

investment

research

access

health

Create a place where **research** can flourish



Consider medical research when scrutinising EU legislation and support initiatives to promote innovation

Legislation that is not focused on research can have unintended consequences. It is crucial that the scientific impact of EU legislation is considered from the outset to prevent issues appearing during implementation that can delay the research process, deter investors and ultimately prevent patients benefiting from new therapies and approaches. Getting EU legislation right and harmonising regulations across Europe can be hugely beneficial for research that often takes place across borders.

Fact...

The UK public supports medical research

Medical research is the UK's most popular charitable cause: a third of all donors giving to charity each month – that is 9.4 million people – donate an average of £10 to medical research.¹

Case study

The EU Physical Agents Directive 2004/40/EC as originally proposed could have seriously restricted the use of MRI for research and diagnosing patients

The EU Physical Agents (Electromagnetic Fields) Directive 2004/40/EC set minimum requirements to protect workers from risks arising from exposure to electromagnetic fields. However, the Directive as originally proposed could have seriously restricted the use of MRI, both in the clinic and for research purposes, because the proposed exposure limits would have prevented workers from standing close to the magnet bore during imaging. In 2007 after concerns were raised from stakeholders, with the backing of MEPs, the European Commission postponed the implementation deadline of the Directive. In June 2011, following extensive consultation and negotiation, they published a revised Physical Agents Directive which included a derogation for MRI, and which was eventually passed in June 2013. Member countries now have until 1 July 2016 to implement the Directive.

Case study

The European Clinical Trials Directive 2001/20/EC contributed to a drop in clinical trials

In 2000 the UK had the third largest share of global trials, behind only the US and Germany. In part as a result of the implementation of the 2001 Clinical Trials Directive 2001/20/EC, which created delays in trial setup, the UK's ranking dropped between 2000 and 2006 to ninth and Britain's global share of patients in pharmaceutical trials fell sharply as trials moved elsewhere. The EU as a whole also saw a decline during this time. Delays resulted from inconsistent implementation of the Directive by member countries, increased bureaucracy and inflexible regulation.² These problems could have been avoided through early consultation with researchers and scrutiny of the proposals. Thirteen years later, a new Regulation is now going through Parliament addressing many of these barriers. The new legislation will be applied in the same way across all member countries making large multi-state trials, many of which take place across multiple EU countries much easier to set up and run.

Allow patient data to be made available for research that saves and improves lives whilst protecting confidentiality and building trust

Personal health records are a valuable resource, revealing the most effective ways of caring for patients and allowing us to better understand the causes and frequency of disease.

The proposal for a new Data Protection Regulation currently under debate in Europe could impact on researchers who use personal data in their work. Amendments adopted by the European Parliament's Civil Liberties, Justice and Home Affairs (LIBE) committee could seriously damage research. They may also impact on the UK government's own initiatives; the *Strategy for UK Life Sciences* included a £60 million investment to establish a new secure data service called the Clinical Practice Research Datalink which would not be workable if the LIBE amendments are adopted.

Case study

Strict requirements for specific consent could make it difficult to recruit patients to trials

Researchers need to be able to contact potential participants to invite them to take part in studies. For example, the UK Collaborative Trial of Ovarian Cancer Screening contacted 1.2 million women by post to invite them to take part. More than 200,000 postmenopausal women without ovarian cancer consented to take part in this study on the effectiveness of screening techniques for ovarian cancer. Were the LIBE committee's amendments adopted, specific consent would have been required to identify and contact the 1.2 million eligible women, even before inviting them to take part in the study itself. This would make recruitment for valuable large-scale studies such as this very difficult and costly to conduct.

Fact...

Patients want to share their data

In 2011, in a survey of 990 people, 80% told us they would consider allowing a researcher confidential access to their medical records.³

Case study

Requirement to gain specific consent could stop largest ever Parkinson's study

Tracking Parkinson's is the world's largest ever in-depth study of people with Parkinson's. It is a 5-year project which aims to speed up the search for a cure by finding 'biomarkers', many of which circulate in the blood. Participants complete questionnaires, donate blood samples and have their Parkinson's symptoms carefully monitored at regular hospital appointments and give broad consent for these data to be shared with researchers. The information and samples collected in the study are made available to researchers studying Parkinson's all over the world free of charge. This study would become unworkable under the LIBE committee's amendments since the form of consent is very narrow.

1. National Council for Voluntary Organisations (Great Britain) and Charities Aid Foundation (2012), *UK Giving 2012: An overview of charitable giving in the UK, 2011/12*. <https://www.cafonline.org/PDF/UKGiving2012Full.pdf>

2. Academy of Medical Sciences (2011), *A new pathway for the regulation and governance of health research*, p51. <http://issuu.com/acmedsci/docs/newpathw>

3. Ipsos MORI (2011), *Public support for research in the NHS*. <http://www.ipsos-mori.com/researchpublications/researcharchive/2811/Public-support-for-research-in-the-NHS.aspx>