Catalyst Awards, Health Technology Assessment Grants and Horizon Europe.

| Public | Private | Grants |
|---|--|---|
| <ul style="list-style-type: none">■ NHS partnering (from GP clinics to ICS-level)■ Innovate UK | <ul style="list-style-type: none">■ VC■ Angel■ Accelerators and incubators | <ul style="list-style-type: none">■ Biomedical Catalyst■ MRC■ Welcome Trust |

Table 1, England Healthtech Funding Opportunities.

When it comes to commercialisation, the UK’s healthtech ecosystem is notably mature. Profit and population-based health solutions are no longer seen as being in conflict. Instead, the public and private sector are increasingly working in partnership with the NHS in value-aligned, mutually risk-sharing agreements. The precedent set by the likes of Novartis and Palantir offers start-ups a blueprint; challenges remain, but the UK’s innovation maturity is robust and poised for continued growth.

These challenges aside, healthtech start-ups in the UK enjoy access to a multitude of funding opportunities.



2.3 France in depth

Taking a long view, the UK and France both continue on an upward trend in drawing and providing VC investment in healthtech. But in 2022, while the UK saw 12% of VC investment go into healthtech, France invested slightly more (13%).² Since Brexit, French healthtech start-ups have boasted the largest percentage increase in attracting funding in Europe. As we've seen, France took ownership of two of the highest funding rounds in 2022 with Alan and Doctolib. It is fast cementing its position as one of the most attractive countries for a healthtech start-up in Europe.

Context and opportunities

Population health and political support

An ageing population living with multiple chronic conditions poses a threat to the French health system.

At 67.9 million,¹⁷ France has one of the largest populations in Europe. It performs strongly on measures such as life expectancy (79 years for men, 86 years for women¹⁵). Crude mortality rates in the country have dropped, from eleven per 1000 in the 1960s to a low of eight per 1000 in 2014. The effect of these improvements is a rapidly ageing population — a quarter of the population are aged 60 or more.¹⁶ In the face of these improvements, as with other high-income countries, a rise in crude mortality rates preceded the COVID-19 pandemic, reflecting the

burden of NCDs such as cardiovascular disease (CVD), Alzheimer's disease (AD) and cancer.¹⁰

CVD and AD cause the most deaths in France – and they are rapidly increasing.

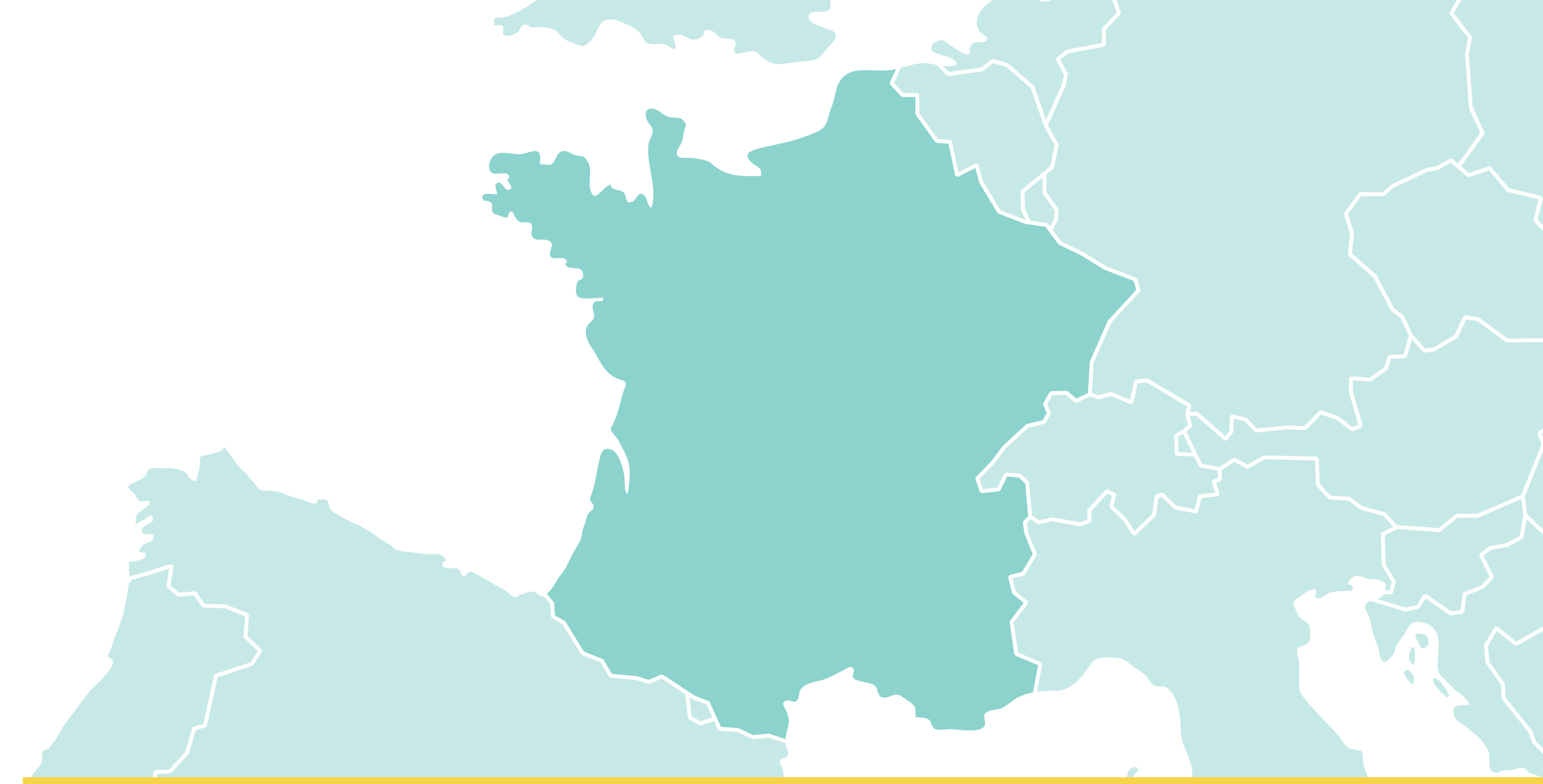
Alongside an ageing population, France is seeing a wave of multiple chronic conditions. Eight out of the top ten causes of death are NCDs, and nine out of the top ten causes of death and disability combined are due to NCDs (Figure 4).

The burden of CVD and AD is particularly dramatic. Between 2009 and 2019, France witnessed a 7% increase in the percentage of deaths due to ischemic heart disease. The increase in deaths due to AD was 48.8%.

The burden of CVD and AD is particularly dramatic. Between 2009 and 2019, France witnessed a 7% increase in the percentage of deaths due to ischemic heart disease.

Health inequalities and out-of-pocket payments threaten the health of the French population.

France is also struggling with the health of its younger population. The country has a high rate of premature male deaths from accidents, and a high prevalence of risk factors such as smoking and alcohol consumption, which are the most common causes of avoidable mortality in France.¹⁸ These health struggles are compounded by profound health inequalities across socioeconomic and geographic groups in France. This inequity in access is concentrated in a limited number of goods and services, including dental healthcare and eye care,¹⁹ for which out-of-pocket expenditure by patients is the highest in Europe.



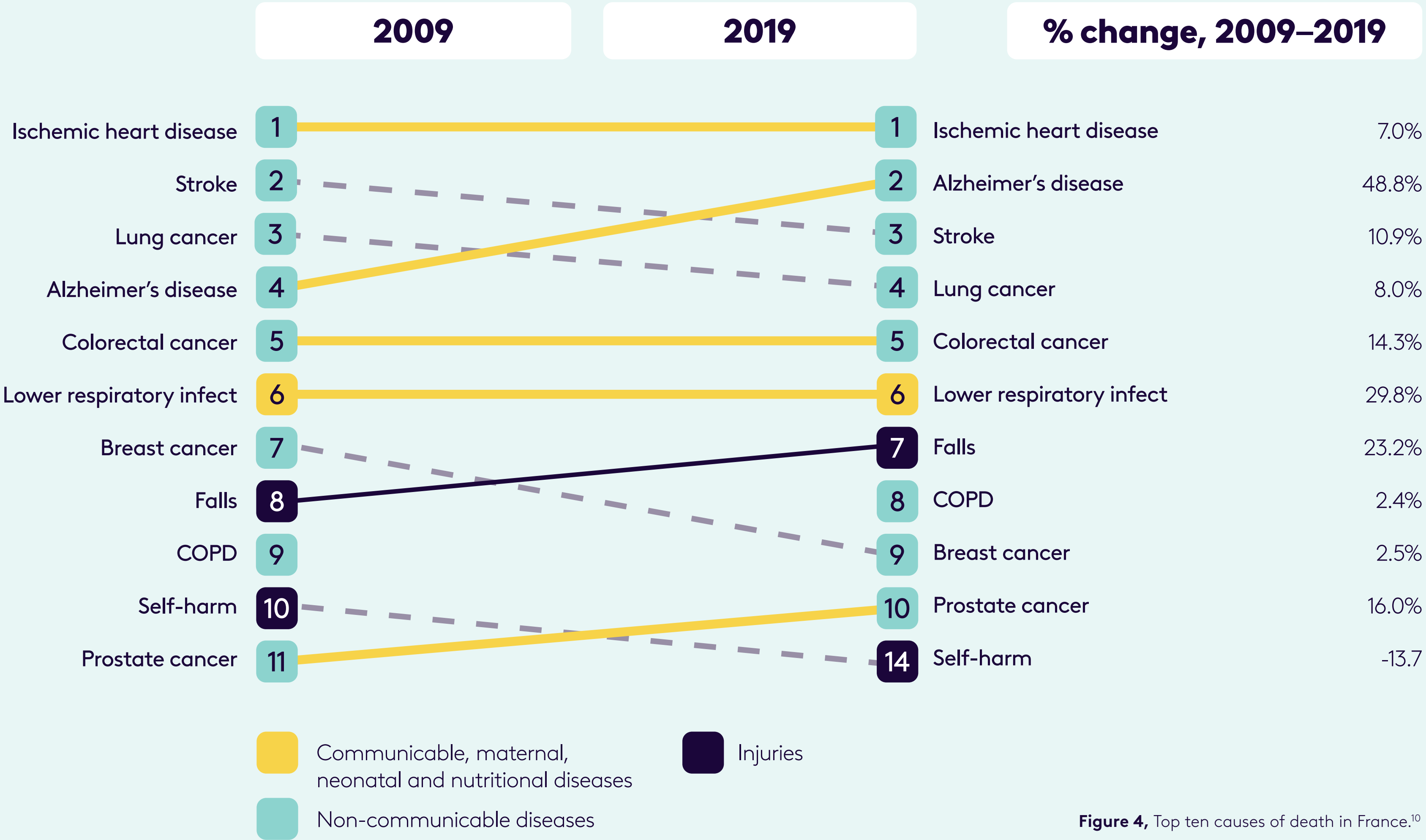


Figure 4, Top ten causes of death in France.¹⁰

France is an innovative, dynamic and internationally recognised healthtech leader.

France is becoming a start-up nation, and support comes from the very top. While France held the Presidency of the Council of the European Union in 2022, French President Emmanuel Macron launched Scale-Up Europe, an initiative that saw tech companies, investors and associations sign a manifesto with the goal of driving ten European tech companies to a €100 billion valuation by 2030.²¹

Strong political leadership and support for healthtech has translated into an enabling legal and regulatory context for healthtech start-ups with clear evidence of success.

France has adopted initiatives from the 2018 Strategic Council for the Healthcare Industries (CSIS), leading to significant reductions in waiting times for clinical trial approval from both the French National Authority (HAS) and the French Economic Committee for Health Products (CEPS).²⁴ In 2022, Ernst & Young (EY) highlighted France as the European leader for incoming foreign investment ahead of the UK and Germany.²²

Rising healthcare costs and sociocultural shifts towards digital solutions present an opportunity for healthtech start-ups to revolutionise health systems.

While the French healthcare system was initially organised on a Bismarckian model, it has seen a transition into a mixed Beveridge and Bismarck model.¹⁸ Health policy and regulation of the system is managed by the Ministry of Health, Statutory Health Insurance (SHI) and local communities. The SHI system provides universal coverage to all citizens and is financed through a mix of employee and employer contributions, in addition to national taxation. Providers are paid by SHI, but patients may have to pay the provider and claim reimbursement by SHI afterwards (e.g. for GP visits). The SHI scheme exists in contrast to sociocultural attitudes towards digital solutions and services, with patients and purchasers keen for instant digital services that are fully integrated, personalised, easy to use, come at a competitive price and offer diverse user choice. This demand created an enabling context for the French start-up, Alan.

France is becoming a start-up nation, and support comes from the very top.

This reflects a wider macro trend across the European health system, with a public desire for digital service and personalisation existing in the face of costly and outdated state-provided services. There is an opportunity for healthtech start-ups to revolutionise key health system functions to deliver cost-effective population health.

The bridge between innovation and commercialisation: the Health Technology Assessment.

For adoption by the French health system, all healthtech must pass a Health Technology Assessment (HTA). The components of the HTA (Evaluation des Technologies de la Santé) are defined by the government and SHI.¹⁸ An innovation must be listed and covered by the SHI before it can be commercialised.

The assessment comprises three questions/assessments:

- I. Is the technology effective? (Relating to the assessment of the medical benefit.)*
- II. Is the technology more effective than the available comparators? (Comparing the innovation to current available treatment/systems.)*
- III. Economic assessment*

Healthtech start-ups that take advantage of the contextual opportunity afforded by the need for better healthcare services (much like Alan for insurance) can avoid this cumbersome bridge between innovation and commercialisation. By emulating innovations that strengthen the health system, providing more efficient, effective and responsive services, founders stand to benefit from a quicker route to commercialisation.

In 2022, Ernst & Young (EY), highlighted France as the European leader for incoming foreign investment ahead of the UK and Germany.

The French healthcare start-up landscape in numbers²

- French healthtech start-ups attracted \$1.7 billion in 2022, growing from \$1.5 billion in 2021 and \$514 million in 2020, showing consistent YoY growth since 2020. 2019 was a very strong year for French healthtech, with \$846 million in funding.
- 2023 has yet to catch up with those figures, with only \$348 million invested so far this year and no mega-rounds as of the time of writing. France may yet prove to be less resilient than the UK this year in total funding and deal count.
- Early-stage investment has increased steadily over the last five years, from \$171 million in 2018 to \$315 million in 2022.
- Deal count for Seed and Series A start-ups has been stable over 2021 and 2022, reaching 70 and 68 deals, respectively, once again demonstrating the resilience of early-stage funding.
- The most significant funding increase comes from Series B and onwards, from \$257 million in 2018 to \$1.3 billion in 2022, two thirds of which are from Series B and C deals.

VC investment in French healthtech

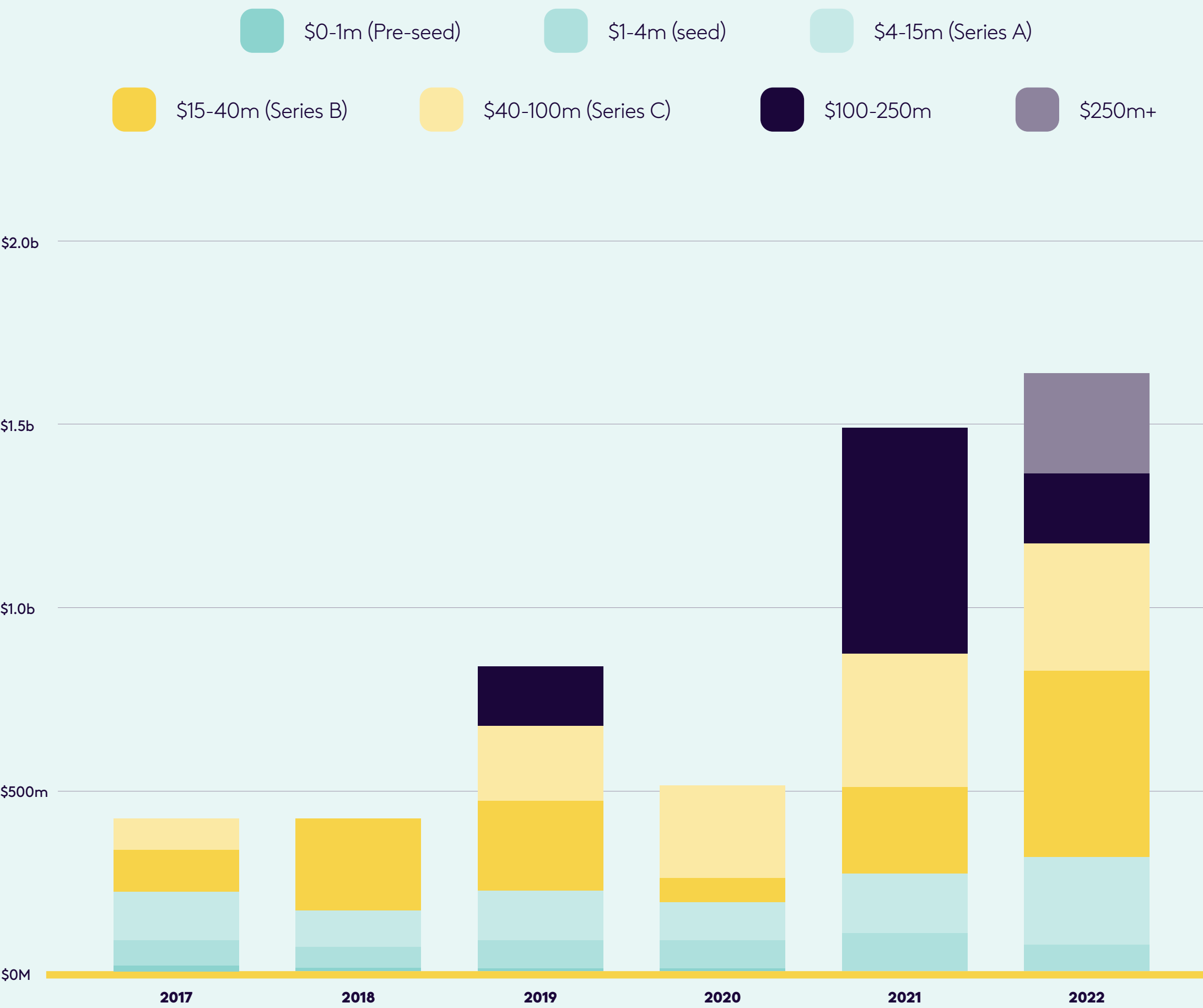


Figure 5, VC investment in French healthtech.²

France summary

France is catching up to the UK fast, with a combination of strong political will and an enabling regulatory environment creating favourable conditions for healthtech start-ups to make a population-level impact. Most European nations witnessed a drop in VC capital invested in healthtech in 2022, but French start-ups weathered this trend effectively, with total investment increasing from \$1.5 billion in 2021 to \$1.7 billion in 2022. Investment in French healthtech, meanwhile, has increased dramatically over the last five years. France was also home to two of the largest VC deals in Europe, Alan and Doctolib, confirming the country’s mature innovation and commercialisation footing in Europe. But France has been off to a slow start in 2023 and shows fewer signs of recovery than the UK.

Still, a wealth of funding opportunities are available to French healthtech start-ups across the public, private and grant sectors. Examples of public funding opportunities include Bpifrance, French Tech Seed and Agence Nationale de la Recherche (ANR).

A wealth of private funding opportunity is also available across VC, angel and accelerator networks. VC firms in France with a particular focus on healthtech include Sofinnova Partners, Partech Ventures and Idinvest Partners. Angel networks include Kima Ventures and Elaia Partners. There are several accelerators and incubators in France such as Paris Biotech Santé, La Paillasse and Hub Healthtech. There is also a strong grant ecosystem, including Eurostars, Horizon 2020 and French Tech Ticket.

Bpifrance

is an investment bank that offers several funding programmes, such as the Innovation Fund, which provides support specifically catering to healthtech start-ups.

French Tech Seed

supports early-stage start-ups.

Agence Nationale de la Recherche (ANR)

supports early-stage start-ups.

| Public | Private | Grants |
|---|--|---|
| <ul style="list-style-type: none">BpifranceFrench Tech SeedAgence Nationale de la Recherche | <ul style="list-style-type: none">VCAngelAccelerators and incubators | <ul style="list-style-type: none">EurostarsHorizon 2020French Tech Ticket |

Table 2, French healthtech funding opportunities.

France makes a bold case for the position of ‘best place for a healthtech start-up in Europe’, with its political, regulatory and funding contexts perfectly aligned. Talent is being attracted, funding is being mobilised and healthtech companies are making the most of it, as evidenced by the two giant tech deals last year. Start-ups and investors would do well to make the most of this opportunity in France and channel the resources the country offers to address the growing burden of CVD and AD and the lack of efficiency and productivity within the system. As the population ages further, these costly chronic conditions are only set to rise, presenting a unique opportunity for healthtech start-ups seeking to have population-level impact. Tackling this burden is a global challenge, but France may well be the place to start.



2.4 Germany in depth

The German healthcare system is vast. It generates an economic footprint of \$798 billion, representing roughly 12% of Germany's GDP,²³ and is linked to one in six jobs in the country. 2022 saw record VC investment in the country's healthtech industry, with some \$1.1 billion USD invested.² While cultural, regulatory and macroeconomic challenges persist, the market is ripe for the healthtech start-ups able to demonstrate the productivity gains they afford.



Context and opportunities

Highs and lows for healthtech

Demographic and epidemiological transitions threaten the German health system.

With a population of 84 million, Germany has entered stage five of the demographic transition model. The country's fertility rate (1.5 per 1000 women) is below the crude mortality rate (12 per 1000 people), with the population projected to fall by 20% (to 66.4 million) by 2100.¹⁷

There are two key trends to highlight:

- I. Germany's crude mortality rate is much higher than other European countries (including both the UK and France). Crucially, this precedes the COVID-19 pandemic, and therefore reflects the rising burden of NCDs.
- II. These demographic trends are resulting in an ageing population.

Taken together, these trends underscore the German healthcare system's biggest challenge: *Caring for an ageing population living with multiple, long-term chronic conditions.*

Healthtech start-ups should seek to address the burden of NCD multimorbidity in the ageing population.

As we've seen in both the UK and France, NCDs represent the leading causes of death (9 out of the top 10). In Germany, the number one cause of death and disability is IHD, followed by stroke then lung cancer. The burden of CVD is growing quickly. The years between 2009 and 2019 saw a 9.5% increase in the number of deaths caused by IHD and a 10.7% increase in the number of deaths caused by stroke (Figure 6).¹⁰

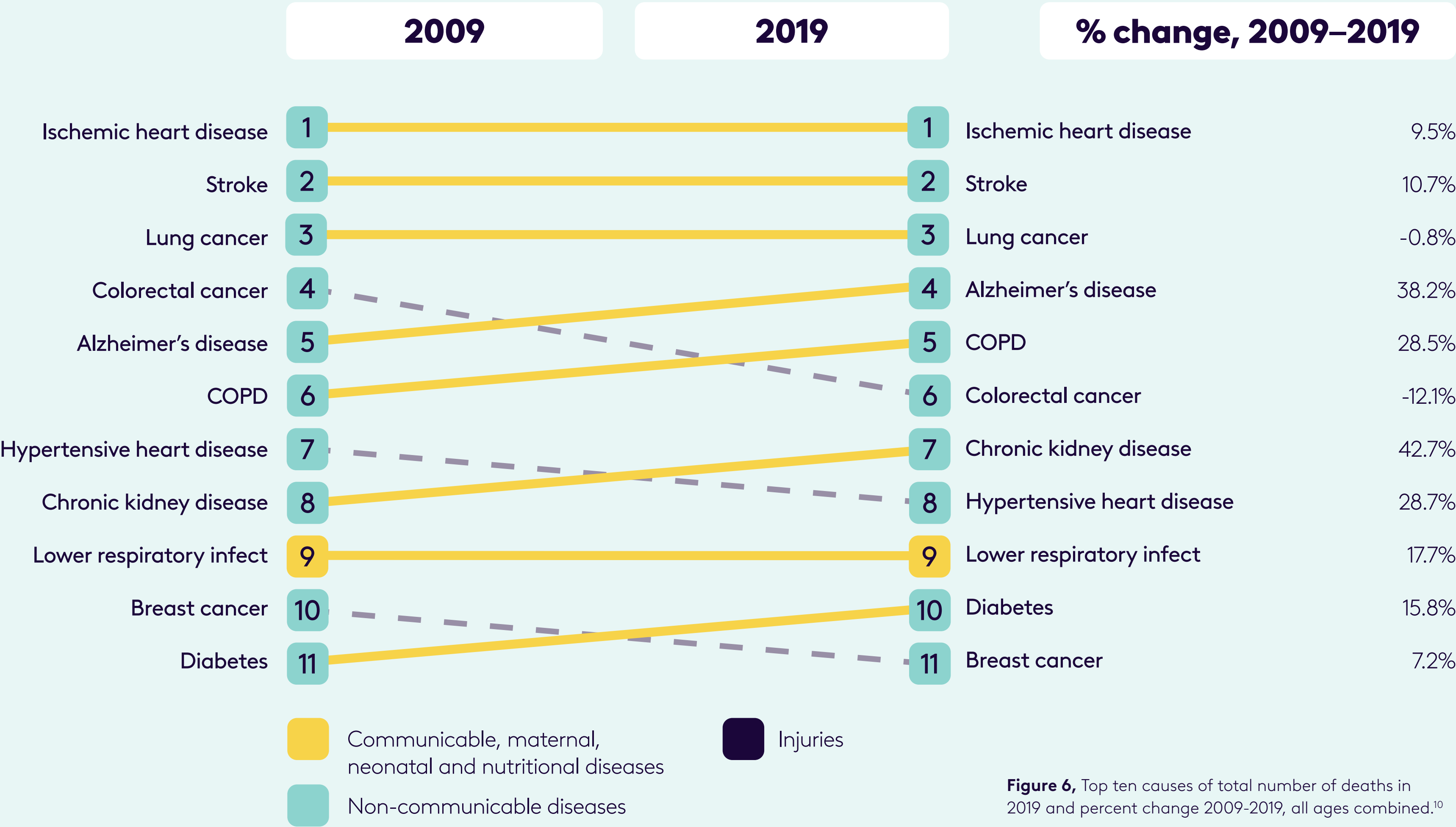


Figure 6, Top ten causes of total number of deaths in 2019 and percent change 2009-2019, all ages combined.¹⁰

The macroeconomic challenges of 2023 are likely to have an impact on emerging healthtech start-ups in Germany.

Germany is at risk of recession in 2023 due to inflationary pressures, which are set to lead to decreased purchasing power and reduced industrial production, and its high reliance on gas from Russia.²⁵ The economic context will force emerging start-ups towards alternative sources of financing, such as angel investment, crowdfunding and debt investment. Existing start-ups will have to adapt and think creatively about finding methods to increase their runway.

The effects of the economic context have already been seen in relation to foreign direct investment (FDI). In 2020, the UK, France and Germany all had equal levels of FDI. But in 2021, Germany's tumbled while the UK held steady and France saw a large increase.²²

The evolving legal and regulatory context holds promise for healthtech in Germany.

Germany has the largest healthcare system in Europe and was the first country to implement social health insurance (SHI), but the health system financing mechanism, by which SHI sends money to sickness funds who then negotiate contracts with providers, has led to

a lack of integration between ambulatory (primary care and outpatient care) and hospital care. In addition, because the payment mechanisms for hospitals (diagnosis-related groups) and physicians (fee-for-service) incentivise these actors to stay within narrow volume limits for payment, the adoption of innovation has been disincentivised. This combination of a lack of integration and lack of motivation has been a major contribution to the German health system's historical sluggishness at the adoption and scale up of healthtech.

Decision-making and financing powers are shared between the Länder, the federal government and legitimised civil society organisations. The government delegates responsibilities to membership-based, self-regulated organisations comprised of payers and providers, including SHI schemes, private health insurance schemes (PHI), physicians' groups, hospitals, 'sickness funds' and public health bodies.¹⁴ This decentralisation has caused a fragmentation of the health system into disparate ambulatory and hospital components, each with competing needs and demands. The primary barrier to healthtech start-ups was the governance and organisation of the health system, which followed the principle of self-governance (whereby the government drafts a legislative framework, with implementation depending on individual stakeholders such as doctors, hospitals and pharmacists).^{26, 27}

In 2019, Germany took strides to adapt its legal and regulatory framework to better facilitate the integration of healthtech into the health system, with the formation of a Health Innovation Hub (HIH).¹¹

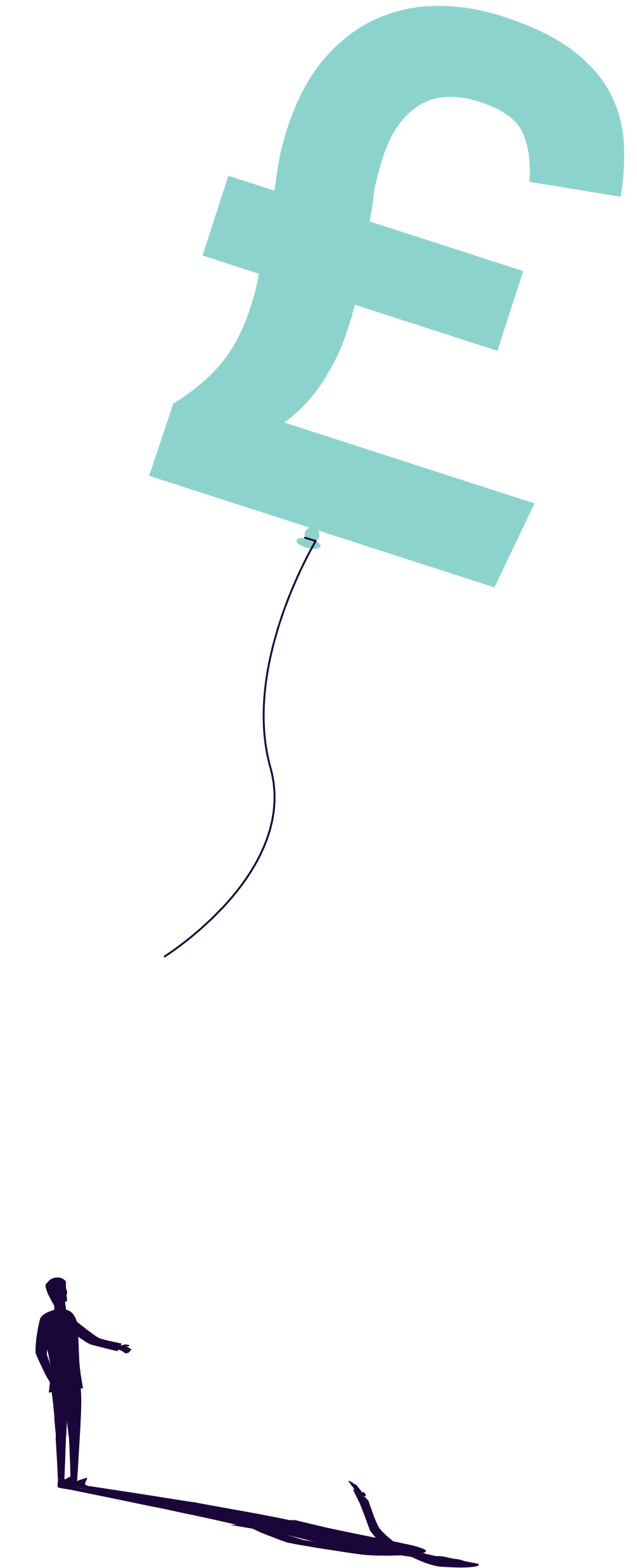
Decision-making and financing powers are shared between the Länder, the federal government and legitimised civil society organisations.

Three key legislations have unlocked a more enabling context for healthtech in Germany:

I. Digital Care Act (DVG): This allows doctors to prescribe digital health applications (DiGas), which can later be reimbursed by health insurance companies. As such, the provider is a payer, beyond just the patient.²⁶

II. Hospital Future Act (KHZG): The government invested €4.3 billion into hospitals for digital health innovation. Hospitals can use the funding to invest in digitalisation and automation initiatives such as patient portals, digital medication management, robotic systems and high-tech medical equipment.²⁶

III. Digital Healthcare and Nursing Care Modernisation Act (DVPMG): This aims to integrate digital health applications in order to improve the quality and availability of nursing care, to increase patient autonomy and to simplify processes such as telemedicine and electronic documentation. Digital nursing services can also be reimbursed by health insurance companies, much like DiGa's reimbursement.²⁶



Despite these huge strides, barriers for healthtech still persist. These include issues like a cultural protectiveness over personal privacy and information. Emerging healthtech start-ups in Germany are required to register their app at the Federal Institute for Drugs and Medical Devices (BfArM) and meet its criteria list of 122 security and functional features. After approval, developers will be provisionally reimbursed for one year if they can offer data evidence of their app practically improving patient care over the same time period.²⁷

The inherent governance and organisation of the financing and the delivery of the system still remains fragmented. In recent years, integration of services has become a priority for the German government, and with the formation of emerging integrated care services there is promise for future healthtech start-ups seeking to be adopted at scale. This is a rapidly evolving part of the German health system, so it's hard to determine the precise qualities in start-ups that will come out ahead.



The German healthtech start-up landscape in numbers:²

- 2022 saw an increase in global VC investment into German healthtech, from \$1.0 billion invested in 2021 to \$1.1 billion in 2022.
- The jump up from 2020 is most impressive, from \$331 million in 2020 to \$1 billion or more in two consecutive years in 2021 and 2022.
- Early-stage investment has seen higher growth in Germany than in the UK or France, growing 29% from \$272 million in 2021 to \$351 million in 2022.
- Later stage investment into Series B and Series C start-ups took a hit in 2022, reducing from \$759 million in 2021 to \$512 million.
- 2023 investment into Pre-seed to Series C German healthtech is showing signs of catching up to 2022, although total investment has only reached 30% of 2022's total at time of writing.

In recent years, integration of services has become a priority for the German government.

VC investment in German healthtech

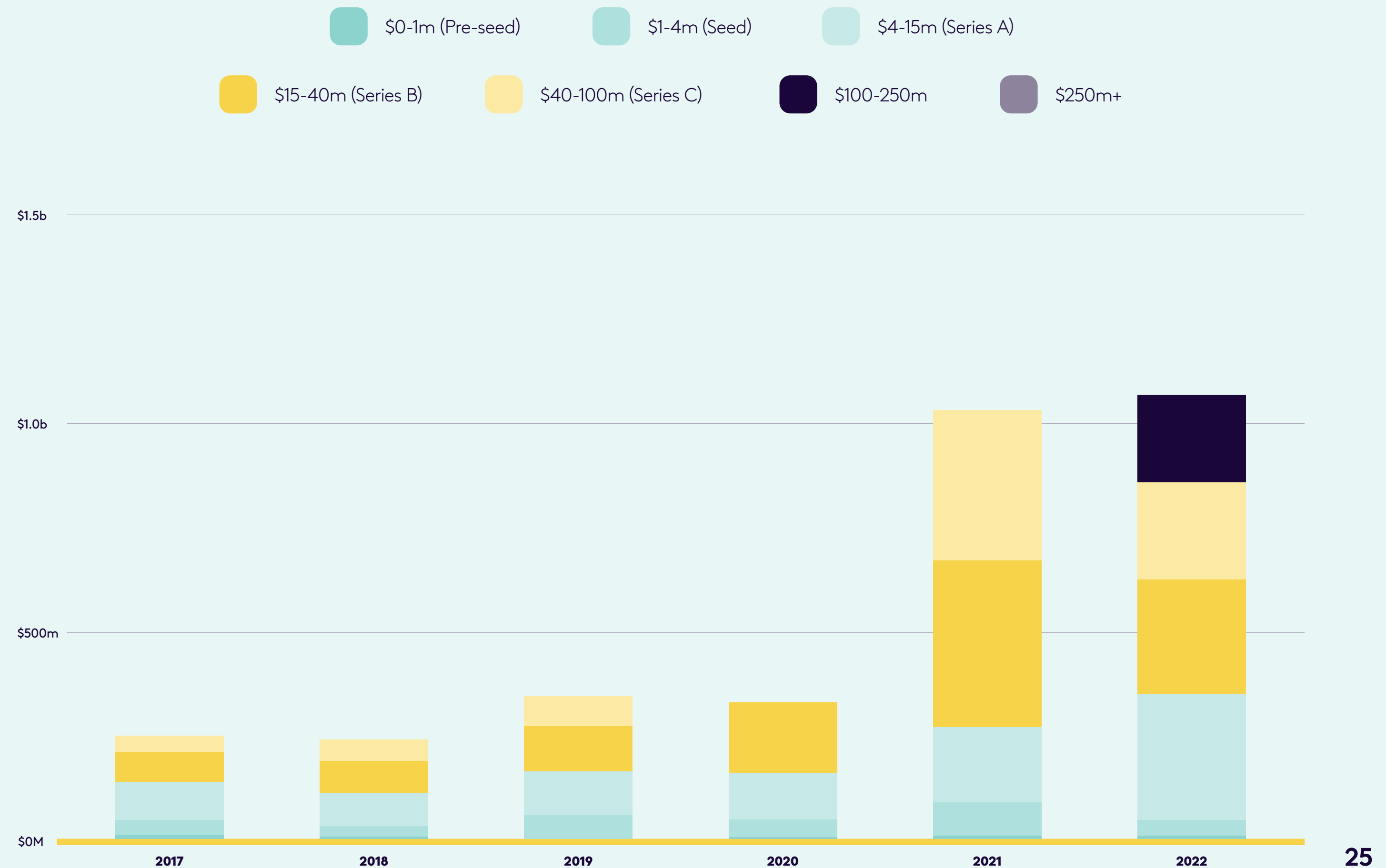


Figure 7, VC investment in German healthtech.²

Germany summary

Many barriers, but poised for huge growth

Germany has a strong reputation for healthtech innovation, but the financing and delivery of the health system has led to a lack of integration, with disparate ambulatory and hospital care services. In combination with complex regulatory and reimbursement mechanisms, this has created an environment that has been, historically, hostile for healthtech adoption and diffusion. Still, recent years have seen the German government make significant legislative improvements, as well as investments aimed at promoting innovation and digital transformation within the healthcare sector.

As a consequence, a thriving healthtech start-up scene has emerged in the country, which has birthed several successful companies including Ada and Kaia Health.

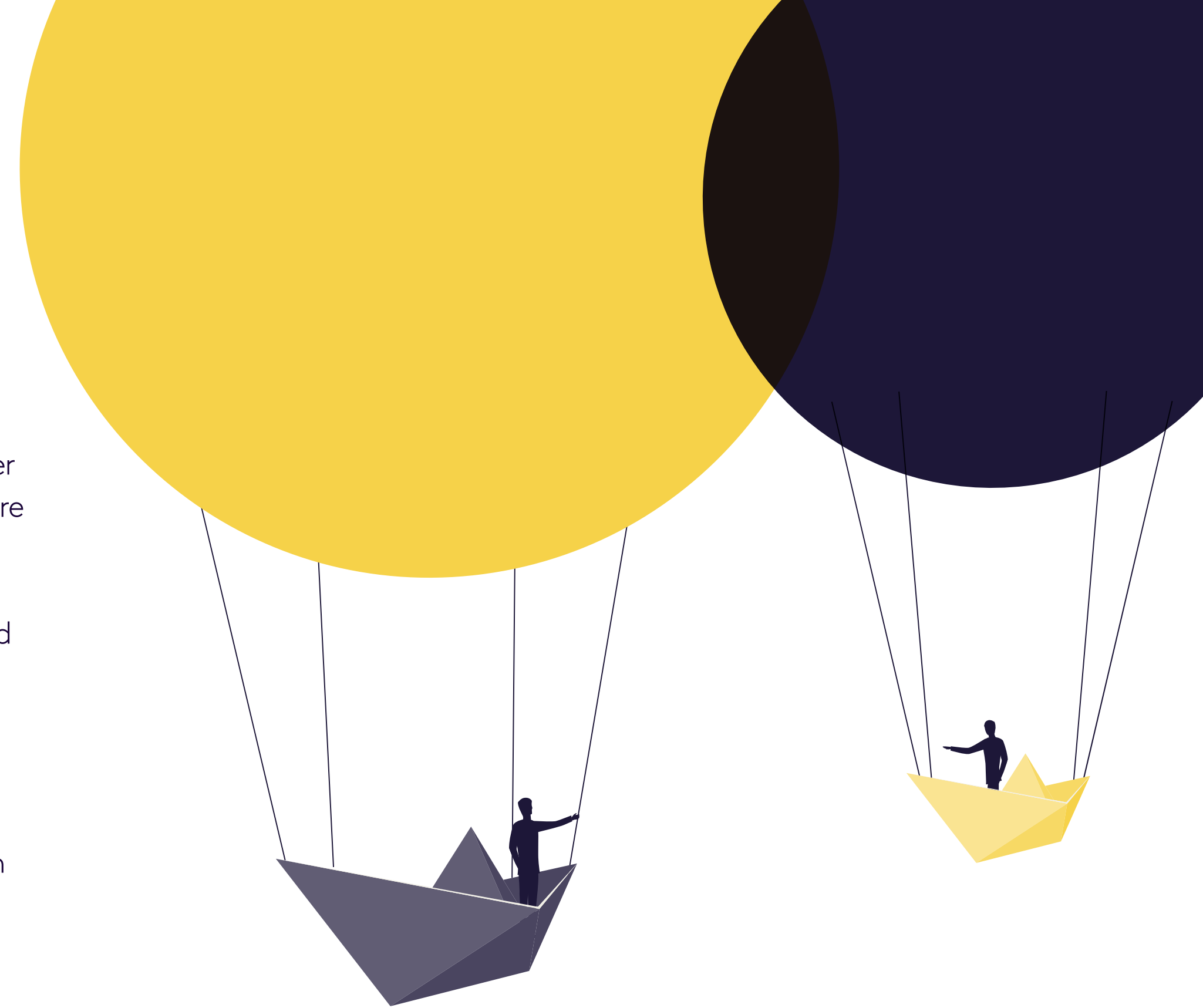
When compared to the UK and France, Germany's healthtech start-up ecosystem is still relatively nascent – but it holds huge potential for growth, with various public, private and grant opportunities available to German start-ups.

The German healthcare system today affords multiple opportunities for collaboration between start-ups and individual hospitals or clinics.

While the ambulatory and hospital services suffer from a lack of integration, the German healthcare system today affords multiple opportunities for collaboration between start-ups and individual hospitals or clinics, either through publicly funded research and development programmes or through the purchasing agencies for hospitals.

There are also grant opportunities available from the Federal Ministry of Education and Research (BMBF), while support also comes from various accelerators and incubators in Germany, including Startupbootcamp, Flying Health Incubator and the Berlin Institute of Health (BIH) Digital Health Accelerator.

The real opportunity for healthtech start-ups is yet to become fully clear. On the one hand, new legislation surrounding DiGas provides a unique European opportunity for DTx. On the other, the move towards integration signals that, like the UK and France, Germany will soon be keen to adopt technology that provides efficiency and productivity gains. Regardless, Germany is building a new health system landscape, and the founders and investors who can connect with change thinkers in Germany's integrated leadership stand to win big.



Trends

03

Staying on top of the ever-evolving trends and convolutions of the healthtech world can be arduous work for founders. But ultimately, the constantly changing landscape is reflective of the strides towards enhanced automation and efficiency in the industry.

Innovation is enabling reduced patient contact time, providing patients with greater knowledge and control over their health. In turn, this increases doctors' capacity, resulting in better accuracy and patient outcomes.

In this section, we take a detailed look into four different areas of healthtech: consumer, technology, go-to-market strategies and regulation. We explore the impact they're having across Europe and how we expect them to evolve the industry in the near future.



Our 4 different trend areas:

- Consumer
- Health technology
- Go-to-market strategies
- Regulatory

3.1 Consumer

Big tech players and bridging the gaps

Things are moving

It's no secret that public health systems across Europe are massively strained. Paired with a consumer-driven, convenience culture, this makes for a lot of dissatisfied customers — or in this case, patients. As seamless, digital consumer experiences become ever more ubiquitous in other areas of life, frustration is growing, as healthtech for accessing medical care continues to fall short of consumer standards.

But change is happening. Consumer healthtech platforms, designed for individuals, are providing users with greater control over both short and long-term conditions, improving patient outcomes and opening capacity for healthcare professionals. Healthtech has the power to remove physical barriers to access, unlocking the ability to reach previously untapped groups and collect new data, which, in turn, holds the potential to make healthcare more equitable across the continent as a whole.



If you can get people to engage with healthtech in a similar way to other consumer experiences, you have better access to them, can treat them more easily and gather more of their data. This creates a highly personalised experience, and consumers will continue to come back.

– Chantal Cox, investor at Octopus Ventures

Consumerisation of healthcare: what the next few years could look like

A survey of 2,000 health consumers confirmed that young adults in particular are seeking a healthcare experience aligned with the other consumer experiences in their lives.²⁸ But healthcare systems don't have the resources and infrastructure to facilitate such a revolution. Enter: tech. Big players are moving in to offer their competencies and get healthcare services up to par.

In February 2023, Amazon acquired primary care provider OneMedical for \$3.9 billion²⁹ in a bid to dramatically improve the experience of getting medical care. The core idea is that users seeking medical attention will enjoy a similar consumer experience to that of shopping online at Amazon. As with products, patients will find a broad range of options with streamlined delivery, offering speedy gratification and rendering them less likely to visit a doctor in person.

While other telehealth start-ups are doing a similar thing, Amazon is uniquely well-positioned to align the experiences of healthcare and digital retail – if only because of its scale. But while Amazon enjoys high levels of trust amongst its existing customer base, the sensitive nature of health information raises serious questions about user engagement.

As Amazon and other tech companies move into healthcare, this question of trust is set to be a huge determining factor of success. Consumers have the power to determine who'll win out, based on their preferences for Amazon or smaller healthcare competitors like Babylon and Doctolib.

The best healthcare platforms will have to work hard to capture and retain patients at the earliest stage, in order to see them through the entirety of their journey – from diagnostics through to treatment and recovery.

How consumers are engaging with European start-ups

Data is continuing to enable patient-centricity. State-of-the-art technology is empowering patients, giving them more control over their health and offloading non-critical care while also accumulating more research, which will improve healthcare in the future.

Chronic conditions have a major impact on an individual's life: beyond the affliction, they introduce further complicated emotional and personal dimensions, as patients have to adjust their behaviour and lifestyle to manage their condition on a daily basis. A major opportunity for healthtech lies in revolutionising the way patients are able to manage a long-term diagnosis while reducing the frequency of the need for direct interaction with healthcare professionals.



I think there's an element of trust that any non-healthcare organisation is going to have to overcome in order to be able to serve people's healthcare needs.

– Chantal Cox, investor at Octopus Ventures



This new wave of wearables for disease management is helping patients gain more control over their condition than ever before. The power of longitudinal data, which not only provides actionable insights to patients themselves but insights to clinicians and researchers remotely, has the potential to revolutionise the way we manage and treat chronic conditions.

– Harry Leeming, Co-founder and CEO of Visible

stitch

Founded in the UK, Stitch is a great example of a patient-centric platform. It harnesses consumer-engagement tactics to overhaul the experience of participating in clinical trials.

visible.

A UK-based start-up, Visible is leveraging the power of data to help patients manage energy-limiting conditions, including long COVID. Patients can use the app to keep a record of their symptoms, daily activities and medication. Visible are also employing wearables to measure personal biomarkers, helping people collect accurate data with superior accuracy and efficiency.

sidekick

Based in Iceland, Sidekick Health is also facilitating digital chronic disease management. It uses gamification to extend and support in-clinic care, helping patients to manage a range of conditions, including arthritis, diabetes, cancer and Crohn's disease. At present, Sidekick Health is only available in the UK to treat eczema, for which it helps patients identify triggers, manage stress and break itching habits.

Healthcare equity: how digital health is paving the way

Race, ethnicity, gender, socioeconomic status and geographical location are factors that can disproportionately affect patient outcomes. Used correctly, healthtech offers a powerful opportunity; used wrongly, it stands to widen inequity even further.

Alongside discrimination, the LGBTQ+ community faces disproportionately worse outcomes and experiences of healthcare.³⁰ Across Europe, the disparities are vast. Gender reaffirming surgery wait times can run as long as seven years,³¹ while as many as 40% of patients don't feel comfortable being open and honest with their doctor, and, in some countries, no provision of care is offered for under 18s.³²

The LGBTQ+ community is at a higher risk of health conditions including sexually transmitted infections, obesity and eating disorders, breast and cervical cancer, substance abuse and mental health issues. A survey conducted by NHS England revealed that the prevalence of longstanding illness is 4% higher amongst lesbian, gay and bisexual adults, who also suffer lower mental wellbeing than heterosexual adults.³³



You could say it is easy investing in the obvious digital health offers- what is more challenging, and indeed rewarding, is investing in tech which is targeting underserved population groups. In that I include drug discovery and delivery for women, services for the LGBTQ community, some areas of fertility and also services for deprived populations. Some investors find it difficult to even discuss these areas and they are missing out, and so are the communities.

– Pam Garside, partner, Newhealth and chair, Cambridge Angels

LGBTQ+ healthtech: the US market

Digital consumer health stands to plug the gaps in traditional healthcare for the LGBTQ+ community, by promoting inclusion and providing safe and accessible spaces that can improve mental and physical wellbeing. Start-ups in the US have taken significant strides towards tackling some of the barriers to healthcare the community faces and hold important lessons for their European counterparts, especially in areas of community-specific healthcare.



Plume sidesteps traditional healthcare, to offer access to gender reaffirming care directly from a user's device. The app enables members to have virtual appointments, exchange messages with the trans-led team and collect their hormone-therapy prescription the same day from a local pharmacy.

Queerly Health

A digital platform that helps members of the LGBTQ+ community connect with culturally competent health and wellness practitioners in person or remotely. Queerly Health also works to increase the numbers of LGBTQ+ friendly professionals by promoting access to training, programmes and certification opportunities.



The world's first gender transition technology designed for people who are unsure how to reach their true identity. Solace guides its users by providing resources and helping set milestones in their transition journey with 'no referral letter or meetings to show up to'.

What's missing from the European market?

European healthtech for the LGBTQ+ community lacks digital platforms for access to inclusive healthcare as provided in the US, but punches above its weight when it comes to mental health support. Here are some of the start-ups doing it best.

kálda

Kalda employs CBT, meditation and mindfulness to help individuals manage the stresses and anxieties that come with being LGBTQ+ in a heteronormative world. App users can also explore a range of topics through on-demand video content and feel validated by daily affirmations and journal exercises.

helsa.

Helsa aims to improve mental health among the LGBTQ+ community and other minority groups through education and training. Helsa also aims to reduce stigmas through a specially developed, immersive, virtual-reality technology called Empathy VR, which allows users to experience everyday discrimination through the eyes of the stigmatised.

lvndr

LVDNR Health is one of the only European healthtech platforms providing remote care for LGBTQ+ and minority communities. The company works alongside the NHS to provide specialised clinical support and free, at-home pre-exposure prophylaxis (PrEP) monitoring and diagnostics.



There currently exists a chasm between advanced healthcare and those who need it the most. In a world where the technology exists to monitor patients remotely, it is an unfortunate reality that socioeconomic barriers often prevent its effective implementation. By employing business models that leverage sustainable strategies, entrepreneurs are overcoming those barriers and creating an ecosystem where technology-enabled healthcare is accessible to all.

– Dr Ahmed Kerwan, NHS doctor
and analyst at KHP Ventures

An opportunity to support an underrepresented group

For LGBTQ+ support and access across the continent, Eastern Europe currently finishes last, thanks in no small part to policy; in Hungary, portrayal and promotion of gender change from birth is banned for under 18s.³⁴ This legislation massively contributes to stigmatisation and has a corresponding impact on the mental wellbeing of young people considering their identities.

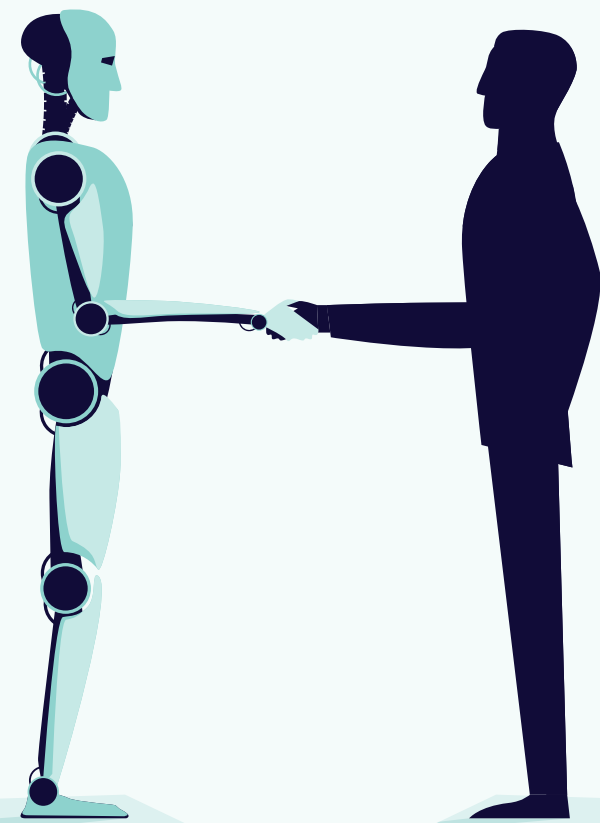
It supports the hypothesis that Europe would hugely benefit from greater provision of specialist remote care, in the interest of avoiding social discrimination and promoting better wellbeing in this community.

3.2 Health technology

The most exciting trends in healthtech include generative artificial intelligence (AI), compliance AI, digital biomarkers and Web3. These technologies will revolutionise healthcare and help healthtech to overcome some of its major obstacles. From using AI to transcribe patient-doctor interactions to using blockchain to securely share medical data, these technologies are poised to significantly disrupt the market.

AI-led automation

Workflow and automation tools are blurring the line between humans and machines. They are transforming the way we deliver healthcare, from patient onboarding through to treatment and discharge.



What ChatGPT means to healthcare

5 days, 1 million users: 2022 also saw the advent of perhaps the most disruptive technology to date, ChatGPT. To put that into context, this same feat took Instagram 2.5 months and Facebook, 10 months. ChatGPT is a language model developed by OpenAI. It is a type of AI that uses deep learning to generate human-like text. It is trained on a massive amount of data, which enables it to understand and respond to a wide range of language-based tasks such as text completion, text generation, text classification and more. Technologies like ChatGPT have the potential to be transformative for healthcare. For example, they could be used to talk to patients and help them schedule appointments or answer questions they have about their health. It could also be used to help doctors write patient notes, making things easier and more efficient. ChatGPT could be used to help researchers figure out new ways to treat disease by analysing data, and also for language translation, which can be really helpful for patients who speak a different language than their doctor.

– And yes, this paragraph was written by ChatGPT.

awel

Awel is developing a no-code workflow development platform to design and optimise care pathways. It automates work and delivers evidence-based care with powerful flows that make care teams and patients move as one.

Ufonia

Ufonia uses AI-led voice automation, automating routine appointments through phone calls to patients, leading to high patient engagement and an improvement in outcomes. Large language models (LLMs) are being used as an additional tool to streamline care plan development and process insurance claims.

Compliance SaaS

With regulation and certification costs sky-rocketing, there's a major opportunity for compliance AI.³⁵ Compliance SaaS describes the use of AI and machine learning to automate the medical device certification process, making it more efficient and cheaper for companies to get their UKCA and/or CE mark.

It has a wealth of applications in healthcare, including making sure that patient data is kept secure and private in accordance with HIPAA laws, preventing medication errors and cross-checking health organisations billing to prevent fraud. Compliance AI is particularly important given the challenges in Europe's digital health infrastructure highlighted by this report.

Digital biomarkers and diagnostics

Every two minutes, someone in the UK is diagnosed with cancer. Keeping up with the challenge it represents requires us to decouple cancer diagnosis from physical capacity. Breast, prostate, lung and bowel cancer account for more than 50% of cancers in the UK.⁵³ The rising cancer incidence, along with a limited number

of pathologists, has resulted in overwhelmed labs, potential delays in diagnosis and treatment and difficulties maintaining quality of diagnosis.⁵⁴

Early diagnosis saves lives. Start-ups leveraging technology to decouple diagnosis from physical capacity will be at the vanguard of health changes over the next decade.

Similarly in the neuro-degeneration space, dementia is a growing global social and economic problem that needs better prevention tools. Dementia has been estimated to cost the UK £25 billion annually — a figure that is only set to rise. The condition carries significant social and economic implications in terms of direct medical and social care costs, as well as the costs of informal care (£10.2 billion). Globally, the figures tell the same story: the estimated total global social cost of dementia was \$1.3 trillion in 2019, projected to surpass \$2.8 trillion by 2030, as both the number of people living with dementia and care costs increase.³⁶ It's essential that start-ups are able to provide earlier diagnostics in order to better manage disease prevention.

Mindstep has developed a multi-condition, neuro-psychiatric screening platform that helps users screen for anxiety, depression,

Start-ups to watch in compliance SaaS and digital diagnostics:

Scarlet

Scarlet provides compliance software to certify SaMD (software-as-a-medical-device) and clinical-grade AI. This allows healthcare companies to iterate, certify and release products at an unparalleled pace in comparison to traditional, consultant-dependent methods.

FLINN

Flinn enables medical device manufacturers to automate quality and regulatory processes to make their compliance work 10x more efficient.

IBEX

Ibex has developed a clinical-grade AI solution for cancer diagnostics and analysis that significantly improves pathologists' diagnosis of cancer, enables AI-powered quality control, reduces occurrence of missed cancers, increases lab efficiency and provides a platform to diagnose cancer at stage three. The company uses a platform called Galen, a clinical-grade, multi-tissue platform, to help pathologists detect and grade breast, prostate and gastric cancer, alongside over a hundred other clinically relevant features. Galen integrates third-party digital pathology software solutions with scanning platforms and laboratory information systems. It was developed using rich datasets, extracted from over ten million slides from pathology and features AI algorithms designed by a diverse team of global pathologists who have labelled slides with over 150,000 image annotations and rigorous deep machine learning algorithms.

early dementia, post-concussion syndrome and migraine. It combines clinical trials and an engaging multi-condition user interface to help people engage and identify the conditions they are susceptible to. By bringing together early screening and new dementia or Parkinson's drugs, which are being approved this year, Mindstep is improving quality of life for patients suffering from conditions that have, historically, been debilitating.

Web3

Secure and decentralised, Web3 promises a new era for patients and their health data through enabling DeSci – or decentralized science. Web3 technology is being harnessed to tackle some of healthcare's most challenging problems: funding structures, lack of interoperability, IP ownership, data privacy and transparency. Web3 technologies, such as blockchain, provide a decentralised, interoperable data platform that enables frictionless sharing of medical data, privacy of data in the hands of patients and transparency of supply chain infrastructure.



With recent advances in cancer screening, diagnostics and treatments rapidly improving survival rates, cancer is beginning to be reclassified as a chronic condition. A hybrid approach using digital health technologies combined with effective human intervention can allow us to create affordable, scalable healthcare models which can be used to support millions of cancer survivors globally.

– Kelly McCabe, Co-founder and CEO of Perci Health

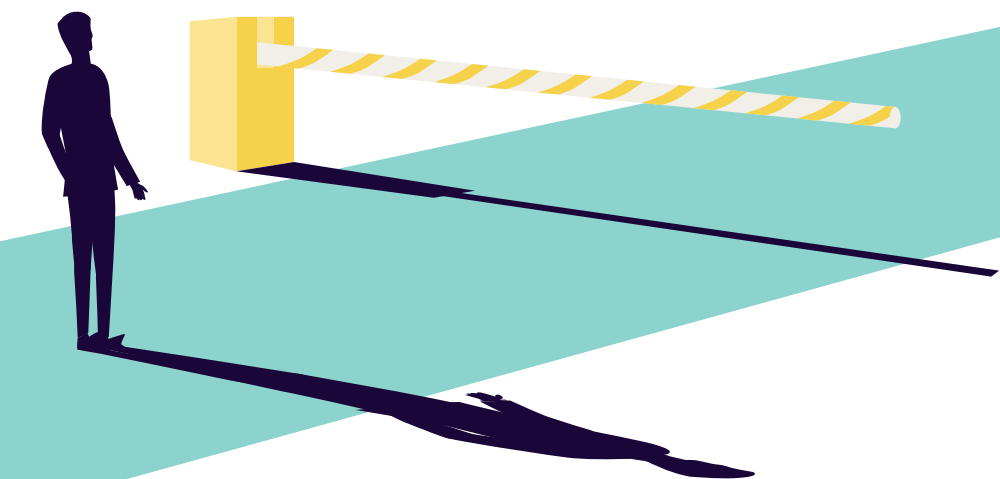
Start-ups harnessing Web3



Medical Chain utilises blockchain technology to provide a decentralised platform for patients to securely store and share their medical records. Additionally, the platform has a telemedicine component, combining these disruptive technologies to make medical care more accessible and secure.

Fleming PROTOCOL

Fleming Protocol is an open-source data economy that fuels collaborative biomedical discovery by incentivising patients or hackers to work with labs, scientists and academia. Fleming Protocol will provide the infrastructure for patients to store all of this data in one place using the InterPlanetary File System (IPFS) as the decentralised data storage solution, giving users full custody and control of their data.



3.3 Go-to-market strategies

What, where and how?

Navigating the waters

It's difficult for founders to hear, but the speed with which their ventures are adopted and scaled has less to do with the strength of their solution and more to do with contextual factors, such as health system characteristics, institutions within the health system and the adopting entities within these institutions like clinicians and healthcare professionals (Figure 8). Human resourcing of the healthcare professionals is a further factor, and there is a direct correlation between stress in the system (often reflected in waiting times) and a slower pace of healthtech adoption.

For founders seeking widespread adoption and rapid scaling, selection of the right go-to-market strategy is pivotal. The most effective go-to-market strategy varies across countries, so founders need to practise agile, system-based thinking and take care to consider the bidirectional relationships between the problem they are addressing, their start-up, the adopters, the health system and the broader context.



What matters is scale. Go-to-market strategies must have scale in sight from the start. Rapid scale up and replication requires a thorough understanding of the characteristics of the health system and the adopters to ensure the innovation can be seamlessly aligned with system elements and workflows. Not doing so means stagnation and the end of the new venture.

– Professor Rifat Atun, professor of global health systems, director of health systems innovation lab, Harvard University

Framework for analysing adoption and diffusion of innovations in health systems

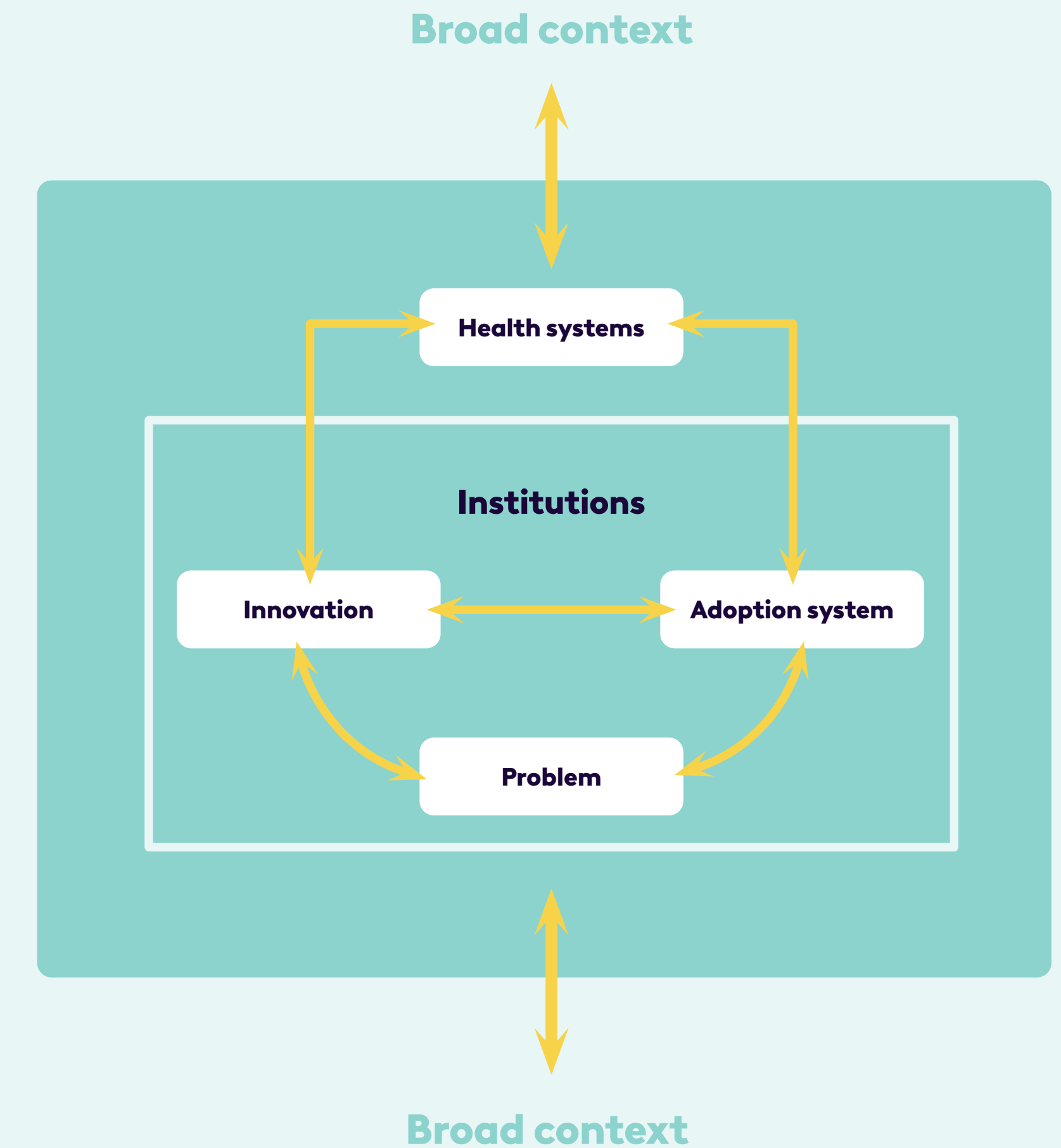


Figure 8, Framework for analysing adoption and diffusion of innovations in health systems.³⁷

In this section, we explore four prominent go-to-market strategies, highlight where they work most effectively and discuss where they should be practiced with caution. Start-ups with the ability to leverage the most effective go-to-market strategy for the context and the agility to pivot depending on the setting can be rapidly scaled and adopted internationally.

Go-to pharma: a marriage of convenience

From a start-up's perspective, pharma companies have numerous entry points. Some have innovation centres; for example, Johnson & Johnson, which is excellent at spotting companies that can integrate into its existing business lines, such as oral care and vision among others. Other pharma companies have developed digital health funds and venture builders. One example is RoX Health, which invests in and supports start-ups and can open doors internally within Roche. However, early-stage companies often prefer to demonstrate revenue rather than investment from pharma or medtech firms. Therefore, start-ups must think carefully about whether to accept investment from strategics early on or continue to develop commercial partnerships with pharma and medtech.

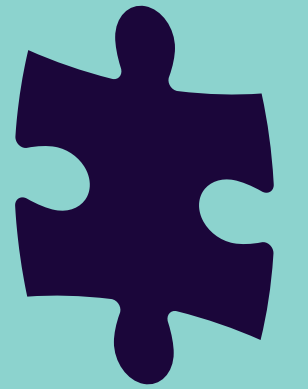
Typically, the most effective way to strike a deal with pharma or medtech companies is to go direct to the general managers of specific existing business lines. Tapping into existing R&D budgets is often more fruitful and quicker to action than tapping into innovation budgets, which usually have more stakeholders involved with different objectives.

For each of their assets, pharma companies have elaborate salesforces that regularly speak to providers, payers and other actors in the healthcare ecosystem. Many digital health companies have offerings that can complement an existing treatment and be sold alongside traditional assets such as drugs or devices. Some of the more successful partnerships between established players and start-ups are the ones where existing sales teams learn to sell new digital offerings alongside their existing product lines. This can be mutually beneficial, helping start-ups to scale while providing pharma with pioneering digital offerings that expand their presence in digital health.



The rise of digital health is fertile ground for the best of what partnerships have to offer – bold and innovative thinking coming together with the ability to quickly launch and scale globally with the trust and reach of our biggest brands.

– David Evendon-Challis, executive board member and chief scientific officer, head of R&D consumer health, Bayer



What and where?

Diagnosis and treatment-based start-ups, such as digital therapeutics, are well suited to the pharma go-to-market. Digital health start-ups that offer innovative solutions for disease management, drug discovery and clinical trial management are also appropriate. The success of these start-ups lies in getting their ventures into the hands of clinicians or researchers, and pharma's network and sales forces can be instrumental. Here are three start-ups who've leveraged this route with major success:



icometrix is a clinical-grade AI company that provides FDA-cleared and CE-marked image analysis to quantify disease-specific brain structures for acute and chronic neurological conditions. icometrix is successfully commercialising its platform within clinical practice and pharmaceutical companies, offering pioneering imaging and data analytical services from early to late-stage clinical development.



Rune Labs is a pioneering computational neuroscience platform leading precision neurology, starting with Parkinson's Disease. Rune has been successful at engaging the entire ecosystem: clinicians, patients and Medtech companies. Rune can gather real-world evidence using wearable technology for patients, engage clinicians with tailored workflows and provide clinical trial support with data collection, recruitment and synthetic control cohorts.



uMed is a patient recruitment platform that links health record data with direct-to-patient SMS outreach to accelerate patient recruitment for Phase II to IV clinical trials. uMed has integrated with the most-used electronic health record platforms in the UK, enabling the company to recruit, pre-screen and engage patients via primary care. uMed is leveraging its differentiated offering for successful collaboration with pharma and medtech companies.



Healthcare costs continue to escalate annually, yet the gains in life expectancy have plateaued. By leveraging technology, we free healthcare practitioners from administrative tasks so they can focus on patients. Our digi-physical model ensures a seamless patient journey and enables clinics to operate more efficiently. This results in a more seamless healthcare experience and enables patients — and doctors — to make better-informed decisions.

– Christopher Muhr, Co-founder and CEO, Patient21

Direct to providers: a UK view

The direct-to-providers go-to-market strategy provides an opportunity for validated learning and organic growth, by scaling from provider to provider. In this strategy, start-ups target providers such as general practice (GP) providers, primary care networks (PCNs), clinics, hospitals and care systems on the premise that these providers are the primary customers of the service that is being offered. Again, it is crucial that founders look at this strategy through the innovation systems-based lens (Figure 8).

Understanding the incentives of the providers helps founders to understand which healthtech lends itself most favourably to this go-to-market strategy. It particularly rewards healthtech start-ups with a value-add geared towards efficiency and productivity. Generally speaking, providers are incentivised by efficiency and productivity gains across the whole European context. With total health expenditure outstripping GDP growth, and almost all European governments financing their health system to some extent from pooled financial resources, there is a focus on productivity and efficiency. This applies even more in the US, where health expenditure is expected to reach almost 20% of the GDP by 2028,³⁸ and health systems are desperate for efficient solutions.

The UK provides the clearest example of this route. The Health and Care Act of 2022 established statutory integrated care systems (ICSs) across England. These geographically based partnerships bring together providers and commissioners of NHS services with local authorities and other local partners to plan, co-ordinate and commission health and care services (Figure 9). As the King's Fund reports, this is part of a fundamental shift in the way the NHS is organised – away from competition and organisational autonomy and towards collaboration, with health and care organisations working together to integrate services.

The ICSs are held to account for delivering a small number of national and local priorities and receive a population-based budget to achieve these ends. The system has become more coordinated, with a central focus on efficiency. The GP partners, PCNs and ICBs/ ICSs have the autonomy to adopt innovations which, if successful (and aligned with the efficiency motives), can then be scaled from one ICS to the next.

α anima

UK-based company Anima exemplifies this route. Anima combines a care-enablement platform with productivity tools on a single platform and has successfully scaled from PCNs to ICSs using champions at each level of the system.

Integrated care systems (ICSs) key planning and partnership bodies 2022

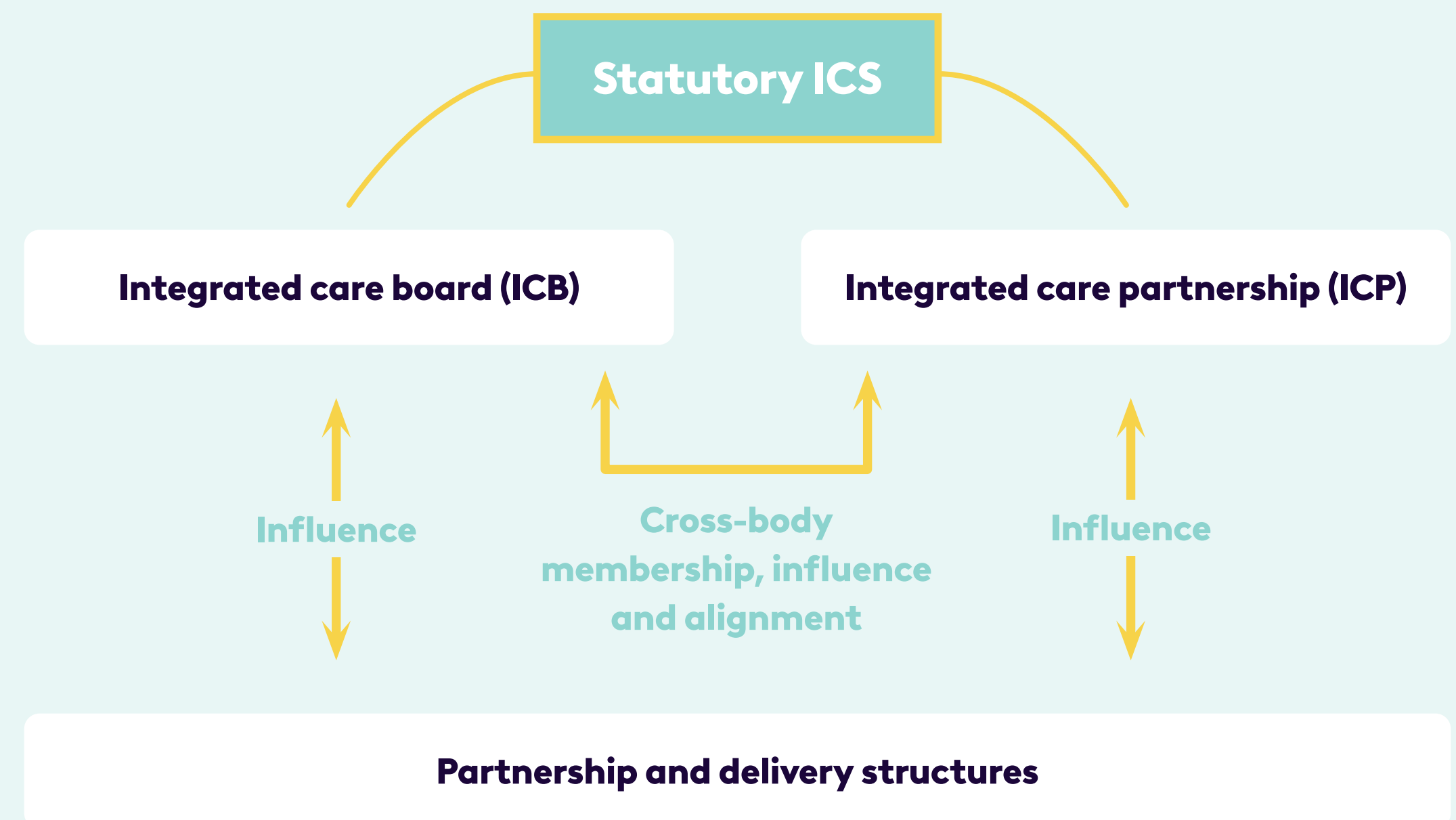


Figure 9, Integrated care systems (ICSs) — key planning and partnership bodies 2022.³⁹

Over-the-counter products for vertically integrated out-of-pocket healthcare

Another promising route to market for start-ups is to tap into the growing out-of-pocket healthcare spend across European countries. Due to the consumerisation of clinical-grade healthcare services, the changing regulatory landscape across certain medical devices and long waiting times within public health services, out-of-pocket healthcare spend per capita in Europe is increasing, with patients opting for faster, more convenient access to the healthcare services they need.

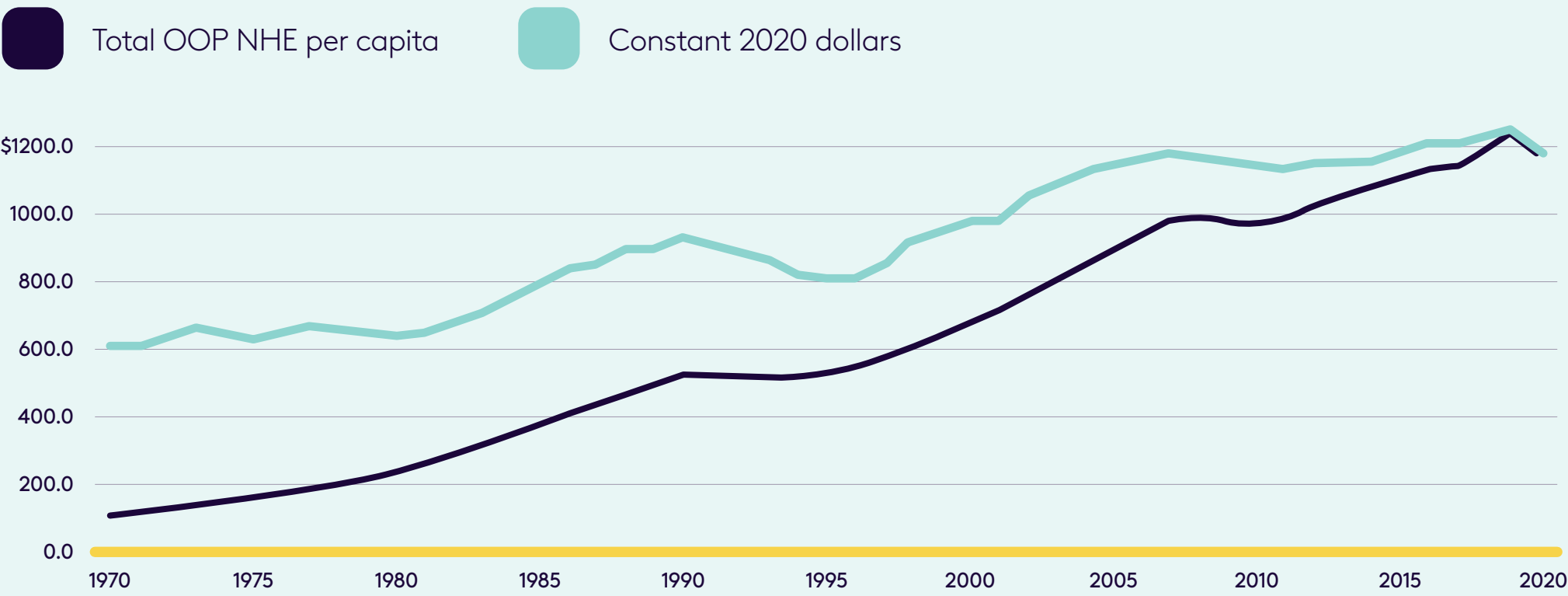
Companies such as Tympa Health – which provides digital ear and hearing care services through both hardware and software services – are partnering with leading companies such as Boots and Hidden Hearing to provide readily accessible services to people in need of care. The equivalent pathways through GPs are more challenging to access, as not all GPs are trained or equipped to provide ear and hearing care during a consultation. This results in a high willingness to pay out-of-pocket across many European countries. With hearing aids becoming

increasingly over-the-counter (OTC) products in the EU and US, companies are tapping into this go-to-market strategy to build leading digital-health businesses.

National procurement and distribution

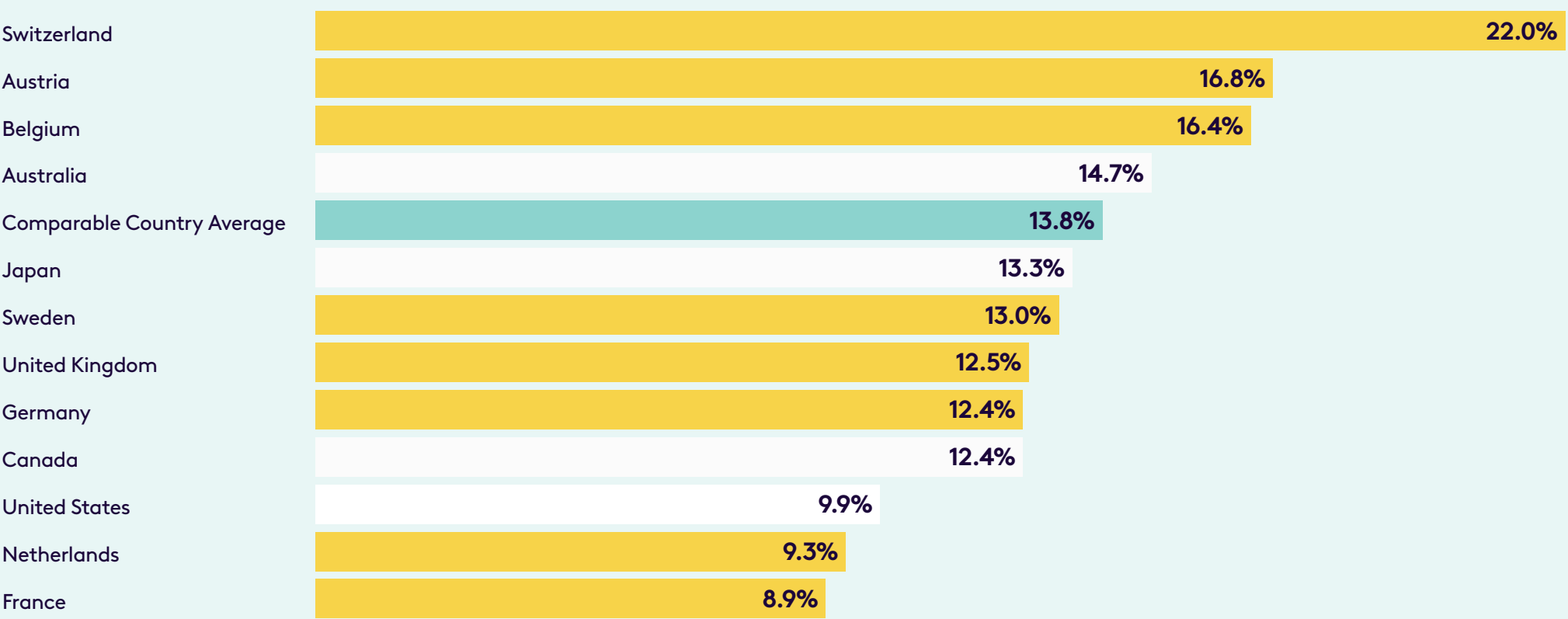
To unlock contracts at the national level, start-up founders need to keep abreast of the priorities of the government and leaders of the respective health system. Start-up technology might be nice to have, but if it isn’t aligned with national priorities, national procurement is unlikely to follow. The start-ups most suited to the national procurement go-to-market strategy offer innovations that require regulation or cost-effectiveness evaluations such as Medical Device Regulation (MDR), National institute for Health and Care Excellence (NICE) or Health Technology Assessment (HTA), and/or are aligned with national priorities. Targeting clinicians would be a mistake for these ventures, as in the highly litigious environment of healthcare, clinicians rely strongly on national guidelines. Clinicians also won’t prescribe without a reimbursement mechanism.

Per capita out-of-pocket expenditures, 1970–2020⁴⁰



Note: A constant dollar is an inflation-adjusted value used to compare dollar values from one period to another.

Household out-of-pocket spending as a share of current health expenditures, 2020 or nearest year⁴⁰



Note: Data from Australia are from 2019. Data from Canada, Germany, Sweden and the United Kingdom are provisional. Data from Austria have a difference in methhodoogy.

Where?

This go-to-market strategy is suitable for healthtech scaling in relatively mature markets, where governments promote digitisation of care and have established national reimbursement mechanisms. These would include the likes of Germany, France, Sweden and the UK. Other European countries, such as Spain, lack clear national reimbursement pathways, making a direct-to-purchaser or provider go-to-market strategy more suitable.⁴¹

The national procurement go-to-market strategy is also appropriate for start-ups tackling issues of national concern. While all start-ups might wish to believe that what they are working on is the biggest problem out there, it's incumbent on founders to ask who the problem they're solving is biggest for. In answering this question, the go-to-market strategy becomes self-evident.

European health systems are, broadly speaking, all facing the same primary challenges and this report has explored many of them in depth. The specific pathways created for founders by health ministers offer insight into which start-ups are best-suited to this go-to-market strategy.

In the UK, over £500 million of funding has been allocated to local authorities and integrated

care boards (ICBs) within the NHS for the integration of care — a major opportunity for healthtech solutions working to tackle this burden. In Germany, DiGa enables procurement and reimbursement for disruptive, cost-effective healthtech at a national level. For founders, the message is clear: ask the right questions, and the right go-to-market strategy comes quickly into focus.

Direct to insurers

This route involves selling healthtech innovations directly to insurers, who can then offer the product to their members as part of their insurance plan. The strategy effectively enables ventures to reach a large user base and quickly establish credibility in the market.

It's particularly effective in countries with an established private health insurance system, such as the UK, Germany and France, and has been leveraged by start-ups including Mindstep. By partnering with insurers, Mindstep is using this strategy to reach insurers' broad covered population, who may not otherwise have had access to multi-condition mental health screening at home. Start-ups looking to scale through this route need to identify the



Where a lot of founders go wrong is that they think if they've had a successful roll-out in one European country, that same strategy will be successful across the rest of Europe, and it's absolutely not the case. Companies need to be aware of the different models and develop a go-to-market strategy accordingly.

– Tanya Yankova, investor at Octopus Ventures

countries where private health insurance plays a significant role in the market, in order to facilitate easy adoption and scale up.

Chosen wisely, the correct go-to-market strategy enables founders to unlock the doors to international scale up themselves. The key lies in a dispassionate assessment of the interaction between the problem they are seeking to address with their venture, the adopters, the health system and the broader context. Most importantly of all, founders must be prepared to iterate their strategy based on the country they are seeking to scale to.

3.4 Regulatory

Medical Device Regulation (MDR)

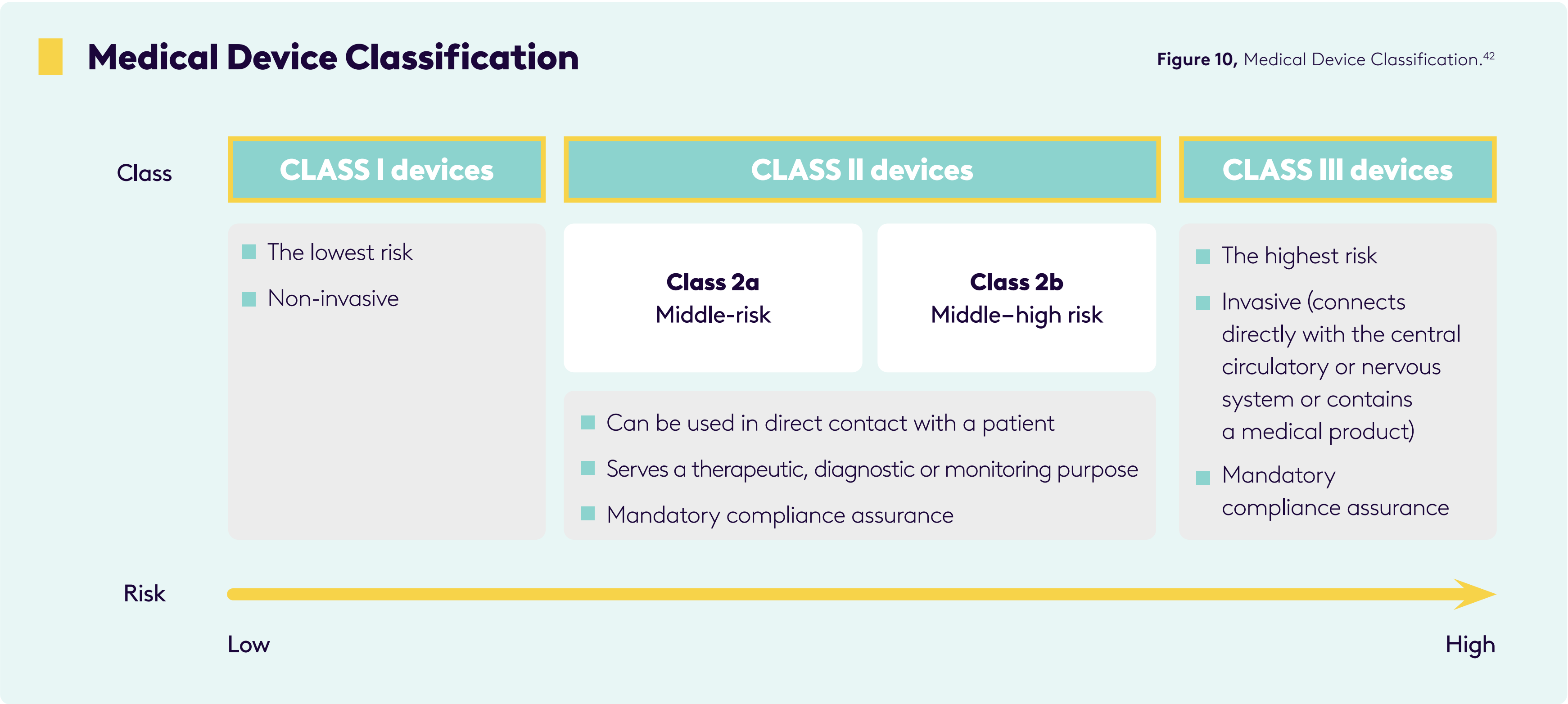
MDR in Europe

MDR was introduced in 2017 and came into effect in 2021.⁴² MDR replaces the Medical Device Directive (MDD) and is the new regulation governing production and distribution of medical devices in Europe. MDR sees stricter medical device classification rules, including changes to the classification of software and greater emphasis on device safety and continued surveillance.

The updated classification was triggered by a demand for increased regulation and transparency, a consequence of various high-profile medical device malfunctions. It has been the subject of heavy criticism because of its short-term impact on European healthtech companies, such as reducing the number of devices available due to costly and complex re-evaluation, and has raised longer-term concerns about its capacity to undermine the innovative potential of Europe.⁴⁴

Medical Device Classification

The MDR introduces notable changes to device regulation, including an expansion of the scope of quality management systems to include procedures for clinical evaluation, and a requirement for a Post-Market Surveillance System (PMS).⁴³



The regulatory challenges facing European healthtech

Europe's regulatory context undermines healthtech innovation and is driving start-ups away from population health challenges. The complexity of MDR processes, in addition to its prohibitive cost, represent a new challenge for European healthtech.

The regulatory barrier to innovation is already evident. The costs of certification are now ten times higher than under MDD, and it can now take up to two years to secure clearance, compared to the previous timeline of just a few months.⁴³ The detrimental impact of this regulatory context is further emphasised by reports that device manufacturers are cutting their products in the European markets due to the regulatory challenges. The European Commissioner for Health and Food Safety announced plans to delay full implementation of MDR given these challenges in January 2023, but this does not tackle the potential long-term impacts.

Robust regulatory processes are required to ensure only safe and effective devices make it to the market. However, the current regulatory context undermines Europe's innovation

capacity and impedes software development to the extent that founders of healthtech cannot overcome the regulatory challenges, and established providers are leaving the market. The more insidious consequence is that the regulatory context that is meant to facilitate safety within innovation is having the opposite effect. A balance needs to be found or we risk healthtech founders shying away and not developing devices which tackle population health challenges, instead focusing their efforts on systems that do not require as much regulation.

Regulation by country

Navigating the regulatory landscape can be a challenge for healthtech start-ups. Here we present the key regulatory considerations for healthtech start-ups seeking to begin in, or expand to, the UK, France and Germany.

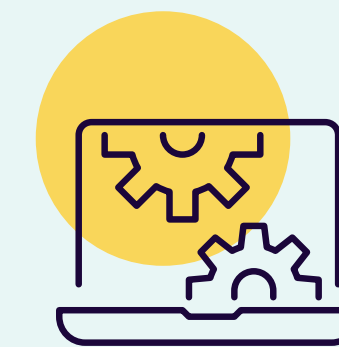
United Kingdom

The UK presents a unique case given that it is no longer part of the EU. Medical devices in the UK are regulated by [The Medicines and Healthcare products Regulatory Agency \(MHRA\)](#).



Stricter equivalence rules to come into place.

Start-ups seeking to expand to the UK should note that the United Kingdom Conformity Assessment (UKCA) regulation will extend beyond the requirements of the EU MDR, and, as such, these healthtech start-ups must be able to evidence entire conformity on a biological, technical and clinical basis. Any new features as part of the device, or products with similar functions and risk profiles to medical devices but without an intended medical purpose, will require clinical investigation before being regulated.⁴⁴



Software classification significantly differs from MDR.

The MHRA will amend its software classification based on the International Medical Device Regulators Forum (IMDRF) 'Software as a Medical Device' framework, so healthtech start-ups need to align themselves with this.^{45,46} In contrast to MDR, there will be no artificial intelligence (AI) specific legislation.



Regulation meets innovation.

Start-ups should seek to take advantage of the 'MedTech Innovation Route' developed by the MHRA. As part of this initiative, the MHRA will support healthtech through innovation hubs, with MHRA granting pre-market approval to make the device available on the market prior to UKCA approval.⁴⁴

In June 2022, the MHRA published new guidance regarding device regulation, primarily based on the EU MDR, with some key differences with regards to 'equivalence' tempered with encouraging proposals for healthtech innovation hubs.⁴⁴

France and Germany

France's [Agence Nationale de Sécurité du Médicament et des Produits de Santé \(ANSM\)](#) is responsible for registering and assessing healthtech. In Germany, the Federal Institute for Drugs and Medical Devices ([Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM](#)), is the institution responsible for regulating medical devices.



The current regulatory environment wasn't designed for software, yet it is software — and especially AI — building the future of health.

– James Dewar, Co-founder, Scarlet



The EU medical device passport: CE-mark, authorised representative and a quality management system.

Healthtech start-ups must obtain the CE-mark for adoption and diffusion through the EU. To obtain this, founders must appoint an authorised representative (AR) who can be based in any of the EU member states.⁴⁷ The AR acts as a liaison between notified bodies and the healthtech company and is responsible for the registration process and post-market surveillance. Additionally, healthtech companies require a Quality Management System (QMS). In summary, the process flow starts with classification of the device followed by QMS certification, analysis of source documents from founders, CE technical application, AR submission to notified body, conformity assessment, issue of CE approval and finally, notification of competent authority.

Our predictions for 23/24

04

Disruption

It's all about the basics

Disruptive technologies in health will be those that empower actors within European health systems to get back to doing what they do best — caring for patients, researching the next breakthrough and building the healthtech that's able to meet Europe's biggest health challenges. From unburdening healthcare practitioners of their administrative backlogs to enabling start-ups to rapidly scale through a disjointed healthtech infrastructure, 2023 in technology empowers, disrupts and resets.



Physicians already spend a sixth of their time on admin, and lots of healthtech tools increase the admin migraine even more — while reducing autonomy. I think the real success is in tools that give a delightful user-experience and unlock even more time to let physicians practice 'real medicine.'

– Dr Mustafa Sultan, doctor and creator of Big Picture Medicine



B2B health procurement of digital health services

Two-thirds of health system executives agree that the pandemic has highlighted the importance of procurement optimisation.⁴⁸ Additionally, companies are experiencing vendor-fatigue, as they are being targeted by a plethora of digital health and digital therapeutic companies aiming to sell their services through attractive employer channels.

A pain point for businesses has been the inefficiency and barrier to procuring healthcare, or the resources needed to deliver healthcare, for their employees. Breakthrough founders able to support companies in ensuring employee wellbeing and health are set to win big in 2023.

As the health and wellbeing of the workforce becomes a bigger priority for industry, investment is likely to gravitate towards these providers.



In 2023, there is a huge talent re-shuffle. Big Tech is shedding top talent, who are in turn founding deeply technical businesses in the healthcare space, pushing the limits of ML development, health SaaS and medical device innovation.

– Matthieu Vallin, investor at Octopus Ventures

Start-ups to watch in this space include:

Syndi⁺

Syndi is a B2B platform that gives businesses the ability to support the mental health needs of their employees and procure validated support. Syndi offers employees consistent mental health clinical self-assessment and vetted digital support recommendations.

HealthKey

HealthKey connects digital health providers, employers and insurance enabling businesses to skip the healthcare procurement process.

Compliance SaaS

Breakthrough software is changing the landscape of health, and regulation hasn't been able to keep up. With the recent changes to medical device regulation, demand exceeds supply for solutions that simplify the increasingly complex legal and regulatory backdrop of European healthtech.

While arguments can be made that regulation is holding healthtech back, there's a unique opportunity for healthtech to shape the solution for regulation. Start-ups that can mobilise their efforts towards this charge are likely to take off in 2023. Innovators already looking to meet this demand include *Scarlet* and *Qairn*.

Scarlet

as mentioned earlier in the report.

Qairn

seeks to simplify and automate the regulatory process for healthcare marketing.

Infrastructure and integration

Innovations that connect the disjointed healthtech infrastructure and pave the way for scaling healthtech start-ups are looking at a huge opportunity. With the EU calling for integration, the context is ripe and investment capital is waiting. It's time for infrastructure and integration start-ups to rise to the opportunity.

Exciting early start-ups already capitalising on this opportunity include:



A B2B SaaS company, Leyr provides an application programming interface (API) aggregator platform to build integrations between systems that operate with health data and medical-record systems. Leyr enables healthtech start-ups to utilise their API to connect to multiple electronic patient records at once through one piece of code.



Keragon provides healthcare-specific automations, without the need for code, in minutes. Keragon enables start-ups to build enterprise-ready integrations and automate HIPAA compliant healthcare workflows.



Basebox provides a secure, regulatory compliant, GraphQL backend, preventing fledgling start-ups from implementing the same functionality repeatedly.

Implementing AI and machine learning

With AI embedding itself ever more broadly into healthtech, machine learning operations (MLOps) are vital for rapidly maintaining, monitoring and scaling ML models. Medical AI adoption is lagging due to a lack of compliant, scalable and ML-friendly data access.

Start-ups that can act as a facilitating marketplace for AI and other disruptive technologies will emerge as some of the front runners in 2023 VC investment.

Start-ups meeting this demand include:



Gesund is a platform that enables clinicians and companies to test and train AI. It orchestrates the AI as-a-medical-device lifecycle, providing privacy-centred access to diverse yet standardised medical data sources and a unique analytical toolbox that fosters clinical validation, regulatory clearance and effective marketing.

Digital screening and diagnostics

The burden of mental illness has been underestimated by more than a third and is the number one cause of disability.⁴⁹ This is due to a combination of factors, including the overlap between psychiatric and neurological disorders, separation of suicide and self-harm as disparate reporting categories, exclusion of mental health conditions such as personality disorders from calculations, and an inadequate consideration of the link between mental health and death. A growing awareness of the burden of mental illness has resulted in a call to action for start-ups, and VC investment will continue to be drawn to start-ups seeking to tackle the challenge. Capital is waiting.

In 2023, digital screening and diagnostic will come of age.

Start-ups in this space include:



As mentioned earlier in the report, mindstep combines a clinical approach to diagnosing patients with an easy-to-use interface. The business deploys validated mental health questionnaires in combination with AI to diagnose a range of mental conditions, from anxiety to memory disturbance, and then provides a tailored treatment plan.



Alena focuses on social anxiety, providing a platform for individuals to assess their beliefs, attentions, thought processes and avoidance tendencies, to help them understand their social anxiety and what they can do to manage it.

Mental health is coming to the forefront of the agenda. The combination of an ageing population, greater diagnostic ability and advancing pathophysiological understanding of mental illness is creating an enabling context for emerging digital screening and diagnostics. Start-ups that can leverage this opportunity are likely to prosper in 2023–2024.

Paediatric digital health and families with additional needs

Globally, 1.2% of children under five years are estimated to have cerebral palsy (CP).⁵⁰ The total medical reimbursement costs for CP in the US alone are over \$58 billion per year.⁵¹ Conditions and patients that have been long overlooked are finally getting the solutions they need.

As demand grows for these traditionally underserved communities, start-ups have the opportunity to be the first movers in this space and provide truly life-changing care to families.

Start-ups in this space include:



Andiamo provides personalised, clinically coordinated care for families living with cerebral palsy.



Hibi provides digital support for families caring for children with additional needs and long-term conditions.

Clinical voice AI and LLMs

Doctors spend nearly a sixth of their time on administrative tasks.⁵² In 2023, we will witness the beginning of a paradigm shift for healthcare providers, away from the burden of administrative tasks and back to providing high-quality, patient-centred care. The time currently spent on such tasks can be better spent exploring patients’ ideas, concerns and expectations; consoling their fears and providing the most valuable piece of healthcare — the human element.

ChatGPT and LLMs are already having a breakthrough year and this surge is likely to continue. Start-ups should continue to address the administrative pain point for health care providers.

Start-ups succeeding in this space include:



as mentioned earlier in the report, Ufonia replaces routine patient healthcare interactions with AI-led automated phone calls, to free healthcare providers from these repetitive tasks and focus on delivering high-quality healthcare.



Hippocratic AI is building a safety-focused LLM, which targets certifications, bedside manner and reinforcement learning from human feedback (RLHF) by healthcare professionals.

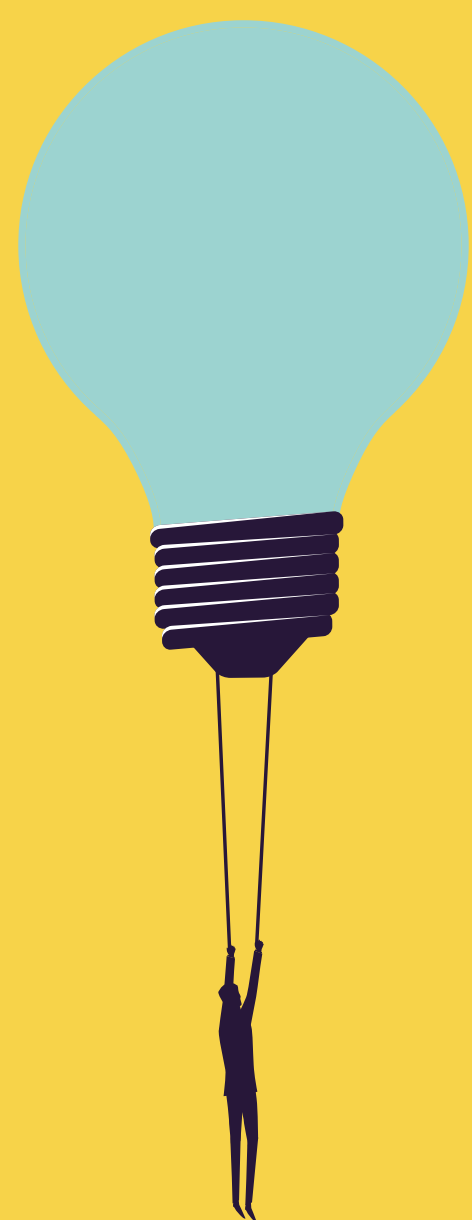


The Tortus mission is to accelerate the intelligent and safe adoption of AI in healthcare for the benefit of patients, payers and clinicians alike.



The focus for the next 12-18 months will be on small scale adoption. Particularly infrastructure and workforce solutions that can save healthcare systems money, while making them more efficient.

– Tanya Yankova, investor at Octopus Ventures



Conclusion

05

Onwards to even better care

The European healthtech landscape has undergone significant changes over the last five years. While growth prospects remain promising, there are signs that investment is slowing towards pre-pandemic levels. But, as we've seen, negative indicators bear closer examination. A dearth of IPO exits, for example, says as much about the exit-route preferences of healthtech founders – who tend more towards M&A exits – as it says about the health of the ecosystem.

Against a complex and uncertain macroeconomic backdrop, the continent is uniquely hospitable to healthtech founders, with three key territories leading the way.

While the last year might have seen the UK's VC investment into healthtech fall, it remains the highest of any European country. The political climate is sympathetic, with a government firmly committed to supporting start-ups, but regulatory challenges and the impact of Brexit present key challenges healthtech founders will have to navigate.

Still, for those willing to do so, major opportunities exist. Beyond a range of grant and public funding initiatives, emergent priorities and major restructuring within the NHS have created new pathways to scale.

The UK's regulatory environment stands in contrast to France, which is fast becoming a hot spot for healthtech. Last year's triumphant funding rounds for Alan and Doctolib signalled the health of a maturing ecosystem, while the country's regulatory environment and population-level patient needs suggest real scope for healthtech start-ups proactively engaged with the demands of an ageing population.

With a truly vast healthcare system under increasing strain from the growing burden of non-communicable diseases, the opportunity for healthtech start-ups in Germany is complicated, principally, by the economic context. But while the risk of recession looms, the country's efforts to integrate healthtech into the country's system can't be ignored.

In our analysis of emergent trends, we highlighted the role healthtech stands to play in bolstering equity in healthcare and we explored the opportunities open to start-ups leveraging cutting-edge software.

While we've chosen to focus on three key countries in this report, it's crucial to remember that the European opportunity is much greater — and more complex. The continent is diverse, and any founder's go-to-market strategy needs to be carefully calibrated around the unique demands of the healthcare system and population of the country they're scaling in.

From connecting with pharma to going directly to providers; from offering consumers over-the-counter treatments (capitalising on the emerging patient appetite for faster, more convenient healthcare) to unlocking contracts at the national level — the approach will depend on the solution and the context.

What we hope to have indicated is that while macroeconomic headwinds remain unpredictable — even challenging — the continent's early-stage healthtech ecosystem remains in good health. With an ageing population, and the prevalence of chronic disease, the continent is ripe for founders aiming to make a population-level impact. But just as critical will be the technology that empowers healthcare professionals to get back to what they do best.

That means providing better care, researching the next breakthrough and improving patient outcomes: these are where the continent's healthcare professionals shine. Automation tools that streamline systems, enhance productivity and generate efficiencies create space for those professionals to do precisely those things that underscore the very purpose of healthtech — making people's lives better.



Resources

1

[Pitchbook](#)

2

[Dealroom - Health funding round](#)

3

[Hit consultant - Digital health funding](#)

4

[CBinsights - Digital health report](#)

5

[Galen Growth Digital Health Ecosystem Report Europe Year End 2022, P.25](#)

6

[Tech.EU - European VC activity](#)

7

McKee M, Dunnell K, Anderson M, Brayne C, Charlesworth A, Johnston-Webber C, Knapp M, McGuire A, Newton JN, Taylor D, Watt RG. The changing health needs of the UK population. Lancet. 2021 May 22;397(10288):1979-1991. doi: 10.1016/S0140-6736(21)00229-4. Epub 2021 May 6. PMID: 33965065; PMCID: PMC9751760.

8

[Dealroom - Digital therapeutics startups report](#)

9

[Mobile health news](#)

10

GBD 2019 Diseases and Injuries Collaborators. Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet. 2020 Oct 17;396(10258):1204-1222. doi: 10.1016/S0140-6736(20)30925-9. Erratum in: Lancet. 2020 Nov 14;396(10262):1562. PMID: 33069326; PMCID: PMC7567026.

11

Reddy CL, Murphy LM, Ross C, Atun R. Strategic Public Private Partnerships to Transform Cardiovascular Health. Health Systems Innovation Lab, Harvard University, May 2022. DOI: 10.54111/0001/HSIL/sppp

12

[Long term plan - NHS](#)

13

[Takian A, Petrakaki D, Cornford T, Sheikh A, Barber N. National NHS Care Records Service Evaluation Team Building a house on shifting sand: methodological considerations when evaluating the implementation and adoption of national electronic health record](#)

14

[NHSconfed - Governing health and care system](#)

15

[Worldbank - France](#)

16

[Institut National de la Statistique et des Etudes économiques](#)

17

[Worldbank data](#)

18

[WHO](#)

19

[Enquête sur la santé et la protection sociale 2012. \(Irdes Rapport 556\)](#)

20

[Healthdata](#)

21

[Techcrunch - France’s strategy for EU startup policies](#)

22

[EY - Attractiveness survey, Europe](#)

23

[Trade.gov - Healthcare and medical technology](#)

24

[Techcrunch: France’s strategy for EU startup policies](#)

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[Globaldata](#)

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[Scaler8 - healthtech in Germany](#)

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[BfArM](#)

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[Oliver Wyman - The Amazoning of healthcare](#)

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[Digitalhealth - Amazon one medical](#)

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30 [NHS England - Patient equalities programme](#)

31 [TGEU - Trans health map](#)

32 [Ilga Europe - Accessing health, context and challenges](#)

33 [Digital NHS](#)

34 [Ilga Europe - Rainbow Europe](#)

35 [Fierce Biotech- devicemakers are cutting product](#)

36 [Dementia statistics](#)

37 Atun R. Health systems, systems thinking and innovation. Health Policy Plan. 2012 Oct;27 Suppl 4:iv4-8. doi: 10.1093/heapol/czs088. PMID: 23014152

38 [CMS.gov - Statistics trends and reports](#)

39 [Kingsfund - Integrated care systems explained](#)

40 [Health System Tracker, Peterson-KFF](#)

41 [Mckinsey - Pharmaceuticals](#)

42 [Spyrosoft - EU MDR regulation](#)

43 [Johner institute - Regulatory affairs](#)

44 [Gov.uk - The future regulation of medical devices in the UK](#)

45 [namsa.com/uk-mhra-medical-device-regulations-published/](#)

46 [IMDRF – Software as a medical device](#)

47 [Regdesk - Medical Device Regulations in Germany](#)

48 [Mckinsey - Optimizing health system supply chain performance](#)

49 [The Lancet](#)

50 [Pubmed](#)

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