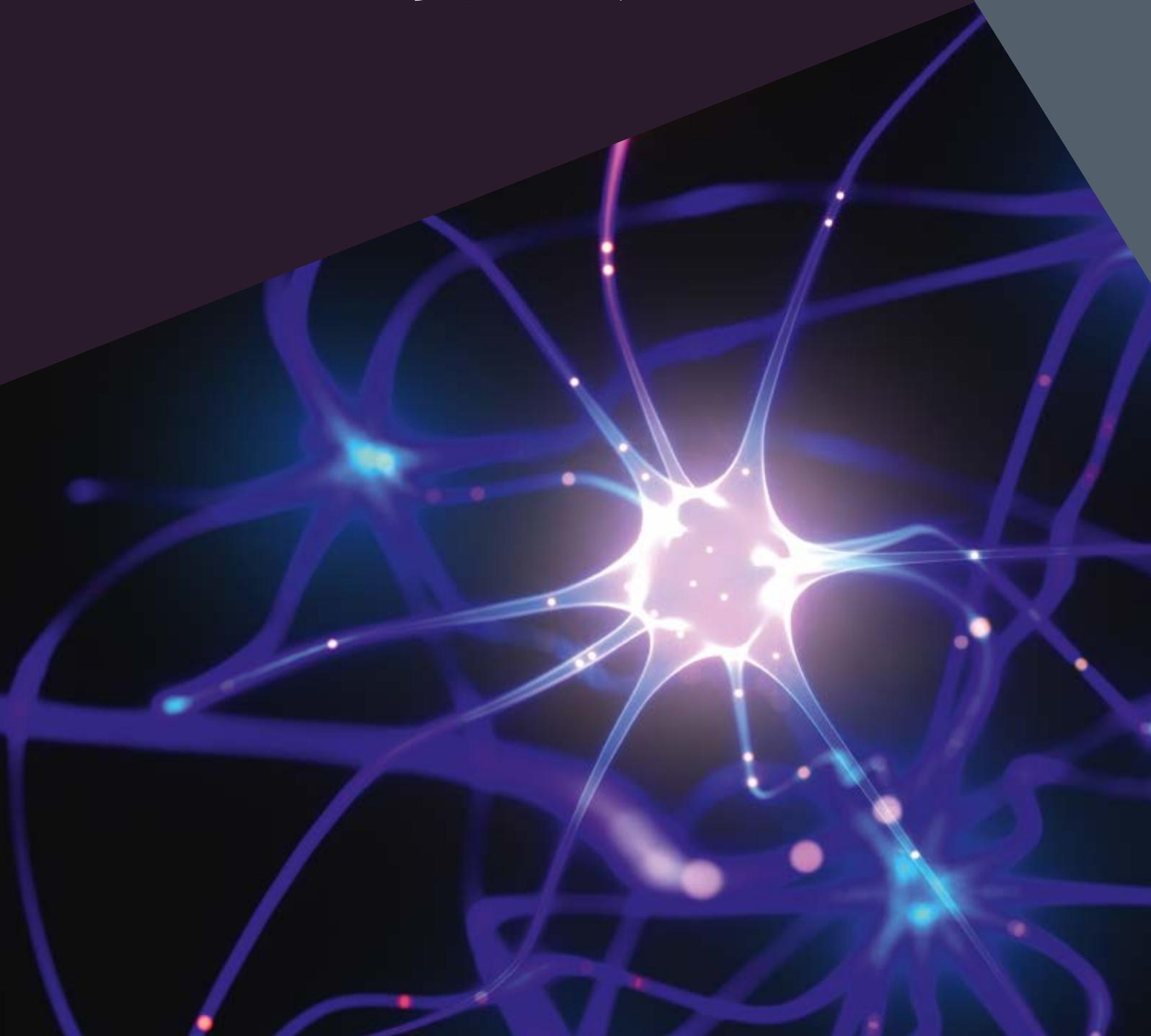


Life Sciences Industrial Strategy Update



Foreword

In the two years the Life Sciences Industrial Strategy has been in existence, there has been very substantial progress in making the UK a more attractive place for life sciences companies to succeed and grow.

These developments are the result of a strong collaboration between all aspects of this diverse industry - pharma, biotech, medtech, digital and diagnostics - the wider research community in the UK, the NHS and government. Together these parties have identified opportunities and acted on them, and have similarly recognised our limitations and worked to overcome them. This coalition has made a significant difference to the sector and has also shown what a clear, well-targeted strategy can achieve.

This report describes the progress made against the targets set in the original Life Sciences Industrial Strategy published in August 2017.

A substantial majority of the objectives in the Life Sciences Industrial Strategy have been met and more are being delivered now.

We have demonstrated that the distinctive aspects of the UK system - a large, single payer health system, unique sets of health records, a globally distinguished science base, leading assets in genomics and cohorts, a strong skills base, and regulatory and ethical standard setters - can all be used to deliver a co-ordinated strategy. Now, with a strong new government that has already demonstrated its commitment to science in general, and life sciences in particular, we need to create opportunities for a new inflexion point taking the sector toward even more ambitious goals. There are opportunities now to capitalise on the wealth of genomic information by turning variants into insights about function, at scale. Similarly, we need to deliver on the ambition to transform our healthcare system to one that identifies disease earlier using risk and stratification to implement a broad strategy for public health.

This is an exceptionally attractive agenda for global companies here and as we improve the quality of NHS data we will strengthen the quality of our research and the health system even further. We will also ensure our regulatory and ethical environment remains world-leading post-Brexit, and take the opportunity to create maximum flexibility for innovative and responsive approaches to regulation, using health data to underpin rapid progress in the field.

One significant advantage of this Life Sciences Industrial Strategy is that it creates not only opportunities for economic growth but it also underpins a more efficient and effective health system. Together, it is hard to see where government can better spend its resources and energy.

Professor Sir John Bell, GBE, FRS
Regius Professor of Medicine,
The University of Oxford

A handwritten signature in dark ink, appearing to read 'John Bell', written in a cursive style.

Introduction

The Life Sciences Industrial Strategy set out a vision to deliver future growth for the sector and highlighted opportunities for the UK to build on its strengths in order to remain globally competitive.

Since publication, the sector has grown and has been supported by a huge number of policy, regulatory and scientific commitments to ensure the UK remains a world-leading global hub for life sciences. We have continued to work closely with the sector throughout delivery and a substantial majority of the recommendations in the Life Sciences Industrial Strategy have been or are being addressed already, from increased capital liquidity to skills programmes, improvements to our clinical research environment, manufacturing infrastructure and innovative commercial arrangements between the NHS and industry. This document brings together the exciting changes and key programmes over the last two years in one place, highlighting the significant strengths of the sector and the UK's ongoing commitment to maintain its position as a global pioneer for life sciences.

The UK is home to one of the strongest, most productive health and life sciences industries globally. This success attests to our strong science base and commitment to building a complete ecosystem that brings together innovation, development, commercialisation and access to patients at world-leading levels, enabling innovators to benefit from a complete development cycle and businesses to grow and thrive.

The make-up of the industry globally is changing: medtech, data and digital-based technologies are informing and changing the sector. The Life Sciences Industrial Strategy signalled the importance of these activities and the UK is now at the forefront of these changes with strong growth in new and emerging sectors. For example, digital health is now the largest medtech segment, and inward investment to the UK artificial intelligence (AI) sector has increased by 17% over the past year, more than the whole of Europe combined. Similarly we indicated the importance of a major shift in therapeutic platforms, taking the move into biologics that occurred 20 years ago one step further, into gene therapy and nucleic acid-based therapy. We are making real commitments to these areas to ensure the UK becomes world-leading in these exciting therapeutic developments.

Underpinning growth in the sector is the UK's powerful research landscape and high-quality science base. The UK is home to three of the top ten universities in the world for life sciences - Oxford, Cambridge and University College London¹ - and UK research accounts for 12% of all life sciences academic citations, with the UK's share of the top 1% of global life sciences academic citations at 18% (second only to the USA in both cases and ahead of Germany, Canada and France)². The UK is also a driving force for innovation and is maximising benefit from its world-leading research. Research shows that 42% of UK life sciences companies have been spun-out from academic institutions - ten times the rate across all sectors³. Between 2013-17, the UK was home to five of the top ten universities in the world (and the only European country) by value of capital raised via their spin out companies, including world-leading Cambridge⁴.

- 1 Times Higher Education, 2019. *World University Rankings data*. Available at: <https://www.timeshighereducation.com/student/best-universities/best-universities-life-sciences-degrees>
- 2 Office for Life Sciences, 2019. *Life science competitiveness indicators, 2019*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/811347/life-sciences-competitiveness-data-2019.pdf
- 3 Beauhurst, 2019. 'The UK's fastest growing life sciences companies' report. Available at: <https://about.beauhurst.com/blog/uk-fast-growing-life-sciences-companies/>
- 4 Global University Venturing, 2018. '2013-17 data review' report. Available at: <https://globaluniversityventuring.com/2013-17-data-review>

Following the recommendations of the Life Sciences Industrial Strategy we have:

- ▶ Continued to invest in the science base, committing to boost UK spending on R&D to 2.4% GDP by 2027 and rising to 3% with an **additional £4bn invested in R&D** since 2017.
- ▶ Delivered a step change in ambition and a **commitment to increase NHS uptake** of the best value new treatments and technologies by establishing the Accelerated Access Collaborative, with a new Long Term Plan and funding package for the NHS now in place.
- ▶ Created a **Commercial Medicines Unit, alongside a new long-term pricing agreement between the NHS and industry** and the launch of a new commercial framework. Together these are supporting faster appraisals and faster patient access to the best-value new medicines, along with growth in branded medicines spend.
- ▶ Supported investment into knowledge intensive sectors like the life sciences through a number of programmes. Most recently, the development of a **dedicated life sciences scale-up investment programme**.
- ▶ Invested in new national infrastructure for the life sciences including the **Alan Turing Institute** for data science and artificial intelligence and the cross-sector **Rosalind Franklin Institute**.
- ▶ Launched the world's largest genomics project to deliver the **whole genome sequencing of all 500,000 UK Biobank participants** following the successful **completion of the 100,000 Genomes Project** by Genomics England.
- ▶ Launched the **new flagship Accelerating Detection of Disease programme, a 5 million volunteer cohort with genomic and phenotypic data** and crucially longitudinal biological sampling, available for research purposes.
- ▶ Launched the Digital Innovation Hub Programme which aims to enable a UK-wide life sciences environment that provides responsible and safe access to **rich, research-ready health data, technology** and science, research and innovation services.
- ▶ Designed and piloted a **centralised data-enabled clinical trials** service fit for the future through the NHS, now being further developed by the NHS DigiTrials Digital Innovation Hub.
- ▶ Simplified and sped up trial set-up by implementing a **new national approach to costing and contracting** for commercial contract research.
- ▶ Enhanced site and workforce capacity for late-stage clinical research by **establishing five dedicated Patient Recruitment Centres**.
- ▶ Continued to develop an **innovative regulatory environment** with a suite of commitments in AI, advanced therapies, genomics and precision medicine.
- ▶ Ensured that we have the best talent, skills and people to support the needs of the sector including: a national programme in the AI sector; Digital Fellowships in Healthcare; and establishing the Advanced Therapies Apprenticeship Community.

In the next few months we are publishing a national genomics strategy, a national data policy framework to support research partnerships and a common gateway for data access, and we are creating a 'single front door' to the UK's markets for investors and innovators.

We will continue to work with the sector through the Life Sciences Council and other routes to deliver the vision of the Life Sciences Industrial Strategy and ensure that the UK is creating a complete ecosystem for the life sciences that will keep us at the forefront of medical research and innovation.

NHS collaboration

NHS Access and Innovation

In the NHS, the UK has a world-leading single payer health system covering 65 million people, globally-leading clinical research, and the biggest single buyer of medicines in the world. By continually improving how the NHS and our life sciences companies work together, we have an unparalleled opportunity to transform the health of millions of patients and to reinforce the UK's position as global leader in life sciences.

Grasping this opportunity requires ambitious and mutually beneficial collaboration between industry, patients and the system. We have already seen a host of successes, from individual innovative schemes, such as the **Salford Lung Study to Europe's first full access deal for Kymriah, a new cell therapy for cancer**. This shows what's possible but now we want and need these to become the rule not the exception.

We know some health systems adopt innovation faster. The NHS's multiple layers and organisations can make approvals and reimbursement difficult to navigate and new personalised treatments challenge our regulatory and assessment systems. But the last few years have seen a step change in ambition and **a commitment to increase NHS uptake** of the best value new medicines and healthtech, with the **expanded Accelerated Access Collaborative, a new Long Term Plan and funding package for the NHS all now in place**. We are also taking huge strides to make the UK the destination of choice for companies to design, develop and deploy their new technologies and treatments.

We are creating the most collaborative and co-ordinated life sciences ecosystem in the world. Leaders from across industry, healthcare and government are now coming together to tackle the major systemic barriers to the adoption and spread of new innovations within the NHS, ensuring the best innovations get from the bench to the bedside faster than ever before. The government has proposed establishing a new **£500m Innovative Medicines Fund**, to give patients quicker access to the most cutting-edge medicines for cancer and other diseases.

The Accelerated Access Collaborative (AAC) is the forum for this collaborative engagement and the **umbrella organisation for UK health innovation**. The AAC is already delivering successes, with ongoing **support to increase the use of a host of proven innovations** which have the potential to benefit **up to 500,000 patients and save the NHS £30m**. We have seen significant increases in uptake of the products that the AAC has identified, and further high-quality innovations will be identified by the AAC later this year. The AAC has also agreed co-ordinated plans to support the regulation, assessment and adoption of three key new technologies: advanced therapy medicinal products (ATMPs), tumour-agnostic therapies, and the use of AI technologies in diagnostics and screening.

In addition, the AAC is creating a single approach to horizon scanning and demand signalling, so innovators know what problems they need to solve, and the NHS is primed to make use of cutting-edge health innovations as soon as they come to market.



The NHS is one of the most commercially effective healthcare providers in the world, with the **flexibility and commercial expertise** to strike innovative and exciting new deals which deliver for industry, clinicians and patients. The expanded **Commercial Medicines Unit (CMU) in NHS England** is backed by a **long-term pricing agreement between the NHS and industry**, and the **development of the NHS's new commercial framework**. Together, these are supporting real-term growth in branded medicines spend, faster appraisals, and a commitment to increase NHS uptake of the best value new medicines.

The impact is already being felt with **Europe's first full access deal for Kymriah, a breakthrough CAR-T therapy**, just 10 days after the treatment's European marketing authorisation. This has been followed by funding for a **revolutionary new medicine (Luxturna), which will ensure up to 100 children living with a retinal dystrophy have access to treatment for the very first time**.

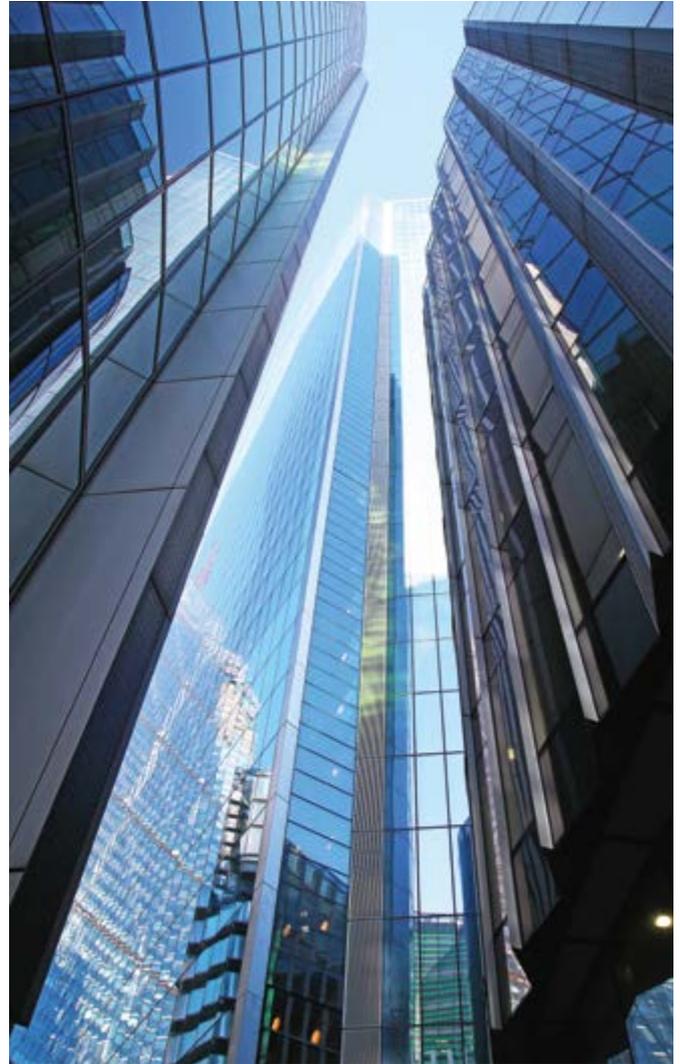
Finally, we are capitalising on the UK's expertise in innovation to build a cutting-edge health system with the technology to tackle some of the most pressing healthcare challenges. NHSX is overseeing over £250m in targeted funding to help the best UK innovators to design, develop and deploy new technologies, utilising AI to improve diagnostics, system efficiencies, knowledge generation and public health. The £130m AI award launching this year will support companies using AI techniques to deploy and scale within the NHS and wider care system. These programmes build on our ground-breaking national Test Beds programme, which brings NHS organisations together with healthtech innovators to test new technologies in real-world settings.

Business Environment

We have a long history of world-leading life sciences research and development in the UK, but a major barrier to scaling innovative UK life sciences companies and sustaining growth has been a lack of long-term investment. A major area of focus in the Life Sciences Industrial Strategy was to ensure that promising health and life sciences companies reach their full potential here in the UK.

The pipeline of innovation in UK life sciences is fed by small, entrepreneurial bioscience firms, which rely heavily on angel investment and venture capital (VC) support. **We have supported and incentivised private investment** into knowledge intensive sectors like the life sciences through several programmes, including increased levels of tax relief support schemes such as the **Enterprise Investment Schemes** and **Venture Capital Trusts**, and by launching British Patient Capital in June 2018. The Financial Conduct Authority has been working with large pension funds to remove impediments that prevent investment into high-risk, high-growth companies. The failure to scale UK biotech companies has been a significant issue in the past and the government is determined to change this situation.

The British Business Bank (BBB), the UK's economic development bank, delivers a range of debt and equity programmes through private finance partners. Most recently, through the BBB, we have **committed to deliver a dedicated life sciences scale-up investment programme, worth around £600m**. UK public sector investment of £200m is expected to leverage a further £400m private funding for the sector, with the ambition to maximise and catalyse future investment in UK life sciences. The programme will provide a vital pool of patient



capital for the sector that will enable more UK life sciences businesses to scale and grow, and ensure that the UK remains a world-leader in life sciences innovation.

A number of targeted initiatives have been established to further increase public and private funding for innovative life sciences companies at all stages of their growth, such as: **the Small Business Research Initiative Healthcare; the Digital Health Technology Catalyst; the SME MedTech Fund; and the "Invention 4 Innovation" (i4i) programme.**



Targeted help at regional level is also in place.

The Academic Health Sciences Network

has made it easier for innovators to navigate sources of funding and local opportunities for entrepreneurs, as well as enabling real world validation, adoption, and spread of innovative products. In the past few years, the Academic Health Sciences Network has leveraged over £150m in industry investment, and supported over 3,600 innovations from over 2,600 companies. And in July 2019, the UK launched a **renewed Life Sciences Opportunity Zone (LSOZ) offer**, which will promote and support science parks and other regional innovation 'clusters' to attract investment and enhance local R&D and innovation collaborations.

Across all sectors, the UK's private equity landscape has grown in recent years, with a record £9.41bn of equity funding deployed in 2019 at Q3⁵. Private sector investment in the UK life sciences has also grown, from less than €0.5bn investment to nearly €15bn from 2011-2017⁶. This is reflected in key subsectors - for instance, in 2018, UK biotech raised a record £2.2bn, an 85% increase on 2017⁷. Internationally, foreign direct investment capital expenditure in the life sciences has also grown, to £1.1 bn in 2018, nearly three times the 2014 level and the highest in eight years⁸.

5 Beauhurst, 2019. 'Equity Investment Market Update: Q3 2019' report. Available at: <https://about.beauhurst.com/blog/equity-investment-update-q3-2019/>

6 European Investment Bank, 2018. *Financing the next wave of medical breakthroughs - What works and what needs fixing*. Available at: https://www.eib.org/attachments/pj/access_to_finance_conditions_for_life_sciences_r_d_en.pdf

7 The BioIndustry Association, 2019. *Confident capital: backing UK biotech*. Available at: <https://www.bioindustry.org/uploads/assets/uploaded/5ba01884-3e05-44e1-a616d88c096e87cd.pdf>

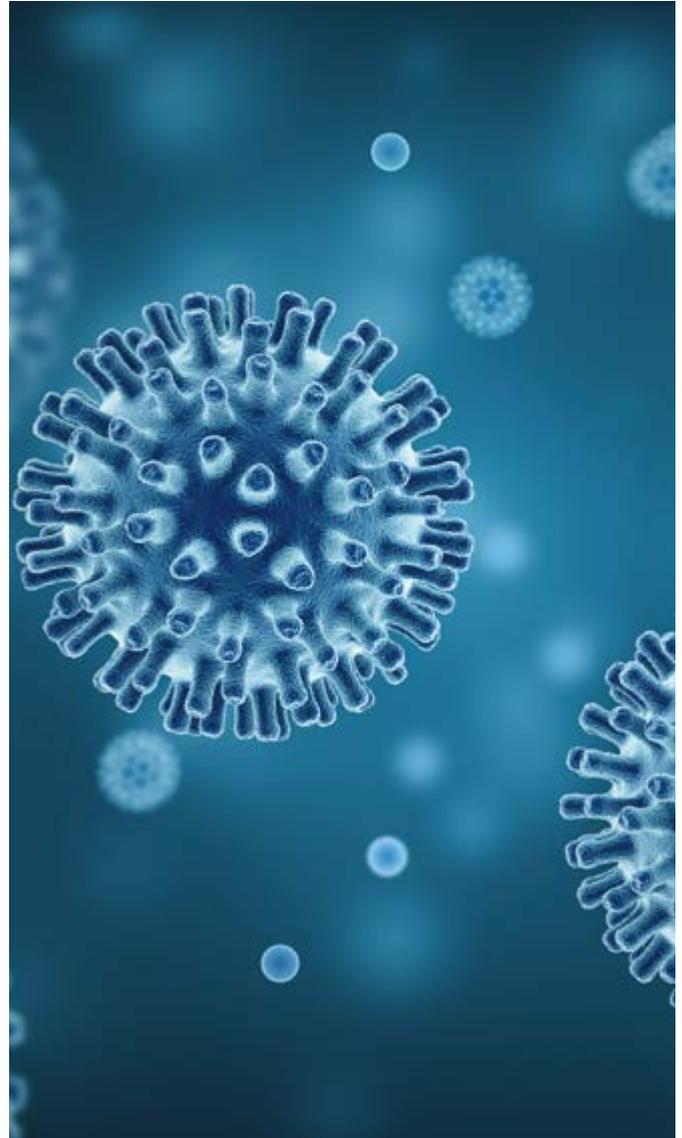
8 Office for Life Sciences, 2019. *Life science competitiveness indicators, 2019*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/811347/life-sciences-competitiveness-data-2019.pdf

Reinforcing the UK Science Offer

The Life Sciences Industrial Strategy highlighted the need to maintain the UK's excellent science base and take nothing for granted.

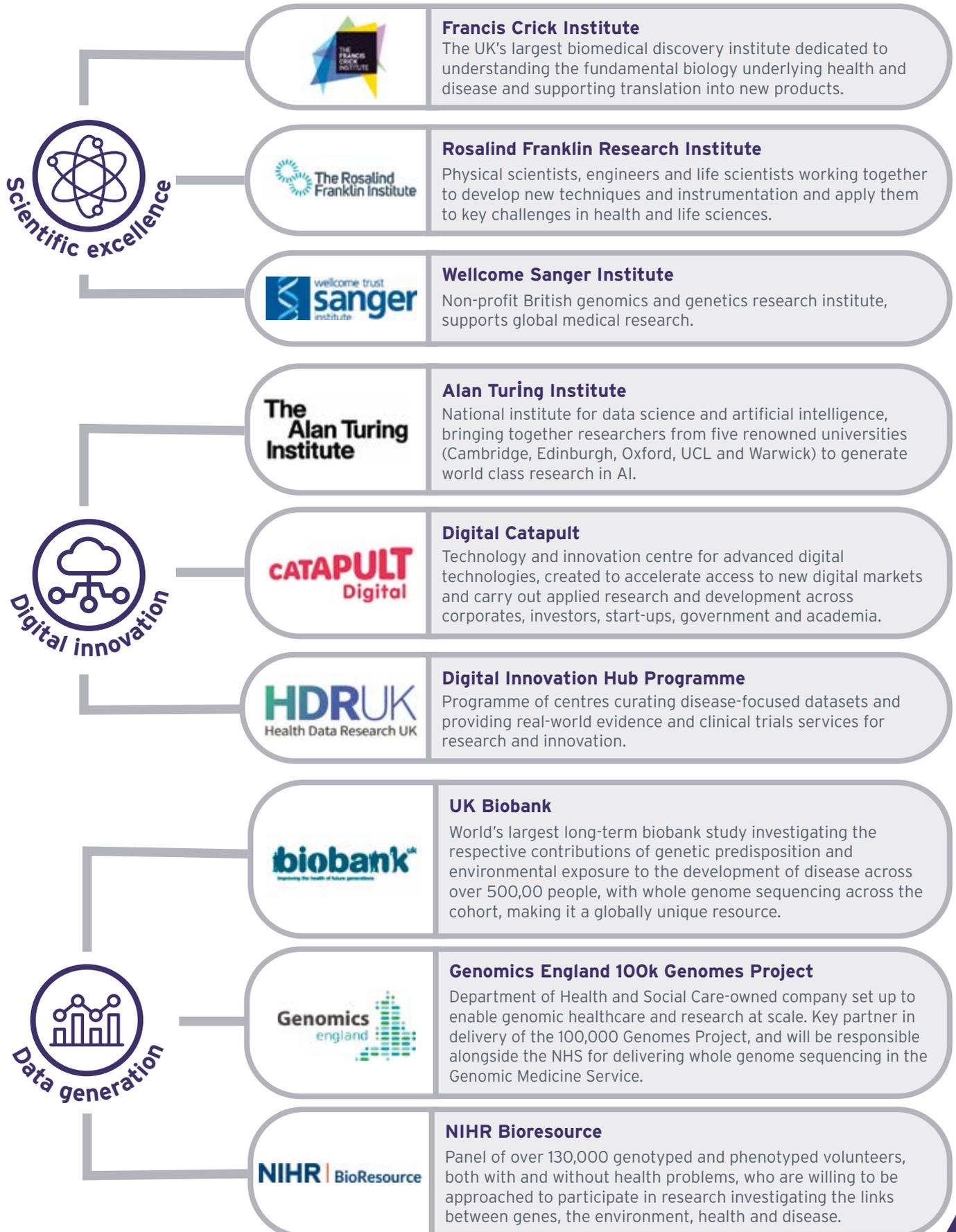
The UK's investment in health R&D is internationally leading, investing \$3bn government funding in 2017 - around double that of Germany, Japan, Canada and other competitors, and behind only the USA globally⁹. Substantial progress has already been made towards the ambitious commitment to boost UK spending on R&D to 2.4% GDP by 2027, with an additional £4bn invested in R&D since 2017.

This uplift has enabled the UK to invest in an impressive national infrastructure that supports the goals of the Life Sciences Industrial Strategy.



⁹ Office for Life Sciences, 2019. *Life science competitiveness indicators, 2019*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/811347/life-sciences-competitiveness-data-2019.pdf

The UK Life Sciences Infrastructure



Clinical Research

The Life Sciences Industrial Strategy highlighted the UK's strength in clinical research and the importance of building further capabilities, including improving speed and efficiency and strengthening our innovative trials offer in order to attract further investment to the UK and bring benefits to patients.

The UK has a central clinical trials service - the National Institute for Health Research (NIHR) - which invests over £1bn per year in the most integrated translational health research system in the world, providing a complete ecosystem for clinical research and supporting companies from early concept through to market.

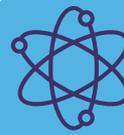
In 2018/19, NIHR research infrastructure supported over 4,400 industry collaborative and contract research studies - an eight fold increase from 2009 - filed 203 patents and created 14 spin out companies. The NIHR Clinical Research Network also had a record year, supporting 1,523 commercial studies and delivering 69% to time and target.

Faster clinical research set up and delivery

To further enhance NHS capacity for late-stage clinical research, the UK **is establishing five Patient Recruitment Centres**, dedicated to late-phase commercial research. These innovative centres will open in early 2020 and will offer dedicated facilities and staff, rapid study set-up, and standardised contracting and delivery approaches. The joint industry-government Clinical Research Working Group will be publishing further recommendations on improving workforce capacity and consulting on delivery in early 2020. By increasing the NHS's capacity to deliver research, we will enable significant growth and provide more opportunities for patients to benefit from early access to innovation - just as the Life Sciences Industrial Strategy envisioned.

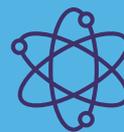
NIHR Support for Industry through the Translation-Evaluation-Evidence Generation journey

NIHR works with companies at all stages of the clinical development pipeline, from early-stage development programmes through to the design, set-up and delivery of studies in the NHS



Research Collaboration

- ▶ NIHR expert investigators
- ▶ Dedicated centres and facilities
- ▶ Ready-formed translational research collaborations and networks
- ▶ Research methodology expertise, including innovative trial designs
- ▶ Funding



Research Delivery

- ▶ Trial planning and study optimisation
- ▶ Feasibility and site selection
- ▶ Study set-up
- ▶ Recruitment and study delivery
- ▶ Performance monitoring
- ▶ National oversight and local targeting of support through regional teams

Record levels of people are participating in clinical research in the UK (over 1 million last year). We are building on this by introducing **mechanisms to ensure all patients can be offered the opportunity to participate**; mapping disease prevalence alongside research activity, so researchers are able to locate their studies in places with the greatest incidence; and developing mechanisms to incentivise NHS Trusts and GP practices acting as participant identification centres. We will be working with the sector on how these can be implemented in the coming year.

We are making it significantly easier to set up a study in the NHS by implementing a new national approach to costing and contracting for commercial contract research, including: a standard costing methodology, model site agreements, and a single contract value review. All eligible trials are being included in the current pilot and we expect it to be business as usual by April 2020.

We are also improving approval timelines with the Medicines and Healthcare products Regulatory Agency (MHRA) and the Health Research Authority working together to deliver approvals in parallel rather than in sequence, giving researchers significantly reduced overall start-up timelines. The average approval is now less than 53 days.

Leading developments in innovative trials

Just as the Life Sciences Industrial Strategy recommended, **the UK is leading the way in undertaking novel and more efficient trial designs** that will develop new medicines, diagnostics and medical devices for patients, making the UK one of the most exciting and innovative places to run clinical trials.

The MHRA is already one of the most innovative regulators in Europe supporting industry, including SMEs, with a scientific advice service through its Innovation Office where informal, exploratory discussions can take place at any point in the trial design process.

To support further **innovation in methodology**, the Experimental Cancer Medicine Centres have published leading multi-stakeholder work with industry, charities, regulators and patients to provide guidance on the design and delivery of complex innovative design trials.

The UK is also leading **innovation in delivery**, such as the ORION-4 trial, co-sponsored by Oxford University and The Medicines Company. With the approval of regulators, ORION-4 is recruiting 12,000 patients through centralised, data-enabled processes, with sites across England handling hundreds of appointments a week.

Innovative trials require a suitable workforce. NIHR provides rapid access to the UK's significant expertise in innovative trials and clinical research experts. We are also building the evidence base to support use of a variety of new methodologies, and increasing skills in innovative trial design and delivery, making this 'business as usual' across the system.

Making data enabled clinical research a reality

To increase speed of participant identification and recruitment, in 2019 we launched NHS DigiTrials to develop a service that will use country-wide NHS data to improve the assessment of clinical trial feasibility and planning for clinical trials in the UK. This service will be rolled out for commercial and academic trials during 2020, with subsequent enhancements as more detailed data becomes available.

Our vision is to expand this to provide new services, including: identifying potentially suitable patients (to enable rapid recruitment tailored to patient needs); effective and timely communication with trial participants; and understanding of key clinical events (allowing comprehensive study of the health effects of different treatments) and follow-up of patients over time.

Data

The UK has some of the richest healthcare and research datasets worldwide and some of the strongest and most innovative data and AI companies.

Data underpins most of the growth trends in the sector - from precision medicine and genomics, to the use of AI and robotic surgery - and the fair, ethical and transparent use of health data has huge potential to make the UK the home of data-driven life sciences research, innovation and development.

The Life Sciences Industrial Strategy presented the industry ask for an improved data system that would make the best use of data and digital tools, including digitisation and AI to transform pathology and linking datasets to real-time data for research across multiple care settings. Our vision is to create a complete package from data curation, access for researchers, skills, and an effective regulatory environment, all the way through to health and social care providers. We are already making huge progress to achieve this.

Making high-quality data accessible

The UK's health data is potentially world-leading but can be hard to access and needs to be made 'research-ready' before it can be used. The Life Sciences Industrial Strategy recommended making data available across multiple care systems as standard.

Accordingly, to make it easier for **researchers to identify and access multiple datasets, NHS Digital already provides a central access service** which enables secure legal and transparent access to, and linkage with, over 16 different national datasets across England. The world-class cancer, rare disease, and congenital abnormality databases held by Public Health England (PHE), are also being brought closer to the assets held by NHS Digital, to make access to linked data easier.

However, this is just one part of the rich data systems in the UK, so to further this we have established the UK Health Data Research Alliance to facilitate common processes for accessing data from its members, including NHS Digital, NHS England, PHE, Genomics England, UK Biobank, and a number of hospital Trusts. A Gateway is currently being developed, which will act as a common portal to access the data held by the members of the Alliance and will be launched by Health Data Research UK in early 2020.

To make research-ready data a reality, the last year saw the launch of the Digital Innovation Hub programme, which brings together NHS data with other wider datasets, such as genomics and disease specific research cohorts, and will provide **rich research-ready datasets**.

In parallel, NHS Digital, NHSX and partners are seeking to establish **a new approach for the utilisation of GP Data** for planning and research, and enabling secure linkage of this to other key datasets such as hospital data, in a way that is supported by the public and medical professionals. We hope to agree a service and would expect it to be incrementally available from summer 2020. Further detail on the specifics of the approach will be available in due course.

To further simplify access and encourage innovation partnerships, in July 2019 we published **revised guiding principles**, which offer support and guidance to NHS organisations that are considering entering into data access agreements with researchers and commercial partners. Further detailed engagement with stakeholders, including a programme of patient engagement commissioned by NHS England and Understanding Patient Data, is ongoing to develop the principles into a full policy framework, which we will publish in the coming months. In addition, we are setting up a **National Centre of Expertise** in NHSX that will provide legal and commercial expertise to NHS organisations when negotiating data partnerships. Together, these will improve the process for researchers and companies seeking to access the data they need to develop new healthcare solutions, while ensuring the NHS receives a fair share of the benefits.

Building new technologies

The UK is in a powerful position to lead in the use of health data and artificial intelligence to support early diagnosis. The Life Sciences Industrial Strategy recommended supporting the use of digitisation and AI to transform pathology and imaging. So, in 2018, the UK established **five digital pathology and imaging centres of excellence**, supported by £50m of Industrial Strategy Challenge Funding, bringing together the NHS, industry and academia. The centres are each curating data from hundreds of thousands of images a year to make new AI systems for analysis of medical imaging. Since their launch, we have committed a further £50m to accelerate and scale-up the work of the centres. The new funding will help to modernise more diagnostic services, strengthen the Centres' partnerships with the NHS, and support research to improve diagnosis and deliver precision treatments.

This year we also launched a **national Artificial Intelligence Lab** to support the development, deployment and diffusion of AI. The AI Lab, supported by funding of £250m, will sit within NHSX and bring together the industry's best academics, specialists and technology companies to work on some of the biggest challenges in health and care, including earlier cancer detection, new dementia treatments and more personalised care.

We are creating a regulatory framework fit for the future and able to keep pace with technological developments, such as AI. The MHRA is already assessing the feasibility of using artificial intelligence to identify safety signals in large datasets of health records, enabling real-time identification of issues arising with medicines. In addition to clear patient benefit, industry will better understand how their products work in a real-world clinical setting. The MHRA is also working with NHS Digital to develop a pilot, with a goal to **test and validate algorithms and other AI used in medical devices**.

Genomics

The UK is a global leader in genetics and genomics. From seminal discoveries of fundamental science, through to translation into clinical practice and improved patient outcomes, the UK continues to make a vast contribution to this frontier of healthcare.

The UK will continue to maintain this lead and be the best place in the world for genomic healthcare and research. Supporting industrial growth is central to this, underpinned with the latest scientific advances, as we work to deliver better health outcomes for patients.

We are at an important turning point in the history of genomic healthcare. **The 100,000 Genomes Project** was completed in 2018, and sequenced whole genomes from cancer and rare disease patients and their families. This data is already the largest single dataset of rare genetic variants with associated clinical phenotypes and healthcare data anywhere in the world. It provides researchers with access to high quality data and informatics and ensures that genomics is at the heart of transforming healthcare in the UK.

Building on this, **the UK aims to generate genome-wide analysis of five million genomes over the next five years**, including polygenic risk scores and at least one million whole genomes.

The **NHS Genomic Medicine Service (GMS)** already offers genomic tests for a range of conditions based on patient need and clinical utility. From early 2020 it will start to offer whole genome sequencing to all children with cancer or suspected inherited disease, and all adults with certain hard to treat cancers. We aim to **sequence 500,000 whole genomes over the next five years**, and we hope that the vast majority of patients will consent to make their data available for research, as in the 100,000 Genome Project.

It is absolutely vital that genomic research continues and flourishes if we are to realise the benefits of genomic healthcare.

So, as recommended in the Life Sciences Industrial Strategy, this year we made huge new investments in partnership with industry to carry out genome sequencing of large volunteer cohorts. **A £200m investment from government, industry and charity will deliver the whole genome sequencing of all 500,000 UK Biobank participants** over the next four years, with sequencing of the first 50,000 individuals to be completed by Spring 2020. The data will be made available to researchers from academia and industry and further cement UK Biobank's reputation as a world-leading health resource. These datasets will link genomic information with deep phenotyping and NHS health records, with participants' consent, making the data securely available to trusted researchers seeking to unlock new treatments and diagnostic tools.

This year we also launched **the flagship Accelerating Detection of Disease** programme, creating a platform for developing effective diagnostics for early, asymptomatic chronic disease in a joint project with charities, NHS and industry partners. This will carry out **up to five million polygenic risk score assessments** on volunteers, who will each receive personalised feedback on their results. It will link phenotypic data to longitudinal biological samples available for research purposes. The data created will allow evaluation of new polygenic risk scoring across millions of volunteers to see if and how we can incorporate them into smarter, more targeted clinical trials, research, and screening programmes. It will be made available to researchers from academia and industry, creating the largest and deepest dataset for medical and diagnostic research in the world.

We will also be embarking on **large variant to function studies** to better understand how genetic alterations influence phenotype, and we will work with the sector to build this vital bridge between our existing genomic datasets and new medicines discovery programmes.

Using techniques such as base editing and single cell analysis it should be possible to define the role of genetic variants in genes and pathways responsible for disease, creating large numbers of new drug targets.

Over the last year we have been working with the sector to **develop a new National Genomic Healthcare Strategy**. In a matter of weeks we will publish the strategy which maps out the UK genomics offer and sets out a clear, unified direction of travel that builds on our investments so far, enabling the genomics industry to coalesce around our world leading genomics assets to drive forward innovation. The strategy will set out how we will use the next ten years to further build on our reputation as a world leader in genomic healthcare, focusing on three areas.

Firstly, for **diagnosis and personalised medicine**, we will set out how we will bring genomics advances into routine healthcare, meaning patients are diagnosed earlier and more accurately, improving outcomes.

Secondly, it will **highlight genomics' potential in prevention**, using the advances in genomics to improve predictive and preventative healthcare, screening programmes and public health.

It will lay the groundwork for the use of polygenic risk scores.

Finally, it will **map the research landscape**, setting out our support for fundamental and translational research. This will help ensure a seamless interface between research and healthcare delivery, maximising the opportunities for patients on the ground to benefit from genomic discoveries.

The strategy will be underpinned by **vital cross cutting themes** on engagement and maintaining trust, growing and training our workforce, driving forward the burgeoning genomics industry in the UK and supporting large-scale data and bioinformatics analysis, without which genomic research is not possible.

There is a huge breadth of world-leading genomic activity in the UK and the following table sets out the key population-level projects across the genomics space. But beyond this, a range of other programmes from major cohorts to small scale studies are underway to understand and enhance the role of genomics in healthcare, united by the commitment to deliver tangible benefits through genomics now and in the future.

Key population-level projects across the genomics space

	Improved Patient Outcomes				
	Diagnosis and Personalised Medicine		Prevention	Research	
					
Key UK Infrastructure:	The 100,000 Genomes Project and Genomic Testing in the NHS		Accelerating Detection of Disease Challenge	UK Biobank	NIHR Bioresource
Population	100,000 participants with rare diseases and cancer	Provision of genomic testing across the UK, including at least 500,000 whole genomes in England by 2024	5 million participants to be recruited to support research into early diagnosis of disease (programme in development)	500,000 participants healthy at the time of recruitment	200,000-400,000 participants with rare or common diseases or healthy at the time of recruitment
Genomic data	Whole Genome Sequencing	Whole Genome Sequencing and non-whole genome sequencing	Genotyping - Polygenic risk scores (PRS)	Whole Exomes and Whole Genome Sequencing	Whole Genome Sequencing or genotyping
Complementary data	Phenotypic and long-term clinical data collection	Phenotypic and long-term clinical data collection	Health-related data	Deep phenotyping and health-related data	Deep phenotyping, metabolomics, health related data, medical records
Bio-sampling	✓	✓	✓	✓	✓
Clinical feedback	✓	✓	✓	✗	✓
Recontact	✓	✓	✓	✓	✓
UK wide	✓	✓	✓	✓	✓



Skills

No life sciences sector can develop and thrive without the right high-quality skills.

The life sciences sector is increasingly dependent on a varied skills base to support and sustain emerging industries in AI, data and digital, and there is a growing need to ensure traditional skillsets in biomedical sciences are complemented by technical skills in areas such as engineering, computer science and data analytics. We will ensure that life sciences organisations have the skills they need to innovate and grow and are able to capitalise on emerging opportunities for the UK to build and diversify its skills base.

Growing our existing skills base

The UK is home to one of the most productive health and life sciences sectors in the world and continues to invest in human capital across life sciences to support the success of the sector. The Life Sciences Industrial Strategy highlighted the importance of a strong skills strategy and action plan to support its aims, so a key focus has been to better understand and target the key skills the sector needs now and in the future. **The Science Industry Partnership (SIP) has worked with government and industry to develop the 2030 Skills Strategy**, which is due to be published in 2020. The report will focus on research and development, medicines manufacturing and emerging technologies such as AI, and aims to build a clear evidence base of the status of life science skills in the UK and future scenarios to 2030.

The UK has also established a number of programmes to develop our scientific, research and commercialisation talent through our universities, including NIHR and Medical Research Council (MRC) funding for over 6,000 doctoral and research fellowship awards each year. In the last year, the MRC has launched a new pilot scheme supported by £10m to enable NHS consultants with a PhD or Master's Degree, who are not research-active, to participate in collaborative high-quality research partnerships with leading biomedical researchers, facilitating engagement and better connecting basic biomedical science to clinical research. The first two rounds of the scheme funded 45 awards, with the next round opening in 2020.

Developing the skills we need for the future

We are investing now to ensure the UK has the skills it needs to support emerging industries, by:

- ▶ **Launching a new joint government-industry programme to drive up skills in the AI sector:** the programme marks the first nationwide effort to address the skills gap at this level - 1,000 students will have the opportunity to become experts in AI through new PhDs at 16 dedicated UK Research and Innovation AI Centres for Doctoral Training located across the country, and 200 new company-funded AI Masters places at UK universities.
- ▶ **Establishing the Topol Programme for Digital Fellowships in Healthcare**, supporting NHS organisations to invest in clinical staff to develop specialist digital skills, giving clinicians time and support outside of clinical commitments to lead digital health improvements and innovations.



Maximising benefit from our research

Commercialisation of university research via spin outs and licensing requires specific skills so in 2019, following a successful pilot, we rolled out the **Innovation to Commercialisation of University Research (ICURe) programme, to help develop commercial awareness and skills amongst academic personnel**, and to strengthen links between academic and industrial communities. So far, an estimated 24 spin outs have been created, valued at £35m.

Facilitating high-quality apprenticeships

The Life Sciences Industrial Strategy highlighted the need to increase uptake of life science apprenticeships, particularly across SMEs. The public sector and industry are working together to build strong vocational life science skills by funding more high-quality sciences apprenticeships through the UK Apprenticeship Levy. **Since April 2019 larger employers are able to support smaller employers to take on apprentices and can transfer up to 25% of their levy**, including to SMEs in their supply chain, supporting the development of a broader life sciences ecosystem. The UK is also ensuring that key skills gaps are addressed, for example, by putting **£1.5m into the Advanced Therapies Apprenticeship Community**.

Advanced Therapies

Advanced therapies are a key growth area, posing new challenges for the sector. The Life Sciences Industrial Strategy highlighted a real opportunity for the UK to capitalise on this, by leveraging its excellent science base to secure advanced therapies manufacturing. In response, we have invested across the ecosystem to build an end-to-end infrastructure that supports innovation in advanced therapies, from discovery and development through to manufacturing and delivery to patients. **£146m was committed to medicines manufacturing in the first Life Sciences Sector Deal** to make the UK a uniquely attractive location for developing technologies and investing in medicines manufacturing. This included new medicines and vaccines manufacturing innovation centres and funding to expand viral vector manufacturing.

The Medicines Manufacturing Innovation Centre, scheduled to open in 2020, is the first-of-its-kind across the globe and is projected to attract £80m R&D investment by 2028. Led by the Centre for Process Innovation (CPI), this state-of-the-art facility near Glasgow will offer transformative opportunities in small molecular and fine chemical manufacturing.

A new dedicated **Vaccines Manufacturing Innovation Centre**, based in Oxford, will accelerate vaccine research in the UK and ensure the UK life sciences industry remains at the forefront of worldwide efforts to tackle life-threatening diseases.

The UK already boasts great science, flagship companies, a 'Good Manufacturing Practice' (GMP) manufacturing centre, Advanced Therapy Treatment Centre test beds, positive health technology assessments, healthcare adoption and market access.



The UK has grown the largest cluster of life sciences companies outside of the US, and is the largest advanced therapies community and leading source of innovation and development of ATMPs in Europe. As of 2019, there are more than 70 companies developing ATMPs in the UK and 25 manufacturing facilities¹⁰ offering a unique opportunity for developers, services and supply partners working in advanced therapies to co-locate and benefit from the unique range of support and pool of talent.

¹⁰ The BioIndustry Association, 2019. *Leading Innovation: The UK's ATMP Landscape*. Available at: https://alliancerm.org/?smd_process_download=1&download_id=4772

Connectivity and acceleration



Commitment and vision:

- ▶ UK Life Sciences Industrial Strategy, Life Sciences Sector Deal 1 and 2, and government funding



Research and University Excellence:

- ▶ Rapid learning and application enabled through the Cell and Gene Therapy Catapult
- ▶ UK is home to four of the top ten universities in the world for clinical and health sciences¹¹



Innovation:

- ▶ Robust systems for routine delivery of ATMPs developed by Advanced Therapy Treatment Centres



Access to Talent:

- ▶ First apprenticeship programme developed through the Advanced Therapies Apprenticeship Community
- ▶ Over 200 cell and gene therapy experts now part of the Cell and Gene Therapy Catapult



Streamlined Regulation:

- ▶ Regulatory Advisory Service for Regenerative Medicine provides a single point of access for regulatory information, advice and guidance



Access to Patients:

- ▶ The NHS serves a diverse population of more than 65 million people, and sees more than 1.4 million people every 24 hours



Adoption and Reimbursement:

- ▶ The NHS is the first health system in Europe to agree access to CAR-T treatments, achieved through the fastest product approvals in the NHS's 70-year history

Industrial cluster



7

Global
Pharmaceutical
Companies



70+

Therapy
Developers



25

Manufacturing
Facilities



High-
Performing
Technology and
Supply Chain
Companies

¹¹ Times Higher Education, 2019. *World University Rankings data*. Available at: <https://www.timeshighereducation.com/world-university-rankings/2020/subject-ranking/clinical-pre-clinical-health>

Developing Advanced Therapies

As part of our ambition to make the UK a leading hub for advanced therapies we provided £70.6m additional funding to further develop **the Cell and Gene Therapy Catapult**, a centre of excellence with the mission to drive the growth of the industry by helping cell and gene therapy organisations across the world translate early stage research into commercially viable and investable therapies. **It now provides clinical trial, technical, manufacturing, regulatory and market access expertise for industry and researchers**, with over 200 cell and gene therapy experts, state-of-the art development and viral vector laboratories.

The first oligonucleotide therapies are now reaching patients and represent a major new opportunity for the industry. These technologies are proven to be clinically efficacious, but challenges remain in manufacturing and delivery. The UK is focussed on participating in resolving these issues.

The impact of oligonucleotide therapies has been limited by the challenges of accurately targeting organs or tissue. Therefore, this year **we launched the Nucleic Acid Therapy Accelerator (NATA)**, hosted at the Harwell Research Campus to directly address the challenges of nucleic acid drug delivery, building interdisciplinary research consortia and state-of-the-art infrastructure to tackle the major questions limiting drug development in this area, including manufacturing and delivery challenges.



Advanced Therapies Manufacturing

We also expanded the **Cell and Gene Therapy Catapult manufacturing centre**, a world-leading facility that enables companies to develop their manufacturing processes at scale, and benefit from the Cell and Gene Therapy Catapult expertise, without the need for a bespoke site of their own. This significantly reduces the risk for companies and increases the speed to market for companies going into clinical trials and commercial manufacturing. In September 2019, construction was completed on the expansion phase, doubling the capacity of the manufacturing centre.

Looking to the future at the manufacturing challenges for advanced therapies, **the MHRA is developing a framework for point-of-care manufacture by March 2021.**



Supporting adoption of advanced therapies

The NHS is the first health system in Europe to agree access to CAR-T treatments. The AAC is developing and agreeing detailed plans across all UK health system partners to support the adoption of advanced therapies, and ATMPs are one of the first classes of transformative early stage AAC products that will be supported for market access and use in the NHS.

To facilitate the uptake of advanced therapies we have invested £30m to develop a network of **Advanced Therapy Treatment Centres (ATTCs)** around the country. These are designed to develop systems and processes to support the routine supply of ATMPs by the NHS. These centres are supporting the opening of multiple ATMP clinical trials in a range of diseases across the country, and are developing and sharing best practice with other hospitals to increase adoption of ATMPs across the UK. The ATTCs are developing the skills and experience required within the NHS to be able to deliver ATMP trials as routinely as other modes of treatment and strengthen the UK's position delivering these trials and licensed products.

For Further Information

For Life Sciences Opportunity Zones:

More information can be found at: <https://www.gov.uk/guidance/life-sciences-opportunity-zones-how-to-apply> or by contacting LSOZ@officeforlifesciences.gov.uk

More information about other programmes referenced can be found below:

- ▶ Claiming research and development tax reliefs: <https://www.gov.uk/guidance/corporation-tax-research-and-development-rd-relief>
- ▶ Venture Capital Tax Relief Schemes: <https://www.gov.uk/guidance/venture-capital-schemes-raise-money-by-offering-tax-reliefs-to-investors>
- ▶ British Business Bank webpage: <https://www.british-business-bank.co.uk/>
- ▶ NIHR i4i webpage: <https://www.nihr.ac.uk/explore-nihr/funding-programmes/invention-for-innovation.htm>
- ▶ AHSN webpage: <https://www.ahsninnovationexchange.co.uk/directory/funding/>
- ▶ UKRI webpage: <https://www.ukri.org>

For the Accelerated Access Collaborative:

<https://www.england.nhs.uk/ourwork/innovation/accel-access/>

For Clinical Research:

Support is available throughout the full product development pathway. Facilitated access and signposting to the UK clinical research system is available via our single point of contact: supportmystudy@nihr.ac.uk

For Data:

For the Digital Innovation Hub Programme further information is available at the following link: <https://www.hdruk.ac.uk/infrastructure/the-hubs/>

For Skills:

Employer guides to apprenticeships, by ESFA: <https://www.gov.uk/government/publications/apprenticeships-guide-for-employers>

For Advanced Therapies:

Further information can be found at: <https://ct.catapult.org.uk/manufacturing-centre> or by contacting comms@ct.catapult.org.uk

And for Advanced Therapy treatment centres please see: <https://www.theattcnetwork.co.uk>



