

Trust Board Meeting: Wednesday 13 November 2013

TB2013.128

Title	Performance on Initiating Trials
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Status	For information
History	This paper updates the Trust Board on the performance of the Trust with regard to achieving compliance with NIHR Metrics for clinical research.

Board Lead(s)	Professor Ted Baker, Medical Director			
Key purpose	Strategy	Assurance	Policy	Performance

Executive Summary

1	The Government's Plan for Growth, published in March 2011, aims to increase efficiency in initiation and delivery of clinical research, focusing on recruitment of the first patient to clinical trials within 70 days of receiving a valid protocol; and delivery of commercial clinical trials to time and target.
2	The current assessment of performance indicates that the Trust does not fully meet the standards set by the National Institute for Health Research, although some improvement is seen.
3	The Trust is now required to publish its performance in a readily accessible page on its website. The first publication is appended to this paper.
4	A critical review of roles and processes within the R and D Team has identified areas where improvements will support improved compliance. There is a need for Divisional Research Leads to support improved management of research performance.

Recommendations

The Trust Board is asked to

- Note the contents of this briefing note and the Trust's current performance against the NIHR Metrics for clinical research.
- Support the proposal to incorporate performance against these metrics into Trust reporting at Divisional and Executive level.

Briefing Note on NIHR Reporting of R&D Metrics

1. Background

- 1.1. The Government's Plan for Growth, published in March 2011, aims to increase efficiency in initiation and delivery of clinical research, focusing on recruitment of the first patient to clinical trials within 70 days of receiving a valid protocol; and delivery of commercial clinical trials to time and target.
- 1.2. NIHR has placed renewed emphasis on reporting metrics for the approvals and initiation of clinical studies, which will be used for monitoring the R&D performance of NHS Trusts. Attainment of key metrics is a requirement for NIHR funding, including BRCs/BRUs, and performance metrics are published for each NHS Trust receiving NIHR funding.
- 1.3. The fifth set of required data was submitted on 30th July 2013. A summary of this submission is provided in Section 2. Similar reports will be submitted to the Trust Management Executive on a quarterly basis, with a recommendation that regular reports are submitted to the Trust Board.
- 1.4. In the interests of transparency, the Trust is now required to publish the information regarding its performance to these metrics in a readily accessible page on the website. The first publication deadline was on 30th July 2013. A copy of this publication is appended to this paper.

2. Summary of Performance for Q1 2013/2014

2.1. Data completion

- 2.1.1. A full set of data was obtained and submitted within the specified timelines.

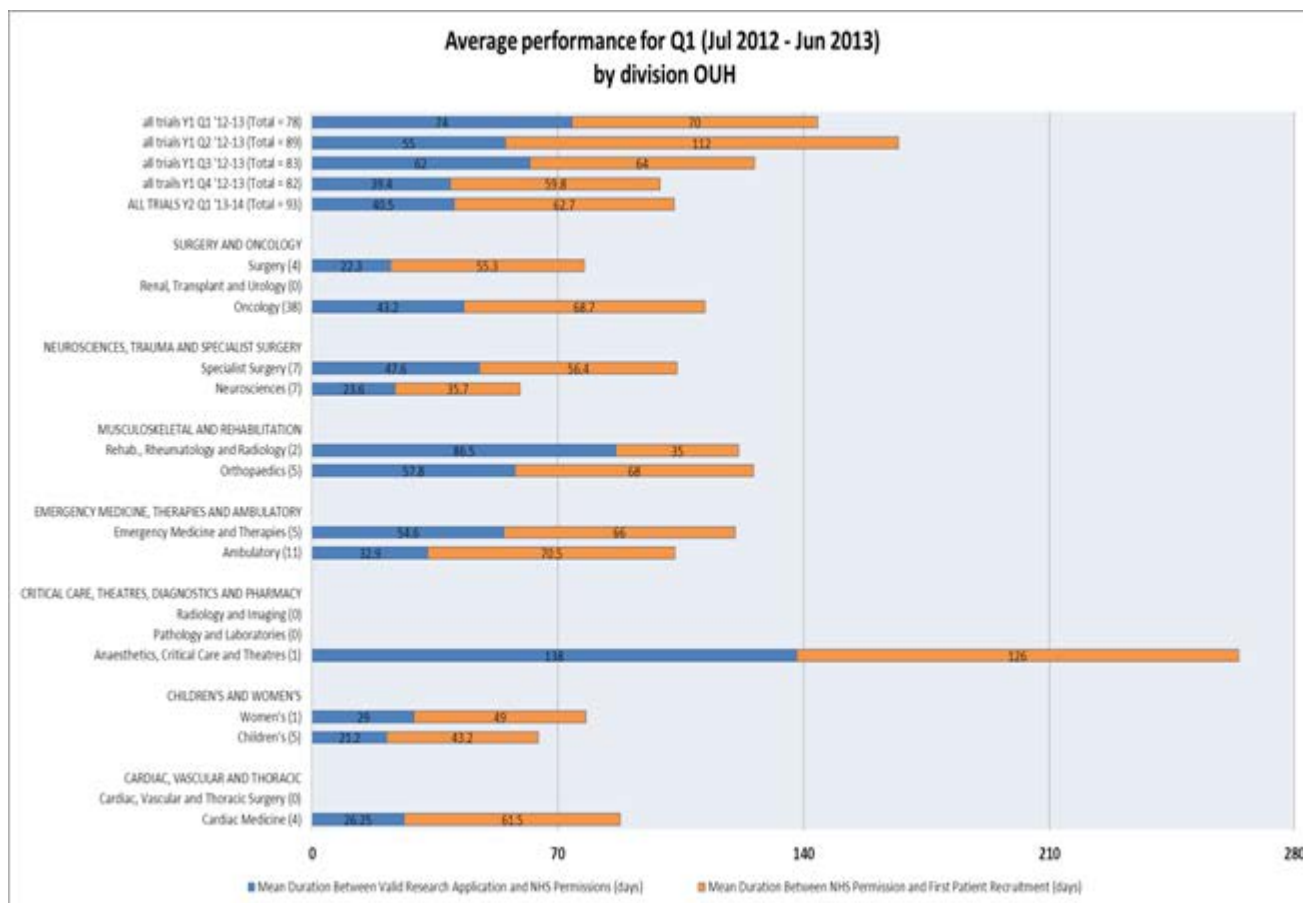
2.2. 70 day Benchmark

- 2.2.1. Average performance by Division is presented in Figure 1
- 2.2.2. This metric applies to all interventional trials and relates to the time taken to set up a study and grant permission within a Trust (target 30 calendar days); and, once that permission has been granted, the time by the investigator team to recruit the first patient (target 40 calendar days).
- 2.2.3. Since the beginning of the reporting period, the percentage of studies meeting the target timelines has shown gradual improvement.

	% meeting benchmark
Q1 12/13	13.5
Q2 12/13	24.7
Q3 12/13	23.6
Q4 12/13	20
Q1 13/14	27.7

2.2.4. Reasons for failure to meet these targets are largely through failure to identify eligible patients; suggesting a lack of readiness or capacity for conducting the research. Recruitment of the first patient remains a challenge that needs to be addressed on a Trust-wide basis.

Figure 1



2.3. Commercial Trials' Recruitment to Time and Target

2.3.1. This metric applies to trials with a commercial sponsor and relates to recruitment numbers within the time period specified in the contract.

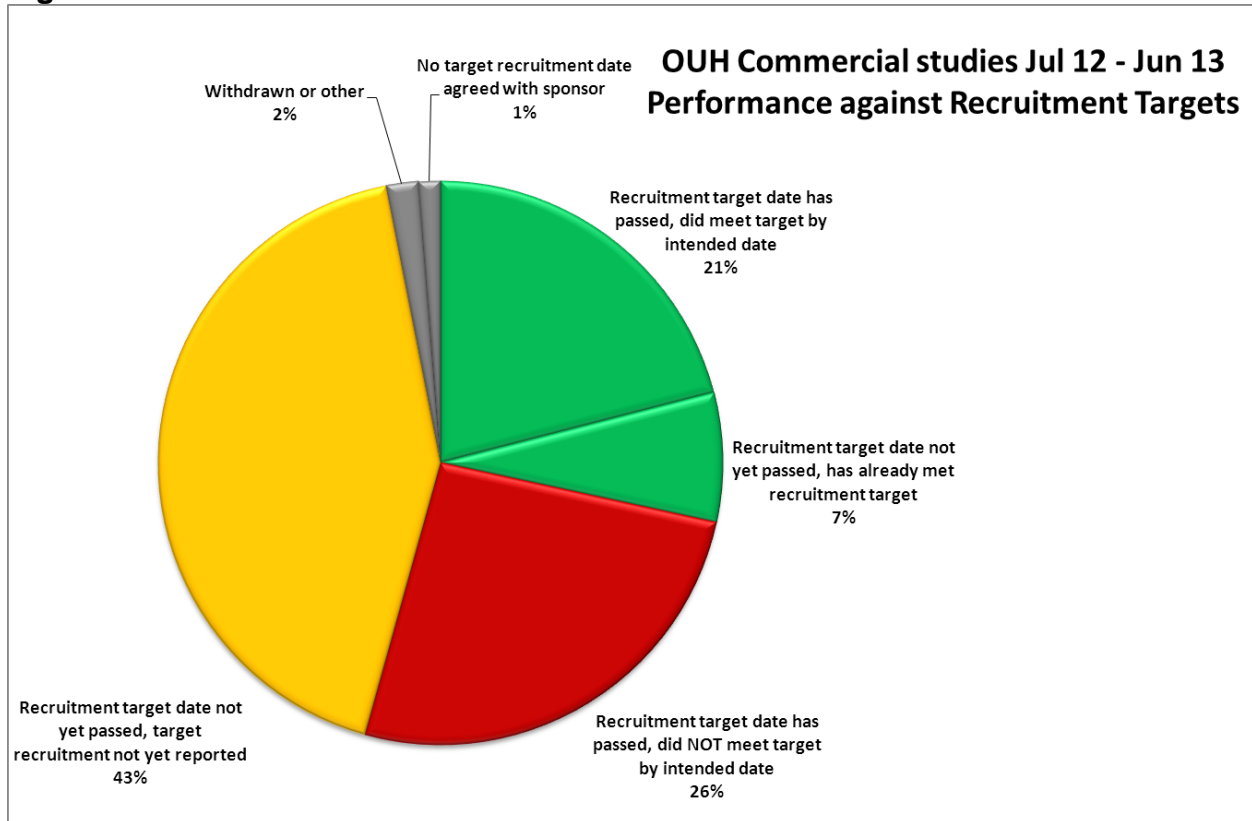
2.3.2. The number of trials reaching target recruitment by or before the target date has shown no real improvement over the past three quarters.

	Number of reported trials	% meeting recruitment target
Q3 12/13	150	46.6
Q4 12/13	157	52.3
Q1 13/14	162	50.5

2.3.3. From Q3 12/13, a marked change in reporting requirements and criteria was introduced, making comparison between the first two quarters and later ones difficult, as they lack equivalence, with approximately 100 extra trials reported in Q3 12/13, these figures have not been included within this table.

2.3.4. The R&D Governance team are focusing attention on the identifying those trials where performance must be addressed to achieve compliance. Figure 2 provides a breakdown of the current situation.

Figure 2



3. Summary and Recommendations

3.1. The Trust Board is asked to note the current performance of the Trust and, in particular, the new requirement to publish performance on the website.

3.2. The Board is also asked to note that the Trust Management Executive are fully appraised of this performance data and are working with the OUH R&D Director to implement performance enhancing measures.

3.3. Such measures will include, but are not limited to, the following:

- Improvement of Joint Research Office systems to support research applications.
- Divisional engagement with R&D metrics being embedded in local performance measurements.

- Applications for NHS permission for future applications will be considered in the light of the previous success of a Principle Investigator.

3.4. In addition, Divisions are in the process of identifying dedicated R&D leads to assist in meeting the required targets.

Professor Edward Baker
Medical Director

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