Changes to the NIHR assessments for the speed of research set-up and delivery: Impact on 2016/17 metrics

This document is jointly produced by NIHR Clinical Research Network (CRN), NIHR Clinical Commissioning Facility (CCF) and the Health Research Authority (HRA). It summarises the position in relation to 2016/17 study set-up and delivery metrics, following changes to both the study approval process and the data collections. It takes an approach of answering a few key questions.

How do the NHS and NIHR report on the speed of research set-up and delivery?

The NIHR focusses the priorities of organisations delivering research in the NHS through two mechanisms involving performance measures:

- The CRN 'High Level Objectives' (HLOs) providing study level information across the CRN portfolio of studies, providing a national view of research delivery and a unique resource for encouraging new research in the NHS.
- The Performance in Initiating and Delivering Clinical Research (PID) exercise – including the 70 day benchmark and recruitment of commercial contract clinical trials to time and target - providing a comprehensive understanding of set-up times and recruitment at a site level, both for portfolio and non-portfolio clinical trials.

	HLOs	**PID**
Scope (Set-up)	All studies in CRN portfolio	All Clinical Trials
Reporting Level	Study	Site

What is the purpose of the benchmark and metrics?

The general purpose is to establish the NHS and the nation as an attractive place to conduct research; stimulating growth and increasing opportunities for patients to participate in research. They demonstrate a level and trend of performance and drive improvement; with each operating through different mechanisms and levers:

- Financial and reputational consequences for providers (70 day benchmark)
- Reputational consequences for providers through the transparency commitment (recruitment to time and target)
- Performance measures for support organisations / networks (CRN HLOs)

Where there are performance issues, the metrics and the associated data sets provide insight into the areas for improvement that might be addressed.

What has changed?

HRA Approval was fully implemented on the 31 March 2016 following a staged roll-out which began in May 2015. As a result, study approval activities and the associated metrics for monitoring set-up times have changed with the removal of the local NHS permission.

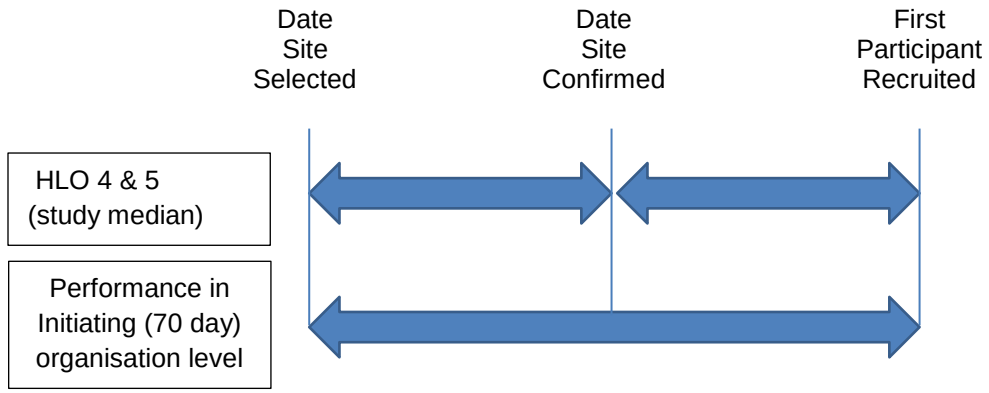
A common minimum data set for study set-up and delivery has been established that feeds both the HLOs and the PID exercise.

How will this affect my NHS organisation?

In support of the new process, the two NIHR set-up and delivery metrics have now been aligned with HRA Approval and with each other, in addition to improvements to remove differing targets and reduce the data collection burden for NHS organisations.

- The **Performance in Initiating (PI)** element of the **PID exercise** measures individual providers of NHS services' performance against a 70 day benchmark from the receipt of a valid research application for provision of NHS Permission (prior to 31 March 2016) or the selection of a site through the sponsor provision of the minimum document set for confirmation of capacity and capability (31 March 2016 onwards) to the recruitment of the first eligible participant into a clinical trial.
- The **HLO4 and HLO5** report on the same overall interval as the 70 day benchmark, but split into two sequential segments to include the date of NHS Permission (prior to 31 March 2016) or the date of confirmation of capacity and capability (31 March 2016 onwards).These measures are given at the overall study level by calculating the median value across all the participating sites.
- The **Performance in Delivery (PD)** element of the **PID exercise** (recruitment to time and target) data collection has been reduced and simplified to only include commercial contract trials closed to recruitment in a rolling 12 month period whilst accommodating ranges for the target number of participants recruited.
- The equivalent **HLO2** measuring delivery to time and target for all CRN Portfolio studies remains unchanged.

Key similarities of set-up metrics:



What impact will this have on my NHS organisation's set-up timelines in 2016/17?

It is anticipated and acknowledged that variation in delivery to these metrics may be reported during this period of transition. In the short term, there may be a number of effects including:

- **Reduced number of reported study and site data** – The HLO reports will only include studies where all participating organisations completed study set-up through the same process, i.e. all issued NHS permission using the system prior to 31 March 2016, or all confirmed capacity and capability using the HRA Approval system. For the PID exercise, organisations will only report their site set-up when the organisation:
    - issued NHS permission for a study (processed through Centralised System for gaining NHS Permission [CSP] or equivalent process outside CSP); or
    - confirmed capacity and capability for a study that received full HRA Approval.

  PID reports do not include cases where an organisation confirms capacity and capability for a study originally processed through pre-HRA Approval systems and only brought under HRA Approval subsequently to add additional sites.
- **Increased set-up time** – real-time applications will be used to determine HRA approval timelines as the process embeds for all parties involved. PID data collection guidance includes specific instructions to explain reporting for clinical trials that have been impacted by HRA Approval timelines to ensure NHS organisations' recruitment performance is not negatively affected during this time.

In the long term, the benefits of the newly aligned and improved data collection include:

- **Single data set** – for all NIHR set-up and delivery metrics to minimise the resource burden of data collection.
- **Comparable metrics** – avoiding differing measures of successful set-up delivery will make it easier to consistently assess the speed and efficiency of research.
- **Realistic reporting** – providing a true timeline for all major start up and delivery activities to facilitate the optimisation of processes.

What does my NHS Organisation need to do now?

NHS organisations are advised to continue to work efficiently and speedily to set up studies, but should not create processes to allow the adjustment of "start" points with the sole interest of meeting targets. Data should be reported accurately and the reasons for timelines documented to provide reliable data to inform future set-up and delivery process optimisations for all.

Where can I get further information?

For further information about the impact of these changes, please contact the R&D department at your NHS organisation, the Clinical Trial Performance team at the Central Commissioning Facility (CTP@nihr.ac.uk) or your supporting Local Clinical Research Network.