

Performance report

Quarter 4 2009/10 (January – March 2010)



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INTRODUCTION

The National Institute for Health Research Clinical Research Network was established by the Department of Health to provide an infrastructure for clinical research in the NHS.

The Clinical Research Network comprises:

- Six “topic” Research Networks, which focus on particular disease areas (cancer, diabetes, dementias and neuro-degenerative diseases, medicines for children, mental health and stroke)
- A Primary Care Research Network
- A “Comprehensive” Research Network, which supports all those health areas not covered by the topics, and which provides full geographical coverage of England

To carry out its work, the Clinical Research Network supports a “portfolio” of research studies by:

- Coordinating the NHS R&D permission that is required for every NHS site engaged in a clinical trial, and minimizing the bureaucracy associated with trial set-up
- Funding trained research support staff within NHS Trusts, so that researchers have access to the “on-the-ground” expertise they need to carry out clinical trials
- Supporting academic and commercial life-sciences researchers, to help them to identify appropriate study sites, and recruit patients onto trials

Each quarter, the Clinical Research Network Coordinating Centre publishes figures to show how well the Network is performing in terms of helping researchers to complete their studies to deadline, and in line with patient recruitment targets.

Unless otherwise stated, the information presented in this report represents cumulative figures for 2009/10 that reflect the recruitment data at the end of Quarter 4 (January, February, March 2010), taken as at 17 May 2010.

However, the figures for tables/graphs 3, 4, 5 and 6 relating to CSP (the Coordinated System for Gaining NHS Permission) are “to date” – ie to 24 June 2010.

The reason for these different timescales is that the timetables for data collection and reporting are not yet aligned. However, this is a matter that is being addressed, and reports for the 2010/11 financial year will report on consistent time periods.

The figures represent the most accurate position that we can produce at the time of compilation. However, please note that some minor adjustments may subsequently be made to figures to reflect “late entry” data that is acquired after 17 May.

Any queries relating to the data should be addressed to:

The Head of Performance and Planning
The NIHR Clinical Research Network Coordinating Centre
Tel: 0113 343 2314

OVERALL PICTURE OF CLINICAL RESEARCH THROUGH THE NETWORKS

1. Total number of confirmed Portfolio studies and recruitment into the Topic Specific, Primary Care and Comprehensive Clinical Research Networks

Data as at 17th May 2010.

TOPIC	Number of Studies Open to Recruitment during 2009/10	Total Number of Studies Reporting recruitment, 2009/10	Total recruitment, 2009/10
Comprehensive	1393	1255	220868
Primary Care	166	156	77235
Cancer	439	420	41440
Dementias and Neurodegenerative Diseases	125	115	8537
Diabetes	164	146	37182
Medicines for Children	115	111	7825
Mental Health	224	202	50179
Stroke	95	90	8896
	2721	2495	452,162

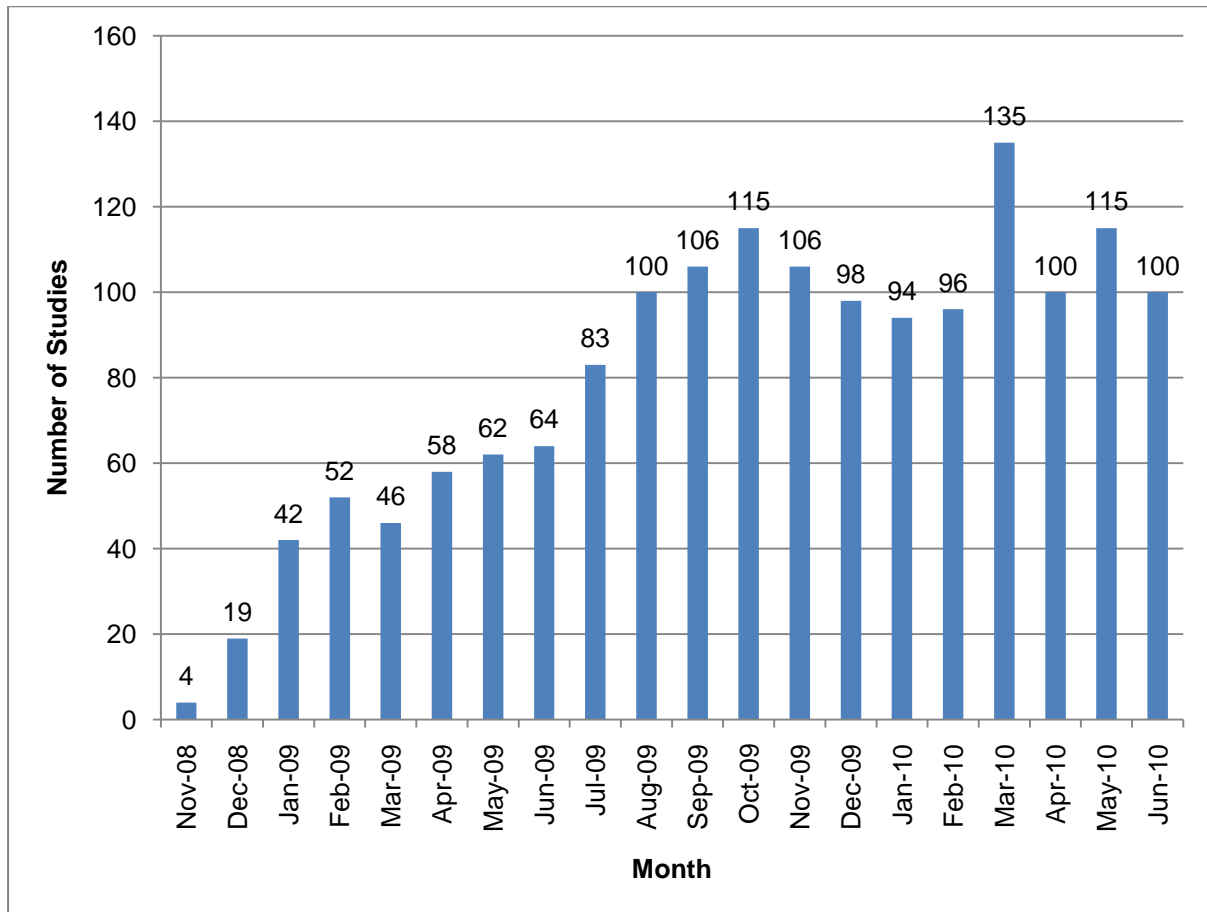
2. Total number of Comprehensive Clinical Research Network studies open or in set-up and associated recruitment in 2009/10, split by health area

Data as at 17th May 2010.

Specialty Group	Current Total Number of Studies Open or In Set-Up	Total recruitment, 2009/10
Age and ageing	19	4222
Anaesthetics	10	629
Cardiovascular	172	13366
Clinical Genetics	27	2337
Critical Care	24	10639
Dermatology	44	3045
Ear, nose & throat	16	1967
Gastrointestinal	47	7967
Health Services Research	51	9569
Hepatology	17	1807
Immunology and inflammation	73	4104
Infectious diseases and microbiology	76	19478
Injuries & Accidents	28	8759
Metabolic & Endocrine (not diabetes)	44	1605
Musculoskeletal	111	13975
Nervous system disorders	86	5131
Non-malignant haematology	9	310
Ophthalmology	37	2567
Oral & Dental	8	344
Other	17	3496
Paediatrics (non medicines)	54	5277
Public Health Research	29	8507
Renal	38	6689
Reproductive Health & Childbirth	96	72231
Respiratory	114	6513
Rheumatoid Arthritis	26	1791
Surgery	11	362
Urogenital	12	4181
	1,296	220,868

3. Number of new applications (validated R&D Forms) received by NIHR CSP per month

Total from 18 November 2008 to 24 June 2010 = 1595

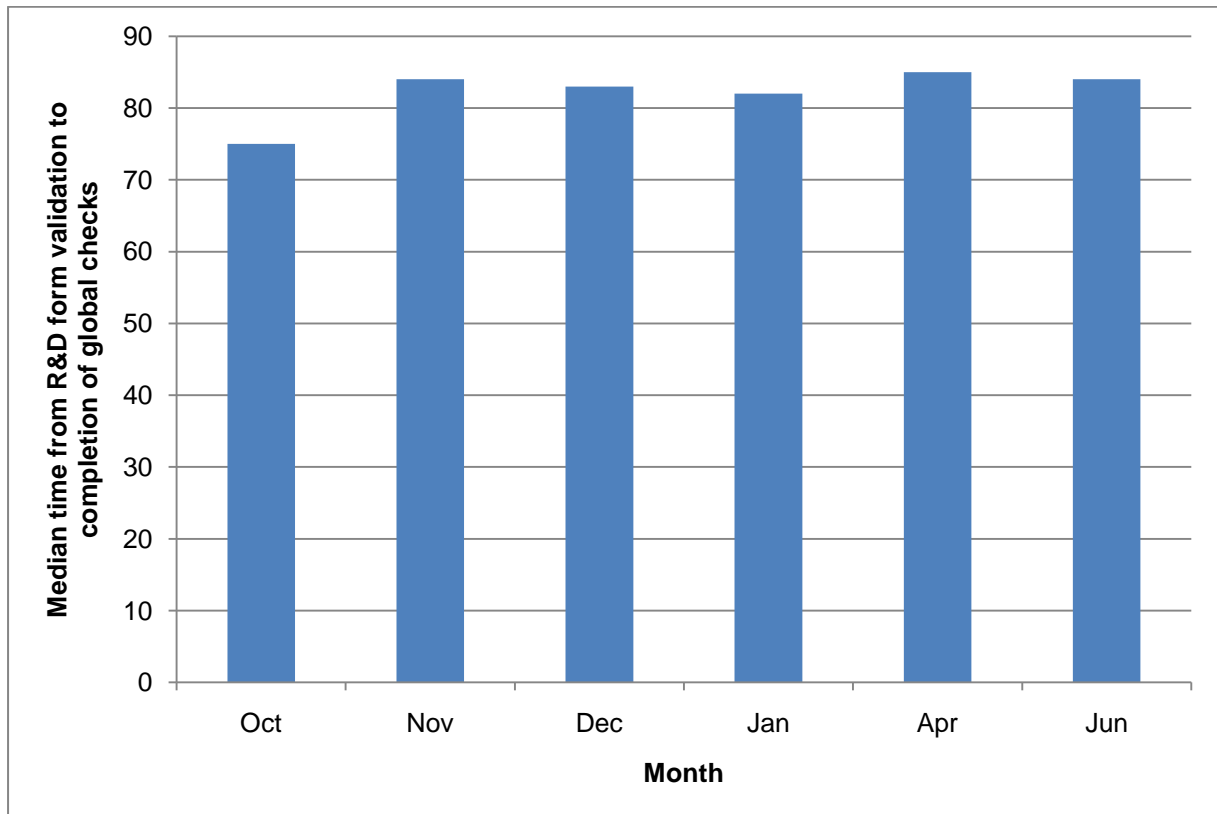


Note that these totals show valid applications to NIHR CSP. At present these data do not show studies which submit a valid R&D form, but are subsequently found to be ineligible for the NIHR CRN Portfolio or are withdrawn by the applicant.

The number of eligible applications to CSP have been relatively consistent since August 2009. This may indicate that all appropriate applications are now being submitted in this way.

4. Global Checks – time (in calendar days) from the validation of the R&D form to CSP global check completed and validated

Median = 84 days
Range = 1 to 513
Number of Records = 885



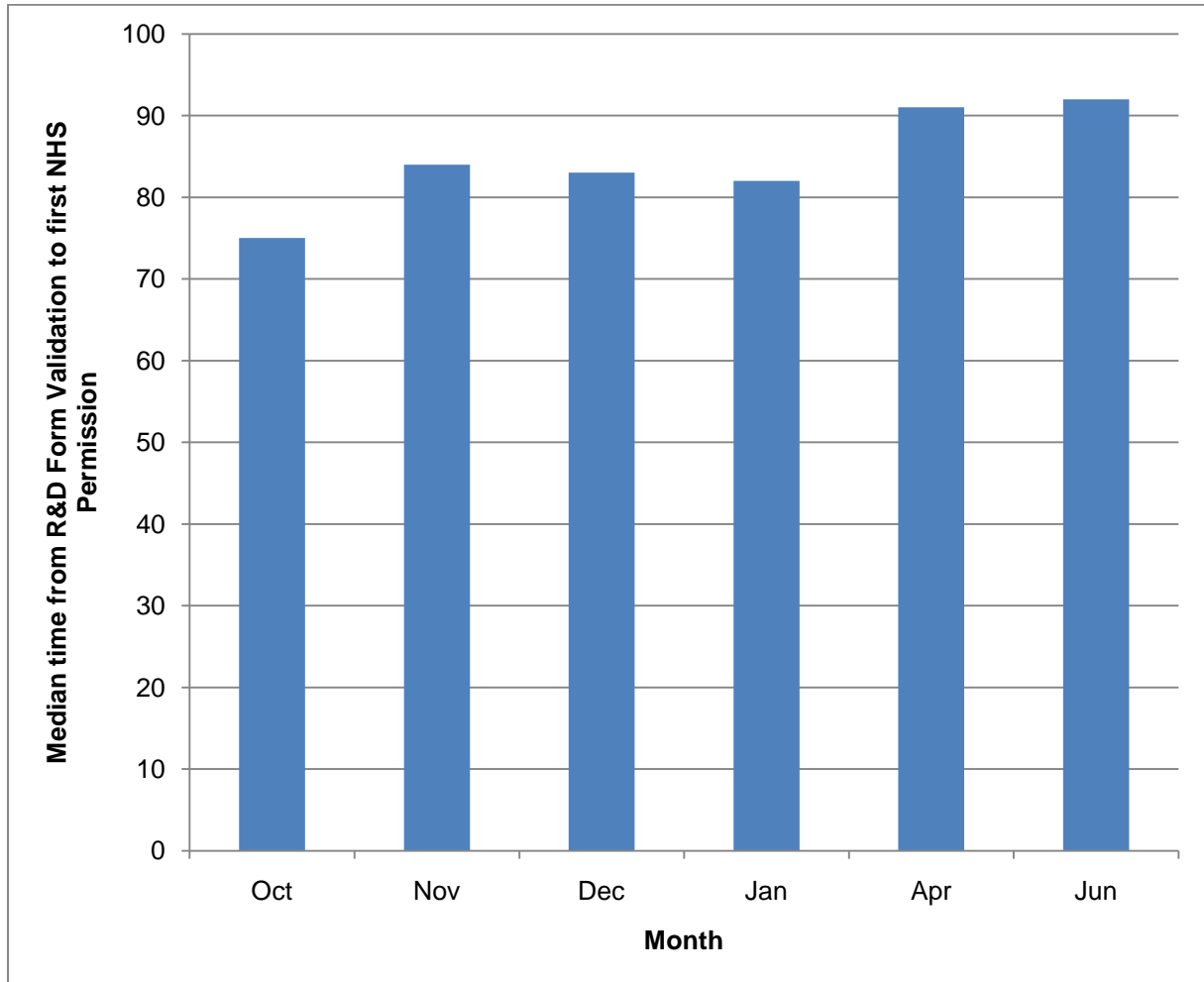
This metric shows how long the first stage of CSP application takes. This stage takes place only once for each application and is undertaken by the lead CLRN.

Note that for studies which completed their global checks prior to 7 September 2009, this metric shows the number of days to all global checks complete. i.e. not including the QA element, previously done at the end of the process by CSP Unit. Since the QA of the global checks by the Lead CLRN RM&G Manager is likely to be completed within 1-2 days of the checks being completed, it was not felt necessary to handle these separately.

The median time taken to complete global checks has not changed significantly in the last 8 months. This may be due to the fact that this metric is cumulative, i.e. the median shown here is the median for all applications into CSP since the system began.

5. NHS permission first site – time (in calendar days) from validation of the R&D form to the date of the first NHS Permission for a study

Median = 92 days
Range = 1 to 454
Number of Records = 888

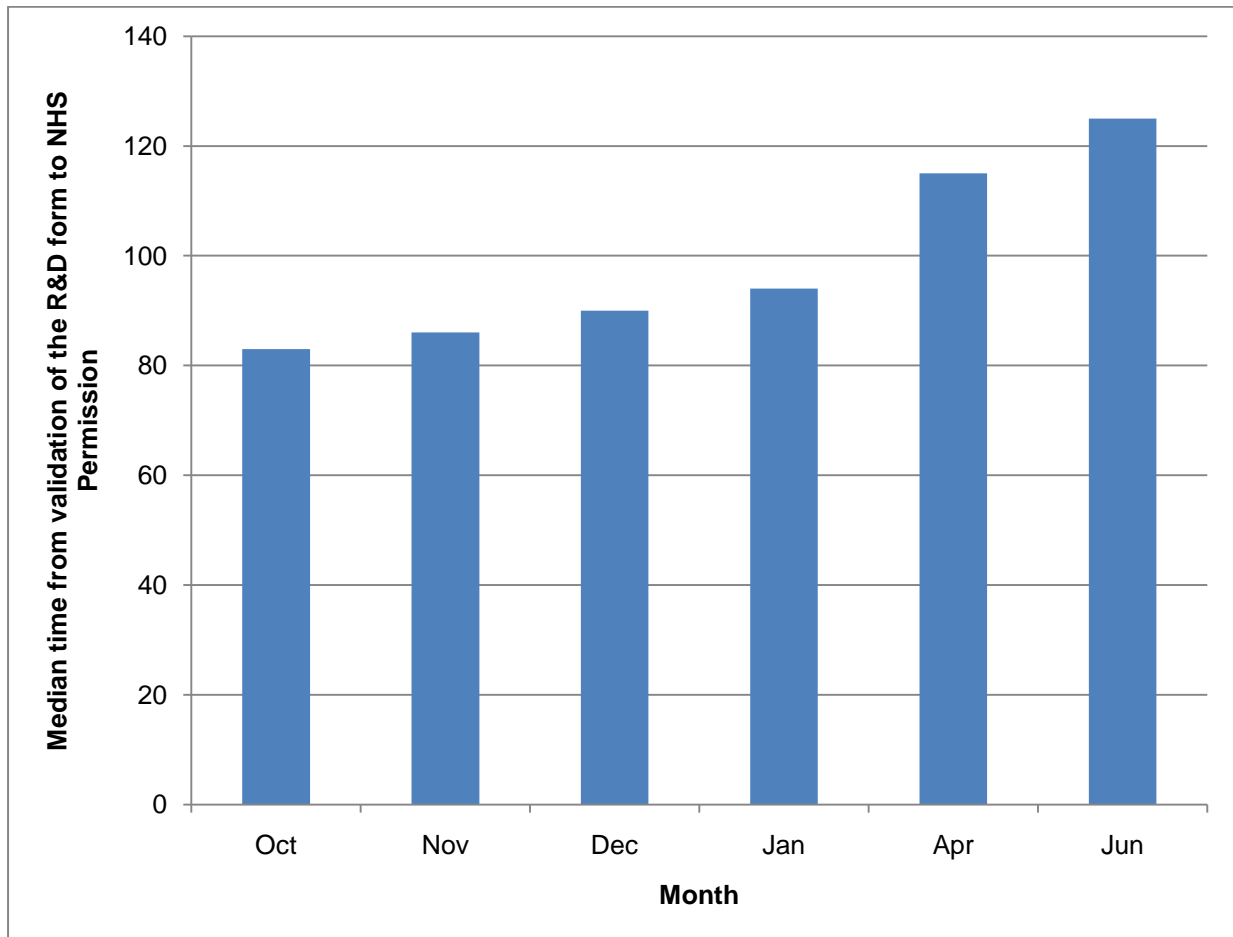


This metric shows the time it takes for global and local organisations to process an application to the point of the first NHS Permission.

The median time taken to achieve first NHS permission has risen in the last 3 months. This may be due to the fact that this metric is cumulative, i.e. the median shown here is the median for all applications into CSP since the system began. Therefore studies taking the longest time to achieve their first NHS permission may only have been counted in the metrics recently.

6. NHS Permission all sites – time (in calendar days) from validation of the R&D form to the date of NHS permission for all sites

Median = 125 days
Range = 1 to 645
Number of Records = 5106



This metric shows how long it takes to process an application from receipt of the application (when the R&D Form is validated) to when NHS permission is granted. These figures include all sites that have gained permission, that is the calculations are applied to both the first NHS permission and every subsequent permission granted thereafter.

The median time taken to achieve these NHS permissions has been rising for the last 6 months. This may be due to the fact that this metric is cumulative, i.e. the median shown here is the median for all applications into CSP since the system began. Therefore studies taking the longest time to achieve their first NHS permission may only have been counted in the metrics recently.

LIFE-SCIENCES INDUSTRY STUDIES

The NIHR Clinical Research Network continues to grow and support the set up and delivery of commercial research in the UK. **Recruitment for 2009/10 reached 14,148 participants from 205 studies.**

- **463** Industry studies were adopted into the Clinical Research Network portfolio during 2009/10
 - **74** new Industry studies were adopted in Quarter 4 2009/10
- For 2009-10, an average of **57%** of closed studies achieved 100% recruitment of the planned UK target
 - **71%** of NIHR CRN Industry studies closing in Q4 achieved 100% of the planned UK target
- **The number of co-adopted studies is increasing** – 72 studies now involve cross-Network collaboration to maximize access to patients and to deliver recruitment targets

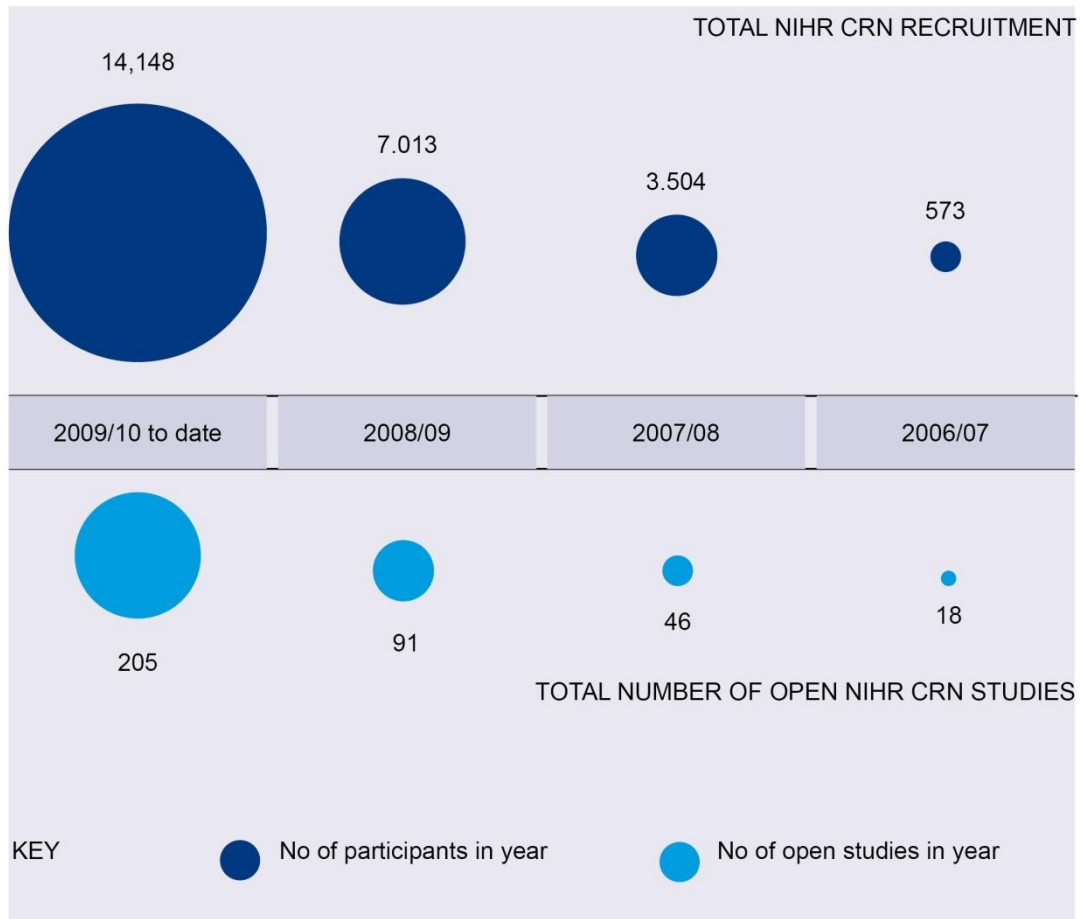
7. Number of industry studies adopted by the Clinical Research Network portfolio, year to date

Network	Total number of adopted studies	Number of studies led by Network	Number of studies coadopted with other Networks	Number of Med-Tech studies	Number of studies NOT adopted
Comprehensive	136	98	36	11	12
Primary Care	42	12	30	0	1
Cancer	127	126	1	0	15
DeNDRoN	45	45	0	1	2
Diabetes	80	76	4	2	3
Medicines for Children	82	79	3	2	2
Mental Health	15	13	2	0	3
Stroke	15	14	1	0	2
TOTAL	542	463*	79	16	40

* Number of unique studies

8. Patient recruitment into commercial studies on the portfolio, year to date

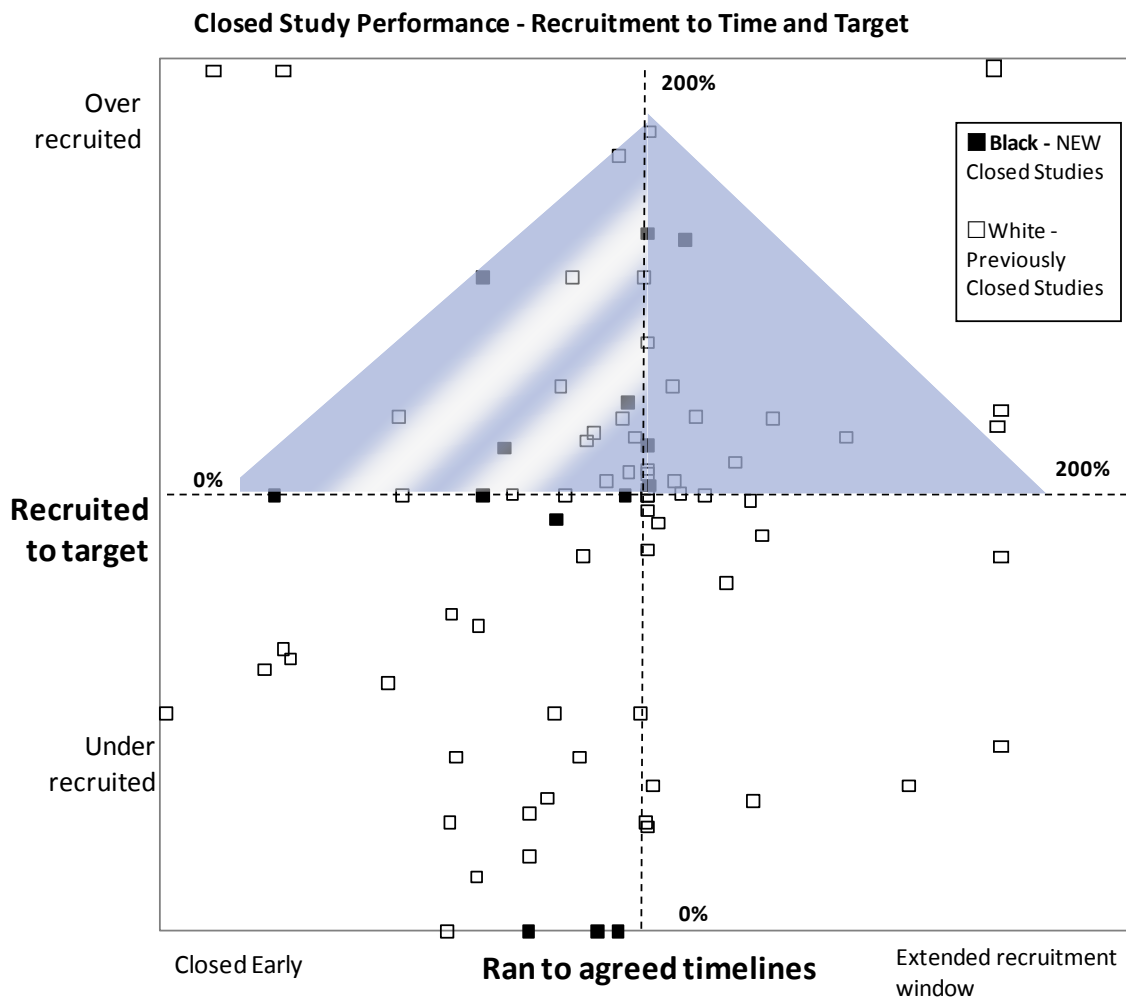
The diagram below presents the total number of participants recruited into NIHR CRN Industry studies on a yearly basis, since April 06/07. All ongoing recruitment data for 2009/10 has been included in this report and is current up to the date when the data was assembled for publishing in this report.



9. Closed study performance: recruitment to time and target

The intersection of vertical and horizontal lines represents 100% achievement of recruitment target (vertical) and study duration to 100% of agreed timeline (horizontal). The shaded region represents positive performance, therefore if a study is mapped in this region it is considered a favourable outcome on delivering to time and target.

The diagram below plots all the NIHR CRN closed commercial studies to date. The data points presented in black are for studies which have closed in Q4 09/10.



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