Global Counsel

# Maintaining innovation: clinical trials post-covid

**Blog post by Research Analyst Olympia Campbell, 15 February 2021**

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Earlier this month, GC hosted a debate on the success and future of clinical trials in the UK. The UK's profile as a global leader in life sciences has been enhanced by the covid-19 pandemic. Industry, the NHS and regulators collaborated effectively to be at the forefront of innovation in vaccines and treatments. The RECOVERY trial and its identification of dexamethasone as an effective treatment for covid-19 is one of many clear successes. For policymakers and pharmaceutical companies looking to capitalise on this innovation, there are two obvious questions: why did it succeed? And how can it be maintained?

There are two key factors that led to the UK success. Firstly, there was alignment between multiple actors for demand and risk appetite. The pandemic created an environment where politicians, regulators, researchers, and clinicians were all willing to take risks in streamlining the clinical trial process. Where trial approval, recruitment of participants, and reporting of results had previously taken years, it now took months. Trial approval in particular took only a number of days.

Regulators were also proactive, with NHS clinicians given licence to use dexamethasone as a treatment prior to a formal peer review process taking place. Secondly, there was clear leadership and approval from ministers and senior government officials that these risks should be taken. In particular, the control of patient information (COPI) notice permitted more relaxed health data sharing – a move that under other circumstances, may have proven politically difficult.

Maintaining this level of collaboration and alignment in a post-pandemic world will be difficult. An exhausted NHS will be focused on delivering care that has been delayed. Of particular importance will be how the regulatory authorities, such as the Medicines & Healthcare products Regulatory Agency (MHRA), update their clinical protocols and make the most of scope to diverge from EU regulation. Providing top-down direction from government may be required to maintain some of the protocol simplification and innovation that has been seen.

Above all, public support for health data sharing must be maintained. Analysis suggests that reporting on health data is heavily politicised, often viewed as part of wider issues such as privatisation of the NHS, or as an asset for private companies to profit from. By contrast, giving consent for data access in covid trials was viewed as being part of a national effort and may provide a potent opportunity to open a wider public conversation about the benefits of health data sharing. Crucial to this will be a decision on whether data could be an asset to be sold, or a shared national repository that is part of a broader investment in UK life sciences and research. The latter may prove more popular with the public, given the negative connotations of data profiteering.

The government pledge to increase R&D spend to 2.4% of GDP by 2027, including investment of £559m to modernise technology across the health system in the 2020 spending review, and the

white paper on NHS reform, may unlock the potential of this data and imbed clinical research within an ever more integrated health system. The white paper proposes legislation that will require healthcare bodies to collect and share data, while the Goldacre review and forthcoming data strategy for health and social care, should include provisions to improve data interoperability, ease data requests, and introduce protocols for data sharing and secondary use. The ultimate objective of research as an integral part of a patient pathway, where hospitals have the time and capacity to contribute to clinical trials, has broad political support.

In a post-pandemic, post-Brexit world, the government will be positioning the UK to improve and maintain its position as a life sciences leader. Making the UK a place where R&D, clinical trials, development, and commercialisation can all occur seamlessly, will be one way to attract international investment. Having integrated and accessible datasets will be crucial to this. However, the window of opportunity for public engagement is slim and risks being wasted. Transforming the way the NHS uses data would be a valuable legacy from the experience of covid-19.