AAC (010)

ACCELERATED ACCESS COLLABORATIVE

RESEARCH UPDATE

Executive summary

Research Activity

- Total research (both COVID-19 and non-COVID-19) activity is higher than pre-pandemic levels, however non-COVID-19 research recruitment remains slower than we would like especially in commercial studies. Some of this may be due to other priorities such as reducing the elective backlog, continuing need to support vaccine and other key COVID-19 studies. In addition, some sites were being asked to stop some recruitment due to the blood sampling tube shortage.

Research Resilience and Growth (RRG):

- The life sciences vision includes the core themes of the clinical research vison published in March which is being implemented through RRG programme. The RRG has been tasked with delivering the vision in 2 key phases. Phase 1 covers this financial year and focuses on recovery of research activity and using the lessons learned from COVID-19 to build back a more resilient research system. The implementation plan was published in June . Planning for phase 2 is underway, activity will depend on the outcome of the CSR.

NHSE/I activity to support RRG

- The cross NHSE/I Research Leadership Group mapping exercise has been completed and analysis is currently underway, this will inform the "NHSE/I research roadmap".
- The NHS excess treatment costs (ETCs) guidance has been published.
- The National Contract Review (NCVR) programme has been restarted following a period of review and refinement.
- Information has been issued to the system to address acute barriers to research caused by:
    - blood tube supply issues
    - lack of ability of Non-NHS or external staff (monitors) to visit NHS provider sites to verify trial data in medical records against the formal trial database.

This paper is for information: AAC Board members are asked to note:

- The publication Research Vision Phase 1 implementation plan
- Progress with NHSE/I led programmes to support research in NHS

Background

COVID-19 Research Activity

1. At the start of the pandemic COVID-19 research studies where badged Urgent Public Health (UPH) COVID-19 studies. Around 80% of these studies have now completed and while there is more we need to learn about COVID-19, future studies will no longer be badged as UPH studies and they will be considered along side other priority research studies.
2. The successful consortium for a new national platform community-based study to research the effectiveness of antiviral therapies will be announced soon.
3. While still important, recruitment into the RECOVERY platform study is low partly because fewer people are being admitted to hospital, and of those that are fewer are eligible for the study.
4. UPH COVID-19 Studies in NHS across the UK have led to policy changes in the way we treat people with COVID-19, including the use of the following treatments:
    - Remdesivir in patients in hospital
    - Dexamethasone in patients in hospital
    - hydrocortisone in patients in hospital
    - Tocilizumab in patients in critical care units
    - Sarilumab in patients in critical care units
    - Budesonide in patients being treated in the community
    - CPAP in patients with acute respiratory failure in hospital

Table 1: Recruitment rates into research between April 2021 and 12 October

Note September figures are incomplete, some studies have still to submit recruitment data

Non-COVID-19 Research Activity

5. Building back non-COVID-19 research continues to be challenging not least balancing a finite research workforce across COVID-19 studies, COVID-19 vaccine and non-Covid-19 research.
6. Total research (both COVID and non-COVID) activity is higher than pre-pandemic, but non-COVID research recruitment remains slower than we would like especially in commercial studies. Some of this may be due to other priorities such as reducing the elective backlog, and balancing the finite research workforce across COVID-19 studies, COVID-19 vaccine and non-COVID-19 research. In addition some sites were being asked to stop some recruitment due to the blood sampling tube shortage (see para 15).
7. In the summer, NIHR published an update relating to managing research recovery for non-COVID-19 studies.They are taking a phased approach to restarting research initially focusing on commercial studies and some priority non-commercial studies. Sponsors were asked to identify their priority studies for research and local NIHR Clinical Research Networks will work with R&D leadership to support this studies through the managed process. Local sites can recruit into other studies based on their local needs and priorities.
8. Between 1 April and 12 October 2021, 232,112 participants (across 7,617 studies) have been recruited into non-COVID-19 studies (an increase of 29,853 in last fortnight) including:

	Type study	Recruitment
Managed Recovery Total 20,938 (+2,084 in last fortnight)	Commercial	325
	non-commercial	20,613 (+2,084 in last fortnight)
Non-managed recovery Total: 211,174 (+27, 769 in last fortnight)	Commercial	7,051
	non-commercial	202,435

9. The number of recruits into the commercial managed recovery is low, many of the studies identified by commercial sponsors and included in the managed recovery process are the most challenging to set up and recruit to, some were having difficulties pre-pandemic, this will be contributing to low numbers. In addition, the implementation of the new process only starting in June and it is taking time to get studies established.
10. ABPI's annual clinical research report (published 29/9/21) demonstrates the exceptional success in the UK of COVID-19 clinical research delivery (1st in Europe and 3rd worldwide, but this is balanced against disruption in other clinical areas, and sector recovery is slower (by some measures) than other key European competitors, meaning fewer opportunities for

patients to participate in research, and less investment into the NHS by commercial partners. In 2020 the UK dropped down the global rankings of the number of commercial clinical trials initiated, at all trial phases.

Research Resilience and Growth (RRG) Programme:

11. The life sciences vision includes the core themes of the clinical research vison and the RRG has been tasked with delivering the vision in 2 key phases.
    - **Phase 1:** Initial work has focused on recovery of research activity and using the lessons learned from COVID-19 to build back a more resilient research system. The implementation plan was published in June and includes NHSE/I lead programmes including some of the activity described below
    - **Phase 2:** Planning for phase 2 is underway and linked to CSR bids via OLS and DHSC, plans will be dependent on the success of those bids.

NHSE/I activity

12. The cross NHSE/I Research Leadership Group mapping exercise has been completed and analysis is currently underway, this will give visibility to support for research across organisation. It will also inform the "NHSE/I research roadmap" which will make the case for research/evaluation in NHS, set out how we as an organisation are supporting research and the action we are committed to take going forward as our contribution to the RRG programme.
13. The NHS excess treatment costs (ETCs) guidance has been published, this document sets out what ETCs are, who is eligible for them and the process for managing these. Responsibility for ETCs will move to ICSs from April, how this will be operationalised is still being discussed.
14. The Research Vision implementation plan reconfirmed the desire to simplify and standardise processes for commercial contract research set up and reporting. The National Contract Review Process (NCVR) had been paused at the start of the pandemic and the work is restarting following a period of review and refinement. The revised principles of NCVR include:
    - NHS Organisations will ensure their current standard organisations-specific tariff is available to inform site identification
    - Industry will be able to compare tariffs across NHS Organisations prior to completion of the iCT in order to select sites

- The Lead NHS Organisation and Industry will work in partnership to undertake a national review to confirm the correct study requirements in the interactive Costing Tool (iCT)

15. The initial guidance to manage the blood tube supply issues did not include research and this caused confusion amongst providers. Some sites were asked to stop recruiting certain studies and others were asked to take fewer samples, which risked the integrity of the study. Interim lines were agreed with the Clinical Reference Group and the updated blood sampling guidance does contain the advice that in the case of shortages of sample tubes research studies should continue to sample as per protocol, clarifying the issue for providers.
16. Initially one of the key barriers to restarting non-COVID-19 research was the lack of ability of non-NHS or external staff (monitors) to visit NHS provider sites to verify trial data in medical records against the formal trial database. We anticipated that this would ease as more services returned to a more normal footing. However, during the summer, a number of sponsors, both commercial and non-commercial were reporting that sites were still not allowing access. After an initial investigation NHSE/I cascaded an operational note to NHS Trusts via the COO's Health Leadership update and the National Incident Response Board's communication system to encourage those involved in decisions about access to NHS facilities to enable the safe access of research monitors to NHS sites.

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