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Health, wealth and growth:

A sector strategy to transform the economic and societal benefits of UK HealthTech

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Table of Contents

Executive Summary

HealthTech is a hidden gem of the UK economy. It contributes £13bn Gross Value Added (GVA, equal to biopharma) thanks to the UK's strengths in medical innovation.[i] But its potential remains barely tapped. Growth in UK HealthTech is limited by shortages in capital and skills, partly because HealthTech investment has been damaged since Brexit by uncertainty about regulatory arrangements.

Given the importance of HealthTech in patient care, as described in the Appendix "HealthTech vs MedTech", the sector has a too-distant, transactional relationship with the NHS, which should be its biggest partner in clinical trials and adoption of technologies that deliver more cost-effective healthcare.

Fixing these problems will add to the nation's economic growth and help ensure that the NHS delivers better health and wellbeing to everyone in the UK.

This report presents specific policies with short, medium, and long-term benefits that:

- strengthen investment flows into UK HealthTech companies from domestic and overseas investors through tax and regulatory incentives, alongside measures to address skills shortages.
- boost investment by UK HealthTech through tax and regulatory incentives to fund clinical trials in the UK.
- increase the attractiveness of the UK for HealthTech companies by providing a collaborative framework for the adoption of HealthTech by the NHS.
- address skills shortages through the establishment by industry of a HealthTech Industry Partnership (HIP).
- achieve sustainability and NetZero goals by incentivising innovation with a UK kitemark, supported by specialised training delivered by HIP.
- boost exports through a programme of overseas customer engagement events supported locally by the Department of Business and Trade (DBT).

These will be achieved by fast-acting and relatively simple measures including:

1. Recognition of regulatory approvals by the FDA, EU, and other trusted jurisdictions as sufficient to grant UKCA approval. This incentivises companies to invest in NHS clinical trials and ensure that the choice of clinical trial participants reflects the UK population. Experts consulted during the development of this proposal said this would also encourage North American and Asian companies to establish their European operations in the UK.

2. Specific R&D tax credits for clinical trials conducted with the NHS. The UK has fallen from 4th to 10th globally in the number of large clinical trials conducted, and this measure will restore the UK's competitiveness in clinical trials. More trials will bring more cash to the NHS and boost corporate recruitment of HealthTech specialists in the UK.

3. Changes to Capital Gains Tax (CGT) and Enterprise Management Incentive (EMI) rules to reward employees of high-risk early-stage companies such as those in HealthTech. These employees generally have lower cash earnings and higher share-based remuneration than comparable roles in established companies. Without a lower tax rate for share-based incentives in high-risk private companies, experienced managers and engineers are discouraged from taking jobs with entrepreneurial innovative companies.

4. Industry to establish and support HIP, endorsed by Government. It will address the skills shortages in the sector. It will integrate this with Office of Life Sciences (OLS), UKRI, and other bodies such as the Health Innovation Networks.

With these and the other initiatives set out in the main body of the report, Government and Industry can transform the attractiveness of the UK to HealthTech investment and unlock growth of high value employment. Just as importantly, HealthTech can make the NHS more cost-effective with products ranging from new diagnostics and treatments to AI in patient care. With few exceptions, new medical devices both improve patient care and save healthcare systems money. HealthTech is a means to improve NHS productivity and the quality of the care it provides to the UK population.

Staged delivery for GVA growth

Growth in the short term will fall to existing companies, primarily SMEs. Large corporates often operate in more mature categories with growth rates in single figures. Therefore, we have modelled an evolving contribution from the sector today (represented by the ABHI's membership) to what we consider to be the likely composition of the sector 5-10 years from the execution of the proposals in this report.

- **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.

We forecast 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.

Acknowledgements: Throughout the development of this proposal, we have been fortunate to have been able to consult widely across the sector, including corporates, SMEs, professional bodies, government, academia, and investors from angels to VCs. Their experience, insights and pragmatic optimism have strongly informed the actions recommended in this report.

Detailed comments arising from the interview processes are included as an Appendix to this document.

In particular, the authors would like to recognise the contributions made by Thomas Aubrey, Paul Benton, Lord Ara Darzi, Peter Ellingworth, Jonathan Evans, Phil Kennedy, Jane Lewis, Rupert Shute, Lord Lionel Tarassenko and the project sponsor, Lord David Sainsbury.

Foreword

The **Independent Investigation of the National Health Service** in England laid bare the challenges faced by a healthcare system reeling from the pandemic, austerity and top-down restructuring. But the vital signs are strong. Innovation will be key to getting the NHS off life support. As we contend with a society facing increasing ill health, the fate of our health system will be inextricably linked with our ability to develop, adopt and sustain health technologies.

The **Independent Investigation** also brought to light the remarkable opportunities that resuscitating the NHS will bring. Innovations which will offer the opportunity of delivering new care pathways at the point of patient need, greater productivity of our health sector, as well as tackling emerging threats to our health security including climate change and antimicrobial resistance. Augmenting a vibrant life sciences sector will offer not only innovations but develop of enterprise and professionals. Above all, a revitalised NHS will offer our patients lives lived to the full, rather than overshadowed by disease.

The HealthTech industry will be pivotal to realising this potential. The **Independent Investigation** provided identified key themes on how the NHS can be resuscitated to bring health back into people's lives and the UK's economy. Shifting paradigms from management of disease to enable wellbeing will empower patients to fulfil their personal end economic potential. Moving care out of hospitals and into primary care will reduce inequality and improve access. Digitalisation will build health systems able to adapt to, and overcome challenges as they arise. The HealthTech sector is uniquely positioned to be the convening force that draws full value out of these themes.

The strategy laid out in this report provides a pragmatic and achievable route to delivering on the value offered by the HealthTech sector. Streamlined regulation stands to promote greater investment in clinical trials. Incentivisation targeted at encouraging entrepreneurialism will promote skills development. Financial incentives will attract R&D and onshore capabilities. Public-private partnerships will support the development of talent. Individually these policies will drive innovation. Applied in concert they will build a HealthTech sector that will be the lifeblood of a reinvigorated NHS that provides health, wealth and growth for generations to come.

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Defining the Wins

	2 Year	5 Year	10 Year
Overall Proposal	Increase in capital raised by UK HealthTech companies. 10% Increase in spending by HealthTech companies on R&D within the UK. Initiate a Willingness to Invest annual survey across corporates, global and UK investors.	Increase in jobs from 162k to 212k. 5 new specialised high value manufacturing facilities planned. 50% Increase in spending by HealthTech companies on R&D within the UK. UK reverses its fall in the ranking of the number of large clinical trials conducted with a corresponding increase in NHS revenues from clinical trials.	Sector GVA output doubled (7% CAGR). UK restored to top 4 locations for Phase 3 clinical trials. UK is a hub for data collection (i.e. clinical trials) for UK, US and European approvals.
HealthTech Industry Partnership	10 of top 20 global corporates participating. Partnership case studies compiled. Develop and publish Business Readiness Levels (BRLs). £20m funding raised by client companies.	Funding for HIP years 6-10 secured. Company exits increase in 25% by value, including UK Initial Public Offerings (IPOs) 50% increased likelihood of funding for supported companies Corporates increase investment in UK by 50%.	80% of top 25 HealthTech globally as sponsor members. £1Bn funding raised by supported companies.
Sustainability	Establish sustainable healthcare UK kitemark. First UKRI collaborative challenge call for new materials launched.	Export related to sustainable devices/ components skills – 10% of total export revenue. Offset government intervention through NHS carbon savings.	Measure against interim NHS NetZero targets for 2035 – majority of NHS suppliers meeting UK kitemark.
Export	Agreement with DBT to provide sector experts on all relevant foreign trade missions. Establish export alumni network – representation from 50% of companies involved in previous DBT and ABHI trade missions. Increase in contracts signed in US $500m (from $150m).	Increase in medical devices export revenue to bring European trade into surplus (currently EUR 4.5Bn deficit). Total Contract Value of deals signed by companies on the programme as an indicator of effectiveness of the accelerator programme.	Global ranking of UK HealthTech improves to 2nd (behind US).
Regulation	UKCA retargeted to first time approvals. All CE marked and FDA cleared/ approved products remain available on UK market.	50% of UK approvals are of FDA-approved products that are not yet on sale under the European system. 50 new products by international manufacturers approved through UKCA but not available in either the US or EU.	Best place to launch new Healthtech products based on survey of corporates UK matches US in terms of regulatory environment that encourages investment and innovation (ABHI / Centre for Process Innovation Survey).
NHS Adoption	Establish strategic working group involving HIP and Shelford Group of research hospital trusts to create transparent network of specialisms responsible for driving innovation adoption within the group's top NHS Teaching Hospitals.	NHS adoption of technologies ranked within top 10 of OECD countries. Establish NHS clinical leads linked to HealthTech categories (e.g. robotics) to identify innovations of interest to the NHS and those that are unsuitable for the NHS. 25% of healthcare professionals involved in evaluation/implementation of new technologies.	UK matches US in terms of adoption of technologies at pace and scale (ABHI / Centre for Process Innovation Survey).
Financial	Investment into HealthTech, and by HealthTech into the NHS both increased by: i) higher R&D tax credits for clinical trials spending with the NHS. ii) SEIS cap increased for companies doing UK clinical trials. iii) CGT levied at a lower rate for investments in private HealthTech companies that IPO in the UK.	Return the UK to the top 4 of large clinical trials locations in the world (currently 10th), boosting revenues for the NHS and to HMRC thanks to high value job creation.	NHS revenues from clinical trials to double to £5 billion per year (at current prices).

Our proposal: For industry by industry

HealthTech Industry Partnership

Context

Despite the UK ranking 3rd in the world for scientific research[ii] and Imperial College, Oxford and Cambridge routinely occupying top places in global university rankings, no UK HealthTech companies rank in the global top 20 based on annual revenue (See Appendices). The highest ranked (Smith & Nephew) is 24th.[iii]

For the UK to translate global research leadership into economic growth, leadership must extend into commercial R&D. HealthTech is the most common category of UK university spinouts, yet there is a shortage of experienced leaders and the multitude of technical specialists needed to take these innovations to market. In other geographies (e.g., US, Switzerland, Ireland) leadership and specialists for HealthTech start-ups and SMEs often come from people leaving large companies. Like other sectors, HealthTech SMEs looking to gain momentum to enter markets often have to move closer to sources of capital and talent. This is the primary reason why 70% of UK businesses across sectors had moved or were planning to move R&D activity abroad by 2023.[iv]

The proposals in this section address the challenges of bringing UK commercial and technical skills up to the level of the UK's technical ingenuity.

Accelerator shortcomings, investment readiness, experience, and global influence

Investors we consulted unanimously identified "people issues" as a common cause of company failure, alongside technology and lack of funding. These issues fall into two categories: (1) founder experience/leadership skills and (2) technical skills such as regulatory affairs or specialist manufacturing (see Appendix: UK MedTech High Value Manufacturing Capabilities). Even for companies that are successful, these factors drive them to scale up outside the UK. Without demonstrably top-class corporate leadership, investors are deterred.

For both categories, skills shortages can be partly ascribed to the relative absence of large HealthTech companies in the UK. These companies' workforces are a source of both entrepreneurial leaders and experienced specialists. Proposals elsewhere in this report, in regulation and investment for example, will attract companies and individuals to the UK in the medium term.

A second cause of this broad skills shortage in HealthTech is the patchy specialist education and training in the UK for both senior managers and technical specialists. Young companies often rely on incubators and accelerators. But the effect is modest: they increase a company's likelihood of raising funding by just <4%.[v] Typically they focus on one phase of the commercialisation journey and operate narrowly either by geography, therapeutic area or a specific investee or university cohort[vi]. What is needed for UK HealthTech is to provide experienced leadership coaching and technical expertise in all aspects of commercialisation. These include:

- International fundraising and business development.
- Regulatory affairs, medical manufacturing and clinical trials operations.
- The development of products that deliver value for money as well as healthier patients.
- The development of products that meet the needs of both the NHS and export markets, especially the US.
- Business planning all the way to product sales to maximise the chance of investment.
- International marketing and sales so that R&D delivers more than just technical solutions. i.e., what healthcare providers want both clinically and in terms of value for money/productivity gains.

This training must be delivered in short intense packages to enable lean companies to spare team members. SMEs are best served by this kind of support.[vii]

This must be organised centrally; as one venture capital investor told the authors of this report "there are so many [SME support] initiatives in the UK it has become very hard to navigate". This is not surprising given that there are over 700 accelerators and incubators in the UK, according to UKRI and Cambridge Health Partners.

For the UK HealthTech sector to succeed in export markets, the NHS can be a powerful validator in terms of evidence generation through clinical trials and clinical adoption. Unfortunately, while 71% of HealthTech firms would like to target the NHS as their first target market, the sector cited NHS adoption process and the complexity of the regulatory environment as the top two barriers to growth in the UK.[vii] The issues of NHS adoption and the importance of performing clinical trials in the UK are addressed elsewhere in this report.

Recommendations

This report proposes the establishment of a UK National HealthTech Industry Partnership (HIP) to upgrade workforce skills as set out above.

To design and validate the HIP components, we have consulted internationally, including growth capital funds in the US and Europe, many SMEs and large corporates including Medtronic, Philips, Siemens, Amazon, ThermoFisher, Illumina, IQVIA, Johnson & Johnson and Roche. Their support will include contribution of senior leadership to HIP programmes as well as financial support based on alignment with their commercial objectives and their Corporate Social Responsibility (CSR) mandates to support the wider sector.

HIP will develop and publish a Business Readiness Level (BRL) framework specific to HealthTech that extends the methodology already in place for start-ups to cover the full commercial development lifecycle. This will be carried out by a working group representing global (including US) investors, leading start-up accelerators and the full range of corporate leadership roles (for example CEO, CFO and CTO). The framework will develop BRLs specific to each regulatory class of devices.

These BRLs will be applied throughout the HIP's programmes and shared with the sector so that incubators and accelerators can use these criteria to prioritise the support they offer to early stage HealthTech. Examples of their application are included in the detailed proposals below.

The HIP will comprise four key components:

1. Leadership Academy
To train senior executives and directors in international leadership in corporate strategy and execution. It will ensure that today's management is equipped, experienced and ambitious to deliver globally competitive businesses, and it will teach and inspire the next generation to sustain the growth trajectory.

- Companies that demonstrate objective performance against relevant BRLs will be able to access masterclasses by international corporate leaders. One goal is to secure mentoring from the best international leaders today to coach UK companies in terms of global expansion, commercial partnerships etc.
- It will provide digital skills training for leaders, partnering with organisations such as the Chartered Management Institute, BioMedEng Association and Institution of Engineering and Technology, to ensure that emerging tools such as large language models are exploited.
- It will collaborate with Higher Education Institutions to develop educational content on regulatory, clinical trials management and health economics, delivered remotely or in person for engineering students. Additionally, it will provide mentors to trainee-led HealthTech entrepreneurship projects. This will mean that trainees (undergraduate, PhD and postdocs) are ready to embark on careers in bioengineering, digital sciences, regulatory, clinical trials management, sales, marketing, and R&D as leaders of new UK HealthTech companies.
- Those passing through the Academy will have access to an alumni network to provide life-long peer support.

2. Scale-up Programme
Masterclasses delivered by investors and corporate leaders and working alongside incubators/accelerators and established SMEs.

- The BRL framework will assess and support participating companies based around clarity on mission: pathways to adoption, investor value propositions, customer value propositions, and market prioritisation.
- It will provide coaching in how to develop these value propositions.
- It will provide investor-led training on how to build a financial business plan from inception to exit.
- Driven by an assessment of market fit, companies will be invited to participate in the global Export Accelerator described elsewhere in this report.
- Companies having reached an appropriate BRL will be showcased to providers/payers both UK (NHS and private) and overseas (e.g. Johns Hopkins, Spire, Kaiser Permanente).
- This same methodology will be used to introduce UK HealthTech companies to overseas investors.
- In addition to syllabus-led programmes, the accelerator will offer tactical support in recruitment, manufacturing, regulation, clinical trials, sales, distribution, and marketing.

3. Partnership Programme
HIP will connect UK SMEs with global corporates to develop relationships that lead to sales channel partnerships, product collaborations, and intellectual property licensing. Early exposure to corporate integration partners (for example, providers of Electronic Health Record systems, diagnostic scanners, and cloud computing infrastructure) will align technical/commercial strategies to make subsequent acquisition or IPOs more likely and more valuable. In doing so:

- SMEs will benefit from pathways to market facilitated by corporates with the requisite distribution channels and marketing expertise.
- HIP will provide a forum for the sector to influence industry standards and codes of practice.
- The sector will better respond to evolving NHS priorities.

4. Sector Knowledge Office
To generate and supply insights that will 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. This will be an extension of the services already provided by ABHI.

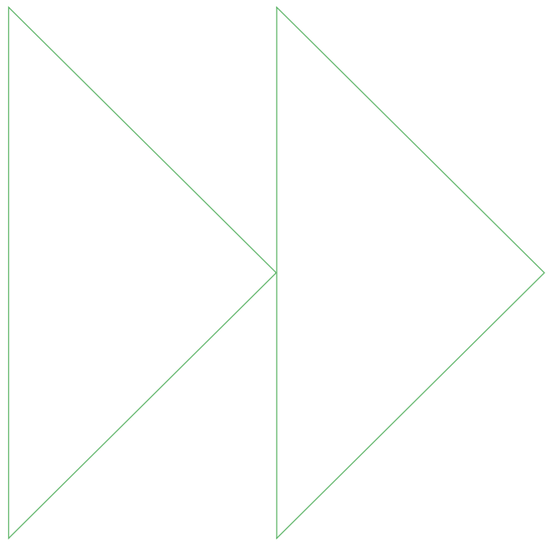
- The Sector Knowledge Office will work with OLS to establish an annual "Willingness to Invest in the Sector" survey to provide a baseline from which the performance of the sector and HIP can be measured.
- In collaboration with the national accelerator and incubator ecosystem, the Sector Knowledge Office will map the landscape to enable any sunset review of government-funded accelerators in the sector.
- The Office will research and report on future directions of HealthTech and emerging markets, recognising that technology advancements, adjacent industries, and geopolitics, will influence the state of the sector.
- Additional functions will include centralised navigation of:
  - Innovation Support landscape, including grant funding, NHS adoption processes and procurement routes.
  - Regulatory pathways.
  - Access to guidance for regulation and market access in export markets.
  - Prevailing government policy.
- The Sector Knowledge Office will also work with professional bodies such as TOPRA (regulatory) to provide a reliable professional services network, in particular providing:
  - An interactive map of services required for the spectrum of HealthTech businesses.
  - Access to organisations providing credible supporting functions such as sales, marketing, HR, legal, IP and regulatory services.

Funding

During the development of this proposal, almost all the corporates consulted said they were willing to make a financial contribution to HIP. Once established, HIP will generate revenue from consultancy and other activities.

Requested actions for government

- Signpost (e.g. via links on government websites) to the HIP.
- Promote HIP to global corporates via Foreign Office representation.
- 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.



Sustainable HealthTech Innovation Centre

Context

In October 2020, the NHS in England became the first healthcare system to embed net zero into legislation. It set two targets:

1. **For emissions that the NHS controls directly (NHS carbon footprint):** net zero by 2040 and 80% reduction by 2028-2032.
2. **For emissions, the NHS influences indirectly (NHS carbon footprint plus):** net zero by 2045 and an interim aim to reach 80% reduction by 2036-2039.

The UK has an unprecedented opportunity to take advantage of this head start in what will be a high-growth sector for decades to come. Medicines and medical devices qualify as 'emissions that the NHS can influence' as part of Scope 3 NHS Carbon Footprint Plus. Medical Equipment accounts for 10% of the NHS carbon footprint[ix] while medicines account for about 25%. Among the biggest contributors are anaesthetic gases and nitrous oxide, which account for around 2% of NHS emissions, and inhalers which account for around 3%.

Nevertheless, as part of the drive to lower emissions, the NHS will by 2030 no longer buy from suppliers that do not meet the commitment to net zero. To meet the NHS's ambitious targets, companies that sell to the NHS must offer products that satisfy new criteria for lifecycles from manufacture to decommissioning. High on the list of priorities is the task of replacing thousands of single-use disposable products with recyclable or reusable alternatives. To do this, companies must develop and validate new medical materials in a classic short-term pain and long-term gain process.

Our proposal, therefore, is to bring together manufacturers and scientific innovators to address this challenge in materials science. This will be done via partnerships with existing private and government-supported facilities. The goal is not only R&D but also the expansion of manufacturing and the creation of a HealthTech circular economy.

Today's landscape: Barriers to sustainability

Challenges to sustainability and net zero goals in HealthTech, and the response, fall into six categories:

The Supply Chain accounts for up to 80% of healthcare's greenhouse gas emissions. Today's procurement requirements do not incentivise sustainable practices.[x]

Product Lifecycle – The HealthTech sector, like many sectors, is wrestling with how to meet NetZero targets. Almost two thirds of ABHI members surveyed are still building the internal capability required.[xi]

Circular economy – Medical products must operate at their best, whether they are new or have been in service for years. In a linear value chain, older equipment can be repaired, refurbished, or remanufactured both to minimise emissions and to make the most of material, labour and capital costs already incurred. In a circular economy, this is extended so that valuable materials, products, and components are cascaded to other uses, and eventually recycled in closed material loops. Pioneering companies already provide circular economy solutions including product life extension, repair, refurbishment and remanufacture. Such actions can reduce the carbon footprint of individual equipment by 50-85% over its lifetime and at lower cost, without any compromise on performance and patient safety.

Materials and components – The reuse and remanufacture of medical equipment can help reduce healthcare's reliance on single-use devices. Single-use plastics have been cited as the biggest challenge (33%) and as the biggest area of concern (19%) to achieve net zero by the sector itself.[xiii] Developing new materials is tough. There are no quick solutions. As well as meeting standards for safety and performance, new materials must convince regulators and clinicians that there is no risk to patients in switching from established safe materials. Bioengineers will be at the forefront of developing sustainable methods for decontaminating and remanufacturing devices such as catheters and surgical instruments.[xiv]

Packaging and Instructions for Use (IFUs) – Paper IFUs are an EU requirement for self-test and near patient IVDs, and for any non-professional use of a medical device. Switching to electronic IFUs is an opportunity to improve on the EU environmental requirements and one that seems likely to be adopted everywhere.[xv]

Digital technologies – Digital technologies can reduce environmental impact in the healthcare supply chain.[xvi] AI also promises to be part of new ways to diagnose disease, stratify risk, predict outcomes, and analyse issues in public health. There are risks: as well as the often-discussed ethical questions about AI, the carbon-footprint of energy-intensive computation should be considered when designing products for widespread use.[xvii]

Recommendations

Establish a Sustainable HealthTech Innovation Centre (SHIC) under the oversight of HIP. It will modelled on the chemical industry's Innovation Centre for Applied Sustainable Economies (iCast), which enabled R&D collaborations and increased productivity and investment. The High Value Manufacturing Catapults and Centre for Process Innovation (CPI) are enthusiastic about working with this new Centre and ensuring that they work with public and private bodies to enable it to be appropriately financially supported.

1 Skills and Methodology
SHIC will develop, promote, and market its skills as services and in product development. It will take advantage of the NHS's first mover status to export services and potentially products into follower healthcare systems. It will partner with University of Exeter's Centre for Circular Economy and Imperial College's iCUBE Laboratory for Circular Economy Research to establish training programmes to address all the challenges related to single-use plastic, material substitution and regulation.

2 Standards and Codes of Practice
The Centre will convene industry groups to co-author and deploy codes of practice for sustainable development. In the case of AI in healthcare, SHIC will promote and improve Sustainability Frameworks for HealthTech to ensure that best practices are codified and implemented. The partners will include Imperial College's Centre for Sectoral Economic Performance (CSEP), The Institution of Engineering and Technology, Institute of Mechanical Engineering, BioMedEng, industry bodies including AXREM and TOPRA, and healthcare providers including the NHS.

Working with HIP's Sector Knowledge Office, SHIC will map out the existing materials used in HealthTech and establish an independent specialist sustainability advisory service.

With the NHS, the SHIC will co-develop a Sustainable HealthTech Kitemark along with associated monitoring criteria that recognises effective sustainable engineering practise in HealthTech to inform their future procurement criteria.

3 Innovation and Manufacturing
The Centre will define and then tackle sector-wide material science challenges (for example, the development of antimicrobial coatings for biodegradable single-use devices) working with experts including universities, CPI, the High Value Manufacturing Catapult Network and iCAST. Behind this, the SHIC will work with UK universities, Engineering Societies and UK HealthTech qualified materials specialists to develop alternative materials and supporting technical data (e.g. biocompatibility, toxicology aging, sterilisation) to enable regulatory approvals and smooth switching.

Given the carbon footprint arising from increased use of data-driven approaches including Artificial Intelligence (in particular, growing concerns due to the energy consumption),[xix] SHIC will establish a dedicated Net Zero Digital Health Lab with backing from corporate cloud computing providers and specialists within Imperial College's CSEP who are working on sustainable practices for data centres.

To enable the UK to build capability in test manufacturing of sustainable or circular materials for HealthTech applications, SHIC will work with CPI and the High Value Manufacturing Catapults. In parallel the SHIC will support government by providing evidence-driven advocacy for re-shoring of manufacturing to help ensure that net zero goals are met.

Funding

SHIC staff will be part of the HIP team. In addition, the Centre will make business cases to leverage funding from government (for example via UKRI R&D) to address specific NHS sustainability targets. As with other HIP functions, SHIC will develop commercial services to generate revenue to support HIP via targeted consulting support services. It is anticipated that commercial entities associated with the High Value Manufacturing Catapult network would provide financial support through their CSR budgets.

Requested actions for government

- Exploit completed research (e.g. Design for Life, CE Hub, Brighton and Sussex Medical School) with dissemination via DHSC and NHS to help deliver Net Zero objectives at an NHS-wide level.
- Provide signposting (e.g. via government webpages, Companies House etc.) to SHIC for both domestic and overseas entities.

Further acceleration of outcome delivery could be achieved by these additional measures:

- Match R&D funding via UKRI/Innovate UK for industry investments to meet NHS NetZero targets: for example, by consolidating existing grant finances into a sustainable materials challenge programme with a payback to the NHS in terms of sustainable procurement within 5 years.
- Provide funding for companies to achieve kitemark accreditations.
- Support and encourage the NHS to adapt procurement models to enable faster uptake of HealthTech that meets sustainability standards but might otherwise not be chosen due to short-term costs or inertia.
- Following the anticipated publication by the DHSC of its 'Design for Life' roadmap, fund work to cut the volume of single use devices by improving capacity for reuse, remanufacture and materials recovery.

Global Export Programme

Context

HealthTech products have global markets. New treatments and diagnostics are equally effective in Europe, the Americas or Asia, with very few exceptions. Export markets make or break life sciences companies because it costs tens or even hundreds of millions of pounds to develop a regulated medical product. The UK market is important but represents only 3% of the world market. To put it bluntly, a business plan that relies on UK sales alone will not attract venture capital funding.

By supporting exports, the UK will be a more attractive place for inward and domestic investment and, in turn, high-value job creation. This is not only about the fortunes of the sector: in spite of the UK's world leading Healthtech research, the UK ranks 30th out of 31 European countries in terms of medical devices trade balance with a deficit of EUR4.5Bn.[xx] The UK invents new lifesaving technologies, but the economic benefit is largely felt elsewhere.

By far the biggest healthcare market is the United States. But others are important too, especially Europe, Middle East, Japan, China, and South Asia. The knowledge of how to access these markets is territory-specific. For example, the processes by which prices are set and products are approved for healthcare systems differ by country, and sometimes even within countries.

UK companies, especially start-ups and SMEs, need specialist advice. The fact that the UK has fallen behind many developed countries in its exports of HealthTech, with databases placing it in 10th (Imperial database) and 12th position (OLS)[xxi] demonstrates both the challenge and the promise before us.

Landscape

Government support for HealthTech exporters lags that in many other nations. The UK needs a suitably resourced HealthTech sector export strategy that addresses the diverse needs of the industry.[xxii] Individual export markets have their own rules and there is not enough specialist export knowledge and market access expertise available. What exists is fragmented, poorly coordinated and hard to find.

One cause may be that general grant support for exporters has all but disappeared. At the same time European funding for the same purposes is no longer accessible following Brexit.

Another contributor may have been a redistribution of public funding for an ever-increasing number of regionally delivered export initiatives. This creates a postcode lottery for companies seeking help, funding, and guidance. It has complicated the support landscape, led to duplication of activities inefficiencies and confusion among international customers as well as UK HealthTech companies.

While the support of embassy staff in the target markets is critical, it is unreasonable to rely on the expertise of multi-disciplinary individuals for export advice in complex specialist areas such as HealthTech.

This presents an opportunity for the sector to come together with government to provide sector specialists to complement and strengthen the capabilities of the DBT).

An example of a successful industry-led export initiative is the ABHI's US Accelerator programme. For over 8 years the programme has supported the growth of over 100 UK HealthTech businesses in the US market, tracking $150m of business won and facilitating over 70 clinical trials or pilots across 12 US states. Further details are provided in the Appendices.

Recommendations

We recommend an expansion of the ABHI's US Accelerator programme to create a HealthTech Global Export Programme that prioritises the sector's needs and delivers a simplified framework of export services. We believe that industry is best placed to both develop and deliver such a strategy with the support of the Government, so leadership of this programme should remain with ABHI.

We recommend that funding be provided to expand ABHI's coverage of North America, Middle East, and Asia. Further funding would allow expansion into more territories. Estimates of funding requested are provided below.

This will also enable sector specialists and the DBT to be more effective in new markets. It will also support recommendations on Foreign Direct Investment made by the Harrington Review.[xxiii]

An expanded HealthTech Global Export Programme would be facilitated by ABHI: support would be provided by HIP's Scale-up Programme to ensure that companies taking part in trade missions have articulated their value proposition for the target market, maximising the value of the opportunity to present their solutions in front of overseas buyers.

1. **Sector Expert Partnership** – ABHI will provide companies with export advice and liaise with regional embassies and consulates. HIP will also provide sector-specific briefings to the foreign service so that they can support in the promotion of the sector in overseas markets.

2. **Expanded US Export Accelerator** – ABHI will identify at least two additional US states with underexploited market potential for UK HealthTech businesses and expand current support through local partnerships and trade missions.

3. **Global Market Launch** – Middle East, Asia: Building on ABHI's established presence at key meetings such as ArabHealth, continue to expand relationships, including those with national and regional trade associations, and launch programme of trade missions for UK companies that have been assessed and supported by the HIP.

4. **Sector Export Alumni Community** – Identification and endorsement of reliable partners in overseas markets has been consistently highlighted as a high value activity by the sector, however government and trade association statutes prevent them offering this service. Therefore, establishing and curating a peer support network including UK companies that have entered overseas markets is a key component of this Export Programme.

Revenue Considerations

The HealthTech Global Export Programme would require £1.75m invested over a 5-year period. This would scale up the US programme and fund expansion into the Middle East and Asia. The programme will increase from 4 missions per year to 18 missions in the 5th year. The number of companies taken on missions would increase from 28 visiting one market to 105 companies accessing 3 markets.

Requested actions for Government

- Facilitate engagement between DBT and HIP/ ABHI to develop detailed operational plans and then deliver collaborative aspects of the Export Programme.
- Promote centralised sector initiatives to foreign counterparts and overseas sectors via Embassy staff.
- Support high profile diplomatic missions for leading sector companies in key markets, noting the huge value reported by the sector when key government figures attend selective visits.

The role of Government

Driving investment into HealthTech, and from HealthTech into the NHS

Context

Innovative HealthTech companies need risk tolerant, long-term capital to propel them through many years of product development and regulatory milestones. Not surprisingly, many investors hesitate to take on that level of risk. As a result, young UK companies, whose products could save lives and improve NHS productivity struggle, die, or move to places where capital is more plentiful, such as the US.

When entrepreneurial companies do raise funding, they are incentivised to spend their development budgets outside the UK where costs are lower and markets are more accepting of new technologies. The NHS and the UK economy have suffered. The UK has fallen from 4th to 10th globally in running the large clinical trials needed for regulatory approvals.[xxiv xxv] These are the most expensive clinical trials to run, and their departure means a loss of high-value jobs, revenue to the NHS and taxes to the Exchequer.

This report presents a package of measures designed both to boost investment into UK HealthTech and divert a greater proportion of those investments into spending in the UK. The same measures could also assist small/medium BioPharma companies. The result of these investment flows would be more high-paying jobs, greater domestic economic activity and additional funding to a more productive NHS.

Recommendations

The measures set out below are designed to deliver four boosts to the UK HealthTech investments, spending in the UK, NHS revenues and economic growth. They will

- increase domestic and inward investment into a defined cohort of HealthTech companies, from start-up to PLC.
- incentivise these companies to conduct R&D in the UK, especially high-value clinical trials. This will bring fresh revenues to the NHS, universities, and UK-domiciled companies, boosting economic growth and tax receipts.
- Increase the attractiveness of the UK stock market for HealthTech companies, which make companies more attractive for investment and encourages them to keep their headquarters in the UK after an IPO.
- Further increase the attractiveness of the UK HealthTech employers for innovative engineers, scientists, doctors and managers.

The measures set out below are not complicated or expensive. They apply only to companies that qualify based on running approved clinical trials. This definition will ensure that the benefits go to companies taking the highest risks and developing products relevant to the NHS. The cost to the Exchequer will be minimised since the additional high-pay employment and spending in the UK will compensate for the cost of tax breaks.

1. Incentivising capital inflows to the UK HealthTech sector from startup to post-IPO

The proposed initiatives are:

- To extend Seed Enterprise Investment Scheme (SEIS) benefits for investments in qualifying HealthTech companies (defined above) to the first £5m invested. This is to reflect the much longer development times needed compared to start-ups in non-medical sectors.
- To improve liquidity in UK stock markets by:
  - Removing the Inheritance Tax (IHT) exemption for AIM shares to discourage investors from holding on to their shares to avoid IHT.
  - Removing Stamp Duty Reserve Tax (SDRT) on sale of shares of qualifying companies (defined above) for shares that were bought when the company was private. This is to increase post-IPO liquidity and therefore boost pre-IPO investor sentiment. SDRT revenues could even increase as more liquidity means more transactions on which these taxes are paid.
  - To extend rollover relief to the reinvestment of post-IPO sale proceeds into qualifying private life sciences company investments, IPOs, and secondary offerings.

These changes would make UK public markets much more attractive for companies seeking to IPO at valuations of under ~£500m. This is a market capitalisation below the typical threshold for a listing on NASDAQ, currently considered the ultimate destination for successful life science companies. Sector leaders interviewed for this report said that trying to compete with NASDAQ would fail but that there was a need to raise finance at this kind of valuation. With a UK listing, the pressure to relocate headquarters and other operations (typically to the US) eases.

Finally, Business Asset Disposal Relief (formerly Entrepreneur's relief) helps business owners, and EMI option schemes help employees. However, the cap on EMI options at £250k is low for the length of time that medical product research company employees must wait before they see an exit. Furthermore, if they leave employment, even after many years of service, they lose the benefit. This deters highly qualified potential employees from leaving large companies to join SMEs and start-ups. We propose two reforms of EMI for qualifying companies (defined above): raise the EMI cap to £500k and ensure that the benefits remain if the employee leaves after no less than five years.

2. Using R&D Tax Credits to benefit the NHS and UK plc

Early-stage companies are always short of cash, and for HealthTech companies this drought lasts for up to ten years before they generate revenues from sales. They are under permanent pressure to cut costs in R&D, their biggest expense. This drives them to conduct clinical trials in low-cost countries with a consequent loss of high value employment in the UK and revenues for the NHS.

The solution is to boost R&D tax credits for qualifying R&D spending in the UK. Industry participants we surveyed said this would increase UK investment by companies in the first year of its introduction, with the amounts increasing thereafter as the proportion of clinical trials conducted with the NHS rises. The same benefit should be extended to qualifying research conducted in the UK public sector (typically universities) and UK tax domiciled private sector specialists such as independent testing labs. In both cases the cost to the Treasury will be offset by higher employment tax revenues from the high value jobs created, and from increased corporation tax revenues from the private sector specialists. In the medium term, such incentives would also attract US companies seeking a European base to the UK, a HealthTech CEO told the authors of this report.

We recommend R&D tax credits for qualifying companies spending on UK R&D to be set at a minimum of 33.3%. For clarity, this level of R&D tax credit would apply only to the costs of pre-clinical and clinical trials conducted in the UK. This would increase revenues and high value jobs at the NHS, UK universities, and UK private sector R&D service providers.

R&D tax credits should also be applied to manufacturing for such trials (i.e. for R&D) provided such manufacturing is in the UK.

3. NHS clinical trials, procurement budgets

Measures designed to make the NHS more attractive run clinical trials, and more supportive of doctors and nurses at the front line of making trials happen, are:

1. Clinical trial sponsors to be permitted to award cash bonuses to health organisations (both acute and community) that outperform in clinical trials. Such cash bonuses to go to the department concerned, not to individuals.
2. Hospital department to be allowed to use revenues from trials to accelerate the adoption of new technologies that have shown both a clinical benefit and a productivity benefit. These productivity-boosting medical devices or pharmaceuticals need not be those that have been in clinical trials at the hospital department.

For item 2, it is important for the productivity benefit to have been shown in clinical trials. This firstly maximises the likelihood that the NHS will be able to deliver more for the same cost (with a consequent shortening of waiting lists) and secondly raise clinicians' awareness of productivity and cost-effectiveness of new technologies in addition to their existing knowledge about clinical benefit and cost. Such data are typically already being gathered in HealthTech clinical trials, so this should not present an additional burden to companies.

By devolving these decisions to the clinicians and departments, the temptation to try to impose a top-down culture change is avoided. Furthermore, giving clinicians more agency will make hospitals more attractive places to work for ambitious clinicians eager to embrace advances in medical technology.

Additional benefits in terms of time and cost saving, and hence increased investment appetite could be accelerated by having:

- A single Institutional Review Board (IRB) (ethics committee) approval process for the entire UK, replacing the current hospital-by-hospital requirement.
- A single NHS clinical trials insurance scheme. As well as simplifying an essential part of running clinical trials, the buying power of a centralised scheme would save money.

4. Feeding the innovation pipeline with UK technologies

HealthTech is the most common sector for UK university spinouts (roughly equal with Biopharma).[xxvi] As discussed above, these companies struggle to raise investment finance because of the time taken and risks over years of pre-clinical and clinical trials.

Many start-ups rely on grants to reduce risks to a level that investors will accept. The main sources for early-stage grant funding are NIHR's i4i program, MRC Developmental Pathway Funding Scheme (DPFS) and Innovate UK (SMART and Biomedical Catalyst). However, NIHR is prohibited from funding animal research, severely limiting the advancement of devices such as implants. MRC DPFS can fund animal research but chooses to allocate most of its funding to Biopharma. When combined with the falling success rates generally in NIHR and Innovate UK grant applications (as the number of applications has increased faster than the funds available) it is easy to see how the risk of a breakthrough UK innovation in HealthTech never seeing the light of day is high.

Establishing a HealthTech-specific DPFS panel with one-third of the total funding would provide a near zero-cost uplift to funding opportunities for HealthTech. The one-third figure is the proportion of external healthcare spending on devices. To fund all applications deemed worthy of funding by experts would require additional funding on the order of £20-£30M for each of i4i and Innovate UK.[xxvii]

Implementation Considerations

Time to economic benefits
The measures set out in proposals 1 and 2 above could be enacted immediately and will have a first-year impact on economic growth and NHS performance, with expected sustained growth thereafter.

Proposal 3 would be coordinated with NHS hospital trusts. It could be piloted with a subset of trusts within two years and extended to the whole of the NHS within three years.

Proposal 4 will have longer-term impacts, and are a mixture of no-cost and costed proposals.

Where do we get in 5 years

The measures above that are designed for short and medium term gains will lead to:

- Increased investments into UK HealthTech (and biopharma).
- Increased grants for UK HealthTech.
- A greater proportion of both those cashflows spent on high value R&D jobs and with the NHS, thereby increasing tax revenues to the Exchequer and increasing the cash available to the NHS.
- Increasing NHS productivity and shortening waiting lists through prioritising the adoption of technologies that improve productivity.
- Successful UK start-ups keeping more of their activities in the UK even as they expand globally.
- Increasing interest on the part of overseas HealthTech (and biopharma) companies to establish in the UK.

What does it look like in 10 years

In 10 years, the UK will be the first choice for investment in HealthTech startups, for the conduct of clinical trials and for the establishment or European headquarters for North American and Asian life sciences companies seeking to expand globally.

Professionalising Innovation Adoption in the NHS

Context

It takes on average 17 years for a new HealthTech device to go from successful clinical trial to adoption by the NHS.[xxviii] This is a "very concerning statistic" (ibid.) given the pace of technological advances designed to improve patient health outcomes and, in many cases, improve NHS productivity. The Darzi report has identified many opportunities for HealthTech companies to improve NHS performance.

The move to Integrated Care in England, and continued efforts on system wide collaboration within the Devolved Administrations, offer the opportunity to consider the wider determinants of health, joining up previously siloed services and delivering care more effectively, efficiently, and equitably. The UK can become a world leader in the evaluation, development, and deployment of HealthTech, but we must do things differently to ensure it is NHS patients, clinicians and the economy that benefit.

Landscape

There are initiatives designed to tackle the slow adoption by the NHS of new technologies that have demonstrated clinical and sometimes productivity benefits. Typically, they identify specific products and provide additional financial or operational support to enable adoption. But with over 500,000 HealthTech products on the UK market, this approach will only ever have a limited impact.

HealthTech companies rank performing clinical/user trials in the top 3 of their concerns. And 71% would prefer to perform their trials in the NHS. Unfortunately, high costs compared to other countries plus NHS Procurement /Access/Adoption deter these mutually beneficial trials.[xxx] Tax incentives for companies to spend more on NHS clinical trials are set out in the section on investment, above. Support for existing initiatives such as the Health Innovation Networks, facilitated by a consistent approach across the NHS, can also yield long-term benefits for UK health, and increased GVA by the HealthTech sector.

Recommendations

We urge government to work In line with its Life Sciences Plan and the NHS to build on the work of the Innovation Ecosystem Programme via the following actions:

1. Ensure there is a framework for the adoption of innovation by the NHS in partnership with the sector. The NHS Innovation Ecosystem Programme is intended to produce a blueprint for technology adoption. This should include a funding plan for the Health Innovation Networks, NIHR HealthTech Research Centres and Centres of Excellence for Regulatory Science and Innovation in line with government's pre-election pledge to set 10-year budgets for key R&D institutions. There needs to be more support closer to the patient – in translational research and commercialisation[xxxi] so that the adoption and spread of innovations is properly funded.

2. Protect time for innovation within clinical timetables while enabling joint posts to allow NHS clinicians to work with industry. The Labour Plan for the Life Sciences highlighted the importance of diverse skills, including those needed to support clinical trials and patients, to enable workforce planning across the NHS and social care. Protecting clinical time to support biopharma research is beneficial because it improves patient outcomes and attracts investment. HealthTech innovation is rarely afforded the same priority, despite the system wide productivity and clinical benefits it provides. Where such time is protected, benefits have been seen from increased innovation through to staff retention.[xxxii] Solutions include dedicated clinical time for innovation (for the same research as described in the Life Sciences Plan), and to enable joint posts between industry and NHS clinical roles.

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. NHS Trust Boards see regular metrics from Executive Directors on finance and performance, quality and safety, and workforce. As part of the CQC "Well Led" inspection framework, NHS organisations are required to have systems and processes in place for learning, continuous improvement, and innovation. But, with few exceptions, no one at a Board level is responsible for this portfolio. Until this is built into a senior job description (potentially within an existing Chief Technology Officer brief), it is unlikely to become business as usual.

4. Centralising some activities that currently lead to unnecessary duplication of work by both the NHS and HealthTech. Local decision making is important but not at the expense of patient care and NHS productivity. Areas where centralisation would benefit all parties include value-based procurement evaluations, information governance, and the assessment of digital technologies and sustainability. Experts we consulted said that the Irish Health Innovation Pathway[xxxiii] could be a model.

5. Bring NHS savings targets in line with wider HMG productivity initiatives i.e. moving from a one-year time horizon to five years. HealthTech can improve NHS productivity but rarely in a 12-month timeframe. These requirements should be changed to a five-years to enable upfront investments that bring medium-term productivity gains.

6. Amend Innovation Adoption Initiatives to encourage innovations that improve NHS productivity. The Medicines and Medical Devices Act 2021 created the test that any new regulations should not detract from the favourability of the UK as a place to develop and distribute HealthTech. Furthermore, the Life Sciences Vision set out an ambition to create an outstanding business environment for the sector. However, the Late-Stage Assessment Programme (LSA) and Rules Based Pathway (RBP) do not do this. The LSA appears to be focused on cost cutting rather than the adopting innovation. We also believe that the criteria for the RBP, as written would render the programme ineffective. It will not use the full range of guidance published by NICE, has a low budget impact limit, and will apply to a limited number of technologies.

Building a Value-Added Regulatory System

Context

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.

The Government can reduce this drag on growth quickly and with minimal expense. The measures set out below would contribute to the attractiveness of the UK for HealthTech investment and improve NHS delivery.

Landscape

Globally, there are two dominant systems for regulatory approval of HealthTech products: the US FDA and the EU CE Mark. For new, sovereign, arrangements post-Brexit the UK has developed UKCA, which is based on an older set of EU CE Marking rules, the Medical Device Directive (MDD). In the EU, MDD is being replaced with the implementation of a new EU Medical Device Regulation (MDR).

The result is that the UK is seeing some established products withdrawn and the introduction of newer technologies delayed. In 2022, ABHI identified that one in five products were expected to be removed from the market over the subsequent five years.[xxxiv] In 2023, nearly half (46%) of HealthTech companies confirmed that they had now done this for part of their portfolios. Two thirds of companies are now delaying bringing innovation to the UK for the second year running.[xxxv] The NHS cannot continue to provide standard of care without a regulatory system that at least maintains availability of current technologies. MDD is not a workable solution because the UK (only 3% of the worldwide HealthTech market) would be the only country using it.

ABHI conducted a survey of its members in June 2024[xxxvi] about the EU and US regulatory systems. Their experience is that the US system is lower cost with shorter timelines in comparison to the EU. One large company reported costs being over 700% higher in the EU, and timelines 150% longer.

The US system is also regarded as being more predictable. All manufacturers reported entering the US system knowing with certainty when they would have approval or otherwise. They told us that the benefits of the 'pre submission' discussions with the FDA drastically reduced timelines and uncertainties. For the EU system, however, all companies faced delays and predicting timelines for business planning and supply chain preparations was 'impossible'. There are signs that the EU is 'righting the ship' on approvals, but these troubles provide an excellent case study that uncertainties in regulatory systems drive companies away from providing their most advanced technologies into healthcare systems.

The UK's MHRA has been developing new sovereign arrangements since Brexit. The process has been plagued with delays and a perception that the resource available may not match the scale of the task. Reform can now ensure that patient access to HealthTech is protected, and to rebuild the attractiveness of the UK as a place to invest.

In March 2023, the Government committed to a regulatory model that included a domestic route for innovation alongside one based on the recognition of approvals from other trusted jurisdictions such as the FDA. A timeline[xxxvii] for implementation was published in January 2023, followed by a statement of intent: international recognition of medical devices[xxxviii] and a draft framework for how international recognition might work. However, the MHRA still has not produced an official policy.

In principle, the policy would extend the number of jurisdictions, but with a move away from the automatic recognition of CE marking, which has been afforded indefinitely to most other manufactured goods. In addition, due to the many exclusions, the MHRA proposals would only apply to 10-15% of products approved in the US.

We conclude that the proposals fail to meet the Medicines and Medical Devices Act 2021 objectives of ensuring the availability of medical devices, and the likelihood of the UK being seen as a favourable place for the HealthTech sector.

Furthermore, at the time of writing, the MHRA is consulting on increasing its fees for manufacturers. Whilst companies recognise the need for the MHRA to recoup its costs, current proposals could add a £16+ million bill on the sector for post marketing surveillance, which is currently supported by the DHSC. This is in addition to the fees the sector already pays directly to Approved Bodies. The MHRA is also consulting on increasing the fees the Approved Bodies pay to the MHRA for designation which will inevitably also be passed onto the sector. We envision HIP as an organisation that can assist MHRA in identifying funding models that work better for the MHRA and industry collaboratively, but MHRA should first define what the regulatory system will be.

Recommendations

In line with the plan for HealthTech, the Government should resource and implement a model of regulation that provides patient safety, access and attracts innovation. This would include:

1. Accepting certain non-UK approvals of HealthTech products by:

a. Accepting all FDA approvals and clearances supported by appropriate assurances and including post-market surveillance.

b. Matching the automatic and indefinite recognition of CE approved goods that is affordable to other sectors.

c. Extending trusted jurisdictions beyond those already identified in the statement of policy intent (EU, USA, Canada, Australia) to include, for example, those under the scope of the Medical Device Single Audit Programme.[xxxix]

2. Developing a process for handling innovations, such as that outlined in the Software as a Medical Device Roadmap, and determining the merits of the Innovative Devices Access Pathway (IDAP). Any UK-specific process should support the aim in the Life Sciences Plan to harness data to improve services for patients and medical research, e.g. early adoption of breakthrough products, and those addressing rare diseases (orphan devices) or NHS-specific needs. IDAP in its current form is not scalable, with the pilot phase currently set to run with only eight products. IDAP and the Software Roadmap should be cornerstones of a wider framework to support innovation and adoption in the UK.

3. Shifting the focus of UK regulatory resource towards post-market surveillance to support innovation: Where possible, the UK should be looking to the post-market surveillance process to build confidence and avoid burdensome and duplicate processes in the pre-market phase (i.e. for approvals). As a universal, single payer system serving a diverse population, the NHS has the potential to lead the world in generating real-world evidence collected in post-market surveillance.

4. Developing innovative approaches to regulation, such as Outcomes Based Cooperative Regulation (OBCR): We support the Government's objective to give Regulatory Horizons Council (RHC) more influence, including a new requirement for government to respond to its reports within a set time. The RHC is a forum for cross-sector learning and longer-term thinking. This could be used to enable wider adoption of OBCR , 'a model for achievement of common purposes and outcomes in a cooperative mode based on engaged relationships built on evidence produced by parties that they can be trusted'.

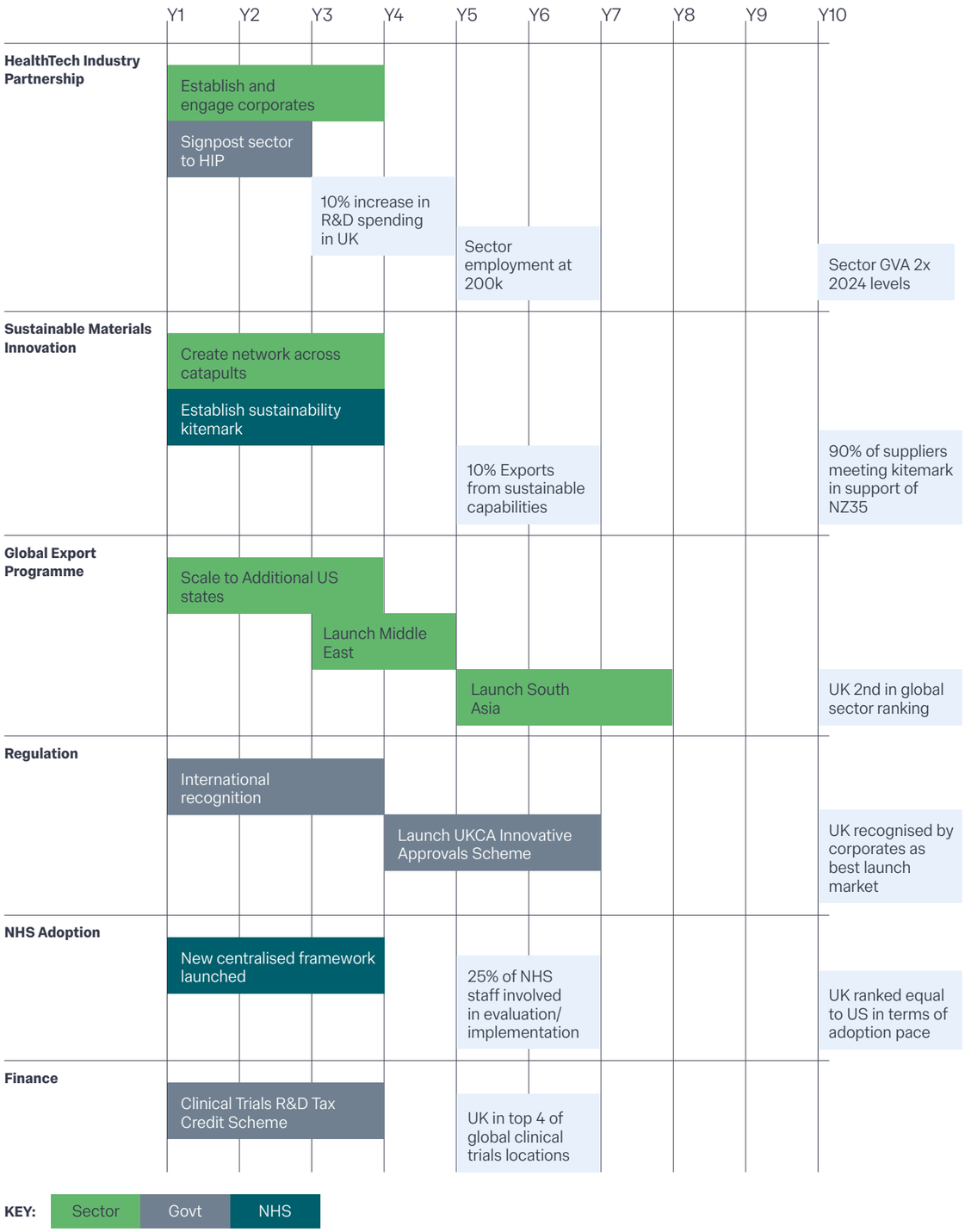
The proposed Regulatory Innovation Office, whose role in the Life Sciences Plan is to hold regulators accountable for driving innovation and for delays holding back innovation, would be tasked with a review of the UK HealthTech regulatory system. As planned, the system would be largely a UK version of EU single market structures. Instead, the UK has an opportunity to remodel HealthTech regulation to improve patient health and national wealth.

One further item: regulators are benchmarked against international comparators, but the metrics only apply to MHRA while HealthTech approvals are granted by Approved Bodies whose timelines are not tracked. As guardians of the system, MHRA should be able to hold ABs to account when delays occur.

5. Train students in relevant disciplines in regulatory affairs: Fewer than half the biomedical engineering undergraduate programs in the UK offer training in regulatory affairs. Making this more widespread is an easy win for the supply of qualified personnel for industry, Approved Bodies and the MHRA. There is a global shortage in HealthTech regulatory skills,[xlii] so the planned reform of the Apprenticeships Levy into a 'Growth and Skills Levy' should prioritise this. The deliverable here is more capacity at ABs to bring the best innovations to the NHS and patients sooner.

Appendix

Delivery Plan



HealthTech

While MedTech is specifically associated with devices, diagnostics and software that fall under medical device regulatory approvals, we have chosen to focus this report on the broader HealthTech sector, some of which may be directly adjacent to the biopharma sector. Today's health and care environment relies as much on traditional MedTech as it does contributors such as cloud computing providers and genomics companies, a situation which did not exist a decade ago. In the same way, health, and care provision ten years from now will and must incorporate organisations and their technologies currently considered outside the scope of the sector if we are to achieve ambitious goals for preventative, sustainable and proactive health. This is commensurate with our strategic approach for phased growth and acknowledges that the future sector can and must be comprised of new companies (either via incorporation or strategic merger facilitated by the initiatives we are proposing) that leverage technologies and business models that are yet established in the sector.

vs MedTech

Development of this proposal took place from March to September 2024. During that time, we consulted with a wide range of stakeholders both within and adjacent to the sector, initially to define and validate the underlying problem statement and later to shape and then sense-check the initiatives documented in this report.

As a result, the feedback captured as contemporaneous notes in this appendix reflects a broad spectrum of perspectives and includes both critical assessment of today's environment as well as feedback on our plan.

Voice of the Sector – HealthTech Industry Partnership

Feedback from stakeholder interviews

Corporates

- Corporates aim to engage with future leaders, access technology, and explore acquisitions, rather than just mentoring SMEs, with a strong focus on accelerating diagnostics and faster customer launches.
- Key barriers to life sciences growth include misalignment on clinical priorities, poor collaboration, lack of clear ROI, and the NHS's lengthy 17-year adoption cycle for new technologies.
- The proposed HIP (Health Innovation Partnership) is widely supported by corporates as it aligns with CSR, provides a unified sector voice, and offers a crucial support network for innovation and long-term value creation.
- The UK risks becoming globally irrelevant due to talent and R&D moving abroad post-acquisition, with companies focusing less on the UK due to its market size and political landscape.
- While the UK is strong in policy development, its weakness lies in execution, especially in creating future regulatory pathways and scaling up innovation.
- OurFutureHealth is a good example of bringing together industry around genomics given Genomics England has been around for 15-20 years.

Investors

- It is difficult to get large MedTech companies interested in early-stage companies compared to pharma, due to challenges like early funding gaps (Seed/Series A) and limited VC involvement before later stages. Defined accelerators focused on specific outcomes (e.g., FDA deNovo, reimbursement) could help, as existing accelerators are too generic.
- Start-ups often struggle to engage with corporate mergers and acquisitions teams, and OEMs lack an entrepreneurial mindset. High turnover in business development roles (2-3 years) forces SMEs to target quick wins for incoming VPs.
- Corporate CEOs should mentor start-ups, and there is a need for documented case studies of successful acquisitions to guide both corporates and SMEs. UK startups are often more focused on science than commercialisation, which contrasts with the US's entrepreneurial approach.
- UK start-ups face barriers such as slow regulatory approvals (IRB), high costs, and difficulty gaining traction with the NHS. While the UK has strong technical skills, gaps exist in business functions like financial management, sales, and HR, especially when expanding internationally.
- Accelerators need to better address challenges like market access, regulatory understanding, and non-technical skill development (e.g., building teams, sales, and leadership). They should foster organic and inorganic growth by combining companies and help early-stage firms adapt their business models to maintain momentum and validate relevance to the industry.

SMEs

- R&D has a high failure rate, leading to limited product offerings, with companies often forced into commoditised, low-margin products with heavy competition. Manufacturing skills are the most needed to address this challenge.
- Most accelerators are geographically constrained; a national accelerator could provide early access to evaluate entrepreneurs' skills and identify major risks. However, current accelerators lack expertise in finance, investor relations, and scaling for future capital needs.
- A HIP could add value by building relationships with Electronic Health Record manufacturers, but companies often lack resources to pursue these collaborations. Similarly, gathering early KPI data is critical for attracting later-stage funding.
- The government must focus on building global product-based companies, like Germany and the US, where scaling takes 10+ years. Aligning university R&D with commercial goals is also crucial, with better incentives needed to promote commercial success.
- UK startups face a risk-averse culture and lack funding, but the right infrastructure exists. What's missing is a tolerance for failure and support for founders with strong networks and proven success. Clusters thrive with educated teams that include regulatory, reimbursement, and manufacturing expertise—similar to Ireland's success model.

Higher Education

- Today's accelerators miss out in supporting overseas expansion and growth, missing opportunities for collaboration with the DBT.
- There is also a critical need for preparing tech leaders in larger organisations, such as CTOs managing teams of 300 or more, to manage these challenges.

Professional Services

- Industry not best served by advisory community who have never been connected with innovative companies.
- Need to build profile around UK HealthTech on international stage to make us an investment destination point.
- The HIP could provide more structure and focused lean into various stakeholders (commissioning, operator, funders): currently hard.
- HIP would be most effective training in market access, regulatory and manufacturing.
- Many companies we see stumble between MVP and market readiness and could benefit from working with corporates to identify the best use case.

Voice of the Sector – Sustainable HealthTech Innovation Centre

Feedback from stakeholder interviews

Corporates

- We see the NHS at the forefront of sustainability ambition, whereas the US is really struggling to deploy Social Values funding, and in some cases being accused of bribery. This is a competitive advantage for the UK.

SMEs

- There are currently no affordable, sustainable polymers, and ETO sterilization remains carcinogenic without viable alternatives. Additionally, no progress has been made in developing sustainable peel packs.
- In Scandinavia, procurement balances cost, quality, and sustainability equally, unlike the UK where cost dominates after quality.
- The NHS eliminated local sterilisation capabilities 30 years ago and lacks the CapEx budget to reinstate them.
- 80% of surgical waste consists of CD-ROMs and paper leaflets—raising questions about the necessity of IFUs at the user end.
- Medical device packaging (paper/film) is a low-hanging fruit for sustainability improvements but currently goes to incineration; NHS recycling standards may not be adequate.
- Private equity-owned companies often face a conflict between sustainability metrics and financial performance, with the latter taking precedence.
- MedTech companies need guidance on achieving net-zero, including knowledge sharing, collaborative funding, and open-source solutions (e.g., Nike's approach to reducing carcinogens in adhesives).
- Legacy products face significant sustainability challenges; silicon-based, patient-contacting materials must be incinerated, and MDD->MDR recertification adds substantial annual costs.

- The UK government offers information but lacks active dialogue on how companies can meet sustainability requirements.
- Sustainability should be recognized as a competitive advantage, with effectiveness measured and prizes awarded to manufacturers prioritising it.

Voice of the Sector – Global Export Programme

Feedback from stakeholder interviews

Corporates

- DBT Ambassadors need to sell the sector and HIP to global companies to go hunting for partners – make them "multipliers of the concept" around single global expert.

Investors

- Have a ready export financing facility – should not have to use investor funds to finance trade.
- Exports and exits are the lifeblood of the sector and economy.
- Organic growth companies need support to address US market, community of support to share models that have worked. Access to executives who have been through this process but recognise no one-size-fits-all, need to be agile.
- Any new HIP needs to have expertise on international reimbursement.

SMEs

- Experiences with DBT trade missions have been mixed, often relying on independent consultants. While some missions offer valuable insights into market decision-making, there can be mismatches in preparation and delivery, leading to disengagement from target market decision-makers.
- Launching new products often requires new factories and substantial market demand for adoption.
- Identifying key market players and influencers is essential, including mapping major players and finding key employees in specific regions.
- Brexit has created significant challenges, but the ABHI has been supportive. DBT recommends consulting local accountants for insights, although accessing the US market remains difficult due to clinician engagement and ethical/IP issues in hospital accelerator programs.
- The focus is shifting to the US market, emphasizing digital and hospital-at-home technologies rather than OR-based devices. However, DBT funding issues have led to a lack of sector-specific expertise, relying instead on generalists with little follow-up on revenue metrics.
- Identifying suitable overseas partners is challenging, as new companies often lack the experience to navigate potential partnerships. An international directory distinguishing no-go partners from recommended ones would be helpful.
- International partners prioritize innovation and sustainability and prefer in-person engagement, while the NHS remains focused on tenders and price sensitivity.
- The ABHI's US Accelerators connect companies with buyers and hospitals, emphasizing the importance of understanding value propositions before discussions to avoid presenting products as commodities.

The London Embassy staff is helpful, and events like MEDICA trade stands and the MEDILINK Innovation Conference offer opportunities to connect with foreign government representatives. Integrating these resources can enhance focus on government trade bodies.

Professional Services

- When considering scale of opportunity (addressable market) - US is much bigger. Need to be clear on how this scales internationally when talking to investors.

Voice of the Sector – Driving Investment

Feedback from stakeholder interviews

Corporates

- Lots of pots of money buried throughout government which are dependent on business case to Treasury. As a sector we need to demonstrate how we help health services and health of the nation.

Investors

- The Enterprise Investment Scheme (EIS) is effective, but it requires investments to remain untouched for three years. However, the UK lacks sufficient depth in capital, leading many successful companies to seek funding abroad, particularly in the US, where they can access larger exit opportunities. The Alternative Investment Market (AIM) is not a viable option for raising capital.
- Most potential buyers, whether corporates or those looking for IPOs, are based in the US, which leads to concerns about the size of UK businesses in that market. The attractiveness of the skilled workforce in the UK is lower, resulting in diminished valuations compared to US counterparts.
- Investors often favor familiar names like Stanford, creating a bias against EU/UK companies. As a result, UK companies struggle to present fully developed propositions to US investors. There is a need for companies to gain insights and tools to effectively communicate their market potential to US investors, as EU investors rarely engage with UK founders regarding the US market.
- A significant hurdle is accessing capital during the commercialization stage to support high-value manufacturing and workforce development, ensuring robust R&D capabilities at the time of acquisition. Many companies falter due to challenges in transitioning from academic to commercial environments, compounded by the high costs associated with developing MedTech products.
- The UK should consider a unified Institutional Review Board (IRB) to streamline processes and attract more clinical trials, as the NHS may have priced itself out of this market. Additionally, while the UK cannot compete directly with NASDAQ, there is potential for public markets to support sub-$1 billion IPOs.
- Attracting top management from successful companies through tax incentives could enhance the sector. Suggestions include removing AIM's Inheritance Tax exemption to improve liquidity and providing proper financing for start-ups with adequate public funding, as family offices should also be incentivised.

Tax incentives could encourage investment, but they need to be straightforward. While management education alone will not resolve issues within the UK's MedTech sector, it is essential to recognize that the challenge lies in motivating investors to commit funds, requiring more than just technical expertise.

SMEs

- Raising capital in the US is easier due to greater availability of venture capital, start-up hubs, and seed funding covering all stages up to post-Series B. The UK struggles with attracting mature capital and engaging US investors due to market differences and insufficient funding requests.
- The financial industry plays a crucial role in growth, with exorbitant exit fees restricting options for companies.
- Countries like France, the Netherlands, and Switzerland offer substantial R&D reimbursement (up to 30% at the pre-clinical level), making them attractive for new businesses.
- The UK should implement tax incentives to attract external investors, especially in employee income tax, and prioritize local companies over large foreign contractors like Palantir and Epic.
- The UK misses out on grant opportunities, which are simpler to navigate in the US (e.g., Melinda Gates Foundation). Effective grants can provide more benefits than venture capital, which often leads to wealth concentration and an overemphasis on commercialization.
- The Enterprise Investment Scheme (EIS) and Enterprise Management Incentives (EMI) are vital for growth, and the EIS cap should be raised to encourage more investment.
- Pre-seed and seed funding rounds should receive significant backing from grants, similar to practices in the EU and US.
- Achieving full approvals based on FDA and EMA/CE Mark standards would significantly boost the UK market.
- The Foundry model, which emphasizes an ecosystem with centralized consulting and its own funding, is more effective than traditional management education. Offering tax incentives for UK clinical trials could attract US companies to invest in the UK market.

Professional Services

- Do not have established, buoyant investor community in UK c/w US. Recent news about listed companies delisting and looking to list in US due to more active coverage of businesses (better understanding of companies' propositions) and more investment.
- Raising CGT for entrepreneurs would drive people away. There should be a carve out for people whose shareholding has been diluted to below controlling by investment.

Voice of the Sector – Professionalising Innovation Adoption

Feedback from stakeholder interviews

Corporates

- We need to be led by getting new therapies to market faster, not led by regulations/ legislation.
- We need infrastructure around evidence, deployment and mass rollout of new technology. We can learn, if only in terms of thinking and ambition, from countries that do it very well (extreme is Chinese innovation zones that operate to a different, more relaxed, regulatory structure to fast track devices and therapeutics within a controlled environment).
- “Winning” and “cash” are not dirty words.
- How are we helping address health equities – underserved populations ending up in A&E.
- NIHR budget needs to be shared with commercialization/ adoption - we need to move away from the well-known penny farthing model, even if not to a full bicycle.
- Companies have quit in the middle of our accelerator programmes so they can move to the US to scale up and sell (too many regulatory barriers and local requirements to demonstrate safety).
- Need to get commercial leaders into NHS who have commercial, innovation adoption mentality.
- What would be beneficial would be an “interoperability sandbox” (all alactronic health records) with data sharing ironed out before trying to deploy in the real world. Look at what travel agencies did with Amadeus middle-layer integration.
- Value-based procurement (e.g., NICE Late Stage Assessments) really mean how can they reduce the price).
- Address fragmentation within sector (e.g. even within Shelford group).
- Should ensure NHS does not place responsibility for innovation delivery on industry. Need to recognise private healthcare sector and its growing role.
- Cost of clinical trials - Economics are not effective: Example of trial costing £30m that was linked to a UK market size of £25m.
- Commercial clinical trials are revenue generating for the NHS – free medicine, care, follow ups, transport costs: don’t have time or capacity.

Investors

- It’s almost impossible to be adopted into the NHS. Expensive runway, example of a digital behavioural therapy app with 60k users - no route to procurement.
- If we’re not going to be the best payer, then at least be fastest adopter.
- Need to help MedTech demonstrate market traction: role of the NHS to help. E.g. Mt Sinai have 2 VC groups that guarantee purchasing (and then exit).
- Getting the NHS to say it wants a new product and getting it through purchasing are very different things. They avoid young companies’ products because they fear [lack of] continuity of support.

SMEs

- It is hard to get the evidence (e.g. 50 use case study) in a form that NHS procurement wants - companies need support here but the result is that currently no one wants to be first to market: how do we encourage people to be first?
- we have a major Med Tech challenge in the UK: procurement process is biased against small UK companies. The bidding process is complex with a large amount of documentation so bidding is very expensive for the company. The success criteria favour established companies with an established product and a large balance sheet. Without a customer hungry for new Med Tech, achieving sales is very difficult, and this feeds back, deterring investor interest. In contrast, the HIH system in Ireland mitigates these issues by providing timely, centralised approvals.
- More meaningful stamp of approval and adoption path through NHS – would give confidence to local investors.
- See export markets as only viable ones as NHS not in position to adopt (they want RWE – already demonstrated through clinical studies – and health economic studies, who are under control of maxed-out frontline staff). Requirement for comparative study means alternative needs to exist and more workforce to carry this work out.
- Lack of preferential procurement for UK companies - we are losing to local companies in Russia, China etc.
- Should consider incentivising Risk-taking by payer (shared upside on improved outcomes) so payer isn’t taking all risk in first 1-3 years of ramp. Investors will underwrite risk appetite.
- Need to be bold and propose new commercial models/ relationships with the NHS - e.g. free use in return for development support and funding.

- Transactional cost of dealing with NHS is prohibitive - the Bounty newborn service had to be negotiated separately with every maternity ward in the NHS.
- Health Innovation Networks – corporate/ NHS funding means they are too led by costs – e.g. £25k to support a £100k grant. Flexible resource access model more attractive.

Higher Education

- There is massive technical debt in NHS – infrastructure, interoperability (e.g. £80m to bring every hospital to Windows10). We need a strategic national infrastructure – like when we first tarmacked the roads.

Professional Services

- Lack of value-based contracting is stopping pilots with compelling cost- and time-saving data from being procured at scale.

Voice of the Sector – A World Leading Regulatory System

Feedback from stakeholder interviews

Corporates

- Today’s regulators, Notified Bodies are here to police, not to consult or advise how to make the process shorter/ more efficient and more likely to succeed.
- UKCA mark is dead: US light years ahead of EU legislation in terms of AI regulation.
- IDAP – government leveraged funding attracted investment where it wouldn’t have existed otherwise. But this came with the catch that all companies had to follow UKCA which wasn’t clear at the outset.
- Addressing regulatory reliance space will Skyrocket UK market trajectory.

Investors

- Companies fail because of the time taken and cash needed before success. Plus the regulations: it takes a lot of money to get through it all.

SMEs

- It is an unprecedented time from a regulatory perspective – we need to tie this to better procurement, leveraging a diverse UK population. We need to advocate for pro-innovation regulatory approach.
- Regulatory changes have made it very expensive to get new products onto market: NHS need to understand that price increase is exceeded by improved value.
- Need more people in the system to work at regulators.
- Build exportable capabilities that drive regulatory innovation (light touch).
- It would be an amazing boost for the UK to have full approvals based on FDA and EMA/CEMark.

Higher Education

Professional Services

- UK being 3% of the global market means it’s unrealistic for multinationals to prioritise.

ABHI US Export Accelerator Supplementary Information

The national programme supports companies over a 12-month period de-risking market entry and catalysing US expansion. The programme is led by ABHI secretariat, industry experts who have significant experience in successfully supporting market entry and expansion for companies in the US and around the world who work with each company throughout the year to achieve their objectives.

ABHI has a series of key health system partners across the US. It began with Dell Medical School at the University of Texas in Austin and now includes UT Health institutions across the State. These partner systems, now across four key States, and including national health systems covering the country, provide in-depth support by wrapping faculty and expertise around participants and defining and delivering key projects, pilots, and clinical trials with them throughout the year.

The ABHI US Accelerator consists of a national US health system network, and is probably the most comprehensive offer of any UK organisation, consisting of over 70 US healthcare systems across the country, including thousands of hospitals and many more sites of care. The relationships with the leadership of those hospital systems enable ABHI to introduce UK innovation to receptive customers, market test and validate solutions and provide access to key opinion leaders.

The Accelerator network extends into the payor, investor, professional services, and consultancy communities and includes formal partnerships with industry bodies both at a national and state level as well as with US Government institutions such as NIH, FDA, Medicare – Medicaid services and the US Military.

The programme has over 150 US mentors regularly helping UK companies from across the US, all of whom hold senior roles in health systems, or as clinicians, GPO's, payers, investors or industry specialists. These leaders enable companies to learn, validate and test their market strategy.

The programme includes a 'Learning Series' providing virtual education and learning opportunities across a variety of market access topics to participants through regular virtual events. A series of in-depth 'US Bootcamps' provide opportunities to practice pitching, create assets to help engage customers and road-test strategy and value propositions with US customers and investors.

ABHI's US Accelerator mission programme takes company leaders and NHS leaders to visit key US States 4 times per year. These in-market visits provide business matching, health system engagement, networking and deep health ecosystem learning, immersing and connecting participants with US health leaders over an intensive week of meetings.

The Accelerator also supports health system to health system collaboration and learning. The programme enjoys the support and engagement of many NHS Trusts and leaders from around the UK. Over the past 8 years ABHI has supported over 10 NHS hospital trusts to engage with their peers from US health systems across the country. This has led to several joint projects and cooperation.

ABHI has invested and continues to invest heavily in the development of the US Accelerator programme, which has become an industry leading market access initiative that is unrivalled. We have recently brought on an additional experienced International Director to help continue to build the offer as well as an additional programme manager and operations executive to work alongside our existing expert Accelerator team.

ABHI is also now building a Middle East Accelerator. The pilot programme will launch in 2025 and will seek to scale quickly. This follows extensive research and industry testing and will mirror our US programme, with some nuances.

ABHI's Accelerator initiative has been proven to work, and the expansion into other important regions is now taking place. The strategy is clear, evidence based, backed by industry and importantly by key partners in the market. It provides a sustainable initiative that allows deep, long-term relationships to be formed over many years.

- Our US Accelerator has tracked more than $150m of business won by participating companies in the US.
- On average participating companies report that they expect to win over $15m of business as a direct result of their participation in the Accelerator in the US over the next 5 years.
- Companies report that they have won contracts valued at between $250k and $60m in value from their participation in the programme.
- 100% of company participants say they would recommend the ABHI US Accelerator to other UK companies.
- 100% of our participants say they have achieved their objectives for being in the programme.
- We have facilitated over 70 clinical trials or pilot studies for UK companies across the US in more than 12 States.

- We have connected and supported over 20 high-level trans-Atlantic health system (provider to provider) engagements and introductions, including taking leaders to the US from NHS England to engage on multiple occasions (such as Roland Sinker, David Prior and Tony Young among others). Some of those NHS Trusts supporting and supported by our Accelerator are below:
  - Cambridge University Hospitals NHS Foundation Trust
  - Oxford University Hospitals NHS Foundation Trust
  - Leeds Teaching Hospitals NHS Trust
  - University Hospitals Birmingham NHS Foundation Trust
  - Sheffield Children's NHS Foundation Trust
  - Manchester University NHS Foundation Trust
  - University College London Hospitals NHS Foundation Trust
  - Imperial College Healthcare NHS Trust
  - Barts Health NHS Trust
- The Accelerator has also supported our inward investment agenda having delivered over 15 US based companies to visit and engage with NHS Hospitals and participate on UK based Accelerator programmes led by the Health Innovation Networks
- ABHI is an honouree member of several healthcare organisations including State and Regional Healthcare Councils for example the Austin Healthcare Council, as well as many Chambers of Commerce and Economic Development Agencies nationwide.

List of Global MedTech by Revenue

	Name	2023 sales	Country HQ	Specialisms
1	Medtronic plc	$31.56B	US/Ireland	Cardiovascular, surgery, orthopedics, neurology, renal and more
2	Abbott Laboratories	$31.27B	US	Diabetes, diagnostics, cardiovascular, pharma and more
3	Danaher Corp.	$29.57B	US	Diagnostics
4	Johnson & Johnson	$27.40B	US	Cardiovascular, orthopaedics, diabetes, neurology, surgical, ophthalmology and more
5	Siemens Healthineers AG	$23.43B	Germany	Diagnostics
6	Fresenius Medical Care	$20.92B	Germany	Dialysis and others
7	Medline Industries*	$20.20B	US	Consumables
8	Becton, Dickinson and Company	$18.90B	US	Diagnostics, lab equipment, consumables.
9	GE Healthcare	$18.46B	US	Diagnostics
10	Stryker Corp.	$18.40B	US	Orthopaedics
11	Koninklijke Philips N.V.	$17.80B	Netherlands	Many/diagnostics
12	Cardinal Health	$15.90B	US	Consumables
13	Baxter International Inc.	$15.28B	US	Dialysis
14	Boston Scientific Corp.	$13.76B	US	Cardiovascular, radiology, endoscopy, urology and more
15	B. Braun*	$9.28B	Germany	Surgery
16	Alcon Inc.	$9.09B	US/CH	Ophthalmology
17	3M Healthcare	$9.05B	US	Consumables
18	Fujifilm	$7.30B	Japan	Diagnostics/medical electronics
19	Zimmer Biomet Holdings, Inc.	$7.28B	US	Orthopedics
20	Intuitive Surgical, Inc.	$6.85B	US	Surgery
21	Tofflon Science and Technology Group	$5.95B	China	Medical manufacturing equipment
22	Edwards Lifesciences Corp.	$5.82B	US	Cardiovascular
23	Terumo Corp.	$5.53B	Japan	Consumables/diabetes
24	Smith & Nephew plc	$5.35B	UK	Orthopedics
25	STERIS plc	$5.23B	US/Ireland	Surgical
26	HOYA Corp.	$4.80B	Japan	Ophalmology and diagnostics
27	Mindray Bio- Medical Electronics Co., Ltd.	$4.72B	China	Diagnostics, intensive care/veterinary
28	ResMed Inc.	$4.38B	US	Respiratory
29	Canon Medical	$4.37B	Japan	Radiology
30	Dentsply Sirona Inc.	$4.25B	US	Dental

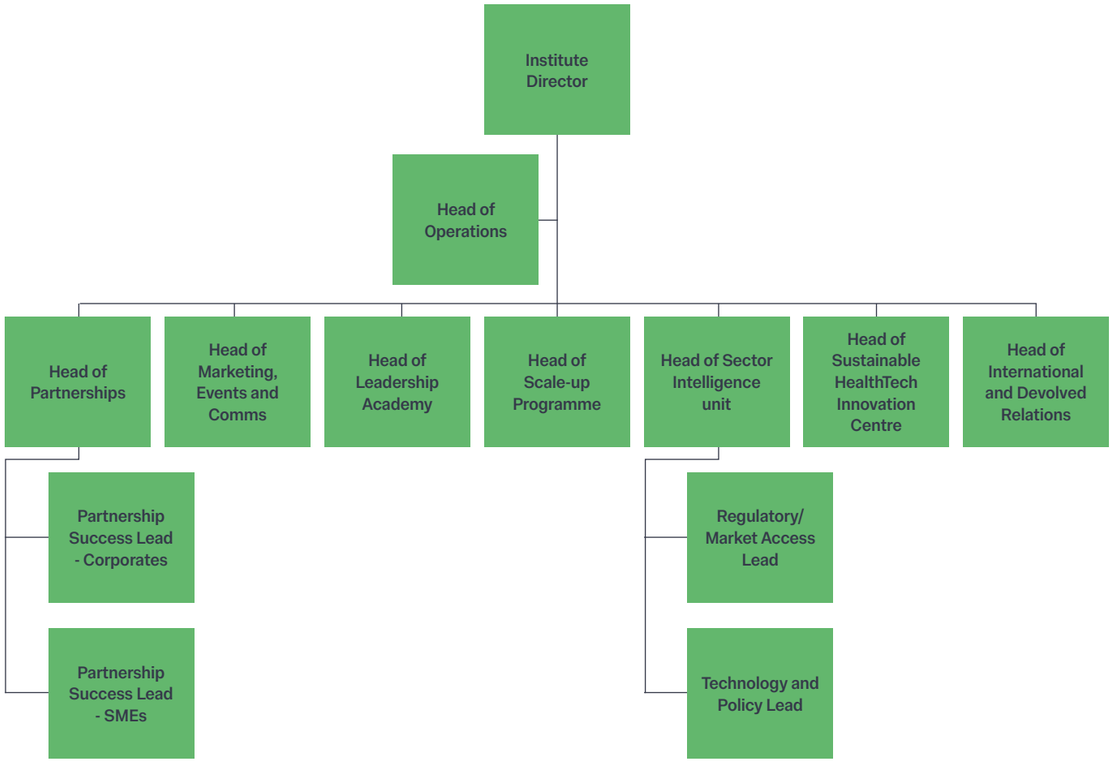
* Privately-held

UK MedTech High Value Manufacturing Capabilities

Name	Source	Turnover 2020	GVA/ employee (2020)
RENISHAW P L C	Data City	£565,559,000	£50,472
METAL IMPROVEMENT COMPANY LLC	Data City	£206,746,852	(Data unavailable)
LUBRIZOL LIMITED	Data City	£184,308,000	£152,146
BRISTOL LABORATORIES GROUP LIMITED	Beauhurst	£93,929,142	£46,497
RENISHAW UK SALES LIMITED	Data City	£93,594,863	£101,223
COORSTEK LIMITED	Data City	£66,585,000	£41,981
ORTHOPLASTICS LIMITED	OLS	£56,382,000	£115,944
SPECIAL MELTED PRODUCTS LIMITED	Data City	£55,309,000	£12,793
CHEMVIRON CARBON LIMITED	OLS	£51,106,000	£110,505
INVIBIO LIMITED	OLS	£43,629,000	£3,005,667
TRUMPF LIMITED	OLS	£40,019,612	£81,370
MORGAN TECHNICAL CERAMICS LIMITED	Data City	£38,341,000	£35,394
AMERICHEM HOLDINGS INTERNATIONAL LIMITED	Data City	£30,072,000	£46,693
SYMMETRY MEDICAL SHEFFIELD LTD.	OLS	£28,573,000	£39,443
ROCKET MEDICAL GROUP LIMITED	Beauhurst	£27,143,317	£57,834
AMETEK (GB) LIMITED	Data City	£25,892,000	£184,541
ROCKET MEDICAL PLC	OLS	£22,667,563	£53,098
RIVERSIDE MEDICAL PACKAGING COMPANY LIMITED	Beauhurst	£22,407,261	£48,270
PRESTIGE PERSONAL CARE LIMITED	Beauhurst	£21,256,045	£37,620
LUCIDEON GROUP LIMITED	Data City	£16,912,595	£52,486
PARAFIX HOLDINGS LIMITED	Data City	£16,810,823	£33,661
A.D.S. GRAPHICS LIMITED	OLS	£15,236,721	£42,677
MEDISAFE UK LIMITED	OLS	£15,164,529	£148,705
PACER COMPONENTS LIMITED	Data City	£14,031,000	£80,312
MITSUBISHI CHEMICAL ADVANCED MATERIALS UK LIMITED	Data City	£13,143,000	£56,886
TECHNIMARK LIMITED	OLS	£11,893,138	£57,301
PERMALI GLOUCESTER LIMITED	Data City	£11,543,762	£44,257
LUCIDEON LIMITED	Data City	£11,082,795	£40,923
BRANDON GROUP LIMITED	Beauhurst	£10,894,383	£63,366
BRANDON MEDICAL COMPANY LIMITED	OLS	£10,894,383	£60,978
AMERICHEM EUROPE LIMITED	Data City	£10,813,071	£8,454

Costed Model for the HealthTech Industry Partnership

We have modelled the costs of delivering the industry proposals in this report based on the following organizational structure for the HIP.



Considering the prerequisite industry experience of the team, and making reasonable allowances for on-costs (including an environmentally responsible but proactive level of travel to actively engage with the sector both domestically and in key overseas markets, rented office space reflecting a distributed hybrid working team, and outsourced support for marketing, finance and IT) annual running costs are estimated to be £2m.

In the first instance we would seek to secure a 5-year funding package, primarily from industry with potential third sector leveraged funding, by bootstrapping the HIP with a core team comprising the Director, Head of Partnerships and Head of Marketing/ Events/ Comms initially working alongside sector intelligence and business methodology teams at Imperial College and the ABHI.

Separately, costs to deliver the Export Programme (currently exemplified by the ABHI US Export Accelerator which is subsidised through central ABHI membership funds plus nominal contributions from the participating UK companies) would add £1.75m over 5 years.

We are considering three separate but potentially complementary funding models for the HIP given its role as an independent organisation that will convene across the sector and deliver economically significant collaborations. These funding models sit alongside any contribution in kind such as senior corporate leadership giving their time to deliver Leadership Academy and Scale-up Programme events and activities.

Funding Model	Pros	Cons
Commercial memberships	Corporates have indicated there is alignment between their CSR budgets and the aims of the HIP. Ecosystem providers (e.g. cloud infrastructure) have suggested even closer alignment between their strategic support for the sector to grow the number of future customers for their services.	5-10 year time horizon of HIP will not align with 2-3 year corporate HealthTech P&L objectives which limits ask from them. Strategic focus of corporates likely to change within a few years meaning considerable effort from HIP staff for ongoing fundraising, detracting from delivery activities.
Philanthropic endowment	Cornerstone endowment has the potential to provide the HIP with a long-term mandate from the outset, enabling more ambitious delivery. Recent exemplars include Gate Wellcome Novo Nordisk $300m scientific R&D programme to tackle global health inequity and the Gillings Foundation support alongside the former Department for Business, Energy and Industrial Strategy of the Academy of Medical Sciences FLIER Programme.	Given inherent alignment of HIP with UK sector performance, unlikely unable to approach larger US philanthropic community. Requires establishing direct alignment of HIP with investment thesis of a specific funder, which may dilute the scope and/ or make harder to find a match.
Retargeting existing public sector spend	There are multiple organizations sitting under OLS, DHSC, UKRI etc, who presently have a remit to support the HealthTech sector through a range of interventions. In this scenario, the approach would be to work collaboratively with key government departments for an initial period to create a business case to optimise existing funding and reduce existing duplication of effort and spend in support of the sector. Our proposal is planned to lead to an increase in sector GVA that in real terms will exceed Innovate UK 7x and NIHR 19x ROI by several orders of magnitude compared to the outlined HIP running costs of approximately £10m over 5 years. Examples such as iCAST (£15m 3-year Research England grant) have shown how sector benefits can be achieved in the Chemicals Industry.	The proposal comes at incredibly tough time financially for the Government and economy as a whole, where a compelling business case for better return on investment may struggle to compete with the requirement for short-term reduction in spend. Relying predominantly on government funding would need to be reconciled with the HIP's independent, industry-led mandate. Funding for Y6-10 of the HIP would need to be considered separately.

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