Trust Board Meeting: Wednesday 8 July 2015
TB2015.94

<table>
<thead>
<tr>
<th>Title</th>
<th>NIHR Reporting of R&amp;D Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td>A paper for information</td>
</tr>
<tr>
<td>History</td>
<td>The Trust Management Executive received an update on the performance of the Trust with regard to achieving compliance with NIHR Metrics for clinical research at its meeting on 25 June 2015 (TME2015.160).</td>
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<tr>
<td>Board Lead(s)</td>
<td>Dr Tony Berendt, Medical Director</td>
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<tr>
<td>Key purpose</td>
<td>Strategy</td>
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</tbody>
</table>
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 is now largely achieving the standards set by the National Institute for Health Research for initiation of research, although improvement is still required in meeting the standards of delivery of research to time and target.

3. The Department of Health threatened the imposition of financial penalties on Trusts failing to meet the initiation targets by withholding NIHR funding. Trusts achieving less than 50% performance at Q2 14/15 and failing to demonstrate an improvement of more than 5% since Q4 13/14 were isolated to receive a 5% cut in Research Allocation Funding for 2015/16. Due to consistent improvement in performance, it has been confirmed Oxford University Hospitals will not be suffering any financial penalty for 15/16.

4. The Department of Health has stated that similar financial penalties will still be a possibility for the 2016/17 RCF allocation, though this remains unconfirmed.

Recommendations

The Trust Board is asked to

- Note the steady improvement in Trust performance, surpassing the minimum improvement expectations of the Department of Health.
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. It was stated that from 2013 there would be funding implications for underachieving Trusts.

1.2 The NIHR has placed renewed emphasis on reporting metrics for the approvals and initiation of clinical studies, which are 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 submission of data to NIHR for Q3 2014/2015 has been analysed by NIHR, against the data submitted 6 months before. The focus of this analysis was on the first metric, outlined in 2.2 below.

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.

2. Summary of Performance for Q3 2014/2015

2.1 Data completion

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

2.2 70 day Benchmark

2.2.1 This metric applies to all interventional trials and relates to the time taken to set up a study and grant permission within a Trust; and, once that permission has been granted, the time by the research team to recruit the first patient (with a combined target of no more than 70 calendar days).

2.2.2 Data submitted is assessed and ‘adjusted’ according to the reasons provided for not meeting the benchmark. For example, if a trial involving rare diseases fails to recruit to the benchmark, this reason is deemed by NIHR to be acceptable and is therefore ‘adjusted’ out of the performance data.

2.2.3 R&D staff work with study teams to ensure that they recruit within the required timescale prior to each NIHR submission.

In the previous Quarter’s analysis, all ‘delay reasons’ offered by OUH were accepted. This contrasts with the national landscape which saw 124 such reasons queried by the NIHR.

This is indicative of the data quality now being provided by R&D as well as the enhanced communication channels, opened and maintained across departments, and the diligence with which these reasons are verified.
2.2.4 Table 1 shows this ‘adjusted’ performance and demonstrates a significant improvement. It should be noted that Q4 14/15 has not yet been assessed and verified by NIHR and is not included in Table 1.

In the context of National NHS performance, for the year to Q3 (1st January 2014 – 31st December 2014) OUH had the second highest percentage of adjusted trials meeting the benchmark, 95%.

Whilst this increase is likely to plateau due to the high percentage now achieved, it is considered to be a sustainable level of performance – reflecting the processes and tools which have driven the observable improvement.

Table 1

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Unadjusted % meeting benchmark</th>
<th>Adjusted % meeting benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2 13/14</td>
<td>19.4</td>
<td>-</td>
</tr>
<tr>
<td>Q3 13/14</td>
<td>21.7</td>
<td>34.7</td>
</tr>
<tr>
<td>Q4 13/14</td>
<td>25.9</td>
<td>42.4</td>
</tr>
<tr>
<td>Q1 14/15</td>
<td>30.6</td>
<td>53.3</td>
</tr>
<tr>
<td>Q2 14/15</td>
<td>42.2</td>
<td>70.3</td>
</tr>
<tr>
<td>Q3 14/15</td>
<td>54.2</td>
<td>95.0</td>
</tr>
<tr>
<td>Q4 14/15</td>
<td>55.1</td>
<td>xxx</td>
</tr>
</tbody>
</table>

2.2.3 Figure 1a shows the overall mean Trust performance, broken down as ‘time to TMA’ followed by ‘time to first patient recruited’ for this unadjusted data, by Quarter. The total mean continues to decrease and is below the 70 day benchmark.

2.2.4 Figure 1b shows the same data for the current Quarter, broken down by Division and Directorate.

2.2.5 As a result of careful streamlining of processes, the average timelines from valid research application to granting trust approval of an interventional project have been reduced to a current mean in March of 3.6 days. This provides researchers with more time to achieve first patient recruitment.
**Figure 1A - Mean OUH performance by quarter (for studies granted TMA in 12 months to Quarter's end)**

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Mean Duration Between Valid Research Application and NHS Permission (days)</th>
<th>Mean Duration Between NHS Permission and First Participant Recruited (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All studies</td>
<td>112</td>
<td>64</td>
</tr>
<tr>
<td>Q1'12-'13</td>
<td>62</td>
<td>64</td>
</tr>
<tr>
<td>Q2'12-'13</td>
<td>59.8</td>
<td>64</td>
</tr>
<tr>
<td>Q1'13-'14</td>
<td>62.7</td>
<td>62.7</td>
</tr>
<tr>
<td>Q2'13-'14</td>
<td>60.3</td>
<td>59.8</td>
</tr>
<tr>
<td>Q3'13-'14</td>
<td>51.4</td>
<td>55.2</td>
</tr>
<tr>
<td>Q4'13-'14</td>
<td>47.7</td>
<td>53.8</td>
</tr>
<tr>
<td>Q1'14-'15</td>
<td>41.4</td>
<td>65.9</td>
</tr>
<tr>
<td>Q2'14-'15</td>
<td>24.8</td>
<td>61.5</td>
</tr>
<tr>
<td>Q3'14-'15</td>
<td>13.3</td>
<td>53.2</td>
</tr>
<tr>
<td>All studies</td>
<td>6.7</td>
<td>51</td>
</tr>
</tbody>
</table>

Mean Duration Between Valid Research Application and NHS Permission (days) Mean Duration Between NHS Permission and First Participant Recruited (days)
Figure 1B - Mean OUH performance by division Q4 2014/15 (for studies granted TMA Apr 14- Mar 15)

- ALL STUDIES LAST QUARTER, Q4 ’14-15 (127)
  - Mean Duration Between Valid Research Application and NHS Permission (days): 51
  - Mean Duration Between NHS Permission and First Participant Recruited (days): 89.3

- SURGERY & ONCOLOGY (68)
  - Gastroenterology, Endoscopy and Churchill Theatres (8)
    - Mean Duration Between Valid Research Application and NHS Permission (days): 33.7
    - Mean Duration Between NHS Permission and First Participant Recruited (days): 46
  - Transplant Renal & Urology (8)
    - Mean Duration Between Valid Research Application and NHS Permission (days): 24.7
    - Mean Duration Between NHS Permission and First Participant Recruited (days): 63.1

- Oncology & Haematology (49)
  - Mean Duration Between Valid Research Application and NHS Permission (days): 61.5
  - Mean Duration Between NHS Permission and First Participant Recruited (days): 87.3

- NEUROSCIENCES, ORTHOPAEDICS, TRAUMA &...
  - Specialist Surgery (3)
    - Mean Duration Between Valid Research Application and NHS Permission (days): 35
    - Mean Duration Between NHS Permission and First Participant Recruited (days): 10.8
  - Neurosciences (7)
    - Mean Duration Between Valid Research Application and NHS Permission (days): 51.4
    - Mean Duration Between NHS Permission and First Participant Recruited (days): 87.3

- CHILDRENS & WOMENS (12)
  - Mean Duration Between Valid Research Application and NHS Permission (days): 45.5
  - Mean Duration Between NHS Permission and First Participant Recruited (days): 65

- CLINICAL SUPPORT SERVICES (3)
  - Mean Duration Between Valid Research Application and NHS Permission (days): 64.3
  - Mean Duration Between NHS Permission and First Participant Recruited (days): 61.7

- Pathology & Laboratories (3)
  - Mean Duration Between Valid Research Application and NHS Permission (days): 56.3

- MEDICINE, REHABILITATION & CARDIAC (31)
  - Cardiology, Cardiac & Thoracic Surgery (13)
    - Mean Duration Between Valid Research Application and NHS Permission (days): 46.7
    - Mean Duration Between NHS Permission and First Participant Recruited (days): 33.7
  - Ambulatory Medicine (13)
    - Mean Duration Between Valid Research Application and NHS Permission (days): 35.5
    - Mean Duration Between NHS Permission and First Participant Recruited (days): 89.3

- Anaesthetics, Critical Care & Theatres Clinical...
2.2.6 In the context of overall performance, Figure 2 shows the mean times between receiving a valid research application to granting of NHS permission, by month, for all research studies (interventional or non-interventional), regardless of whether they are NIHR Portfolio trials.

2.2.7 Despite the current high-level performance, sustained identification and successful recruitment of eligible patients will remain a challenge. The importance of maintaining improved performance has been communicated on a Trust-wide basis. JRO staff are frequently in contact with research teams and communication of recruitment has become more timely. All research teams for interventional trials that have not yet recruited within the 70 day window are contacted on a weekly basis.

2.2.8 The costings, contracts and governance teams are all very much involved in feasibility assessments for interventional trials at the earliest possible stage of the research pathway. This not only optimizes the chance of successful recruitment, but helps promote the view that performance is a Trust-wide issue, requiring collaboration and careful planning.

2.2.9 The improved communication and processes allow for sustainable performance in study initiation. In light of the developing research landscape, particularly forthcoming HRA reforms, it is important these systems are constantly developed and remain flexible in order to meet developing requirements.

Fig. 2 - Mean Duration between VRA and NHS Permissions (days) - All Research Categories
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 agreed contract.

NIHR evaluation of this metric is limited to closed trials and so improvements in R&D processes will take time to translate to improved metric performance.

2.3.2 The number of trials achieving their target recruitment by or before the target date now shows some improvement, but much remains to be achieved. Table 2 presents the improvement in the percentage of trials meeting the benchmark by quarter.

Table 2

<table>
<thead>
<tr>
<th>Period</th>
<th>Number of reported trials</th>
<th>% of evaluable trials meeting recruitment target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3 12/13</td>
<td>150</td>
<td>46.6</td>
</tr>
<tr>
<td>Q4 12/13</td>
<td>157</td>
<td>52.3</td>
</tr>
<tr>
<td>Q1 13/14</td>
<td>162</td>
<td>50.5</td>
</tr>
<tr>
<td>Q2 13/14</td>
<td>191</td>
<td>47.4</td>
</tr>
<tr>
<td>Q3 13/14</td>
<td>198</td>
<td>46.0</td>
</tr>
<tr>
<td>Q4 13/14</td>
<td>181</td>
<td>40.5</td>
</tr>
<tr>
<td>Q1 14/15</td>
<td>186</td>
<td>49.0</td>
</tr>
<tr>
<td>Q2 14/15</td>
<td>176</td>
<td>55.0</td>
</tr>
<tr>
<td>Q3 14/15</td>
<td>171</td>
<td>59.2</td>
</tr>
<tr>
<td>Q4 14/15</td>
<td>192</td>
<td>60.5</td>
</tr>
</tbody>
</table>

2.3.3 Again, accurate feasibility assessments optimize the chance of successful recruitment to target. This earlier involvement is used to ensure achievable recruitment targets are agreed in workable timelines, reflecting OUH capacity and capability.

R&D teams maintain robust communication channels with research teams, to monitor ongoing recruitment figures and review feasibility, where significant changes have been made to trial arrangements; whether through substantial amendment to the protocol or arising from resource challenges.

2.3.4 Figure 3 provides a breakdown of the current, overall situation and offers a snapshot of directorate performance.

R&D can provide a detailed, study by study, breakdown of performance to R&D Divisional Leads upon request.
Figure 3 - performance in recruitment to time and target in recruiting commercial trials by directorate (as of 31st March 2015)

- Recruiting to time and target
- More than 50% of expected performance
- Less than 50% of expected performance
3. **Summary**

3.1 The achievements detailed above are illustrated by the improvement in the metrics actually submitted. The R&D team have a more proactive performance management of recruitment of first patient and to time and target of commercial research.

3.2 The ‘adjustment’ of performance data by NIHR serves to ensure that there is no pressure on the Trust to avoid undertaking research into rare diseases; thus maintaining our reputation as a centre of excellence for the treatment of, and research into, rare diseases.

3.3 The R&D teams are utilizing the improved functionality of our trial management systems (specifically, the recently developed research management tools) to improve recruitment in commercial trials to time and target.

3.4 Successful recruitment must not be at the expense of good and ethical research practice, ensuring that approach and recruitment is always appropriate. The R&D Governance team undertakes monitoring, risk based audits and more brief compliance checks on interventional trials and research studies, to ensure this.

3.5 The appointment of Divisional Managers for Research & Development would enhance the communication currently undertaken between R&D and research teams, providing a structure within which the current rate of improvement can be sustained and augmented.

3.6 In addition, these managers will enable the Trust to ensure a greater level of compliance with good research practice, in addition to continued focus on performance metrics.

3.7 Now that the Trust is consistently attaining exceptional levels of performance in Initiation and demonstrating steady improvement in Delivery, we will become a more attractive research partner and can highlight this achievement nationwide.

4. **Recommendation**

The Board is asked to note the report.

**Dr Tony Berendt,**
**Medical Director**

Report prepared by:
Professor Keith Channon, R&D Director

**July 2015**