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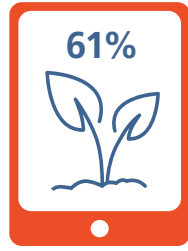
Law . Tax

# Vital Signs

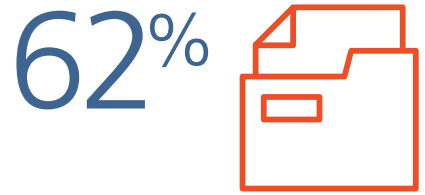
A digital dynamic promises growth for UK life sciences



Potential



**61%** say digital technologies have the greatest potential to drive life sciences growth if supported by the government.



**62%** think healthcare records management is one of the greatest commercial opportunities for digital technology in the life sciences industry.

Concerns

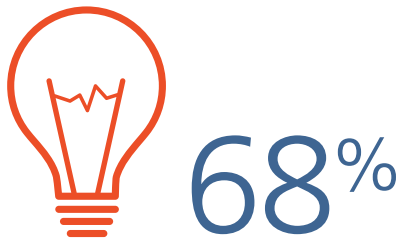


**95%** say the government's strategy needs more clarity on implementation.

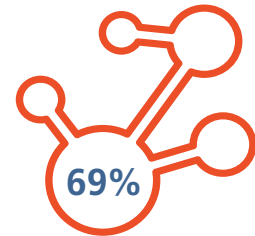


**93%** say that Brexit will undermine the ambitions of the Life Sciences Industrial Strategy.

Optimism

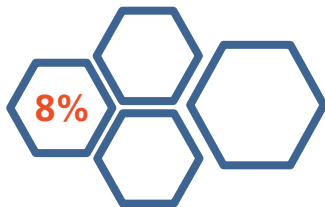


**68%** think the UK can enter the top quartile of comparator countries for the adoption of innovative products within five years.



**69%** believe the target of establishing digital innovation hubs to give researchers access to large healthcare datasets is achievable.

Doubts



Only **8%** believe it is possible to create four UK companies valued at over £20bn in the next ten years, as proposed in the Life Sciences Industrial Strategy.



Only **13%** say it is feasible to create two entirely new industries in the next ten years.



55%

55% think the creation of a long-term investment vehicle to deploy capital in scale-up and R&D businesses is a key way to encourage industry growth.

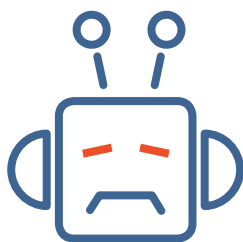


Only 37% think the UK will be able to attract the 2,000 new discovery scientists envisaged by the Life Sciences Industrial Strategy.



12%

Only 12% think a lack of political will to intervene in the sector is a major challenge to life sciences growth.



Fewer than 25% think headline-grabbing developments such as healthcare apps, virtual nursing assistants and robot-assisted surgery have strong commercial potential.

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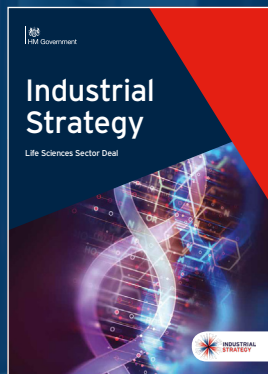
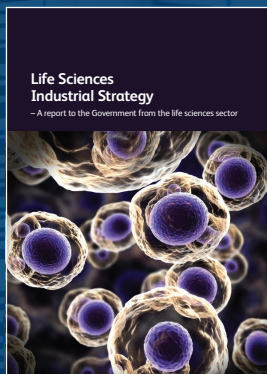
## Methodology

This report is based on findings from an online survey of 103 senior life sciences executives from private sector companies, academia, charities and investment institutions. The survey was commissioned by CMS and was conducted in August and September 2018 by Longitude, a division of the Financial Times.

The survey findings are complemented by insights from a roundtable discussion hosted by CMS in September 2018. Participants are listed on page 9. Two contributors were interviewed separately: John Colenutt, COO & Director of Genomics PLC, and Steve Dodsworth, CEO of DHealth.



## The UK Life Sciences Industrial Strategy: four key documents



Sir John Bell's report, **Life Sciences Industrial Strategy – A report to the Government from the life sciences sector** (the 'Bell Report'), released in August 2017, outlines an ambitious vision for the sector, and puts forward a series of recommendations for how this can be realised.

In December 2017, the government published the first phase of its **Life Sciences Sector Deal**.

The House of Lords Science and Technology Select Committee published its report on the strategy in April 2018. **Life Sciences Industrial Strategy: Who's driving the bus?** (the 'Lords Report') is particularly critical of the lack of detail provided by the government on implementation, and on issues of oversight and co-ordination.

The government published a response to these criticisms in June 2018. Lord Patel, the chair of the Lords committee, observed that the **government's response** "is comprehensive and detailed, but it is not much of an approval of our recommendations. In fact, much of it showed disapproval." However, he added that "since then some of our messages and recommendations have been, or are being, progressed."

# Vital Signs

In 2017, Professor Sir John Bell published the well-received Life Sciences Industrial Strategy. But, despite its title, Bell's report is not officially the government's strategy for life sciences. Rather, as the government has said, it is "independent advice to government, setting out the actions the sector wanted to see to grow life sciences."

The government followed the publication of the Bell Report with a **Life Sciences Sector Deal** which, in its own words, "set out commitments and funding to implement some of the major asks from industry set out in the Strategy." It sees the deal as "an important first step towards realising the Strategy's vision".

The initiatives in the sector deal are obviously welcome, but many are relatively small in scale, while some of the grandest (such as the construction of an expressway between Oxford and Cambridge) are not primarily life sciences-focused.

Notably, the sector deal is largely silent on the Bell Report's proposal for the **Health Advanced Research Programme** (HARP), in which industry, charities, the NHS, universities and the government would collaborate on long-term projects. The deal says only that the government's "approach to delivering the vision" of HARP will be laid out at a future point.

One of the things that the life sciences industry responded to most positively in the Bell Report was the scale of its ambition – even though there is scepticism about the achievability of some of its more ambitious goals. The industry believes it is better to aim high, even though there is more risk of falling short. But is there now a danger that we may miss potentially game-changing developments by playing it safe?

Whilst the sector deal will be subject to further government review, this is an opportune time to reflect on some of the Bell Report's core recommendations – such as HARP – and objectives. In particular, we wanted

to assess which of the report's many recommendations have the greatest potential to create long-term growth and which of its objectives stand most chance of success.

To explore these themes, we surveyed over 100 life sciences executives from companies, academia, charities and investment institutions. We also discussed the issues at a roundtable of senior life sciences executives. This report presents the findings of our research.

Our research was conducted before the Department of Health & Social Care published its paper: 'The future of healthcare: our vision for digital, data and technology in health and care'. Described as "setting out the government's vision for the use of technology, digital and data within health and care", the paper is relevant to many of our respondents' concerns about NHS processes.

The policy paper certainly advances a vision, and is frank in its acknowledgement of many of the challenges faced by healthcare in the UK. But it focuses more on principles, frameworks and statements of support than on the realities of implementation and investment – the same issues that concern our survey respondents in the context of the government's overall approach to life sciences.

Our research also explored which sub-sectors identified in the Bell Report could best drive growth, and examined the key challenges to accelerating the economic activity of the life sciences sector and how these can be overcome.

We hope you enjoy reading this report. Please contact us if you have any questions or comments about it.

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# Executive summary

## Digital technologies offer huge growth potential

Digital technologies, including AI, are primed to drive the creation of a new life sciences industry. Some 61% of survey participants say digital technologies have the greatest potential to drive sector growth if supported by the government through the proposed Health Advanced Research Programme – an initiative that the strategy recommends should be established to undertake large research infrastructure projects and high-risk ‘moonshot programmes’.

Specifically, digital technologies that aid healthcare records management and treatment design are felt to offer the most immediate commercial opportunity.

61% say digital technologies have the greatest potential to drive life sciences growth if supported by the government.



## Data is golden

Clinical and real-world data will be vital to unlocking life sciences growth. Data analytics is becoming increasingly important for the development of the new drugs, technologies and medtech devices that will propel the sector forward. The wealth of patient data held by the NHS means the UK should be exceptionally well positioned for this – but there are many practical and regulatory issues with using such data for commercial purposes.

It is, therefore, unsurprising that the respondents to our survey rank strategy recommendations that improve data access very highly in terms of their ability to unleash industrial growth. They say that the joint-second most effective strategies for kickstarting growth are improving the quality of and access to NHS data, and establishing digital innovation hubs housing healthcare information on 3m-5m people.

## A renewed focus on implementation

A staggering 95% of those we surveyed say more clarity is needed on the implementation of the strategy. The House of Lords Report complained strongly of a lack of clarity about which organisation or organisations are ultimately responsible for driving the strategy forward, and about the nature of their accountability.

The government subsequently explained which bodies are in charge of implementation – preferring its own scheme, centred on two very large committees, to the plans proposed by the Lords. But our survey shows that the sector either still finds the arrangements inadequate or is simply not aware of them.

Furthermore, while the Bell Report outlines a series of recommendations and objectives, it is unclear whether these are actual government targets – as we noted above, despite its title the Bell Report is not official government strategy.

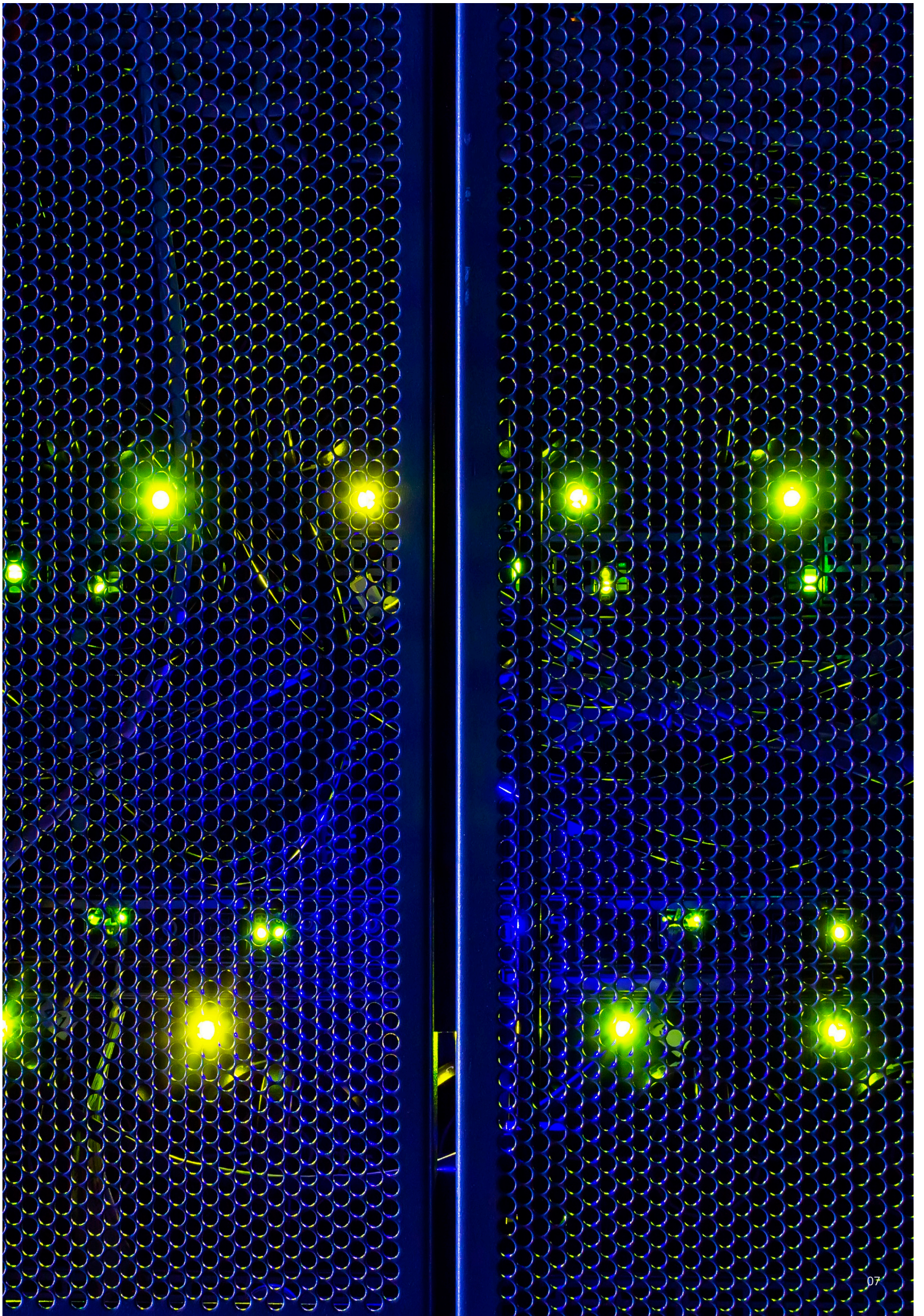
This lack of clarity on implementation partly explains why the sector believes some of the strategy's more ambitious objectives are unachievable. Only 8% of our respondents believe it is possible to create four UK companies valued at over £20bn in the next ten years, for example, and only slightly more (13%) think it is feasible to create two entirely new industries over the same period.

## Risks to the strategy

Implementation challenges aside, our respondents warn that a number of other obstacles stand in the path of industrial growth. They highlight an unhelpful regulatory environment – specifically, data protection and privacy regulation – as the most significant challenge.

A lack of early-stage and growth financing for life sciences companies is seen as the second-greatest challenge. Our respondents are enthusiastic about the idea of a long-term capital-investment vehicle that deploys capital in scale-up and R&D businesses, as recommended by the government's 2017 Patient Capital Review report.

Finally, and very tellingly, 93% of our participants say that Brexit will undermine the ambitions of the strategy.



# A roundtable on the strategy

In September 2018, we were joined by industry figures at our offices in London to discuss the life sciences strategy. Reflecting industry sentiment, attendees were upbeat about the general direction of the strategy, but had a number of reservations about whether all its objectives are feasible and how it will be implemented. Many also queried whether the right areas are being prioritised.

## Focus on data is welcome, but challenges remain

Data is crucial to the development of the new drugs, digital technologies and medtech devices that will catapult UK industrial growth, so the strategy's emphasis on this is welcome.

"Data is going to be the future of healthcare, so funding for the digital innovation hubs and initiatives to integrate and provide access to appropriate data pools is really crucial to providing the foundation for industrial growth going forward," confirms Andrew Davies of ABHI.

“ The strategy is very domestically focused, which is fine, but biotech and life sciences is an international field ”

*Melissa Coutinho, formerly MHRA*

The UK should be well positioned to provide data that the private sector can use to fuel development, because the records of millions of patients are housed in the NHS.

But our attendees lament the difficulties in accessing this data and want to see a focus on easing this process. "One of the critical issues we struggle with is how to extract data from NHS systems," argued Cengiz Tarhan, who recently retired as MD of UCLB. "Those responsible for the data need to tell us about any restrictions on its use, any obligations they have, and their validity so we can properly address these when licensing out."

## A global approach is key

Our roundtable debated whether the strategy's objectives are realistic. Attention naturally focused on the objective outlined in the Bell Report to create four UK

companies valued at over £20bn in the next ten years. The industry does not believe this is remotely realistic, unless UK companies are assisted in competing globally.

"I noticed one of the ambitions was to have a number of companies with a £20bn market cap, which is profoundly challenging and is going to be very difficult unless we have real clarity and alignment between the reimbursement framework and the regulatory framework," said Paul Mussenden of BTG. "You are simply not going to be a £20bn company unless you are globally competitive. So, whatever the strategy does must be set in a global context."

"One area that is missing in the report is encouraging a more global outlook in the industry," adds Melissa Coutinho of the MHRA. "The strategy is very domestically focused, which is fine, but biotech and life sciences is an international field."

## Boosting domestic adoption is also crucial

Roundtable participants believe the strategy needs to pay more attention to ensuring there is a vibrant commercial environment for adopting innovative new life sciences products and technologies and rewarding that innovation. Otherwise, international companies may choose to conduct research and development in countries where the domestic market is more receptive to paying for and using the innovative products that have also been developed there.

"I think the market access elements are quite light touch and only covered in rather general terms in the report – it is one of the bigger omissions in the strategy" says Robert Juhasz of Janssen UK. "Many life sciences companies active in the UK are headquartered overseas, and a receptive commercial environment here matters as much to them as a receptive R&D environment. You can't have a holistic life sciences strategy where the downstream adoption and use of innovative medicines is not given as equal importance and reward as the R&D that creates them. It's not a complete strategy in that sense."



NHS institutions are primarily responsible for the adoption of new life sciences products and technologies in the UK. The Bell Report recommends implementing the recommendations of the 2016 Accelerated Access Review (AAR) to streamline the adoption of innovative solutions by the NHS. Roundtable participants say this is absolutely essential to unleashing industrial growth.

“One of the greatest challenges of accelerating industrial growth is adoption, specifically in the NHS,” confirms Cengiz Tarhan. “We’ve developed a number of innovative products, but they have failed to get through the adoption phase, not because the products are not good or are expensive. It’s not necessarily a cost issue because even when products are provided free they are often not adopted. The bigger issue is that the systems struggle to operationalise new products because it takes time and effort to integrate new solutions into existing clinical pathways.”

“ The role for a life sciences strategy should be to take on the hard projects, the really difficult things, for which the prize is huge if you can get there ”

*Stephen Parker, Sareum*

### **Be bold, enter uncharted territory**

One of the most headline-grabbing recommendations of the strategy is the HARP initiative to foster high-risk ‘moonshot’ programmes. The Bell Report outlines a series of areas on which HARP could focus, including digital technologies, healthy ageing and genomics. Roundtable participants believe this initiative would better accelerate industrial growth through investing in riskier areas that the private sector is not currently exploring.

“The role for a life sciences strategy should be to take on the hard projects, the really difficult things, for which the prize is huge if you can get there but which no one wants to invest in at the early stage,” says Stephen Parker of Sareum. “For example, there is real potential around stem cells and microbiomes. An initiative to provide the umbrella to get the enormous amount of data on microbiomes wouldn’t be truly funded elsewhere and represents a real role for the life science strategy.”

## Roundtable participants

### **Andrew Davies**

Director, Market Access,  
ABHI

### **Jonathan Tobin**

Investment Director,  
Arix Bioscience

### **Paul Mussenden**

General Counsel,  
BTG

### **Tony Hickson**

Chief Business Officer,  
Cancer Research UK

### **Leo Gribben**

Partner – UKI TAS Life Sciences,  
EY

### **Robert Juhasz**

Legal Director,  
Janssen UK

### **Melissa Coutinho**

Senior lawyer,  
Formerly MHRA

### **Ben Howlett**

Director,  
Public Policy Projects

### **Stephen Parker**

Non-executive Chairman,  
Sareum

### **Cengiz Tarhan**

Formerly Managing Director,  
UCLB

# All-in on digital?

## Dawn of a digital life sciences industry

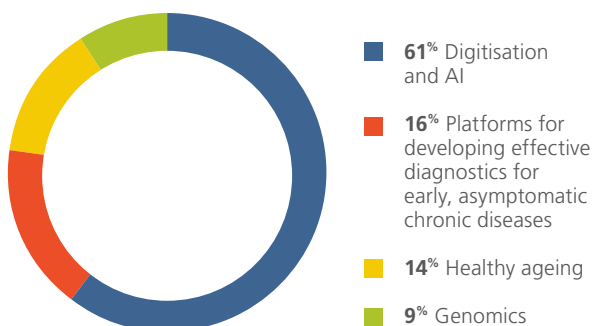
The UK life sciences sector is widespread and diverse. For example, the 'golden triangle' of Cambridge, Oxford and London has three of the world's top universities, major research institutions and a vibrant community of start-ups. Other parts of the UK, such as the Edinburgh-Glasgow corridor, also have strong academic and research infrastructure and are fertile ground for both start-ups and a wide range of more established companies. And Greater Manchester's unique devolved health and social care partnership is now attracting investor interest. But diversity creates a fundamental question for the strategy: which sub-sectors should it try to catapult?

The answer from the life sciences industry is clear: it should bet big on digital. When we asked where HARP should focus, some 61% of our survey participants said digitisation and AI have the greatest potential to drive the creation of an entirely new industry in the next ten years, if supported by the government.

A further 16% selected platforms for developing effective diagnostics for early, asymptomatic chronic diseases; 14% chose healthy ageing; and 9% picked genomics in medicine. These are the four initiatives suggested in the Bell Report as opportunities for unlocking growth. All clearly have potential, but our survey shows that digital technologies are felt – by a wide margin – to offer the most immediate commercial opportunities

It makes sense for the government to back the creation of a digital life sciences sector. The UK is already at the forefront of AI innovation, and the government has also put the creation of an 'AI & Data Economy' sector at the heart of its overarching industrial strategy.

*Which of the following proposed new areas have the most potential to underpin the creation of an entirely new industry in the next ten years if supported by government?*

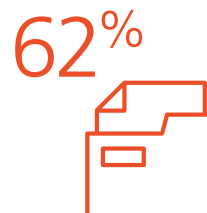


## Records management and treatment design offer immediate digital opportunities

Which digital technologies should the strategy support? The Bell Report states that pathology and imaging are ripe for innovation and that systematic digitisation of pathology images could create huge efficiencies by removing the need for every hospital to have an on-site pathologist. It also says that AI tumour-grading algorithms could be developed based on these images.

While digital technologies could no doubt revolutionise pathology and imaging, the industry players we surveyed believe healthcare records management applications offer the most immediate commercial opportunities, with 62% seeing significant commercial opportunities in applying digital technologies to this field. In this area, digital technologies could automatically classify, tag, archive, retrieve and even dispose of records.

62% think healthcare records management is one of the greatest commercial opportunities for digital technology.



Treatment design was highlighted as offering strong commercial potential by 42% of participants. Many research initiatives have already shown that AI tools can, for example, reduce the time needed to develop cancer treatment plans.

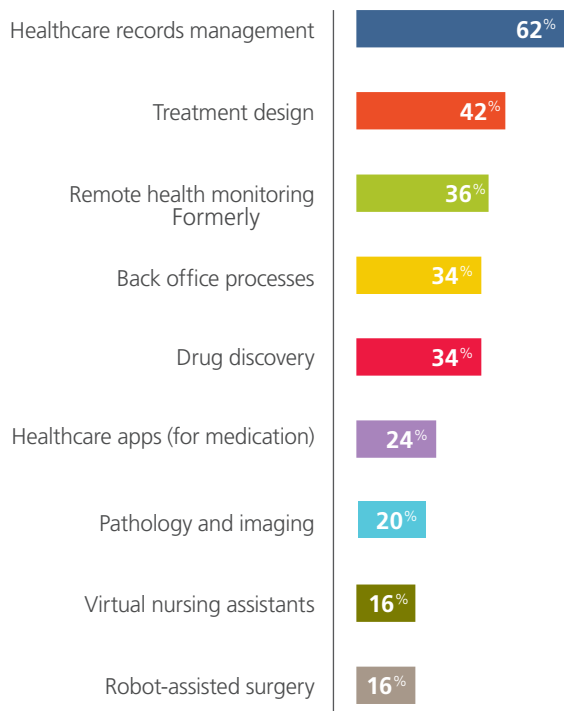
"Using AI to look at whether different treatment and care pathways succeed in different situations would be a good place to explore," says Leo Gribben of EY. "There's an immediate opportunity around this that is within a five-year timeframe."

After treatment design, participants identify remote health monitoring, back-office processes and drug discovery as commercially attractive applications of digital technologies. (Only 20% felt the pathology and imaging highlighted by the Bell Report were among the strongest commercial opportunities.)

Remote health monitoring, especially of elderly patients, ought to be an exciting application of digital



Where are the greatest commercial opportunities for digital technologies (such as AI) to be applied in the life sciences industry? (Please select up to three areas.)



technologies. The Bell Report highlights 'Healthy Ageing' as a major challenge and also a significant opportunity for the UK, given its ageing population and the opportunity for the NHS to act as a testbed.

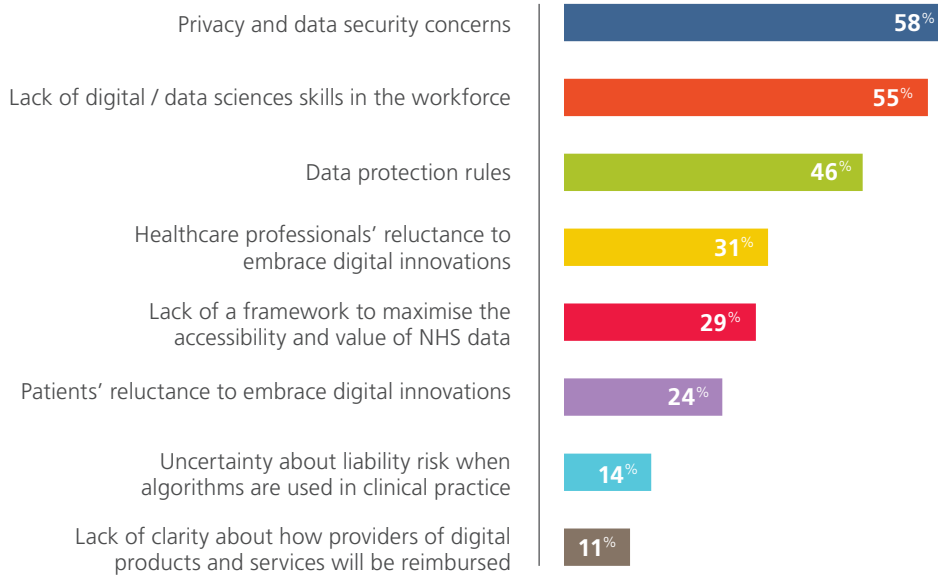
"An interesting application of digital technologies is the use of non-intrusive, smart sensors for elderly care," confirms Stephen Parker of Sareum. "You can monitor whether a person is turning over in bed frequently enough or moving sufficiently around their house. If they are not, an emergency response can be triggered."

Many of these technologies already have a degree of commercial traction. A key question for the government is whether it should back digital technologies that are already demonstrating value, or instead attempt to kickstart new ones that may offer greater potential rewards but may also be more challenging.

"There is a huge market for solutions for people with learning difficulties, but it is too complicated to study, so biotech companies don't target this at all," explains Jonathan Tobin of Arix Bioscience. "It is totally untouched. But it is economically a bigger problem than Alzheimer's disease and maybe even cancer. For me, this should be the real application of state sponsorship – using digital technologies and genomics and other things we are good at to tackle these sorts of problems. But it is not mentioned at all in the strategy."

# Digitisation and data dilemmas

What are the greatest challenges to the growth of a life sciences digitisation and artificial intelligence industry?  
(Please select up to three challenges.)



Our survey participants provide a sobering view of the challenges to growing a digital life sciences sector.

Top of the list are privacy and data security concerns, cited by 58% as a top-three challenge. This relates to fears that organisations might compromise personal data when using it for research, and that individuals might not consent to their data being used if they believe it will be compromised or exploited. In parallel, 46% say compliance with data protection rules is a major challenge.

Data protection issues are front of mind given the recent entry into force of the General Data Protection Regulation (GDPR), which enables regulators to levy heavy fines on organisations that misuse personal data.

The sense that data protection rules might hinder digital life sciences growth has also been heightened by some well-publicised data breaches that happened when patient data was shared to develop digital healthcare technology. For example, the ICO ruled in 2017 that London's Royal Free Hospital failed to comply with the Data Protection Act when it transferred the personal data of 1.6m patients to a company developing a detection and diagnostics app for kidney injuries.

Developers of digital technologies must comply not only with GDPR, but also with the stricter requirements and security standards for patient data set out by the National Data Guardian (NDG).

Data protection issues are certainly not insurmountable. Indeed, GDPR clearly specifies the lawful basis upon which data processing can be used for research, leaving little ambiguity about the requirements for organisations that wish to use it. Nevertheless, timely and appropriate planning is important to ensure that data privacy is appropriately managed.

The participants in our survey felt that a lack of digital skills is the second-greatest challenge to growing the digital life sciences sector. The Bell Report acknowledges this to be a major issue and calls for the government to create an apprenticeship scheme focused on data science.

More fundamentally, the government must decide whether it wishes to 'pick winners' to support in the strategy and, if it does, which these should be. After all, many other life sciences sub-sectors could propel UK industrial growth. If it does want to prioritise digitisation, it should make bold, practical commitments to doing so.

This could involve carving out some of the £2.5bn investment fund incubated in the British Business Bank for companies developing digital innovations specifically for the life sciences sector. Only 1% of our respondents expect this fund to unlock growth – which is understandable because its investment priorities are not specified.

# Data to power growth

## Backing for data initiatives

Just as coal was essential to powering the UK's first industrial revolution, data will be vital to the growth of tomorrow's digital life sciences sector. And beyond digital technologies, the evaluation of clinical and real-world data is critical to developing new drugs and products to drive future life sciences growth.

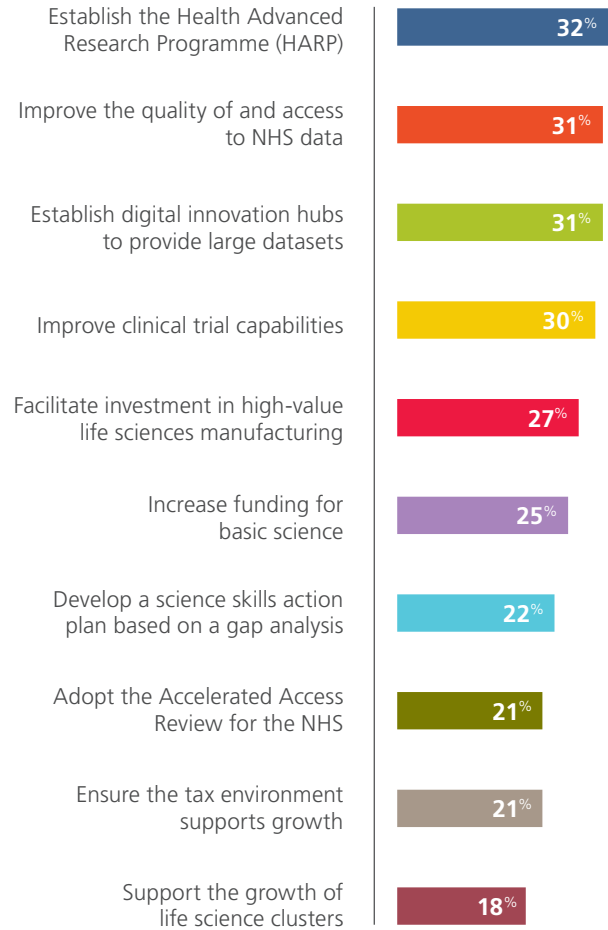
The NHS holds healthcare data on many millions of individuals. The UK should be well positioned to gather this data and use it for commercial purposes. But, in reality, there are many practical issues with harnessing NHS data. Because it is not collected with clinical research in mind, it is often not structured or standardised and may be incomplete. There are also, of course, significant regulatory factors to consider.

"NHS data is always going to be patchy, because it is collected for clinical purposes, not for research, evaluation and commercialisation," explains CMS partner Carina Healy. "But it is not just about NHS data. NHS data needs to be combined with real-world data and convincing the public to give you access to their data from wearables. This completes the picture."

The strategy acknowledges the importance of data in propelling the sector forwards and the practical issues of obtaining and managing it, and makes a number of recommendations to provide the private sector with access to anonymised datasets.

Our survey participants are particularly bullish on the potential for these data-unlocking initiatives to unleash life sciences industrial growth. Their joint-second ranked initiatives to achieve this are: improving the quality of and access to NHS data; and establishing digital innovation hubs that each house healthcare information on 3m-5m people.

*Which of the UK Life Sciences Industrial Strategy proposals have the greatest potential to create long-term industrial growth? (Please select up to three proposals.)*



**National data standardisation is a huge challenge, so build on specific successes**

There are many difficulties with obtaining data from the NHS and there is no simple solution for resolving them. Instead, the government and the NHS must implement a series of initiatives to improve access to NHS data.

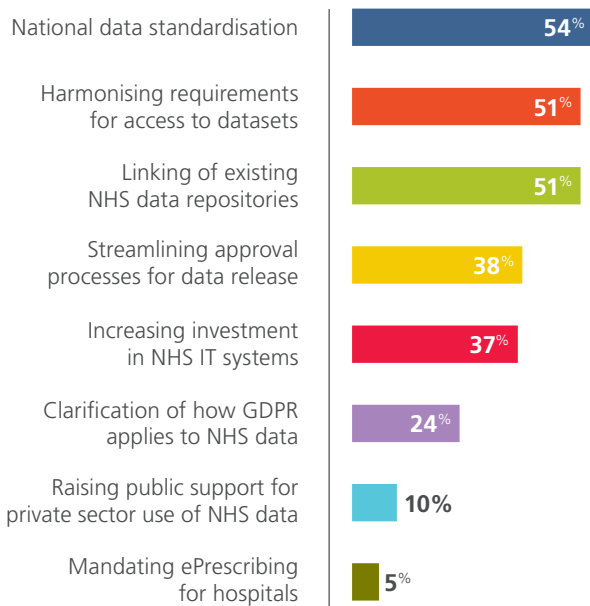
Our respondents believe the three most promising initiatives are: national data standardisation; the linking of existing NHS data repositories; and the harmonisation of regulatory requirements for access to datasets.

Data standardisation will not be easy. For a start, no such standards currently exist. To resolve this, the strategy recommends that “NHS Digital and NHS England should set out clear and consistent national approaches to data and interoperability standards.”

But, even if they did, huge investment would be required to update IT systems to enable data to be collected in a truly standardised format. And that would only create data standardisation moving forwards. Much data contained in historical records would still not conform to the new standards.

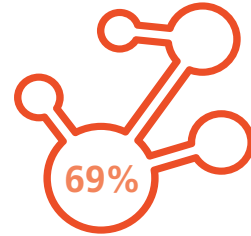
Instead, a more practical and cost-effective step forward may be to identify specific potential datasets that, if collected in a standardised format, could be used for research into new products and technologies.

*Which of the following initiatives are most likely to improve the quality and quantity of data that can be obtained from the NHS? (Please select up to three initiatives.)*



There are already examples of this approach working very successfully in practice. The UK Biobank, for instance, holds healthcare data on 500,000 UK residents and has become a valuable data resource for scientists.

**69%** believe the target of establishing digital innovation hubs to give researchers access to large healthcare datasets is achievable.



Another success story is Genomics England, which is nearing its target of sequencing 100,000 whole genomes from NHS patients with a rare disease, plus their families, and patients with cancer – creating the world’s largest database of whole genome sequences with associated clinical data. The government recently announced that the programme will be expanded, so that a million whole genomes will be sequenced by the NHS and the UK Biobank in the next five years. This is an important theme in the sector deal. According to the Health and Social Care Secretary Matt Hancock, it also forms part of a wider “bold aspiration” to sequence 5m genomes over the same period by working with various partners. The government has not yet spelled out exactly how it hopes to achieve this ambitious goal.

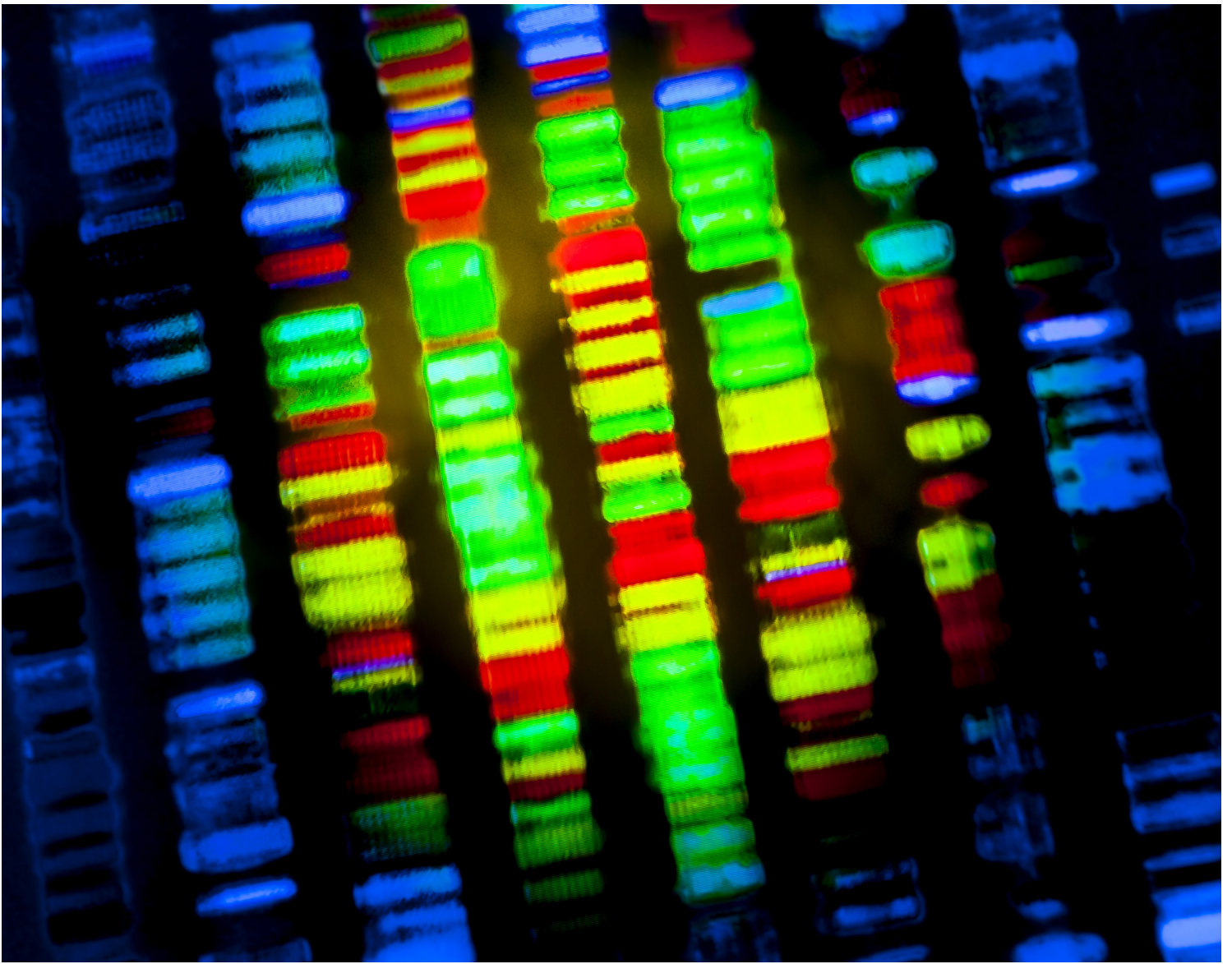
**Rules for accessing data must be clear and consistent**

It is not only data that needs to be standardised. The regulatory and compliance requirements for access to it also need to be made more uniform. As the Bell Report points out, requirements for accessing NHS data often vary by region and by type of institution.

It is, therefore, no surprise that our survey participants rank harmonising regulatory requirements for access to datasets as the joint-second most important initiative in improving the quality and quantity of data that can be obtained from the NHS.

At the moment, private companies wishing to access NHS data are often unsure what the main regulatory requirements are in relation to securing it.

The Bell Report’s recommendation to set out clear and consistent national approaches to the requirements for data access should be implemented and, importantly, communicated effectively to the whole life sciences sector.



### **Don't forget data governance**

Although there are significant industrial growth opportunities linked with opening up NHS datasets, it is imperative to proceed with caution. If patients believe that their data could be used for purposes other than legitimate scientific research, there is likely to be a decline in confidence (and a lack of consent) that will undermine data sharing.

It is therefore essential to implement robust data security and governance processes that the public will trust. Encouragingly, this work has started. In September 2018, the government released an 'Initial code of conduct for data-driven health and care technology'. It establishes some core principles for safe and effective use of NHS data.

Certain data initiatives, such as Genomics England, also provide a good example of effective data governance that others can follow.

"Data shared in the wrong way can end up having negative implications for the patients that trust you," explains Ben Howlett, Director at Public Policy Projects. "They will question what you are doing with their data. Genomics England is a good example of getting this right. They allow researchers and even private companies to go in and use their data, but they have various safeguards in place, one of which is that you can't take any data out of their systems. But this doesn't actually prevent any interesting research from being done with the data."

# Focus on implementation

## Many objectives are unrealistic

There is deep scepticism about whether some of the goals set out in the Bell Report can be met. In particular, only 8% of our survey participants believe it is possible to create four UK companies valued at over £20bn in the next ten years and only 13% say it is feasible to create two entirely new industries in the same time period.

Fewer than half our participants believe that in the next five years the UK can attract 2,000 new discovery scientists, or ten large (£50m-£250m) capital investments in life sciences manufacturing. And only about half (49%) believe the number of clinical trials in the UK can be increased by 50% in five years.

Only 8% believe it is possible to create four UK companies valued at over £20bn in the next ten years

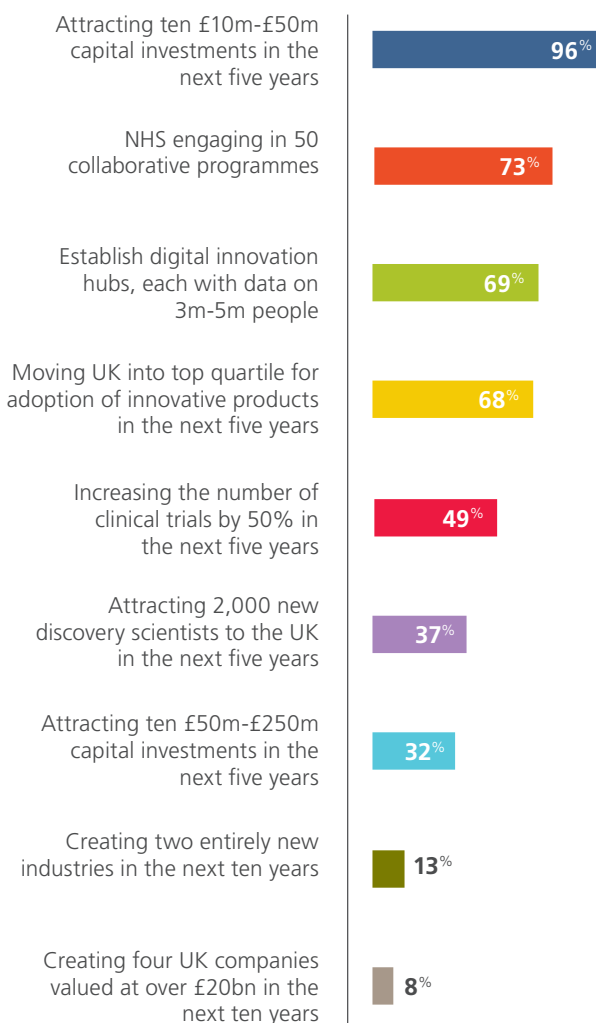


Our respondents highlighted a number of reasons for their doubts about whether the strategy's objectives are achievable. These include an unhelpful legal and regulatory environment, a lack of early-stage and growth funding for life sciences companies and a lack of NHS funding. These are explored in detail in the next section.

Another major factor is a lack of detail about how the strategy will be implemented. Tellingly, a resounding 95% of our participants want more clarity on implementation.

"The objectives will either succeed or fall by the wayside depending on implementation," says Leo Gribben of EY. "There are huge hurdles to some of them. For example, the UK market is only 3% of the global market in revenue terms for pharma products. Will an AAR programme really encourage big pharma to run lots of trials here, given the size of the UK market? The objectives are laudable, but the strategy is currently missing the implementation piece of the jigsaw."

To what extent do you believe the following objectives of the industrial strategy can be achieved? (Bars demonstrate the percentage that believe the objective is achievable.)



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Leo Gribben, EY

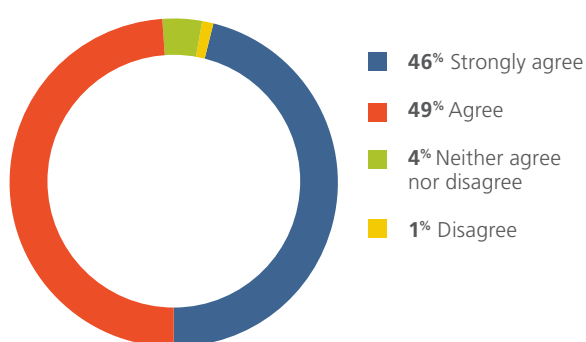


The House of Lords Report put forward a number of proposals to improve implementation, including the creation of a clear plan with milestones, the establishment of an independent body to drive implementation of the plan, and a governance structure that would hold this body to account on progress. However, the government largely ignored the Lords' recommendations in this area and pressed ahead with setting up two large committees to oversee implementation: the Life Sciences Council and the Life Sciences Industrial Strategy Implementation Board. Our survey findings suggest that the sector does not believe this arrangement is adequate.

Providing clarity on implementation will be crucial to ensuring that the strategy's objectives have the best chance of success. Indeed, the House of Lords Report cited much evidence that the 2011 industrial strategy was not successful due to the lack of an implementation plan.

Even more fundamentally, the government must make clear whether it plans to adopt the recommendations outlined in the Bell Report in full and whether its objectives will be translated into actual targets.

*To what extent do you agree that the strategy needs more clarity on implementation?*



### Partially achieving objectives still counts as success

Fulfilling some of the recommendations in the strategy will be, to say the least, challenging. Inevitably, some will not be achieved. None the less, scepticism about whether the strategy's objectives will be met does not mean that the recommendations should not be pursued and adopted.

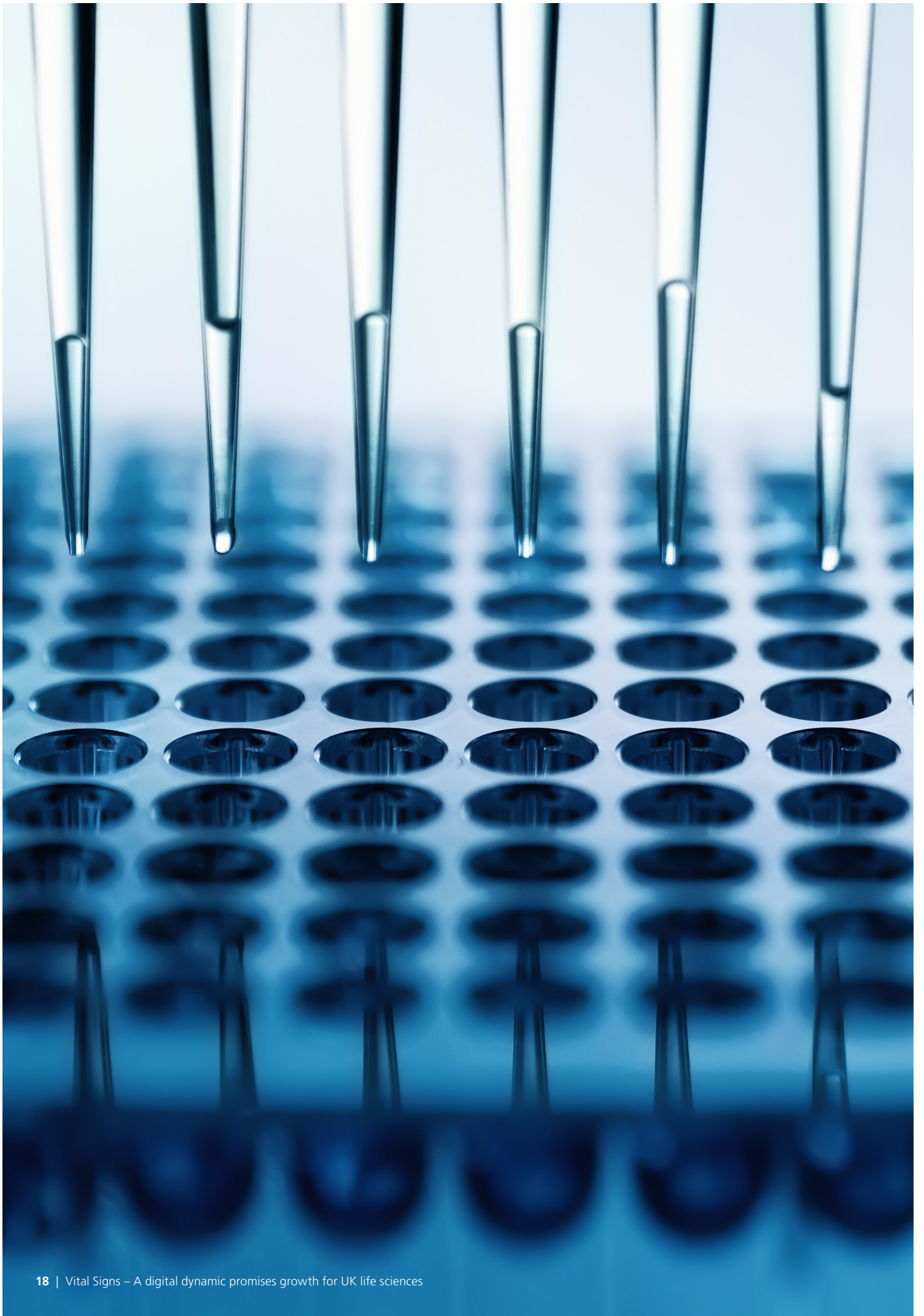


Only **13%** say it is feasible to create two entirely new industries in the next ten years.

Indeed, while very few of our respondents believe it is realistic to create two entirely new industries, they were happy to support the recommendation to establish HARP because of its potential to create long-term growth.

However, there is also a sense that some of the objectives are unrealistic, even if all of the aforementioned implementation issues are resolved. For example, the UK simply does not have a strong track record when it comes to growing companies into multi-billion-pound enterprises.

"Setting targets to create huge companies or new industries looks great to politicians, but, actually, you need to do many things to build a company of that size," says Stephen Parker of Sareum. "A whole set of attitudes are needed, which, frankly, the UK has shown itself not to have in the same way that US companies do. Many have sold out. Some of these targets are making rods for the sector's back."



# Navigating the obstacles to growth

## Regulatory barriers loom large

Our respondents feel an unhelpful regulatory environment is the most significant challenge to accelerating growth, with data protection and privacy regulation being of most concern. Some 93% believe that data protection and privacy laws impede life sciences innovation and 89% say legal issues impede NHS data sharing.

GDPR clarifies specific provisions for the use of data for research and the government has issued initial guidance about handling NHS data. But, importantly, this has not yet filtered down to those in charge of releasing NHS data.

“Regulatory restrictions can be a real blockage to progressing innovation,” confirms Paul Mussenden of BTG. “We need to continue to translate the existing framework and positive policy sentiment across a range of issues into practical decision-making.”

Uncertainty about how data must be properly handled undoubtedly drives the perception that data protection and privacy laws impede innovation and data sharing. The private sector and research institutions must consider data access issues right at the outset of a research project, so that any challenges can be identified and tackled early on.

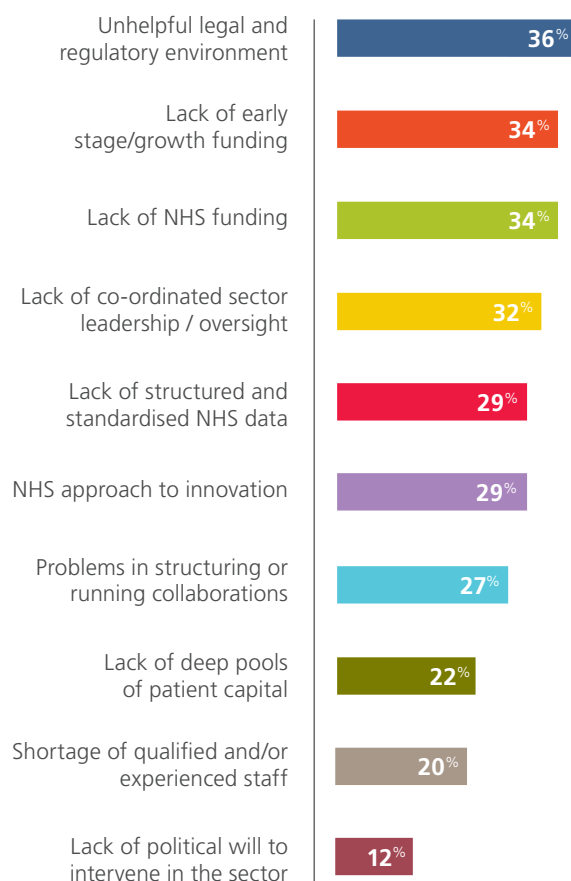
Data protection aside, the participants in our survey highlight a number of other regulatory issues that slow life sciences industrial growth. Indeed, 70% say there is a lack of clarity as to how existing regulatory guidelines apply to new digital technologies, such as AI algorithms, which evolve after being released into the field.

We also saw calls for a number of regulations to be updated in order to unlock growth. To boost investment in the sector, 90% of our respondents said allocation rules that limit pension fund investment in illiquid, long-term projects should be relaxed. To ensure the life sciences sector has access to the skills it needs, 81% thought immigration controls for the sector should be relaxed.

## NHS adoption

Research by the Office of Health Economics indicates that the UK lags behind other countries when it comes to the adoption and uptake of new products for patients. It is not even in the top quartile of comparator countries on this measure.

*What are the greatest challenges of accelerating life sciences industrial growth? (Please select up to three challenges.)*



A lack of NHS funding is a major reason why the adoption of innovative solutions is slower than in other countries. Understandably, when budgets are tight, budget-holders focus on procuring products that are essential to maintaining core services, rather than on new solutions. In addition, the non-monetary costs of introducing new products, especially new technologies, are significant if they involve training and integration with legacy systems.

What’s more, NHS procurement of innovative solutions is often fragmented, meaning that new products are reviewed multiple times by different NHS bodies.

“It can be relatively easy to get government funding and do a pilot with the NHS, but it is much more challenging to get your first NHS contract,” adds Steve Dodsworth, CEO of DHealth. “It is often a real shock when you get your contract, approach another part of the NHS and find out that you have to start over again because the evidence you have from the first organisation is not considered to be valid.”

To improve the situation, the Bell Report proposes that the recommendations of the AAR be implemented in full. These include making NHS expenditure on technology more predictable by undertaking collaborative horizon scanning, an accelerated adoption pathway for strategically important and transformative products, and the use of incentives to support local uptake of innovative solutions.

The implementation of these measures would certainly help to give companies and investors confidence that the NHS will not be resistant to adopting new solutions. But spending priorities and resourcing will remain major issues. It is worth remembering that, as the Lords Report notes: “Sir John Bell told us that one of the reasons why the NHS struggles with adopting innovations is because ‘[it is] struggling to do even simple things well. The idea that you are going to put a whole lot of this really sexy tech-related stuff on top is challenging’.”

**Lack of investment**

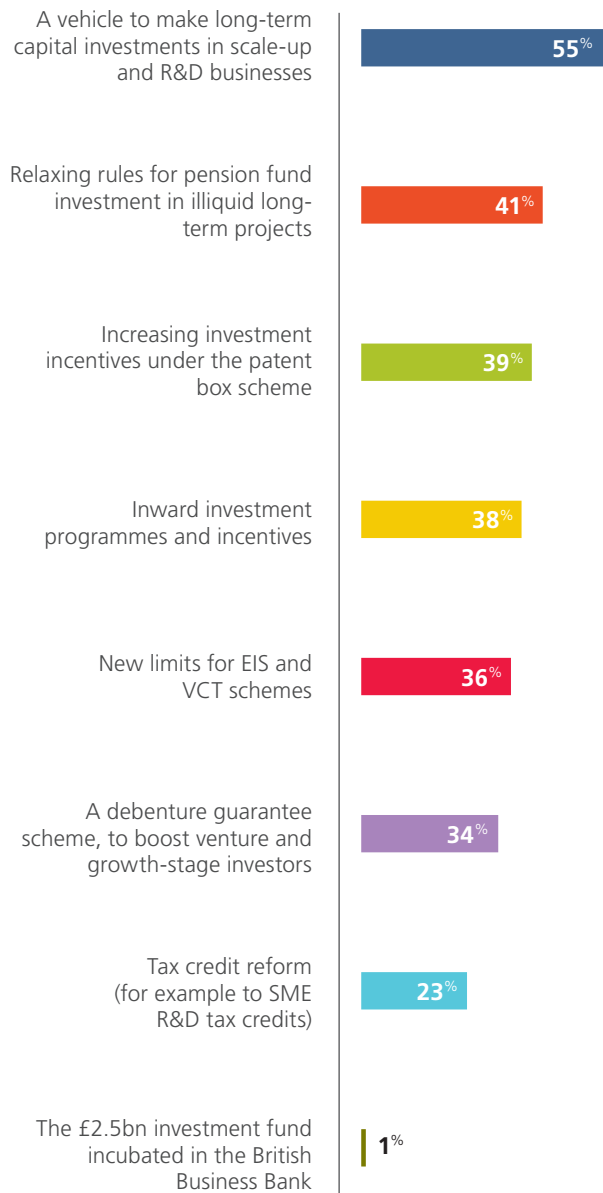
However, a greater threat to long-term life sciences growth than NHS funding or processes is a very familiar one: lack of capital. Our respondents ranked the lack of early-stage/growth financing for life sciences companies as the joint-second most significant challenge to accelerating growth.

How can this funding gap be plugged? The most popular solution among those we polled was the creation of a long-term investment vehicle to deploy capital in scale-up and R&D businesses, as recommended by the Patient Capital Review.

Collaboration between the government, the private sector, charitable funds and investment institutions will be essential to financing long-term projects, especially the ‘moonshot’ programmes envisaged by HARP. The key question for the strategy is: who should be responsible for identifying the best opportunities and driving collaboration?

“To fund long-term projects that are beyond the investment horizon of venture capital and private equity, the government needs to team up with venture philanthropy and charities,” says Tony Hickson of Cancer Research UK. “There is an opportunity there, but the question is, ‘what’s actually happening and who’s convening it?’ I know there have been some early discussions around early detection, but it needs a push.”

*Which of the following would be most effective in encouraging long-term capital investment into life sciences companies? (Please select up to three initiatives.)*



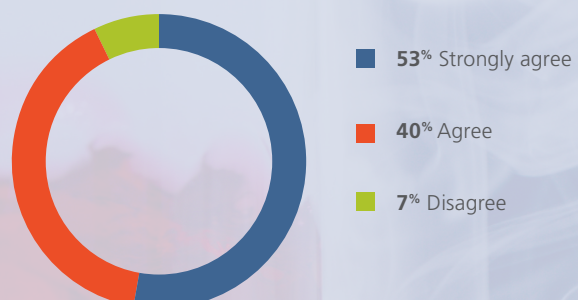
## Brexit

The Bell Report arose from the government's green paper on building an industrial strategy post-Brexit. It does not assume any particular structure for the future relationship of the UK and the EU, although it recommends that in the area of life sciences regulation "the focus should be on alignment" and UK participation in EU systems and processes. It also advocates "an immigration system which allows talented and skilled students, researchers and workers to enter and remain in the UK".

Over 90% of our survey participants say Brexit will undermine the ambitions of the Bell Report. There are certainly numerous ways in which it could affect the life sciences industry – such as discouraging investment, restricting access to talent, imposing barriers to international trade, removing EU research funding, disrupting supply

chains and complicating the process of obtaining regulatory approvals. In a very visible symbol of the changes to come, the European Medicines Agency is leaving Canary Wharf and moving to Amsterdam.

*To what extent do you agree that Brexit will undermine the ambitions of the strategy?*



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Our global Life Sciences & Healthcare Sector Group has over 300 lawyers. We support the top 20 global pharmaceutical companies and the top 10 global medical device companies around the world, as well as many other industry players, including charities, universities, investors and start-ups.

We are one of only a handful of law firms with the strength and depth of expertise to advise and assist life sciences clients on all aspects of their business and strategy. We work on matters ranging from complex and strategic transactional, financing and structuring problems to day-to-day business concerns such as public procurement, tax, competition, IP protection, exploitation and enforcement, product liability, supply chain issues, outsourcing and other commercial agreements, and employment and pensions matters, as well as authorisations, regulation, disputes, risk and compliance.

Unlike most firms, we also have own team of dedicated patent attorneys, dealing with patent prosecution, EPO opposition and regulatory exclusivity and product life extension.

Our experts cover all the sub-sectors in which life sciences companies operate, including medical devices, e-health, pharmaceuticals, diagnostics and biotechnology. Many of them have also worked as

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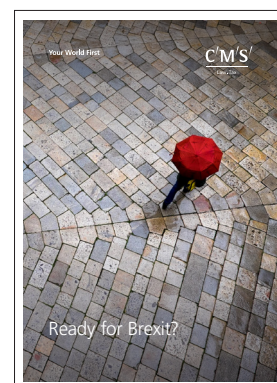
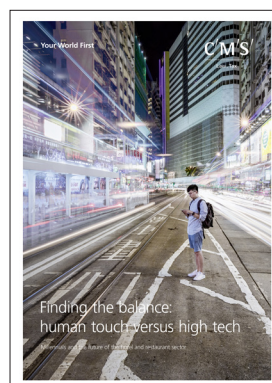
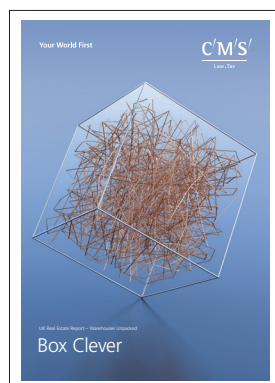
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