Progress Report

Back on Track? A Progress Report on the Commercial Environment for Life Sciences in the UK

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British American Business

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Introduction

In May 2023, BritishAmerican Business (BAB), in partnership with MSD, published a white paper on the commercial environment for life sciences in the UK.[1] The premise of the paper was that the UK had reached an inflection point, risking its competitive advantage in life sciences, as other countries, eager to grow their share of the global life sciences industry, vied for future investment.

Although the UK has longstanding strengths in life sciences, – with the sector being a major destination for US investment – the paper reflected government and industry recognition, that areas such as commercial clinical trials and medicines manufacturing capacity had declined in recent years, amongst other worrying trends reflected in the UK's life sciences competitiveness indicators.

The consensus from business was that tangible action is needed from government to maintain a viable commercial environment, attract foreign investment, and achieve the UK's ambition: to cement its position as a global science superpower by 2030.

In its recommendations, the paper made a set of specific proposals in three key areas:

1. **Commercial Environment:** that policymakers review the environment to ensure tax, available workforce, and other investment determinants support UK innovation and growth. This includes establishing a successor to the voluntary pricing scheme for branded medicines.

2. **Clinical Trials:** that action is taken to shorten and streamline set-up and approvals processes, and to more effectively integrate research activity into the National Health Service (NHS).

3. **Trade and IP:** that both the US and UK pursue a global trade agenda that enhances economic cooperation in life sciences, delivers for the industry, and maintains the highest standard of IP protection.

Delivering on these recommendations, the paper argued, would ensure that the UK remains a globally competitive market for life sciences, which would lead to greater international collaboration and investment - particularly in a transatlantic context, given the prominence of US life science companies and their desire to have a footprint in the UK.

One year on, we seek to offer a progress report through the lens of the three key areas above. This report has been produced in consultation with leading American and British life sciences firms within the BAB membership, all with a significant presence in the UK. The report determines where progress has been made, where work is still needed, and most importantly, whether there has been tangible action to create an internationally competitive environment for the life sciences industry in the UK.

Summary

When our 2023 white paper was published in May 2023, the UK life sciences sector had reached a critical inflection point - one which risked the nation's historically strong competitive advantage - as other countries accelerated sector development and eagerly grew their share of global market investment, against a backdrop of lower FDI flows to OECD economies.[2]

One year on, we can state that the sector is getting back on track. Whilst there is insufficient data to confirm the sector is fully on the road to recovery, the general sentiment is one of cautious optimism. Perhaps most importantly, there is consensus from the industry and across sector stakeholders, on both the state of play and steps needed to chart the UK's journey back to global leadership. Recognizing that the impacts of various interventions, including the Harrington Review and O'Shaughnessy Review, will emerge over time, our

1 The UK Life Sciences Sector is at a Turning Point. Now is the Time to Commit to its Future - BritishAmerican Business, MSD, May 2023

2 FDI in Figures April 2024 - OECD, April 2024

report notes upticks in the short term, including improved upstream regulatory performance for clinical trials, and bright spots of investment, both at a public and private level. However, there are still deeply embedded challenges that the industry faces, particularly in downstream access, for innovative drugs and technologies to reach patients & caregivers. Progress is also not equally observed sector wide. Whilst biotech and early-stage research booms, larger firms continue to view the commercial environment in the UK as challenging.

Despite the mixed results, the UK is making progress to regain ground lost since the pandemic. However, there is still a long way to go for the UK to recover its former position, let alone embed itself as a frontrunner in the newly defined global leadership race. There is a clear consensus from industry, that long term implementation of recommendations, sustained momentum and effective delivery, are essential in ensuring that the UK life sciences sector remains a top destination for innovation and growth on the global stage.

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By mid-2023, the declining vibrancy of the life sciences sector had been widely noted by both private and public sector stakeholders. The UK government had been examining the landscape to identify key intervention points to promote recovery, including through dedicated strategic reviews on clinical trials led by Lord O'Shaughnessy (published in May 2023)[3] and on improving Foreign Direct Investment (with life sciences as a priority sector), led by Lord Harrington (published in November 2023).[4]

The government also attempted to kickstart sector recovery by improving the broader commercial environment, through a spate of incentives and investments, particularly across the 2023 Autumn Statement and 2024 Spring Budget. This included a £650m "war-chest" of growth incentives for the sector, labeled the 'Life Sci for Growth' package (although we note that some of the elements had been integrated from previous announcements). The package focused on enhancing life science manufacturing capability, driving R&D through better relief claim processes, funding boosts for early-career researchers, and support for SMEs & start-ups by improving access to capital through venture capital and pension fund initiatives.[5]

More widely, the government announced a move to digitalization in the National Health Service, with a £3.4bn allocation for digital infrastructure enhancements, with the intention that this would create a knock-on effect for the life sciences sector. For example: by connecting research hubs; streamlining administrative processes; and allowing for greater access to real-time data & monitoring.[6] Digitalization has proven to be transformative for clinical trials. For example, NHS DigiTrials accelerated set up for COVID-19 treatment in just 9 days, recruiting 10,000 people in 2 months.[7]

Further, the government looked at making other interventions outside these announcements to bolster the sector, for example by addressing specialist & advanced manufacturing skills gaps, with new training through programs like the Cell and Gene Therapy Catapult (Advanced Therapies Skills Training Network)[8] and, perhaps more significantly, by negotiating the UK's rejoining of the EU Horizon program, which opens the door to European research talent and funding support for businesses until 2027.[9] Another area had been in SME and early-stage R&D support, through the Mansion House reforms for example, to increase funding

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3 Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report - Department for Science, Innovation & Technology, Department of Health & Social Care, May 2023

4 Harrington Review of Foreign Direct Investment - Department for Business & Trade, HM Treasury, November 2023

5 Chancellor reveals life sciences growth package to fire up economy - HM Treasury, Department for Science, Innovation & Technology, Department of Health & Social Care, Office for Life Sciences, May 2023

6 HC 560 - Spring Budget 2024 - HM Treasury, March 2024

7 NHS DigiTrials enables improved treatments to transform lives - NHS England

8 About the Advanced Therapies Skills Training Network - Advanced Therapies Skills Training Network

9 UK joins Horizon Europe under a new bespoke deal - Prime Minister's Office, 10 Downing Street, Department for Science, Innovation & Technology, The Rt Hon Michelle Donelan, The Rt Hon Rishi Sunak, September 2023

liquidity for high-growth science and technology businesses.[10]

There had also been efforts to renew and re-negotiate a government – business agreement on drug pricing - one that balanced innovation with long term sustainability for the National Health Service. This attempted to address access issues around procurement, which other initiatives and policy mechanisms were not able to do. After strenuous sector-wide negotiations, a new pricing scheme for medicines - now known as the Voluntary Scheme for Branded Medicines, Pricing, Access and Growth (VPAG) - was successfully negotiated by the end of 2023.

1. Commercial Environment

Concluding a successor agreement to the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) was a key recommendation of our 2023 white paper. Left untouched, the existing scheme required companies to pay rebate rates from sales revenues of up to 26.5%, nullifying investment and growth.[11] The new scheme specifies controlled growth rates year- on- year to 2028 on branded medicine revenues, alongside differentiated payment mechanisms between newer and older medicines. It attempts to create more headroom for newer, innovative medicines through these structures. The scheme also channels money back into the ecosystem through a built-in investment program, which seeks to improve, amongst other areas, the UK clinical research environment.

Reaching an agreement on what is now called the Voluntary Scheme for Branded Medicines and Access and Growth (VPAG) in late 2023 was an important compromise between industry and government. It has found a level of acceptance among life sciences firms, given the alternative was viewed as untenable. VPAG at its simplest, provides a greater level of environmental certainty for business and investors over the next five years. Whilst the scheme is more palatable for some companies over others (depending on product portfolios and sale volumes), it trends towards becoming internationally competitive towards the second half of its term (with rebate rates for newer medicines hitting approximately 7.2% by 2028, based on industry forecasts).[12]

However, beyond the achievement of its formalization, only time will determine if VPAG will be a truly effective mechanism. Success will depend on: the delivery of competitive rebate rates; implementation of commitments to improve medicines access; introduction of innovative payment models & indication-based pricing; and the avoidance of market distortions, for example in medicine supply. It is important to recognize that VPAG is not immediately placing the UK in a more competitive position. Rebate rates in the short term remain high, and this in combination with wider environmental changes (including the 25% corporate tax rate that took effect last year), continues to create a challenging environment for businesses operating in the sector.[13]

Outside of VPAG, the life sciences sector was given a prominent place in the Lord Harrington Review into the UK's approach to FDI. The review (amongst several recommendations) stressed a need for: better integration of investment thinking into policy making across government; developing a long-term strategy for investment that consistently builds upon the Life Sciences Vision & associated policies; and a more targeted, reformed approach to incentive schemes/tax breaks for R&D in the wider corporate environment.[14] Addressing these issues - as highlighted in our 2023 white paper - is essential in ensuring that the UK continues to be an attractive place to invest in life sciences.

Whilst it is too early to determine the full impact of the review to date on FDI performance, the UK is making

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10 The UK Science and Technology Framework: update on progress (9 February 2024) - Department for Science, Innovation & Technology, Prime Minister's Office, 10 Downing Street, February 2024

11 UK life science inward investment in freefall - ABPI, July 2024

12 Navigating the Impact of VPAG: Opportunities, Challenges, and Strategic Considerations for Pharmaceuticals - Windrose Consulting Group

13 Government update on Corporation Tax - HM Treasury, October 2022

14 Harrington Review of Foreign Direct Investment - Department for Business & Trade, HM Treasury, November 2023

some progress. Broadly speaking, the UK's FDI position has been improving - it recorded a 6% increase in FDI growth from 2022 to 2023 (although we note this is not reflective of the life sciences sector specifically).[15] It also maintained its position in the top 10 countries globally for ease of doing business.[16] On the ground, government incentive mechanisms are also bearing some fruit. Its co-fund competition - the Life Sciences Innovative Manufacturing Fund, announced in 2023, whilst not directly designed as an FDI tool, improves the investment environment by supporting growth for businesses of all sizes. In addition, a new, dedicated Expert Advisory Panel will provide targeted support on administration of R&D tax reliefs in the sector. As such, there is evidence of new large-scale capital investment projects emerging, including the new £650 million investment by BAB member AstraZeneca across sites in Cambridge and Speke near Liverpool, which will boost the UK's vaccine development and wider R&D capacity.[17] The government also built upon a £1bn deal struck with BAB member Moderna, by signing an MOU with its parent company Flagship Engineering, as the company's first overseas hub outside the European Union.[18] Further, Industry confirms that access to skills within the sector remains positive (for example lab technicians & specialist researchers), noting that long - term success here rests on the UK's ability to home-grow talent over importing it.

Despite these improvements, FDI project flows into the sector remained lower in 2022/23 than in 2016/17, meaning that investment has not yet recovered from pre-pandemic levels.[19] Whilst the formulation of a new strategic approach to FDI in life sciences is a noteworthy achievement in and of itself, the Harrington Review's success is fully dependent on effective implementation and uptake to drive sustained investment flows. It is also important to note the distinction between FDI, venture capital & private equity investment to understand wider performance. Many of the UK's recent investment wins, particularly in London (61% year-on-year growth in life sciences company incorporations), are skewed towards early-stage research and development.[20] Evidence suggests that venture capital investor confidence is trending upwards, particularly for BioTech & MedTech start-ups & early-stage research SMEs. The demand for lab space (2.2m sqft sought between Oxford, Cambridge & London and less than 1% vacancy rate in Cambridge at the end of 2023)[21] [22] highlights surging growth in the space, with the UK alone accounting for 41% of the total biotech venture capital investment across Europe.[23] Arguably this creates a misleading investment picture as many smaller life sciences companies germinate and scale in the UK, and then quickly leave without returning, in part, due to commercial environmental conditions. True progress across the ecosystem must ultimately include the full-scale up of product manufacturing through to deployment and be reflective of the wider sector.

Interactions between key stakeholders within the ecosystem, to improve coordination and increase the speed of patient access to therapies, are particularly important in creating a more attractive commercial environment to retain firms. Data recently released by the European Federation of Pharmaceutical Industries & Associations (EFPIA) ranks England 7th in terms of the time it takes between regulatory approval and availability within the NHS, with other economies such as Germany ranking first (at less than half the average time).[24] The pathway between the Medicines and Healthcare products Regulatory Agency (MHRA) (UK regulator), the National Institute for Health and Care Excellence (NICE) (availability and quality control within the NHS) and the NHS itself, is significant here.

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15 Foreign Direct Investment: UK's project total grows as Europe's falls - EY, May 2024

16 Ease of Doing Business rankings - Doing Business (Work Bank Group)

17 AstraZeneca plans £650 million investment in the UK - HM Treasury, March 2024

18 Flagship Pioneering Marks Official Opening of UK Hub with Event Convening Life Science Leaders - Flagship Pioneering, November 2023

19 Why is the UK struggling to attract foreign direct investment? - Financial Times, November 2023

20 UK Life Sciences Forecasts 2024 - Knight Frank, December 2023

21 UK needs more lab space if it wants to be science superpower, ministers told - Julia Kollewe, The Guardian, November 2023

22 The Case for Cambridge - HM Government, March 2024

23 Life Sciences - UK Government

24 EFPIA Patients W.A.I.T. Indicator 2023 Survey - IQVIA, June 2024

In conclusion, the commercial environment has improved for the sector since last year, albeit more for smaller R&D businesses over larger firms. We could continue to see further improvements across the environment in the long run, particularly if both the Lord Harrington Review and VPAG are implemented effectively, rapidly and in full, by the government, in close partnership with industry. However, it is important to note that, holistically, this environment is still not an outstandingly attractive one for life sciences firms. Access is top of mind for industry and much has to do with the tight fiscal conditions of the National Health Service - the UK's biggest employer and central conduit for the delivery of therapies. If innovative products cannot be procured, even if they are deemed cost-effective, this is neither good for business nor society. More needs to be done towards managing medicines more effectively into the market (although we note the planned redevelopment of the Innovation Licensing & Access Pathway)[25] and viewing health as a strategic investment. Evidence demonstrates interlinkages between improved health and economic outcomes, and actions that support the former – such as improved access to innovation, will provide a more conducive environment for growth.[26] The 10th round of life sciences competitiveness indicators, released by the government in the coming months, will also be a key data set to track ongoing progress.[27]

2. Clinical Trials

Improvement in the quantity and quality of clinical trials was another key focus of our 2023 white paper. Despite the UK's historic strength in clinical trial research, analysis had shown that it had fallen behind in performance due to structural issues since 2017, including in trial approval times and participation numbers. The sharp decline in global performance indicators (as reported by the Association of the British Pharmaceutical Industry) (ABPI) is indicative of the future health of the sector, given growing international competition from economies like Australia and Spain for example, who have spotted the opportunity to expand their slice of the global market.

Towards the end of 2023, we note that the commercial clinical trial performance in the UK had begun to improve. Some performance indicators, particularly across regulatory timeframes, are now reflecting this, whilst others have yet to see a marked change. We expect to see any improvements translate into international rankings after a lag period. These improvements are being built upon in a targeted way through the Lord O'Shaughnessy Review (2023), commissioned by the UK government in an attempt to revitalize the clinical trials landscape in the UK. The Review was comprehensive and offered eight key problem statements and 27 recommendations.[28]

BAB's proposals were fed into the review process. There is agreement across industry that the publication has been highly effective in bringing stakeholders together across the sector towards a shared understanding of the steps required to achieve future success. The government's prompt uptake of the Review's recommendations, alongside a funding allocation of over £120m, demonstrates seriousness in adoption of the plan, and that the right recommendations have been put forward.

The government (in its response) committed to revising national performance indicators for clinical trial activity and within the UK regulator – the Medicines and Healthcare products Regulatory Agency (MHRA) - as waiting times, for trial approvals for example, had ballooned to over ten times the standard timescale. Since the Review's release, we note the MHRA's performance improvements.[29] Through the re-deployment of

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25 Innovative Licensing and Access Pathway - Medicines and Healthcare products Regulatory Agency, April 2024

26 Health and economic growth: new evidence from a panel threshold model - Mohamed Chakroun, Cogent Economics & Finance, Vol.12, March 2024

27 Life sciences competitiveness indicators 2023 - Department for Science, Innovation & Technology, Department of Health & Social Care, July 2023

28 Government response to the Lord O'Shaughnessy review into commercial clinical trials in the UK - Department for Science, Innovation & Technology, Department of Health & Social Care, Office for Life Sciences, May 2023

29 MHRA performance data for assessment of clinical trials and established medicines - Medicines and Healthcare products Regulatory Agency, April 2023

resources, streamlining of processes and wider organizational transformation, the MHRA is delivering within statutory timeframe requirements for trial assessments and amendments. Backlogs have been cleared, which allow clinical trials to be approved more quickly. However, we note that in the short term, resource reallocation negatively impacted other regulatory functions within the MHRA, such as licensing approvals. Moving forward, the MHRA is actively implementing the recommendations of the O'Shaughnessy Review through its 2023/24 Business Plan.[30]

As a result, there has been a notable, albeit marginal improvement in global performance figures. At the end of November 2023, ABPI reported that the number of initiated industry clinical trials rose marginally from 2021/22 to 2022/23 (by 4.3%). It also reported an annual increase in trial recruitment by 15%.[31] However, this still sits below the UK's performance in 2017/18, meaning that the rates have not yet recovered beyond former levels.[32] Whilst this is not a dramatic comeback, it does demonstrate that the UK's decline in clinical trial numbers has slowed, and that wider regulatory performance may be starting to recover. At such an early stage, recovery is not a certainty, however as speed is vital for success, this does offer some promising evidence for the revitalization of regulatory processes.

Looking at the wider clinical trials system, there are still fundamental issues to be addressed. The UK is still underperforming on (sluggish) clinical trial set-up and delivery timelines, which is viewed by industry as key to recovery. For example, indicators show that active recruitment within two months after receiving regulatory approval currently sits at 39%.[33] Without addressing important downstream phases of the clinical trials process (including resourcing, coordination, costing & deployment at site), true progress cannot be realized. Whilst the deployment of trials can take many forms and involve different stakeholders - the NHS as a delivery partner is central to this ambition. There is little evidence to conclude that research is being better integrated into the culture of the NHS as a core function since last year, emphasizing the need for further efforts in creating the right downstream environment for clinical trials to thrive. This is compounded by a lack of resources, training and on-the-ground support. Inconsistencies across the National Healthcare System, in equitable access to a shared standard of resource and care for patients, inhibits firms from undertaking later stage clinical trials (Phase III), as they cannot compare their investigative candidate(s) to a consistent benchmark. This ultimately has a wider impact on investment decision making relating to clinical trials.

3. Trade and IP

In our 2023 white paper, we stated that the UK Government's international trade agenda presents an opportunity for life science firms to continue exporting UK innovations globally, while also accessing the talent and imports needed from abroad. Medical and pharmaceutical products have continued to sit at the top of the trade agenda for both the US and UK, constituting approximately £8.8bn exports from the UK to the US - a growth rate of around 30% from 2022 (based on four quarters to end of Q4 2023).[34]

The paper argued that the liberalization of trade with likeminded partners can reduce regulatory barriers, encourage inward investment, and promote closer regulatory alignment - each an important step towards strengthening the industry in the UK. A year on, the UK has continued to advocate and push for a pro-trade agenda, while elsewhere in the world, the principles behind a liberalizing trade policy are increasingly being questioned.

Mechanisms such as the International Recognition Procedure (IRP) (which came into force early this year), have supported trade imports, from overseas markets including the US, by expediting market authorization across products, where certain criteria are met.[35] Further, the UK's proactive trade agenda, including accession to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), as well

30 MHRA Business Plan 2023-24 - Medicines and Healthcare products Regulatory Agency, September 2023

31 Getting back on track: Restoring the UK's global position in industry clinical trials - ABPI, November 2023

32 Global rankings - Number of industry clinical trials initiated in 2017, by country, by phase - ABPI, September 2023

33 UK clinical research update May 2024 edition - the Future of UK Clinical Research Delivery, May 2023

34 Trade and Investment Factsheets - United States - Department for Business & Trade, May 2024

35 International Recognition Procedure - Medicines and Healthcare products Regulatory Agency, May 2024

as the current negotiations for a UK - Switzerland trade deal, will support commercial conditions and future opportunities for the sector in the UK. For example, through CPTPP, the UK has an opportunity to address trade barriers in Malaysia, a country with which the UK does not have a pre-existing FTA.[36]

Furthermore, the announcement by the UK and the US to form a new strategic partnership to tackle increased biological threats was very welcome.[37] The partnership works towards a greater shared understanding - it enhances collaboration across R&D, including next generation vaccines and therapeutics, as well as threat detection & responsiveness, and in the development of new methodologies & standards for biosecurity.

Beyond that, we welcomed continued efforts by both the UK and the US to strengthen IP standards across platforms. Robust IP protections ensure the life sciences sector is secure from systemic threats and allows for firms to freely innovate and collaborate knowing their inventions are protected. For example, the dedicated partnership between the US and UK on AI safety, as a result of the UK's leadership in the field through the inaugural AI Safety Summit held at Bletchley Park, is an important global forum which will support the strengthening of IP protection in a new world of AI.[38] This is significant for the life sciences sector, particularly across drug discovery and patent protection. As such, we welcome the establishment of the UK's first AI Safety Institute (office) based overseas in San Francisco, California. This transatlantic collaboration builds on a pooled base of research talent and technical expertise, to effectively assess the risks and developments of frontier AI systems.[39] Moving forward, we also welcome greater industry engagement on IP, as part of a dedicated bilateral, industry-led IP Working Group, established by BAB and the US Chamber of Commerce in 2023, which will amplify alignment. Within the WTO, we note efforts by the UK to oppose extension to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Waiver for COVID-19 diagnostics and therapeutics. Industry commends the advocacy work of the UK Department of Business and Trade (DBT) to date, to maintain the highest standards of IP protection.

Overall, we have observed enhanced collaboration across both the Trade and IP agenda that will result in greater support for the UK's domestic life sciences sector. Whilst many of these initiatives are still emerging, there is scope across many, to build a strengthened transatlantic partnership to secure better outcomes and ensure the future prosperity of the sector.

Charting the Future - Recommendations to Policymakers

A. Commercial Environment

- It is critical that the commitments within the VPAG agreement are delivered. To ensure sustained progress, we encourage greater alignment between stakeholders in the life sciences ecosystem, to maintain consistency and to avoid undermining VPAG. This would include, for example, activity by NICE on changes to medicine affordability policy. Accelerating the agreed metrics within VPAG would also be impactful in improving the adoption and uptake of medicines. To more effectively balance innovation, pricing and access for medicines, we encourage the government to address some of the ongoing issues with the VPAG scheme at the next review consultation in 2025. One example is the lack of flexibility in accommodating new, innovative administrative methods and reformulation of existing drugs. As such, innovation is not being recognized beyond the 'primary' drug patent, and affected firms are being hit with higher rebates, potentially leading to companies withdrawing medicines from the market. Another example is around combination medicines, where pricing via the scheme is difficult to determine. More broadly, developing a framework where innovative payment models are routinely delivered, and through the incorporation of indication and combination-based pricing, substantial improvements in the commercial environment can be unlocked.

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36 Trade Barriers in Malaysia - GOV.UK

37 U.S. – UK Strategic Dialogue on Biological Security - The White House, January 2024

38 U.S. and UK Announce Partnership on Science of AI Safety - U.S. Department of Commerce, April 2024

39 Government's trailblazing Institute for AI Safety to open doors in San Francisco - Department for Science, Innovation and Technology, AI Safety Institute and The Rt Hon Michelle Donelan, May 2024

- Particular attention should be given to coordination improvements across the MHRA-NICE-NHS pathway and be addressed in the context of process, capacity and approach to data management & continuity. It is important that all stakeholders understand, that the speed at which patients can access new innovations is strongly determined by the efficient interaction between key partners in the sector. We also welcome schemes that promote greater connectivity (access pathways) for innovators, including the Innovative Licensing and Access Pathway (ILP) 2.0.[40] We further recommend the review and updating of evaluation methodologies within NICE & JCVI for example, to improve effectiveness and to keep pace with new technology and product development.

- Improved, streamlined structures that prioritize inward investment across departments, starting with the UK's Department for Health and Social Care (DHSC), will drive improved investment flows. Further, embedding a shared (actionable) investment strategy across departments alongside these structures, for example with the Home Office (employment Visa approvals), will allow for more holistic investment packages to be offered to prospective investors in the sector. Empowering the Office for Investment (OFI) or Office for Life Sciences (OLS) to act across government in this interest is one approach. BAB also welcomes the formation of a Cabinet-level Investor Committee, which seeks to integrate investment responsibilities across government departments and directly within Ministerial portfolios. Beyond this, the government should consider adjusting the UK's R&D tax relief system, to include capital spend in qualifying R&D expenditure, to keep pace with the global competition for investment.

B. Clinical Trials

- We urge the government to sustain momentum on implementing the O'Shaughnessy Review's recommendations, with greater clarity on timelines, accountability and funding, to avoid piecemeal progress. We caution against simply redistributing resources to meet siloed objectives, which may put wider regulatory functions at risk. For example, within the MHRA, industry notes that faster clinical assessment timescales, although helpful, are coming at the cost of performance in other areas, such as product approval rates for medical technologies & licensing.

- Greater focus needs to be applied to the downstream phases of commercial clinical trial deployment, particularly at site level, to ensure the UK can deliver competitive setup and recruitment timelines beyond regulatory approvals. Better synchronization within the ecosystem, such as between regulator, trial administrator and site can help. We welcome the proposal from the MHRA to work closely with industry to create holistic guidance for patient recruitment & participation. Perhaps most importantly, addressing structural and fiscal fundamentals to adequately support the NHS (deploying people, training and equipment), as well as embedding a strong research culture, are critical to improving overall performance. To support these new approaches in trial deployment, public-private partnerships or regional models to increase efficiency could be explored. Ensuring the VPAG investment program provides additional ring-fenced financing for trials, with clear routes for industry review, will also be a significant support mechanism.

C. Trade and IP

- We continue to encourage the UK towards championing a gold-standard of IP protection in a domestic, bilateral and multilateral context. Regarding the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Waiver, we maintain that the UK oppose any further expansion of the TRIPS waiver to include COVID-19 diagnostics and therapeutics, should the issue reopen, or as part of a wider review process.[41] We also encourage the US government to resume their historically strong voice on robust IP across multilateral platforms, recognizing the significance of IP for transatlantic business in life sciences. Alongside this, we welcome new avenues to promote greater IP protection and alignment, for example through both the UK and US' official status as ASEAN dialogue partners.

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40 The future of the UK life sciences sector: Balancing innovation and regulation - Eversheds Sutherland, February 2024

41 TRIPS Council finalizes preparations for MC13 - World Trade Organization, February 2024

We support transatlantic leadership across IP protection in the context of AI development, where the life science sector is particularly at risk. Industry supports a pro-innovation, risk-based approach to AI which recognizes and supports the role of existing regulators (such as the MHRA).

- We recommend enhanced transatlantic exchanges in life sciences, to continue to harmonize across regulation, standards and processes. A strengthened MHRA – Federal Drug Authority (FDA) dialogue, in consultation with industry, may be particularly impactful to maintain agility in areas such as medical devices, where regulation often becomes outdated given the speed of technological advancement. It may also be useful in the context of licensing and data exchange. We commend the recent work by the MHRA on the development of a new policy framework, aligning the assessment of medical devices with the US, to reduce timelines and work duplication.[42]

- To unleash innovation, we advocate for focused collaboration across biotechnology and in cutting-edge research in biosciences, such as genomics and gene therapeutics. This works together with alignment on responsible governance to prevent abuses. Both the US and UK are already home to many of the world's leading biotech companies from start-ups to multinational corporations, which underpins such cooperation.[43]

Conclusion

The UK life sciences sector is in a better place since May 2023. We note there is not enough evidence at this juncture to confirm that the UK has fully turned a corner, however despite a dynamic backdrop of political and economic volatility, there have been both structural and performance improvements, across the Commercial Environment, Clinical Trials and Trade & IP space.

It is important to note that this progress, whilst working to slow sector decline, has not yet reversed the trajectory. Whilst the negotiation of the VPAG and improvements in clinical trial approvals are important milestones for the sector, viewed in isolation, they cannot be allowed to paint an overly positive picture. There is agreement within industry, that the UK now has the plans and strategies in place to reverse decline, and through work like the Lord Harrington and O'Shaughnessy review, there may also be enough strategic guidance to eventually begin to unleash the sector's full potential.

It is vital that the UK government follows through on implementation, recognizing that it is still playing catchup in the global race for continued investment. Agreement on both sides of the political aisle on what is needed to grow the sector and solve its complex problems will help ensure this regardless of the outcome of the general election.[44] Unlocking real progress for bigger more mature firms in the space, as well as investor appetite, will center around downstream access improvements to ensure deployment of innovation. Much will also rest on the capability and capacity of the NHS, and within the corridors of local Trusts - for many, this will make or break the recovery of the sector.

We view the transatlantic partnership as essential for the future of the sector's resurgence, not only because of the deep trade and investment interlinkages, but also due to the unique opportunities for transatlantic cooperation that cannot be replicated elsewhere, such as in: IP diplomacy; as well as cutting edge biotechnology & biosciences, including its responsible governance & securitization. We maintain that building on UK-US initiatives such as the Atlantic Declaration[45] across these areas will unleash further innovation and maximize the development of the UK life sciences sector, at home and abroad.

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42 MHRA announces a proposed framework for international recognition of medical devices - Medicines and Healthcare products Regulatory Agency, May 2024

43 A New National Purpose: Leading the Biotech Revolution - Tony Blair Institute for Global Change, January 2024

44 A Prescription for Growth - Labour's plan for the life sciences sector - Labour Party

45 The Atlantic Declaration: A Framework for a Twenty-First Century U.S.-UK Economic Partnership - The White House, June 2023

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