Update on Performance in the Initiation of Clinical Research in Relation to the HRA Approval

This note is to confirm the DH position on the performance in the initiation of clinical research from 1st April 2016, following the expansion of HRA Approval to all study types.

For clinical trials going through HRA Approval, a new metric will replace the established 70-day benchmark. The new metric will be drawn from the minimum data set that has previously been agreed collectively between the Health Research Authority (HRA), NIHR Clinical Research Network (CRN) and NIHR Central Commissioning Facility (CCF) and DH – and has been communicated by HRA, CRN and CCF. The new metric will be measured from "Date Site Selected" (i.e. from the date of provision of the local information package by the sponsor including the HRA Initial Assessment Letter) to "Date First Participant Recruited" and the "benchmark" for this interval will initially be set to 70 days, consistent with the benchmark that it supersedes. The new metric is also consistent with the revised NIHR CRN High Level Objectives (HLOs) 4 and 5 for 2016-17. Both metrics use common end points and definitions to provide a site and study level perspective on performance. The targets for the two HLOs combine to an equivalent overall interval, but reflected at a study level. DH reserves the right to adjust the benchmark interval through the experience of collating and analysing the national data and in response to the actual operation of the HRA Approval process.

Clinical trials that are in progress and have already embarked on the NHS Permission / NIHR Coordinated System for gaining NHS Permission (CSP) route will continue to be monitored against the original 70-day benchmark through the established mechanism. Providers of NHS services should continue to utilise the fields available within the submission (delay reasons, delay sources and the comment field) to explain the circumstances of any delay, including where any apparent delay is a consequence of the transition to HRA Approval and closure of NIHR CSP.

NHS providers who would like advice on the capture and reporting of Performance in Initiating and Delivering Clinical Research should consult the relevant guidance material at http://www.nihr.ac.uk/policy-and-standards/Performance-in-initiating-and-delivering-research.htm or contact the CCF Clinical Trial Performance team at CCF: ctp@nihr.ac.uk