News story: Clinical Trials Regulation

As part of exit negotiations, MHRA is working to ensure that we continue to have the best possible environment in which to support clinical trials. Our overall aim is to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicines.

In March, the UK and EU negotiating teams reached agreement on the terms of an implementation period that will start on 30 March 2019 and last until 31 December 2020. During this time, the UK will no longer be a Member State of the European Union, but market access will continue on current terms – and the UK and the EU have agreed that EU rules and regulations will remain in place in order to provide continuity and certainty to businesses and citizens.

The EU's new Clinical Trials Regulation (CTR) specifically is expected to be implemented during 2020 and would therefore apply to the UK under the terms of the time-limited implementation period. The new regulation is a major step forward: it will enable a streamlined application process, harmonised assessment procedure, a single portal for all EU clinical trials and simplified reporting procedures, including for multi-Member State trials. The UK was involved in developing the new regulation that has been widely welcomed by Europe's research sector, including academia, medical research charities and industry.

However, if the new regulation does not come into force during the implementation period, the Government has confirmed that UK law will remain aligned with parts of the EU's CTR legislation that are within the UK's control, in order that researchers conducting clinical trials can plan with greater certainty. The UK's access to networks, information systems and databases will continue on current terms for the duration of the implementation period. The two key elements of the regulation that the UK would not be able to implement on its own after this time are the use of a shared central IT portal and participation in the single assessment model, both of which would require a negotiated UK/EU agreement regarding UK involvement following the end of the implementation period. We cannot pre-empt the outcome of these negotiations, but the Government has always been clear on its preference for close cooperation with the EU across all aspects of medicines regulations.

It is in the interest of patients and the Life Sciences industry internationally for the UK and EU to find a way to continue cooperation in the field of clinical trials, and for continued sharing of data, even if our precise relationship with the EU will by necessity change.

No matter what the outcome of negotiations, the UK is committed to offering a competitive service for clinical trial assessment.

If the UK is outside of the EU network following the end of the implementation period, it will still be possible for sponsors to run

multistate trials involving the UK. Sponsors would have to apply to MHRA, as well as to the EU concerned states; but MHRA would take every effort to ensure this parallel submission is as streamlined and efficient as possible (for example by using the same application dossier). MHRA and UK ethics committees are already internationally recognised for their robust yet timely assessment of trial applications, and the UK would provide an assessment outcome no later than the European timeframe.

The current regulatory approval legislation will stay in place until such time as any changes are needed, so there will be no interruption in UK clinical trials approval (whether for academic or industry-led clinical trials).

The UK's commitment to offering a competitive clinical trials environment does not just cover regulatory approval from MHRA – it also covers services from the Health Research Authority (HRA), the Devolved Administrations, ethics services, National Institute for Health Research (NIHR) and the NHS. For example, MHRA and the HRA, in partnership with the Devolved Administrations, have been exploring opportunities to improve services to sponsors through the Combined Ways of Working Pilot. This is testing a new process that will result in a single UK decision on a clinical trial (consisting of the current ethics opinion and MHRA clinical trial authorisation), in addition to a single clinical trial application route that incorporates both the Research Ethics Service and MHRA.

Following the agreement in March of the implementation period, work to finalise the Withdrawal Agreement as a whole is continuing – with the intention to do so by October, alongside the framework for the future partnership. The Government has always been confident that we will get a good deal – and now that good deal is clearer and closer than ever. Of course as a responsible Government we continue to plan for all scenarios, but with increased confidence that we will leave with a deal and that a 'no deal' scenario in March 2019 is significantly less likely. The Government recognises that in the unlikely scenario of no deal between the UK and the EU, it would be important to reach a suitable resolution to the supply chain questions that would arise, particularly regarding Investigational Medicinal Products.

The Government has been consistent in saying that a key priority through the negotiations is to ensure that the UK remains one of the best places in the world for science and innovation. The Life Science Industrial Strategy set out a clear ambition to remain at the forefront of innovation, which includes a commitment to increase the number of clinical trials and to ensure the UK remains an attractive location for trials to take place, with a view to getting medicinal products licensed in the UK and elsewhere.

In February, Dr Ian Hudson CEO at the Medicines and Healthcare products Regulatory Agency wrote to Dr Wollaston, chair of the Health and Social Care Select Committee about clinical trials.

We are fully committed to continuing a close working relationship with the EU, in the interests of public health and safety.