

# HRA Approval Programme Assurance Report: HRA Approval Delivery

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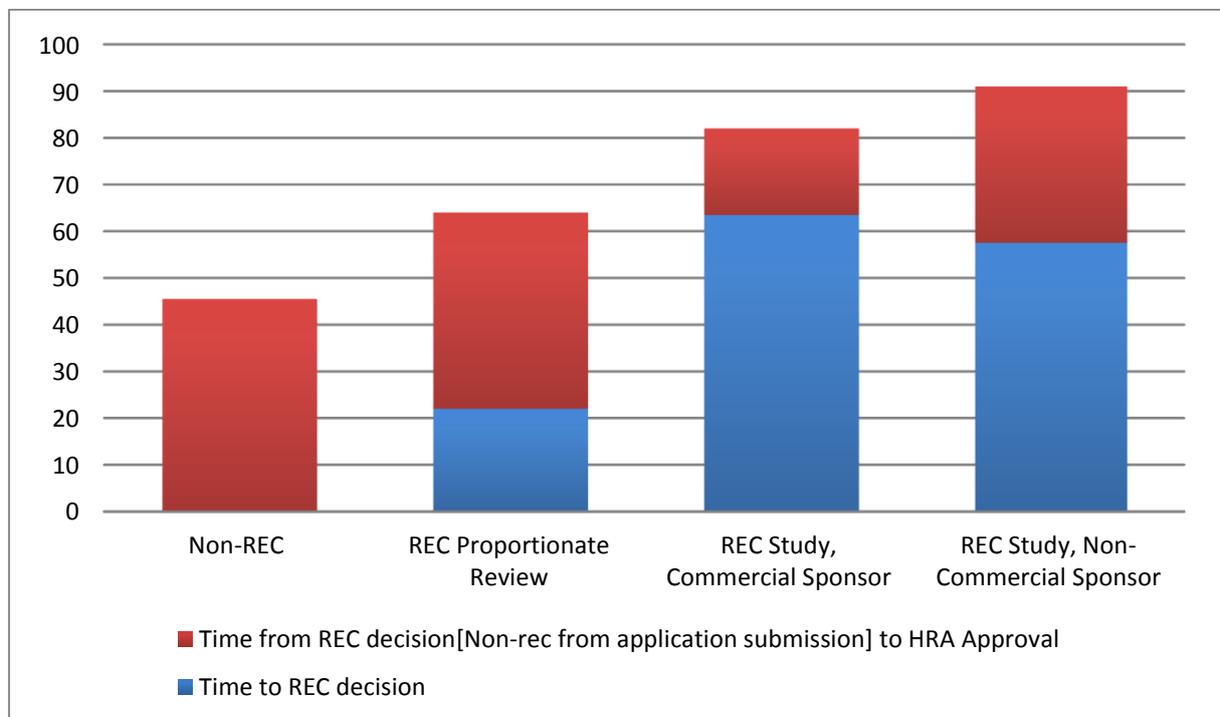
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## 1. New applications to the HRA

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 validated for REC review (this does not necessarily mean that all documents for assessment are present), or for non-REC studies the date of validation for assessment.

The studies approved include some submitted in the initial roll-out period.

Figure 1: Median Timelines for studies approved in December



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

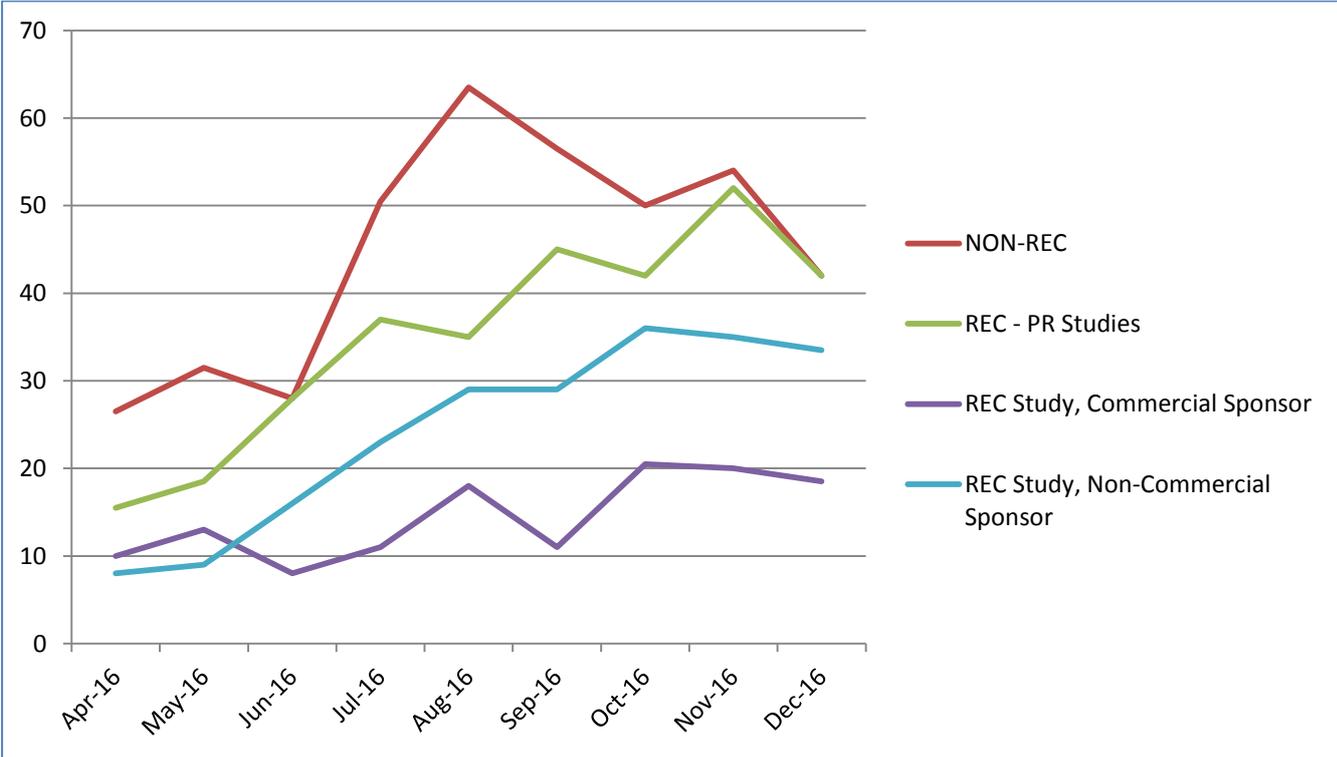
Figure 2 shows how timelines for the time from REC final decision to HRA Approval have changed over time (from application to HRA for non-REC studies).

For all study types the timelines have reached a plateau or decreased, rather than increasing further as had been happening over previous months. This illustrates the control that is beginning to be achieved for studies. Many studies that meet the criteria for proportionate

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review raise complex issues for the NHS but they are now showing a decline in Approval timelines this month, as control arrangements are extended from clinical studies to all study types. It should be noted that assessors are not yet chasing applicants to respond to queries, although this will be brought in shortly to match the arrangements in use in the RES service. Timelines shown are full elapsed time including delays by applicants in responding because applicants don't tend to distinguish between the cause of the time taken.

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



Collaborative work between assessors and REC Managers has been agreed that will enable the assessors to be more proactive when prioritising their studies. Once a study has a REC Favourable Opinion the REC Manager will alert the Assessment team who will then be in a position to speak directly to the REC Manager and attempt, where possible, to sync the issuing of both the HRA Approval and REC Favourable Opinion letters. The conversation at this point will enable both team members to ascertain whether it would be possible to 'hold' the REC Favourable Opinion letter for a brief period of time (but still within KPIs) whilst the final Assessment issues are arranged. This process should make the system more integrated for applicants.

Figure 3 shows numbers of initial assessment letters by month of issuing the letters, showing an increasing number. 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.

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The initial focus was on commercial studies, as companies have historically been more likely than non-commercial studies to undertake approval and site set-up in parallel. The detailed breakdown is also shown for the sub-set of commercial trials.

Resource from within the Assurance Team has been temporarily moved to support the issuing of the Initial Assessment Letters (IAL) to enable the sponsor to begin the arranging phase of their study set up with their sites. However, a significant number of the applications are still being found to be not valid for assessment despite being valid for REC, limiting our ability to increase the percentage of commercial studies issued an initial assessment within intended timelines.

Figure 3: number of initial assessments issued by month

Month	No. of All IA letters sent	No. of All Commercial IA letters	No. of Commercial (rec)Valid Submissions (full REC)	No. Commercial (rec) Valid Submissions issued IA (Full REC)	% Commercial (rec) Valid with completed IA (full REC)
April	33	15	64	7	11%
May	36	17	48	2	4%
June	63	28	67	1	1%
July	37	20	50	6	12%
Aug	71	33	72	6	8%
Sep	94	61	69	35	51%
Oct	88	62	54	31	57%
Nov	103	59	58	23	40%
Dec	188	45	52	20	38%

Figure 4 shows the number of valid REC submissions for full review in November and December for both commercial and non-commercial studies, and the numbers of these not valid for assessment on receipt. A new system of early checking has been implemented to ensure that the assessors receive a complete application before starting their review. The Application Administration team conduct a check on the documents submitted against a checklist and only allocate for assessment those applications that are complete. If anything is missing they will contact the sponsor and request the missing information.

Figure 4 Document Submissions for HRA Approval

	Nov			Dec		
	No. of REC Valid Submissions (full REC)	Missing HRA full doc set at submission	Full doc set for HRA Assessment outstanding at 3/1/17	No. of REC Valid Submissions	Missing full doc set at submission (full REC)	Full doc set for HRA Assessment outstanding at 3/1/17
Non commercial	149	38	6	119	29	10
Commercial	58	20	2	52	17	11

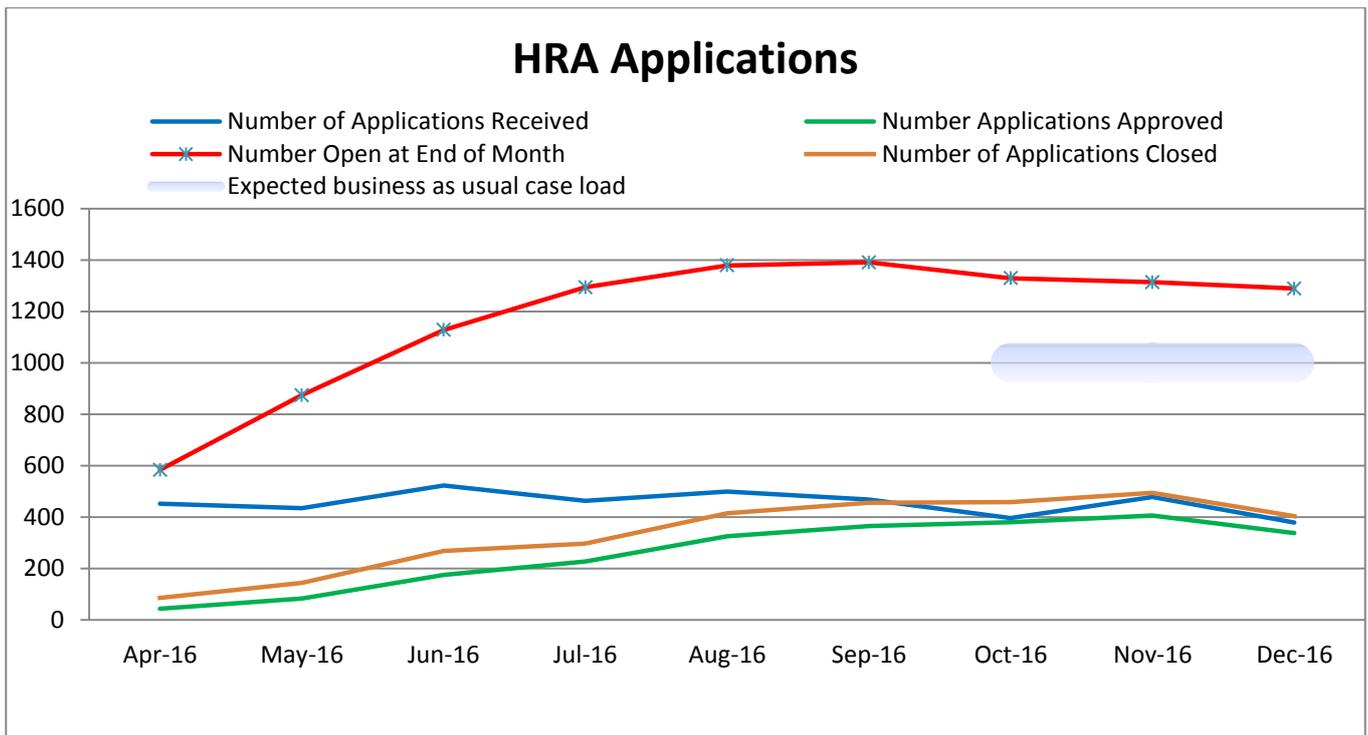
The high percentage of commercial applications with missing documents is surprising given that the document set is the same as that previously used with CSP, and for R&D submissions in the devolved administrations. Feedback has been given to companies through training to companies and via ABPI groups.

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.

As expected there was a drop in the number of applications in December due to the holiday period, and a similar decrease in number of applications processed due to staff being on leave, as well as a two day training course for the whole team. However, it is encouraging that the number of studies closed per month continues to exceed the number received.

Importantly, the open case load continues to decrease even though the emphasis over the last few months has been on getting the beginning of the assessment process (initial assessment) working effectively to support the right actions by sponsors and sites, and maintaining the control on the processing of amendments.

Figure 5: HRA Application numbers



**Content of open studies**

Of the open studies requiring REC review, around 790 do not yet have REC opinion and cannot be approved as Approval is the final step in the overall process (increased from 760 last month). Around 380 have REC favourable opinion in place, but approval has not been issued (reduced from 450 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. Although the overall case load has decreased to a small extent in the last month, within the open case load the proportion of the open case load outside the REC process fell from 43% to 39%.

Figure 6: Open Studies: All Submissions

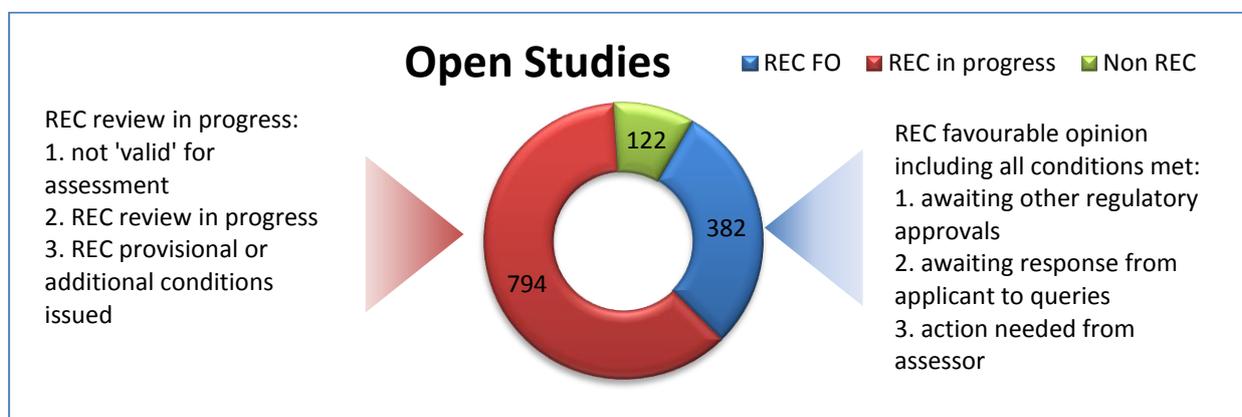
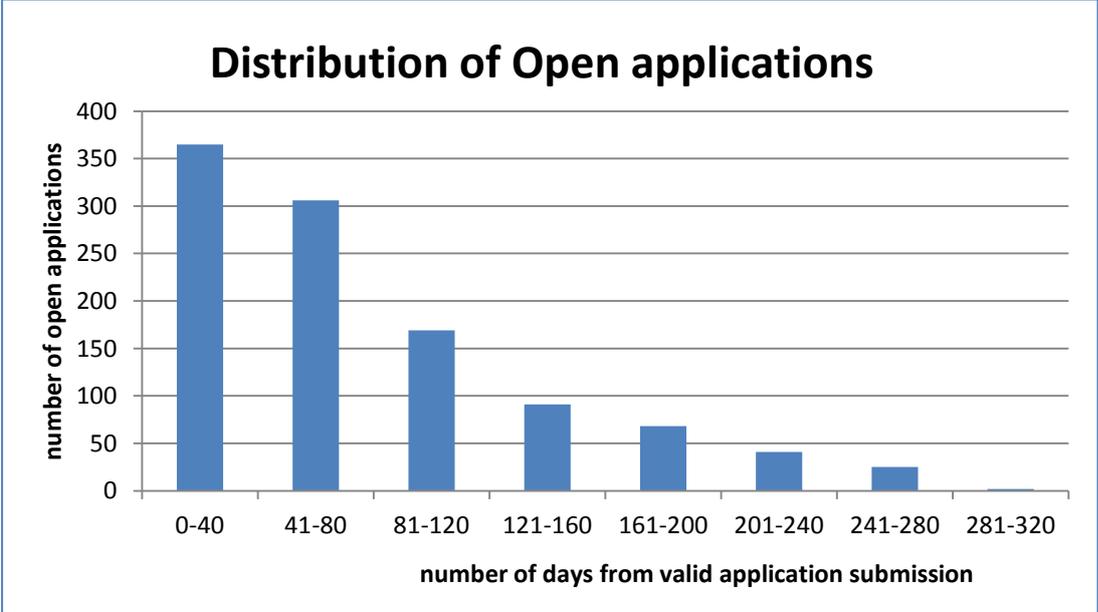


Figure 7 shows the number of elapsed days since submission across all open studies that are valid and progressing through the Approval process. As the median and mean number of elapsed days are less than the median time to Approval, this confirms that the open case load does not consist of a backlog that is not being addressed. 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 the open case load consists of studies that are being actively progressed and approved.

Figure 7: Breakdown of open studies: Valid Submissions

Number of open applications	Number of days elapsed since submission			
	Mean	Median	Min	Max
1132	80	62	2	381

Figure 8: Distribution of open studies Valid Submissions



A continued focus on the early stage of the assessment, maximising processing in parallel with the REC review will ensure that the proportion of the open studies outside the REC process continues to reduce and the overall approval time decreases. The following actions are underway to further drive a decrease in the open case load, and reduce the timelines.

1. Mechanism to report in detail on status of open studies

A new system whereby the ‘open’ studies can be reported in more detail is being implemented which will allow the Assessment team to indicate via a list of statuses where a study is in the HRA Approval system. This will allow easy identification of applications awaiting action from the assessor, and those that are awaiting action from the applicant or a

third party. This will make re-allocation of studies easier, allowing workloads to be balanced across staff.

## 2. New staff starting in January

Five new assessors come into post in January, and while they will take some time to get up to speed based on their respective experiences, there will start to be more people involved in assessing the studies.

## 3. Reallocation of experienced staff to supporting applications on receipt

A number of the most experienced staff has so far formed a taskforce focussed on clearing studies with REC favourable opinion that had not started the assessment process. This team will be reallocated back to the normal processing of studies in a controlled way during the course of January to aid the focus on the early part of the assessment process.

## 4. Closing open studies where applicants do not respond after reminders

There will also be an implementation of a system to close those studies from whom we have not heard for a period of time. Mirroring the REC process, the Assessment team will issue a non-approval letter (after a formal reminder requesting contact) and so reduce those studies in the 'open' list which have been stagnant for some time.

## 5. Reducing the administrative burden of amendments to free up time for assessment

Changes have been made to the administration of amendments requiring assessment as set out in section 6, thus freeing up assessor time to focus on assessing applications.

## 6. Amendments submitted to the HRA

We are now receiving between 10 and 70 amendments each day (compared with 100+ initially). 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 in November, 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. This new tracking process began with amendments submitted in November and the median time to review was therefore expected to increase as amendments that were awaiting REC and/or MHRA review complete.

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Figure 9: Number of amendments to Assessment Monthly data from November

Data correct at 03/01/2017

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

The number of escalations received to the HRA has dropped significantly and Assessors are beginning to clear their amendment workload in a timely manner. Where there are spikes in submission numbers there is additional resource that can top-slice the amendments, and ensure a swift response to the applicant.

To further support the Assessors in having time to create Initial Assessment Letters for their new studies, a new process of administration back-up has been implemented which takes on an individual amendment’s final co-ordination of approvals. The Assessor will continue to assess those that have been triaged as needing review, but they can then be handed back to an administrator to complete the bringing together of the regulatory approvals and the creation and issuing of the HRA Approval letter to the sponsor.

## 7. 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 10: Pre-HRA Applications

