The UK Life Sciences Ecosystem

Update of a 2020 Review by the JPG

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The voice of Japanese Life Sciences in the UK

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Overview – about this project

In 2020 the JPG conducted a comprehensive review of the **UK Life Sciences ecosystem from the perspective of the Japanese industry.**

In 2023 we have undertaken an exercise to explore **any changes in perception** over the last three years

We are keen to explore ways in which we can work with other system players to leverage UK strengths to attract inward investment and **increase awareness of the UK offer in Japan**.

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Key findings since 2020

In basic research, **the UK has retained its position in the premier league of R&D countries**: leading academics, great science, supportive funding institutions, a rich biotech ecosystem and willingness to collaborate.

The UK's position on late-stage trials has declined since Covid. Recruitment to late-stage trials is decreasing but there are green shoots due to action taken by MHRA to tackle delays and O'Shaughnessy review and implementation.

The UK should continue to leverage its world-leading data. The NHS has taken constructive steps that address the need for greater diversity in UK datasets since our last review.

The digital health landscape in the UK is dynamic and evolving. **The combination of innovative start-ups, supportive policies, and robust research and development initiatives places the UK at the forefront of digital health globally.**

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What actions could improve competitiveness?

The system must keep its foot on the accelerator across the value chain as other countries are continually investing and improving. Rejoining Horizon is an important step forward since the 2020 review.

With MHRA as a sovereign regulator there is an opportunity for the UK to distinguish itself. But it is now EU4 plus UK and the UK needs to hold its own or better EU counterparts. Government needs to ensure MHRA is adequately resourced for this dual challenge.

The implementation plan of the O'Shaughnessy Review of Clinical Research should **prioritise actions that contribute to increasing speed of patient recruitment to trials.**

The system should seek to improve co-ordination and consensus across regulators (MHRA, NICE, NHSE) on acceptance of new types of data. From genomics through to RWE, PROs and research on health inequalities. The NHS dataset can be turned into a competitive advantage as payers' interest in RWE grows.

UK could adopt a leadership position as an enabler of international research. Better linkage between primary and secondary care NHS datasets should continue to be prioritised**.** The system should aspire to greater integration of genomics datasets with the NHS.

Any future new administration should be pragmatic, focus on implementation of existing Life Sciences Policy rather than attempt to reinvent it. An increase in R&D investment to 3% of GDP would place the UK in the top 5 of countries.

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JPG Priorities for the O'Shaughnessy review of trials

Increase MHRA resourcing

Measures for UK performance in trials will enable companies to have objective discussions at global HQs about inclusion of UK in trials. Critical KPIs

- Time to CTA from submission needs to be achieved in less than 60 days
- Recruitment rates – patients/site/month for specific patient populations
- Time for amendment review
- Time to first patient enrolled

Mandatory centralised process for approval and costing and contracting by 2025 by expanding the National Contract Value Review process

Better use of UK datasets to connect patients to clinical trials

Action to address NHS resource challenges

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Decline in UK late-stage trials post Covid

Key strengths	• Government commitment to reversing performance decline • A leading country for rare disease trials
Risks/gaps	• **MHRA performance and resourcing** post COVID has caused delays, trials moving to other countries and confidence diminishing in UK • **Being outside Europe & requirement for separate UK submissions** • Approval timelines extremely poor- **many bottlenecks that don't exist in other countries** • **Lack of resource** in NHS
Remedial actions	• **Implementation of the recommendations of the O'Shaughnessy Independent Review** • The system must continue to apply measures to help improve speed of enrolment **including increasing NHS resource** • **Turn the NHS dataset into a competitive opportunity** as payers interest in RWE grows
Key competitor countries	• **China, EU under CTR, South Africa, Thailand, Italy, Spain, Eastern Europe, US, Japan** mentioned as being more favourable locations

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UK an emerging global leader in digital

Strengths

- The digital health sector has had substantial investment and funding to foster innovation
- UK is home to numerous healthtech startups and companies that develop innovative solutions, from AI-driven diagnostic tools to wearable technologies and apps for mental health to chronic condition management
- Several UK academic and research institutions involved in cutting-edge R&D projects, focusing on developing new technologies, methodologies, and interventions to address healthcare challenges
- AI and data analytics being employed in predictive analytics, drug discovery, personalized medicine, and improved service delivery. The Alan Turing Institute and Data-Driven Health and Social Care are prominent entities facilitating R&D in this area
- mHealth applications are prolific, focus on a variety of health and wellness aspects
- Significant growth in telehealth post Pandemic
  - HDRUK has been added to the ecosystem, strengthening multimodal data use and safeguarding personal information
  - NICE & MHRA governance of safety, quality, efficacy

Risks/gaps

- **NHS digital offerings not standardised across the system**
- Brexit impact on CE mark in medical devices. New regulator for UKCE marking in early testing stages

Remedial actions

- FDA process for marking Software as medical devices is quicker, cheaper and easily translatable to other markets. Focus globally and use FDA
- Focus on safeguarding patient data and health information systems against cyber threats, to ensure data security and privacy
- Efforts underway to enhance integration and interoperability to allow seamless sharing of patient data across various healthcare settings and improving care coordination.

Competitor countries

- **US, Germany**

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World-leading Datasets – Biobank and 500,000 Genomes

Strengths	• **UK Biobank and 500,000 Genomes have already been used extensively worldwide** and researchers are developing fluency in these datasets
	  • Vetting process is rigorous and promotes high quality research
	  • Balanced approach to release of derived data encourages private investment and broad scientific utility

Risks/gaps	• Public concerns over use of data • Low genetic diversity • Red tape means data applications are burdensome
Reinforcing actions	• **Increased need for genetic and socioeconomic diversity is being addressed** • Improve transparency and agility of the application processes
Competitor countries	• **No other countries have equivalent offer. Counterparts to Biobank/500,000 Genomes in US but closed to industry or require high upfront payments**.

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World-leading datasets - Real World Data

Strengths	• **UK datasets have an excellent reputation and provide a wealth of data for epidemiology across all care settings** • **Guidance to help researchers increase diversity of participants in clinical research supported by UK Policy Framework for Health & Social Care** • **NHS Data Saves Lives programme** • CPRD data can support NICE dossiers and appraisals in other settings • **NHS Commitment to implementing HER for all hospitals and community practices by 2025**
Risks/gaps	• Inadequate linkage between primary and secondary care • Time lag in data availability • Industry is over-reliant on third-party vendors
Reinforcing actions	• Ensure data collection aligns to changes in treatment paradigms. • Improve speed and access to data • **Action to position UK as enabler of international research** • **Data protection and public support** • **Linkage of health records to other socioeconomic determinants of health**
Competitor countries	• Netherlands and Sweden • Can vary according to disease area

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