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Complex regulation system means UK not delivering vital health research for patients

Urgent changes are required to the regulation and governance of health research in the UK because unnecessary delays, bureaucracy and complexity are stifling medical advances, without additional benefits to patient safety. A report by the Academy of Medical Sciences sets out a new regulatory and governance pathway that will increase the speed at which healthcare innovations become available to patients, whilst eliminating unnecessary bureaucracy.

Professor Sir Michael Rawlins FMedSci, Chair of the Academy of Medical Sciences working group that prepared the report, said: *"A fertile research environment is vital for the health and wealth of the UK. The current system of regulation is making it increasingly difficult to initiate health research in the UK and is preventing patients from participating in studies. This is ultimately denying patients early access to new drugs and hindering improvements to public health for the wider society.*

"We have found unequivocal evidence that health research in this country is being jeopardised by a regulatory and governance framework that has become unnecessarily complex and burdensome. Further, we received no evidence that this increased regulatory and governance burden has led to enhanced safeguards for participants in research. The changes we propose will streamline and improve the process to create a better environment for research, while protecting the interests of patients and the public."

The report recommends the establishment of a new independent Health Research Agency (HRA) to bring together existing approval processes. The Agency would work with regulatory and governance bodies in the devolved nations to develop an integrated approvals system for the UK. The report recommends that the Department of Health should establish a new National Research Governance Service (NRGS) for England, to be housed within the HRA. The NRGS would facilitate rapid approval of research studies conducted in single or multiple NHS sites by assuming responsibility for all study-wide checks that are currently duplicated by each participating NHS Trust.

Sir Michael added, *"The delay in obtaining NHS permissions is a major failure of the current pathway and is the biggest single barrier to all types of health research studies. There is a highly inefficient emphasis on process rather than outcomes, which has led to delays of over a year to gain permissions for simple studies."*

The UK has created nearly a quarter of the world's top 100 medicines and its share of world citations in both the clinical and health sciences is currently second only to the US. However, recent data show a decline in the UK's global share of clinical research activity. There is widespread agreement that the regulatory and governance framework is one of the main contributing factors to this decline. Implementing the changes outlined in the Academy's report will allow the UK to realise the health and wealth benefits of our world class health research base and maximise the value of our public, charitable and commercial investment.

Sir Michael Rawlins concluded, *"It is vital that the HRA is established as soon as possible. To achieve its goals it will have to be a genuine single regulator and not a mere façade hiding the continuation of many separate existing bodies. We recommend that it is established as soon as possible to start making necessary changes to start making necessary changes right away and then confirmed in primary legislation in due course."*

On publication of the report, Professor Sir John Bell FRS FREng PMedSci, President of the Academy of Medical Sciences, said, *"The UK has historically supported vibrant research-intensive medical science industries and world-renowned academic medical science centres, but a cumbersome regulatory and governance environment is driving this work abroad. Health research must be subject to robust regulation that both protects patients and facilitates globally-competitive research. This report sets out a realistic and achievable framework by which this can be achieved."*

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For further information and copies of the report, 'A new pathway for the regulation and governance of health research' please contact: Nick Hillier, nick.hillier@acmedsci.ac.uk, 020 3176 2154, 07788 585563

Notes for Editors

The independent Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated into benefits for patients. The Academy's Fellows are the United Kingdom's leading medical scientists and scholars from hospitals, academia, industry and the public service. www.acmedsci.ac.uk

The Government commission of the Academy of Medical Sciences to conduct an independent review of the regulation and governance of medical research was announced by then Health Secretary Andy Burnham on 24 March 2010. The Academy received over 300 submissions of written evidence from stakeholders in health research including academia, industry, the NHS, regulators and medical research charities; and oral evidence including through a patient and public involvement workshop.

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