Simplifying regulation of medical research in England

The English regulatory and governance system in which medical research operates in is **complex**. The government expressed concern that this system was **hindering research activity and excellence**, creating inefficiencies in time and cost to undertake research and driving such research activity overseas.

In the Department of Health's 2010 White Paper **Equity and excellence: Liberating the NHS** committed the government to:

> '...cut the bureaucracy involved in medical research. We have asked the Academy of Medical Sciences to conduct an independent review of the regulation and governance of medical research. In the light of this review we will consider the legislation affecting medical research, and the bureaucracy that flows from it, and bring forward plans for radical simplification.'
>
> *Source: Department of Health, Equity and Excellence: Liberating the NHS*

The review, led by **Sir Michael Rawlins, Chair of the Academy of Medical Royal Sciences**, found evidence that supported the government's concern.

> 'As a specific example, a recent analysis from Cancer Research UK showed that after its funding for a study has been agreed, it now takes an average of 621 days to recruit the first patient.'
>
> *Source: The Academy of Medical Sciences, A new pathway for the regulation and governance of health research*

The review was mindful of the need to **protect patient safety in research** while at the same time looking for ways to **simplify** the research process so that new discoveries can be more quickly identified and introduced into patient care. Several features of the current regulation and governance system were identified as burdensome and the following recommendations were made to address them:

- Creating a new **Health Research Agency** to rationalise the regulation and governance of all health research
- **Improving the UK environment** for clinical trials

- Providing **access to patient data** that protects individual interests and allows approved research to proceed effectively
- Embedding **a culture that values research** within the NHS

The review was well received by the leading medical research organisations in the UK, as well as the government who is now considering how to implement the recommendations.

A new pathway for the regulation and governance of health research

Source: Academy of Medical Sciences