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Dear colleagues

URGENT ACTION TO ADDRESS THE CURRENT CLINICAL RESEARCH DELIVERY CHALLENGES IN THE NHS

Further to our letter of 17 February 2022, we are writing to update you on revitalising the NHS research portfolio starting with immediate effect. As part of this, we are asking funders and research sponsors to review their portfolios now to take firm action on studies that are struggling to deliver. We recognise, and are very grateful for, the sustained efforts of all involved in research during a time of unprecedented activity. But action is needed to build back a thriving, sustainable and diverse R&D portfolio within the NHS which remains open to new studies, using this opportunity to achieve the ambitions of the [Clinical Research Delivery Vision](#).

Working with a group of expert leaders in R&D, we have developed an approach to managing the research portfolio that will enable recovery of research delivery as soon as possible. Our objective is to give as many studies as possible the chance of completing and yielding results, generating the evidence needed to improve care and sustain our health and care system. However, it will require closure of studies that are not viable in the current context.

We acknowledge that funders and research sponsors already review their portfolio and take decisions on study continuation or closure. In line with good portfolio management, we are asking sponsors and funders to take a critical look at their portfolios based on the following guidance:

1. Studies which have closed to recruitment should complete follow up as planned (as long as achievable within current clinical context).
2. Studies which have achieved 100% of planned recruitment (have met target) but are still recruiting should close to recruitment (as would be expected under ethical approval) and complete follow up as planned.
3. Studies that had difficulty recruiting before the pandemic and have persistent problems should be considered for closure (noting there will be occasions where low recruitment would be expected, such as rare disease studies).
4. Studies which were recruiting well pre-pandemic or have been set up since, but are struggling to meet recruitment targets, should be assessed to determine the major factor in the lack of progress

and whether it can be overcome in the current environment. If there are major issues such as the scientific question no longer being relevant, the delivery plan not being practicable, care pathways having changed or issues with NHS capacity and capability (e.g. limited access to clinical support services and space), then consideration should be given to closure.

5. Studies in set-up, particularly those that have been in set-up for some time, should be assessed to consider whether there are similar issues (as listed in point 4) so these can be addressed before opening.
6. Portfolio review should include patient and public involvement in order to help attend to the health, well-being and experiences of participants in the research and the interests of the relevant public contributors. It should also ensure that learnings from studies that may close are also captured and disseminated in the interests of patients and the public.

Whilst we wish to increase the practicability of studies, this does not mean complex studies that are inherently resource intensive should not proceed; a study can be both resource intensive and practicable. It is essential we maintain a balanced and rich portfolio of studies designed to answer a range of scientific research questions.

We have asked the NIHR Clinical Research Network (CRN) to identify studies that are behind their targets and potentially 'at risk' of closure to recruitment or set-up based on the principles outlined above. NIHR CRN is currently reviewing the integrity of the data on study recruitment to ensure that it reflects the current position. Funders and sponsors are asked to support this process by providing accurate, up-to-date data and to respond promptly to CRN requests on data integrity. This will enable lists of these studies to be shared with funders and sponsors in April.

Availability of both R&D and research delivery staff, including those supported through the NIHR CRN and the wider NHS, will be a major factor in the practicability of studies. Pressures on NHS R&D Departments remain high as they support large portfolios of studies and follow-up activities. Our aim through this work must be to make delivery of the portfolio achievable and sustainable within the resource and capability we currently have in the NHS.

In addition to this request to sponsors and funders, we also ask that NHS sites provide sponsors with realistic assessments of whether they can deliver a study to meet the recruitment targets and timelines indicated. NHS sites are asked not to accept new studies or continue set-up activities if they realistically do not have the capacity to deliver to time and target. We plan to incorporate a new 'deliverability' requirement as part of the eligibility criteria for NIHR CRN portfolio adoption.

We will continue to monitor the situation to ensure we can continue delivering against NHS priorities and ensure the approach is having the intended effect of releasing capacity and making delivery of the remaining portfolio possible. We are also undertaking work to address potential impacts on individual study participants, early career researchers and investigators. The UK remains open for business and committed to supporting commercial clinical studies across all phases, study types and disease areas. We are working with colleagues in ABPI to explore what additional operational and strategic opportunities could be bought to bear to support global commercial studies, in particular.

Whilst we recognise that decisions about individual studies lie with funders and research sponsors and the sites they contract with, we shall seek to move to nationally mandated action if substantial improvements in study delivery cannot be achieved.

We understand this is a challenging moment, but we need to reset and put the NHS R&D system back on course, preserving a world-leading, vibrant and flourishing R&D system in the NHS that gives as many people as possible the opportunity to participate in and benefit from research. It is only by taking this action that we will be able to fully realise the potential benefits for patients and the ambitions set out in the [Life Sciences Vision](#) and [Saving and Improving Lives: The Future of UK Clinical Research Delivery](#).

We have seen how well the system came together to respond to the unprecedented challenge of COVID-19, and we ask you now to come together again and support us in taking this necessary action.

Yours faithfully



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Director of Science, Research & Evidence



Dr Tim Ferris

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