

INTRODUCTION

The Life Sciences Industrial Strategy highlighted the difficulties UK-based Life Sciences companies face in scaling-up and made a number of recommendations around the need to support innovative health companies. As part of this the Office for Life Sciences (OLS) is developing a programme of work to attract more capital into the UK Life Sciences, with a particular emphasis on HealthTech. The Association of BritishHealthTech Industries (ABHI) and the British Venture Capital Association (BVCA) have been involved in a number of discussions with government representatives and industry stakeholders over the last 12 months to establish what can be done to encourage investment in this sector. This culminated in a joint workshop with the Office for Life Sciences (OLS), where investors and UK SMEs exchanged views on the access to capital and the shortfalls within the current system. From the workshop, a survey was constructed that was sent to ABHI and BVCA members to ascertain the key priorities and areas of maximum impact from both the investment and manufacturing communities.

The ambitious challenge laid out in the Industrial Strategy was to create four UK companies valued at >£20 billion market cap in the next ten years. To achieve this it was envisaged that the SME sector of UK life sciences would need to migrate increasingly to new sources of long-term capital. This would require incentives for longer-term investment that will help new biopharmaceutical and HealthTech companies to achieve regulatory approval of products and be capable of both making and selling these locally and overseas, whilst remaining domiciled in the UK.

SUMMARY

There are a number of positive drivers in the UK that should help build and sustain a constructive environment for investment in UK-domiciled SMEs, yet at present there exist significant hurdles to achieving this. There are three broad areas where government can help:

- 1. The most consistently cited barrier is the track record and ability of the NHS to systematically and rapidly identify, adopt and scale use of innovation. This issue has been clearly identified and reported over many years. Over 75% of survey respondents highlighted this as a high impact area that should be addressed by Government this was particularly pronounced in the manufacturers responses. The latest analysis of the innovation landscape was the Accelerated Access Review (AAR), which has culminated in the establishment of the Accelerate Access Collaborative (AAC). This initiative needs to have the continued support of government and the NHS to deliver on the promises and programmes outlined in its remit.
- 2. Whilst the US is held up as a key competitive market, our recommendation is that the UK seeks to create its own area of advantage rather than compete on a like-for-like basis. The UK should focus on the early stage incubation of companies and the provision of incentives to funding.
- **3.** Create the necessary infrastructure to support early stage growth, focusing on incentivising clusters that can provide a "full service" offer. There is a particular need to broaden the range of skills available within the NHS to support more spin-outs. This needs to happen at both local and national levels.

The participants concluded that whilst a successful business (i.e. one that could be listed) could not be created based on success only in the NHS, product recommendation and adoption in the UK is still a characteristic highly valued by other jurisdictions. A business strategy that includes US and Asia is vital to build critical mass suitable for exit but should not necessitate a physical relocation of head office to a different jurisdiction.

DISCUSSION AND DETAILED RECOMMENDATIONS

The discussion focused on the current situation and the underlying reasons why the UK equity market has not developed or responded to demand in the HealthTech sector.

It was outlined that the underlying trend for investment in Life Sciences was positive, but the headline figures masked a mixed picture at sector level, with certain disease states, such as oncology, dominating investment and industrial sectors such as HealthTech being underserved, particularly medical devices. There was a drop in 2018 in both the number of deals and the capital for HealthTech.

The attendees highlighted four issues that were key drivers of the current situation:

- 1. US is the dominant market both in terms of acquisition of health technologies and size of the equity market.
- 2. NASDAQ listing is the primary exit route and requires a market capitalisation of \$25m.
- 3. Poor access in the UK for early stage products.
- 4. Acquisitions have declined and 70% are now post-regulatory (FDA) approval.

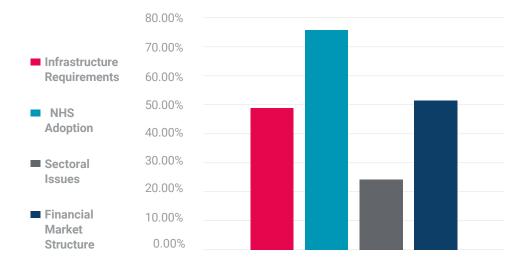
From an international competitive perspective, the US was highlighted as the dominant factor, however other countries, for example Israel, have a strong ecosystem, albeit on a relatively small scale. However even these countries look to NASDAQ for their exit. The US, for example, gets 5X the investment compared to the UK and it is estimated that in the UK there was a £17-25bn gap between supply and demand.

Equity investment in SMEs has declined and there is a particular issue with investments in the UK being too small to be sustainable, requiring companies to keep looking for further funding rounds.

The meeting suggested that there were four, interlinked, macro factors behind the problems faced by UK companies when accessing funding in the UK:

- Structural issues in the UK equity market.
- Sectoral issues.
- Infrastructure to support start-ups and spin-outs.
- Poor adoption of innovation by the NHS and wider health and social care system. As previously noted NHS adoption is the clear priority, followed equally by sectoral issues within the equity market and thack of infrastructure. See Fig A below.





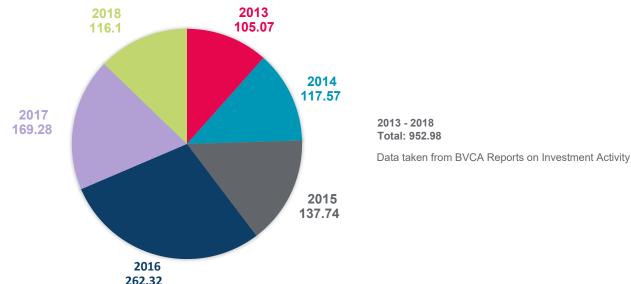
FINANCIAL MARKET STRUCTURE

- Whilst it was acknowledged that there was sufficient Angel finance available for early stage development, it is generally only available in small amounts and is difficult to find.
- Patient capital has been seen as a critical element of funding for health technologies, however it should not be seen as a panacea and other forms of investment are required.
- UK pension funds tend to take a risk adverse approach to their investments. This is partly driven by their resourcing/outsourcing modeland the regulatory restrictions in place.
- Institutional investment is required to have plurality in market with different financial flows at different stages of company development.
- 83% of capital goes to clusters. This is at odds with the very diverse geographical spread in the UK.

Recommendations

- Need to make VC/Angel money easier to find via a local exchangeand to link-up government funded projects with these exchanges.
- The tax system should be utilised to provide an incentive for pension funds to invest in the sector.
- The Digital Health market particularly could be bolstered through incentives to encourage corporate capital investments from "big tech" companies.
- There should be a better flow of capital by joining-up grant funding (e.g. the NIHR Invention for Innovation [i4i] funding) with the next stage of venture and development capital.
- VCs view i4i as too early to invest, therefore Angel investors have been seen as likely sources of follow-up funding. We would be very interested todiscuss ways of allowing more patient capital or less riskadverse VCs to provide follow-on funding.
- Enterprise Investment Scheme and capital gain tax are both important. We must ensure these programmes and policies are continued.
- UK government should establish a co-investment early stage fund (like Israel and France), focusing on a limited number of key areas of competitive advantages, to be aligned with the Life Sciences Industrial Strategy.
- Enterprise Capital Funds to operate alongside pension funds.

Figure B. HealthTech investment from Venture Capital and Private Equity in the UK (Amount invested in £ millions).



SECTORAL ISSUES

There are a number of factors specific to the HealthTech sector that need to be taken into consideration and addressed in the development of policy:

- HealthTech returns take too long to generate and offer relatively lower financial returns compared to pharma, meaning UK firms will end up having to take their products to the US in order to produce a return. This is a macro issue, irrespective of adoption.
- Experience from US market shows that it will require 20 years to build a substantive business.
- Increasing regulatory burden with the introduction of MDR compared to the more flexible arrangements being introduced by the FDA.

Recommendations

- A more flexible approach to regulation is needed with faster and more adaptable processes. ABHI are
 making separate recommendation on future regulation.
- A (hopefully) short-term, but critical, issue is the need to address the capacity issues with notified bodies.



INFRASTRUCTURE REQUIREMENTS

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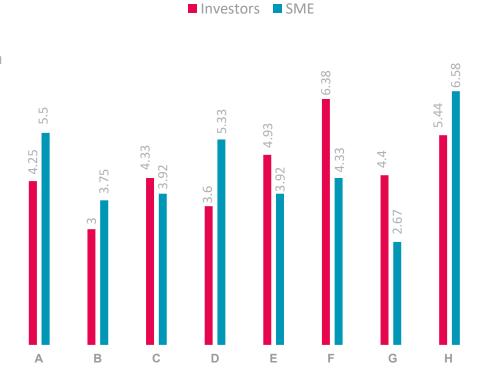
- Academic Health Science Networks (AHSNs) to be funded to take a stronger role in fostering collaboration between clinicians and academics and identifying and facilitating the formation of spin-out companies.
- There should be integrated support within NHS organisations to identify and encourage innovation opportunities.
- Establishmentand promotion of "skunkworks" to look at rapid prototyping.
- Create incentives both for "cornerstone" companies and the investment community to develop HealthTech Clusters. These clusters should feature:
 - o Complete supply chain
 - Low cost lab space
 - o People/expertise
 - o Links to manufacturing in low cost locations
 - o Grant funded incubator
 - o Professional support services, patents, IP etc.
- Focus on specifics, picking winning sub-sectors to support. These should not be based purely on financial return on investment, but also patient and system needs.
- Establish an advisory/mentoring service for start-ups, government sponsored but staffed by external people "giving back to industry".
- Greater role for bio/engineering teams within NHS organisations.
- A national centre of excellence to provide support to spin outs/start-ups should be developed in a similar way to that envisaged to support the commercial, legal and governance frameworks regarding data agreements within the NHS.
- To ensure sustainability, national networks should be established to support skill capacity and development in local areas.

The survey identified NHS spin out support and incentives for cornerstone companies as the top two areas. It is worth noting that there was some significant divergence between manufactures and investors in this area as regard to priorities. See figure C below. This was particularly noted in regards to establishing an advisory/mentoring service for start-ups. This was quite highly rated by SMEs, but poorly supported by investors.

Figure C. Survey responders were asked to rank the following in terms of biggest impact on improving access to investment:



- **B.** National networks should be established to support skill and capacity development in local areas.
- **C.** A national centre of excellence to provide support to spin outs/start-ups should be developed.
- **D.** Establish an advisory/mentoring service for start-ups, government sponsored but staffed by external experienced resource.
- **E.** Fully featured HealthTech Clusters with supply chain, lab space, expertise, Grant funded incubator.
- **F.** Create incentives both for "cornerstone" companies and the investment community to develop.
- **G.** Establishment and promotion of "skunkworks" to look at rapid prototyping.
- **H.** Integrated support within NHS organisations to identify and encourage innovation opportunities.





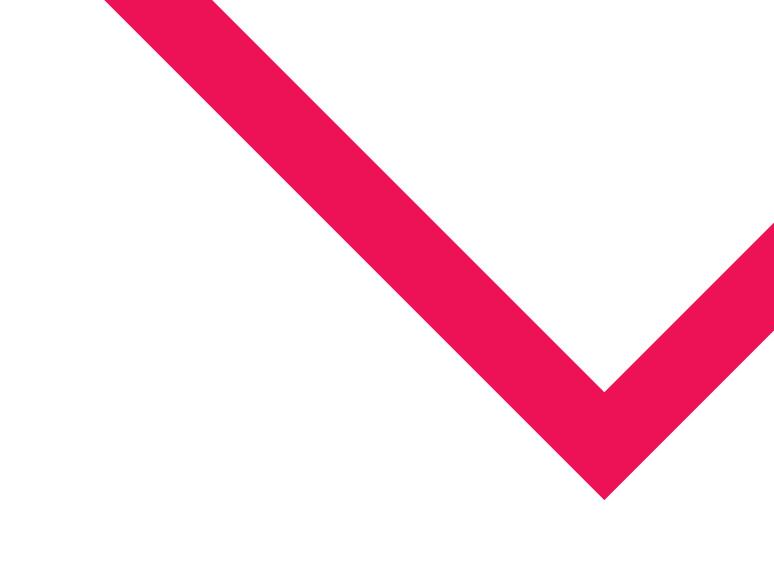
NHS ADOPTION

The poor record and long timelines for adoption of new technologies in the NHS was cited as a critical reason for lack of investment. There remains a view from many investors that revenue forecast from sales to the NHS should be discounted and many will not back a proposition that has the NHS as a cornerstone of their commercialisation plans. The additional risk imposed on SMEs by not having a vibrant home market means that the trade-off between holding period for an investment and the associated risk was mismatched. Specific adoption barriers cited were:

- Benefits of new technology difficult to prove due to siloed budgets.
- Scalability is time and resource consuming as each Trust/Clinical Commissioning Group requires interaction.
- Each trust is opaque and different as regards entry possibilities.
- The lack of homogeneity across AHSNs can cause confusion and capacity limitations mean that they do not add system-wide value.
- Market pricing is being aggressively and inappropriately challenged via procurement.

Recommendations

- AAC should be resourced and supported to deliver on its stated ambitions.
- The NHS should pursue a value-based approach to product procurement, looking at savings across the system, rather than effects on individual departments' budgets.
- The NHS needs to address adoption of technology through a more systematic process with clear ownership at national, regional and local levels, alongside a clear statement of needs in the short, medium and long-term. Value based procurement was shown to be of greatest importance overall, rated highly by both manufacturers and investors.





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