The Burden of Regulation on UK Clinical Research

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An increase in government expenditure on biomedical research across the UK, administered through the Medical Research Council (MRC) and the National Institute for Health Research (NIHR), was delivered through the last comprehensive spending review and this week has been enhanced still further through an additional £180 million to the life sciences industry to support a catalyst fund for new medical breakthroughs. The basis for this funding is to look to the life sciences industry to increase UK economic growth, and to develop novel NHS/university/pharma partnerships that will reinvigorate the discovery of new drugs and rapidly translate these to patient benefit.

One identified barrier to rapid translation is the regulatory process that has hindered the initiation of research, patient participation in clinical trials, and rapid access to new and emerging therapies. A 'one size fits all ' approach to regulation has slowed the process of clinical research without any evidence of improved patient safety. Despite the well publicised events in a pharma research unit within Northwick Park in 2006, clinical research remains a safe process; indeed many studies have shown additional health beneficial effects of participation in clinical trials. There were several examples of the regulatory delay accelerating patient death rather than 'protecting' them from any ill effects.

The announcements by David Cameron, Andrew Lansley, and David Willetts on 5 December go a long way to addressing and implementing the recommendations set out by the Academy of Medical Sciences Report, 'A new pathway for the Regulation and Governance of Clinical Research,' compiled by Professor Andrew Rawlins less than a year ago, visit: www.acmedsci.ac.uk/p99puid209.html. 'Opt-out' rather than 'opt in' to models for clinical trials are to be considered and all NIHR research contracts will mandate a 70-day benchmark to recruit patients to clinical trials. Performance metrics are to be placed on the Medicines and Healthcare Products Regulatory Agency (MHRA) – the body that must approve all new Investigational Medicinal Products prior to use in man. An early access scheme will ensure that MHRA fast tracks new drugs for patient benefit.

The University of Birmingham is rising to this challenge. With key partners, notably one of the largest hospitals in Europe – University Hospitals Birmingham Foundation NHS Trust, we have formed an Academic Health Science Centre (Birmingham Health Partners), that oversees the full circle of translational medicine, from discovery science, to first in man/ phase I studies, it is one of the largest clinical trials centres in Europe, complemented by health economic evaluation and implementation. World leading researchers have access to one of the largest Experimental Medicine Clinical Research Facilities in the UK that houses a new gene therapy and cell based facility and an adjacent tissue biorepository. Over £70M of current NIHR/ MRC investment exploits this infrastructure, underpinning major advances in Leukaemia research and bone marrow transplantation, Liver disease (NIHR Biomedical Research Unit), new mechanisms and drugs for Cancer (CRUK Cancer Centre), and improving outcomes from trauma, be it within the civilian or military population (NIHR Surgical reconstruction and Microbiology Centre).

Crucially we have directly 'busted bureaucracy', through a joint clinical research office that addresses many of the above regulatory hurdles. For example, research is now implemented within a three week timescale with pharma partners exploring new treatments for arthritis (NOCRI Translational Research Partnership).

A more streamlined and monitored, risk based approach to research governance, will ensure that the new government investment in biomedical research will more rapidly improve patient health, invigorate pharma and increase UK growth. The University of Birmingham with its strong NHS partners will be at the forefront of this process.

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