

Trust Research Governance Activity
Combined Trust Metrics
2015/2016 - QTR Ending 31-Mar-16

Full R&D Applications - Total Received 77

	All Studies	Commercial Studies	Non-Commercial Studies
Number Approved	77*	13	64
Median Time for Approval (calendar days)	24	18	25
Mean Time for Approval (calendar days)	31	22	24

Amendments - Total Received 217

Proposals reviewed not deemed research 39

Explanatory note:-

1. A maximum period of 84 Calendar Days (60 Working Days) is allowed for Trust Research Governance Permission to be granted.

2. Median and Mean Time for approval of Studies is calculated in Calendar Days on the following basis:-

- a) From the date a complete document set (IRAS R&D Form, Checklist, SSI and supporting documentation) is received by -
 - i) The Gateway if a multi-centre Study or
 - ii) The Trust Research Office if a single centre Study

b) To the date the Trust letter of permission for the Study to commence is issued.

3. The calculation of the number of Working Days to approve Studies will be interrupted if any problems are identified with the documentation provided by the researcher and/or regulatory approvals are awaited. The calculation will not recommence until the problems have been rectified by the research applicant and/or the regulatory approvals received.

***17 of the above Studies involved more than one Trust, 60 Studies were single site**

NB One application exceeded 84 days approval due to contracting issues, the Sponsor would not recognise NI law and negotiations were difficult and protracted