

## Response quotes

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### **Responses to the publication of 'A new pathway for the regulation and governance of health research', a report by the Academy of Medical Sciences**

**Andrew Lansley MP, Secretary of State for Health** said: "National regulation and local governance of health research are too complex and scattered across too many different bodies. The Academy's report makes the case for simplification under a health research agency that will streamline and co-ordinate regulatory and governance processes. The Government welcomes the report and will consider carefully how to implement its recommendations."

**David Willetts MP, Minister of State for Universities and Science** said: "As the government works to rebalance and grow the economy, it is vital that the UK continues to be an attractive environment to undertake clinical trials. This activity is a core part of the UK's strong life sciences industry, an important growth sector. It also ensures the NHS gains early clinical experience of innovative medicines. I welcome the AMS' recommendations on improving conditions in the UK for conducting health research."

**Sir Mark Walport, Director of the Wellcome Trust**, said: "This report and its recommendations are both welcome and timely. The UK is a global leader in medical research, with benefits to health and the economy, but is prevented from maximising its potential because of unnecessarily complex and bureaucratic regulation. We must strike a better balance between protecting participants involved in research and not unduly or inappropriately obstructing the progress of research that will bring important health benefits. There should be symmetry in regulation - regulators should be held accountable for decisions to delay or prevent research as well as decisions to approve it."

**Sir John Savill, Chief Executive of the Medical Research Council (MRC)**, said: "This report is very timely, and takes forward many of the issues discussed at the MRC/Wellcome Trust workshop on research regulation held in May 2008. It is essential that the regulatory system for clinical research in the UK is simplified and made more risk-proportionate. The MRC considers that the recommendations identified by the AMS are a pragmatic way forward, and would be happy to work with Government and others to put them into effect".

**Harpal Kumar, chief executive of Cancer Research UK**, said: "The process for getting clinical and health research up and running in the UK is unacceptably slow. Cancer patients are missing out on taking part in clinical trials because of the unnecessarily complex and bureaucratic processes that researchers have to navigate to set up their studies. And there's no evidence to suggest that the current way of approving research actually brings any additional benefits in terms of patient safety.

"We strongly welcome the report and support its recommendations. We believe that a single health research agency could reduce the time it takes our researchers to get approval for their studies to 60 days – around a fifth of the time it takes them now.

"We urge the government to take forward these recommendations without delay to make it easier for cancer patients and the public to benefit from the world-class research that takes place in this country."

**Allison Jeynes-Ellis, Medical and Innovation Director, The Association of the British Pharmaceutical Industry (ABPI)**, said: "The ABPI recognises the importance of this report from the Academy of Medical Sciences in addressing the key barriers that continue to hamper the UK maximising its full potential as a leader in clinical research

In particular, it very much supports key recommendations that focus on streamlining the processes around clinical trials and address the cultural issues that still exists within some parts of the NHS, which represent a significant hurdle in conducting clinical research

The timely endorsement and implementation of this report by all stakeholders is vital if the UK is to be seen as a serious player in clinical research in an increasingly competitive arena"

**Simon Denegri, Chief Executive, Association of Medical Research Charities (AMRC)**, said: "The Academy's report does not only chart a way forward for improving the current regulatory system for conducting clinical trials. Its recommendations also presents us with an opportunity to make health research a truly public endeavour with the full engagement of the NHS, its staff and, above all, patients. It is the active support of patients which is central to the successful conduct of health research and we are pleased that the Academy has listened to their views during the course of its review. AMRC and its 125 member charities welcome the report and urge the Government to move swiftly to take forward its proposals."

**Alan Morrison, Chair of the BioIndustry Association's Regulatory Affairs Advisory Committee**, said: "The Academy of Medical Sciences report includes recommendations which are a step in the right direction towards improving the governance framework and creating a better environment for health research in the UK. However, the BIA continues to believe that it would be more efficient and effective to build upon and expand existing competencies within MHRA rather than create a new body to oversee the regulation and governance of health research, as recommended by the AMS report."

**Professor Alan Silman, Arthritis Research UK's Medical Director** said: "Arthritis Research UK agree that a new health regulatory agency could be helpful to reduce unnecessary bureaucracy. Too much red tape slows down clinical research and in particular recruitment to clinical trials. As a funder, we have established resources and national networks to support front rank clinical trials, but excessive regulation creates delays and increases costs."

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