JANUARY 2024

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A New National Purpose: Leading the Biotech Revolution

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***A New National Purpose: Leading the Biotech Revolution* is a joint report by Tony Blair and William Hague.**

01

Foreword

In our first joint report last year, *A New National Purpose: Innovation Can Power the Future of Britain*, we argued that the world is undergoing the fastest technological and scientific revolution in the whole history of human civilisation, with profound implications for the United Kingdom. The challenge of responding to that revolution is so urgent, the danger of falling behind so great and the opportunities so exciting that we urged all political parties to make their response to it nothing short of creating a new national purpose.

We set out how the UK could harness the power of technology and reimagine the state and public services by restructuring Whitehall, making better use of data, and improving the access of tech companies to skills and finance. Our second paper, *AI Promises a World-Leading Future for Britain*, published in June, described how artificial intelligence (AI) could help achieve these aims.

This paper is the third in the series and argues that biotechnology is an absolutely critical part of the revolution and one which Britain must lead. Accelerated by new discoveries, AI and the availability of data, biotech is offering a future with new cures and treatments for many diseases, more personalised and effective health care, and the unlocking of new materials and transformed manufacturing processes. An era of gene therapies, of discovering new antibiotics and of building molecular factories has begun.

In Britain, pioneering initiatives like Genomics England and the UK Biobank have already become world leaders. British scientists showed their excellence in responding to the Covid-19 pandemic. But the competition to lead the world in biotech is intensifying rapidly. The United States is home to many of the world's leading biotech companies, at the forefront of synthetic biology, biofuels and biopharmaceuticals, with an ability to turn research into commercial scale more easily than many other countries. Denmark and Switzerland have developed world-leading companies. China is investing vast

sums in the sector.

In this report we set out what we believe Britain could do to build on our early advantages and avoid being left behind by surging global competition. We call for a new laboratory, the Laboratory of Biodesign, to focus on the invention of new biotechnology that is at too early a stage for commercial investors. It would design and build new biotechnologies, biomolecules and therapeutics, helping to produce innovative ideas, build a strong pool of talent and bring biology together with computation.

Second, we advocate a new approach to using health-care data to support breakthroughs in medicine. We propose establishing an NHS Data Trust, with a controlling stake owned by the NHS and additional investments from companies. While strictly preserving privacy and preventing misuse, this structure would permit health data to be of massive benefit to research, public health and patient treatment. Ultimately, personalised AI doctors would support health-care professionals in delivering more cost-effective and timely treatment.

None of this will succeed without finance. Our third set of proposals focuses on making it easier for biotech companies not only to start up but to scale up, building the great companies of the future here in the UK. We call for an expansion of the work of the British Business Bank, improved rules for Venture Capital Trusts and consideration of scale-up grants where companies will list in Britain.

The revolution in biotechnology brings major opportunities to the world, with the chance to extend healthy lifespan and to relieve great suffering. But it also brings the dangers of any new technology that can be used for harm as well as benefit. We call for the UK to lead the way in global biosecurity needed for this new age, with a new taskforce helping us prevent the next pandemic. There should be strong safeguards to prevent misuse of DNA synthesis and to control research on the creation of powerful pathogens. Responsible governance of biotechnology will be indispensable to realising its immense benefits.

We both believe that whether Britain can establish a leading position in science and innovation will be the single most important determinant of our future prosperity, and therefore of the jobs, living standards and security of British people. That great opportunities could spring from artificial intelligence

has become well understood in the last year. Biotechnology now also brings the prospect of fundamental change in how we work and live. There is not a moment to lose in making the most of it.

Tony Blair and William Hague

02

Executive Summary

In February 2023, the first report in the *New National Purpose* series set out a bold and optimistic future for Britain: a fundamentally reimagined state, with technology at its heart, that transforms everything from how government works to how our public services are delivered.

The second report followed through on that vision with practical solutions, showing how we can shape and harness the most important technology of our generation – artificial intelligence (AI) – and position the United Kingdom as a leader in its safe and successful development.

A New National Purpose: Leading the Biotech Revolution, the third in the series, shines the spotlight on biotechnology. Done well, biotech can be another building block in a reimagined state that improves and extends lives, hosts the companies of the future and sets up the UK for a century of success.

The Life Sciences Vision was critical to kick off this strategy. But it is an area that requires sustained effort to remain at the cutting edge of research and to turn this into commercial success.

This report is not intended to be a comprehensive life-sciences strategy or an industry analysis that addresses every area of biotech. Instead, it highlights critical areas of focus for Britain: 1. how we can seize the global opportunity that biotech represents in the AI era; 2. how data can be harnessed better to drive research and help create AI doctors that can complement GPs' expertise by acting as personalised health advisors; 3. what we should do to become home to the next generation of superstar companies; and 4. how to keep ourselves and the rest of the world safe from global biothreats.

Some recommendations are technical solutions to the policy and organisational problems biotech faces in the UK, but they feed into the broader theme of how strategic application of innovation and the right infrastructure can power a reimagined state in which people lead better, longer, safer lives.

The common thread throughout this report is a question: building on Britain's existing strengths, what does "reimagining the state" look like for biotechnology and the opportunity it presents? The report's recommendations answer that question in a variety of ways, including by proposing the establishment of new institutions to secure Britain's place at the cutting edge of biotech invention, putting our unmatched wealth of national health data to work, protecting ourselves and others from biothreats, and more. These new institutions and endeavours include:

- **The UK Laboratory of Biodesign**, which would use experimental and computational methods to design, build and test new biotechnologies, biomolecules and therapeutics under one roof. It would need to be empowered to recruit first-rate international talent, incentivise commercial spinouts and have world-leading facilities, such as state-of-the-art computational-biology tools. Similar efforts in the United States fusing science and engineering under one roof are using generative AI to produce novel proteins and are driving a biotech boom. By learning from these efforts and adopting a novel institutional structure – creating the first "Disruptive Innovation Lab" recommended in previous *New National Purpose* reports – the Laboratory of Biodesign would help the UK move to the frontier of applied biotech research.

- **The MediMind laboratory network to work towards personalised AI doctors in partnership with industry and the National Health Service (NHS)**, using artificial intelligence to help doctors treat people in a way that is cost-effective, relieving the pressure on our struggling NHS. AI doctors will be able to find connections humans can't between disparate sets of data to drive individual and collective health. The UK should lead this endeavour, pioneering a research laboratory with a well-resourced core institute that has the ability to fund researchers and clinicians around the country. These will complement and assist, not replace, human doctors. The acquisition of quality human data is a global bottleneck for AI, but the UK Biobank and the establishment of an NHS Data Trust, proposed below, would together offer a competitive edge.

- **A new NHS Data Trust (NHSDT)** to capitalise on the opportunities of health data. Owned and controlled by the NHS in collaboration with trusted external partners, the NHSDT would treat NHS data as a

competitive asset whose value can be realised for the benefit of the public. This would involve providing anonymised data to research entities, including biotech companies, in return for financial profit that would then benefit our health service. A transparent governance model would ensure that our data remain safe and that NHSDT's operations align with public-health objectives, not private capital's.

Beyond proposing the institutions that will futureproof our infrastructure, *Leading the Biotech Revolution* poses new strategic directions for government – an essential mindset shift towards a practical focus on the priorities for British biotech. Securing our place at the frontier of global research, building high-value biomedical data for discovery, making the UK a place where high-potential companies can grow and become giants of the global economy – these are the essentials. This report sets out how Britain can:

- **Orient to produce high-scale companies** and become home to the superstars of the future. Globally, the biotech sector is already worth more than $6 trillion in market capitalisation, and companies in the United States are responsible for over half of that. Notably, the UK is a major exporter of technology, and the US a key beneficiary. We need to shift the balance, aiming to build trillion-dollar companies that will form the next wave of biotech by ensuring that we can scale and list companies at home. This will require fostering a more vibrant ecosystem and expertise in which emerging managers, solo GPs and operators running funds can increase the competitiveness and depth of capital in the UK, setting spinout terms that incentivise and reward entrepreneurs, as well as reforming pension funds and capital markets.

- **Pioneer 21st-century biosecurity** to keep Britain and the rest of the world safe from biotech accidents and bad actors. Many of the core technologies underpinning biotech advances are inherently "dual use", meaning that with enhanced capabilities come enhanced risks. The UK should set up a new UK Biosecurity Taskforce: a rapid, agile, focused effort to learn from Covid-19 and develop practical plans for biosecure societies. These should include new, low-friction safeguards on advanced biotech.

As with the AI technologies that underpin so much of biotech's progress, Britain has a chance to capitalise on this next wave of innovation. From putting the conditions in place to make Britain home to the companies and inventions that will help people live healthier, longer lives, to opening up economic opportunity, to protecting the world by prioritising biosecurity, the payoffs of investing now will be vast in the years ahead.

Download a PDF of this report

03

Introduction

When we look for reasons to be optimistic about our collective future, progress in biotechnology may be the most reliable force to count on.

Biotech's track record is already remarkable: over the past century it has become one of the great success stories of human history. Life expectancy has extended dramatically, not only because of treatments for disease, but also from improvements in agriculture, animal husbandry and the replacement of toxic approaches with less harmful ones, allowing healthier lifestyles at lower cost.

Industrial processes are also being made more environmentally friendly, for example through bioethanol, while disasters such as oil spills can be addressed by using organisms to break them down. And its impacts are far broader: from cosmetics and textile production to forestry and more, harnessed carefully, biotechnology has been a tremendous net force for good.

This field is now accelerating further. The scale, precision and predictability of such technology has improved dramatically due to breakthroughs in gene editing and synthetic biology. In particular, CRISPR-Cas9 has significantly increased the accuracy and efficiency of gene editing, while mRNA delivery mechanisms have been pivotal in developing novel vaccines and therapeutics. On top of these advances, AI offers the ability to learn highly complex patterns and relationships from vast amounts of biological data, such as those found in living organisms, and make predictions in a high-throughput way for the first time. These technologies are maturing together and synergistically.

The leap in knowledge made by the AlphaFold team – ushering in a 10,000-fold increase in coverage of protein structures for researchers to study and build on – has completely transformed early-stage biological research and sparked an AI renaissance in modelling biological systems, with real-world implications for medicine and biotech.

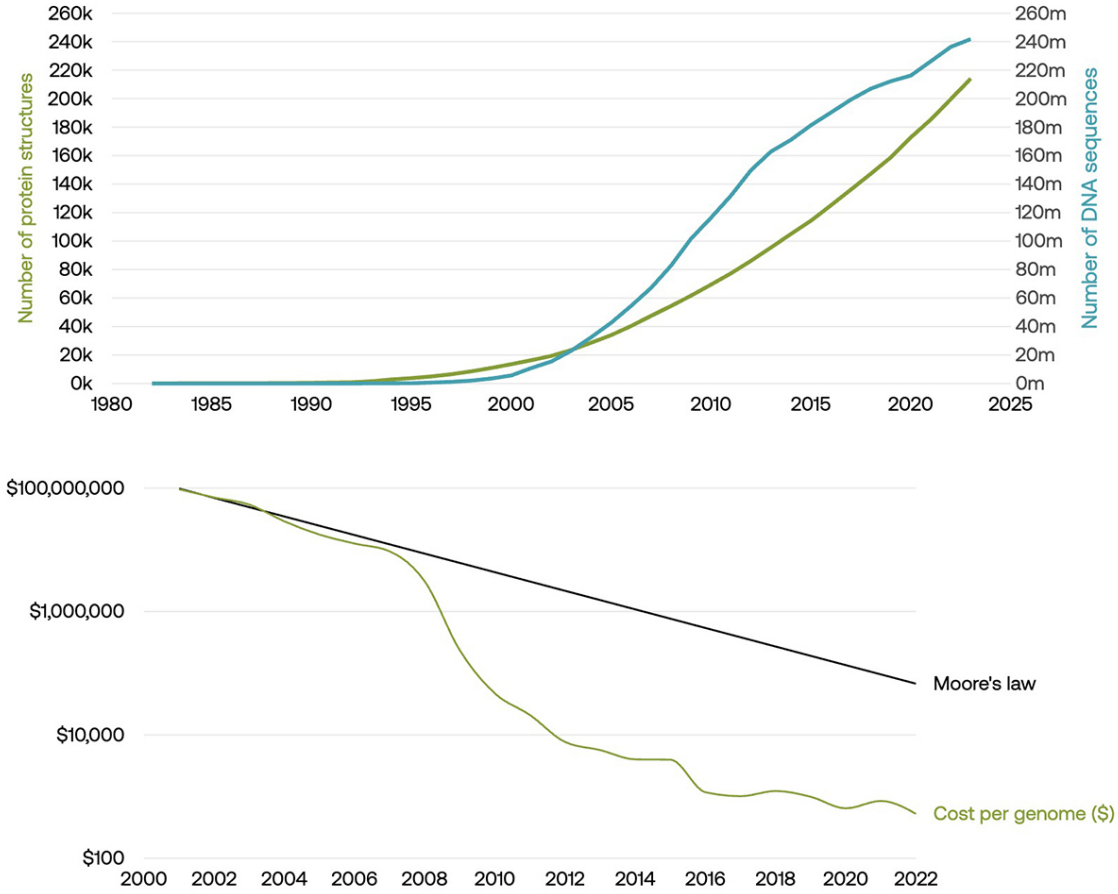
What was deemed impossible only a few years ago is now beginning to be adopted in health-care systems. Computer vision is being applied to predict genetic variations in lung-cancer tumours.[1] New protein models, using advanced computation algorithms, can predict DNA mutations by analysing

how changes in DNA sequences might alter protein structure and function, enabling early detection and treatment of genetic disorders.[2] AI-assisted screen reading identified 13 per cent more cases of breast cancer than doctors had initially recognised.[3]

The collision of AlphaFold's triumph and progress in generative AI has led to enormous improvements in the ability of AI systems to design new protein structures, known as de novo protein design, and allows us to design highly novel biological nanomachines not seen in nature. One of the most impactful methods in this area, RF-diffusion, holds the promise of making entirely new classes of medicines, vaccines, diagnostics and even biomaterials.[4] These innovations in AI for biology are only possible due to steep reductions in the cost to acquire biological data in recent years, especially in genetic sequencing, and the near-exponential growth of biological databases.

FIGURE 1

The growth of protein structures and DNA sequences (top); the cost of sequencing a human genome (bottom)



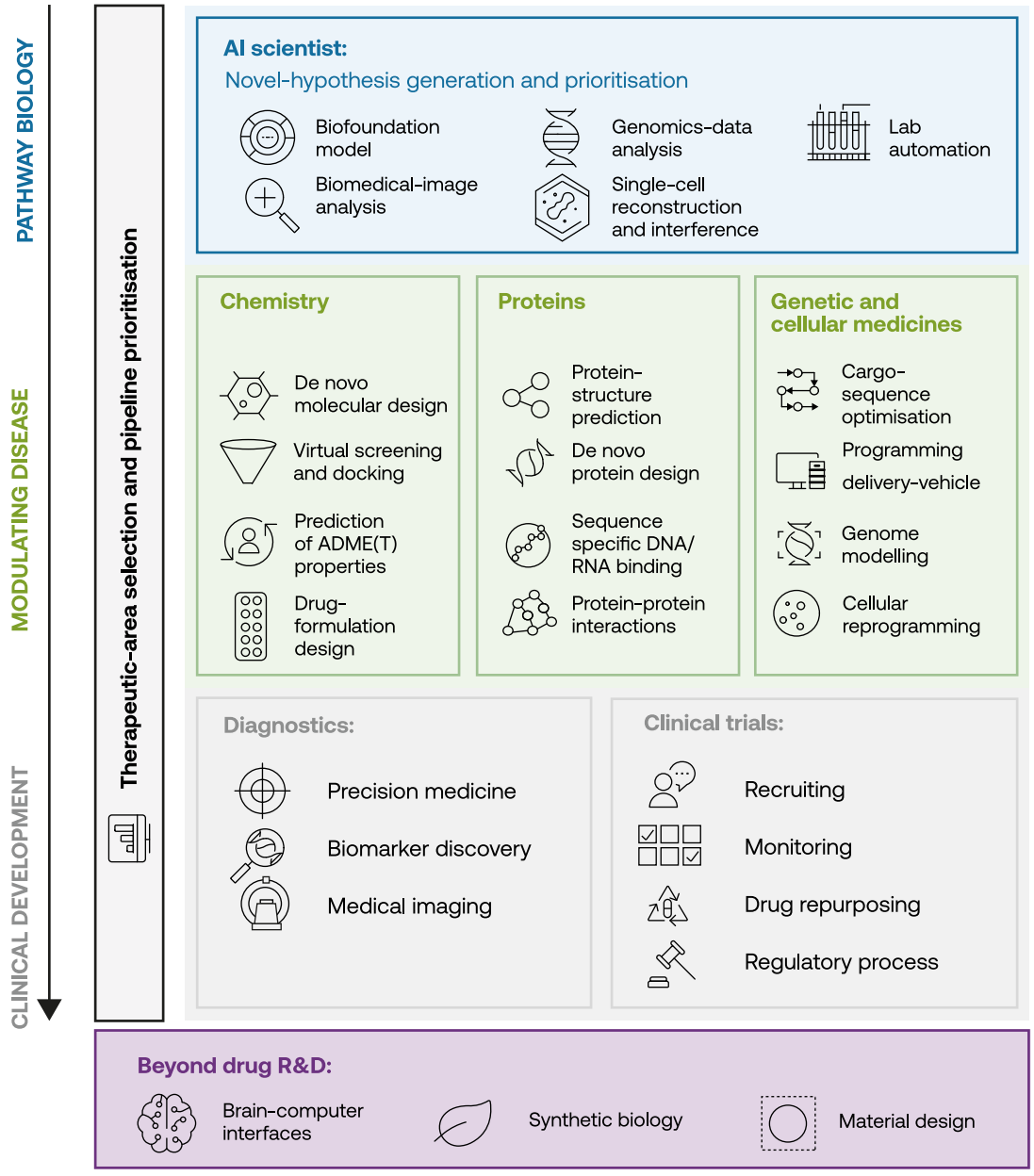
Source: National Human Genome Research Institute; RCSB Protein Data Bank

These recent developments, along with many others at the intersection of health care and large-scale computation, make it clear that we are entering a new era of biology, increasingly expanding it from descriptive science to include engineering too. Although there are still technical limitations to current applications of state-of-the art methods, the pace of innovation means that a

strategic policy agenda can support accelerated science at scale.

FIGURE 2

How AI is transforming the process of drug development at all stages



Source: Andreessen Horowitz analysis

The UK has substantial strengths to build on. Thanks to sustained investment from successive governments, the UK can genuinely claim to be the world leader in genomics. The 100,000 Genomes Project was made possible by strategic investments, such as via the establishment of Genomics England. British health data was not always widely heralded, but the ambition of the Wellcome Trust and the Medical Research Council (MRC) has helped UK Biobank become a uniquely useful global asset.[5] Thanks to the Biobank, as well as an elite cluster of talent and research institutions in Cambridge, Oxford, London, Edinburgh and Glasgow, the UK has an unmatched wealth of health data. To access this data, Secure Data Environments (SDEs) – the National Health Service's (NHS) adaptation of the Trusted Research Environments (TREs) – were set up with £200 million in investment. SDEs are specialised data platforms designed to ensure the secure handling and processing of sensitive information to enable ease of access to data.

The UK is also placing other new bets on biotech: at least two of the founding programme directors for the Advanced Research & Invention Agency (ARIA) are centred in this space, focusing on neural-machine interfaces and engineering of plants,[6] signalling the government's intention to continue building on the UK's strength in this area.

Biotech companies are beginning to define the mosaic of the global economy. In the previous decade, the growth of leading biotech companies outperformed the growth of other leading technology companies by almost double.[7]

This strength is reflected in our industrial composition. Two of the ten largest companies in the UK, AstraZeneca and GSK, are biopharma firms – pharmaceutical firms that engage deeply with biotech – and they are also the two largest companies in the UK classed as R&D intensive (with qualifying R&D expenditure constituting at least 40 per cent of their overall expenditure).

Nevertheless, increasingly, the seeds of this revolution are being sown in Britain, but the long-term success is being realised elsewhere. The UK itself has $350 billion in biopharma-company market cap – 10 per cent of the US's market cap for the same type of company. However, almost two-thirds of the UK biopharma market cap comes from pharmaceutical company AstraZeneca, which contributes $206 billion.[8] Of the 23 UK biotech initial public offerings (IPOs) between 2018 and 2022, worth a total of $2.8 billion in the gross amount offered, 14 have chosen to list on Nasdaq in the US,

including Achilles Therapeutics ($172 million), Vaccitech ($108 million; now known as Barinthus Biotherapeutics), Exscientia ($358 million), Centessa Pharmaceuticals ($320 million) and Immunocore ($258 million).[9] This underscores the profound impact and reach of UK innovation and expertise, but also a failure to capture maximum value at home.

The UK is not reliably at the frontier of the biotech field, especially when it comes to engineering advances, and risks falling behind amid intensifying competition.

US dominance in the sector is partially a result of being at the forefront of areas such as synthetic biology,[10] biopharmaceuticals and biofuels, with its leading research being commercialised at a much greater scale than its rivals.

China's biopharma sector is also entering a new dawn,[11] with billions of dollars invested in collecting genetic data and a constellation of new tech-focused stock exchanges. The value of IPOs in China in 2022 was £4.4 billion[12] – more than 150 times the value of the UK's IPOs. The promise of the biotech boom is so great that even ByteDance, the company behind social-media giant TikTok, is now recruiting computational biologists.[13] Other countries such as France, Germany, Canada, Japan and the United Arab Emirates are also charging forward in the race to build industries of the future.

Recent announcements in the Autumn Statement – such as pension consolidation, which would support investment in British innovation; the £520 million investment in medicine manufacturing; and the £2 billion investment over the next decade for engineering biology for medicine, food and environmental protection – demonstrate that the government is taking some of the right steps to support the biotech ecosystem. But the level and pace of ambition need to be sharply raised in the next Parliament to build on this foundation.

While much can be done to support our biotech industry by leveraging private capital, the effective implementation and renewal of the Life Sciences Vision[14] – central to the UK's industrial strategy in this area – will require additional public investment, as will some of this report's policy recommendations. Given the industry's potential for long-term growth and to drive reduced costs for the NHS, investment in biotech should be a top priority as the economy improves and the government's fiscal headroom increases. This would also be consistent with the government's stated ambition to increase R&D spend to

£22 billion by 2026–27, and Labour's commitment to spend 3 per cent of GDP on R&D by 2030.[15] This sustained investment in life sciences – across R&D, translational capabilities, training and data infrastructure – will be necessary for the long-term accumulation of knowledge required to fuel a new age of discovery.

Given the breadth of this topic, it is inevitable that many high-value areas are not covered here. Areas such as clinical trials, regulatory pathways and NHS absorptive capacity are important areas to industry and clinicians, and have been the subject of many thoughtful policy and industry reports. This report specifically poses emerging questions for government to consider at the interface of biology, data and large-scale computation, and proposes an agenda that can enable Britain to advance the biotech frontier.

The term biotechnology is used in a broad sense in this report, defined as "technologies to directly harness and improve biological systems". For example, the use of AI in medicine and biological research are included as a form of biotechnology. The authors think this is necessary to avoid silos and dichotomies arising. Outcomes, not semantics, are what matter.

04

Strengthening the Foundations of Our Biotech Ecosystem

REFOCUSING ON GLOBAL COMPETITIVENESS

Past scientific revolutions have shown that there are strong first-mover advantages in technology-intensive industries. The UK's speculative MRC Laboratory of Molecular Biology (LMB), opened in 1962, drew generations of the world's most sought-after talent to Cambridge, resulting in 12 Nobel prizes to date. Fast forward to the present day: the Cambridge Biomedical Campus boosted the UK economy by £2.2 billion in gross value added in 2021 alone.[16] Likewise, the greater Boston area and San Francisco, where gene-editing tools such as CRISPR-Cas9 were honed in the 2010s,[17] are the world's leading hubs for synthetic-biology investment.[18] Similar trends are in play for personal computing and AI. This sets out the opportunities in harnessing biotechnology and AI where the UK can take the lead in the 2020s and beyond.

Being at the frontier of biotech is important for seeding wider agglomeration effects around the laboratories making the advances. These effects are particularly important in knowledge economies.[19] Countries that are home to frontier laboratories not only provide cutting-edge training but also exert a powerful pull for the next generation of top entrepreneurs, researchers and other globally mobile talent.

The UK has a good position in the biotech sector and an excellent opportunity to build many more unicorn companies. But its research base is also at risk of complacency – as highlighted in Sir Paul Nurse's review of the UK's R&D landscape[20] – and overstating its strength relative to the very best environments globally.

Recent analysis suggests that the country does not perform nearly as well as assumed in the areas central to synthetic biology, such as protein engineering, gene editing, therapeutic delivery and bioinformatics. The UK is only present in one of the biggest 27 synthetic-biology advances of the past decade,[21] which came from the LMB in Cambridge. UK authors contribute just over 3.5 papers' worth of co-authorship to the top 50 most-cited synthetic biology papers – about half of what we might expect, according to the commonly used metric

that Britain contributes 13 per cent of the most important work.[22]

These metrics in nascent fields indicate a need to bolster the UK's competitiveness and attractiveness at the frontier. We have little data on whether the postgraduates of the world's top biology laboratories, including our own, are moving to or staying in the UK to begin their research.

A recommendation of the first *New National Purpose* report, that the Economics and Social Sciences Research Council (ESRC) should embark upon metascience research, has been implemented by its new executive chair, Stian Westlake, with the creation of a new metascience unit in partnership with the Department for Science, Innovation and Technology (DSIT). The unit should be leveraged to analyse the issue of competitiveness.

Recommendation: *The Economics and Social Sciences Research Council-Department for Science, Innovation and Technology metascience unit should fund the development of methodology to assess talent flows of the most globally sought-after researchers, rather than rely on bulk numbers alone, as is conventional.[23] For example, this effort should identify the extent to which graduates of the world's leading synthetic-biology labs, who understand the cutting edge, move to the UK. Such research should also seek to engage 1:1 with first-rate international talent, particularly at early-career stages, and identify key factors that would motivate people to move to the UK, such as salary, child-care support and research freedom. This could utilise the UK's Science and Innovation Network.[24]*

Researchers are also burdened by extensive bureaucracy: on average, it takes 230 days for the MRC to approve a funding application.[25] Scientists carrying out basic research often have to spend significant amounts of time cleaning and organising data, while early-stage researchers face enormous obstacles to beginning careers.[26]

Recommendation: *The government should direct UK Research and Innovation to restate a commitment to excellence as the sole determinant of talent funding, and to prioritise quality over quantity, with particular focus on early- and mid-career stages. This should be informed by the programmes of the Wellcome Trust, the European Research Council's Horizon programme and the Howard Hughes Medical Institute. However, there is a strong case to make it a condition of such awards that other sources of funding are excluded, so that the focus is on research. Otherwise, such a policy risks further empowering*

empire-building behaviour (see below).

These programmes relieve academic researchers in universities from a grant-writing treadmill, allowing them to explore and take long-term, high-risk bets. However, we also need to begin moving UK R&D in a direction that works to include a diversity of skills within teams over longer periods of time, adapting to global changes in research.

REFORMING RESEARCH ORGANISATION TO PRIORITISE BIODESIGN

The organisation of UK R&D has changed little in 70 years. It is highly dependent on an academic model whereby principal investigators manage and mentor laboratories of temporary trainees. While the UK is fortunate to have some of the world's historically great universities, as well as many with unique specialisations, globally this model of organisation research has come under increasingly serious strain, as the previous *New National Purpose* reports highlighted.

The global challenges of this model are increasingly well recognised,[27] and are particularly pressing for biotechnology. There are at least three major and interrelated challenges.

1. **Hypercompetition:** The default academic career path is under strain due to the number of trainees exceeding available positions by much more than an order of magnitude. This has created an increasingly pyramidal career structure[28] in which senior academics use limited grants to fund an ever-increasing number of early-career researchers, despite a scarcity of long-term positions or prospects for career development. This has serious negative impacts on research culture, leading to an increasing exodus of the best up-and-coming talent.[29]

2. **Poor talent utilisation:** As biotech-related science has grown more complex, individual projects can require a combination of skills and methods from areas as diverse as AI, big data, materials science, genetics, virology, robotics and synthetic biology, with resulting growth of group sizes.[30] It is not possible for a single person, or even a small lab, to possess the required expertise in all of the necessary areas.

   AlphaFold's work in protein-structure prediction, for instance, required a team of individuals with not only cutting-edge machine-learning expertise but also

the ability to pair that expertise with a deep understanding of structural biology. Few UK-based organisations and institutions offer training or research positions at the forefront of interdisciplinary work.

Furthermore, UK academia can often be so focused on studying biology as it is found in nature, rather than the design of new biological systems, that there are few people being trained in how to design and evaluate new biological designs at rapid scale. This can make it unattractive to start and scale a company working on the most novel biotechnologies in the UK, as opposed to in the US where the academic talent pool is more well balanced across the continuum of scientific discovery and technological invention.

Globally, these changes are motivating the creation of new types of research laboratory and support that differ markedly from conventional academia, a topic that has recently been well explored by Sam Rodriques.[31] The recently announced UK Research Ventures Catalyst is a step in the right direction but is small in scale.[32]

3. **Large and atypical labs are increasingly the only ones able to consistently compete internationally:** A prominent structural change in biotech-related academia has been the growth of large groups working for a single professor. We could not find clear data on this, but it appears to be particularly prominent in elite US academia, with individual professors having groups of 50 to 100 trainees. There are also now some examples of such labs in UK universities. These large groups allow pooling of resources to bring a critical mass and concentration of diversely skilled talent, which can be especially important in technology-intensive areas of research such as biotech.

However, such an approach to organising biotech research also fundamentally changes research in a way that cannot be sustainable nor to the collective benefit of science. Such a research environment can become increasingly hierarchical, with a career system to be gamed, incentivising resource acquisition and the exploitation of junior scientists at the expense of pushing the boundaries of human knowledge. It is doubtful, for example, that a professor with almost 100 people in their lab can be meaningfully involved in the mentoring or work underlying the research for which they take credit, collect prizes and hold patents. The system ends up rewarding administrators and empire-builders, not creative scientists actively engaged in research and mentoring. Gone are the days of the early LMB when Fred Sanger did the work

for his second Nobel prize with his own hands at the bench.

This poses a challenge for the UK: how can the benefits of such large groups be reaped to enable global competitiveness in biotech research, without the downsides that they entail? Globally, an increasing number of US laboratories – including Arcadia, Arc, Janelia and Future House – are utilising strong, shared resources and a specific mission or vision to enable the small groups within them to access the resources required for interdisciplinary research, without the downside of large groups. Further, rather than siloing discovery scientists from engineers, these labs combine their skillsets by bringing them together under one roof, promoting "cycles of discovery and invention".[33] Some of these institutions have explicitly learnt from the organisation of industrial labs such as Bell Labs, which lacked principal investigators altogether. This is part of a larger US trend in philanthropic funding towards finding fundamentally new organisational models of scientific research, the majority of which is focused on biotech.[34]

In addition to the US's pioneering new organisational models, it also has leading conventionally organised institutions focused on supporting early-stage, pre-commercial invention alongside discovery. For example, at the heart of much of the de novo protein-design revolution is the Institute for Protein Design (IPD).[35] Under David Baker's leadership, the IPD has crafted synthetic proteins with the capacity to bind viruses to ward off infection and perform instant diagnostics. The IPD alone is attracting substantial private-sector spinouts, which have raised more than $1 billion[36] and triggered a biotech boom in Seattle. Pharmaceutical giants are taking notice, with one of IPD's spinouts, the vaccine company Icosavax, being acquired by AstraZeneca for $1.1 billion.[37] The success of IPD and other engineering-heavy organisations like the Broad Institute demonstrates that engineering-oriented biological-research facilities can be transformational and that private-sector approaches alone are insufficient.

While the government's recent £2 billion commitment to engineering biology is to be strongly welcomed, without reforming how it approaches this topic at the institutional level the UK risks getting left behind.

The interdisciplinary, engineering-oriented mindset and organisation outlined above is relatively underrepresented in our most exceptional and best-funded laboratories. While the UK has two stand-out biology laboratories that have some of these features – the LMB and the Francis Crick Institute – neither

prioritise the use of engineering approaches to biological problems. The LMB is not primarily focused on biotech engineering, instead prioritising discovery-science early-stage research in molecular, cellular and mammalian physiology-level fields, which are just a subset of biotech. Similarly, at the Francis Crick Institute those directly interested in the creation of new technology make up a small minority of the faculty. While the LMB and the Crick produce discoveries of value to biotechnologists, there remains a strong need for an institution specifically focused on biodesign, resourced to compete internationally and staffed with researchers from younger generations.

Recommendation: *Britain should build a new laboratory, focused on the invention of biotechnology that is at too early a stage for commercial investors and companies. It should be of sufficient scale to pursue a range of topics and benchmarked in funding per researcher to leading international competitors.*

The UK Laboratory of Biodesign would:

- Use experimental and computational methods to design, build and test new synthetic biotechnologies, biomolecules and therapeutics under one roof.
- Provide a space for highly innovative design that the industry is not currently incentivised to build, such as inventions with lower technology-readiness levels.
- Train interdisciplinary talent at the intersection of biology, computation and scaling biotechnology. This has the double benefit of being a competitive academic environment and also producing a large talent pool of scientists with the right combination of skills to incentivise other entrepreneurs to consider starting and scaling companies in the UK.

To achieve this, the laboratory should aim to:

- Be set up in a way that incentivises the commercial spinout of frontier biotechnologies. Other major research labs have previously failed in this endeavour, limiting the scale of industrial transformation available.
- Be able to recruit first-rate talent internationally, with a particular focus on early- and mid-career researchers.

- Have world-leading core facilities, such as state-of-the-art tools for computational-biology, genetic screening and sequencing, and molecular imaging, powered by GPU clusters.
- Link computational facilities with complementary wet-lab facilities capable of running rapid iterative prototyping, as seen in advanced engineering.

When a new laboratory is set up in the UK, there is a risk that it inherits a bureaucratic, hierarchical academic-research structure. This default model poses challenges for technology-intensive, interdisciplinary research.

Recommendation: *One of the Laboratory of Biodesign's founding missions should be to pioneer a new institutional model that does not rely on principal investigators employing teams of graduate students and postdocs. It should be the first instance of the "Disruptive Innovation Labs" recommended in previous New National Purpose reports.*

To address the challenges outlined above, the laboratory's leadership should closely study organisations that have been pioneering new approaches to structuring the pursuit of science, with a view to replicating their success.

These approaches include:

- Full core funding, with resources to compete with leading global labs, including strong, shared central resources.
- A flat hierarchy with small research groups, and all researchers engaged in research with their own hands.
- Focusing specifically on recruitment of exceptional junior (not necessarily young) talent.
- Employing the majority of staff as junior fellows, professional staff scientists, technicians and engineers, rather than using the postdoctoral system.
- Using highly technical managers, rather than tenured principal investigators, to allocate research resources, as in industrial labs.

It is important to note that many of the emerging paradigms, such as sequencing the human genome at the LMB, or Google DeepMind's protein-

folding breakthrough, were not top-down approaches. Rather, they occurred through the evolution of a field over time, by assembling the right groups of people. In this sense, the Laboratory of Biodesign should aim to create the conditions for a greater number of brilliant people to form a greater number of brilliant teams.

Furthermore, the Laboratory of Biodesign could be focused on the following research pillars, presented here as illustrative examples.

- **Synthetic-biology research to develop novel biotechnology**, including DNA synthesis and genome engineering across various organisms, as recommended by a recent letter from the Council for Science and Technology (CST).[38] This would grow from existing work, including that from Jason Chin's group at the LMB.

- **Development of novel types of therapies and drug-delivery technology**; in other words, new ways of curing diseases and delivering the drugs to specific tissues (for example, the next CRISPR) that are considered too exploratory and risky to be investable by large pharma companies.

- **State-of-the-art capabilities in de novo protein and biomolecular design, engineering and validation** under one roof – allowing for fast testing cycles that aren't possible in small groups with little specialisation.

- **AI-first biological design and modelling**. This would require significant investment into data-generation capabilities to train the best models, and compute infrastructure to tempt the best AI talent away from big tech.

- **In-house researchers specialising in the upscaling and manufacturing of biotechnology breakthroughs** developed at the laboratory, coupled with innovation-friendly spinout and commercialisation policies,[39] similar to what the Whittle Laboratory at the University of Cambridge is trying to do for physical engineering.

An institution of this kind should be able to generate significant sponsorship from early-stage investors in a more efficient way than the norm. One option to help drive this, both in terms of funding for optionality projects and for expertise, would be to set up a non-profit sponsored by early-stage investors.

This would then be a way to compete with the US venture-creation groups, like Flagship and Third Rock, at scale in the UK. Ultimately, the commercial success of its research should be more important than its volume of publications.

The Laboratory of Biodesign should have substantial autonomy from central government bureaucracy, as this is important for enabling cutting-edge research; but it should also have two additional founding missions that are key to UK national strategy. First, the laboratory should adopt a role in setting standards and metrics. One of the issues with AI for bio models is that many laboratories have poor metrics for validating whether a model has been effective or not; it is rare that those with the skills to design and train such models are also able to give them a rigorous biological appraisal. This runs the risk of creating a "replication crisis" in machine learning for biology.[40] This is not purely an academic issue, as companies founded on potentially dubious AI models will eventually hurt the UK biotech ecosystem when they fail. The Laboratory of Biodesign should help to change this.

Recommendation: *The Laboratory of Biodesign should use its interdisciplinary skills to lead the development of new machine learning for science-research standards and metrics, supporting the establishment of a DSIT bio-sector measurement standards and metrology board as recently recommended by the Council for Science and Technology.*[41] *This board should adopt an open-source approach to developing such standards, drawing on insights from a range of research disciplines and international collaborators.*

Second, the Laboratory of Biodesign should provide biosecurity advice to the UK government. Few organisations in the world have the relevant institutional knowledge to understand both frontier-AI capabilities and major biosecurity risks. The final section of this report deals with these issues in greater detail, but the Laboratory of Biodesign has a role to play in this endeavour.

Recommendation: *The Laboratory of Biodesign should contribute to the state's capability to monitor and evaluate the biosecurity risks of frontier biotechnologies and AI models, and assess relevant future technological trends to enable pre-emptive, not reactive, policy. It should work closely with the AI Safety Institute to develop new bioevaluation methodologies. In particular, it should focus on risks from "narrower" biology-focused models, an area that risks being neglected by the current approach to evaluating frontier models.*

This is necessary but insufficient to bring the UK back to the frontier of early-stage engineering-intensive biotech research. This report focuses on a specific institutional landscape change, as our earlier reports outlined additional ecosystem-reform steps, and because the government has already begun working on a broader engineering-biology funding programme for the wider community, as referenced above.

RESEARCHING THE REGULATORY FRONTIER

The proposed Laboratory of Biodesign can help the UK move to the frontier of applied biotech research. However, research needs to be upgraded not just at the level of the laboratory, but for the regulatory ecosystem itself.

Currently, the pace of technological change is far outstripping our regulatory capacity, meaning biotech products cannot get to the market fast enough. Our current medical-regulatory institutions are not configured for a landscape where devices and products are constantly improving as the state-of-the-art models update. With the recent announcement of the Rare Therapies Launch Pad[42] – a pilot programme that will offer, for the first time, a pathway to approval for customised drugs – the UK is taking the right steps. But the science of regulatory research still needs to be improved further if we are to enable a more nimble approach.

The US has rewired its regulatory ecosystem in this manner. Its Centers of Excellence in Regulatory Science and Innovation (CERSI) programme[43] was established to foster robust and innovative approaches to advance regulatory science. Through collaborative interactions with Food and Drug Administration (FDA) scientific experts and funding offices, the CERSIs develop new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products. The CERSI programme's work has helped to improve Covid-19 treatment[44] and furthered the development of new antimicrobial approaches. There is no reason why the UK could not follow suit. In addition to encouraging the Medicines and Healthcare products Regulatory Agency to accept decisions from the European Medicines Agency and the US Food and Drug Administration for standard drug approvals, safety monitoring protocols and clinical trial guidelines, the UK must set up a proactive and forward-looking mechanism that constantly searches for the frontier of regulatory science, in order to become a super-fast and specialist regulator of cutting-edge technologies.

Recommendation: *Innovate UK should establish its own CERSI-style programme, developing new tools and standards to assess regulatory products, and offering information-sharing opportunities such as workshops, fellowships and competitions. Although this programme should eventually be deployed across multiple regulators, initial centres of excellence should begin their pilots in health, working alongside the Medicines and Healthcare products Regulatory Agency and the Regulatory Horizons Council to improve regulatory-science standards.*

The CERSI model would also assist with the challenge of regulators lacking tech expertise. In the short run they can alleviate some of the immediate capacity constraints on regulators, while also training up future generations of technical experts who can eventually join those regulators themselves through secondments (via DSIT's Expert Exchange programme) or full-time hires. In a world where technological change will force states to frequently revisit their modes of governance, regulatory science can help a reimagined state respond flexibly to emerging policy challenges.

Alongside this model, a more coordinated approach across government is needed to support biotech startups through the regulatory process.

Recommendation: *The government should establish a Regulatory Observatory that brings together insights on biotech applications for regulators across sectors. The responsibilities of this observatory would include: coordinating horizon-scanning activities among regulators; establishing dialogue with biotech startups and small- and medium-sized enterprises to support them through their regulatory processes; and acting as a focal point for coordination with international regulators. This was also recommended by the CST in March 2023.*[45]

05

Harnessing Health-Data Collection in the AI Era

The public sees health care as a key area that can benefit from AI.[46] Over the coming decades, AI systems will be created that can understand each individual's composition and lifestyle, and harness that information to provide highly personalised lifestyle and treatment suggestions on demand, with little marginal cost for each additional patient. Training and implementing AI will require excellent population-level data sets and innovation in institutional structures. The UK, therefore, has an opportunity to create the first truly personalised AI Doctor, helping GPs and clinicians deliver the highest standard of care across an entire population.

Seizing this opportunity will require a degree of strategic intervention by the state. Expertise in modern AI is not yet well represented at senior levels in decision-making structures, due to the sudden and recent emergence of this technology.[47] State intervention is also needed due to the scale of ambition required and the urgency with which it must be pursued, and to overcome potential vested interests in the status quo and allow a new generation of leaders with a new perspective to emerge.

The UK has used strategic direction highly effectively to become the global leader in genomics, building on a strong bottom-up ecosystem. It is important that this support continues. However, a similarly ambitious agenda is now needed to make the UK the global leader more broadly in the era of AI medicine. This requires a diversification, not a replacement, of our approach.

This section focuses on the need to reform how we approach data and its collection. This is an area in which the UK has a unique global advantage and hence an opportunity to address what is currently a major international challenge. Other areas of AI research such as machine vision and natural-language processing depended on vast data sets that could be acquired at low cost and with little friction. In health care, just as data are crucial to human doctors, they will be crucial for AI.

However, in the medical space collecting data presents unique and significant challenges both practically and ethically, and is highly bottlenecked. Current

data collection is fragmented. Typically, different and quite narrow types of data are collected on each different patient cohort; many studies only measure limited aspects of an individual. This prevents the resulting AI models and research efforts from understanding how different features of a patient – their lifestyle, genetics, personality and physiology – relate to one another, limiting efforts to generalise beyond the subjects studied and holding back the transformative potential of AI.[48]

Addressing this challenge supersedes the capabilities or scope of any one company, university or even research funder. Rather, it requires a coherent national effort to make coordinated changes across multiple areas. The UK has extraordinary advantages in this space owing to the NHS, exceptional medical researchers and an ability to build on existing institutions highlighted in this report that set a global standard. However, global competition is fierce.

The first steps to pursue this long-term agenda involve:

- **Harnessing UK health data securely,** reforming and innovating in terms of how the UK uses the health data it already has. These data are vital not just for AI-centric approaches, but medical research more generally.
- **Rebalancing UK biomedical research for the era of AI medicine to create an AI Doctor.** This means seeding the early-stage research that will forge a path to the creation of a personalised AI Doctor for every citizen and supporting NHS adoption of these AI technologies to help, not replace, clinicians.

HARNESSING UK HEALTH DATA SECURELY

The UK's biotech sector stands on the brink of transformative growth, propelled not only by scientific breakthroughs but also by the innovative application of the NHS's vast health-data assets. This hinges on effectively harnessing comprehensive genomic and phenotypic information, and linking it to clinical records, imaging and disease registries from the UK's nearly 70 million residents.

Pioneering initiatives like Genomics England (GEL) and UK Biobank are central to this endeavour. GEL's 100,000 Genomes Project has been instrumental in embedding genome sequencing in routine health care, leading to new

advances in personalised medicine. UK Biobank, with its extensive genetic and health-data collection, plays a pivotal role in advancing medical research, as further highlighted during the Covid-19 pandemic.

UK biotech innovation thrives when we deploy NHS capacity imaginatively to tackle health challenges. For example, the Our Future Health programme leverages NHS resources to generate new data that can advance our understanding of diseases and improve our approach to early detection and prevention.

Given this enormous opportunity, more should be done to unblock significant structural challenges that prevent the UK from realising the potential of its existing health data, especially the data within the NHS.

- Current data are not "AI ready" in terms of structure, particularly for multimodal models that can deal with both images and words.
- Under the NHS's "data controller" model, stewardship of public data is fragmented; it typically lies with health-care providers and entities, leaving individuals disempowered.
- Large amounts of NHS data are left in poor quality (including in terms of timeliness, digital capture capacity, linkability and accessibility), as well as being poorly input due to a lack of appropriate incentives.

These challenges are compounded by the lack of a viable commercial strategy that drives value for patients, the public, the NHS, and research and innovation.

New health-care institutions are beginning to put the UK on the right footing. The Our Future Health programme, which is shaping up to be the UK's most ambitious health-research project, aims to enrol 5 million participants, with 1 million already enrolled. Secure Data Environments[49] (SDEs), the NHS equivalent of Trusted Research Environments (TREs), will securely handle and process sensitive health data, acting as "reading libraries" where accredited researchers can access and analyse data in a privacy-preserving manner. Additionally, Health Data Research UK (HDR UK) has trained more than 12,000 health-data scientists[50] and adopted new models for data interoperability.

However, much greater steps are needed to transform the UK's robust status as a health-research and life-sciences innovation hub into an asset that

catalyses biotech innovation and reinforces the UK's leadership in this field.

ENHANCING DATA READINESS FOR AI IN HEALTH CARE

AI has the potential to transform health care in areas ranging from improved speed and accuracy in diagnostics to better operational planning, all of which support a move towards preventative care and reliability in understanding patient flows. For this to be possible, the platforms on which data are held must be able to support the training of AI models.

Technical Readiness for AI in Research and Innovation

The growing role of AI in health care underscores the need for secure access to robust, high-quality data for general research and innovation. TREs are set up to meet this purpose, but they generally lack the capability to effectively support the training of AI models, primarily due to their existing infrastructure and processes, which are tailored for traditional statistical analysis. Applying AI models would mean that relevant data could be identified and mined much more rapidly to find connections between different data sets, reducing labour.

AI training requires vast computational resources and the ability to handle large, diverse data sets in ways that traditional TRE setups do not generally support. TREs often lack the technical capabilities needed for the sophisticated assessment of data-privacy risks that AI models require. Furthermore, TREs are key to developing AI for medical devices but often are not set up to comply with strict regulations in this field.

Recommendation: *The government should invest significantly in enhancing the capabilities of Trusted Research Environments. Investment should focus on developing the technological framework required for AI training, as well as privacy-preserving technologies for secure data analysis.*

Recommendation: *A standardised methodology for running machine-learning projects within Trusted Research Environments should be established. This should streamline tooling and processes across different systems, facilitating the use of diverse data sources for AI without compromising data integrity and security.*

Building Workforce Readiness for AI

Workers will need to be upskilled to manage these upgraded systems. The NHS workforce lacks the skills needed to manage the commercial and technical aspects of using data for biotech research and innovation. As data become more complex, enhancing these capabilities is vital, as is forming partnerships with the right companies. These partnerships – exemplified by the fruitful and mutually beneficial collaboration between Great Ormond Street Hospital for Children NHS Foundation Trust and Roche[51] – can be designed to resource workforce training and organisational transformation without increasing demands on clinician time or imposing financial strain on hospitals.

Recommendation: *The skills gap in the NHS workforce is a key challenge that needs greater attention. Partnerships with industry leaders are key to resourcing workforce training and providing the expertise necessary for the NHS to effectively manage the technical and commercial aspects of biotech-data use. Funding to attract, retain and deploy workers skilled in data architecture, commercial partnerships and AI development should be made available. Stability in the model used for technical transformation is also needed to ensure staff retention.*

Recommendation: *Encourage pharmaceutical companies to reinvest their apprenticeship levy in developing the NHS workforce. Encouraging pharmaceutical companies to second workers to the NHS in this way would address the underutilisation of the scheme and bring in diverse talent essential to the digital transformation of the NHS and greater adoption of AI in health-care services.*

DEMOCRATISING DATA ACCESS: ENHANCING PUBLIC TRUST AND EMPOWERING INDIVIDUALS

Data control within the NHS and public trust in who has access to health data have long been points of contention. Building public trust is critical to ensuring the true value of NHS data can be realised.

The collaboration between Moorfields Eye Hospital NHS Foundation Trust and Google DeepMind[52] is one notable example of the value of NHS data. Initiated in 2016, this partnership harnessed AI to detect eye diseases using extensive retina-scan data, setting a benchmark for NHS technology partnerships. However, the project attracted some criticism[53] in terms of whether patients

were adequately informed about how their data would be used.

Additionally, lessons can be learned from the failures and ultimate closure of the care.data platform.[54] Like SDEs, the care.data platform aimed to bring together health and social-care data for patient care, research and quality-assessment purposes. But it failed to gain public trust due to poor communication and concerns around opt-outs, access and privacy.

Public confidence has been dented amid insufficient public engagement around the General Practice Data for Planning and Research (GPDPR) programme proposed in 2021 and more recently around the announcement of Palantir as a key supplier of NHS England's Federated Data Platform (FDP).[55] Opt-outs, introduced in 2018, remain high[56] (as of July 2023 they stood at 3.3 million people; in some areas the opt-out rate is as high as 7 per cent). Even relatively low opt-out rates can undermine the representativeness and utility of NHS data, which is crucial for biotech research.

Politicians have historically been wary of wading into these debates, but UK polling suggests that the public is generally inclined to support the use of its data for health innovation. Some 81 per cent of respondents[57] are happy to provide the NHS with data about themselves to develop new health-care treatments, while 74 per cent[58] say the public should be involved in decisions about how its health data are used.

Recommendation: *As iterated in the Goldacre Review,[59] NHS England should serve as a steward of public information, alongside other key advocacy voices, on the use of public-health data for commercial research. This should include campaigns on data literacy and the role of research to limit the spread of misinformation and reduce opt-out rates. Helping people make informed decisions about their preferences and making it easy to opt back in via the NHS App, as with organ donation, should be a priority.*

Recommendation: *The NHS should engage in additional consultations on the public's views on use of data. Citizen juries, as used in the OneLondon Citizens Advisory Group considering the London SDE,[60] as well as other forms of public consultation such as focus groups, as recommended in the Goldacre Review,[61] ought to be considered. NHS England has begun this process, with up to £2 million in funding allocated.[62]*

The UK also faces challenges unlocking the potential benefits of NHS data

due to the absence of a unified legal and contractual framework comparable to the US Health Insurance Portability and Accountability Act (HIPAA) regulations.[63] This gap results in a risk-averse mindset and inefficiencies in data access.

Moreover, multiple data-access processes cause lead times of many months to years when accessing data for research. During the Covid-19 pandemic, linking data effectively was critical for research. Control of Patient Information (COPI) notices were issued disapplying the common-law duty of confidentiality for pandemic research and somewhat simplifying data access, but these have now expired.

Recommendation: *The NHS, alongside UK Research and Innovation and all controllers of health and health-relevant data in the UK (such as UK Biobank, Genomics England and Our Future Health), should develop a transparent, streamlined, unified and holistic contractual and governance framework for data usage, standardising the anonymisation/pseudonymisation and data-access processes across health-data controllers. This framework should provide clear guidelines on usage, privacy, data-access costs and intellectual-property rights, enabling a balanced data-commercialisation approach that delivers public benefit.*

Additionally, the current "data controller" model in England poses challenges. Currently, under the UK General Data Protection Regulation, individual GPs control their patients' data and are responsible for compliance with the common-law duty of confidentiality between doctor and patient. This results in a system that is fraught with access challenges, places significant liability on GPs and can lead to a cautious approach to data sharing. It compounds the wider challenge of bringing together data sets scattered across NHS systems.

This risk-averse approach was evident when the British Medical Association (BMA) chose not to recommend that GPs share patient data[64] with UK Biobank, even though the data came from patients who had consented to their data being shared for that very purpose.

Recommendation: *NHS England should adopt a shared model for data controllers similar to the model in Scotland (where NHS Scotland shares data control), effectively co-owning both the data and associated liabilities. This approach would alleviate individual GP liability and facilitate data sharing and*

collaboration. Before any changes are made, meaningful engagement should take place so that patients and the public are properly consulted about who controls their data.

The public's lack of access to health records is another foundational aspect of its trust deficit. People currently have limited access to, and authority over, their own health data. As the UK moves towards a more secure and improved data-access model for researchers and health-care providers, it should also transition to a progressive model in which individuals, rather than playing a passive role, are empowered with direct access to their data and ownership over it.

This would take the form of a central, secure, cloud-based system enabling individuals to access their health data – from imaging to primary- and secondary-care records, as well as data held in wearable technologies such as smart watches – in a Personal Health Account[65] (PHA) via the NHS App. The PHA would differ from the FDP, which connects data only for use at an operational level, as well as from SDEs, which enable researchers to access NHS data. Enabling public access in this way would allow individuals to interact with their health data and better understand how their information was contributing to research and innovation.

Anonymised PHAs should be integrated into the broader NHS data ecosystem, providing a comprehensive, longitudinal view of individual health data. Longitudinal linkage stands as a cornerstone for comprehending long-term health trends and outcomes; it is instrumental in driving tailored, more efficacious health-care interventions such as personalised mRNA cancer vaccines.[66] The cloud technology behind PHAs would help solve interoperability problems seen in current electronic patient-record systems, making data more accessible.

Recommendation: *Establish Personal Health Accounts to empower members of the public to take ownership of their health-data management. These accounts would serve as a single, cloud-based platform connecting individual health data. The NHS App would act as the digital front door; individuals could use their information to manage health-care interactions such as booking appointments, accessing medical records and managing treatments. Ensuring that PHAs were user-friendly, secure and fully integrated with existing NHS data sources would be key to their success.*

ADDRESSING DATA-QUALITY ISSUES: IMPROVING STOCK AND FLOW

Enhancing the quality of data within the NHS is key to advancing the UK's biotech sector. Addressing issues related to data accuracy, completeness and transparency is crucial to the data's utility in clinical applications and research. As suggested by Lord O'Shaughnessy and Lord Darzi, this effort must include funding for data-quality infrastructure and capability programmes.[67]

Understanding the concepts of "stock" and "flow" is key to addressing NHS data-quality challenges. The "stock" of data refers to health records accumulated within the system. Enhancing this stock means ensuring historical data are not only accurate and complete, but also readily accessible for clinical and research purposes. The "flow" of data involves the ongoing process of data entry and capture. Under the current system, clinicians are largely responsible for recording data accurately, leading to gaps.

Addressing the issue of incentivising data input is crucial to improving the stock of NHS data. Currently, the primary motivation for accurate data entry often links to billing, as evidenced by the higher quality of GP data linked to Quality and Outcomes Framework payments. The challenge, therefore, lies in encouraging clinicians to capture data accurately from the outset. Implementing real-time audits or spot checks would increase the likelihood of identifying poor data capture and serve as an oversight mechanism.

Leveraging AI as an auditor could enhance this process. An AI system designed to understand what good data capture looks like for specific care interactions could actively prompt clinicians when data entry does not meet expected standards, thereby ensuring higher data accuracy and completeness.

Recommendation: *The NHS should implement bottom-up, real-time quality audits and feedback mechanisms to ensure complete and usable data for research. These should involve external experts in regular reviews. A dedicated NHS team should be established to implement insights that can significantly elevate the quality of existing data.*

Recommendation: *For data flow, the Incubator for Artificial Intelligence established by 10 Downing Street and the Cabinet Office should focus on using AI for automated data entry to alleviate the data-coding burden on clinicians. This technology would not only streamline the data-entry process*

but also enhance the accuracy and timeliness of the data recorded, making them more valuable for clinical decision-making and research.

PHAs can also play a vital role in improving the stock of data by providing the public with direct access to their health data, so that they can review, update and enrich their own records.

ESTABLISHING AN NHS DATA TRUST: REALISE VALUE FOR THE PUBLIC

NHS data are an extremely valuable resource. Comprehensive longitudinal human data sets are central to the research and development of new treatments, and could drive a new cohort of cures. Additionally, at a time when funding is in crisis, the NHS could harness available data to more than recover sunk costs emerging from providing data via SDEs and other mechanisms for research purposes.

This necessitates broader reflection on the role and value of data within the public sector. As the value of the data collected by the state becomes better quantified, and the societal gains the data could generate more apparent, new questions about how data are managed and how the public derives benefit emerge. As highlighted in the first *New National Purpose* report, the government must conceptualise data as a competitive asset that is transformative for the health and biotech sectors, where private actors lack the coordination and scope to produce such data. This is exemplified in the way consumers trade data with companies like Google in exchange for valuable free services like Google Maps. The data set's true worth is realised when companies extract substantial value from it – a principle that can be extended to how the government must make use of data sets for its citizens. In health, this means identifying creative ways to deliver public returns in addition to the general societal benefits arising from technological progress.

Steps to leverage NHS data in a more productive manner are being taken. The Data for R&D Programme[68] is starting to make NHS data more accessible for research, with the creation of 12 SDEs bringing together thousands of siloed data points.[69] But transforming data quality and availability requires engagement with the private sector, which in turn can present concerns about privacy. This issue, together with a lack of negotiating experience, means that the NHS has not approached the management of data assets in a strategic and purposeful way; in most cases demanding only a small fee for external access and use of anonymised data for research, or sometimes no

fee at all.

Finding a way to share the value of its data set with private enterprise – while addressing privacy, security and misuse concerns – would be of great benefit to patient and public-health outcomes, to the economy, and to help fund the NHS itself. There is already a strong precedent for giving controlled access to anonymised data to third parties through the UK Biobank programme, something that was perceived to be in the public's interest at the OneLondon deliberations.[70]

In July 2023, NHS England published its Value Sharing Framework[71] for NHS data partnerships, but this guidance does not go far enough. The framework provides advice to NHS organisations but not support; the skills needed to determine the best reimbursement mechanisms or negotiate value-generating data-sharing agreements remain in short supply in the NHS.

The BBC model serves as a practical way of blending public service with commercial success. The broadcaster provides a service to the public while also running BBC Studios to generate revenue. Its commercial ventures align with its mission and profits are reinvested back into the public institution, enhancing its ability to serve. The NHS can adopt a similar approach. Research serves a dual purpose; it is both a public service enabling technological advances and a commercial opportunity. There's an ongoing need for advocacy around the importance of research within the NHS to ensure it is a priority. At the same time, given the pressures and constraints faced by the NHS, there is a clear need for an entity dedicated to the research function that can also handle commercial matters.

This kind of entity would focus on leveraging NHS data not just for public-health benefits, but also to generate revenue that could be reinvested into NHS research and development.

Recommendation: *Establish an NHS Data Trust, a company in which NHS England has a controlling stake, with additional investments from other companies. With a clear purpose to benefit the NHS, the NHSDT would be tasked with managing NHS data and forging effective partnerships with external entities. This model would reshape NHS data management into a strategic, ethical and patient-centred system. It would unlock significant benefits in terms of public empowerment, health-care research and the overall economic wellbeing of the NHS.*

The NHSDT would:

- Be responsible for implementing strict patient confidentiality and data-privacy rules, ensuring that individuals could not be identified from the shared data and that the data remain solely owned and controlled by NHS England.
- Provide professional curation and management of NHS data, ensuring data are accessible in well-structured, standardised formats.
- Provide research entities with access to the anonymised data in return for financial profit, which would benefit the NHS. This could happen via a range of mechanisms, varying from direct financial payment to negotiating cost-price access for the NHS to any medicines developed based on the data provided.

A clear governance model would ensure that the NHSDT would be a collective asset designed for public benefit:

- It would be majority-owned by NHS England, ensuring that its operations were aligned with public-health objectives, rather than private capital.
- It would negotiate data-sharing agreements with external organisations, with options for profit-sharing from successful new treatments, benefitting both the NHS and patients.
- Strong legal protections should be in place to ensure the data are never sold to third parties and are always strictly anonymised.
- Financial gains from data usage would be reinvested into the NHS, creating a sustainable model that benefits the health-care system. Funding would also go towards improving public engagement, bolstering public input into the NHSDT.

From a delivery perspective, the NHSDT would initially be built on the SDEs and use an opt-out model, allowing people to actively choose to contribute their data to R&D with their privacy and autonomy fully protected.

To enable a successful and sustainable NHSDT, further requirements should be met:

- The senior leadership of integrated care systems, one of the key stakeholders for driving uptake, should be accountable for opt-out issues, and incentivised to reduce opt-outs and drive public engagement.
- The NHSDT must adopt competitive recruitment practices to ensure it operates efficiently and effectively, aligning with the best private-sector standards.
- Additionally, the NHSDT should be operationally flexible to attract and retain talent, and act as a savvy commercial entity maximising value for the NHS and patients.

With national engines to drive foundational research breakthroughs and institutions specifically designed to improve real-world health-data quality, the UK could become the best place in the world to conduct research and establish the next generation of biotech companies. However, it must also move ambitiously in terms of the kinds of data that are collected and how they are utilised by individuals to unlock an era of personalised AI doctors.

TOWARDS AN AI DOCTOR FOR EVERY CITIZEN

Rapid progress in AI and biotechnology motivates thinking ambitiously about personalised health care that is not only more efficacious but also more cost-effective. Already, leading companies and philanthropists in the US are looking a decade-plus into the future, for example pursuing the creation of "AI scientists" able to process data, formulate scientific hypotheses and develop plans for experiments.[72]

Greg Brockman, president of OpenAI, recently highlighted the creation of personalised AI doctors as a major future benefit of advanced AI systems.[73] OpenAI has already entered into a partnership with fitness-tracking company WHOOP to combine the utility of ChatGPT with the personalisation offered by wearable devices.[74]

Developing an AI Doctor for every citizen is a long-term challenge that will involve innovation in diagnostics, advances in AI to parse physiological data and revamping health care to incorporate these tools. Owing to the NHS and population-level data collection via UK Biobank, the UK is particularly suited to pioneering an AI Doctor distributed at scale.

To understand this concept and the motivations driving it, this report examines some of the limitations and challenges of the predominant approach to biomedicine and health. It then examines recent work pointing to a way this approach could be complemented and outlines steps the UK should take in the next Parliament to assume a leadership position on the path to creating a personalised AI Doctor for all.

Diversifying the UK's Approach to Biomedicine

Health-care systems around the world are struggling with ever-rising costs. The NHS is particularly struggling. Without substantial innovation, ageing populations will only worsen this problem, creating an unsustainable situation. Over the next 20 to 30 years, a profound change in how countries approach medicine and the promotion of health is needed.

Furthermore, many conditions, especially chronic ones, remain intractable to standard methods of western biomedical research such as molecular target-based drug discovery. Long Covid has cast a spotlight on these "mystery illnesses", but they have been a long-standing and growing problem.

A considerable amount of valuable biomedical research is taking place in the UK. However, early-stage biomedical research is relatively strongly focused on genetic and molecular approaches, partly due to the UK's tremendous success in creating these fields in the past century, and to sustained and highly successful government support in genomics. This means departments and decision-making structures around early-stage biomedicine in the UK predominantly comprise people with backgrounds in more genetic and molecular approaches to early-stage biomedical research.[75]

As highlighted earlier, the UK's genomics history is a tremendous success story; highly important advances are being made – and will likely continue to be. However, in order to develop a robust health-innovation ecosystem, world-class genomics capabilities need to be complemented by additional infrastructure. Without this, we potentially face significant limitations:

- Genetics captures a fixed, static impression of an individual, and one that is difficult to selectively change across the whole body.
- Genomics is increasingly revealing that most complex traits and disease risks are influenced by many, even thousands, of positions in

the genome.[76] This reduces researchers' ability to identify clear molecular targets from the data. Common diseases such as heart disease or certain cancers can have many genetic factors, preventing simple gene-therapy approaches. This pattern also appears in psychiatric disorders, which are notoriously polygenic.[77]

- Genetic data are far removed from directly measuring aspects of a person's health over which they have control: how their lifestyle choices influence their health over time.

  In technical terms, the UK has focused on and excelled in understanding genotype (the organism's genetic sequence), and should now aim to emulate these successes to understand phenotype (the characteristics of the organism), the non-genetic influences on that phenotype and how these each relate to one another.

  There are significant signs even in the highly molecular-centric pharmaceutical industry that the genetic-molecular scale approach needs to be complemented with discovery at other scales.[78] Research analysing the origins of new first-in-class drugs over a decade-long timescale found that the substantial majority of these drugs were discovered by identifying a change in phenotype, rather than identifying a molecular target. A phenotypic drug-discovery approach has been proposed for some time as a way of improving declining pharmaceutical productivity in more typical molecular target-based approaches.[79]

  For example, the blockbuster drug Ozempic was first developed for diabetes, with the suggestion it could be useful for weight loss. However, as more patients have taken it, there have been increasing reports of powerful effects on addiction, suggesting a much broader utility of the drug than expected based on its molecular target.[80] This highlights the opportunity inherent in gathering and observing phenotypic data to understand how environmental, behavioural and social factors influence them, and the value of using this insight to drive therapeutic discoveries.

  To achieve this at scale will require a substantial increase in our ability to collect and interpret data from individuals. Some UK companies, such as Exscientia, are already exploring improving phenotypic drug-discovery approaches through AI. Diversifying earlier-stage, non-profit research to be better aligned with this agenda could therefore be impactful and synergistic

with the private sector.

This should motivate efforts to complement the successes of the genomic-oriented approach. This report next examines how a combination of AI and new data-collection methods would enable us to better understand and treat these determinants of health to diversify our approach to biomedicine.

AI-Enabled Monitoring and Promotion of the Physiology of Health

The information about individuals that informs both their primary health care and provides data for medical research remains limited. This is especially true for macroscopic features; measures such as weight and resting heart rate have long been used in medicine, but these offer limited insight into bodily patterns and changes, and few new measures have emerged for frontline health monitoring. While the cost of genotyping has fallen dramatically, there has been relative stasis in assessing physiology, with the exception of hospital-based medical-imaging technology, which is not used in routine frontline health monitoring.

The intersection of AI and biology offers a path to addressing this in a way that could positively transform the NHS and also generate prosperity for the UK through sharing the resulting technology globally.

Two recent global developments motivate a strategic rebalancing of the UK's approach and converge to suggest a path to the creation of an AI Doctor.

The first of these developments is the emergence of funding programmes and proofs of concepts supporting the idea that new kinds of physiological data and mechanisms are highly informative about a person's health. There has recently been substantial growth in these areas internationally, with more organisations probing the physiology of living systems and developing technology to improve these measurements.

This can be seen in early-stage research and technology development. Mechanistic research is now probing unappreciated links between the dynamic activity of the brain and body in disease.[81] There is also renewed focus on processes such as breathing patterns in our physical and mental health as well as basic physiology.[82] In the US, the Defense Advanced Research Projects Agency (DARPA) has launched multiple programmes aimed

at finding new sensing technologies to monitor individuals' physiology over time, such as the Smart Non-Invasive Assays of Physiology (SNAP) programme launched in 2022.[83]

This new activity is already manifesting in outcomes with direct clinical relevance. Stanford researchers have used data from simple wearable devices to alert people to likely infection with Covid-19, identifying 80 per cent of presymptomatic and asymptomatic cases in their sample.[84] Building on this, new work is incorporating diverse, dynamic data from mental-health patients to better understand these conditions and how they respond to treatment.[85] AI systems are already able to detect subtle changes in breathing that could indicate the onset of an illness such as Parkinson's disease.[86]

While the UK government has funded projects in the context of using data from wearables,[87] the research is not prominently developing the sensing technology itself, which is where much of the patentable, commercial opportunity lies. There are of course exceptions to this trend, such as Cambridge's BIOS Health and ARIA's neural-machine interface programme.

The second of these developments is the emergence of advanced AI systems able to detect patterns that humans either cannot find or objectively quantify in new kinds of large-scale physiological data, with seemingly unrelated physiological data types providing insight into diverse disease likelihoods. This involves combining AI algorithms with large data sets, as in other AI areas.

The UK is uniquely positioned to generate large data sets suited to AI analysis. As a part of UK Biobank's work, last year researchers published the largest functional magnetic resonance imaging (fMRI) study ever of its kind, mapping the relationship between brain and heart function across 40,000 human participants.[88] While researchers and clinicians have long suspected medically relevant connections between these two organ systems, using new kinds of phenotypic data in concert with genetics provides a clearer picture. For example, the authors found that heart structures indicative of poor heart health correlated to brain structures indicative of poorer brain function.[89] However, to make much fuller use of this rich medical data set, which includes 3D images of heart and brain structure layered onto individuals' genotype and written medical history, AI would be required. This would enable a search for features that humans have not thought to incorporate into analyses by producing a new foundation model.

Foundation models are the core of today's most capable AI tools, including ChatGPT. In the context of medical data, a foundation model refers to a versatile machine-learning model trained on a population representative of human health and disease. It can use a new patient's heart or brain fMRI to generate a more comprehensive health score for that patient given this population data; for example, using images of a person's heart to predict other features of their health. This model can then serve as a basis to support general clinical tasks such as disease diagnosis or personalising a health plan.

The best example of this so far has come from the UK, through the collaboration between Google DeepMind and researchers at Moorfields Eye Hospital NHS Foundation Trust, discussed above.[90] Building on this work, researchers at University College London's Institute of Ophthalmology and Moorfields Eye Hospital produced a new AI model called RETFound to analyse retinal images. RETFound is a foundation AI model that can not only match human performance in diagnosing eye disease, but also predict other disease risks such as that of heart disease and Parkinson's disease from retinal images alone. While the UK has led on this and remains ahead, researchers in other countries are close behind, with research from China earlier this month applying deep learning to retinal scans to predict progression of retinal degeneration.[91]

However, applying this approach on a much broader level will require significant change in how we think about the use of our personal data and medical treatment, and substantial innovation.

THE AI DOCTOR FAMILY OF SYSTEMS: A PERSONALISED DATA-COLLECTION, INTERPRETATION AND CONTROL SYSTEM

The work from the Google DeepMind-Moorfields collaboration and UK Biobank hints at a new model of medicine in which a wide range of seemingly unrelated data sets could be combined through AI to offer an assessment of an individual's health and unique physiology that no doctor could provide – a so-called "AI Doctor". While today's human doctors receive extremely limited and intermittent updates about patients' lives, AI can be ever-present, understanding each person and what promotes their health. An AI Doctor would be a powerful complement to conventional human doctor-patient relationships by creating more time for human-human contact where needed, as well as making the health-care practitioner much better informed and

enabled.[92]

A personalised AI Doctor would:

- Capture and track diverse data from an individual over their lifetime, and determine the meaning of changes from their baseline.
- Integrate these data to assess disease likelihood and wellbeing. This could serve as a starting point as a personal-health-information repository.
- Use the information it has to make tailored treatment and lifestyle advice, in collaboration with a patient's human doctor.

However, an AI Doctor would not:

- Replace GPs or other doctors, or have prescribing power. Instead, this tool would complement them, just as much more rudimentary fitness watches provide information for health and physical-training practitioners.
- Share patient data with anyone, including a patient's doctor, unless authorised by the patient. It would be up to patients to decide which data are shared even with the AI Doctor and whether to have an AI Doctor at all. Patients could choose to share their data and be participants in broader research to improve the algorithms, akin to UK Biobank, but this would rely on informed consent and strong data-confidentiality rules (see the section on an NHS Data Trust).

An AI doctor would likely not be a single device, but rather a shorthand term for a family of interconnected technologies loosely akin to both "internet of things" systems interfacing with patients at home and in the clinic, and also cloud-based computing to deliver insights and recommendations through a central organising node like a specialised device or app. Individuals could choose which elements of this system to utilise and which data to share externally, for example with cloud-based analytical models, medical professionals and researchers.

Some elements of this AI Doctor system would be best developed in the private sector, others through non-profits and others through state-funded entities such as the NHS. Precise governance and delivery mechanisms would

need to be developed over time as relevant elements mature. For now, this report focuses on the initial steps required in the next Parliament to begin this journey.

A MediMind Laboratory Network: A UK Pathway Towards an AI Doctor

Creating an AI Doctor requires a sustained feedback loop between device development, basic physiology, machine learning and the end users, physicians and patients. While this is a long-term path, there are clear steps the UK can and should take now to build on its early lead in much of the underlying technology and capability needed to become the global leader in this space:

- Build new foundation AI models for different types of data and for combining them into a single portrait of health.
- Prioritise research into new physiological-sensing technologies to provide the necessary data for training and deploying personalised AI Doctor systems.

This envisaged 20-year effort will demand a new institutional structure, with a core focused research hub and the ability to fund, coordinate and utilise the many excellent and relevant research efforts nationwide, growing in a more bottom-up way. This kind of institutional structure, if set up in a sustainable way with sufficient investment, would embed and anchor an agenda over time. Just as investment in the Wellcome Sanger Institute and the MRC's LMB anchored molecular and genetic biology as each field became accessible, the UK needs to anchor this new agenda firmly with a substantial investment.

Recommendation: *The UK should create an institute focused on research necessary for the creation of an AI Doctor, the MediMind laboratory network. This network should operate through a hub-and-spoke approach: a well-resourced core institute with the ability to fund collaborating researchers and clinicians around the country. As with the Laboratory of Biodesign, the MediMind laboratory should not inherit standard hierarchical academic organisation but pioneer new models as outlined earlier. This should include a focus on pursuing commercialisation.*

As a first step, the UK's existing strength as the world leader in medical

foundation models should be built on, utilising the capabilities outlined earlier to produce other foundation models and then identify how to incorporate progressively more data types over time.

Recommendation: *As an early step, MediMind should build directly on cutting-edge research with the retinal model RETFound, creating foundation models for several other types of health data.*

Currently, data in resources such as UK Biobank and the envisaged Our Future Health programme remain relatively focused on the molecular level and on coarse physiological properties such as weight, heart rate and height, though there are patient subpopulations with additional imaging data such as brain scans as described earlier.

However, work highlighted earlier shows that gathering new kinds of physiological data can provide insights into seemingly unrelated areas of medicine and provide a powerful ingredient for AI systems. These data are the vital partner of such systems and of such an agenda, not an optional add-on. This should motivate the development of new tools to gather data from patients, including for use at home and continuously over time.

Recommendation: *The MediMind laboratory network should have a strong physical-engineering component, focused on the development of technologies for monitoring intact physiological systems over time. This would feed into and provide data for new foundation models and continuous utilisation by an AI Doctor. MediMind should be set up in a way that prioritises ongoing collaboration with the private sector.*

The following are four broad classes of signals that overlap and interact substantially, which is the key point of recording them in parallel:

- **Macroscopic physiological state:** These are instinctively thought of as vital signs but can now be extended technologically to identify much richer states of physiology more akin to embodied emotions. This includes tracking sleep patterns, breathing patterns, heart activity, brain activity, skin patterns and conductance, metabolic rate and body composition[93] as simultaneously as possible. Many of these can already be tracked individually using existing wearables. Others, such as assessing emotional state and “state of mind” readily, require advances, though clear paths to many of these now exist.

- **Biomarker molecules:** These are molecular indicators of different organ systems in the body and their changes over time. They include metabolites such as ketones and glucose, hormones such as testosterone and oestrogen, and drugs that influence cell and tissue state.[94] Technologies are now emerging that can accomplish this continuously over time in individuals. Recent advances in protein engineering, accelerated by generative AI models,[95] and laboratory instrumentation for screening new proteins[96] make engineering new biosensors at scale tractable.

- **Behavioural measures:** This is what the world sees by directly observing individuals, including movement patterns and body language, communication and other social behaviours, and cognitive performance.[97] AI is already being widely used to start automatically assessing this, and this information can and is increasingly being applied to biomedical research.

- **Environmental exposure:** This includes pollutants in air and water, noise levels, light and radiation exposure, and biological agents such as bacteria or viruses. Recently, the term "exposome" has been coined to define the relationship between these exposures and an individual's physiological state.[98]

  Scientific understanding of how these different aspects of an individual fluctuate and relate to one another, both across a population and in an individual, would be greatly assisted by the approach outlined in this report. A simple way to describe it would be "deep phenotyping of individuals" to complement genotyping work.

  These data are in addition to, not exclusive of, the wealth of existing data that UK researchers have already obtained, for which AI foundation models and other kinds of AI models would be trained.

  The development of primarily low-cost, personal devices to measure these and other biomarkers, would catalyse bottom-up research programmes. Combining molecular information with the other three broad categories of physiological data referred to above would require a concerted effort inspired in part by examples such as UK Biobank's heart-brain-disease fMRI study.

  The use of these measurement devices would then be partnered with existing

large-scale medical-data collection in the UK to provide the knowledge base for the development of personal AI systems.

Recommendation: *The MediMind laboratory network should be staffed and funded to collaborate with existing and planned resources like UK Biobank and Our Future Health to pilot new recording technologies and data-collection methods in a subset of patients, allowing the creation of AI-ready biobanks incorporating dynamic, changing properties of the body at finer and more continuous timescales than currently collected.*

For example, a physiological biobank could capture data from a substantial cohort for all the data types for which MediMind would build foundation models, such as movement patterns, dermatological (skin) imagery, retinal scans, breathing and voice patterns, and also more molecular measures where relevant, in addition to the existing collection plans for programmes like Our Future Health.

Together, the ingredients outlined in this report would provide a platform in which an individual's unique data could be analysed through foundation models to provide a personalised portrait of their health and how their actions are shaping it. Structured correctly and supported with globally competitive funding, these initiatives could drive broader transformative research and building the leading global ecosystem for companies innovating in this space.

However, turning these and other biotech-related companies into sector-defining powerhouses remains a challenge as this report now addresses.

06

Scaling Superstar Biotech Companies

With the foundations of research supported, cutting-edge breakthroughs can be made. With the UK's data architecture fundamentally transformed, real-world data can be leveraged to generate new products and companies. However, to convert ideas into products that improve health, the right conditions to scale companies into the next generation of superstar organisations need to be in place.

Companies such as Novo Nordisk in Denmark and Eli Lilly in the US, which have recently delivered breakthroughs in obesity drugs, will become the trillion-dollar companies of the future. The UK needs to be home to many of these powerhouses. Yet from a financing perspective, it currently lacks the conditions in which these companies can thrive.

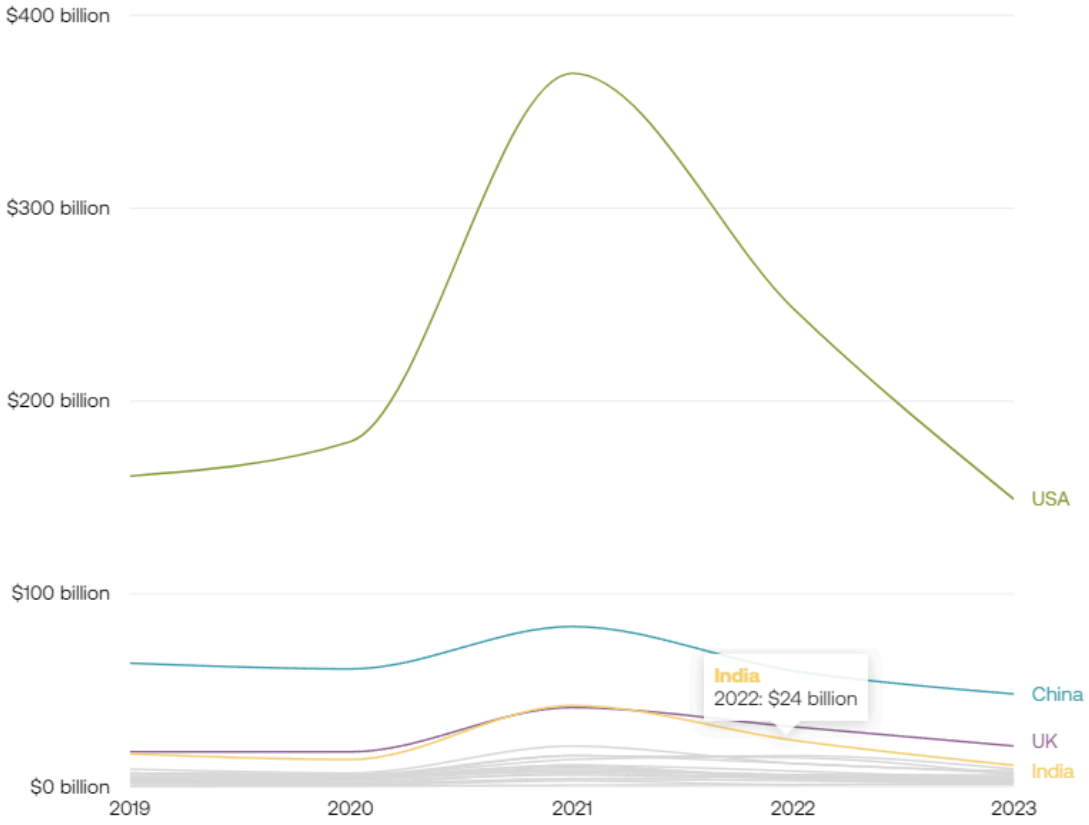
Historically, the UK has been one of the world's leading financial capitals. But its status has been slipping and modernisation is needed to ensure it is home to the next wave of technology companies. This includes enhancing efforts to seed, scale and list global super-companies in UK public markets. This will mean increased efforts to foster vibrant early-stage ecosystems so that ideas and research are developed into more companies, huge efforts on scale-up capital, including pension reforms, so that many more companies can grow, and ensuring UK capital markets are attractive places to list and prosper.

SEEDING POTENTIAL BIOTECH COMPANIES

The UK venture-capital (VC) ecosystem is one of the best in the world. Ranked only behind the US and China in terms of investment, this ecosystem has helped position the UK as one of the leading global tech powers. In terms of unicorns, again the UK is only behind the US and China, and the emerging giant of India. In biotech, the UK's unicorns include BenevolentAI, Oxford Nanopore, Immunocore and Exscientia.

FIGURE 3

US, China and UK lead on VC investment



Source: Dealroom

Although government-backed funds have helped build this ecosystem, the world has changed considerably over the last decade. Government is not as significant a source of capital today when university endowments, non-profit institutions, family offices, fund of funds, sovereign-wealth funds and corporates are all players in this sector.

This shift therefore presents a new opportunity for the UK to foster a more vibrant ecosystem in which emerging managers, solo GPs (the sole general partner of a fund) and operators running funds can increase the competitiveness and depth of capital in the UK. The government can do this through existing mechanisms including British Patient Capital and the British Business Bank to modernise how these organisations operate.

Recommendation: *The British Business Bank should set up a programmatic follow-on fund (which pays carry) that invests in UK companies that have their Series A or B round led by a Tier 1 firm. Firms would make more money this way and provide a valuable product to small managers in the UK who don't have the capacity for pro-rata follow-up funding. This would be a better option than the Future Fund: Breakthrough programme, which is not a priority source of capital for the best companies. Crucially, this fund should not be used to prop up Series B+ companies that struggle to raise capital – it should be used for supercharging proto-winners that have a chance of returning capital to the taxpayer.*

Furthermore, available capital needs to be deployed with greater expertise. In 2021 Sir Patrick Vallance and Lord Browne recommended the government work with a range of industry and academic partners[99] to develop new "specialist education and training programmes to build the understanding of the value of intangible assets, science and technology expertise, and entrepreneurial experience among UK investors and asset owners". The recent announcement to create VC fellowships for science and technology investors is a welcome one, as is the heavy focus of the Department for Business and Trade's (DBT) Venture Capital Unit on technology,[100] but the government can go further.

Recommendation: *Set up a real emerging-manager anchor programme, where a large investor commits significant capital to support the growth of new, often smaller investment firms. This should be a quick process, with no more than six months to secure 20 per cent of a fund.*

These measures can be used to attract foreign managers such as ARCH Venture Partners, Atlas Venture, 8VC, S32 and 7percent Ventures to set up in the UK, joining recent successes such as Andreessen Horowitz and Flagship Pioneering. But it is also important for new funds to emerge to increase the competitiveness of our VC. As it stands, barriers to entry are high; UK requirements mean that no matter the size of the fund, it needs either a full-time compliance officer in-house or to rent a licence from an Appointed Representative. This requires annual compliance reviews, courses, monthly reporting, and profit and loss reporting, as well as reviews of every investment made and risk assessments.

As a result, it is easier and cheaper to run an equivalent fund in the US.

Recommendation: *Reform these requirements by making a sandbox that allows small managers to launch and run without the same overheads as the big funds. Areas such as Anti-Money Laundering and Know Your Customer should still be kept, but removing other requirements would present a significant opportunity to attract managers across Europe to base themselves in the UK. Ways to incentivise full-service large venture-capital firms to incubate emerging managers via their regulatory permissions should also be explored.*

Eliminating Barriers to Academic Commercialisation

As well as requiring more efficient, expert-led funding for early-stage companies, founders face additional challenges that prevent breakthrough ideas developing into mature firms.

As argued in the first *New National Purpose* report, turning cutting-edge research from university laboratories into commercial successes remains a critical challenge in the UK. Eliminating barriers to academic spinouts is therefore critical to supporting biotech. The government recently accepted[101] the recommendations of an independent review by Professor Irene Tracey and Dr Andrew Williamson; these included new equity terms for life-sciences spinouts, set between 10 to 25 per cent university equity.

These are welcome reforms, building off wider progress that has seen the average stake universities[102] take in spinouts fall from 24.8 per cent to 17.8 per cent over the last ten years. In the US, for example, the range is typically 3 to 5 per cent and as the startup incubator Y Combinator warns,[103] a stake above 10 per cent "will cause problems" not least for raising external capital from VC. This is particularly true for companies rich in intellectual property (IP), which are often in biotech. This is because biotech often requires high levels of capital to maintain research and use of IP such as patents to safeguard investments.

Universities such as Stanford, which has spun out some of the world's most successful companies, take the approach that the entrepreneurs should take the upside, while the university gains by remaining at the forefront of science, technology and talent.

Recommendation: *The government should build on the independent review*

by acting boldly on spinout terms, setting an equity range of 0 to 5 per cent dilutable.

Additionally, our academic system is not geared towards supporting researchers founding companies based on their scientific work. By contrast, the founder-led culture in the US empowers PhDs and postdocs to depart academia to build their own startups based on their research. This model, exemplified by companies ranging from Genentech in the 1970s to recent IPO successes like Ginkgo Bioworks and AbCellera, has been instrumental in driving world-changing innovations in biotechnology. [104]

More product innovations now rely on acquiring inventions from universities and small firms.[105] However, while industry rewards the commercial utility of inventions, market entry is simply not a priority for university researchers. This incentives problem in academia inhibits market innovation.

Recommendation: *The International Science Partnerships Fund should establish a multinational Venture Science Doctorate, funding specialist organisations to work with universities and train thousands of PhD candidates to plan and then spin out companies based on their intellectual property. This programme should compound economic growth in important areas such as health, climate and other industries of the Catapult Network. It should combine scientific, personal-performance and venture-design training through established, high-yield methodologies from science-venture builders. Following a policy proposal from the Federation of American Scientists, a pilot of this kind has been established by Deep Science Ventures, supported by Schmidt Futures, Anglo American and Innovate UK.*

With these measures implemented, the UK will become one of the best places in the world to start a biotech company. But barriers still persist to making it the best place to scale one.

SCALING OUR COMPANIES

In order to ensure that the next generation of superstar biotech companies develops in the UK, deepening the available pool of capital is critical. In particular, the UK's biotech industry lacks late-stage scale-up capital, with at least two-thirds of the funding raised in the last quarter going to seed or Series A funding.[106] The government must address this fast.

As a first step, ministers must urgently deliver on their existing commitments to improve the UK's investment regime. The chancellor's announcements in the Autumn Statement on pension reforms represented a step forward in consolidating pension funds and investments to create a broader and deeper pool of growth capital in the UK.[107] Furthermore, the proposals of the Harrington Review of Foreign Direct Investment, which are targeted at the life-sciences industry and four other growth sectors, have the potential to bring in greater foreign direct investment for biotech.[108]

Recommendation: *Implement the Harrington Review as quickly as possible. Prioritise the five critical technologies identified by the government, including engineering biology, in the proposed Business Investment Strategy and ensure the technology secretary sits on the new cross-government Investment Committee.*

Going further, the UK's venture-capital tax-relief schemes should be overhauled to better support knowledge-intensive companies (KICs). In 2018, the Enterprise Investment Scheme and Venture Capital Trust scheme were reformed to encourage investment in KICs through more generous investment and company-age limits.[109]Alongside these schemes, it is equally important to highlight the fundamental role of R&D tax credits in this ecosystem,[110] which directly reduce the cost of experimentation and innovation, and enhance the financial viability for KICs to pursue groundbreaking research. A range of experts including the Treasury Committee and Imperial College London have questioned whether these KIC limits, eroded by inflation, are sufficiently generous to incentivise investment in UK biotech and life sciences. The UK BioIndustry Association has urged the government to raise the £20 million lifetime cap for KICs to £50 million.[111]

Additionally, there are grounds for reviewing the criteria to qualify as a KIC. At present, companies must meet either an "innovation condition" (working to create intellectual property which will constitute a majority of your business within 10 years) or a "skilled-employee condition" (have 20 per cent employees with a master's or higher degree carrying out research).[112] But as the overlap between AI and life sciences grows, UK biotech companies are likely to increasingly rely on AI specialists, who tend to come from industry rather than academia. Consideration should therefore be given to reforming the 20 per cent master's-degree threshold to include those with extensive industry experience.

Recommendation: *Uprate the Venture Capital Trust scheme limits for knowledge-intensive companies to incentivise investment in tech. At a minimum, increase limits to account for inflation since the thresholds were last set in April 2018. Revise the "skilled-employee condition" for KICs to account for industry experts from outside academia.*

Deepening the pool of available capital and tailoring the capital more specifically to the biotech sector will allow many of the firms that come to define the sector to emerge from the UK. However, keeping these companies from listing abroad remains a challenge. The current environment means high potential firms have significant reasons to not believe Britain is the right place to build.

LISTING WORLD-LEADING COMPANIES

UK IPOs fell to their lowest level in a decade last year.[113] Less than half of UK funding came from +$100 million mega-rounds[114] last year, showcasing dwindling scale-up capital for leading British companies. When compared internationally, the UK has disproportionately less scale-up finance relative to startup finance. What growth capital it has is dominated by international funding. For example, overseas pensions invest 16 times more in British VC and private equity than domestic public and private pensions do.[115] As a result, people in countries such as Canada are reaping the economic benefits of the UK tech revolution.

Solving this problem is essential to our industrial strategy. If Britain's most dynamic science and technology firms are too reliant on international VC, they may become dislocated from UK markets and lose the local knowledge necessary to deploy technology effectively in the UK economy. And even if they do stay, grow and succeed in the UK, the beneficiaries are often investors and pension funds in other markets, meaning people in the UK are not benefiting from the success of British companies. Looking at IPOs and acquisitions combined, 44 per cent of all exits from UK tech companies between 2011 and 2021 were by overseas investors, rising to 61 per cent if the company had received overseas investment at the equity-funding stage.[116] The UK is losing valuable assets from the technology sector to overseas investors.

Respondents to Rachel Kent's Investment Research Review noted that life-sciences companies "generally lean towards listing in the US" and that better

investment research "could help strengthen the UK's position as a listing venue" for the sector. As Kent says, this is because investment research "supports a 'virtuous circle', contributing to better valuations, which in turn encourages investors, leading to greater liquidity and increasing the overall attractiveness of the UK as a place to list". Acting fast to deliver on the review's recommendations, already accepted by the government, is therefore crucial to the UK's biotech industry.[117] Delays would lead to more tech companies moving abroad.

Recommendation: *Implement the Investment Research Review as quickly as possible. Given the review's extensive consultation with industry, the government should consider skipping or truncating its forthcoming consultation on implementation.*[118] *Also, build on Rachel Kent's proposal to involve academic institutions in supporting investment-research initiatives by including specialist not-for-profits that can support more accurate life-sciences valuations.*

But these actions alone are not sufficient. Multiple reviews, from Hill[119] to Kalifa,[120] have not resulted in the leaps required to create new options for tech companies looking for financing in the UK. In 2021, the Financial Conduct Authority took welcome steps towards making listing domestically more attractive, including allowing certain forms of dual-class share structures and lowering the free-float requirement from 25 per cent to 10 per cent.[121] But more can be done to make listing in the UK more attractive.

Recommendation: *The Financial Conduct Authority should accelerate its plans to allow companies with multiple-class share structures to be listed in the commercial-companies category*[122] *and consider further reducing free-float requirements.*

The UK could also explore providing late-stage scale-up funding for biotech companies, provided they agree to list domestically for a specific time period. Singapore announced a similar initiative in 2021, through a $366 million Growth IPO Fund, focused on Series B and later funding for domestic companies and listing grants for small companies worth up to $732,000.[123] The UK could consider offering similar initiatives for companies linked to the "five critical technologies" set out in the Science and Technology Framework, including engineering biology.[124]

Recommendation: *Explore late-stage scale-up grants and listing grants for*

critical-technology companies, including engineering biology, tied to a commitment to list domestically for a specific period.

The Science and Technology Framework sets out Britain's ambition to gain strategic advantage in technologies such as life sciences, AI and engineering biology – but this ambition will not be realised without further examination of how the UK can create the conditions that empower emerging companies to stay, scale and succeed. Without the appropriate scale-up funding and a listing environment that supports mature, growth-ready companies, Britain's aim to lead in biotech will never be achieved.

07

Bolstering Pandemic Biosecurity for the 21st Century

This report has an optimistic vision of the benefits the UK could reap if it builds on its successes, balances coherence of strategy with nurturing bottom-up approaches and thinks long term. The positives of developing biotech can exceed the negatives.

However, this final section highlights the importance of learning from the response to Covid-19 and mitigating the rising threat of pandemics. While such an agenda might seem pessimistic, it actually offers a number of major opportunities if given focused attention in the right way:

- **Genuine global leadership:** The UK's proficiency in rapid vaccine development and deployment stems in part from its substantial long-term investment in vaccine research (at the Jenner Institute, for example). This means that the UK is well positioned to be a leader in the 100 Days Mission, a global initiative aimed at accelerating the development and distribution of vaccines, therapeutics and diagnostics within 100 days of identifying a health threat.[125] Pandemic security is global leadership – and the UK has a major role to play.

- **Positive externalities:** Investment in societal resilience through technology generates benefits for everyday health care. The development of mRNA vaccines – the culmination of more than 30 years' research, including early Moderna seed funding from DARPA[126] – is a prime example. This breakthrough, pivotal in the fight against Covid-19, has opened new frontiers in routine health care, with promising applications such as novel vaccines and cutting-edge cancer treatments.[127]

- **New approach to science and technology:** The UK's response to Covid-19 provided useful insights into working practices across various parts of government, as well as different ways of approaching the interaction with science and technology. The most successful world-leading programmes of Covid-19 – the vaccines taskforce and the RECOVERY trial – were achieved outside the normal mechanisms of

government operation. Therein lie vital lessons.

IMPROVING PANDEMIC RESPONSES

The UK should move from narrowly viewing pandemics as a public-health issue to acknowledging that they are a much broader national-security issue, which means bringing a wider range of perspectives and skills to bear on the challenge of preparing for and confronting them. Covid-19 revealed huge vulnerabilities around the world, crippling economies, education and human wellbeing on a scale not seen since the second world war; economic costs to the UK alone have been estimated to be as high as £400 billion.[128] Yet by historical standards, Covid-19 was relatively mild: the Black Death killed up to half the people it infected, while the 1918 Spanish flu was particularly lethal in young adults. We should be prepared for the fact that what comes next could be much worse.

The success of technology in managing pandemics is dependent on the effectiveness of the machinery of government implementing it. Covid-19 highlighted the need to reimagine the state's role in shaping science and technology to deal with societal challenges.[129] Some of the most exceptional UK achievements since the second world war were made during the pandemic, such as the rapid formation and actioning of the Vaccine Taskforce, and it is important that this momentum be both formalised in improved plans for the next pandemic and generalised across the system.

A business-as-usual approach to pandemic preparation is not sustainable, especially with the risk of another one on the increase. Yet the UK has not yet sufficiently altered its readiness since Covid-19; if a novel pandemic arose today, the UK and other nations would still be vulnerable. In many countries, leaders would be faced with a similar set of options to those that they faced in early 2020.

While it is important that a forensic legal analysis of the UK's response to Covid-19 is conducted through the public inquiry, waiting on its conclusions to begin a reform programme will create too great a delay in making the country biosecure; given the time it would take to make the necessary changes after the inquiry concludes, well over a decade could pass between the emergence of Covid-19 emerging and the enactment of a credible reform plan. The government's latest National Risk Register states that the chances of a new "significant" or "catastrophic" pandemic between now and 2028 could be as

high as 25 per cent. Given the costs that would result from this, a focused government mission to develop specific, actionable plans would help the UK would respond to the emergence of new pandemic-potential pathogen.

In 2020 the government recognised the importance of reforming its approach to pandemics and replaced Public Health England with the UK Health Security Agency (UKHSA). In early 2021[130] the Tony Blair Institute argued that what is now the UKHSA should be recreated as a "focused but nimble and high-quality organisation [specifically focused on pandemic prevention and serious infectious disease], more akin to a national-security service, and keep traditional public health as a separate entity", with strong links to other crisis-response elements. This emphasised the need to address the UK's vulnerability to pandemic threats in the short term.

Recommendation: *The UK needs to pursue a focused and urgent mission inside government that would result in a coherent, integrated plan for addressing the UK's systemic vulnerability to pandemics, which should be deemed a national-security issue . The government cannot wait for the conclusions of the inquiry to begin addressing the well documented failings around the pandemic, before then building on its world-leading successes to make them business as usual.*

Within the next 18 months, the government should publish initial preparation documents (including costed options and a plan to enable them) for responding to a new pandemic. Wherever possible, the documents released for public scrutiny should be those that will be presented to ministers when the relevant plans are activated (with redactions for genuinely sensitive information). These documents should then be iteratively improved and published annually, based on feedback and changing circumstances. They should be published freely without veto power from other government departments; for example, the Treasury should not be allowed to censor cost estimates and options.

For this to happen, the UKHSA should concentrate on pandemic vulnerability as its highest priority, including the biosecurity risks posed by technological advances. It should also reach across the whole of Whitehall to develop plans for reforming structures outside its direct control, as the levers of a pandemic response are not located in any one department.

The UKHSA is currently not set up to achieve this. In its recent three-year

strategic plan, it outlined six Strategic Priorities. None are focused narrowly on pandemic prevention and response reform, although there is reference to delivering the UK's role in the 100 Days Mission.

Further, its senior organisational structure lacks a full-time point person on addressing the systemic national-security threat arising from our pandemic response weakness and technological trends, even at director level.[131]

This indicates that UKHSA has lost some of its founding focus. There was always a risk that UKHSA would drift too much in the direction of being a like-for-like replacement of the organisation it was designed to replace, Public Health England, losing its focus on and prioritisation of the specific deficiencies exposed by Covid-19 and the need to treat pandemics as a security, not solely a health, threat. There is a danger that more regular public-health issues being rebranded as a security issue without clearly prioritising the most critical threats. This risk was part of the motivation for TBI's 2021 recommendation that a clearer division between these national-security impacting and public-health roles exists in the machinery of government to ensure mission focus.

The UK will be incapable of enacting a reform agenda on pandemic biosecurity until this is corrected, as the issue requires strong mission focus and a specific, purpose-built team.

Recommendation: *The UK Health Security Agency must undergo restructuring, along with strategic reprioritisation, to enable a strong focus on pandemic-response reform and biosecurity around potential pandemic pathogens. This should include an overarching focus on pandemics posing systemic consequences on the scale of Covid-19 (or greater) until credible plans have been made and withstood public scrutiny. This should also include a review of the UKHSA's ownership in government and its ability to reach across Whitehall, to ensure it is truly prioritising based on the scale of any given security threat.*

As part of this, UKHSA should quickly assemble a taskforce-like structure to deliver on the need for a rapid reform programme.

Recommendation: *The UK Health Security Agency should create a Biosecurity Taskforce, led by an external figure appointed with a direct reporting line to a senior cabinet minister. Effort should be focused on identifying and delivering a*

policy framework to prevent a repeat of what happened in 2020.

Identifying and publishing the successful elements of the standout parts of the UK's Covid-19 response will be key. The taskforce should take ownership of existing UKHSA roles here, such as its interaction with the 100 Days Mission. To achieve this it will need a small team made up of members with a range of skills, including but not limited to medical experts, data scientists, technical generalists and biotechnologists (as well as those with experience of crisis management and biosecurity). It will need the ability to quickly and flexibly hire outside of usual civil-service recruitment and pay processes.

The UK needs a single and precise plan (made publicly available for scrutiny) for how the different stages of a pandemic could be dealt with in the context of its machinery of government and institutions, plus levers of power and influence. The Frontier AI Taskforce has already shown that it is possible to rapidly produce technical documents thanks to a small team of experts, not least with its clear assessment of AI risks in collaboration with the security services.[132]

ADOPTING A SECURITY MINDSET

The upsides of developing advanced biotech can greatly exceed the potential downsides, but governments need to be wary of and takes steps to mitigate the risks. One of the most acute of these risks is that posed by the inherently "dual use" nature of many of the core technologies underpinning biotech advances, and how this applies to the enhancement of potential pandemic agents. (For clarification, "dual use" technologies are those that can cause harm as well as benefit. For example, AI tools that can improve the binding of a therapeutic protein to a human receptor also make it easier to modify a virus surface protein to bind to that receptor.)

Last week the US-UK Strategic Dialogue on Biological Security was launched, and discussed the rapidly changing threat landscape in biosecurity, in part due to technological advancement.[133] Three trends are increasing the likelihood of a severe pandemic resulting from rogue actors or accidents: advances in dual-use bioengineering, riskier research by scientists and a proliferation of high-risk laboratories. Fortunately there are clear and relatively low-cost steps that can be taken to mitigate these issues, with minimal impact on the positive uses of biotech advances. However, it requires a shift in perspective towards a security mindset, recognising that not all research is

beneficial and not all knowledge can be made public.

Tracking Advances in Dual-Use Bioengineering

Ongoing improvements in bioengineering are making it easier and cheaper to design and produce potential pandemic pathogens (PPPs). Genetic-sequencing costs have fallen dramatically[134] and ongoing improvements in nucleotide-editing technology, such as CRISPR, make precision editing easier.[135] Such improvements allowed Canadian scientists to reproduce an extinct horsepox virus in 2017, using sections of DNA they ordered online.[136] Last year a similar approach was used to reconstruct monkeypox.[137]

Most major synthetic-DNA producers screen purchases for suspicious activity through the International Gene Synthesis Consortium (IGSC), but participation remains voluntary. It risks being upturned by the proliferation of benchtop synthesis machines that enable people to print arbitrary sequences without supervision. These devices can print up to 200 bases in length, but some experts predict that they will be able to print between 5,000 and 7,000 bases within two to five years, approaching the range of entire viral genomes.[138]

Advances in AI have also created the potential for misuse in this area.[139] For example, in 2022 a group of researchers working with small, non-protein molecules found that tools to discover new drugs could be repurposed to invent tens of thousands of potential chemical weapons in less than six hours, some of which were similar to the deadly nerve agent VX.[140]

De novo protein design creates broader challenges. As tools such as AlphaFold improve over the coming decade they could be used to design new virus surface proteins, resulting in viruses with enhanced transmissibility that can evade existing vaccines and protection (humans may have no pre-existing immunity for viruses with highly novel surface proteins). A number of these powerful tools have already been made open-source and widely proliferated; for example, the models RF-diffusion and Chroma have already been open-sourced and made widely available.[141] And while not the primary threat, AI chatbots are increasingly able to provide advice on deploying bioweapons.[142]

This changes the threat space considerably. As these technologies decrease in cost and increase in prevalence and efficacy, the potential for a devastating artificial pandemic could increase substantially unless swift action is taken. The UK has the opportunity to take action on access to DNA synthesis, as has

been called for by a range of expert groups and individuals.[143] President Joe Biden's recent executive order on AI, which requires DNA-synthesis screening for federally funded biological research, is a good first step but insufficient on its own.[144] While the UK government expressed some interest in this problem in its recent Biosecurity Strategy,[145] ministers must now take robust action both domestically and internationally.

Recommendation: *The government should introduce strong domestic safeguards for DNA synthesis, including:*

- *All DNA-synthesis firms to have their orders screened for suspicious activity.*
- *Licensing requirements for all benchtop synthesisers.*
- *Manufacturers of benchtop synthesisers to monitor, screen and approve DNA synthesis against a regularly updated cloud-based database of sequences before synthesis can begin.*
- *An independent team of experts to red-team all screening programmes used by UK-based companies and individuals, probing them for weaknesses.*
- *A screening-support service within the new UK Biosecurity Taskforce, through which synthesis firms can access best-practice guidance and screeners can report suspicious activity.*

Similar safeguards should be explored for protein-design software and DNA-sequencing devices. For example, there could be a requirement that protein-design software report attempts to develop novel binding proteins for known viral targets, and that sequencers automatically report suspicious sequences.

Recommendation: *Ministers should build on the Biological Weapons Convention with a new international agreement on DNA-synthesis screening safeguards, including leading biotech nations such as China. In the meantime, the UK should work with liberal democracies to encourage them to introduce domestic guardrails, align standards and agree to share intelligence on suspicious synthesis activity.*

The notion of illicit, secret labs containing dangerous pathogens is not speculation: recently, for example, one in California containing HIV, coronavirus,

hepatitis, herpes and more was shut down by the US Centers for Disease Control and Prevention.[146] Its purpose remains unclear.

Monitoring Riskier Research by Scientists

Scientists are increasingly performing riskier experiments, most notably gain-of-function research, whereby a pathogen is genetically edited to become more dangerous. Such research is not needed to develop vaccines. Following concerns over the engineering of a high-lethality influenza virus, President Barack Obama banned federal funding for such research through an executive order in 2014.[147] However, such work continued despite risk warnings and the US ban was overturned in 2017.[148]

Information relevant to this kind of research is shared openly. In the space of four months between the end of 2023 and the beginning of 2024, a number of journal articles[149] were published sharing information on PPPs that could be used maliciously by rogue actors. These include:

- Identification of which historic viruses would most likely cause another global pandemic if re-released today.
- The characterisation of multiple new PPPs, including steps taken to increase their ability to infect human cells.
- New technical approaches to rapidly identify how to modify a viral spike protein specifically to escape existing antibody protection.

Information directly relevant to creating pandemic agents is now routinely appearing in journals. In an era when the ability to weaponise such information at low cost is increasing rapidly, having it in the public realm poses serious risks.[150] There is growing awareness that action is needed, with the US National Science Advisory Board for Biosecurity[151] and the UK Biological Security Strategy[152] acknowledging the importance of reducing information hazards. Some degree of increased restriction on information that could be used to build pandemic agents now needs to happen.

Recommendation: *The government should work with scientists and journals to agree a voluntary code of best practice covering what information relating to pandemic-capable pathogens should be publicly available. This specific guidance would build on existing broad advice on publishing sensitive*

research.[153]

The government should also commission an external review of the risks of having potentially highly dangerous information in the public sphere over a decadal time scale, as technology continues to advance at a rapid rate. This should incorporate consultation with specialists in a range of fields, including frontier bio-AI labs, synthetic biologists, the virology community and technical experts in biosecurity. The review should identify what trigger points might establish a need to more strongly enforce restriction of information sharing. The review should be led by someone who is clearly independent of vested interests in this space.

The UK also needs to end gain-of-function research on PPPs. While any individual experiment may be comparably low risk, the high global frequency of laboratory escapes, even at high biosafety levels (BSL), makes it a matter of time before there is a leak. Notably, in Taiwan in 2021, Covid-19 escaped from a BSL3 laboratory.[154]

This will have a negligible impact on UK research, as the UK conducts few if any studies that actively seek to increase the virulence and/or transmissibility of PPPs. However, an outright UK ban on such research could significantly reduce the risk of an accidental pandemic if it sets an example and helps spur other nations to adopt similar policies.

Recommendation: *The UK should impose an indefinite ban on gain-of-function research on potential pandemic pathogens, with definitions of said research used being in line with January 2023 recommendations by the US National Science Advisory Board for Biosecurity.*[155] *Specifically, gain-of function research on PPPs should be illegal. Moreover, both public and private UK funding agencies should be prohibited from financing gain-of-function research on PPPs worldwide.*

Such rules could have exemptions for crisis situations, such as during a pandemic. However, such decisions should rest with a minister.

The government should also make it mandatory for any work on PPPs to be reported to the proposed UK Biosecurity Taskforce. This would be low friction, as similar measures already exist – reporting requirements within the Control of Substances Hazardous to Health Regulations, for example.

While some argue there are benefits to such research by allowing

development of vaccines and therapies before a pathogen emerges naturally, the truly extreme consequences of an uncontained accidental leak seriously outweigh the benefits.[156] Further, despite the extraordinary risks, gain of function is not needed for vaccine or therapeutic development.[157]

Scrutinising the Proliferation of Laboratories Containing High-Risk Pathogens

There are many laboratories around the world that hold dangerous pathogens for legitimate and beneficial research; the number of laboratories operating under the highest BSL, known as BSL4 facilities, are increasing. Analysis shows that there are 51 operational BSL4 labs worldwide (the vast majority in Western countries), with a further 18 planned or under construction.[158]

The risk of an accident in a laboratory causing a pandemic has been understood in biosecurity circles for a long time; a recent study showed that at least 309 lab-acquired infections and 16 known pathogen-lab escapes occurred between 2000 and 2021.[159] A key issue is that some of the new laboratories are in countries with poor biorisk-management scores; for example, seven of the new BSL4 laboratories are in such countries. As such, the government should help developing countries improve safety standards, leveraging the UK's leading role within the International Experts Group of Biosafety and Biosecurity Regulators. This should include BSL3 laboratories, which often house work on viruses with the most potential to bring about a pandemic, such as SARS and influenza.

Recommendation: *Ministers should use the aid budget to create a new Biosecurity Safety Fund. This would support safety measures in developing countries with biosafety level 3 and biosafety level 4 labs and poor biosecurity standards, plus the placement of UK experts to share best practice. This could be either a standalone UK initiative or a joint endeavour with other countries in the International Experts Group of Biosafety and Biosecurity Regulators.*

As noted above, almost all viruses with the highest pandemic potential are housed not in BSL3 or even BSL2 laboratories, but rather BSL4 labs. The latter tend to be reserved for lethal viruses for which no treatments exist, with less weighting on how transmissible a virus is. However, as the number of BSL3 laboratories studying these viruses continues to grow, statistically it becomes ever more likely that something, somewhere, will go wrong.

Recommendation: *The UK should order a comprehensive global review of the literature on which virus classes are handled at which biosafety levels. The review should also examine the advantages and disadvantages of regulation that would result in all viruses credibly described as potential pandemic pathogens being handled at biosafety level 4, weighting towards current and potential transmissibility.*

It is important that the UK take the steps outlined in this section to set an example and provide global leadership on biotech norms; the government cannot expect others to do what they are not. That said, it is unlikely that the next threat will arise in the UK; as a result, the country also needs to prepare to respond to threats emerging overseas.

08

Conclusion

The UK faces a pivotal juncture. Innovations in biotechnology and AI have the potential to reshape critical sectors like health care and agriculture, transforming lives and powering national prosperity – but with great opportunity comes great responsibility. These technologies also carry risks if not developed prudently.

By spearheading breakthroughs and pioneering safeguards, we can drive improvements in the lives of people in the UK and worldwide while mitigating catastrophic outcomes. But realising this future compels a reimagined state to lead – scaling research, enabling infrastructure and nurturing talent through strategic investments and public-private collaboration. This demands interdisciplinary thinking and foundational realignment of priorities across research, data, financing and more.

Equally, prudent governance necessitates oversight attuned to emerging risks. With foresight and vigilance, we can contain novel threats while unleashing innovation's benefits. Building on our recent international leadership in AI safety initiatives, Britain now has the chance to cement its role forging accountability in biotechnology.

The UK led the first scientific revolution; now, it can shape this century's biotech revolution.

09

Acknowledgements

Sir Patrick Vallance

Tamsin Berry – Population Health Partners

Sir John Bell – University of Oxford

Nathan Benaich – Air Street Capital

Claire Bloomfield – insitro

Hans Bishop – Altos Labs

Nick Swanson – Google DeepMind

Juan Mateos-Garcia – Google DeepMind

Sébastian Krier – Google DeepMind

Justin Kinney – Cold Spring Harbor Laboratory

Kevin Esvelt – MIT

Martin Turner – BioIndustry Association

Alasdair Thong – Selvedge Venture

Emily Jefferson – Health Data Research UK

Cassie Smith – Health Data Research UK

Pearse Keane – UCL Institute of Ophthalmology and Moorfields Eye Hospital NHS Foundation Trust

Paul Blakeley – Newmarket Strategy

Sir Ron Kalifa – Network International

Jack Scannell – Etheros Pharmaceutical

Clíodhna Ní Ghuidhir – Apollo Research

Lennard YW Lee – University of Oxford

Corinna Bull – Global Pathogen Analysis Service (GPAS)

Rebecca Pope – Roche Products Limited

Neil Sebire – Great Ormond Street Hospital for Children NHS Foundation Trust

Andrew Taylor – Great Ormond Street Hospital for Children NHS Foundation Trust

Hakim Yadi – Closed Loop Medicine Ltd

Hardeep Jhutty – Moderna

Michael Kipping – University of Manchester

Charlie Foreman – Cambridge University Health Partners

Mark Saxon – Satellite Applications Catapult

Charles Dunn – SV Health Investors

Audrey Yvernault – GSK

Parker Moss – Exscientia

James Peach – Precision Strategy

Iain Buchan – University of Liverpool

Annemarie Naylor – University of Liverpool

Manish Patel – Jiva.ai

Adam Manhi – Flatiron Health

Meredith Leston – University of Oxford

Martin Yuille – University of Manchester

Euan Cameron – COHESION Medical

Alessandro Riccombeni – Axia Medicine

Sam Rodriques – Future House

Carolyn Heaney – Precisia Life Sciences

Sheuli Porkess – Precisia Life Sciences

Jeffrey Almond – University of Oxford

Gaurav Venkataraman – Trisk Bio

Mark Andrews – British Patient Capital

Rajarshi Banerjee – Perspectum

Keri Hildick – Perspectum

Paul Smith – BC Platforms

Joseph Ewing – LifeArc

James Anderson – International Federation of Pharmaceutical Manufacturers & Associations

Daniel O'Connor – The Association of the British Pharmaceutical Industry

Connor Rochford

Charlie Norell – Global Counsel

It would be impossible to do justice in the short space we have here to the list of esteemed experts who contributed their time, expertise and insights to this report. To those whom we worked with, our heartfelt thanks and appreciation – without your contributions, this report would not have been possible.

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