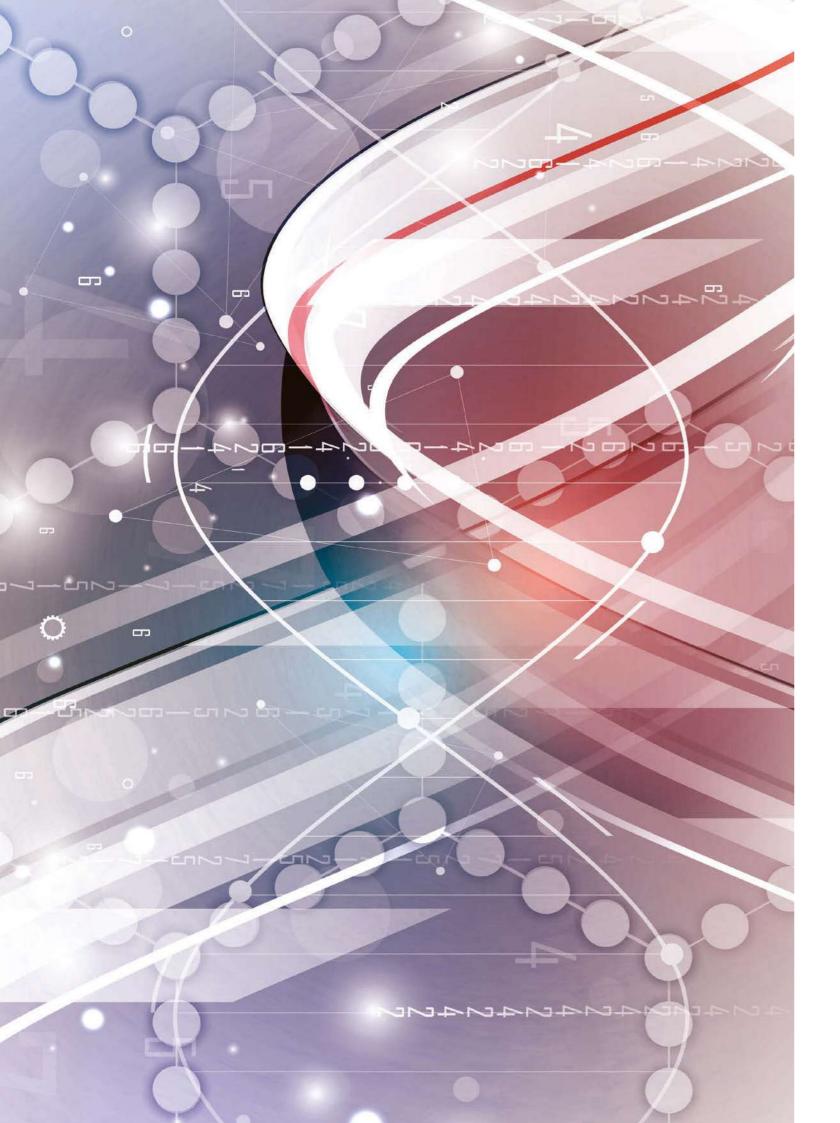




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### Editor's message

SBRI Healthcare has successfully secured funding from NHS England for the past 7 years. Future outcomes are looking impressive – with 150+ companies under contract, £185m of additional funding leveraged by the companies we support, and more than £30m of savings secured for the NHS.

But what can we learn from this innovation creation programme? What lessons can we take from the SBRI Healthcare process and apply to the wider NHS Innovations landscape?

Here we draw together the learnings from three recent investigations into SBRI Healthcare, we look at what has been achieved so far and what needs to happen in order to make the most of opportunities in the future.

The opportunity is certainly there, as Connell states in his report:

"The public sector spends around £265 billion a year through procurement, equivalent to 14% of GDP. This covers a very wide range of products and services. Helping UK companies, especially SMEs, take advantage of this market opportunity provides them with a springboard to grow sales at home and abroad."

Despite making excellent progress so far, the three reports highlight some key areas of future focus for us, in particular it will be important to consider multiyear funding arrangements; enhanced connection to the emerging adoption infrastructure and building wider NHS knowledge and understanding of the SBRI Healthcare programme and its supported projects.

Funded by the NHS, our priorities are to improve patient care, improve efficiency in the NHS, and support the UK economy by helping smaller companies grow. The success of the programme so far has been noted in these reports. We also hope that the findings will help us to build on that work, and move us further towards achieving the lifetime goals envisioned for the

Karen Livingstone, National Director, SBRI Healthcare



SBRI enables the government to replicate the important 'lead customer' role played by large corporations and the US government in getting new innovative companies off the ground. By doing so it also provides "market pull" to complement the more "technology push" element of some other policies. (Connell 2017)



### About SBRI Healthcare

SBRI (Small Business Research Initiative) Healthcare is an NHS funded programme that provides funding to innovative companies to solve healthcare problems.

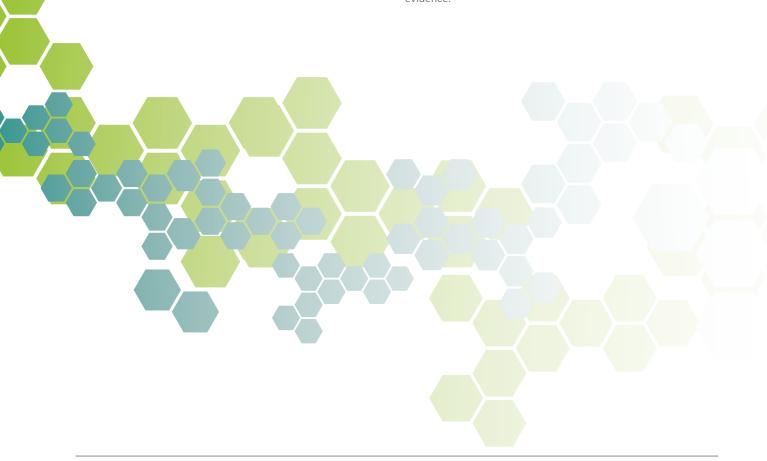
The team works closely with clinicians and frontline NHS staff to identify key challenges from within the NHS, focussing on specific areas identified as important by NHS England and the 15 Academic Health Science Networks (AHSN).

SBRI Healthcare priorities are to improve patient care, improve efficiency in the NHS, and support the UK economy by helping smaller companies grow.

Launched in 2009, NHS East and NHS Midlands were the first regional health authorities to develop an SBRI scheme to find solutions for identified healthcare problems. Going forward SBRI East worked to bring together business, health, technology and government partners to deliver a series of competitions for businesses to address major unmet health needs.

Unlike many research and development projects which offer grant or match funding, SBRI contracts are 100 per cent funded and the inventor retains the Intellectual Property.

The SBRI Healthcare programme has set the industry challenges in a series of health related competitions which have resulted in fully funded development contracts between the awarded company and the NHS. The programme is based on a two-phased development approach. Projects start with initial feasibility and can then move on to more detailed product development. Phase 1 contracts for feasibility testing are valued at up to £100,000 and last for six months. Phase 2 contracts for prototype development are worth up to £1 million over two years. Phase 2 contracts for prototype development are worth up to £1m over two years and where funding has permitted Phase 3 funding has supported the development of 'real world evidence.'



### SBRI Healthcare - our year in numbers (2017/18)

£16m



22 Phase 1 contracts awarded with a total value of £2m



contracts awarded



20 Phase 2 contracts awarded with a total value of £14m



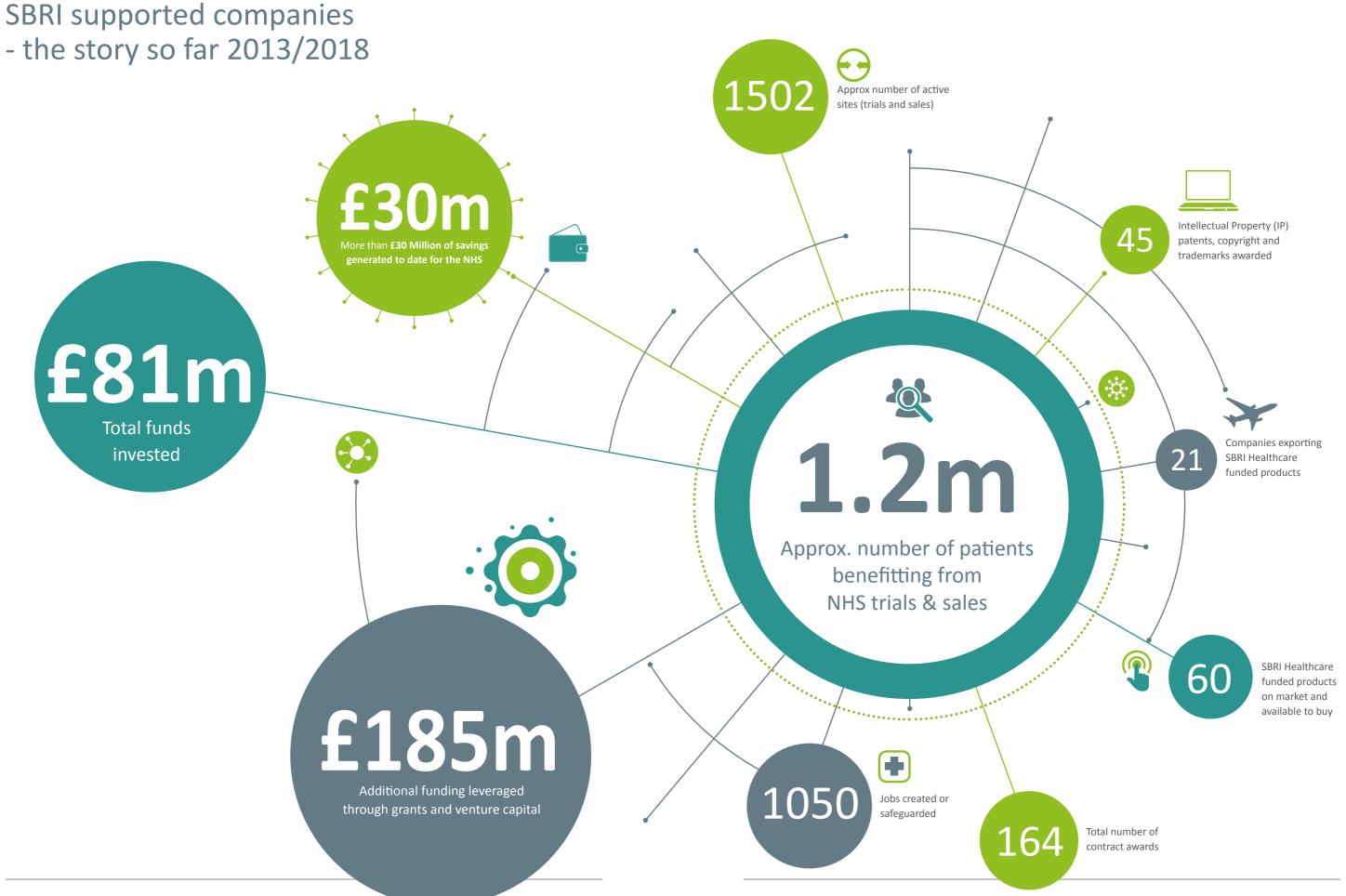


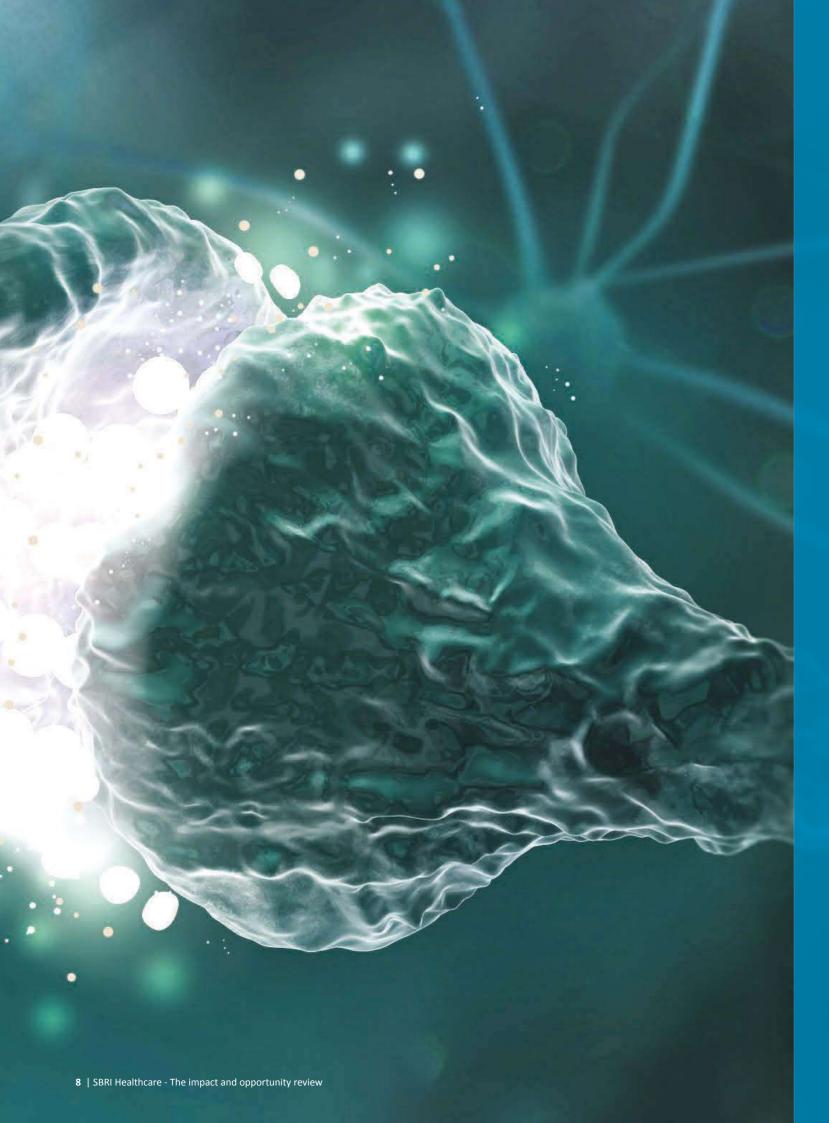


new clinically-led competitions where NHS needs have been articulated for business to respond to



applications from industry assessed and supported or feedback given





**Report 1 - key findings** 

# David Connell

Leveraging public procurement to grow the innovation economy: an independent review of the Small Business Research Initiative (SBRI)

Published: 27 November 2017

**Commissioned by:** Department for Business, Energy & Industrial Strategy

### Introduction

David Connell's 2017 review provides an in-depth analysis of the UK Government's crossdepartmental involvement in the Small Business Research Initiative (SBRI). He outlines how government can maximise the impact by better supporting and stimulating innovation by SMEs and increasing the development of new technology and services. He also explores an equivalent model in the USA, the Small Business Innovation Research (SBIR) programme, drawing out important lessons learned and best practice for UK teams.

#### **Setting up for success**

Connell makes compelling points on the importance of setting up an SBRI programme in the most effective way.

He states that, "SBRI programmes need to be conducted on a long term, systematic basis, and run by stable teams with innovation programme management expertise. Challenge selection is a key part of this. And multifunctional teams, including users, decision makers and budget holders, must be involved throughout the process, from problem definition to product testing and first deployments.

To transform the public sector's ability to use external innovations to drive improvements in cost effectiveness and service quality, open innovation processes of this kind must be embedded within spending departments and other agencies. By adopting this systematic methodology, SBRI could also encourage outcome based thinking generally, identify opportunities for innovation that do not involve funding product development, and help drive wider cultural change."

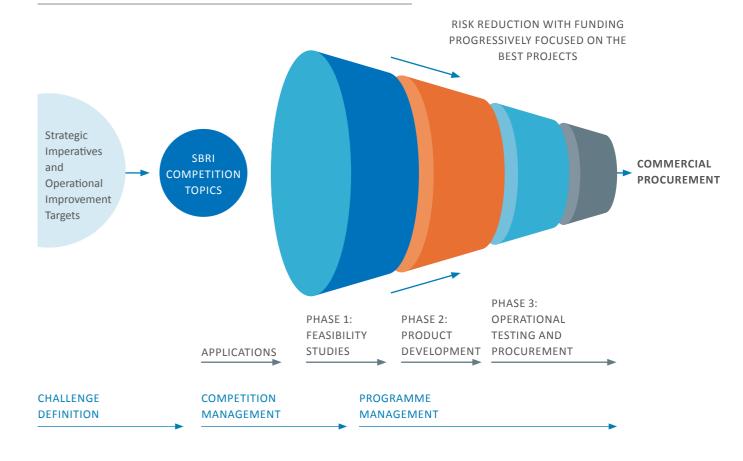
The business model itself works by "providing new ventures and SMEs with contracts to develop innovative products that address unmet public sector needs, offering a 'win-win' opportunity for both the public sector and UK businesses alike."

# According to Connell, key features of the SBRI model include:

- Competitive process to fund development of innovative science and technology based products and solutions to meet public sector needs as a customer or to address policy challenges
- Operates under the EU Pre-Commercial Procurement legal framework
- Any organisation can apply providing there is a route to commercialisation, but particularly appropriate for SMEs
- Phased to reduce risk and focus on best projects
- Phase 1 Feasibility Study: typically £50-100k over 6 months

- Phase 2 Development and Testing of Demonstrator or Prototype: typically £250k-£1m over 18-24 months
- 100% funded contract, not a grant
- Awardee retains any IP, subject to limited public sector rights

### SBRI PROGRAMME MANAGEMENT\*



Connell also explains the differentiating features of SBRI when compared to other programmes:



Both R&D tax credits and Innovate UK grants programmes are essentially subsidies, based on the principle that reducing the cost of R&D will encourage companies to do more. In other words, they act on the supply of R&D.

In contrast SBRI is designed to increase the demand for R&D. It also has other differentiating features:

- It is an outcomes-based contract, enabling development projects to be tied to clear customer needs and bringing greater credibility than grants
- It is phased to manage risks, and through an early evaluation of an awardee's ability to deliver the project and build a successful business, it focuses funding on the most promising projects
- It provides 100% funding, allowing innovation projects to progress in SMEs that have not raised venture capital, and without having to spend the considerable time and energy required to do so before a new product idea is well validated
- SBRI contracts do not require collaboration
- SBRI is designed to be transformative, with Phase 2 contracts large enough to take projects to a key milestone over up to two years. SBRI guidelines specify contract values designed to be significantly larger than most Innovate UK single company grants."

10 | SBRI Healthcare - The impact and opportunity review | SBRI Healthcare - The impact and opportunity review | 11

<sup>\*</sup> This diagram is also featured as Exhibit 8 on page 67 of the Connell report

### Cross-departmental analysis

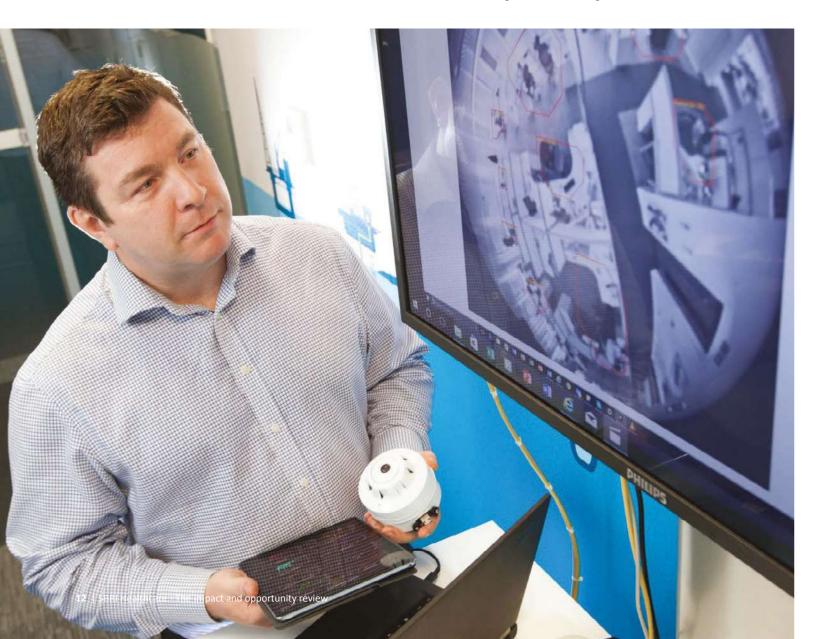
Measuring the impact of SBRI across government departments presented Connell with a number of challenges:

"Monitoring SBRI and measuring its impact is complicated by the wide variations in funding and approach across departments, and by the lengthy development, testing, approvals, and purchasing cycles entailed for many products. It is further complicated by the fact that spending departments have no obligation to share data with Innovate UK. This situation contrasts strongly with the US SBIR programme, where agencies are required to operate transparently and publish information on award winners, project objectives, and contract amounts. This is available on a free, searchable, public database."

His findings demonstrate a sharp difference in funding and support from each department:

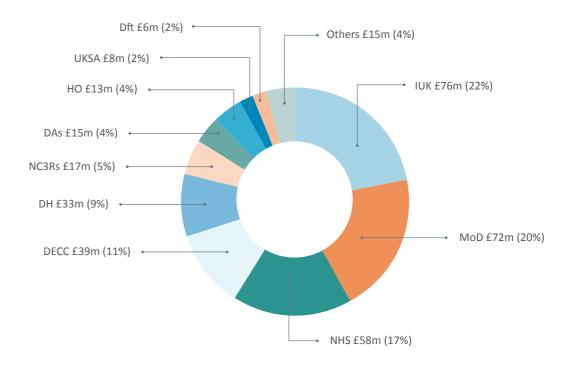
"Despite the encouragement of Downing Street and the Cabinet Office, and the strong practical support provided by Innovate UK, total annual SBRI funding has failed to reach the Treasury's 2013-14 £100m target, let alone the 2014-2015 £200m target. Indeed, it moved into decline as this top-level pressure has lessened; in 2015/16 spending was 24% below its peak the previous year. The NHS England SBRI budget has been cut by nearly 40% from its peak and, at the time of the Review, successful SBRI programmes in several departments seemed unlikely to be continued.

Amongst the larger SBRI programmes, NHS England, DECC, DfT Future Rail, NC3Rs, and the MOD have all had SBRI management teams that have been in place for several years, with clear strategies and processes for managing SBRI with their own resources. The systematic way in which they approach the task, and the learning they have gained through successive competitions, is very apparent. In the case of DECC, DfT, Future Rail and NC3R other grant based funding models are also used."



### **BREAKDOWN OF SBRI SPENDING\***

between 2009 and October 2016 by department



### **BREAKDOWN**

by type of recipient and company size

		Proportion of contracts awarded (%)	Proportion of total contact value (%)
Firm size	Large	23%	25%
	Medium	13%	13%
	Small	23%	22%
	Micro	28%	27%
	Academic	12%	12%
	Public Sector	0.1%	0.1%
	Not for Profit	1%	1%

Source: Innovate UK management data; based on incomplete data. <sup>36</sup>



A better directed and managed SBRI programme should be expected to lead to an increase in the share of awards going to SMEs, particularly at the lower end of the size

<sup>\*</sup> This diagram is also featured as Exhibit 3 on page 43 of the Connell report

The feedback from those interviewed provided a fairly consistent opinion on the challenges being faced by each



Budget restrictions or pressures are reported by all departments and agencies. Amongst departmental SBRI management teams interviewed for the Review, most expressed strong support for the programme as a valuable way of identifying and addressing the challenges facing departments and accessing innovative solutions from SMEs outside their traditional supply base... Altogether, the experience of SBRI over the last 7 years indicates that a different approach to funding and managing it is needed if the full potential benefits are to be derived – by the public sector, by businesses and by the economy at large.

### SBRI strengths and weaknesses -

According to Connell, at its best SBRI has:

 provided highly innovative and potentially cost effective solutions to public sector challenges (like PolyPhotonix in the treatment of diabetes related blindness and Ancon Technologies in airport security)

• provided a phased mechanism

for managing major policy

challenge programmes, like

wave energy in Scotland and

vaccines for global epidemics

(ODA/DoH)

- funded the development of specialist technologies, like biomass energy generation, to meet departmental objectives for which commercial funding is not readily available
- led to the creation of new companies like Owlstone Medical and RepKnight that have gone on to raise significant funding
- enabled existing start-ups like Fuel3D not just to sell into the UK public sector, but through the credibility gained, to raise finance to successfully commercialise its technology in other applications globally
- made it possible for established SMEs, like Global ASV, to develop products for applications outside its existing customer base

But there is also a long tail of SBRI projects that have been awarded contracts that are too small to make much of an impact. Average SBRI contract values have been significantly below the US SBIR, and UK departments with average Phase 2 contracts less than the much lower, minimum SBRI guideline accounted for 84% of SBRI projects. Partly as a result of this, the number of finished products procured by government has so far been quite small. The final operational testing and adoption stages of the SBRI process remain problematic across many departments. In some cases, such as the NHS, making sales is complicated by a complex, impenetrable and geographically dispersed approvals and commissioning process."

#### Connell's view of NHS England and SBRI Healthcare

The NHS England/SBRI Healthcare programme is highlighted in Connell's report as "the single best role model for future programmes from other public sector organisations, though there are important features of other management approaches that could usefully be shared across government." He also notes that it is the longest running programme.

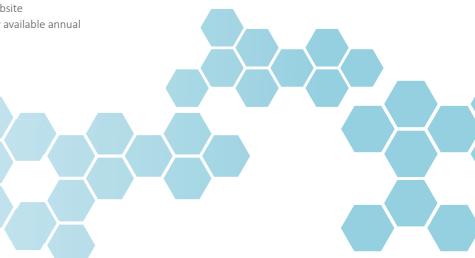
He states that the key positive features of the NHS England SBRI management approach are:

- A programme board, including people from business as well as the NHS, and a permanent core team able to run all aspects of SBRI competitions
- Access to NHS specialisms and potential customers through the regionally based Academic Health Sciences Networks
- A systematic process for identifying future competition themes and defining challenges
- The use of 'dragon's den' interviews at Phases 1 and 2, drawing on outside business and technical expertise as well as clinicians and NHS commercial managers to assist project selection, rather than relying on a paper based ranking
- Contract terms ensuring long term access to progress monitoring information
- Close monitoring of projects
- Award transparency, a comprehensive website (www.sbrihealthcare.co.uk) and a publicly available annual

**Challenges:** "The key innovation challenge is perceived, correctly, by senior members of NHS management to be the adoption and spread of existing innovations irrespective of where they come from, rather than funding the development of new ones. Once again departmental objectives are not completely congruent with those of the Industrial Strategy.

A larger NHS England SBRI budget, facilitated through a central fund could address this problem. Better collaboration with the Department of Health's National Institute of Health Research to fund clinical trials of SBRI funded developments would assist progress through to NHS procurement.

There is also scope for a more systematic DoH SBRI programme in the biotechnology and genomics arena, particularly in fields where private sector investment interest is weak, like antibiotics, vaccines and research tools. Past competitions have been on an occasional, ad hoc basis."



### International learning – USA SBIR programme

In his report, Connell provides relevant analysis and lessons learned from the US Small Business Innovation Research (SBIR) programme, it is useful to note the following:

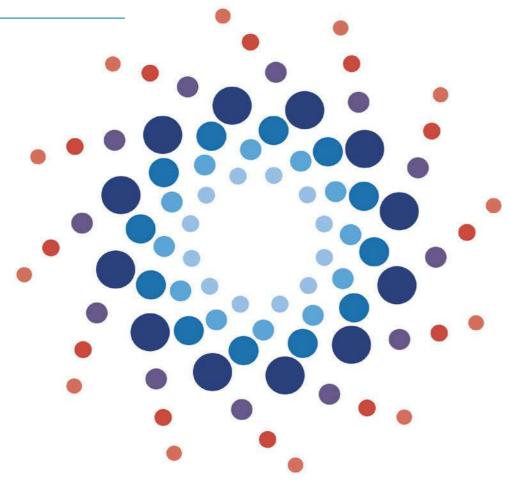
The US SBIR programme has been independently endorsed by Congressional committees and independent reviewers at intervals throughout its 35-year history and is highly regarded by government agencies, entrepreneurs, venture capital firms and policy makers.

The Small Business Administration describes SBIR as America's Seed Fund.

Today, Phases I and II of the SBIR and STTR programmes are worth around \$2.5 billion per annum.

\$2.5 billion

Specialised firms often use SBIR projects as an entry point to mainstream DoD R&D contracts and the supply of specialised products. One of the most frequent SBIR contract winners, Foster Miller, was acquired by QinetiQ in 2004 and has a strong focus on developing and supplying robots and other specialised niche technologies. Physical Optics Inc., the most frequent DoD SBIR contract winner in recent years received \$100m in DoD supply (i.e. non-R&D) contracts in 2016 alone.



### Key lessons for UK SBRI from US SBIR

Key features of the US SBIR include:

- Its ring fenced funding and clearly defined approach and funding rules. This underpins the longevity and consistency with which it has been run, bringing clarity for programme managers and companies, and allowing continuing improvements to be made to the process
- The strong SBIR brand, creating Its ability to provide significant a sense of community through conferences and awards
- Its phased model, focusing funding on the best projects, with amounts large enough for companies to get to a deliverable justifying subsequent transitioning into procurement of the resulting product and wider commercialisation
- funding through multiple contracts at an early stage in the development and commercialisation of new technologies

• The journey from Phase II contracts to commercial procurement is often lengthy and difficult. A series of measures have been put in place to lubricate this process

#### They include:

- Significant follow on funding through Phase II extensions and Phase III funding from non-SBIR budgets for innovations where agencies have a strong interest
- Commercialisation training and consulting support for businesses
- Initiatives to involve the larger defence contractors in the case of DoD

The UK can learn from this experience and the Review has shown a clear need for Phase III funding.

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#### Case study taken from the Connell report:

The history of Photobit, illustrates this process and shows how programmes like the US SBIR and UK SBRI can provide some of the application challenges and funding to drive the commercialisation process.

### Photobit: How SBIR and other lead customer funded development contracts helped create our camera phones

Photobit Technology Corporation was founded by Dr Eric Fossum, Dr Sabrina Kemeny, and associates from NASA's Jet Propulsion Laboratory in 1995 to commercialise the CMOS image sensor technology they Intel, Hitachi and Basler A.G. The following year, Micron had invented there.

Photobit's early development was funded, in part, through US government R&D contracts. These included an SBIR contract from the US Army to develop highmissile launches, and other SBIR awards from DARPA, NASA, the US Navy and the Ballistic Missile Defence

As the power of the technology increased it became increasingly used in a range of commercial applications. SBIR awards help companies that wouldn't otherwise Photobit's non-defence contracts included industrial machine vision, high-speed scientific imaging, a pillcamera for medical imaging, and animation systems for motion pictures, television and video games. Cameras using its technology were used in several Hollywood films, including Star Wars Episode II.

By 2000 Photobit had annual revenues of \$20M, and in manufacturing costs had begun to open up

opportunities for volume applications in digital cameras and mobile phones. As a result, the company was able to attract a \$26M venture capital investment from Technology Inc. a major specialist US semiconductor company, acquired Photobit to enable it to enter this fast growing market.

In February 2017 Eric Fossum was awarded the Queen resolution, high speed image sensors for recording test Elizabeth Prize for Engineering at the Royal Academy of Engineering in London.

> "I am a strong advocate of the US SBIR programme as I think there need to be channels other than traditional venture capital to seed new technology businesses. attract venture capital funding because they have a slow growth profile, or a niche market appeal.

They help entrepreneurs because they allow more 'self-start' and less dilution for the founders of such companies. But they are also very helpful to the government on many levels, seeding businesses that are developing technologies useful to government agencies – and, often, to us all." - Professor Eric Fossum



### Is SBRI having a wider economic impact?

#### **Supporting small businesses**

Connell states that:



SBRI is highly valued by businesses that have used the programme. Around 62 per cent of SBRI funding goes to SMEs and econometric evidence suggests that, even at this relatively early stage, SBRI contracts have a positive impact on company revenues.



18 | SBRI Healthcare - The impact and opportunity review SBRI Healthcare - The impact and opportunity review | 19 "Products backed and already on the market range from a non-invasive therapy for diabetes related blindness to autonomous, long endurance, ocean research vessels, to military clothing with built in networking technology.

Businesses reported a number of positive impacts from SBRI, including providing an accelerated route to market, business growth and an increase in sales turnover. It has also built credibility and generated a "buzz" in their markets.

# Key advantages seen over other programmes included:

- 100% funding, frequently mentioned as a key benefit, both by micro and small businesses (i.e. those employing less than 50 people) and by larger businesses for which it made riskier R&D projects more feasible. (For companies without other revenue streams or investment, providing co-funding can raise difficulties)
- Retention of IP, also regarded as a critical advantage compared with development contracts from private sector customers, allowing companies to sell applications to other customers
- The market-pull implicit in SBRI and the fact that there was potential for a first (product) customer. A number of those consulted regarded it as the most appropriate government innovation programme for their kind of business

A vital feature of the SBIR and SBRI models is that contracts are of sufficient size to take successful projects to major deliverables milestones. By enabling companies to engage seriously with potential public and private sector customers for the resulting products and generate serious interest from potential partners and investors this can have a transformative impact on company prospects.

For companies with a profitable consulting business model, based on using their skills to undertake design and development contracts for different clients, SBRI offers a way of building a more scalable product business on the back of their existing consulting operations over a timetable that is longer and more consistent with the timescales over which the markets for disruptive products tend to be created."

#### **Barriers to growth**

Connell's report states that "There are barriers to commercial procurement that need to be addressed."

"The main weakness in SBRI highlighted in company feedback was the weak pull through to public sector procurement; the final operational testing and adoption stages of the SBRI process remain problematic across many departments. This partly reflects the lack of phase 2 product development contracts, and low levels of funding in many SBRI programmes. The point at which commercial sales can take place is also affected by the long lead times involved in developing and testing many technologies, particularly where there are regulatory hurdles or long design-in times. However, weak procurement pull through is also the result of institutional and cultural factors."

"In the case of the NHS, which has purchased more SBRI funded products than any other programme, the problem is aggravated by a complex, impenetrable and geographically dispersed approvals and commissioning process, so sales have tended to be small and localised. Though recent data suggest that the speed of adoption is increasing.

"The NHS England SBRI model needs to be enhanced to ensure that successful projects lead on as quickly as possible to products sales. Many recipients of SBRI contracts from the UK health sector have called for a 'Phase 3' to help address this problem though it is also needed for SBRI programmes involving other parts of the public sector."

There are often cultural and administrative barriers to public sector procurement of innovative products whose value has already been proven. This is nowhere clearer than in the NHS. Though the NHS England SBRI's has probably led to the procurement of more products than any other SBRI programme, the amounts involved are small and restricted to a few locations. Dissatisfaction with the NHS' commercial procurement process continues to be widespread. The problem is well recognised by NHS management and the final report of the Accelerated Access Review published by the Government in October 2016, offers some solutions. The Government announced a series of measures as a "first step" in taking it forward in July 2017.

Some SBRI backed healthcare companies are therefore focusing first on the US market. An example is 11Health, started by Michael Seres, the 11th full intestinal transplant patient in the UK, and already a successful entrepreneur. 11Health has developed a digitally connected ostomy bag enabling users to "avoid surprises" and improve their quality of life.

It also allows hospitals to save around £4000 per patient a year through a 30% reduction in readmissions. 11Health has found the NHS process for setting up clinical trials and gaining NHS tariff approval complex and ill defined. Interest amongst US hospitals has been much greater and by 2015 there were already 300 patients using the device there. On the back of this, the company was able to raise \$5.5m of venture capital to scale the business from US investors, including Sir Michael Moritz, backer of Google, PayPal and Skyscanner. UK based VCs turned down the investment because of lack of significant sales."

#### **Attracting further investment**

Connell states that "in some cases, SBRI contracts have triggered the creation of a new product company, which has gone on to win further public sector funding and venture capital. Owlstone Medical is a good example. In others it has played a significant role in demonstrating a platform technology opening wider applications. Fuel 3D, awarded an SBRI contract by NHS England and RepKnight, funded by The Home Office are both examples.

Connell concluded that "SBRI has the potential to help grow significant STEM based companies over the long term."

"R&D contracts and lead customer development funding – from both the private and public sectors - have played a key role in the early stages of many of the most successful UK science and technology based companies to have been started over the last forty years. For some, venture capital was simply not available. For others, customer funding has enabled them to delay, minimise, and sometimes avoid, significant external investment, thereby retaining control by the founding team. The histories of ARM Holdings (a spin out from Acorn Computers), Autonomy (a spin out from Cambridge Neurodynamics) and Vodafone (a spin out from Racal) can all be traced back to a "first break", in the form of a public sector innovation contract that their parent companies received as start-ups.

By playing this lead customer role in a systematic manner, SBRI could:

- help companies develop to the point where they are 'VC ready'
- help entrepreneurs who want to build a substantial UK business over the long term retain managerial independence and avoid pressures for early trade sales"

### 4. Future focus points and recommendations

Connell concludes that a reinvigorated SBRI needs to address the following challenges:

- It needs enduring, high level ownership within government. SBRI is effectively an orphan policy
- It must stimulate and harness spending departments' appetite for innovative solutions in a way which is consistent with their funding priorities and pressures.

  Funding for SBRI is a major
- It must be financed and organised in a way that encourages and rewards participation across government, and is seen as an opportunity rather than a tax
- SBRI programmes must be embedded within the spending departments and agencies running them, and run by stable teams that include the appropriate strategic and technology programme management skills as well as the right connections across the sponsoring organisation
- SBRI programme
   management processes
   must be designed to deliver
   innovations that departments
   want and are able to procure
- SBRI contracts must be large enough to enable companies to get to key milestones likely to lead on to procurement and commercialisation
- Programmes must incorporate a way of bridging the disconnect that inevitably exists between precommercial procurement to fund product development, and the customising, testing, and trial deployments required before commercial procurement can take place

- It must move closer to the US model in terms of project funding levels
- It must be configured in a way which is appropriate to the UK's much smaller public sector budgets, (and proportionally smaller number of businesses). To do so it must be better than the US SBIR at focusing on projects and businesses with the best chances of delivering successful procurement and commercialisation outcomes. Achieving better procurement outcomes requires the adoption of best practice innovation programme management approaches that engage with potential users, specifiers and purchasers throughout the SBRI process
- An effective SBRI programme requires predictable, three to five year rolling budgets over several years, adequate to do the job, and in a form that enables two year Phase 2 contracts to be awarded to companies

#### **Funding recommendations**

He also recommends that a different approach to funding and managing is needed if the full potential benefits are to be derived – by the public sector, by businesses and by the economy at large.

### Recommendation 1

#### a new central SBRI fund

A central fund should be established with a rolling 5-year budget profile into which teams from public sector organisations can bid to fund a programme of SBRI competitions.

### Recommendation 2

#### a national SBRI fund board

The fund should be overseen by a small National SBRI Board reporting to the Cabinet Office and comprising officials bringing commercial, innovation and operational perspectives from the public sector, including Innovate UK, together with individuals from the private sector with business and venture finance expertise.

### Recommendation 3

#### Phase 1 and Phase 2 funding guidelines

SBRI contracts financed through the central fund must be sufficient to take projects to a meaningful milestone. The amounts required will depend on the task. But in general programme guidelines for Phase 1 and Phase 2 contracts (£50-£100k, and £250k-£1m respectively) should be closely adhered to.

### Recommendation 4

### selective new Phase 3 contracts for evaluations and trial deployments

SBRI programme bids should include an element for Phase 3 funding where appropriate. However, contracts should be awarded very selectively, and only when the viability of the technology has already been well demonstrated and there is strong interest in an operational scale evaluation by prospective customers.

### Recommendation 5

### embedding best practice innovation programme management within departments

The National SBRI Board should ensure that the SBRI programmes it funds are fully embedded within departments and operated in a systematic manner using best practice, innovation programme management processes. They must be directed, managed and supported in a way that maximises the probability of commercial procurement and commercialisation of successful developments.

### Recommendation 6

#### transparency, monitoring and evaluations

All SBRI programmes receiving central funding should be required to provide details of awards, including recipients, contract amounts and summary project descriptions through a publicly searchable database similar to SBIR's TECH-Net. Future monitoring information obligations should be included in SBRI contracts with companies.



**Report 2 - key findings** 

# PA CONSULTING

SBRI HEALTHCARE: A review of the benefits of the Small Business Research Initiative in Healthcare

Compiled and reported: September 2017

### 1. Market success and potential of SBRI supported products

The 2017 PA Consulting review was commissioned by NHS England to assess the value from SBRI Healthcare realised in England so far, and the potential value from projects still in the pipeline.

#### The review was tasked to:

- Establish the number of SBRI supported products on market with degree of adoption, current sales values and estimated market value
- Examine the social and health impacts of SBRI supported products on the market
- Evaluate the savings arisen as a result of uptake thus far (with evidenced costings and examples)
- Estimate the ROI showing the investment that was made (in each company/call area) and the 'real value' or savings secured to date in the NHS
- Examine the market potential of those products still in the pipeline

"According to the PA review as of July 2017, SBRI Healthcare has funded 176 projects and awarded contracts to the value of £73M. Within this group, 37 projects are showing some deployment in the NHS, either through sales or trials. These are the projects with the potential to have already achieved an impact on the NHS.

The proportion of digital projects with NHS sales within the group of 37 is 73%, higher than the overall proportion of the 176 SBRI Healthcare projects (53%). This reflects the expected difference in the speed to market for digital innovations given the timing of this review."



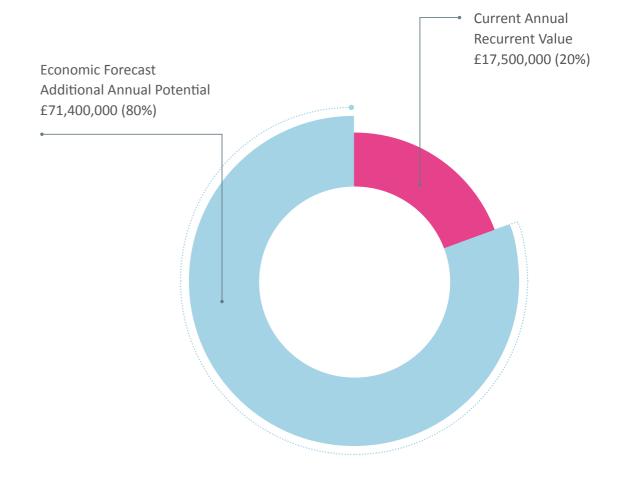
As of July 2017, SBRI Healthcare has funded **176 projects** and awarded contracts to the value of **£73M**\*



The level of recurring annual benefits from the companies studied for current impact reinforces the view that there is significant further potential. For the 7 companies reporting impact on the NHS, the market penetration is just 20% of their estimated market potential, which itself is already adjusted down for an expected maximum market share.

### MARKET POTENTIAL

current annual value and further NHS market potential of 7 health innovations from Competitions 4 & 5 that have achieved sales to the NHS in England



<sup>\*</sup> Data sourced directly from the SBRI Healthcare PA Consulting report 2017

### 2. Barriers to market: pace of adoption

The PA report explored the pace of adoption and spread by the NHS citing it as a key issue:

"Figures show companies achieved twice the level of sales internationally as they have with the NHS. This is despite the fact that the innovations are an industry response to priority needs identified by NHS and endorsed by NHS England. While this may be disappointing, it is perhaps not surprising given past experience of adoption by the NHS. Digital projects have been faster to market than the medical devices."

## MEDICAL TECHNOLOGIES INNOVATION PATHWAY\*

Creation  Development (Prototype)  Development (Trials)  Regulation  Endorsement/ Reimbursement  Commissioning and adaption  Timescales by stage  1+ year  1-2 years  6 months - 1 year  1 month - 1 year  9 months - 3 years  2 years +  Total time along pathway  >2 years  2-3 years  2-3 years  2-3 years  2-4 years  2-5 - 4 years  2-6 - 5 years  3.3 - 9.5 years  5.3 - 11.5+ years  Activities  Phase 1 Proof of Concept/ Technology Demonstrator  Proof of Con						
1-2 years 6 months - 1 year 1 month - 1 year 9 months - 3 years 2 years +  Total time along pathway >2 years 2-3 years 2.5 - 4 years 2.6 - 5 years 3.3 - 9.5 years 5.3 - 11.5+ years  Activities  • Phase 1 Proof of Concept/ Technology Demonstrator  • Phase 2 project Working Prototype  • Scaling to production • Clinical trials (if needed) • Clinical trials (if needed) • Evidence base to support approvals  • Evidence of fit for intended use or of substantial equivalence • In use in early adopters for trials • NICE HTA	Creation	·	)	Regulation		
pathway >2 years  2-3 years  2.5 - 4 years  2.6 - 5 years  3.3 - 9.5 years  5.3 - 11.5+ years  Activities  Phase 1 Proof of Concept/ Technology Demonstrator  Prototype  Prototy	,	1-2 years	6 months - 1 year	1 month - 1 year	9 months - 3 years	2 years +
Activities  • Phase 1 Proof of Concept/ Technology Demonstrator  • Phase 2 project Working Prototype  • Scaling to production • Clinical trials (if needed) • Evidence of fit for intended use or of substantial equivalence • Evidence of substantial equivalence • In use in early adopters for trials • NICE HTA						
<ul> <li>Phase 1         <ul> <li>Proof of Concept/</li></ul></li></ul>	>2 years	2-3 years	2.5 - 4 years	2.6 - 5 years	3.3 - 9.5 years	5.3 - 11.5+ years
Proof of Concept/ Working Prototype Demonstrator  Proof of Concept/ Working Prototype Demonstrator  Proof of Concept/ Working Production  Clinical trials (if needed)  Evidence of fit for intended use or of substantial equivalence  Fin use in early adopters for trials  NICE HTA	Activities			-		_
• Clinical trials (if needed) or of substantial equivalence • Evidence base to support approvals • Clinical trials (if needed) • In use by the NH • In use by the NH • In use in early adopters for trials • NICE HTA	Proof of Concept/	Working			efficacy including	
<ul> <li>Evidence base to adopters for trials</li> <li>support approvals</li> <li>NICE HTA</li> </ul>		Prototype		for intended use or of substantial equivalence	ntended use analysis	• In use by the NHS
• NICE HTA					,	
• ITT/IPT tariff			Support approvais		NICE HTA	
					• ITT/IPT tariff	

Source: Office of Life Sciences: A guide to navigating the innovation pathway in England

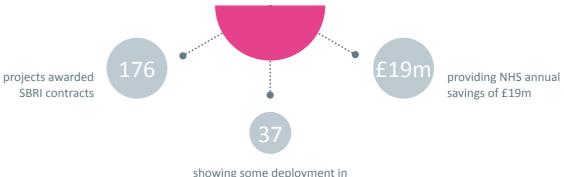
In the PA review, it is noted as per the diagram above that: "a medical device project could take anything between 3 and 9 years to first reach the NHS market. As SBRI Healthcare is principally addressing projects that are early on in the development cycle, it suggests typical project durations will be towards the higher end.

The equivalent pathway for digital health technologies provides no standard timescales, reflecting a wide range of possibilities offered by digital innovations, from simple apps for appointment reminders through to complex remote monitoring technologies that impact on patient safety and require major service changes. It is likely that most digital projects that need early stage support are more likely to fall in the latter category and will follow similar pathways and timescales to medical technologies."



Projects are progressing relatively quickly compared to expectations for the medical device innovation pathway. As we would expect, digital projects have made up the majority of innovations currently in use, while in the longer term greater returns are expected from a few 'breakthrough' medical device innovations.

### **Projects providing NHS savings in the first 6 years**



showing some deployment in the NHS, either through sales or clinical trials

These were predominantly digital technologies with relatively short development times and no requirement for lengthy clinical trials.

Further to this, the PA review goes on to state that: "on completion of the SBRI scheme there remains significant additional work which participating companies need to undertake before the NHS adopts their products and services.

#### This includes:

- Managing the process of scaling to production standard and commercialisation
- Regulatory approvals (e.g. CE marking as a medical device)
   [A lack of resources to complete development and obtain regulatory approval is another challenge cited by survey participants]
- Economic endorsement (including securing relevant NICE Health Technology Assessments). NHS England has recently introduced two new mechanisms to accelerate the uptake of innovations:
- The Innovation Technology Tariff (ITT) which aims to support clinicians and innovators in getting uptake and spread across the NHS. To date one SBRI project, myCOPD, has been supported by ITT. The sales reported by myCOPD suggest that the ITT has started to make an impact although it is still early days and from the response to this work it is apparent that the company is currently focussed on selling overseas. The ITT has recently been relaunched as the Innovation Technology Payment (ITP), and a new round is planned
- The NHS Innovation Accelerator (NIA) delivered in partnership with the AHSNs which seeks to mentor and support innovators, creating the conditions and cultural change necessary for proven innovations to be adopted faster and more systematically through the NHS. To date 6 companies involved in SBRI have participated in the NIA programme Nervecentre Software, Join Dementia Research, My mHealth (myCOPD), Docobo, Sleepio and Dr Doctor

<sup>\*</sup> This diagram is also featured as Figure 2 in the PA Consulting/ SBRI Healthcare report 2017

It is clear that diffusion remains problematic. It may be early in the lifecycle to see an impact from new mechanisms such as the Innovation Technology Tariff (ITT), its replacement the Innovation Technology Price (ITP) and the NHS Innovation Accelerator (NIA) schemes. These difficulties in securing diffusion are illustrated by the experience of 365Response with their Healthcab service (see case study). The service would appear to have very strong economic benefits and positive impact on outcomes, yet the company reported making slow progress as a result of having to 'make the case to 100 separate buyers, each with their own views'."

### 365 response case study

365Response has developed the Healthcab service to provide a streamlined and enhanced system for urgent patient transfer using a range of qualified ambulance service providers. The core market is for non-emergency patient transfers, graded under 'Green 4', officially classified as having a 4 to 6 hour response target

In all cases the interaction with 365Response is via the Healthcab service accessed either via an app or through a web portal. This avoids a problem of GPs and/or practice staff having to access standard ambulance service call lines which are attributed a low priority by ambulance trusts. In addition to providing a direct on request service, Healthcab can manage mini-competitions offered to qualified (screened) providers, which can be prioritised by the user to give recommendations based on either cost or speed of response.

Claimed savings in the region of £1M per year per CCG.

The 365 Response ambulance commissioning innovation is now been used by 18 CCGs and Trusts across the North of England.





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The 365 Response ambulance commissioning innovation is now been used by 18 CCGs and Trusts across the North of England.



365 RESPONSE

### Wider public sector benefits



The review captured benefits to the wider public sector, with recurring annual savings from the nine most commercially advanced currently running at up to £30m.

The PA report also concluded that different types of innovations encounter different types of challenges.

"Perceptions of barriers to uptake varied according to the type of innovation respondents were seeking to introduce to the NHS. Resistance to IT innovation appeared particularly acute, although the results from the survey of successful applicants indicated that IT innovations were more likely to generate sales.

According to the survey for successful applicants, 83 per cent (10 respondents) of companies with IT innovations identified resistance to change within the NHS as a barrier to them, compared with 45 per cent (9 respondents) of medical device companies and only 29 per cent (2 respondents) of diagnostics companies.

Whereas resistance to innovation was the most frequently mentioned barrier to medical devices and IT innovations, companies with diagnostic innovations viewed a lack of resources for product development as the biggest obstacle to their product's uptake.

This barrier was highlighted by 57 per cent (4 respondents) of diagnostics companies, compared with 25 per cent (5 respondents) in medical devices and 17 per cent (2 respondents) in IT."

the following recommendations were made in the PA report:

01

 There is a potential for NHS Improvement and NHS England to take a stronger line in championing diffusion of innovations that have been

shown to work

02

- A stronger commitment to buy the most successful innovations from each competition would be expected to have a significant impact in improving adoption
- 03
- A commitment to offer the ITP tariff for the most successful innovations in each theme would provide a clearer route to market for innovators

### 3. Social and health impacts

It was noted in the report that there are a range of broader benefits that are significant in their own right. These wider benefits can be considered in three main groups:

### Non cash releasing

One of the major benefits of non-cash releasing benefits is the ability to free up capacity within the healthcare system and direct scare resource to where it is most needed e.g. saved clinician time, increased capacity related to non-tariff generating encounters. For instance:

- Careflow Connect's TACTIC system has been shown to save time related to paging clinicians for queries and passing on details on shift handovers. This is in addition to the cash-releasing impact seen from improving the management of AKI
- Isansys' automated bedside monitoring system, currently used in a children's hospital, frees nursing time from taking observations and calculating early warning scores to caring for patients

### Improve quality/outcomes

Where there are established economic impacts, such as reduced lengths of stay, reported outcomes have been incorporated into the financial analysis. Quality improvements include those related to patient safety, patient outcomes and operational performance and patient experience. Many of these align with wider strategic objectives. For instance:

- 365Response reported that the
  use of the service in one area
  had corresponded with a marked
  improvement in ambulance
  related performance, including a
  reported improvement in cardiac
  survival to discharge (from 0% to
  12.7%) and a 17% improvement in
  Red 1/Red2 performance
- Bespak in a broader example, Bespak's drug delivery device will impact the NHS indirectly, when pharmaceutics companies offer formulations enables by the new technology
- Mayden's PRISM service is improving access to digital IAPT services, improving the availability of services and timeliness of referrals

### **Patient experience**

For example improved patient engagement, improved quality of life, improved access to service

- ADI's MyPathway allows patients to re-book appointments, and provides reminders and useful information, such as hospital maps and transport timings, contributing to a reduction in DNA16s
- unnecessary overnight carer attendance, roles which often were given additional duties such as laundry. The system has shown moving to right care has resulted in reductions in disturbed sleeping patterns



PA identified additional impacts to the economy from new jobs valued at £14.6m.

SBRI funded projects have made over £6,929,100 worth of non-NHS sales, with the vast majority of this as a result of European or American export sales. There were a further 13 companies that had reported non-NHS sales in the survey but they were unable to provide a value.



While it is still early in the innovation pathway to be expecting tangible benefits for the NHS, there are positive signs to indicate that SBRI Healthcare is operating effectively and is on track to deliver significant value for the NHS as well as the UK economy as a whole.

Additional impacts for the economy as a whole as of September 2017 were valued at

£125m

£14.6m

from job creation

£6.4m

non NHS sales
(US/European exports)

£104m

of private investment funding in SBRI backed companies

### 4. Savings and return on investment

#### **NHS** savings

PA Consulting's assessment of current benefits focused on a cohort of 9 projects assessed as having the highest potential to be achieving an impact based on reported sales, forecast economic potential and SBRI Healthcare team knowledge of the companies. Together, the 9 projects account for 88% of current NHS sales and provide a sound basis for estimating the total impact to date.

The report identified projects estimated to have secured savings to date of between £24.4m and £29.9m to date.

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### **SAVINGS**

savings based on secured information for shortlisted SBRI projects

#### Totals (to nearest (£100,000)

NHS in England savings	Other UK NHS/social care savings	Recurring annual NHS savings
£13,100,000	£11,500,000	£19,100,000
to		to
£18,600,000		£22,200,000
		_

The amount of annual recurring savings is forecast to increase as adoption spreads.

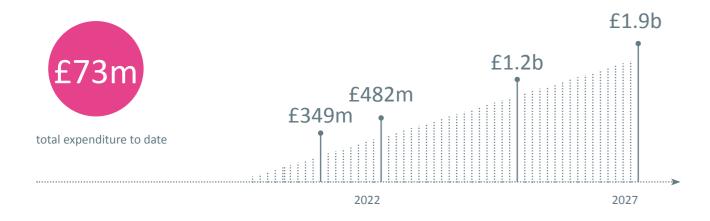
The PA report notes that "Due to the complexity of assessing financial impacts there are a large number of assumptions driving these calculations. Reporting financial impact in this way has not been the central focus for these companies, nor has this been part of the mandate for SBRI Healthcare and therefore has not formed part the data regularly collected by SBRI Healthcare through surveys. Hence the available data does not fully cover all the possible financial benefits, nor does it always assess a direct impact."

"The assessment of future potential was based on a further cohort of 14 projects from the list of 176. These have been identified jointly with the SBRI Healthcare team as currently showing the greatest potential for successful adoption and impact. While some are on the market, they have yet to achieve any significant NHS sales and they are not included on the projects reviewed for current impact."

"The estimated cumulative future savings to the NHS enabled by the SBRI Healthcare portfolio is expected to be of the order of £350-£480m in 5 years (2022), rising to between £1,200M-£1,800m in 10 years."

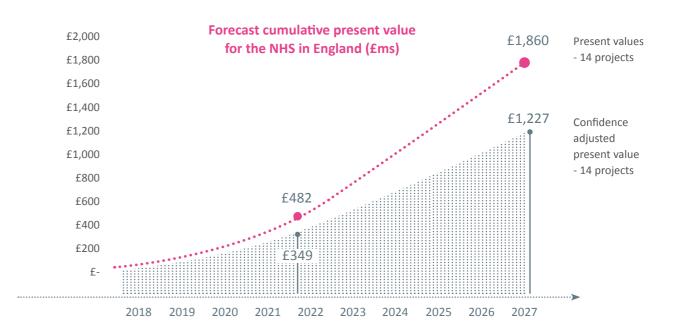
#### **Cumulative value to the NHS**

When a further 14 projects, including diagnostics and therapies currently undergoing extended clinical trials were included, the report forecasts that the cumulative present value to the NHS will rise to between £349m and £482m by 2022, and to between £1.2 billion and £1.9 billion by 2027. This derives from total SBRI expenditure to date of £73m



"This group of 14 projects represents 12.5% of the total project portfolio. The estimate, shown in Figure 1, has been confidence-adjusted to account for the quality of the information used to develop the estimate. It takes account of the expected increasing returns as projects gain adoption by the NHS."

### Forecast SBRI present value to the NHS in England with confidence adjustments



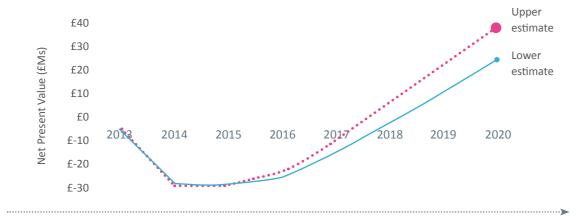
#### **Return on investment**

The review looked at the projects in the first two competitions run by SBRI Healthcare to understand the value returned by a whole investment portfolio. They are the NHS England funded competitions most likely to have seen products reach the market.

They concluded that: "the estimated savings for the NHS in England to date are in the range £13.0M-£18.6M against an investment of £25.6M, with annual recurring savings currently running at a rate of between £14.4M and £17.5M. The present value is shown in the graph below and this indicates that the break-even point for projects in Competitions 4 and 5 will occur by mid 2018."

### SBRI HEALTHCARE COMPETITIONS 4 & 5

net present value of projects showing current and recurring annual savings

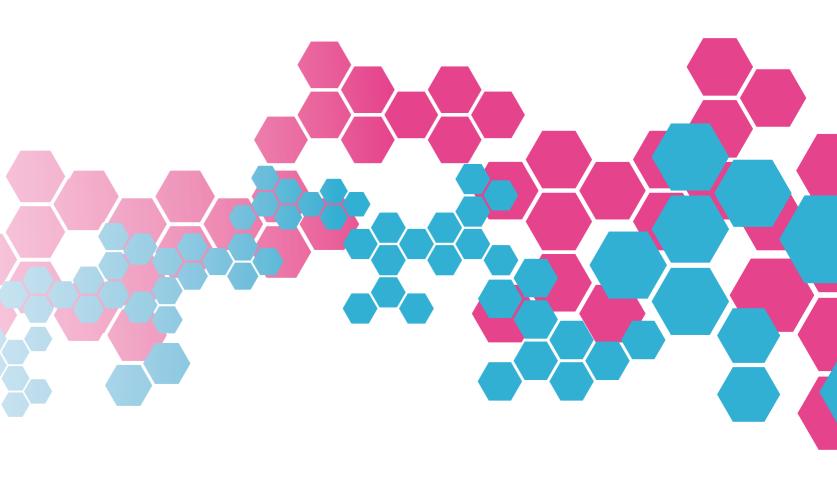


"This is a strong performance given that it is only four years since the initial investments were made in Phase 1 early-stage feasibility studies. The longer term prospects for a return from these projects are still more positive. All projects that have been

reviewed in detail would be expected to continue to deliver savings, most at a rate that will increase significantly as adoption spreads. In addition, there are three medical device projects from within this cohort showing strong long term potential."



The PA report also highlighted that: "If the speed of the returns is to be a driving factor, the mix between digital and medical device projects should be considered. Some caution is needed. While digital innovations have been faster to market, medical device innovations are likely to generate more significant long term returns."





## **Report 3 - key findings**

# RAND

The Small Business Research Initiative (SBRI) Healthcare programme - An evaluation of programme activities, outcomes and impacts

Published: 2017

**Commissioned by:** UK Department of Health Policy Research Programme.

Author: RAND Europe - Catherine Lichten, Calum MacLure, Anton Spisak,

Sonja Marjanovic, Jon Sussex

The 2017 study undertaken by RAND Europe focuses solely on the contribution of the Small Business Research Initiative (SBRI) Healthcare programme to innovation in the NHS.

The research team based their conclusions on the findings from a series of stakeholder surveys and interviews exploring four main key areas of focus:

# 01

What does the SBRI Healthcare programme do and how does it fit into the wider funding landscape fo health-related innovation in the UK?

03

What are the barriers and enablers to achieving impact?

02

What is the range of outcomes and impacts generated by the programme and its awardees

04

The challenges and opportunities for the future pased on the comments of interviewees and survey respondents.

Method	Participant profile
Telephone interviews with 16 stakeholders	Representatives of NHS Academic Health Science Networks (AHSNs), the healthcare and technology industry, innovation networking organisations, and the SBRI Healthcare programme delivery team.
Survey of unsuccessful applicants	Representatives of organisations that applied unsuccessfully for SBRI Healthcare funding during 2009-2015. (177 responses from 173 businesses, 22% response rate).
Survey of successful applicants	Representatives of organisations that were awarded SBRI Healthcare funding during 2009-2015. (45 responses, 45% response rate).
Telephone interviews with 5 funding recipients	Representatives of companies that were awarded SBRI Healthcare funding and responded to the survey of successful applicants.

### 1. What does the SBRI Healthcare programme do?

Comments in relation to the wider funding landscape from participants in the research was somewhat mixed:

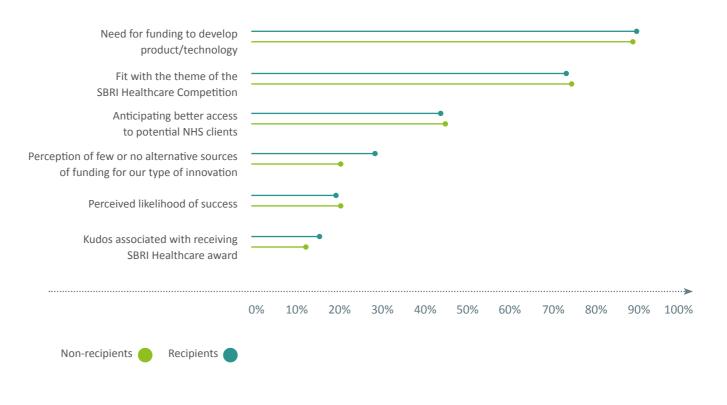
- "One survey respondent stated that the programme fills an important gap in the funding landscape by supporting SMEs
- Five stakeholder interviewees said there is a shortage of early-stage biomedical innovation funding, while two commented that there are many schemes in this space
- Survey results support the idea that applicants can also access other funding sources, but that SBRI Healthcare funding has been important to them."

In conclusion, the RAND report found that "overall, the SBRI Healthcare programme performs a valuable role for the NHS in the early-stage innovation funding landscape. Going forward it will be important to consider how best to coordinate the SBRI Healthcare programme with wider policy developments (including the Accelerated Access Review) and initiatives to progress the adoption, diffusion and scale-up in the NHS of the innovations it supports."

When asked about overall strengths of the SBRI Healthcare programme, interviewees highlighted the same two areas: the articulation and identification of unmet needs and the fact that the programme provides needed funding for companies.

## THE MOST COMMON REASONS FOR APPLYING TO SBRI HEALTHCARE\*

(Responses from both successful and un-successful applicants)



<sup>\*</sup>This also features as Figure 3 in the SBRI Healthcare Rand report 2017

Many identified the demand-led approach as the main characteristic that sets it apart. As one said:

### There are a plethora of schemes that directly incentivise the supply end of innovation... but that is usually less likely to meet the requirements than demand-led innovation.

#### **Supporting small businesses**

The RAND report's evidence indicates that the SBRI Healthcare programme "does appeal to and suit small, early-stage businesses. The majority of respondents to the surveys (both successful and unsuccessful applicants) were microenterprises, one survey respondent stated that the programme fills an important gap in the funding landscape by supporting SMEs.

The programme has a number of strengths, including low administrative burdens for applicants and awardees, effective processes for identifying and articulating needs, and a beneficial provision of health economics support in Phase 1."

Additional feedback on the SBRI Healthcare programme's appeal for SMEs included the following:

- "Applicant companies cited their need for funding and a fit with the themes of the calls as their main motivations for
- The health economics support provided by SBRI Healthcare was highly valued, but experience of other potential forms of support, such as brokering access to prospective NHS clients and other investors, varied
- According to companies awarded SBRI Healthcare support who replied to the survey, awards are valuable not only for the funding they bring but also for the associated kudos (77 per cent found this helpful) and because the Phase 1 awards are accompanied by useful health economics analysis (72 per cent of awardees responding considered this helpful)
- Over 90 per cent of successful applicants, and nearly 70 per cent of unsuccessful applicants, who responded to the surveys said that they would apply to another SBRI Healthcare competition in future. We see this as a vote of some confidence from the small businesses that have been in contact with the programme."

#### Is SBRI funding key to driving innovation?

The RAND report states that "among unsuccessful applicants, 55 per cent of them went on to develop their ideas without support from SBRI Healthcare and obtained funding through various means. However, among those that did not go on to develop their ideas, 92 per cent (72 out of 78) cited a lack of R&D funding as the main reason. Similarly, among the successful applicants, 52 per cent (51 respondents, or 23 out of 44) reported that they probably or definitely would not have undertaken the SBRI Healthcare-funded project if they had not received that funding."



"Asked what would have happened if they had not succeeded in obtaining the SBRI Healthcare funding, **four** of the **five** SBRI Healthcare awardees who were interviewed said they would probably still have advanced but that the process would have been much slower or a little bit slower."



**93 per cent** of successful applicant respondents (40 out of 43) considered that the funding they received from SBRI Healthcare had helped their project.

"One respondent noted that SBRI Healthcare funding had enabled their small company to bring together a group of collaborators to work on product development in a way that SMEs are usually not able to do."



#### **Programme processes**

The RAND report states that "overall, the SBRI Healthcare programme is seen to run well by most interviewees and awardees who responded to the survey, and in particular in terms of effective processes for identifying and articulating healthcare needs and a reasonable administrative burden. Respondents to the survey of awardees generally felt that monitoring was appropriately light touch for SMEs."

They also stated that it was "managed with good organisation, processes and staff continuity. They highlighted the programme's general governance and way of working as an overall strength . Some unsuccessful applicants were notably positive about the value and contribution of support from SBRI Healthcare, saying, for example:

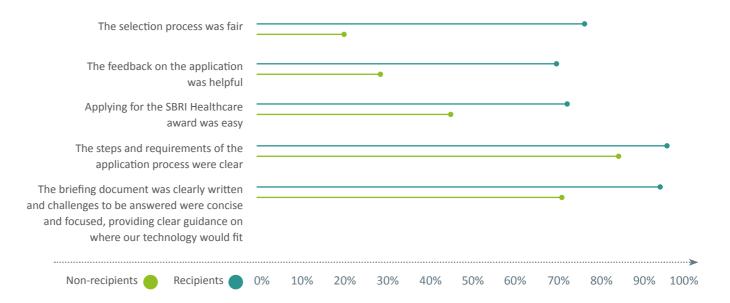
"Of all the things that we applied for, SBRI Healthcare was by far the best. It was professional, well organised, light touch, nonbureaucratic and sensible. Would definitely apply again." "Our experience of the SBRI Healthcare processes has been excellent, and this is the best programme we have ever engaged in"

While 74 per cent of successful applicant respondents to the surveys agreed that the application and selection process was fair, only 20 per cent of unsuccessful applicants agreed with that view (although another 40 per cent of unsuccessful applicants neither agreed nor disagreed). Some concerns were raised by unsuccessful applicants about the level of technical expertise demonstrated by the review panels when assessing proposed technologies and about the quality of the feedback provided; only 28 per cent of unsuccessful applicants who responded to our survey agreed that the feedback they had received was helpful. "



A key concern raised by some companies surveyed related to the quality of the assessment and feedback received.

# Responses from successful and unsuccessful applicants on the SBRI Healthcare application process (n=43 successful; 163 unsuccessful)\*



### Assessment of feedback from SBRI Healthcare regarding their application (successful applicants)



**68** per cent agreed that the feedback they received on their application was helpful



16 per cent disagreed

Unsuccessful applicants had more mature innovations at time of application; successful applicants were more likely to have proposed ideas they wanted to develop into a proof-of-concept, while unsuccessful applicants were more likely to have prototypes they wanted to trial.

This finding indicates that there may be a need to make it more explicit in guidance and other communications that the SBRI Healthcare programme intends to support early-stage ideas in Phase 1, not more developed ideas."

<sup>\*</sup>This also features as Figure 6 in the SBRI Healthcare Rand report 2017

#### The role of Academic Health Science Networks

The RAND report conducted some useful research into the role of the Academic Health Science Networks (AHSNs). "AHSNs are responsible for running calls and working with companies in their region that receive SBRI Healthcare support. As part of these responsibilities, an important task of the AHSNs is the identification and articulation of needs. One member of the SBRI Healthcare board explained that the 15 AHSNs across England

cooperate to decide challenges they will address and which AHSN will lead in developing each challenge. AHSNs also offer clinics to help companies prepare for the competition. According to the awardee survey, 44 per cent of successful applicants consulted their local AHSN while preparing their application and 57 per cent reported receiving support in the form of links to their local AHSN."



"There are active discussions about what works best and what can be improved... I don't think those conversations happened a couple of years ago. It is mostly because AHSNs are taking more ownership of that."

"England is quite diverse and complicated in terms of admin and governance systems. The AHSNs provide a pretty good channel to local or regional clinical networks – they don't do it evenly but there are some good things going on."

"We've seen a growing and rich engagement with AHSNs. That relationship is very solid now."

"Some of the AHSNs are very proactive about asking what companies are located in their area... They'll help promote those companies, and work alongside them to make sure they understand procurement routes and clinical trials... The AHSNs' role is very much about opening doors, helping understanding, really supporting the companies."

"Two stakeholder interviewees stressed that there was good emphasis on regional spread and avoiding undue focus on eastern England (the home region of Health Enterprise East and Eastern AHSN, which manage SBRI Healthcare competitions) and London (a traditional focus of research and innovation activity). Some commented that this was achieved through collaboration among AHSNs.

There was a lack of clarity about the AHSN-led process for developing specific calls to action. While there was recognition that evidence informed the identification of needs for calls, there was less consistency in views on the quality of this evidence. For example, one interviewee believed that assessments on the existence of market gaps were not underpinned by systematic

reviews, horizon scanning or detailed needs assessments, while another said that market analysis was part of the process.

Together, these responses point to a need for more awareness raising, transparency and communication about the processes for selecting themes and identifying specific needs within them."

"The best sort of support is clarity for people from the industry who might have an incomplete view of how the NHS works – they are very likely to produce a product which is incompatible with the processes, financing and culture of the NHS."

"A view expressed by six stakeholder interviewees was that the SBRI Healthcare programme, through identifying and articulating NHS needs to industry, creates an important direct link between industry and the NHS as a customer, and that it is a useful process for the NHS to engage in via the AHSNs and clinicians."

there should be more support to give companies insight and links to the NHS and that AHSNs can help with this, and one believed that only some AHSNs are currently providing this help. Another said that some AHSNs wrongly believe that if they are involved in the assessment process, then it would be a conflict of interest to give companies further support."

### 2. What are the outcomes and impacts?

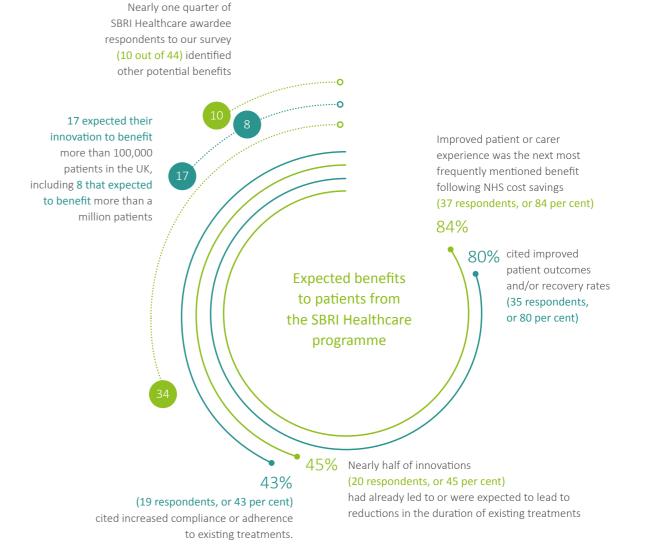
The RAND study participants "felt that it was still too early to identify impacts on patients and the NHS, but a range of expected impacts were reported by awardees. **Eighty-six per cent** (38 out of 44 awardee respondents) stated that their innovation had generated or would generate net **cost savings for the NHS**. Fifteen of these respondents also provided estimates of expected cost savings per annum as part of the earlier Health Enterprise East (HEE) survey. Of those 15, most expected their innovation to generate **annual cost savings** to the NHS in the **tens of millions of pounds**.

The RAND study also noted that data on potential savings for the NHS were also gathered in the 2014 OHE impact evaluation and 2016 HEE survey, both of which used the health economics reports prepared for the SBRI-funded companies. The OHE evaluation reported that SBRI funded innovations were expected to benefit between 6,300 and 11.2 million patients per technology per year and generate potential savings to the NHS of £7.2-171 million per technology. According to the 2016 HEE report, the average annual potential savings to the NHS or local authorities was £16 million per company for the SBRI 7 programme and £21 million per company in SBRI 8.

### Patient care, efficiency, productivity

The RAND report states that "as more of the supported innovations reach the NHS market over the coming years, it will be desirable to monitor their impacts on patients and NHS costs in practice."

"Nine interviewees agreed it was too early to see impacts in the form of improved patient care, and their statements are consistent with other evidence gathered for the evaluation. Most positive impacts of SBRI Healthcare-supported innovations were on treatments and their delivery, on patient and carer experience, or on savings of NHS costs."



Most related to the efficiency of the NHS, and these included increased productivity of healthcare professionals and data-driven improvements to management processes, as well as reductions in admission and readmission rates, accident and

emergency (A&E) attendances and unnecessary follow-up appointments. Respondents also identified achieved or expected improvements in access to diagnosis and treatment."

### 3. What are the barriers and enablers?

The RAND research project found that "the SBRI Healthcare programme is providing effective support for small companies to develop innovations that address NHS needs. The programme has a number of strengths, including low administrative burdens for applicants and awardees, effective processes for identifying and articulating needs, and a beneficial provision of health economics support in Phase 1.

### The RAND report also states that clinician involvement and local pilots help promote uptake of innovations



77 per cent of companies (33 respondents) reported that the involvement of clinicians in product development had been a key enabling factor

### Although engaging clinicians was the most mentioned enabler overall, companies with IT innovations placed more emphasis on local pilots of their technology

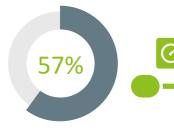


**83** per cent (10 respondents) of those companies identified local pilots as a key enabler of their innovation's uptake

#### compared with







**57** per cent (12 respondents) medical device companies

#### **Adoption and spread**

Asked about how the impacts and successes of the SBRI Healthcare programme should be measured, the stakeholders interviewed discussed the need to look at adoption and spread through e.g. products entering the market and the number of sales contracts, and whether the adoption and benefits had come through as anticipated."

"Several stakeholder interviewees explained that supporting adoption by the NHS was outside the programme remit. A few said that the responsibility of SBRI Healthcare was not to make sure that adoption happens, but to ensure that connections are in place to enable it, with e.g. the National Innovation Accelerator (NIA), National Institute for Health Research (NIHR) and business support organisations. On the other hand, one stakeholder interviewee said that SBRI Healthcare programme only adds value to the health innovation landscape if it goes

beyond business support to actually get innovations adopted in the NHS."

There was a range of views from SBRI Healthcare awardees about the extent to which they had received support with commercialising their innovation.

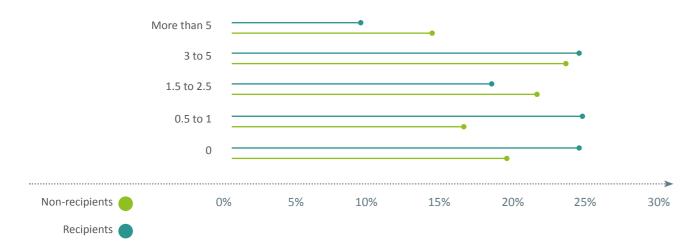
One awardee stated: "It's ok to say this is a development contract... but in terms of facilitating commercial introductions to the NHS, I don't think that is accurate marketing. On the other hand, another awardee reported that SBRI Healthcare had provided a useful contact with central NHS procurement staff (averting the need to make contacts with local bodies).

Eleven stakeholder interviewees pointed to the AHSNs as bearing more responsibility than the SBRI Healthcare programme for ensuring adoption. But two stakeholder interviewees said that AHSNs' resources are also too limited to do all that is necessary in this area."

#### Sales

"Given the early- stage of development of most innovations supported by SBRI Healthcare, it is uncertain how many will reach the market. But among the respondents to our own survey of successful applicants, more than one quarter report product sales to date. These are still modest, totalling £4 million of sales so far (of which £3 million was in the NHS) by 13 of the 45 companies who responded to the survey."

Responses from successful and unsuccessful applicants on the SBRI Healthcare application process (n=43 successful; 163 unsuccessful)



Over £3 million of the £4 million of sales reported by SBRI Healthcare-supported companies were made to the NHS. Fourteen per cent of sales were to international customers outside the EU, 7 per cent to non- NHS UK customers and 3 per cent to non-UK EU customers.

IT innovations generated 65 per cent of all sales despite representing just 26 per cent of respondents.

Medical devices accounted for 24 per cent of sales.

### Barriers to growth

A number of comments were gathered in the Rand report relating to perceived barriers when targeting the NHS market in order to increase adoption and spread of innovations and support small business growth.

"Fifty-seven per cent (25 respondents) stated that the adoption of their product had been hindered by a lack of motivation and accountability for innovation uptake within the NHS, combined with inertia and resistance to change."

"One awardee explained in an interview that it was helpful to be able to say that they were a company that had been funded by the NHS to develop a product that meets a specific NHS need, because otherwise NHS staff would likely be more resistant to their potentially disruptive innovation"

"SBRI Healthcare awardees report facing obstacles to uptake of their products, including resistance to innovation within the NHS, complex and bureaucratic procurement

systems and a shortage of resources to complete development and obtain regulatory approval." "The issue of procurement and adoption in the NHS... it is a nightmare, and it's not getting any easier with the NHS deficit."

"A lot of companies have come out of the process still needing more handholding to get them further along.... Looking at the NHS as a customer as a whole, some fundamental, systemic changes need to happen to bring innovation in so it's not technology pushing at a closed door... you've already got it slightly open with SBRI, but more work needs to be done to open it wider."

"One awardee explained in an interview that it was helpful to be able to say that they were a company that had been funded by the NHS to develop a product that meets a specific NHS need, because otherwise NHS staff would likely be more resistant to their potentially disruptive innovation"

The RAND report authors also highlighted the following suggestions in response to the concerns regarding access to the NHS market:

"The general view was that the challenges to innovation in the NHS are a systemic problem that the SBRI Healthcare programme cannot overcome on its own. However, an idea raised by stakeholders interviewed was that the SBRI Healthcare programme could be helping to bring about culture change by encouraging more openness to changes in the approach to clinical problem solving and by building a dialogue between the NHS and industry:

There's really something about engaging the NHS in a dialogue around innovation and using that to drive improvements... Identifying needs and communicating them to industry is not something the NHS has ever had a mechanism for... To address falls they'll tender for a pendant alarm because they know it exists. What they don't do is tender for stuff that they don't know exists."

#### **Attracting further investment**

According to the RAND report "SBRI Healthcare funding enabled the 68 companies who responded to the survey in 2015, subsequent to receiving the SBRI Healthcare award, obtain a total of £36.7 million of additional investment funding from other sources."

It goes on to say that "the most common source these organisations received funding from was downstream private equity (obtained by 34 per cent of respondents to this question

in our survey of awardees, or 15 out of 44), followed by government R&D grants (27 per cent, or 12 out of 44) and loans (also 27 per cent, or 12 out of 44). The top three sources of government R&D grants for SBRI Healthcare awardees were Innovate UK Smart grants (obtained by 3 respondents), EU funding through FP7 or Horizon 2020 (3 respondents) and funding from the UK Biomedical Catalyst (2 respondents).



Percentage of successful and unsuccessful applicants that received co-funding from the following sources (n=44 successful; 88 unsuccessful)\*:



Awardees that had reached Phase 3 were most likely to seek additional funding (60 per cent, or 3 out of 5 did so), followed by those in Phase 2 (32 per cent, or 8 out of 25) and those in Phase 1 (13 per cent, or 2 out of 16).

These findings as well as findings from the HEE survey and from interviews with SBRI Healthcare awardees support the ideas that organisations do not need additional external financing while they have the SBRI award and that they tend to wait until their innovation is more developed before obtaining additional funding.

<sup>\*</sup>This also features as Figure 6 in the SBRI Healthcare Rand report 2017

### 4. Challenges and opportunities for the future?

A stakeholder and an awardee discussed how there may be a need to provide resources enabling the NHS to actually purchase products. As one said: "You've got to incentivise all sides of the party, otherwise you do just have technology push."





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Four respondents called for Phase 3 funding to be made available to support the commercialisation and translation into practice of SBRI Healthcare-supported innovations.

Additional suggestions put forward for facilitating NHS uptake of innovations included funding fewer projects but following them all the way through to commercialisation and sharing ownership of the innovations with NHS England.

The awardee proposed that there might be "partnered applications" involving the industry partner and their local Trust, with the industry partner receiving money to develop the product and the Trust to purchase it: "If we were able to apply with a partner so they can purchase the device for early adoption or training or early clinical trials, that would be vastly more efficient for commercial translation." This awardee, who had made early sales of their device through charities in the UK, suggested emulating the approach the charities take when they provide funding that enables new products to be adopted in

specific regions.

Two interviewees suggested there could be more interaction with other innovation funders, such as NIHR and the Catapult centres.



Another awardee suggested ways that SBRI Healthcare could do more to help companies find paying customers in the NHS. These included arranging events to bring companies together.





Three commented that there is now a good opportunity for joined-up thinking with other programmes, such as the NIA, which was seen as a promising next step for SBRI Healthcare products to feed into.





### RAND concluded that:

"Addressing NHS needs goes beyond innovation development to include uptake and use of the innovations. This step constitutes a fundamental challenge and will require collaboration with other innovation programmes at regional and national levels. Part of this could usefully include:

- Providing networking opportunities for companies to learn from one another about
- Exploring opportunities to engage with other national and regional funding programmes (e.g. National Institute for Health Research designations proposed in the 2016 report





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