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| **Agenda item:** | **10** |
| **Attachment:** | **C** |

**HRA BOARD COVER SHEET**

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| --- | --- |
| **Date of Meeting:** | 12th April 2017 |

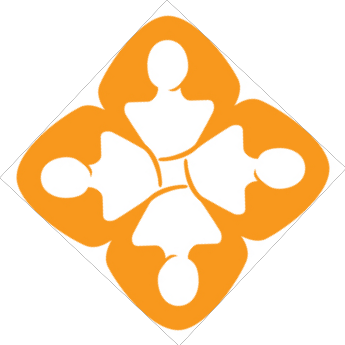
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| **Title of Paper:** | HRA Assessment Performance Report |
| **Purpose of Paper:** | To provide a summary of HRA Approval operational performance |
| **Reason for Submission:** | To give visibility of progress towards achieving stable operational delivery following implementation on 31 March 2016. |
| **Details:** | The report includes data to the end of November. It will focus on the 3 main work streams of:   1. HRA Applications 2. Amendments   3. Studies set up using pre-HRA Approval processes |
| **Time required for item:** | 15 mins |

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| **Recommendation / Proposed Actions:** | **To Approve** | |  |
| **To Note** | | **x** |
| **For Discussion** | |  |
| **Comments** |  | |

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| **Name:** | Janet Messer |
| **Job Title:** | Director of Research Systems, Standards and HRA Approval Programme |
| **Date:** | 04 April 2017 |

HRA Approval Programme Assurance Report:

HRA Approval Delivery



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| --- | --- |
| Title:: | HRA Approval Delivery Report |
| Document  Version Number: | 1.0 |
| Issue Date: | 04/04/17 |
| Author: | Janet Messer |
| Sign-off Authority | Janet Messer |
| Status: | Report to Programme Board |

1. **New applications to the HRA**

Figure 1 shows the median timelines for Approval of different study types, splitting out the time period to REC decision and the remaining time to issue HRA Approval. The REC decision, for the purposes of HRA Approval, is defined as the date of the final REC output, which is either the date of the ‘Favourable Opinion Letter’ or the date on the ‘Further Information Favourable Opinion letter’ if there are no additional conditions, or the date the REC acknowledges that these conditions have been met. The start date is the date the application is valid for REC review (this does not necessarily mean that all documents for assessment are present), or for non-REC studies the date valid for assessment.

The graph shows the range of timelines, in full elapsed days, showing the maximum time that has been taken due to applicant response time. The studies approved include some submitted in the initial roll-out period.

Figure 1: Median Timelines in calendar days for studies approved in February 2017 compared to previous month.

*Time to REC decision does not include the clock stop for provisional opinion. REC timelines are reported separately and remain within the RES KPIs.*

Figure 2 shows how timelines for the time from REC final decision to HRA Approval have changed over time (from application to HRA for non-REC studies).

The approval of studies that have been open for some time have caused a slight increase in the timelines for REC full review studies in January, as we concentrated on clearing those from the system. February has subsequently seen a significant drop in timelines for all study types, reflecting the increasing focus on the front end of studies and progressing more activity in parallel with the REC review process. The additional staff brought in during January are also beginning to increase the capacity of the team.

This is elaborated in figure 8, which shows the distribution of open days and demonstrates a reduction in those studies open for a longer period (41- 80 days) , and an increase in the 0-40 days range.

Figure 2: HRA Approval Timelines in Calendar days from REC final decision to HRA Approval by month of Approval

Figure 3 shows numbers of initial assessment letters by month of issuing the letters, showing a further reduction in the time to issue the letter. There has been an increasing focus on producing initial assessment letters in order to support parallel site set-up. The initial assessment letter is part of the local information pack provided by the sponsor to sites.

Production of the letters continues to be hampered by the high percentage of applications missing key documents for assessment as shown in figure 4.

Volumes of information to REC which had seen a steady increase over the past 6 month, have slightly dropped off in February, this could be due to an overall decrease in Full REC valid submissions made, along with the time taken for applications to be valid for REC (often necessitating additional or revised documents), which means that there is no time for the initial information to REC to be undertaken prior to the REC cut-off date. Therefore, even where information to REC is produced, it may not be reaching REC members in time.

Figure 3: Number of initial assessments and information to REC issued by month

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| --- | --- | --- | --- | --- | --- | --- |
| **Month** | ***No.* Submissions [Valid Full REC]** | ***No.* of Info to REC sent [Full REC]** | ***Info to REC Median days [Full REC]*** | ***No.* Submissions [Valid for REC (all RECS) or HRA(non-rec)]** | ***No.* of All IA letters sent [All submissions]** | ***IAL* Median days [All submissions]** |
| **April** | 234 | 52 | 13.5 | 383 | 35 | 26 |
| **May** | 227 | 18 | 16 | 354 | 37 | 40 |
| **June** | 252 | 25 | 11 | 405 | 63 | 49 |
| **July** | 221 | 20 | 7 | 377 | 37 | 49 |
| **Aug** | 247 | 16 | 5 | 386 | 71 | 41 |
| **Sep** | 218 | 24 | 5.5 | 360 | 94 | 31 |
| **Oct** | 194 | 27 | 8 | 315 | 88 | 19.5 |
| **Nov** | 234 | 38 | 6.5 | 382 | 103 | 24 |
| **Dec** | 196 | 47 | 16 | 321 | 180 | 32 |
| **Jan** | 233 | 81 | 10 | 381 | 188 | 18.5 |
| **Feb** | 216 | 49 | 10 | 379 | 125 | 11 |
| **Mar** | 195 | 44 | 7 | 326 | 176 | 9 |
| Median days: Calendar days, from date Application was assigned to Assessor to issue of Letter | | | | | |  |

Figure 4 shows the number of valid REC submissions since November for both commercial and non-commercial studies. It also indicates of the valid REC submissions made the number with missing documents required for HRA Assessment. This has remained study over the past few month with non-commercial studies missing full documents sets at ~30%, and commercial studies ~40% , mostly due to a validated costing template not being provided.

Figure 5 shows the number of applications processed for HRA Approval over time. Application receipt is shown by month of receipt, and approval by month of output. The number of closed studies includes all applications submissions closed by month of output including, REC invalidation, ineligible, Not Approved, Withdrawn, Approved. The number of open applications includes studies carried forward from implementation phase and is cumulative from month to month.

There was an increase in both the number of applications received and the number open during March. However the timelines and data on open studies clarify that the increase in open studies simply reflects the increase in the number received and this should not be regarded as a deterioration of performance.

Figure 4 Document Submissions for HRA Approval



Figure 5: HRA Application numbers

**Content of open studies**

Of the open studies requiring REC review, around 610 do not yet have REC opinion and cannot be approved as Approval is the final step in the overall process (down from 741 last month). Around 260 have REC favourable opinion in place, but approval has not been issued (down from 333 last month). Some may be pending other approvals (e.g. MHRA, CAG, ARSAC), or awaiting responses from applicants. We would expect to routinely have studies with REC favourable opinion but completing other regulatory approvals or awaiting changes by the applicant to meet HRA Approval standards.

Figure 6: Open Studies: All Submissions

**Previous Month- Jan 2017 Open studies**: **99 Non-REC, 333 REC FO, and 741 REC in progress**

Figure 7 shows the number of elapsed days since submission across all open studies that are valid and progressing through the Approval process. As the median and mean are less than the median time to Approval, this confirms that the open case load does not consist of a backlog of studies that have been in the system for a long time. The median is less than the mean, indicating that the data is skewed to the left of the distribution curve, as shown in figure 8, which again confirms that there is not a large open backlog.

The total number of open applications valid for REC has reduced further from 1015 last month to 840, and both the mean and median number of days elapsed since submission for these open studies has reduced. The decrease in open applications is not as great as the previous month when a number of long standing studies were cleared. There is therefore more of a balance between the number coming in and the number being closed, with median number of elapsed days since submission standing at 48 days. The number of days shown is full elapsed days including any time taken for applicants to respond. All the longest running applications are awaiting response from applicants.

Figure 7: Breakdown of open studies: Valid Submissions



Figure 8: Distribution of open studies Valid Submissions

1. **Amendments submitted to the HRA**

We are now receiving between 30 and 50 amendments each day via HRA Amendments inbox for categorisation (this does not include amendments submitted to REC). Of all amendment Submissions (via HRA amendments and REC), 15 – 40 amendments each day are identified as requiring HRA Assessment. Categorisation is routinely being completed within the five working days set out in UK-wide standards.

Figure 9 provides information on the number of amendments which have been assessed, the open caseload, and the median time in calendar days to be assessed. Start date is from date of receipt. The number of amendments marked as requiring assessment is the open caseload, and includes amendments awaiting REC and/or MHRA review as well as those undergoing assessment.

Figure 9: Number of amendments to Assessment Monthly data

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| --- | --- | --- | --- | --- |
|  | **Dec-16** | **Jan-17** | **Feb-17** | **Mar-17** |
| **Number of Amendments Assessed** | 436 | 524 | 561 | 685 |
| **Number of Amendments Marked as Requiring Assessment** | 616 | 549 | 589 | 721 |
| **Median Time to Review (Working Days)** | 17 | 13 | 12 | 15 |

Figure 0 Monthly breakdown of Amendments with HRA

1. **Pre-HRA Applications**

Volumes are now at operational levels where approval outputs balance volumes received. Applications coming in are now matched on a weekly basis by approvals issued.

**Figure 11: Pre-HRA Applications**