ABHI Response to Industrial Strategy Green Paper, November 2024

Sector Methodology

1. **How should the UK government identify the most important subsectors for delivering our objectives?**

The UK Government should adopt a qualified data driven approach to identifying the most important subsectors. Tools such as total GDP and GVA, alongside their growth rates are useful for quantifying the scale of sectors, however these should be qualified alongside other interdependencies. For example, how sectors can support not only the UK Government's economic growth mission, but also in the case of HealthTech, how it can support the creation of an NHS fit for the future, and if remote technology is deployed effectively, reducing the health system's environmental impact, thus contributing to HMG's net zero ambitions. There are also some external effects that could be considered. For example, HealthTech contributes to the efficient and productive delivery of the NHS, and the delivery of healthcare is associated with huge economic output in its own right. Standard metrics should also be combined with qualitative and quantitative insights gathered from consultations with industry stakeholders, healthcare professionals, and academic experts. For example, ABHI's annual survey reports provide a clear indication that a third of the sector intends to increase its manufacturing and R&D investments in the UK, possibly more if barriers are removed.

2. **How should the UK government account for emerging sectors and technologies for which conventional data sources are less appropriate?**

For emerging sectors where conventional data sources may be less applicable, the government should look to build in other sources. In the short-term, conventional data sources often lack the depth or interconnectivity needed for newer, rapidly evolving technologies, particularly in HealthTech. By linking datasets such as those held NHS Supply Chain, The NHS Innovation Service, Hospital Episode Statistics (HES), and Clinical Registries, the government can create a more comprehensive view of the collective impact of HealthTech innovations. Feedback from our members indicates that in HealthTech, there are concerns around the NHS's ability to manage and curate high-quality research-ready datasets. Members suggest a realistic approach focused on improving data accuracy, relevance, and accessibility, leveraging public-private partnerships to fill resource gaps and monetise NHS data. To attract private investment, national policies should support localised data partnerships and have clear guidelines, with the end goal of enabling the faster integration of data-driven innovations.

Alongside this, government should look to see if new economic data capture is required to build a stronger evidence base in the long-term. Traditionally, government has been averse to doing so, being conscious of increasing the reporting burden on government departments and Arm's Length Bodies, however existing sources such as The Bioscience and Health Technology Sector Statistics, do not yet fully capture the impact of the HealthTech industry.

The Office for Life Sciences commissioned report 'Unlocking the potential of HealthTech' recommends 1.) the establishment of a comprehensive data collection programme is crucial to address existing data gaps and ensure a continuous, up-to-date information source on the sector and 2) the introduction of a Standard Industrial Classification (SIC) code. Both would improve understanding and more completely evidence the scale and impact of the sector.

3. **How should the UK government incorporate foundational sectors and value chains into this analysis?**

Healthcare delivery one of the most fundamental foundation sectors and HealthTech interlinks closely with the health and care system. The two have a symbiotic relationship, technologies developed by the industry are deployed by the NHS (indeed the sector has no other customer) and those technologies improve service efficiency and clinical outcomes. HealthTech is a complex sector which distinct value chains, including Research and Development, materials science, particularly with a move to a circular economy, manufacturing, distribution, service delivery, sterilisation and regulation. Many of these activities will also typically take place outside the UK. To successfully support the sector, the government should appropriately map activity and ensure suitable value is placed upon each element. Sterilisation and clean room capacity, for example, are two areas upon which significant innovation and service delivery depends, yet are under supplied. Any HealthTech sector plan should look to audit such capacity and mitigate challenges.

Sectors

4. **What are the most important subsectors and technologies that the UK government should focus on and why?**

ABHI obviously welcomes the fact that the Life Sciences, but it is important to recognise the subtleties of the different subsectors. As the largest employer in wider Life Sciences industry, the HealthTech sector (including medical devices, diagnostic and digital health technologies) employs 154,000 people in 4,465 companies, with a combined turnover of £34.3bn. Its Gross Value Added (GVA) is almost equal to that of biopharma at £13bn and it contributed the second largest number of applications for new European patents in 2022, and 30% of the sector is already looking to increase its R&D and manufacturing presence. The industry has enjoyed annual growth of around 5% in recent years. Data from the Office for Life Sciences suggest that in the decade up to 2022, the number of companies had increased by 13%, the number of employees by 29% and turnover by 16%. A recent report co-authored by the Imperial Centre for Sectoral Economic Performance and ourselves, *A sector strategy to transform the economic and societal benefits of UK HealthTech'* was bullish about what the sector might be able to achieve with a well-articulated strategy, concluding:

- 0-2 years "quick wins" in three categories: First enabling young companies to attract more VC (and other) investment. Second is to incentivise those companies themselves to invest in highly skilled employees, clinical trials, and specialist manufacturing. Third is to support those high skill R&D and manufacturing companies to sell overseas.

- 2-5 years – above-trend CAGR rate for GVA and employment growth, initially generated by SMEs but increasingly by global corporates attracted by the changes in the UK environment for HealthTech.
- 5-10 years – transformed growth in GVA and high-skill employment, taking advantage of the UK's world-leading innovation and the rapid growth of both SMEs and large corporates in the first 5 years.

Furthermore, the report forecasted a 50% increasing in global R&D HealthTech spending in the UK with an increase of 50,000 skilled jobs within 5 years leading to an overall doubling of sector GVA over 10 years.

Crucially however, government should also consider the sectors' impact beyond its direct growth. The appropriate use of HealthTech can enable the "three shifts" required in the NHS, while reducing long-term costs and improving broader economic productivity through better health of the general population. For example, newer technologies such as quantum, genomics, AI, 3D printing and robotics underpin exciting and important developments in prevention, earlier and more accurate diagnosis and precision medicine. More traditional HealthTech continues to enable high-quality, cost-effective care for millions of NHS patients every day. More effective use of green technologies, both existing and developing, such as novel materials and circular solutions would also help the NHS to reduce its environmental impact.

The potential of HealthTech is very considerable, but it requires very different consideration from other parts of the Life Sciences sector. It is incredibly diverse, with a large number of companies, the vast majority of which are SMEs. The pace of iteration is also very rapid. For example, pharmaceutical products tend to iterate over a period of 10-12 years, whilst for traditional HealthTech this figure is typically 12 -18 months. For those technologies that rely on algorithms based on AI and deep learning, iteration will be almost instantaneous with each new data input. The implementation of new HealthTech often also requires changes in how and where services are delivered. Whilst this is consistent with the "three shifts" approach of the NHS, it provides peculiar challenges for the introduction of new, disruptive innovation. How HealthTech is approved, regulated, paid for and introduced therefore needs careful and bespoke approaches.

As such HealthTech must be a key sub sector of focus within the UK Government's Industrial Strategy.

5. What are the UK's strengths and capabilities in these sub sectors?

The UK boasts a particularly vibrant small business HealthTech community, with SMEs accounting for approximately 85% of the 4,465 of the companies here, alongside significant R&D and manufacturing capabilities across a variety of subsectors such as wound care, orthopaedics, genomics and in-vitro diagnostics (IVDs). The UK HealthTech sector is also highly innovative, with it accounting for one in every twelve of UK patent applications in 2021 submitted to the European Patent office annually.

The UK has significant strengths in clinical research, regulatory expertise, and a thriving ecosystem for health technology innovation. Industry data demonstrate the UK is ranked

above the EU and US for its research environment, and in its ability to evaluate technologies for their effectiveness and value for money. The research environment is bolstered by the fifty universities which are research-active in HealthTech, and institutions such as the National Institute for Health Research (NIHR) and the National Institute for Health and Care Excellence (NICE) are globally renowned. The NHS is also recognised globally as the largest single-payer health system and has a brand of quality associated with it that allows companies to accelerate their export activity if they can demonstrate that they have significant adoption in their home market.

6. **What are the key enablers and barriers to growth in these sub sectors and how could the UK government address them?**

Key enablers to growth in the UK HealthTech sector include the robust research environment and technology evaluation structure. In addition, there are three current barriers, which, if addressed could act as enablers.

First, the potential to develop a sovereign regulatory system to support growth offers a once in a generation opportunity to position the UK as a global leader in HealthTech. However, the UK's regulatory environment currently acts as a barrier. Regulatory uncertainty, alongside increasing costs and lengthy timelines, has had a detrimental impact on investment into the UK, with over half of companies now delaying bringing innovation as a consequence. Companies report regulation costs have continued to rise at pace since 2023, and the MHRA's proposed fee increases will exacerbate this further.

Delivering a framework of the recognition of approvals from other, trusted jurisdictions is the clear enabling priority for the sector, with four times as many companies in a recent ABHI member survey indicating it as 'likely to considerably improve attractiveness' as compared to any other initiative.

However, at the time of writing, the MHRA is currently consulting on their approach and the proposals are a matter of serious concern for the industry. The first is a recognition model, allowing CE-marked devices from the EU to enter the GB market without additional reviews. Thus is the situation that has existed since Brexit and will continue indefinitely for the majority of other sectors where goods have required a CE Mark. However, this is proposed to be limited to 2028/2030, after which (apart from low-risk devices) the model would cease. A second pathway, a reliance model, leverages approvals from trusted regulators, such as the EU and USA, but requires additional GB-specific conformity checks carried out by third-party Approved Bodies. These proposals introduce several challenges. Key concerns include the high costs and extended timescales associated with the reliance model, as the requirement for conformity assessments by Approved Bodies could make it prohibitively expensive, particularly for complex and higher-risk devices. Experience in the EU suggests that these assessments can take an average of 18 months, significantly increasing costs and delaying market access. As a result, such processes may discourage manufacturers from prioritising the GB market, potentially affecting the availability of HealthTech for patients. In addition to these costs, the proposed MHRA registration fees are estimated to total £16.5 million annually across the industry, with further compliance costs potentially adding up to £30 million per year industry-wide. These financial pressures could impact business

sustainability and risk limiting access to innovative and established HealthTech solutions, ultimately affecting patients and the sector's competitiveness.

Second, the UK's tax and reporting burden also continues to grow. ABHI has identified 30 separate areas where costs to businesses are increasing, straddling employment, property and assets, energy and manufacturing, transport and reporting. As HealthTech manufacturing processes are people intensive, UK SMEs are particularly exposed to these changes. One medium sized, family-owned company is facing an additional £1m increase in employment taxes resulting from the October budget, alongside ever-increasing regulatory costs. The company provides 300 UK jobs and is having to explore offshoring manufacturing. Inheritance tax changes also present the real possibility of the family being forced to sell the business in the future to a private equity firm, impacting both the growth and innovation it can support.

Finally, whilst the world's largest single-payer health system could act as the greatest enabler for the sector, its procurement system instead acts as a barrier to growth. It continues to focus on price rather than value in procuring HealthTech. Almost a quarter of companies are removing products from the market because the price the NHS was prepared to pay was below cost. It also has increased burden through ineffective application of social value questions in tenders.

The government could address these barriers by:

1.) implementing, at pace, a regulatory system that includes both the recognition of approvals from other, trusted jurisdictions, and a domestic route synonymous with innovation and early access,
2.) exploring how the collective financial burden on HealthTech SMEs may be mitigated,
3). by reforming NHS procurement processes to place more emphasis on value and
4) create a fit for purpose adoption pathway, reducing duplicative activity, rewarding and supporting innovation and creating funding flows that support front line adoption.

Business Environment

7. **What are the most significant barriers to investment? Do they vary across the growth-driving sectors? What evidence can you share to illustrate this?**

All data in this section is drawn from the ABHI / CPI Pulse of the Sector 2024 Business Survey. The most significant barriers to investment for HealthTech are the regulatory and adoption landscapes alongside the existing approach to reaching NHS Net Zero.

It is now eight years since the Brexit referendum, and the lack of a clear future for the UK regulatory system continues to limit patient access to existing and innovative HealthTech. Our recent member survey indicates that for a third year in a row, this has had a detrimental impact on investment into the UK with over a third of businesses prioritising approvals in other markets and half of companies continuing to delay bringing innovation here.

The NHS procurement system is also commonly highlighted as placing unnecessary burden on HealthTech. Three in ten companies chose not to bid on a tender in 2024 due to unworkable

requirements, and 22% have removed products from sale because the price the NHS was prepared to pay was below cost. It is commonly stated that it takes 17 years for a technology to reach fully adoption in the NHS, and we must shorten this pathway if we are to realise HealthTech's full potential.

Finally, the existing NHS approach to NHS Net Zero (NHS Net Zero Roadmap) has emerged this year as the most unattractive factor for the sector, with twice as many companies indicating its detrimental impact compared to any other ongoing or developing initiative by the UK Government. The HealthTech sector is committed to reducing its carbon emissions, companies are investing heavily to do so, and good progress has been made. However, NHS requirements are extremely challenging. To be able to achieve the transition, clearer guidance and further education for both procurement teams and suppliers is necessary. ABHI data show the most helpful thing the government can do is to provide clear measurement guidance as nearly two-thirds of the sector call for greater standardisation as to how to define and measure 'environmental impact' or associated terms.

It also needs to be recognised that unlike other growth driving sectors, HealthTech companies have, effectively, only one customer in the UK, the NHS. As such policy decisions particularly on adoption, and sustainability, have more severe ramifications than in other sectors as companies simply have nowhere else to go.

Business Environment – People and Skills

8. **Where you identified barriers in response to Question 7 which relate to people and skills (including issues such as delivery of employment support, careers, and skills provision), what UK government policy solutions could best address these?**

To support UK HealthTech government policies should prioritise the development of skills in two discrete areas, regulation and the operating in the circular economy. Regulatory expertise is essential for navigating complex approval processes and accelerating commercialisation. HealthTech companies urgently need a workforce skilled in regulatory science to meet UK, EU, and global standards. The government should invest in targeted training and apprenticeship programmes, with a strong focus on regulatory skills alongside digital health and advanced manufacturing. Facilitating partnerships between HealthTech companies and academic institutions would further align courses with industry needs, ensuring graduates gain practical, job-ready skills. There is a global shortage of regulatory professionals in both companies and regulators themselves, and the UK has the opportunity to become a global powerhouse in the discipline by developing innovative approaches, potentially afforded by Brexit, such as those based on the principles of Outcomes Based Collaboration. Given its unique position, there would seem to be a particular opportunity for Northern Ireland in this regard.

Given the UK's preeminent position is advancing net zero, particularly through the ambitions of the NHS, investment to develop a workforce to support the circular economy would be beneficial across all sectors. This would include materials science, product design, decontamination, sterilisation and bespoke engineering.

Additionally, raising awareness of HealthTech as a career path through early education and outreach initiatives would attract more talent to a sector that remains relatively low-profile. These policies would build a robust, adaptable workforce to support the UK HealthTech sector's growth, fostering innovation and advancing patient care.

9. **What more could be done to achieve a step change in employer investment in training in the growth-driving sectors?**

The UK government should provide targeted incentives and structured support to encourage skill development within growth-driving sectors like HealthTech. Offering tax credits or co-funding opportunities for companies investing in high-demand skills, such as regulatory science, digital health, advanced manufacturing and the green economy, would make training more accessible and financially viable, especially for SMEs. Additionally, creating sector-specific training funds would allow employers to collectively invest in talent pipelines, ensuring that industry needs are met with a skilled workforce. Facilitating partnerships between employers and educational institutions to co-develop curricula and on-the-job training programmes would further align skills with real-world demands. Promoting HealthTech as a dynamic, rewarding field through government-backed campaigns would also help attract talent, encouraging employers to invest confidently in training, knowing they can retain a skilled workforce essential for sustained growth and innovation.

In addition, in the CSEP / ABHI report '*A sector strategy to transform the economic and societal benefits of UK HealthTech',* a methodology for an Industrial Strategy for HealthTech, we propose an industry led, 'HealthTech Industry Partnership', focused on skills development. With the right support such a proposal would work to upgrade the workforce skills through a leadership academy, a scale up programme, a partnership programme connecting UK SMEs with global corporates and a sector knowledge office to guide the sector through the current state of regulation, clinical trials strategy, market adoption, overseas markets, technology horizon scanning, and navigation of the wider ecosystem of universities, accelerators and conferences. All that would be required of government for such an initiative would be signposting, and as a further catalyst to the industry-led measures, offer matched funding alongside investors, based on the examples such as the Innovate UK Investor Partnerships Programme. Prioritise matched funding for pre-market de-risking milestones, including evidence generation (e.g. clinical trials) and regulatory approvals.

The existing Apprenticeship Scheme is well received, although simplifying use of the levy would be welcome, as SME's often struggle with the administration and need for a structured programme along with the additional costs to run apprenticeships.

Business Environment – Innovation

10. **Where you identified barriers in response to Question 7 which relate to RDI and technology adoption and diffusion, what policy solutions could best address these?**

Whilst the UK HealthTech ecosystem has tremendous strengths in innovation and early-stage research, supported by infrastructure such as the NIHR, IUK and a plethora of funding bodies and charities, gaps arise in translation, adoption and spread.

Funding support specifically falls off in the translational research phase and is an area that capability was rated behind the US and EU in our recent industry survey. Crucially, the likelihood of adoption could help to pull technologies through this phase. However, it takes on average 17 years for a new HealthTech device to go from successful clinical trial to adoption by the NHS. Given the pace of technological advances designed to improve patient health outcomes and, in many cases, improve NHS productivity, this has consequences on the quality of care that can be delivered in the NHS.

Many initiatives have aimed to overcome these challenges with varying degrees of success. One however that the HealthTech sector remains optimistic for is the Innovation Ecosystem Programme (IEP). It stands out from previous, similar, initiatives, in that it was done by the NHS for the NHS. The stumbling block in almost all the previous exercises was the lack of engagement of the operational service. This element, we believe, is particularly important for HealthTech versus the Life Sciences more broadly. HealthTech has traditionally been developed by close collaboration between industry and the clinical community, a relationship that remains vital for adoption and spread, especially where innovation leads to changes in clinical practice, location of care delivery, or diagnosis earlier in the patient pathway.

In the short term, the CSEP / ABHI report '*A sector strategy to transform the economic and societal benefits of UK HealthTech'* that provides a methodology for how deliver a HealthTech industrial strategy, recommends six immediate key actions to professionalise adoption in the UK. 1. Ensure there is a framework for the adoption of innovation by the NHS in partnership with the sector, 2. Protect time for innovation within clinical timetables while enabling joint posts to allow NHS clinicians to work with industry, 3. Appoint Board level Chief Innovation Officers in all NHS organisations and provide the resource and mechanisms to ensure innovation is managed and measured, in part through the CQC well-led framework, 4. Centralising some activities that currently lead to unnecessary duplication of work by both the NHS and HealthTech, 5.Bring NHS savings targets in line with wider HMG productivity initiatives i.e. moving from a one-year time horizon to five years, 6, Amend Innovation Adoption Initiatives to encourage innovations that improve NHS productivity.

11. What are the barriers to R&D commercialisation that the UK government should be considering?

Key barriers to R&D commercialisation within the HealthTech sector include fragmented funding and limited scale up capital, navigating the complex regulatory environment and the development and acceptance of real-world evidence.

HealthTech companies often lack access to late-stage funding necessary for prototyping, regulatory processes, and market launch. While early R&D is supported, scale-up capital is scarce, particularly for SMEs. Increased funding targeted at commercialisation could help bridge this gap and support robust innovation pipelines.

Navigating the UK's evolving regulatory landscape is challenging, especially for smaller companies. Regulatory complexity and delays add time and cost to commercialisation. Greater support for regulatory navigation and alignment with major markets like the EU would

reduce these burdens and encourage investment. Initiatives such as Health TRIP and MAARS have received positive feedback from manufacturers and should be replicated where possible. Real-world evidence (RWE) is critical for HealthTech commercialisation, but there is currently no clear gold standard for such data, creating inconsistency and uncertainty for companies. Establishing standardised frameworks and guidance for RWE collection would help HealthTech companies validate their products effectively, enhancing their commercial capabilities.

Business Environment - Data

12. How can the UK government best use data to support the delivery of the Industrial Strategy?

To support the Industrial Strategy, the UK government should leverage NHS data to drive innovation, improve patient outcomes, and boost economic growth. Establishing a national resource through a network of federated Subnational Secure Data Environments (SNSDEs) would enable HealthTech researchers and companies to access vital healthcare data securely and ethically, fostering advancements in HealthTech solutions. The network must integrate NHS data systems across different departments, regions, and care providers to create a seamless, unified, multi-modal data landscape.

Unlocking NHS data would allow HealthTech firms to develop evidence-based products, services and AI tools that address pressing health challenges, aligning with government goals to enhance population health and stimulate the economy. For this approach to succeed, it is crucial that these data environments are designed with meaningful stakeholder engagement, ensuring they meet the needs of researchers and innovators.

Embedding user-centred design and robust security frameworks from the outset will protect patient privacy while promoting trust in data-sharing practices. This strategic use of data positions the UK as a leader in health innovation, accelerates R&D commercialisation, and maximises the economic impact of the HealthTech sector, ultimately supporting the UK's Industrial Strategy.

13. What challenges or barriers to sharing or accessing data could the UK government remove to help improve business operations and decision making?

To improve business operations and decision-making, the UK government should address several key barriers to data sharing and access to enable the development and deployment of HealthTech. These include streamlining Access to NHS Data for Research and Innovation and overcoming existing challenges with information governance.

The key barriers currently include disparate systems and a lack of standardisation leading to poor interoperability and low GP support, partly due to the unclear liability risks of data sharing and perspectives of patient trust. The most evident direct barrier for HealthTech development and deployment is the current approach to information governance. Data Sharing Agreements (DSA) and the associated Data Protection Impact Assessments (DPIA) are regularly cited as barriers to adoption at scale rather than enablers. Whilst the need for Data protection

assessment is more a legal (GDPR and DPA) and ethical requirement, the lengthy and bureaucratic implementation at a local level leads to duplication of activity, for both industry and the NHS, long and unpredictable timelines, and a lack standardisation and consistency in the outcome of assessments. It is recognised that the processes are valuable in protecting patients and systems from undue risk, however, it is believed that the benefit can be maintained while deploying the processes in a more streamlined fashion.

There is also a significant skills gap in data expertise across many NHS Trusts, which hampers effective data stewardship. To address this, we recommend the NHS expand training and capacity-building programmes to improve the baseline level of data literacy among all NHS staff. We also suggest for the widespread implementation of training for frontline staff to equip them with the skills needed to work with digital tools, data, and AI as these technologies become more central to improving NHS performance and patient outcomes.

Public confidence in allowing personal data, albeit in a non-identifiable format, is crucial if we are to maximise the potential of the NHS dataset. ABHI had previously advocated for a national public awareness campaign about the benefits of data sharing, including to the individual in the near term. High profile data breaches have, and continue to damage public confidence and need to be addressed. For example. They could be reforms to the NHS national data opt-out, allowing patients more nuanced and informed choices about how their confidential information is used beyond direct care. One example would be that the NHS national data opt-out currently asks people if they allow their 'confidential patient information to be used for research and planning'. Splitting this choice out into the use of data for planning and research, and even use cases beyond these, would give patients more control. Improving transparency and communications around data use and its impact on research could enhance patient confidence and unlock more opportunities for data-driven innovation.

ABHI recommends taking a more integrated approach, adopting a centralised 'passporting' approach to information governance approval, where companies / technologies are approved once at a national level.

Whilst not specifically related to data use, but containing elements related to data privacy and security, the Digital Technology Assessment Criteria (DTAC) process currently suffers from similar issues of duplicative and non-standard approaches. A constructive dialogue is on-going between industry, DHSC and NHSE to move to a more appropriate implementation aligned to international standards and recognising the checks and balances already in place for regulated medical devices. We urge government support to ensure this programme is fast-tracked and resourced towards implementation.

Business Environment – Infrastructure

14. **Where you identified barriers in response to Question 7 which relate to planning, infrastructure and transport, what UK government policy solutions could best address these in addition to existing reforms? How can this best support regional growth?**

To address barriers related to planning, infrastructure, and transport, the UK Government can implement policy solutions that streamline processes to support the HealthTech sector's growth within regions. Local initiatives, such as Single Conversation Investment Group pilots in the Humber region, offer a valuable model for coordinated planning that could benefit HealthTech companies nationwide. ABHI would recommend extending the model to other regions across the UK. By bringing together all relevant agencies, including environment, highways, and local councils, into a single coordinated forum, this model simplifies the planning process, allowing HealthTech companies to receive integrated feedback on their development plans. The creation of such groups should also sit alongside increased autonomy for local authorities to allocate resources and incentivising regions to focus on illness prevention and leverage HealthTech to support the local economy. Investing in sustainable infrastructure aligned with NHS net-zero goals would also create green jobs and support SMEs, fostering inclusive growth, and support for local bus routes and subsidies could encourage a broader workforce to access these jobs.

Critically, the UK Government should also expand investment in digital infrastructure, including high-speed broadband and 5G, in regions targeted for HealthTech growth. HealthTech companies often require secure, high-bandwidth digital networks essential for data-heavy operations, such as remote diagnostics, real-time monitoring, and data processing.

Flooding is also a significant barrier to regional investment in areas that can be flood-prone. By addressing flood risk proactively, the government can make high-potential areas viable for HealthTech investment. This ensures that companies do not need to rule out valuable regions due to flood concerns, allowing for more diversified regional growth and sustained economic development.

15. **How can investment into infrastructure support the Industrial Strategy? What can the UK government do to better support this and facilitate co-investment? How does this differ across infrastructure classes?**

Investment in infrastructure is essential for advancing the UK's Industrial Strategy, particularly in the HealthTech sector. ABHI recommends prioritising infrastructure improvements that maintain and support HealthTech manufacturing, innovation, and scale-up capabilities.
Clean rooms and sterilisation services are fundamental, particularly for HealthTech products that must meet stringent regulatory and safety standards. Increasing the availability of these facilities across the UK would directly support the Industrial Strategy by enabling more HealthTech manufacturing and reducing reliance on international facilities. The government could provide support in this space by creating initiatives that allow for the co-investment in such facilities. One small company is unlikely to be able to manufacture at the scale required to make a single clean room efficient, yet by acting as a catalyst for co-investment, the UK Government could reduce the risk of a joint initiative, stimulate further investment and provide companies with the confidence to scale up UK-based production.

Business Environment - Energy

16. **What are the barriers to competitive industrial activity and increased electrification, beyond those set out in response to the UK government's recent Call for Evidence on industrial electrification?**

The HealthTech sector faces significant barriers to electrification, primarily due to inadequate grid infrastructure in many regions. Current grids often cannot meet the high energy demands required for HealthTech manufacturing and sterilisation processes, limiting large-scale transitions to electrification. Transitioning to electric processes involves substantial upfront costs, that are particularly prohibitive for SMEs, which would benefit from government-supported green financing options like low-interest loans, grants, or tax incentives, similar to successful models in mainland Europe and the US. The lack of clear, long-term pricing signals for electricity and carbon also adds uncertainty, making a predictable pricing framework essential. Volume contracts or access to government-funded energy pools would allow businesses to secure renewable energy at stable rates, enhancing sector attractiveness.

In addition, whilst the UK HealthTech sector is committed to reducing its collective environmental impact, infrastructure and energy challenges impede progress, particularly when compared to international competitors with ready access to a sufficient supply of renewable energy. To remain globally competitive and support regional growth, the UK Government needs to address these issues with both immediate and long-term solutions.
For the long-term, ABHI would strongly support the allocation of funds to upgrade the UK electrical grid's capacity to meet the energy demands of HealthTech and other advanced manufacturing sectors. The provision of clear government-backed incentives for HealthTech manufacturers to adopt hybrid energy systems that combine reliable renewable sources with existing gas usage would also work as a short-term solution until grid capacity improves. This would allow companies to balance the need for resilient energy solutions with the move toward sustainability.

In the short-term, government could implement time limited, government-backed support schemes to offset the higher costs of sustainable energy in the UK. These could include energy subsidies, tax reliefs, or direct financial assistance for HealthTech manufacturers committed to renewable energy use while waiting for grid improvements. The UK Government should also explore co-investing in expanding EV charging infrastructure across business parks and industrial areas, especially where companies are encouraged to adopt electric company vehicles.

17. **What examples of international best practice to support businesses on energy, for example Purchase Power Agreements, would you recommend to increase investment and growth?**

Business Environment – Competition

18. **Where you identified barriers in response to Question 7 which relate to competition, what evidence can you share to illustrate their impact and what solutions could best address them?**

The greatest competitive barrier the UK HealthTech sector is seeing currently is within the UK's existing model of regulation. Currently, as planned, our regulatory system will be largely a UK version of a construct designed to manage the free flow of products within the single market and would maintain the peculiarities that exist in the roles and responsibilities of different organisations. As such, the regulator for HealthTech, the MHRA, does not actually regulate, rather it is the guardian of the system which relies on the use of third-party organisations (Approved Bodies) to certify conformity with regulations.

Current arrangements limit the ability of the UK Government to performance manage and improve the system, rather they rely on competitive market forces to drive performance. However, in reality there is a supply shortage as the capacity of Approved Bodies is heavily constrained by the skills availability of technical assessors, and the ability for companies to switch if service is poor or overly expensive, is heavily limited. In addition, transitioning between Approved Bodies can take between two and three years and limit the ability for an organisation to deliver innovation in the meantime. Consequently, competitive forces are not playing their role as intended and the costs of Approved Body services have skyrocketed, alongside a deterioration on the timelines for regulatory approvals. Recent ABHI data reported costs could be over 700% higher, and timelines 150% longer in the UK/EU when compared to the US, and there is little the regulator, MHRA, can do to intervene.

Simultaneously however, MHRA is currently consulting on increasing costs further by adding a £16+ million bill on the sector for post marketing surveillance, in addition to the fees the sector already pays directly to Approved Bodies. MHRA is also consulting on increasing the fees the Approved Bodies pay to the Agency for designation, which will inevitably also be passed onto the sector. The current system is leading to ever-increasing costs, extended delays and is drastically impacting the attractiveness of the UK market. There is an opportunity, post-Brexit, to think again about how we want our system to function.

ABHI recommends that, the Regulatory Innovation Office (RIO), working alongside the Regulatory Horizon Council, MHRA and Competitive Markets Authority, urgently carries out a review that determines how our regulatory system might best be reformed including the existing designation model for Approved Bodies.

19. **How can regulatory and competition institutions best drive market dynamism to boost economic activity and growth?**

As noted in questions 18 and 20, ABHI believes there is an opportunity to drive market dynamism by 1.) looking at the competitive market forces relied upon to drive performance between the designated third party organisations that deliver UK HealthTech regulation (Approved Bodies), and 2.) shifting towards a dual model regulatory system that includes both the recognition of approvals from other, trusted jurisdictions, and a domestic route synonymous with innovation and early access.

Business Environment – Regulation

20. **Do you have suggestions on where regulation can be reformed or introduced to encourage growth and innovation, including addressing any barriers you identified in Question 7?**

The UK regulatory environment currently requires extensive and unnecessary duplication of effort. Post Brexit modifications to the system have been slow, creating a high degree of uncertainty in the single most important process that improves healthcare for NHS patients and allows young HealthTech companies to start making revenues. The uncertainty deters investors and drives HealthTech companies away. There are a series of measures however that Government can deliver to reduce this drag on growth quickly and with minimal expense. The CSEP / ABHI report 'A sector strategy to transform the economic and societal benefits of UK HealthTech' that provides a methodology for how deliver a HealthTech industrial strategy, sets these out.

They include:
1.) Accepting certain non-UK approvals of HealthTech products including the US and EU,
2.) Developing a process for handling innovations, such as that outlined in the MHRA's Software as a Medical Device Roadmap, and determining the merits of the Innovative Devices Access Pathway (IDAP),
3.) Shifting the focus of UK regulatory resource towards post-market surveillance to support innovation,
4.) Developing innovative approaches to regulation, such as Outcomes Based Cooperative Regulation (OBCR), and
5.) Training students in relevant disciplines in regulatory affairs.
Collectively these measures would contribute to the attractiveness of the UK for HealthTech investment and improve NHS delivery.

Business Environment – Crowding in Investment

21. **What are the main factors that influence businesses' investment decisions? Do these differ for the growth-driving sectors and based on the nature of the investment (e.g. buildings, machinery & equipment, vehicles, software, RDI, workforce skills) and types of firms (large, small, domestic, international, across different regions)?**

For HealthTech companies, the factors impacting business investment decisions are the speed and cost with which companies can reach their next milestone. These decisions could range from spending on R&D, regulatory processes, etc. through to considerations of the speed with which a product can reach adoption.

We differ as a sector significantly because of the appropriately high level of regulation required to ensure patient safety, leading to high development costs. The pace of adoption within the NHS means the risk of a company running out of finance before a return is realised is high. This significantly inhibits the amount of investment available for HealthTech SME businesses. Buildings, machinery and equipment present a mixed challenge as they are often rented in scale up phases, reducing high entry costs however increasing the risk if a return is delayed by slow adoption.

For larger firms, business certainty is a key factor, alongside the costs to do business. The most detracting and costly barriers as described above are regulation, adoption and the NHS

current approach to Net Zero reporting, which is costly, burdensome and out of step with requirements in many other jurisdictions.

Business Environment – Mobilising Capital

22. **What are the main barriers faced by companies who are seeking finance to scale up in the UK or by investors who are seeking to deploy capital, and do those barriers vary for the growth-driving sectors? How can addressing these barriers enable more global players in the UK?**

HealthTech companies in the UK face significant barriers when seeking finance to scale up, including complex regulatory requirements, fragmented procurement processes, and inconsistent reimbursement frameworks. These challenges limit access to essential growth capital, forcing many innovative HealthTech firms to look abroad, particularly to the US, where investment pathways are larger, more streamlined and supportive. This shortage of scale-up capital in the UK hinders domestic growth and stifles innovation. For investors, navigating inconsistent market access and a lack of targeted R&D funding creates hesitancy. Addressing these policy barriers through streamlined regulation, enhanced procurement transparency, and dedicated financial support for high-growth sectors, alongside proposed pension reforms which should target SME finance, will make it easier for UK HealthTech companies to access domestic funding. This shift is crucial to positioning the UK as a global leader in HealthTech, attracting international investment and enabling homegrown companies to scale. The HealthTech sector in the UK is a global ecosystem, and supporting SMEs builds the attractiveness of the market for all players.

23. **The UK government currently seeks to support growth through a range of financial instruments including grants, loans, guarantees and equity. Are there additional instruments of which you have experience in other jurisdictions, which could encourage strategic investment?**

While the UK government's financial instruments, such as grants, loans, guarantees, and equity, are vital for supporting HealthTech growth, the focus should be on improving the access, availability, quantum and effectiveness of these existing tools. Enhancing current offerings through streamlined application processes and targeted awareness could yield substantial benefits. However, it is crucial that any financial support considers the need for follow-on capital; otherwise, we risk merely postponing the "valley of death," where companies struggle to secure the next stage of funding. In successful jurisdictions, robust Government backed co-investment schemes and targeted venture capital funds have proven effective, not only in bridging early-stage gaps but also in providing sustained financial backing through scale-up. By ensuring that follow-on capital is integrated into the UK's financial support strategy, we can create a more resilient pathway for growth. This will help UK HealthTech companies scale domestically.

Business Environment – Trade and International Partnerships

24. **How can international partnerships (government-to-government or government-to-business) support the Industrial Strategy?**

There is a significant opportunity for government to work with Trade Associations and other international organisations to increase the support HealthTech companies are receiving on trade within Industrial Strategy.

Existing support for export is heavily fragmented and has deteriorated in value in recent years. Companies report seeing wide variation in the level and quality of export support received. Some companies report being content, citing help from Embassies as being particularly strong, whilst others observe that the help they are able to access is limited in quality. Whilst multiple organisations are currently engaged in supporting companies, they should be seen as partners in a network with a common goal, utilising collective expertise. However, in practice, the process has been viewed as competitive by various government organisations, making collaboration unnecessarily difficult and confusing.

In addition, in the CSEP / ABHI report '*A sector strategy to transform the economic and societal benefits of UK HealthTech',* which represents a methodology for an Industrial Strategy for HealthTech, proposes the benefits of a Global Export Programme that prioritises the sector's needs and delivers a simplified framework of export services. Such an initiative could be led by industry, in partnership with government to drive economic growth.

25. **Which international markets do you see as the greatest opportunity for the growth-driving sectors and how does it differ by sector?**

As a highly regulated sector, for HealthTech the number one factor that determines which market they will target first is the complexity, cost and certainty of regulatory systems. Over a quarter of exporting HealthTech companies this year identified the USA as their biggest overseas market by turnover, as it was in 2023, and significantly above any other market. The only caveat is that not all product portfolios will suit the US market, depending on accepted clinical practice in any give speciality. GCC countries, notably UAE and KSA are also attractive. Otherwise, Australia tends to rank highly as a high value market where clinical practice is recognisable to UK companies

Place

26. **Do you agree with this characterisation of clusters? Are there any additional characteristics of dimensions of cluster definition and strength we should consider, such as the difference between services clusters and manufacturing clusters?**

We broadly support the characterisation of clusters but recommend that any framework includes flexibility to capture the specific dynamics of HealthTech. While there are overlaps with life sciences, HealthTech clusters often emerge in distinct regions and serve unique functions, which should be acknowledged in sector planning. Leeds, for instance, is a significant hub for HealthTech, but not traditionally part of life sciences clusters focused on pharmaceuticals or biotechnology. A tailored approach that recognises these differences would ensure that HealthTech clusters receive appropriate support and investment.

Growth in HealthTech businesses is also inextricably linked with access to the NHS. Facilities that support the development of HealthTech are valuably co-located with large NHS organisations in centres such as Cambridge, Birmingham, Manchester and Nottingham. The Midlands, especially, with a very large, ethnically diverse and stable population has great potential across both HealthTech and the broader life sciences.

Additionally, we believe there is value in categorising clusters by type. Not all clusters follow a traditional innovation or manufacturing model, and they often form serendipitously around key companies or regional strengths. Recognising these different types of clusters could reveal opportunities for systematic development across the UK. HealthTech, for instance, benefits from various forms of clustering that support diverse needs in the sector including;
1.) Administrative Clusters: In Watford, companies Medtronic and Smith + Nephew have operational and administrative functions. Such clusters contribute significantly to regional employment and skill development, even if they are not directly linked to manufacturing or R&D, and
2.) Training and Education Clusters: In Solihull, companies Arthrex and Abbott have established training centres, providing specialised skills and knowledge that support HealthTech adoption across the NHS and private providers. They also offer training to healthcare professionals from across the world, providing opportunities for local hospitality and service sectors. These clusters are critical to fostering sector-wide expertise and should be supported in sector planning.

27. **What public and private sector interventions are needed to make strategic industrial sites 'investment-ready'? How should we determine which sites across the UK are most critical for unlocking this investment?**

For the HealthTech sector, targeted interventions are required from both public and private sectors, focusing on infrastructure, incentives, and local ecosystems.

It should be noted that HealthTech is a sector that is already well established beyond London and the Greater South East. However, we can further encourage companies to locate more widely through collaboration with established local investment communities, such as regional venture capital networks. Government could help attract private investment by connecting sites to capital, talent, and sector expertise. Public-private partnerships could further support the development of regional HealthTech clusters by fostering connections between industry, academia, and local healthcare providers. Developing sector-specific training programmes in collaboration with nearby educational institutions would also ensure a skilled workforce and attract businesses to the region.

Deploying some of the policies outlined in consultation questions focused on infrastructure, energy and regions would also be helpful.

28. **How should the Industrial Strategy accelerate growth in city regions and clusters of growth sectors across the UK through Local Growth Plans and other policy mechanisms?**

To accelerate growth in city regions and key HealthTech clusters, the Industrial Strategy should leverage existing local expertise and infrastructure. The HealthTech sector benefits

from a range of established local organisations and initiatives, and often, convening these groups to focus on shared objectives can be the most effective approach. The establishment of 14 Healthcare Research Centres by the National Institute for Health and Care Research, each with a specific focus, but having a degree of central coordination offers a model that might usefully be built upon.

Trade associations have valuable insight into the regions with highest growth potential. The Industrial Strategy should prioritise partnering with business groups, especially those with sector specific knowledge, to identify key HealthTech clusters such as Leeds, Birmingham and Manchester for HealthTech, and engage local leaders to support existing initiatives. Rather than creating new programmes, empowering the efforts already underway will allow regions to capitalise on current momentum, driving targeted, efficient growth. There is also scope to build existing initiatives that fall under the auspices of Combined Authorities, such as the West Yorkshire HealthTech Cluster and the West Midlands HealthTech Innovation Accelerator.

HealthTech also needs to engage the local health and care infrastructure. Integrated Care Boards (ICBs), with their specific objective of supporting economic growth, offer a unique opportunity to support regional HealthTech development. The NHS is Europe's largest employers and, as anchor institutions, large healthcare providers play a central role in their communities, driving local economic activity and employment. By including ICBs in Local Growth Plans, the Industrial Strategy can promote collaborations between HealthTech companies and healthcare providers, fostering innovation that meets the Government's ambitions in both its economic and healthcare delivery goals.

Finally, there are also opportunities for the delivery of private healthcare services to contribute significantly to the economy, especially in clusters such as London's Harley Street, where private healthcare delivery attracts inward investment and drives economic output. In the US, the Mayo Clinic in Rochester, Minnesota describes itself as being the place where "healthcare meets hospitality," its facilities attracting insured and self-pay patients from across the globe. Recognising the economic role of healthcare delivery in individual regions will strengthen the business case for HealthTech investment. The Industrial Strategy should consider these areas as vital contributors to the Life Sciences sector, positioning healthcare hubs as foundational to growth and regional economic resilience.

29. **How should the Industrial Strategy align with devolved government economic strategies and support the sectoral strengths of Scotland, Wales, and Northern Ireland?**

The Industrial Strategy should actively align with the distinct economic strategies of Scotland, Wales, and Northern Ireland to leverage each region's unique strengths in HealthTech, fostering a cohesive UK-wide approach to innovation and growth. Recognising and supporting the specific capabilities of each Devolved Administration's economic plan will maximise the UK's collective impact in the global HealthTech market, presenting a unified front with complementary strengths rather than competing regional agendas. It is important that UK regions recognise that their competitors are not each other, but rather areas such as Singapore, Germany and Kendall Square.

Each Devolved Administration contributes peculiar advantages. For example, Northern Ireland's position, bolstered by the Windsor Framework, allows it unique access to both the EU regulatory framework and the UK market. This dual access creates a valuable bridge for HealthTech companies that want to operate across both regulatory systems, making Northern Ireland an attractive location for businesses focused on international market access. Similarly, Scotland and Wales each have strong health innovation ecosystems with active HealthTech clusters, academic research, and healthcare delivery models.

A strategy that supports these devolved government strengths while positioning the UK as a unified leader in HealthTech will help attract international investment and drive innovation across all regions, ultimately strengthening the UK's competitive edge in the global HealthTech landscape.

Partnerships and Institutions

30. **How can the Industrial Strategy Council best support the UK government to deliver and monitor the Industrial Strategy?**

To foster investment and growth in HealthTech, collaborative policymaking that considers the sector's unique needs is essential. The Life Sciences Council (LSC) has demonstrated the value of such collaboration, especially in HealthTech regulatory reform, where it has worked closely with industry to create pragmatic solutions and provide a clear direction of travel.

Where this approach has fallen down however, and where we would like to see the Industrial Strategy Council and associated groups focus on, is implementation and delivery. We recommend formalising sector-specific forums that feed into the LSC. HealthTech has distinct requirements necessitating tailored support. Dedicated forums would allow HealthTech leaders to provide detailed insights and expertise, enabling the wider LSC to shape policies that address the sector's particular challenges, with the most relevant aspects being monitored to ensure we effectively drive growth. Given the inextricable links between HealthTech growth and the receptiveness of the NHS as its only market, there needs to be significant and meaningful engagement with the operational NHS, and, in turn, the service must see itself as a driver of economic growth as well as a provider of care.

By continuing to work closely with HealthTech leaders, the Industrial Strategy Council can deliver policies that support the sector's growth and competitiveness, ensuring the UK remains a global leader in HealthTech innovation.

31. **How should the Industrial Strategy Council interact with key non-government institutions and organisations?**

For HealthTech, the Industrial Strategy Council should prioritise close collaboration with representative bodies from industry and the operational health and care system. There is a track record of such organisations making valuable contributions to the development of relevant policy, and continues engagement would ensure strategies are informed by specialist knowledge and are deliverable in the systems we work within.

We should also ensure that underneath senior interfaces for CEOs in fora such as the LSC, expert groups on topics such as HealthTech are created allowing industry experts to share insights on unique challenges, such as regulatory requirements and innovation adoption.

32. **How can we improve the interface between the Industrial Strategy Council and government, business, local leaders and trade unions?**

The LSC has enjoyed success in setting an ambitious direction of travel on regulation, however it also needs to focus on implementation. Implementing structured feedback mechanisms, such as public reporting and progress updates, could improve accountability. Regular updates on how input has shaped Council decisions will also build trust and enhance collaboration across all groups involved.

ABHI also believes that the LSC needs to be more balanced across the Life Sciences, including more HealthTech representation, supported by an expert HealthTech specific group to ensure priority issues are not overshadowed by the biopharmaceutical industry.

Finally, whilst the existing Life Sciences champions have stalwartly stewarded the broader sector through some significant periods of change, and deserve our thanks for their leadership, by their own admission they come almost exclusively from a biopharmaceutical background. HealthTech follows a fundamentally different innovation pathway, with different regulation, assessment and procurement methodologies required, and where we see some the greatest unintended consequences of poorly crafted policy, are when these peculiarities have not been adequately recognised. Current initiatives such as the development of a Rules Based Pathway and the NICE Late-Stage Assessment process, betray a lack of appreciation of how HealthTech differs from other parts of the life sciences sector. ABHI would strongly urge the government to appoint a HealthTech Champion to support the work of the LSC. The individual, supported by officials and feeding into the cross-government missions, would ensure we realise the full opportunity of HealthTech.

Theory of Change

33. **How could the analytical framework (e.g. identifying intermediate outcomes) for the Industrial Strategy be strengthened?**

To enhance the analytical framework underpinning the Industrial Strategy, the Government should embed feedback loops that facilitate continuous improvement and adaptation to market dynamics. We would stress the importance of incorporating real-time qualitative data and stakeholder input into the decision-making process, ensuring that strategies remain relevant and effective.

We would also propose that the CSEP / ABHI report *'A sector strategy to transform the economic and societal benefits of UK HealthTech'* at its essence provides a methodology for how an industrial strategy can be co-created. It includes a number of recommendations for government that have been included in this consultation response, however it also includes three activities that the industry can do with appropriate governmental support. These are a

UK National HealthTech Industry Partnership focusing on skills, a sustainable HealthTech Innovation Centre and a Global Export Programme.

The analytical framework used in Invest 2035 could be strengthened by ensuring a similar co-creation approach is used across the development of industrial strategy.

34. What are the key risks and assumptions we should embed in the logical model underpinning the Theory of Change?

ABHI welcomes the Government's use of a Theory of Change to simplify complex economic growth pathways, but highlights areas for refinement, particularly for HealthTech. The model risks generalising sector needs, overlooking specific challenges such as regulatory hurdles and fragmented market access for HealthTech. Assumptions about business engagement may not hold for smaller firms with limited capacity, requiring additional support measures. Finally, sector-specific metrics, like time-to-market, patient outcomes, and R&D investment, are essential for meaningful evaluation.

35. How would you monitor and evaluate the Industrial Strategy, including metrics?

ABHI recommends a comprehensive approach to monitoring and evaluating the Industrial Strategy, using both quantitative and qualitative metrics tailored to the HealthTech sector. Key indicators should include growth in sector investment, increased R&D activity, and improvements in adoption of HealthTech products. Tracking job creation, export performance, and patient outcomes will also provide a clear measure of success. Regular stakeholder feedback, through a HealthTech specific ministerial forum reporting into the Life Sciences Council and an adaptive review process will ensure that the strategy remains responsive to industry needs. Aligning these metrics with broader health and economic goals will enable effective evaluation and drive continuous improvement across the sector.

Additional Information

36. Is there any additional information you would like to provide?

ABHI is committed to fostering a collaborative environment that drives innovation and investment in the HealthTech sector in the UK. We welcome the opportunity to engage with the Government in developing an Industrial Strategy, and Life Sciences Sector Plan that reflects the potential of the HealthTech sector. We look forward to working with the Government to create a thriving ecosystem that promotes health innovation, enhances patient care, and drives economic growth.