

# 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.](#)

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## [News story: Carillion contracts complete transfer](#)

The liquidation trading period, which commenced on 15 January 2018, ensured the continued provision of essential public sector services across hospitals, schools, roads, rail and other key infrastructure without any service disruption or major incidents.

Commenting on this milestone, the Official Receiver, Dave Chapman, said:

Carillion is the largest ever trading liquidation in the UK. The continued uninterrupted delivery of essential public services since the company's collapse in January reflects the significant effort put in by its employees, supported by my team and those employed by the special managers.

During this period 83% of the original workforce have either transferred with the contracts or resigned with another job to go to. Staff have been very professional throughout the liquidation and I want to thank them for their support as we worked to find new suppliers.

The focus of the liquidation will now shift to the provision of limited transitional services for some supplier and finalising Carillion's trading accounts to ensure that payment is made to suppliers who have provided goods and services to the various liquidations. Suppliers are asked to ensure they supply their final accounts as soon as possible.

My investigation into the cause of the company's failure, including the conduct of its directors, is also underway.

### **Further information:**

- a further 429 roles have transferred to new suppliers taking the total jobs saved to 13,945 jobs (76% of the pre-liquidation workforce), while

nine staff will leave the business this week taking total redundancies to 2,787 (15%) positions to date. Further information about rights in redundancy is available on [gov.uk](http://gov.uk)

- a further 1,272 employees have left the business during the liquidation through finding new work, retirement or for other reasons
- around 240 core employees are currently being retained to help close out the remaining activities
- the Official Receiver is investigating the causes of failure of the company and has wide-ranging powers to obtain information, material, and explanations

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## [News story: Projects to improve education for children with additional needs](#)

Children taught in alternative provision are set to benefit from new projects to help them fulfil their potential, including work placements, careers advice and behaviour mentoring.

School Standards Minister Nick Gibb today (6 August) announced nine innovative schemes across the country to benefit from a £4million fund to develop new ways of improving alternative provision, to support children educated outside of mainstream or special schools and help them succeed later in life.

Evidence shows children educated in alternative provision are less likely to achieve good GCSE grades and are less likely to be in education, employment or training post-16. The projects announced today aim to tackle these injustices by supporting children back into mainstream education when it is suitable, encouraging parents and carers to be more involved in their child's education, helping young people make good academic progress, and moving on to further education or employment.

From September the projects are set to improve outcomes through literacy and maths tutoring, summer holiday activities to support transition to further education, and the introduction of robots to enable children in hospital to participate virtually in lessons. Other schemes include parent and carer coaching to improve involvement in education and mental health support, helping young people to build positive relationships.

School Standards Minister Nick Gibb said:

Every child, no matter the challenges they face in their life, should have the opportunity to fulfil their potential through an

excellent education. School standards in this country are rising, but for some children – those who are excluded or cannot attend mainstream or special schools – this quality varies greatly, with low expectations about their outcomes and futures.

There are some excellent examples of alternative provision in the education system, but we need to raise standards across the board if we want to give every young person the opportunity to succeed. These new projects, backed by £4 million, will develop new ways of doing this which can be shared around the country, so that we can improve education for every child and make sure they receive support to meet their individual needs.

Dame Christine Lenehan, Director of the Council for Disabled Children, said:

The Council for Disabled Children believes that every child, whatever additional needs they have, should be able to access a good education which supports them to get the best outcomes in adult life. We welcome the Government's renewed focus on children whose needs are not met by the current system, and look forward to seeing how innovative approaches can help turn around alternative provision when it is of poor quality.

The nine projects, spanning the East Midlands, West Midlands, London, East of England, Yorkshire and Humber, South West, and the South East will be funded by the £4 million Alternative Provision Innovation Fund which launched in March 2018.

The projects include:

- Three projects to help get children back into school, led by Bradford Central Pupil Referral Unit, Francis Barber Pupil Referral Unit in London, and Hospital and Outreach Education in the East Midlands.
- Three projects to help young people into further education or employment, led by Cognus in Sutton, Futures Advice, Skills and Employment in Nottingham, and Salford City Council.
- Three projects to support parents and carers to be more involved in their child's education, led by the Anna Freud National Centre for Children and Families in London, The Tutor Trust and Talk Listen Change in Greater Manchester, and Portsmouth Education Partnerships.

The Innovation Fund was launched alongside the Department for Education's vision for reforming alternative provision which outlined steps to improve quality– including reviewing unregistered settings, developing a new framework and making the role of schools, alternative providers and councils clearer in delivering alternative provision.

This is also supported by the ongoing review of exclusions, externally-led by Edward Timpson, exploring how schools use exclusions and why some groups of children are disproportionately excluded from school.

Sir Kevan Collins, Chief Executive of the Education Endowment Foundation, said:

On far too many measures – whether around education, health or employment – outcomes for these young people are poor. These nine new projects provide a much-needed opportunity to focus time and resources on these vulnerable learners. Evaluating these projects robustly – so that we gain evidence and insights to share across the system and spread what is most effective – will be crucial.

Notes to editors:

- The nine projects awarded are to: Cognus; Futures Advice Skills and Employment; Salford City Council; Bradford Central Pupil Referral Unit; Francis Barber Pupil Referral Unit; The Tutor Trust and Talk Listen Change; Hospital and Outreach Education; Anna Freud National Centre for Children and Families; and Portsmouth Education Partnerships. Many of the projects involve working in partnership with other organisations.

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## **[Press release: Joint statement on the re-imposition of US sanctions on Iran](#)**

Joint statement by High Representative Federica Mogherini and Foreign Ministers of E3 (Jean-Yves Le Drian of France, Heiko Maas of Germany and Foreign Secretary Jeremy Hunt:

We deeply regret the re-imposition of sanctions by the US, due to the latter's withdrawal from the Joint Comprehensive Plan of Action (JCPOA).

The JCPOA is working and delivering on its goal, namely to ensure that the Iranian programme remains exclusively peaceful, as confirmed by the International Atomic Energy Agency (IAEA) in 11 consecutive reports. It is a key element of the global nuclear non-proliferation architecture, crucial for the security of Europe, the region, and the entire world. We expect Iran to continue to fully implement all its nuclear commitments under the JCPOA.

The lifting of nuclear-related sanctions is an essential part of the deal – it aims at having a positive impact not only on trade and economic relations with Iran, but most importantly on the lives of the Iranian people. We are determined to protect European economic operators engaged in legitimate business with Iran, in accordance with EU law and with UN Security Council resolution 2231. This is why the European Union's updated Blocking Statute enters into force on 7 August to protect EU companies doing legitimate business with Iran from the impact of US extra-territorial sanctions.



The remaining parties to the JCPOA have committed to work on, inter alia, the preservation and maintenance of effective financial channels with Iran, and the continuation of Iran's export of oil and gas. On these, as on other topics, our work continues, including with third countries interested in supporting the JCPOA and maintaining economic relations with Iran. These efforts will be intensified and reviewed at Ministerial level in the coming weeks.

Preserving the nuclear deal with Iran is a matter of respecting international agreements and a matter of international security.