

Results of a Review by the JPG



Overview – about this project

For the first time the Japanese Life Sciences industry has collaborated to assess the UK ecosystem.

We have done this through a three-stage process between January and April 2020: meeting in person, a series of one to one interviews, and a final validation exercise.

We sought to map where companies are engaging, what the perceived **strengths and weaknesses** are of the UK system, as seen through the eyes of Japanese life sciences companies, and what **improvements** would be valued.

We also discussed which are the **key competitor countries** in different parts of what we consider to be the UK Value Chain.

The **COVID crisis** hit midway through the project and was not in scope but we provide some high level thoughts on the UK Life Science community's response.

In the course of the exercise we found that there is **low** awareness of the Life Sciences Strategy and Sector Deals in the Japanese life sciences R&D community.

We would welcome the opportunity to work with Government in developing ways to enhance communication of the UK's Life Sciences offer and improve cut through at a global level in the Japanese Life Sciences industry.



Key findings – the UK as a base for basic research and clinical trials

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

JPG companies are involved in various **research consortia, scout for talent** and have **significant investments in UK biotech**.

Japanese companies see the UK as a **world leader in early stage trials** with a unique mix of leading clinical pharmacology expertise, high quality facilities and an experienced regulator.

As a result JPG members have international hubs for clinical trials based in the UK and a significant proportion of global early phase trials take place here.

Views are mixed on late stage trials – the UK has a lot going for it and particular strength in rare diseases, but in other areas the view is the UK cannot compete with Eastern Europe and China.



Key findings – digital and data landscape

JPG companies welcome Government and NHS efforts to embrace cutting edge digital technology and the evolving ecosystem it is building around it.

NICE is the only agency in the world that is currently producing guidance in this area and **NHS** is collaborating well with industry.

However **significant barriers** to diffusion need to be overcome before the UK can be an important global player.

The UK's **Biobank and 500,000 Genomes projects** have been used extensively worldwide and place the UK in the premier league for genomics.

JPG companies are actively seeking to work with these datasets and believe they would benefit from greater genetic and socioeconomic diversity.

The UK is considered to be a global leader in real world data. UK datasets have an excellent reputation and provide a wealth of data for epidemiology across all care settings.



UK Life Sciences' response to COVID

The way in which the **UK Life Sciences community has pulled together** in response to the COVID crisis is unprecedented.

Collaboration by all actors in the system, with important support from Government, has enabled implementation of the ACCORD-2 platform trial, a model approach that has long-been aspired to in the scientific community.

Together with a drive to recruit all COVID patients into trials, JPG believes that **UK Life Sciences is at the** forefront of the global drive for effective treatments and vaccines.

The experience has provided a springboard for a more agile clinical research architecture in the future, as well as trials that are more patient-centred. JPG believes it is crucial the opportunity to build on the significant UK response is not lost.

We recommend a review of what has worked well through this experience that can be taken forward in a new and innovative approach to clinical trials eg accelerated trial approvals and digital, innovative trial designs.

JPG companies are committed to playing their role in supporting such changes, and in the search for effective treatments for COVID, as well as other diseases, and to continue to collaborate so that progress can be achieved at pace.



Key findings – 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. Stakeholders, including JPG, should be part of a process of ongoing review in order to reflect the most current thinking and to drive improvements.

UK Government needs to be realistic about the shadow cast by EU Exit among Japanese Life Sciences companies. Clarity and **transparency on EU exit future** is needed to rebuild confidence. This includes the role of MHRA and future research funding.

In digital there is a need to address barriers to adoption in order to speed diffusion of innovation.

Tackling red tape would enable greater agility in industry's access to genomic and real world data sets.

There are further quality dimensions that would enhance the UK offer: such as greater population diversity in 500,000 Genomes and better linkage between primary and secondary care NHS datasets.

Leveraging the investment and experience from the COVID clinical trials approach would enable the UK to become world-leading in this space.

JPG would like to work with the UK Government to maximise the opportunities of its Life Sciences strategies. We recommend more concise version of reports and updates, a supporting narrative on the UK Biobank and 500,000 Genomes opportunities, creating a tailored set of messages for Japanese companies.



JPG view of the Life Sciences Ecosystem in the UK Overall Project Conclusions

| | Capabilities | | | | Data Assets | |
|--------------------------|--|--|--|--|--|---|
| | Basic Research | Early Stage Trials | Late Stage Trials | Digital Technology | Genomic Datasets | RWE Datasets |
| Strengths/ Advantages | Academia – global leaders Fundamental science expertise Pre-competitive & translational research consortia English language iCURE programme Genomics datasets Government commitment & investment | Expertise – particularly in clinical pharmacology MHRA reputation Expertise in phl proof of concept studies Talent pool Centralised research authority | Quality of trials Ability to execute trials Early phase trial leadership Leadership of EU collaborations NHS dataset Government and NHS willingness to collaborate with industry Response to COVID | Use of digital growing across all aspects of clinical practice Growth of public and private investment Collaborative ecosystem NICE HTA & early scientific advice Google/other tech have UK research centres | Substantial body of literature & derived datasets that can be readily leveraged Requirements for release of derived data fair, encourage private investment High quality | Reputation for excellent datasets Wealth of data for epidemiology across all care settings CPRD data acceptable in NICE dossiers Rare disease registries |
| Risks/gaps | Loss of funding due to Brexit and COVID-19 impact on GDP Loss of talent if science budgets fall/Brexit | Rapid growth of other markets Brexit - loss of talent Brexit - loss of leadership in international research collaborations | Future of MHRA Lack of motivation in hospitals to participate in trials Small market, high cost Lengthy approval processes Tough reimbursement environment Global competitors invest more | Landscape fragmented Diffusion is slow Data privacy & governance Lack of real world experience using digital Knowledge gap among health care professionals | Public concerns over use of data Administrative process for data applications slow and cumbersome | Lags in data Over reliance on third party vendors to access data Inadequate data linkage between primary and secondary care |
| Areas for improvement | Business training for academia Government commitment to R&D funding of 2.4% GDP enshrined in law Replace lost EU funding, maintain EU collaborations and flow of talent | Continue to enable Innovative studies Allow EU collaborations to continue post Brexit Ensure MHRA leadership role continues | Improve enrolment in hospital setting Harmonise site costs Develop capability for remote trials in post COVID world Speed up ethics approvals Unrealistic to try and compete with other markets? | National guidance on adoption at local level Training for HCPs More Al-based trials beyond imaging eg predictive outcomes based treatment optimisation | Low genetic diversity, socioeconomic skew Transparency AND responsiveness in application process Visibility/accessibility of derived data | Experience tends to be shaped by vendor Speed and access to data Data adapts to changes in treatment paradigm |

Global leader

Premier league

Behind the curve



JPG's contribution to the life sciences ecosystem Types of investment made by members in the UK



Business to business



Academic/science

- Pure & translational
- Pre-competitive



NCRI, NIHR

CROs



Phase 1



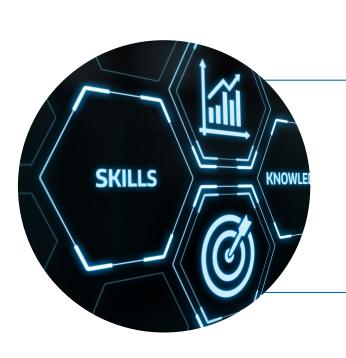
Proof of concept



Charitable sector research



University collaboration



Skills development



| Sector | Examples of JPG member company investment |
|---|--|
| Acquisitions, licensing & business partnerships | Astellas Quethera, Nanna Therapeutics, Adaptimmune; preparing for a UK based office for early stage partnering in 2021 Eisai Wren Therapeutics collaboration Takeda has 22 active partnerships within the UK (> 10% of company's global partnerships). Significant investments in UK biotechs including: GammaDelta; Silence Therapeutics; Cerevance; in 2020 Takeda agreed R&D partnerships with Evox and Engitix in the UK, worth a potential \$1.3bn |
| Academic/science base Pure & translational Pre-competitive | Eisai UK DRI post doctoral Programme (UCL, Imperial, Kings, Cambridge, Cardiff, Edinburgh) Eisai-Wolfson PhD Programme in Neurodegeneration (UCL) Milner Therapeutics Institute Accelerate@Babraham Dundee University collaboration CASE PhD studentships Training of undergraduate Industrial Placement students in drug discovery research (various universities) Shionogi 6 ongoing collaboration projects primarily in the areas of Neuroscience and Infectious Diseases with the University of Cambridge and the Milner Therapeutics Consortium, Imperial College London and with University College London. The total value of those collaborations is in excess of £1.6 million. 2 collaboration projects have been completed with academic institutions with a total value of £800K 3 new collaboration projects in preparation with University of Cambridge, the University of Glasgow and the University of Birmingham. Takeda 17 Innovative Medicines Initiatives Public Private Partnerships with participants from the UK |
| CROs | Chugai is working with global CROs in Ph1, and speciality Lab/CMO/CROs in exploratory studies Eisai is working with many UK-based CROs in discovery and development |

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| Sector | Examples of JPG member company investment | | |
|----------------------------|---|--|--|
| Phase 1 | Chugai to start several Ph1 and Mass Balance studies in the UK Eisai several Ph1 trials of oncology programs have been conducted in the UK over the past decades Mitsubishi Tanabe in the past 20 years all non-Japanese Phase I 'First in Human' studies have been performed in the UK Shionogi has 4 early phase (Ph1 or Ph2) clinical trials ongoing or in preparation in the UK. The total investment in 2019/2020 is in excess of £800K. The UK is within the 3 top locations for early phase clinical trials, along with Japan and the US Takeda has a disproportionately high number of trials in all phases in the UK compared to other markets | | |
| Late stage research | Daiichi Sankyo has 10 studies running at the start of 2020 Sunovion 5 active UK sites in a Parkinson's Phase III study Takeda has 31 actively recruiting PIII and PIV studies in the UK, with 2454 patients across 31 hospitals | | |
| Charitable sector research | Eisai • AR-UK Dementia Consortium • AR-UK Oxford Drug Discovery Institute | | |
| University collaboration | Eisai CL Drug Discovery Collaboration in Neurodegeneration Santen collaboration with UCL on ophthalmic research where funding International PhD students at the Institute of Ophthalmology in London. To date 8 PhD student projects have been initiated and the collaboration will continue till 2025 Takeda Cardiff University partnership to identify new approaches for treating schizophrenia and other psychiatric disorders; London School of Hygiene and Tropical Medicine endowed a chair in Global Child Health (first fully endowed corporate chair) | | |

