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1. INTRODUCTION

The NIHR Clinical Research Network

The National Institute for Health Research (NIHR) Clinical Research Network (CRN) is an essential element in achieving the government's vision "to create a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public."

The Clinical Research Network comprises eight national networks:

- Six 'topic' Clinical Research Networks, which focus on specific disease areas: Cancer, Diabetes, Dementias and Neurodegenerative Diseases, Medicines for Children, Mental Health, and Stroke
- A Primary Care Research Network
- A 'Comprehensive' Clinical Research Network, which supports all those health areas not covered by the 'topic networks', and which provides full geographical coverage of England. The Comprehensive Clinical Research Network also provides NHS Research Management & Governance (RM&G) activities for NIHR supported studies.

The role of the Clinical Research Network is to provide the infrastructure required to deliver a portfolio of high-quality research studies in the NHS in England. This 'NHS infrastructure' ensures that CRN Portfolio studies can be conducted and completed successfully, and includes:

- Clinician sessions, and trained research support staff, such as nurses, clinical trials officers, administrative staff, and GP practice staff
- Dedicated staff time in pharmacy, radiology, pathology, and other NHS service departments, and funding for additional investigations, assessments, tests, and extra inpatient stays
- Streamlined NHS RM&G support for NIHR supported studies, and a local RM&G advice service
- Groups of national subject experts that review study plans and protocols, and advise researchers on NHS feasibility and delivery issues
- Local support for site identification, NHS site set-up, and general support for study delivery.

Information included in this report

This report provides key activity data from the Clinical Research Network. The data are presented in three parts:

- CRN Portfolio activity data
- NHS Research Management & Governance activity data
- Key data for life-sciences Industry studies

Reporting against the CRN's High Level Objectives for 2010-15 will commence in April 2011.

It is **important to note** that data on studies and patient recruitment are uploaded to the CRN Portfolio by the Chief Investigator (or their delegate) on an ongoing basis. Investigators are encouraged to upload data promptly, so that data reporting is accurate. However, to ensure maximum data capture, this data upload can occur up to six weeks after the end of each quarter, with an absolute cut-off imposed at 30 June each year. For this reason, data reports for the same quarter may change over the course of the reporting year.

Period covered by this report

This report reports activity in the period 01 April 2010 to 30 June 2010, which is Quarter 1 of the 2010/11 financial year.

Where figures are given for 'year to date', this refers to the Clinical Research Network financial year, which is 01 April 2010 to 31 March 2011.

The information contained in the report represents the most complete information available at the time of publication.

Dissemination

This report is produced by the Clinical Research Network Coordinating Centre, which is responsible for collating and publishing activity and performance data for the NIHR Clinical Research Network as a whole.

It is the policy of the Clinical Research Network Coordinating Centre to be open and transparent in its activities and its associated impact. All Quarterly and Annual Reports will be published on our website, and can be accessed using this link:

http://www.crncc.nihr.ac.uk/about_us/performance_objectives.htm

The data presented in this report may be quoted in presentations and papers. However, we would ask that the title and issue date of the report is used, to avoid any confusion about the period to which the figures relate and the time at which the data were reported.

Further information

For feedback on, or queries relating to, the information contained in this report, please contact:

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2. CLINICAL RESEARCH NETWORK PORTFOLIO ACTIVITY DATA

2.1 Recruitment activity for Portfolio studies

The NIHR CRN Portfolio is a collection of high quality research studies that receive support from the Clinical Research Network in set-up and delivery. Some studies receive support more than one component of CRN. Where this is the case, a “Lead” Network is appointed and for the purposes of this report, the number of studies and recruitment are shown only against that Network.

| Network | Number of Studies Entered on to the Portfolio in Q1 2010/11 | Number of Studies Open to Recruitment during Q1 2010/11 | Total Number of Studies Reporting Recruitment in Q1 2010/11 | Total Recruitment Q1 2010/11 |
|--|---|---|---|------------------------------|
| Comprehensive | 116 | 1,268 | 1,008 | 40,591 |
| Primary Care | 25 | 96 | 94 | 8,135 |
| Cancer | 12 | 388 | 314 | 17,080 |
| Dementias & Neurodegenerative Diseases | 9 | 107 | 83 | 2,134 |
| Diabetes | 33 | 155 | 120 | 8,455 |
| Medicines for Children | 8 | 94 | 83 | 1,842 |
| Mental Health | 20 | 162 | 125 | 12,478 |
| Stroke | 2 | 85 | 74 | 2,074 |
| TOTAL | 225 | 2,355 | 1,901 | 92,789 |

Table 1: Total Number of NIHR CRN Portfolio Studies that are open, and recruitment into Topic-Specific, Primary Care and Comprehensive Clinical Research Networks

Number of studies entered onto the Portfolio this quarter

This figure gives an indication of demand for support from the Clinical Research Networks. The expectation is that the Clinical Research Networks should have the capacity to meet this demand. However, this will need to be carefully monitored as the number of studies entered onto the Portfolio increases.

Number of studies open to recruitment

The number of “open” studies gives a broad indication of the scale of opportunities for participants to take part in clinical research in the NHS in England through the Networks.

It is also an indicator of the current levels of recruitment-related work being carried out by the Clinical Research Network.

We would aim to see the number of open studies increase over time, although this will be limited by issues such as the capacity of the Clinical Research Network and NHS sites, the levels of funding available to commission research and the number of high quality study proposals developed and submitted for funding.

Total number of studies reporting recruitment

This figure shows how many of the studies that are ‘open to recruitment’ actually have participants recruited to and taking part in the study. These figures may represent an underestimate of the actual numbers of participants, as there may be some studies that have recruited participants but that have not yet provided this recruitment data for inclusion in this report.

One of the roles of the Clinical Research Network is to provide advice to researchers in the planning stages of Portfolio studies in order to support their successful delivery. This includes offering local knowledge about participant populations, and whether or not there is likely to be sufficient eligible participants for the study. We would therefore aim for the number of studies reporting recruitment to be as close as possible to the figure for open studies, as this indicates that studies have attracted appropriate involvement.

Total recruitment figure

This gives a “snapshot” of the number of participants engaged in clinical studies that are supported by the Networks. An objective of the Clinical Research Network is to increase the level of NHS patient participation over time, however there are external factors which place limitations on the numbers of participants engaged in trials which should be taken into account when considering the performance of the NIHR CRN.

External limiting factors include:

- The type of study: observational studies tend to recruit large numbers and are often less complex to deliver, whilst interventional studies where a new treatment or device is being investigated are more complex and may recruit fewer participants for the same time and effort invested
- The nature of the disease area: studies investigating rare conditions will, by their nature, recruit fewer participants
- Seasonal variations in terms of patient flow, such as a reduction in number of patients attending clinics over the key holiday periods.

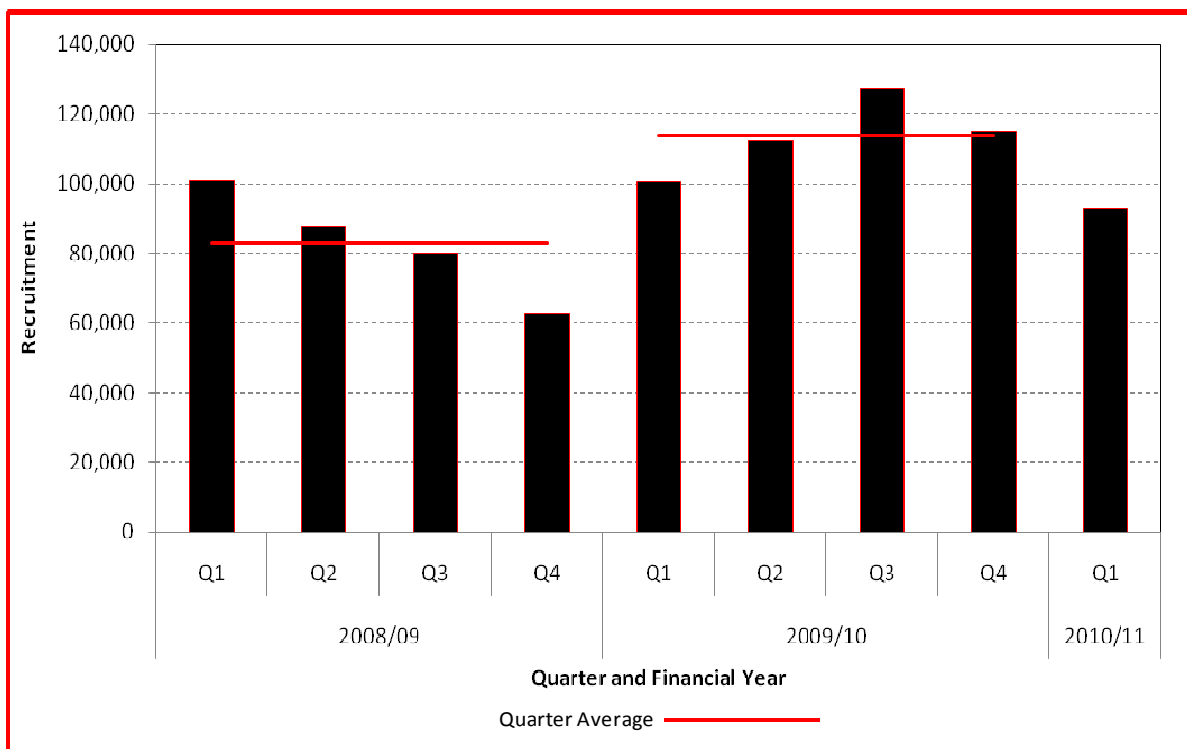


Figure 1: Recruitment per quarter

Trend information:

- Compared with the (mean) average quarterly recruitment for the previous year (2009/10), derived by taking the total annual recruitment figure and dividing by four quarters, the number of participants recruited into open NIHR CRN Portfolio studies for this quarter is down by 18% (Figure 1). This cannot be taken as a rigorous measure of performance, given that the number of participants recruited is dependent on the type of study and how many participants it requires. Since data can be uploaded retrospectively by individual studies this total is likely to increase throughout the year.
- Compared with the previous quarter, the number of open studies reporting recruitment is down by 3%. The most likely reason for this is that some studies are slow to provide recruitment data, resulting in a reporting lag. Data on the number of participants into Portfolio studies provides an important indicator of the impact of the CRN Network. The Coordinating Centre is taking steps to address this, and will continue to monitor this. This suggests that recruitment information contained in the report for this quarter is likely to understate actual levels of participation into CRN Portfolio studies.

2.2 Total number of Open Comprehensive Clinical Research Network studies and associated recruitment,

The Comprehensive Clinical Research Network covers 26 therapeutic areas not covered by the Topic Networks or the Primary Care Research Networks. Each area has a national “Specialty Group”, chaired by a research active clinician, which encourages recruitment into studies in that particular Portfolio and monitors study delivery. There is also an “Other” specialty group category for studies that do not obviously fit any group (although every effort is made to keep the number of studies in this category to a minimum).

Table 1 provides *total* figures for the number of open studies and recruitment for the Comprehensive Clinical Research Network. These totals can be broken down to gain a more detailed picture of Comprehensive Clinical Research Network activity by specialty area (shown in Table 2).

Table 2: Number of Open Studies and Associated Recruitment, by Comprehensive Clinical Research Network Specialty Group

| Specialty Group | Number of Studies Open to Recruitment During Q1 2010/11 | Total Recruitment Q1 2010/11 |
|--|---|------------------------------|
| Age and Ageing | 13 | 178 |
| Anaesthesia, Peri-operative Medicine & | 12 | 190 |
| Cardiovascular | 159 | 4,746 |
| Critical Care | 26 | 7,777 |
| Dermatology | 39 | 704 |
| Ear, Nose & Throat | 19 | 743 |
| Gastroenterology | 45 | 1,293 |
| Genetics | 33 | 519 |
| Health Services Research | 46 | 1,123 |
| Hepatology | 15 | 383 |
| Immunology and Inflammation | 69 | 445 |
| Infectious Diseases & Microbiology | 76 | 1,879 |
| Injuries & Emergencies | 19 | 1,193 |
| Metabolic & Endocrine (not diabetes) | 45 | 212 |
| Musculoskeletal (including rheumatoid | 141 | 3,469 |
| Nervous System Disorders | 88 | 2,214 |
| Non-Malignant Haematology | 8 | 298 |
| Ophthalmology | 36 | 627 |
| Oral & Dental | 8 | 149 |
| Other | 14 | 36 |
| Paediatrics (non medicines) | 55 | 1,171 |
| Public Health Research | 23 | 2,610 |
| Renal | 41 | 2,228 |
| Reproductive Health & Childbirth | 99 | 4,167 |
| Respiratory | 117 | 1,251 |
| Surgery | 12 | 100 |
| Urogenital | 10 | 886 |
| TOTAL | 1,268 | 40,591 |

Trend information:

- The number of open studies for this quarter, compared to last quarter, has risen from 1031 to 1268 – a 23% increase
- The percentage of open studies reporting recruitment has remained constant at 79.5% in Q1 2010/11 compared to 80.5% in Q4 2009/10
- Four Specialty Groups have seen significant proportional increases in recruitment this quarter, of particular note:
 - The Critical Care Specialty Group has achieved total participant recruitment of 7,777 this quarter, compared to 5662 last quarter - an uplift of 37%. The main reason for this increase is due to the work of the Specialty Group on a study entitled FIRE (Fungal Infection Risk Evaluation). This study had been struggling to recruit, but the Specialty Group working with the CLRNs, has been able to reverse this situation, and significantly increase the number of sites delivering the study.
 - The Non-Malignant Haematology Specialty Group has achieved total participant recruitment of 298 this quarter, compared to 108 last quarter – an uplift of 176%. This is a relatively new Group, with a newly-appointed Chair, that is now successfully driving recruitment in this disease area.
- Two Specialty Groups (Gastroenterology and Reproductive Health & Childbirth) have seen significant decreases in the number of participants recruited this quarter, both as a result of the closures of high recruiting studies.
- Figures for the “Other” category have dropped but this is due to the realignment of studies into Specialty Group healthcare areas where they are more appropriately managed. This should therefore be interpreted positively.

3. RESEARCH MANAGEMENT & GOVERNANCE ACTIVITY DATA

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

The NIHR Coordinated System for gaining NHS Permission (CSP) is a system comprising both IT and Clinical Research Network resources, to support researchers in gaining the necessary permissions to carry out an NIHR study quickly and efficiently, with the minimum of bureaucracy. CSP was introduced in the NHS in England in November 2008.

Figure 2 below shows the number of studies accepted for processing through CSP per month. Some fluctuation month by month is expected, particularly in response to funding rounds and seasonal variations in academic activity. The number of non-commercial studies entering the Portfolio may be reaching a steady state as measures are now in place to ensure that all eligible studies are processed through CSP. However, we anticipate that the volume of commercial studies processed through CSP will rise gradually over the course of this financial year if the benefits of CSP and network infrastructure can be demonstrated to pharma, biotech, and medical devices companies.

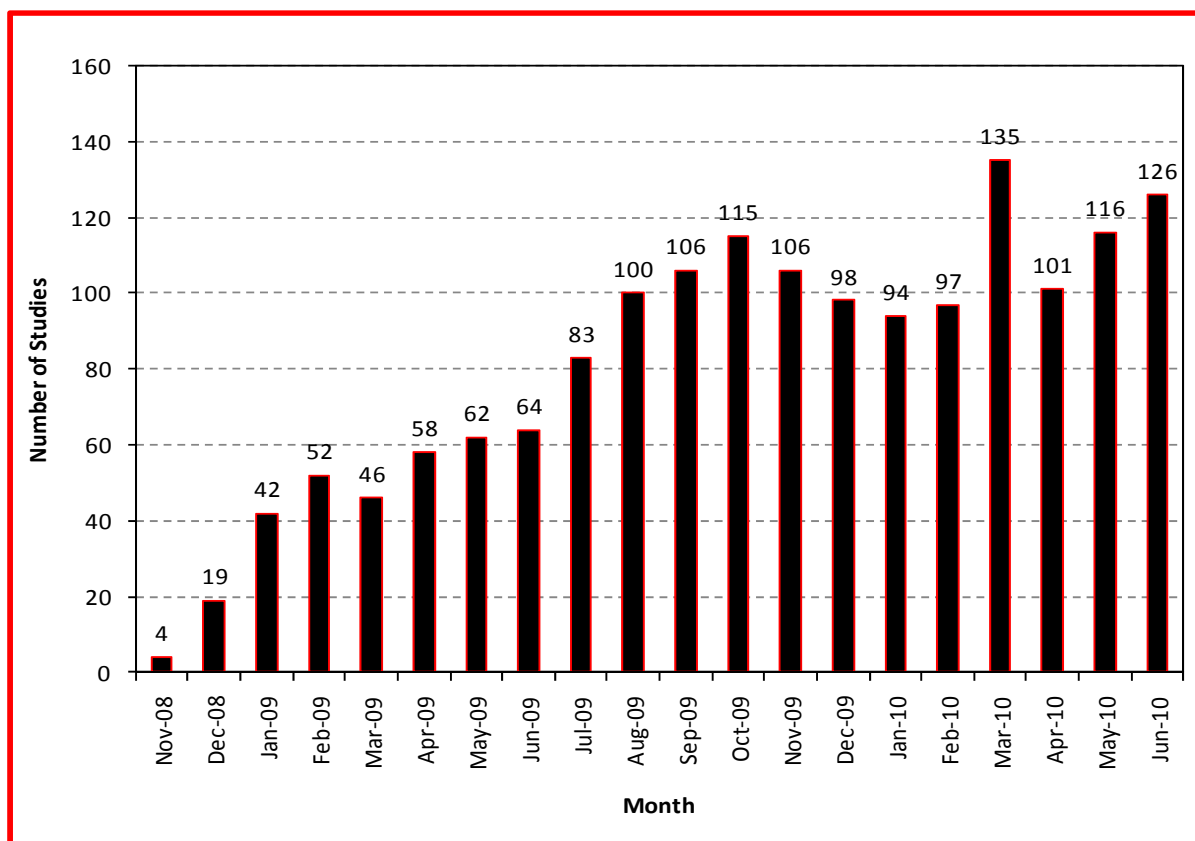


Figure 2: Number of Applications Received via CSP by Month

Trend information:

Last year, the total number of applications through CSP was 1118 (an average of 280 per quarter). This quarter we have received 343 applications – higher than the average. We can therefore assume that strong demand for Clinical Research Network support continues, and is on target to equal or surpass last year’s level of demand.

3.2 Study set-up time (in calendar days, from validation of the R&D Form, to the date of the first NHS Permission for a study)

Responsibility for the various aspects of study set-up (regulatory authorities, NHS research ethics, NHS Permission) sits with a number of bodies. The Clinical Research Network provides a framework for NHS Permission, but is not in a position to control other parallel processes. However, as the CSP system tracks both the beginning of the study set-up process (submission of a valid “R&D form”) through to receipt of NHS Permission to commence the study (which is only given when all other necessary approvals are in place), the Clinical Research Network is in a unique position to be able to report on study approval times as a whole, as they are experienced by researchers.

Figure 3 shows overall approval time, from receipt of a valid R&D form for the study, to the date of receiving NHS Permission at the first study site. These are therefore good data on the time taken for research studies to pass through all the approvals processes – **however it is not an indicator of the Clinical Research Network’s ‘performance’ in relation to study approval.**

Figure 3 shows the (median) average time to permission for studies per quarter; i.e. the median time for the approvals process for those studies for which NHS permission was issued in that quarter. The rising trend during the last quarter of 2009 and the first quarter of 2010 is a reflection of the inclusion of some long-standing studies which finally completed the approvals process and for which NHS Permission was issued. During these two quarters, greater emphasis was placed on proactively managing studies and addressing issues with studies that had got ‘stuck’ in the system. Once these long-standing studies have worked through the system, the median times per quarter should start reducing.

The current CSP information systems do not currently allow us to separate out the part of the approval process that is under the management of the Clinical Research Network (i.e. NHS Permission), therefore we cannot offer interpretative commentary on these data in respect of CRN performance. The introduction of the NIHR R&D Management Information System (RDMIS) in 2011 will provide this transparency.

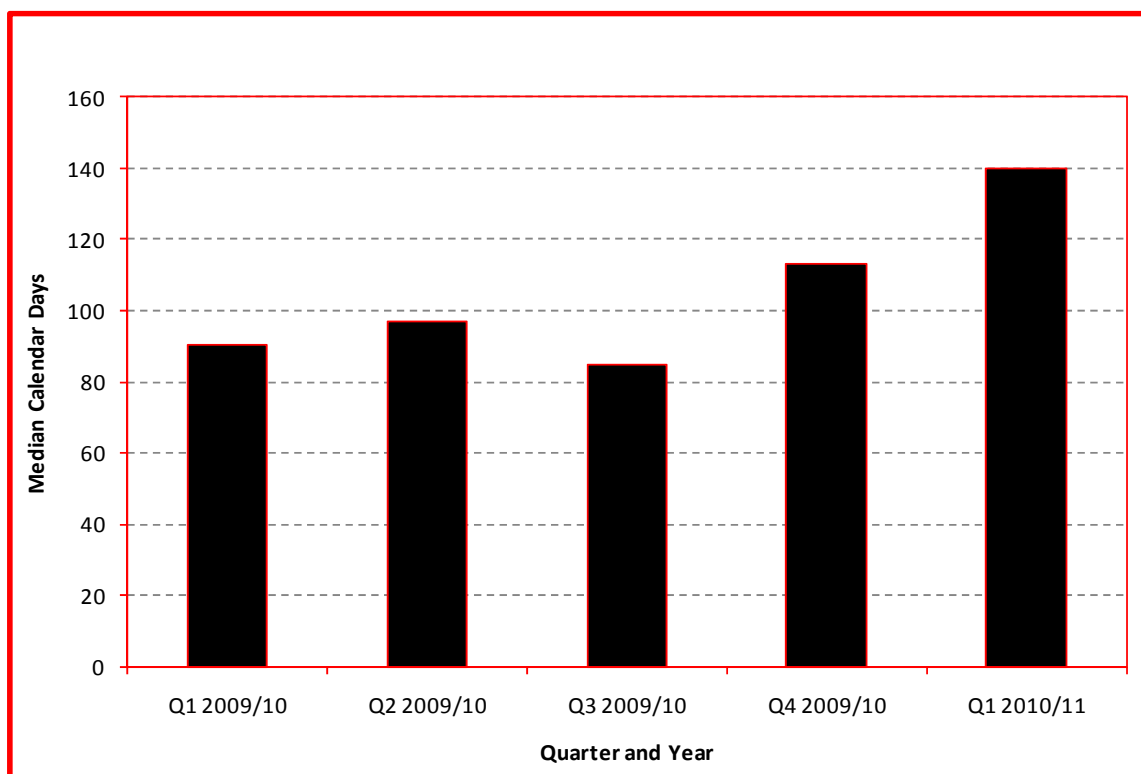


Figure 3: Median Calendar Days Taken to Obtain First NHS Permission

4. KEY DATA FOR LIFE-SCIENCES INDUSTRY STUDIES

4.1 Number of Industry studies adopted by the Clinical Research Network

The life-sciences industry continues to be of significant strategic and economic importance to the UK, which is why the Clinical Research Network actively encourages and supports life-sciences companies to undertake clinical research in the NHS in England.

Each quarter, we measure how many NIHR CRN Portfolio studies are funded and sponsored by commercial life-sciences companies, as an indicator of the extent to which commercial companies are engaging with the Clinical Research Network and the extent of opportunities for patients to participate in these studies.

Some studies are co-adopted, which means that more than one Network is engaged in supporting the research. Where this is the case, a “Lead” Network is appointed. The figures in table 3 show this. Co-adoption occurs to support cross-Network referral and participant identification, for example a patient may be identified in Primary Care, but go on to receive treatment through the trial in a secondary care unit. The ability to work “cross-Network” is a benefit of the Clinical Research Network to Industry as it facilitates recruitment of participants across often complex patient treatment pathways.

Med-tech is a specific area of focus and growing area for the Clinical Research Network and specific data on the number of studies in this area is detailed in table 3.

Finally, we produce a figure for the number of commercial studies that apply for Network support but which are NOT adopted onto the NIHR CRN Portfolio. When compared with the number of studies that have been adopted, this gives an indication of the relatively small number of studies that progress through the adoption process but are not able to be supported for a variety of reasons.

Trend information:

- The total number of unique life-sciences studies on the Portfolio at the end of this quarter is 535, compared with 463 for the final quarter of 2009/10. Study numbers have therefore increased by 16% compared to the last quarter, so we can infer that the Clinical Research Network is increasingly valued and utilised by the life-sciences industry.
- The number of co-adopted studies on the Portfolio has increased by 26% (from 77 studies to 97 studies) compared with the last quarter. This demonstrates that the Networks are increasingly introducing cross-Network systems to ensure that the patient treatment pathway mirrors how patients are recruited into studies. The growth in this area is driven principally by the two Networks: the Primary Care and the Comprehensive Clinical Research Network (which includes 26 Specialty Groups).
- The number of Med-tech studies was up 50% (from 16 to 24 studies) compared with the last quarter. This follows a specific six month drive by the NIHR CRN Industry team to engage with Med-tech companies and highlight the benefits of working with the Networks.

Table 3: Life-Sciences Industry Studies

| Network | Number of Adopted Industry Studies by Lead Network | Number of Adopted Industry Studies by Co-adopting Network | Total Number of Adopted Industry Studies by Network | Number of Medical Device Studies Included in Total | Number of Studies Which Have NOT Been Adopted |
|---|---|--|--|---|--|
| Comprehensive | 140 | 52 | 192 | 17 | 17 |
| Primary Care | 12 | 34 | 46 | 0 | 1 |
| Cancer | 134 | 0 | 134 | 0 | 17 |
| Dementias & Neurodegenerative Diseases | 51 | 0 | 51 | 1 | 4 |
| Diabetes | 87 | 4 | 91 | 4 | 3 |
| Medicines for Children | 85 | 4 | 89 | 2 | 2 |
| Mental Health | 13 | 2 | 15 | 0 | 3 |
| Stroke | 13 | 1 | 14 | 0 | 2 |
| TOTAL | 535* | 97 | 632 | 24 | 49 |

*number of unique studies

4.2 Recruitment into life-sciences Industry studies

Figure 4 shows the level of participant recruitment into Portfolio studies funded and sponsored by the life-sciences industry. This represents an increased number of participants recruited into studies running in the UK, which are actively supported and performance managed by the Networks.

Trend information:

The trend is for a year on year doubling of the number of participants recruited into NIHR CRN Portfolio studies sponsored and funded by Industry. Figure 4 for this quarter is in excess of the average quarter for 2009/10, therefore we can infer that this trend continues.

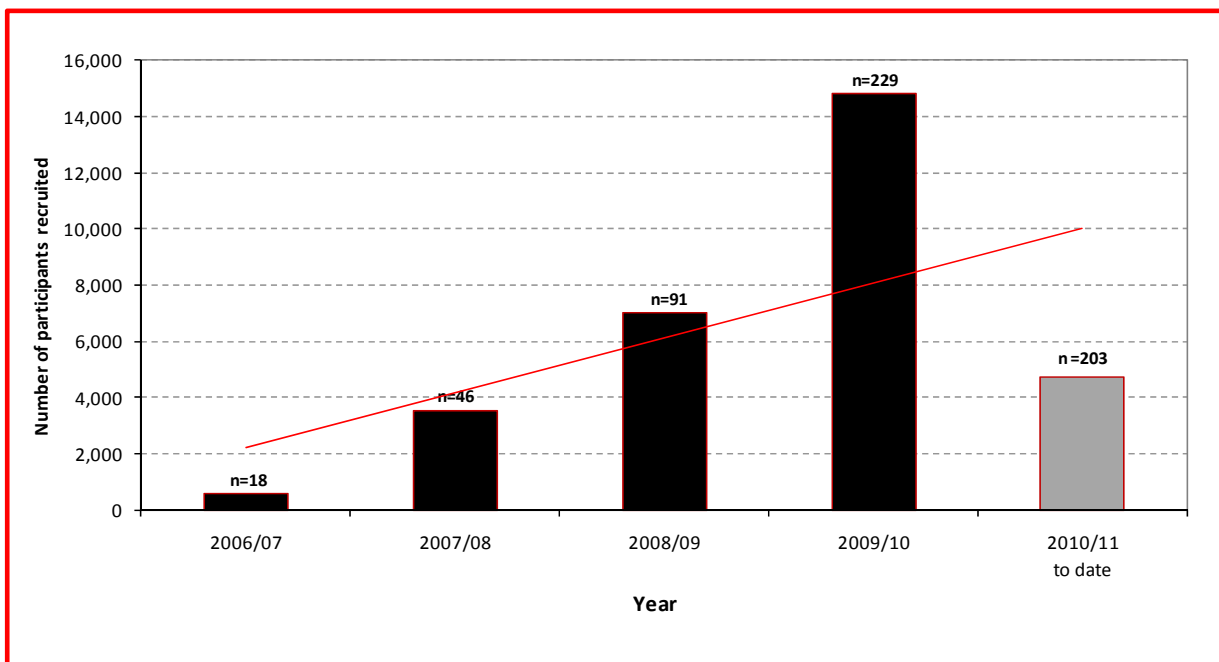


Figure 4: Total Recruitment into Industry Studies for each Operating Year

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