Department of Health & Social Care

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Dear colleagues,

Statement on expediting commercial contract research

In March 2022, the Reset process was launched to help recover the UK's capacity to deliver clinical research in the context of the challenges facing the NHS due to the pandemic. Portfolio data shows increasingly encouraging changes as a result of the actions of sites, sponsors and funders. However, the data demonstrates that commercial contract research is not recovering at the same rate as non-commercial. As of January 2023, commercial contract research makes up 31% of the NIHR CRN portfolio but comprises the majority of studies in set-up (55%) and a disproportionate number of these have passed their planned opening date by a significant period.

To address this, we are asking sites to **expedite the setup and delivery of commercial contract studies with immediate effect.** This aims to clear the backlog of commercial contract studies in setup and make the set-up of studies within globally competitive timelines the norm. For clarity, this should not be interpreted as an ask to take on commercial contract studies which are not viable in the current context. But rather where sites have committed to delivery of commercial contract research, they should take urgent action to fulfil that commitment. We acknowledge a percentage of the delays will be due to delays across regulatory approvals and sponsor side of set-up. Alongside this ask, we will continue work to address the barriers to set-up and delivery with industry and partner organisations including regulatory bodies.

Capacity across the system remains challenging and targeting of resources to meet globally competitive timelines will inevitably impact on sites' ability to do other studies. These pressures further reinforce the need for action on studies which are not progressing. Over 700 studies in Reset have been confirmed as off track but are still ongoing. We ask that **sponsors take immediate action to get these studies on track or, if this is not possible within the current context, close them to recruitment or close them completely**. Continued collective action across the research system, in line with good portfolio management, remains necessary to recover the system and to enable scientifically strong,

deliverable research to be delivered for the benefit of patients and the public. We are grateful for the collective responsibility taken so far to resolve the backlogs in the research portfolio. We have heard that this approach is helping sponsors to assess the progress of their studies in a more proactive way and helping sites to deliver research more effectively. Reset is also helping us to improve our approach to portfolio monitoring underlining our commitment to sustained change which better serves all our partners.

We have asked the CRN to support sites in expediting commercial contract studies, working strategically with partners to identify where CRN resource could be targeted and help to address cross-cutting issues. This may include deployment of agile teams where this would be helpful. Implementation of the National Contract Value Review (NCVR) will also help streamline set-up, reduce the workload for NHS R&D teams and enable a 'no surprises' approach to contract review.

By taking this action now we continue the aim to fulfil the ambitions of the Clinical Research Delivery Vision and build back the thriving competitive life science sector in the UK, alongside the wider portfolio of research funded by government and the charity sector. We recognise, and are very grateful for, the sustained efforts of all involved in research during a time of unprecedented activity.

Prof. Lucy Chappell

DHSC Chief Scientific Advisor

Dr Gail Marzetti

DHSC Director of Science, Research and Evidence

Dr Tim Ferris

NHSE Director of Transformation

Background information and links

Commercial contract research

Commercial contract studies are an essential part of a thriving life sciences ecosystem. Partnering with life sciences industry to deliver their research is critical to develop new medicines and devices for the benefit of patients and the NHS. A strong portfolio of commercial contract research also helps to sustain non-commercial research taking place across the NHS. Delivered on a full cost recovery basis plus a percentage for capacity building, it provides vital income to maintain and grow research delivery in NHS sites.

The global life sciences industry works to fast timelines, and companies aim for all countries in a study to deliver simultaneously. For the UK to be an attractive place to deliver commercial contract studies, we need to meet industry timelines – especially when it comes to regulatory approval, ethics review, and the time it takes to set-up at a site and recruit the first participants.

Timely set-up is now critical to recover and improve the UK's attractiveness as a destination for commercial contract research. The ABPI's recent report 'Rescuing patient access to industry clinical trials in the UK' highlights how far we have fallen behind other countries in the number of studies initiated, with a drop of 44% in commercial clinical trials in the last five years taking us from 4th to 10th in the global standings. The Government's Life Science Competitiveness Indicators 2022 highlight that the time between the first application to a regulatory authority and the first participant receiving a first dose is longer than in the majority of comparator countries, and lengthened between 2018 and 2020. As of November 2022, commercial contract research makes up 31% of the NIHR CRN active portfolio but comprises the majority of studies in set-up (58%). Furthermore, a disproportionate number of commercial contract studies in set-up have passed their planned opening date by a significant period of time. We need change to re-enable the clinical research system to maximise growth and productivity.

Research Reset

- Information on Reset can be found at the Reset section of the RRG website
- The latest data can be found on the Reset Progress Update page.

National Contract Value Review (NCVR)

- The national contract value review (NCVR) is a standardised, national approach to costing for commercial contract research.
- From 1 October 2022 all new commercial research proposals submitted for a study resource review will undergo a review by the lead site. Following this review eligible studies will enter into the NCVR process.
- Eligible studies are all those commercial studies which will be conducted in acute, specialist and mental health trusts in England and counterparts in the devolved administrations, with the exception of phase I – IIa and advanced therapy medicinal product (ATMP) studies. Primary Care settings are not included at this stage.
- Further information is available on the NCVR pages of NHS England's website.