New proposals for the future of UK clinical trial legislation

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‘Better regulation…for better trials…for better health’

The Medicines and Healthcare products Regulatory Agency (MHRA) has today launched a public consultation on a set of far-reaching proposals to improve and strengthen the UK clinical trials legislation to make the UK the best place to research and develop safe and innovative medicines.

Clinical trials are vitally important for achieving advances in medical treatment. Clinical trials may be conducted for a range of purposes, for example to test whether a new treatment or combination of treatments is safe and effective, or to explore new ways to use existing medicines – as has been seen with the rapid introduction of new vaccines and therapeutics for COVID-19.

This eight-week consultation seeks your views on new proposals to improve regulation of clinical trials in the best interests of patients. In line with the ambitions of the Life Sciences Vision these proposals for UK legislation seeks to make the UK the leading global centre for innovative research design and delivery, across all types of trials. This consultation aims to develop a system which promotes patient and public involvement in clinical trials, improves the diversity of participants, streamlines clinical trial approvals, enables innovation and enhances clinical trials transparency.

June Raine, Chief Executive of the MHRA said:

This is a once-in-a-generation opportunity to review and update the UK legislation for clinical trials in order to make the UK the go-to place to develop new and innovative healthcare products.

Through the proposals outlined in this consultation we aim to

reframe the legislation that underpins our regulation of clinical trials to deliver a more streamlined, transparent and flexible regulatory regime whilst always protecting patients and trial participants.

We are seeking the views of the wider public, clinical trial participants, researchers, developers, manufacturers, sponsors, investigators, healthcare professionals to help shape improvements for the future of clinical trials. We encourage you to get involved and help shape this important future legislation, for the ultimate benefit of patients.

This consultation will run from 17 January until 14 March 2022. All responses will be carefully reviewed and will inform decisions to finalise the drafting of the secondary legislation.

Notes to editors

The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK.

The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care.

The current UK legislation, The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, transposed the EU Clinical Trials Directive 2021/20/EC into national law.

This consultation will run from 17 January, 11:00 until 14 March 2022, 23:00.

Find the full list of the consultation proposals and executive summary here.

Media Assets

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