CHALLENGES and OPPORTUNITIES for the UK HEALTHTECH INDUSTRY

An output from the HEALTH TECHNOLOGY REGULATORY and INNOVATION PROGRAMME

Project funded by

UKRI Innovate UK

Partners

cpi

ABHI HealthTech for Life

CATAPULT High Value Manufacturing

Contents

The Executive Summary

The process, findings, and recommendations

The Executive Summary

About the programme

The Health Technology Regulatory and Innovation programme (HTRIP) was formed to deliver support to the UK SME HealthTech community. It supported the industry through non-dilutive grant funding to access regulatory consultants, free-to-access training on regulation and through developing a roadmap to support the IVD subsector of the industry.

How this report was developed

We developed this insights report based on work carried out by the project partners, CPI and ABHI who sourced this information from companies that applied for and received grant funding, through surveys, and face to face discussions at round tables that took place in 11 locations across the UK.

Insights and recommendations

Summaries of insights and recommendations

Regulatory insights

The biggest challenge to UK HealthTech SMEs is considered 'regulatory' in nature. The main concern from SMEs was that they "do not know what to do at which point"; that is, they struggle to understand how to progress along their appropriate regulatory pathways. Many SMEs do not have much, or any, internal regulatory knowledge, so they rely on external consultants that they consider to be often highly priced. In addition, it can be challenging for SMEs to identify consultants with the right expertise.

A significant blocker to innovation in the UK HealthTech industry is the lack of Notified Bodies / Conformity Assessment Bodies. The inability to engage these bodies is both costly and time consuming, and it is taking organisations up to 18 months to do this. Once engaged, the existing Notified Bodies are taking up to a further year to assess the relevant documentation. In contrast to the regulatory uncertainty in the UK, the USA Food and Drug Administration (FDA) route of utilising predicate devices (510(K)) is an increasingly attractive route for faster access (it only takes 90 days to obtain a 510(k)) to market clearance in a stable and transparent regulatory environment). Attractive re-imbursement, innovation adoption and market size compound this view for the US market.

SMEs need to be supported more on their regulatory journey in the UK. In the short term, through funding more regulatory support including repeating this HTRIP programme as well as continuing training and support. There needs to be an increased pool of regulatory professionals, for external support and as in-house experts. The MHRA should be enabled to provide more guidance and support to HealthTech companies, along the lines of what is provided by the FDA in the USA or Health Canada.

The industry needs a simple, easy to understand Regulatory Roadmap (how to guide) for UK HealthTech SMEs that will help them understand the pathway they should take to gain regulatory approval and crucially, what steps they need to take, in what order, for them to gain this approval.

There needs to be an increased number of notified bodies / conformity assessment bodies to reduce the current backlog and delays.

Funding insights

Public funding schemes and competitions are considered by many SMEs to be too complex, too focused on the earlier stages of innovation and require SMEs to be experts in proposal writing, taking them away from their innovation and development direction.

SMEs are, in general, struggling to gain support from the Life Sciences investment community. There are more and larger investment opportunities outside of the UK which is encouraging companies to move overseas. This is a significant issue, particularly when the early stages of innovation, including early development at Universities, is supported, and funded well in the UK. Unless this is acted upon, the UK will continue to invest in early-stage innovations only for their impact to be realised outside of the UK.

Fast start, simple funding schemes, potentially following the funding approach demonstrated in HTRIP should be encouraged. For the existing public funding landscape, we need to review what support is available and look to fill gaps in the innovation journey. Private investments in HealthTech need to be incentivised through public-private partnerships and increased visibility to UK SMEs.

Technical and ecosystem insights

SMEs feel that the early stages of innovation are very well supported, but as they move through the translational stage and closer to the commercial market, the support weakens. This is in relation to not only the grant funding that is available, but also the support by the innovation ecosystem in the UK.

The UK is lacking capability and capacity for scale-up and manufacturing of HealthTech. SMEs are struggling to find the capabilities they need to produce enough of their products for clinical trials or for commercialisation, often resorting in seeking support from overseas. Digital health is called out as having a significant lack of support which needs consideration.

There needs to be UK capability built to support innovation and scale up of HealthTech in the UK. Initially, a detailed mapping should be carried out to identify gaps followed by augmentation of capabilities of existing stakeholders within the ecosystem. The UK should invest in Digital Health Centres of excellence, focused on development, scale-up and adoption within the UK as well as providing support and advice on sustainability and regulatory matters[1].

[1] UKRI are currently assessing a call for a Digital health hub pilot scheme (https://www.ukri.org/opportunity/digital-health-hub-pilot-scheme/) which may provide an opportunity to support the digital health ecosystem as we are suggesting. A multi-agency advisory service (MAAS) for AI and data-driven technologies has also already been formed to support digital health development and adoption https://www.nice.org.uk/about/what-we-do/digital-health/multi-agency-advisory-service-for-ai-and-data-driven-technologies#find-out-more

Supply chain insights

Post pandemic and post-Brexit, there are still significant challenges in the supply chain. There are issues with long lead times, high minimum order quantities, rising prices as well as shortages. A wide variety of materials and components were mentioned which included reference to the well-known shortages of silicon chips that was affecting a sub-set of the SMEs questioned.

Many SMEs are sourcing significant proportion of their materials and components (as well as finished product) from overseas as materials and components are either not available in the UK at a competitive price or SMEs do not know where to look for UK-based supply.

The UK is lacking a supply chain directory for HealthTech which would enable companies to find customers and suppliers promoting onshoring or reshoring. This would also be of benefit to the UK Government in planning interventions where supply chain gaps exist.

Target market insights

Many SMEs see the UK and the NHS as their primary target market, because it is local, they have good knowledge of how to proceed and they consider it to be a reasonably sized market. Cited as further positives are established clinical champions and a network that includes the AHSNs. However, a barrier that is cited by SMEs is NHS procurement and adoption.

The USA is increasingly seen as a strong target market with stable regulation and good investor engagement. Access is seen as improving for UK SMEs; they see this as an opportunity to be taken. This is particularly the case for digital health companies; the USA can bring quicker results that can subsequently be used to build a UK and EU business.

Post-Brexit, the EU looks considerably more challenging to UK companies to access. However, the market is large, near the UK, and can be a strong market if companies are supported with access.

UK SMEs need support to access not only the UK market but also global and personal healthcare markets. Accelerator programmes to support access to global markets, directories of consultants and experts on global markets as well as working with the Department for International Trade to facilitate introductions to attractive markets globally will support the UK SME network.

Sustainability insights

The NHS has taken a lead amongst healthcare providers worldwide by setting out plans to achieve net zero by 2045 or earlier. This is a whole new challenge for HealthTech SMEs at a time when they have many other demands on their resources.

Most SMEs recognise the importance of sustainability and environmental issues in relation to how they operate their businesses. What is concerning is that around a third of the SMEs did not know how to proceed towards net zero and have no plan. HealthTech SMEs therefore need support to achieve net zero by the NHS deadline, with the biggest impacts being single-use plastic and recycling at end of life.

The industry needs to understand which materials are least sustainable and fund research and innovation into materials science and the regulatory challenges changing materials may make. To support this, an

independent specialist sustainability advisory service could be set up to support, especially where materials and process innovation can have significant impact.

IP insights

SMEs are that are wanting to protect intellectual property (IP) through legal routes such as patents are often finding the costs prohibitive, including searches for freedom to operate, or they lack the resource to defend patents.

SMEs need supporting to understand the basics of know-how, IP and how to protect it. Training, improving visibility of networks or even funding to support the protection of IP through patents (as is offered in the EU) would help.

Skills insights

Skills shortages were identified in regulatory affairs and quality assurance. There are very few professionals in the UK that have these skills and they are in such high demand that they typically work as consultants rather than take full time positions within HealthTech companies, especially within SMEs.

Digital skills were also identified as lacking. Software, artificial intelligence (including machine learning) and app development skills need to be improved in the digital health space. Recruiting staff with these skills is difficult in the HealthTech sector as professionals move into other industries that often offer better employment packages.

Furthermore, individuals with engineering, sales and marketing skills tailored towards HealthTech are also lacking. This is not only focusing on the UK market as a sales channel but also for overseas sales.

There needs to be targeted plans to promote careers in quality assurance (QA), regulatory affairs (RA) as well as broader careers in engineering, sales and marketing for MedTech. There is ongoing work taking place by The Organisation for Professionals in Regulatory Affairs (TOPRA) to develop professional qualifications in regulatory affairs specifically for the MedTech sector, which could be utilised to increase the number of individuals in this space. In addition to trainings geared towards industry, webinars and an annual Symposium where regulatory professionals, consultants, early-stage medical device developers, SMEs can keep up-to-date and discuss the latest regulatory advancements.

Detailed recommendations at a glance.

The Following pages show an overview of the recommendations described throughout this document. The diagram on page 11 shows a visual map of how the recommendations group together.

Regulatory Challenges

1. Develop a simple, easy to understand, Regulatory Roadmap (how to guide) for UK HealthTech SMEs 2. Continue to offer online high-level regulatory training through "one to many" and interactive webinars 3. Develop an online high level training programme on digital health technologies 4. Innovate UK to repeat the HTRIP programme of funding for SME regulatory support	5. To improve the UK ecosystem for SMEs, encourage the MHRA to be more accessible for guidance in the manner of the FDA in the USA. 6. Publish and maintain a free to access directory of UK based regulatory consultants 7. Encourage more UK universities to offer regulatory training for Life Science and related courses 8. Develop the UKCA system to recognise EU and USA regulation approvals in its alignment 9. Support the designation of more UK based CABs to overcome current delays and monitor the current availability of existing services.

Funding Challenges

10. Funding bodies should review all HealthTech funding schemes and consider "fast start" funding and staged funding as an option. 11. Funding bodies such as Innovate UK and NIHR should be encouraged to cover across the entire development cycle for health technologies, funding not only "good projects" but also "good companies". 12. AHSNs and their devolved equivalents, should be encouraged to focus more heavily on the market adoption, and commercialisation end of innovation	13. Evaluate geographical variations in grant funding 14. Create and share a directory of investment companies that are interested in engaging with HealthTech companies 15. Support UK SMEs through pitch training 16. Incentivise schemes with public:private co-funding to extend resources and share risk. 17. Increase the involvement of clinicians for 'best value' funded programmes through NHS Trust Innovation Officers

Sustainability Challenges

18. Establish an independent specialist sustainability advisory service. 19. Map out the existing materials used within HealthTech applications 20. Behind this, work with UK universities, Engineering Societies and UK HealthTech qualified materials producers to develop alternative materials and supporting technical data (e.g. biocompatibility, toxicology aging, sterilisation) to enable smooth switching. 21. UK to build capability in test run/small pilot manufacturing of sustainable or circular materials for HealthTech applications	22. Encourage re-shoring of manufacturing capability 23. Encourage the NHS to create an award scheme for suppliers who are driving sustainability 24. Promote and enhance Sustainability Frameworks for HealthTech in the UK 25. Establish training programmes run by academic and industry experts for health personnel that addresses all the challenges related to single-use plastic, material substitution and regulation. 26. Develop a HTRIP grant funding scheme to encourage UK SME manufacturers, especially for disposable and single-use plastic products

Target Market Challenges

27. Create a UK NHS Accelerator programme with a clear "lit runway" 28. The NHS should introduce bridging loan schemes 29. Leverage existing USA accelerator programmes to support UK SMEs to access the USA market 30. Work with AHSN and Innovation Hubs to identify SMEs with a preference to see the USA as their primary target. 31. Leverage the UK's connection with EU embassies to facilitate UK SME introductions to EU stakeholders	32. Launch a grant funded programme to support companies currently supplying to the UK/USA market to export to the EU. 33. Establish a directory of experts for these global markets 34. Encourage the relevant commercial sections of the UK embassies in countries such as Canada, Australia, Japan, Brazil, UAE and Singapore to develop more proactive engagements

Supply Chain Challenges

35. Development and maintenance of a supply chain directory to enable mapping and visualisation of companies within HealthTech relevant sectors.

Technical Challenges

36. Map out the innovation support landscape for HealthTech in the UK and provide support for gaps 37. Develop initiatives that encourage UK Universities to work more closely with translational research partners 38. Review the UK clinical testing/investigation landscape	39. Carry out a 'deep dive' into UK HealthTech capability gaps focusing on scale-up and manufacturing, with funding to build capability as a follow on. 40. The UK invests in a Digital Health Centre of Excellence

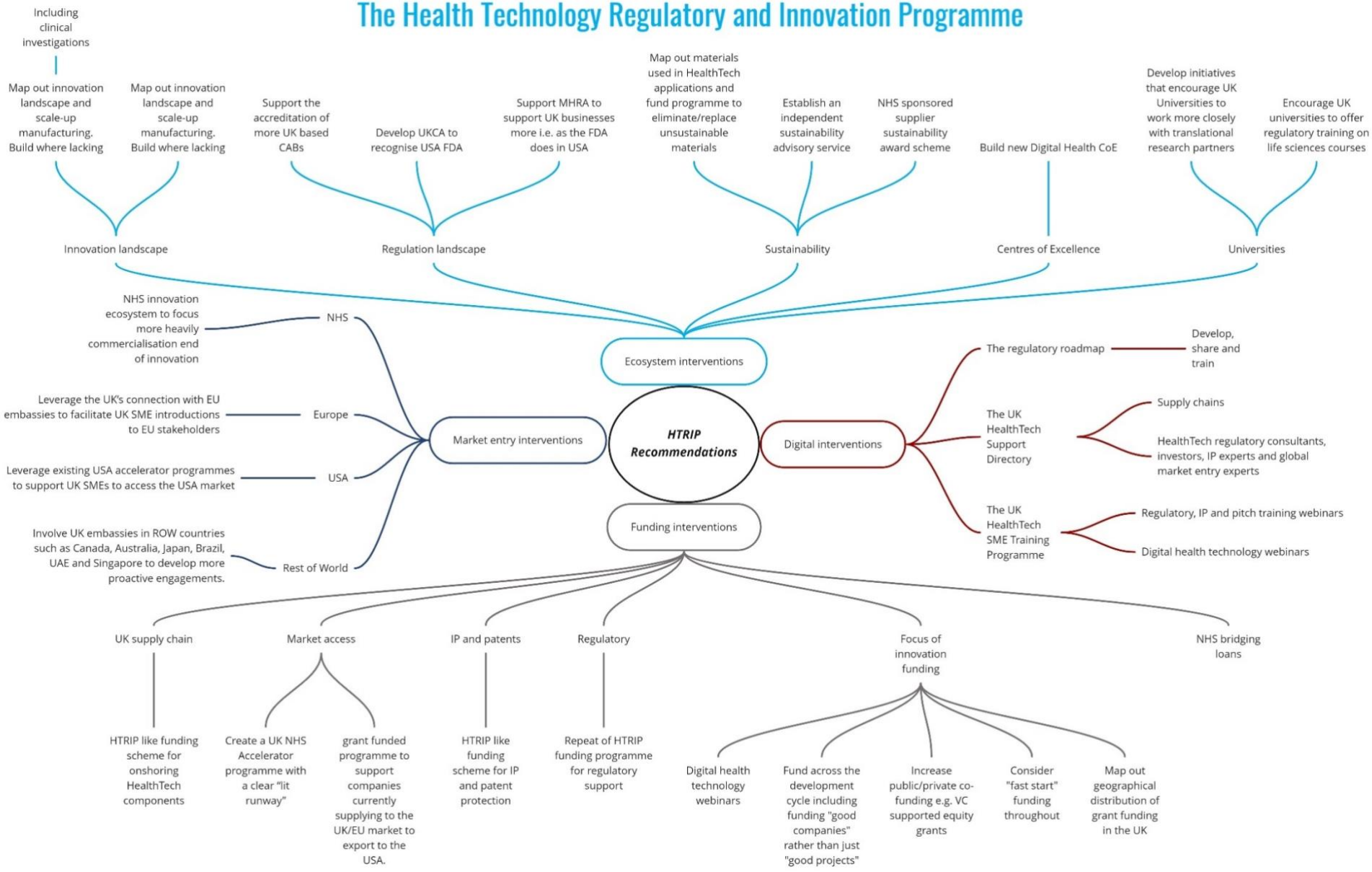
IP Challenges

41. Deliver high level training for UK SMEs to give them the basics understanding of IP and protection 42. Create and share a directory of IP advice services/shared specialists available for the different HealthTech technologies/devices.	43. Create a funding scheme to support SMEs to protect their IP.

Skills Challenges

44. Develop a targeted plan to promote careers in digital sciences, quality and regulatory affairs, sales, marketing, and engineering.	45. Offer an accelerator style, targeted training programme for those currently working in HealthTech SMEs

The Health Technology Regulatory and Innovation Programme



About the Health Technology Regulatory and Innovation Programme

Why the programme was needed, what it did and who was involved

The Health Technology Regulatory and Innovation Programme

Background

The UK health technology sector is a key component of the Life Sciences sector and is crucial to the health and wealth of the UK. The Office for Life Sciences reported that in 2021 the Medical Technology sector in the UK was made up of 4,353 businesses (~98% of which in England are SMEs[2]) and had £30bn turnover. It employed over 145,600 employees over 4,802 sites in the UK[3].

The term health technology or HealthTech, covers many thousands of unique products globally, with industry estimates being around 600,000. These range from brain-computer interfaces, diagnostics and wound dressings to medical 3D printing and medical robotics. Medical technology or MedTech is a subset of HealthTech which falls under medical device regulations such as having claims of an intended patient benefit.

The European Union (EU) is a key market for UK health technology companies and represents around 26% of the global market (the UK is around 4%)[4]. However, recently there has been a shift in regulations in the EU, with medical devices and active implantable devices changing from the Medical Device Directive (MDD) and the Active Implantable Medical Device Directive (AIMDD) to the Medical Device Regulation (MDR). For in-vitro diagnostic medical devices (IVD) there has been a change from the In-vitro Diagnostics Directive (IVDD) to the In-Vitro Diagnostics Regulation (IVDR). Both new regulations are significantly more complex than the preceding directives. Furthermore, approximately 80% of IVDs will be going through a Notified Body process for the first time. Compounding this, we also have the introduction of the UKCA mark demonstrating conformity to a UK-specific regulatory regime, which is in development. As well as an alternative situation for Northern Ireland resulting from the (Brexit) Northern Ireland Protocol[5]

As a result of this, a key issue amongst industry is how to navigate regulatory requirements to understand where they have evidence gaps, and for some SMEs, even what they need to do to get started under the new regulatory rules. Also, for products that are on the market, there are many that may be withdrawn due

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[2] MedTech landscape review, The AHSN Network. Available at https://www.ahsnnetwork.com/wp-content/uploads/2019/02/MedTech-Landscape-Review-AHSN-Network.pdf , accessed on 08/12/22

[3] UK Medical Technology Sector, Bioscience and Health Technology Sector Statistics 2021, OLS. Available at https://www.gov.uk/government/statistics/bioscience-and-health-technology-sector-statistics-2021 , accessed on 08/12/22. Figures quoted are Medical Technology Core and Service and Supply.

[4] The European Medical Technology in Figures, MedTech Europe, 2022. Available at https://www.medtecheurope.org/datahub/market/, accessed on 04/10/2022

[5] General guidance is herehttps://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr however the standstill period was extended recently https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period

to the increasing regulatory burden, compliance costs coupled with lack of capacity in Notified Bodies[6][7]. If this happens, it could severely impact healthcare systems' ability to diagnose and treat patients leading to reduced quality of care ultimately impacting the healthcare system in the long term.

Initiatives

Innovate UK funded the Health Technology Regulatory and Innovation Programme (HTRIP) to support SMEs in this challenging market. The programme was made up of the following initiatives.

1. **Non-dilutive grant funding for SMEs to receive advice and support from regulatory experts**

A funding scheme that awarded £6,390,000 of grants to UK SMEs was delivered by CPI. UK SMEs developing medical devices were able to apply for grants of up to a maximum of £30,000 to enable them to pay for regulatory advice and support. A total of 232 companies were awarded funding[8].

2. **Training programme**

The Association of British HealthTech Industries (ABHI) delivered a series of webinars, some recorded, and others live and interactive as "ask the expert" sessions. This will improve background knowledge for UK SMEs who lack regulatory experience or training[9]. The training has been accessed 10,240 times.

3. **IVD roadmap development**

CPI and Cambridge Design Partnership (CDP) developed an actionable technology and capability roadmap for IVDs which will support innovation planning and inform future UK interventions in the IVD field. Through this work, a number of direct introductions were facilitated between UK SMEs and large, multi-national corporates.

4. **Insights**

All recipients of the HTRIP grant funding completed a survey on their business and outlined the challenges they were facing in the development and commercialisation of their products and services. Concurrently ABHI held a series of round tables and engaged with over 150 companies across the UK (including Scotland, Wales and Northern Ireland) where stakeholders, SMEs and others, discussed their challenges in a

[6] PREDICTING A SCRAMBLE TO IVDR READINESS - UK Medical Diagnostic (IVD), Iso Life Sciences Ltd Sectorhttps://www.ukri.org/wp-content/uploads/2021/07/IUK-130721-PredictingScrambleIVDRReadiness-UKMedicalDiagnosticSector.pdf#:~:text=A%20report%20describing%20the%20progress%20by%20UK%20Medical,the%20sector%20Predicting%20a%20scramble%20to%20IVDR%20Readiness , accessed on 18/10/2022

[7] Medical Device Survey 2021 – Team-NB https://www.team-nb.org/wp-content/uploads/2022/05/Survey-2021-20220516-1.pdf accessed on 07/11/2022

[8] The programme was extended in November 2023 enabling another approx. 60 companies to be supported

[9] Training is available via this link: https://www.abhi.org.uk/what-we-do/informing-regulation/the-regulatory-roadmap/

workshop. A further short survey was also answered by a number of SMEs to provide additional information.

This report is a summary of the data and findings from those activities, combined with other insights from throughout the programme.

Statistics

- 412 UK SMEs applied for grant funding, of which 232 were awarded, based on their requests for funding, a total £6.39m
- 221 grant recipients completed an 83-question survey on their challenges
- 49 responses of the shorter (ABHI) survey were completed
- 11 round tables were conducted, and we engaged with 112 SMEs and over 69 other stakeholders (NHS, AHSNs, Universities etc.)
- Over 132 consultant companies engaged with grant funding recipients to provide regulatory support throughout the programme

Project partners

This report was developed in partnership between CPI and ABHI

CPI

At CPI, our vision is to enable a healthier and more sustainable future through deep-tech innovations. Our mission is to catalyse advanced technologies for manufacturing solutions that benefit people, places and our planet. CPI acts as a catalyst bringing together academia, businesses, government, and investors to translate bright ideas and research into the marketplace. We do this by giving our customers access to the right experts, equipment, networks, funding and more – connecting the dots for effective innovation.

We are a leading independent deep tech innovation organisation and a founding member of the UK Government's High Value Manufacturing Catapult. Established in 2004, our teams apply their many years of experience to ensure that every great invention gets the best opportunity to become a successfully marketed product or process. We work with our partners across diverse markets in the UK and around the world, driving their innovations forward and helping them to reduce the risk and cost associated with product development.

The main markets of focus for CPI are

- Pharma
- HealthTech
- Sustainable Materials
- AgriFoodTech
- Energy Storage

CPI was the overall project lead for the Health Technology Regulatory and Innovation Programme

More information about CPI can be found here:- https://www.uk-cpi.com/ and https://www.uk-cpi.com/HealthTech

ABHI

ABHI supports the HealthTech community to provide products and services that help people live healthier lives. As the voice of the industry, we show the value of health technology and overcome barriers to people benefitting from it now and in the future. Members include leading multinationals through to small and medium sized enterprises. We represent the HealthTech industry to key stakeholders, such as governments, healthcare systems and regulators.

ABHI supports the HealthTech community to provide products and services that help people to live healthier lives though:

- Shaping digital health
- Leading access to HealthTech
- Informing regulation
- Guaranteeing trust
- Supporting sustainability
- Building UK diagnostics
- Promoting equality, diversity, and inclusion
- Fostering growth

More information on ABHI can be found here:- https://www.abhi.org.uk/

The training developed as part of this programme by ABHI can be found here:- https://www.abhi.org.uk/what-we-do/informing-regulation/the-regulatory-roadmap/

Funding

Innovate UK

Innovate UK is the UK's national innovation agency. We support business-led innovation in all sectors, technologies and UK regions. We help businesses grow through the development and commercialisation of new products, processes, and services, supported by an outstanding innovation ecosystem that is agile, inclusive, and easy to navigate.

More information on Innovate UK can be found here:- https://www.ukri.org/councils/innovate-uk/

How this report was developed

We used information from the sources below:

1. Information submitted by the companies that applied for the HTRIP grant funding in their application.
2. Information submitted by regulatory consultants when due diligence was carried out on them
3. HTRIP grant funded recipients survey responses (82 question survey)
4. Shorter (ABHI run) survey shared with the ABHI membership and others (including roundtable partners and through social media)
5. Round tables and face to face workshops carried out across the length and breadth of the UK (11 locations)

For more information on the breakdown of grant applicants, recipients and information on round tables, please see the appendices.

The report was a combined effort between CPI and ABHI. The views expressed within this report are those of the companies we engaged with throughout the process, of which the majority were SMEs. Their views may not be fact but are how they observe the world. Any recommendations in this document are based on the information provided by SMEs and CPI/ABHI expert opinion.

Note that when we discuss percentages throughout this report, unless otherwise clarified, we are referring to the survey in point 3 above. Other sources of information were used to formulate the discussions, insights and the recommendations in this document.

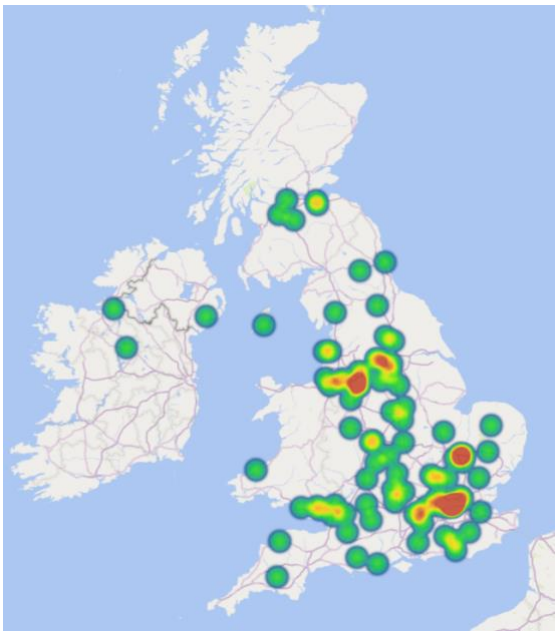
The UK Regulatory Consultant Landscape

A breakdown of the support available from regulatory consultants/consulting companies that engaged with SME grant recipients as part of the HTRIP grant funding programme

The HTRIP programme provided grant funding for SMEs to receive advice and support from regulatory experts on meeting the relevant medical device or IVD regulations in their target market. SMEs were required to identify the regulatory affairs consultants they wished to work with and in total,132 different companies were nominated.

Consultants were asked to answer a short questionnaire about their business, professional memberships, and areas of expertise as part of the funding competition due diligence. Note that the data utilised herein is self-reported by the regulatory consultants/regulatory consultant companies that provided support to the HTRIP grant recipients.

Data and findings



Country	Number of consultants
UK	105
USA	12
Republic of Ireland	4
Netherlands	3
Germany	2
Italy	2
Belgium	1
Denmark	1
France	1
Switzerland	1

Figure 1 – Hotspot chart showing the geographical location of the UK-based consultants engaged by programme SMEs and table showing the number of consultants per country. Note that grant recipients were allowed to use consultants that were outside of the UK if they could provide a reasonable justification.

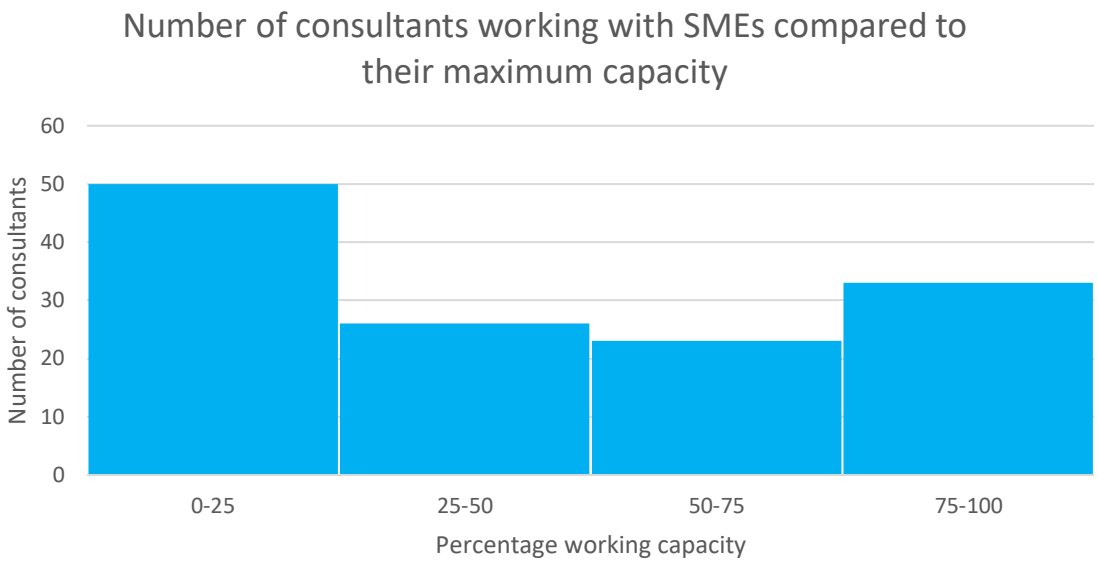


Figure 2 - Shows the percentage working capacity of regulatory consultants, determined as the number of projects being delivered for HTRIP at £30K each compared to the maximum number they could deliver in the duration of the project

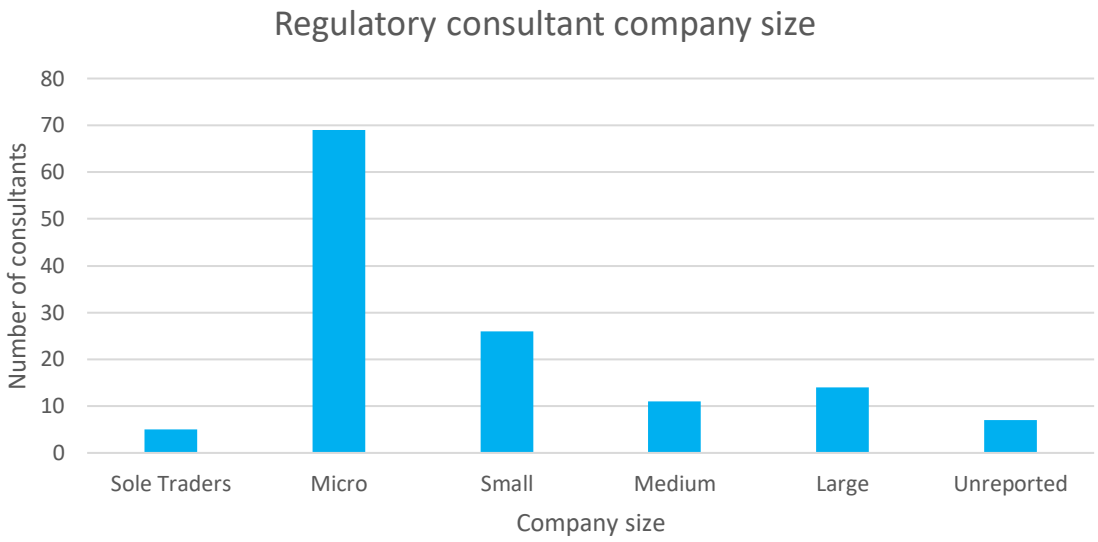


Figure 3 - Consultants size according to Endole[10] (sourced from Companies House)

Insight 1 – There is regulatory consultant capacity to support UK HealthTech SMEs

A strong emphasis was placed within the grant funding application on utilising a UK-based regulatory adviser. Unsurprisingly therefore, 79% (105 of the 132) of the regulatory affairs consultants used by the

[10] Available at:- www.endole.co.uk

funded SMEs were UK-based. When looking into the UK-based consultants, many appear within the "golden triangle" of HealthTech, with high volumes of consultants being based in the London, Cambridge and Oxford areas, mirroring locations of HealthTech SME counterparts.

Where an SME was planning on using a consultant that was not located in the UK, this had to be supported with a valid justification. The most common justification given was that SMEs sought to use consultants geographically based in the market they are targeting, as they know the medical device regulations better or they afforded good links with local appointed representatives or Notified Bodies. Within the section on target market challenges, we explain that SMEs often struggle to find regulatory support and advice for non-UK geographies where the support is located in the UK. 90% of the non-UK consultants were based in Europe and 9% (12) consultants were based in the USA.

"This grant will be used for a US FDA 510(k) application. As such, we approached [a] US-based … regulatory consulting firm with 20 years of experience with preparation and submission of FDA 510(k). In addition, they have a very good reputation and relationship with FDA; therefore they are considered the best placed to conduct this work on our behalf." – SME working in neonatal care, based in Nottinghamshire

Another reason for using a non-UK based consultant was due to seeking specific advice for a niche product.

"There is a scarcity of people with deep experience and expertise in new ground breaking diagnostics who can advise us about how to navigate the regulatory challenges we face. We have not been able to find anyone of [this] calibre based in the UK." – SME developing IVD, based in Cheshire

Regulatory consultants were asked about their capacity to conduct projects (of up to £30,000 in value) under the HTRIP programme. Their stated capacity was compared to the number of SMEs the consultants were working with and a percentage working capacity was calculated (as seen in the equation below, note that this is calculated over the duration of the HTRIP project only).

$$Percentage\ working\ capacity = \frac{Number\ of\ £30k\ projects\ being\ delivered}{Total\ number\ of\ £30k\ projects\ that\ can\ be\ delivered} \times 100$$

This showed that around 50 % of consultants were working with under half of their maximum working capacity. This indicates that there is capacity for regulatory consultants to take on work, but a number of SMEs were unable to engage with their first choice of supplier. Most consultants worked with one or two SMEs, yet a handful of consultants worked with anywhere between 7 and 21 SMEs. This suggests that there is capacity in the UK and, if the snapshot we observed is usual, this capacity is under-utilised.

SMEs, the most common size of regulatory affairs consultants utilised by SMEs were micro-sized, with just over half (52%) of the consultants being a micro-company. Sole traders were the least utilised, with only 5 SMEs opting to use them, though this could be due to the number of sole traders and consultants potentially preferring to operate as a limited company.

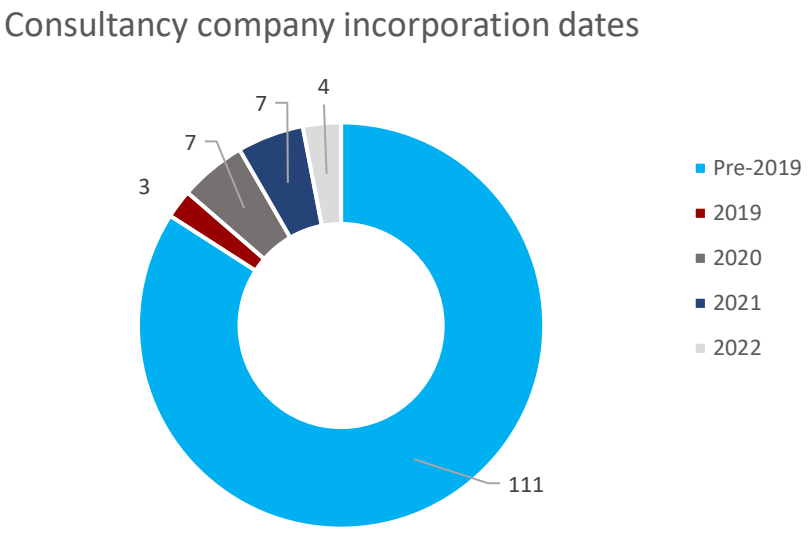


Figure 4 –The number of consultancy companies founded within the last three taxation years compared to the number founded pre-2019.

Insight 2 – The majority of consultants have been active prior to 2019

Of the consultants used by the successful applicants, roughly 16% (21 of the 132) were incorporated within the last 3 taxation years, none of which were located in the United States. The geographical chart shows that 85 % of those consultants incorporated within the last 3 years were incorporated within the United Kingdom, with the other 3 companies being foun3 central Europe. Of the 105 consultants based in the UK, just over 17 % were founded within the last three years

Figure 5 - Regulatory consultants' memberships. Upper figure shows the number of different memberships the consultants had. Lower figure shows number of consultants with membership of specific organisations

Insight 3 – There are globally a large number of industry bodies relevant to HealthTech

The 132 consultants have a total of 183 memberships to 61 different industry bodies, trade associations, boards, and professional societies. Most consultants only had one membership, with 24% being members of the Regulatory Affairs Professionals Society (RAPS). The Organisation for Professionals in Regulatory Affairs (TOPRA) and Medilink each had 22% of the consultants as members. 6% of the consultants used by the SMEs had four or more memberships to different organisations.

A list of memberships identified by regulatory consultants is in appendix 6.

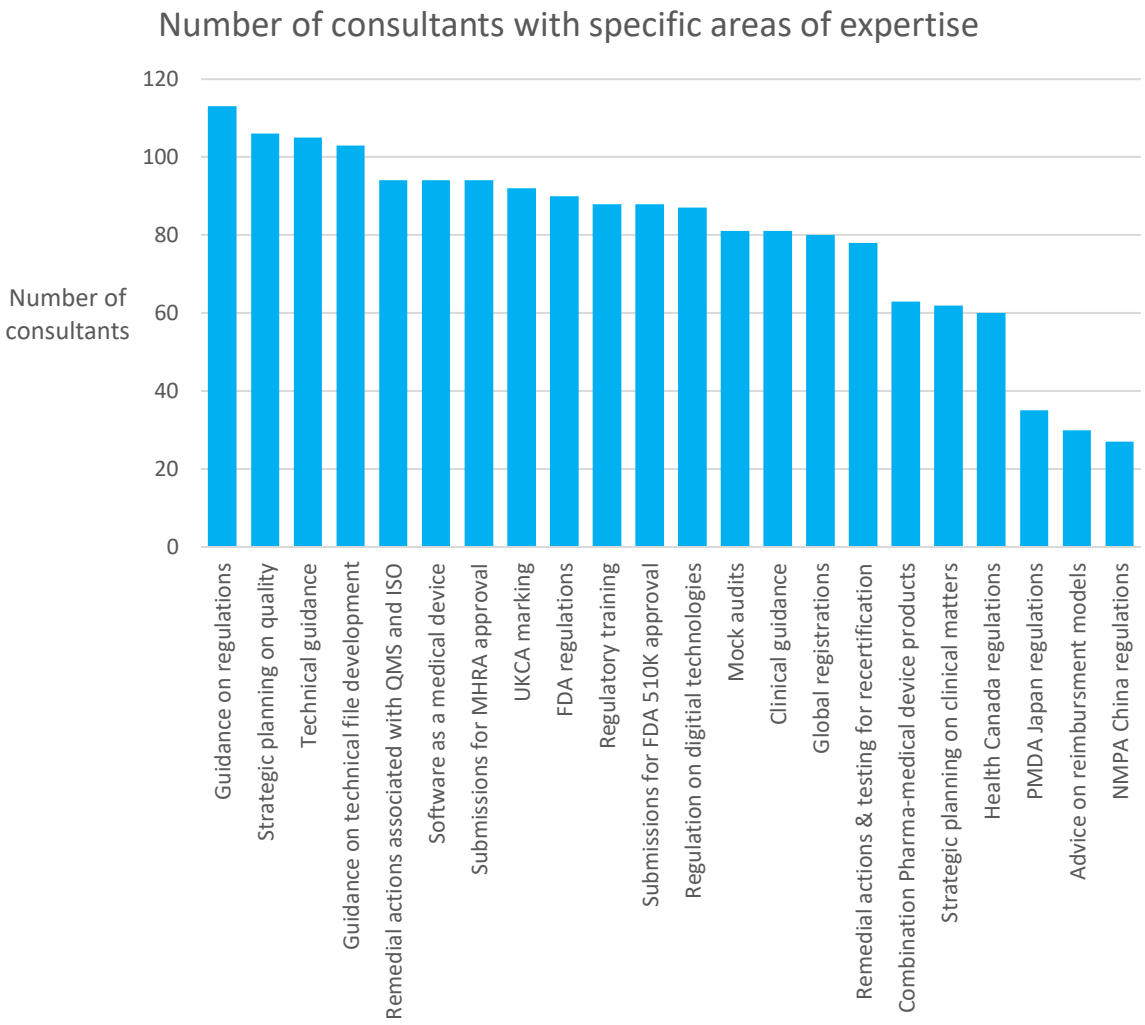


Figure 6 - Areas of expertise, as self-identified by regulatory consultants

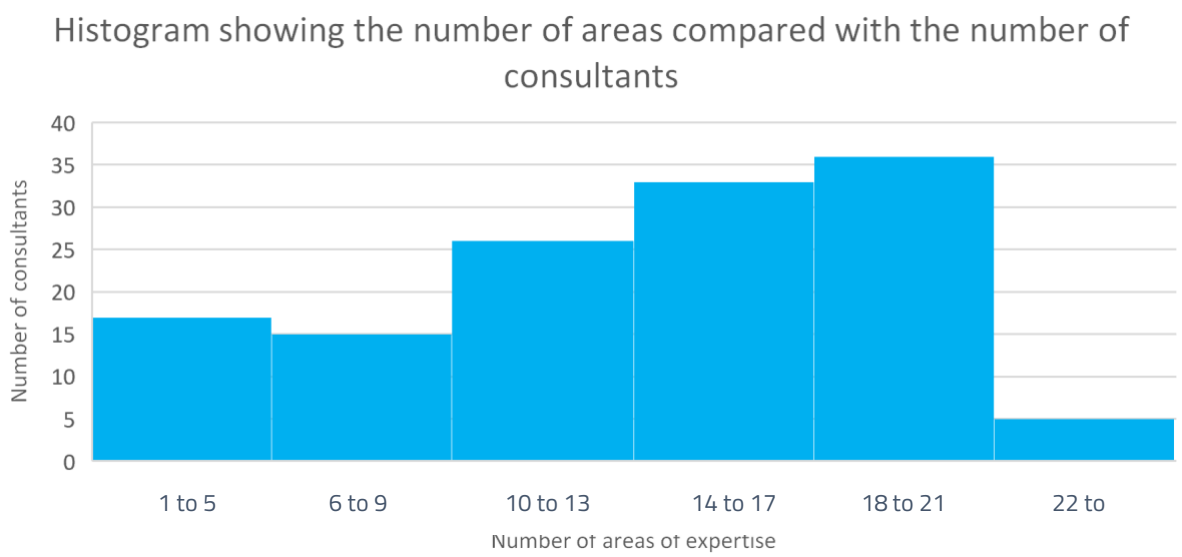


Figure 7 - Number of specialism areas per consultant

Insight 4 – Regulatory consultants providing support to UK SMEs have a broad range of areas of expertise

The consultants were asked to state their areas of regulatory expertise. Overall, the consultants gave a list of 22 different areas. Many of the consultants had more than one area of proficiency, with the average number of areas of expertise being 13. Many offered technical development and technical file guidance with a significant number listing software as a medical device (SaMD) as a specialism.

Many of the consultants had a very clear overlap with their areas of expertise. For example, the consultants that perform mock audits also have experience in remedial actions associated with Quality Management System implementation. Although companies justified the use of non-UK consultants by asserting experience in the local market, these results indicate that UK-based consultants have expertise in non-domestic regulation. For example, there were twelve consultants based in the USA, but 90 consultants asserted experience with FDA regulations. Therefore, the issue may be one of identification.

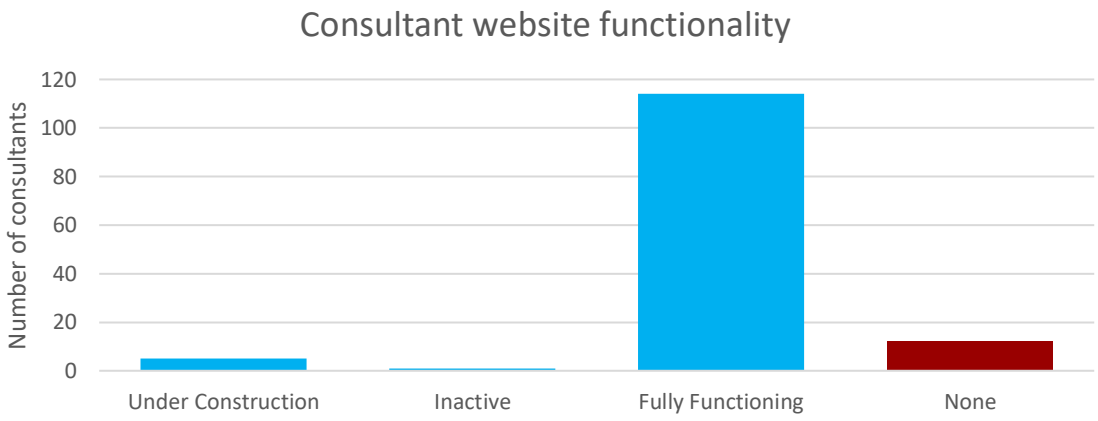


Figure 8 - Graph showing the corporate website functionality of the regulatory consultants

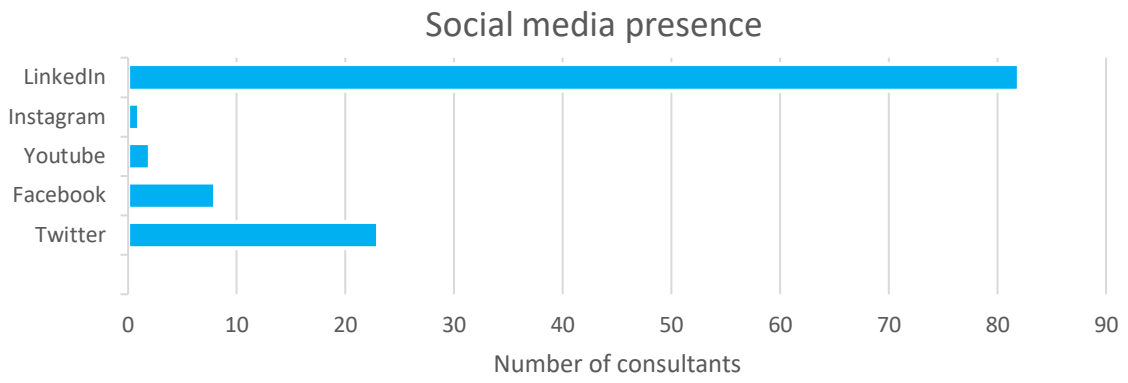


Figure 9 - Graph showing the social media presence of the regulatory consultants

Insight 5 – Regulatory consultants' online presence is primarily limited to websites and LinkedIn

Numerous requests were received by the Programme team for assistance with finding a suitable regulatory consultant. The online presence of consultants was inspected and 86% had a functional company website. There were a number of companies that did not have an active website, nor social media presence, with 9% using generic domain email providers.

A large number of consultancy companies (62%) had a presence on LinkedIn but other social media sites were less utilised, with 17% of the regulatory consultants using Twitter. The companies that had YouTube, Facebook or Instagram accounts usually paired these accounts with a Twitter account. A higher percentage of sole traders and micro sized companies have a LinkedIn presence than their small company counterparts, with just under 27% of the small companies having a LinkedIn account, compared to over 60% of micro-sized companies with an account.

"No longer have website. I decided to take it down… as I was unable to take on more clients" – Micro-SME Regulatory Consultant

"My work is obtained through industry contacts." - Micro-SME Regulatory Consultant

The data, indicates it may be a challenge for new entrants to identify suitable regulatory consultants, potentially shepherding companies towards the best known names, those with the most significant online presence, or relying on recruitment specialists. The area is dominated by personal recommendations and networks. The alternative is to go through trade bodies, but as observed above, the vast majority of consultants could not be identified by viewing the membership of a single organisation as they are not members.

SME Challenges

What we have learnt from SME engagements and what are our recommendations for change

Regulatory Challenges

The HealthTech industry is highly regulated to ensure patient safety and health outcomes. However, there are currently an unprecedented number of regulatory changes affecting organisations supplying the UK and EU. This was recognised in the HTRIP funding call which resulted in oversubscription in view of the demand.

This section deals with the regulatory landscape as an inherent part of the overall picture and all SMEs are adversely affected by the current situation, exemplified by the quote:

"Supportive regulation underpins success – [regulation] needs to be faster and easier." – participant of Edinburgh Roundtable.

The biggest 'technical' challenge is considered by SMEs to be regulatory in nature, which includes evidence generation from clinical investigations and laboratory testing to compile technical documentation for submission.

Data and findings

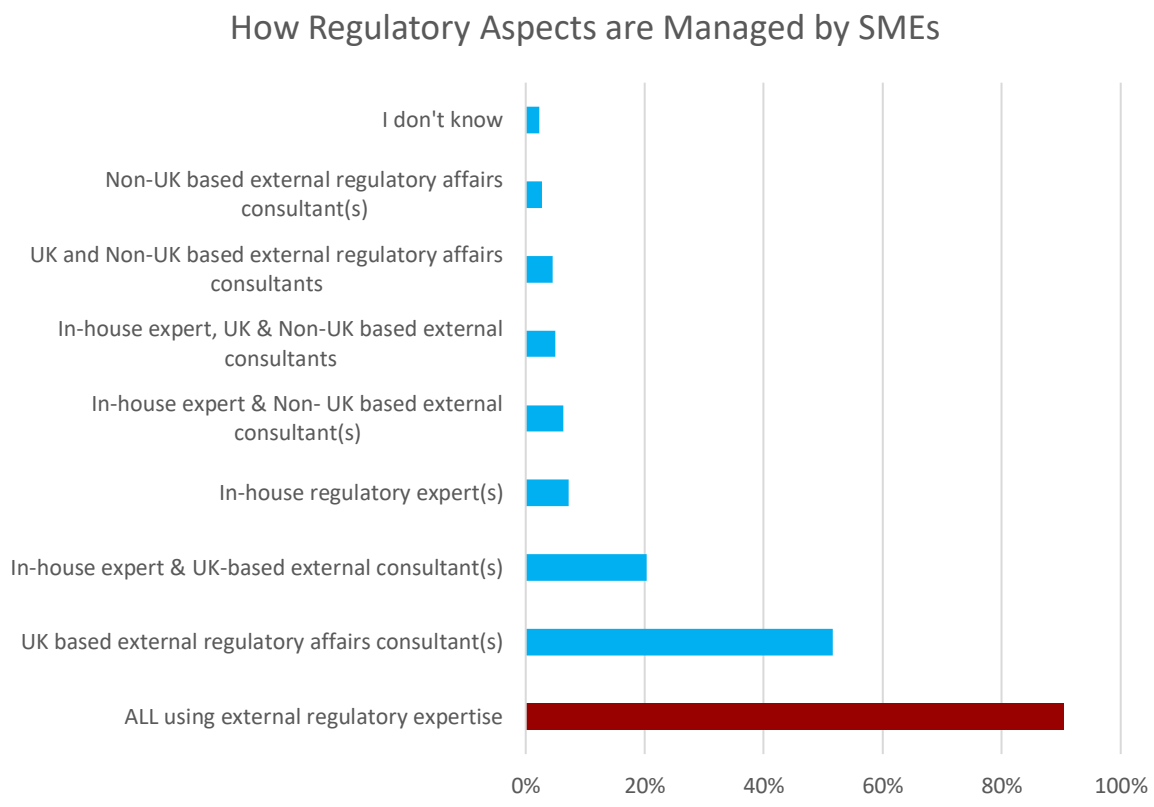


Figure 10 – Data from the multi-choice survey question "How do you currently manage the regulatory aspects of you product/service?" The bar in red has been added to show the percentage of respondents who are reliant on some form of external regulatory expertise (~90%)

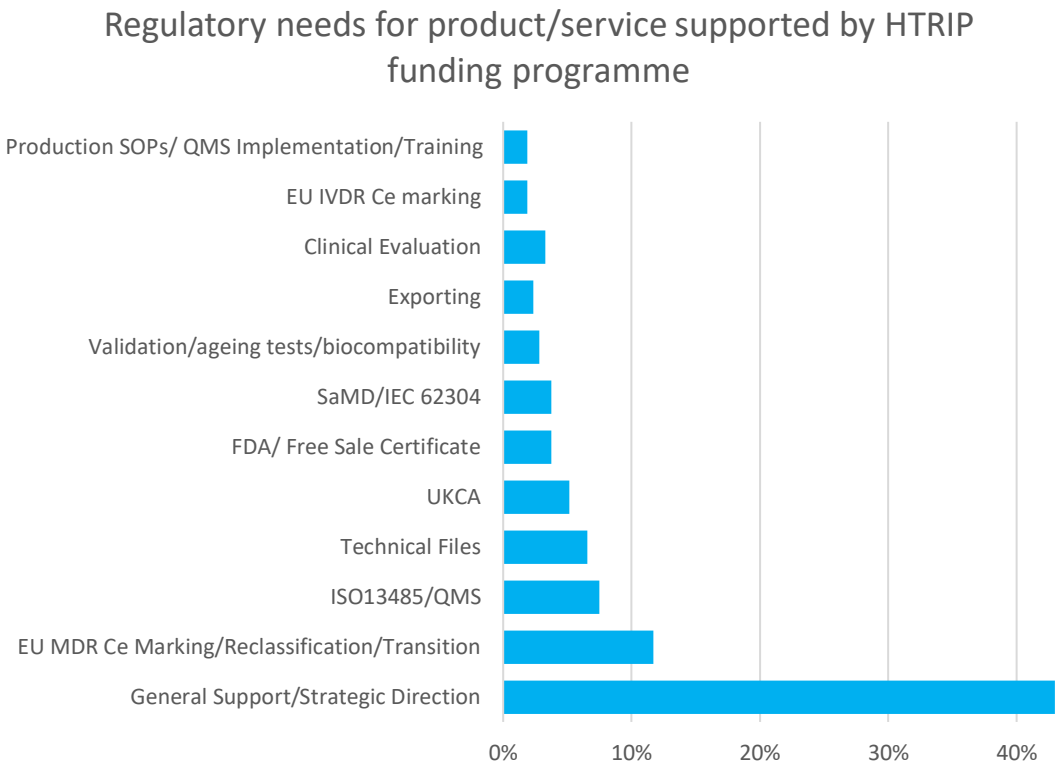


Figure 11 – When asked the question: "Please give … a brief non-confidential description of the product/service you are requesting support for" many of the survey respondents, whom are all SMEs funded under the HTRIP programme gave information on what their specific regulatory challenges were. This was for the product or service they were gaining support for under the HTRIP programme. Here we show a percentage of the challenges mentioned by these survey respondents.

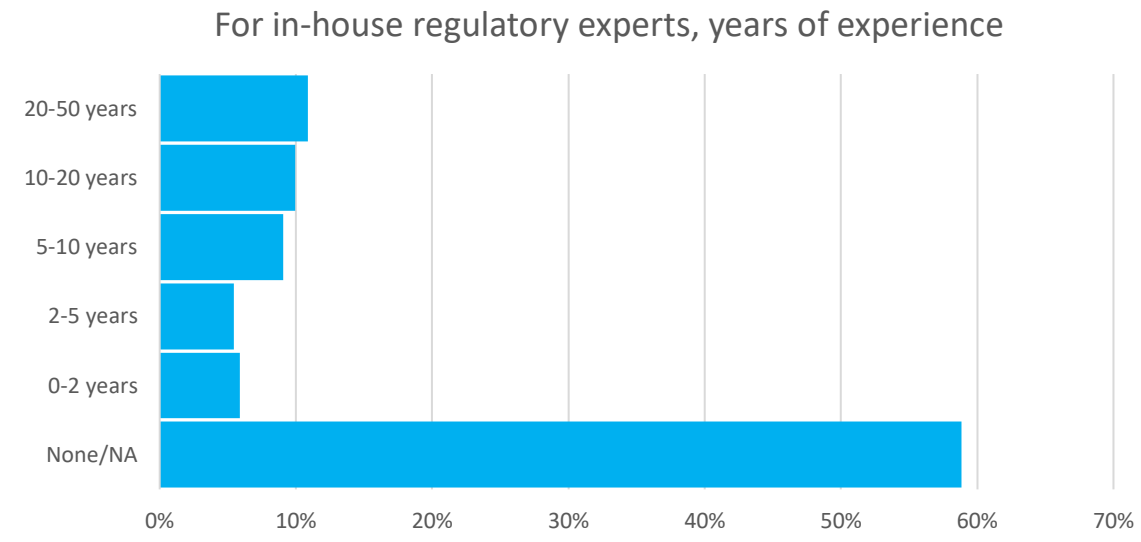


Figure 12 – Results of the tick-box survey question "If you are using in-house regulatory experts how many years of experience has most experienced team member?"

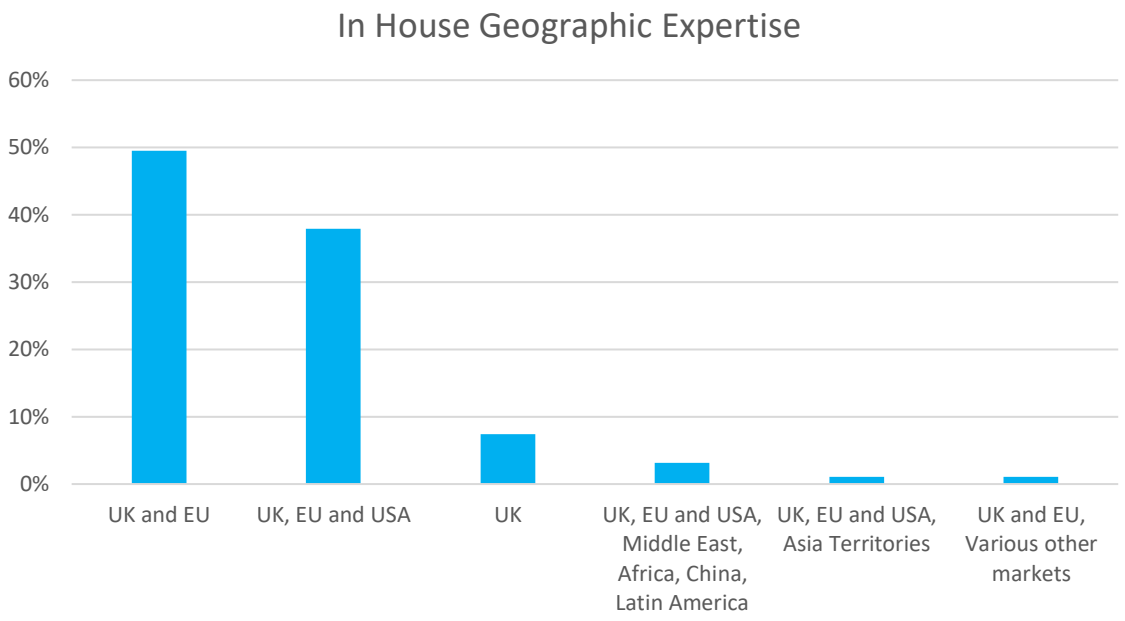


Figure 13 - Results of the tick-box survey question: "If you are using in-house regulatory experts how broad is their expertise in terms of regulation for the different geographical markets?

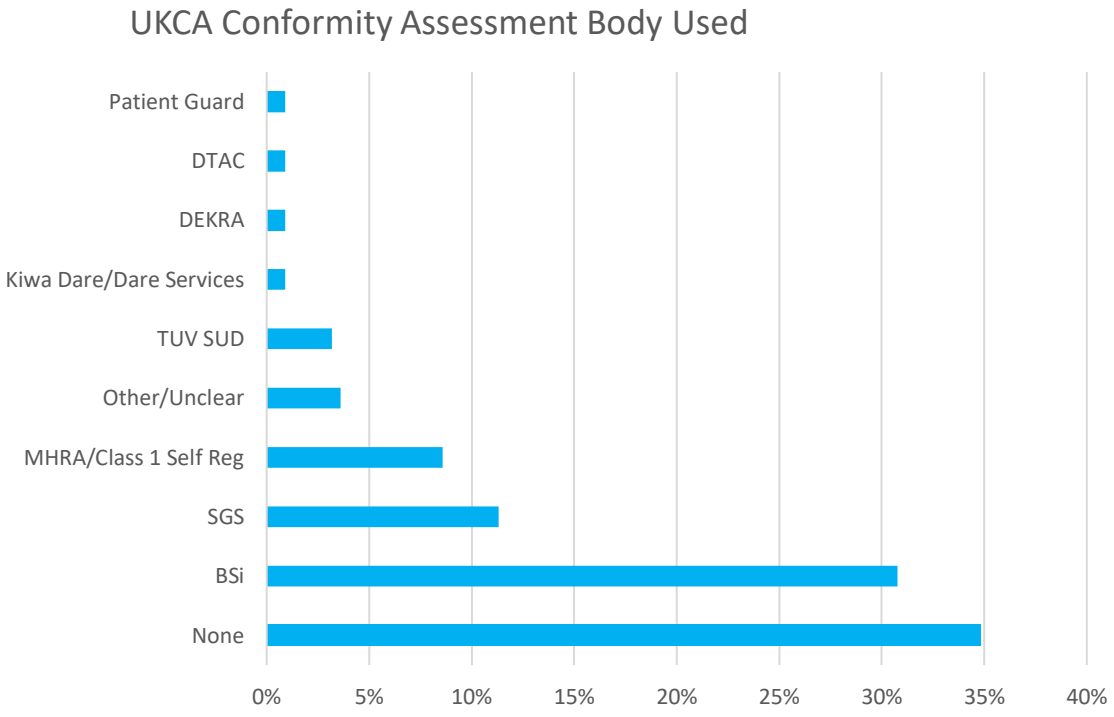


Figure 14 – The CABs identified by companies responding to the survey question "Which Conformity Assessment Body for UKCA are you using or plan to use. Note that the only CABs on this list are SGS, DEKRA and BSI. Others are not CABs. This shows the lack of understanding of regulatory affairs within some of the HealthTech SMEs.

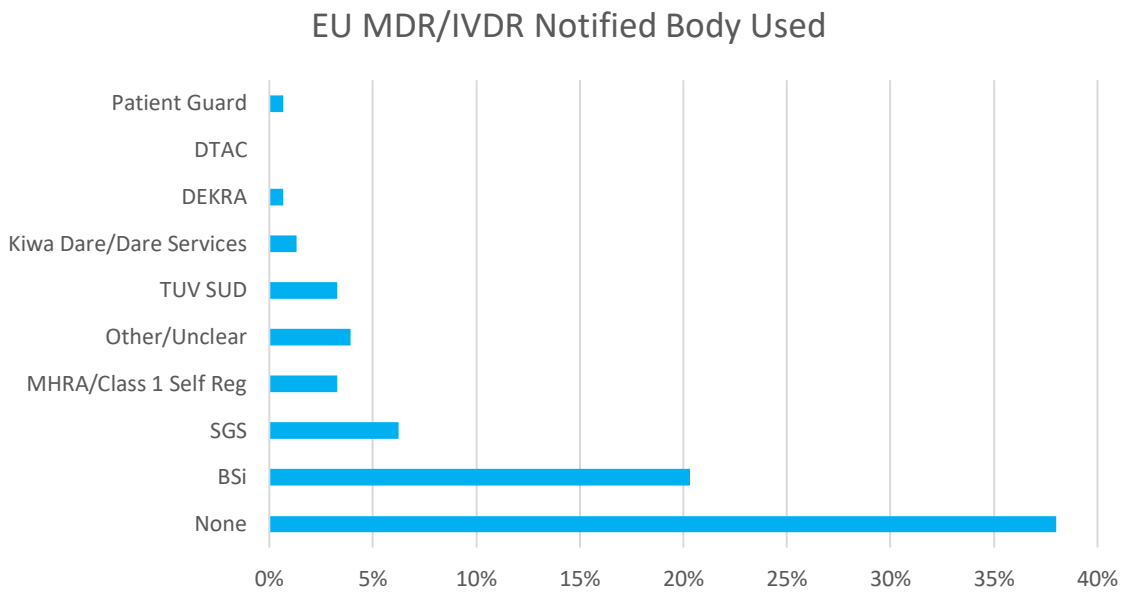


Figure 15 – The Notified Bodies the SME respondents identified that they were using/working with for their MDR/IVDR certifications. Note that the only NBs on this list are SGS, DEKRA, TUV SUD and BSI. Others are not NBs. This shows the lack of understanding of regulatory affairs within some of the HealthTech SMEs.

Insight 1 - Need for a clear regulatory roadmap

The current landscape is confusing with the Medicines and Healthcare products Regulatory Agency (MHRA) still developing the updated United Kingdom Conformity Assessed (UKCA) regulatory regime following their consultation that took place during part of this work. In June 2022 the MHRA published the government response to the public consultation on the future regulation of medical devices in the UK[11], and in October it was announced that there would be a 12-month extension to the implementation of the future Medical Device Regulations[12]. These new regulations are aimed to be brought into force by July 2024. At the same time, the EU MDR is also in a state of flux with Notified body accreditations and implementing legislation still taking place, as reported by MedTech Europe in their survey[13] indicating that over 85% of 500,000 devices previously certified under Medical Device Directive (MDD) or The Active Implantable Medical Device Directive (AIMDD) do not have MDR certificates. The situation for IVDs also remains complex, with amended transitional timelines being implemented in January 2022, extended the existing transition periods up to 2028 in some cases.

The demand for a clear Regulatory Roadmap for health and medical technologies to follow was ranked as the second highest challenge by SMEs, second only to funding in 80% of face to face roundtables. During HTRIP, we delivered two "Ask the Expert" webinars where SMEs had a chance to ask regulatory experts

[11] Consultation on the future regulation of medical devices in the United Kingdom, MHRA, https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom, accessed on 19/09/22

[12] Implementation of the future regulation of medical devices and extension of standstill period, MHRA, https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period, accessed on 19/09/22

[13] "Analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation", MedTech Europe, 14th July 2022

questions on regulation and regulatory pathways. There was considerable demand with 139 attendees for these webinars.

SMEs want this Regulatory Roadmap to be a clear, easy to follow, step by step guide of what they would need to do to achieve conformity in their chosen markets. Currently, there is confusion for SMEs of all sizes, including IVD and digital health/AI businesses. The most common comment was "What do I do, when?". Knowing "what to ask and when?" is a must and an initial reference point could save a considerable amount of time and effort.

"We have found the change in regulation from MDD to MDR challenging in so far as the implications of some of the new requirements are not explicitly spelled out."- North West-based Orthopaedic SME

SMEs expend a considerable amount of time, energy and resources dealing with the ongoing regulatory challenges. They feel these changes and the impact are not recognised by policy makers. Innovation is supressed and the introduction of new products that could improve patient lives are delayed as a consequence. For UK businesses, this also prevents early export potential being realised.

Adding to this, the threat, recognised by MedTech Europe in their report, is that 33% of medical devices are planned for discontinuation[5] due to the regulatory changes imposed. This removes choice for clinicians and their patients, which will impact directly on the UK and NHS.

"Biggest challenge and cost was the change from MDD to MDR and subsequent UKCA marking. It was impossible to locate a notify [body] party for almost 1 year. The cost of certification is a significant challenge to an SME." - East Midlands-based Ophthalmic and digital device SME

Regulation regarding digital health and software as a medical device (SaMD), apps and AI/machine learning is still evolving with much regional variation within the UK, often down to individual trusts. Digital Technology Assessment Criteria Standard (DTAC) does exist from NHSx[14] but it is not UK wide. The National Institute for Health and Care Excellence (NICE) have set up a multi-agency advisory service (MAAS) for AI and data-driven technologies[15]

[14] Now integrated with the Transformation Directorate at NHS England, information on this can be found here - https://transform.england.nhs.uk/blogs/nhsx-moves-on/

[15] Multi-agency advisory service (MAAS) for artificial intelligence (AI) and data-driven technologies, NICE, https://www.nice.org.uk/about/what-we-do/digital-health/multi-agency-advisory-service-for-ai-and-data-driven-technologies#find-out-more , accessed on 29/09/22

"We find it particularly difficult to find actionable practical advice relating to the areas of regulation and quality management in connection with software as a medical device." - Digital/AI London based SME

The global systems for regulating SaMD are still developing, and the UK is working closely with international organisations (such as International Medical Device Regulators Forum (IMDRF) and national partners (such as the US and Canada) to develop fit for purpose systems. Recently, MHRA updated their guidance[16] on software apps to include specific guidance covering symptom checkers, clinical calculators, devices which 'drive or influence the use of a device', and field safety warnings. These are welcomed, but this area needs further development.

Some SMEs also expressed their frustration around regulation and digital health, some said that the regulatory frameworks that existed were not always very well suited to software-based solutions so detailed discussions with the MHRA or FDA were required to navigate through the existing regulatory environments.

Post-regulatory approval, several European countries have developed reimbursement programmes in specific areas. Most notable of these is the German DiGA (Digitale Gesundheitsanwendung, translated as Digital Health Application) system which provides a contingent reimbursement scheme for low-risk apps. Following health technology assessment under the DiGA system, apps can be provisionally listed for prescribing for a 12-month period during which further evidence can be collected to show a positive healthcare effect. The app is fully reimbursed during this phase.

"The German Digital Health act is an example to look at as they provide a period in which companies can already sell their product while collecting necessary data. Also, the Digital Health Act gives a good indication of reimbursement options for digital health tools." - London based digital health SME

"The regulatory process is administratively and financially challenging for an innovative company. The administrative process takes significant time away from founders and the company's ability to scale and develop the business. There are only a few regulatory bodies and there is a significant backlog. Some are not taking new applications. The UKCA process isn't clearly defined and still in early process. There is not enough regulatory support for companies that believe in the process but are overwhelmed with the paperwork." - Pre revenue Medical Imaging/ultrasound digital AI South East-based SME

[16] Medical devices: software applications (apps), UK GOV.https://www.gov.uk/government/publications/medical-devices-software-applications-apps, accessed on 26/10/2023

Recommendations

1. **Develop a simple, easy to understand, Regulatory Roadmap (how to guide) for UK HealthTech SMEs**

That will be freely available to companies in the HealthTech industry and regulatory updated when regulations change. The MAAS[17] work may support SMES in AI and data-driven technologies, but broader support is needed.

2. **Continue to offer online high-level regulatory training through "one to many" and interactive webinars**

This would support the sharing and dissemination of the Regulatory Roadmap in the industry. This could include promoting the existing initiatives such as the HTRIP funded "Regulatory Roadmap" series, which has had thousands of views. These online webinars included talking head, pre-recorded training sessions and also interactive "Ask the Expert" webinars. In order to keep the industry up to date on the latest regulatory changes this training would need to be continually refreshed[18]. We suggest that this training should be refreshed on at least a quarterly basis as the regulatory landscape evolves and be available to all

3. **Develop an online high level training programme on digital health technologies**

This would follow a similar approach to the training already offered artificial intelligence through this HTRIP programme but with a specific focus on digital health e.g. focusing on areas such as AI and Software as a Medical Device (SaMD).

Insight 2 - Importance of external regulatory advice

With 90% of SMEs depending on external regulatory consultants, it is clear this needs to be readily available to the whole ecosystem so they have qualified expertise to rely on. This is symptomatic of the current regulatory landscape, as mentioned above. The lack of clarity drives SMEs towards those who understand the complexities of the regulations and the detailed changes. As one put their needs simply: -

"Access to quality assurance consultants." - Wales based IVD SME

HTRIP identified 132 external regulatory consultants as part of the grant application process, and this could be a valuable resource for all UK SMEs to find a local provider with the right expertise quickly and efficiently.

The primary need from external consultants is general/strategic direction which was mentioned by 42% of surveyed SMEs. This is important to set them in the right trajectory and give them the confidence in producing the right technical documentation and working to the right classification.

[17] Multi-agency advisory service (MAAS) for artificial intelligence (AI) and data-driven technologies, NICE, https://www.nice.org.uk/about/what-we-do/digital-health/multi-agency-advisory-service-for-ai-and-data-driven-technologies#find-out-more , accessed on 29/09/22

[18] The ABHI delivered "Regulatory Roadmap" training can be found here https://www.abhi.org.uk/what-we-do/informing-regulation/the-regulatory-roadmap/ , accessed on 29/09/22

There are digital tools like Reg Metrics[19] that can help identify an individual SME's regulatory direction. These tools specifically help companies work through the regulations by asking structured questions and in-line guidance. It is designed to work with companies who understand their technology but may have knowledge gaps in regulation. The quality of the output clearly depends on the quality of the input and although targeted to any SME, as outlined in the product T&Cs, "*the usage of the RegMetrics tool is not intended to be used as a substitute for consultation with legal and regulatory professionals and authorities*". Other tools such as Syntacog are in development for regulatory markets beyond UK, EU, USA and Australia [20] but the HTRIP project team have not had any discussions with the Syntacog team so cannot comment.

Help with EU MDR CE marking including MDD transition is the second largest need from 12% of SMEs and in the current landscape such a high dependence on external providers is to be expected, with higher classification of MDR and IVDR products that previously may have been self-certified under the MDD/IVD. These changes require detailed gap analyses and the production of more comprehensive technical documentation which often cannot be performed in house, due to a lack of internal capability.

External UK-based consultants, in addition to strategy and guidance, are used for most other aspects of regulation and technical documentation development with 6 to 9 topics mentioned per company. External, non-UK consultants are used primarily for international registrations including local expertise and contacts with the national regulator. This applies particularly in the USA with the FDA, who are seen as open and accessible for advice. By comparison, the MHRA is not viewed as having this approach and an SME is more likely to pay an external consultant for guidance. This is because the current regulatory system prevents Competent Authorities and Notified Bodies/approved bodies from acting in any way that could be considered consulting.

Recommendations

4. **Innovate UK to repeat the HTRIP programme of funding for SME regulatory support**

To continue to support UK SMEs, at least until the UKCA, and MDD to MDR uncertainty is resolved. In the future, this funding could also be focused on specific areas that struggle with regulation such as Digital Health or on a particular market, such as USA regulation.

5. **To improve the UK ecosystem for SMEs, encourage the MHRA to be more accessible for guidance in the manner of the FDA in the USA.**

6. **Publish and maintain a free to access directory of UK based regulatory consultants**

Which includes online guidance on for innovators around how to engage with regulatory consultants.

In view of the reliance on external regulatory consultants and the identification of over 130 regulatory consultants as part of the HTRIP programme, it is proposed that this list be published in perpetuity in a digitally accessible format. This shall be kept updated as an on-going resource for all UK companies to ensure relevance. ABHI, as partners on this project, have offered to take a lead on this. BIVDA currently has a publicly available list of organisations offering UK Responsible Person services which could be linked to such a database.

[19] Can be accessed via:- https://www.reg-metrics.com/

[20] Can be accessed via:- https://www.syntacog.com/medical-devices

Insight 3 - Importance of In-House QA/RA Expertise

A significant 59% of SMEs have no in-house QA/RA expertise (Figure 12). This is a major issue in a regulated environment with frequent quality and regulatory decisions to take, and the annual audit cycle to prepare for and follow up. This obviously fuels the need for external regulatory support, which can be costly and difficult to use on a routine basis for annual inspections or any unannounced audits leaving an inexperienced SME exposed to tougher outcomes and remedial demands.

Of those with in-house personnel, on average there are only 1.5 persons per company despite the growing regulatory burdens and changes. More mature SMEs are more likely to have in-house expertise and an average of 2.2 people/company. With 59% lacking in-house expertise, these averages indicate a significant staffing impact for an SME.

For young SMEs, the need for a fulltime equivalent may be too much, but for manufacturing and on the market companies these numbers are probably lower than desired due to the difficulty recruiting staff, which is covered in the Skills Challenges section.

For those with in-house experts, there is an average of 15.0 years' experience, which is a retention and reward challenge to keep these people from switching to external consultancy or an alternative regulatory environment. As expected, these individuals have good UK, EU and USA experience, but across all SMEs just 16% know about FDA regulations.

Recommendations

7. **Encourage more UK universities to offer regulatory training for Life Science and related courses**

To bring more expertise into all parts of the UK life science ecosystem, regulatory training must be a priority for universities to produce graduates in regulatory science. It should be offered as elective modules within technical degrees and a mandatory or shorter 'industrial/regulatory knowledge' course that introduces students to these core skills.

There is ongoing work taking place by TOPRA to develop professional qualifications in regulatory affairs specifically for the MedTech sector, which could also be utilised to increase the number of individuals in this space.

Insight 4 - Growing Attraction of USA FDA Registration

In direct comparison with the regulatory uncertainty in the UK and EU, the USA FDA system utilising predicate devices (510(k)) is an increasingly attractive route for earlier access to market in a stable environment. This applies especially to younger digital companies who have no existing establishment, manufacturing, distribution channels or customs to contend with. Reimbursement, innovation adoption and market size compound this view.

17% of companies now see the USA as their key target market which is a concern for those involved in fostering the UK Life Science Ecosystem where there is a risk of companies physically moving to the USA. In fact, a digital SME founder who attended the Edinburgh roundtable has actually done just that, taking their SME business with them. Such a perspective would have been difficult to contemplate a few years ago, but

UK and EU regulatory instability and transparency, lack or loss of regulatory harmonization across the region, the free-market of Notified Bodies/Approved Bodies, lack of competent authorities commitment to specific approval/submission dossier timelines, absence of direct channels to communicate and obtain guidance from the regulator alongside funding challenges, has clearly impacted the HealthTech ecosystem. When considering the primary Target Market challenges, it can be expected this trend will continue for the foreseeable future.

The FDA is recognised as providers of valuable and openly accessible guidance to make the regulatory pathway and market entry much clearer. By comparison, this is generally not seen as an MHRA or Conformity Assessment Body service function, leading to early use of expensive external consultants.

"The US is the world's largest medical device market and has a much easier access facility through the FDA. This choice was a big advantage when speaking with investors and partners as they appreciate the significant opportunity in the US market." - Northern Ireland-based Neurology SME.

Recommendations

8. **Develop the UKCA system to recognise EU and USA regulation approvals in its alignment**

In the medium term through expansion of IMDRF/MDSAP programmes to make the UK regulation more attractive to all SMEs.

Insight 5 – Notified Bodies (or Approved Bodies) are a major challenge

Previous work from Medtech Europe[1] has identified up to 30% of SMEs have no access to an MDR-designated Notified Body and a similar situation was seen in this work.

Access to a notified body (NB) or approved body (AB) Conformity Assessment Body is a major challenge and the frustrations and comments indicate this is still significant with 35% or more having no UK or EU body and 87% lacking one for accessing markets outside of UK/EU. This is also reflective in the IVD sector where there are only 7 Notified Bodies designated to the IVDR.

"None yet, we can't find a NB to take us on board!" - South East-based Orthopaedic SME

"Currently unknown due to inability of possible incumbents to quote for the full process There is a very long waiting list and we are still discussing with them." - Musculoskeletal North West based SME

The inability to engage a designated Notified Body is reported frequently by SMEs, which is both costly and time consuming. Even once a NB/AB is contracted, there are significant audit and approval delays impacting on cash flow, product launch and revenue earning capability. The widespread perception is the situation is getting worse post-Brexit and pandemic.

"The lack of Notified Bodies and resources available to support the regulatory requirements under MDR is equally problematic. Our Notified Body offered to audit us to MDR in 2024. We will long be bankrupt by then unless this changes." Wales-based surgical hardware SME

"This is very different from an environment perspective to 5-10 year ago when Assessment Bodies would make space to support Start Ups and SMEs." South East-based Neurovascular SME

"There is lack of timely response and adequate resources at regulatory service providers. We have noted a major change in behaviour away from client centric approach of Notified Bodies." South East-based Surgical SME

The dominance of BSI is apparent for HTRIP grant recipients that responded to the survey with BSI supporting 30% of them for UKCA and 20% for EU MDR. Notably, BSI does have a presence in both the EU market for MDR/IVDR conformity assessments and in Great Britain for UKCA conformity assessments. This may be representative of why they survey indicates them being used at a more frequent level. DEKRA also have both designations, however their UKCA designation was not yet completed at the time of the survey.

From the survey, SGS would appear to be the only current alternative (12% UK & 6% EU) with certain accreditations for individual classes even more restricted, however UL, DEKRA and TUV SUD are also designated to conduct conformity assessments. Overall, SMEs are telling us that they believe this lack of competition is not healthy for the UK, and the development and growth of all SMEs. They also tell us that they are concerned that prices are rising and timetables are set unrealistically by CABs to the detriment of the UK HealthTech community.

"Not many to be able to choose." - East of England-based Diagnostic Equipment SME.

"The generally reduced number of Notified Bodies enables pricy and inefficient oligopolies to form, creating a huge entry barrier for small start-ups with reduced financial means." London-based IVD SME

Recommendations

9. Support the designation of more UK based CABs to overcome current delays and monitor the current availability of existing services.

This should include supporting new UK based NBs/CABs and actively encouraging more EU NBs to have a UK base (e.g. TUV/DEKRA) to conduct UKCA conformity assessments. Including actively monitor the availability of CAB/NB services to the whole range of HealthTech SMEs through the MHRA and others to ensure a good flow of assessment support for UK and EU registrations, including QMS assessments.

The EU Medical Device Coordination Group recently published a list of recommendations to address the 'significant and urgent challenges' arising following the MDR and IVDR transition[21]. The MHRA and NBs/CABs should consider the recommendations within for the UK regulatory ecosystem to improve access for HealthTech SMEs.

[21] MDCG Position Paper: Transition to the MDR and IVDR, Notified Body capacity and availability of medical devices and IVDs https://health.ec.europa.eu/system/files/2022-08/mdcg_2022-14_en.pdf, accessed on 29/09/22

Funding Challenges

HealthTech innovation continues to advance and consequently there is always a cohort of new SMEs being created or spinning out of universities with new technology. Developing new technology is costly and time consuming, demanding significant levels of funding to take an innovation to market.

Beyond regulation there are many other challenges but there is a strong and direct link between regulation and funding, with some reporting investment being contingent on having regulatory approval.

"Regulatory uncertainty causes financial uncertainty." Plymouth-based SME.

Across all roundtables, funding ranked as the biggest issue (90%), surpassing regulatory challenges at such a difficult time. It is notable that at the Harlow roundtable, with delegates from the Cambridge part of "the golden triangle", funding was still considered the biggest challenge.

The HTRIP programme focused on the regulatory landscape for all HealthTech SMEs and companies were able to apply for up to £30,00 grant support. Of survey respondents (who were the recipients of this grant funding), 56%were pre-revenue and 44% were revenue generating. Appendix 1 gives details of all grant applicants which shows that 29% of applicants had products on the market showing that there is a need for regulatory support not only in product development but also for commercialised products. The changes in regulation are therefore clearly impacting companies at all stages of development including those already selling their products.

Data and findings

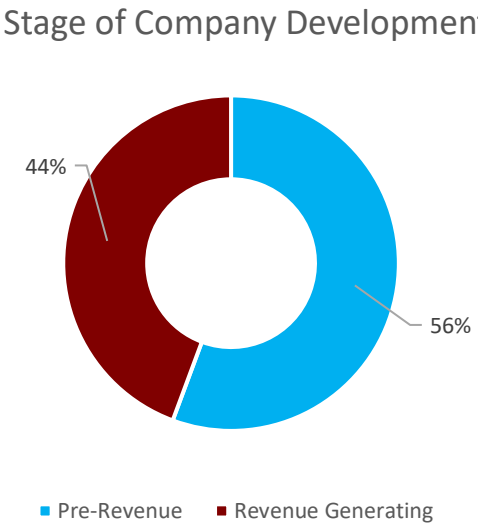


Figure 16 - Breakdown of HTRIP grant recipients (survey respondents) in terms of revenue development stage

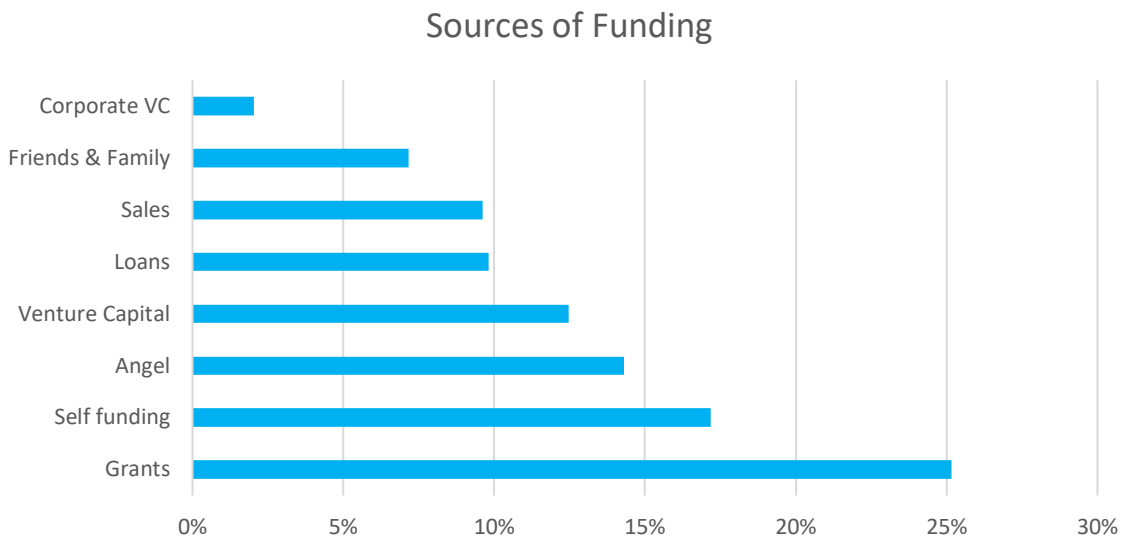


Figure 17 – Sources of funding for HTRIP grant recipients (survey respondents)

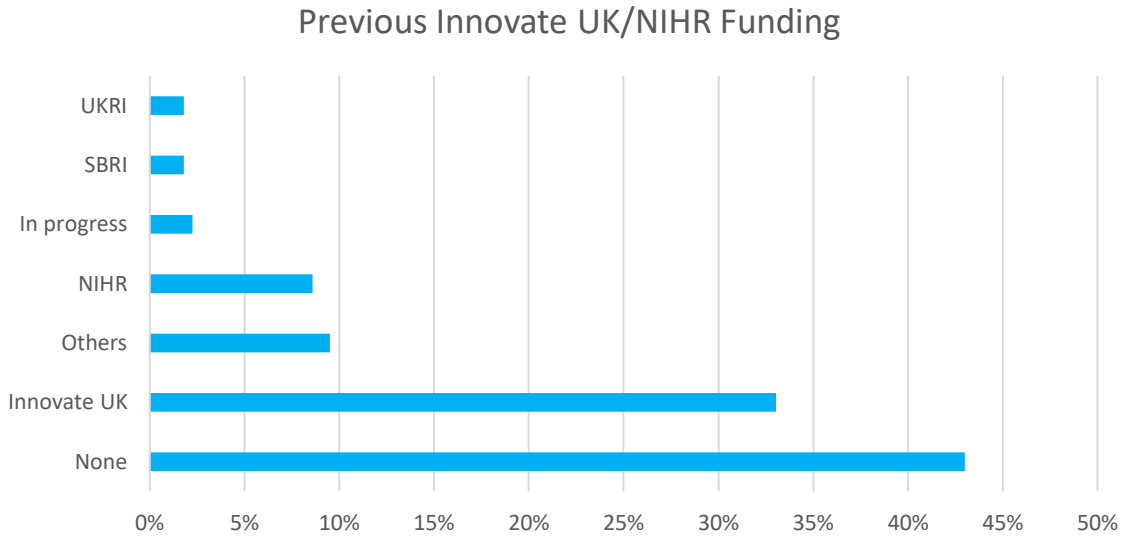


Figure 18 – Survey respondents answers to the question "Have you won IUK/NIHR funding before?"

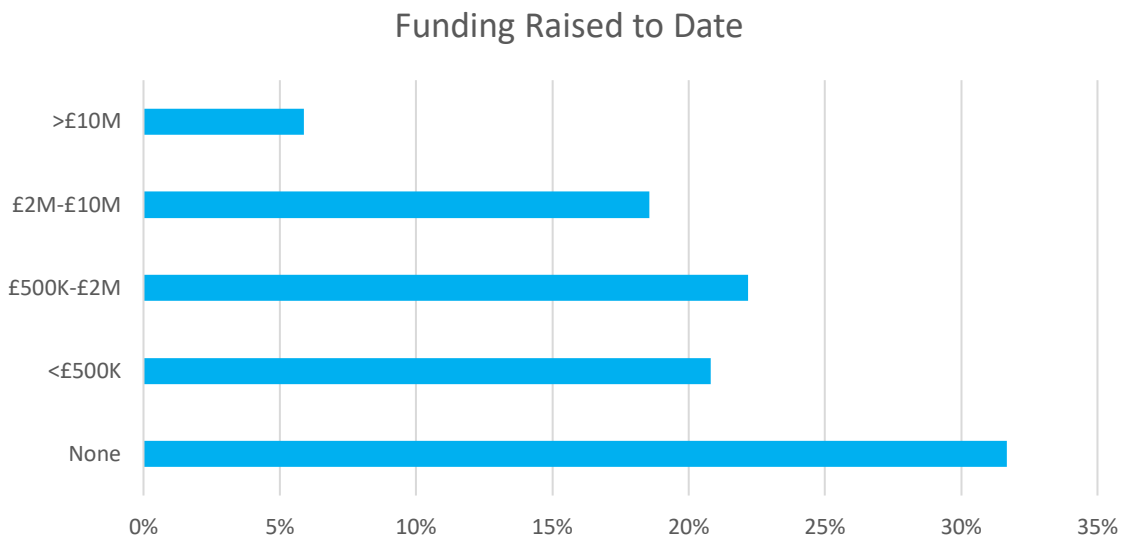


Figure 19 - Survey respondents answers to the question "Have you fund-raised to date and if so, how much?"

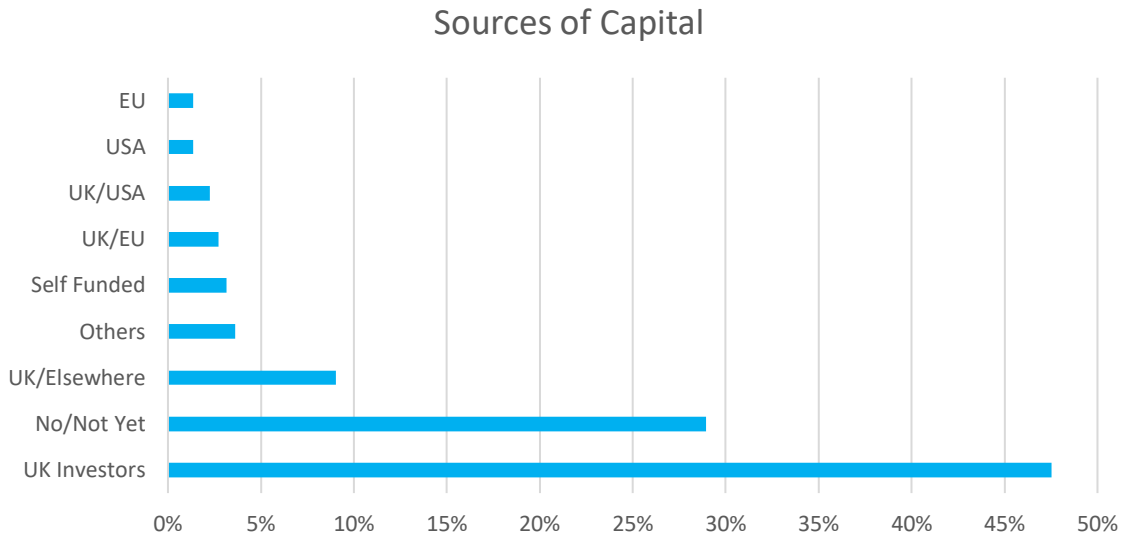


Figure 20 - Survey respondents answers to the question "Did you raise this capital from UK investors? If not, why did you seek capital elsewhere?"

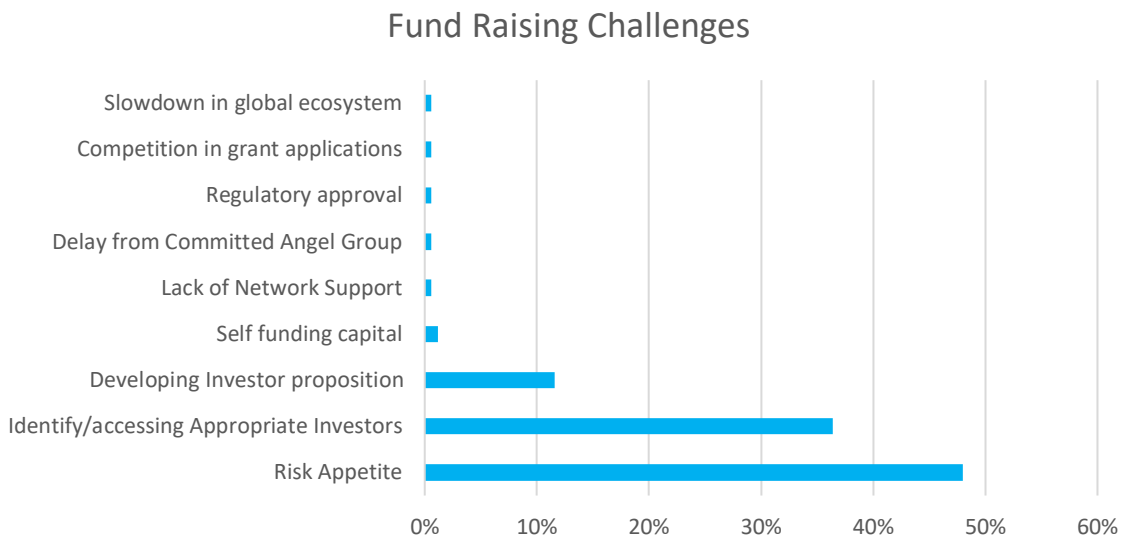


Figure 21 - Survey respondents answers to the question "Did you raise this capital from UK investors? If not, why did you seek capital elsewhere?"

Across the broad range of SMEs there is typically a mix of funding, using 2.2 different sources on average and almost all will be looking for funding is the next 6 to 24 months. 25%used grant funding and this is the largest single source, highlighting the importance especially to the pre-revenue SMEs.

The second most common source is self-funding, as mentioned by 17%, which for early-stage S MEs is probably personal funds and for more established companies from internal revenues. A further 10% specifically mention sales as a funding source.

Private investment from Angels, Venture Capital, Loans, and Corporate VC in total account for 39% of funding sources underlining the importance of a good mix of capital for SMEs.

Insight 1 – Public funding schemes are too complex for SMEs

The simple application process for HTRIP serves to make this an exemplar for Innovate UK and other public bodies. The approach is totally compatible with an SME need for size of grant, ease of application, speed of decision and prompt payment. Funding needs to be accessible across all demographics and not require SMEs to be experts in bid writing or divert resources to hire external bid writers. It is significant 43% of SMEs were new to Innovate UK or NIHR support.

The gratitude for the HTRIP programme is outstanding and sends a strong message for the future direction of effective and valuable support.

"Thank you very much indeed. The process was superb." – London-based SME developing software as a medical device

"This Regulatory Grant is a massive help to [us] ...and one of the rare funding awards available. It will mean so much in supporting our growth not just in financial terms b-t more importantly in time and expertise. Thank you." Yorkshire & Humberside based Orthopaedic Manufacturer

"Congratulations to all involved in the HTRIP initiative. It strikes an excellent balance, I believe, between cost, administrative burden to grant holders and benefits delivered to both recipients and the UK overall." South East-based Single-use technology SME

"Thank you for the regulatory award - it really helps with all the uncertainty there currently is in the system." Northern Ireland-based digital assistive technology SME

Grant funding from public bodies is very welcome but the funding ecosystem is often seen as complex and confusing with many names, sources, rules and low success rates. Completing an application can be an extremely lengthy, painful and sometimes costly process which may deter some from applying. As reported at the London roundtable, the lack of feedback after a time-consuming application is challenging, as is repeated unsuccessful applications.

Competitive schemes may suit the needs of responsible control of public funds, and they may suit well-resourced larger companies, but for HealthTech SMEs they present a major challenge that can distort a company's aims with the "valley of death" ever present especially for pre-revenue businesses.

A difficult application process can be complex and time consuming, taking 6 to 9 months and often require external help to produce the paperwork, which can be costly with no guaranteed return on this investment.

"Grant processes need to [be] better tailored to align with commercial company-needs and shift from treating companies like academic institutions" - South East based Digital SME

"Seem to be more suited to spin outs with academics who can "play" the grant application game." - South East-based IVD SME

Specifically, some schemes receive more criticism than others:-

- Some SMEs (especially those recently spun out of universities) cited that UKRI didn't understand SME challenges as well as they could. Some were concerned that they struggled to engage.
- There was concern that the NIHR funding rules requires companies to get UKCA approval first whereas some SMEs may want to have CE or FDA approval as their first markets are not planned to be in the UK.

Recommendations

10. **Funding bodies should review all HealthTech funding schemes and consider "fast start" funding and staged funding as an option.**

To make it more suitable for SMEs to take up the opportunities presented, this should include a review from application to award and the stages in between. The HTRIP funding award process could be used as a template for rapid SME award to ensure more successful outcomes and support for growth of the UK ecosystem. It should be considered in communication and competition design that SMEs may not be familiar with how public funding competitions work.

To support SMEs with a larger number of small, up-front grants, to support with feasibility, business case development etc and follow-on larger funding with a more rigorous process available to a smaller number of the initial applicants.

Insight 2 – There is a perceived lack of public funding for later stage innovations

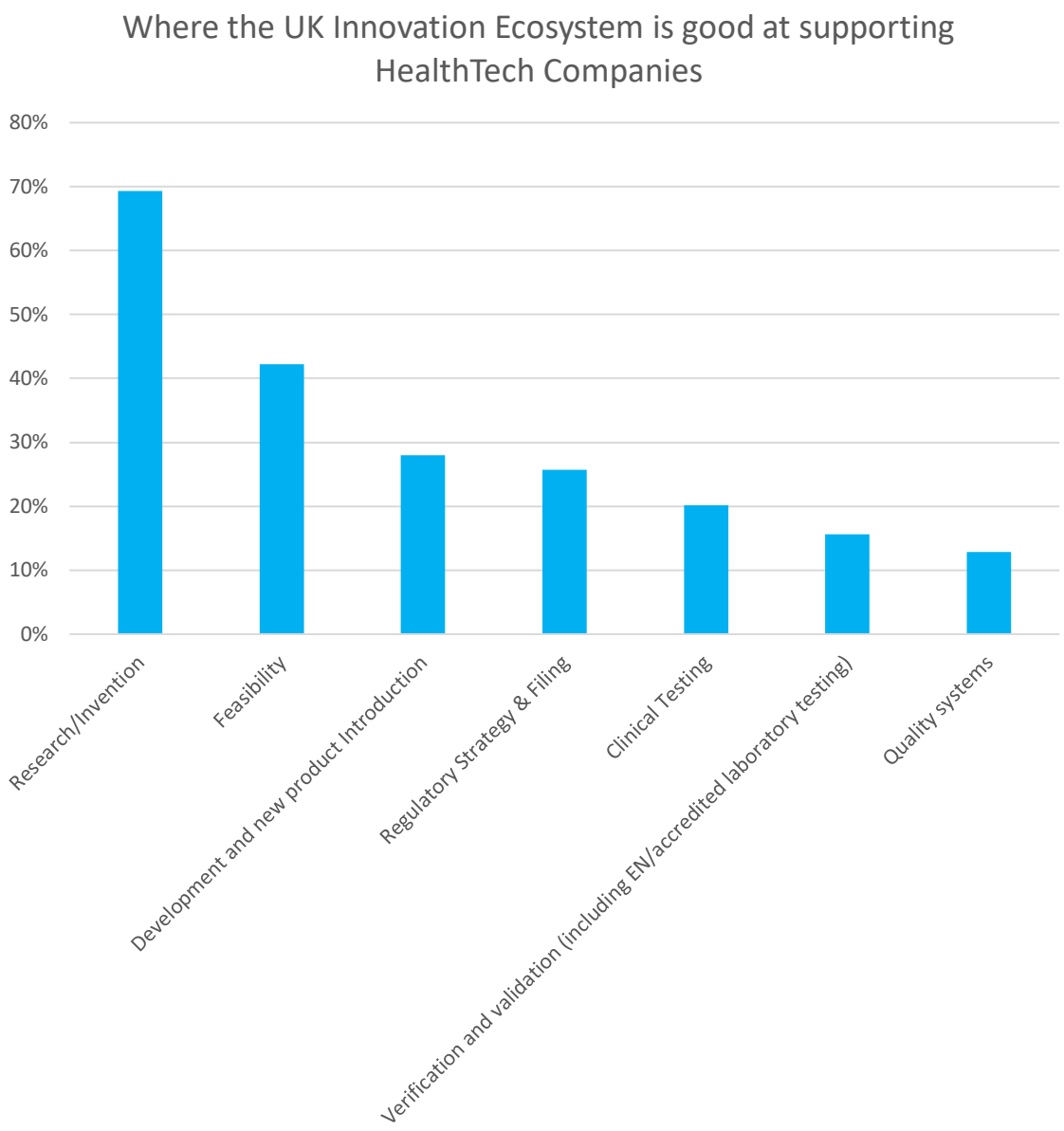


Figure 22 - The response to the survey question 'From the stages below, which ones do you feel the UK innovation ecosystem is particularly good at supporting HealthTech companies with?"

SMEs see the UK as strong in the early stages of innovation and university/academic research, with development well supported, but as products move towards commercialisation and adoption public funding support evaporates.

As one Roundtable delegate expressed it: - "there is a dead end after trials."

One experienced SME summarised the overall funding scenario: -

"……No one is funding the bridge across the valley of death: Manufacture to ISO13485:2016." East of England-based Cardiovascular & digital device SME.

This has been a long-term problem for the UK nationally, whereas other countries, most notably the USA, have taken British inventions and supported development and scale-up.

The problem is compounded by market access and NHS adoption, which in itself is a massive challenge for SMEs. National Institute for Health and Care Excellence (NICE), NHS Accelerated Access Collaborative (AAC), MedTech Mandate, the NHS Innovation Service and its predecessor HealthTech Connect are all attempts to resolve this for a select few innovations, but even here funding support is uncertain.

An SME with AAC support for a high-profile project still has serious funding concerns and faces a "cliff edge" in funding within a year with no certainty of reimbursement or further funding. This company has grown UK employment from 10-15 to 100 within a year or so, so this threat is significant. This real-world example demonstrates the risk that is associated with being an SME in the MedTech sector.

With the strong academic and university influence of the London-Oxbridge golden triangle this 'front loading' of early-stage funding penalises other regions to the extent that at the Birmingham Roundtable it was highlighted there is a drain of personnel towards the triangle due to the close proximity of this region, to the detriment of SMEs outside this area.

"A lot of investment has been put into the Golden Triangle however for structured growth and sustainability this needs to be consistent across other areas." - South East-based Neurology SME.

Recommendations

11. **Funding bodies such as Innovate UK and NIHR should be encouraged to cover across the entire development cycle for health technologies, funding not only "good projects" but also "good companies".**

This should be monitored by an independent body over a period of 5 or more years to ensure support is providing impact. Good companies would need to be defined but we would suggest potential for growth, export potential and societal impact is a good starting point.

12. **AHSNs and their devolved equivalents, should be encouraged to focus more heavily on the market adoption, and commercialisation end of innovation**

This would include market introductions and reduce the focus on earlier academic to early-stage clinical investigations. This may require a re-balance of funding between government departments i.e., AHSNs are currently funded two thirds from NHS England and one third from the OLS.

13. **Evaluate geographical variations in grant funding**

Rebalance through positive action, if required, to ensure levelling up is part of the programme for a UK-wide successful ecosystem.

Insight 3 – The need for stronger participation of the Life Science investor community

43% have sought funding in excess of £2 million, which is beyond most public schemes. With the demands of regulation, testing, scale up and adoption, we believe that there can be few HealthTech SMEs, outside perhaps the digital space, that can achieve successful returns without significant capital resources of £2 million or more. For this reason, it is essential the UK ecosystem has a proactive life science investment community for all stages of funding.

Of those raising capital, 66% of SMEs achieved this with UK investors but despite this, most see UK investors as very difficult.

> "However, our current raise of £2m is overseas since all the UK investors has become non-responsive of medical devices which doesn't have a regulatory approval." - London-based Digital Neurology SME

Investor 'risk appetite' is the major obstacle for raising capital, as mentioned by 48% of those with investor experience. However, it is likely this is directly linked to the 36% who also find it difficult to identify and access appropriate investors. Chances of success are further limited by the difficulty, or lack of experience, in developing the investor proposition or pitch.

Whilst most experience is UK-based, those looking to the USA see another attraction in that US investors are more approachable and prepared to take on more risk. It makes sense to build an investor community that includes US associates especially for those that see this as their primary target market.

Mentioned by some is the loss of EU investors post-Brexit, which has impacted on the overall landscape.

From the SME perspective, dilution of ownership and loss of control are factors that need addressing in the context of adequate resources to achieve success.

Some SMEs suggested less funding is needed if a collaborating clinician or NHS Trust was actively involved with an innovation as with NHS access the clinical investigations can be established cost-effectively.

Recommendations

14. Create and share a directory of investment companies that are interested in engaging with HealthTech companies

Actively mobilise the investor community, primarily in the UK and USA, who are interested in life sciences/HealthTech and create a directory of interested angels, VC's and other funders and it can continue to be kept up to date. It is important to determine how this should be managed so it is a long-term initiative.

15. Support UK SMEs through pitch training

To enable UK SMEs to have the greatest chance of receiving funding from investors. We should sponsor training schemes to work with UK SMEs. A number of organisations are available in the UK that could support this training, but we recommend that this training is provided by those who are experts in both HealthTech and HealthTech funding.

16. Incentivise schemes with public:private co-funding to extend resources and share risk.

Innovate UK has recent examples of funding where has matched investor funding at a 50% rate, which can reduce risk for investors and enable them to invest in companies and technologies that may be outside of their existing risk appetite. We suggest a review of the success of these schemes and, if impact is positive, IUK should use some its budget to incentivize schemes like this.

17. Increase the involvement of clinicians in innovation for 'best value' funded programmes through NHS Trust Innovation Officers

SMEs need access to clinicians, motivated to champion new innovations that they believe are truly needed. The appointment of Chief Innovation Officer positions on each NHS Trust Board) could drive this and aid adoption of new, life changing HealthTech. Generating clinical papers and citations is always valued and raises the profile of the collaborating trust. Ultimately there may be a mutually beneficial commercial arrangement between SMEs and the NHS, which could include research personnel funding and royalty payments upon a successful product launch.

Sustainability Challenges

Healthcare is recognised as contributing up to 5% of global warming carbon emissions. The NHS has taken a lead and set out plans to achieve net zero by 2045, or earlier[22]. NHS England has set out supplier roadmaps and the devolved nations have similar plans, all of which require HealthTech providers to produce their own Carbon Reduction Plans (CRP). These started with larger suppliers and SMEs with contracts worth over £5M who need to have a CRP by April 2023. Other SMEs will see increasing impacts of these policies, and by 2030 will be required to have published CRPs, targets, and annual reporting in order to be a supplier to the NHS.

This is a whole new challenge for HealthTech SMEs at a time when they have many other demands on their resources. From the NHS engagement to date and the wider publicity regarding climate change including COP26 in Glasgow, most recognise the importance of sustainability and environmental issues, with survey respondents scoring an average of 4.0/5 when asked "How important do you rate the impact of sustainability & environmental issues in the current and future operations of your business?" (Figure 23).

With sustainability and environmental issues being relatively new, research such as this into the views and position of the industry is vital'

Data and findings

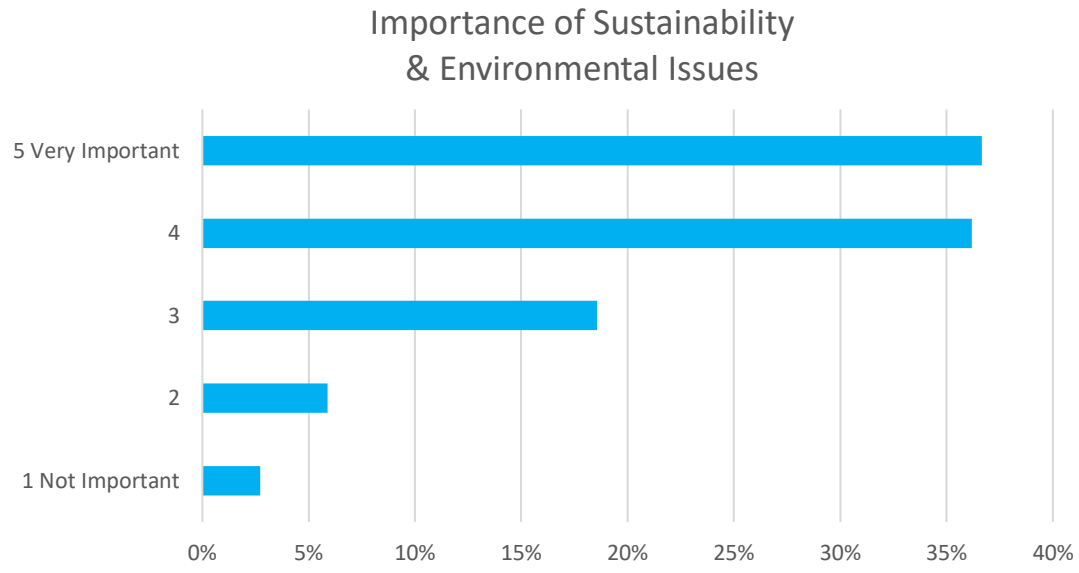


Figure 23 - The importance of sustainability to companies responding to the survey question "How important do you rate the impact of sustainability & environmental issues in the current and future operations of your business?". The scale was from 1-5.

[22] Delivering a 'Net Zero' National Health Service, NHS, 2020. https://www.england.nhs.uk/greenernhs/publication/delivering-a-net-zero-national-health-service/ accessed on the 28/9/2022

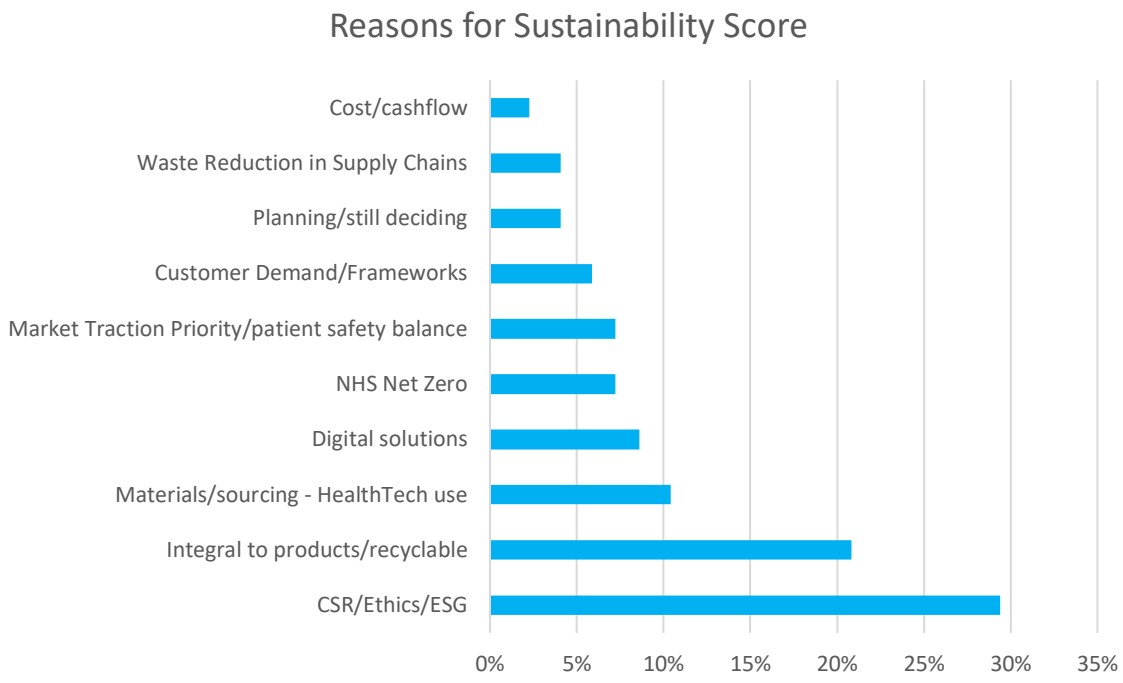


Figure 24 – The reasons given by survey respondents as to why they scored as they did (1-5) from the previous question/graph.

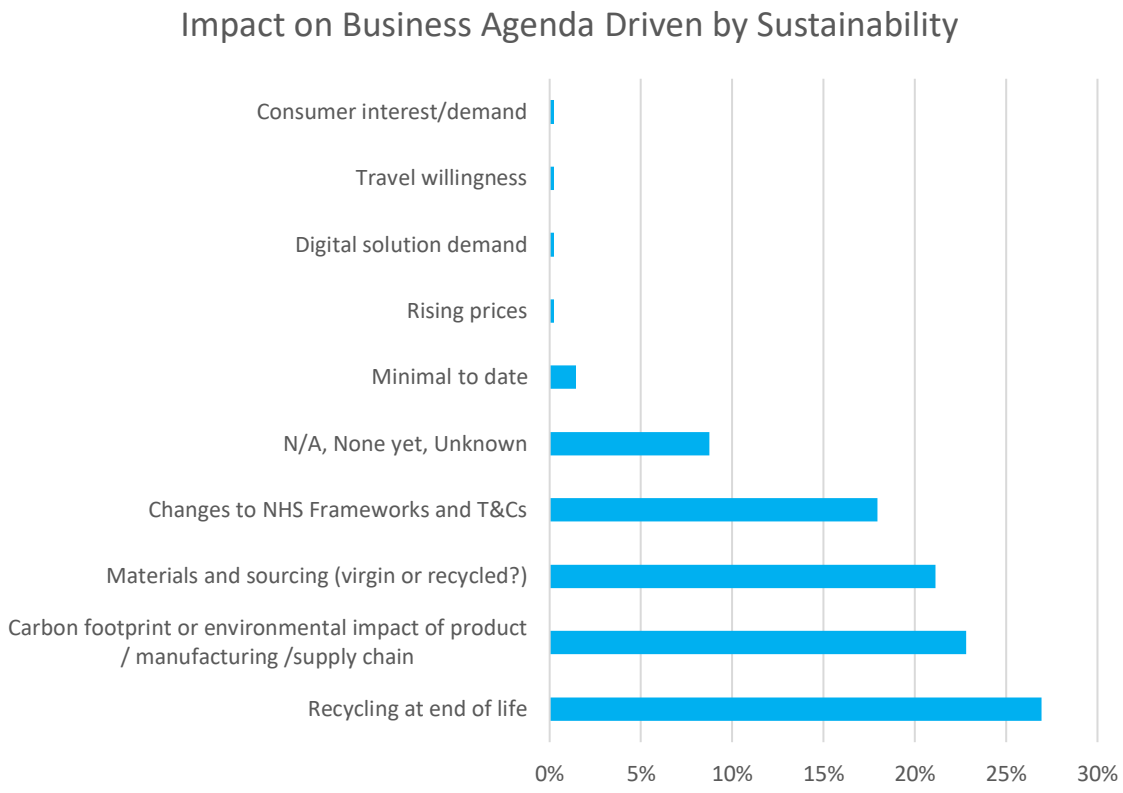


Figure 25 – Where survey respondents are seeing an impact on their business from sustainability.

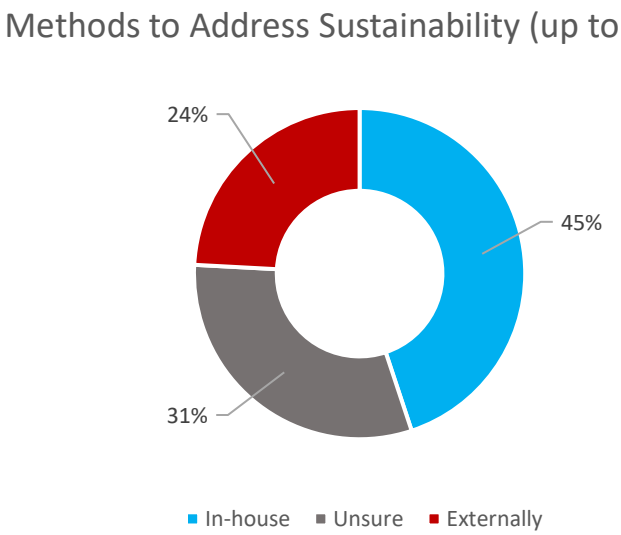


Figure 26 – Survey respondents answers to the question "As this becomes more critical up to 2030, how would you address this challenge?".

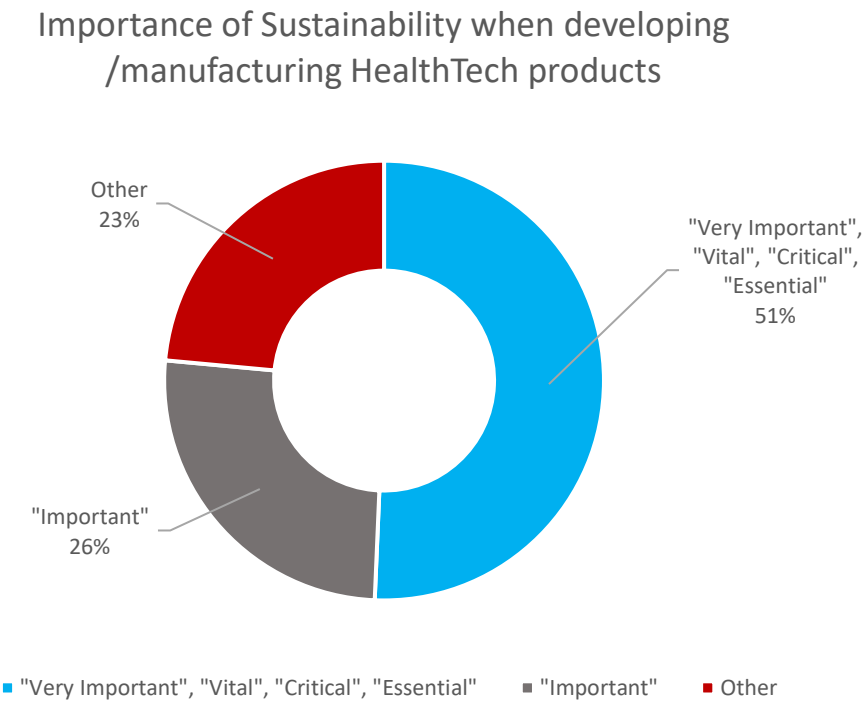


Figure 27 - Survey respondents answers to the question "How important do you think that sustainability should be taken into account when developing and manufacturing HealthTech products? Why?".

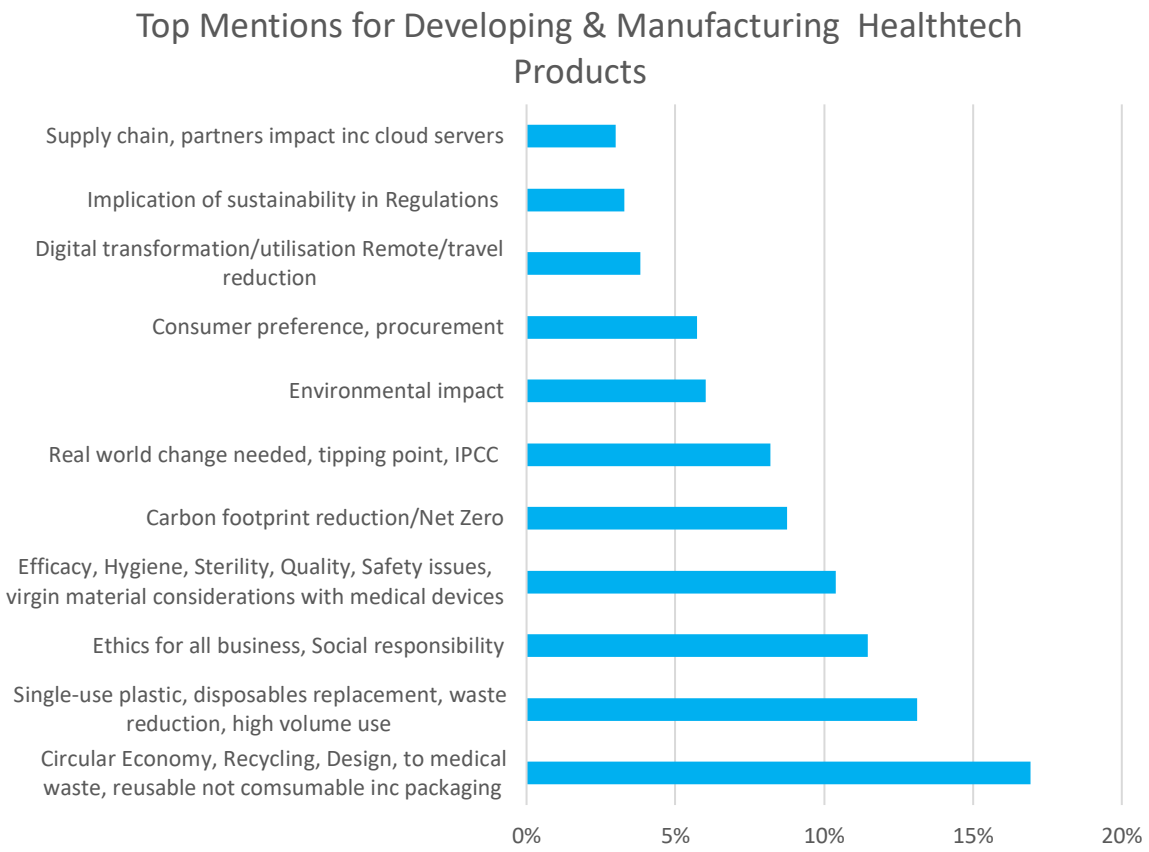


Figure 28 - Survey respondents answers to the question "How important do you think that sustainability should be taken into account, when developing and manufacturing HealthTech products? Why?".

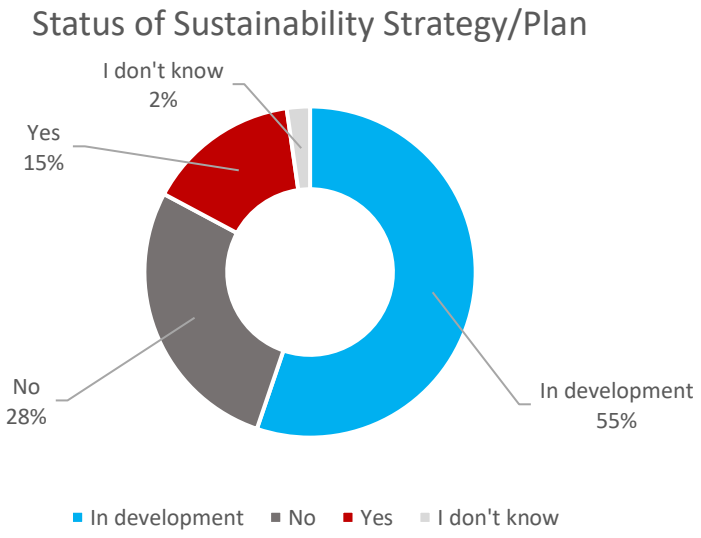


Figure 29 - Survey respondents answers to the question "New frameworks of healthcare providers encourage a sustainability plan. Does your organisation have a sustainability strategy?"

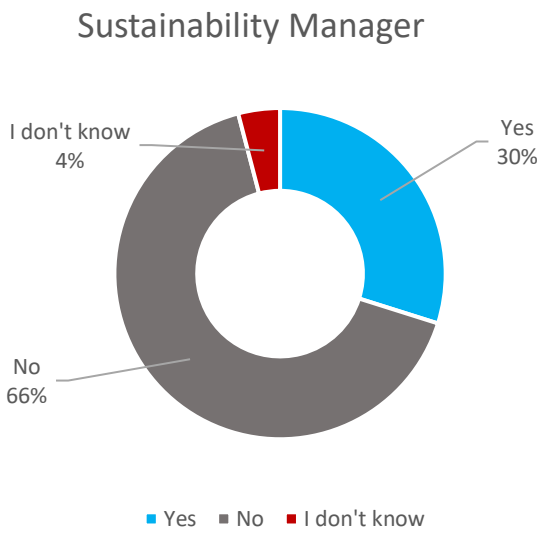


Figure 30 - Survey respondents answers to the question "Does your organisation have a department or individual who manages sustainability actions?"

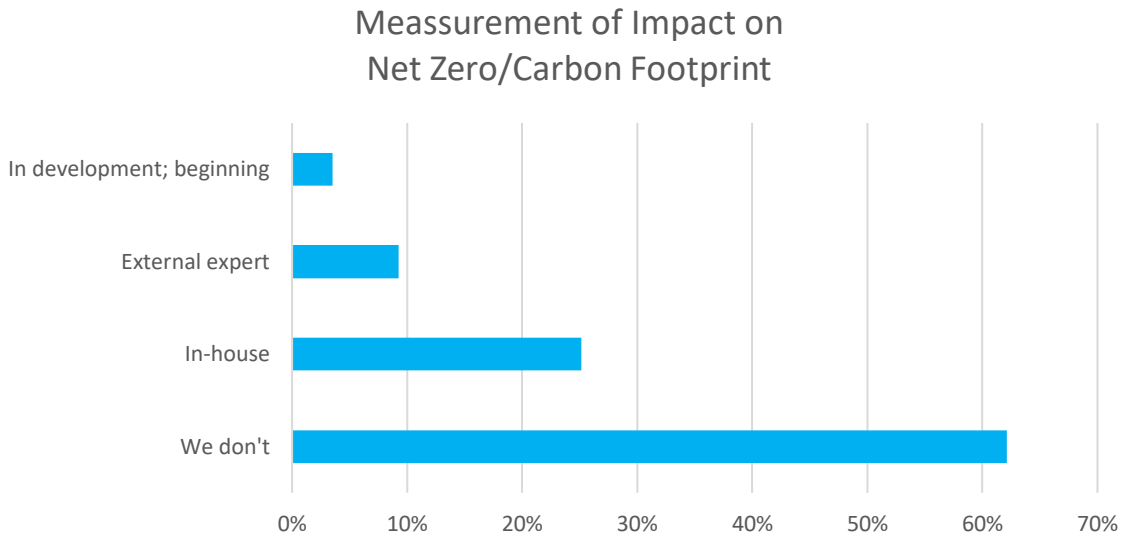


Figure 31 - Survey respondents answers to the question "How do you measure your impact on net zero/carbon footprint?"

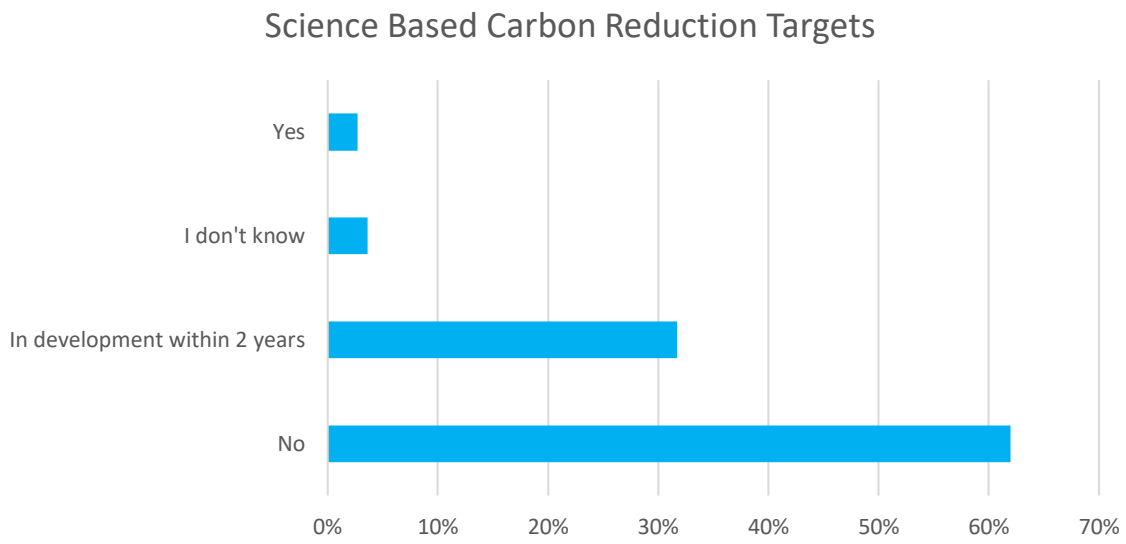


Figure 32 - Survey respondents answers to the question "Does your organisation have science-based carbon reduction targets?"

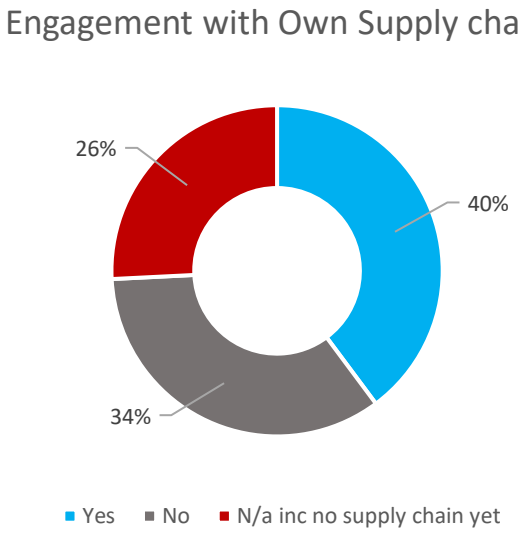


Figure 33 - Survey respondents answers to the question "Are you currently engaging with your supply chain on the topic of sustainability?"

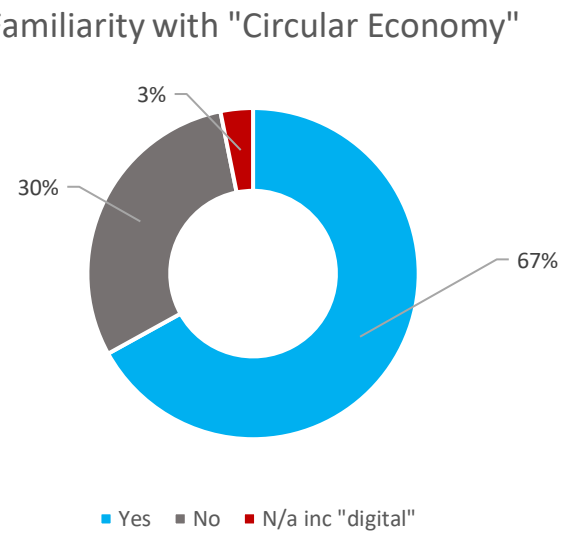


Figure 34 – Survey respondents answers to the question "Are you or your organisation familiar with the term circular economy and the role it plays in improving sustainability?"

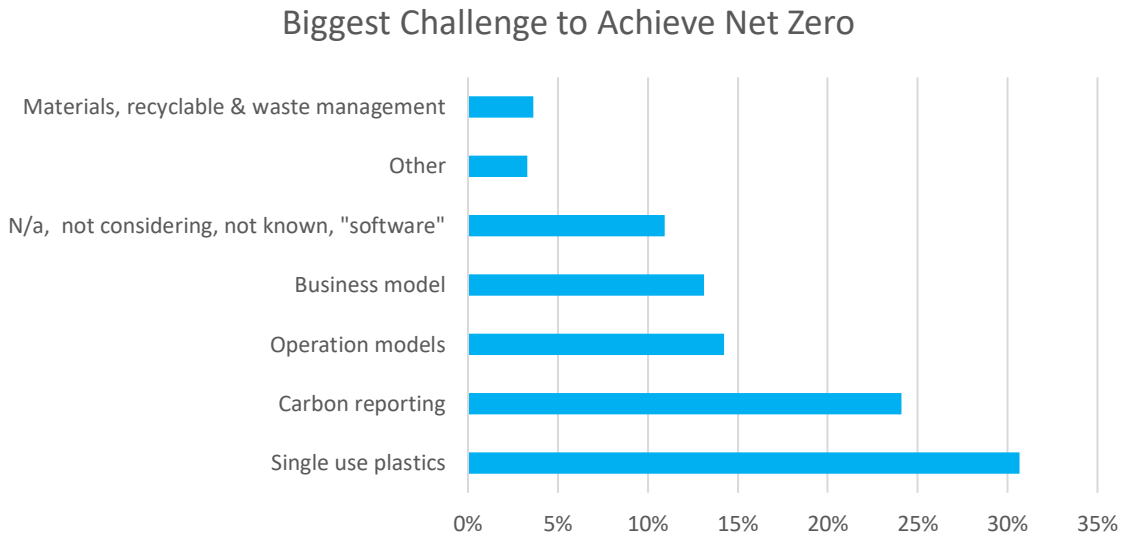


Figure 35 - Survey respondents answers to the question "What is the biggest challenge(s) you are facing to achieve Net Zero?"

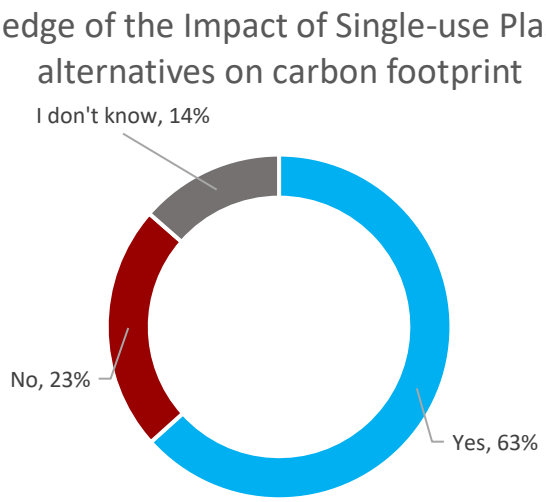


Figure 36 – Survey respondents answers to the question "Does your organisation know the impact on using single use plastics on carbon footprint (vs use of alternative materials) and environment?"

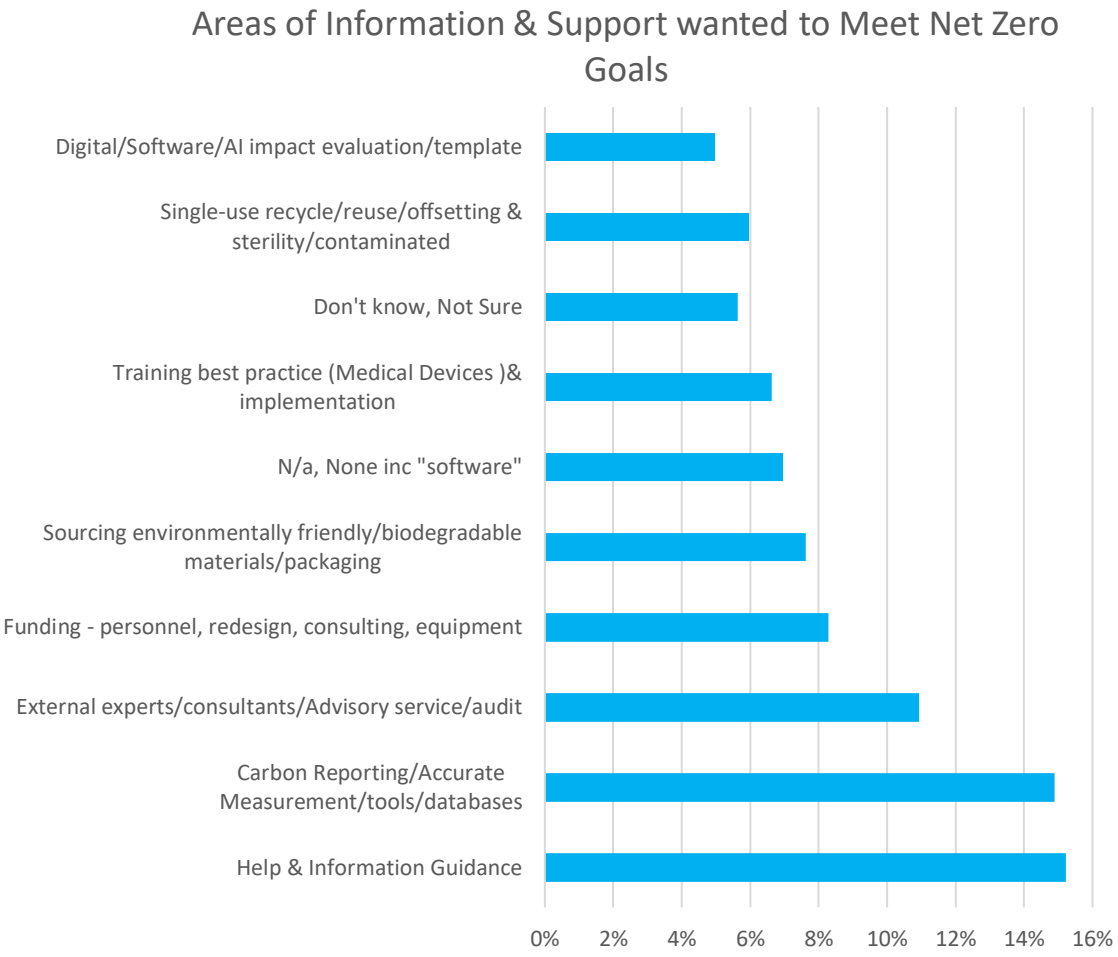


Figure 37 - Survey respondents answers to the question "What kind of information/support you would like help with in order to meet your net zero goals?"

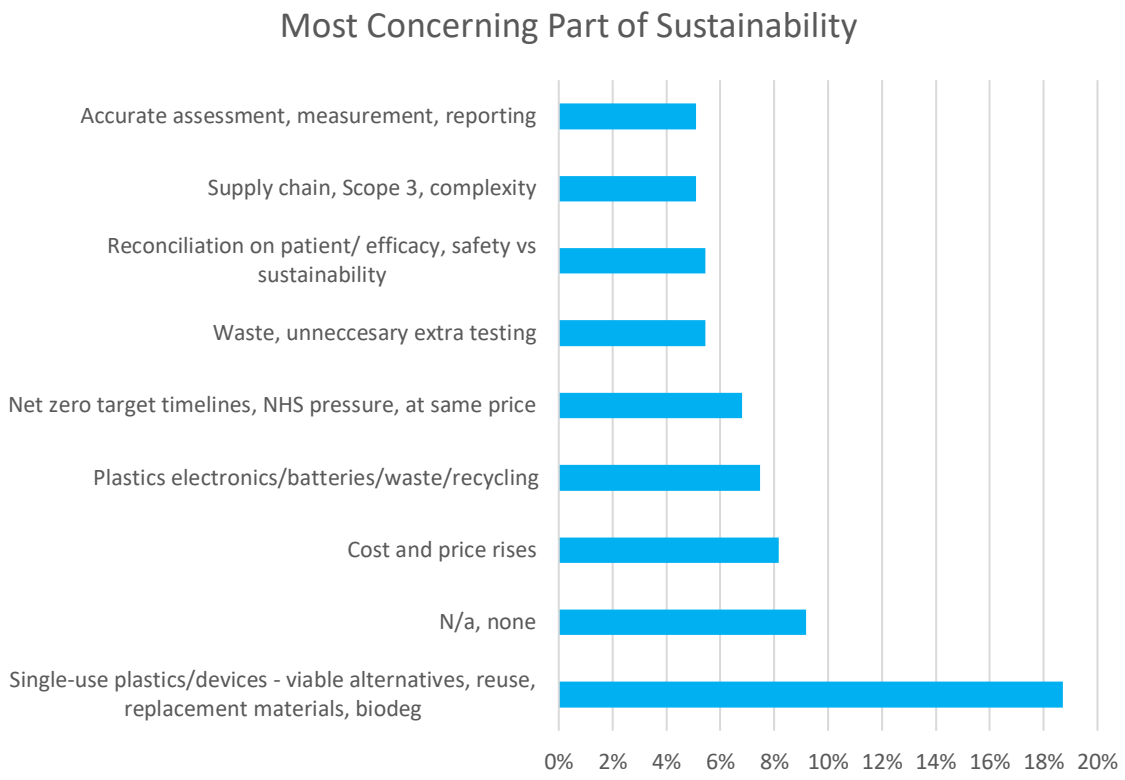


Figure 38 - Survey respondents answers to the question "What specifically relating to sustainability, are you most concerned about?"

It is very clear SMEs recognise the importance of sustainability, with Corporate Social Responsibility (CSR), Environmental Social & Corporate Governance (ESG) or simple human ethics as the primary reasons for high scores.

"It is everyone's responsibility to conduct business sustainably." (SME scored 5 to the question asked in Figure 23, London-based IVD SME

Some of those scoring lower took the view they were not working to the highest standards themselves due to other pressing priorities.

"We all have to play our part in saving the planet, but an SME has to be realistic in the number of initiatives it has to carry out with governance and regulatory affairs." (SME scored 3 out of 5 when assessing the importance of sustainability), East of England Reusable Diagnostic SME

Others gave high scores because their product or service has integral net zero benefits including the NHS aims.

"Sustainability & environmental issues are critical for our business. Indeed, a key commercial driver is increasing [our product's] use as a replacement for conventional anaesthesia by gases, as the latter are extremely potent greenhouse gases (accounting for 5% of the total NHS carbon footprint), and the class of drugs singled out in the government campaign for NHS net-zero." - South West-based Digital IVD SME.

Awareness of the importance is high. However, the challenge for SMEs is how to meet customer and social demands in a timely manner with many other challenges to balance. This research suggests a number of ways this can be delivered.

Insight 1 – UK HealthTech SMEs lack expertise in sustainability

Regarding the 2030 NHS deadline (in relation to the NHS Net Zero plans), 45% plan to handle this in-house, whilst 24% expect to use external experts to help including supporting in house personnel. 31% are still unsure how they will proceed.

At present, 66% do not have a designated individual responsible for sustainability, and whilst 30% do, this gap is something that will change in the next two years, especially as 76% of companies see sustainability as important or very important when developing and manufacturing HealthTech products, with some using words like "critical" and "vital."

With strong concern expressed over recycling at end of life, 'Circular Economy, Recycling, Design, to medical waste, reusable not consumable inc. Packaging' was mentioned by 17%. 13% mentioned Single-use plastic, disposables replacement, waste reduction, high volume use with 11% highlighting the ethical and social responsibility reasons for the planet and not just healthcare. However, there were many qualifications in view of other HealthTech factors: efficacy, hygiene, sterility, quality, safety issues, virgin material considerations with medical devices.

"Vital. Single use nature drives this requirement. Current consumables are considered medical waste, which dictates a high demand for plastics." - London-based Reusable diagnostic SME (r7).

"Safety and effectiveness are the priority but we wish to do that in a sustainable way" - East of England-based Digital Respiratory Technology SME (r160).

"As much as possible. It is understandable, however, that 'bad' materials such as plastics and other such materials, may be deemed necessary due to the benefits to society in healthcare." - South East-based Ophthalmic Surgery SME.

In view of the importance of sustainability, 55% have a strategy in development and a further 15% already have a plan. However, there are still 30% of SMEs who do not or are unsure, of their strategy.

When considering how they will measure the impact of their carbon reduction plans (net zero/carbon footprint), 25% intend to do this in-house with 9% using external experts. However, a significant 62% do not know, which is a troubling statistic considering the NHS' Net Zero plans.

Only 3% already have science-based carbon reduction targets using a range of delivery methods (tools, policy, offset, mileage, net zero manufacturing) with 32% developing these within two years. Again, a similar 62% have no such targets indicating a significant shortfall in knowledge that needs to be address in order to engage these SMEs with the NHS Supplier Roadmap and safeguard their future business prosperity.

With carbon emissions scope 1-3 in mind (definitions from UK Government as part of their procurement FAQs are found here[23]), 40% are engaging with their supply chain and for 26% it is too early in their product development, or they are digital only, where the energy requirements of supercomputing cloud servers are likely to be the primary impact.

"As a software company, we are always concerned with the hosting facilities and how much energy is used in computing. We believe the industry will have to move into more efficient solutions for data storage and computing" – Wales-based Digital Health SME

A significant 30% are still not engaged with their supply chain showing there is more work to do. There are also a number of SMEs (11%), particularly those in the digital and software space who believe they are not affected by environmental issues as they only have a virtual presence.

"It should be a consideration, not least because at some point it will influence customer decision making. Relevant to physical products, but not digital." - South West based Digital Health SME

Insight 2 – SMEs need Practical Support to Achieve Net Zero by 2030 NHS Deadline

On average, HealthTech SMEs see several impacts from sustainability and environmental issues on their business agenda, however, most are still at an early stage in their progress towards sustainability.

[23] Procurement Policy Note 06/21: Taking account of Carbon Reduction Plans in the procurement of major government contracts, Government Commercial Function https://www.gov.uk/government/publications/procurement-policy-note-0621-taking-account-of-carbon-reduction-plans-in-the-procurement-of-major-government-contracts/ppn-0621-frequently-asked-questions, accessed on 29/09/22

The biggest impact on their business agenda is recycling at the end of life (27%), which is to be expected due to recycling now being routine. However, end of life for single-use or multi-use materials is an important challenge for HealthTech to resolve. The introduction of Extended Producer Responsibility (EPR) for packaging in 2023, following the plastic packaging tax (PPT) implementation in 2022 are new initiatives beginning to affect some HealthTech SMEs.

23% now recognise the impact of their carbon footprint on product, manufacturing and supply chains, and 21% see sourcing and materials as a key impact but raise questions concerning the use of virgin or recycled plastic use in medical devices. Regulation restricts the use of recycled materials for most HealthTech products and would be a significant effort if it were to become widely introduced, extending way beyond an individual company.

18% of respondents recognise changes to the NHS frameworks and the associated terms and conditions as making an impact on their business and these are more likely to be existing suppliers than new start-ups.

The most mentioned areas where SMEs want help to meet net zero goals are general help and guidance (15%), carbon reporting/accurate measurement/tools/databases (15%), and external expert help, advisory service and audit (11%). This is followed by funding (8%) and sourcing environmentally friendly/biodegradable materials and packaging (8%). Also of note is the 7% or respondents who specifically mention training on best practice and implementation with medical devices.

it is likely the cost of implementation and material price increases are more unknown, with only 8% and 7% being concerned about the Net Zero timelines for the NHS.

On top of the above hurdles for organisations to overcome, the UK is in the process of implementing EU environmental legislation into UK law (such as REACH and RoHS). There is a risk that these new UK requirements could diverge from the EU making UK conformity even more complex.

Recommendations

18. Establish an independent specialist sustainability advisory service

We recommend this to run until 2030 to answer sustainability questions from HealthTech companies and companies in other markets as these questions emerge. This should be free of charge and be equipped to recommend practical actions or expert help. This would include support specifically for software and digital SMEs to raise awareness of their responsibilities for Scope 3 emissions even if they have minimal scope 1 & 2.[24]

19. Map out the existing materials used within HealthTech applications

To enable the UK to understand where it should focus to tackle sustainability within HealthTech. We expect that this work would focus on single use materials primarily.

20. Behind this, work with UK universities, Engineering Societies and UK HealthTech qualified materials producers to develop alternative materials and supporting technical data (e.g. biocompatibility, toxicology aging, sterilisation) to enable smooth switching.

[24] Trade associations such as BIVDA have developed a sustainability hub which provides BIVDA members with access to the relevant information and requirements to meet the NHS Net Zero needs. Currently, this is only a benefit for organisations within the BIVDA membership.

21. **UK to build capability in test run/small pilot manufacturing of sustainable or circular materials for HealthTech applications.**

Through direct award or grant funding calls, we recommend empowering and expanding existing university/academic advanced manufacturing centres and UK Catapults to pursue sustainable materials development, small run capability for trial, test, or soft launch use. Positive outcomes can be driven by agreed deliverables.

22. **Encourage re-shoring of manufacturing capability**

This links in with recommendations in the "Technical Challenges" section around mapping UK supply chains and understanding capability gaps and encouraging growth in capability in the UK where identified gaps exist.

23. **Encourage the NHS to create an award scheme for suppliers who are driving sustainability.**

This award scheme could be run by the NHS sustainability or similar group to promote progress and awareness of new applications and resources (some of this may exist but is in its infancy and focuses on internal NHS achievement only).

24. **Promote and enhance Sustainability Frameworks for HealthTech in the UK**

This would enable accurate monitoring that achieves the desired environmental results without imposing a huge additional burden on individual SMEs[25].

Insight 3 – Single use plastics are a concern, but their use is promoted by current regulations

On a positive note, at least 67% are aware of the concept of "Circular Economy" even if plans and actions are still in their infancy. 31% see single-use plastics as the biggest challenge to achieve net zero, closely followed by carbon reporting (24%) with changes to business and operating models both mentioned (14%). There is a high awareness of the impact of single-use plastics versus alternatives on the carbon footprint with 63% claiming knowledge of this.

"Single use nature drives this requirement. Current consumables are considered medical waste, which dictates a high demand for plastics." - London-based Reusable diagnostic SME.

"Safety and effectiveness are the priority but we wish to do that in a sustainable way" - East of England-based Digital Respiratory Technology SME.

[25] A recent example is the ABHI Sustainability Framework which was developed in collaboration with Large MedTech companies and Arup for the benefit of the whole sector. We believe that this framework is UK market leading and encourage its widespread introduction, along with valuable carbon measuring and reporting tools.

"It is understandable, however, that 'bad' materials such as plastics and other such materials, may be deemed necessary due to the benefits to society in healthcare." - South East-based Ophthalmic Surgery SME.

Of all the sustainability issues, single-use plastics and viable alternatives or re-use in the medical device regulated space is the biggest concern, mentioned by 19%. This includes the issues of shelf-life versus biodegradable or compostable materials.

Recommendations

25. **Establish training programmes run by academic and industry experts for health personnel that addresses all the challenges related to single-use plastic, material substitution and regulation.**
26. **Develop a HTRIP grant funding scheme to encourage UK SME manufacturers to engage with sustainability, especially for disposable and single-use plastic products**

This group are probably the biggest area of impact on environmental mileage and NHS waste reduction. Again, exemplify leading examples with an award scheme.

Target Market Challenges

The traditional market strategy for a UK based SME is to launch in the UK (primarily to the NHS) with clinical contact, locality, market knowledge and cost key factors influencing this. However, a combination of challenges, post Brexit and pandemic are disrupting this thinking and at least 1 in 5 SMEs are now looking elsewhere. This is particularly true for digital/AI SMEs used to operating in a virtual world compared to those with a physical manufacturing base.

60% of the round tables ranked access and contacts as a key challenge and 50% see NHS innovation and adoption a key challenge. The common question is 'how to engage with NHS clinicians and procurement', particularly with multiple decision makers to 'make the money flow'.

For the UK Ecosystem, a strong home market is desirable and international customers expect good traction at home with NHS use offering good credibility. As one Edinburgh Roundtable attendee put it:-

"Access to the domestic market is the key to internationalization."

The technical, regulatory and funding challenges directly influence the selection of the first target market. Actions need to be focused on resolving these to make the route to market clear, with minimal barriers.

Data and Findings

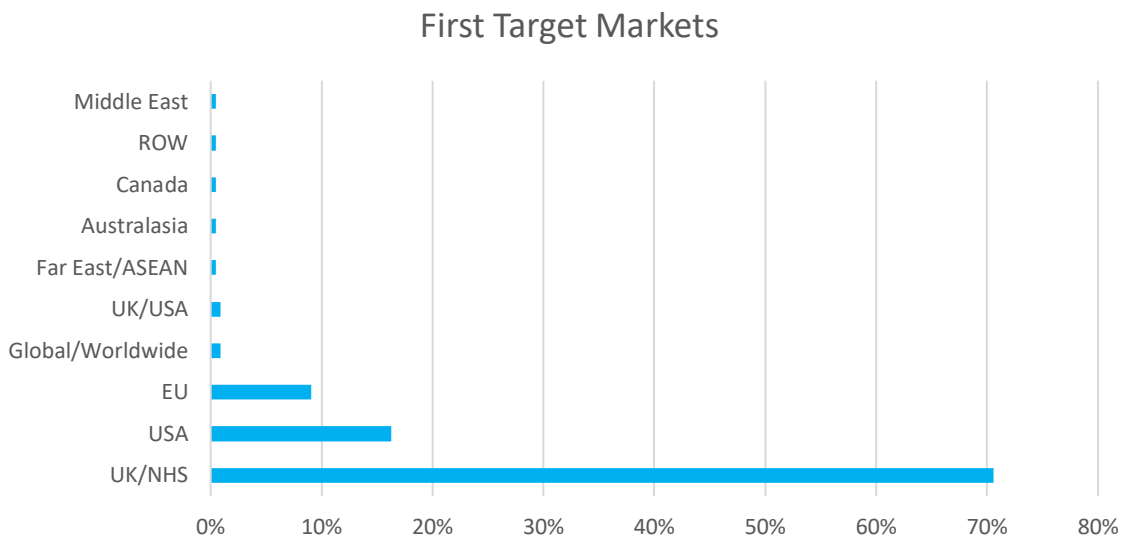


Figure 39 - Survey respondents answers to the question "What is your first target market?"

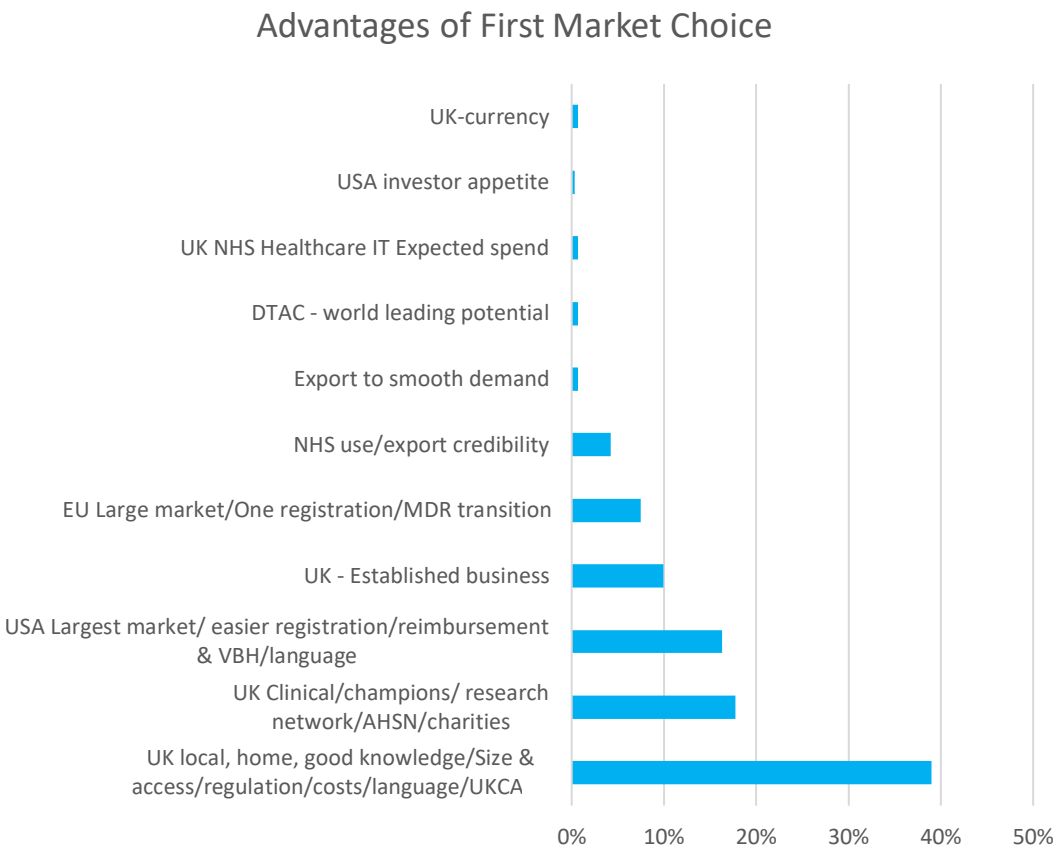


Figure 40 - Survey respondents answers to the question "What are the advantages/disadvantages of the choice you made (for your first target market)? Here we focus on the responses considered to be advantages.

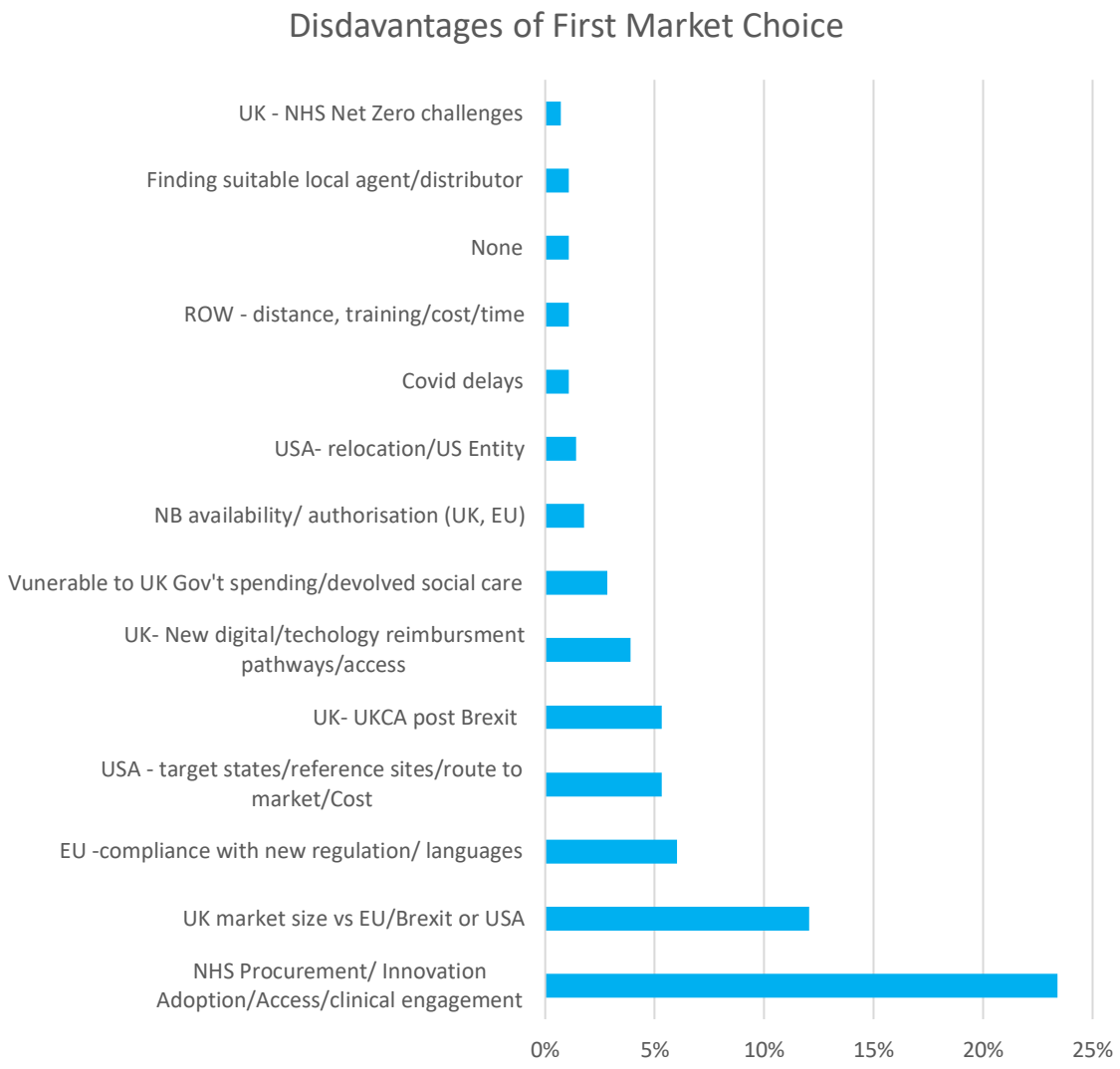


Figure 41 - Survey respondents answers to the question "What are the advantages/disadvantages of the choice you made (for your first target market)? Here we focus on the responses considered to be disadvantages.

One SME summarised the situation;

"UK is a market we know well but it is very fragmented in terms of its procurement in our sector. This creates volume challenges and makes growth harder. A combination of domestic and export sales is ideal." Yorkshire & Humberside-based Assistive Technology SME.

A 2022 report "Interstates and Autobahns" on Global Medtech Innovation and Regulation in the Digital Age[26] flagged:

"In our survey, 53% of respondents say they are deprioritizing the CE mark relative to US FDA approval."

With only 10% of survey respondents being EU businesses, this was thought to be US perspective, but this work highlights that UK SMEs recognise a similar trend. At least 17% see the USA as their primary target market due to its much larger potential and perceived ease of access. Notably, the ABHI online survey indicated a higher 24%.

"USA has a much bigger market and better reimbursement strategy for us." South East-based Ophthalmic Device SME

The strategic view is changing towards a faster impact in the USA exemplified by one SME at the Manchester Roundtable:

"Why try with the NHS for six years when you can get 120 customers in one year in the USA?"

As mentioned previously, a digital SME attendee at the Edinburgh roundtable physically moved his business to the USA two months after the event.

As another put it; "The NHS is our ideal client but is tough to sell to. Takes time and money to enter. That is why we are focusing on monetizing earlier in the out-of-pocket market in the UK. This will allow us to create the necessary traction and real world data to come back to the UK and sell here." - London-based Digital IVD SME

Whilst the USA is gaining favour, the same is not the case for the EU, with only 9% seeing this as the primary target with the larger size and single CE marking for 27 countries as the chief advantages. For a UK SME, there can be extra registration hurdles for each of these markets, so prioritisation is focussed on Germany and France as the largest markets, and the Nordic countries due to similar adoption and reimbursement pathways.

[26] Interstates and Autobahns Global Medtech Innovation and Regulation in the Digital Age from Boston Consulting Group and UCLA Biodesign Programme
March 2022 By Christian Johnson, Jennifer McCaney, Kwame Ulmer, Meghna Eichelberger, Pete Lawyer, Gunnar Trommer, and Barry Rosenberg

Other markets, such as the other IMDRF participating countries (Brazil, Japan, Canada, Australia as well as USA), the Middle East and East Asia, hold potentially lucrative sectors and largely recognise established registrations. This makes these areas worth considering for export programmes based, for instance out of the UAE and Singapore, that target other regional markets.

Insight 1 - UK SMEs need proactive and clear support to access the UK (NHS) as a target market

71% of SMEs still see the UK and NHS as their primary target market because it is local, they have good knowledge of how to proceed, and regulation and costs are achievable in a reasonably sized market. Other attractors are established clinical champions and a network that includes the AHSNs.

However, in almost every case the UK choice is measured against the huge barriers of NHS procurement and adoption. It is known that NICE, AAC and the MedTech Mandate have focussed attention on early adoption routes for HealthTech, which is seen as offering strong value to the system. It is likely this will increase with "Early Value Assessment" (EVA) proposed in the new NHS Innovation Service, although HealthTech Connect experience suggests capacity of the programme to review and respond will be a challenge.

"Advantages: Easier logistics and the credibility we have built in the UK. Disadvantages: In the NHS, the left hand doesn't know what the right hand doing due to its size." London based Orthopaedic/Mobility Digital SME.

"Advantages: We know the market and have a network to build collaborations and work together on trials.
Disadvantages: NHS is highly fragmented so it is extremely hard work and slow (relatively expensive) to scale up as every Trust has to be engaged separately, and integration with systems are needed every time (and not necessarily generic)." Yorkshire & Humberside-based Digital Health SME.

"NHS very difficult, slow moving, hard to monetise - pilots often drag on for free and do not lead to contracts in spite of good patient outcomes." Yorkshire & Humberside-based Software SME.

"Advantages include;
- straight forward UKCA self-certification

- known market
- large single customer (NHS)
- product champions working within NHS

Disadvantages include;
-Complexities of becoming an NHS supplier" South East-based IVD SME

Recommendations

27. Create a UK NHS Accelerator programme with a clear "lit runway"

That enhances the post innovation stages beyond prototype and feasibility including the assignment of clinical champions to a wide range of products with merit. This programme should include engagement with NHS procurement and market access specialists in order to educate newer SMEs on the evidence and adoption pathway as well as sustainability/Net Zero procurement aspects. Digital Health companies are especially struggling with NHS market access and an accelerator should have strong relevance to this type of company.

28. The NHS should introduce bridging loan schemes

A 'NHS bridging loan scheme' that would allow NHS organisation to fund new innovations that only produce savings after 3+ years and can't be funded in the 1 year budget timescales of the NHS. This could be piloted in individual trusts to generate evidence

We would also light to highlight here that recommendation 12 (*AHSNs and their devolved equivalents, should be encouraged to focus more heavily on the market adoption, and commercialisation end of innovation*) also applies to this insights section

Insight 2 - UK SMEs need support to access the USA as a primary market

With stable FDA regulation and USA market access options seen as improving for UK SMEs, this is an opportunity to be taken but carefully managed; we clearly want SMEs to be commercial successes but for UK PLC we want to encourage them to stay based in the UK for their research and manufacturing, i.e. we want to encourage export but not relocation. For established companies with routes to market, the opportunity is more about growing their export potential, but for newer digital business, the USA can bring quicker results that can subsequently be used towards building UK and EU businesses. The risk of poor commercial traction is seen as lower in the USA because of clear payer reimbursement steps.

Some SMEs want to access the US market but are less familiar with US reimbursement models and conducting 'long distance' project management is a challenge. Also, some SMEs are remarking that they may have to carry out clinical studies or investigations in the USA, as not all studies carried out outside of the USA are automatically accepted towards US clinical evidence requirements.

"We require FDA approval to be able to market it in the larger US... Following approval, we expect sales to expand rapidly and are targeting a minimum of $1m sales in 2023 (subject to approval in 2022)." Wales- based Digital Health SME

"Advantages: Largest market, navigable regulatory environment compared to EU/ England/ N Ireland, likelihood of 510(k) clearance, leverage of +FDA decision with EU/ England/ other regulators, RPM codes for US reimbursement, appetite for new technology

Disadvantages: distance, selecting targeted states, finding reference sites, building clinical support, finding correct RTM" - Northern Ireland-based Digital Assistive Technology SME.

Recommendations

29. Leverage existing USA accelerator programmes to support UK SMEs to access the USA market

An accelerator programme can smooth the downsides and enhance the upsides for a typical USA primary market SME. A current programme is the ABHI USA Accelerator Programme. The scheme took 40 companies across several US states, including Texas, California, Florida and Tennessee and set up meetings with local healthcare trusts, universities and companies. The infrastructure and processes, which can take up to 5 years to build and leverage, are therefore established and could be used to extend to support more UK companies in the coming years.

The desire for a USA accelerator programme should be tempered by a view from the Manchester Roundtable concerning "Accelerator Hell", where new entrants are required to re-start at the beginning of most publicly funded programmes rather than building on what they have already achieved.

30. Work with AHSN and Innovation Hubs to identify SMEs with a preference to see the USA as their primary target.

This can include NHS innovators who may see faster USA adoption as a quicker route to market, especially if they have established clinical relationships. For AHSNs, this would be a pivot from their current focus of NHS improvement and bringing UK innovations into the NHS. However, in the long term, this could benefit the NHS if products are proven and commercially established in another market.

Insight 3 - UK SMEs need support to access the EU as a primary market

At present the EU is seen as a "difficult to access" sector when for many exporting to these markets has previously been the norm, if not the first step in sales to the Republic of Ireland.

Post Brexit, the EU looks considerably more challenging, even once an EU representative is engaged. There are 27 potential language and national registration demands that did not apply before; it is not quite the single market anymore.

These markets however do remain in proximity to the UK, are large, and UK suppliers are well regarded so this trend must be countered by supporting companies with a clear route to market.

"EU is a large economic area and the products are widely accepted and purchased by tender in large parts of this region. One certification also covers the whole territory. It is disadvantageous that the UK is no longer within this territory, and the new incoming EU regulations also pose significant challenges in maintaining this EU access." Yorkshire & Humberside-based Orthopaedic, Ophthalmic & Dental Devices SME.

"EU was chosen as the 1st choice due to its 'easier' regulatory pathway, free market access and close vicinity in distance. However, this has changed due to Brexit plus MDR. There are now a lot more barriers and added costs for regulatory approval and compliance, and marketing & sales operation etc." Scotland-based Cardiovascular/Vascular SME.

"EU -CE mark remains the preferred route before UK CA marking. Access to a larger (EU) market and other overseas market." Wales-based Wound Care SME

Recommendations

31. Leverage the UK's connection with EU embassies to facilitate UK SME introductions to EU stakeholders

Using the German, French and Scandinavian Embassies, which are generally the key target geographies, facilitate regular introductory sessions to Europe with partner and EU representation directories established to help SMEs get into dialogue quickly.

32. Launch a grant funded programme to support companies currently supplying to the UK/USA market to export to the EU.

Look to fund EU CE Marking grants to SME targets that are market ready, with an established UK or US business that needs new regulatory approval to access the EU/part of the EU.

Insight 4 - SMEs need support to access wider, global markets

Although not as high profile, there are other markets that should not be overlooked - certainly so for more established businesses where faster expansion will increase the UK attractiveness and SME ecosystem.

The post-Brexit MHRA membership of IMDRF and the benefits of MDSAP mutual recognition programmes for audits will help remove some of the barrier to entry to other significant world markets and the ecosystem needs to be ready to respond. However, this should be taken with caution. It is possible that such programmes could be difficult for SMEs, as they are forced in some cases to go through expensive audits representing markets they may not intend to enter.

Recommendations

33. Establish a directory of experts for these global markets

Identify consultants who can advise on regulatory and other market requirements, given the focus on UK, EU and US regulatory expertise seen in the Regulatory Consultants Section.

34. Encourage the relevant commercial sections of the UK embassies in countries such as Canada, Australia, Japan, Brazil, UAE and Singapore to develop more proactive engagements

These engagements could include compiling directories of distribution partners and regulatory experts. DIT could potentially facilitate this service, with external support and close liaison with the embassies. Over many years, individual searches have been conducted but now the need is broader. These lists could then be made more widely available for UK SMEs to utilise.

Supply Chain Challenges

Having a healthy supply chain is an integral part to any business that manufactures or distributes products. Supply chain disruptions significantly affect companies causing them to lose revenue and potentially market share.

When a company is developing an innovation or product, their supply chain needs to be considered to ensure that it is possible to manufacture to the expected demand for their target markets and revenue projections.

Supply chain resilience has become more important recently in the wake of global disruption, and having more than one approved supplier can mitigate losses from future supply chain shocks. UK NHS is also focussed on stronger UK resilience and re-shoring to avoid issues such as PPE shortages during a pandemic.

Data and findings

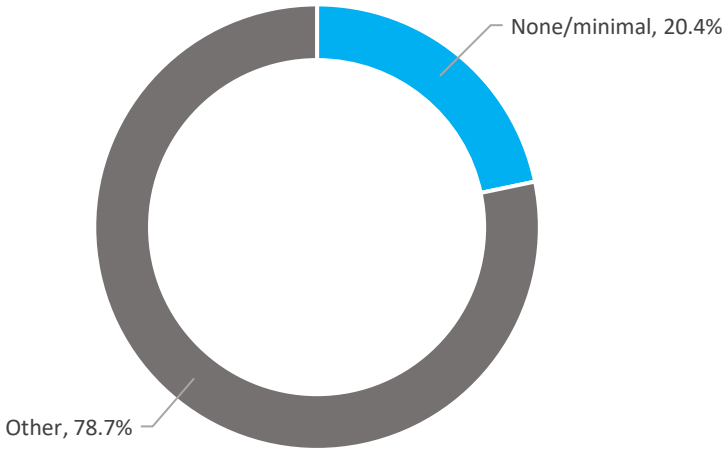


Figure 42- When asked "What are you main challenges with supply chain for your product/service?" 22% said they had no supply (or minimal supply chain issues). This was often because they were a digital health/software-based company with no apparent supply chain or they were too early in their development to have a supply chain set up.

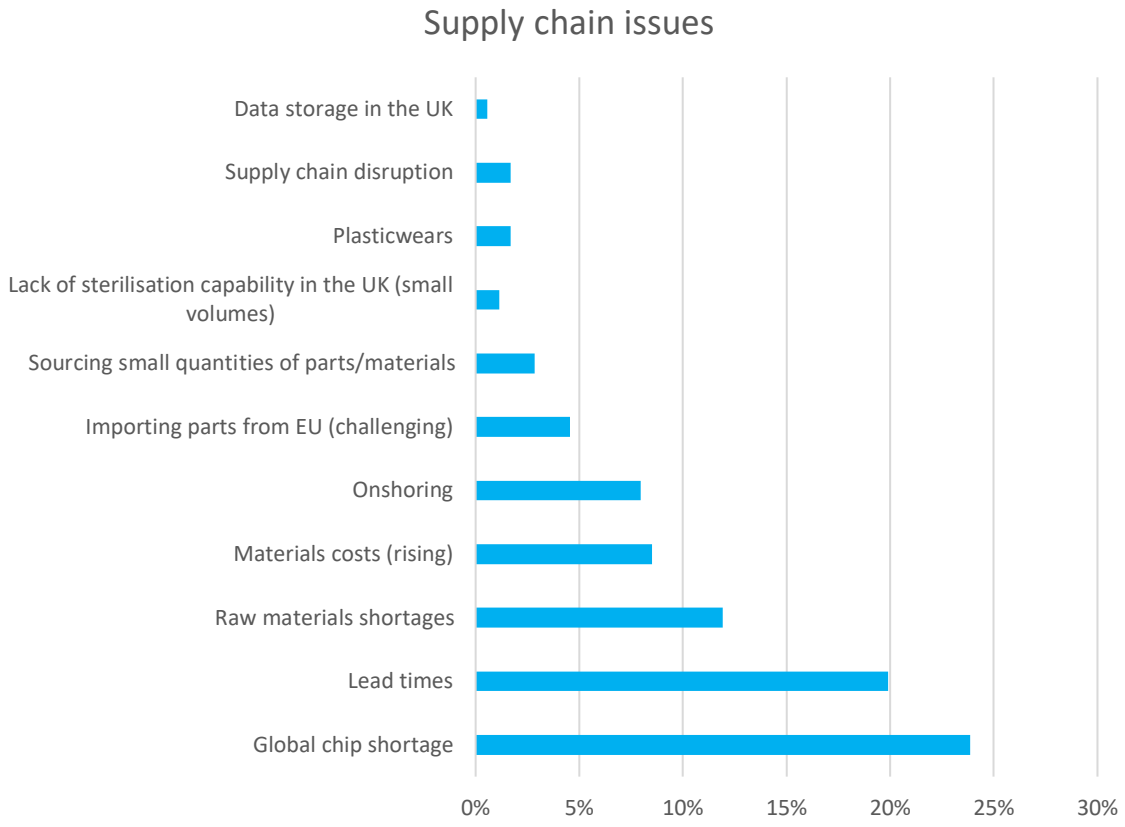


Figure 43 – In answering "what are you supply chain issues" -percentage of topics mentioned by the respondents to the mostly remarked topics. Note that respondents that said their supply chain issues were none, negligible or minimal were removed. Therefore, this figure is only for the remaining companies.

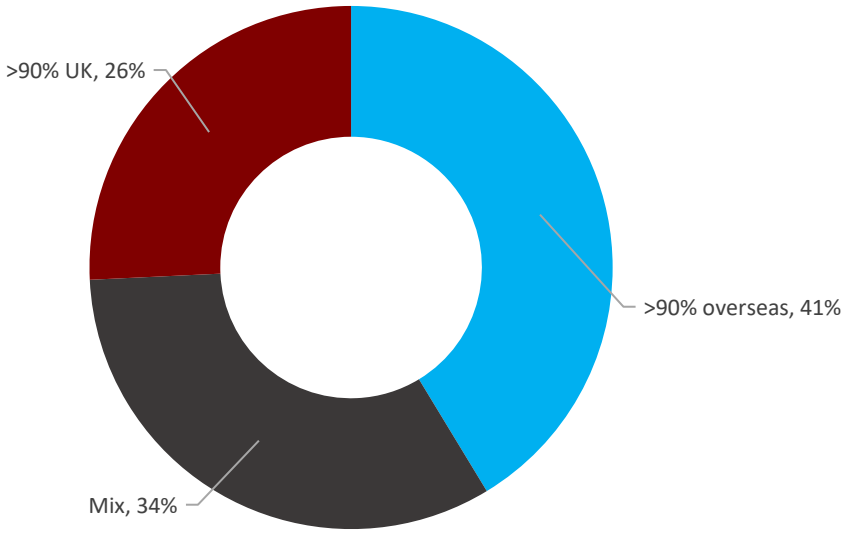


Figure 44 - Percentage of respondents answers to the question 'how reliant are you on overseas supplies vs UK-based supply'. 54 responses were removed as they answered 'not applicable' or 'too early', i.e. they were working on digital health

applications that they considered to have no supply chain, or it was too early in the product development for the respondent to be able to comment on potential supply chain issues.

In view of the number of SMEs engaged, companies are at various stages in their development. Those selling physical products understandably have more supply chain issues than digital, software-based solutions including Software as a Medical Device (SaMD). 20% believed supply chain questions were not applicable to them, mainly as they were developing software-based solutions, or it was too early in their product development journey. However, some did comment that they had no supply chain issues at all and were not being affected by current global issues.

79% were affected by supply chain issues and the data analysis focuses on this group. Those with more than 90% reliance on overseas supply chains accounted for 41% whilst 26% had a greater than 90% reliance on the UK supply. With this low number, we infer that this is showing the underlining relative weakness of the UK supply and manufacturing base identified in the earlier MOD/DHSC UK resilience work.

Insight 1 – Post pandemic supply chain problems exist for a range of materials including semiconductors

Of the SMEs that were experiencing supply chain issues, the most frequently responded comment was in relation to the current, well documented global shortage of semiconductor chips/integrated circuits and components.

Long lead times were often mentioned by many UK SMEs for a whole range of products, components and raw materials compounded by rising costs. Discussions at the round tables gave more information on this topic with most of the product-based companies claiming they were facing post-pandemic problems in their supply chains. Generally, the supply chains for manufactured components were undergoing a slow recovery. The companies remarked issues with shipping, staffing, delays with manufacturers and, what they deemed to be, excessive costs.

"Chips for electronic products are on 18 month lead times" –London-based SME developing orthopaedic products

SMEs commented on the shortage of UK contract manufacturing capability, with many having to go abroad to source this. A number of organisations said they would like to: 1. Have this capacity at home and 2. Have at a competitive price. A further issue is that suppliers often prioritise large orders or have very large minimum order quantities that cause problems for UK SMEs in the earlier stages of development. Some SMEs even remarked that suppliers are reluctant to work with the SME if they are known to be supplying the NHS.

"Rising prices of the raw materials, long lead time for parts (up to a year for some parts)" – London based SME developing an IVD device

SMEs told us that there is currently a significant global disruption to supply chains (particularly in the US, EU and in China) which is causing issues. The Ukraine conflict, Covid pandemic and Brexit were specifically mentioned by some as causing them issues with receiving parts and materials from overseas.

"Our raw material costs have increased and following Brexit, our freight charges are higher. We have to allocate in-house resources and appoint external customs agents to arrange customs declarations in order to receive raw materials from overseas" – Yorkshire/Humber based-SME manufacturing and selling surgical items

Some of the SMEs are mitigating this through purchasing additional warehousing space in the UK; others are actively seeking UK manufacturing sites. However, some do remark that many of the components or materials they need are either not manufactured in the UK, or the price of these in the UK are significantly higher than from overseas. To compound this, the quality of imported materials and parts from the Far Eat was questioned by some SMEs.

"After manufacturing in [The Far East] for a year, we had huge delays where we had to turn down huge opportunities with retails (sic) and distributors as I did not have the confidence that our supply chain could deliver. We had to check 100% of stock that drained resources and time." - London-based dermatology and wound care SME

For companies with existing supply chains, 41% of them were almost totally reliant on overseas materials, components and parts for their HealthTech products. Another 33% had some reliance on products from overseas and 26% declared that most of their supply chain materials were sourced from the UK. However, some that had mostly UK direct supply chains did remark that they believed their supplier was importing some of their parts and materials from overseas.

"We have deliberately ensured that the majority of the manufacture is in the UK however, certain electronic components are only manufactured in the Far East. About 85% of the cost of the product is spent in the UK." – Yorkshire/Humber-based SME developing CV devices

That some remarked over 90% of their components came from overseas indicates some sectors are very dependent on overseas supply chains for their products.

Many claim to have good visibility of their supply chains and a number mentioned that they would much prefer to have UK suppliers, but they have concerns around cost, as well as capability, of supply locally.

"UK based supplier can provide majority of the supplies we need, however due to cost considerations we get approximately 60-70% of our parts from overseas suppliers. Therefore, if need be, we will use UK based suppliers if cost is not of a concern." – London-based SME going through clinical trials of an IVD device

Some utilising UK suppliers did so due to the quicker response times and ease of communication.

"Upholding a high level of quality and consistency with our [Far East] suppliers is a huge challenge, we are currently in the process of moving our full supply and manufacture to the UK..... Moving to the UK will speed our manufacturing turn around and allow us to full-fill the demand for our products" – London based SME developing medical devices for skincare

Although mentioned only by a small number of SMEs, there were comments on supply chain limiting capabilities in the UK, including sterilisation and clean room assembly. This was having significant issues for the SMEs in question.

"There are various clean room facilities available for rent in UK, but the costs for a small company are an obstacle. Especially as [a] specialist equipment need requires us to purchase our own items. Which is why many decide to build these clean room facilities in house, even if their use is restricted only to a few months per year. This is not the best use of innovation space. There are medical device / biologic clean room parks and support structures for early stage companies operating as non-for-profit organizations across EU. [We need] access to clean rooms for medical device/ biologic manufacturing at a 'reasonable for an SME' cost." - South East -based wound care SME

"Product manufacturing by collaboration with a manufacturing partner having R&D capability, cleanroom facilities and the necessary expertise." - South West-based IVD SME

Recommendations

35. **Development and maintenance of a supply chain directory to enable mapping and visualisation of companies within HealthTech relevant sectors.**

In order for companies to manage their supply chains effectively, visualisation of supply chains are key. Also, to build resilience in supply chains and prevent future resource, part and material constraints, companies should seek to have multiple suppliers. With several respondents remarking that they would like to source from the UK the UK manufacturing/HealthTech sector need to enable better visibility of capability and capacity across the UK.

An example of a tool which will enable this is currently already in development under Made Smarter and is known as the Digital Supply Chain directory[27]. However, for UK based HealthTech companies to gain value from this, knowledge of the tool and engagement with it is required. This team recommends investment in not only building and maintaining the tool, but also advertising and building a strong, engaged user base. Launch a programme to understand ways in which the UK can be more resilient against HealthTech related materials-based supply chain shocks.

In May 2021 the UK Government announced that, considering the supply chain issues caused by COVID, they had assessed 65 "critical global supply chains to the UK" in a huge amount of detail. This was known as "Project Defend"[28]. We propose that the team involved in that project work with HealthTech related stakeholders (which could include UK Universities, Trade Associations, HealthTech companies, Catapults and NHS Supply Chain) to follow a similar exercise for the wider HealthTech industry.

Visibility of supply chains is likely to become a significant differentiator for future NHS procurement following the pandemic PPE experience and this work will support SMEs in their adoption pathway.

[27] Available at https://digitalsupplychainhub.uk/get-involved/supply-chain-directory/

[28] "Project Defend maps critical supply chains to boost UK resilience", Supply Management, May 2021, available at https://www.cips.org/supply-management/news/2021/may/project-defend-maps-critical-supply-chains-to-boost-uk-resilience/ accessed on 04/10/2022.

Technical Challenges

In this section we look at the challenges faced by SMEs in developing their technology and bringing it to market. We consider where they have struggled in their development and how the UK innovation ecosystem has supported them.

Regulation comes up as a significant technical hurdle and challenge to UK SMEs with the need for studies and testing to compile the technical documentation and meet regulatory requirements., create the technical file and meet regulatory requirements. There is considered to be a lack of support in this area in the UK in the opinion of the organisations involved in this report. When we consider the innovation ecosystem in the UK, many consider it to be very front loaded, with excellent university research and invention, however, as we move closer to market, that level of innovation support drops.

There is a challenge in the UK for SMEs to carry out cost effective clinical activities such as clinical investigations, clinical verification and testing.

SMEs are looking for more support with scale-up and manufacturing, which they would prefer to conduct within the UK, however, there appears to be a lack of options to do this. Companies involved in digital health are especially finding it difficult to scale and deploy within healthcare systems such as the NHS.

Data and findings

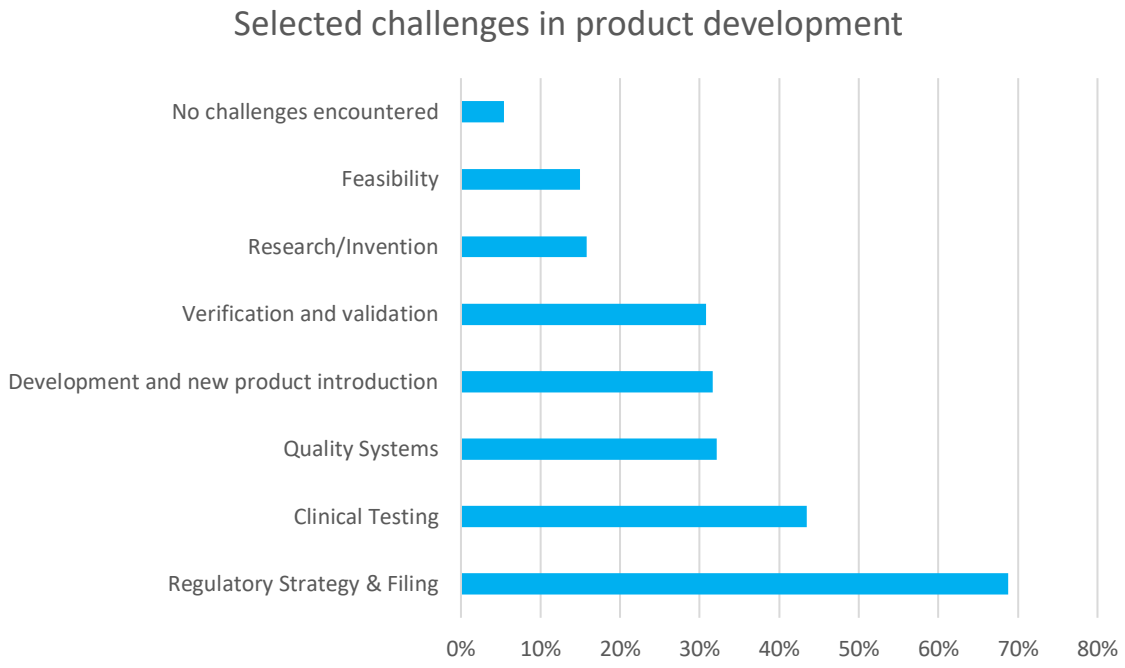


Figure 45 Survey respondents answers to the question "During the development of the product/service you are seeking support for, have you encountered any challenges?" – multiple choice question .

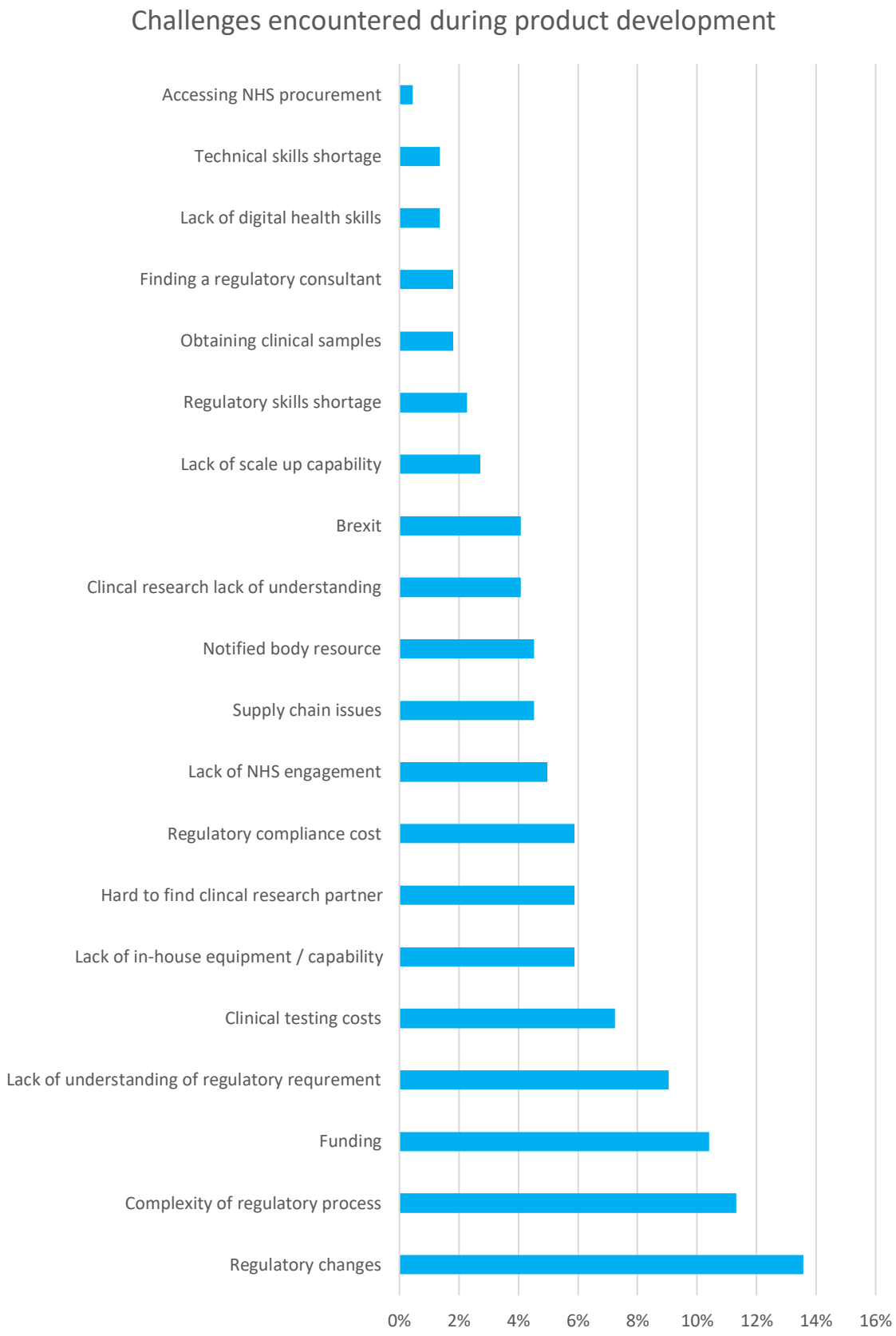


Figure 46 - Survey respondents answers to the question "Please specify … the challenges you encountered?" – a free text question as an extension to the question in figure 45, enabling the respondent to give more information.

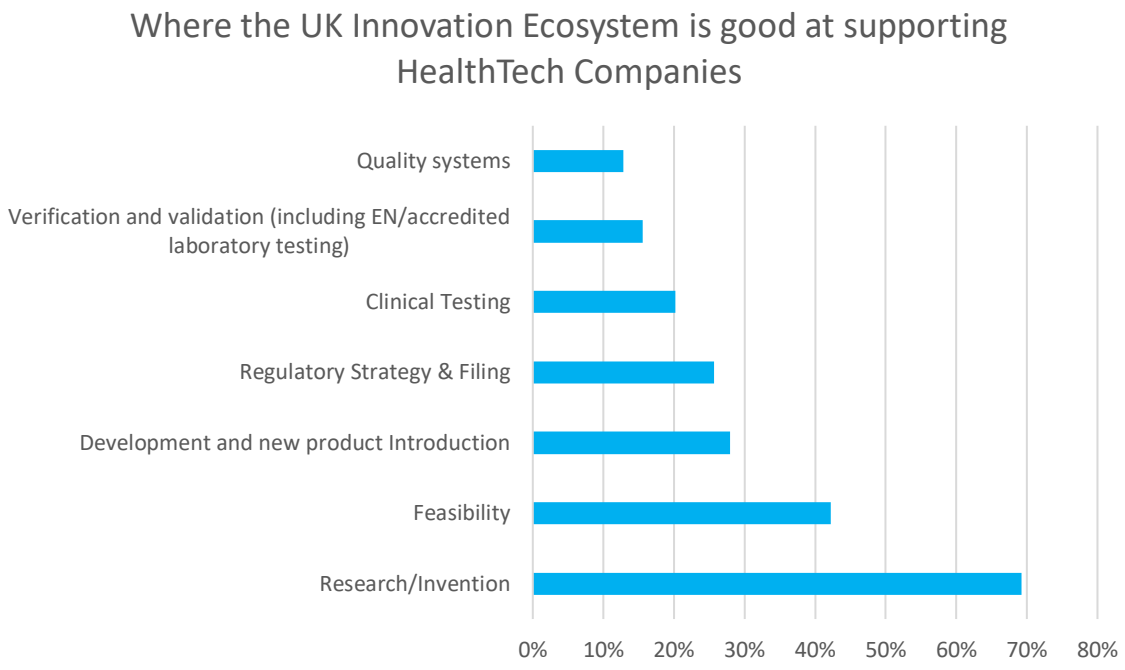


Figure 47 - Survey respondents answers to the question "From the stages below, which ones do you feel the UK innovation ecosystem is particularly good at supporting healthtech companies with?"

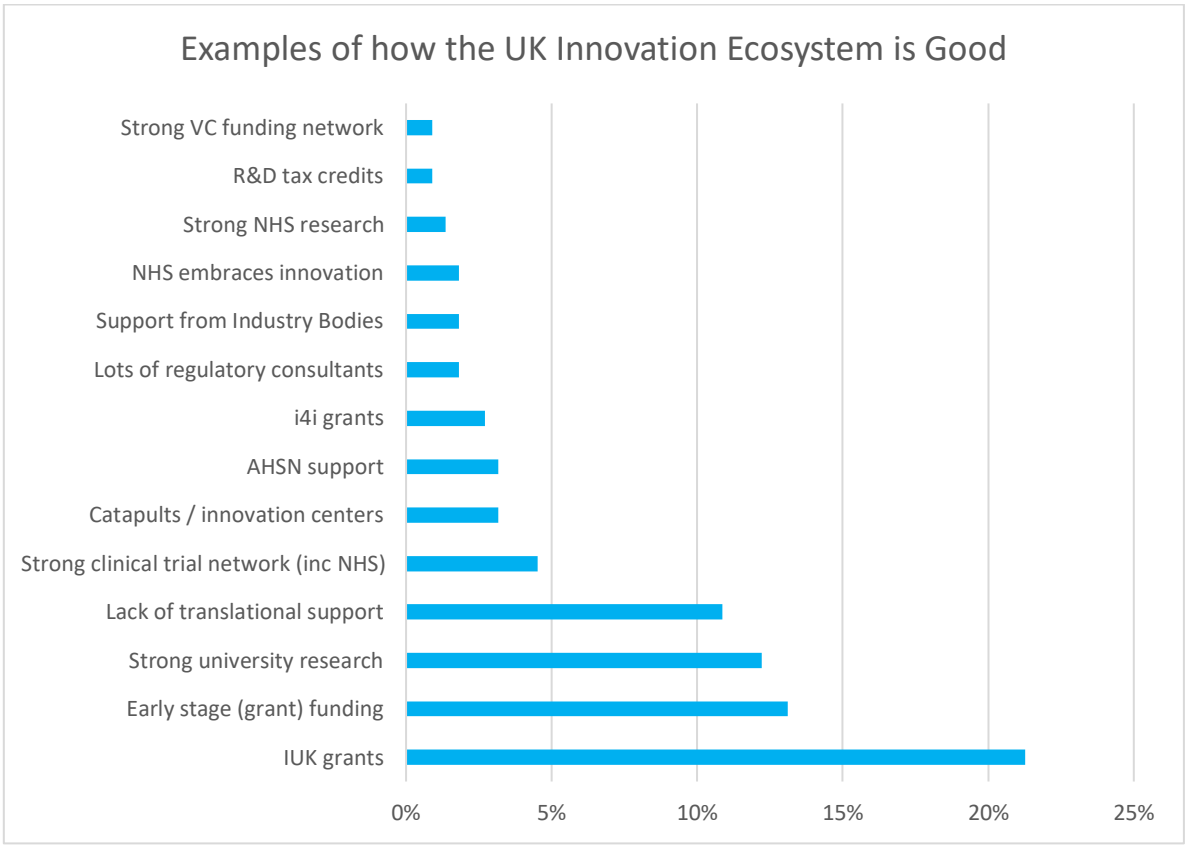


Figure 48 - Survey respondents answers to the question 'Please give examples on why you think the UK is particularly good at the stages you selected above?' (Relating to Figure 47)

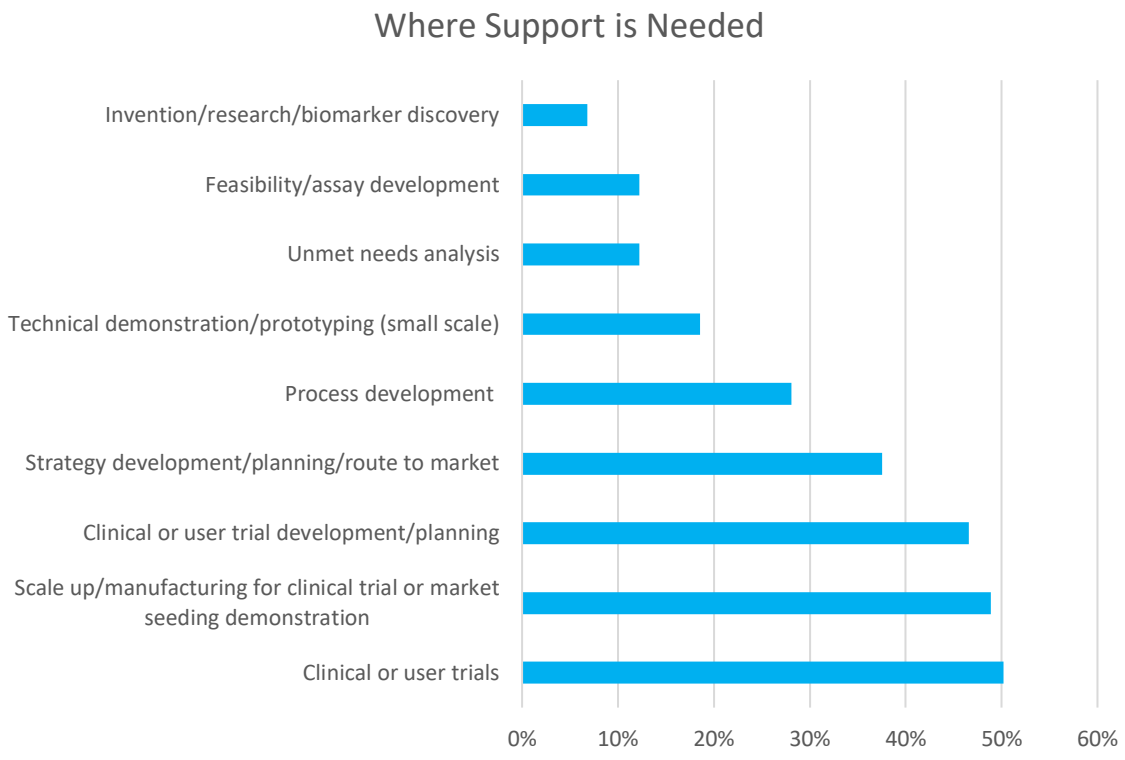


Figure 49 - Survey respondents answers to the question 'During the development of the product/service you are seeking support for, at which point do you think you will need support?"

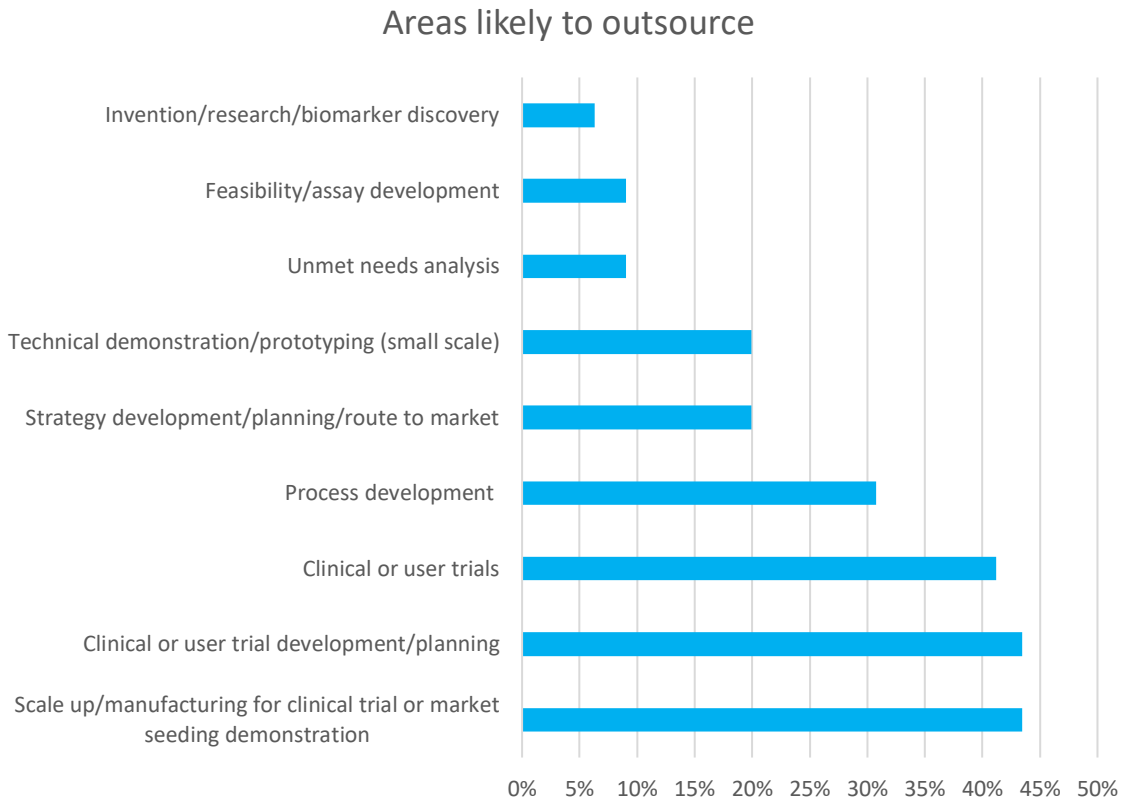


Figure 50 - Survey respondents answers to the question "Which of the areas are you likely to outsource?"

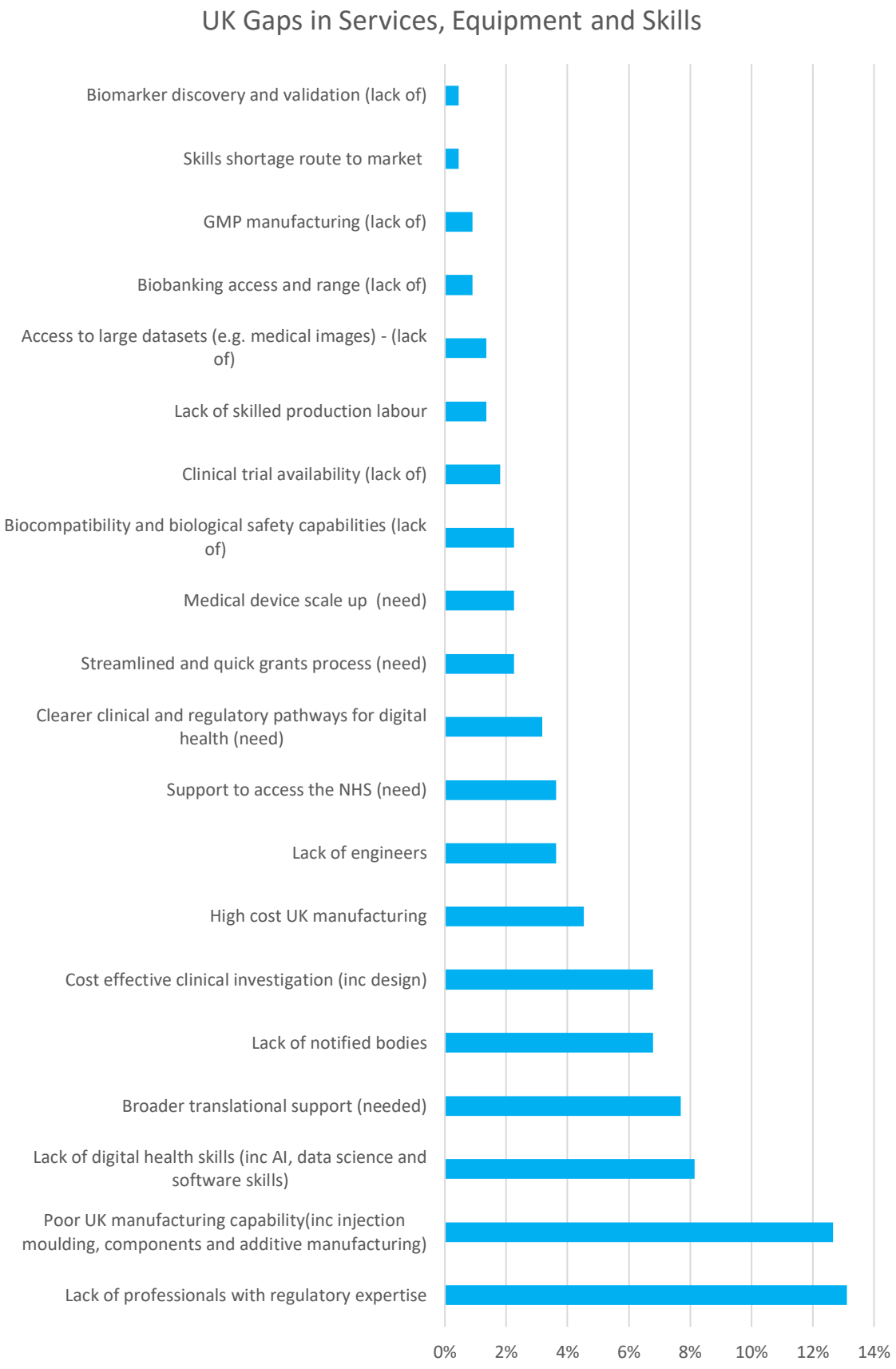


Figure 51 - Survey respondents answers to the question "What are the gaps in services, equipment and skills that you need, and which are not available in the UK now?"

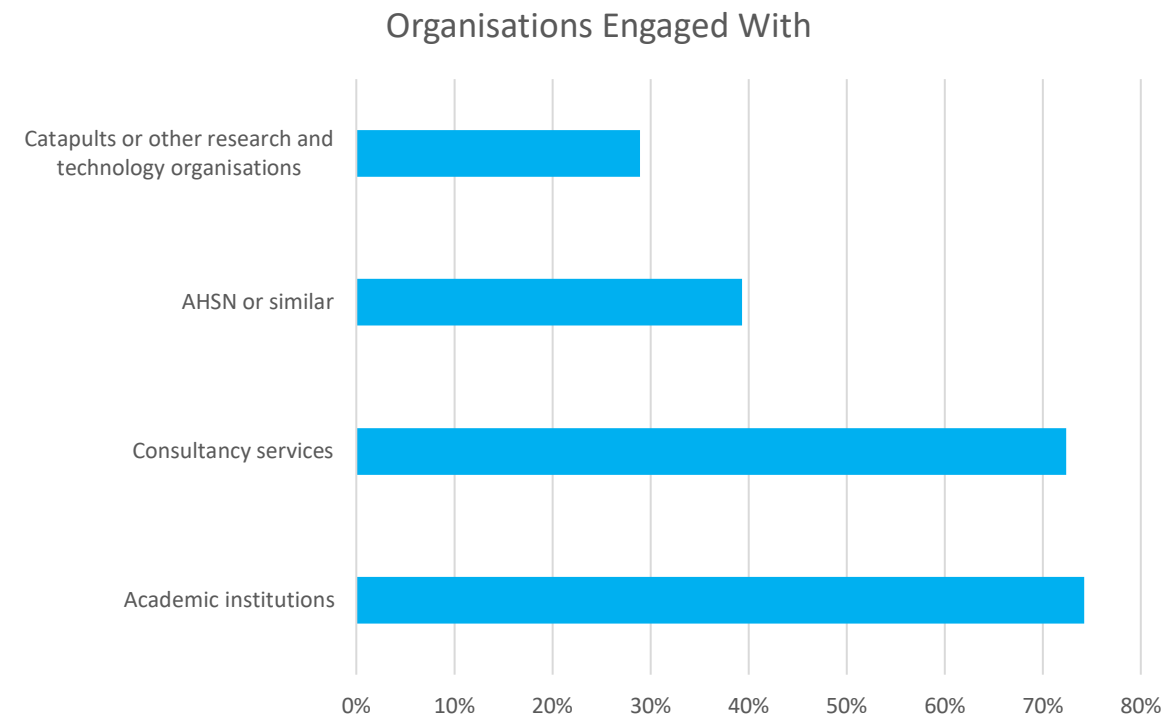


Figure 52 - Survey respondents answers to the question "Which of the following organisations have you worked with during the development?"

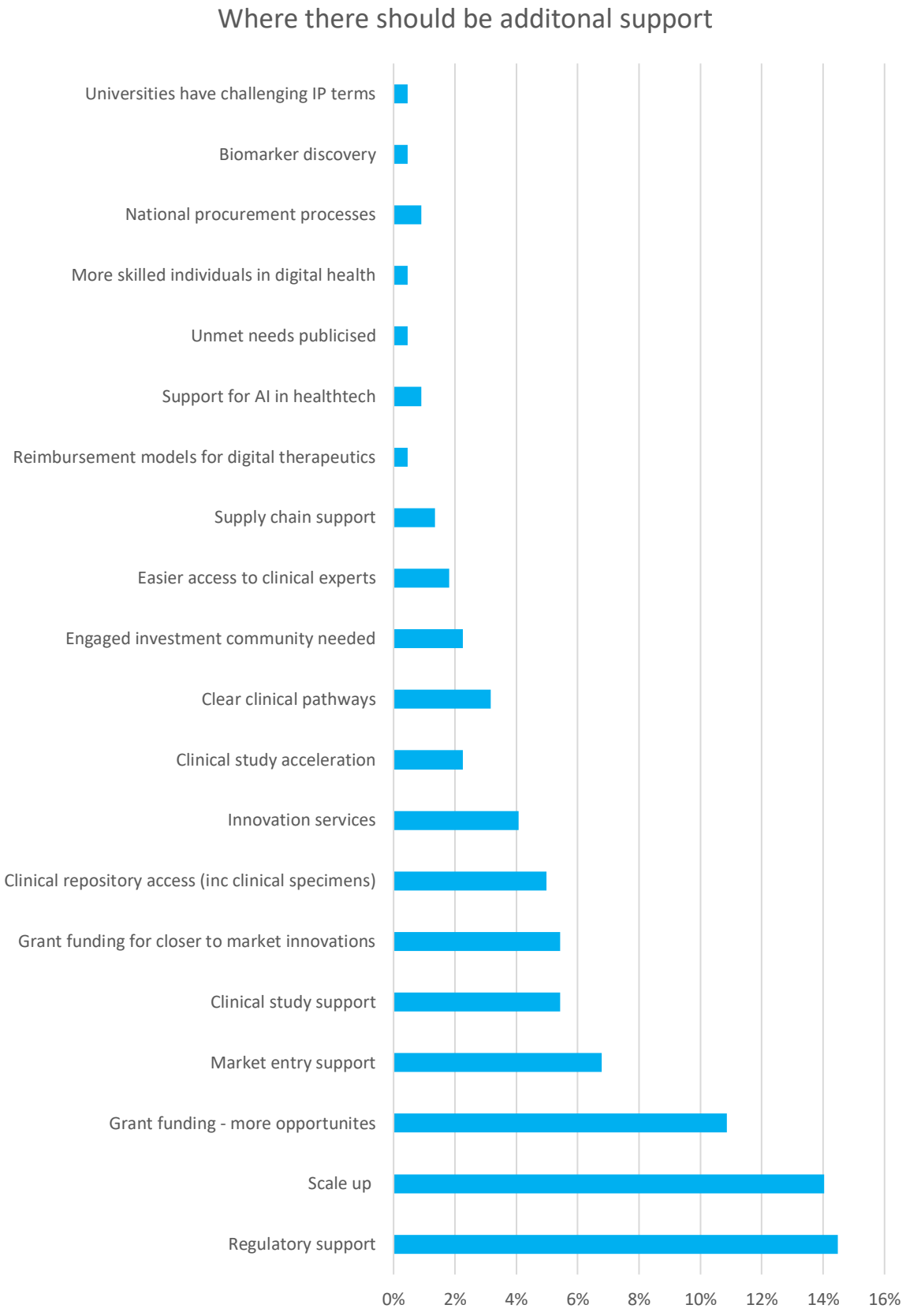


Figure 53 - Survey respondents answers to the question "Please highlight below where you think there could be additional support for HealthTech companies in the UK?"

Insight 1 – Regulatory landscape and support is a challenge

Regulation as a technical challenge was frequently remarked on by SMEs in surveys and round tables alike. From the HTRIP grant recipient survey, almost 70% of SMEs said it was a challenge for them to overcome. We will not repeat the details from the "Regulatory Challenges" section of this document but shall highlight any further comments and messages reported by SMEs throughout the "Technical Challenges" sections of the SME engagements.

Regulatory changes and complexity of regulatory processes were mentioned by approximately 14% of survey respondents and were the highest reported challenges encountered during product development. Many SMEs do not have in-house regulatory expertise and so are reliant on external consultants to support them through this process. Comments relating to the inability to access Conformity Assessment Bodies in the UK due to lack of resource were also echoed.

"The regulatory landscape in the UK and Europe has changed dramatically in the past three years. Brexit has led to the introduction of the UKCA mark and associated regulatory framework, and the replacement of the Medical Device Directive (MDD) with the Medical Device Regulations (MDR) has introduced enormous complexities that smaller companies are having to address. Furthermore, there is a limited pool of expertise in the United Kingdom and the company has been unable to recruit a highly experienced Regulatory Manager to lead these activities" -SME developing a gas control system

Recommendations for this insight are included in the "Regulatory Challenges" section of this report.

Insight 2 – The Early-Stages are well supported but translational and innovation support is Lacking

Over 70% of SMEs have worked with consultants and/or academic researchers and Universities, but less (40%) have worked with AHSNs (or regional equivalents) and even less (29%) with RTOs or Catapults. Positive experiences were mentioned on the whole in relation to these organisations however some did remark that university intellectual property terms could be challenging.

"Clinical Testing – The NHS is a respected healthcare brand and a good test bed for clinical investigations.

Research/invention – World-class universities act as research partners for medical devices.

" – London-based SME developing SaMD[29]

The UK ecosystem is considered especially good at supporting HealthTech in the earlier stages. The highest level of support was for research/invention, with 69% of survey respondents selecting this answer when asked where the UK HealthTech ecosystem was good at supporting companies. Feasibility was selected at 41% and development/new product introduction at 27%. When all stages were considered, the support appears to reduce as products move closer to market.

"The ideation (invention) phase is very well supported; however, it is challenging to move from this stage to actual integration and validation." – London-based SME developing pain management system

Innovate UK funding and specifically, early-stage grant funding, received the most positive comments from survey respondents (20% and 13% respectively) with strong university research remarked on by 12% of SMEs. However, 11% of SMEs mentioned "lack of translational support" in their answers. Furthermore, SMEs mentioned clinical networks (5%) and Catapults / innovation centres (3%) less frequently, but they were considered in a positive sense.

"Plenty of 'early stage' funding available for academia/SMEs to tap into to develop early stage proof of concept systems, and even lab-scale prototypes. Good access in the UK to design/manufacturing houses (e.g. CPI) to help design and scale up new products. Good labs and hospitals across UK NHS willing to help validate new tech, and in time, perform clinical trials. We are not looking anywhere else right now for this early stage clinical validation." – Scotland-based SME developing an IVD device

When we consider where SMEs believe they need support, 50% of survey respondents selected: clinical or user trials. Also, 46% selected: clinical or use trial development/planning. A similar number of SMEs said they were likely to outsource this (41% and 43% respectively). This is not surprising as this kind of service is usually carried out by specialist organisations or the NHS and is less likely to be in-house for SMEs. When discussing gaps in the UK innovation ecosystem, some SMEs (6%) said that there was a gap for cost effective clinical investigations and trials. Some are finding it difficult to engage and remark about the high costs associated with these.

[29] Although this is a very positive comment about the NHS. Most survey responses and discussions at the round table were to the contrary. However, we want to provide a balanced set of quotations as some did feel very strongly that the NHS was very supportive.

"Currently, CRO's are prohibitively expensive. If the UK go the same route as EU (Regulations) with [an] increase in clinical requirements then the obligations of UK device manufacturers may mean that the devices do not reach the patient (market)." – London-based Trichology SME

The SME views on the NHS were mixed; some SMEs citing excellent support and praising the NHS, however some citing challenges. The post-pandemic NHS is still struggling with a patient backlog which is restricting some parts of the NHS's ability to conduct studies. This is making it difficult for SMEs to engage and move forward with their investigations. Often having a "clinical champion" can help with this process. Some SMEs have worked through charities to identify these individuals. In addition, it was thought by some SMEs that the NHS appeared to be prioritising large pharma/biopharma over HealthTech; potentially due to the level of finances behind some pharma companies. To be more supportive of the UK HealthTech ecosystem, the NHS needs to set realistic prices reflective of what is possible for HealthTech SMEs who often do not have the same level of finances as what is typically seen in biopharma companies.

Clinical Safety Officers in each Trust or Health Board are sometimes considered as rate limiting factors, especially in digital health, as their qualifications are required to sign off on standards such as DCB0129/160 (Clinical Risk Management: its application in the Manufacture of Health IT Systems[30].

"Engagement with the NHS and other health authorities is very complex and difficult. New products are often developed here but sold abroad. This also results in companies leaving the UK...." – East of England-based SME developing an in-vivo POC device

Scale up / manufacturing for clinical investigations or market seeding demonstrations was selected by 48% of SMEs with 43% of SMEs saying they were likely to outsource this. Again, SMEs often do not have the equipment and skills in-house when it comes to manufacturing at any type of scale and are likely to outsource this to a contract manufacturing organisation, university innovation/manufacturing centre or Catapult. This clearly shows that there is a huge demand from UK HealthTech SMEs for clinical and scale up services. If we link this to the perceived lack of translational support (i.e. moving closer to market away from the invention stage), there is an innovation gap in the UK for SME support as we move to larger scale prototyping.

Some SMEs remarked that they need help with route to market or commercialisation, further making the point that the UK needs to consider its support offered to SMEs; ideally towards an end-to-end offer from invention right through development to launch and market share growth.

[30] "DCB0129: Clinical Risk Management: its Application in the Manufacture of Health IT Systems", NHS, https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb0129-clinical-risk-management-its-application-in-the-manufacture-of-health-it-systems accessed on 29/09/2022

Recommendations

36. Map out the innovation support landscape for HealthTech in the UK and provide support for gaps

With funding and support considered by SMEs to be 'front loaded' (i.e. towards lower Technology Readiness Levels), we recommend that a detailed analysis of the UK's HealthTech innovation support landscape should be carried out. Where gaps are identified such as: funding, mentoring, capabilities/equipment, training; we recommend that government sponsored initiatives are launched to help fill those gaps.

37. Develop initiatives that encourage UK Universities to work more closely with translational research partners

With the UK having strong University research and a lack of translational support, we suggest that the UK needs to build programmes of support that encourage UK Universities to work with other UK innovation partners such as Catapults and AHSNs to support translation of innovation to market.

38. Review the UK clinical testing/investigation landscape

With particular focus on NHS clinical support activities to understand how HealthTech (including digital health) innovations can be accelerated. This will help focus future interventions to enable more support for HealthTech and help stakeholders like AHSNs to support UK SMEs better.

Insight 3 – UK capability and capacity for scale-up and manufacturing are lacking

When we consider gaps in the UK ecosystem, SMEs are remarking that there needs to be improved manufacturing capacity in the UK. This is for both scale-up of products for users or clinical investigations but also for full-scale manufacturing. Many unique manufacturing capabilities are not available in the UK, forcing UK-based SMEs to go overseas to find that capability.

Some specific examples were called out by SMEs which included: lack of clean room capability for assembly (including automation where appropriate), Integrated Circuits (microprocessors and other PCB components mentioned), moulded plastics (injection, compression – especially medical grade) and additive manufactured parts were difficult to source in the UK. When companies could find components in the UK, they often remarked they were not cost competitive with overseas suppliers.

"The manufacturing capacity in the UK is very limited and completely uncompetitive on price - this forces companies who would rather create strong value chains in the UK to look abroad for collaborating organisations who can keep their services within reasonable costs for SMEs..." – SME developing orthopaedic devices

There is a desire to have lower cost and easy access to capabilities in the UK such as electronics and product design at a price that SMEs can afford. Current design services in the UK are considered expensive and potentially cost prohibitive for all but the best funded of SMEs.

Many SMEs remarked simply that there was a gap for scale-up in the UK and those same companies described that their next level of scale up was ranging from 5 units to over 1,000. This need is described in the quotes below:

"Resources and facilities for scale up manufacturing of health-tech devices would be enormously helpful if these could be accessed on a part-funded or subsidised model. To do this in-house is vastly expensive and would require enormous amounts of risk capital. Being able to access resources like this in the UK would be a great advantage and would also prevent so much work going overseas in search of affordable and even justifiable costs" – SME developing IVD

"Hardware MedTech Catapult? To help prototyping, usability and regulatory support. It seems most the medical support is surrounding pharmaceuticals/medicines etc" – SME developing surgical device

"HealthTech incubator/catapult with shared resources for design & development, Quality and Regulatory planning" – SME developing IVD

The move from proof of concept to pre-production is the area where the least support is available. For us, we would appreciate additional support with technical development – SME working with ophthalmic device

Recommendations

39. Carry out a 'deep dive' into UK HealthTech capability gaps focusing on scale-up and manufacturing, with funding to build capability as a follow on.

SMEs are identifying that there are gaps in the UK for scale-up capabilities (i.e., manufacturing enough of their products to enable them to either carry out a clinical investigation, or for early market adoption). Furthermore, they are also mentioning gaps in the UK's larger-scale manufacturing capability meaning they are forced abroad to source materials, components or devices they need.

As the breakdown of companies is so broad in this survey and their needs are diverse, all that can be asserted is that SMEs consider there are gaps. We suggest that work is carried out to understand where the UK has gaps. For scale-up, we should consider where existing capability within UK universities of innovation centres/Catapults can be augmented. Where there is a specifically large need for a new capability, we should look at establishing that in the UK. A report which shows where the UK has

manufacturing gaps could be shared with existing, contract manufacturing organisations to enable them to plan their strategies effectively.

Insight 4 – Lack of support for digital health

A lack of support and innovation infrastructure for digital health (SaMD, apps etc) was mentioned by SMEs throughout all SME interaction channels. This lack of support was broad, ranging from a lack of specific funding for digital health, to difficulty in accessing the quality and quantity of data required for software validation or AI/ML training.

Digital health is poised to change the landscape of healthcare significantly and is moving at an exponential pace. SMEs say that sometimes they struggle to get engagement with the NHS as their innovations can change existing pathways significantly. Route to market is therefore an issue for digital heath innovations especially where they are disruptive innovations.

With this being such a new avenue of innovations, the support infrastructure is not as strong as for other technical areas. IUK have and do support digital health innovations through the previous Digital Health Catalyst and will continue to do so as part of the Biomedical Catalyst for at least the next several years.

MHRA have also recently updated their guidance associated with healthcare apps which may be beneficial to some SMEs[31]. However, a broader offer of innovation and translational support is required.

"There are an abundance of systems in place for clinical testing however digital health is moving at a speed that is ahead of the rigorous testing system which is a challenge. Patients want information and support through mobile technology and the healthcare system can't adapt quickly enough" – SME developing digital health for paediatric patients

"Challenges to get hospitals to embrace digital health technology that is patient facing to reduce hospital workload and improve patient experience." – SME developing digital health applications.

Recommendations

40. The UK invests in a Digital Health Centres of Excellence

This would be a broad offer that would provide SMEs with a whole suite of innovation and translational services. Examples of the support that these centres could offer would include: regulatory support, standards development, SME/AHSN/NHS engagement and signposting, rapid (software and hardware) prototyping, expedient access to data/clinical data, (compliant) digital health software development under correct QMS, testbeds for digital health which include interoperability for apps etc. UKRI/EPSRC are funding

[31] Medical devices: software applications (apps), MHRA https://www.gov.uk/government/publications/medical-devices-software-applications-apps , accessed 15/11/2022

a scheme to set up a number of digital health hubs that are designed to promote knowledge and skills sharing across healthcare, academia and business to drive innovation in digital health. This may support elements of this recommendation.

IP Challenges

Protecting the ideas that underpin processes, products or services is as important as the concept itself. From patents to copyright, registered design rights to know-how, intellectual property must be safeguarded. However, SMEs face several challenges. Over 70% use patents as the primary source of protection with most also using know-how.

Over 50% of SMEs identified cost as the major challenge with complexity, time and freedom to operate frequently mentioned. The value of protection and finding the right advisor or patent attorney were amongst the other challenges highlighted.

Data and findings

Over 70% of SMEs are safeguarding their IP using patents and most of them use know-how too, as shown in Figure 54.

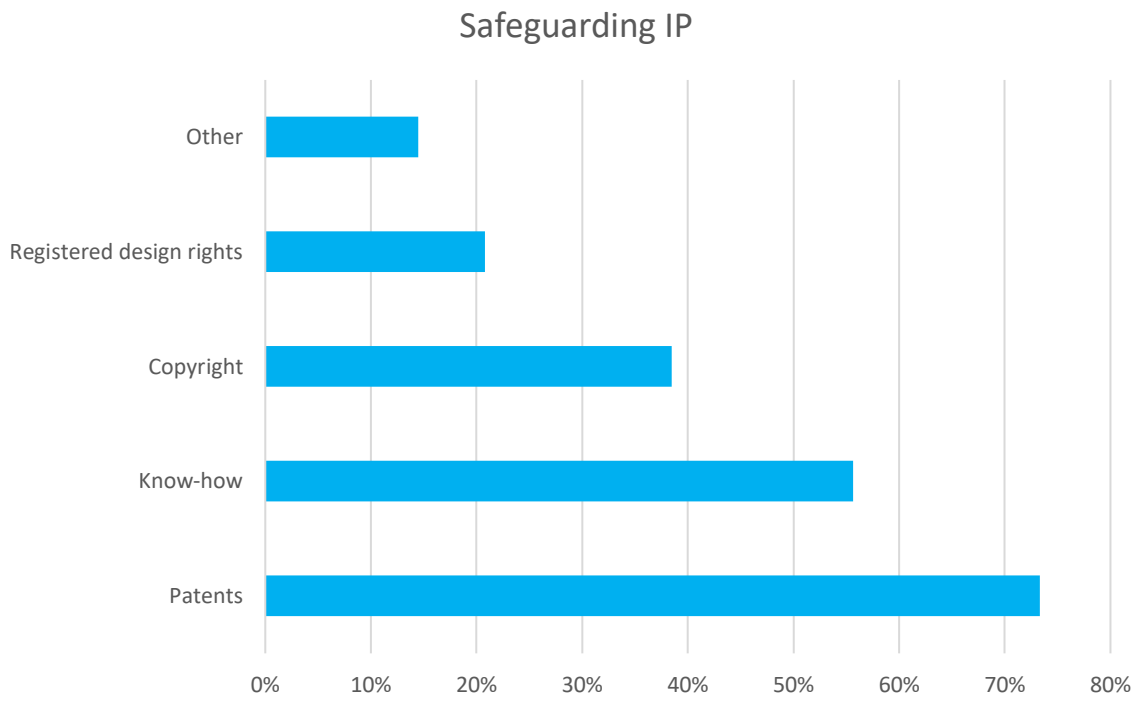


Figure 54 - Survey respondents answers to the question 'How are you safeguarding your IP at the moment?'.

76% of SMEs found various challenges when trying to protect their IP. A summary of the most frequently mentioned challenges faced by SMEs when trying to protect their IP are shown in Figure 55.

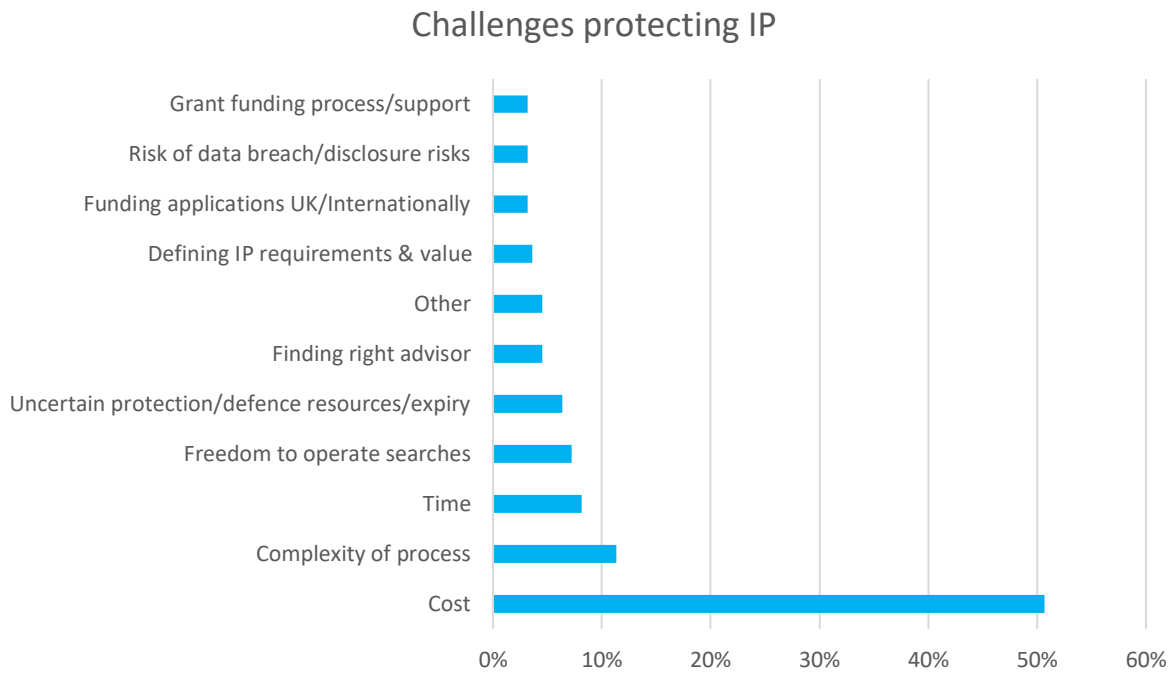


Figure 55 - In answering 'What were the biggest challenges you faced when trying to protect your IP?' -percentage of mentions by the respondents to the mostly remarked topics. Note that respondents that said their IP challenges were none were removed.

Insight 1 – Cost, time and complexity of safeguarding IP (a challenge)

Safeguarding IP is generally seen by SMEs as a fundamental tool in protecting their technologies. It provides investor reassurance as it is part of their due diligence, and therefore adds value to the company in addition to the benefits such as reductions in corporation tax for example via Patent Box.

Over 50% of SMEs identified cost as the major challenge: cost of advice, patent filings and protection, especially if looking for coverage across multiple territories. Some SMEs point out that even if they could afford to file for protection, they would lack the ability to identify infringement and the money to defend it.

"Length, cost and complexity of registering IP across multiple territories." – East Midlands-based SME developing dental and maxillofacial technology

IP is generally regarded as costly with unclear protection that is difficult to enforce. Some grant recipients specifically remarked on difficulties around strategies to keep IP cost down such as recognising the correct moment to 'drop' a patent family so as not to incur ongoing costs, when that technology became non 'core', and/or it is unlikely to provide a return on investment through sale or licensing. A few SMEs remarked that IP theft is prolific in the industry with infringers relying on the high cost and uncertainty of actions against

them, to infringe with impunity. A number also recognised other forms of protecting their IP such as: first to market, regulatory approval and evidence as important aspects to dissuade competition.

"Finance, it is very costly. Also concerns on how robust this process is, as a small company if a large global competitor wanted to copy or challenge, we could not afford to challenge this in court." – Yorkshire and the Humber-based SME developing orthopaedic devices

"As a small company the risk of publishing a patent and then not having the ability to identify infringement or the financial resources to ensure enforcement." – Scotland-based SME developing Dental and maxillofacial technology

Freedom to operate refers to whether it is commercially 'safe' for a particular company to make or sell products in their chosen country/geography, without infringing existing third-party rights. Freedom to operate analysis is usually the best step companies can take to help minimize the risks of infringing existing IP rights and approximately 8% of SMEs remarked on the difficulties around this.

The main comments were around exactly what technologies to protect, which markets to go for and how confident they were regarding the results, as it is extremely difficult to be 100% certain that a product/service is not infringing existing third-party rights. Several SMEs did mention that this analysis is extremely important when defining the right IP strategy, with 5% of SMEs having difficulties in finding the right advisor for their particular product or service.

"As newcomers, to deciding on an IP strategy, we had to pull in both legal expertise as well as commercial expertise to understand our options. Understanding how IP works... for example, understanding that a patent does not necessarily protect your whole product." – South East-based SME developing audiology technology

"Searching the IP landscape to see if it exists elsewhere and finding out if we would be infringing on any IP." – Wales-based SME developing Digital Health & AI technology.

As previously specified, the SMEs we engaged with or who responded to the surveys are companies at various stages in their product development cycle. They included companies developing or selling physical products such as medical devices and diagnostic tests as well as companies developing and/or selling software-based solutions such as SaMD. SMEs developing software-based solutions often face specific challenges when choosing the best way to protect their IP. Specifically mentioned was the challenge of choosing between patent registration versus trade secrets. Some SMEs decided to protect in the form of trade secret and copyright to avoid disclosing their algorithm source code in the public domain. Others

mentioned the difficulty to protect machine-learning and AI algorithms due to the frequency of parameter changes and the nature of these technologies.

"Biggest challenge has been choosing between patent registration versus trade secrets. We decided to protect in the form of trade secret and copyright to avoid disclosing our algorithm source code in the public domain. – London-based SME developing Digital Health & AI technology

"Protecting software is very difficult, in practice." – London-based SME developing Digital Health & AI technology

From SMEs protecting patents in the EU and in the USA, they are finding that the EU Patent Office (EPO) is very slow, but the United States Patent and Trademark Office (USPTO) is much quicker. With other comments around the relative ease of finding clients/investors in the USA and SMEs telling us that they are getting more guidance and support from the FDA than European equivalents, the USA is becoming even more of an attractive proposition for UK HealthTech SMEs.

SMEs also highlighted that they are not having great experiences with their patents in China, and they believe that stakeholders there do not appear to respect patents.

Recommendations

41. **Deliver high level training for UK SMEs to give them the basics understanding of IP and protection**

In collaboration with patent lawyers, develop a basic training package freely available to SMEs that explains the basics and importance of IP. Many SMEs do not understand the options that are available to them, what the patent process will cost, what it protects, how long it will take and what risks appear with publishing your ideas and innovations. We are proposing a high level 'one to many' training course, with webinars and online resources delivered in an easy-to-understand format. This could be focused on deep tech to support not only the HealthTech sector but also the wider high value manufacturing sector in the UK.

42. **Create and share a directory of IP advice services/shared specialists available for the different HealthTech technologies/devices.**

Like the regulatory consultant directory described in the "Regulatory Challenges" section, an online list of patent lawyers (and other relevant individuals in this space) that SMEs can engage with to help them protect their inventions/innovations. This would help companies find the support they need.

43. **Create a funding scheme to support SMEs to protect their IP.**

Innovate UK grants do often allow some costs to be allocated towards protecting IP and assists commencement of the patenting process. However, this is often minimal compared to the full cost of developing and maintaining a patent. A broader programme of support like the "SME fund" offered by the

EUIOP is recommended[32] which could also include support for Freedom to Operate searches and IP strategy advice.

[32] SME Fund, European Union Intellectual Property Office - https://euipo.europa.eu/ohimportal/en/online-services/sme-fund?pk_campaign=COSME&pk_medium=SEM&pk_content=IE-ENG&pk_campaign=Paid-AdWordsSearch&pk_kwd=intellectual%20property , accessed 29/09/2022

Skills Challenges

Summary

The demand for highly skilled workers continues to grow as the world innovates. A skills shortage represents an area of competency or expertise whereby recruitment demand outstrips the talent pool. A significant challenge many HealthTech companies are facing is a shortage of skilled workers. While advancements in Industry 4.0 technologies have brought a surge of innovation to the sector, ultimately, it's having people with the right skills that is key to driving the industry forwards.

Almost 70% of SMEs replied 'yes' when asked if they could predict or have identified any future skills gap as shown in Figure 56. The top four areas where SMEs identified or predicted a gap of skilled workers were: Software/AI/ML/App development (28%), Regulatory and Quality (20%), Sales and Marketing (13%) and Engineering (13%). A combined set of recommendations is presented at the end of this section.

Data and findings

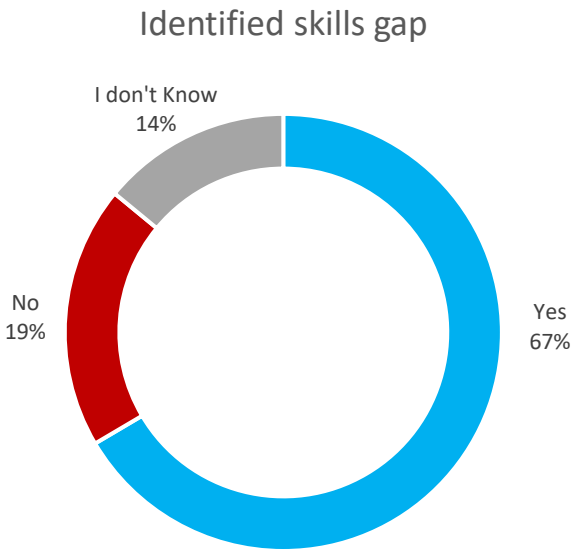


Figure 56 - Survey respondents answers to the question 'Have you identify/predict any future skills gap?'

A summary of the most frequently mentioned areas where SMEs have identified/predicted a skills gap is shown in Figure 57.

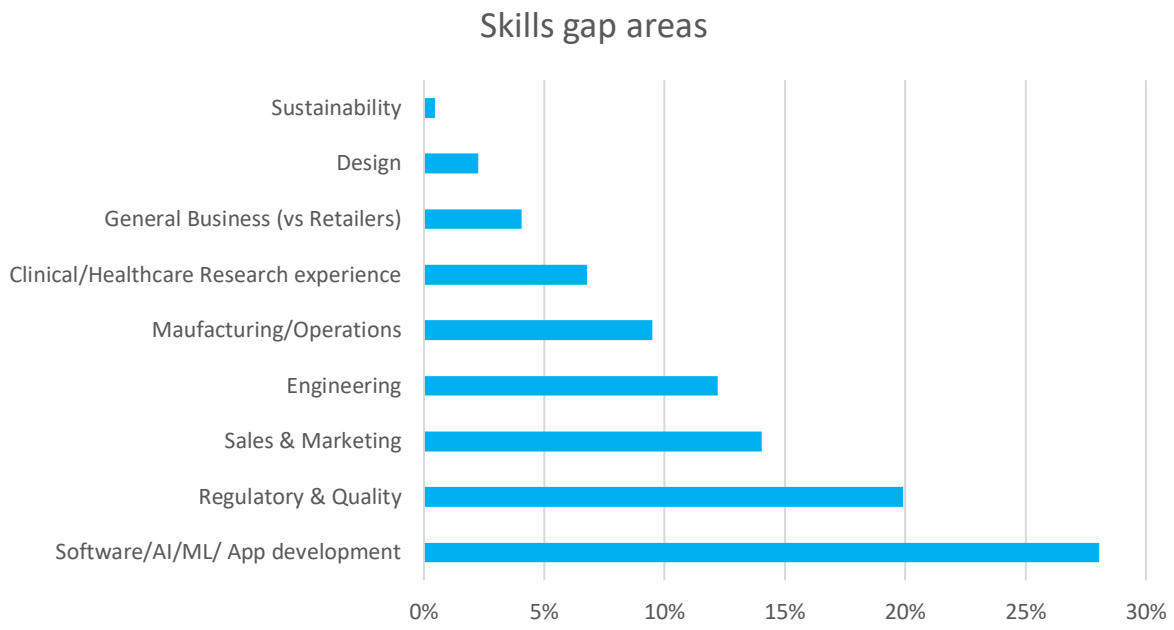


Figure 57 - In answering "Could you please give some examples of the skills gap you have identify/predicted?" the percentage of mentions by the respondents to the mostly remarked topics was calculated. Note that respondents that said their skills gap were none often due to the fact that they outsource some services, were removed.

Insight 1 – There is a gap for professionals with advanced digital skills

Software, artificial intelligence, machine learning and app development skills were identified as lacking in the UK by 28% of SMEs, primarily operating in digital health. SMEs mentioned that there is a recruitment crisis and it's hard to recruit such professionals into the healthcare sector as other industries often offer better salaries.

"We will need talented back-end software developers who are familiar with the latest ML frameworks [and] regulatory guidance around software as a medical device." – London-based SME developing Dental and maxillofacial technology

"Software developers and data scientists are already in high demand with salary expectations increasing significantly." – Wales-based SME developing Digital Health & AI technology

Insight 2 – There is a skills gap in the UK for regulatory professionals

Approximately 20% of SMEs identified quality and regulatory affairs as areas where there is a clear skills gap in the UK. Many SMEs highlighted that very few professionals have the correct skills, and they are in such high demand that they prefer to work as consultants rather than take in-house positions. Regulatory compliance is increasingly complex with the transition to UKCA, EU MDR and IVDR and there is a chronic

shortage of experienced and skilled professionals at a time when both industry, Notified Bodies and the competent national authorities are competing for such a limited resource.

Consequently, recruitment, training, employment and retention costs are a significant burden on SMEs where an average of 1.5 people are responsible for QA/RA in those with established teams, as previously mentioned in the regulatory challenges section. For the pre-revenue businesses seeking to build their teams the challenge and resource requirements slows their progress.

"We need a Regulatory Affairs Manager but those experienced enough are mostly contracting and prefer not to take full time employment positions. We cannot afford full time contractors at £1,000 per day rates." – London-based SME developing hospital hardware single use technology

An SME explained their need in "Gaining experienced and pragmatic, quality and regulatory skills in an individual who is on an affordable salary." South East-based SME developing Anaesthetic and respiratory technology

Insight 3 – There is a skills gap in the UK for sales, marketing, and engineering professionals

Sales and marketing (14%) and Engineering (12%) were part of the top four skills identified as lacking in the UK. For the SMEs that identified a gap in sales and marketing areas, some mentioned that the commercial talent in the UK is mainly in large companies selling legacy products which require a different commercial skill set . Other SMEs remarked on the lack of sales and marketing skills for global markets.

"Knowledge of market access strategies for foreign markets. Knowledge of regulatory requirements outside Europe eg. FDA, Health Canada." – South West-based SME developing anaesthetic and respiratory technologies

"...Staff who are familiar with the commercialisation of medical devices across multiple global markets." – North East-based SME developing IVDs

"Availability of engineers (trained and In-training) especially in younger applicants." – East of England-based SME developing anaesthetic and respiratory technologies

"Desperate need for skilled engineers/technicians in the biotech space, particularly those with knowledge of diagnostics. We need a really multidisciplinary team, and need microbiologists, although we often have to train engineers in the art of microbiology, which is ok, but not ideal." – Scotland-based SME developing IVDs

Recommendations

44. Develop a targeted plan to promote careers in digital sciences, quality assurance, regulatory affairs, sales, marketing and engineering.

This can include better signposting of new talent to the opportunities in those areas, targeted training to match what the UK market needs and creating better schemes to promote placements, apprenticeships or internships between universities and SMEs.

45. Offer an accelerator style, targeted training programme for those currently working in HealthTech SMEs

This would involve a targeted education and training programme, where SME staff 'learn through doing' under the guidance of an expert. This would differ from generic, high-level tutorials or engaging with consultants who conduct the work on behalf of a company.

The training programme could include regulatory, quality, technical documentation development, clinical need, IP and marketing. Testing could identify the initial level of knowledge, followed by retesting to assess the impact of the programme. Skills learned within the training programme could then be utilised to support the SME going forward, and any subsequent work in the HealthTech space.

Conclusions and final remarks

Final thoughts and what to do next

Discussion and Conclusions

The UK health technology sector is a key component of the Life Sciences sector and is crucial to the health and wealth of the UK. The Office for Life Sciences reported that in 2020 the Medical Technology sector in the UK was made up of 4,140 businesses (98% of which in England are SMEs[33]) and had £27.6bn turnover. It employed 138,100 employees over 4,560 sites in the UK. Businesses supplying the UK medical sector contribute an additional £5.6bn of turnover and 31,600 employees[34].The US medical device market is 43.5% of the World market with Europe making up around 27.3%. The UK is around 10% of the European market or about 3% of the global market[20]. The UK is also a net importer of HealthTech with a trade deficit in 2021 of over 2.2bn Euros. Germany, conversely, is a net exporter of HealthTech with a surplus of almost 9.5bn Euros. This is despite the UK having not only a strong health service and university research, but also the second highest number of HealthTech patents globally and over 10 technical areas studied in the HTECH IVD roadmap in 2021-2022. We must support this industry correctly, encouraging its growth to follow Germany in trade surplus, and to become world leading whilst there's promise for it to grow. Should we follow suit with Germany, this will drive inward investment and trade surplus whist improving the health and care of UK patients.

As a country we need to focus on developing and supporting our SMEs to grow within the UK. Their initial target markets, whether they be UK or overseas based, should be chosen based on what is most likely to make the company successful. However, we do need to create the environment for UK companies to deploy their technology within the NHS as soon as is practicably possible. Being the largest publicly funded healthcare system globally, the NHS has significant potential to become an excellent test bed to develop, test and deploy technologies, but it doesn't have to be the first market of choice for UK companies.

We need to support SMEs through appropriate funding, encouraging investment, and by providing the right innovation assets/capabilities and support throughout their innovation journey. We need to help them understand their regulatory pathways, assess the conformity of their technology in a quick, and cost-effective manner as well as having a UK regulatory framework that is simple enough to follow while maintaining its need to be robust. This will encourage UK SMEs to stay in the UK as well as encourage inward investment. With the right support for this industry, we will see increasing returns on investments, gross value added (GVA) for the industry as well export sales, increased employment and better patient outcomes. For the UK HealthTech sector to be successful in future, we need to support SMEs making the journey to market.

If this support is not provided, then our universities and innovators will continue to produce world leading research which is deployed overseas. Strengthening the UK ecosystem for SMEs will naturally improve the desirability of home market with prioritisation to benefit UK patients.

[33] MedTech landscape review, The AHSN Network https://www.ahsnnetwork.com/wp-content/uploads/2019/02/MedTech-Landscape-Review-AHSN-Network.pdf, accessed on 23/09/22

[34] UK Medical Technology Sector, Bioscience and Health Technology Sector Statistics 2020, OLS. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1037540/Bioscience_and_Health_Technology_Statistics_2020_Infographic_-_Medical_Technology.pdf , accessed on 23/09/22

Final remarks

We have carried out what we believe is the largest programme of information gathering in the UK for HealthTech industries including both surveys and face-to-face workshops. We have engaged with over 350 SMEs in the programme and from the survey responded to by HTRIP grant recipients, we have had over 18,000 individual responses.

We encourage the UK Government to read and respond to this document.

Appendix

Further supplementary information is available at www.uk-cpi.com/HTRIP

Appendix – Overview of insights and recommendations

- **Regulatory Consultants**

Insight	Recommendations
A. There is regulatory consultant capacity to support UK HealthTech SMEs B. The majority of consultants have been active prior to 2019 C. There are globally a large number of industry bodies relevant to HealthTech D. Regulatory consultants providing support to UK SMEs have a broad range of areas of expertise E. Regulatory consultants' online presence is primarily limited to websites and LinkedIn	None, insights only

- **Regulatory Challenges**

Insight	Recommendations
A. Need for a clear regulatory roadmap	1. Develop a simple, easy to understand, Regulatory Roadmap (how to guide) for UK HealthTech SMEs 2. Continue to offer online high-level regulatory training through "one to many" and interactive webinars 3. Develop an online high level training programme on digital health technologies
B. Importance of external regulatory advice	4. Innovate UK to repeat the HTRIP programme of funding for SME regulatory support 5. To improve the UK ecosystem for SMEs, encourage the MHRA to be more accessible for guidance in the manner of the FDA in the USA.

	6. Publish and maintain a free to access directory of UK based regulatory consultants
C. Importance of in-house QA/RA expertise	7. Encourage more UK universities to offer regulatory training for Life Science and related courses
D. Growing attraction of USA FDA registration	8. Develop the UKCA system to recognise EU and USA regulation approvals in its alignment
E. Notified Bodies (or Approved Bodies) are a major challenge	9. Support the designation of more UK based CABs to overcome current delays and monitor the current availability of existing services.

- **Funding Challenges**

A. Public funding schemes are too complex for SMEs	10. Funding bodies should review all HealthTech funding schemes and consider "fast start" funding and staged funding as an option.
B. There is a perceived lack of public funding for later stage innovations	11. Funding bodies such as Innovate UK and NIHR should be encouraged to cover across the entire development cycle for health technologies, funding not only "good projects" but also "good companies". 12. AHSNs and their devolved equivalents, should be encouraged to focus more heavily on the market adoption, and commercialisation end of innovation 13. Evaluate geographical variations in grant funding
C. The need for stronger participation of the Life Science investor community	14. Create and share a directory of investment companies that are interested in engaging with HealthTech companies 15. Support UK SMEs through pitch training

	16. Incentivise schemes with public:private co-funding where appropriate to extend resources and share risk. 17. Increase the involvement of clinicians for 'best value' funded programmes through NHS Trust Innovation Officers

- **Sustainability Challenges**

A. UK HealthTech SMEs lack expertise in sustainability B. SMEs need Practical Support to Achieve Net Zero by 2030 NHS Deadline	18. Establish an independent specialist sustainability advisory service. 19. Map out the existing materials used within HealthTech applications 20. Behind this, work with UK universities, Engineering Societies and UK HealthTech qualified materials producers to develop alternative materials and supporting technical data (e.g. biocompatibility, toxicology aging, sterilisation) to enable smooth switching. 21. UK to build capability in test run/small pilot manufacturing of sustainable or circular materials for HealthTech applications 22. Encourage re-shoring of manufacturing capability 23. Encourage the NHS to create an award scheme for suppliers who are driving sustainability 24. Promote and enhance Sustainability Frameworks for HealthTech in the UK
C. Single use plastics are a concern, but their use promoted by current regulations	25. Establish training programmes run by academic and industry experts for health personnel that addresses all the challenges related to single-use plastic, material substitution and regulation.

	26. Develop a HTRIP grant funding scheme to encourage UK SME manufacturers, especially for disposable and single-use plastic products

- **Target Market Challenges**

A. UK SMEs need support accessing the UK (NHS) as a target market	27. Create a UK NHS Accelerator programme with a clear "lit runway" 28. The NHS should introduce bridging loan schemes
B. UK SMEs need support to access the USA as a primary market	29. Leverage existing USA accelerator programmes to support UK SMEs to access the USA market 30. Work with AHSN and Innovation Hubs to identify SMEs with a preference to see the USA as their primary target.
C. UK SMEs need support to access the EU as a primary market	31. Leverage the UK's connection with EU embassies to facilitate UK SME introductions to EU stakeholders 32. Launch a grant funded programme to support companies currently supplying to the UK/USA market to export to the EU.
D. SMEs need support to access wider, Global markets	33. Establish a directory of experts for these global markets 34. Encourage the relevant commercial sections of the UK embassies in countries such as Canada, Australia, Japan, Brazil, UAE and Singapore to develop more proactive engagements

- **Supply Chain Challenges**

A. Post pandemic supply chain problems exist for a range of materials including semiconductors	35. Development and maintenance of a supply chain directory to enable mapping and visualisation of companies within HealthTech relevant sectors.

- **Technical Challenges**

A. Regulatory landscape and support is a challenge	No recommendations as covered in "Regulatory Challenges" section
B. The Early-Stages are well supported but translational and innovation support is lacking	36. Map out the innovation support landscape for HealthTech in the UK and provide support for gaps 37. Develop initiatives that encourage UK Universities to work more closely with translational research partners 38. Review the UK clinical testing/investigation landscape
C. UK capability and capacity for Scale-up and manufacturing are lacking	39. Carry out a 'deep dive' into UK HealthTech capability gaps focusing on scale-up and manufacturing, with funding to build capability as a follow on
D. Lack of support for digital health	40. The UK invests in a Digital Health Centre of Excellence

- **IP Challenges**

A. Cost, time and complexity of safeguarding IP (a challenge)	41. Deliver high level training for UK SMEs to give them the basics understanding of IP and protection 42. Create and share a directory of IP advice services/shared specialists available for the different HealthTech technologies/devices. 43. Create a funding scheme to support SMEs to protect their IP.

- **Skills Challenges**

A. There is a gap for professionals with advanced digital skills	44. Develop a targeted plan to promote careers in digital sciences, quality and regulatory affairs, sales, marketing, and engineering. 45. Offer an accelerator style, targeted training programme for those currently working in HealthTech SMEs
B. There is a skills gap in the UK for regulatory professionals	
C. There is a skills gap in the UK for sales, marketing, and engineering professionals	

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