16 April 2018

We would like to see the UK Government commit to align with the EU Clinical Trials Regulation. UK research expertise was a driving force behind the new Clinical Trials Regulation, and as a Member State we fully agreed to it. Yet because it is now due to come into effect after we have left the EU, it will not automatically become UK law.

This leaves the real possibility that we will fall out of alignment with our European partners on clinical trials; a significant hurdle for UK patients and researchers, as well as our world-leading life sciences industry. In this scenario we would miss the opportunity to move to a regulation that the research community agrees is a vast improvement for patient safety and trial efficiency.

A failure to adopt the Regulation would make continued collaboration with our closest partners significantly harder. International collaboration is vital for clinical research, and means UK patients can continue to access potentially life-saving experimental treatments. It is particularly important for rare, less common and paediatric diseases, where patient populations in individual countries are often too small to recruit sufficient numbers. 75% of clinical trials in the EU involve cross-national collaboration, and this rises to 86% for rare disease trials.

Clinical trials can run over many years, and require significant planning. If researchers lack clarity as to the ease of conducting cross-national trials, and the underlying conditions of the UK's research environment, planning ahead becomes immeasurably difficult. With continued uncertainty around the future of internationally collaborative research in the UK, Government commitment to align the UK with the EU Clinical Trials Regulation and to seek UK access to its underpinning infrastructure would help provide the reassurance our research community so desperately needs.

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