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Commentary

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Advancing UK regulatory science and innovation in healthcare

Melanie J Calvert[1,2,3,4,5], Eliot Marston[4], Mark Samuels[6], Samantha Cruz Rivera[1,2], Barbara Torlinska[1,2], Kathy Oliver[7], Alastair K Denniston[1,4,5,8,9] and Steve Hoare[10]

[1]Centre for Patient Reported Outcomes Research, Institute of Applied Health Research, University of Birmingham, Birmingham B15 2TT, UK
[2]National Institute for Health Research (NIHR) Applied Research Centre West Midlands, Birmingham B15 2TT, UK
[3]NIHR Birmingham Biomedical Research Centre, NIHR Surgical Reconstruction and Microbiology Research Centre, University of Birmingham, Birmingham B15 2TT, UK
[4]Birmingham Health Partners Centre for Regulatory Science and Innovation, University of Birmingham, Birmingham B15 2TT, UK
[5]Health Data Research UK, London NW1 2BE, UK
[6]Lifesci Ltd, London WC2H 9JQ, UK
[7]International Brain Tumour Alliance (IBTA), Tadworth KT20 5WQ, UK
[8]University Hospitals Birmingham NHSFT, Birmingham B15 2GW, UK
[9]Regulatory Horizons Council London SW1H 0ET, UK
[10]The Association of the British Pharmaceutical Industry, London SW1E 6QT, UK
Corresponding author: Melanie J Calvert. Email: m.calvert@bham.ac.uk

As the UK exits the European Union, there is a pressing need for the UK to invest in regulatory science and innovation if it is to be globally competitive and internationally collaborative. Innovation in life sciences, including digital tools, robotics, artificial intelligence and new therapeutic approaches, such as cell and gene therapy, will play a crucial role in continued improvement in health outcomes and life expectancy. The UK is powerfully positioned to lead in the discovery, development and evaluation of these new approaches, enabling accelerated routes to market, increasing benefits to public and individual health, improving patient safety, influencing international practice and promoting investment in the UK.[1,2]

Advances in regulatory science, or 'the application of the biological, medical and sociological sciences to enhance the development and regulation of medicines and devices in order to meet the appropriate standards of quality, safety and efficacy',[3] matter more than ever to inform and evaluate new approaches to regulating these innovative technologies. In this commentary piece, we argue that the UK has a unique opportunity to advance regulatory science and innovation and drive global advances in this area and make a series of recommendations to this end based on key findings from Birmingham Health Partners Advancing Regulatory Science and Innovation in Healthcare Report (Box 1).[4,5] The UK should take a coordinated approach to foster and prioritise advances in regulatory science and innovation and build a workforce to ensure its sustainability and continuing evolution. We should actively support the emergence of both existing and new clusters in regulatory science. Support for these clusters should draw on world-leading academic expertise, leverage increasingly integrated regional ecosystems, connecting industry, policy and the NHS and – crucially – the voices of our patients and citizens (Box 2).

Current context for regulatory science

Life sciences are vital to the UK's health but also its economic wealth. The industry supports around 482,000 jobs in the country and the activities of life sciences companies directly contributed £14.5bn to the national economy in 2015, with an additional £15.9bn provided through the life sciences supply chain and employee spending.[6] UK life sciences businesses face unprecedented challenges in both near-term viability and long-term sector sustainability due to regulatory uncertainty following Brexit and the global COVID-19 pandemic.

As a European Union member, the UK Medicines and Healthcare Products Regulatory Agency was integrated in the European Union Medicines Regulatory Network, including the European Medicines Agency. Now that the UK has left the European Union, the Medicines and Healthcare

Box 1. Recommendations.[a]

Strategic leadership and coordinated support
• A specific national healthcare/life sciences strategic advisory committee should be established to provide dynamic oversight to complement the UK's new Regulatory Horizon Council, enabling multidisciplinary and cross-sector input to advance UK healthcare regulation and promote innovation informed by regulatory science. Dynamic oversight should be provided in accordance with principles specified by the Wellcome Trust blueprint (inclusive, anticipatory, innovative and proportionate).
• The Medicines and Healthcare Products Regulatory Agency should work with stakeholders – including the devolved administrations in Scotland, Wales and Northern Ireland – to develop a UK strategy for regulatory science to create a roadmap for national efforts, to maximise the speed of UK medicines regulation and health technology evaluation.
• Major UK funding bodies – including UK Research and Innovation, the National Institute for Health Research and members of the Association of Medical Research Charities – should identify potential funding mechanisms for regulatory science which could deliver major benefits aligned to their respective remits and communities.
Enabling innovation
• Given challenging timelines around the Brexit transition period, multi-stakeholder work is needed to understand and prioritise specific technological or methodological areas in which the UK's capability for regulatory innovation could enable a global leadership position, delivering major economic and healthcare benefits. The UK should maintain high levels of regulatory compatibility and fully understand the threats and opportunities posed by any divergence.
• Emerging technologies should be identified through horizon scanning and where uncertainties arise about how to regulate certain emerging technologies; we need joint working processes enabling regulatory bodies and industry to flag where evidence and innovation are required in regulatory science to justify research and development investments.
• Innovation in regulatory science is needed to underpin an R&D environment that mitigates 'high-risk' areas of investment with significant promise – for example, antimicrobial resistance or new medications for pregnancy-related conditions.
• Specific consideration should be given to supporting regulatory science aligned to the Accelerated Access Collaborative, establishing how the uptake of innovation within the National Health Service can be better enabled, and how local good practice can help drive wider national behaviours.
Implementation and evaluation
• We need to establish coordinated national and international approaches for promotion of new guidance, including development of implementation tools and resources and training and establishing how regulators, industry bodies, funders, healthcare providers and other agencies can act in concert to accelerate implementation.
• An evaluation framework with agreed metrics should be developed to assess the impact of regulatory innovation and implementation.
• International stakeholders must work collaboratively to understand the benefits and challenges of changes in regulation, such as those arising from COVID-19, and how this could be applied to other settings.
Workforce development
• A scoping exercise should be undertaken to more fully understand specific training needs across various stakeholder groups to support regulatory science innovation and improve uptake/use of innovative technologies and medicines.
• The UK should seek to establish clear career pathways in regulatory science, via internships, fellowships or PhDs involving academia, industry, National Health Service, patient partners and regulatory bodies as key collaborators, mentors and beneficiaries.

[a]Recommendations taken from Birmingham Health Partners Advancing Regulatory Science and Innovation in Healthcare Report, 2020, based on a scoping review and stakeholder input.[4]
MHRA: Medicines and Healthcare Products Regulatory Agency; R&D, research and development.

Products Regulatory Agency will 'continue to support the UK Government to deliver its legal obligations under the Withdrawal Agreement and prepare for its new relationships with the European Union and the rest of the world'. To do this, they continue to work closely with the Department of Health and Social Care to ensure the UK regulatory environment works in the best interests of patients, industry and

Box 2. The need for meaningful and sustained patient and citizen involvement.

Patients and society are beneficiaries of scientific discoveries, new technologies and improved medications; but they also can and should be able to contribute to these discoveries through participation in clinical studies and in the co-design of research. Patients, as well as our wider, diverse communities, can provide unique insights into which specific healthcare problems and priorities these discoveries, technologies and medications should be targeted; what kind of evidence validates their effectiveness; and what 'value' truly means in terms of our health and treatment outcomes. Trust and transparency are more critical than ever. Patients want better treatments as quickly as possible, but not at the cost of safety, privacy or awareness of risk. Laws, regulations and standards play a vital role in enshrining patients' and citizens' requirements and innovators' responsibilities. Where these are adapting – which we recognise they must, to respond to the scale and pace of opportunity in healthcare – it is essential that patients and citizens have a voice and are accepted as true partners in these endeavours. Patients and citizens can provide the lived experience and deeply meaningful insights into all aspects of healthcare and in regulatory science initiatives. 'We need to develop a more sophisticated model of engagement where ethical and moral issues arise and ensure that issues such as risk and uncertainty are discussed appropriately. We need to build trust and enable consumers to have confidence in innovations and businesses to have confidence in our stable and proportionate regulatory system.'[1]

our partners across the health and care system.'[4,7] The Medicines and Healthcare Products Regulatory Agency Business Plan 2020–2021 highlights key strategic areas for change 'in response to the need to develop a new and effective regulatory model, but this also reflects a new focus on involving and engaging with patients, enabling patient access to new innovative medicines and devices, and speedier response to risks to patient safety and public health.'[7] A key strategic objective is to improve regulatory science. Post-transition, we should use the European Union–UK negotiations to maintain their current high level of regulatory compatibility, while contributing to advancing global regulations. How should the UK do this? First, it must take account of clear clinical and academic strengths to inform regulatory innovation. Second, it must factor in the opportunity for UK industry to invest in innovation and create a national testbed to drive global progress.

The life sciences industry has already invested significant effort and funds to prepare for new European Union frameworks, and incompatibility from the UK brings risks around complexity, competence and capacity. Our UK trade associations – providing insight and ongoing engagement – have given us a robust framework that we should harness to mitigate these risks. The Government's White Paper on 'Regulation for the Fourth Industrial Revolution' noted that:

> We need to reshape our regulatory approach so that it supports and stimulates innovation that benefits citizens and the economy. At present, only 29% of businesses believe that the government's approach to regulation facilitates innovative products and services being efficiently brought to market. The need for reform is urgent: 92% of businesses from a range of sectors think they will feel a negative impact if regulators don't evolve to keep pace with disruptive change in the next two to three years.[1]

COVID-19 has severely impacted life sciences research and development, while also demonstrating the impact of a more collaborative effort and regulatory flexibility. The sector is looking at resilient recovery while recognising the continued risk of disruption. During this recovery phase, pharmaceutical and medical technology companies have asked for continued, (national *and* international) regulatory flexibility. They have used flexibility as they accelerate product development in medicines, devices and vaccines, and move to re-initiate trials, mitigate missing data and implement new models of working (including telehealth and remote monitoring). The unprecedented events of the pandemic have offered a paradigm shift in healthcare regulation.[8,9]

Strategic leadership and coordinated support

The UK Government's White Paper, Regulation for the Fourth Industrial Revolution, notes:

> As we leave the European Union and forge a new path for ourselves, we will continue to play an important role in shaping how regulation is developed internationally. We will collaborate with like-minded international partners to reduce regulatory barriers to trade, through mechanisms such as the adoption of international standards, mutual recognition agreements and free trade agreements. We will encourage our regulators to play an active role in shaping international thinking on how innovation should be regulated.[1]

For the UK to maximise opportunities in the future regulation of healthcare innovation, it must work cohesively and collaboratively while creating an environment that gives innovators faster ways to demonstrate benefit. The UK must leverage the high profile and excellent stakeholder engagement processes of the leading players. These organisations include: the NHS, patient organisations, National Voices, academia, the Medicines and Healthcare products Regulatory Agency, the NICE and Health Research Authority, as well as the Association of the British Pharmaceutical Industry, Association of British HealthTech Industries, Accelerated Access Collaborative, the British In Vitro Diagnostic Association and Health Data Research Alliance, coordinated by Health Data Research UK, which aims to establish best practice around the ethical use of UK health data for research and innovation at scale.[10] Expert regulatory science should support them.

To gain these crucial inputs, we will need collaboration across multiple stakeholders and strategic leadership. Meaningful patient and citizen involvement should be central to all activities (Box 2). Additionally, we require alignment with the new Regulatory Horizons Council.[11] This independent expert committee identifies the implications of technological innovation; it provides the government with impartial, expert advice on the regulatory reform required to support the rapid and safe introduction of new technologies.

The growth of the Academic Health Science Networks has complemented the emergence of significant academic–NHS partnerships.[12] Additionally, Life Science Opportunity Zones support major industry-facing centres of gravity. Together, these areas have become ready-made research 'clusters' for innovation – and an ideal springboard for regulatory science to flourish in the UK.[13] Through increased ease of collaboration, clusters foster shared knowledge and talent pools, support collaborative cross-sector innovation and generate synergistic value. They provide essential accelerators and testbeds to inform broader systems thinking.

An ongoing commitment to international collaboration will also be key. It would be highly damaging for the UK to attempt to operate fully in isolation of other regulatory systems and international excellence in approaches to supporting emerging technologies and regulatory science.[2] Indeed, we can and should learn from global regulatory science initiatives such as the research programmes and centres of excellence supported by the Food and Drug Administration (FDA) in the US and the Clinical Trials Transformation Initiative.[5,14]

Prioritisation and shared risk

Regulatory science – where appropriately targeted – offers a way to provide clarity and collaboration between stakeholders. There are several emerging technologies and trends in regulation which need collective visions on how best to move forward, as highlighted by recent Regulatory Science Summits organised by the Innovative Medicines Initiative in collaboration with the European Medicines Agency and FDA and the European Medicines Agency's Regulatory Science to 2025 strategy.[15,16] These technologies include: advanced therapy medicinal products, artificial intelligence, digital tools for data collection and analysis, digital therapeutics, immunology and the microbiome, big data and digital health, as well as real-world evidence and clinical trials.

International horizon scanning should proactively identify emerging healthcare technologies. Where uncertainties arise about appropriate regulation, we need joint working processes that enable regulatory bodies and industry to flag where evidence and innovation are required in regulatory science to justify research and development investments. Interaction with patient organisations and enhancing methods to incorporate patient-relevant evidence in benefit-risk evaluation and regulatory decision making is key. Tools include patient-reported outcomes and patient preference data.[15] Products, services and business models with high potential benefit for UK society and the economy should be prioritised. Innovation in regulatory science is vital to underpin a research and development environment that mitigates 'high-risk' areas of investment with significant promise, such as antimicrobial resistance or new medications for pregnancy-related conditions, to facilitate the rapid and safe introduction of these products and services.[17] Early engagement of innovative developers with multi-stakeholder scientific advice (for example, joint meetings offered by the Medicines and Healthcare Products Regulatory Agency Innovations Office and NICE), offers benefits to all; facilitating navigation of the regulatory landscape and identifying challenging areas for regulators to address.[18]

Implementation and evaluation of regulatory innovation

New tools and methodologies will be needed to properly evaluate the impacts of regulatory change and support continuous iteration – the building blocks for these have already been established nationally and internationally. In 2012, the Organisation for Economic Co-operation and Development (OECD) published a framework for systematically

evaluating the performance of regulations and regulatory policies.[19] Measuring regulatory progress in a meaningful and credible way requires indicators to measure relevant outcomes and appropriate research designs. Both are needed to support inferences about the extent to which a regulation or regulatory policy under evaluation has actually caused a change in the measured outcomes. Indicators may include: (1) impact/effectiveness (changes in the problem or other outcomes of concern such as patient safety, mortality); (2) cost-effectiveness (costs for a given level of impact); (3) net benefits (all beneficial impacts minus all cost impacts); and (4) equity/distributional fairness of impacts. In addition to equity or distributional concerns, sometimes other outcomes of interest are used as criteria, such as impacts on technological innovation, macroeconomic growth, and employment. Building on the Organisation for Economic Co-operation and Development framework, the European Medicines Agency has developed a conceptual framework for the review of the impact of regulatory science projects on its regulatory processes and activities – with implications for resources and further iterative improvements (Box 3).[19]

We believe that we need 'parallel not series' evaluation, regulation and implementation processes, underpinned by training. Additionally, we require development platforms that: bring together innovators, regulators and end-users to map out innovation journeys; create consensus for the use of novel technologies; devolved flexibility to enable real-world testing of regulatory adaptation before scaling nationally.

Workforce development

Developing a coherent UK programme of training in regulatory science will be crucial to delivering workforces for industry, the NHS, policy and academia and to support patients and the public involved in regulatory science initiatives. This is an urgent priority to bridge the potential expertise gap resulting from leaving the European Medicines Regulatory Network and to advance regulatory science in the UK. It will provide a sustainable skills pool to ensure that technological innovation in healthcare can be supported successfully – and the corresponding health and economic benefits are realised – while robustly protecting patients. However, we also need to understand what each of these diverse stakeholders in regulatory science need – and what they can offer – so that we can assemble a clear national framework and strategy. Current UK-based training is somewhat limited, comprising master's level training/apprenticeships and continuing professional development, emerging technologies will require a higher level of capability.[20] To keep pace with innovation and international counterparts, the programme needs to be expanded via internships, fellowships and PhDs involving academia, industry, professional bodies, National Health Service and regulatory bodies as key collaborators, mentors and beneficiaries. The UK should seek to establish clear career pathways in regulatory science.

The UK can learn from, and engage with, international initiatives. In the US, the FDA offers a programme of internships and fellowships via its Oak Ridge Institute for Science and Education partnership.[21] The programme allows the FDA to target and accelerate key areas of regulatory science which will support its future activities with successful Fellows often going to work for the regulator and in turn mentoring future Fellows. In the European Union, the European Medicines Agency is currently designing two curricula through the Strengthening Training of Academia in Regulatory Science 'STARS' initiative to support both the professional

Box 3. European Medicines Agency conceptual framework for the review of the impact of regulatory science projects on regulatory processes and activities.

Key considerations include:
(i) When are results of regulatory science projects matured enough to form a basis to implement changes in regulatory or clinical practice?
(ii) Depending on the types of outcomes, to what extent should results/recommendations from regulatory science projects be validated, scrutinised and peer reviewed in the scientific community before their implementation?
(iii) Should there be a trade-off between timing of implementation and scientific replication/validation?
(iv) Which outcomes should be prioritised for implementation? Regulatory science projects delivering both the highest impact and efficient use of resources should be prioritised.

training of clinical scientists and a broader programme to support a shared post graduate educational agenda,[22] while the global association for people working in Regulatory Affairs (TOPRA) offer significant training opportunities for professionals.[23] It will be crucial to leverage their expertise, insights and professional standing to create an appropriately competitive and ambitious, forward-looking training programme for the UK.

> Underpinning the advancement of the sector is also a need for people with regulatory skills, across industry, the health service and academia as well as regulators, not only to do the core work of medicines development, regulation and delivery to patients but to be resourced to develop standards for emerging technologies and methodologies.[2]

Conclusion

The UK's current situation brings significant complexities, challenges and risks. However, our uniquely collaborative and dynamic national ecosystem for regulatory science is more than capable of rising to tackle them and ensuring this is the time of unique opportunity and benefit.

Why do these proposals matter? We have recommended actions that – crucially – can put the UK in a leadership position for regulation. This position will attract the most exciting ideas and strategic resources from the global industry. It will further accelerate the co-creation and adoption of innovation by the NHS. Critically for regulators, it will create all-important academic insights into the tools, technologies and methodologies they need. And most importantly, it will give our patients and the public an integral voice in the design, development and delivery of innovative new treatments, diagnostics and medical devices. This is an opportunity to develop our regulatory science strategy for the UK to benefit the world.

Declarations

Competing interests: KO states that she has no real or perceived conflicts of interests with regard to her co-authorship of this paper but for the sake of transparency she states the following: Between 2005 and 2020, the IBTA has received unrestricted educational grants and financial support and/or support in kind either as an individual organisation or as part of a wider grouping of patient organisations, from the following companies and trusts: AbbVie, Accuray, Antisense Pharma, Apogenix, Archimedes, Ark Therapeutics, Astra Zeneca, Bayer, Boehringer Ingelheim, Brain Tumor Network (USA), Brain Tumor Resource and Information Network (USA), Bristol-Myers Squibb (BMS) Celldex Therapeutics, Celgene, Crusade, Dijon Designs (UK), Elekta, Eli Lilly, Gerry & Nancy Pencer Brain Trust (Canada), Gosling Foundation (UK), GlaxoSmithKline (GSK), GW Pharmaceuticals, Incyte, Ivy Foundation (USA), Lilly, Link Pharmaceuticals, MagForce, Medac, Merck Serono, Merck, MGI Pharma, MSD Oncology, NeoPharm, Neuroendoscopy (Australia), Northwest Biotherapeutics, Novartis, Novocure, Pediatric Brain Tumor Foundation (USA), Pfizer, Photonamic, Roche, Schering-Plough (Global), Sontag Foundation (USA), Spink (UK), STOPheresetumoren.nl, to-BBB, Vane Percy (UK), VBL Therapeutics and the Wallerstein Foundation (USA). KO, on behalf of Kathy Oliver Consulting, has also in this same period received consultancy fees from Lilly, GSK, Bayer, SPAEN and Novartis. For further details of the IBTA's sponsorship policy, please see https://theibta.org/become-a-corporate-sponsor/. MC has received personal fees from Astellas, Takeda, Merck, Daiichi Sankyo, Glaukos, GSK and the Patient-Centered Outcomes Research Institute (PCORI) outside the submitted work.

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ORCID iD: Melanie J Calvert https://orcid.org/0000-0002-1856-837X

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