

## HRA/HCRW Approval performance to April 2019

Performance report data cut was taken on 1 July 2019.

The data published below now includes combined data for HRA Approval and Health & Care Research Wales (HCRW) Approval as these systems are now delivered together.

Figure 1 provides a breakdown of the number and types of applications received for HRA/HCRW Approval by month. The upward trend in non-REC applications previously noted has continued with a corresponding increase in REC proportionate review applications. REC commercial applications appear to have remained stable. Although REC non-commercial applications have decreased slightly, the overall trend for total applications is stable.

Figure 1 Types of Applications submitted for HRA/HCRW Approval

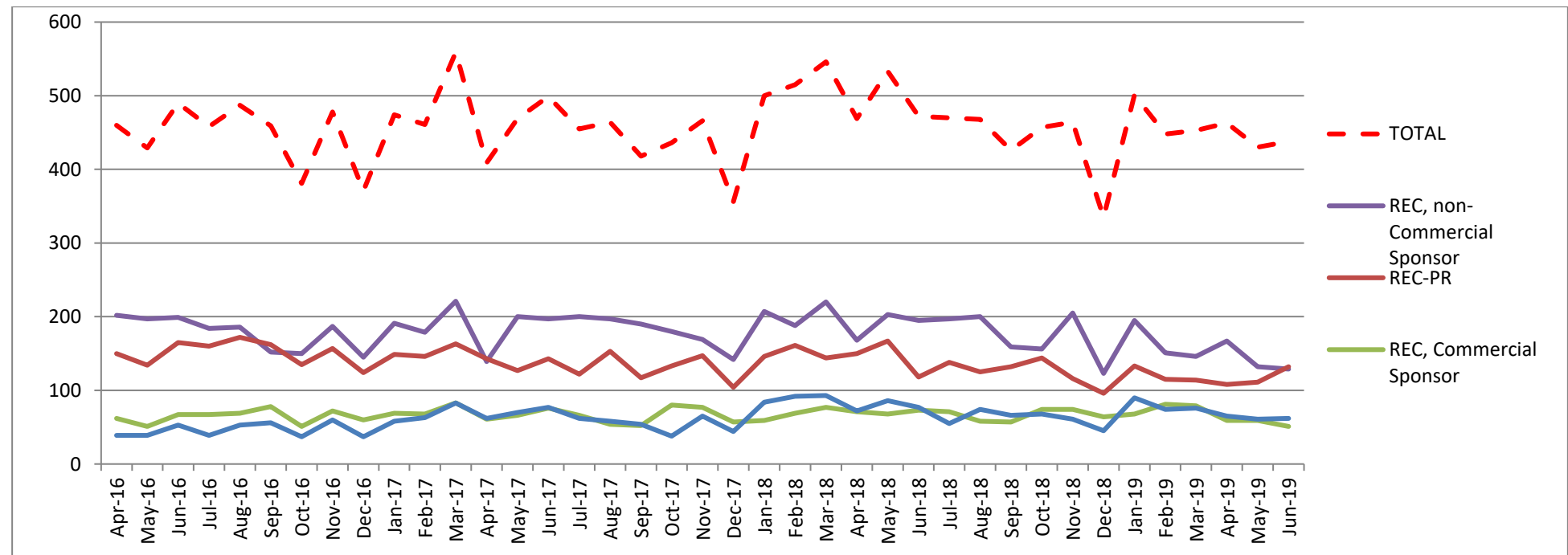


Figure 2 shows the median timelines for Approval of different study types, splitting out the time period to REC decision and the remaining time to issue HRA Approval. The REC decision is defined as the date of the final REC output, which is either the date of the 'Favourable Opinion Letter' or the date on the 'Further Information Favourable Opinion letter' if there are no additional conditions, or the date the REC confirms 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 REC timelines show some monthly variation, some of which relates to holiday periods when either REC members or applicants are on leave and therefore timing of meetings are changed, or applicants are not available to respond to queries. We continue to focus on achieving greater consistency in overall timelines, noting that part of this time relates to applicant response to requests for further information.

Figure 2: Monthly Median Timelines in calendar days for studies approved through HRA/HCRW Approval

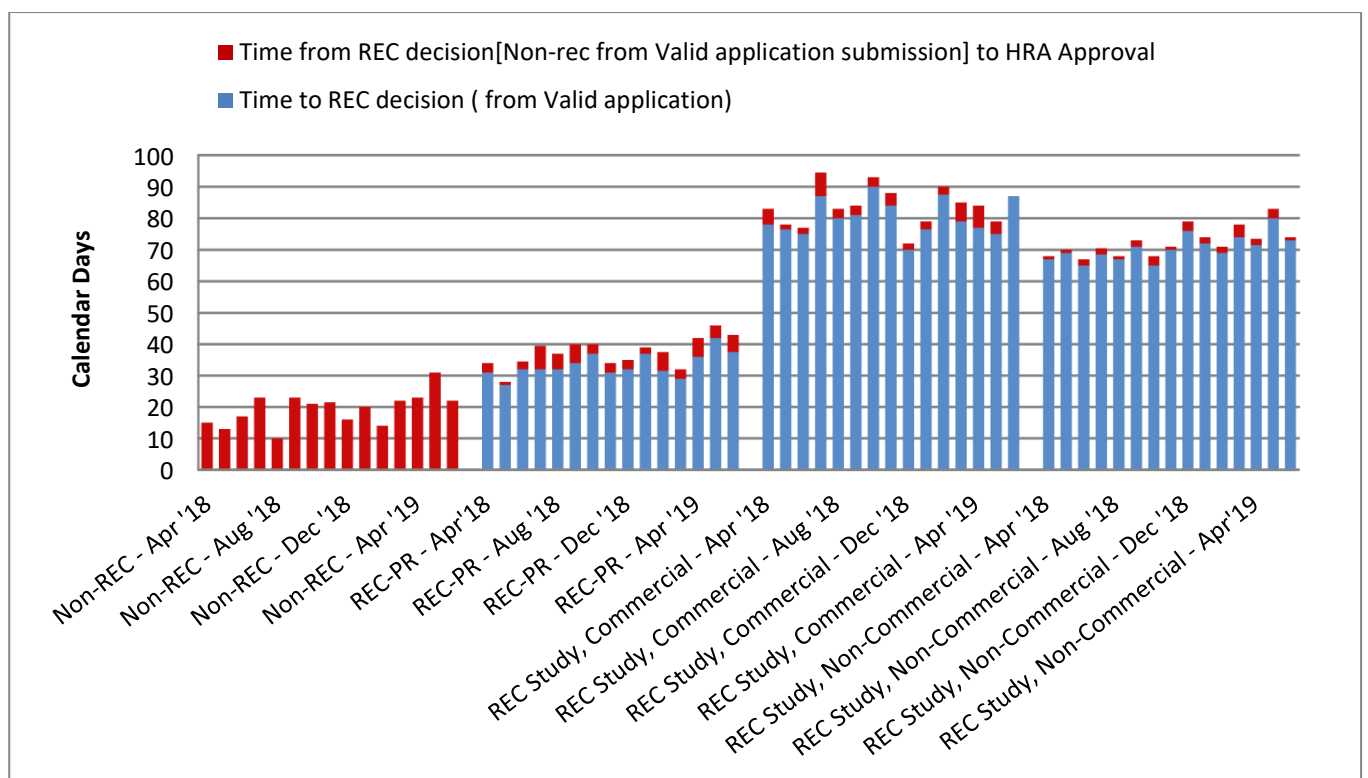


Figure 3 shows the time for REC review excluding the time for the applicant to respond across all study types.

Figure 3: Mean time for full REC review (England) excluding time for applicant to respond.

	07/18	08/18	09/18	10/18	11/18	12/18	01/19	02/19	03/19	04/19
Mean time to complete full review	35	36.4	34	35	34.6	33.2	35.7	36.1	36.0	37.0
% full reviews complete in 60 days	99.2%	98.6%	99.0%	98.9%	98.8%	100%	98.6%	99.0%	98.4%	95.7%

Figures 4-7 show the 1st, medians and 3rd Quartiles for Studies Approved each month. Timelines are calendar days from application submission to HRA/HCRW Approval, including time for applicant to respond.

Figure4 Non-REC Studies Submission timelines 1st, median and 3rd Quartile

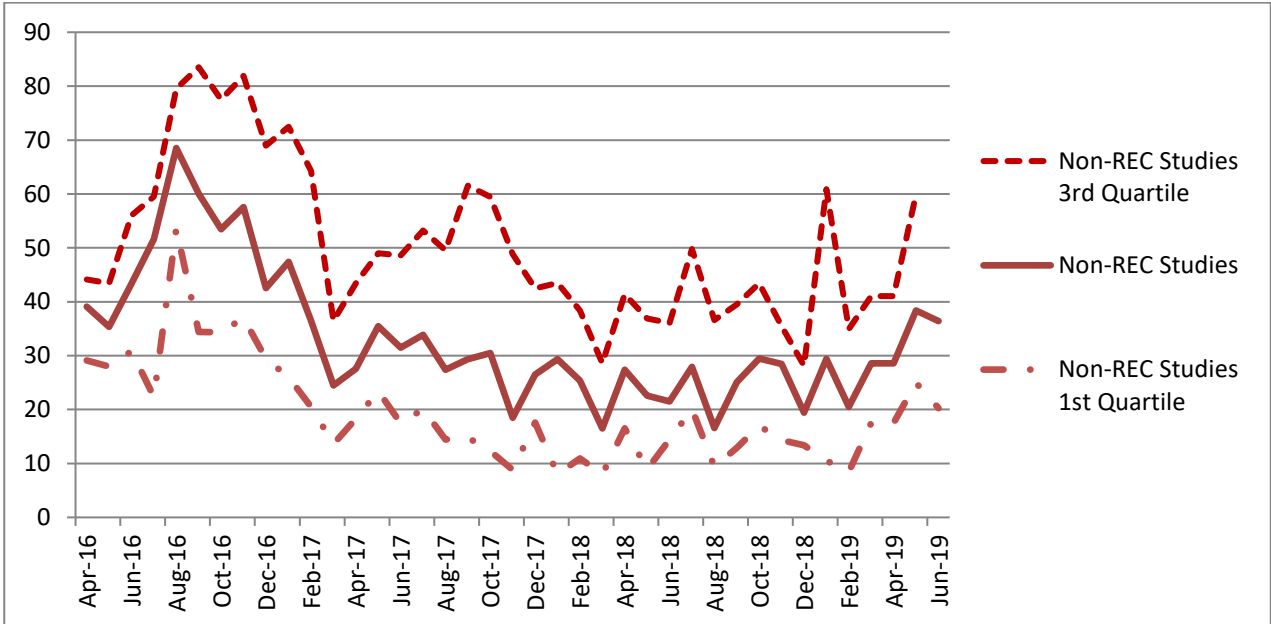


Figure 5 REC-PR Studies Submission timelines 1st, median and 3rd Quartile

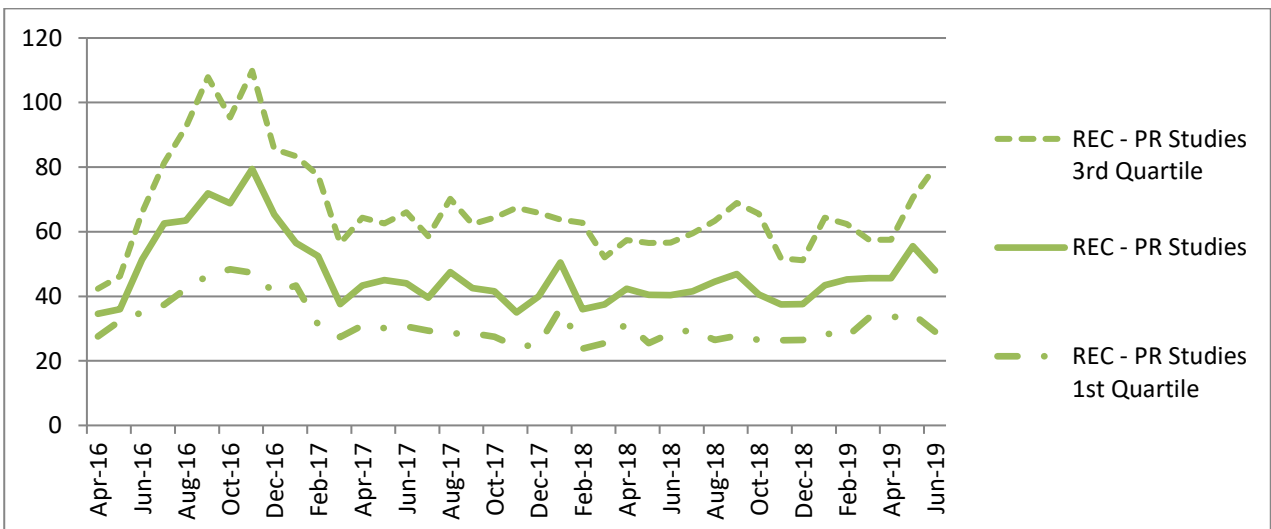


Figure6 REC-Commercial Studies submission timelines 1st , median and 3rd Quartile

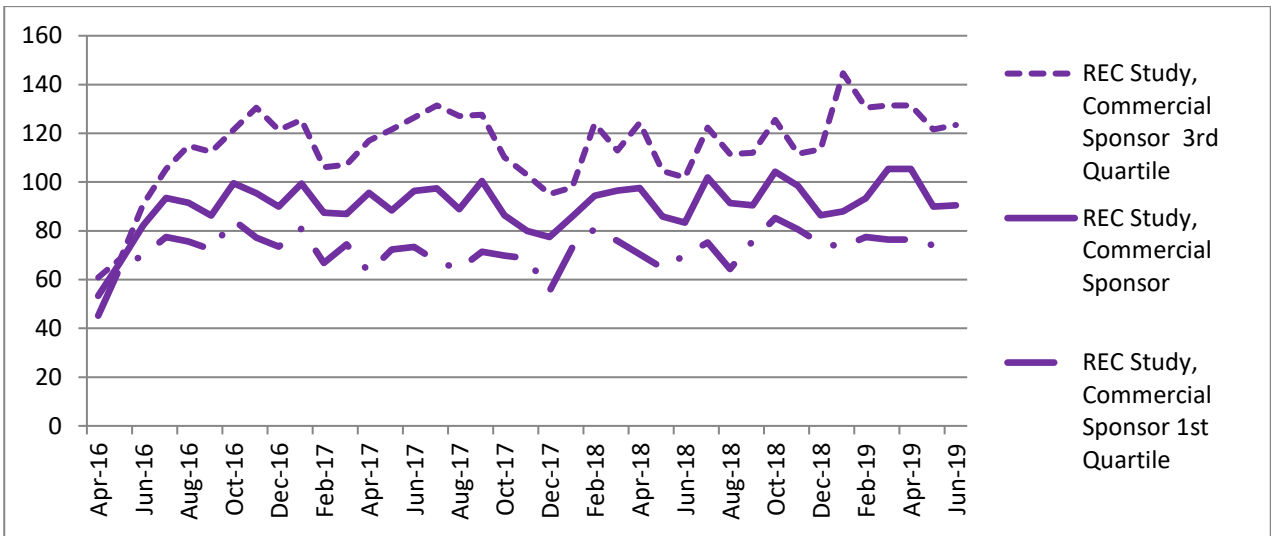


Figure7 REC-Non-Commercial Studies submission timelines 1st, median and 3rd Quartile

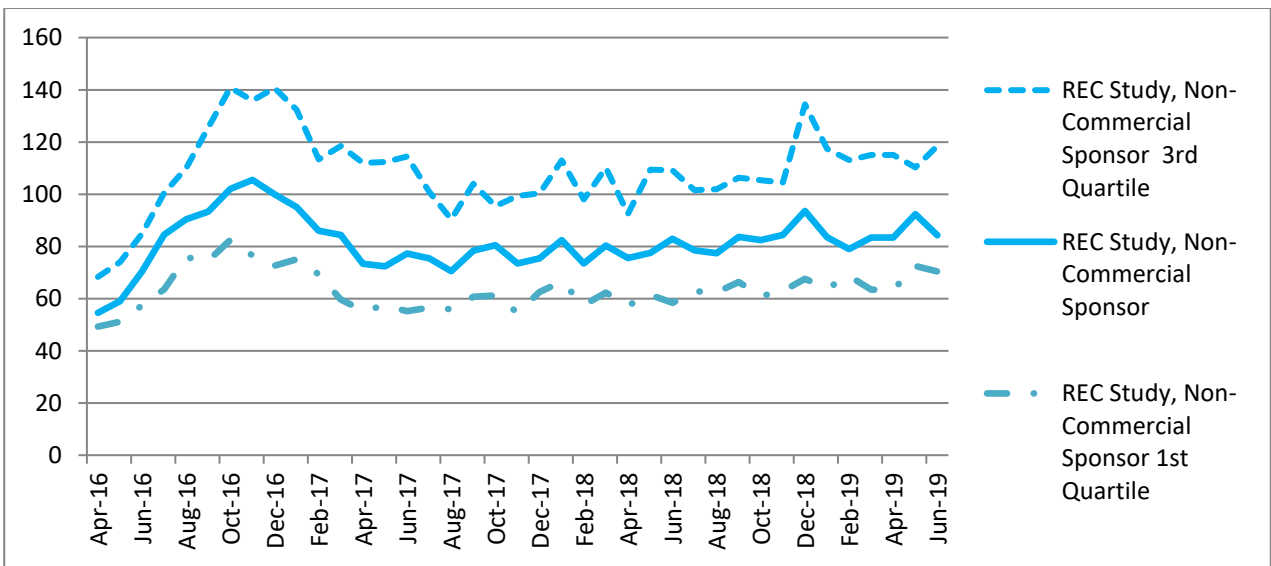
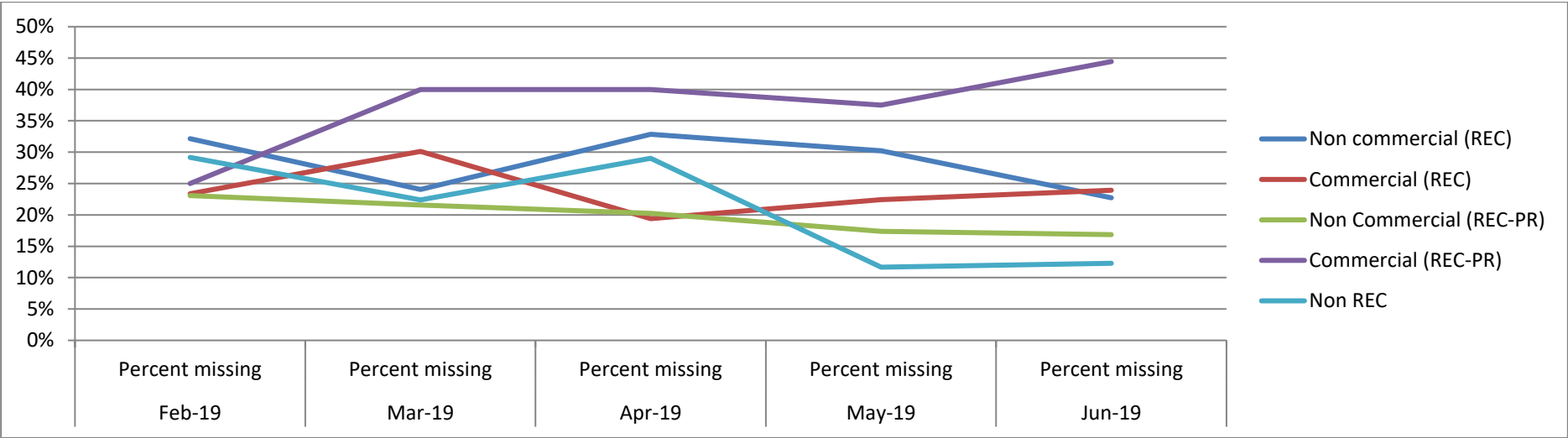


Figure 8 shows the percentage of valid REC applications with missing documents required for HRA/HCRW Assessment only (SoA/SoE, Contract, 'Validated' ICT, funding letter). Following the implementation of the verification tool in IRAS in April 2018 and delivery of training to industry and academic researchers, although we have seen an ongoing decrease in invalid applications for non-REC and non-commercial proportionate review applications, the rate of invalid applications from commercial proportionate review applications remains high. This probably reflects that this area of applications is still relatively unusual for commercial sponsors and the numbers are small (fewer than 20 applications per month) and therefore susceptible to higher variations.

Incomplete applications cause delay in the review of applications. Despite a number of actions by HRA, a significant proportion of applicants fail to submit applications that are valid for both REC review and assessment.

Figure 8: Document Submissions for HRA/HCRW Approval Percentage line graph



## Amendments submitted to the HRA/HCRW

Figure 10: Mean time to Amendment Categorisation

	07/18	08/18	09/18	10/18	11/18	12/18	01/19	02/19	03/19	04/19
Mean time to issue categorisation email	2	3	3	3	2	2	3	3	2	3

Figure 11 Median and Mean times to HRA/HCRW Approval

	07/18	08/18	09/18	10/18	11/18	12/18	01/19	02/19	03/19	04/19
Mean time taken to issue HRA/HCRW Approval after REC FO	11	14	12	11	11	10	12	10	9	14
Median time taken to issue HRA/HCRW Approval after REC FO	6	6	5	4	4	2	2	2	3	6
Mean review time	22	25	24	22	22	21	25	22	23	28
Median review time	22	25	24	22	22	21	25	22	23	28