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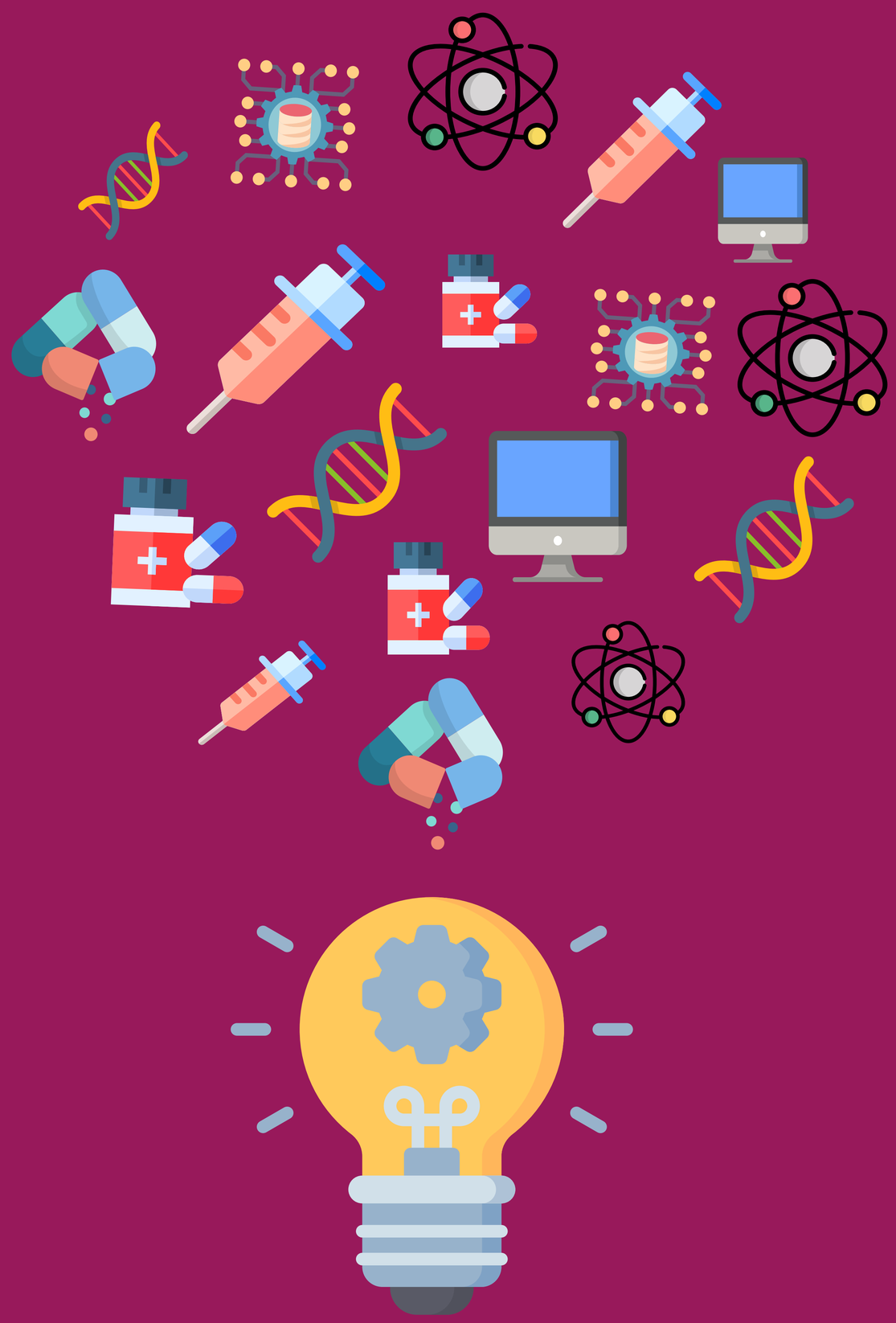

The future of post-Brexit regulation

abbvie

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We work on core sectors such as health and social care, education, home affairs and justice, and work and pensions. Our work also covers issues that cut across these sectors, including public service design and delivery and digital public services.

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Introduction

Regulating the future

The UK life sciences industry has a record of developing ground-breaking medicines and medical devices, and regulation has been crucial to this. It is not only there to protect patients, but also exists to "guide" innovators on how to safely develop new medicines or products. However, COVID-19 has highlighted how the regulatory framework can be made more flexible and adaptable in order to develop treatments faster.

When the UK leaves the EU on January 1st 2021, decades of regulatory alignment could end. This will force some changes to the way the life sciences sector works in the UK with possible disruptions to access to medicines and flows of funding for research and development (R&D).

In spite of these challenges, the authors in this *Reformer Thoughts* suggest that the UK is well positioned to remain a world-leader in medical innovation after Brexit. This could potentially carry forward the post-pandemic economic recovery. To secure the future prosperity of the UK's life sciences industry, the Government will need to create a smart post-Brexit regulatory landscape.

Preserving similar standards and levels of scrutiny to the EU are important, but there is also potential to improve. As highlighted by the recently published Independent Medicines and Medical Devices Safety Review, there needs to be a renewed commitment to patient safety with a potential strengthening of the role of existing regulators.

Other improvements could lie in finding ways to simplify the current complex and siloed regulatory landscape. By streamlining pathways to regulatory approval, the Government can make post-Brexit Britain a more attractive place for R&D capital.

Crucially, however, this investment needs to be more equitably distributed across the country and reach areas outside of the Cambridge-London-Oxford Golden Triangle. This would allow the life sciences industry to strengthen regional economies outside of the South-East.

Post-Brexit regulation will need to be forward looking and consider how innovative treatments will be developed in the future. The pharmaceutical industry, like many other areas of life sciences, stands to be completely transformed by the use of data and technologies like Artificial Intelligence to accelerate the discovery of new drug compounds. Improving ways in which data can be accessed whilst ensuring patient privacy will be key.

There are huge opportunities for the life sciences industry to flourish post-Brexit. This *Reformer Thoughts* brings together leaders in the sector to consider how these can be seized . The Government will have to safeguard patients whilst supporting innovation and promoting the UK as an attractive place to invest in the future of medicine.

Matt Fetzer

Researcher, *Reform*

"To secure the future prosperity of the UK's life sciences industry, the Government will need to create a smart post-Brexit regulatory landscape."

Beyond Brexit: realising the opportunities

On January Ist 202I, the UK will begin a new chapter outside the EU, presenting opportunities to enhance the life sciences ecosystem at home, and be world-leading abroad. Much of the discourse on medicines and medical devices in relation to this transition necessarily focuses on safeguarding for patients and how to mitigate against disruption in supply; but it is important to also explore the opportunities the UK has in forging a new path forward.

AbbVie highly values the relationship between the UK and EU, which allows for coordinated research and development activities, aligned approaches to clinical trials, and the regulation of medicines and medical devices, however we also recognise that the UK's exit will necessitate a new type of partnership.

In order for both the UK and EU to maintain some of the benefits of the existing partnership and mitigate against disruption of supply, AbbVie strongly supports the establishment of a Mutual Recognition Agreement on manufacture, testing and release.

The UK Government has presented an ambitious vision for the country to become a leading global hub for life sciences and an internationally competitive trading partner with the EU and the world – a vision that AbbVie shares. But in order to deliver on this, the coming months need to be used to transform the UK life sciences environment and to attract inward R&D investment from around the world.

This could be done by offering an agile regulatory and access pathway for medicines and medical devices. UK patients could be being amongst the first in the world to access the most innovative and ground-breaking medical interventions, transforming patient care.

There are several key opportunities the UK can focus on to improve patient access and retain its position as a world leader in research and development. First, the pathway for developing innovative medicines and devices can be supported with programmes such as the Early Access to Medicines Scheme and the Accelerated Access Collaborative. However, these must evolve to present an agile pathway to bring the most important innovations through regulatory approval and into the healthcare system, including allowing for iterative evidence generation.

Second, the Government should support efforts to align the different elements of the development pathway in order to ensure faster, more efficient patient access to innovative treatments. This would prevent the situation where an innovative medicine is accelerated through the regulatory process, only to be delayed by a separate follow-on access process.

Third, the Government should seize on this opportunity to transform the life science landscape and set out a bold vision for the future. This should include new approaches to evidence generation and managing benefit/risk assessment to ensure that transformative therapies are able to reach those who need them.

The UK is well placed to take advantage of the opportunities at the turn of the year. With its integrated healthcare system, innovation focused regulator, the baseline strength of research and development, and a strong technology sector that will underpin the healthcare and life science industries of the coming decade.

COVID-I9 has highlighted the global role that the UK can play in medicines and medical devices development, and the Government must build on this as it plans a route beyond Brexit.

Emma Du Four

Head of International Regulatory Policy and Intelligence, AbbVie

"the coming months need to be used to transform the UK life sciences environment to attract inward R&D investment from around the world."

Accelerating new medicines: the opportunities after the EU

If Brexit is to mean something positive to a new generation, we need to show a new generation that global Great Britain can be a leading international force for progress and that our best days are ahead of us.

After a 15 year career in bioscience venture finance before coming to Parliament in 2010, I have always believed that the UK can be a true science superpower and innovation nation: moving from over-dependence on the City and consumer spending to an economy that starts, finances and exports the technologies of tomorrow.

Our departure from the EU in six months has triggered an understandable concern in the UK R&D Community, for whom collaboration with EU scientists and programmes like Horizon 2020 are key. But the combination of freedom from EU regulations which stifle bioscience commercialisation, and continued UK participation in EU science programmes, does creates a major opportunity.

I voted Remain at the EU referendum because, on balance, I felt it was in the best interests of my agricultural and food processing constituency. However, I have always been a vocal critic of the way Brussels has approached regulation around science and innovation. That's why, in the last Parliament, I led and authored the report on EU biotechnology regulation with the Fresh Start Project and the think tank Open Europe.

As I highlighted in the report, the growing hostility of the EU to biotech has had a hugely damaging effect on the EU bioscience economy. Just as the genomic revolution has been starting to offer untold opportunities across medicine and agriculture, the EU has been developing an increasingly hostile regulatory framework which has undermined Europe as a hub of biotechnology.

We should be in no doubt how game-changing the biotech revolution is. In cancer, as a result of breakthroughs in tumour genetics, we can now detect, prevent and eradicate cancer tumours in people who 20 years ago would have died. As a result of stem cell science, we can now reverse blindness with one injection. These are stunning UK innovations which we could take global and commercialise.

We are now living in an age of digital drugs like those developed by British start-up Proteus, or the contact lens that monitors and maintains blood drug levels. These developments invite further questions: how do the old silo regulatory classifications of 'drug', 'device', 'diagnostic' or 'data' apply in the 21st-century life science landscape?

I would have preferred to lead reform from inside the EU, but Brexit offers us a unique opportunity to forge our destiny as the crucible of the bio-economy industrial revolution. We have the chance to pioneer the new technologies with the potential to help feed, fuel and heal the developing world.

To do that we don't just need to invest in R&D, we must also start leading the way on creating a new regulatory framework for 21st-century bioscience innovation.

We need to be strategically clear that we will develop a British regulatory regime which is pro-innovation, pro-consumer, pro-transparency.

George Freeman MP

Former Parliamentary Under-Secretary of State for Life Sciences

"I would have preferred to lead reform from inside the EU, but Brexit offers us a unique opportunity to forge our destiny as the crucible of the bio-economy industrial revolution "

7 - The future of post-Brexit regulation

We face a once-in-a-generation chance to maximise our leadership of Europe from outside, as we always used to. If we get this right, we can make the UK the 'Gateway Testbed' for new 21st century technology and appropriate regulation, which the City can then finance to take global.

Done properly, we could become the global capital for the research, development and financing of the innovations in the core markets of food, medicine and energy around the world. This really could be a win-win moment for the UK to become one of the world's leading knowledge economies of the 21st century.

That is the prize waiting for us if we get the question of regulatory alignment right and put innovation at the heart of our negotiating strategy. It is the duty of all of us, no matter how we voted during the referendum, to seize this moment. Future generations will not thank us if we fail.

Regulation in the era of digital innovation

Regulation has always been considered a 'hurdle' to those who build products for the most complex of systems, healthcare. This reflects how much change is needed to implement medical devices that are both safe for patients and technologically advanced.

Regulation is not a barrier, it exists for the protection of patients and the public; developers must understand the standards and guidance, gather technical and clinical evidence, write up and maintain all regulatory documentation as they build their product, and keep track of how it performs after release. If digital innovation is to truly transform healthcare, the first step has to be building a consensus that regulation should be seen as part of the culture, and not an obstacle.

The apparent tension between regulation and innovation ignores how the regulatory process can itself be a guide to developing medical devices, so that the best products get to market fast. From the intended use definition to understanding what post-market activities will be required to prove a device performs as intended, European and international standards clearly set out steps to deliver safe products to market.

Fulfilling both technical and clinical regulatory requirements should be the North Star for every developing team. The equation market access = clinical validation + regulatory approval will be even more important in a post-pandemic landscape.

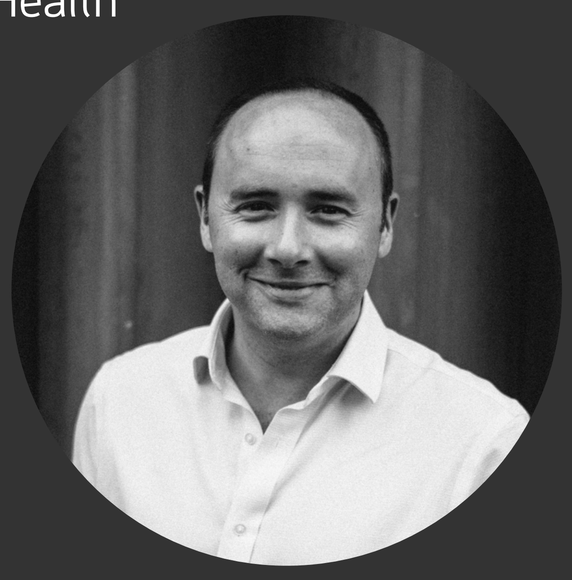
Whilst the validation roadmap for medical devices, including artificial intelligence-based software for medical applications, does not directly mirror that of drug development, the risk to patients of unintended consequences mandates gatekeeping for these devices. We should therefore treat algorithms and devices like drugs.

As digital innovation evolves, so too must knowledge of standards within the tech community and streamlining of processes by regulatory authorities. Researchers are not exempt from regulation and the academic community – which is increasingly spinning out companies – must understand these processes before a business model is developed.

It is still uncertain what the UK regulatory landscape will look like post-Brexit and whether leaving the EU will provide opportunities to improve understanding and adherence to the regulatory processes. Whilst there have been no official statements from the Government or MHRA (the UK regulatory body), rumours of a UK Certification (CE) mark process aligned with the EU Medical Device Regulation (MDR) have circulated.

For digital health products to be able to sell across borders without additional effort and time delays for validated technology, it would make sense to continue to accept the EU MDR in the UK to avoid impeding the dissemination of useful technology. That being said, the UK is in a good position to mandate testing of all products intending to be implemented here, to be tested on NHS datasets - especially for diagnostic algorithms. The creation of a UK database of CE marked and approved devices, quite like the FDA does for American data, would be a positive step.

Dr Stephanie Kuku,
Senior Consultant, Hardian Health



Dr Hugh Harvey
Managing Director, Hardian Health

"Researchers are not exempt from regulation and the academic community – which is increasingly spinning out companies – must understand these processes before a business model is developed."

9 - The future of post-Brexit regulation

Current regulations are evolving to produce globally standardised methodologies (MDSAP), ensuring developers do not have to apply for multiple regulatory stamps to implement their products in different countries.

There will be better transparency with the EUDAMED registry (the database developed to document MDR-approved devices), and the increased focus on safety and follow-up will keep the bad actors in the market at bay. Improvements are needed to ensure the regulatory requirements provide more clarity on the quality of data required for 'validation' and the way in which that data is reported.

The goal of any system, especially one where human lives are at risk, should remain aligned with the purpose of digital innovation. Regulation will be increasingly important as the gatekeeper to ensure the safety of patients and the public, and to ensure digital innovation puts humans first.

Data supporting innovation in drug discovery

The discovery and commercialisation of new therapies is a costly, lengthy, and highly regulated process. On average, a new drug takes approximately 10 years to get to market and costs USD ~one billion to develop. Despite significant R&D investment, the chances of success for a compound entering first in human trials has not changed significantly in the past decade, and is about 10 per cent. New approaches to drug discovery are needed to accelerate the discovery of novel therapeutics, if we are to effectively address the increased disease burden and increased costs of healthcare.

The availability of data is transforming the drug development process. Open-access, population level genotype-phenotype datasets, such as UKBiobank, have enabled technology-startups such as Genomics PLC to discover risk scores for 16 common diseases. These genomic tests are a pivotal step towards prevention. They combine information from large numbers of genetic variants to assess how people's genetic make-up affects their risk of developing diseases.

Data access is also transforming clinical trials, the most expensive stage of drug development. Patient data captured from electronic patient records has been used to run an alternative to a control group, for a classical clinical trial. Amgen's Blicyto is one example of a drug that obtained regulatory approval using synthetic control arms. Further, the COVID-19 pandemic has accelerated the use of remote monitoring solutions to run virtual clinical trials.

Despite these advances, significant challenges remain.

Firstly, in order to power AI algorithms, large, structured and normalized datasets; and clear data-access regulatory frameworks; are required. Access to such datasets continues to be challenging. The UK has established initial initiatives within this space, such as Local Health Care Record Exemplars and NHS Global Digital Exemplars, but ways for commercial entities to engage with these multiple boards – and the associated regulatory frameworks for commercial use – remain vague.

Secondly, standardised datasets mapped to the same dictionaries with similar structures are needed for use with AI algorithms. Currently, datasets within the NHS are not standardised. For instance, a patient "encounter" can be defined as an entire hospital admission in one NHS Trust, and time spent in one ward in another. Subtle differences like this mean that companies need to spend significant resources and time cleaning and curating data. There is a significant skills gap here and looking forward, I project that "data cleaners and curators" will be the most scarce resource, rather than the machine learning researchers.

Curated and linked data sets are pivotal to powering the industry that is charged with addressing our increasing healthcare burden. With data collection and data generation moving into the hands of the patient/consumer, it is likely we will soon have large connected data sets to power the next generation of life sciences companies.

These companies have the ability to transform the drug discovery process as we know it. It will be possible to use genetic data to create polygenic risk scores for high-risk diseases, create personalized lifestyle plans, and monitor outcomes using digital apps. This technological revolution will shift healthcare from focused on treating, to one that is focused on prevention. In a digital-first healthcare system, patients will be able to consent to clinical trials virtually, and patient data and complex analytical tools will be able to model clinical trials in silico, reducing the patients that need to enroll.

By applying machine learning to the aggregation of these complex data types (genetics, continuous data from wearables, etc.), it will be possible to redefine disease taxonomies, moving away from a century-old symptom-based International Classification of Disease (ICD-10) to an understanding of the mechanism of the disease, that will allow us to better predict patient outcomes and discover novel therapeutic interventions.

Dr Rabia Khan

Managing Director, Discovery Sciences Division, Sensyne Health

"Curated and linked data sets are pivotal to powering the industry that is charged with addressing our increasing healthcare burden."

II - The future of post-Brexit regulation

Attracting investment and protecting patients with smart regulation

The recent Independent Medicines and Medical Devices Safety Review, or Cumberlege Review, identified systemic failures in patient safety, emphasising the importance of strong regulation of medicines and medical devices to reduce the risk of avoidable harm.

It details the harrowing experiences of patients treated with three type of medicines and devices (i.e. Primodos, sodium valproate, and pelvic mesh devices). The lack of appropriate channels for reporting adverse incidents and zero post-manufacture surveillance on device safety experienced in these cases require a strengthening and rethink of how existing regulation is actually implemented.

Regulatory change in this area is already on the table due to Brexit. The Medicines and Medical Devices Bill 2019-20 is moving apace through Parliament, but in its current form will not provide the necessary prioritisation of safety. Changes to the Bill, including strengthening the role of the MHRA, are needed to provide much needed safeguards, as well as to ensure opportunities for scientific and regulatory innovation.

The UK needs to remain a desirable place to develop and market medicines and medical devices post-Brexit. The Medicines and Medical Devices Bill addresses this by requiring that any new regulations have regard for the "attractiveness" of the UK in relation to these activities. However, since no definition of "attractiveness" is provided in the Bill, there is a real and present danger that, in its current form, this may be detrimental to patient safety. Unamended, the application of this requirement is open to interpretation, leaving the question as to how this interacts with patient safety unanswered.

Although it is contained within the Bill, patient safety is not explicitly prioritised. Given the findings of the Cumberlege Review, a failure to make safety the primary concern would call into question the strength of commitment by the Government to building a fit-for-purpose regulatory regime for medicines and medical devices.

One of Review's recommendations is for the strengthening of the role of the MHRA. It recommends that it take on the role of a licensing authority for medical devices, akin to its role in medicines, and that it creates and controls a medical device registry. Whilst the current Bill includes powers to create a medical device registry, it would be controlled by NHS Digital (the Health and Social Care Information Centre in the Bill), not the MHRA. This risks making the regulatory landscape even more disparate, decentralised, and disconnected than it already is, as yet another body takes on a governance role.

The MHRA has a wealth of experience working with various European organisations, including the European Medicines Agency. Post-Brexit the Authority will take over much of the European Medicines Agency's remit in relation to pharmacovigilance. There is a strong argument to be made for greater central oversight over medical devices.

Brexit provides the potential to restructure devices regulation to enable tighter domestic oversight concentrating regulatory oversight and enforcement for both areas in the one agency. There is an opportunity for the role of the MHRA to be strengthened with regards to both medicines and devices in order to ensure patient safety.

The Medicines and Medical Devices Bill could facilitate this, as well as providing some much-needed regulatory clarity. However, it does not do so in its current form. The opportunity to remedy this should be taken as the Bill enters the next stages in its passage through Parliament.

Dr Laura Downey, Dr Rachael Dickson, Professor Muireann Quigley and Professor Jean McHale

University of Birmingham

"Changes to the Bill, including strengthening the role of the MHRA, are needed to provide much needed safeguards, as well as to ensure opportunities for scientific and regulatory innovation."

The future of clinical trials: how will the UK landscape thrive?

Cancer Research represents the best of science but also symbolises hope for those patients and families living with the disease. It is now greatly under threat.

Research was to be a key component of a productive post-Brexit Britain. In Boris Johnson's maiden speech as PM he spoke of the power of UK innovation, Matt Hancock's NHS Framework launch pledged to increase public and patient participation in research, and the Government said it will double spending on research and development by 2027. Despite being merely months ago, this pre COVID-19 financial package comes from another era.

This is compounded by the contraction of charitable giving. Cancer Research UK funds nearly 50 per cent of cancer research in the UK, committing over half a billion pounds in 2018/19. Now the charity predicts a £300 million drop in income.

How can cancer research best adapt to these events which follow workforce shortages and may precede a brain drain after Brexit? Can a community that works in discovery innovate itself through this crisis?

Hope for the future is no better exemplified than by the RECOVERY trial. This study has leveraged the linked networks of the NHS to deliver useful results faster than anywhere else in the world. Flexing the muscle of the large-scale collaborative networks provided by socialised medicine could allow the UK to remain influential in biomedical research beyond COVID-19, in a way that competitive institutions overseas cannot.

RECOVERY showed the importance of agility, going from a draft protocol to patient recruitment in a matter of days. Looking forward, COVID-19 could teach us to match this unprecedented speed through simplifying trial development.

As the world axis rebalances away from COVID-19, researchers will all seek to assert the priority of their own individual areas of work as they are forced to fight for funding. Some areas of study are likely to be relatively well protected; Big Pharma will always need to continue to develop and test new products and the appetite for genomically driven studies remains unsated.

Yet, it is those areas of cancer research that have always struggled to gain funding – psychological and emotional support, late side effects, end-of-life care and radiotherapy – that are likely to suffer. A second consequence of the funding fight is junior talent losing a platform, as these monies are more easily won by experienced researchers with pedigree.

A conventional response to a funding shortfall is to consolidate, often at the expense of equity. In 2011 56 per cent of research monies were spent in the 'Golden Triangle' of London, Cambridge and Oxford. COVID-19 has shown how digital collaboration and networking can be upscaled and with relatively low investment – digital tools should permit research to remain more nationally inclusive.

To deliver on the Government's ambition for Britain to be a "science superpower" it must invest in, and draw on, the capability of researchers across the country. Almost exactly a year on from the Prime Minister's first address, he has now given his Rooseveltian 'New Deal' speech, promising to "double down on levelling up". The government still claim to want Britain to be a "science superpower". The originally promised 2.4 per cent of GDP is now worth much less in cash terms than it was 6 months ago, but it may just be a lifeline for science now and for cancer patients in the future.

Dr Richard Simcock

Consultant Clinical Oncologist, Brighton and Susex University NHS Hospitals Trust

"Flexing the muscle of the large-scale collaborative networks provided by socialised medicine could allow the UK to remain influential in biomedical research beyond COVID-19, in a way that competitive institutions overseas cannot."

Conclusion

A path forward

The UK is seeking to establish itself as a world leader in the life sciences post-Brexit. The sector is vibrant employing about 249,000 people across almost 5,900 businesses and producing a turnover of £73.8 billion in 2018. The pandemic has further reinforced the strength of the UK's life sciences industry, from the successful RECOVERY trial – seeking to identify treatments that may be beneficial for adults hospitalised with confirmed COVID-19 – to the world-leading Oxford-AstraZeneca COVID-19 vaccine project. Maintaining this momentum will require a framework that streamlines regulation, supports innovation and protects patients.

The regulatory pathway from idea generation through to post-market surveillance will need to be improved with some reforms. At present, a medicine could be accelerated through one process only to be stalled by a separate follow-on access process – highlighting the need to improve and optimise the pathway . This can have both an impact on the accelerated development of drugs as well as devices.

The successful RECOVERY trial shows the benefits that streamlining the process can deliver. Joined-up NHS networks, cutting down the amount of data needed to be collected by health workers, and simplifying informed consent enabled the UK to deliver faster results than anywhere else in the world. In doing so, the team from the University of the Oxford reduced the burden on doctors and enabled cooperation even by the most overloaded hospitals.

Companies in cutting edge sectors such as medtech and biotech should be seen as a way for the UK retain a competitive advantage in a post-Brexit economy. Artificial Intelligence (AI) can be used to transform the way the pharmaceutical industry works and improve the quality of treatments available to patients. The UK is home to companies who have taken AI developed drugs to clinical trials. To capitalise on this, post-Brexit regulation must prioritise improving ways of securely accessing data.

The amount of rules and bodies overseeing data-driven technologies can be confusing for developers, as previous *Reform* research has shown. To remedy this, regulators will have to start thinking of ways to optimise the efficiency of the regulatory process. Getting regulation right will be key for the UK to become a global science superpower. NHSX has taken the lead on this and is working with regulators to establish a more joined-up approach to regulation with harmonised standards and patient safety at the centre.

The recent Cumberlege Review is a harrowing reminder of the need to have a strong regulatory infrastructure in place to protect patients, and this must be the central concern of any reforms after Brexit.

The optimisation of the regulatory process will also have to be coupled with a greater understanding and awareness on behalf of innovators that regulation is not a burden, but a necessary tool to uphold patient safety and quality standards . As argued by Dr Kuku and Dr Harvey, innovators should view regulation as a "guide" to product development.

The UK has a unique opportunity in time to strengthen its reputation as a leader in the life sciences by building a smart regulatory environment that puts patient protection at the centre, whilst supporting innovation.

Matt Fetzer

Researcher, *Reform*

"Companies in cutting edge sectors such as medtech and biotech should be seen as a way for the UK retain a competitive advantage in a post-Brexit economy."

Key developments in medicines and medical device regulation as the UK prepares to leave the EU

Key **MHRA:** Medicines and Healthcare products Regulatory Agency

Source: *Reform* Think Tank.

Note: The 'Cumberlege Report' refers to the 'First Do No Harm' report published as part of the Independent Medicines and Medical Devices Safety Review, chaired by Baroness Julia Cumberlege.

Pathways for post-Brexit regulation

Delivering an agile regulatory pathway for medicines & medical devices post-Brexit

	Regulation of clinical trials & medical research	Licensing of medicines	Regulation of medical devices	Post-market surveillance of medicines & devices
MHRA Post-Transition Guidance from 1 January 2021 Covers 'standstill' provisions until end of 2023 for medicines; provisions for medical devices until 20 June 2023; provisions for application of the Northern Ireland Protocol (NIP) for medicines.	▸ Clinical trials remain a national competence for the UK, MHRA and HRA will continue to review and assess clinical trial applications for the whole of the UK (GB & NI). ▸ The sponsor or legal representative for a clinical trial can be in the UK or in the EU/EEA. ▸ A UK MIA will be required to import investigational medicinal products (IMPs) from EU to GB.	▸ MHRA guidance takes into account the different approaches that will be needed for licensing of medicines in Great Britain (GB), compared to Northern Ireland (NI) which will continue to follow the EU requirements as required by the implementation of the Northern Ireland Protocol (NIP).	▸ All medicals devices and in vitro diagnostics placed on the UK market will need to be registered with the MHRA ▸ CE marking will continue to be recognised for the GB market until 30 June 2023. From 1 July 2023, a UK Conformity Assessment (CA) will need to be completed - this UK CA assessment will be available from 1 January 2021 on a voluntary basis.	**MHRA remains responsible for safety surveillance of medicines and devices in the UK (GB & NI).** ▸ Adverse events will need to be reported directly to MHRA and also to EudraVigilance for events occurring in NI. ▸ The Qualified Person for Pharmacovigilance (QPPV) can be based in the UK or EU/EEA, but a UK contact person is required.
Future UK Regulatory Framework Innovative regulatory approaches are being explored to develop approaches to reduce the time to patient access for new medicines and technologies. Continued cooperation between the UK and EU on regulation is dependent on the outcome of Brexit negotiations.	▸ UK will not implement the CTR, but will consult on the development of agile ways of working and collaboration to support the research infrastructure in the UK.	**MHRA becomes the sovereign regulator for human medicines in the UK market.** ▸ Introduction of an innovative regulatory pathway, including rolling reviews, conditional authorisation and accelerated assessment.	**MHRA remains responsible for UK medical devices market.** ▸ UK will not implement the MDR and IVDR and MHRA will consult stakeholders on proposals for strengthened regulations for medical devices and in-vitro diagnostics in the coming months.	**MHRA remains responsible for surveillance of devices & pharmacovigilance in the UK.** ▸ UK sets up its own unified national registry for post-licensing surveillance. ▸ The MHRA retains responsibility for pharmacovigilance across the UK. Specific requirements for products placed on the market in the UK with respect to GB and NI.

Factors that will influence the process

- UK Government will consider international standards and global harmonization will be in the development the future system.
- UK Medicines & Medical Devices Bill 2019-21 provides the structure to change/update the current regulatory framework.
- Independent Medicines & Medical Devices Safety Review puts strengthened focus on patient safety in the regulation.
- Northern Ireland Protocol might impact the approach to regulation to medicines & medical devices.

Key

EEA: European Economic Area
EMA: European Medicines Agency
EUDRAVIGILANCE: European data processing network for reporting suspected adverse reactions to medicines.
CESP: Common European Submission Portal
CTR: Clinical Trials Regulation
HRA: Health Research Authority
IVDR: In vitro diagnostic Devices Regulation
MIA: Manufacturing Import authorisation
MDR: Medical Devices Regulation
MHRA: Medicines and Healthcare products Regulatory Agency
MRAs: Mutual Recognition agreements

Source: *Reform* Think Tank, September 2020

Note: Elements of the new proposed regulatory model outlined in this document are subject to the outcome of Brexit negotiations and parliamentary approval of the Medicines & Medical Devices Bill 2019-21 .

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