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Lessons from COVID-19 for the future of the life sciences

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REVIEWERS

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INTERVIEWEES

The author would like to express their gratitude to the individuals and organisations who were interviewed as part of the research for this paper:

- Alex McLaughlin, Deputy Director for Innovation and Growth, Office for Life Sciences
- Darius Hughes, General Manager for the UK and Ireland, Moderna
- Stuart Carroll, Director of Market Access and Policy Affairs, Moderna
- Ian Connatty, Managing Director of Direct and Co-Investment, British Patient Capital
- Professor Sir John Bell, Regius Professor of Medicine, University of Oxford

The quotes included in this report are a mix of attributed and anonymised, reflecting the preferences of those we interviewed.

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IDEAS

Idea 1: Conduct a rapid review of best practice in the four existing innovation hubs – based in Manchester, Dorset, Cambridgeshire and Peterborough, and Bradford and the Craven – to evaluate how they are driving uptake of new products at the local level.

This review should inform a two-year trial of innovation hubs in each Integrated Care System across England, to make local health systems more practically accessible to innovators and to support the development of a pro-innovation culture across the NHS.

Idea 2: Place the MHRA on a stable and long-term financial footing, by introducing an annual re-pricing mechanism by which the regulator can increase, maintain or reduce fees for individual services in response to changing costs.

This would avert a repeat of the current situation facing the MHRA, where a longstanding freeze in statutory fees (since 2016-17 for medicines and 2017-18 for medical devices) has placed financial pressure on the regulator, resulting in calls for a major hike in fees.

Idea 3: Develop a data-sharing pathway within the NHS App. This should enable users to proactively opt-in to sharing data for clinical research and allow researchers to contact patients eligible for clinical trials or who have data that could facilitate medical research.

This process should include clear explanations of the purpose, risks and benefits of data sharing or participation in clinical trials. This section of the NHS App should also contain general information about how TREs work and how can they can protect patient privacy.

Idea 4: Present a clear package of measures to ensure the UK has a globally competitive market for growth capital in the life sciences. This should primarily be achieved by the introduction of a version of the French Tibi scheme, which aims to connect funds held by institutional investors with high-growth venture capital opportunities.

Alongside this, the Government should publish the recommendations included in the final report of the Life Sciences Scale-up Taskforce in 2021, with a commitment to either adopt the ideas suggested by this expert panel or explain why they will not be carried forward.

Idea 5: Develop new technologically-specialised growth clusters outside of the Golden Triangle, by focusing Investment Zones (and any related government funding) on academic institutions with a track record of exemplary research in the life sciences.

This should include the life sciences clusters directly cited in the ‘Levelling Up White Paper’ (Aberdeen, Greater Manchester, Northern Ireland, the Glasgow-Edinburgh Central Belt, the North-East), as well as other areas with untapped academic expertise and potential.

INTRODUCTION

The life sciences sector is one of the UK's most productive industries. As the 'Life Sciences 2030 Skills Strategy' points out, the annual gross value added (GVA) for each person employed in this industry is £104,000, more than double the UK average of £49,000 per worker, while the UK attracts more life sciences FDI than anywhere except for the US and China.[1] We also have an exemplary research base to fuel new innovations, including several of the world's top-ranked academic institutions in this discipline – an essential asset to an industry which relies on highly skilled employees.[2]

As Professor Sir John Bell, UK Life Sciences Champion and author of the 'Life Sciences Industrial Strategy', noted in an interview for this project: "It's one of the few sectors of the British economy where we're widely acknowledged to be globally competitive." But despite being a global player in the life sciences, the UK's performance on some key metrics is trending negatively and we have long struggled to match our global competitors in some areas, especially access to finance and growth capital. Nonetheless, the successful and rapid development of a world-leading COVID-19 vaccine provides proof of the overall capability of the UK's life sciences offer.

To the credit of successive governments, they have recognised the opportunities offered by the life sciences sector. The development of the 'Life Sciences Industrial Strategy' in 2017 and the current 'Life Sciences Vision' (published in 2021) have set clear ambitions. The Prime Minister also laid out his own plan to make Britain "a science and technology superpower" during his first leadership bid.[3] But there remains a risk of complacency: that bold ambitions will not be underpinned by the practical action needed to protect our position as a global leader in the life sciences. If the lessons from our recent life sciences success – the COVID-19 vaccine – are not applied, the UK may fail to harness the opportunities the industry presents to fuel economic growth.

In this paper, we discuss a series of policy ideas for making the most of the UK's life sciences offer. Drawing on interviews with leading figures in academia, government and private industry, we identify which factors facilitated the development of the COVID-19 vaccine, the key lessons policymakers should draw from this, and how these can be applied to the preconditions for success set out in the UK's 'Life Sciences Vision'.

The potential prize, in terms of growth and innovation, is enormous. This paper sets out what the Government can do to ensure we all benefit from it.

[1] Science Industry Partnership, *Life Sciences 2030 Skills Strategy*, 2020.
[2] Department for Business, Energy & Industrial Strategy, *Life Sciences Vision*, 2021.
[3] Ready4Rishi, 'Rishi Sunak: I Will Make UK a Science and Technology Superpower', Press Release, 23 August 2022.

1. Developing the COVID-19 vaccine

On the 31st December 2019, the World Health Organization identified a cluster of then unknown viral cases in Wuhan, China.[4] A month later, the UK reported its first two coronavirus infections,[5] with the first case of community transmission recorded a further month after that.[6] Then, on the 23rd March 2020, the UK was placed into its first national lockdown to prevent the spread of COVID-19, with unprecedented restrictions on work, travel and schooling. The country was paralysed in the face of this terrifying new virus.

Yet, on the 9th December 2020, less than nine months after the first lockdown began and less than one year since the UK recorded its first COVID-19 cases, Margaret Keenan became the first person in Britain to receive a coronavirus vaccine outside of a clinical trial.[7] This was despite the April 2020 warning from the Chief Medical Officer, Sir Chris Whitty, that the chances of a Covid vaccine "in the next calendar year are incredibly small."[8]

Developing this vaccine so quickly was a remarkable outcome, reflecting the collective efforts of academics and companies across the life sciences sector working closely with regulators and the NHS at a time of national crisis. It showed the incredible breakthroughs that this industry is capable of delivering if the conditions are right. As a joint report from the House of Commons' Health and Social Care and Science and Technology Committees points out: "The UK experience in vaccines is replete with lessons... which can help us, and other nations, build on this success, and do even better in the future."[9] So what were the common factors that enabled the COVID-19 vaccine to be developed so rapidly? What lessons should we be drawing for the future of the life sciences?

1.1 Collaboration

In almost all accounts of the development of the COVID-19 vaccine, the highly collaborative approach taken across the life sciences ecosystem is recognised as one key enabler.

The 'Life Sciences Vision' describes how private and government investment came together to develop vaccines via "a seamless collaboration between our scientists, pharmaceutical companies, regulators, and NHS."[10] Professor Sarah Gilbert, a key figure in the development of the Oxford-AstraZeneca vaccine, has also written about the essential role that this partnership approach played in delivering vaccines.[11] In an interview for this project, Stuart Carroll, Director of Market Access and Policy Affairs at Moderna, added that: "the pandemic

[4] World Health Organization, 'Listings of WHO's Response to COVID-19', Web Page, 20 June 2020.
[5] Ibid.
[6] 'Coronavirus: Latest Patient Was First to Be Infected in UK', *BBC News Online*, 29 February 2020.
[7] 'Landmark Moment as First NHS Patient Receives Covid-19 Vaccination', Web Page, NHS England, 8 December 2020.
[8] '"Incredibly Small" Chance of Mass Vaccine or Treatment in next Year - UK Official', *Reuters*, 22 April 2020.
[9] Health and Social Care Committee and Science and Technology Committee, *Coronavirus: Lessons Learned to Date*, HC 92 (London: The Stationery Office, 2021).
[10] Department for Business, Energy & Industrial Strategy, *Life Sciences Vision*.
[11] 'The Story behind the Oxford-AstraZeneca Covid-19 Vaccine Success', Web Page, UK Research and Innovation, 1 October 2021.

showed the advantage of industry, government, the health system and academic institutions coming together to work with that high level of collaboration."

Of course, different vaccines benefitted from different models of collaboration, with one academic paper dividing between "sharing of knowledge and technological expertise (abbreviated *'knowledge sharing'*) and transfer of materials, technical infrastructure & IP rights (abbreviated '*materials transfer*')."[12] As the authors set out, the Oxford-AstraZeneca vaccine was more akin to a materials transfer partnership, in which the academic institution led the scientific work while the commercial partner delivered the manufacturing heft and regulatory know-how. By contrast, the BioNTech-Pfizer vaccine was a more integrated, knowledge sharing partnership between these US and German businesses, with less reliance on government funding to enable scale-up.[13] Industry leaders also recognise the scale of collaboration involved, with the CEO of Sanofi describing his company's partnership with GSK to deliver a COVID-19 vaccine as an "unprecedented alliance of two vaccine giants", during a 2020 earnings call.[14]

To some extent, the willingness of partners across the system to pull together amid deep national crisis is to be expected. The challenge is replicating this model outside of 'wartime', where the risks – such as diseases like cancer – are similarly lethal, but are more slow-moving, continuous, even 'routine' threats, that are more challenging to coalesce around. Learning how to replicate these new models of collaboration is essential for the life sciences.

1.2 Finance

A second factor that facilitated the vaccine development was simple: the availability of funding.

Access to finance has long been recognised as one of, if not the, most significant weakness in the UK's life science offer – with the Government's launch of the £200 million Life Science Investment Programme in 2021 designed to address some of this problem.[15] Several of our interviewees agreed that the lack of later-stage, growth capital is a major challenge, with Darius Hughes, General Manager for the UK and Ireland at Moderna), citing this as the cause of "why we don't often get the translation of great science into great companies", while another interviewee termed it "a vicious cycle" that prevents breakthrough success.[16] *The Economist's* view, that "the relatively small pools of capital available through Britain-based investors are simply insufficient for the winding path to viability", is a good summary of the problem at hand.[17]

For the COVID-19 vaccine, this problem was avoided. Considerable capital was made available to help scale up manufacturing and take vaccines from the petri dish to the population. Dame Kate Bingham, who chaired the Vaccine Taskforce, describes this in her

[12] Louise C. Druedahl, Timo Minssen and W. Nicholson Price, 'Collaboration in Times of Crisis: A Study on COVID-19 Vaccine R&D Partnerships', *Vaccine* 39, no. 42 (2 September 2021).
[13] Ibid; Hannah Kuchler, Donato Paolo Mancini and David Pilling, 'The inside Story of the Pfizer Vaccine: "A Once-in-an-Epoch Windfall"', *The Financial Times*, 30 November 2021.
[14] 'Sanofi (SNY) CEO Paul Hudson on Q1 2020 Results - Earnings Call Transcript', Web Page, Seeking Alpha, 24 April 2020.
[15] British Patient Capital, 'British Patient Capital Launches Life Sciences Investment Programme', Press Release, 7 July 2021.
[16] Several interviewees also attributed challenges with accessing finance to cultural conservatism among investors in the City of London, in particular contrast to their American peers.
[17] 'The Life-Sciences Industry Is a Jewel in Britain's Economy', *The Economist*, 20 July 2022.

Romanes Lecture, noting that Oxford's Jenner Institute had only "a small-scale production capability in the university, suitable for manufacturing clinical trial material, but it was never intended for the industrial manufacture of millions of vaccine doses."[18]

Instead, the Jenner team worked first with the "UK Bioindustry Association's bio-processing manufacturers to scale up their vaccine in February 2020, before striking a deal with pharmaceutical giant AstraZeneca to develop this vaccine on a non-profit basis around the world."[19] This was underpinned by considerable funding from government too, with one study finding that over 95 per cent of R&D spend on the Oxford-AstraZeneca vaccine in the critical period between January 2020 and October 2020 came from this source.[20] This again highlights the value of collaboration, but also demonstrates why funding is so critical: the Oxford lab's scientific breakthrough only became a globally-adoptable health product (that saved countless lives) because of the ready availability of growth capital from government and private industry.

When resourced correctly, innovative companies and world-leading academic institutions can transform scientific discoveries into deployable products at remarkable speed. The pandemic experience highlights how this can work. Renewing our efforts to increase the supply of growth capital available to UK life sciences firms is essential.

1.3 Regulation

A third factor that played a critical role in the development of the COVID-19 vaccine was the flexible and innovative approach taken by the Medicines and Healthcare products Regulatory Agency (MHRA) – a body widely praised for its work throughout the pandemic.

Chris Whitty's April 2020 warning that a vaccine was unlikely in the next year reflected the lengthy timescales usually involved in developing and approving medical products, with various studies finding that the entire process takes on average around 17 years.[21] Vaccines similarly take many years to develop, in part because they must pass a series of sequential clinical trials, with the full dataset then submitted to the regulator for final approval before any product can be used on the wider public.

In response to COVID-19, the MHRA took a radically different approach, reflecting the urgent need for vaccines in the midst of a lethal global crisis. As Dame June Raine, CEO of the MHRA, explained in evidence to the House of the Commons, her organisation "adopted a novel, or innovative regulatory process known as a rolling review... we reviewed data in packages or tranches as soon as they became available from the ongoing studies, on a staggered basis."[22] By reviewing data continuously, rather than via a single evaluation after

[18] Oxford University, '"Another War Is Coming", Kate Bingham DBE, Delivers Romanes Lecture', Press Release, 24 November 2021.
[19] Ibid.
[20] Samuel Cross, Yeanuk Rho et al., 'Who Funded the Research behind the Oxford–AstraZeneca COVID-19 Vaccine?', *BMJ Global Health* 2021, no. 6 (22 December 2021).
[21] Zoë Slote Morris, Steven Wooding and Jonathan Grant, 'The Answer Is 17 Years, What Is the Question: Understanding Time Lags in Translational Research', *Journal of the Royal Society of Medicine* 104, no. 12 (16 December 2011).
[22] Health and Social Care Committee and Science and Technology Committee, *Coronavirus: Lessons Learned to Date*.

completing every stage of the clinical trial process, vaccines were able to gain much quicker approval than would usually be the case.

This approach was remarkably effective. The Pfizer vaccine, for example, was approved in the UK before anywhere else in the world as a result of this streamlined process. The MHRA's model has been rightly recognised as one of the great successes of the pandemic: Kate Bingham has described it as "an exceptional regulator: flexible, collaborative and quick",[23] while industry groups have argued that the "rapid introduction of regulatory flexibilities has been critical to supporting the response to the COVID-19 pandemic."[24] A joint House of Commons select committee report, as well as several of those we interviewed for this project, agreed with this view.[25] It is a crucial lesson to draw from the pandemic response.

1.4 Research Base

A fourth factor that enabled the development of the COVID-19 vaccine was the UK's exemplary and diversified research base.

While much of the scientific work that underpinned COVID-19 vaccines occurred once the pandemic took hold, these breakthroughs (like any other scientific discovery) relied upon an existing research base and longstanding academic expertise. Professor Sarah Gilbert has argued that the Oxford-AstraZeneca vaccine built upon "a decade of investment" from UK Research and Innovation (UKRI) that meant "all the pieces were in place for us to be able to develop a novel coronavirus vaccine at speed."[26] This story is true of vaccines across the world. The editor of leading science journal *Nature* has described how various prior scientific developments contributed to different types of pandemic-era vaccines.[27] For example, the Pfizer-BioNTech and Moderna vaccines were the first commercially available immunisations to adopt novel mRNA technologies that had been in development for some time.[28]

This highlights both the value of a world-class existing research base, but also the need for a diversified approach in which a range of technologies – some of which may not prove immediately useful when first discovered (such as mRNA) – can be developed in parallel.

Investing in a diverse research base can enhance our resilience when responding to fast-moving crises, by effectively placing bets on multiple horses. As a House of Commons joint committee report notes: "it was not knowable at the outset that the Oxford research team would achieve the breakthrough they did, while the Imperial programme has experienced setbacks on the way."[29] Investing in different institutions can increase the chances of success, with one of our interviewees concurring that: "if we try all these different things and you end up with enough high-risk shots on goal, it tends to work out." They also noted that this can

[23] Oxford University, '"Another War Is Coming", Kate Bingham DBE, Delivers Romanes Lecture'.
[24] The Association of British HealthTech Industries (ABHI), the Association of the British Pharmaceutical Industry (ABPI), et al., *Life Sciences Recovery Roadmap*, 2020.
[25] Health and Social Care Committee and Science and Technology Committee, *Coronavirus: Lessons Learned to Date*.
[26] 'The Story behind the Oxford-AstraZeneca Covid-19 Vaccine Success', 2021.
[27] Philip Ball, 'The Lightning-Fast Quest for COVID Vaccines — and What It Means for Other Diseases', *Nature* 589 (18 December 2020).
[28] Jennifer Abbasi, 'Covid-19 and MRNA Vaccines—First Large Test for a New Approach', *Journal of the American Medical Association* 324, no. 12 (3 September 2020).
[29] Health and Social Care Committee and Science and Technology Committee, *Coronavirus: Lessons Learned to Date*.

help to provide different types of scientific breakthrough by creating hubs of "more spatial, geographic specialisms that have clustering effects."

The 'Golden Triangle' of Oxford, Cambridge and London will always remain essential to the UK's life sciences offer. But building a more geographically diverse research base could make us more resilient, both by leveraging the scientific talent base present across the country and by developing alternative areas of expertise and specialisation. For a government that is committed to levelling up less prosperous parts of the UK and maximising the talents of those in every region, this should be an especially compelling lesson to carry forward.

1.5 Public Participation

A final factor that aided the development of the COVID-19 vaccine was public participation, via the mobilisation of nearly half a million volunteers to support clinical trial activity.

Through the pandemic, public awareness of epidemiology, public health, and the process of vaccine development was greatly enhanced. As our lives were disrupted by COVID-19 and daily press briefings about the virus became a major TV event, previously unknown concepts like the R value became features of everyday conversation. And – whether through a desire to help tackle the virus or through restlessness in a time of national lockdown – the public stepped up and sought to participate in health research. The clearest example of this was the ZOE Covid Symptom App run by Tim Spector, a Professor of Genetic Epidemiology at KCL, which had over 1.3 million users reporting their symptoms by March 2020.[30] This dataset was partly used to estimate the incidence of COVID-19, but was especially effective in identifying additional manifestations of the virus, including "anosmia as a key symptom of COVID-19 in general" and "delirium as a key symptom in older people."[31]

However, the development of the vaccine also benefitted from public participation through the NHS COVID-19 Vaccine Registry, a database which allowed members of the public to state their interest in taking part in clinical trials. Much like the ZOE App, the registry was an enormous success: launched in July 2020, it had secured 100,000 sign-ups within two months.[32] As of the 28th November 2022, it contains the information of over 542,000 volunteers.[33] This success likely reflected both a profound public-spiritedness in a time of crisis and a desire to help the NHS, underpinned by what the Vaccine Taskforce's clinical trials lead has described as a "massive communications campaign."[34]

Sourcing appropriate volunteers for clinical trials is often an extremely time-consuming process. As the Government's 'Life Sciences Competitiveness Indicators 2022' report notes: "In the UK, the set-up and recruitment of patients takes longer than the approval process."[35] By securing over 500,000 willing volunteers (including 100,000 within two months), the

[30] 'Who Are the 1.5 Million Citizen Scientists?', Web Page, ZOE Health Study, 28 March 2020.
[31] Linda Birkin, Eleftheria Vasileiou and Helen Stagg, 'Citizen Science in the Time of Covid-19', *Thorax* 76, no. 7 (2 March 2021).
[32] Department for Business, Energy & Industrial Strategy and The Rt Hon Alok Sharma MP, 'Public Encouraged to Register for COVID-19 Vaccine Trials as 100,000 Already Sign-Up', Webpage, 17 August 2020.
[33] NHS Digital, 'Coronavirus Vaccine Studies Volunteers Dashboard', Web Page, accessed 21 November 2022.
[34] Channel 4, 'Jabbed! Inside Britain's Vaccine Triumph', 10 May 2021.
[35] Department for Business, Energy and Industrial Strategy, Department of Health and Social Care and Office for Life Sciences, *Life Science Competitiveness Indicators 2022*, 2022.

Vaccine Registry drastically reduced these timescales, paving the way for streamlined clinical trials which enabled the vaccine to be developed at much greater speed. There are clear lessons here about the value of public participation beyond the pandemic. Indeed, the fact that the NHS Vaccine Registry was saved from closure by Robert Jenrick (during his tenure as Minister of State for Health) and can now be used to source participants for non-Covid trials augurs well for the future of the life sciences.[36]

[36] House of Commons Science and Technology and Health and Social Care Committee, *Oral Evidence: Coronavirus - Lessons Learnt*, HC908 (The Stationary Office, 2022); Chris Smyth, 'Covid Database Revived to Fight Other Diseases'.

2. The future of the life sciences

The development of the COVID-19 vaccine was a singular achievement, reflecting the collective endeavours of academia, industry, government and the NHS to deliver a world-leading innovation. And yet, despite the existence of this best practice model in recent memory, there is a real danger that policymakers will fail to carry forward crucial lessons from the pandemic.

Most of those we interviewed for this project raised concerns about this risk of drift, in which policymakers and others involved in the life sciences sector are failing to build on the pandemic model. One interviewee talked of the danger of momentum "seeping away", adding that "this is our real challenge now." Another interviewee put this even more starkly, discussing "an assumption that because our fundamentals are good and we've been a life sciences superpower for decades, that will naturally continue", adding that "the risks of the UK losing status and investment are significantly underpriced."

Realising the opportunities offered by our life sciences sector requires a commitment to applying the lessons from the pandemic: what went well and how we can replicate it. In this chapter, we set out what practical steps the Government should take to ensure the long-term thriving of the life sciences industry, through applying the lessons we identified in the development of the COVID-19 vaccine. These policy ideas are aligned to the four overarching preconditions for success included within the UK's 'Life Sciences Vision'.

2.1 The NHS as an innovation partner

The first precondition for success identified in the 'Life Sciences Vision' is making the NHS a more effective innovation partner, reflecting a particular concern "about the uptake and spread of proven products" within the health system.[37] This issue was repeatedly identified as a weakness of the UK's life sciences offer during the interviews we conducted, with one interviewee memorably stating that: "We've got a racehorse in terms of R&D activity, but the healthcare system is a bit of a donkey."

For this first precondition for success, there are useful lessons to learn from both the collaboration involved in developing the vaccine and the regulatory model adopted by the MHRA. Through a series of partnerships across the life sciences ecosystem, most obviously between Oxford and AstraZeneca, new innovations were taken from petri dish to population at unprecedented speed. This was underpinned by the MHRA's more flexible rolling review model, which reduced the time required to pass clinical trial procedures.

To make the NHS a better innovation partner, opening up the health system by providing clearer routes for collaboration is essential. There are considerable structural barriers to innovation (such as the "incredibly Balkanised" approach to investing in new products

[37] Department for Business, Energy & Industrial Strategy, *Life Sciences Vision*.

described by Professor John Bell) which will require long-term systemic change, perhaps via a transformed reimbursement model for innovations. But given the urgency of addressing this problem, more immediate measures are also needed to make the NHS more accessible in the short-term. Fortunately, there are already some positive signs. The recent launch of the NHS Innovation Service – an online tool where innovators answer a series of questions about their products and are directed towards potential partners who can help them through complex processes – is a good example of this approach at the central level.[38]

National measures which provide a useful routing function through the wider healthcare system are undoubtedly beneficial, but local mechanisms are needed as well. There is already some evidence of this too, with the initial rollout of four local innovation hubs (partly funded by the Health Foundation) to help "provider organisations to build knowledge, skills and confidence to successfully adopt and adapt innovations in local health economies."[39] This includes working with local Academic Health Science Networks and other regional stakeholders to improve the uptake of innovations – offering a local routing function that seeks to build collaboration between different stakeholders.[40] Developing similar bodies across local health systems is essential to improving the NHS' position as an innovation partner.

Standardising some of the agile regulatory approaches we saw in the pandemic would also make it easier for the NHS to adopt new innovations. But this effort is hamstrung by the MHRA's current funding settlement, with several interviewees – who praised the work done by the regulator in the pandemic – raising concerns about the tight financial envelope it is currently operating within.

This partly reflects the fact that the "MHRA's statutory fees have not been increased since financial year 2016/17 for medicines, financial year 2017/18 for devices, and financial year 2010/11 for blood components for transfusion", while "numerous areas of the MHRA's work are under-recovering [costs]".[41] In response, the MHRA has launched a consultation on three sets of fee increases: "a 10% indexation uplift" to cover staff and other cost rises since 2016, an "uplift for 61 significantly under-recovering fees… to achieve full cost recovery", and "22 new fees" to cover new areas of activity.[42]

Measures such as these are likely necessary, but a wider set of reforms that place the MHRA on a sounder financial footing would enable it to return to more flexible pandemic-era regulatory practices. One interviewee told us that the MHRA is "entirely up for that way of working" and claimed that more funding would help: "If they had 25 per cent more budget for the next 5 years, I would think by 2027 they would be operating the way they did in the pandemic." Though there already clear signs of intent from the MHRA (such as the Innovative Licensing and Access Pathway launched in 2021, a process to speed products to market),[43] the next step is to provide the regulator with the financial means to deliver on its ambitions.

[38] Health Innovation Network (South London), 'New NHS Innovation Service Streamlines National Support for Innovators', Web Page, 5 August 2022.
[39] The Innovation Agency, 'Local NHS "Innovation Hubs" to Be Created', Press Release, 5 October 2020.
[40] Ibid.
[41] Medicines and Healthcare products Regulatory Agency, *MHRA Consultation on Statutory Fees*, 2022.
[42] Ibid.
[43] Medicines and Healthcare products Regulatory Agency, 'Innovative Licensing and Access Pathway', Web Page, 24 June 2022.

Idea 1: Conduct a rapid review of best practice in the four existing innovation hubs – based in Manchester, Dorset, Cambridgeshire and Peterborough, and Bradford and the Craven – to evaluate how well they are driving uptake of new products at the local level.

This review should inform a two-year trial of innovation hubs in each Integrated Care System across England, to make local health systems more practically accessible to innovators and to support the development of a pro-innovation culture across the NHS.

Idea 2: Place the MHRA on a stable and long-term financial footing, by introducing an annual re-pricing mechanism in which the regulator can increase, maintain or reduce fees for individual services in response to changing costs.

This would prevent a repeat of the current situation facing the MHRA, where a longstanding freeze in statutory fees (since 2016-17 for medicines and 2017-18 for medical devices) has placed financial pressure on the regulator, resulting in calls for a major hike in fees.

2.2 A trusted approach to the use of NHS health data

The second precondition for success listed in the 'Life Sciences Vision' is the need for a simpler and more trusted approach to governing the data opportunities available within the NHS.[44] Much of this relies on adopting new digital approaches, but it is also about winning the support and consent of the public to participate – whether through data or clinical trials – in efforts to develop new healthcare innovations.

The pandemic experience provides an instructive case study of successful public engagement. The COVID-19 Vaccine Registry, which has secured over 540,000 sign-ups, shows that individuals are willing to contribute their personal data when they understand why it is being used, how it can help to tackle health threats and, crucially, what part it can play in supporting the NHS. The extension of this registry to cover diseases beyond COVID-19 may soon offer a further example of how effective public engagement can aid health research.[45]

By contrast, we also have a recent example of the dangers involved in failing to engage in transparent public engagement. In May 2021, the General Practice Data for Planning and Research (GPDPR) programme was announced, with the goal of sharing aggregated GP patient data to benefit health research. But rather than explaining the potential opportunities, the Government introduced a mere six-week period to opt-out and pursued what the National Data Guardian described as a "soft, quiet launch… without much in terms of communication and engagement."[46] After critical press coverage, 1.3 million people opted out in just a few

[44] Department for Business, Energy & Industrial Strategy, *Life Sciences Vision*.
[45] Chris Smyth, 'Covid Database Revived to Fight Other Diseases'.
[46] House of Commons Health and Social Care Committee, *Oral Evidence: General Practice Data for Planning and Research*, HC 581 (London: The Stationary Office, 2021).

months, a number that could have been lower if the Government had clearly explained the purpose and potential benefits of this programme.[47]

By July 2021, the project had been postponed, with the National Data Guardian calling for further engagement, with an explanation of the "benefits and risks of data sharing, the safeguards in place to protect people's data (including who can access it for what purposes), and what choices people have in regard to it."[48] GPDPR is now passing through a far longer consultative period with no set end-date, during which NHS Digital is engaging with key stakeholders and "redesigning the programme from the ground up."[49]

These two case studies offer contrasting lessons for maximising the data held, and used, by the NHS. While a transparent approach can build trust and encourage participation, failing to engage with public concerns around issues like privacy can lead people to withdraw, squandering potential opportunities. In this context, the Government's recent decision to invest £200 million into "Trusted Research Environments (TREs) and digital clinical trial services", which not only facilitate efficient access to healthcare data but are explicitly designed to provide "the highest levels of privacy", is laudable.[50] Addressing public concerns about privacy and security – by placing these principles at the very heart of NHS data architecture – is key to the trusted approach needed to persuade patients to share their data for health research.

But the Government and the NHS can do much more to facilitate these opportunities, with signs that the public is keen to take more ownership over their healthcare decisions. This is demonstrated by the success of the NHS App which, having been "the most downloaded free iPhone app in England in 2021",[51] has now received over 30 million sign-ups. Via this platform, users have made 448,000 organ donation decisions for the first time (since launch), while also arranging 19.3 million prescriptions and 1.4 million GP appointments in the last year alone.[52] Between the rollout of privacy-focused TREs and this desire from patients to have a greater role in how they engage with the NHS, there is a clear opportunity to encourage more participation and data sharing – ideally via the NHS App, which is set to become "a front door for the NHS... [where patients] do much more to manage their health and access services."[53]

Idea 3: Develop a data-sharing pathway within the NHS App. This should enable users to proactively opt-in to sharing data for clinical research and allow researchers to contact patients eligible for clinical trials or who have data that could facilitate medical research.

This process should include clear explanations of the purpose, risks and benefits of data sharing or participation in clinical trials. This section of the NHS App should also contain general information about how TREs work and how can they can protect patient privacy.

[47] Chaminda Jayanetti, 'NHS Data Grab on Hold as Millions Opt Out', *The Guardian*, 22 August 2021.
[48] National Data Guardian, 'National Data Guardian Statement on the General Practice Data for Planning and Research (GPDPR) Programme', Press Release, 20 July 2021.
[49] NHS Digital, 'About the GPDPR Programme', Web Page, 4 August 2022.
[50] Department for Business, Energy & Industrial Strategy and Department of Health and Social Care, '£260 Million to Boost Healthcare Research and Manufacturing', Press Release, 2 March 2022.
[51] NHS Digital, 'NHS App Turns Three with 22 Million Users', Web Page, 31 December 2021.
[52] NHS Digital, 'Milestone Hit with over 30 Million NHS App Sign-Ups and Almost 450K New Organ Donation Decisions', 28 September 2022.
[53] Ibid.

2.3 Access to finance

Another precondition for success is access to finance, a long-recognised weakness of the UK's life science offer and one that has been highlighted in successive national strategies.

Though there have been signs of improvement on this metric, the diagnosis offered by the government-commissioned and industry-led Patient Capital Review in 2017 remains accurate: "the challenges faced by high potential businesses seeking to scale up are substantial. In particular, accessing long-term, patient finance is difficult in the UK's under-developed and fragmented ecosystem."[54] Our interviewees also agreed with this: "it's why we don't often get the translation of great science to great companies."

In the pandemic, the usual constraints around funding were absent, as an abundance of capital was made available by both government and private backers.[55] This included the Vaccine Taskforce, which was equipped with considerable resources to identify and scale-up candidate vaccines. Similarly, Dominic Cummings has described his efforts to fast-track funding for Covid-related therapeutics in evidence to the House of Commons.[56] This was a microcosm of what the ideal condition would be: promising innovations able to attract funding and scale-up rapidly, delivering products that benefit large numbers of people. But in the UK, this is rarely the norm, as the patient capital needed to take innovative start-ups through to fully-fledged providers of health products is often lacking.

To its credit, the Government has recognised this challenge and has created novel funding vehicles that are designed to break this "vicious cycle", as one interviewee put it. This includes the new Life Sciences Investment Programme (LSIP), a £200 million programme run by British Patient Capital (a subsidiary of the British Business Bank) which aims to attract partner investment of around £600 million.[57] This fund is designed to directly address the key finance problem that the UK's life sciences sector faces: the absence of the growth capital needed to scale up companies and drive innovations through to finished products.

There are, therefore, positive signs here too, with one interviewee suggesting that there has been an "absolute step change in terms of the financing available in the UK." Similarly, the Government's decision to launch a Life Sciences Scale-up Taskforce (co-led by Sir John Bell and Sir Jon Symonds) which examined financial barriers to growth and provided recommendations based on global best practice was also promising, though this report has not been made publicly available and its implementation is therefore unclear.[58]

However, while the UK's funding environment has undoubtedly improved in recent years, this overall remains an area of relative weakness in our life sciences offer. Global competition for life sciences investment is becoming ever fiercer, with other major economies adopting novel means to improve the supply of capital.

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[54] Sir Damon Buffini, *Patient Capital Review: Industry Panel Response* (HM Government, 2017).
[55] Research by the Global Health Centre from July 2021 suggests that the bulk of funding for Covid-19 vaccine R&D came from public sources – see: *Covid-19 Vaccine R&D Investments* (Global Health Centre, 2021).
[56] Health and Social Care Committee and Science and Technology Committee, *Oral Evidence: Coronavirus: Lessons Learnt*, HC 95 (London: The Stationary Office, 2021).
[57] Department for Business, Energy & Industrial Strategy, *Life Sciences Vision*.
[58] George Freeman MP, 'Life Sciences Task Forces: Answer to Written Question' (UIN 110353, 24 January 2022).

A notable example of this is the Tibi scheme introduced by the French Government in January 2020, whereby "institutional investors agreed to allocate a small proportion of their funds to VC [venture capital] firms accredited through the scheme."[59] By June 2021, this had raised more than €3.5 billion for French tech companies, a remarkable success which "exceeded the Government's expectations."[60] Both the UK BioIndustry Association and the ScaleUp Institute have called for the UK Government to adopt a similar policy, to enhance the growth capital offer within our own economy.[61]

Idea 4: The Government should present a clear package of measures to ensure the UK has a globally competitive market for growth capital in the life sciences. This should primarily be achieved by the introduction of a version of the French Tibi scheme, which aims to connect funds held by institutional investors with high-growth venture capital opportunities.

Alongside this, the Government should immediately publish the recommendations included in the final report of the Life Sciences Scale-up Taskforce in 2021, with a commitment to either adopt the ideas suggested by this expert panel or explain why they will not be carried forward.

2.4 Growing investment in science and research

The final precondition for success in the 'Life Sciences Vision' is ensuring that investment in science and research continues to rise, in line with the target of 2.4 per cent of GDP being spent on R&D by 2027. The Vision also references the need to ensure the UK is a "Science Superpower",[62] an ambition that the Prime Minister personally endorsed during his 2022 leadership bid.[63] Notably, Mr Sunak also emphasised the importance of "providing opportunity and spreading prosperity in every part of our United Kingdom" as part of this announcement.[64]

It is hard to know how close the UK is to achieving this goal. Following statistical changes to improve measurement of R&D investment by SMEs, new ONS figures from September 2022 suggest that this target has in fact already been achieved, constituting a major increase in the recorded level of R&D.[65] Yet this may only be an artefact of the new metrics, particularly given that other projections had suggested the 2.4 per cent target was far higher than the existing level of UK activity. Regardless of the precise level, the life sciences sector offers valuable opportunities which further R&D spend can unlock, especially if the UK can outperform its international competitors and secure additional funding from globally mobile investors.

Aside from the need for a competitive level of R&D spend, the pandemic provides a useful allocative lesson: highlighting the value of funding institutions in different places that can

[59] ScaleUp Institute, 'VCM0040: Written Evidence to the Treasury Select Committee', Web Page, 20 June 2022.
[60] French Ministry of Economy, Finance and Recovery, *Financing the Fourth Industrial Revolution: An Initial Assessment*, 2021.
[61] ScaleUp Institute, 'VCM0040: Written Evidence to the Treasury Select Committee'; UK BioIndustry Association (BIA), 'VCM0003: Written Evidence to the Treasury Select Committee', 20 June 2022.
[62] Ibid.
[63] Ready4Rishi, 'Rishi Sunak: I Will Make UK a Science and Technology Superpower'.
[64] Ibid.
[65] Helen Thomas, 'The UK Cannot Declare Victory on R&D', *The Financial Times*, 4 November 2022.

develop their own specialisms. In delivering COVID-19 vaccines, the diversified nature of our research base (in terms of technologies) was a major asset, providing much more resilience and the opportunity to utilise local clusters of expertise. The pandemic also showed that diversification is crucial as, per the House of Commons, the various competing vaccine programmes delivered at different speeds and it was not obvious from the outset which would bear fruit most quickly.[66] With parallel programmes operating in different parts of the country and benefitting from alternative specialisms, the chances of success were greatly enhanced. In tackling other scientific challenges, a deepened version of this approach – geographically diversified and technologically versatile – is the wisest course to pursue.

Of course, even the pandemic example ultimately reflects the dominance of the 'Golden Triangle' (London, Oxford and Cambridge), a powerful engine in the UK's life sciences sector. While the Government should build on existing assets in these places, the aim should be to fund and develop a more spatially diverse research base throughout the UK. This would improve our resilience, but also aligns closely with the ambitions of the levelling up programme to spread opportunity across the country.

In short, the Government must ensure that the promise set out in the Life Sciences Vision, to "build upon the rich geographic diversity of the sector", is achieved in the coming years.[67] The recent Autumn Statement suggests one way of achieving this, with the Chancellor stating that the Government would: "change our approach to Investment Zones, which will now focus on leveraging our research strengths by being centred on universities in left-behind areas to help build clusters for our new growth industries."[68] Applying the lessons from COVID-19, the Government should deliver on this promise and use refocused Investment Zones to develop new life sciences clusters beyond the Golden Triangle.

Idea 5: The Government should look to develop new technologically-specialised growth clusters outside of the Golden Triangle, by focusing Investment Zones (and any related government funding) on academic institutions with a track record of exemplary research in the life sciences.

This should include the life sciences clusters directly cited in the 'Levelling Up White Paper' (Aberdeen, Greater Manchester, Northern Ireland, the Glasgow-Edinburgh Central Belt, the North-East), as well as other areas with untapped academic expertise and potential.

[66] Health and Social Care Committee and Science and Technology Committee, *Coronavirus: Lessons Learned to Date*.
[67] Department for Business, Energy & Industrial Strategy, *Life Sciences Vision*.
[68] 'Autumn Statement' (BBC 2, 17 November 2022).

Conclusion

The life sciences sector is one of the flagship assets in the UK's industrial offering. It is a highly innovative and dynamic industry with a skilled and productive workforce, underpinned by a world-class academic research base. It is also globally competitive and produces innovations – such as the COVID-19 vaccine – which can benefit millions of people and help to reduce pressures facing the NHS. Successive governments have rightly recognised these opportunities and have set clear ambitions, while also introducing an overarching Life Sciences Vision that provides an accurate diagnosis of the strengths and weaknesses of the UK's life sciences offer.

Yet there remains a real risk of complacency. As one interviewee argued: "There's a bit of an assumption that our fundamentals are good, we're a life sciences superpower and have been for decades and so that will naturally continue... that isn't actually the case." In an increasingly competitive global marketplace, the weaknesses in the UK's life sciences offer – such as limited access to finance and poor use of data – are significant and risk us losing out on lucrative investments from globally mobile companies.

However, we also have a clear case study of what the UK can achieve when the entire life sciences ecosystem pulls together. The rapid development of a COVID-19 vaccine, defying the predictions of the UK's Chief Medical Officer and many others, was truly remarkable. The enablers of that success – collaboration, funding, flexible regulation, a diverse research base and significant public participation – provide valuable lessons that should be built upon in the post-pandemic world.

The policy ideas in this paper offer a starting point, and a way to help ensure that the UK's life sciences sector continues to enjoy a world-class footing. The potential prize for the UK is vast. The Government now needs to take practical action and seize the opportunity, before our global competitors in the life sciences get there first.

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