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| **Agenda item:** | **9** |
| **Attachment:** | **B** |

**HRA BOARD COVER SHEET**

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| **Date of Meeting:** | 22 February 2017 |

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| **Title of Paper:** | HRA Approval 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 October. 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 minutes |

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| **Recommendation / Proposed Actions:** | **For Discussion** |
| **Comments** |  |
| **Name:** | Janet Messer  |
| **Job Title:** | Director of Research Systems, Standards and HRA Approval Programme |
| **Date:** | 15 February 2017 |

HRA Approval Programme Assurance Report:

HRA Approval Delivery



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| Title:: | HRA Approval Delivery Report |
| DocumentVersion Number: | 1.2 |
| Issue Date: | 15/02/17 |
| Author: | Janet Messer |
| Sign-off Authority | Janet Messer |
| Status: | Report to 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 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 January 2017

*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, as we have concentrated on clearing those from the system. The expectation is that the timelines will begin to plateau again once those studies that have been in the system for some time have been cleared. These studies were focussed on as part of the new process of chasing, and if appropriate withdrawing, studies from which we had not had a response for 2 months.

This is elaborated in figure 8, which shows the distribution of open days and demonstrates a reduction in those studies open for a long period. Following up with applicants for a response to queries previously raised, and then approving or closing these long-running studies has reduced the open case load, but has caused a skew to the median timelines.

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.

Furthermore, the time taken for applications to be valid for REC (often necessitating additional or revised documents) means that there is no time for the initial assessment to be undertaken prior to the REC cut-off date. Therefore, even where initial assessment letters are produced, REC members may not receive an initial assessment.

Figure 3: Number of initial assessments issued by month

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| --- | --- | --- | --- |
| **Month** | ***No.* Submissions [Valid for REC]** | ***No.* of All IA letters sent** | ***IAL* Median days** |
| **April** | 357 | 35 | 25 |
| **May** | 361 | 37 | 39 |
| **June** | 403 | 63 | 48 |
| **July** | 369 | 37 | 48 |
| **Aug** | 375 | 71 | 40 |
| **Sep** | 373 | 94 | 30 |
| **Oct** | 309 | 88 | 18.5 |
| **Nov** | 363 | 103 | 23 |
| **Dec** | 295 | 181 | 31 |
| **Jan** | 358 | 184 | 18.5 |
| 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.

Figure 4 Document Submissions for HRA Approval

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| --- | --- | --- | --- |
|   | **Nov** | **Dec** | **Jan** |
| *No.* of **REC Valid** Submissions [all REC] | Missing **HRA** full doc set at submission | *No.* of **REC Valid** Submissions [all REC] | Missing **HRA** full doc set at submission | *No.* of **REC Valid** Submissions [all REC] | Missing **HRA** full doc set at submission |
| Non commercial | 289 | 71 | 226 | 49 | 270 | 91 |
| Commercial | 69 | 28 | 65 | 23 | 65 | 29 |

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. The number of studies approved per month continues to rise, surpassing 400 in January.

It is worth noting that the expected business as usual case load did not anticipate such a high rate of non-valid applications. Given that 30-40% of applications that are valid for REC do not contain all documents needed for assessment, the open case load will include a higher than expected load of non-valid applications.

This reinforces the importance of achieving an integrated validation process, as an early output of the Service Improvement Programme. Work is already underway on more integrated guidance for applicants, to be accompanied by communications with ‘Top Tips’.

Figure 5: HRA Application numbers

**Content of open studies**

Of the open studies requiring REC review, around 640 do not yet have REC opinion and cannot be approved as Approval is the final step in the overall process. Around 400 have REC favourable opinion in place, but approval has not been issued. 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 shows that at the end of December there were 794 studies in progress in the REC process, with the high number probably due to the timing of REC meeting around Christmas. The data for the end of January shows only a small increase in the number of open studies that have completed the REC process and remain open despite the significant number of studies that have completed the REC process. This reflects the improved rate of clearing studies as evidenced in figures 7 and 8.

Figure 6: Open Studies: All Submissions

**Boxes show data previously reported end December 2016**

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 1132 last month to 1051, and both the mean and median number of days elapsed since submission for these open studies has reduced. This is a result of clearing a number of long-standing applications where responses from applicants were awaited. This is reflected in the change in the distribution curve of open studies illustrated in figure 8, with 70% of all open studies being open for less than 80 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 REC Submissions

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| **Number of open applications** | **Number of days elapsed since submission\*** |
| **Mean** | **Median** | **Min** | **Max** |
| 1051 | 73 | 53 | 2 | 411 |

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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|   | **Nov-16** | **Dec-16** | **Jan-17** |
| **Number of Amendments Assessed** | 250 | 436 | 524 |
| **Number of Amendments Marked as Requiring Assessment** | 683 | 616 | 549 |
| **Median Time to Review (Working Days)** | 7 | 17 | 13 |

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**