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**MIDLANDS
ENGINE**

Creating a UK Centre of Excellence for Regulatory Science & Innovation

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The role of regulatory science in the UK's future health and wealth



Why is the Regulatory Science agenda critical to the UK?



*“To maximise the economic benefits of the UK Government’s significant investments in research and development (R&D) and build a more innovative and productive economy, **the UK needs a regulatory system that is pro-innovation.** Currently only 29% of businesses believe that the government’s approach to regulation supports them in bringing new products and services to market.”*



*“We need to do more to ensure our world-leading strengths in research are complemented by strengths in development... This means ensuring that the UK has **a world-leading research and innovation system with** the infrastructure, skills and **regulation** which can support the development, demonstration and deployment of new technologies and solutions towards commercial success or practical application.”*



*“While the UK has world-leading strengths across our regulatory frameworks, we must continuously improve the regime to facilitate the increasing pace of innovation and change... We will use the opportunity of EU Exit to **create the world’s most agile regulatory system**, focussed on continual adaptation to new products and technologies.”*

What has Government proposed?



Independent expert committee that identifies the implications of technological innovation, and provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction.



"...a UK Regulatory Innovation Hub... would advance regulatory science to speed innovation, improve data informing regulatory decision-making, and accelerate public/patient access to novel healthcare technologies. It would aim to improve safety, helping businesses and accelerate trade, while protecting and promoting the health and wealth of our nation and the global community."

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Why is healthcare a critical pathfinder for Regulatory Science?

- **Health & life sciences sector**
 - **256,100 skilled workforce across 6300 companies**
 - turnover of £80.7bn; exports >£30billion.
- **MHRA vital to UK COVID-19 response and global leadership:** undergoing ~25% budget/staffing cut.
- **>75% UK med tech businesses unprepared for future regulatory change; foreign companies sceptical of additional UK regulatory burden**
 - potential loss to the NHS >20% of current technologies for patient care within next 5 years.
- **Global/UK pharma ~20% of all UK R&D investment:** openly stated need to move R&D investment overseas if UK fails to remain a globally-relevant regulator and site for innovation.
- Anti-vaccine movement and Cumberlege review 'First Do No Harm' highlight urgent need to **promote public and patient trust in healthcare regulation.**

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How has Birmingham
responded?



BHP Centre for Regulatory Science & Innovation



The Centre's activity is broadly grouped into three pillars: **policy** development; **research** and innovation; and capacity building and **education**. In line with these pillars, CRSI will:

- Generate evidence to support advances in regulation
- Convene national and international debate between key stakeholders
- Provide training and support in regulatory science
- Develop international consensus-based guidance for healthcare in cutting edge disciplines.

-  Patient-centred drug development
-  AI in healthcare
-  Accelerated access to medicines
-  Real-world data collection
-  Innovative trial design
-  Medical technologies

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<https://www.birminghamhealthpartners.co.uk/programmes/bhp-centre-for-regulatory-science-innovation/>


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Recommendations

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 MHRA 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.

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.

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 is 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 NHS can be better enabled, and how local good practice can help drive wider national behaviours.

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, NHS, patient partners and regulatory bodies as key collaborators, mentors and beneficiaries

CRSI in action: delivering regulatory science innovation through world-leading international guideline development

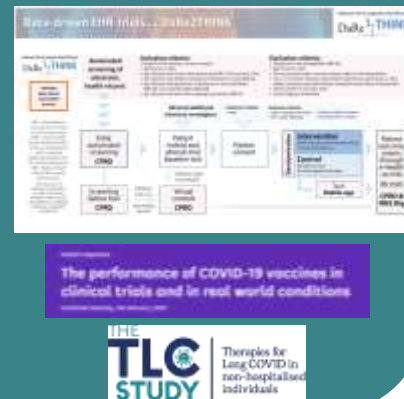
AI in healthcare



Patient-centred drug and device development



Innovative trial designs



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BHP CRSI in action: responsive and proactive models

Informing new
UK medical
device
regulations



Safe and effective
medicines in
pregnancy as UK
priority and USP



Establishing new
UK regulatory and
standards
frameworks for AI



NICE
National Institute for
Health and Care Excellence

Developing ethical
frameworks for AI
datasets to ensure
representation to
tackle, rather than
worsen, healthcare
inequalities



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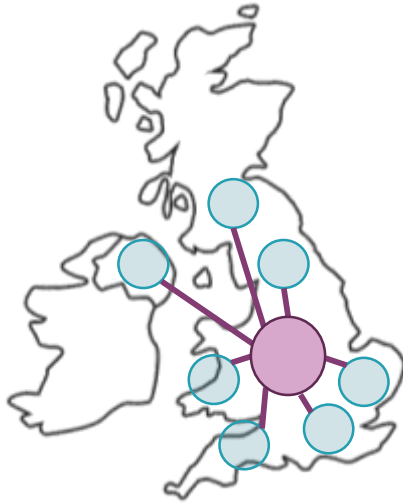

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What would a UK Centre of Excellence
in Regulatory Science & Innovation
mean for the UK, and for the
Midlands?



A UK Centre of Excellence for Regulatory Science & Innovation



FDA-like UK 'Hub and Spoke' model for regulatory science and innovation

Focus on key growth markets in which the UK seeks to retain and further develop a competitive edge; levelling up nationally via coordinated leadership.



Centers of Excellence in Regulatory Science
and Innovation (CERSIs)

Concept supported by:



A UK Centre of Excellence for Regulatory Science & Innovation

“Driving innovation in regulatory science to promote efficient, safe and cost-effective implementation of new therapies, to benefit patients, society and the UK economy.”

Three integrated programmes at a national level:

- **Informing regulatory innovation**
Multi-disciplinary, multi-sector research incl. gap analysis, consensus development, evaluation and implementation tools
- **Enabling business compliance and competitiveness**
Integrated national regulatory support service; funding for SMEs to accelerate growth
- **Targeted training and capacity building**
Ensuring UK resilience, creating new services and embedding knowledge in businesses, nurturing cross-sector mobility and leadership

Concept supported by:



A distinctive Midlands opportunity for Levelling Up

HEALTH

Accelerated access to novel health tech and therapies, helping tackle major health inequalities in diverse communities by piloting representative development of emerging tech e.g. AI.

WEALTH ££

UK 'RegTech' centre of gravity to **relocate and cluster multi-sector businesses as well as public sector jobs** to participate in innovation and benefit from early deployment.

LEADERSHIP

Midlands leading national and global collaborations with industry, scientists, regulators and patients to co-create and implement new global standards, tools and regulations in health and beyond (e.g. Net Zero, AI deployment).

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What do we need?

1. Support making an effective case for UK investment
2. Support making an effective case that the Midlands should lead this UK initiative
3. Help to ensure that UK CERSI's operating model delivers greatest benefit to our businesses, our communities and our regional profile as a global engine for growth

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Many thanks – look forward to discussions!

