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**BIG
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Healthy Innovation? Collaboration between NHSScotland and the MedTech Sector

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Table of Contents

Introduction	4
1. The scale of the MedTech Opportunity	5
2. Building a healthy environment for open innovation	8
3 Existing evidence on the challenges of innovation within the NHS and Med Tech businesses	10
4. Assessing performance – business perspectives.....	16
5. Assessing Performance – Stakeholder Perspectives	25
6. Recommendations to unlock greater collaboration	29
Appendix: Good practice examples to support recommendations	33
Contact details.....	39

Introduction

The health service is facing an era of unprecedented challenges: rising demand driven by changing demographics and increased customer expectations; a tightening fiscal environment; alongside the need to respond to rapid technological change. Harnessing innovative healthcare technologies, both for the benefit of the patients of NHSScotland and for the Scottish economy, has been recognised by the Scottish Government as a way to turn these challenges into an opportunity.

To this end the Scottish Government has put forward an ambitious vision for the development of Scotland as "... a world leading centre for innovation in health through partnership working between Government, NHSScotland, industry and the research community".¹

This paper focuses on how the NHS in Scotland and the Scottish MedTech sector work together to support innovation.

This report is structured as follows:

- **Section 1** – Sets out the scale of the opportunity for the medical technology sector in Scotland
- **Section 2** - Introduces the concept of open innovation and the role of collaboration
- **Section 3** – Reviews existing evidence on the challenges of innovation
- **Section 4** – Reports the key findings from the interviews with businesses
- **Section 5** – Identifies the key messages from interviews with stakeholders
- **Section 6** – Makes five recommendations on how to improve collaborative working between NHSScotland and MedTech firms in Scotland

¹ The Scottish Government (2012) Health and Wealth in Scotland: A Statement of Intent for Innovation in Health

1. The scale of the MedTech Opportunity

The Medical Technologies (MedTech) sector has been identified as a key strength in the Scottish Life Sciences market², with MedTech growing at double the rate of the rest of the Life Sciences sector over the last decade. The drivers of future growth appear clear and include changing demographics, a focus on prevention and changing patterns of care. Yet the sector faces a number of challenges including competition from emerging markets, increased regulation, as well as pressures from tightened health care budgets.

1.1 The Medical Technology Sector

"Medical technologies (MedTech) are defined as any healthcare product that is used to diagnose, prevent, monitor, treat or alleviate disease or injury. MedTech excludes devices whose principal intended action in or on the human body is by pharmaceutical, immunological or metabolic means."³

The UK is a world leader in the global life sciences (pharmaceuticals, medical technology and medical biotechnology) market. The industry is high-tech and invests over £5 billion in R&D in the UK.⁴

MedTech is a significant sub-sector within Life Sciences in the UK and is estimated to be worth £16 billion to the UK's economy.⁵ Evidence suggests that the sector held up well in the face of the global economic crisis: financial data for 2009-2012 show a 1 per cent increase in turnover and a 4 per cent increase in employment between 2011 and 2012 despite a 6 per cent fall in the number of operating businesses.⁶

And the sector is certain to see further growth. Rapid technological development coupled with demographic changes in developing countries and growing demand for healthcare solutions from emerging economies are creating new markets. These trends can be most clearly observed in: improving treatment and prevention of chronic diseases; a growing emphasis on assisted and independent living; rising expectations for increased wellbeing in later life; increased pressure for cost effective solutions; and a focus on moving from

² Life Sciences Scotland (2011) Scottish Life Sciences Strategy 2011: Creating Wealth, Promoting Health, 2020 Vision

³ Scottish Enterprise (2011) Medical Technologies: Global Trends and Scottish Strengths, An Overview

⁴ UK Trade and Investment, Office for Life Sciences (2010) Life Sciences The UK: Collaboration for Success

⁵ Department for Business Innovation and Skills (2012) Strength and Opportunity 2012: The Landscape of medical technology, medical biology, industrial biotechnology and pharmaceutical sectors in the UK

⁶ Ibid

treatment to prevention.⁷

Yet, there are also significant challenges facing the future development of the sector. The healthcare industry is characterised by very high R&D costs for new products and all subsectors are experiencing downward pressures on prices with reduced healthcare budgets, increased regulatory burdens, alongside an increasing demand for evidence of the cost-benefit value of new products.⁸

Increasing medical device regulation – driven, for instance, by fears of patient safety highlighted by recent high-profile product recalls involving breast implants and artificial hip implants – as well as pressures on health care budgets. Yet, even without the recent increase in regulation, the regulatory aspects of medical devices represent a challenge particularly if you are an SME or micro SME, as many of the businesses in the sector are. The sector also faces intense competition from emerging economies: overseas markets have experienced significantly higher rates of growth than European markets in recent years, with the Chinese market recording growth close to 11 per cent per annum until 2008.⁹

1.2 Medical Technology Sector in Scotland

The MedTech sector has been identified as one of the key strengths of the Scottish Life Sciences business market.¹⁰ It is estimated that in 2010 there were around 192 diagnostics and medical devices business sites in Scotland, employing around 7,200 people. In 2010 this accounted for around 36% of total life sciences sector turnover in Scotland, making it a significant sub-sector.¹¹ The sector has performed strongly over the last decade, with average annual growth (CARG) at around 13 per cent between 1998-2008 according to ONS figures.¹²

The MedTech business base in Scotland is diverse, with companies represented across all major sub-sectors, including: therapeutic medical devices; imaging; non-imaging diagnostics; and surgical (and research) equipment.¹³ The majority of businesses are small and companies tend to be clustered in the West of Scotland with others based around the other major Scottish cities.¹⁴ A number of sub-sectors have been identified as particular strengths in Scotland, these include¹⁵:

- Non-imaging (in Vitro) diagnostics
- Cardiovascular therapies

⁷ Life Sciences Scotland (2011) Scottish Life Sciences Strategy 2011: Creating Wealth, Promoting Health, 2020 Vision

⁸ PWC (2012) Operating performance in the Medtech industry: trends and imperatives

⁹ Outec Ltd (2010) Commercialising Medical Devices: A Guide for UK Based Small Companies

¹⁰ Life Sciences Scotland (2011) Scottish Life Sciences Strategy 2011: Creating Wealth, Promoting Health, 2020 Vision

¹¹ Office for National Statistics, 2010 Annual Business Survey

¹² Scottish Enterprise (2011) Medical Technologies: Global Trends and Scottish Strengths, An Overview

¹³ Ibid

¹⁴ Ibid

¹⁵ Ibid

- Surgical instruments
- Orthopaedics and spine
- Ophthalmic surgery

The future prospect for the sector looks promising and the Scottish Life Sciences Strategy has identified three major opportunities for the growth of the MedTech market in Scotland¹⁶:

- **Accelerating demand** for more user-friendly diagnostics as use shifts from hospital labs to GP surgeries to homes;
- **Growing popularity** of digital-enabled devices to help the elderly live independently and be professionally monitored; and,
- **Increasing need** for devices to minimise invasive surgery, reduce healthcare costs and improve patient recovery.

¹⁶ Scottish Life Sciences Strategy 2011: Creating Wealth, Promoting Health, 2020 Vision, Life Sciences Scotland, 2011

2. Building a healthy environment for open innovation

Our future prosperity will depend on our ability to innovate in important areas such as MedTech. In recent years we have developed a stronger appreciation of innovation as a social phenomenon dependent on complex interactions and relationships between individuals and organisations. The notion of innovation as a linear process, with ideas moving from invention to commercialisation, has been tested and found wanting.

The challenge for public and private sector players alike is to build an environment which supports the productive relationships that unlock innovation. A powerful concept for understanding success and limiting factors here is the notion of Open Innovation. This focuses on the ability of organisations to share ideas and to collaborate and forms the foundation for our analysis.

2.1 The Open Innovation challenge

Innovation – the commercially successful exploitation of new ideas - simply means doing things better in new and improved ways. Innovation comes in many forms and includes product, process or organisational innovation. It can be radical or incremental and includes ideas which are new to the market as well as ideas which are new to the firm.¹⁷ Innovation has always been important for economic success, but the rise of the knowledge economy has made it a determining factor for prosperity. Developing new or improved products and services is crucial for the sustainability of the MedTech sector, where it's often reported that 80 per cent of revenue for established companies comes from products introduced in the past five years.¹⁸

The ways in which firms and organisations innovate are changing, with more explicitly adopting Open Innovation business models and strategies. The term “open innovation” refers to a model of innovation in which firms utilise external as well as internal sources for both accessing innovations and in order to exploit those innovations.¹⁹

In practice, however, the core concept of Open Innovation is much broader and reflects a more engaged practice than simply the sharing of ideas. Successful Open Innovation typically involves close collaboration between multiple stakeholders in addressing a business or social opportunity and challenge. Common features are the sharing of risk and using collaboration to harness the creative abilities of multiple stakeholders - such as technologists, scientists, businesses, entrepreneurs, intermediate and consumer demand, universities, skilled workers, public agencies, government and other institutions.

¹⁷ Crowley, L. (2011) Streets Ahead: What makes a city innovative. The Work Foundation, London

¹⁸ Unleashing the Innovation Lion: How Medical Technology Companies Can Capture True Innovation through Collaboration in Emerging Countries, A Frost & Sullivan White Paper

¹⁹ Levy, C. and Reid, B. (2011) Missing an Open Goal, Big Innovation Centre. The Work Foundation, London

The increasing significance of Open Innovation practices is creating new opportunities for public and private sector organisations to create value. There are potentially many new forms of collaboration available to an organisation as more players in our economy pursue open strategies.

The biggest purchaser of MedTech in the UK is the NHS (National Health Service) and as such it has a key role to play in driving the demand for innovative products and services. Yet, evidence suggests that the adoption and absorption of innovative healthcare technologies with a proven ability to deliver increased patient benefits and significant efficiencies is perceived to be slower in the NHS than other healthcare economies.²⁰

This project was established to focus on perceived challenges that NHSScotland and Scottish MedTech firms face when attempting to collaborate to bring forward innovations. We use the notion of Open Innovation as a framework to assess and understand this performance.

2.2 Three key areas of Open Innovation performance

The extent to which the relationship between the Scottish NHS and the MedTech sector in Scotland fosters successful Open Innovation can be assessed in three areas:

- **Sharing challenges and ideas.** Are the two groups able to effectively communicate what they need, and what is possible? Can the NHS communicate the challenges they are facing? Can they look beyond tightly specified product requirements where appropriate? Are companies able to respond to these challenges and suggest what might be possible? Can NHSScotland engage with the ideas being proposed by MedTech firms?
- **Feedback loops and collaboration.** How well do processes for collaboration, trial testing, and other joint activities help both companies and the Scottish NHS learn what works in practice?
- **Trading relationships.** How well do knowledge and ideas flow through procurement channels?

This paper looks to assess the extent to which these conditions hold in the industry and identify what could help to improve performance.

²⁰ Robert, G., Greenhalgh, T., MacFarlane, F. and Peacock, R. (2009) Organisational factors influencing technology adoption and assimilation in the NHS: a systematic literature review, Report for the National Institute for Health Research Service Delivery and Organisation Programme, http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1819-223_V01.pdf Accessed May 2013

3 Existing evidence on the challenges of innovation within the NHS and MedTech businesses

Previous research indicates that there are significant challenges in the adoption and absorption of innovation into the NHS, including, but not limited to: the procurement process; the complexity of the organisation; cultural factors; insufficient evidence of the cost-benefits of new products; and lack of understanding of NHS needs. Many of these challenges have been recognised and there is a substantial programme of work, as set out in the Statement of Intent²¹ (2012), underway aimed at addressing many of these. For instance: the establishment of MedTech Health Innovation Partnership; the proposed national scheme of joint training, secondments and exchanges introduced between industry and the NHS; and the proposed adoption of developmental procurement.²²

3.1 Innovation, Adoption and Absorption – the NHS

The complexity of adopting innovation into the NHS should not be underestimated. A systematic review of factors influencing such adoption outlines this complexity. Specifically, 10 UK-wide NHS based studies identified:

- “the importance of the history, culture and quality of inter professional relationships
- that there is often no single adoption decision
- the vital role of power and politics in determining the outcome of decision-making processes relating to innovation adoption and assimilation
- the impact of different types of decision-making processes (and that a short-term perspective predominates)”.²³

These findings have been echoed across a number of other studies as well, for instance in 2004 the Healthcare Industries Task Force²⁴ which identified a similar range of barriers to the uptake of new technologies by the National Health Service. In addition a number of other barriers were identified:

- complexity of the NHS – including multiple entry points for suppliers marketing products. In particular, each NHSScotland Board controls its own budget.
- no formal mechanism to disseminate device evaluation advice and guidance, or to share experience and best practice amongst purchasers – which leads to risk-

²¹ The Scottish Government (2012) Health and Wealth in Scotland: A Statement of Intent for Innovation in Health

²² Ibid

²³ Robert, G., Greenhalgh, T., MacFarlane, F. and Peacock, R. (2009) Organisational factors influencing technology adoption and assimilation in the NHS: a systematic literature review, Report for the National Institute for Health Research Service Delivery and Organisation Programme,

²⁴ Healthcare Industry Task Force (2004) Better Health Through Partnership: A Programme for Action

averse purchasing decisions

- insufficient data available to purchasers about the cost and value of new products and technologies and limited sharing of information between purchasers/clinicians/industry
- lack of financial and technical support for companies in translating promising new ideas into marketable products
- bureaucracy around procurement procedures and instigating clinical trials in the NHS
- the cost of retraining NHS staff in the use of new medical technologies and products, as well as the need for better training

3.2 Innovation in the MedTech Sector

Innovation in the MedTech sector²⁵ is in many ways quite different than in other parts of the life sciences. Some of the key features of the innovation model include:²⁶

- **Short development cycles based on engineering** – MedTech innovation in many cases involves addressing mechanical or electrical engineering challenges and is therefore seen as less risky, or complex, than other parts of the life sciences sector such as drug development for instance. For some MedTech products the development cycle is near 18 months rather than the very long development cycles seen in pharma and biotech. As medical technologies can often be diagnostic devices or external aids, clinical trials do not need to be as long term, involving fewer stages and with generally considerably less risk and cost.
- **Collaborative and iterative innovation** – the innovation process is often characterised by collaboration. Products are often developed with customers, both physicians and patients, and product innovation and improvement continues well after the approval phase for the first generation product. The innovation cycle has been compared to that of IT products. These collaborative elements are key to effective development and mean that access to clinicians and patients, or patient samples and data, are crucial. The inability to access this can be very detrimental and can slow product development.

Businesses in the MedTech sector face a number of challenges when seeking to develop and commercialise new products and services. Commonly reported barriers include:

- **Access to finance** - investment in innovation and product development requires finance, yet MedTech businesses are faced with the challenge of dwindling financial resources threatening the sustainability of the sector. On-going regulatory and pricing pressures have made venture capitalists increasingly

²⁵ Please note that although we refer to the challenge of innovation in the MedTech sector in this section the sector itself covers an incredibly diverse range of technologies representing different levels of complexity and patient risk, with varying innovation cycles and different customers.

²⁶ Ernst & Young (2010) Pulse of the Industry: Medical technology report 2010

cautious. This is affecting smaller, and younger, firms more; despite overall levels of venture capital funding remaining steady across European and US markets, investments have primarily been in more mature companies that offer the promise of quicker, more predictable exits.²⁷

- **Access to clinicians** – The importance of collaboration with and feedback from clinicians has already been described. Identifying clinicians who are both working in the right field and interested in collaborating is a challenge, particularly for small MedTech companies.
- **Information on NHS need** – It is particularly challenging for small MedTech companies to identify the areas of need for NHSScotland (as opposed to general medical advances or need).
- **Developing the evidence base** - pressure on health care budgets means that MedTech businesses are facing increasing pressure to demonstrate improved outcomes and the cost-benefit of new, or improved products, with expanded use of comparative effectiveness.²⁸ This is leading to increasingly costly lengthy and complicated procedures and longer product developing cycles.
- **Navigating the regulatory environment** – MedTech companies have to navigate an increasingly complex and time consuming regulatory environment. For instance, if MedTech businesses want to bring their product to market in America they face significant challenges. The US Food and Drug Administration (FDA) used to only require clinical trials for Class III medical devices (which have higher levels of complexity and patient risk) but now are applying scrutiny to a much larger set of products including those classified as Class II. These regulatory changes pose a major challenge. Medtech companies must now plan and budget for longer, more stringent product development with no guarantee of successful commercialisation.**Access to data and tissue** – In order to test diagnostic technologies MedTech companies require access to tissue samples and patient data. These in turn require the company to navigate stricter regulation and more onerous bureaucracy.
- **Setting up clinical trials** – Variation between the responses of different hospitals and also the level of paperwork required to set up trials are problematic for MedTech companies – although support is available through NHS Research Scotland, who provide assistance with the research and testing process to businesses with promising product ideas.

The extent to which these challenges affect businesses depends on the level of complexity of the technology and patient risk as well as the size of the businesses, with small and micro businesses particularly affected. It should also be noted that many of these challenges relate to the barriers identified in the previous section around adoption and

²⁷ Ernst & Young (2010) Pulse of the Industry: Medical technology report 2010

²⁸ Ibid

absorption of innovation in the NHS.

3.3 Driving Innovation in the MedTech Sector in Scotland

NHSScotland is in an interesting position as its role can be as a user, developer, customer/procurer of new technologies. In this respect NHSScotland already naturally engages in some Open Innovation practices, for example developing technologies externally (through Scottish Health Innovations Ltd (SHIL)) and utilising externally developed technologies. As a public sector organisation the roles are complex and in some ways competing. Two relevant questions are:

- What are the opportunities for greater collaborative efforts between companies and NHSScotland?
- And
- Is there a greater need for official calls for innovation, collaboration, or even co-option?

It is clear from statistics relating to medical technology in the UK that Scotland is home to one of the larger clusters of such companies.²⁹ A key point for this study is the capture of value from these companies. However, before turning to look at the evidence gathered for this study, it is important to place the research within the context of the current policy environment, the programme of work already underway, as well as the existing supporting infrastructure.

3.4 Action to overcome these challenges

There are several policy documents which provide important context for this research report. These include Life Sciences Scotland's *Scottish Life Sciences Strategy 2011: Creating Wealth, Promoting Health (2011)*, and *Health and Wealth in Scotland: A Statement of Intent for Innovation in Health (2012)*. The Life Sciences strategy sets out a vision for growth of the sector, and includes the ambition that Life Sciences in Scotland will double in size by 2020. Additionally the *Health and Wealth in Scotland: A Statement of Intent for Innovation in Health (2012)* document sets out the practical steps the Scottish Government is taking, through partnership working, to identify innovative solutions that improve healthcare and increase commercial opportunities for the life sciences sector. Another important strategy document is the Scottish Government's strategy document for improving health outcomes in NHSScotland – *The Quality Strategy for the NHS in Scotland (2010)*.

These documents which set out the policy environment as well as the programme of work underway are summarised below, followed by a snapshot of existing innovation infrastructure.

²⁹ HM Government (2011) Strength and opportunity 2011, The landscape of the medical technology, medical biotechnology, industrial biotechnology and pharmaceutical sectors, Department for Business, Innovation and Skills; Department of Health

Scottish Life Sciences Strategy 2011: Creating Wealth, Promoting Health

This document describes Life Science Scotland's vision for how they want the sector to develop by the year 2020, and sets out some steps it intends to take to achieve the vision. The document sets out a central ambition that the Life Sciences sector in Scotland will double both in turnover and Gross Value Added by 2020, to £6.2 billion and £3 billion respectively. Other ambitions include:

- Attracting more inward investment
- More Scottish firms to achieve international scale and high growth.
- That Scottish people benefit from the faster adoption of new products and services.

The strategy identifies Scotland's strengths in the sector as its company base, its business diversity, its research and innovation capabilities, its high rate of business creation and in Scotland's small size (because it allows greater partnership working and coordination) and its infrastructure.

Health and Wealth in Scotland: A Statement of Intent for Innovation in Health

This document places 'innovation' as the link between growing the Life Sciences sector in Scotland and improving health outcomes for patients. The document sets out an ambition to improve links between NHSScotland and industry. This, it is argued, would promote the development of newer, better technologies and products in Scotland, thereby benefiting patients, NHSScotland, and Scottish business.

The document sets out changes across a number of areas, including the establishment of Health Innovation Partnerships, which are intended to promote joint working between NHS Hospitals and business.

Organisational infrastructure and partnership working in MedTech

For the purpose of this report, it is also important to recognise that a supporting infrastructure for the MedTech sector already exists within Scotland. There are a number of organisations, partnerships and other agencies which work within the MedTech sector to support businesses, and to foster collaboration across businesses, universities and NHSScotland. Some of the main organisations, partnerships and relevant agencies are detailed below:

- **Health Innovation Partnerships (HIP)** – The purpose of a HIP is to support partnership working between NHSScotland and business in various health sectors. A HIP for MedTech has been established by the Innovation Partnership Board. Amongst other activities, it is intended to provide businesses with better information on NHS clinical requirements.
- **Scottish Enterprise and Highlands and Islands Enterprise** – provide expertise and advice to businesses in Scotland. They help companies find investment and develop their products and services.

- **Scottish Development International** – connects Scottish companies with international investors.
- **Life Sciences Advisory Board** – enables the strategic partnering of the public sector and industry in the Life Sciences sector. It is responsible for, among other things, setting out the strategy for growth in the sector.
- **The Office for Strategic Coordination of Health Research** – This was set up to coordinate major public health research funders in the UK. This is an England-based body although Scotland and the other devolved administrations also have input.
- **The Technology Strategy Board** – This is a business-led body that operates at arm's length from the UK Government and is funded by the Department for Business, Innovation and Skills. Its purpose is to promote technology-enabled innovation in the UK.
- **Scottish Health Innovations Ltd** – Supports the commercialisation of innovations that arise within NHSScotland and was formed in 2002.
- **NHS Research Scotland** – Supports the testing and trialling process for Life Sciences businesses. NRS is a partnership of NHSScotland Boards, and is funded through the Chief Scientist Office of the Scottish Government.
- **Health Science Scotland** - is a partnership of medical universities and their associated NHS Health Boards in Scotland. Its objective is to increase the level and quality of health research in Scotland.
- **Scottish Life Sciences Association** – is a membership and support network group for Life Sciences companies in Scotland.
- **Life Sciences Scotland** – is an organisation which brings together and represents the Life Sciences community in Scotland – industry, healthcare providers, and Government.
- **Association of British Healthcare Industries** - is the industry association for the medical technology sector in the UK.

Within policy there is a clear recognition of the challenges and activities that are already underway to address the issues outlined in section 3. However, there is limited evidence on how things are currently working. The remainder of this report therefore examines the interview data relating to both successes and to the barriers to successful development of medical technologies by Scottish-based companies. It will also explore a particular area for further development which has been identified, that is the exploitation by NHSScotland of medical technologies developed in Scotland.

4. Assessing performance – business perspectives

This section outlines the findings from our primary research stage, which comprised of interviews with Scottish medical technology businesses as well as interviews with key stakeholders. The aim was to assess the extent to which Scottish based MedTech businesses were currently engaging with NHSScotland, as well as the mechanisms that they would ideally like to see put in place to enable increased collaborative work.

4.1 Characteristics of businesses interviewed

Semi-structured interviews were conducted with 24 businesses; in most cases the interviewee was the Chief Executive of the business. A diverse range of businesses were interviewed: they were different sizes, based in different parts of Scotland, and operated across a number of medical technology subsectors.

The 2011 Scottish Life Sciences Strategy³⁰ suggested there were 140 businesses in Scotland's medical technology sector, so our sample of 24 offers a good cross-section. However, it should be noted that, as with many types of survey research, there is likely to be an element of selection bias. For instance, it may be the case that the companies who agreed to be part of the research were particularly engaged with the NHS or alternatively had encountered particular difficulties.

4.11 Size

There was a range of sizes within the interview sample. Most of our interviewees were 'micro' businesses – employing ten or fewer people. Three businesses employed 11-50 people; two employed over 50 but were still SMEs (employing fewer than 250 staff). The remaining three were large, multinational corporations.

Our sample reflects the size of businesses in the Scottish MedTech sector reasonably well. In 2010 there were around 140 companies in the sector, ranging from multinational companies to micro enterprises employing fewer than 10 people.³¹

4.12 Location

The businesses we interviewed were located in different parts of Scotland. Postcode analysis by Scottish Enterprise shows that the majority of Scotland's MedTech businesses

³⁰ Scottish Enterprise (2011) Medical Technologies: Global Trends and Scottish Strengths, An Overview

³¹ Ibid

are located in the West of Scotland – in and around Glasgow – with other concentrations in Edinburgh and on the East coast. Our sample was similarly located, although more of the businesses in our sample were based in northern Scotland than is the case in the overall sector.

4.13 Business types

The MedTech sector covers all the different technologies that 'diagnose, prevent, monitor, treat or alleviate disease or injury'.³² As such, the sector is as diverse as the diseases and injuries addressed. Our sample of MedTech businesses represent most of the key sub-sectors: imaging, in-vitro diagnostics, orthopaedics and spine, urology and renal, wound care, and ophthalmic surgery are all represented by at least one of our interviewees. The main sub-sectors our sample did not cover are dental care, endoscopy, and drug delivery.

The 24 businesses also vary in where their activities fit on the value-added chain. Businesses within the sample lie on a spectrum – from those that conduct research only, through to businesses that design and manufacture products, to those that sell the products produced by others, as well as those that sit across the whole value chain.

- Three of the companies interviewed are involved in making software for medical purposes. These businesses have similar business models – they mostly respond to commissions from health providers to develop new software products.
- The other 21 businesses either research technology for, produce, or sell medical devices or diagnostic tools.
 - Two of the businesses we interviewed principally act as sellers and distributors of products produced by other companies, although one of these does engage in some production activity
 - All other 19 businesses engage in research and development. Two of these businesses just do research and development – they do not make the products their technologies are used in, but rather sell or license their technologies to other companies. Across the remaining 17 companies that conduct research, all make products, although some also offer a service linked to the products they design and sell.

4.2 Key findings from research

The section below details the main findings from the business interviews. Interviewees were asked to provide details of previous and current experience of engaging with NHSScotland, as well as the mechanisms that they would ideally like to see put in place to enable increased collaborative work.

³² Scottish Enterprise (2011) Medical Technologies: Global Trends and Scottish Strengths, An Overview

All of the businesses we interviewed had engaged with NHSScotland at various points of the product development process. These can be summarised in three stages:

- Gaining initial feedback on an idea from NHSScotland
- Testing and trialling of products in a clinical setting via NHSScotland
- Selling to NHSScotland (engaging with local / national procurement)

4.21 Engaging with NHSScotland - gaining initial feedback on challenges and ideas

NHSScotland is important to the Scottish MedTech sector as a consumer of goods and services. It is therefore useful for companies developing new ideas for products to gain feedback on their ideas from NHSScotland to gauge the likely demand for their product from NHSScotland itself. Feedback from NHSScotland can also inform a business about the likely reception from other health service providers; even if a business doesn't sell directly to the NHS it may still benefit from feedback from NHSScotland.

Timely feedback may prompt a business to adjust or adapt their product in some way. Identifying necessary changes earlier in the product development process inevitably makes the process faster and less costly for the developer. Businesses also consider feedback from NHSScotland important if they are likely to require access to NHS patients when conducting clinical testing. Seeking feedback early in the process can also help identify any barriers a product is likely to face at that stage of the development process.

19 of the 24 businesses interviewed are engaged in designing new products and services. Two businesses are not included in this group because they do not undertake research and development, and the three IT companies interviewed have been excluded because their business model involves responding to commissions from the NHS and others. These companies wait for their clients to announce their needs rather than coming up with new ideas for products and services and seeking feedback.

Scottish based MedTech businesses would value more feedback from both clinicians and patients

The businesses interviewed considered it most valuable to speak to clinicians and other (potential) end users of their product. 'Users' here includes NHS staff, who may give some feedback about whether they would potentially use a product, but also patients. Patients are of course involved in the clinical trialling stage, but one business interviewed said they sought to gather patients' opinions while still in the development phase. In most cases businesses said they had multiple points of contact for feedback, including both local GPs and clinicians in hospitals.

Many established businesses rely on their existing network of contacts for feedback; newer businesses have more difficulty gaining access to NHSScotland

In the majority of cases, the businesses considered the contacts they used for this process to be informal – they were past acquaintances who could be contacted on an informal basis. The line between informal and formal contacts is somewhat blurred, since many of the businesses’ contacts appeared to have been formed through past work engagement – i.e. formal contacts that had over time become informal ones. However, it was clear that most businesses did not use official NHS channels to discuss their ideas. The channels identified, for example in the MedTech Road Map, appear to be rarely used.

This was reflected in the fact that the businesses that were more established, or which worked in partnership with the NHS, found contacting the NHS for feedback much easier. This may be because they had been able to develop informal contacts within the NHS through their longevity, or through their close working, which they then used to seek feedback on new product ideas.

A minority of our interviewees had had difficulty accessing clinicians or other NHS staff to discuss their ideas. These businesses tended to be more recently established. This might suggest again that informal contacts are important (since newer businesses have had less time to develop these contacts) though might also be because newer businesses are less adept at negotiating formal channels.

The businesses that had difficulty gaining feedback said they found formal channels difficult to navigate and were unsure who they were meant to talk to. Formal channels include specified points of contact within NHSScotland who have responsibility for interacting with research businesses – in particular those set out in the ‘roadmap’ to introducing new technologies to NHSScotland³³. Businesses interviewed either were unaware that such channels existed, or expressed concern that the people they contacted were not in an appropriate position (for example, because they lacked seniority) to provide support and advice.

Business size may also be an issue here. Smaller businesses are less likely than larger businesses to have staff dedicated to managing their contacts with external partners such as NHSScotland. This can make it harder to pursue and maintain contact with large organisations like NHSScotland. This issue was raised by an interviewee who had experience of both large and small businesses.

4.22 Engaging with NHSScotland - testing and trialling of products in a clinical setting

Ten of our 19 R&D active interviewees had engaged with NHSScotland to test or trial their product in a clinical setting (two had done so through NHS England, and one in America). Others had not tested or trialled their products in a clinical setting because either their

³³ NHSScotland (2010) Introducing new technologies into the NHS in Scotland: A practical guide for industry

products were at too early a stage for testing, because their product had been turned down for testing, or because clinical testing was not relevant for their product.

Most of our interviewees had concerns about the process of testing or trialling their products through NHSScotland. Various issues were raised, in general relating to the cost to the business of conducting such trials. Naturally businesses want this process to be as low cost, and to take as little time as possible. In most cases the complaints raised were felt more keenly by the smaller businesses interviewed, especially those with a smaller portfolio of products. For these businesses, a lot rides on the outcome of the trials process. These businesses suggested that, having fewer other products to work on, they were more vulnerable to time delays caused by lengthy trial processes.

Two businesses, on the other hand, were positive about the clinical trials process. One company in particular was engaged in a research partnership with the NHS (and a local University) and so had been able to successfully 'streamline' the product development and testing process.

Timescales

A commonly held perception among our interviewees was that the trialling process is too slow. Several businesses said clinicians supporting the trials took too long to release the results of a trial. A related concern was that there were often delays in providing businesses with timely information throughout the trials process. Businesses felt poorly informed about the progress of their trial.

Cost

Some interviewees considered the cost of trialling products through NHSScotland to be high compared to elsewhere – America and India were two locations mentioned that were perceived to offer cheaper trials processes. This appears to be backed up by broader studies.³⁴ These suggest that not only is the UK uncompetitive in terms of costs (with costs being amongst the highest in Europe) it is also slower and has a poor record at delivering on patient recruitment targets. However, the studies do not have data specific to Scotland.

Regulation

Several businesses considered the trials process to be over-regulated, and thought this contributed to greater costs. One source of concern was high insurance requirements on businesses engaging in a medical trial. Some interviewees felt this made trialling unaffordable and discouraged them from developing products. Some smaller businesses said these requirements were particularly hard for small businesses, and also made it harder to compete with larger businesses. Some businesses also suggested that

³⁴ See for instance – McKinsey (2005) Clinical Research in the UK: Towards a single system that reliably delivers distinctive quality and rapid access at reasonable cost and Quotec Ltd (2010) Commercialising Medical Devices: A Guide for UK Based Small Companies

NHSScotland's demands for pre-trial evidence are too high.

It is worth noting that the Scottish Government has taken steps to address some of these issues raised. NHS Research Scotland (NRS) is a partnership of NHSScotland boards and is funded by the Scottish Government through the Chief Scientist Office. It helps businesses through the clinical trials process, and has succeeded over the past 4-5 years in reducing the time taken to approve clinical trials. NRS was not mentioned by any of the businesses interviewed – even those that had experienced the problems NRS seeks to help address – so it may be that there is a problem with awareness of the support available among the business community.

4.23 Engaging with NHSScotland - selling to NHSScotland

Businesses that want to sell to NHSScotland must engage with local or national procurement. 16 of our 24 interviewees had done so. Most of these businesses sold their own products to the NHS, but a small proportion sold others' products.

Those eight interviewees that had not engaged with NHS procurement had not done so either because their products were not yet ready for sale or because they did not sell their products to the Scottish public health sector. Two of these businesses did not sell their products in Scotland, but did sell overseas - one because they considered the Scottish market too small, and one because they had received no domestic interest in their product and had turned to overseas markets instead.

Selling to the NHS is important for Scottish MedTech businesses – but some prefer to sell overseas

Several businesses stressed how important it was to sell their products to the NHS. In part because this provides them with a lot of their revenue, but also because selling to NHSScotland helps drive sales elsewhere – to private health providers in Scotland and to other countries. The reverse was also found to be true for some businesses – failing to sell to NHSScotland could inhibit sales elsewhere.

However, while NHSScotland is an important customer for many of the businesses we interviewed, some said the technologies they had developed had been easier to sell abroad. This was attributed to:

- Tighter regulations from NHSScotland – for example on clinical testing procedures
- Issues related to competitive advantage for private clinics, for example in the US (new technology seen as attractive to private consumers of health care – particularly new/better diagnostic tests).
- The fact that it was easier to gain some approvals / sell products in Japan, Germany, France Italy and the US. In most cases this was attributed by interviewees to either less regulation or faster approvals processes.

A concern was expressed by some interviewees that “home grown” new technologies

developed in Scotland are not benefitting NHSScotland (or arguably the Scottish economy) to the level that they might.

While most interviewees recognised and mentioned the importance of the NHS achieving value for money in the way it procures goods and services, many businesses nevertheless thought that NHSScotland's processes for procuring products could be improved.

Financial considerations versus clinical needs

Several businesses shared a perception that NHS procurement prioritises financial considerations over clinical needs. Of course, this somewhat misrepresents the purpose of procurement services, which is to strike a balance between what NHSScotland is able to afford and what is most desirable for clinical purposes. Financial considerations are not pursued as an end in themselves, but rather are part of a process that aims to achieve maximum value for money with the funding available. Businesses nevertheless felt that clinical considerations are undermined by the desire to cut or limit spending.

In general, businesses expressing this opinion believed they had products which were improvements on existing products used by the NHS, and which they felt would deliver better health outcomes for patients. It is perhaps not surprising, therefore, that they believed that a failure to procure their products (or difficulties or delays in doing so) represented the prioritisation of financial over clinical needs.

More useful, perhaps, was the perception that there was too little involvement of clinical experts in the procurement process. Several businesses suggested that individuals with a strong clinical background would be better able to 'spot' valuable products – both in terms of the benefits to patients but also in cases where the product developers believed their product would save NHSScotland money overall or in the long term.

Taking a Holistic View to Procurement

A significant number of interviewees expressed a concern that the way NHSScotland's procurement system operates makes it reluctant to invest in products which can save money either in the future or in the short-term when spending is looked at across the board. Products can save money even if they are more expensive, either because they are more effective, or because they save money in other elements of treatment, for example if new equipment reduces the demands on staff time.

In the case of saving money from future budgets, it was alleged that spending decisions are short-termist because of political considerations and the immediate pressure to reduce budgets. In the case of saving money from other parts of the NHS, it was suggested by a minority of businesses (two) that a 'siloes' procurement in NHSScotland is responsible. By this it was meant that procurement decisions failed to evaluate overall benefits to NHSScotland, thereby overlooking products which might save NHSScotland money overall but where the savings might not accrue directly to the department using the products. This can be due to greater effectiveness or possibly as costs associated with other elements in a treatment, for example equipment or staff time, are reduced.

These suggestions, however, are difficult to substantiate without a fuller examination of the procurement policies operating in NHSScotland, which was outside the scope of this research.

Other interviewees, by contrast, suggested that in some cases NHS procurement is too long-term. In particular, concern was expressed about framework contracts, which interviewees said in some cases could last up to 7 years³⁵, and which it was suggested have a number of negative effects:

- Long-term contracts stifle competition (in years other than when a new contract is being awarded) and thereby also stifle innovation.
- There is little incentive for the contractor itself to innovate once it has secured the contract – and 7 years is a long time to continue using the same technology in a fast-moving field such as medical technology. Shorter contracts would allow faster adoption of newer technologies.
- Framework contracts often require that the contractor be able to deliver (or at least sub-contract) a whole range of services, which can disadvantage smaller, more specialist businesses.
- Framework contracts often require substantial 'due diligence' processes, which smaller companies cannot afford to carry out. This also disadvantages smaller businesses.

It was argued by three businesses that NHSScotland's approach to procurement of commodity products (such as hospital beds, or other widely used stock items) versus more specialist items was not working as well as it might. For the latter, strict value-for-money processes are less relevant because it is not a case of multiple companies offering similar products but competing on price. Rather, interviewees argued, procurement should be more flexible and recognise that with smaller, innovative companies developing specialist products, more subtle procurement processes are required.

View on procurement services in NHS England

A minority of respondents (two of the 24 interviewees) said they preferred the procurement system in England. In both cases this was partly because they considered the English system to be more transparent. One interviewee said they had received better feedback on the reasoning behind the decision, and how their products compared to successful products, when their products had not been procured. This feedback encouraged the business to keep developing the product. The interviewee had requested similar feedback when failing to sell to NHSScotland but had not received it.

They also expressed the view that current healthcare reforms in England, and in

³⁵ It should be noted that the guidance within the Legislation is that frameworks should be a maximum of 4 years unless specific circumstances dictate otherwise, (for example high initial investment costs, etc). NHS National Services Scotland manages approximately 250 frameworks covering £900m of annual expenditure. 1% of this total is for over 4 years, with the vast majority (80%+) having a break option at 2 years.

particular, the move towards GP-led commissioning may provide more potential routes to market. Another interviewee was vaguer in explaining his preference for English procurement, but the reasoning appeared highly specialist to their particular field. The interviewee believed that the new commissioning system would give patients greater say over procurement decisions and would lead to greater uptake of his product since patients would be better able to appreciate the value of his product.

4.3 Mechanisms for collaboration

All interviewees apart from one expressed a desire for changes within NHSScotland to improve how the organisation works with businesses. Below is a quick summary of the main points raised. It is also worth remembering however, that interaction is a two sided process and that there may be ways in which businesses could change to improve their interactions with the NHS. However, the businesses interviewed did not make any such suggestions, and appeared to believe that the onus for change lay with the NHS.

The most commonly desired change was **improvement to the NHS's procurement process**. Desired changes related to: involving more clinicians in the procurement process; making it easier for SMEs to sell to the NHS (for example, by lowering due diligence requirements); and adopting different procurement strategies for commodity as opposed to more specialist products.

Several businesses wanted **better access to information about unmet needs**, and **contact with clinicians** or clinician conferences or meetings.

The **difficulty of cultural differences** came up with several interviewees. Small companies are unable to devote resource to overcoming this cultural barrier. A department or group within NHSScotland which acted as a liaison particularly for SMEs would help.

Another suggestion was **a register of what projects are being run**, what clinicians are involved and whether they're interested in being approached by other companies offering medical devices or services.

A couple of businesses expressed **approval of reforms to healthcare in England**. One business thought the new system would provide greater patient voice and provide more flexibility on products purchased.

5. Assessing Performance – Stakeholder Perspectives

As well as 24 interviews with businesses in the MedTech sector, we conducted 10 interviews with key stakeholders. These were from NHSScotland, as well as various organisations which represent or work with businesses in the MedTech sector.

The stakeholder interviews supported some of the findings from the business interviews, although responses were less tied to the different stages of the product development cycle. In part this is because the questions asked in these interviews were slightly different – but also because the stakeholders tended to have a broader outlook than the business interviewees. The stakeholders considered, as did the businesses, that there are several ways that interactions between NHSScotland and MedTech could be improved. The stakeholders reiterated some of the points that emerged in the business interviews:

- That some Scottish MedTech businesses prefer to sell their products overseas due to difficulties in doing businesses in Scotland.
- That there are 'cultural' differences between NHSScotland and the businesses in the sector.
- That the way NHSScotland procures its products could be improved to better encourage innovation.
- That smaller, newer businesses find it harder to engage with and sell to NHSScotland than larger, more established businesses.

However, several points were made in the stakeholder interviews which were not specifically raised by the business interviewees. The points raised by the stakeholder interviewees can be grouped into two themes. Firstly, general points were raised regarding the interaction between MedTech businesses and NHSScotland. Second, points were raised regarding NHSScotland, in particular its strategic purpose and how it procures.

5.1 Interactions between NHSScotland and MedTech businesses

Interviewees suggested:

- **That collaboration between NHSScotland and MedTech businesses would benefit from greater central coordination.** This could help spread examples of good practice (how best to go about collaborating) as well as technological solutions to common problems.
- **That collaboration would be easier if there was a clear enabling mechanism in place.** It was noted that there is a mechanism to help technologies developed within the NHS 'spin out'. This is Scottish Health Innovations Limited.

However, nothing is in place to support the opposite process – providing businesses with new technologies the support and positive environment required to develop their products.

- **That, as well as NHSScotland, MedTech businesses have some responsibility to increase or improve collaborative working.** For example while NHSScotland should seek to make the process simpler for businesses, businesses themselves could do more to raise their understanding of the process.

5.2 NHSScotland – procurement and broader issues of leadership, culture and strategy

Stakeholder interviewees mentioned a variety of ways in which NHSScotland might change to either encourage greater innovation among MedTech businesses or to encourage greater collaboration with businesses in the sector. With regard to procurement, suggestions included:

- That NHSScotland should not procure specialist, technical items in the same way that it procures 'commodity items'. This point was also raised in the interviews with businesses.
- That perceived problems with EU law regarding using procurement to promote or support local companies are a 'myth'. The interviewee suggested that other EU countries already use their procurement power more actively, and that Scotland should do so.
- That the 'siloes' nature of procurement in NHSScotland can form a barrier to investing in new technologies. This point was also raised in our interviews with businesses. Multiple interviewees raised this problem, though most also recognised the difficulty of implementing a more flexible procurement system with an organisation as large as NHSScotland.
- That the use of large contracts makes it difficult for smaller companies to compete for business, and also discourages innovation for the duration of the contract.

Interviewees also made suggestions relating to broader strategic, leadership and cultural issues concerning the NHS that affected the ability to work in partnership with industry or the ability to procure 'innovative' products and services:

- Interviewees pointed out that NHSScotland has a significant impact on the economy with the scale of its spending, but that it was unclear whether the organisation sought to 'leverage' its spending to achieve economic as well as health related outcomes.
 - It is perceived that there is an 'anti-risk' culture within NHSScotland which discourages the adoption of new technologies or processes. Because the NHS is a very large, highly bureaucratic organisation, which inherently leads to a degree of stasis;
 - Because the NHS is spending large amounts of public money, and so has a responsibility to spend it wisely, which leads to a degree of conservatism in

- its spending choices;
- Because clinicians are dealing with patients' lives, and so are naturally reluctant to move away from products and processes which they trust, and which have worked well in the past.
 - Because some new technologies can be important enough to require that services be re-designed, which is a costly process. For instance, technologies which allow patients to be treated away from hospitals require that services be re-designed to match.
- That clinicians have little time or incentive to engage with MedTech businesses. NHSScotland's overall strategic objectives feed through to the demands placed on clinicians, and the prevailing culture of the organisation also affects their desire to engage with business.

5.3 Summary

The table on the next page provides a summary of the similarities and differences in perspectives between the key stakeholders and businesses interviewed for the research.

Table 1 Commonality and differences identified in the perspectives of business and other stakeholders interviewed

Key Elements	Similarities in perspectives	Differences in perspectives
Contacts	<ul style="list-style-type: none"> • A “lack of awareness” among business about ways to engage with NHSScotland. • That the NHS needed to make the process simpler. • That businesses tend to work through informal networks of contacts, and that formal channels can be difficult to navigate. 	<ul style="list-style-type: none"> • Stakeholders felt that businesses should do more to raise their awareness of the formal process.
Collaboration	<ul style="list-style-type: none"> • That newer, smaller businesses find it harder to engage than more established businesses. 	<ul style="list-style-type: none"> • Stakeholders felt that greater central coordination would aid collaboration.
Testing and Trialling	<ul style="list-style-type: none"> • Businesses encountered some difficulties in the process of testing or trialling products through NHSScotland • Stakeholders suggested a clear enabling mechanism would provide businesses with the support required. (This could include support to expedite testing and trialling.) 	
Feedback		<ul style="list-style-type: none"> • Businesses want greater feedback from both clinicians and patients on new products and technologies
Selling/ Procurement	<ul style="list-style-type: none"> • Both recognise that changes to procurement could encourage innovation • Both recognised a difference in the way specialist and commodity items should be procured • Both recognised silos between different parts of the NHS can lead to a misunderstanding of the ‘value proposition’ of new products and technologies • Businesses and stakeholders mentioned that some Scottish Med Tech businesses sell products in the EU and further overseas due to difficulties in selling to NHSScotland 	<ul style="list-style-type: none"> • Stakeholders understood businesses’ suggestion that there is a ‘risk averse’ culture within the NHS. However, they pointed out that this is better described as a balance that NHSScotland must find – between the need to protect patient safety and to operate within public spending constraints on the one hand, and the desire to adopt new technologies on the other. • NHSScotland’s attitude to risk might be better described as a ‘rationale’ than as a ‘culture’. The latter implies it is a practice that has emerged accidentally from historical norms rather than a response to the need to protect patient safety.
Culture	<ul style="list-style-type: none"> • Both stakeholders and businesses recognise the ‘cultural’ differences between NHSScotland and business in the Med Tech sector. 	

6. Recommendations to unlock greater collaboration

This chapter sets out a short series of recommendations to support greater collaboration between Scottish based MedTech companies and NHSScotland. We have identified four measures to help facilitate the sharing of ideas, challenges, possibilities and to help better connect the innovation ecosystem, as well as a fifth measure specifically designed to practically support better collaborative activities.

The recommendations draw on discussions with stakeholders and interviews with MedTech companies, alongside desk research about what works elsewhere (please see Appendix for an overview of similar mechanisms) and suggest a series of mechanisms that could support greater collaboration between industry and NHSScotland. It also needs to be considered alongside the work already being taken forward under the Statement of Intent and identified in Chapter 3 of this report.

1. Develop an enabling mechanism to support the 'spin-in' of new technologies to NHSScotland

Infrastructures have been set up to support the 'spinning out' of ideas from clinicians in the NHS, however there could be an opportunity to match these support arrangements to help the NHS absorb ideas from Scottish based MedTech SMEs – that is, to help new technologies 'spin in' to NHSScotland. For many MedTech SMEs engaging with the NHS can prove challenging. New institutional arrangements could: help to hide the wiring for businesses; help to communicate NHS needs; put industry in contact with the right individuals; streamline clinical trials and the testing process; and support industry to navigate the regulatory environment. The majority of large corporates already have similar functions in place in their organisations allowing them to engage much more effectively with health service providers.

Scottish Health Innovations Ltd (SHIL) already exists to support the development of new innovations from healthcare professionals in NHSScotland. However currently no organisation exists to support the opposite process. Such an organisation could either be independent or part of an expanded SHIL.

SHIL Ltd was set up in 2002 – by Scottish Ministers, Scottish Enterprise and Highlands and Islands Enterprise – to exploit intellectual property arising from NHSScotland. The service provides support around: project management; market research; sourcing funding; Intellectual Property Protection; spinout set up; and regulatory consultancy.

Interviews with MedTech business, as well as stakeholder interviews, have suggested that a similarly designed service providing support to small and micro businesses to engage with the NHS and provide support around the commercialisation of innovations would be desirable. This would help to address a number of the barriers identified by businesses around clinical trials, regulations, and difficulties in accessing information. As mentioned earlier in the report, NHS Research Scotland does already provide some support along

these lines. It supports a range of companies – from large, multinational pharmaceutical businesses to small MedTech product developers – to access clinical trials. It has different models to suit these different engagement. These include:

- Providing a streamlined clinical trials application process (mainly for large businesses, with which NRS has long-standing relationships).
- Providing extensive administrative support throughout the trials process (particularly useful for small businesses with limited capacity).
- Engaging more collaboratively to develop products alongside a business – including the placement of an NRS consultant within a business (mainly useful for smaller companies).

However, while the work of NRS is important, and has helped many businesses, it only covers one aspect of the product development cycle, and is more geared to supporting larger firms and pharmaceutical firms. Therefore, we recommend the establishment of a more comprehensive support service which provides support across a range of needs – from feedback on initial ideas, identification of sources of potential finance, communication of NHS needs, access to clinicians as well as referrals of to other appropriate support services such as NRS.

2. Enhancing the MedTech roadmap – developing an online platform and a Clinical Expertise Database

Introducing New Technologies Into The NHS In Scotland: A Practical Guide (the 'MedTech RoadMap')³⁶, is a useful guide which provides contacts and information to help companies navigate the NHS in Scotland by knowing who to contact and at which points in the product development journey. However, knowledge of the MedTech roadmap amongst our sample of businesses was very limited. In addition, the problem with documents is that they can quickly become out of date as key contacts move or are replaced. To enhance its visibility and usefulness we recommend that the document should become an expanded online updateable version.

Further, one of the most commonly voiced concerns of MedTech businesses was around gaining access to clinicians who were interested in their specialist area. Expert clinical opinion is vital to the medical technology industry to address unmet clinical needs and to ensure new products are 'fit for purpose'. As part of the updated online roadmap, a Clinical Expertise Database could be created as a potential way of addressing this. The Clinical Database would have to be managed by an organisation who acts as a facilitator and a gatekeeper to the process. The Clinical Expertise Database could:

- Provide a list of clinical stakeholders who are willing to engage with industry
- Provide a mechanism to readily identify NHS experts by their clinical and research interests

³⁶ <http://www.scotland.gov.uk/Publications/2010/11/02085517/0>

- Speed up the process of clinical engagement for business by only approaching those who have already indicated a willingness to collaborate
- Provide an access point for product developers who would otherwise struggle to identify and engage with the right stakeholders

There are a number of potential models that could be adopted, for instance Health Enterprise East Limited (HEE), the NHS Innovation Hub for the East of England, created Clinical Insight (<http://www.clinical-insight.com/>) a database that now holds the details of more the 400 stakeholders and is helping to provide rapid access to clinical stakeholders across a number of long term conditions.³⁷

3. Facilitating greater networking opportunities between clinicians and businesses – mapping current networks

Networks can be an important mechanism for stimulating innovation via collaboration and the development of new business models. They facilitate the diffusion of ideas, skills, and expertise – providing a forum for collaboration and learning.

Interviews with MedTech businesses suggested that businesses felt that there were not enough opportunities to network with NHSScotland, and in particular with clinicians. It was also felt that some of the networking opportunities that did exist were prohibitively expensive for small and micro firms. It would be useful to map out the types of networks that do exist, as well as who attends and for what purpose, to understand whether any additional networks are required or whether existing networks can either be publicised better or amended to support better links between businesses and clinicians.

4. Development of an enterprise fellowship scheme

Knowledge exchange mechanisms are often created to overcome market failures relating to information and co-ordination. In academia for instance, the justification is that although the UK has world class universities and colleges, it is often difficult to transfer the knowledge created in these institutions to the organisations that can make practical use of it. And on the other side it is argued that businesses face information failures – that is, they often have difficulty in accessing or exploiting new knowledge to improve their competitiveness.

The Statement of Intent has already identified an action to develop "*a national scheme of joint training, secondments and exchanges [...] between industry and the NHS*". We would support this action and suggest that as part of this national scheme an enterprise fellowship programme be developed for clinicians from NHSScotland. Fellowships are often used to support knowledge exchange between organisations and to develop collaborative approaches, the aim being to facilitate long term cultural change within participating institutions and to strengthen the relationship between businesses and agencies at the strategic and personal level. The development of such a scheme between

³⁷ Clinical Expert Database: Final Report October 2012, Health Enterprise East

Scottish-based MedTech companies and NHSScotland could help to overcome some of the barriers identified in this report.

5. Procurement for innovation – Calls for Innovation

As highlighted in the business and stakeholder interviews there were felt to be a number of barriers in the procurement process to the adoption of innovative new products and services. This has already been recognised by the Scottish Government and partners and Developmental Procurement has been suggested as one route to “foster innovation”. This has been outlined in the Scottish Government’s Statement of Intent for Innovation in Health:

“In line with a strategic outlook to product development, NHSScotland will additionally adopt developmental procurement. This will mean scanning the environment for future requirements and working with selected suppliers to identify and define solutions that meet the requirements of the NHS on a partnership basis as opposed to a competitive one. Developmental procurement will foster innovation.”

The establishment of an online Developmental Procurement Innovation Portal, and the suggested switch to procurement of ‘outcomes’ rather than products, should help address many of the concerns/barriers identified by businesses (in Chapter 4). Businesses interviewed also expressed the desire to see more clinician engagement in procurement. This could potentially be built into the screening process suggested for the portal. In addition to this, the TSB Small Business Research Initiative (SBRI) and other challenge led procurement processes could form part of the approach.

Appendix: Good practice examples to support recommendations

Recommendation 1. Develop an enabling mechanism to support the 'spin-in' of new technologies to NHSScotland

Good Practice examples provided include programmes in which support is supplied, especially to SMEs, to aid development, testing/trialling and commercialization of new technologies. These demonstrate the range of support offered to/needed by SMEs. Some of these initiatives have involved financial support from the European Union through schemes such as the European Regional Development Fund (ERDF).

Scheme	Link	Supporting Agencies	Elements	Good Practice Evidence*/ Contacts
Scottish Health Innovation Ltd (SHIL)	http://www.shil.co.uk/	NHSScotland and Scottish Enterprise. Funding provided by Chief Scientist Office, part of the Scottish Government.	SHIL essentially provide similar services to inventors from within NHSScotland to those we are suggesting are required for external SMEs. SMEs wanting to collaborate with the NHS or to have access to information, clinical trials, tissue samples, patient data, IP and legal expertise etc. to aid innovation require support as they have limited resources.	Case studies: http://www.shil.co.uk/Case-Studies/health-care-products.html
Bio-Incubators e.g. Manchester University	http://www.umic.co.uk/locations/mancbio/	Project part-financed by the European Union, European Regional Development Fund (ERDF) as well as University of Manchester	The Manchester Incubator Building is managed by the University of Manchester Innovation Centre Limited (UMIC) which offers: In-house business mentoring and professional services (e.g. IP, legal, marketing) Fully accredited laboratories for bioscience and biotech standards Full laboratory management services Site services associated with a fully operational biotechnology facility	Case studies available: http://www.umic.co.uk/casestudies/
NHS Innovation Hubs	NHS Innovations Yorkshire and Humber - www.medipex.co.uk NHS Innovations East - www.hee.org.uk NHS Innovations North West - www.trustech.org.uk NHS Innovations South East www.innovationssoutheast.nhs.uk/innovations NHS Innovations South West www.nisw.co.uk NHS Innovations West Midlands www.midtech.org.uk NHS Innovations North http://www.nhsinnovationsnorth.org.uk/	Regional Development Agency and Strategic Health Authority	England had nine regional NHS Innovation Centres (hubs), aligned to Regional Development Agency and Strategic Health Authority boundaries. The Innovation Hubs helped local NHS staff to identify, develop and commercialise innovations and also help with issues around Intellectual Property. They also facilitated commercial partnerships between companies and the NHS to develop new products. For example from the NHS MedTech Hub website: “INTRODUCING COMPANIES TO NHS EXPERTISE We can provide access to the clinical knowledge and expertise required for the development, evaluation and validation of new healthcare products and technologies. We have access to a wide range of specialties in more than 30 NHS organisations. FACILITATING COLLABORATIVE PARTNERSHIPS We work with our client NHS organisations at a strategic level to identify and qualify their needs, establishing priority areas that require innovative solutions. We then aim to find industrial partners to work alongside clinicians to develop new ideas in those areas.”	Case studies are available on the individual websites

*Where available

Recommendation 2. Enhancing the MedTech roadmap – developing an online platform and a Clinical Expertise Database

Good Practice examples provided include two databases set up to connect industry with clinical expertise in England.

Scheme	Link	Supporting Agencies	Elements	Good Practice Evidence*/Contacts
Clinical Insight	http://www.clinical-insight.com/	Developed by Health Enterprise East, with support from the Cambridge and Peterborough Health Innovation Education Cluster (HIEC) and the UK Intellectual Property Office	The aim of this service is to facilitate the process of engagement between with key opinion leaders and technology businesses seeking to access the NHS market. For commercial companies we can provide market access services ranging from focus groups, workshops and observational research, through to finding suitable sites for clinical evaluation of new technologies. For clinical experts we can provide the opportunity to see new technologies and potentially influence the direction in which new products are developed.	Contact: <i>CTBI</i> <i>Papworth Hospital NHS Foundation Trust</i> <i>Papworth Everard</i> <i>Cambridge</i> <i>CB23 3RE</i> enquires@hee.org.uk + 44 (0)1480 364925
ACTNoW	http://www.nhsinnovationsnorth.org.uk/resources/actnow.asp	TRUSTECH® for the North West (www.trustech.org.uk) Medipex® for Yorkshire and Humberside (www.medipex.co.uk) NHS Innovations North for the North East of England (www.nhsinnovationsnorth.org.uk) and Northern Way (project closed in 2011)	Discontinued Sept. 2012 ACTNoW® (Accelerating Clinical Trials across the Northern Way) is an online searchable database of active NHS investigators and clinical research expertise. It is a resource aimed at Pharmaceutical and Medical Device industries to facilitate the placement of clinical trials in the NHS, and also serves NHS and University collaborative researchers. The aim of ACTNoW® is to link NHS, industry and patients and ultimately increase the number of clinical trials hosted across the North of England.	

*Where available

Recommendation 3. Facilitating greater networking opportunities between clinicians and businesses

Good Practice examples provided: Networking Schemes

Scheme	Link	Supporting Agencies	Elements	Good Practice Evidence*/Contacts
Knowledge Transfer Networks (KTN)	http://www.innovateuk.org/deliveringinnovation/knowledgegettransfernetworks.ashx	Technology Strategy Board	KTNs connect people and companies with common interests in 15 areas.	Over 70,000 members in the KTN networks. Healthtech and Medicines, one of the KTNs, includes Emerging Medical Technologies as a theme Contact: Sue Dunkerton Co-Director t: +44 (0)1223 899000 sue.dunkerton@healthktn.org
The Innovative Medicines Initiative	http://www.imi.europa.eu/	European Union and pharmaceutical industry association EFPIA (European Federation of Pharmaceutical Industries and Associations)	IMI is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.	Project information available: http://www.imi.europa.eu/content/ongoing-projects Contact available: http://www.imi.europa.eu/content/executive-office
_connect	https://www.innovateuk.org/-/_connect?redirect=https%3A%2F%2Fwww.innovateuk.org%2Fnetworking-and-partnerships%3Fp_id%3D101_INSTANCE_sajS8AxtgxUn%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-1%26p_p_col_pos%3D1%26p_p_col_count%3D2	Technology Strategy Board	_connect is an online business networking and open innovation portal. The site currently has over 70,000 active user profiles, is home to 15 Knowledge Transfer Networks and a wide range of other special interest and networking groups. New functionality 'ConnectMe' has recently been developed on the site which enables individuals to be matched with other registered people with similar innovation and technology interests. Innovators are able to use free, online tools in a secure and confidential setting to explore some of the challenging projects and issues they face together in specific sectors.	To view _connect and register as a user visit https://connect.innovateuk.org/web/guest/home .
BioDundee	http://www.biodundee.co.uk/Home/	Dundee Life Science organisations	Public/private partnership of Life Science organisations in and around Dundee. Established in 1997 and provides networking opportunities, training, and	Contact information is available on the website: http://www.biodundee.co.uk/

			also organises trade missions.	Contact/
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*Where available

Recommendation 4. Development of an enterprise fellowship scheme

Good Practice examples provided: Enterprise fellowship schemes in a variety of disciplines and well as a scheme to connect business and academia to encourage innovation (KTP)

Scheme	Link	Supporting Agencies	Elements	Good Practice Evidence*/Contacts
BBSRC Enterprise Fellowships	http://www.rse.org.uk/638_BBSRCEnterpriseFellowships.html http://www.bbsrc.ac.uk/business/commercialisation/enterprise-fellowships.aspx	Royal Society of Edinburgh and BBSRC	Aim to increase exploitation of ideas with commercial potential from BBSRC supported research.	Case Studies available: http://www.rse.org.uk/1020_CaseStudies.html Contacts: Mary McDonagh mary.mcdonagh@bbsrc.ac.uk tel: 01793 413275 fax: 01793 414674 Anne Fraser, Research & International Awards Manager, Royal Society of Edinburgh afraser@royalsoced.org.uk 0131 240 5013
RAEng Enterprise Fellowship scheme	http://www.raeng.org.uk/research/researcher/eef/	Royal Academy of Engineering	Enterprise Fellowships provide funding and support to outstanding entrepreneurial engineering researchers, working at a UK University, to enable them to develop a spin-out business around their technological idea.	Contact: Katie Melton research@raeng.org.uk Examples of current awards: http://www.raeng.org.uk/research/researcher/eef/current.htm
Medici Programme	http://www.birmingham.ac.uk/partners/business-services/professional-development/The-medici-programme.aspx	Higher Education Innovation Fund (HEIF)	The Medici Enterprise Training Programme has been training internal and external entrepreneurial academic and research staff for 12 years to helping them to realise the commercial potential of their research.	The Medici training programme has been awarded 'Recognised Course Provider' status from the Institute of Knowledge Transfer. Medici was cited as an exemplar of good practice by the Higher Education Funding Council for England (HEFCE) in 2007. Contact (University of Birmingham): Catherine Mansell c.mansell@bham.ac.uk 0121 414 4905.
RSE/STFC Enterprise Fellowships	http://www.stfc.ac.uk/1905.aspx	Royal Society of Edinburgh and the Science and Technologies Facilities Council	The fellowship gives one year's salary and business training to the Enterprise Fellow - the aim being to give someone the time and skills to set up a viable business.	Case studies available: http://www.royalsoced.org.uk/1019_CaseStudies.html Contacts: Anne Fraser(RSE) afraser@royalsoced.org.uk Phillip Tait (STFC) phillip.tait@stfc.ac.uk
Knowledge Transfer Partnerships	http://www.ktponline.org.uk/	Technology Strategy Board with 12 other funding	Somewhat different but related to Fellowships. Formerly the teaching	Knowledge Transfer Partnerships was launched in 1975 as Teaching Companies Scheme (TCS). In 2003 Knowledge

(KTP)		organisations (see below). All the Research Councils in the UK support KTP http://www.ktponline.org.uk/funders/	company scheme. KTPs support businesses through the use of graduates employed on a project within the company, but receive supervision from university academics.	Transfer Partnerships replaced TCS and, since 2007, the programme has been managed by the Technology Strategy Board. Case studies are available: http://www.ktponline.org.uk/casestudies/
Scottish Enterprise Fellowship scheme	http://www.scottish-enterprise.com/start-your-business/enterprise-fellowships.aspx	Scottish Enterprise and Royal Society of Edinburgh	Successful applicants receive a year's salary, training, business development funding and access to advice.	Via Royal Society of Edinburgh http://www.royalsoced.org.uk/contactus.php

*Where available

Recommendation 5. Procurement for innovation – Calls for Innovation

Good Practice examples provided: Government schemes to support business innovation

Scheme	Link	Supporting Agencies	Elements	Good Practice Evidence*/Contacts
Small Business Research Initiative (SBRI) Model	http://www.innovateuk.org/deliveringinnovation/smallbusinessresearchinitiative.aspx	Technology Strategy Board (TSB)	The SBRI programme uses government procurement to drive innovation. It provides opportunities for innovative companies to engage with the public sector to solve specific problems. The Small Business Research Initiative (SBRI) matches business ideas to government challenges through a simple procurement process. 100% of the funding is provided through a contract not a grant. Any organisation can submit an application, although it is expected that SBRI opportunities will be particularly attractive for SMEs. This programme may be closest UK example to the recommendation.	Case studies available: https://www.innovateuk.org/government-contracts-sbri#comps Contact: SBRI@tsb.gov.uk
Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR)	SBIR and STTR main website: http://www.sbir.gov/about/about-sttr Programs at the National Institutes of Health (USA): http://grants.nih.gov/grants/funding/sbir_announcements.htm	USA Federal Government: The US Small Business Administration serves as the coordinating agency	The Small Business Innovation Research (SBIR) program is a competitive program that encourages domestic small businesses to engage in Federal Research/Research and Development that has the potential for commercialization. Each year, Federal agencies with extramural research and development budgets that exceed \$100 million are required to allocate 2.5 percent of their R&D budget to these programs. Currently, eleven Federal agencies participate in the program including the Department of Health and Human Services (National Institutes of Health) Small Business Technology Transfer (STTR) is another program that expands funding opportunities in the federal innovation research and development arena. Central to the program is expansion of the public/private sector	Examples of funding opportunities available: http://grants.nih.gov/grants/funding/sbir_announcements.htm

	nih.gov/grants/funding/sbirs.htm		partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations.	
Technology Strategy Board (TSB) Competition Funding	https://www.innovateuk.org/funding-competitions	TSB often through or partnering with other agencies and research councils	Already an accessible programme for Scottish Med Tech Companies depending on whether the call is topic related or based on company size (i.e. SME). These may provide a model for more targeted approaches relating to Med Tech companies in Scotland.	Technology Strategy Board telephone: 01793 442700 or email: support@innovateuk.org

*Where available

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