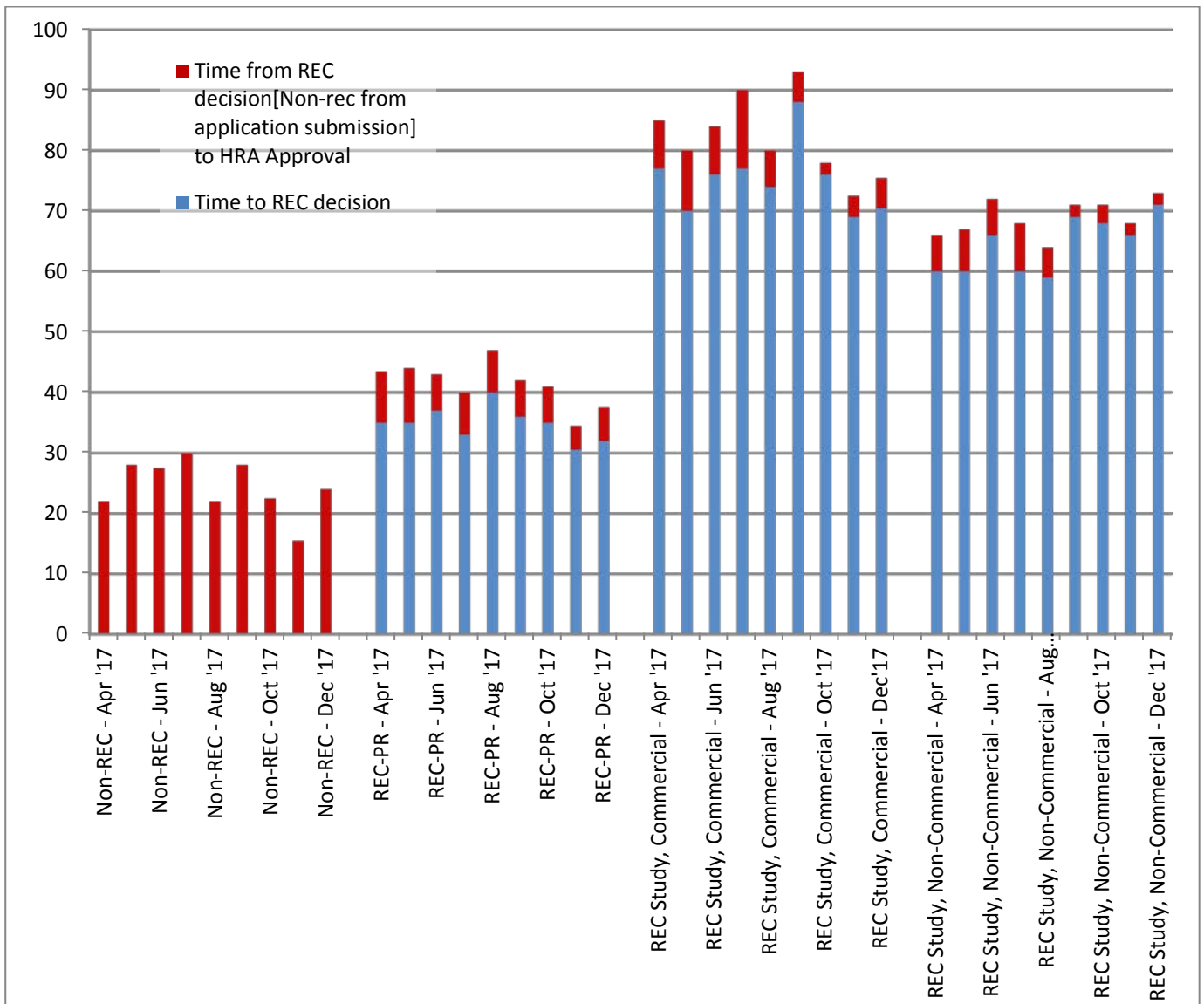


Update on performance of HRA Approval – December 2017

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 for these purposes 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.

Figure 1: Monthly Median Timelines in calendar days for studies approved in last 9 months.

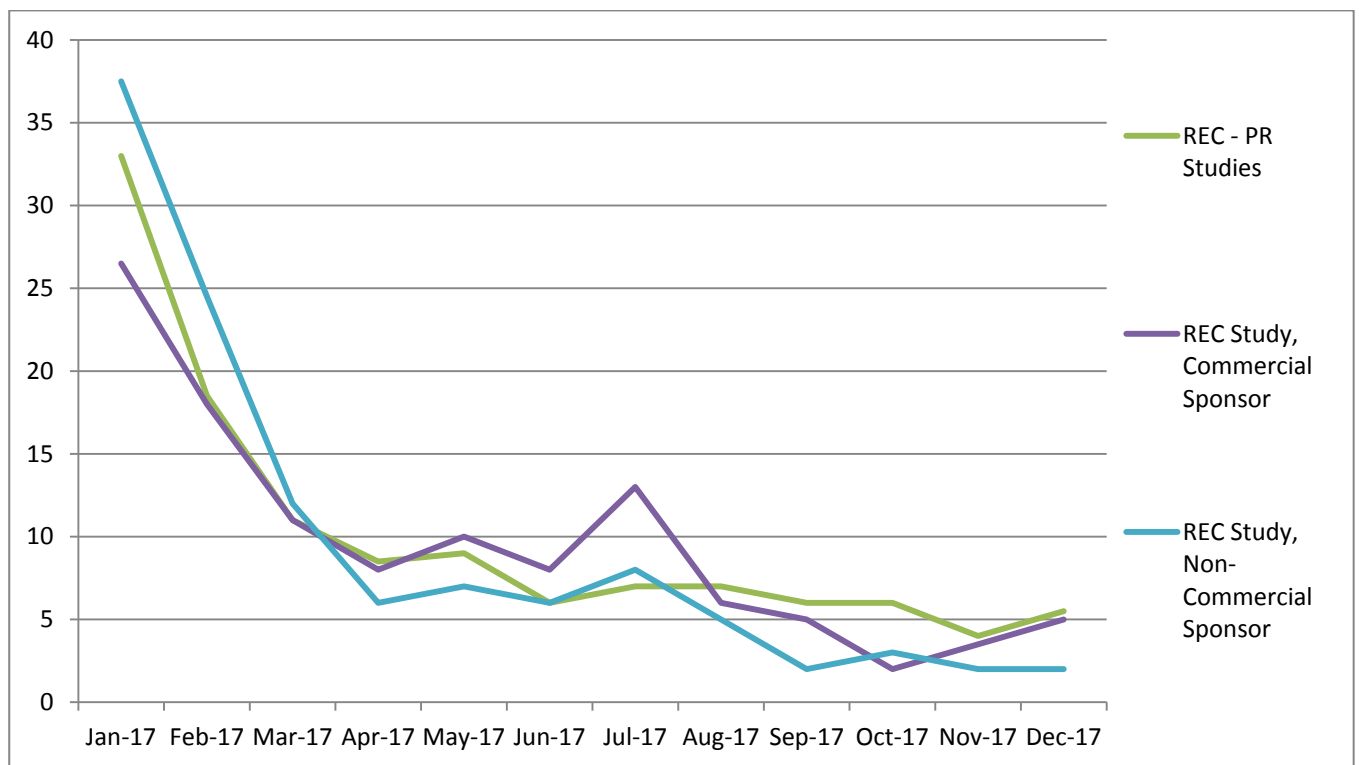


The REC timelines (in blue) reveal normal monthly variation. All timelines in this report are measured in elapsed calendar days with no clock stop. REC timelines are measured separately outside this report with a clock stop for response from applicants to a provisional opinion, and remain within the KPIs.

Figure 2 shows how timelines for the time from REC final decision to HRA Approval have changed over time.

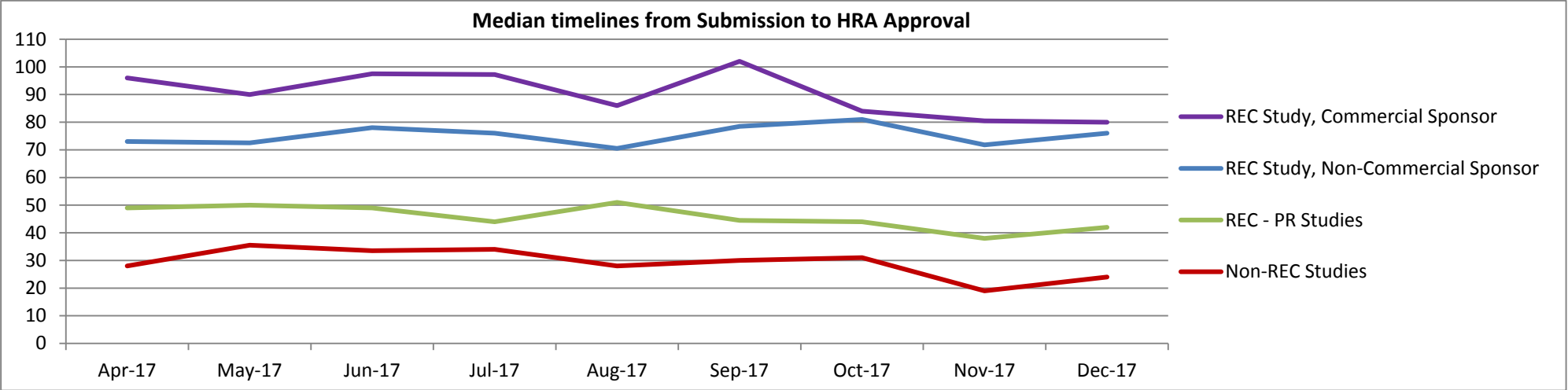
HRA Approval timelines from final REC FO have seen significant decreases to March 2017 down to less than 10 days, followed by a further continued decline in timelines resulting from collaborative working between Assessors and REC teams issuing joint approvals.

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



The full elapsed time in calendar days for an application to receive HRA approval from receipt date of original submission, including the time for applicants to respond, is shown in Figure 3.

Figure 3 Median Timelines from Submission to HRA Approval



The breakdown of HRA Approval timelines from receipt date of original submission are shown in quartiles in Figure4 below. This information should help applicants to predict the time for review of their application. As the timelines are end to end, it should be noted that the longer timelines relate to where HRA is waiting on information from applicants or for approvals from other regulators.

These timelines start at application submission and therefore include time taken for the application to be validated. The vast majority of applications are not valid at initial submission' and following up with applicants to request the correct documents with the right authorisations takes up time. Changes have been made to the IRAS checklist to make it easier for applicants to submit the correct documents, but applicants and sponsors are strongly recommended to check applications carefully before submission.

There has been an increasing focus on producing initial assessment letters in order to support parallel site set-up, and to provide information to the Research Ethics Committee. The initial assessment letter is part of the local information pack provided by the sponsor to sites. However, production of this information continues to be hampered by the high percentage of applications missing key documents for assessment. The data for the minimum and first quartile will help applicants to understand the potential timelines achievable from a good quality application.

Figure 4 Timelines from application submission to HRA Approval shown in Quartiles

	Jul-17					Aug-17					Sep-17					Oct-17					Nov-17					Dec-17				
	Min	1st Quartile	Median	3rd Quartile	Max	Min	1st Quartile	Median	3rd Quartile	Max	Min	1st Quartile	Median	3rd Quartile	Max	Min	1st Quartile	Median	3rd Quartile	Max	Min	1st Quartile	Median	3rd Quartile	Max	Min	1st Quartile	Median	3rd Quartile	Max
Non-REC Studies	1	20	34	54	120	2	15	28	49	112	3	16	30	62	136	3	13	31	60	439	3	9	19	50	204	3	16	24	43	104
REC - PR Studies	12	33	44	63	355	16	31	51	79	259	10	30	45	70	395	15	28	44	73	356	10	25	38	80	379	8	27	42	72	268
REC Study, Commercial Sponsor	36	67	97	123	407	38	63	86	122	244	49	72	102	131	373	29	71	84	107	237	50	69	81	104	279	39	59	80	97	186
REC Study, Non-Commercial Sponsor	20	58	76	107	288	27	56	71	91	403	28	58	79	104	509	30	62	81	95	298	22	55	72	101	519	22	63	76	103	305