

Unlocking the potential of UK HealthTech

Data driven insights and recommendations to unlock the potential of UK HealthTech

Commissioned by the UK Office for Life Sciences

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01

Executive summary

Executive summary

The UK's HealthTech sector plays a pivotal but often underestimated role in the advancement of healthcare, offering a diverse array of technologies with the potential to save lives and enhance wellbeing. These innovations hold a position of global significance, benefitting healthcare systems worldwide, including the NHS. Consider the emergence of AI-driven diagnostic tools, for example, which analyse medical images with remarkable accuracy, expediting disease detection and enhancing the prospects of early treatment, ultimately contributing to the Nation's health.

With a prominent Biopharmaceutical sector in the UK, HealthTech is often less celebrated. This report presents the results of an extensive examination, combining a review of existing research, insights gathered through a survey of HealthTech enterprises, and interviews with key sector stakeholders. The objective was to identify opportunities for growth and enhancement within this important sector. The recommendations encompass critical areas such as research and development, manufacturing, funding, NHS procurement, sector representation and data infrastructure.

Key findings

The HealthTech sector is a key sector for the UK, with growth potential

The HealthTech sector is a significant contributor to the UK economy with an annual turnover of £34 billion in 2022 and offering employment to more than 150,000 professionals. In a recent report by Imperial College London, the sector Gross Value Added showed a 19% compound annual growth rate between 2016-2020 for MedTech (which adopts a narrower definition than HealthTech).

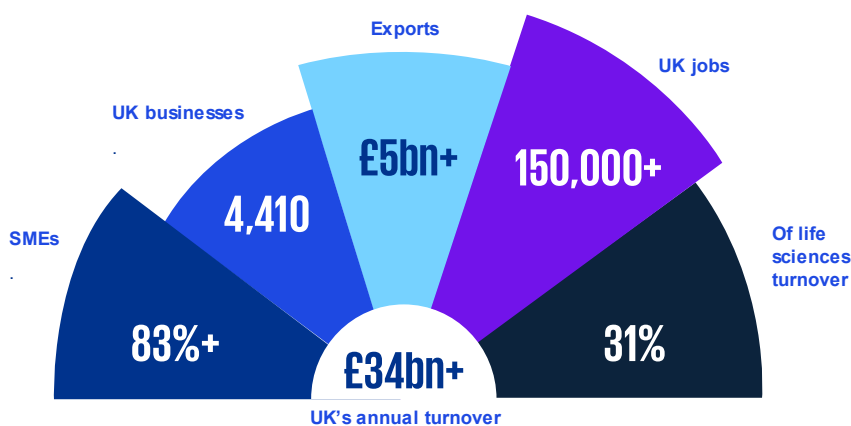
The UK is a net importer of HealthTech products and services

According to the Medicines and Healthcare products Regulatory Agency ("MHRA"), there are approximately 2 million products registered for use on the UK market. The UK is a net importer of HealthTech, exporting over £5 billion worth products and services annually, and importing around £7.5 billion of HealthTech products.

The geographical spread of the UK HealthTech sector goes beyond London and the Golden Triangle

The Golden Triangle, encompassing London, Oxford (South East), and Cambridge (East of England), is undeniably a prominent hub for research and development in the field of life sciences and medicine. It boasts five universities ranked among the world's top twenty-five, alongside some of the globe's largest research institutions, including the Sanger Centre, the Francis Crick Institute, and Research Complex at Harwell.

However, it's essential to recognise that the UK's HealthTech sector extends well beyond the Golden Triangle's borders. This sector exhibits significant diversity and a substantial presence throughout the country. While the South East region leads in employment, turnover, and the number of HealthTech sites, Small Medium Enterprise ("SME") HealthTech businesses are dispersed evenly across various UK regions. Focusing funding and support solely within the Golden therefore excludes a substantial quantity of SME businesses that require support.



The UK HealthTech sector is dynamic and requires redefinition to ensure emerging activity is effectively captured

The growth of digital health technologies (including Artificial Intelligence) is adding a new dimension to the sector. A formal redefinition of UK HealthTech is required to encapsulate emerging technologies and reduce ambiguity surrounding what does and does not constitute HealthTech activity.

While large UK HealthTech businesses typically engage in R&D and manufacturing, this is not the case for SME businesses

SME businesses are much more likely to engage in Technology Readiness Level (“TRL”) 1-6 activities only (from basic research and proof of concept, to testing and validation). This means the ‘operational’ aspects of commercialisation, such as scale-up manufacture and pre-production manufacture, are rarely performed. SME businesses currently opt to license their Intellectual Property (“IP”) to a third- party or seek outright sale of the business / IP Rights as a means of generating a return and commercialisation.

SME businesses are more reliant on public sector funding, but find timely HealthTech specific opportunities scarce and the application process onerous

SME businesses are less likely to be able to “self-fund” R&D than large businesses, and therefore rely on public sector funding support. Respondents feel that the scope of funding opportunities is not aligned with HealthTech business requirements and application processes are too complex and time-consuming.

The format of public sector funding and its availability hinders R&D activity

HealthTech businesses can see significant delays in development processes caused by rigid funding time scales. SME businesses would benefit from the capacity to access funding when they require it. Lengthy review and approval processes exacerbate the challenges UK HealthTech Businesses face in getting technologies to market on time. An opportunity exists to introduce an ‘Open Call’ for HealthTech funding to eliminate synergy challenges in scope and time-scales.

Few UK HealthTech businesses have applied for public sector grants to support manufacturing activity

Regardless of business size, less than 1-in-5 HealthTech businesses surveyed have applied for public sector grant support for manufacturing activity.

The majority of UK HealthTech businesses are planning to maintain or increase UK R&D activity

Both large and SME businesses surveyed appear committed to conducting R&D in the UK over the next 5 years, including those with an overseas Head Office.

The current regulatory landscape is a barrier to innovation, affecting R&D and manufacturing

Respondents of all sizes cite regulatory approval as their biggest challenge. The transition from EU to UK specific regulations has amplified some long-standing issues and introduced new concerns. The effect of the complex regulatory environment is that time to market / revenue for new products / services is extended and the cost of development projects increases.

UK HealthTech businesses are committed to manufacturing in the UK

Of those businesses surveyed that manufacture in the UK, the majority are planning to maintain or increase manufacturing in the UK, including those with an overseas Head Office. The majority of manufacturing is conducted internally, rather than through contract manufacturers.

UK HealthTech SMEs often seek indirect commercialisation of their technologies

Despite displaying a willingness and desire to manufacture in the UK, small businesses continue to encounter challenges when translating R&D outputs into commercialised technologies. This is demonstrated by the sizable number of surveyed small businesses that opt to either license the intellectual property rights to their technologies to a large business or seek outright sale of the technology to a large business.

The sector demonstrates a strong awareness of the significance of IP rights protection

Respondents, regardless of size, exhibit strong IP awareness. Those surveyed safeguard R&D results through formal mechanisms, including Non-Disclosure Agreements and patents.

The NHS is an important customer for UK HealthTech, but procurement policies suppress innovation adoption

The NHS is recognised as the largest buyer of health technologies in the UK (spending an estimated £10+ billion a year on HealthTech). However, procurement is increasingly focused on cost optimisation through supply base reduction and the prioritisation of lowest cost products. While this may provide short-term value for money there is concern that patient outcomes and product quality are being compromised by marginalising higher priced technologies that provide patient benefits and improved product longevity.

Respondents feel that tax incentives are not fit for purpose

Respondents voiced concerns about the complex tax credit system and expressed frustration at the reduced rates R&D tax credits for SMEs. The data shows a lack of awareness and understanding of the Patent Box relief scheme, particularly among SMEs.

There is lack of detailed public information regarding HealthTech SMEs despite their significant presence in the sector

Although HealthTech represents 31% of all turnover in the UK life sciences sector and more than 85% of HealthTech businesses are SMEs, there is a lack of granular information in the public domain pertaining to these businesses.

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Recommendations

Recommendations

By embracing these recommendations, the UK can foster a thriving HealthTech ecosystem that not only spurs innovation but also enhances patient care, secures economic growth, and solidifies its position as a global leader in health technology. With strategic and targeted interventions, including improved data collection and granular reporting, we can maximise the capability and capacity of the sector. This not only bolsters the sector's significance in the UK's long-term prosperity but also ensures a more comprehensive understanding and representation of the HealthTech landscape.

Research and development

- **Fostering late-stage HealthTech R&D activity:** the UK's HealthTech sector faces challenges in retaining late-stage research and clinical studies within the country. While the UK effectively supports academic research and early-stage spin-out businesses, it encounters difficulties when R&D progresses into a clinical setting. Many companies tend to move their activities outside the UK due to delays in NHS Trust approvals for clinical studies and high R&D costs. Large companies see potential in the NHS for world-class clinical studies, given its access to diverse patient populations. However, the pressure on NHS Trusts and the slow flow-through rate of clinical studies prompt UK HealthTech businesses to choose overseas locations. To optimise the HealthTech innovation landscape and harness commercial opportunities, it is imperative to address how UK-based clinical studies can be accelerated, including funding support for SMEs in this domain.
- **Facilitate clinical testing partnerships:** promote and establish partnerships between industry and prominent clinical settings, such as major hospitals for real-world testing within the UK. For example, additional funding and resources are required to make Academic Health Science Networks ("AHSNs") even more proactive in facilitating innovation and collaboration between end-users, healthcare providers, HealthTech businesses, and consumers.
- **Enhance regulatory pathways:** UK Government should consider mechanisms to enhance two critical areas of concern; improving the regulatory pathway for innovation and streamlining the process for adopting new health technologies. For example, increased collaboration with organisations like National Institute for Health and Care Excellence ("NICE") and overseas regulators (such as Food and Drug Administration ("FDA")) to ensure efficient routes to market for all subsectors of HealthTech, including digital health and AI.
- **Improve demand signalling for health technologies:** the conceptualisation of relevant UK technologies is hampered by the lack of data available to HealthTech companies for demand signalling. It is particularly difficult for small businesses to develop innovative "market pull" technologies without a clear view of the requirements that patients, clinicians, and HealthTech professionals have. Without improved demand signalling there is a danger that R&D resources are being allocated to areas that do not maximise value and/or return on investment.

Manufacturing

- **Long-term plan for UK HealthTech manufacturing:** there is a need for an extended-term plan to boost HealthTech product manufacturing in the UK, to ensure economics of production in the UK and product pricing remain competitive. Identification and addressing skills gaps coupled with improved access to infrastructure funding and favourable incentives must be considered.
- **Harmonised guidelines for NHS trusts:** lack of harmonisation and consistency across healthcare providers, including NHS trusts, is problematic for manufacturers. Developing harmonised guidelines for purchasing decisions (for example, sustainability and social value definitions) across the trusts will make meeting NHS trust requirements easier, thereby increasing the likelihood for commercial return.

Funding

- **Introduction of an open funding call for HealthTech businesses:** public funding for the sector should be available at the point of need. It is difficult for SME businesses to plan development programmes when the availability and scope of external funding are unknown.
- **Simplify application processes:** funding bodies must streamline and simplify application processes and enhance transparency and feedback loops.
- **Balance the HealthTech sector funding environment:** target increased funding to businesses, particularly SMEs, outside the Golden Triangle and South East.
- **Increase focus on funding for translation of research to production:** a reform of the funding landscape that supports SME businesses transitioning from R&D to production manufacturing is required. While early-stage R&D is well-supported under current funding structures, the UK misses an opportunity to leverage this activity for the growth and preservation of high-value HealthTech jobs by not adequately facilitating the transition to large-scale production.
- **De-risk private HealthTech investment:** appetite for private sector debt/equity funding increases when public funding supports new technologies with a higher associated commercialisation risk. HMRC should continue the SEIS / EIS programmes, and policymakers and industry stakeholders must collaborate to create an environment that attracts national and foreign direct investment to support HealthTech innovations and encourages long-term investments in the sector.
- **Optimise tax incentives for SMEs:** optimise incentives for SMEs by restoring R&D tax credits to at least previous levels, refining the targeting mechanisms to ensure distribution among SMEs (not just R&D-intensive SMEs).

Commercialisation and NHS procurement

- **Access to global markets to increase exports:** targeted export support should be provided to SMEs, including funding, guidance and support for access to global markets. Particularly focused on helping SME's with efficient launch and routes to overseas markets.
- **Value-based procurement:** re-evaluate NHS procurement methods to broaden support for UK products. Embrace a value-based approach that prioritises long-term innovation and healthcare benefits over cost considerations, while championing UK businesses engaged in R&D and manufacturing within the country through enhanced support in tenders, tariffs, and reimbursements.
- **Generate greater awareness of Patent Box for wider adoption:** prioritise efforts to boost awareness and understanding of Patent Box scheme to drive greater adoption, with a particular focus on SMEs.

Sector representation and data infrastructure

- **Establish a research and data collection programme:** this report offers valuable insights into the current activities of the UK HealthTech sector, marking an essential initial exploration. However, for robust strategic planning and well-informed policymaking, ongoing research engagement with the sector is essential. The establishment of a comprehensive data collection program is crucial to address existing data gaps and ensure a continuous, up-to-date information source on the sector.
- **Introduction of a Standard Industrial Classification (SIC) code:** bringing business activity related to HealthTech under a single SIC code (or group of codes) and agreeing a standardised definition of HealthTech in the UK will facilitate the collection of more insightful sectoral data, greater representation of fringe cases, and a better understanding of UK HealthTech activity for policy and planning purposes.
- **Annual innovation system assessment:** due to the rapid pace of technological change in the UK HealthTech sector, it would be valuable to conduct an annual assessment of the HealthTech innovation system. Such a report would serve to optimise innovation within the sector, monitor the impact of technological changes, and ensure that interventions are appropriately directed toward addressing the sector's current challenges.

- **Greater reporting transparency and granularity:** improve the transparency of the HealthTech sector by increasing the granularity of data in public reporting, including the inclusion of specific data points like HMRC R&D claims data, Patent Box claims data, public funding award allocations, Bioscience and Health Technology Sector Statistics, and the Life Science Competitiveness Indicators. Enhanced reporting transparency should also encompass providing detailed information about key contracts awarded under various NHS procurement frameworks, while government statistics collection should consistently expand to include key characteristics such as postcode, employee numbers, and turnover.
- **Geographic data should be collected for both head office location and UK registered address:** company registered address does not necessarily equal the location of principal activity. The geographical spread of UK HealthTech businesses is more effectively ascertained using Head Office location rather than UK registered address. Data on both locations will improve the relevance of future research programmes within the sector and ensure equitable allocation of resources among businesses.
- **Use business size as a dependent variable for future sectorial research:** HealthTech is not a homogenous sector. There is a pressing need to consider how small businesses can input into UK HealthTech sector reporting. The views of these businesses must be reflected in future policy decisions. While accepting the importance of large HealthTech businesses to UK plc, our findings strongly suggest that SME and large HealthTech businesses are not a homogeneous group and have differing needs and challenges that must be given consideration.
- **Mechanisms for the capture of sub-sector inputs via trade associations should be defined:** the UK HealthTech sector is represented by several trade associations. While some of these bodies do not represent a significant volume of businesses, it is vital that their views are heard, reported, and acted upon through policy decisions.

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Background to the research programme

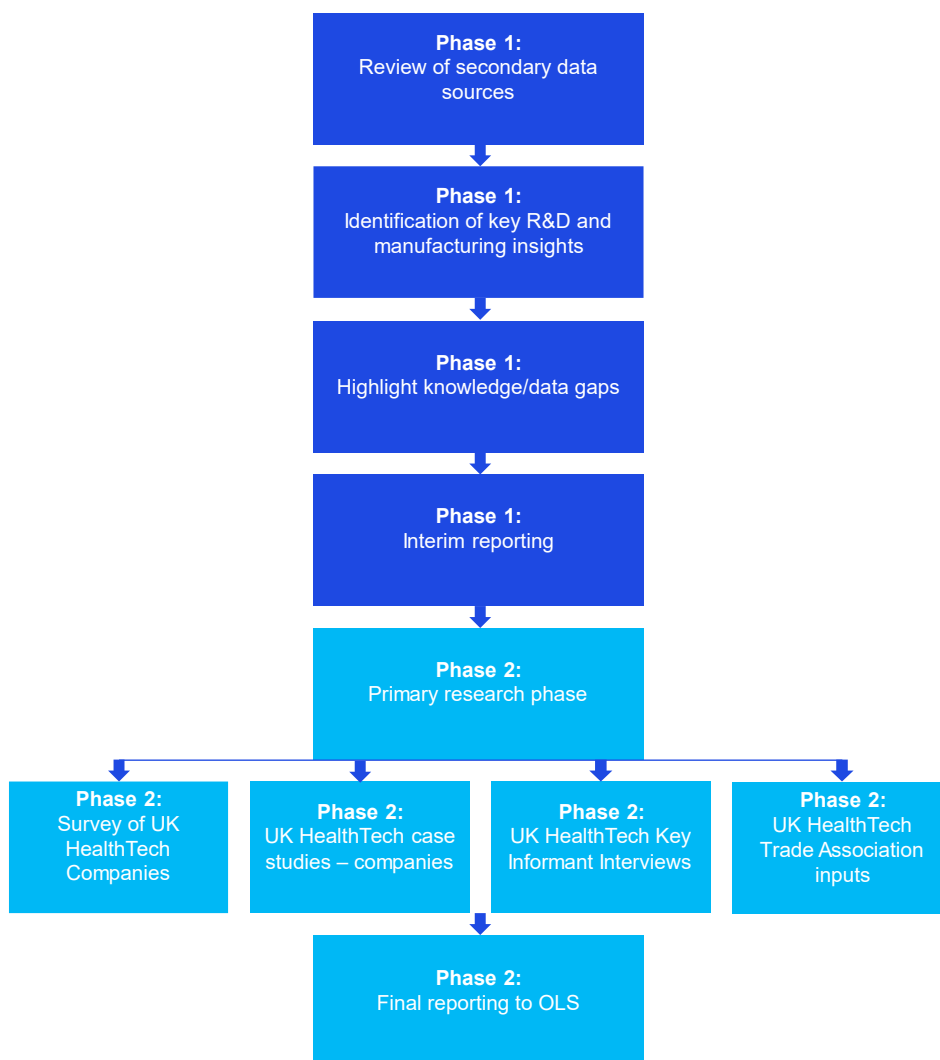
Research purpose and structure

In 2023, the UK Government Office for Life Sciences (“OLS”) commissioned an evaluation of the R&D, manufacturing and funding landscape of the UK HealthTech sector. This evaluation seeks to assess the sector’s characteristics and economic performance with particular emphasis on the manufacturing and R&D activities performed across the United Kingdom.

The evaluation comprised of two phases of activity:

1. An initial review of existing published research regarding the UK HealthTech sector.
2. A subsequent primary research phase that sought to confirm (or not) the findings of the initial review and deliver new insights into the UK HealthTech sector. The primary research phase included:
 - a. A survey of UK HealthTech businesses
 - b. UK HealthTech Key Informant Interviews
 - c. UK MedTech Trade Association inputs.

The knowledge established through this evaluation is to be used to enable policymakers to offer enhanced support and resources to the UK HealthTech sector.



Research design

Phase 1: Review of published research

In Spring 2023, a review was conducted of published reports and publicly available data sets pertinent to the UK HealthTech sector. The purpose of the analysis was to identify key R&D and manufacturing insights and identify gaps in the current research / knowledge base. A list of sources can be found in the “References” section of this report.

Phase 2: Primary research phase

Survey

A survey of the UK HealthTech sector was conducted between 29th June 2023 and the 17th August 2023. The survey was made accessible to UK HealthTech businesses using an online platform: Qualtrics. Participation in the survey was restricted to HealthTech businesses that were registered in the UK.

The Association of British HealthTech Industries and the UK Office for Life Sciences distributed the survey through their business networks.

The questionnaire sought to gather data on five areas of interest:

1. Organisation information – context
2. R&D
3. Manufacturing
4. Funding
5. IP and commercialisation.

Survey responses

The UK is home to more than 4,300 businesses that meet the established definition of a HealthTech business. These businesses constitute the “Population” in sampling terms. A total of 68 complete and usable survey responses were received. A confidence level of 90% and a margin of error of 10% can therefore be assumed for the study. This means that for this data, we can be 90% confident that the results we achieve are within 10% of the results that could be expected to be found had all UK HealthTech businesses responded to the question-set.

Respondent classification

Respondents were classified as either a “small business” or “large business”. For the purposes of this research programme the following definitions were used:

- “Small business” – a business that meets the EU definition of an SME: fewer than 250 employees and annual turnover below €50 million or balance sheet below €43 million.
- “Large business” – a business that does not meet the EU definition of an SME.

Throughout this report we will use the terms small business / SME interchangeably.

Table 1 shows the survey responses categorised by business size. The ratio of SME to large business survey respondents aligns with the conclusions drawn from the Phase 1 research’ the sector is predominantly comprised of SME businesses.

Table 1: Survey respondents by business classification

Categorisation of respondent	Number	% of population
SME respondents (<250 employees)	51	75.00%
Large respondents (<250 employees, but turnover ≤ € 50m)	4	5.88%
Large respondents (>250 employees)	13	19.12%
Grand Total	68	100.00%

Key Informant Interviews

Key Informant Interviews were conducted with the purpose of validating and extending the outputs of the review of published research and survey results.

A key informant is an expert source of information. Such expertise is typically a result of the individual's position within the sector that enables them to form a more detailed insight into an issue than the average person. To this end, the results of the interviews add substantial supporting evidence to the discussion of findings.

The interviews were intensive, semi-structured interviews based on a series of interview prompts. Each interview was scheduled to last approximately thirty minutes. Each key informant was interviewed once and the interview was digitally recorded and transcribed. Interviews comprised large and small enterprises, and three trade associations: Association of British HealthTech Industries, The British In Vitro Diagnostic Association, and British Healthcare Trade Association.

Key informants were given the opportunity to comment upon the transcribed interview text if they wished. The verbatim comments derived from the interviews are used throughout this report to supplement the findings of the survey data.

UK MedTech Trade Association feedback

A summary of the key findings from Phase 1 and Phase 2 of this research programme were presented to the MedTech Trade Association Forum on the 12th September 2023. The option to provide input into the research programme was provided to all attendees. All trade association inputs are included within each relevant report section.

Defining HealthTech

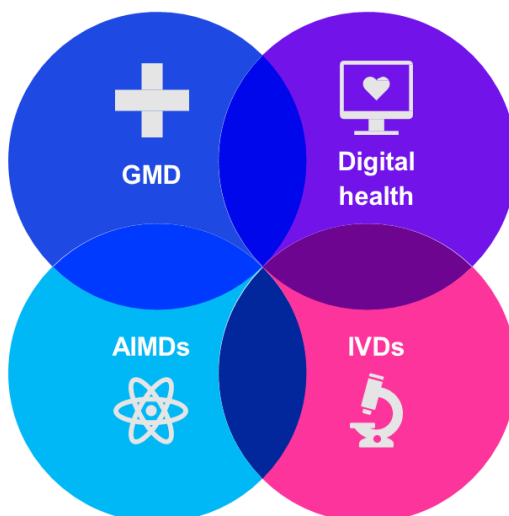
The following definition was used to establish the parameters for the examination of the HealthTech sector.

General medical devices

Includes syringes, heart valves, dressings, ECG monitors, surgical robots, CT scanners, and dialysis machines. General medical devices also includes any software used to power them.

Active implantable medical devices

Includes implants such as cardiac pacemakers, nerve stimulators, cochlear implants, and active monitoring devices.



Digital health

Digital health technologies encompass computing platforms, connectivity, software, data analytics and sensors when used to identify and manage health risks, diagnose or manage conditions, track health data, support clinicians in service delivery, or improve the efficiency and effectiveness of health systems. Digital health technologies include categories such as mobile health and apps, health information technology, wearable devices, telehealth and telemedicine, and personalised medicine.

In vitro diagnostic medical devices

IVDs are equipment or systems used in vitro to examine specimens. This includes all instruments, software, reagents and calibrators, such as blood grouping reagents, pregnancy test kits and Hepatitis B test kits.

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Research findings

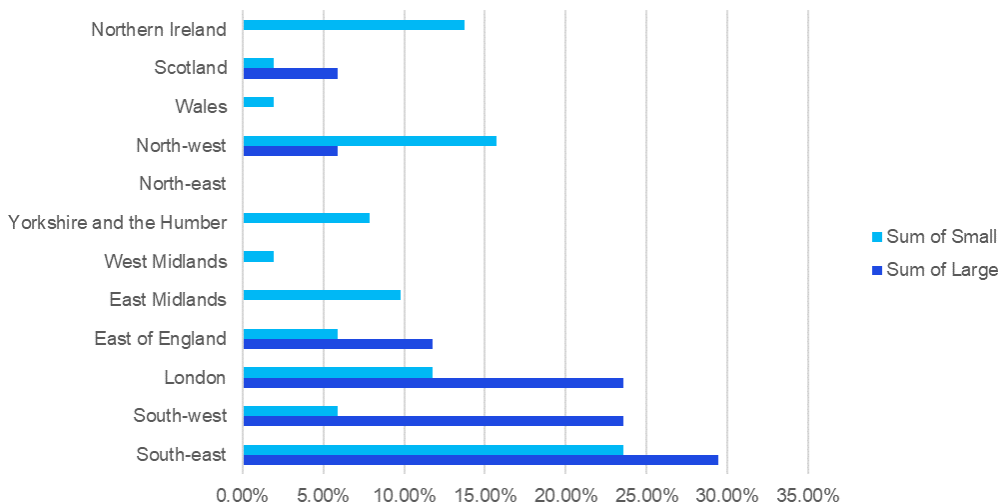
Sector context

Where are UK HealthTech businesses located?

An important observation made within Phase 1 of this research programme is that the geographical location of UK HealthTech businesses is often determined using their registered company address (as opposed to their Head Office address). This leads to the conclusion that HealthTech businesses are heavily concentrated within the South of England, in particular within the Golden Triangle (London, Oxford, and Cambridge). Consequently, resources and support for the sector is often directed towards the Golden Triangle at the expense of other locations. An objective of this research was to establish whether the perceived concentration of businesses within the Golden Triangle is an accurate reflection of geographical spread once Head Office location was utilised as the indicator of business location.

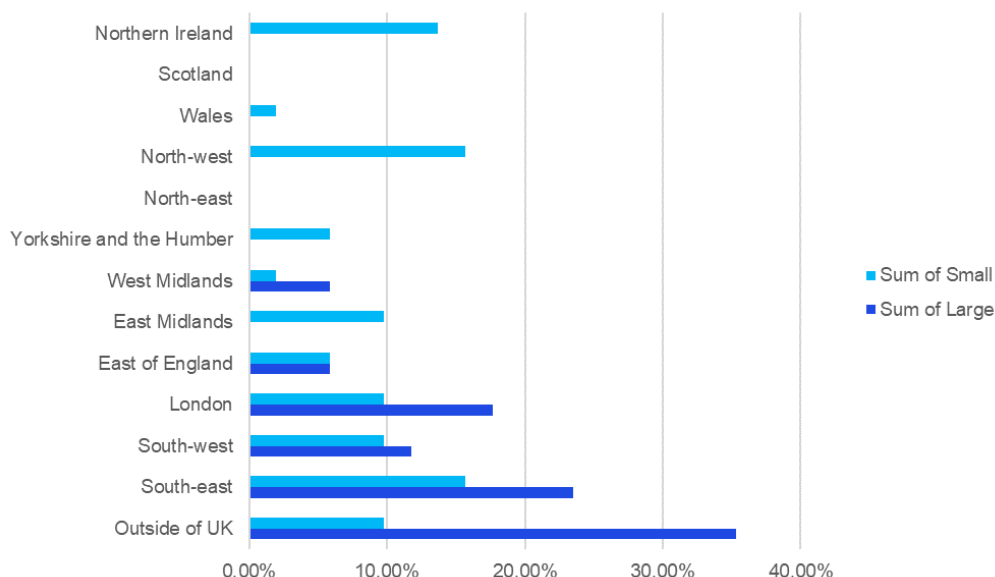
Our findings suggest that within the UK HealthTech sector, registration of SME businesses occurs across most regions of the UK with the South East of England the most common company registered address location. For large businesses surveyed there is evidence of a cluster of registered businesses within the South of England and London. 47% of respondents have a registered address inside the Golden Triangle. This data is consistent with the findings of Phase 1.

Figure 1.1: Where is your organisation's registered address in the UK?



Interestingly, when the location of the business is determined by Head Office location, then we see some deviation from published data. First, it is noted that a sizable portion of large businesses surveyed have a Head Office located outside of the UK. Of those surveyed, large businesses have a head office in the USA and Ireland, and SME businesses having a Head Office in a broader set of locations including Estonia, Japan, Australia, Sweden and Canada. For large businesses with a UK Head Office, we do see the anticipated clustering around the South of England and London. What is evident is that for SME businesses, Head Office location is more evenly distributed throughout the UK. This is an important finding with respect to how resources and support for HealthTech businesses is directed. It is essential that all UK regions are equipped to support these emerging HealthTech businesses, so as to capitalise on their activity and grow the sector. 35% of respondents have their Head Office inside the Golden Triangle (compared to 47% of respondents with registered addresses within the Golden Triangle).

Figure 1.2: Where is your organisation's head office located?



The analysis of registered addresses versus Head Office locations reveals patterns among survey respondents. Notably, in Northern Ireland and Wales, all respondents report that their registered address aligns with their Head Office location. However, in the England, a divergence between registered and head office locations is observed.

The South East, London, and the North West regions had the highest population of registered HealthTech businesses. In the South East, 44% of businesses registered in the area have Head Offices located elsewhere, with 32% of them situated in other regions of England and 12% outside of the UK. Similarly, in London, 40% of businesses with registered addresses in the region have Head Offices elsewhere (20% within another region of England and 20% outside the UK). Conversely, the North West exhibits a lower disparity, with only 11% of businesses having head offices located elsewhere, all of which are situated outside of the UK. In the Golden Triangle region, 39% of businesses registered in the region have Head Offices located elsewhere. Among this group, 26% have their Head Office in another region in England, and 13% are situated outside of the UK.

This implies a pattern where organisations opt to register their businesses in particular regions while operating from different locations, potentially on an international scale. This observation aligns with the conclusion drawn in the first phase; that registered addresses may not reliably indicate the actual locus of business activity.

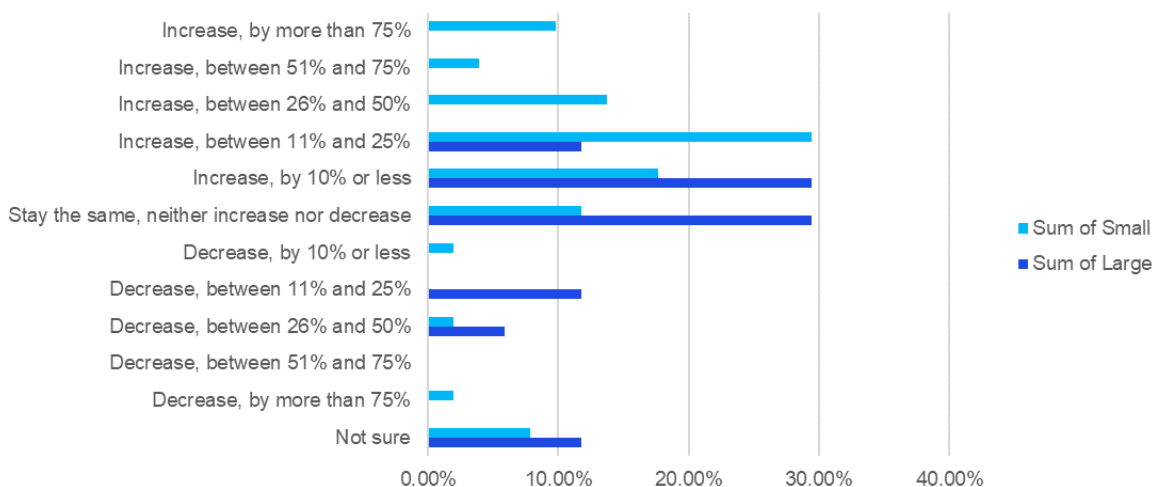
Interestingly, 20% of large businesses surveyed with a Head Office outside of the UK that conduct R&D in the UK expect to decrease the level of UK-based R&D activity in the next 5 years, while 80% expect to maintain or increase activity (see also Figure 2.2). 25% of large businesses with a Head Office outside of the UK that manufacture HealthTech products in the UK expect to decrease UK-based manufacturing activity in the next 5 years, and 75% expect to increase. Rationale given for the increases include:

- “Increasing global demand for products.”
- “Level of change dependent on securing internal investment verses other worldwide sites within the manufacturing network. Increase driven by product demand growth and network strategy to improve business continuity by dual sourcing and agility through regional supply.”
- “Projected annual demand increase of approximately 3%.”

Headcount

For survey respondents, headcount expectations for large UK HealthTech businesses over the next 2-years are positive, but relatively modest. Approximately 60% forecast the workforce to remain at current levels or increase by less than 10%. SME businesses in the sector are also positive with regards to headcount expectations. An increase in employee number of between 11%-25% is forecast by over a quarter of respondents.

Figure 1.3: How do you expect your headcount in the UK to change in the next 12-24 months?



There are respondents from all regions that anticipate an expansion in their headcounts. The most substantial growth (>51%) is expected by respondents in Northern Ireland, London, South West, and North West regions.

A review of the OLS 2021 Bioscience and Health Technology Sector Statistics (“BaHTSS”) found that for core medical technology businesses, the South East region is the largest employer by a significant margin, followed by Yorkshire and The Humber, East of England and West Midlands. The South East region also dominated with the number of industrial sites and revenue attribution associated with core medical technology, and the medical technology service and supply chain industry

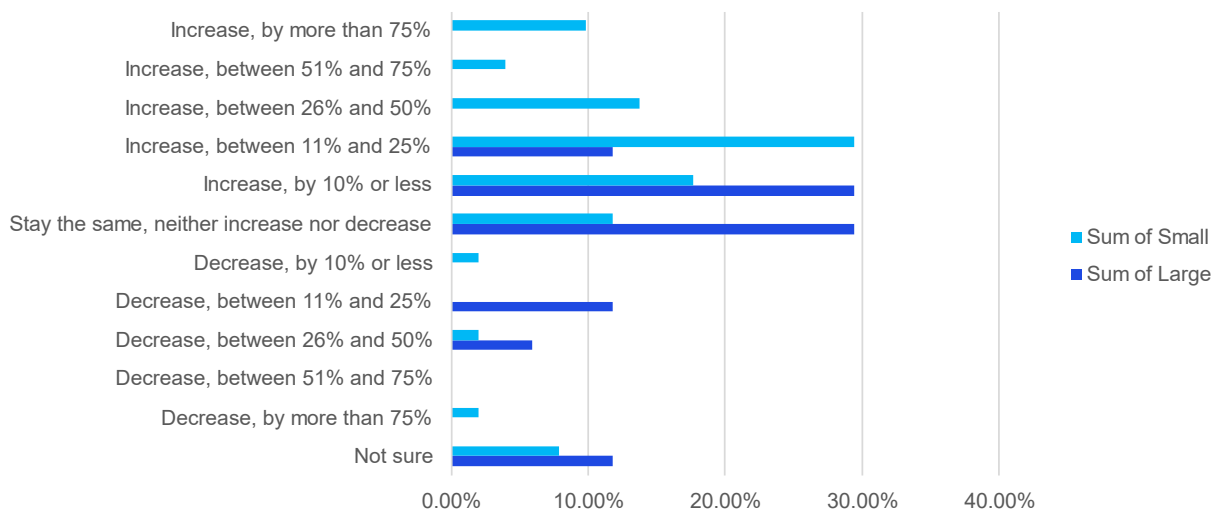
The average size of businesses in the South East, Wales, North East, Yorkshire and the Humber and South West are two or more times larger than the London region. This is likely owing to there being a small number of larger sites (and employers) in these regions, and the high concentration of start-ups in the London region.

The South East has the highest average revenue per site, followed by the North East and Wales. Again, this is driven by a small number of large businesses in these regions. London region has the lowest turnover – linked to start-up population. The West Midlands and Northern Ireland underperform in commercial productivity. The turnover per employee is the highest in the South East region followed by East of England and North West. The West Midlands and Northern Ireland on the other hand have very low employee productivity.

Export activity

Data suggests a substantial difference in export activity between large and SME UK HealthTech businesses. Almost half of surveyed SME businesses do not currently export or sell products / services in overseas markets. More than 40% of large businesses, by comparison, generate more than 75% of their sales revenue from non-UK markets.

Figure 1.4: Approximately what proportion of your UK organisation’s product / service revenue is derived from export?



Encouragingly, for SME businesses that do not currently export or sell products / services to non-UK markets, almost a third, 32%, intend to begin exporting in the next 2-years.

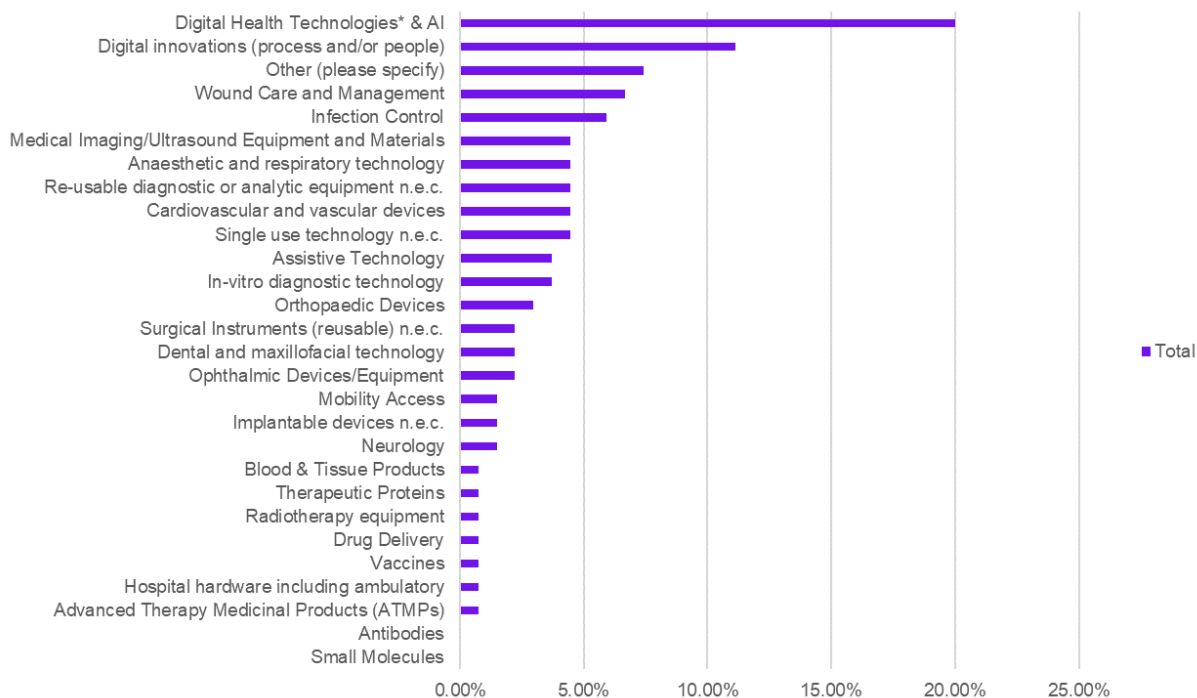
Large businesses that already conduct significant export activity forecast that they will remain committed to non-UK markets, with over half, 57%, of large businesses that already derive more than 75% of their sales from non-UK markets stating that they expect export sales to increase over the next 2-years.

Defining UK HealthTech

An challenge that arose during the review of published data was the absence of a standard definition of what constitutes a HealthTech business. There is some concern within the sector that the multitude of definitions results in some “HealthTech” activity being omitted from published data, particularly within non-traditional sub-categories such as ‘digital innovations’. In response to this challenge, one prominent trade association has made the decision to align with the classifications used in the Government’s medical technology strategy. We understand that this has entailed a significant investment of time and resources as they diligently categorise their extensive membership base according to these standardised definitions. A formal redefinition of UK HealthTech is required to encapsulate emerging technologies and remove ambiguity surrounding what does and does not constitute HealthTech activity.

The results of the survey identify the proportion of businesses that are engaged in activities as per the OLS BaHTSS classifications.

Figure 1.5: In which HealthTech subsector(s) does your organisation primarily operate?



The importance of ‘digital innovations’ to the UK HealthTech sector is demonstrated by the large proportion of respondents currently engaged in this sub-sector. 20% of SME businesses are involved in digital and AI health solutions (twice the proportion of large businesses engaged in this activity). It is our view that the proportion of businesses performing activity in digital innovations justifies a more granular approach to classifying this activity, so as to fully understand the work that is being conducted. According to the BaHTSS, the ‘digital health’ core medical technology sector has the highest employment and number of sites. Interestingly, single use technology generates 50% more turnover than digital technology, despite digital technology having 60% more employment and nearly 3x more sites.

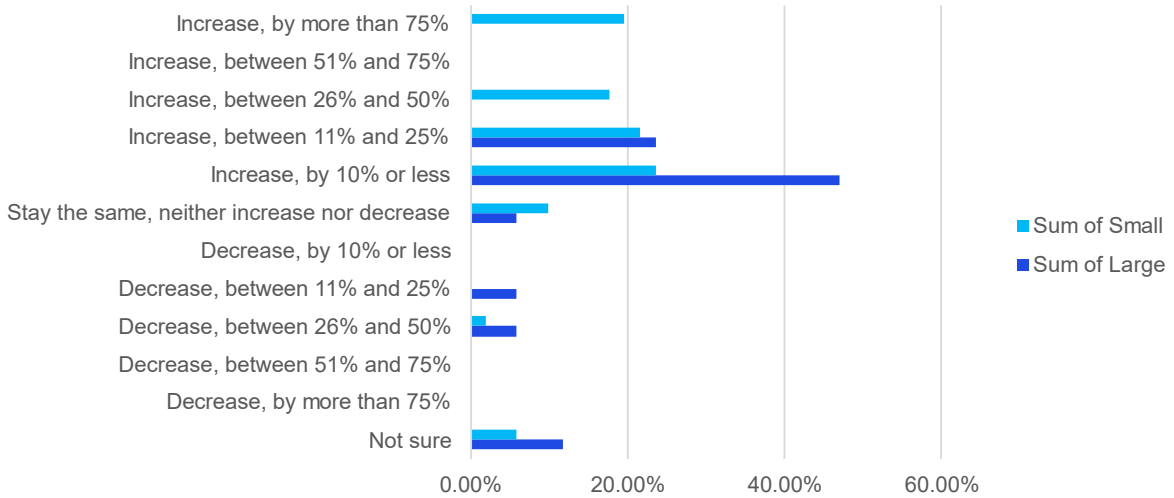
There are sub-sectors where large businesses are dominant in terms of engagement frequency: cardiovascular and vascular devices, implantable devices, drug delivery, and hospital hardware are all domains in which SME business engagement is low.

Importantly, we note that more than 77% of large business respondents and more than 72% of SME respondents had products in 7 or more subcategories of HealthTech. Furthermore, 8% of large business respondents and 15% of SME respondents operate in 2 or fewer product categories. The number of respondents operating within a single product category is about the same for SMEs and large organisations (at 4% and 3.6% respectively). This multi-sector engagement poses significant challenges when navigating distinct routes for regulatory approval, supply chain management, and securing funding within this dynamic and multifaceted industry.

Forecast revenue from UK operations

It is positive for the UK HealthTech sector that the majority of UK HealthTech businesses are expecting their turnover to increase by up to 10% over the next 2-years. Understandably, the turnover growth expectations of SME businesses are greater with approximately one-fifth suggesting an increase of more than 75% on current levels.

Figure 1.6: How do you expect your turnover from UK operations to change in the next 12-24 months?



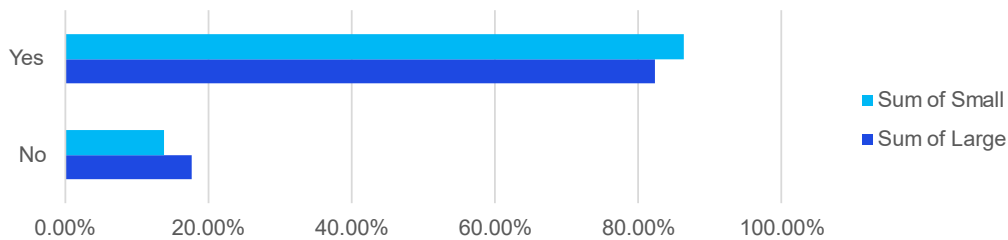
There are respondents from all regions that anticipate turnover growth. The most substantial growth (>51%) is expected by respondents in the following regions: Northern Ireland, East of England, London, North West, Yorkshire and Humber, and South East.

Research & development

UK based R&D activity

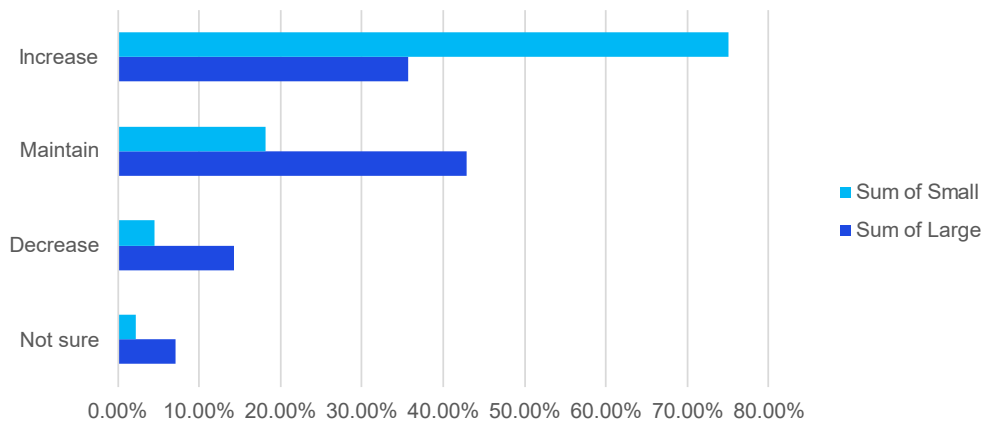
HealthTech businesses surveyed overwhelmingly conduct some form of R&D activity within the UK. The proportion of SME to large businesses undertaking R&D shows a minor level of variation.

Figure 2.1: Does your organisation carry out any R&D activity in the UK specific to HealthTech?



The majority of UK HealthTech businesses surveyed are planning to either maintain or increase the amount of R&D activity they perform in the UK during the next 5-years. SME businesses, in particular, plan to increase their UK R&D with three-quarters of respondents indicating that was their intention. This will require targeted interventions to support these ambitions. Large businesses are less likely to plan for an increase in UK based R&D. This may reflect the satisfaction of large businesses with their current UK R&D capability, and a general optimism amongst SME businesses that their R&D efforts will expand.

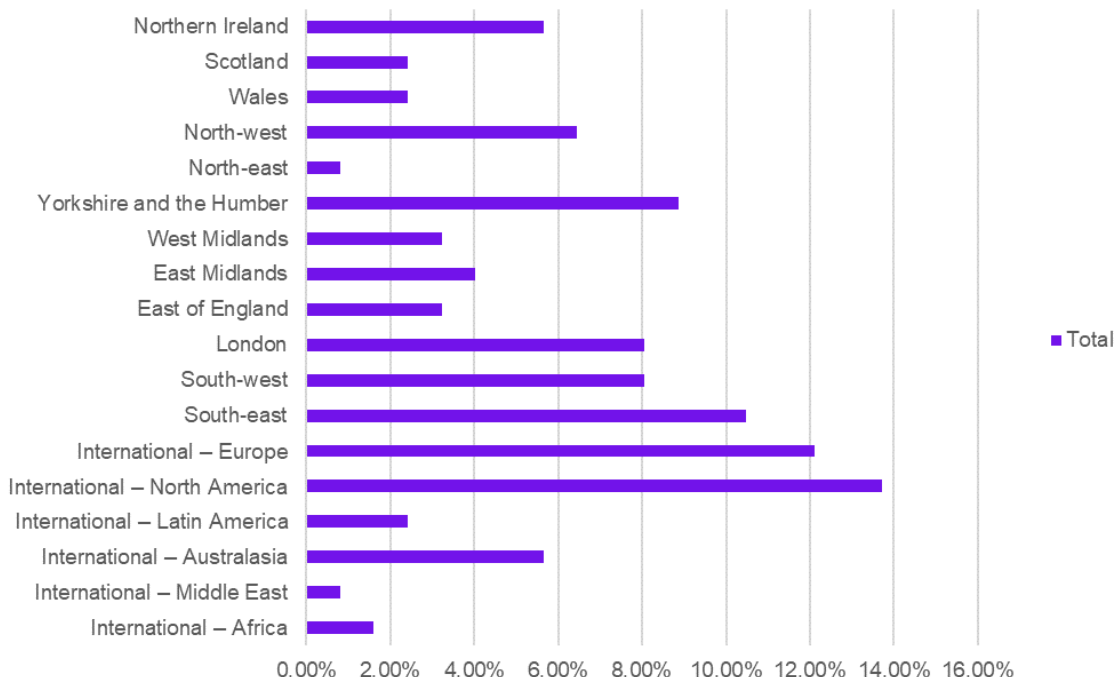
Figure 2.2: Do you plan to maintain, increase or decrease UK R&D activity specific to HealthTech in the next 5 years? (Respondents that stated “yes” to Does your organisation carry out any R&D activity in the UK specific to HealthTech?)



Location of R&D activity

Within the UK, surveyed HealthTech businesses are most likely to have their primary R&D facility in the South East region. Outside of the UK, there is a notable proportion of UK HealthTech businesses that conduct their R&D in North America and mainland Europe. 21% of respondents carry out R&D activity in the Golden Triangle.

Figure 2.3: In which location(s) does your organisation primarily conduct its R&D activities specific to HealthTech?



The findings of the survey broadly confirm the results published within existing UK HealthTech reports where the South-East hosts the most R&D sites with significant clusters in London and the East of England.

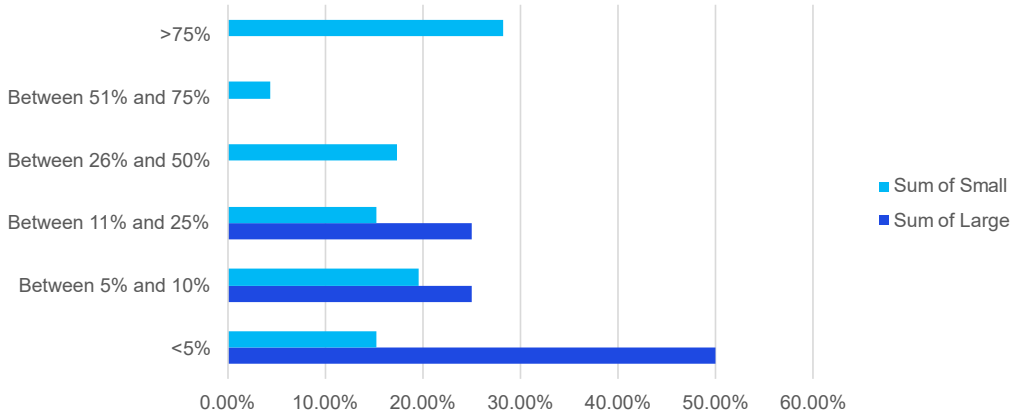
Some respondents voiced concerns about conducting late-stage development and commercialisation within the UK, with one respondent stating, “late-stage development and commercialisation done overseas - NHS notoriously difficult to work with”. The hurdles faced by organisations attempting to conduct clinical trials in the UK were evident, as highlighted by another respondent’s experience: “despite clinical trials being approved by the US FDA and the Irish HPRA... MHRA did not allow the trial to be extended to the UK. Their reason for this was extremely unclear. Moving forward, we will focus our R&D efforts in the US and Ireland unless it’s absolutely necessary”.

Access to resources and patient samples played a crucial role in shaping R&D strategies. Interestingly, it is the perception of participants that R&D activities in the UK are concentrated in academic institutions, spin-out businesses and SMEs, with larger organisations opting to conduct their research overseas. Additionally, concerns about a lack of demand signalling from the NHS, clinicians and patients, and the high cost of conducting research in the UK were evident among respondents.

R&D workforce

Three-quarters of surveyed large HealthTech businesses have 10% or fewer of their workforce engaged in R&D activity. For SME businesses more than a quarter of the workforce is directly involved in performing R&D activity. This demonstrates the relative R&D intensity of SME businesses within this sector.

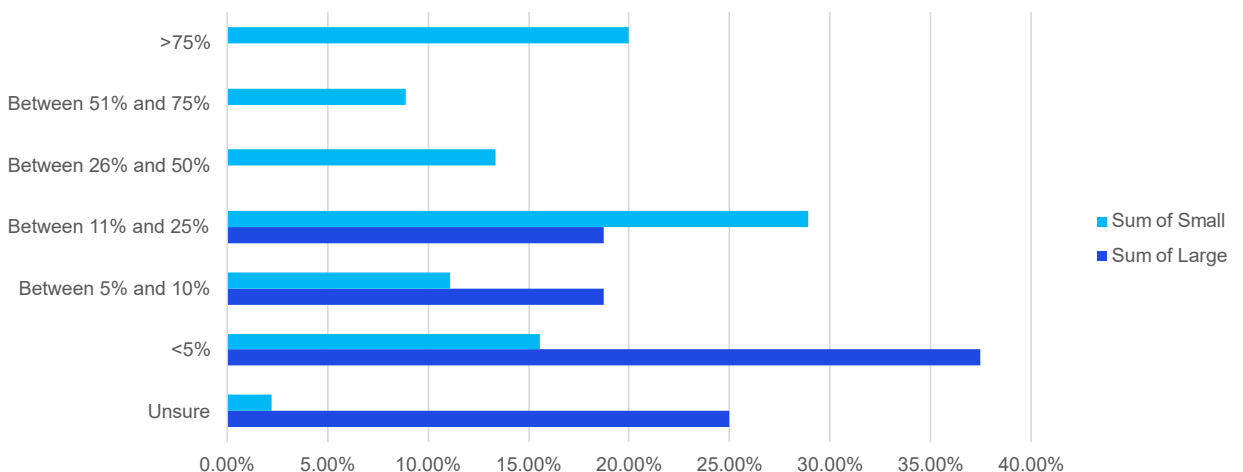
Figure 2.4: Approximately what portion of your workforce in the UK is engaged in R&D activities specific to HealthTech?



Business expenditure on R&D activity

Over a third of surveyed large UK HealthTech businesses allocate less than 5% of their business expenditure to R&D. For SME businesses, the majority of respondents allocate between 11% and 15% of their business expenditure to R&D.

Figure 2.5: Approximately what portion of your business expenditure in the UK is allocated to R&D activity specific to HealthTech?

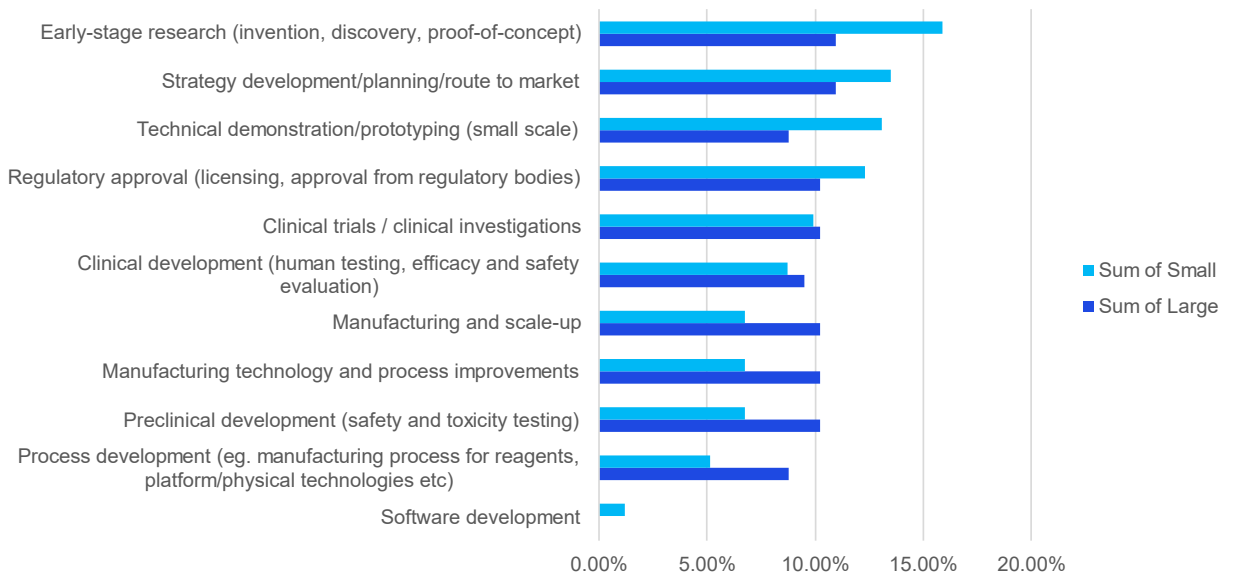


R&D activities performed

The survey data illustrates that UK HealthTech businesses are engaged fairly evenly across R&D activities. SME businesses are slightly more likely to be performing early-stage research, prototyping and strategic development than large businesses. However, manufacturing related activities and process improvement were more likely to be performed by larger businesses. There were few businesses engaged in software development across all respondents.

Software development responses include: development of AI algorithm; and software development in consultation with clinical collaborators.

Figure 2.6: Please indicate the R&D activities that your organisation engages in the UK and overseas specific to HealthTech

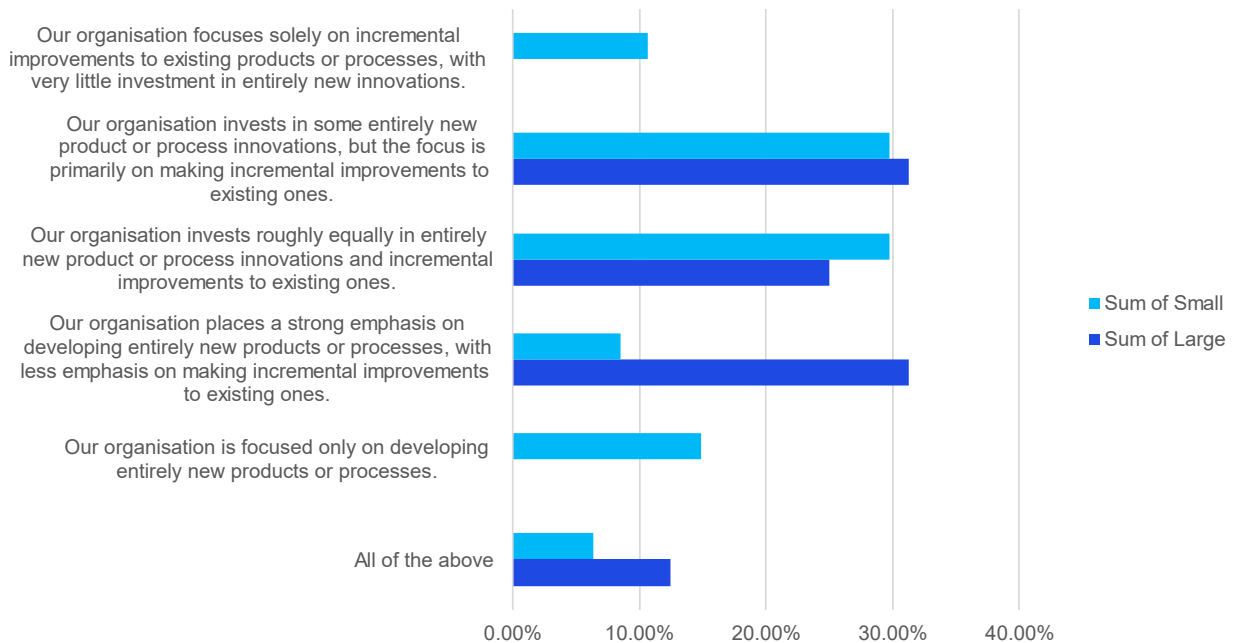


Novelty of R&D outputs sought

UK HealthTech businesses surveyed are concerned primarily with R&D that yields incremental improvements on existing products / services, although large businesses seek to balance this activity with some radical new product development. Interestingly, SME businesses are substantially more likely than their large counterparts to focus exclusively on developing entirely new products and processes.

Some participants explained that their R&D focus has evolved over time. Initially, the focus was on enhancing existing products for quicker market entry. However, the introduction of more stringent regulations like the Medical Device Regulation (“MDR”) prompted a shift in strategy; with organisations emphasising step-change innovations, often collaborating with UK universities and NHS Trusts on these projects

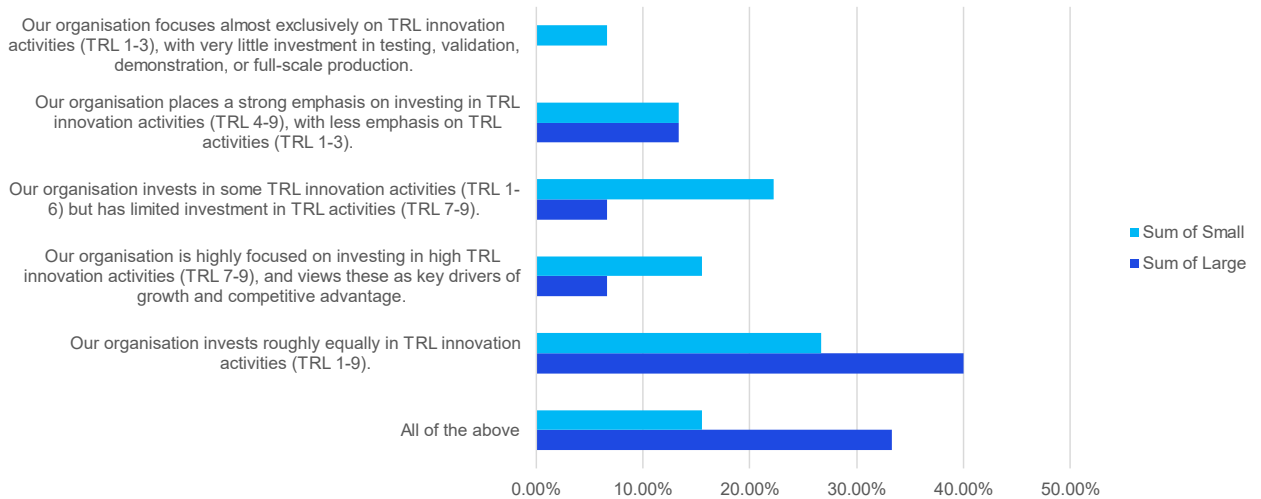
Figure 2.7: Which of the following best describes the focus of your organisation’s R&D activity specific to HealthTech?



R&D focus by Technology Readiness Level

Of those surveyed, Large UK HealthTech businesses are most likely to conduct R&D activity across all TRLs, from ideation and initial research through to commercialisation. SME businesses are substantially less likely to carry out R&D activity across all TRLs, instead more often engaged in TRLs 1-6. This suggests that a fair proportion of SME businesses may have an R&D focus before seeking alternate routes to commercialisation that do not involve in-house manufacturing; e.g. acquisition or technology transfer / licensing.

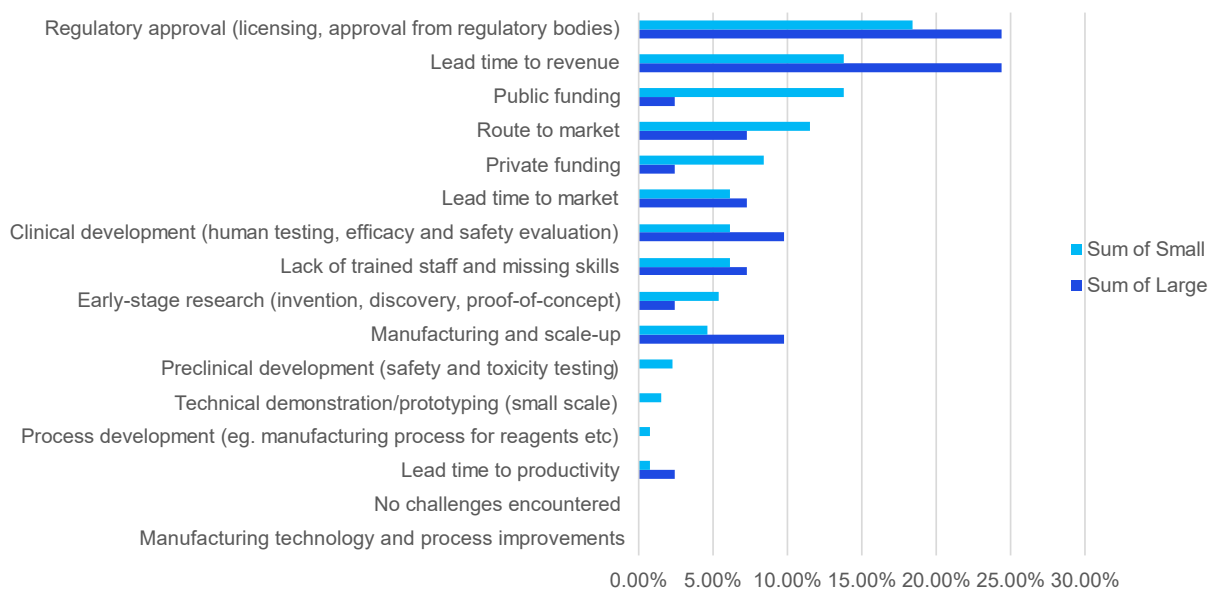
Figure 2.8: Which of the following best describes your organisation’s investment in R&D activities specific to HealthTech across the range of Technology Readiness Levels (TRLs), from basic research and proof of concept (TRL 1-3), to testing and validation (TRL 4-6), to demonstration and full-scale production (TRL 7-9)?



Prominent challenges faced when conducting R&D activity specific to HealthTech

The results of the survey illustrate the challenge posed by the existing regulatory landscape. Both large and SME UK HealthTech businesses cite “Regulatory Approval” as their biggest challenge. This is also a likely contributor to the extended time to revenue issue that surveyed UK HealthTech businesses identify as being a major challenge to their activity. Interestingly, given the importance of public funding to SME businesses, they suggest obtaining grant funding is their second most challenging issue when conducting R&D.

Figure 2.9: What are the top 3 challenges your businesses faces in its R&D activity specific to HealthTech?



Participants elaborated on the challenges:

- The requirement for extensive testing in hospitals and clinical settings can impede the adoption of innovative technologies.
- Significant pressures on NHS partners and restricted access to patient samples for testing, particularly for meeting the minimum requirements for Clinical Trials and Device Applications (“CTDA”), slows clinical development

The shortage of skilled professionals emerges as a prominent challenge:

- Leadership capabilities were deemed lacking in some instances, potentially affecting the commercial success of HealthTech ventures. Some felt that while individuals may possess exceptional technical expertise, there are gaps in their commercial acumen.
- A shortage of skilled professionals in critical areas such as HealthTech software / electronic engineering and regulatory expertise.

Regulatory approval

Respondents in the HealthTech sector consistently highlighted the multifaceted challenges related to regulatory approval, with a common thread being the complexity and evolving nature of medical device regulation in the UK. One major concern centred on extended timelines and increased uncertainty due to the requirement for new clinical data, especially regarding safety and efficacy, unless products are equivalent to pre-existing devices. This ambiguity regarding clinical evidence added notable risk to project timelines and market entry, with one respondent stressing, “business cases for new product development are built on the assumption that launches in Europe (including the UK) will be at a minimum of five years after launch in the US”.

Moreover, the introduction of the MDR was seen as a significant hindrance to bringing innovative products to the EU market. High costs associated with regulatory approval, including compliance with the UKCA mark alongside the CE mark, were emphasised as a drain on resources and funds, posing challenges to development work and creating obstacles for manufacturers.

The need for data to support innovation

Research participants highlighted the critical role of data in supporting innovation within the HealthTech sector. They called for access to a diverse range of data types, including clinical data, prevalence data, and health economics data, in particular, the need for clinical datasets and methodologies for assessing cost-effectiveness. A lack of published data can pose challenges, particularly when sizing the market for specific healthcare products.

A recurring theme was the significance of long-term cost savings and benefits. Participants stressed the importance of having comprehensive data that demonstrates the economic and societal value of healthcare products and services over time. Such data would enable organisations to make compelling cases for investments, even when these investments involve higher initial costs but promise substantial savings in the future.

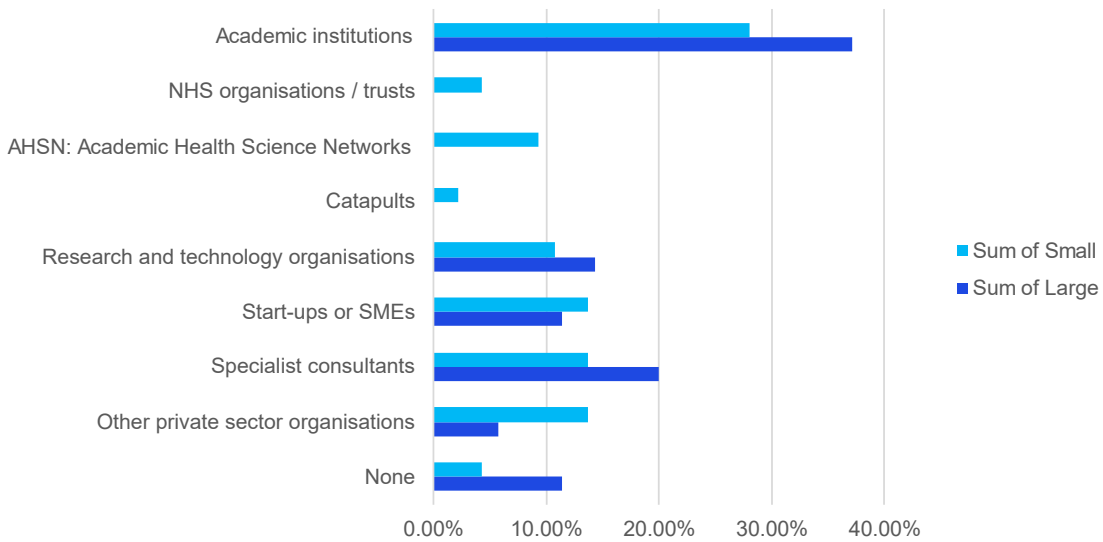
Additionally, respondents pointed out the complexity of attributing the benefits of a product or service within the healthcare value chain to various parts of that chain. Often, downstream benefits are not adequately recognised or attributed to the businesses that provide innovative solutions.

Participants also felt that there is a lack of data regarding skills gaps in relevant healthcare professions, such as occupational therapy. Understanding the demand for specific skills in the healthcare sector could be valuable for addressing workforce shortages.

Collaborative R&D

The most likely collaborative partners for both large and SME respondents are academic institutions. This suggests that many HealthTech businesses originate from University spinouts, and/or that obtaining expert knowledge and access to specialist facilities are critical to HealthTech R&D activity. Academic institutions may also be viewed as a source of innovative new products / services. Collaboration with specialist consultants is also critical to the R&D activity performed by these businesses. Given the challenge posed by achieving regulatory approval, it would be unsurprising to see collaboration between skilled regulatory / compliance consultants and HealthTech businesses. Perhaps surprising is the low-levels of collaboration between UK HealthTech businesses and NHS organisations / trusts. Such collaborations, if effectively fostered, could yield access to important data to inform R&D (indication incidence / demand signals) and validate R&D outputs through patient access or in-clinic testing.

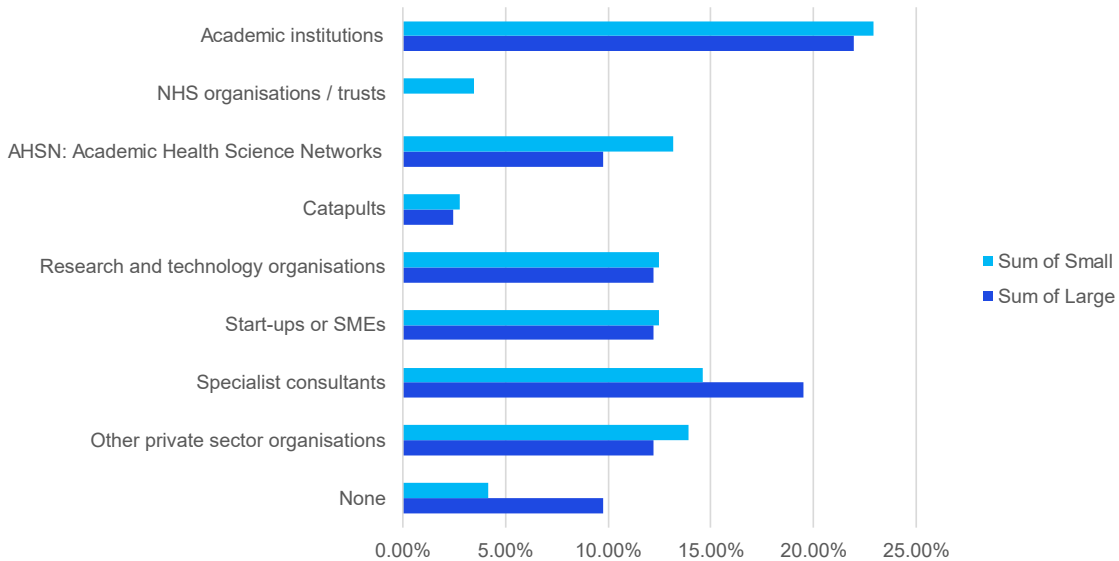
Figure 2.10: Which of the following organisations have you collaborated or partnered with on an R&D project / initiative in the past 2 years specific to HealthTech?



Future collaborative R&D

Partnering with academic institutions and specialist consultants will continue to be a priority for surveyed UK HealthTech businesses, regardless of size. There is also an intention on behalf of large businesses to partner with smaller businesses. This may be a reflection of the R&D intensity of smaller HealthTech businesses and the strategic decision many take to commercialise their R&D outputs via merger / acquisition and/or technology transfer / licensing.

Figure 2.11: Which of the following organisations do you plan on partnering or collaborating with in the next 24 months specific to HealthTech?



'NHS organisations / trusts' include: NHS, NHS trusts, NHS Cancer Alliances, individual NHS clinicians, cancer centres associated with hospitals.

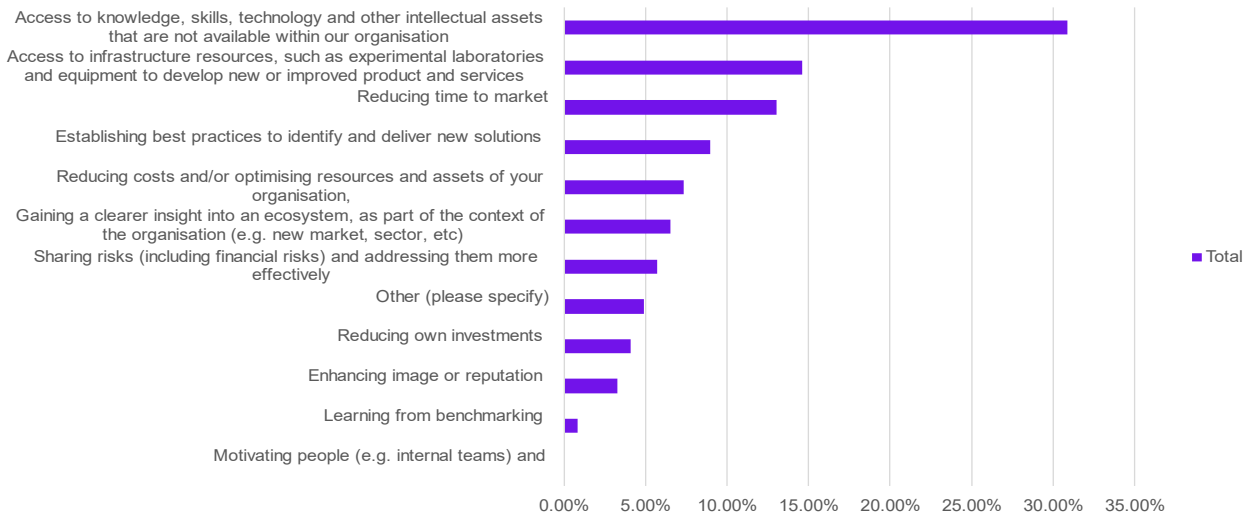
Survey responses reveal a mixed landscape of collaboration and partnership experiences. While some respondents mentioned unsuccessful attempts to partner with AHSNs, others highlighted positive changes in AHSN collaboration approaches. One respondent cited a successful collaboration with AHSNs, emphasising their role as an essential bridge between the NHS, healthcare businesses, and consumers.

However, challenges persist in getting products trialled and adopted within the UK healthcare system, leading to some trials being conducted abroad. These challenges are partly attributed to delays and barriers to adoption in the UK market. Additionally, conducting clinical trials within the NHS was cited as a complex endeavour. Despite these challenges, some respondents commended the NHS's willingness to participate in real-world data collection and testing trials, facilitating product performance evaluation in real healthcare settings.

Desired collaborative R&D outcomes

Collaborative R&D is viewed by both large and SME respondents as a means to increase access to knowledge, skills, technology and intellectual assets not available within their organisation. Accessing infrastructure resources such as laboratories and equipment. This speaks to businesses filling competence and resource gaps in their organisations through collaborative R&D. Interestingly, for SME businesses, collaborative R&D is seen as a method for reducing time to market (potentially by navigating regulatory requirements more efficiently).

Figure 2.12: If you have partnered or collaborated (or plan to in the next 24 months) with one or more external organisation(s), select up to top 3 reasons for doing so

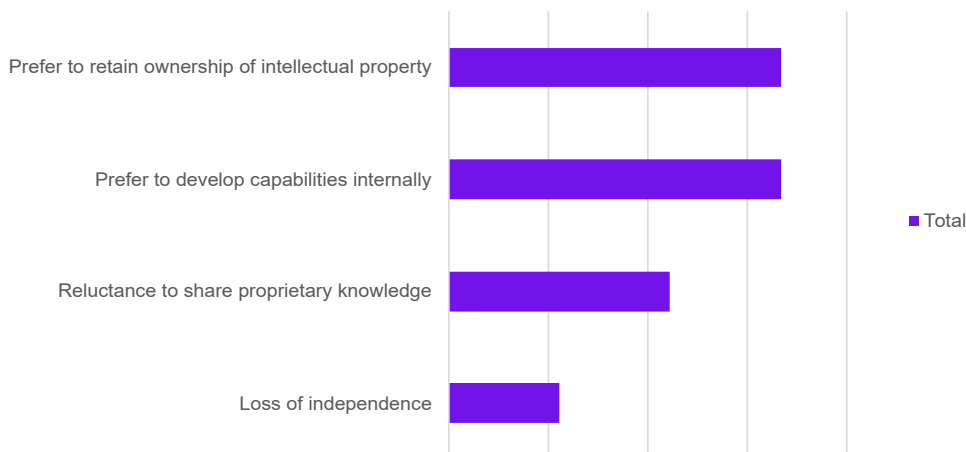


The value of diverse businesses working collaboratively, each contributing their expertise, emerged as a top motivation. Such partnerships foster the development of innovative ideas and solutions. A real-world example provided involved collaboration with American and Canadian businesses to address a specific need for medical-grade polymers in catheter production, reflecting the lack of suitable partners in the UK. Selecting partners strategically was highlighted as essential, particularly considering regulatory and infrastructure readiness.

Justification for non-participation in collaborative R&D

The most common reason for respondents not engaging in collaborative R&D is a preference on behalf of the organisation to retain ownership of intellectual property.

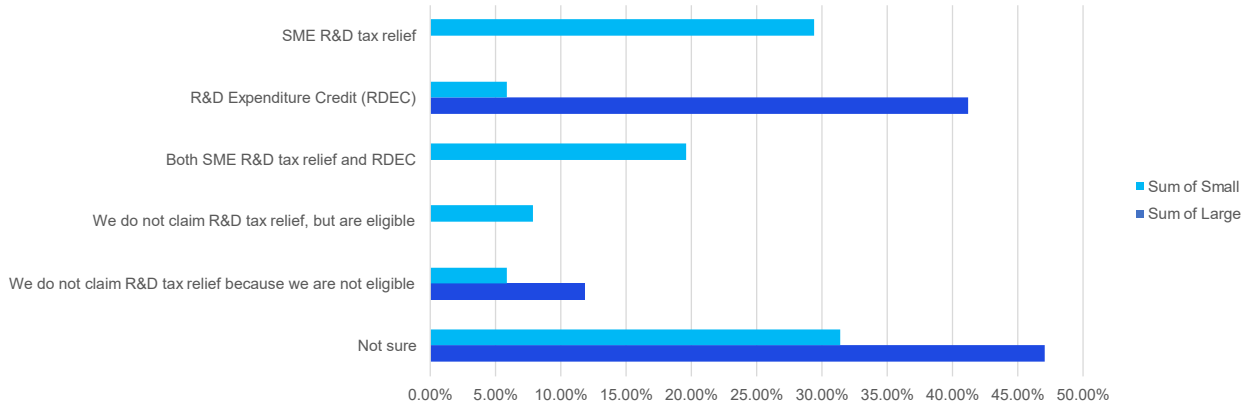
Figure 2.13: If you have not partnered or collaborated (or plan not to in the next 24 months) with any external organisation(s), please explain why?



R&D tax incentives

Of those respondents that have oversight of the tax position of their organisation, approximately 80% claim R&D tax relief (whether the SME R&D regime or R&D Expenditure Credit, or both). 11% do not claim any R&D tax relief because they believe they are not eligible, while 9% respondents who believe they are eligible do not make use of any R&D tax relief.

Figure 2.14: Which R&D tax relief regime does your organisation submit to in the UK?



Respondents expressed concerns about the complexity of the tax credit system, noting that many SME businesses engage advisors to support with applications for tax incentives. However, this approach can be costly if not managed carefully. Furthermore, they expressed frustration over the reduction in R&D tax credit rates for SMEs.

Manufacturing

HealthTech manufacturing in the UK

The UK hosts a relatively modest population of HealthTech manufacturers, encompassing approximately 3,000 specialized entities engaged in orthopaedic, imaging, diagnostics, and cardiovascular device manufacturing. Notably, 31% of these enterprises are located within the Golden Triangle.

Figure 3.1: Numbers of HealthTech manufacturers in 2020

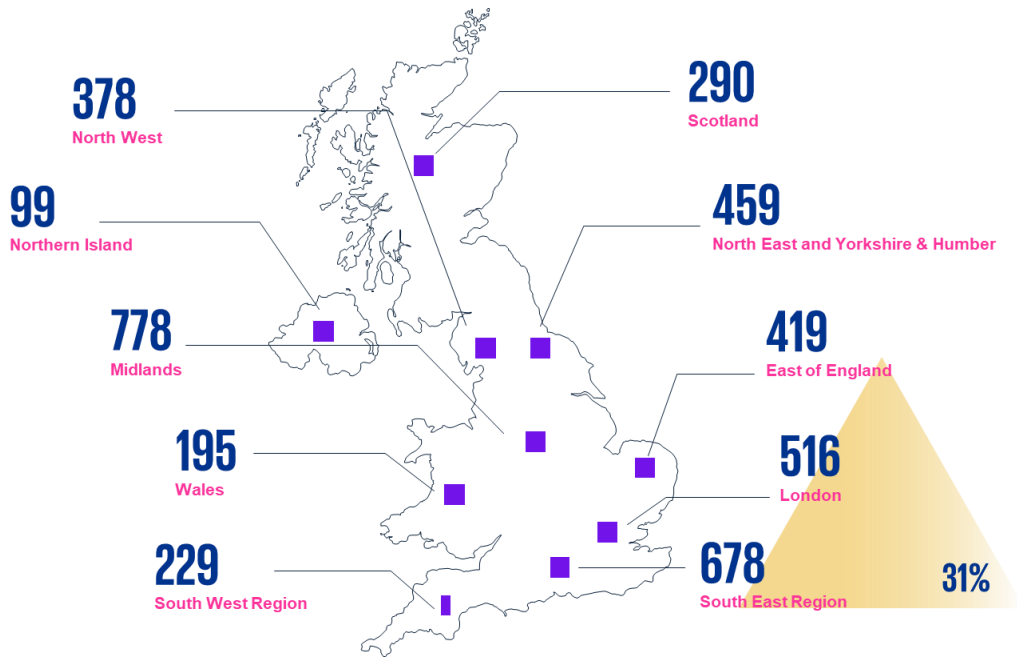
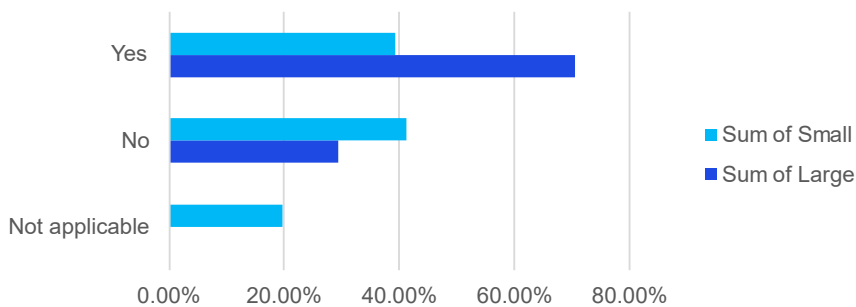


Figure 3.2: Does your organisation carry out manufacturing activity in the UK specific to HealthTech?

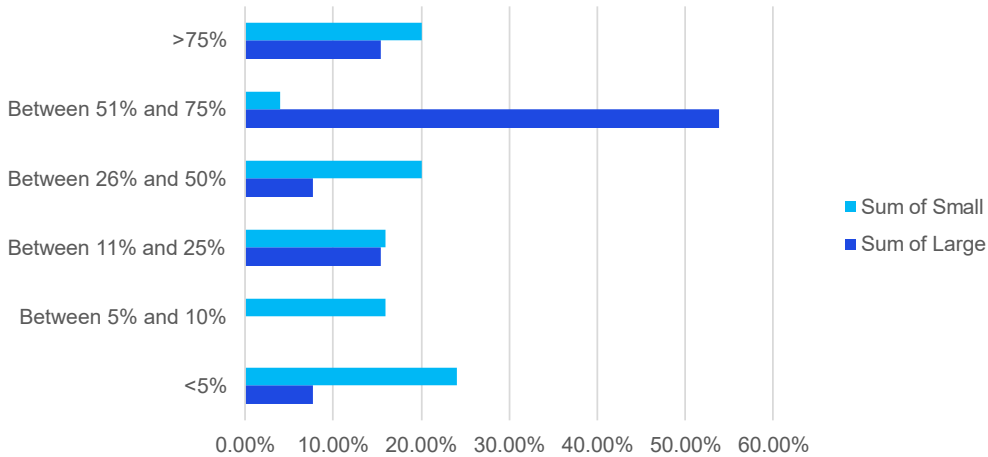


Within the survey data, large businesses are substantially more likely to manufacture in the UK than SME businesses. Almost three-quarters of large business respondents have some manufacturing activity for HealthTech products within the UK.

Manufacturing workforce

For large UK HealthTech businesses surveyed the proportion of employees engaged in manufacturing activity is substantially higher than their SME counterparts. In excess of 50% of the workforce in over half of surveyed large businesses are engaged in manufacturing activity.

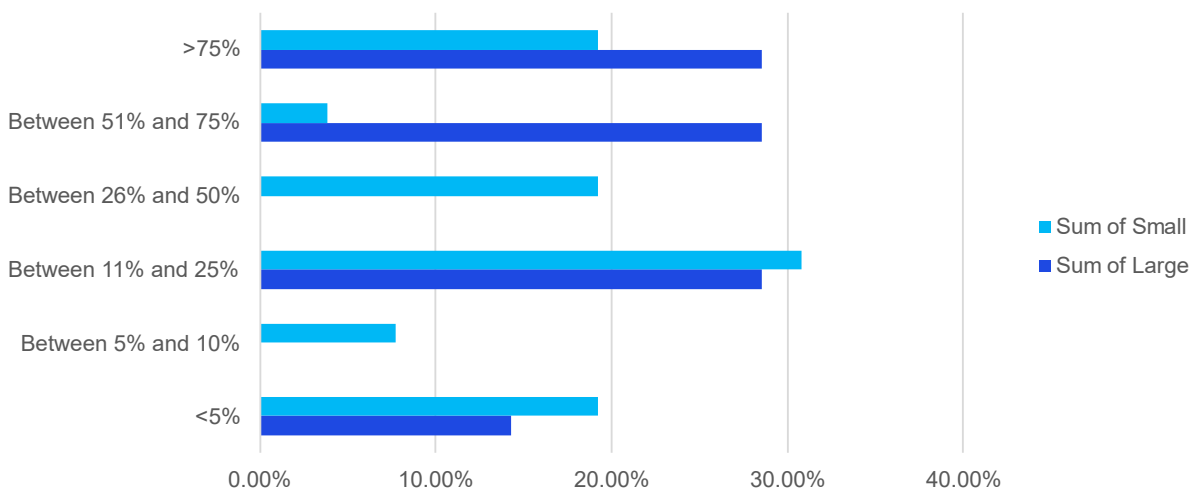
Figure 3.3: Approximately what portion of your UK-based workforce is engaged in manufacturing activity in the UK specific to HealthTech?



Business expenditure on manufacturing

For those respondents that provided a numerical response, SME businesses typically spent between 11% and 25% of their UK-based operational expenditure on HealthTech manufacturing. Large businesses were more likely to spend a greater proportion of their UK business expenditure on manufacturing (between 51% and 75%).

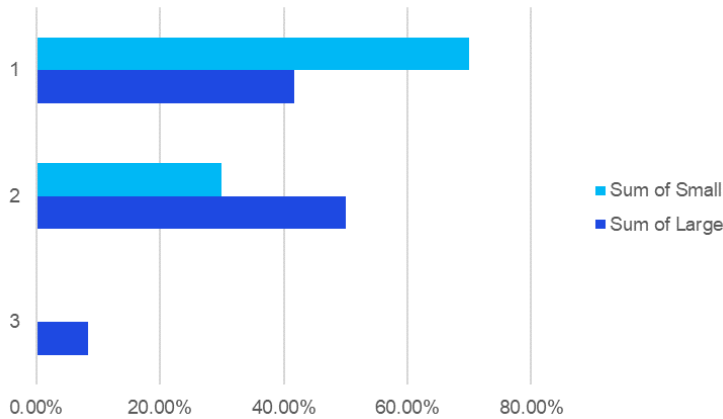
Figure 3.4: Approximately what portion of your UK-based business expenditure is on manufacturing activity in the UK specific to HealthTech?



Scale of HealthTech manufacturing

UK HealthTech manufacturing occurs most commonly within businesses registered in the South of England, with the South-East home to the most businesses operating manufacturing facilities. Of those surveyed businesses that have UK manufacturing capability large businesses are most likely to have 2 manufacturing sites, while the majority of SME businesses operate a single UK manufacturing facility.

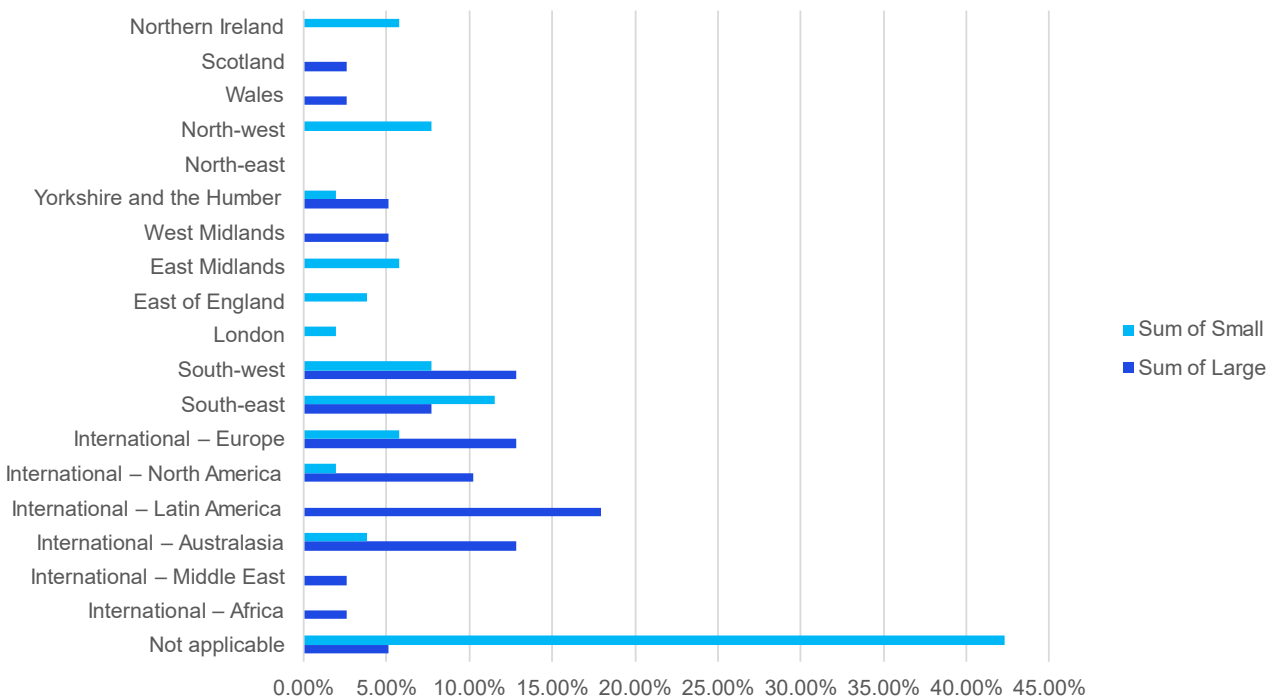
Figure 3.5: How many manufacturing sites that produce HealthTech products does your organisation currently have in the UK?



UK and international manufacturing locations

It is perhaps logical that large business respondents are more likely to locate their manufacturing activity in international territories than SME businesses. Latin America is the most common location for manufacturing of HealthTech products for those surveyed. For SME businesses surveyed, the South of England, in particular the South-East, is the most frequent region in which to base manufacturing. It is important to note that London was not a location popular with regard to locating manufacturing facilities despite the prevalence of London registered HealthTech businesses. 18% of businesses had manufacturing activity inside the Golden Triangle.

Figure 3.6: Where is your organisation’s manufacturing activity located specific to HealthTech?

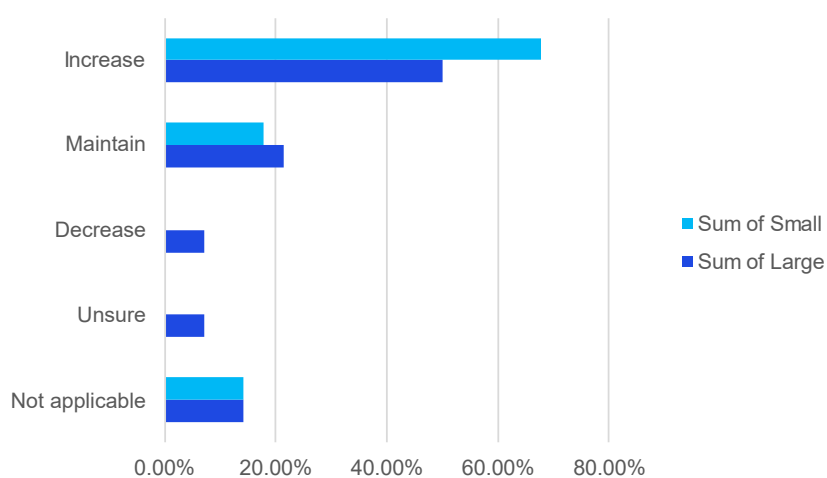


Respondents' perspectives on the location of manufacturing activities reflect the interplay of various factors. Cost considerations emerged as a dominant driver, with some participants opting for overseas manufacturing in response to competitive pressures from global giants. Historically, Eastern Europe has been favoured for its lower labour costs, partially due to EU funding support. Labour cost competitiveness in the UK is raised as a challenge, coupled with a lack of NHS-driven incentives to promote local manufacturing, and a shortage of skilled workers. Conversely, some respondents emphasised that value and manufacturing excellence, rather than cost alone, guide their investment decisions, highlighting the importance of quality, efficiency, and productivity in shaping manufacturing locations, therefore supporting UK-based manufacturing operations.

Future manufacturing activity

Survey data shows a positive position regarding UK based manufacturing over the next 5-years. Half of surveyed large businesses are seeking to increase their manufacturing activity in the UK, while two-thirds of SME businesses plan to increase their UK manufacturing activity for HealthTech products.

Figure 3.7: Do you plan to maintain, increase, or decrease the level of UK-based manufacturing activity in the next 5 years specific to HealthTech?



Intentions to increase UK-based manufacturing activity were typically driven by factors such as market expansion, growth in demand for products, and increased investment and development. One respondent highlighted the business's accelerated growth phase, saying, "the company is now entering a phase of accelerated growth with the awarding of a number of large contracts in our favour. We would hope to expand manufacturing activity by around 50% per annum over the next 5 years". Another respondent mentioned plans to scale up manufacturing to support expansion in both the United States and larger UK contracts, stating, "we are planning to scale up our manufacturing over the next 5 years to service the expansion in the states and other much larger UK contracts too". Additionally, some respondents noted the availability of additional capacity at their UK site(s), which was in demand due to disruptions in global supply chains.

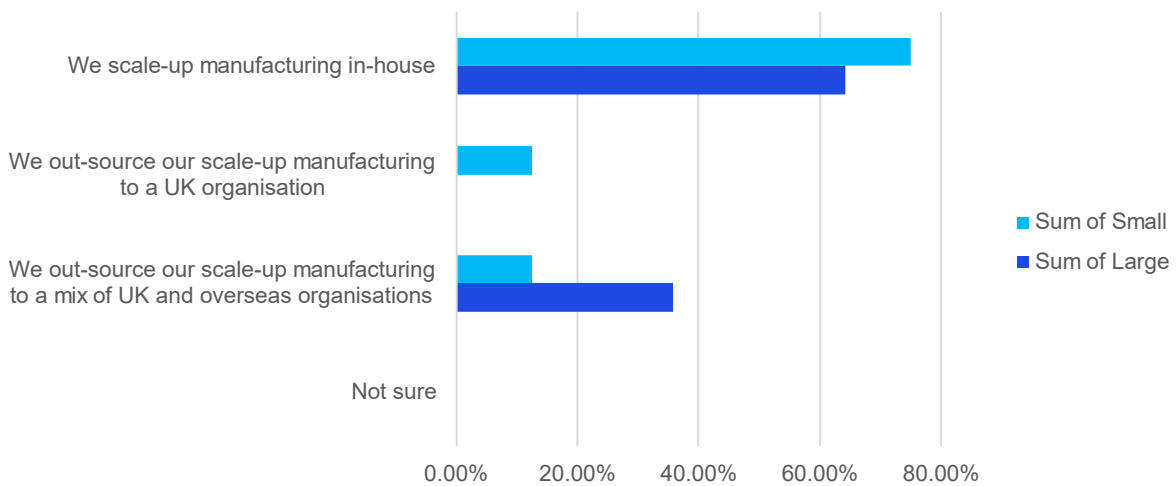
Rationale for N/A responses included that manufacturing operations were not located in the UK at all. Others cited factors such as the high cost of manufacturing in the UK, as one respondent explained, "it is preferred to seek alternatives based on favourable tax regimes, availability of skilled engineering workforce and abundance and availability of materials".

Approach to manufacturing scale-up

When increasing manufacturing capacity from pilot scale operation to full production, UK HealthTech businesses, regardless of size, most commonly seek to scale-up their in-house capability. While large business respondents are substantially more likely to utilise contract manufacturers in the UK and overseas, the most common method of scaling-up manufacturing is to utilise / build in-house capacity. This approach was common across both SME and large UK HealthTech businesses surveyed.

Figure 3.8: How does your organisation scale-up* its manufacturing activity?

*Scale-up in this context is taking a manufacturing process from pilot scale to a scale at which it is commercially feasible



Respondents highlighted that their UK-based manufacturing sites play a vital role in the scaling-up process, contributing to product development and innovation. While some organisations may not have a dedicated R&D function in the UK, they leverage their UK manufacturing facilities for line testing and product testing. This approach allows them to continually evolve core products that have been on the market for many years. These UK plants serve as crucial hubs where commercial feasibility is achieved through ongoing refinements and enhancements to existing product lines.

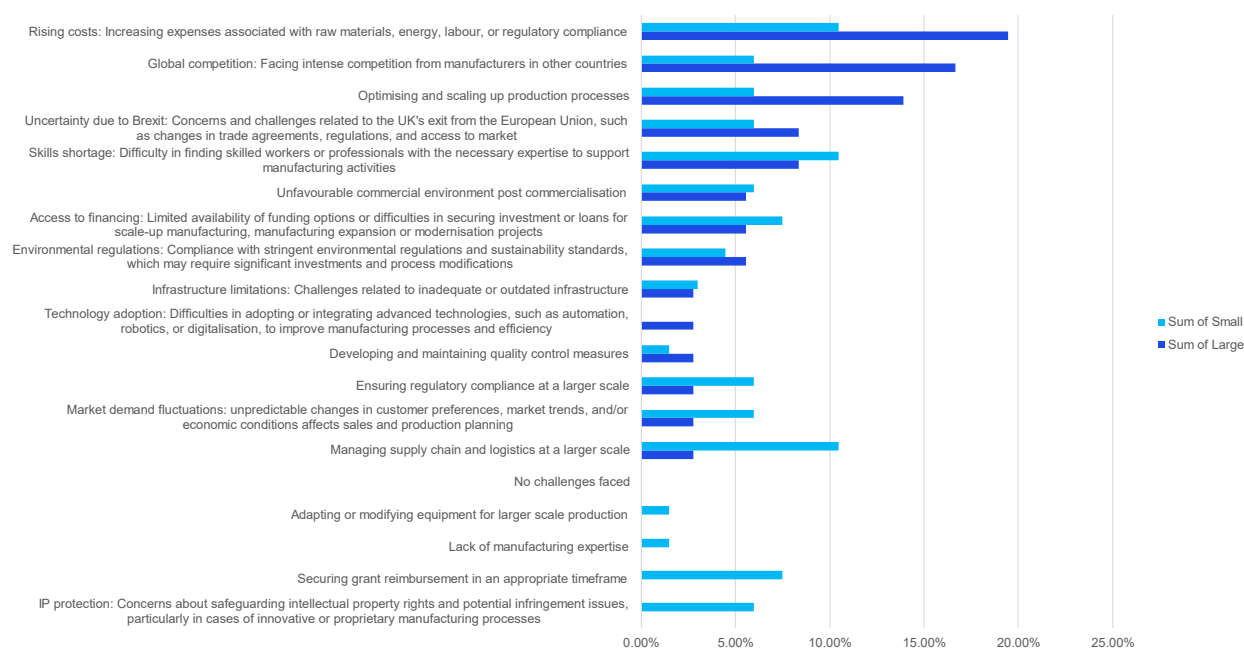
Challenges faced by HealthTech manufacturers

Rising costs associated with price increases in raw materials, energy, labour, and regulatory compliance is the most substantial challenge for both large and SME respondents that are looking to scale up from R&D to production manufacturing. These cost pressures impact the overall economics of production and can affect pricing and profitability.

For large UK HealthTech businesses pressure from global competition and optimising the processes connected with scale-up are other noted challenges. Unique product requirements may necessitate bespoke equipment and validation, resulting in extended lead times and complexity. As one respondent stated, “Manufacturing scale-up is a challenge due to unique products requiring bespoke equipment to manufacture - lead time on equipment and validation time can be up to 2 years”.

For SME businesses surveyed, skills shortages and managing the supply chain at higher production rates are key issues to be overcome.

Figure 3.9: For those that manufacture, what are the top 3 challenges your business faces when scaling up from R&D to production manufacturing specific to HealthTech?



Respondents highlighted the intricate nature of regulatory requirements as a major challenge. Navigating the regulatory landscape, including conformity assessments and compliance with quality standards, can be time-consuming and resource-intensive. Achieving harmonisation within the HealthTech sector and conformity to evolving standards were recurrent themes; consistency in definitions and requirements across different regions could streamline product development and market access.

Complex supply chains also emerged as a significant challenge which can lead to inefficiencies and disruptions. Respondents noted that navigating new trade routes and customs requirements post-Brexit added another layer of complexity to the supply chain. The need to address export barriers and navigate the evolving trade landscape posed considerable challenges.

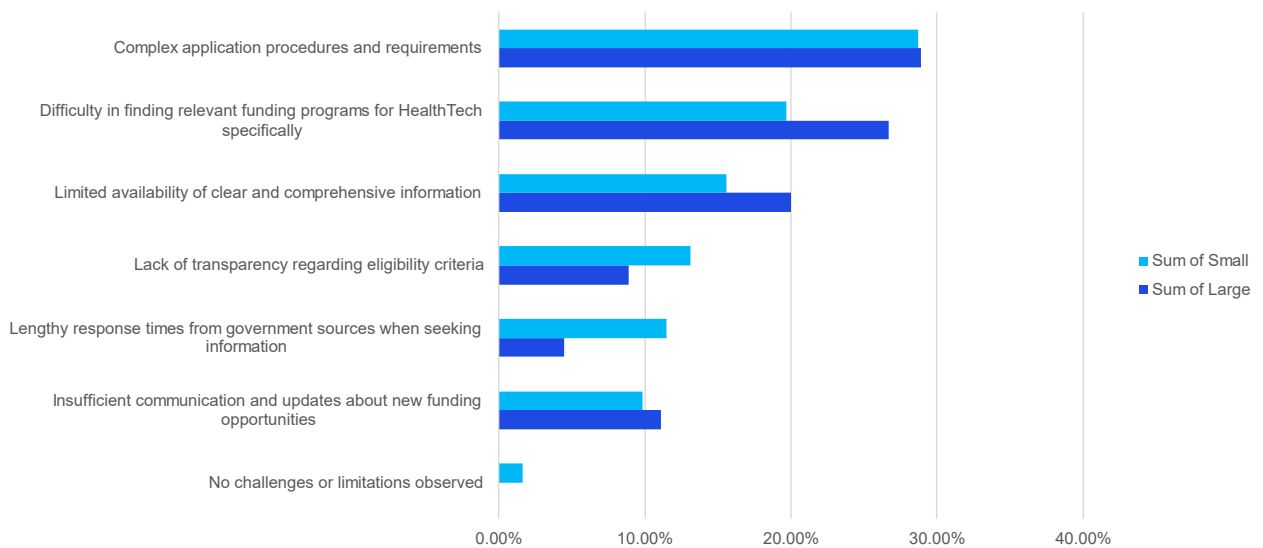
SMEs, which are often more vulnerable due to limited resources, faced specific challenges related to supply chain shocks, pricing fluctuations, and procurement hurdles. Balancing cost-effectiveness with sustainability demands also proved challenging, particularly when dealing with procurement practices that may prioritise cost savings over other factors.

Funding

Accessing public funding

The main challenges faced by respondents seeking to access public funding programmes are the complexity of applications, difficulty in identifying HealthTech specific funding programmes, and the limited availability of clear and comprehensive information to support funding applications. The size of the HealthTech business had little bearing on the proportion of businesses stating these challenges were important.

Figure 4.1: How would you rate the ease of accessing information about government funding programs for your industry?



The survey responses reflect a range of sentiments and experiences regarding the intricacies of application processes and requirements in the HealthTech sector. As one respondent noted, “generally there is an assumption about the solution sought, rather than looking for left-field thinking”, suggesting a need for more open-mindedness and flexibility in the application process. Others mentioned that while the effort required is substantial, it is not excessive. Public funding is criticised for being insufficient, complex to acquire, unpredictable in availability and too focused on early-stage research, with one respondent stating that there is “no easy access to funding opportunities and application processes are complex” and another criticising “focus for investment is often on high tech innovation - it needs to be broader and consider the HealthTech in a wider context”.

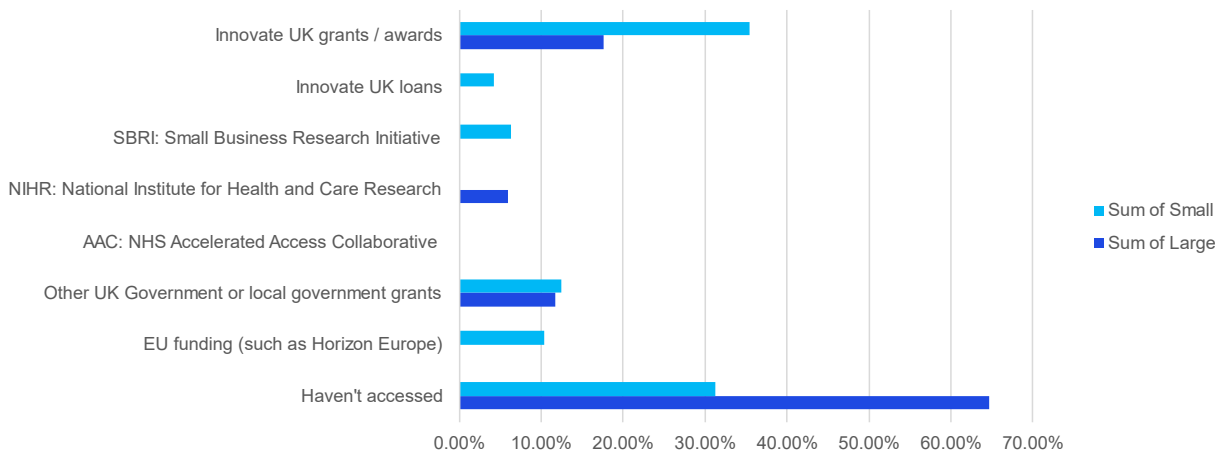
Additionally, there was recognition of improvements, with one respondent stating, “very complex navigation of what is available but vastly improved”. However, a common theme emerged regarding the misalignment between the academic timelines of funding agencies and the real-time demands of businesses. There are place-based considerations too, with respondents feeling that core funding from UK agencies posing a particular challenge for Northern Ireland-based entities.

Respondents highlighted the “convoluted and time-consuming” nature of the existing funding landscape, with selection criteria often falling short of reflecting market realities. A consistent sentiment was that funding is perceived as opaque and challenging to access, underlining the pressing need for greater transparency and accessibility in the funding ecosystem.

Funding sources accessed

Within the UK HealthTech sector we can see that the majority of large firm respondents have not accessed public funding support for R&D / Manufacturing in the last 2-years. This may be because large businesses have the resources to self-fund R&D / Manufacturing activity or seek such funding from non-public sources. It is also plausible that large businesses have not identified suitable sources of public funding for such activity, or the eligibility conditions for such funding programmes limit large business engagement.

Figure 4.2: Which types of government funding has your UK organisation accessed in the past 24 months, specifically related to R&D and/or manufacturing within HealthTech?

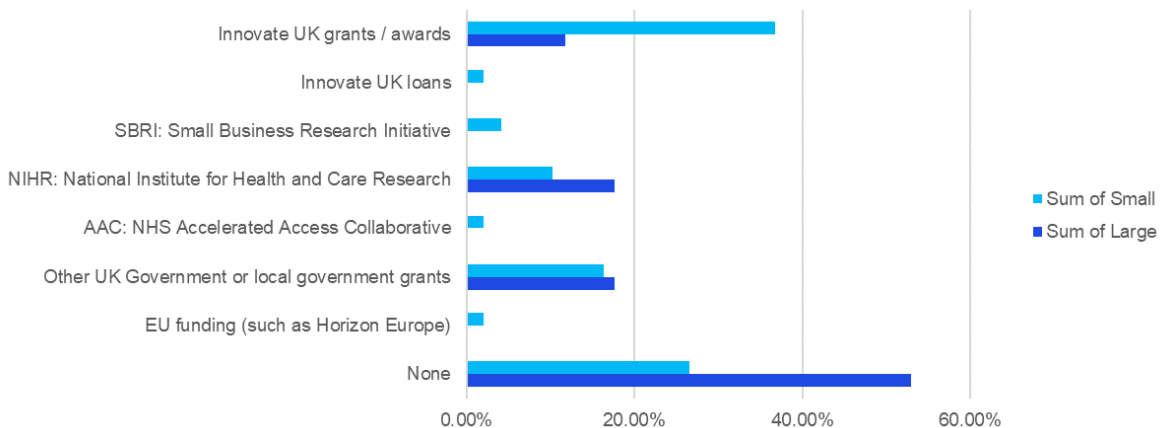


Other UK or local government grants include: R&D tax credits, Belfast City deal (G11 grant), Invest Northern Ireland R&D funding, and DIT export grants.

When consideration is given to future plans to secure public funding in support of R&D / Manufacturing activity (Figure 4.3), then we see that over half of large businesses surveyed do not have any plans to apply for such funding. This is compared to just a quarter of SME businesses. This is perhaps an indication of the importance public funding plays in supporting R&D / Manufacturing capability within SME businesses that understandably have fewer organisational resources to draw upon.

While some respondents indicated 'None', it's important to note that this category includes individuals who may consider applying for grants in the future, contingent upon factors such as timing, value, location, and specific project requirements. "The UK is competing for funding on the global stage and must therefore ensure it remains an attractive proposition for investors".

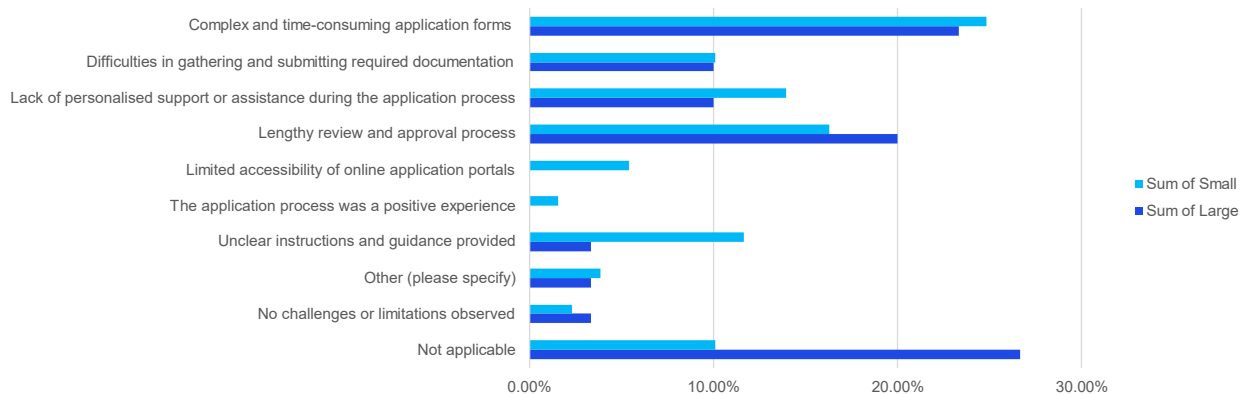
Figure 4.3: Which types of government funding does your UK organisation plan on applying to in the next 24 months (specifically related to R&D and/or manufacturing within HealthTech)?



Challenges of applying for public funding

Of those HealthTech businesses that have applied for public funding, the most substantial challenge was the complexity of the application forms and the associated time commitment required to complete the submission. The time it takes for funders to review applications and provide approval was also seen as problematic given the need to move through R&D in a planned timeframe. This challenge may be particularly problematic for businesses that require short-term access to funding to meet a time-sensitive R&D / Manufacturing challenge.

Figure 4.4: If you have applied for government grants, have you encountered any of the following challenges during the application process?

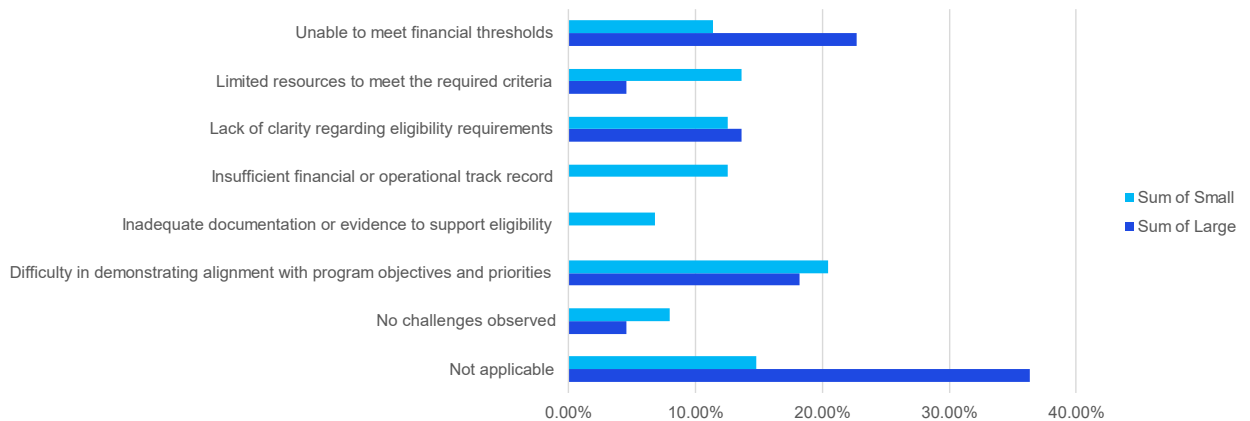


Survey responses from participants reveal challenges faced by SME businesses in securing funding for their development initiatives: “we are small and are focused on product development. Our time spent submitting grants and seeking funding detracts from development”. This sentiment is echoed by another participant who noted that existing funding mechanisms are often ill-suited for early-stage businesses due to the lengthy and resource-intensive application processes, stating, “they are not set up for early-stage businesses as plans change in the length of time from generating an application to receiving funds; the amount was too large to apply for and complex”. Participants also highlighted the need for more flexible and accessible funding options, emphasising the importance of year-round application opportunities and less resource-intensive grant structures.

The survey findings emphasise the critical need for tailored funding solutions that align with the realities and constraints faced by HealthTech innovators, ensuring that valuable development time is maximised and not impeded by funding application processes.

For large businesses that have sought public funding for R&D / manufacturing activity, there is an issue around meeting financial thresholds (see Figure 4.5). It seems likely that the revenue generated by these organisations precludes them from some forms of funding; making applications unviable. For HealthTech businesses of all sizes there is a challenge in demonstrating alignment between the business requirements and the scope of the funding programme. This suggests that specific HealthTech funding programmes are required to support the R&D and manufacturing needs of the sector.

Figure 4.5: Have you encountered any of the following challenges in meeting the eligibility criteria for public funding programmes in your industry?



A recurring concern emerges regarding the expertise of grant assessors, with one respondent expressing their viewpoint on a “lack of relevant commercial experience amongst grant assessors”.

Furthermore, there is a perception among some that the funding process may lean towards academics, as one respondent points out that “reviewers are often the same people as the businesses that offer bid writing services,” suggesting potential bias towards academic projects.

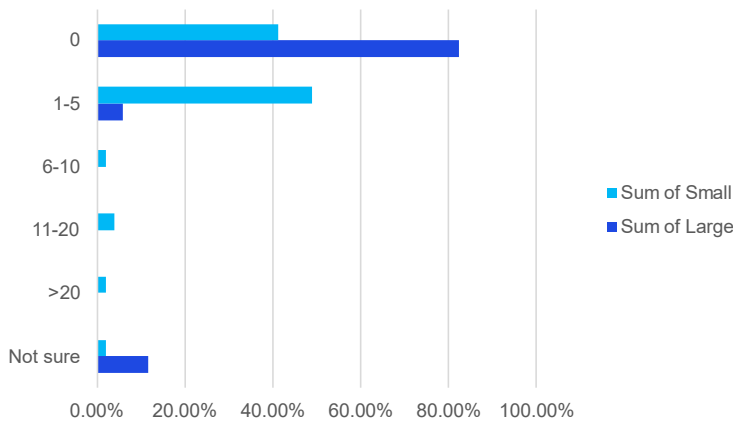
The issue of restrictive fund usage also surfaces, with the viewpoint that “while funding exists, restrictions on how it can be used can be problematic”. These respondents also highlight the need for funding calls to align better with a business’s stage of development and advocate for greater flexibility in fund usage, allowing innovators to adapt to project-specific needs.

Additionally, there is a call for governments to consider supporting businesses within the £5m-£100m revenue range in critical sectors to scale and grow, rather than solely focusing on larger corporations or blue-sky projects.

Grant funding for R&D

Over three-quarters of large HealthTech business surveyed have not submitted an R&D grant application in the last 2-years, while approximately half of SME businesses have made between 1 and 5 applications for grant support relating to their R&D activity. This reinforces the importance of public funding in supporting R&D activity conducted by SME businesses.

Figure 4.6: How many UK-based R&D grant applications has your organisation submitted in the past 24 months specific to HealthTech?



Several reasons and insights emerged from respondents. Concerns were voiced regarding the exclusion of clinical studies from funding opportunities, with one respondent citing that “clinical studies are typically excluded from funding”. Moreover, respondents highlighted limitations in grant usage, particularly regarding clinical studies, as certain grants only cover equipment or supplies, overlooking personnel and data analysis costs. Some expressed the belief that criteria for advancing trials are overly stringent, applying pharmaceutical industry standards to other areas of HealthTech.

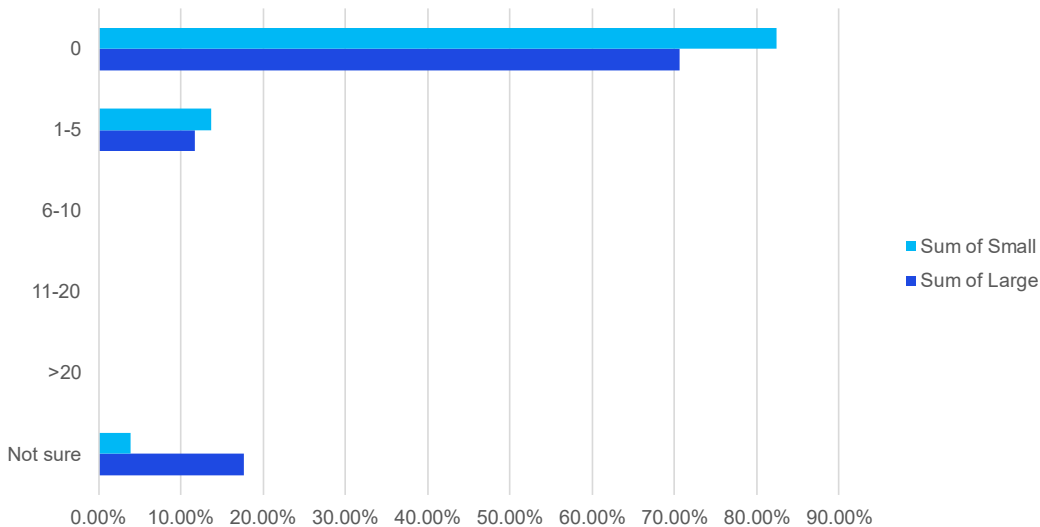
Respondents cited delays caused by the time-consuming processes of applying for grants and obtaining ethics approvals in the UK were a significant factor in their decision to focus on European markets instead of conducting clinical R&D activities in the UK.

Interestingly, there was some conflict in respondents’ perspectives, with one expressing scepticism towards the UK’s support for blue-sky research funding, while another perceived a focus on blue-sky projects and high-tech products rather than core healthcare essentials in the current grant landscape.

Grant funding for manufacturing / production

The results indicate that respondents have generally not applied for grants to support manufacturing / production in the UK. There is very little variation in propensity to apply for grants of this nature relative to business size. The data suggests that R&D grant support (Figure 4.6) is more widely accessed by HealthTech businesses than manufacturing grant support. This may be an indication as to the availability of grant support for this activity, or a reflection of the difficulty in translating R&D activity into manufacturing output within the UK.

Figure 4.7: How many UK-based manufacturing / production grant applications have been submitted in the past 24 months specific to HealthTech?



UK Research and Innovation offers HealthTech related funding through Innovate UK, and the Engineering and Physical Sciences Research Council (“EPSRC”) amongst others. As of 17 March 2023, the EPSRC has disbursed 281 distinct grants related to HealthTech since its inception, with a total grant value of £266.3 million. Only 9 grants (totaling £0.7m or 0.26% by value) have been awarded in the ‘manufacturing technology’ theme.

There is a perception by participants that government intervention tends to focus on funding R&D rather than facilitating the transition to manufacturing, hampering the growth of the sector. Respondents also expressed concern about other countries outpacing the UK in manufacturing investments and job creation.

There is a call for a more balanced approach to government support, with one respondent suggesting that middle-level projects in the range of £1-10 million require increased support, particularly through dedicated manufacturing investment funds.

“Currently, we fund our R&D costs via cashflow and the use of R&D tax credits. Moving forward, we will need to invest in substantially larger sums in regulatory and manufacturing set-up with suitable accommodation to match. Receiving funding assistance in the short-term would reduce the cash-flow pressure the business faces and funding would assist in planning for manufacturing set-up.”

Private funding

The private sector funding and investment landscape for HealthTech in the UK, as viewed through the perspectives of survey respondents, presents a complex picture. One recurring concern is the trend of smaller HealthTech businesses being acquired by larger corporations, as one participant expressed, “SMEs end up selling out to large businesses - removes competition, removes innovation, future ideas taken away”. This phenomenon, while providing exit strategies for SMEs, erodes competition and stifles innovation within the sector.

Another notable observation pertained to the limited private market interest in funding R&D activities in the HealthTech sector in the UK. Respondents noted that the absence of guaranteed reimbursement (through commercial success) for products, even if they prove safe, effective, and cost-effective, acts as a deterrent to private investment. Additionally, the challenges of navigating investment rounds, especially in the current global financial environment, were highlighted, as one respondent mentioned, “We are currently in an investment round, and this is being protracted as a result of the current global financial environment”.

A report by Beauhurst found that between 2014 and 2019, the investment in MedTech and HealthTech increased by £477m. However, since the onset of the pandemic, investment in MedTech and HealthTech has increased by 96% from 2020 to 2022. Despite this, the availability of private funds in the UK was perceived as limited, with one respondent stating, “We’ve been running for 12 years and have not taken seed or series A funding as there are few private funds for MedTech in the UK”.

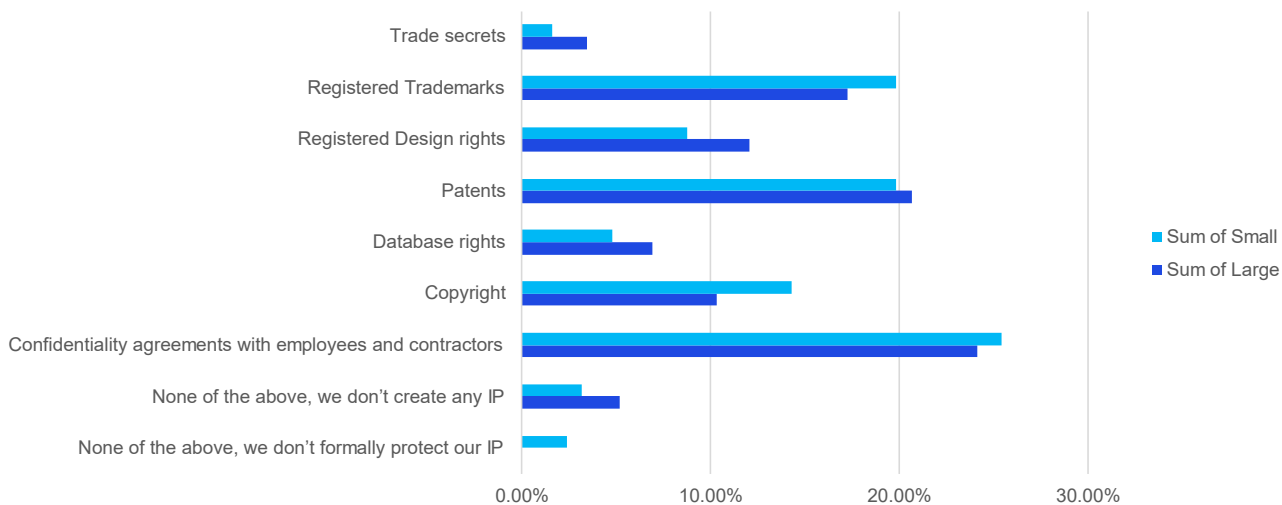
Respondent sentiments echoed the findings of Lord Harrington’s Review of Foreign Direct Investment that the UK needs to do more in an increasingly competitive environment for investment. They stressed the importance of maintaining a favourable tax, legal, and regulatory environment to retain the UK’s status as a hub for investment in HealthTech.

Protecting and commercialising IP

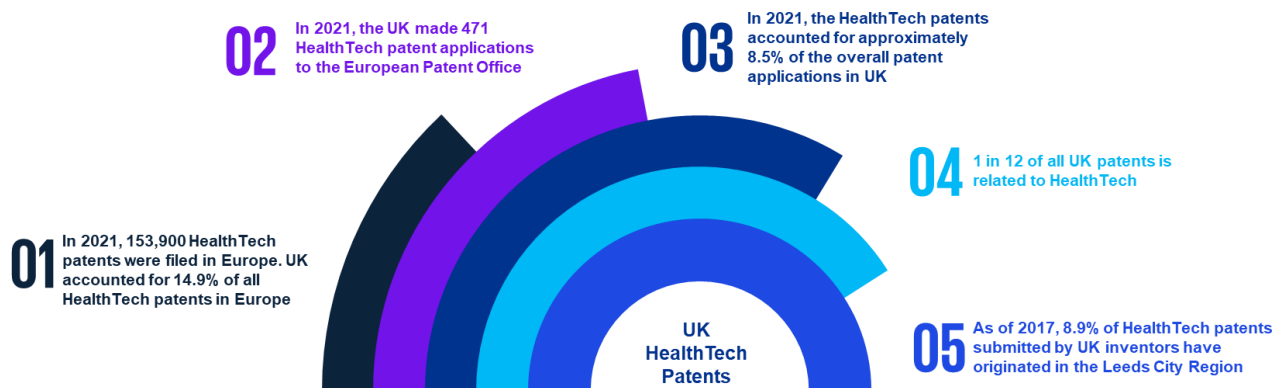
Methods deployed to protect Intellectual Property

The use of Confidentiality Agreements to maintain control of intellectual property generated by respondents is the most utilised form of intellectual property rights protection for UK HealthTech businesses. In terms of registered rights, patents and registered trademarks are used by approximately one-fifth of businesses. Encouragingly, awareness of IP protection issues appears wide-spread in the UK HealthTech sector given the low proportion of businesses that do not formally protect their intellectual property.

Figure 5.1: How do you currently protect IP generated in your UK-based organisation?



The UK is considered one of the popular regions for filing HealthTech patents. In 2021, the UK accounted for 14.9% of all European HealthTech patent applications. Whilst the UK has seen a declining trend in the number of life sciences patents filed per 1,000 population between 2016 and 2020, the UK has risen to fourth up from sixth compared to other comparators due to a similar declining trend seen in other similar countries.



Innovation reliefs and incentives

The Patent Box scheme allows profits attributable to patents held by a company to be taxed at 10% rather than the main rate of corporation tax. The scheme therefore provides an incentive to engage in R&D activity. Interestingly, a substantial proportion of large and SME businesses surveyed do not claim Patent Box tax relief. Of those businesses that do make a claim the majority are large businesses, with large businesses being 3-times more likely than SME businesses to be claiming.

Figure 5.2: Do you currently claim UK Patent Box tax relief?

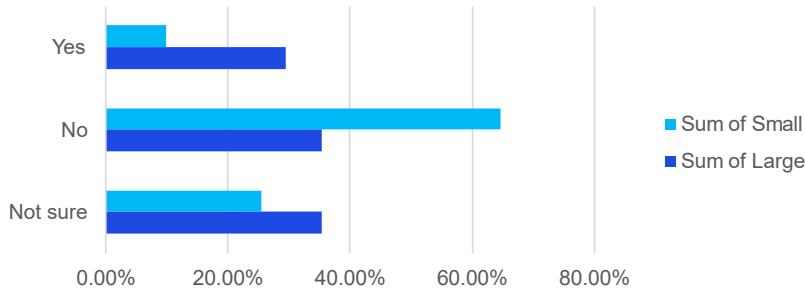
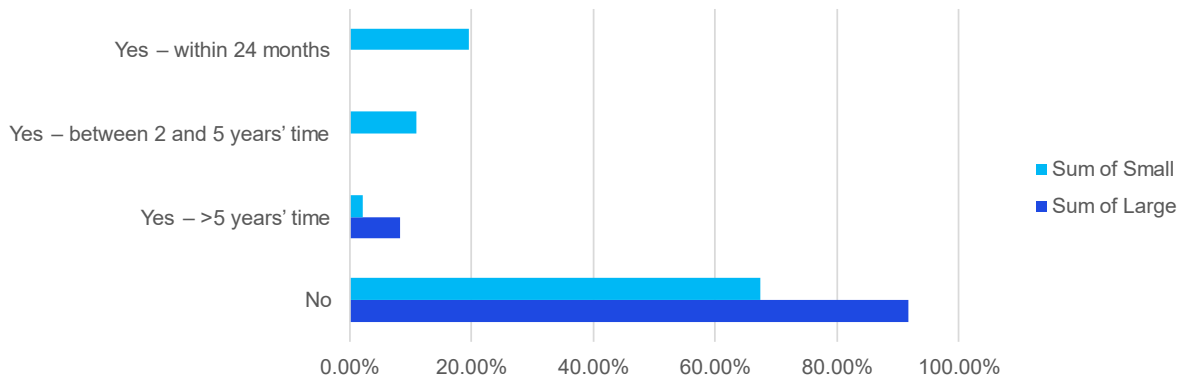
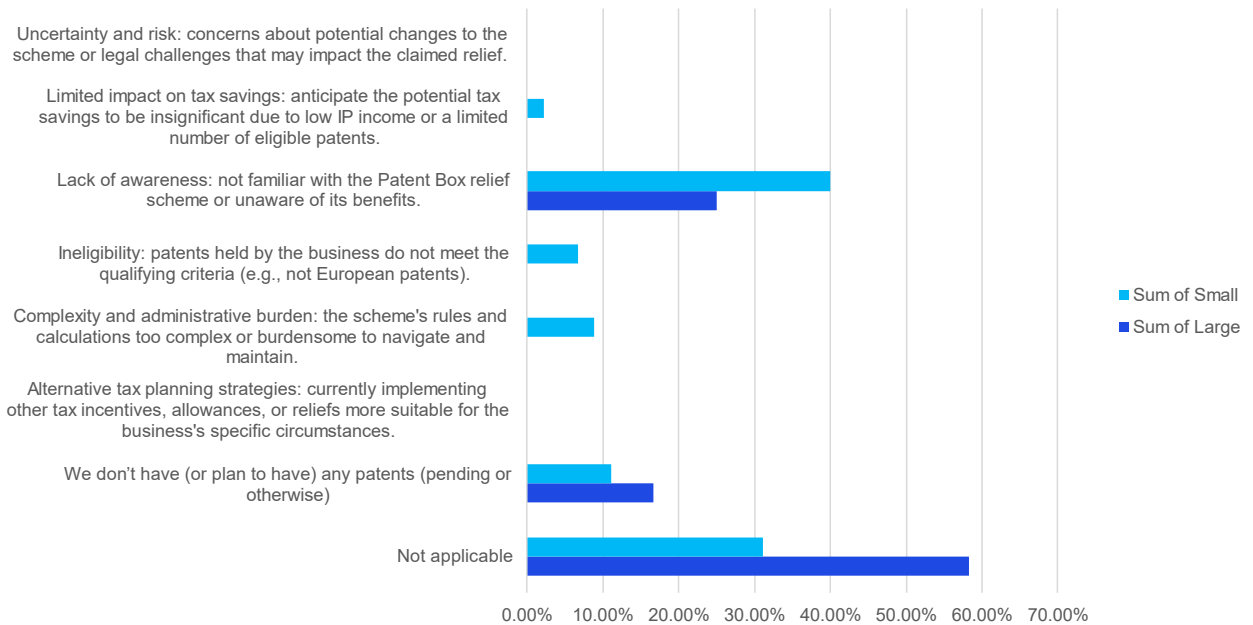


Figure 5.3: If no, do you plan on claiming Patent Box tax relief in the future?



Of the respondents that protect IP via patenting, 57% of them do not utilise Patent Box relief (91% of this population is made up of SMEs), and attribute this to perceived ineligibility and a lack of awareness of the scheme and its benefits. 43% of respondents that hold patents do make use of Patent Box relief, with the split of large vs SME businesses about the same at 55% and 45%, respectively.

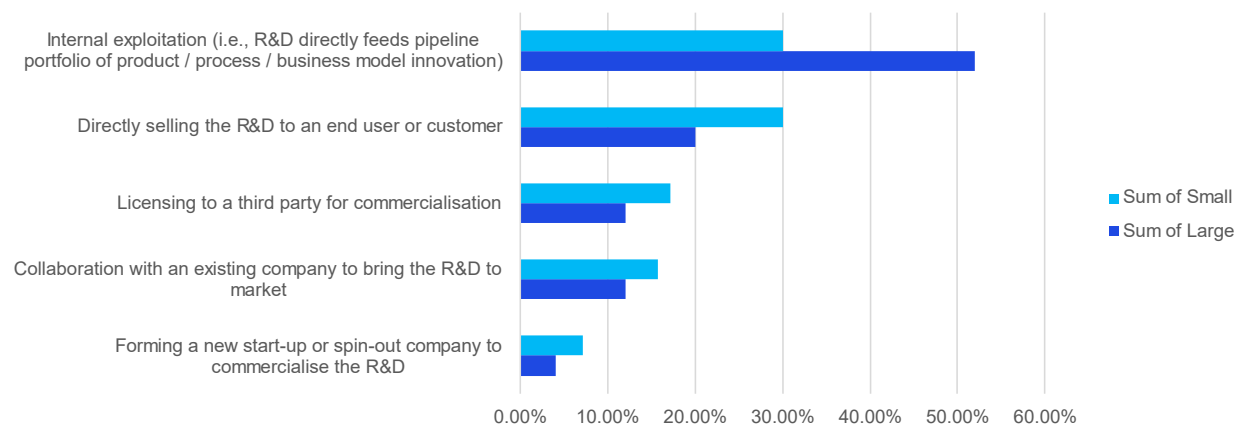
Figure 5.4: If you do not plan on claiming Patent Box tax relief now or in the future, please tell us why.



Commercialisation routes

Over half of large UK HealthTech businesses surveyed exploit their R&D output internally. Internal exploitation of R&D outputs is also common among SME businesses, although there is clear evidence that commercial exploitation via technology transfer (outright sale of R&D and licensing to a third-party) is very important to SME UK HealthTech businesses that may not have the capabilities and resources to successfully commercialise their product / technology. One respondent called for improved export support targeted at SMEs, stating “we can’t afford to travel and exhibit and register and certificate in all the overseas markets we would like to”.

Figure 5.5: What methods or pathways does your organisation utilise to commercialise your R&D specific to HealthTech?



NHS and the HealthTech supply chain

NHS as the largest buyer of HealthTech in the UK

The NHS plays a pivotal role as the largest buyer of HealthTech in the UK. This position presents both significant opportunities and challenges for the HealthTech sector.

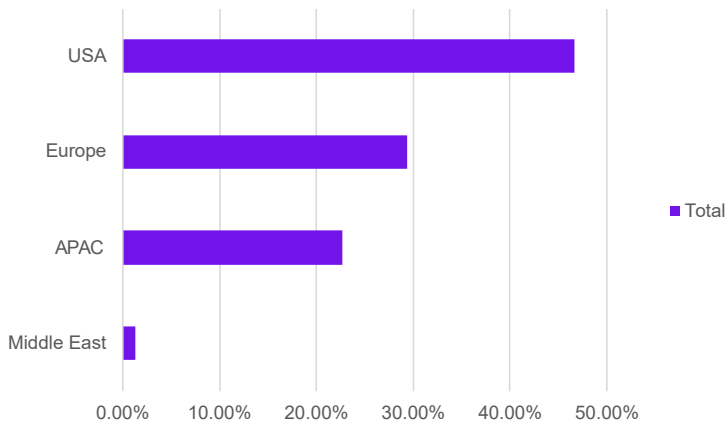
- Respondents pointed out that the NHS procurement process can be intricate and challenging, particularly for smaller businesses with limited resources. The lengthy and “convoluted” nature of the process can hinder the growth and development of the sector.
- While the NHS’s policy of reducing the number of suppliers aims to achieve cost savings and economies of scale, it can stifle innovation and limit access for smaller businesses. This policy may discourage investment in new and improved products, hindering the entry of innovative solutions into the market. Respondents suggest that certain products, particularly innovative ones, should be excluded from these long-term contracts or have their inclusion limited to shorter durations to foster innovation.
- The focus on short-term cost savings within the NHS procurement process may hinder the adoption of innovative technologies, even when these technologies offer substantial long-term benefits and cost savings. This approach can be frustrating for HealthTech businesses aiming to improve patient lives and save costs.
- Discrepancies in sustainability and social value definitions across NHS trusts can create challenges for manufacturers. Differing trust requirements may make it difficult for businesses to meet sustainability and social value goals consistently.
- The desire for ‘proof of benefit’ by the NHS and other healthcare systems, coupled with a focus on cost over quality, can create a challenging environment for HealthTech businesses. This approach may deter investment in innovative solutions, as it places undue emphasis on cost rather than the potential benefits to patient care.
- The NHS sales cycle is described as long and complex, and has been cited as dissuading private investors from engaging in investments where the NHS is the intended customer. This protracted process can significantly impact the time it takes to realise revenue.

The NHS’s immense scale offers HealthTech businesses the prospect of wide-reaching market access and the potential for significant revenue generation. However, these challenges must be navigated to unlock these opportunities fully.

International benchmark

The global landscape of HealthTech is evolving rapidly, with various countries striving to gain a competitive edge. While the UK boasts a robust healthcare ecosystem, respondents and research insights shed light on several key aspects affecting international competitiveness.

Figure 6.1: Which geography would you describe as the UK's main competitor when for HealthTech R&D / manufacturing organisations?



USA

Participants highlight the significance of the United States as the UK's principal competitor in the sector.

- Respondents expressed concerns that innovative healthcare solutions often take too long to reach UK patients, with many novel technologies (which are the result of UK-based R&D activity) being commercialised in the US first. This delay in adopting cutting-edge healthcare innovations can deprive UK patients of the benefits of timely access to advanced medical solutions.
- Many businesses choose to launch their innovations in the US first due to its robust and dynamic healthcare ecosystem. The availability of funding, a skilled workforce, and a clear regulatory framework contribute to the USA's attractiveness.
- The large HealthTech community in the US benefits from readily available VC money, which can fuel the development and scaling of innovative healthcare technologies.
- Respondents pointed to the clear and well-defined regulatory environment. The FDA's responsiveness, fast-track programs, and direct communication with innovators make navigating the regulatory landscape smoother and more predictable, compared to the UK and EU medical device regimes, which were viewed as less satisfactory.

Europe

Within Europe, participants highlighted the strategies of Germany, Ireland, France, and Switzerland.

- Since the UK's departure from the EU, Germany has increasingly become an attractive market for non-EU businesses. The presence of private hospital groups with intensive care units simplifies access to various medical specialties and fosters an environment conducive to innovation. Germany's NUB (Neue Untersuchungs- und Behandlungsmethoden) method, offering temporary reimbursement for new treatment methods beyond existing tariffs, is a notable feature attracting businesses, including those from the US, to conduct R&D activities in the German market.

- Respondents applauded Ireland for its targeted strategy within the HealthTech sector. They acknowledge Ireland's understanding of the sector, emphasising its ease of engagement with initiatives. Ireland is recognised for providing substantial financial support to HealthTech ventures, creating a conducive environment for innovation. Its ability to facilitate small-scale pilot projects through government grants and the agility to scale rapidly are highlighted as distinctive advantages. Additionally, the presence of a skilled workforce and reduced bureaucratic hurdles contribute to Ireland's competitiveness, as perceived by survey respondents.
- France and Germany are recognised for offering guaranteed reimbursement for digital therapeutics, creating an appealing market for HealthTech businesses. This emphasis on reimbursement provides a clear pathway for digital health innovations, attracting both innovators and private investors.
- Participants cited the following reasons that Switzerland is attractive for HealthTech businesses: low corporate tax rates, funding mechanisms and government grants, skilled workforce, and capability to support small-scale pilot initiatives and expedited scaling.

APAC

The Asia-Pacific ("APAC") region, particularly China, emerges as a notable competitor for the UK.

- One of the key reasons cited for China's competitive edge is its low manufacturing costs coupled with strong government support for investment in healthcare technology. This combination has made China an attractive destination for HealthTech businesses looking to optimise production expenses.
- Respondents noted that the APAC region, including China and Asia in general, has made significant strides in improving the quality of healthcare technology over the last 15 years. This enhanced quality, along with cost advantages, adds to the region's competitiveness. However, there still exists some concerns over product standards and durability.
- China, in particular, has transitioned from being primarily a manufacturing partner to becoming a hub for the development of emerging technologies. This shift is exemplified by China's increasing focus on internal development rather than simply manufacturing designs from Western countries. The emergence of a robust healthcare system in China further contributes to the Country's rise as a formidable competitor.
- China's sheer scale and the existing manufacturing capacity and infrastructure, combined with strong government support for domestic manufacturing, bolsters its competitiveness.

Summary of the UK's performance in the Life Science Competitiveness Indicators

The Life Science Competitiveness Indicators are a set of high-level indicators used to measure the performance of the UK's life science sector by benchmarking the UK against comparator countries. It is worth noting that the UK's performance in the research environment has mostly been calculated for the medical and health sciences sector, not specifically HealthTech.

While the UK Government has a high budget allocation for health R&D, coming behind only the USA, the UK generally places around the centre of the rankings for R&D performed by government, higher education and private non-profit sector. The UK saw a decline in its global share of patients recruited to commercial trials in 2021 to 2.2% compared to 3.0% in 2020. The UK has also seen a continuous increase in the length of time taken to approve and set-up commercial clinical trials between 2018 and 2021 with the median time reaching 271 days in 2021, up from 222 days in 2018. Due to these increases, the UK now ranks ninth out of 10 comparators in set-up and approval times, a decline from seventh in 2020.

The share of patients in commercial trials and the time taken to approve and set-up these trials up have been heavily influenced by the COVID-19 pandemic in the years 2020 and 2021. Many other comparator countries have seen decreases in these along with the UK. In 2021 the UK's value of medical technology imports reduced for the first time since 2016. Out of the 9 comparator countries, all saw an increase in their value of medical technology imports between 2020 and 2021.

	Metric	UK rank	Notes
Research environment	Government budget allocations for health R&D as % of GDP	2nd out of 15	The UK government's budget for health R&D was £3.2 billion, which equated to 0.15% as a percentage of GDP. This ranked the UK second out and in terms of the proportion of GDP, behind USA.
	Gross domestic expenditure on medical and health sciences R&D performed by government as a % of GDP	6th out of 10	UK government institutions performed £267 million of medical and health sciences R&D, amounting to 0.01% of GDP
	Gross domestic expenditure on R&D performed by the private non-profit sector as a % of GDP	4th out of 10	The amount of R&D performed by the UK private non-profit sector was £899 million, or 0.04% as a percentage of GDP, which placed the UK in the middle of the ranking of comparators
	Gross domestic expenditure on medical and health sciences R&D performed by the higher education sector as a % of GDP	6th out of 10	The UK higher education sector performed £2.2 billion of medical and health sciences R&D, amounting to 0.10% of GDP
	Share of medical sciences academic citations	3rd out of 12	In 2022, the UK's share of global medical sciences academic citation counts was 11.7%, declining from 12.7% in 2020
	Proportion of each country's medical sciences publications which are amongst the most highly cited (top 1%) globally	1st out of 12	In 2022, 2.0% of the UK's medical sciences publications were in the top 1% of the most-cited medical sciences publications globally. However, the UK has seen a decline in the proportion of medical science publications
	Life science patent applications per thousand population	4th out of 13	Despite a slight decline in the applications per thousand population since 2016, the UK has risen in the rankings of comparator countries in 2020 to fourth up from sixth in 2019
Production environment	Number of people employed in manufacture of medical technology products	4th out of 12	In the UK, 43,000 people were employed in medical technology in 2020
International collaboration	Global exports of medical technology products	10th out of 20	The value of UK exports of medical technology products in 2021 was \$5.4 billion, an increase of 16% since 2020
	Global imports of medical technology products	7th out of 20	The value of UK imports of medical technology products in 2021 was \$6.3 billion, a reduction of 9% since 2020
Investment environment	Life sciences inward foreign direct investment – projects	5th out of 18	The expected amount of FDI coming into the UK in 2021 was produced by 49 projects there
	Life sciences inward foreign direct investment – estimated capital expenditure	9th out of 18	In 2022 the value of estimated inward FDI into the UK was at £1.0 billion
	Share of global life science initial public offerings	7th out of 27	Sharp declines were similarly seen across most comparators in equity finance and IPOs between 2021 and 2022 due to changes in the life sciences investment environment following the COVID-19 pandemic and because of broader economic factors
	Amount raised in global life science initial public offerings (where known)	10th out of 27	In 2022, UK IPOs in life sciences raised £7.1 million from 3 IPOs, raising the lowest amount seen since 2018
	Equity finance raised by life science companies	4th out of 20	Equity finance raised by the UK life sciences industry fell to £3.3 billion in 2022, down from £7.2 billion in 2021
Access to skilled labour	Percentage of graduates from tertiary education graduating from natural sciences, mathematics, and statistics programmes, both sexes	2nd out of 14	9.2% of tertiary education graduates in the UK in 2021 were in the natural sciences, mathematics, and statistics fields. Whilst the UK maintained a ranking of second in 2020, the percentage of graduates completing these degrees substantially declined from 13.4% in 2019

05

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Please note that a full list of references from Phase 1 is available on request.



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