

THE RESEARCH RESET PROGRAMME: NEXT STEPS FOR SPONSORS, FUNDERS AND INVESTIGATORS.

Update August 2022

The reason we do research is to generate the evidence patients and the health system needs to provide high quality care and improve outcomes. Since March 2022 partners across the research system have been working on the Reset Programme because the research sector is not achieving this aim.

While we have already seen good levels of engagement, we need collective action to move faster to ensure we can get the research system back 'on track' and we are able to complete the greatest number of studies within the available resources and capacity. This is how we will have the best chance of benefiting patients

This requires collective action across the research system. This bulletin highlights specific actions Sponsors, Funders and Chief Investigators must take now in line with good portfolio management.

Action for Sponsors, Funders and Chief Investigators

Sponsors, Funders and Chief Investigators should immediately:

- Close studies in set-up which have passed their planned opening date by more than 90 days.
- Close recruitment to studies that have not recruited any participants in the last 6 months (unless this is in line with expected recruitment e.g. because the study relates to a rare disease, or the study opened in this period), either moving to follow up or close down.
- Close recruitment to studies that have met their recruitment target in England and move into follow-up.

Sponsors and Chief Investigators will have the most in-depth knowledge of their portfolios and should take action in line with the criteria set out above. To support this DHSC and NHS England have asked NIHR CRN to identify studies that fit into these criteria and NIHR will share that information with sponsors, funders, CTUs and CROs.

DHSC and NHS England have also asked NIHR CRN to identify studies where Sponsors, Funders or CIs have not responded to attempts to contact them for over three months. For these, NIHR CRN portfolio support will be withdrawn, as per the DHSC Portfolio Eligibility policy, once all avenues to attempt contact have been exhausted.

Actions for new study set up

Study sites should consider which studies they have in their portfolios that meet the [HRA eligibility criteria for fast-track ethics review](#). Studies do not need to have gone through the fast-track REC review, but **Sponsors, CIs, CROs or CTUs can carry out a self-assessment** of their eligibility. These should be sequenced first for set-up where capacity is available to deliver new studies.

Data related actions for all

We appreciate efforts across the system to update data held by NIHR CRN to support effective portfolio management and the implementation of Reset and for feedback on the process and App. Acting on this feedback NIHR CRN has updated the Reset App to allow sponsors to indicate that a study is on track to deliver the milestones agreed with funders, and for funders to validate this feedback.

Sponsors should review and update the intentions section within the Reset App to ensure they reflect the latest position. This should be completed for all studies no later than **16 October**.

We need all parties to ensure study data is regularly updated as part of business-as-usual processes. Updating your data as close to in real time as possible it will help ensure the data, we review reflects the status of studies and the system as a whole.

Thank you for your continued support

The actions described above will release resources to enable delivery of other studies, demonstrate progress with Reset and contribute to our aim of supporting as many studies as possible to deliver. It will help ensure that patients can access and benefit from research and evidence that will improve health and care, while also restoring the NHS R&D as a world-leading R&D system.

Alongside this we are undertaking work to learn lessons from Reset to consider how this will inform our strategic approach to managing the research portfolio in a more sustainable and resilient way in future to deliver on the ambitions set out in the [Clinical Research Delivery Vision](#).

The Reset Oversight Group will continue to monitor progress and recommend further action if significant progress is not made. Additional information including the case for change, previous correspondence and progress can be found on the Reset section on the [RRG website](#).

Thank you for your continuing engagement and support with the Research Reset programme. If you have further questions, please contact reset@nihr.ac.uk.

Louise Knowles- Deputy Director
Science, Research and Evidence
Directorate
Department of Health and Social Care



Department
of Health &
Social Care

Lindsey Hughes
Director of Research and Engagement
Innovation, Research and Life Sciences
Group
NHS England



