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| **Agenda item:** | **7** |
| **Attachment:** | **C** |

**HRA BOARD COVER SHEET**

**Date of Meeting:** 16 November 2016

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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.  |
| **Lead Reviewer:** |  |
| **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 |
| **Suitable for wider circulation?** | Yes |
| **Time required for item:** | 15 minutes |
| **Recommendation / Proposed Actions:** | **For Discussion** |
| **Comments** |  |
| **Name:** | Janet Messer  |
| **Job Title:** | Director of Research Systems, Standards and HRA Approval Programme |
| **Date:** | 11 November 2016 |

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 that valid for assessment. It is important to note that the timelines shown are full elapsed time, including the time taken for applicants to respond.

Figure 1: Median Timelines for studies approved in October

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). We expected an increase in HRA Approval timelines in September for proportionate review and non-REC studies, as the assessment team has focussed on prioritising clinical studies where there is potential clinical implication for patients. It is important to note that historically a large number of studies, particularly non-commercial studies, did not apply to R&D until many months after completing the REC review process. Studies processed through HRA Approval do not incur this delay in application. The data for October show a reduction in non-REC and proportionate review timelines as these studies begin to come under control. There may continue to be fluctuations in the REC study timelines as some older studies are cleared.

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

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| --- | --- | --- | --- | --- |
|  | **Time to IA Letter (working days)** | **No. of Commercial REC Valid Application Submissions** | **No. of Commercial REC Valid Submissions issued IA** | **% with completed IA** |
|  | **Mean** | **Median** | **Min** | **Max** |
| September | **13** | **7** | **1** | **41** | 69 | 35 | 51% |
| October | **6** | **4** | **1** | **21** | 50 | 31 | 62% |
| November (1st week) | **3** | **3** | **1** | **4** | 10 | 7 | 70% |

An increasing focus has been placed on providing Initial Assessment (IA) Letters for commercial studies, as these letters are included in the local information package provided by the sponsor to sites. Early provision of the Initial Assessment Letter allows sponsors to set up sites in parallel to HRA Approval, maximising the opportunity to start recruitment as soon as Approval is issued. Our initial focus has been commercial applications as we know that more commercial sponsors are ready and able to set up sites in parallel, compared with non-commercial sponsors. Figure 3 shows the percentage of commercial full REC applications receiving Initial Assessment letters increasing and the timeline for issuing them decreasing. Companies have indicated that a 5 day timeline is acceptable. Alongside this, initial assessments are also being issued for studies already received so that they can progress site activities.

Figure 3: number of initial assessments for commercial applications for full REC review, issued by month of application

It is worth noting that of commercial studies determined to be valid for full REC review, about 50% are currently found to have documents for assessment missing: the validated industry costing template, or the template study contract. Assessment administrators are now identifying these on receipt in order to avoid delays to issuing the Initial Assessment Letter.

Figure 4 shows the number of applications processed for HRA Approval. Application receipt is shown by month of receipt, and approval or closure 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 open case load has now started decreasing with the number of applications being closed continuing to be greater than the number received, and the rate of decrease is further improving based on data in the first week of November.

Expected business as usual case load

Figure 4: HRA Application numbers

Of the open studies requiring REC review, neearly 750 do not yet have REC opinion and cannot be approved as Approval is the final step in the overall process. 475 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, although we know that a high proportion are awaiting action from assessors. 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.

The figures below elaborate some of the detail of the nature of the open studies. The monitoring systems do not include ‘clock stops’ to measure time taken to receive responses from applicants. However, figures 6 and 7 below show that the median number of elapsed days since submission is not significantly higher than the current timelines for issuing HRA Approval, suggesting that there is not a build-up of delay to studies, although there continues to be a high case load.

**Figure 5: Open Studies**

Figure 6: breakdown of open studies

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| **Number of open applications** | **Number of days elapsed since submission** |
| Mean | Median | Min | Max |
| **1343** | **77** | **65** | 3 | 321 |

Figure 7: Distribution of open studies

1. **Amendments submitted to the HRA**

A substantial amount of work has been completed to enable a level of control of the amendment submission and management process. We are now receiving between 25 and 70 a day (compared with 100+ initially). The pilot of categorisation and triage of REC substantial and non-substantial amendments by REC staff will be reviewed as planned in December. The outcome of the evaluation will inform service improvement work.

Amendments are now routinely categorised within the 5 working days set out in the UK process. The number of amendments requiring assessment was significantly reduced in the summer following the introduction of a triage alongside the categorisation. The median time in October for assessment of amendments, including REC and other approvals, is 50 elapsed days (reduced from maximum time of 86 in August). There is potential to reduce this time further, but staff need to balance time spent on amendments vs time spent on new studies. It should be noted that historically many applicants submitted amendments to REC many weeks, and sometimes months prior to providing them to R&D.

We introduced changes to the tracking system for amendments in October to reduce administrative burden. We have also published clarifications for applicants on the handling of amendments, agreed with the devolved administrations, on the IRAS website. This will be communicated in the next edition of HRA Latest and through DA communication routes.

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, as shown in figure 8.

**Figure 8: Pre-HRA Applications**

**Figure 9: Number of applications for Pre-HRA approval received requiring assessment**