

ACCELERATED ACCESS COLLABORATIVE

RESEARCH RESILIENCE AND GROWTH UPDATE

Executive summary

Research Activity

- Recruitment to UHP Covid Platform trials (e.g. RECOVERY, REM-CAP and PRINCIPLE) has fallen significantly with under 50-80 people recruited a week compared to around 4,000 a week at the height of wave 2. Recruitment into the PRINCIPLE community-based study is of concern.
- Focus for Covid Research is shifting from therapeutics and vaccines to prophylaxis such as antivirals or monoclonal antibodies and Long Covid.
- Recruitment to non-Covid research remains low at around 7000 people a week but numbers of trials restarting is slowly increasing. Action is being taken through the Research Resilience and Growth Programme to support sites and give guidance as they switch back to non-Covid Research.

Research Resilience and Growth (RRG):

- In March the UK government and the devolved administrations launched an ambitious vision to transform the delivery of clinical research in the UK. This is very high level and has 5 key aims and 7 areas of actions.
- A two phase national implementation plan is being developed, an initial phase covering 2021/22 focusing on recovery of non-covid research and a second phase which will set out the longer term plans.

To support the return of non-Covid-19 research, NIHR has published an [update](#) relating to managing research recovery and DHSC has published Managed Recovery Guidance <https://www.nihr.ac.uk/documents/guidance-on-the-managed-recovery-of-the-uk-clinical-research-portfolio/27749>

NHSE/I activity to support RRG

- NHSE/I along with other AAC partners are contributing to the development of the Implementation plan. Phase one of the plan focuses on restarting activity underway or committed to pre-COVID, for example demand signalling.

- A cross NHSE/I Research Leadership Group has been set up to bring together leads with roles/ interest in research and evaluation from across NHSE/I. For the first time this group is mapping research & evaluation related activity across NHSE/I. This will enable us to develop a cross NHSE/I approach to supporting research and evaluation in the NHS. At this stage it is not clear what this planned approach will include nor whether it will lead to a published document. This group will report into AAC through IRLS and further details of the approach will be submitted in the summer.

Board members are asked to note:

- The publication of the research vision and plan to publish an implementation plan on 23rd June
- The creation of the cross NHSE/I research leadership group and the plan to develop an organisational approach to support research in the NHS
- Paper to note, members to email their comments to aac.innovation@nhs.net by 7 July.

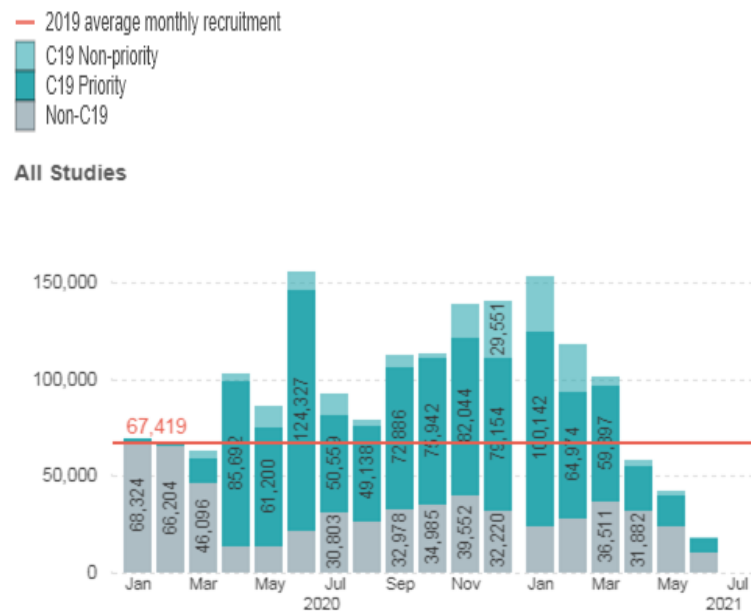
Background

COVID-19 Research Activity

1. At the start of the pandemic NHS research switched to focus on recruiting to Urgent Public Health (UPH) COVID-19 studies and subsequently vaccine studies. In 2020/21 over 1 million people were recruited into COVID-19 studies across the UK and in many hospitals across the country Covid research was embedded in treatment pathways early on, resulting in many more patients getting recruited, speeding up the time it took to get the results of research which led to policy changes in record time; improving survival rates and outcomes, giving hope to patients and healthcare staff not only in the UK but worldwide.
2. At the start of the pandemic a system was set up to prioritise key COVID-19 research studies, over 80 studies were badged Urgent Public Health (UPH) studies, including the 5 Platform studies and the ONS Infection Study (which has recruited over 440,000 healthy volunteers). UPH studies were prioritised for support by NIHR. 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.
3. Unsurprisingly recruitment to UHP Covid Platform trials (e.g. RECOVERY, REM-CAP and PRINCIPLE) has fallen significantly mirroring the fall in COVID-19 cases and the reduced number of people who are requiring hospitalisation. Currently between 50-80 people are being recruited a week compared to around 4,000 a week at the height of wave 2 (see table 1).

4. Continuing to recruitment into the PRINCIPLE community based study remains important as we continue to investigate how best to treat COVID-19 to prevent the need for hospital admission. To date the PRINCIPLE study has recruited over 5000 people, it is a multi-arm study that has changed treatment regimen in primary care by demonstrating positive benefit of Budesonide but equally important the lack of benefit of antibiotics.
5. Currently 2 arms are live researching the impact of Colchicine and Favipiravir, both against standard care. The platform will play a key role in investigating the impact of antivirals already in trial or licenced for other viral infections. The study leads are keen to further increase the diversity of people taking part in the study and currently working with NIHR, NHSE/I and other partners to understand how to do this

Table 1: Recruitment rates into research between January 2020 and 16 June 2021



Non-COVID-19 Research Activity

6. There is no doubt that the pandemic had a very serious impact on non-Covid research, as many routine NHS services were disrupted and in wave one research staff were diverted to frontline care, or UHP COVID-19 studies. Building back non-Covid research has had its challenges not least balancing a finite research workforce across Covid-19 studies, COVID-19 vaccine and non-Covid-19 research.
7. There is evidence that the impact of wave 2 on non-Covid research was not as severe as in wave 1, in January weekly recruitment was around 7-8,000. The rate may be increasing slowly however given the weekly variation in figures it hard to say for definite, however more studies are starting to report being open to recruitment. The reasons for lower recruitment rates are complex and multifaceted including a mix of:

- Research staff having to balance non-covid research with UPH, vaccine and now long-covid studies.
 - The pressures of addressing the backlog in NHS services, front line staff not having the time to think about research
 - The general exhaustion of staff in the NHS
 - Not knowing where to start and which trials to focus on
 - The pressures on some services eg Radiology/Labs and reluctance of the managers of these services to sign up to “additional” work
8. This is being monitored weekly and action is being taken through the RRG programme to support the restart of non-Covid research. NIHR has recently published an [update](#) relating to managing research recovery for non-COVID studies and DHSC has published Managed Recovery Guidance <https://www.nihr.ac.uk/documents/guidance-on-the-managed-recovery-of-the-uk-clinical-research-portfolio/27749>. They are taking a phased approach to restarting research initially focusing on commercial studies and some priority non-commercial studies.

Research Resilience and Growth (RRG) and the National Research Vision:

9. In Autumn last year the cross sector RRG programme was established with membership from Government bodies such as the Office of Life Sciences, Devolved Administrations, NICE, NIHR and MHRA through industry bodies such as ABPI to research funders through AMRC. The aim of this group is to learn from COVID-19 and work collectively to support clinical research in the UK to ensure we continue to be seen as a world leading place to carry out commercial and non-commercial research.
10. In March 2021 the Government published its National Vision For Clinical Research (<https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery>), this sets a clear ambition for research across the UK. This vision is very high level setting out 5 core themes, underpinned by 7 actions (see figure 1) which does not commit to any new activity. The aims are to create:
- Streamlined, efficient and innovative research – so the UK is seen as the best place in the world to conduct fast, efficient and cutting-edge clinical research;
 - Clinical research embedded in the NHS – to create a research-positive culture in which all health and care staff feel empowered to support and participate in clinical research as part of their job;
 - Patient-centred research – to make access to and participation in research as easy as possible for everyone across the UK, including rural, diverse and under-served populations;
 - Research enabled by data and digital tools – to ensure the UK has the most advanced and data-enabled clinical research environment in the world, which

capitalises on our unique data assets to improve the health and care of patients across the UK and beyond; and

- A sustainable and supported research workforce – which offers rewarding opportunities and exciting careers for all healthcare and research staff of all professional backgrounds – across the length and breadth of commercial and non-commercial research.

Figure 1: National Vision for Clinical Research



11. 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 to build back a more resilient research system. Laying the groundwork for future growth – the details are being finalised and the plan will be published on 23 June
- **Phase 2:** Over the summer we will be delivering on the plan but also making detailed plans for the future, which will deliver on our vision and unleash the true potential of UK clinical research

NHSE/I activity

12. Alongside restarting paused programmes such as Horizon Scanning, Demand Signalling and the National Contract Value Review, the research team in IRLS has been actively involved in the RRG and raising the awareness of research across NHSE/I. A fortnightly research activity report is sent to Simon Steven's Office, Amanda Pritchard and other

National Directors, this includes the latest recruitment figures, case studies and impact of COVID-19 research on health policy. It has been well received, raising the awareness of research and starting a dialogue.

13. The research team has held a series of meetings with regional leads and, starting with the North West, they are actively working to support regions develop their understanding of how research fits into the new models of care and ICS landscape – new models of care: new models of research. We are also in early discussions with the North East, London and the South West Peninsular. Each region receives a region specific research activity report on a monthly basis.
14. There are a number of Directorates and teams across NHSE/I who currently have or could have a role in supporting research in the NHS, for example the People Directorate, Nursing and Office of the Chief Scientific Officer. As we consider NHSE/I longer term action to support the RRG and research and evaluation in the NHS more widely, we wanted to ensure we had a cross NHSE/I voice and approach. And so, a cross NHSE/I Research Leadership Group has been established to inform England’s action plan and consider how we could support research and evaluation in NHS more broadly. As it develops it’s plans and implements them this group will report into the AAC via the research update.
15. An NHSE/I mapping process is underway as we do not currently have a clear picture of research and evaluation activity across the organisation. Having this will make our activities more transparent, allow us to demonstrate our collective commitment to improvement through research, as well as identify synergies, gaps and opportunities.

Board members are asked to note:

- The publication of the research vision and plan to publish an implementation plan in June
- The creation of the cross NHSE/I research leadership group and the plan to develop an organisational approach to support research in the NHS
- Paper to note, members to email their comments to aac.innovation@nhs.net by 7 July.

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