ABHI cpi

PULSE OF THE SECTOR: 2024 BUSINESS SURVEY

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EXECUTIVE SUMMARY

The Pulse of HealthTech: 2023 Business Survey captured the industry's lived experience as one of "increased challenge," and being "at risk." Since then, we have seen some well-intended initiatives and the new Government has emphasised the potential of the Life Sciences sector, particularly HealthTech, to drive economic growth in our country. The industry welcomes a renewed focus on innovation and its role in improving both the nation's health and wealth. It is especially pleasing to see then, that in this year's survey over 30% of HealthTech companies are set to expand their research and development (R&D) and manufacturing investment into the UK. However, future risks remain high, and significant challenges persist and must be addressed.

Regulatory uncertainty continues to impact the industry. It is now eight years since the Brexit referendum, and the lack of a clear future for the UK regulatory system has limited patient access to existing and innovative HealthTech. For a third year in a row, this has had a detrimental impact on investment into the UK .Over a third of businesses are prioritising approvals in other markets and half of companies are continuing to delay bringing innovation here. 82% of the sector is affected in some way by regulatory uncertainty. Capacity challenges within the system are also increasing, with twice as many companies citing this as an issue compared to 2023.

Alongside this, the NHS Net Zero Roadmap has emerged as the most unattractive factor for the sector, with twice as many companies indicating its detrimental impact compared to any other ongoing or developing initiative by the UK Government. The HealthTech sector is committed to reducing its carbon emissions, companies are investing heavily to do so, and good progress has been made. However, NHS requirements are extremely challenging. This survey indicates that one in three HealthTech companies will not be able to meet the 2045 target as set out in the NHS Net Zero Roadmap without further clarity, pragmatism and support.

Finally, the NHS procurement system is also singled out as placing unnecessary burden on HealthTech. Three in ten companies chose not to bid on a tender in 2024 due to unworkable requirements, and 22% have removed products from sale because the price the NHS was prepared to pay was below cost.

This year's survey has seen perceptions of the UK's ability to adopt HealthTech innovation at pace and scale, provide a translational research environment, and to be a supportive place to grow a business all drop behind the EU and US markets. Furthermore, costs in regulation, sustainability, freight services, and labour have all risen at pace, almost matching those rises seen in 2023 despite the subsequent fall in inflation. The Medicines and Healthcare products Regulatory Agency's recently proposed fee increases are also set to exacerbate them further.

The 2024 Survey has, however, revealed some optimism from industry in initiatives to address these issues and, if delivered effectively, there is an opportunity for the UK to demonstrate global leadership. First and foremost, recognition of product approvals from other trusted jurisdictions is the sector's overwhelming priority. It was identified as 'likely to considerably improve attractiveness' by four times as many companies as compared to any other initiative. Secondly, despite the clear concerns over NHS Net Zero, companies have identified areas where government support could ease transition, present opportunities for research and development and upskill both procurement teams and suppliers. Finally, the sector reports enthusiasm for initiatives that could be included in the upcoming NHS Innovation and Adoption Strategy. These include providing clarity on real-world evidence (RWE) development, and ensuring dedicated local resource for innovation, such as Chief Innovation Officers in all NHS organisations.

Realising the full potential of HealthTech is in reach, and survey data support this. We must, however, act to address the challenges that reduce patient access to lifesaving and life-enhancing technologies and stifle innovation. In doing so we pave the way to cementing the UK's position as a global hub for HealthTech.

THE UK HEALTHTECH SECTOR

HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. It is the largest employer in the broader sector, employing 154,000 people in 4,465 companies, with a combined turnover of £34.3bn.

The potential that HealthTech offers the UK is vast. Technologies newly finding valuable applications in HealthTech such as AI, quantum sensing, 3D printing and robotics underpin exciting and important developments in prevention, earlier and more accurate diagnosis and precision treatments. More traditional HealthTech continues to enable high-quality, cost-effective care for millions of NHS patients every day, and the use of these technologies needs to be optimised if we are to realise operational efficiencies and tackle some of the most pressing challenges facing the NHS, such as the elective backlog. With the right support, it can also be a major driver of the UK Government's mission to kickstart economic growth; the industry has delivered growth of around 5% in recent years.

With the position and potential of the UK HealthTech sector in mind, companies were asked to pick the most attractive location out of the UK, USA, and EU, considering various factors.

Most Attractive Geographies

Please select the MOST attractive market (geography) for each of these statements.

Figure 1

A translational research environment (support over the valley of death)

Only 2024 data available

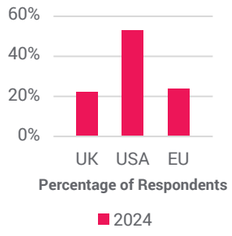


Figure 2

Collaboration between the Health System and Industry

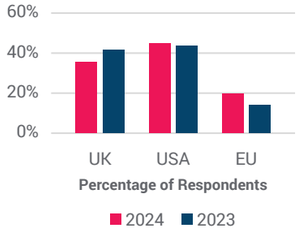


Figure 3

The Cost of Doing Business

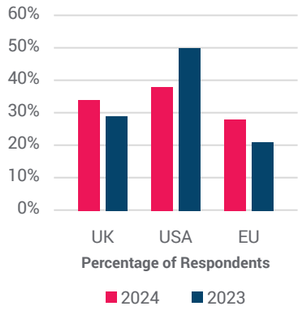


Figure 4

Ability to adopt innovation at pace and scale

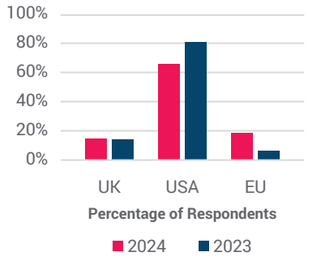


Figure 5

A supportive manufacturing environment

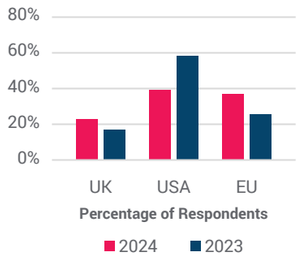


Figure 6

A research friendly environment

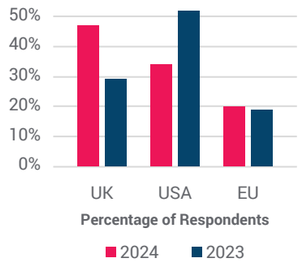


Figure 7

A regulatory environment that supports innovation

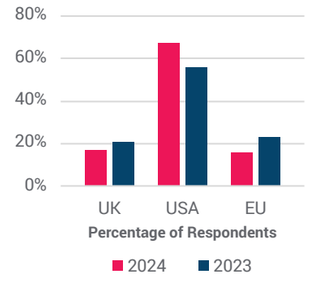


Figure 8

Ability to evaluate technologies for their effectiveness and value for money

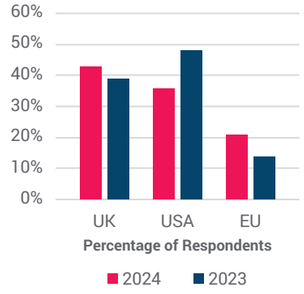


Figure 9

A regulatory environment that encourages business investment

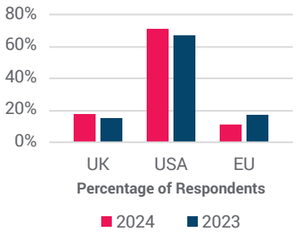
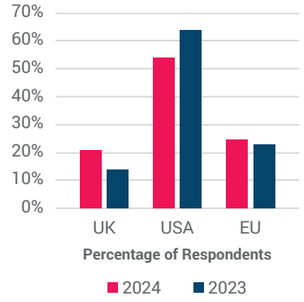


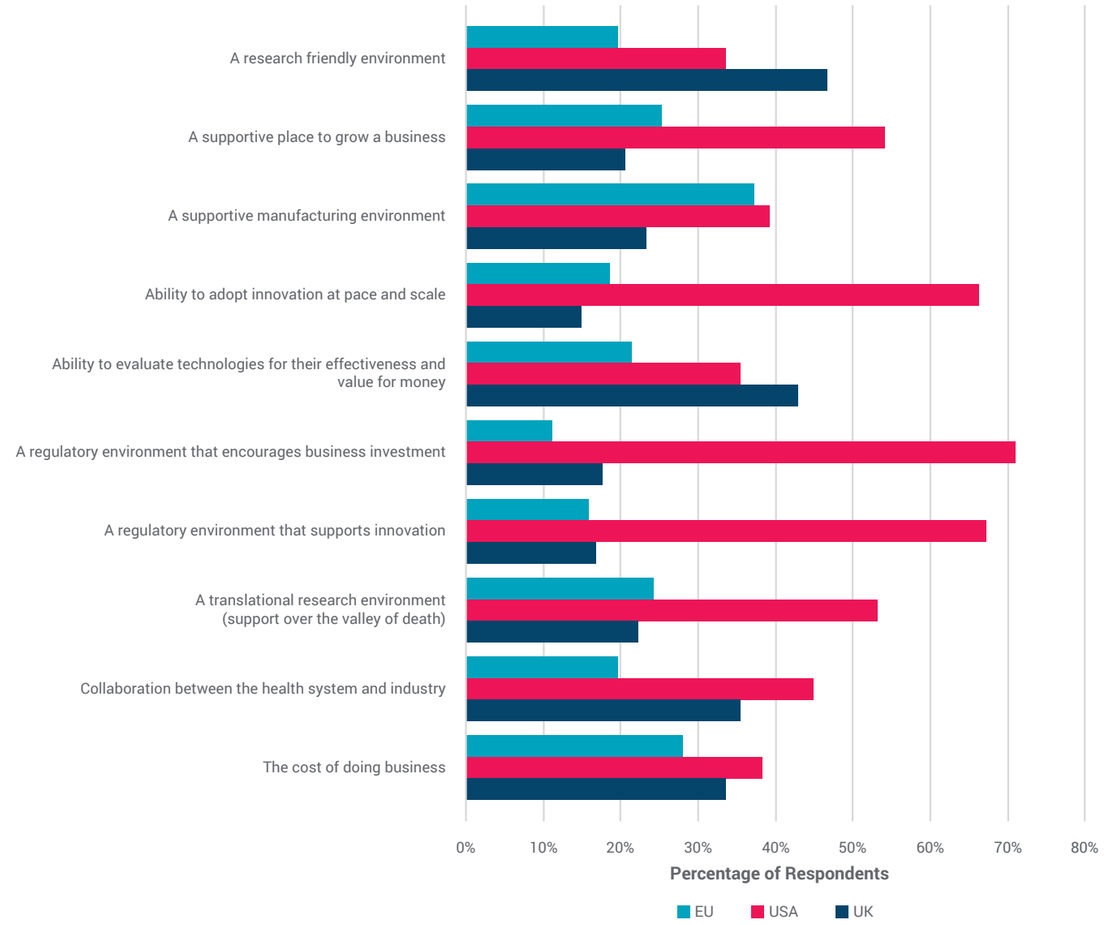
Figure 10

A supportive place to grow a business



Please select the MOST attractive market (geography) for each of these statements (2024 data only)

Figure 11



Continuing the trend from recent years, the HealthTech sector is increasingly viewing the US as the most attractive market. The US polled most favourably across the majority of factors, some of which markedly so. Conversely, the UK polls behind both the EU and US in being a supportive place to grow a business, being able to adopt innovation at pace and scale, and having a translational research environment. The most concerning differential exists in creating a regulatory environment that encourages business investment and innovation, where the US has extended its lead.

There are, however, causes for optimism. The sector views the UK as the most attractive globally for its research friendly environment and ability to evaluate technologies for their clinical and cost effectiveness. These have historically been two areas of strength in the UK, with globally renowned institutions such as the National Institute for Health Research (NIHR) and the national Institute for Health and Care Excellence (NICE).

Investment in The UK

Are you considering increasing, keeping the same or reducing the investment in the UK under the following categories?

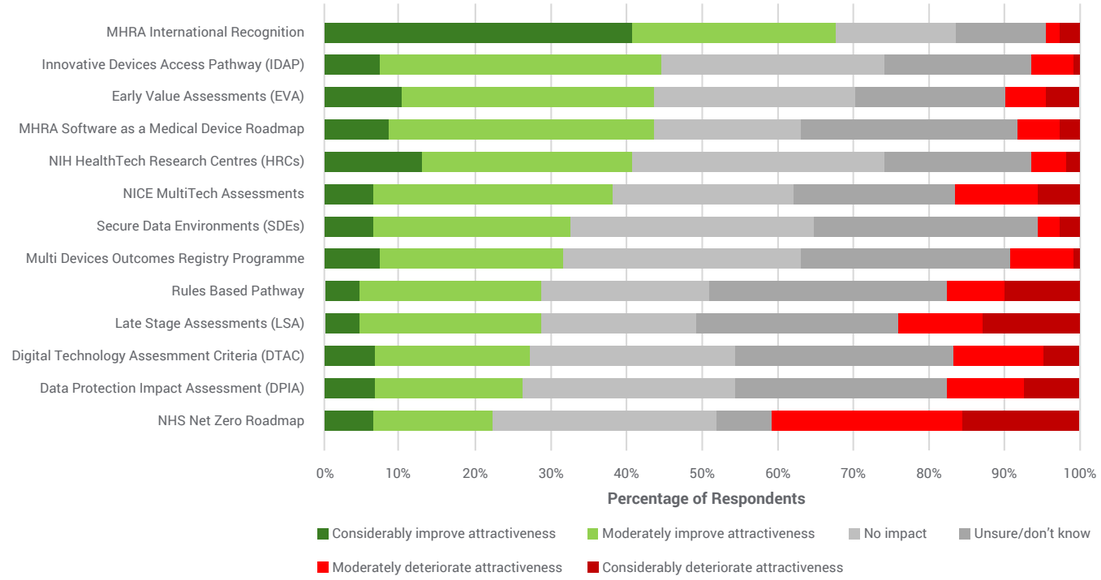
Figure 12

The investment environment of the UK provides further optimism. In all categories highlighted in Figure 12, HealthTech companies report an overall increase in investment into the UK. Especially encouraging is that in manufacturing, which tends to signify a long-term commitment to the UK and leads to the creation of high-skilled, capital-intensive jobs, one-third of companies are considering increasing investment.

Initiatives

The UK has recently implemented a number of initiatives related to our sector. How do you view their impact (or how will you if yet to be implemented) on the attractiveness of the UK HealthTech market?

Figure 13



Ongoing and planned HealthTech initiatives are pivotal in shaping the business landscape, with recent efforts aimed at enhancing sector support. However, their overall impact is perceived as variable.

Key initiatives are shown in Figure 13. International recognition (IR), the acceptance of product approvals for other, trusted, jurisdictions, remains the sector's major priority, with over two-thirds of companies believing IR would improve UK attractiveness. The Innovative Devices Access Pathway (IDAP) is also well perceived, with over four in ten companies positively rating its attractiveness. However, with the IDAP pilot limiting its initial scope to just eight technologies, the data demonstrate a clear opportunity for its expansion. There are several other initiatives that are positively rated; Early Value Assessments (EVAs) and the Medicines and Healthcare products Regulatory Agency's (MHRA) Software as a Medical Device (SaMD) Roadmap both scored well.

The primary factor negatively impacting UK attractiveness is the delivery of the NHS Net Zero Roadmap, which is cited as detrimental by twice as many companies compared to any other UK Government initiative. Despite currently affecting only eight technologies, Late-Stage Assessments also rates poorly, with survey respondents marking it as the second most detrimental factor to UK attractiveness.

Much of the sector is heavily split, or uncertain, on the impact of many initiatives. Just two, IR and the Net Zero Roadmap, have 'unsure' or 'no impact' responses below 40% of total answers. Such uncertainty could stem from a lack of awareness, and more could be done to inform HealthTech companies of the impact and nature of plans for the sector. The heterogeneity of the HealthTech industry must also be recognised. No one programme will affect each company in the same way, and policies which take sectoral diversity into account will likely be more successful. Many of these initiatives are explored in further detail later in this report.

RESEARCH AND DEVELOPMENT

The UK has a strong R&D and manufacturing base in HealthTech. In the UK, 3,460 sites operate in the sector, and around 50 universities research-active in HealthTech. Additionally, HealthTech is a hugely innovative industry. The sector contributed the second-largest number of applications for new European patents in 2022, with the UK providing one in twelve of those.

Traditionally, UK HealthTech excels in early research, with a strong collaborative ecosystem and solid funding structures. Figure 11 reflects this.

Clinical Areas with Greatest Potential

The attractive research environment that the UK has cultivated means its HealthTech sector has enormous potential to address the priorities of the country's health and care system. When asked which clinical areas the sector could contribute to most, companies listed the NHS priorities that are laid out in the Long Term Plan and the Major Conditions Strategy. The earlier diagnosis and treatment of cancer and cardiovascular disease (CVD) was mentioned frequently, as was prevention. Other common responses included the contribution to the digitisation of healthcare, the management of chronic and long-term conditions, the treatment of orthopaedics and musculoskeletal health conditions, and the role of HealthTech in tackling mental health problems. In all these areas, the orthopaedic industry can play an instrumental role in driving innovation and enabling the NHS to meet the evolving health needs of the UK population.

HealthTech Catapult Capability Build

The Innovate UK Catapult Network, comprising nine technology and innovation centres across 65 UK locations, plays a crucial role in supporting HealthTech companies to accelerate technology development and commercialisation. In this year's survey, companies were asked which technical innovations they would like the Network to focus on to best support new products and process innovation. Responses highlighted a diverse range of interests, with a notable emphasis on sustainability and advancements in materials, particularly in device recyclability and sustainable polymers. This focus reflects the move to achieving Net Zero targets, as HealthTech firms seek to reduce carbon footprints in packaging and single-use plastics.

Another focus was support with digital health, including applying AI to HealthTech. This involved assistance with analysis of large datasets, innovation in digital platforms, and remote technologies, such as wearable monitoring devices. The potential for both AI and these technologies to create productivity gains is vast.

There were also calls from companies for support with enhanced diagnostics capabilities, including point-of-care as well as genomics, proteomics, and multi-omics, with specific innovation in biologics and reagents mentioned by some. Additionally, links to personalised medicine were requested. Lastly, companies called for the Catapult Network to support the acceleration of innovations in the regulatory process, for example through digitisation and the use of AI.

REGULATION

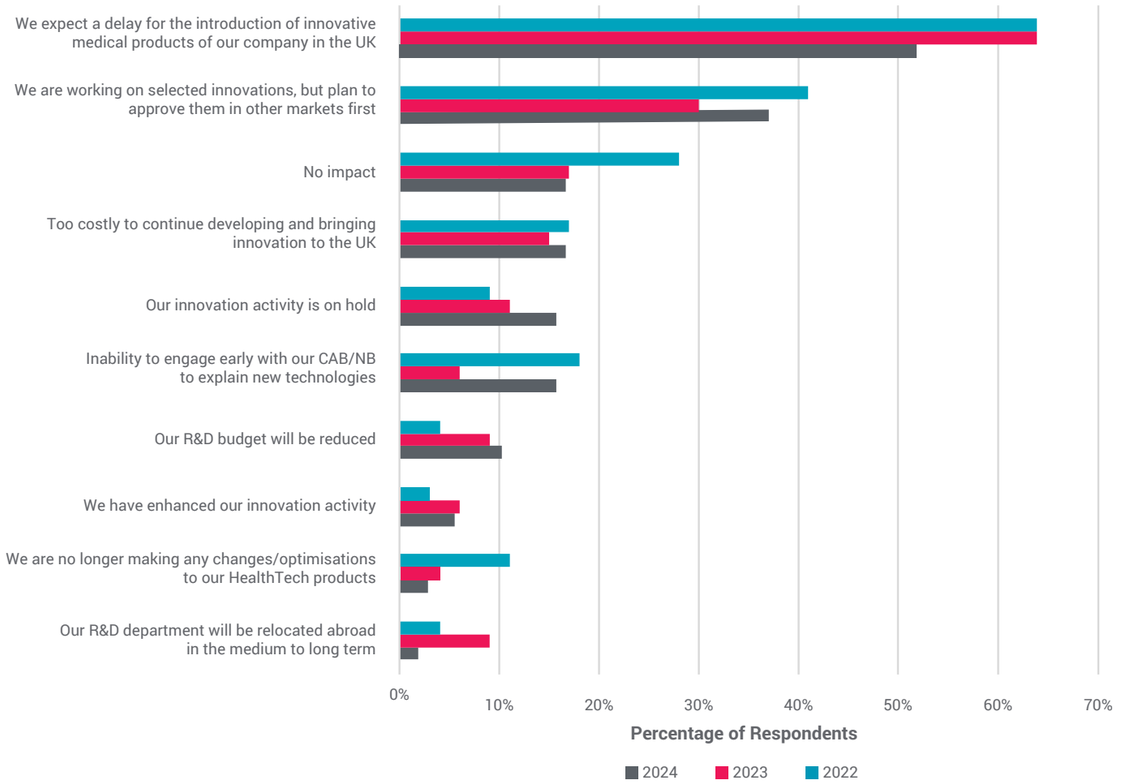
A sovereign UK HealthTech regulatory system offers a generational opportunity to support the growth of a sector that provides many of the solutions which are necessary to improve patient outcomes and also facilitates the necessary transformation to more sustainable models of health and care delivery. The potential benefits from the industry's growth for the UK health and care system, clinicians, patients, and the economy, are significant.

However, difficulties are being seen in the EU, the system on which UK arrangements are currently most closely based, and uncertainty in the UK continues to lead to challenges and increased costs.

Regulatory Uncertainty

Recent years have seen a period of change and uncertainty in the UK regulatory environment. Has this impacted your activity in the UK in the period since?

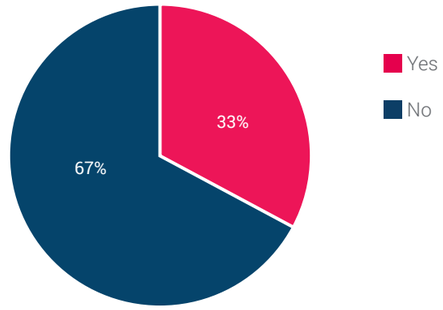
Figure 14



Maintenance of Product Portfolio

Have you taken any products off the UK market as a result of this uncertainty?

Figure 15



It is now eight years since the Brexit referendum, and the lack of a clear future for the UK regulatory system has been demonstrated to have limited patient access to existing and innovative HealthTech. This uncertainty has also discouraged investment in the UK market for the third consecutive year.

Since the publication of the 2023 Business Survey, there has been activity to recognise and address the challenges experienced by HealthTech companies. However, the situation remains far from ideal. Over a third of companies are prioritising approvals in other markets before the UK and half are continuing to delay bringing innovation here. 82% of the sector is impacted in some way by this uncertainty. Capacity challenges are also increasing, with twice as many companies being impacted as in 2023. Concerningly, as shown in Figure 22, almost one in ten companies are experiencing rises in regulatory costs of over 50% at a time at which the MHRA has proposed further increases.

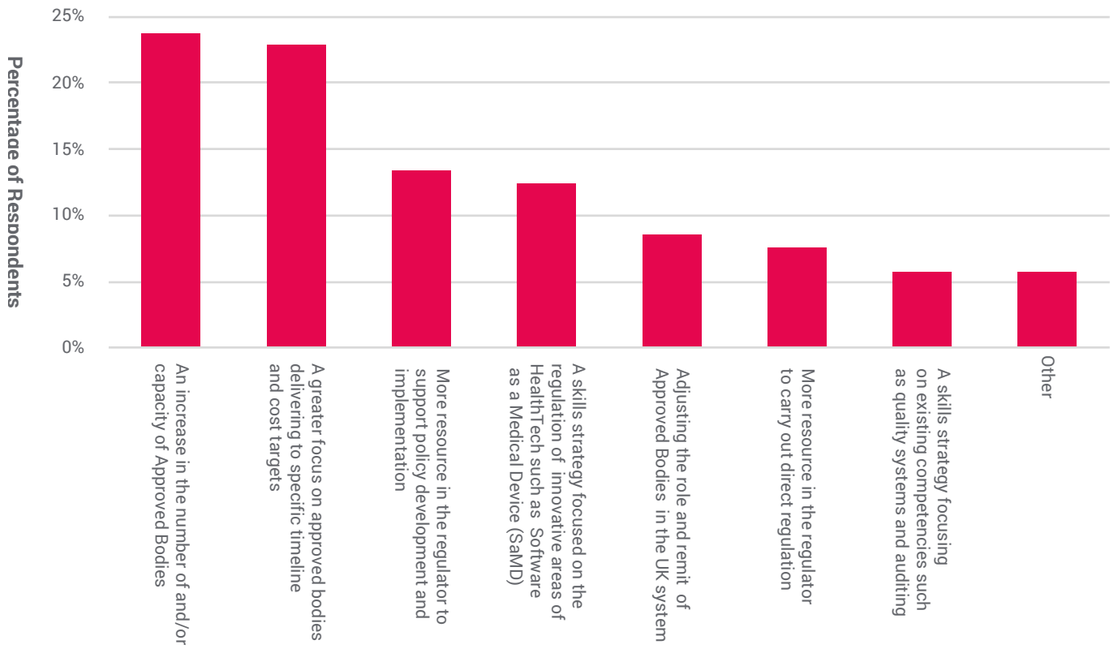
In 2024, 33% of companies removed products from the UK, and for those that did, they reported that on average 20% of their portfolio was at risk. This compares to 46% of companies who removed UK products in 2023. The moderate improvement in the number of companies removing products may indicate that some initiatives have started to have an impact.
The announcements of the extension of the CE marking transition period, made during the data collection period of the last survey, for example, as well as the intent for the MHRA to recognise the approvals of other jurisdictions, may be starting to improve the outlook for the UK. The reduction in product removals could also be a consequence of the rationalisation of portfolios since 2023, although as 20% of some companies' products remain at risk, there continues to be a threat to the continuity of supply in the UK.

Capacity in the Regulatory System

There is a consensus that the development of the UKCA process and the use of IR must also address the operational issues which hinder the current regulatory system.

How would you like to see the capacity in the regulatory system addressed?

Figure 16

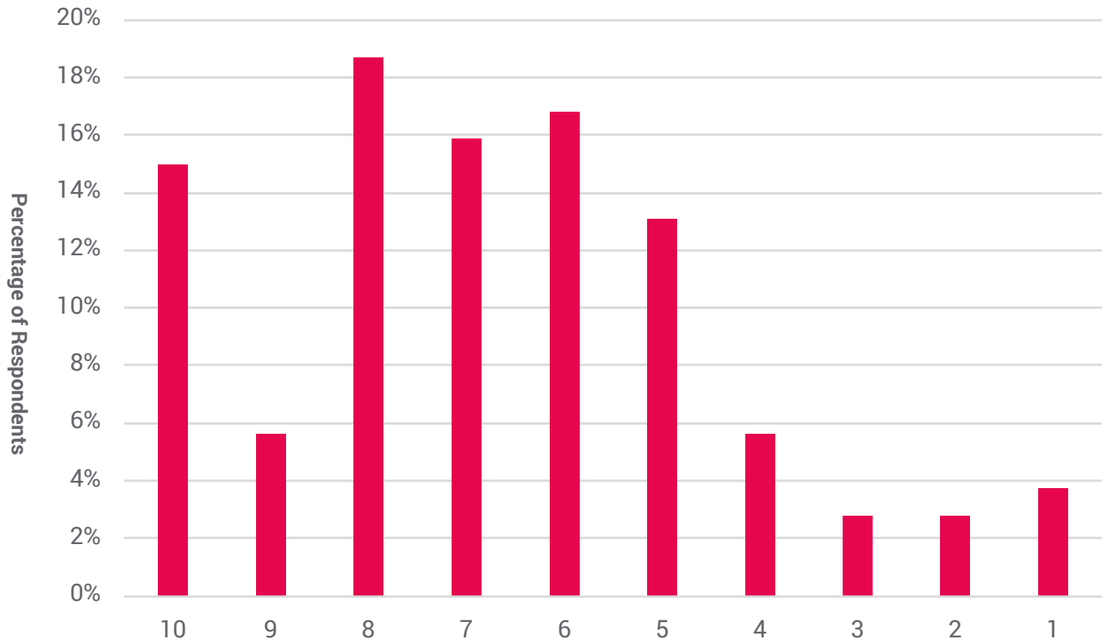


One such issue is the capacity of the regulatory system, a problem which continues to hold back progress in both the UK and the EU. Persistent capacity issues contribute greatly to the increasing costs and uncertainty experienced by companies. The majority of the HealthTech sector would like to see improvements in, or reform to, the existing model of the regulation that utilises Approved Bodies. There is equal support for increasing the number and capacity of Approved Bodies and focusing them on delivering to specific timelines and cost targets. There is also a perception that more resources for the regulator, along with a skills strategy for HealthTech regulation, would have great value.

International Recognition

On a scale of 1-10 with 10 being most attractive, how attractive is the proposed International Recognition Framework to your organisation?

Figure 17



There is overwhelming consensus within the sector on the need for IR. Indeed, the single greatest thing, by a substantial margin, that the UK Government can do to support HealthTech is deliver an effective and efficient model of IR within our regulatory framework. IR was identified as 'likely to considerably improve attractiveness' by four times as many companies, compared to any initiative in any other policy area by the UK Government.

On the proposed framework for IR published in May 2024, 73% of companies view it positively. Respondents noted its huge potential to reduce cost and duplication in the UK system, protect patient access to HealthTech and to provide the opportunity for the UK to lead in global regulatory harmonisation. Additionally, the framework was seen as encouraging HealthTech innovation in the UK, for example by allowing US-approved products into the UK market faster.

Of those that didn't see the framework as attractive, companies shared the number of limiting factors and exceptions. There was a need for further clarity from the Government, particularly a timeline regarding the introduction of IR. Some said the process would still place a duplicative burden on the SMEs which make up much of the sector. Finally, many based their judgement of IR on how the framework will align with the FDA's 510k offer.

The Development of UKCA

The development of the UK Conformity Assessment (UKCA) mark may offer opportunities for the sector if it is synonymous with early access and innovation. For HealthTech, it represents a chance to establish a regulatory system which learns lessons from the experiences of other systems such as the EU and the US Federal Food and Drug Administration (FDA).

Concrete measures would involve UK alignment with the FDA's 510(k) process and the CE mark. Respondents also highlighted the need for processes to be streamlined, calling for reduced bureaucracy, clear guidance, and predictable timelines. There were demands for more proportionate requirements for lower-risk devices to facilitate quicker market entry and innovation, for example by providing a fast-track process.

There were also calls for the UKCA to be linked with procurement processes. This aligns with the recommendations of the 2023 McLean report. Companies would like to see the UKCA focus on emerging technologies, aligning with global requirements where possible, but coming with access to advice and support, akin to the FDA's approach. E- labelling was also heavily encouraged.

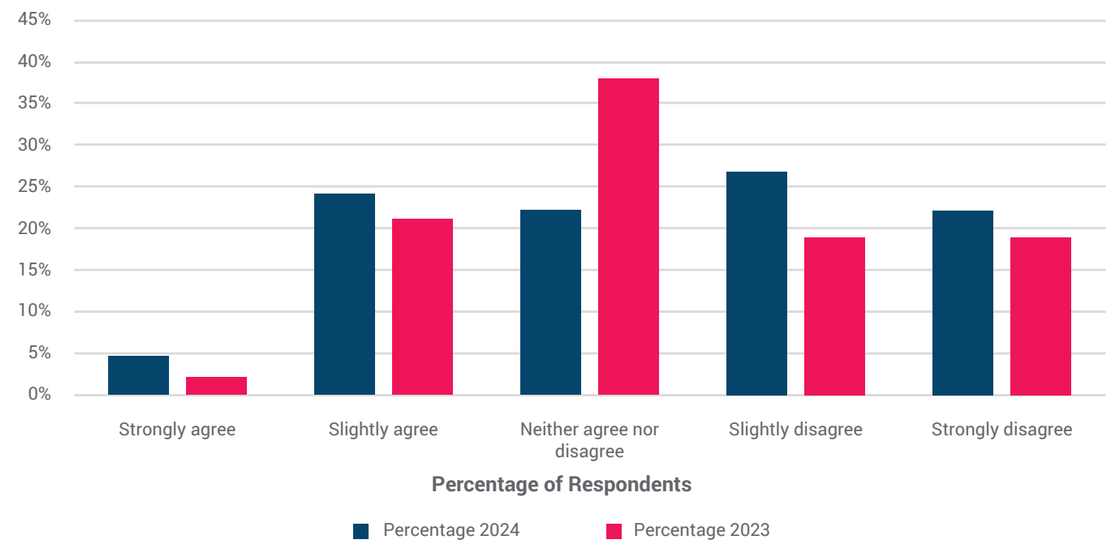
There were some frustrations voiced, citing the limited market size of the UK and that any UKCA will come with additional cost, and some companies questioned the value of UKCA altogether.

Nevertheless, companies expressed optimism about the chance the UKCA mark represents to increase the UK's attractiveness globally to those developing innovative technologies.

Best-in-Class Regulatory Regime

To what extent do you agree with the statement "the UK is developing a best-in-class regulatory regime"?

Figure 18



Despite much activity, it appears perceptions of the UK's inability to develop a best-in-class regulatory regime are solidifying. Whilst modest improvements have been seen, half the sector now disagrees that the UK is developing such a regime, an increase of 10% compared to 2023. Regulatory uncertainty and increasing costs have detrimentally impacted the sector's products and businesses.

Despite this, optimism remains about the direction the UK is taking regarding regulatory reform for HealthTech. The data demonstrate the need to ensure we continue with swift and effective implementation of the future model, and the UK Government must ensure the Regulator has sufficient resources to do this. This will take time, and whilst we are aware of ongoing discussions, progress must be communicated internationally to restore confidence in the UK's ambitions for the future.

The announcement made in late September 2024, as this report was going to publication, have begun this process, and we encourage further concrete commitments alongside associated implementation timelines and resource reassurances as soon as possible.

Recent ABHI findings show that the US regulatory system has considerably shorter timelines for regulatory approval than the EU, with UK timelines likely comparable to those of the latter due to the similarity of the two jurisdictions' regulatory frameworks. This demonstrates the significant impact that an effective implementation of a future UK regulatory model could have. The success of an IR framework, the IDAP, and the continued development and success of other initiatives shown in Figure 13 could reduce the UK's timelines dramatically while maintaining patient safety.

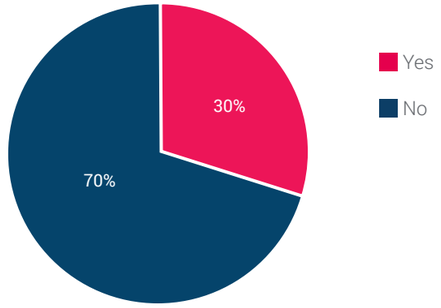
PROCUREMENT

It has long been recognised that the NHS struggles to adopt HealthTech at pace and scale. Procurement is often focused on unit price and in-year savings as opposed to the total value achieved across clinical pathways.

NHS Procurement Requirements

Have any NHS procurement requirements resulted in you choosing not to bid on a tender?

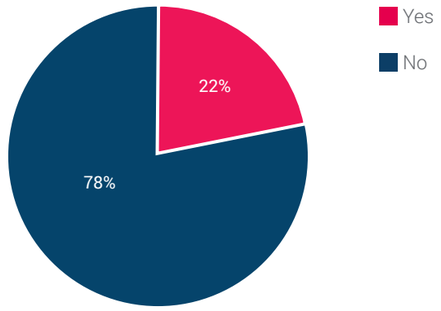
Figure 19



Products Removed

Have you had to remove a product from sale due to your selling price being below cost price because of inflation and the NHS's refusal to accept a price increase?

Figure 20



Most HealthTech companies remain dissatisfied with the current procurement and adoption system. Almost one in three companies in the sector have chosen not to bid on a tender due to NHS procurement requirements, and 22% of HealthTech companies have removed products from sale because the price the NHS was prepared to pay was below cost. Though these proportions have fallen slightly since the 2023 survey, both figures represent a significant number of technologies not available to transform productivity, improve patient pathways, or save lives. The UK has fallen further behind the EU and US this year in its perceived ability to adopt innovation at pace and scale (Figure 4).

Additionally, the UK adoption pathway involves several initiatives, shown in Figure 13, which have an impact on the rate of adoption of HealthTech; some are seen positively, some negatively. The Early Value Assessment (EVA) programme, for example, is commended by 40% of companies, suggesting it should be expanded in scope and continued. NICE Multitech Assessments (MTAs) are also seen favourably by industry as a way to accelerate technology evaluations and provide patients with quicker access to innovative treatments. However, initiatives such as the rules-based pathway (RBP) divide the industry, with around half of all companies responding with 'unsure' or 'no impact'. It is recommended that the criteria for the pathway should be revised to ensure it can improve adoption at scale.

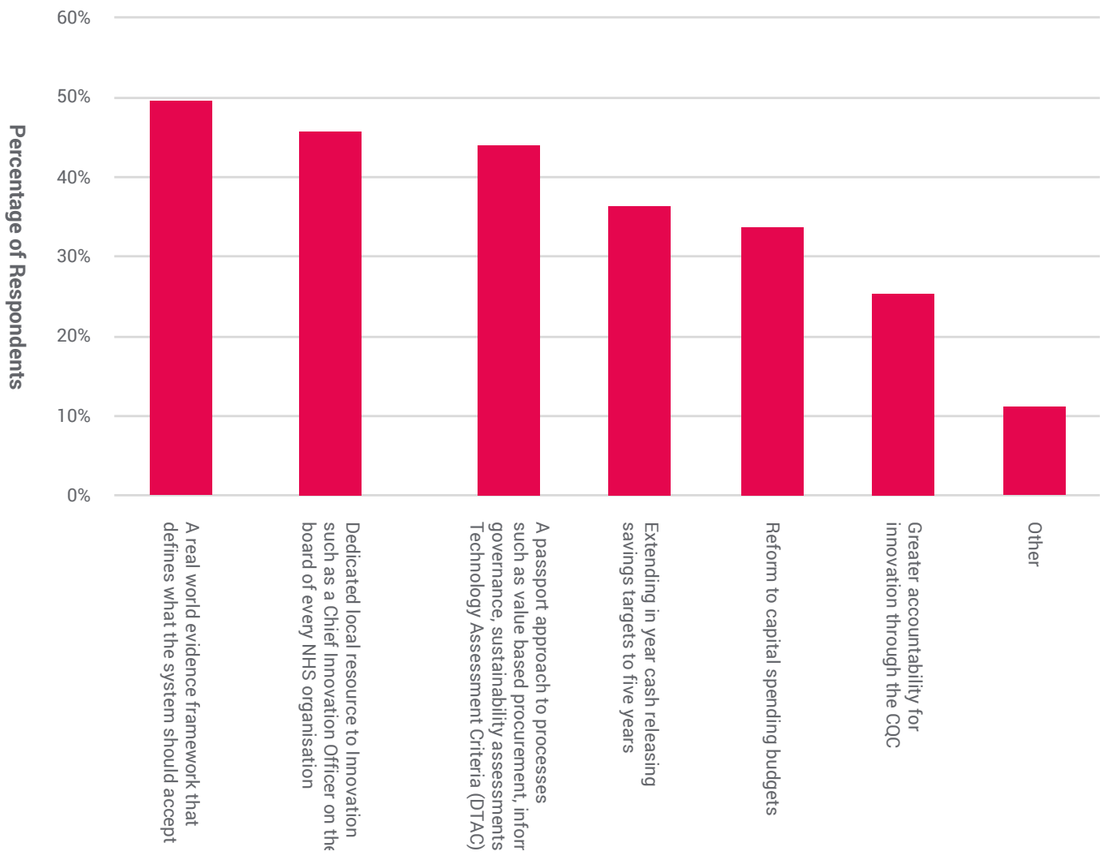
The initiative with the second greatest detrimental impact on UK attractiveness is the Late-Stage Assessments (LSAs) programme. Despite currently affecting only eight categories of technology, its perceived negative impact is reported more widely.

The HealthTech industry welcomes the increased focus on resolving adoption challenges, however, as indicated by these data, the impact has been mixed. The new Government should aim to elevate ambition and ensure that existing initiatives genuinely contribute to achieving goals for advancements in health and economic growth.

Innovation and Adoption Strategy

The new government have committed to developing a new NHS Innovation and Adoption strategy, with a focus on procurement. What do you feel the strategy should commit to in order to ensure greater access to HealthTech?

Figure 21



The Government's commitment to a new NHS Innovation and Adoption strategy is applauded by the sector. It has the potential, if implemented, to reduce adoption timelines, improve NHS productivity, and consequently the experience and treatment of patients.

When asked 'What do you feel the strategy should commit to in order to ensure greater access to HealthTech?', companies focused on three areas. Firstly, the highest proportion (49%) wanted a clearer real-world evidence (RWE) framework. Though NICE have an existing framework, more guidance could be provided on how RWE is used in Health Technology Assessment (HTA) and procurement decisions. This is a response consistent with those seen in the 2023 and 2022 Surveys; in 2023, around 45% of respondents detailed a lack of clarity as the biggest barrier to the creation of RWE, and in 2022, 70% of companies gave the same response. Evidence is obviously a requirement for a product to be adopted by the NHS, and companies do, of course, respect the necessity for products to be properly evaluated. However, many believe current guidance does not it make clear what qualifies as quality RWE, and companies collecting such data find it expensive to gather, especially SMEs.

Secondly, 46% of companies would like to see local resources dedicated to innovation, for example by having a Chief Innovation Officer on the board of every NHS organisation. Such roles could provide the resource and mechanisms to ensure innovation is managed and measured, in part through oversight by the Care Quality Commission (CQC).

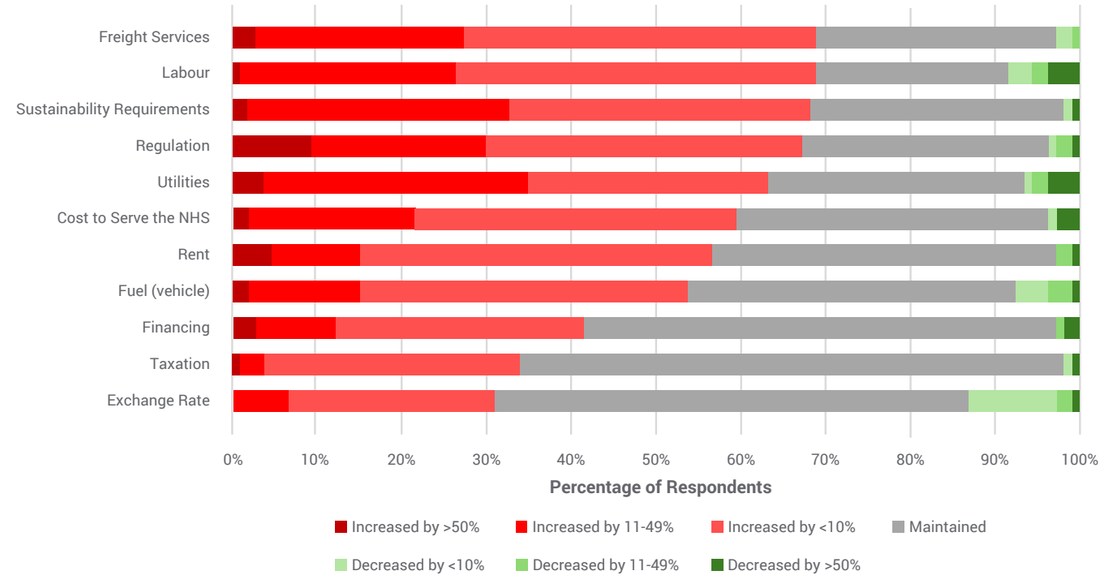
NHS Trust boards see regular metrics on finance and performance, quality and safety, and workforce, with Executive Directors responsible for these important areas. As part of the CQC "Well-led" inspection framework, NHS organisations are required to have robust systems and processes in place for learning, continuous improvement and innovation. But, with few exceptions, nobody at a Board level holds this portfolio. Until this is actively built into a senior job description, it is unlikely to become business as usual. This approach would also make the CQC more accountable for innovation, which was supported by a quarter of respondents. Finally, 44% of HealthTech companies would welcome a passport-based approach to adoption and compliance processes, by which products already established in parts of the NHS would be seamlessly adopted elsewhere. This would reduce the need for companies and the health system to duplicate processes.

The sector also remains heavily in favour of value-based procurement as a solution to adoption challenges.
The majority (69%) of 2023 respondents reported that a shift in focus towards the development of value-based procurement would increase the attractiveness of the UK for the sector. Other responses to this question also emphasised the need for greater focus on value throughout the procurement pathway. An adjustment to in-year cash releasing savings targets to include extended five-year periods was supported by around a third of respondents, as was reform to capital spending budgets (most notably the Capital-Departmental Expenditure Limits (C-DEL)).

Factors Affecting Cost Base and Staff Recruitment

What factors have affected your cost base over the last 12 months?

Figure 22



Companies continue to report increasing cost pressures. Although some significant cost rises can be attributed to macroeconomic factors, such as persistently high UK inflation in the first half of this year, others are directly influenced by policy decisions. This trend is illustrated in Figure 22.

Despite a slight easing in overall inflation, costs related to utilities, fuel, and servicing the NHS continue to escalate. Particularly notable are the persistent or growing increases in costs related to labour, sustainability requirements, regulatory compliance, and freight services since last year. In these four categories alone, approximately two-thirds of the sector has experienced varying degrees of cost escalation, often surpassing inflation rates; nearly 40% of these increases have exceeded 10%.

The reasons given by companies falls into several categories. Brexit caused rises in the costs of EU imports and instituted trade barriers, which in part contributed to increased freight service costs. The implementation of the NHS 2045 Net Zero policy is also mentioned as a consistent contributor to cost rises in sustainability requirements. Additionally, wage increases are reported to be outpacing the selling prices of HealthTech.

Related to the increasing labour costs are issues with recruiting staff, which are affecting at least 28% of companies. The specific competencies which companies struggle to recruit for include aseptic and sterilisation services, sales, technical staff such as engineers, and, most commonly, regulatory professionals.

The sustained rise in regulatory costs from the system, and labour inputs for companies, is of increasing concern. Regulatory changes such as the Medical Device Regulation (MDR), In Vitro Diagnostic Medical Devices Regulation (IVDR), and the UKCA have played a part in increasing these costs for companies, but most worrying is that almost one in ten companies are seeing over 50% increases in regulatory costs, even before MHRA's proposed increases this year.

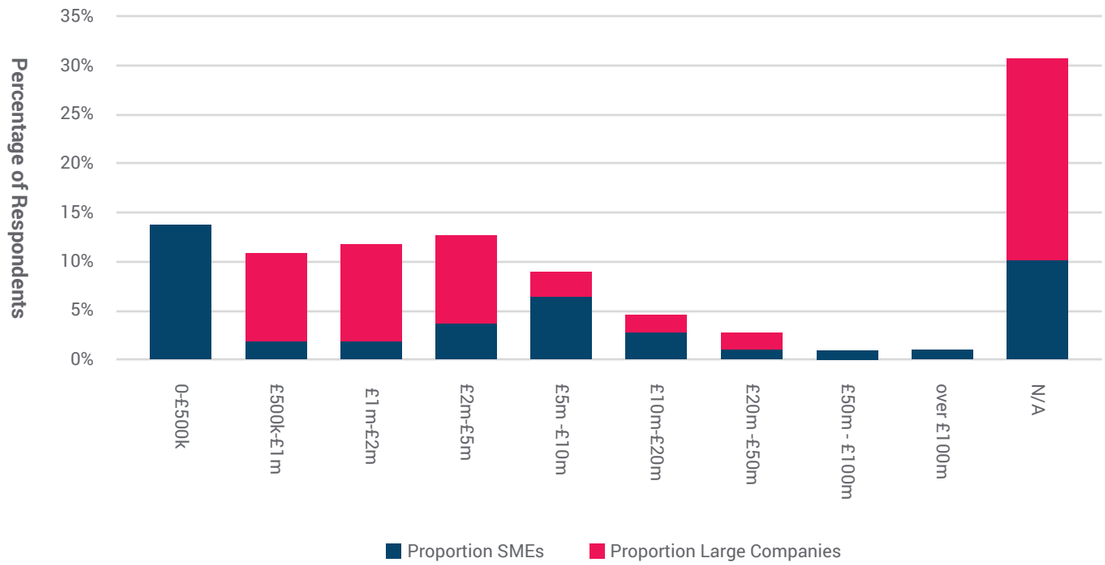
For much of the HealthTech industry in the UK, there is only one customer: the NHS. The NHS and the NHS Supply Chain (NHSSC) have had a policy of aggressive procurement and continue to pursue their long-held zero price inflation expectations from HealthTech suppliers. Companies understand the immense financial pressures that the NHS faces, but this approach is unsustainable. Whilst a process is in place to request a price increase, suppliers' experience is variable, and timelines are protracted. To ensure that the NHS can realise the full potential of HealthTech, and remain an attractive place for business to invest, procurement must shift towards a greater appreciation of value through meaningful strategic and collaborative approaches.

MANUFACTURING

Manufacturing Grant Schemes

The UK has set up a variety of manufacturing grant schemes in recent years. If a grant scheme was to be created what level of capital investment threshold would be most likely to encourage your organisation to consider applying?

Figure 23



HealthTech is a major manufacturer in the UK and there is a significant opportunity to increase existing investment. A key part of the support available for HealthTech manufacturing companies are grant schemes. However, HealthTech manufacturing investment in the market follows a fundamentally different route to that of pharmaceuticals. Often, for example, a company may need to make a very modest investment to establish a pilot manufacturing line. If that proves to be successful in relation to that company's facilities in other parts of the world, a significantly larger investment may follow. Therefore, for both large and small HealthTech companies, relatively small grants must be available.

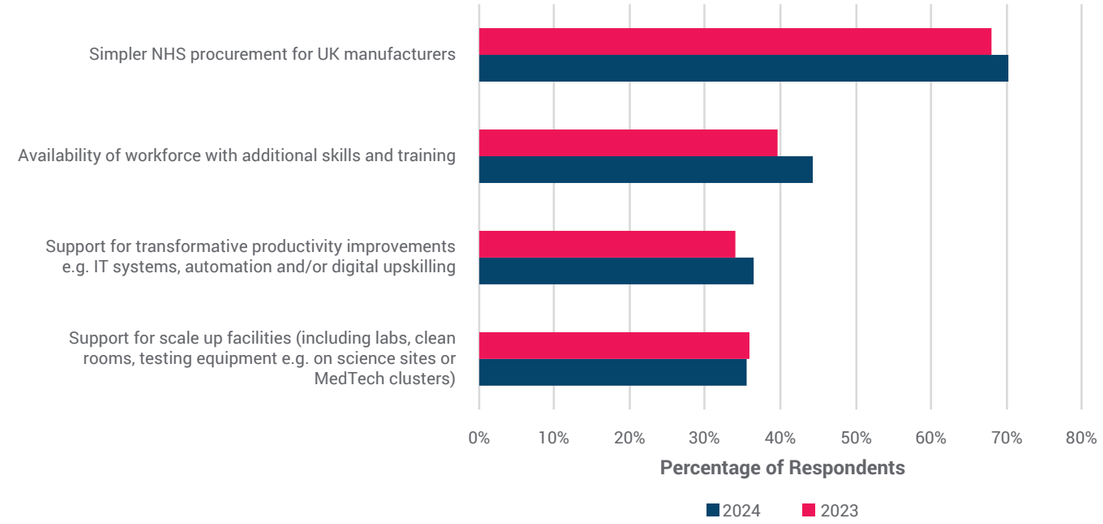
ABHI and CPI welcome the Government's ongoing commitment to the £520 million Life Sciences Innovative Manufacturing Fund and 69% of companies indicate they could consider a grant scheme with the correct funding threshold. However, this year's data demonstrate the need for lower qualifying thresholds. Only 19% of HealthTech companies view a manufacturing grant of greater than £5 million as appropriate. This suggests existing initiatives miss a significant opportunity to support the full breadth of the industry.

The UK has a strong, high-value manufacturing sector, often underpinned by complex international supply chains for raw materials and components. Within HealthTech, the UK has strengths it can build on. However, the data suggest that support infrastructure must be more holistic.

Support to Grow Manufacturing

Where, or how, do you think the UK industry needs support in order to grow its HealthTech manufacturing?

Figure 24



With the UK HealthTech sector growing at roughly 5% a year, investment in its manufacturing capabilities offers huge potential to deliver the 100,000 jobs by 2030 as committed to in the Life Sciences Plan, while also ensuring UK patients have greater access to the best healthcare treatment available.

By a considerable distance, respondents suggested the greatest thing that could be done to support growth in UK manufacturing would be to simplify the NHS procurement process. This was endorsed by seven in ten companies, echoing the 2023 Survey in which 68% of companies selected this option. The current NHS procurement system poses significant challenges, with multiple layers of approval and documentation, varying requirements across NHS Trusts, delays in decision-making processes, and the need to engage with several purchasing bodies at once. Other barriers noted include the UK having high overheads, a comparatively poor tax regime, and high supply chain costs.

Once again, the lack of skilled staff is a persistent issue for manufacturers. The proportion of companies citing issues with workforce availability has risen 5% since 2023. Support for productivity improvements, particularly in digitisation and automation, is also listed as a key area by 37% of companies. Ensuring the manufacturing sector is equipped to supply the NHS during its burgeoning digitisation is critical if the health and care system hopes to make productivity gains. Finally, scale-up facilities are another priority, with a third of companies wishing to see manufacturing support concentrated in this area.

ACCESS TO FUNDING

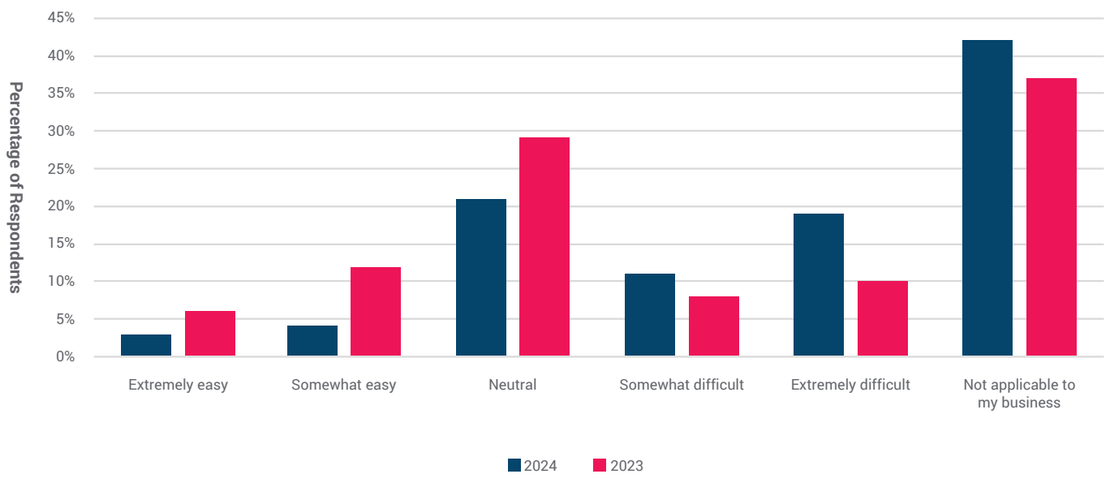
Developing new HealthTech products is a long, high-risk, and resource-intensive process, often with significant delays between invention and first revenue. This can cause serious cash flow issues, especially for entrepreneurs and start-ups. In the UK, there are mechanisms companies can use for support, largely from bodies such as Innovate UK and the National Institute for Health and Care Research (NIHR). In general, the country also has a strong private funding ecosystem through private equity, angel investors and venture capitalists.

However, as products move closer to the market, support tends to drop off, with many companies struggling to secure private or public funding towards the clinical research and manufacturing phase of product development. This is shown in Figure 1.

Ease of Securing Private Investment

In terms of securing private investment in the UK, how easy have you found it to secure such investment?

Figure 25



Asked how easy they found accessing private funding, HealthTech companies were significantly less optimistic than last year. Just 7% positively rated the accessibility of private funding, with 30% rating it negatively. Concerningly, many companies highlighted issues specifically with UK-based private investors. They reported that UK investors had lower risk thresholds, lower understanding of certain markets, or offered worse terms as compared to investors such as those from the US or the Middle East. This is a worrying sign and justifies the Government's current economic focus on mobilising UK-based capital. Other companies noted a lack of specialist venture capitalists in the UK for early-stage HealthTech companies, and a high regulatory burden which discourages investment. There are also reports that investors have simply found other markets to be more attractive.

Overall, larger companies did find securing investment easier than SMEs did, but still rated the environment negatively.

Furthermore, the UK also lacks in funding for companies attempting to scale-up and grow. Indeed, the data suggest the UK has fallen behind the EU and US in recent years, and that a thriving research environment is not matched by support later in companies' development. A scale-up funding environment must be encouraged by the Government if we are to produce larger and more successful HealthTech companies. Such support from the Government would lead to a greater contribution from the sector towards both economic growth and the Life Sciences Plan goal of 100,000 more jobs in the sector by 2030.

Public Funding for Innovation

Companies were also asked for their thoughts on the mechanisms by which public funding is provided to support innovation. Many respondents emphasised the need for substantial funding to support clinical trials, particularly within the NHS.

There was strong demand for increasing and improving R&D tax credits and linking those credits to sustainability incentives. This is particularly important given the data shown in Figures 30 and 31; companies clearly want and need Government support with the transition to Net Zero. Some companies also expressed dissatisfaction with the current grant competition process, citing low success rates and a lack of focus on commercial viability. Finally, respondents also mentioned the need for funding to cover regulatory costs, specifically for Notified/Approved Body changes.

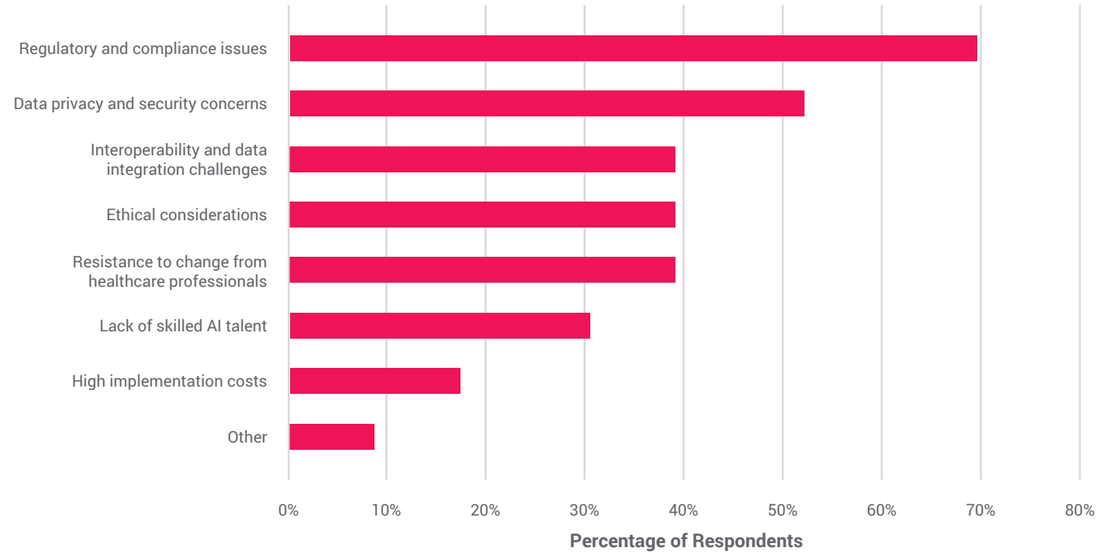
DIGITAL AND AI

The digital sector within HealthTech presents a challenge for the regulators compared with traditional devices. With increasing levels of digitisation and Artificial Intelligence's (AI) potential to revolutionise how healthcare is delivered, a simple, safe, effective and efficient process for regulating digital health technology is necessary.

Digital Regulation and AI

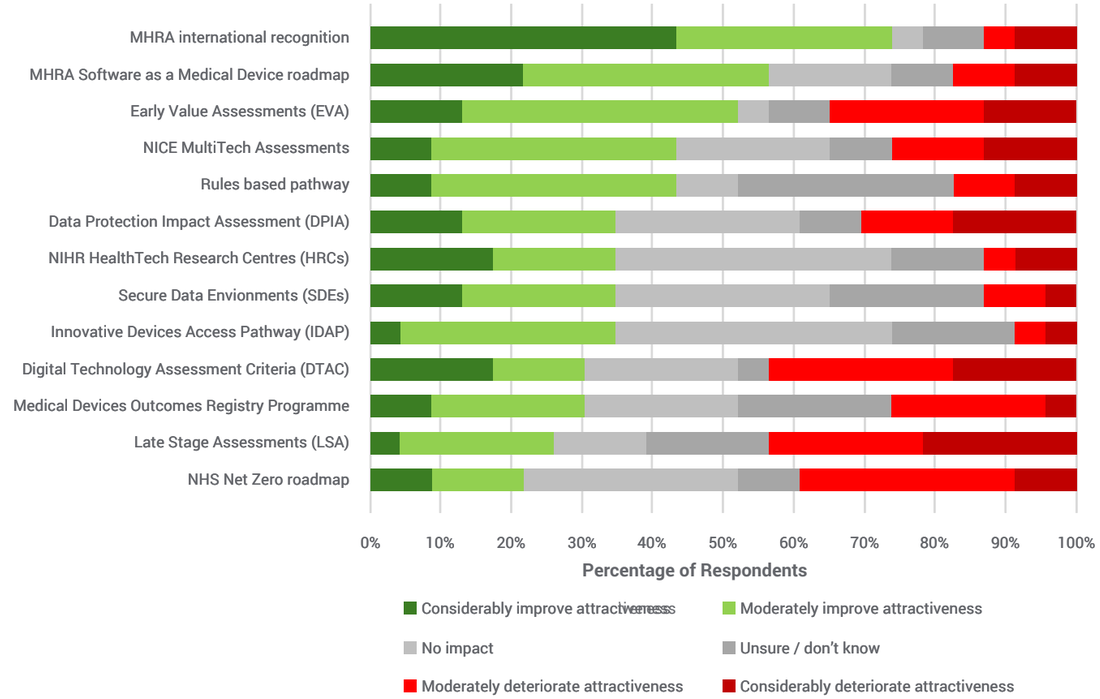
The UK is aiming to be seen as a global leader for the use of AI, in part in healthcare. What are the main challenges your company faces in implementing AI solutions in the health sector? (Digital Health companies only)

Figure 26



The UK has recently implemented a number of initiatives related to our sector. How do you view their impact (or how will you if yet to be implemented) on the attractiveness of the UK HealthTech market? (Digital Health companies only)

Figure 27



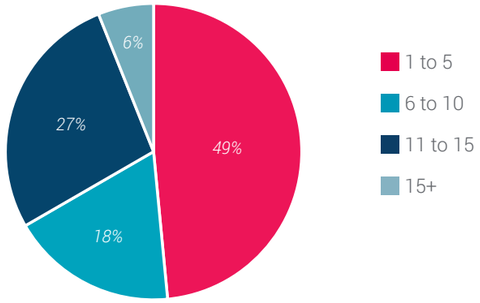
Asked about the biggest challenges in implementing AI solutions in the health sector, 70% of digital health companies listed regulatory and compliance. This is an ongoing and increasing concern. In the 2023 survey, 45% of companies cited data and security concerns and 40% regulatory and compliance. To that end, help from the UK Government or the regulator to encourage the use of AI in HealthTech should focus on the regulatory requirements which companies need to meet. Clarity should be given as to the regulatory direction of travel on AI in medical devices, and attention paid as to how to integrate AI systems into the wider NHS. Incentives to attract skilled AI talent into the sector should also be a priority.

As a subsector, digital health companies also gave somewhat different responses to the initiatives described in Figure 13 as compared to respondents overall. Those in the digital space indicated stronger support for the recognition of product approvals from other, trusted jurisdictions, while more found initiatives such as LSAs, the DTAC, and the EVAs unattractive. The MHRA Software as a Medical Device roadmap (SaMD), a key initiative for digital health companies, was rated positively. Over half of companies think it improves UK attractiveness for HealthTech, and two in 10 said it would do so considerably. This is an area where the UK has ambitions to be a global leader, and should, therefore, prioritise the resource and expertise required.

Information Governance

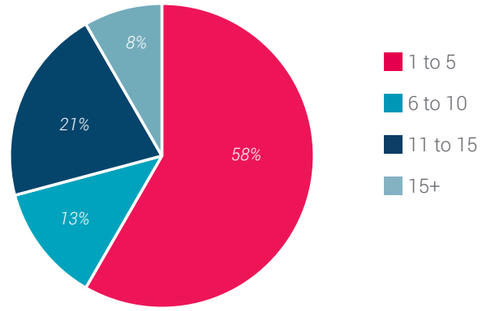
If relevant to your product, can you provide average timelines in number of weeks to complete a Data Protection Impact Assessment (DPIA)?

Figure 28



If relevant for your product, can you provide average timelines in number of weeks to complete a Digital Technology Assessment Criteria (DTAC) process?

Figure 29



Three processes, intended to enable the deployment of digital solutions, are cited as obstacles to adoption at scale. Data sharing agreements and the associated Data Protection Impact Assessments (DPIA), and Digital Technology Assessment Criteria (DTAC), are regarded by industry as barriers rather than enablers. Whilst the processes are centrally governed, either via legislation in the case of data sharing or via NHS England in the case of DTAC, they are implemented at a local level. This approach leads to duplication of activity, for both industry and the NHS, long and unpredictable timelines, and a lack of standardisation and consistency in the outcome of assessments.

A third of companies experience average DPIA and DTAC timelines of over ten weeks, and, in some cases, over twenty-five weeks. Since the processes require specific expertise, the burden of DPIA and DTAC falls heaviest on SMEs, as they may lack a dedicated compliance team, and will have fewer financial resources with which to outsource. In both DPIA and DTAC it is recognised that the processes are valuable in protecting patients and systems from undue risk. However, it is also believed that this benefit can be maintained while deploying the processes in a more streamlined fashion.

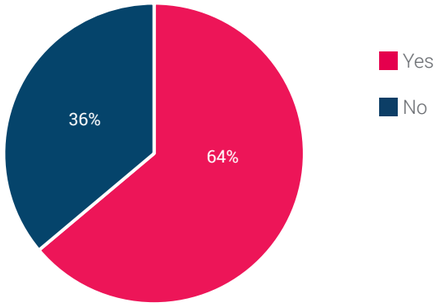
SUSTAINABILITY

The HealthTech sector is committed to reducing its carbon emissions, and companies have invested heavily to achieve this. However, as our HealthTech and Sustainability: The Opportunities and Challenges for the Sector paper details, the implementation of the NHS Net Zero Supplier Roadmap has been challenging. The NHS has made progress in reducing its carbon impact, educating suppliers and procurement teams with their limited resources, but the size of the task is such that it requires further support from government.

Net Zero by 2045

Do you feel that your organisation will be able to meet the target of Net Zero by 2045?

Figure 30

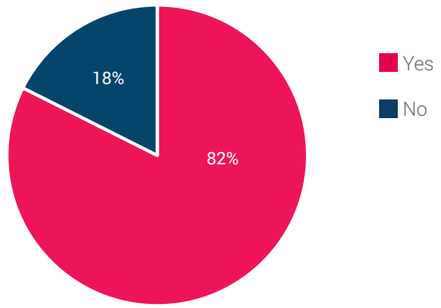


This survey demonstrates that, whilst good progress is being made, one in three HealthTech companies will not be able to meet the target of Net Zero by 2045 as set out in the Roadmap (Figure 30). Whilst more can meet the target of 2050, almost one in five companies still cannot (Figure 31). Large companies in particular need to align any requests from the NHS with their global commitments and be reassured that there are robust mechanisms in place for validation.

Net Zero by 2050

Do you feel that your organisation will be able to meet the target of Net Zero by 2050?

Figure 31

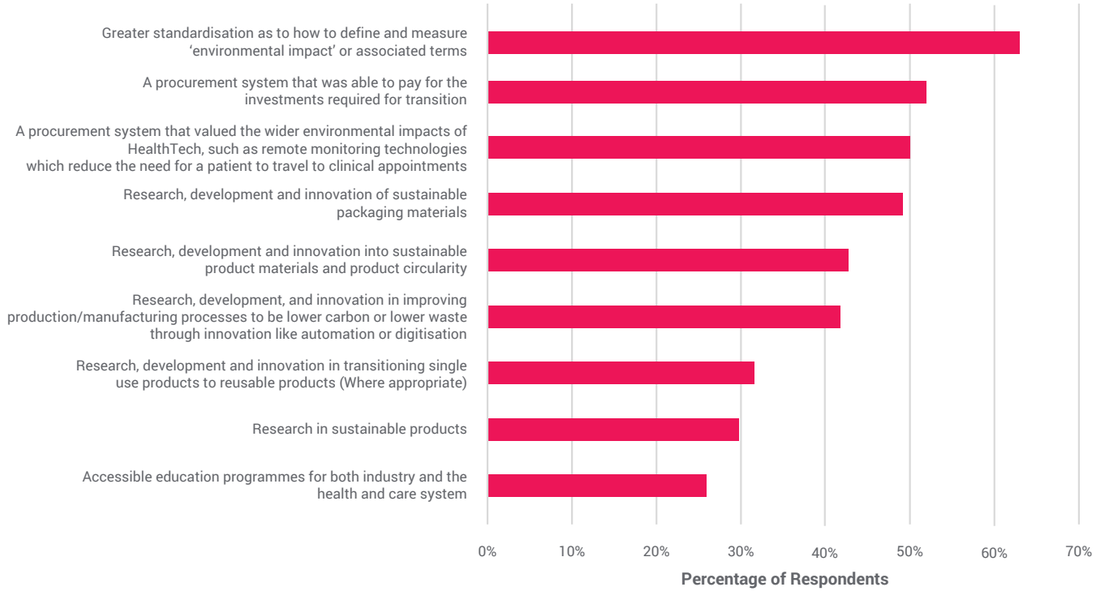


Whilst the industry remains supportive of the ambition, the sector needs a more pragmatic approach and assistance from Government to be able to meet it. The greatest thing negatively impacting UK attractiveness is the delivery of the Roadmap (Figure 13), with twice as many companies indicating its detrimental impact as compared to any other initiative by the UK Government; four in ten believe it is detrimental to UK attractiveness. This sentiment aligns with the data in Figure 22, in which sustainability costs are the third largest increases for HealthTech companies in 2024. Two-thirds of the sector is suffering increasing costs in this category. As we progress through the Roadmap, policies need to be developed collaboratively, utilising the expertise and experience of the industry. Fundamentally, targets must be achievable and support available to help companies to transition as effectively and swiftly as possible.

Support to Achieve Lower Environmental Impact

What may support your organisation to achieve a lower environmental impact?

Figure 32



To be able to achieve the transition, clearer guidance and further education for both procurement teams and suppliers is necessary. This survey shows the most helpful thing the government can do is to provide clear measurement guidance; nearly two-thirds of the sector call for greater standardisation as to how to define and measure 'environmental impact' or associated terms. If the entire sector is to achieve the transition, this support is necessary, and we are pleased that NHS England has committed to working through the detail to provide the necessary clarity. It must also be acknowledged that this transition requires investment; a procurement system that can account for such investment was second in companies' priorities for support. This again mirrors the sector's desire to secure an approach to procurement which recognises value across patient pathways and not merely the acquisition price of individual products. The procurement system currently relies on industry incurring costs at risk with no guarantee that the NHS will or can adopt more sustainable solutions. A third priority is the research and development of more sustainable materials, technologies, and products, which we believe the government should incentivise. Such work needs to be driven through the Department of Health and Social Care's (DHSC) 'Design for Life' programme.

There is still confusion for suppliers as to what is being asked, how they should answer, and how the responses are scored. For companies of all sizes, this is absorbing resources that could be better used elsewhere in bringing proven technologies to patients. Without adjustments and increased support, with one in three companies currently unable to meet Net Zero by 2045, the Roadmap is verging on being unachievable as it is currently set out without risking supply resilience, patient access, and UK attractiveness. We look forward to continuing to work with officials to ensure this is mitigated.

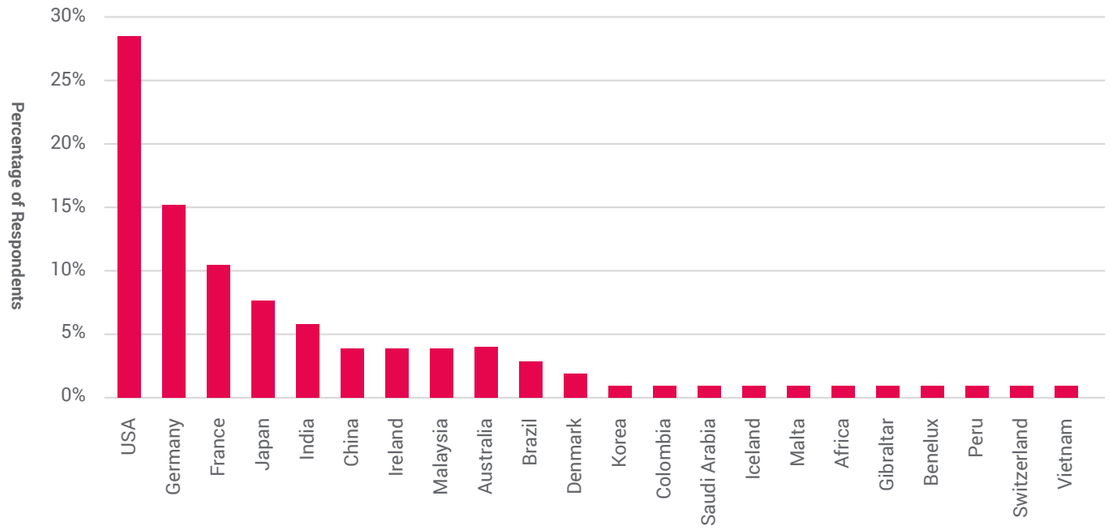
EXPORTING

Despite strong growth between 2013 and 2019, the total value of exports from the UK HealthTech sector has flatlined recently. This is in comparison to a global growth trajectory of 5.29% annually. A doubling in the growth of HealthTech exports seen between 2013 and 2019 would have delivered an additional £2.5 billion to the UK. A future expansion of that scale would help to alleviate the UK's substantial trade deficit, which is one of the worst in Europe.

Overseas Markets

Which are your biggest overseas markets by turnover?

Figure 33

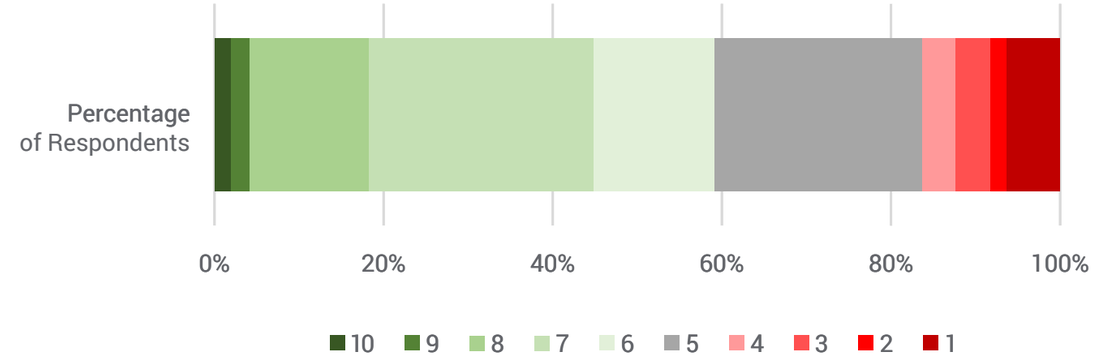


Over a quarter of HealthTech companies that do export identified the USA as their biggest overseas market by turnover, as it was in 2023. Germany and France follow in second and third respectively. Compared to 2023, responses suggest that the export market is more fragmented. Whilst the top three export markets (USA, Germany, and France) accounted for 68% of all responses in 2023, this has fallen to 54% this year. Nevertheless, the importance of the US as an overseas market is clear, especially given that it remains a first-choice for many UK companies.

Export Support Offer

On a scale of 1-10, where 10 is excellent, please rate the UK's support offer for UK businesses looking to export

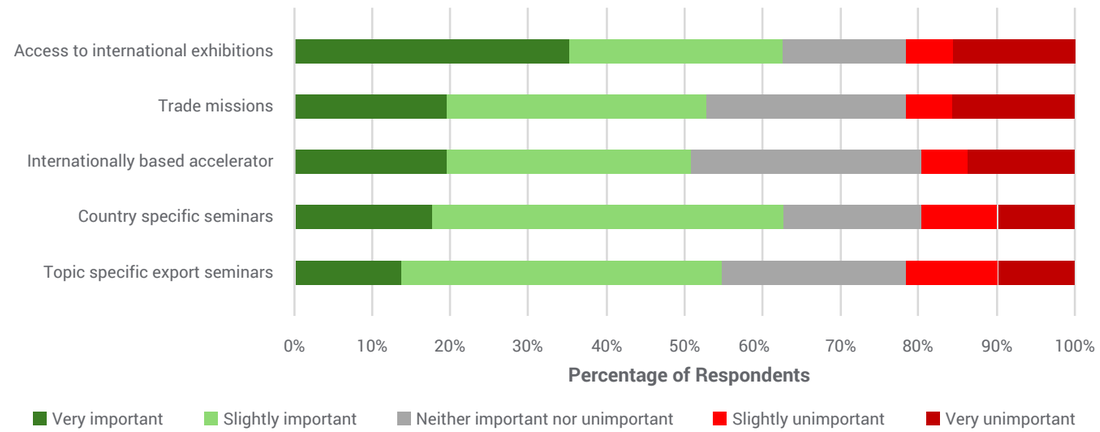
Figure 34



Export Products and Services Support

How important are these products or services to your business?

Figure 35



With the potential for the sector's exports to continue to grow, and more companies becoming export-oriented, support is critical so that the UK can keep pace with international competition. However, despite a modest increase in positivity from 2023, exporting companies' feedback on UK support rates it only as moderate. The main responses companies gave included reasonable satisfaction with the grants the Department for Business and Trade (DBT) offers, for those who did receive them. Negative ratings centred around companies' lack of awareness about support, a reduction in incentives available from government, and a perception that the DBT has received less resource over time.

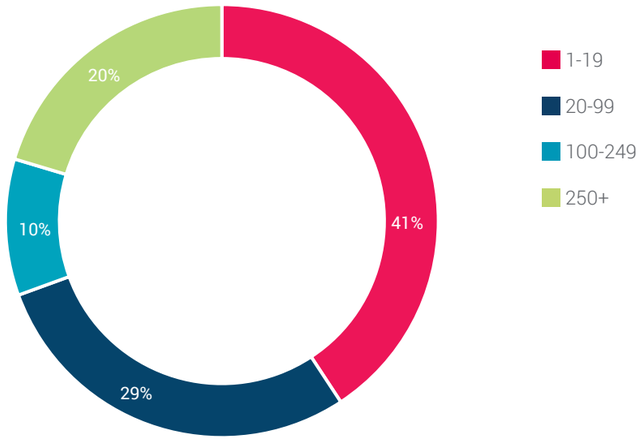
In terms of specific support, access to international exhibitions was hugely significant, with almost two in five companies rating it 'very important' to their business. However, there was general support for all measures surveyed, with at least 40% of companies finding each important.

BREAKDOWN OF RESPONSES

Companies by Size

What is the size of your company? (Number of People)

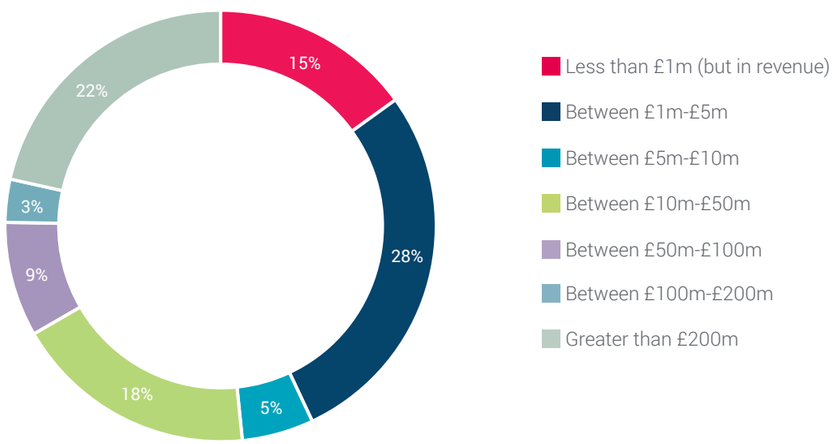
Figure 36



Companies by Turnover

What is the turnover of your company?

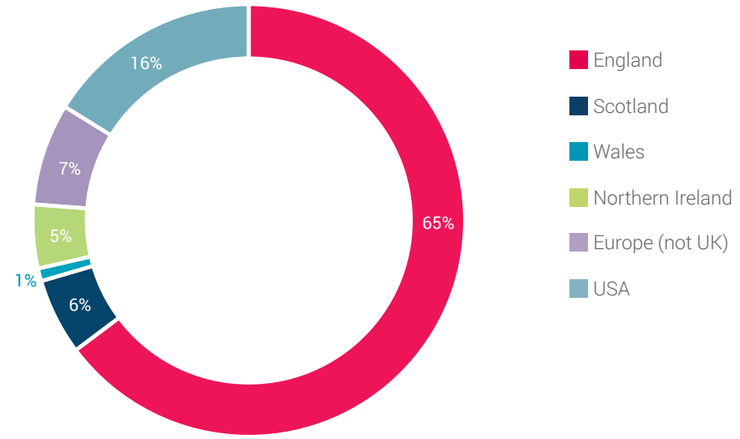
Figure 37



Companies by Location

What is the location of your headquarters?

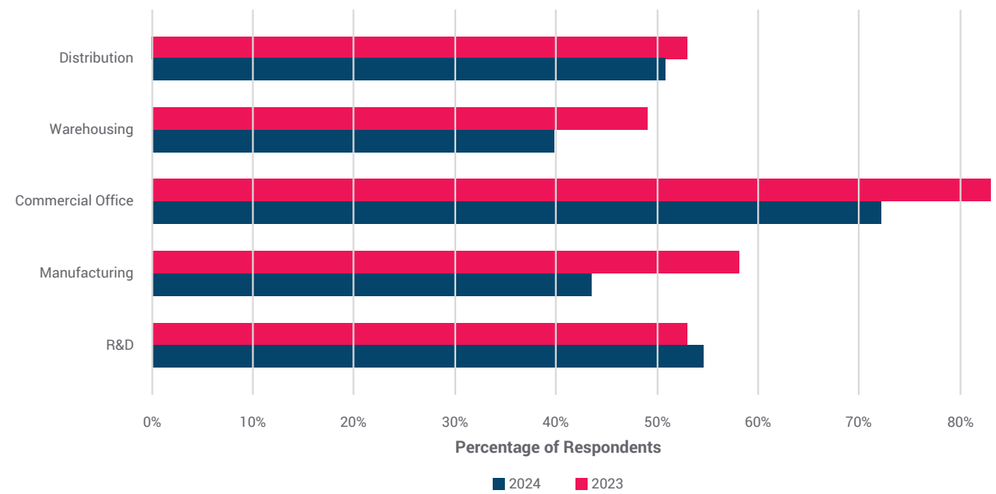
Figure 38



Companies by UK Presence

What is your presence in the UK?

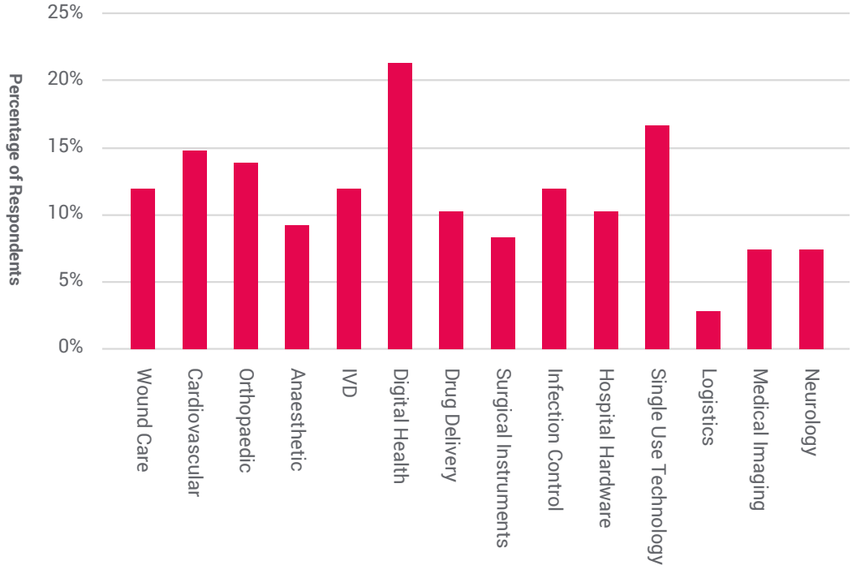
Figure 39



Companies by Sub-Sector

What are the main activities of your company?

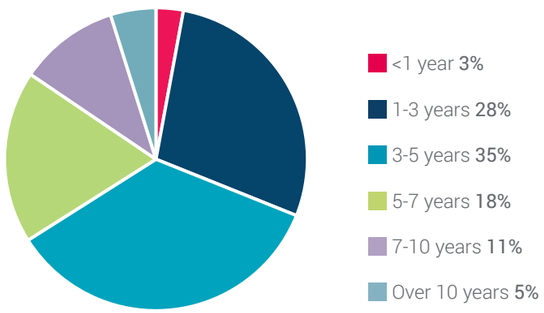
Figure 40



Time from Idea to Approval

What do you currently believe is the average time to market for a new product for your company, starting from a feasible idea to regulatory approval for sale in the UK?

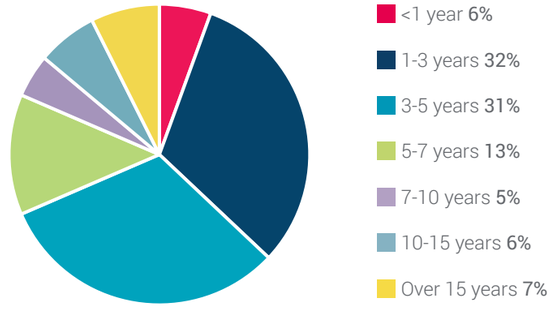
Figure 41



Time from Regulatory Approval to Adoption

What do you currently believe is the average time to market for a new product for your company starting from regulatory approval to full adoption in the UK?

Figure 41



Data collected in July and August of 2024.

ABHI