

Rt Hon Greg Clark MP
Chair
Science and Technology Committee
House of Commons

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Dear Greg,

Thank you to the Science and Technology Committee for inviting me to attend. I appreciated the opportunity to speak about the challenges facing universities and what the Russell Group is doing to mitigate these as we play our part in helping Britain recover from the crisis.

I hope that we will continue to stay in touch and I, or my colleagues, can join you again in future to update you on the progress being made.

I have consulted with the Russell Group members who are most involved in testing and so offer a summary of their answers as well as an attached case study from UCL.

With 24 members, experiences will vary but all have faced some degree of delay to non-Covid related clinical trials in the face of the pandemic. This is a picture replicated across the Home Nations – though the challenges to research capacity in each of these can differ depending on the amount of support offered by devolved administrations.

Non-Covid trials are now resuming at a variable rate. Most Russell Group members have reported that the majority of clinical trials initially delayed by the pandemic are restarting, though for some members their restart rate is at around 50%. With the very particular role it has played in developing a vaccine, much of Oxford University's capacity is still committed to fighting Covid, so remains especially impacted by a pause in trials for non-Covid research. Indeed, as a result of the considerable resource still being devoted to Covid work, Oxford's ability to prepare for the next REF, due in March, has also been negatively impacted. The university has shared with us concerns that this could then have negative repercussions for their QR funding for a number of years to come, primarily due to the contribution they have made in supporting the UK's Covid response.

A small number of other universities will also have been significantly affected and there is real concern that they too could effectively end up being penalised for doing the right thing. We hope the Government will work with Oxford and other universities to ensure that those who have contributed the most to supporting national efforts are properly recognised in the upcoming Spending Review.

In my own case at the University of Manchester, with the Manchester University NHS Foundation Trust (MFT), 174 studies remained open throughout the pandemic, as they were clinical trials classed as saving life and limb. These studies equated to 30% of clinical trials running at the Trust. Since restart in May, MFT has resumed another 107 clinical trials. In addition to this, another 80 clinical trials are in the process of restarting, although 209 clinical trials are still paused.

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In general, other challenges faced by members when restarting non-Covid research include:

- Sponsors needing to coordinate multiple restarts across UK sites and even internationally
- Nervousness of volunteers to return to a clinical setting and general patient recruitment
- The limitations of virtual engagement over face-to-face sessions
- The challenges of social distancing and additional safety measures
- Limited capacity of specialist staff in high demand areas such as testing and imaging. Many are currently working on Covid-specific projects or supporting the Government test and trace programme.
- Several of our universities are working on developing vaccines and treatments for Covid so for those organisations the pressure to deliver vaccine trials and to prepare for increased clinical Covid workload are important factors when prioritising work

Members have been working hard with NHS and industry partners to get our non-Covid trials open. However, while they have been able to open trials, some have reported challenges in getting patients entered onto them.

Alongside the issue of restarting existing trials, members report challenges of opening new trials which face higher thresholds for approval than they may have done prior to the pandemic because of new Covid-related requirements. This appears to be a particular issue for early phase studies, which are the first steps in trialling new medicines.

Further to this, there are concerns that as we approach the possibility of a second wave, further capacity will once again be necessarily diverted to Covid and additional limitations on activity (such as local lockdowns) may lead to further pauses of clinical trials.

If the UK enters into a second wave, it is suggested that local public health, NHS and university actors are empowered to take decisions at a local level in order to put local patient safety needs first and deploy staff as needed.

I attach a case study from UCL that highlights the challenges faced but also exemplifies the adaptability Russell Group members have shown in rising to the challenge of the pandemic.

If the Russell Group can be of any further assistance, please do not hesitate to say.

Yours sincerely,



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Chair, Russell Group
President and Vice-Chancellor, University of Manchester

Case Study: UCL

We do not consider that there has been an undue delay to the restart of clinical trials at UCL following the initial wave of Covid-19 in the UK, although we acknowledge that it will take time for our clinical trials to return to equivalent levels of patient recruitment that we had prior to the pandemic.

As is the case with all UK universities, most UCL clinical trials and other UCL sponsored clinical studies were paused to new recruitment and the initiation of new studies in March 2020 to create capacity in our partner hospitals for the care of Covid-19 patients, safeguard participants and to enable the establishment of a Covid-19 research portfolio. The exception made by our partner hospital (UCLH) was to enable continued recruitment and initiation to clinical trials and other studies which involve the administration of treatments in life-threatening or serious conditions. Follow-up of participants already recruited onto UCL sponsored trials continued supported by risk assessment and guidance from the MHRA.

Our UCLH/UCL Joint Research Office (JRO) handles the sponsorship and NHS approvals for all our clinical trials and other studies. This integrated NHS-HEI model of research management has enabled UCL to restart its clinical trials portfolio in close alignment with the recovery of clinical services in our partner hospitals. This has been an important feature of our restart strategy.

Having commenced the restart process in June, the majority of the clinical trials portfolio at UCL has now restarted to either new recruitment or on-site follow up. Some studies remain in remote follow-up. Prior to restarting each trial, a comprehensive risk assessment is performed by our JRO and the UCL Clinical Trials Units to assess the impact of COVID-19 and the need for additional Covid-19 mitigations. Our process of reopening trials has been implemented at pace in attempt to enable patients to remain in the trials as it many cases participation in the trials is an important part of patient care, and to keep the trials viable with data continuing to be collected. We also moved at pace in attempt to mitigate any uncertainties related to the availability of funding from grants; some of which have been delayed due to the Covid-19 slow down.

Although, we do not consider that the process of restart has been unduly delayed, we do note some significant complexities and challenges that continue to impact the return to a fully active clinical trials portfolio, including:

Trials considerations:

- Viability of the Investigational Medicinal Product which may have expired during lockdown.
- Additional PPE requirements for staff and patients travelling for site visits.
- The extent to which clinical trial follow up visits to hospital can be converted to remote consultations.
- The need to reassess each component of each trial, including the trial endpoint measurement and the trial design, to ensure required adaptations to the pandemic can be identified and acted upon.
- In some cases, the temporary closure of University laboratories has impacted on the speed of restart.
- The need to retrain trials teams on restart processes and the clinical delivery of trials in the times of Covid-19. Public sector sponsors do not enjoy the same level of resources as commercial sponsors to implement widespread protocol changes and training at speed.
- In some cases, additional funding has had to be sought for costs that were not included in original trial budgets, including for new equipment and processes such as PPE, delivery of IMP via couriers to patients' homes; and patient travel via private transport for clinic visits.

NHS considerations:

- Research delivery resources within the NHS are extremely stretched as NHS Trusts are faced with the competing pressures of staff who are shielding or working remotely; the rate at which staff have been released back from clinical duties to clinical trials/research; and the priority placed on Government prioritised Urgent Public Health studies in Covid-19.
- Recruitment to clinical trials will likely take some time to recover due to the lower footfall of patients in hospitals as society continues to adapt to the Covid-19 pandemic.

- Less of an issue for our largest NHS partner – UCLH – but we are aware that capacity within NHS service support departments (pharmacy, radiology and pathology) has been a challenge for some organisations when restarting studies.
- NHS Trust face a tough capacity challenge balancing the restart of paused studies with the start of new clinical trials and other studies.
- We are aware that uncertainty over future waves of Covid-19 infections, and the impact on the NHS, is a challenge for some of our NHS partners.

In summary, although Covid-19 has had a very disruptive impact on the UCL clinical trials/research portfolio, early initiation of restart planning, adaptation of trials processes, close working with funders, study teams and key stakeholders and crucially our integrated management model, through our Joint Research Office, has enabled us to manage the impact and be poised to ramp up recruitment of patients to our studies as conditions in the NHS permit it.