The NIHR Performance in Initiating and Delivering Clinical Research (70 day benchmark) and the NIHR Clinical Research Network High Level Objectives: a description of purpose, definition and differences

Introduction

This document explains the main differences between two sets of performance metrics:

1. The NIHR Performance in Initiating and Delivering Clinical Research exercise, relating to the 70-day benchmark and delivery of trials to time and to target by individual providers of NHS Services which have entered into a contract with NIHR since Autumn 2011; and,

2. The NIHR Clinical Research Network (CRN) High Level Objectives (HLOs) which relate to the initiation and delivery of clinical research studies included on the NIHR CRN Portfolio.

What are the NIHR Performance in Initiating and Delivering Clinical Research metrics and why have they been introduced?

The Government wishes to see a dramatic and sustained improvement in the performance of providers of NHS services in initiating and delivering clinical research. The Performance in Initiating and Delivering Clinical Research metrics, announced in the Government’s Plan for Growth\(^1\), require providers of NHS services to submit performance data on a 70-day benchmark to recruit first patients into clinical trials. They also include the Performance in Delivery exercise, which measures delivery of commercial contract trials to time and target so the incentive for trusts to set up studies quickly is balanced with an incentive that trusts will not do so without proper feasibility and then fail to deliver. Submission by providers of NHS services\(^2\) of data on their performance against these benchmarks has been a condition of all new NIHR contracts since Autumn 2011. The NIHR Performance in Initiating and Delivering Clinical Research exercise encourage accountability for performance in the initiation and delivery of clinical trials within individual providers of NHS services.

What are the NIHR CRN High Level Objectives?

The NIHR CRN High Level Objectives are the CRN’s agreed performance objectives for CRN activity. The High Level Objectives include targets to increase the proportion of studies in the NIHR CRN Portfolio that deliver to their planned recruitment time and target, to reduce the time taken to achieve NHS permission through the Coordinated System for gaining NHS Permission (CSP), and to reduce the time taken to recruit first participants into NIHR CRN Portfolio studies. They were introduced in April 2010. The CRN High Level Objectives encourage improved performance across whole clinical research studies, which are likely to be taking place across several providers of NHS services.

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2. [http://www.nihr.ac.uk/systems/Pages/ClinicalTrialPerformance.aspx](http://www.nihr.ac.uk/systems/Pages/ClinicalTrialPerformance.aspx)
Do the NIHR Performance in Initiating and Delivering Clinical Research exercise and the NIHR CRN High Level Objectives share the same aims?

Yes, both sets of performance metrics share the same overall aims, which are to increase the number of patients able to participate in research and enhance the nation’s attractiveness as a host for research. The two sets of metrics complement each other: the NIHR Performance in Initiating and Delivering Clinical Research encourages accountability within individual providers of NHS services, while the CRN High Level Objectives encourage improved performance across whole studies.

However, there are several key differences between them which are outlined below.

What are the main differences between the NIHR Performance in Initiating and Delivering Clinical Research and the CRN High Level Objectives?

The focus of the NIHR Performance in Initiating and Delivering Clinical Research is within individual providers of NHS services. The focus of the NIHR CRN High Level Objectives is on the performance of entire clinical research studies included on the NIHR CRN Portfolio.

Further important differences between the two sets of metrics:

1) Inclusive research

<table>
<thead>
<tr>
<th>NIHR Performance in Initiating and Delivering Clinical Research</th>
<th>Data is collected for clinical trials only, as described in the first four definitions of question 2 of the IRAS Filter, regardless of funder or inclusion in the NIHR Portfolio.</th>
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<tbody>
<tr>
<td>NIHR CRN High Level Objectives</td>
<td>Apply to all studies that are processed through the NIHR CRN systems and apply to all types of research that are eligible for CRN support and included in the NIHR Portfolio, not just Clinical Trials of an Investigational Medicinal Products (CTIMPs).</td>
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2) Two separate data collections

<table>
<thead>
<tr>
<th>NIHR Performance in Initiating and Delivering Clinical Research</th>
<th>Submitted directly from NHS Provider to the NIHR Central Commissioning Facility (CCF) on a quarterly basis, via the Clinical Trials Performance Submission Platform.</th>
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<tbody>
<tr>
<td>NIHR CRN High Level Objectives</td>
<td>Performance data on the HLOs are collected on an ongoing basis via the NIHR CRN information systems.</td>
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3) Comparing and contrasting the NIHR Performance in Initiating and Delivering Clinical Research and 40 and 30 day High Level Objective Targets: Measurements start points, clock-stopping and end points

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<tr>
<th>Measurements</th>
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| NIHR Performance in Initiating and Delivering Clinical Research | a) The Performance in Initiating (70-day) benchmark is a single measure taken from the date of receipt of Valid Research Application to the date of First Patient Recruitment. Measures performance at an individual provider of NHS Services. Data collection does include time taken to gain NHS Permission, but this does not constitute a separate benchmark.  
  b) Measuring performance at individual providers of NHS services. |

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**NIHR CRN High Level Objectives**

| | a) Include two separate targets: firstly, a median target of 40 days for the time taken for an NIHR CRN study to achieve NHS Permission at all sites; secondly, a target of 30 days for time taken to recruit a first patient in to an NIHR CRN study once Permission has been issued.  
| | b) Measuring performance across a whole study. |

### Start-points

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<thead>
<tr>
<th><strong>NIHR Performance in Initiating and Delivering Clinical Research</strong></th>
<th>For CSP studies, the start point metric is the date of receipt of Valid Research Application (Site Specific Information and associated documents) for local review. For non-CSP studies, the start point is the receipt of an entire Valid Research Application package, as described on the associated IRAS Checklist.</th>
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| **NIHR CRN High Level Objectives** | The start point of the HLO4 metric, relating to the median time taken across all sites to achieve NHS Permission through CSP is the receipt of the Valid R&D Submission. |

The CRN’s High Level Objective 4, “reduce the time taken to achieve NHS permission through CSP for NIHR studies”, captures *all* applications received through CSP, which also includes BRC, BRU and CLAHRC studies.

Eligibility of research studies for inclusion on the NIHR CRN portfolio and thus access to CSP are defined at [http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_eligibility](http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_eligibility)

### Clock-stopping

<table>
<thead>
<tr>
<th><strong>NIHR Performance in Initiating and Delivering Clinical Research</strong></th>
<th>There is no ‘clock-stopping’ for NIHR Performance in Initiating and Delivering Clinical Research. The NIHR understands that, especially at the beginning of the exercise, there will be a number of reasons why the Performance in Initiating (70-day) benchmark is not met. Providers of NHS services are therefore asked to provide explanation as to the nature of delays to initiation of clinical trials that do not meet the benchmark.</th>
</tr>
</thead>
</table>

| **NIHR CRN High Level Objectives** | The NIHR CRN High Level Objectives include ‘clock-stops’, as these objectives aim to exclude factors that are completely outside the CRN’s remit; for example the time from NHS permission to first Network Site Initiation Visit for commercial contract studies. |

### End-points

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<thead>
<tr>
<th><strong>NIHR Performance in Initiating and Delivering Clinical Research</strong></th>
<th>For the 70-day benchmark, the end point is the date of First Patient Recruitment. The date of First Patient Recruitment means the date that the first patient (or legal representative) provided informed consent, as recorded on the associated informed consent form.</th>
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| **NIHR CRN High Level Objectives** | The High Level Objective relating to the recruitment of the first patient is measuring performance across a whole study, so the end point of the metric is the date that the first patient is recruited to the whole study, across all sites. The date of first patient recruitment means the date that the first patient consented to the study. |

### 4) Delivering Clinical Research for NIHR Performance in Initiating and Delivering Clinical Research and Recruitment to Time and Target for NIHR CRN High Level Objectives

| **NIHR Performance in Initiating and Delivering Clinical Research** | The initial focus is on commercial contract clinical trials. The NIHR CCF collects performance data from providers of NHS services on recruitment to time and target for every... |
NIHR CRN High Level Objectives

commercial contract clinical trial which the provider has hosted within the previous 12 months.

NIHR CRN High Level Objectives

The NIHR CRN collects performance data on recruitment to time and target for all commercial contract and non-commercial studies in the NIHR CRN Portfolio which started on or after April 1st 2010 (HLO2).

5) Excluded research

NIHR Performance in Initiating and Delivering Clinical Research

Data is not collected for any studies other than clinical trials, as described in the first four definitions of question 2 of the IRAS Filter.

NIHR CRN High Level Objectives

Certain studies are excluded from the measurement, with the aim of eliminating factors completely outside the control of the NIHR CRN. For example, commercial contract studies which are terminated by the sponsor for safety issues.

Can data collected NIHR CRN High Level Objectives also be used for reporting to the NIHR CCF on the NIHR Performance in Initiating and Delivering Clinical Research?

The NIHR Performance in Initiating and Delivering Clinical Research and the NIHR CRN High Level Objectives measure separate aspects of clinical research, however some of the data points may overlap. It is important to note that the NIHR CRN High Level Objectives only apply to Portfolio studies which are processed through CSP and therefore the data collected for these measures is not comprehensive enough to provide the full dataset required for the NIHR Performance in Initiating and Delivering Clinical Research data which covers both Portfolio and Non-Portfolio studies.

When collating returns to CCF, providers of NHS services can use relevant NIHR CRN High Level Objective data points for those studies processed through CSP to contribute to the data submission for calculation of the NIHR Performance in Initiating (70-day) benchmark: for example, the time to complete local processes and issue permission.

Dates for the first patient recruited at individual sites for studies on the NIHR CRN Portfolio are not currently collected in national NIHR CRN information systems to enable use by providers of NHS services. This is because the NIHR Performance in Initiating and Delivering Clinical Research metrics are currently collected by CCF on an individual provider of NHS services basis, whereas the CRN HLOs are recorded in CRN information systems on a whole study basis.

Where are the NIHR Performance in Initiating and Delivering Clinical Research Data and the NIHR CRN High level objectives published?

The NIHR Performance in Initiating and Delivering Clinical Research data is published by each provider of NHS services with a relevant NIHR Contract on their own website. There is a minimal data set which must be published at the end of each quarter. The latest list of providers of NHS services can be accessed via the NIHR website at:
http://www.nihr.ac.uk/systems/Pages/ClinicalTrialPerformance.aspx

The CRN High Level Objectives are published in quarterly performance reports written by the Clinical Research Network and can be accessed via the Coordinating Centre Website at:
http://www.crncc.nihr.ac.uk/about_us/performance_objectives.htm
Figure 1: Differences between the NIHR Performance in Initiating (70-day) benchmark and the CRN High Level Objectives.

Performance in Initiating (70-day) benchmark

- Receipt of Valid Research Application
- NHS Permission from providers of NHS services
- First subject recruited at site
- Trial recruitment closes

NIHR CRN High Level Objectives

HLO #4: 40 days (Median)
- Receipt of valid R&D submission for study
- NHS Permission at all sites (median)

Start point: Day 0
End-point: Day 40

HLO #5: 30 days
- First Network site NHS Permission or Site Initiation Visit
- First subject recruited into study

Start point: Day 40
End-point: Day 70

HLO #2: Study specific recruitment target in planned recruitment period
- First subject recruited into study
- Trial recruitment closes – time and target met?

Start point: Day 70
End-point: Day X

NIHR Metrics Comparison v2.0 November 2013