

# Access Consortium regulators pledge support to tackle COVID-19

## News story

The Access Consortium regulatory authorities have pledged our collective support in countering the COVID-19 global pandemic.



To address this worldwide public health crisis, Access Consortium members are collaborating to advance the regulatory science needed to support the rapid development of diagnostic tests, as well as vaccines and treatments against COVID-19. Members are committed to sharing vital information as we all investigate and evaluate medical products for quality, safety and efficacy, and strive to ensure that the benefits of any new medical product outweigh its risks.

During these unprecedented times, the Consortium is building on its proven ability to benefit from work-sharing that has recently led to the approval of numerous medicines. Consortium members remain committed to review and collaborate on COVID-19 vaccine candidates and treatment options, with the goal of expediting their review and availability on the market. Through this partnership, Access will reduce regulatory duplication and increase each agency's capacity to ensure that, globally, there is access to high-quality, safe and effective solutions to address the COVID-19 emergency.

We remain committed to work together to find innovative solutions to counter COVID-19, the largest, most severe and most complex international disease outbreak in a generation.

## Notes

- The Access Consortium was formed in 2007 by 'like-minded' regulatory authorities to promote greater regulatory collaboration and alignment of regulatory requirements.

- The Consortium was initially formed by the regulatory authorities from Australia (Therapeutic Goods Administration), Canada (Health Canada), Singapore (Health Sciences Authority), and Switzerland (Swissmedic). More recently, the United Kingdom's Medicines and Healthcare products Regulatory Agency joined the Consortium.
- Its goal is to maximise international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products.

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## London office closed

### News story

Customer filing services suspended until further notice.



Following the introduction of new restrictions, as part of the national lockdown in England, the IPO's London office has been closed to all but critical workers with immediate effect.

This means that customers are unable to gain access to file in person. It also means that the London post room is not operating so no paperwork will be processed after today (Thursday 7 January).

If customers need to submit papers by post then Concept House, our Newport office, remains open.

The London office will remain closed at least until 18 February when current restrictions will be reviewed.

If you have any further questions please contact our Information Centre on

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## NHS patients to receive life-saving COVID-19 treatments that could cut hospital time by 10 days

- Patients in intensive care units across the UK are to receive potentially life-saving treatments for COVID-19
- Government ensures life-saving drugs will be available in NHS healthcare settings with immediate effect

Patients across the UK who are admitted to intensive care units due to COVID-19 are set to receive new life-saving treatments which can reduce the time spent in hospital by up to 10 days, the government has announced today (Thursday 7 January).

Results from the government-funded REMAP-CAP clinical trial published today showed tocilizumab and sarilumab reduced the relative risk of death by 24%, when administered to patients within 24 hours of entering intensive care.

Most of the data came from when the drugs were administered in addition to a corticosteroid, such as dexamethasone – also discovered through government-backed research through the RECOVERY clinical trial – which is already provided as standard of care to the NHS.

Patients receiving these drugs, typically used to treat rheumatoid arthritis, left intensive care between 7 to 10 days earlier on average. The rollout of these treatments could therefore contribute significantly towards reducing pressures on hospitals over the coming weeks and months.

Updated guidance will be issued tomorrow by the government and the NHS to trusts across the UK, encouraging them to use tocilizumab in their treatment of COVID-19 patients who are admitted to intensive care units, effective immediately.

Supplies of tocilizumab are already available in hospitals across the UK and clinicians will be able to treat all those admitted to intensive care units, potentially saving hundreds of lives. The department is working closely with Roche, who manufacture tocilizumab, to ensure treatments continue to be available to UK patients.

Health and Social Care Secretary Matt Hancock said:

The UK has proven time and time again it is at the very forefront of identifying and providing the most promising, innovative treatments for its patients.

Today's results are yet another landmark development in finding a way out of this pandemic and, when added to the armoury of vaccines and treatments already being rolled out, will play a significant role in defeating this virus.

We have worked quickly to ensure this treatment is available to NHS patients without delay, meaning hundreds of lives will be saved.

I am hugely proud of the significant role our NHS and its patients have played in this international trial, and grateful to the outstanding scientists and clinicians behind REMAP-CAP who have brought this treatment to our patients.

Deputy Chief Medical Officer Professor Jonathan Van-Tam said:

This is a significant step forward for increasing survival of patients in intensive care with COVID-19. The data shows that tocilizumab, and likely sarilumab, speed up and improve the odds of recovery in intensive care, which is crucial for helping to relieve pressure on intensive care and hospitals and saving lives.

This is evidence of the UK's excellent research infrastructure and life sciences industry advancing global understanding of this disease, which we have done both through our own programme of clinical research and through our ability to make very large contributions to international studies.

In June last year, the UK government approved dexamethasone as the world's first treatment proven to reduce mortality for COVID-19. The REMAP-CAP trial found that the rate of death for those in intensive care units on corticosteroids, such as dexamethasone, and respiratory support alone was 35%, which was reduced to 28% when tocilizumab was also administered.

The government continues to work in partnership to ensure global equitable access to safe and effective treatments. Only multilateral collaboration can deliver at the speed and scale needed to end the global pandemic, and the government remains committed to participating in international trials such as this that seek to answer important questions about the virus.

The UK has played an integral role in these international efforts: three-quarters of patients enrolled globally have been NHS patients, in 142 hospitals across the UK – roughly half of the 289 total sites across the world. A quarter of all patients in intensive care with COVID-19 have enrolled and continue to volunteer to enrol in the REMAP-CAP trial – all of whom have made a vital contribution to the research needed to beat this disease.

Support also came from the UK's National Institute for Health Research (NIHR), its well-established Clinical Research Network and the UK's Chief Medical Officers. The UK government has, to date, provided £1.2 million to support the REMAP-CAP trial.

Professor Stephen Powis, NHS national medical director, said:

The fact there is now another drug that can help to reduce mortality for patients with COVID-19 is hugely welcome news and another positive development in the continued fight against the virus.

This signals how the NHS is working all the time to find new treatments and therapies, but the best advice for individuals is to remember the hands, face, space guidance.

The REMAP-CAP analysis has not yet been peer-reviewed.

Tocilizumab is administered intravenously in a one or two-dose regime. It has been demonstrated to be effective for patients requiring organ support when administered soon after admission to ICU.

Other trials such as the RECOVERY trial are assessing efficacy in wider patient groups outside of intensive care settings, but these are still ongoing. REMAP-CAP has not tested the effectiveness of tocilizumab in primary care settings.

Tocilizumab will be used to further reduce mortality from COVID-19 and in addition to dexamethasone, which is already standard of care for hospitalised patients receiving supplemental oxygen.

Tocilizumab and sarilumab have already been added to the government's [export restriction list](#), which bans companies from buying medicines meant for UK patients and selling them on for a higher price in another country. This will protect supply for UK patients by enforcing regulatory action on those who flout the restrictions.

The REMAP-CAP trial showed that mortality was 35.8% for patients receiving current standard of care alone, and that this was reduced to 27.3% using tocilizumab and sarilumab. This was a 24% relative reduction in risk of mortality for patients who entered intensive care.

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## [Highways England Chair announces](#)

# Acting Chief Executive

Press release

Highways England Chair Dipesh J Shah OBE today announced Nick Harris will be Highways England's Acting Chief Executive from 1 February when Jim O'Sullivan steps down from the role.



Nick Harris, currently the company's Executive Director of Operations, joined the company in 2016. Nick is a civil engineer with extensive experience in delivering multi-million pound infrastructure programmes.

Since joining Highways England in 2016, he has been responsible for the operation and maintenance of our network, including the traffic officers who work around the clock to resolve incidents and protect road users. In this role, he has spearheaded changes in the way we work with our supply chain and introduced innovative ways of working to provide the best possible quality of service to road users and local communities.

Nick Harris is a Member of the Institution of Civil Engineers. His career includes senior roles in water utilities across the UK and overseas.

Dipesh said:

I am pleased Nick has agreed to act as Chief Executive. I'm confident he'll build on the work we have all done since 2015 to make Highways England the successful organisation it is today.

I'd like to thank Jim O'Sullivan for all he has achieved at Highways England. Since he joined the company in 2015 he has been instrumental in so many positive things. He leaves behind a reputation for delivery that is on time and on budget as well as improvements in the culture of customer service and safety that runs through everything we do.

Nick said:

Our road network has always played a vital role in connecting the country and boosting the economy, and now even more so.

I'm delighted to be taking over, as we move into the second year of our second roads programme.

## **General enquiries**

Members of the public should contact the Highways England customer contact centre on 0300 123 5000.

## **Media enquiries**

Journalists should contact the Highways England press office on 0844 693 1448 and use the menu to speak to the most appropriate press officer.

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# **Give schools extra money to let pupils retake school year**

In a statement, the commission outlined its concerns over contingency plans for pupils affected by the global COVID pandemic.

It said: 'We, like teachers and parents across the country, share with the Education Secretary his concerns over young people missing out on education, and deeply regret that schools and colleges are now closed.

The loss of a normal exam season is also unfortunate.

'But exams are only the test of knowledge – the bigger issue is the huge and growing learning loss during a year of massive disruption.

'We need to think far more carefully, moving beyond sticking plaster solutions, and consider options such as allowing some children to retake a year, funded with extra resources.

'The lesson of the pandemic has been that delay is costly. This is as true in education as it is in healthcare. The plans put forward in the statement yesterday are adequate – but they are late, and they are incomplete. In future, we would hope that government and the teaching profession can come together, with mutual trust, to plan effectively and holistically for all eventualities, so that plan A can switch to plan B with the minimum of fuss.

'It is unfortunate that the Education Secretary has not chosen to share with

schools the contingency plans he states he has already made so they could move seamlessly to delivering the necessary teaching, remote or otherwise.

## **Risk of losing motivation**

‘And it is a significant problem that these plans are still not at a stage where teachers can get on with engaging year 11 and 13 students with a deliverable assessment process at the critical point when they are most at risk of losing all motivation.

‘All of this was foreseeable – in fact, we, like many others, called for a clear system of gathering centre assessed grades to be published at the beginning of the academic year- and it is not enough for the secretary of state to say the contingency plans are in operation when they so clearly are not ready yet.

‘When it comes to securing the futures of our most vulnerable children, we support the government’s efforts to ensure quality remote learning. But this needs to be backed up on the ground by speedy distribution of technical resources – both laptops and broadband access.

‘The initiative to make access to education sites free is welcome, as is the content being delivered by the BBC. The use of Ofsted to monitor remote learning, however, must be managed very carefully to avoid either the fact or the impression of being punitive – it has a role, but only to support and share best practices.

‘It is good that pupils without access to devices, functioning high speed broadband, or lack of learning space within the home are now considered vulnerable and are free to go back to school during lockdown. ‘Unfortunately, government has failed to communicate this effectively either to parents or schools and teachers. Efforts must be made quickly and loudly to rectify this.

## **Inequality gap widening by the day**

‘The challenge now lies in two things – the speedy delivery of these promises, and the long-term support of the young people for whom this last year represents a catastrophic disruption in their lives. The inequalities in our schools are widening by the day – not just for those labelled as disadvantaged, but also for those who have huge struggles, both socially and economically, even if they don’t fall into limited and blunt categories like free school meals.

‘Vital steps must be taken now:

- The system for teacher assessment must be communicated to schools as a matter of absolute urgency.
- Those whose learning loss is too significant to make up must be offered the possibility of resit years – and schools and colleges must be funded properly to provide this.
- And Government must convene a new body to plan educational recovery and reassessment over the next five years.



'We cannot look away from the disaster that will unfold if we yet again do not learn our lesson, and yet again fail to plan for the long term. '