NHS
National Institute for Health Research

Clinical Research Network

# Activity Report

## Quarter 4 2010/11 (January to March 2011)

**Issued: 15 June 2011**

**Contents**

# 1. INTRODUCTION

## The NIHR Clinical Research Network

The National Institute for Health Research (NIHR) Clinical Research Network 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 role of the Clinical Research Network is to provide researchers with the practical support they need to make clinical studies happen in the NHS, so that more research takes place across England, and more patients can take part.

This practical support includes:

- Reducing the "red-tape" around setting up a study
- Funding the people and facilities needed to carry out research "on the ground", so research activity does not drain core NHS resources
- Helping researchers to identify suitable NHS sites, and recruit patients to take part in research studies
- Advising researchers on how to make their study "work" in the NHS environment

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 and governance activities for NIHR supported studies

## Information included in this report

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

- Clinical Research Network High Level Objectives
- Clinical Research Network Portfolio activity
- NHS Research Management and Governance activity
- Life-sciences Industry studies

It is **important to note** that data on studies and patient recruitment are uploaded to the Clinical Research Network 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 January 2011 to 31 March 2011, which is Quarter 4 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 are therefore 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

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## 2. CLINICAL RESEARCH NETWORK HIGH LEVEL OBJECTIVES

### 2.1 Introduction

The Clinical Research Network High Level Objectives are our overarching objectives for the five-year period 2010-15. However, High Level Objective 1 takes 1 April 2009 as the start point.

The objectives are focused on delivery outcomes. They act as a management mechanism for driving forward our performance, and provide defined and agreed criteria for gauging improvement over time.

Table 2.1 presents the following information:

- Objective: the organisational goal for the Clinical Research Network
- Measure: the number or quantity that will be used to measure progress against the objective
- Target: the value of the measure that is the target value
- Timescale: the date by which the target value will be achieved, and therefore the timescale for the Clinical Research Network to reach the target (from the start date of 1 April 2010)

The introduction of the High Level Objectives has necessitated some new information gathering requirements and also some changes to underlying information systems.

These changes are being rolled out in a phased way, with full reporting on all High Level Objectives commencing from April 2011.

**Table 2.1: Clinical Research Network High Level Objectives 2010-2015**

| Objective | | Measure | Target | Timescale |
|---|---|---|---|---|
| **1** | Double the number of participants recruited into NIHR CRN Portfolio studies | Number of participants recruited in a reporting quarter into NIHR CRN Portfolio studies | 125,000 | 4 years (31 March 2014) |
| **2** | Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time | **2A:** Proportion of **commercial** contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed Network sites | 80% | 2 years (31 March 2012) |
| | | **2B:** Proportion of **non-commercial studies managed by Registered CTUs** achieving or surpassing their recruitment target during their planned recruitment period | 80% | 3 years (31 March 2013) |
| | | **2C:** Proportion of **non-commercial studies not managed by Registered CTUs** achieving or surpassing their recruitment target during their planned recruitment period | 80% | 5 years (31 March 2015) |
| **3** | Increase the percentage of commercial contract studies delivered through the NIHR CRN | Number of commercial contract studies on the NIHR CRN Portfolio as a percentage of the total commercial MHRA CTA approvals for Phase II–IV studies, on an annual basis | 60% | 4 years (31 Dec 2013) |
| **4** | Reduce the time taken to achieve NHS permission through CSP for NIHR studies | Proportion of studies obtaining NHS permission within 40 calendar days (from receipt of a valid complete application) | 80% | 3 years (31 March 2013) |
| **5** | Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies | **5A:** Proportion of **commercial** contract studies achieving first participant recruited within 30 calendar days of NHS Permission being issued, at confirmed Network sites | 80% | 2 years (31 March 2012) |
| | | **5B:** Proportion of **non-commercial studies managed by Registered CTUs** achieving first participant recruited within 30 calendar days of NHS Permission being issued | 80% | 3 years (31 March 2013) |
| | | **5C:** Proportion of **non-commercial studies not managed by Registered CTUs** achieving first participant recruited within 30 calendar days of NHS Permission being issued | 80% | 5 years (31 March 2015) |
| **6** | Increase the percentage of NHS Trusts participating in NIHR CRN Portfolio studies | Proportion of NHS Trusts recruiting each year into NIHR CRN Portfolio studies | 98% | 3 years (31 March 2013) |

## 2.2 Summary data on performance to date

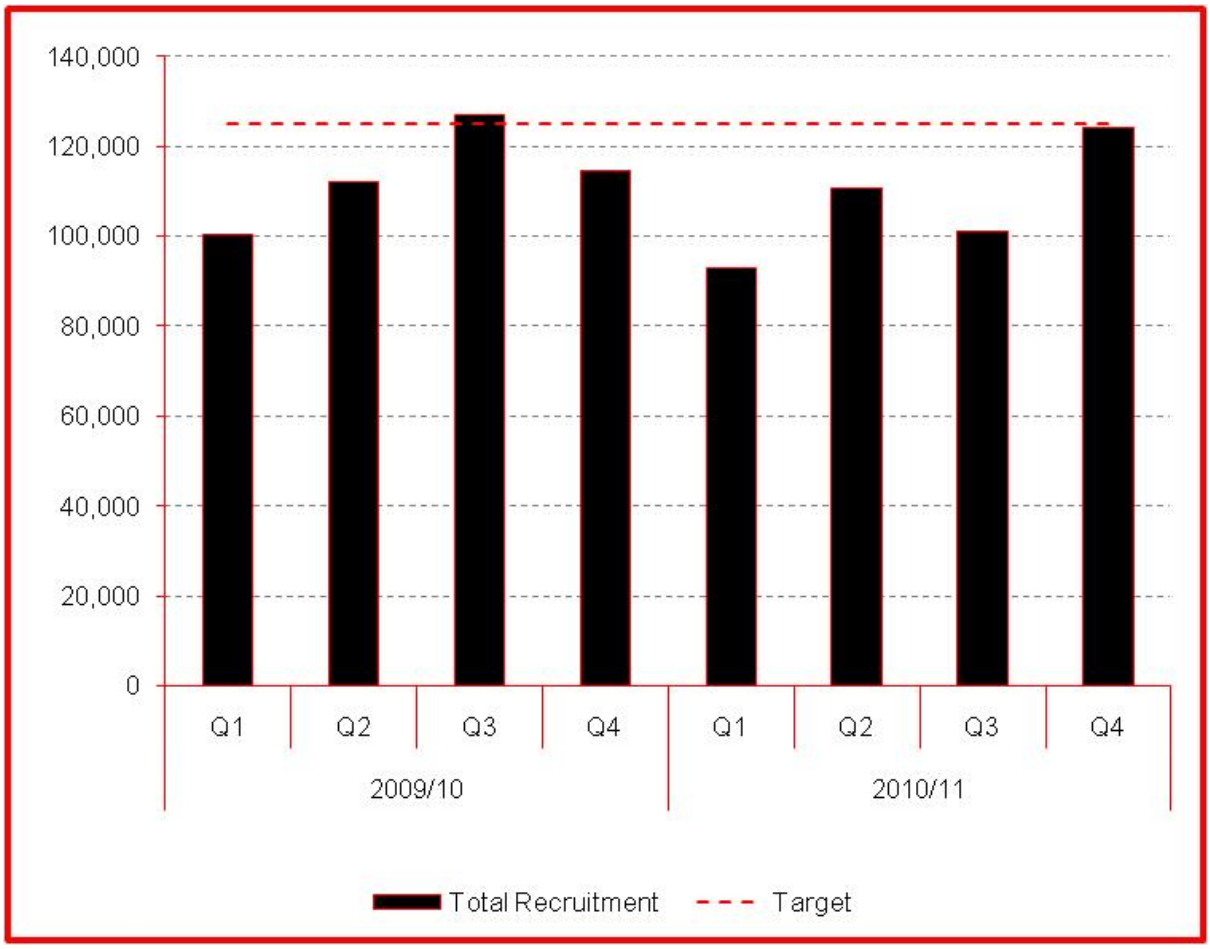
**Table 2.2: Clinical Research Network High Level Objectives – summary on performance to date**

| Objective | Target | 2009/10 | 2010/11 | | | |
|---|---|---|---|---|---|---|
| | | Quarterly average | Q1 | Q2 | Q3 | Q4 |
| 1 | 125,000 | 113,534 | 92,789 | 110,490 | 100,956 | 124,201 |
| 2 | 80% | N/A | Reporting will commence from Quarter 1 2011/12 | | | |
| 3 | 80% | N/A | Reporting will commence from Quarter 1 2011/12 | | | |
| 4 | 80% | N/A | Reporting will commence from Quarter 1 2011/12 | | | |
| 5 | 80% | N/A | Reporting will commence from Quarter 1 2011/12 | | | |
| 6 | 98% | 95% | 96% | 96% | 97% | 96% |

## 2.3 High Level Objective 1

### Double the Number of Participants Recruited into NIHR Clinical Research Network Portfolio Studies

**Fig 2.3: Total Number of Participants Recruited into NIHR Clinical Research Network Portfolio Studies**




A total of 124,201 participants were recruited to CRN Portfolio studies in this quarter, against the quarterly target of 125,000.

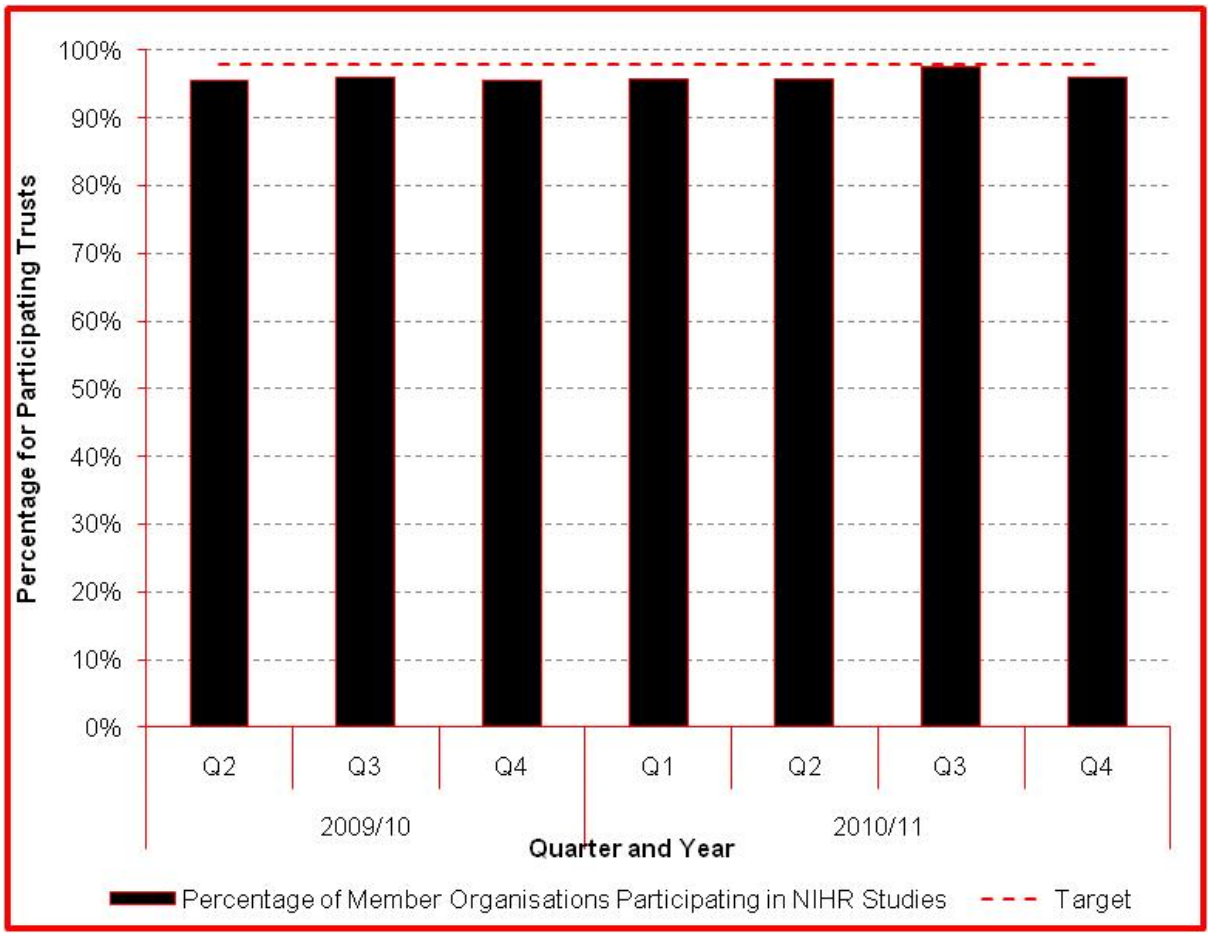
This represents the highest quarterly recruitment in 2010/11. This increases the mean average quarterly recruitment for 2010/11 to 107,109; this compares to the quarterly average of 113,534 for 2009/10.

Bearing in mind the present CRN Portfolio recruitment reporting process (see Section 1), we are content that the current data represent satisfactory progress towards consistent attainment of the target recruitment level by the 31 March 2014.

## 2.4 High Level Objective 6

**Increase the percentage of NHS Trusts participating in NIHR Clinical Research Network Portfolio studies**

**Fig 2.4: Percentage of Trusts Participating in NIHR Clinical Research Network Portfolio Studies**




The level of NHS Trust participation moved one percentage point lower in this quarter, from 97% to 96%. In this quarter, 378 of the 394 local NHS Trusts in England were actively recruiting to NIHR CRN Portfolio research.

As figure 2.4 shows, the trend for the level of NHS participation appears to be flat, at just below the 98% target level. Work continues, through the NIHR Comprehensive Local Research Networks (CLRNs), to identify and address the issues that are preventing research participation in the small number of non-active NHS Trusts. These non-active Trusts are primarily ambulance Trusts and community mental health / social care Trusts.

We remain confident that the 98% goal will be attained by the target date of 31 March 2013.

## 3. CLINICAL RESEARCH NETWORK PORTFOLIO ACTIVITY

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

The number of studies eligible for NIHR Clinical Research Network support in each quarter is illustrated in figure 3.1. Non-commercial studies including those that are automatically eligible for inclusion in the NIHR CRN Portfolio and those that are required to go through the non-commercial adoption process make up the greatest proportion of studies on the NIHR CRN Portfolio. This is a trend observed across all quarters since 2008/9 which is maintained in Quarter 4 of 2010/11.

Quarter 4 of 2010/11 has seen a decrease in the number of studies eligible for the NIHR CRN Portfolio in all study categories (i.e. commercial and non-commercial) compared to Quarter 3. Moreover, Quarter 4 has the fewest number of studies eligible for the NIHR CRN Portfolio per quarter in 2010/11. This Quarter 4 decrease on Quarter 3 has not been observed in previous years. In previous years (2008/9 and 2009/10) a decrease is observed between Quarters 2 and 3 perhaps reflecting changes in the timing of funding calls in 2010/11 compared to previous years. It may also be a reflection of the changes in the NIHR CRN Portfolio application process which means that all studies now apply for inclusion in the NIHR CRN Portfolio earlier in the research study lifecycle than previously i.e. in parallel to applying for NHS Permission; resulting in a reduction in the time between funding decision and Portfolio application and hence a shift in the number of new studies being included on the NIHR CRN Portfolio in each quarter.

**Fig 3.1: Number of Studies Entered onto the Portfolio by Eligibility Type**

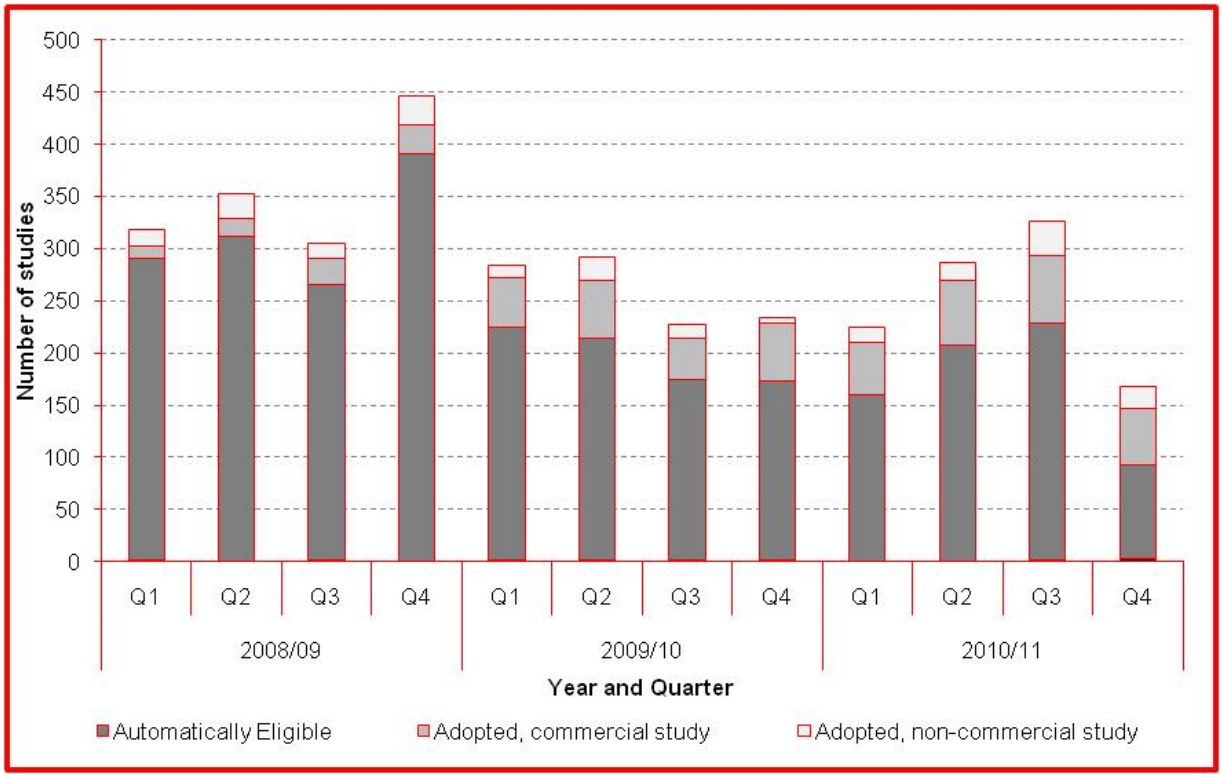
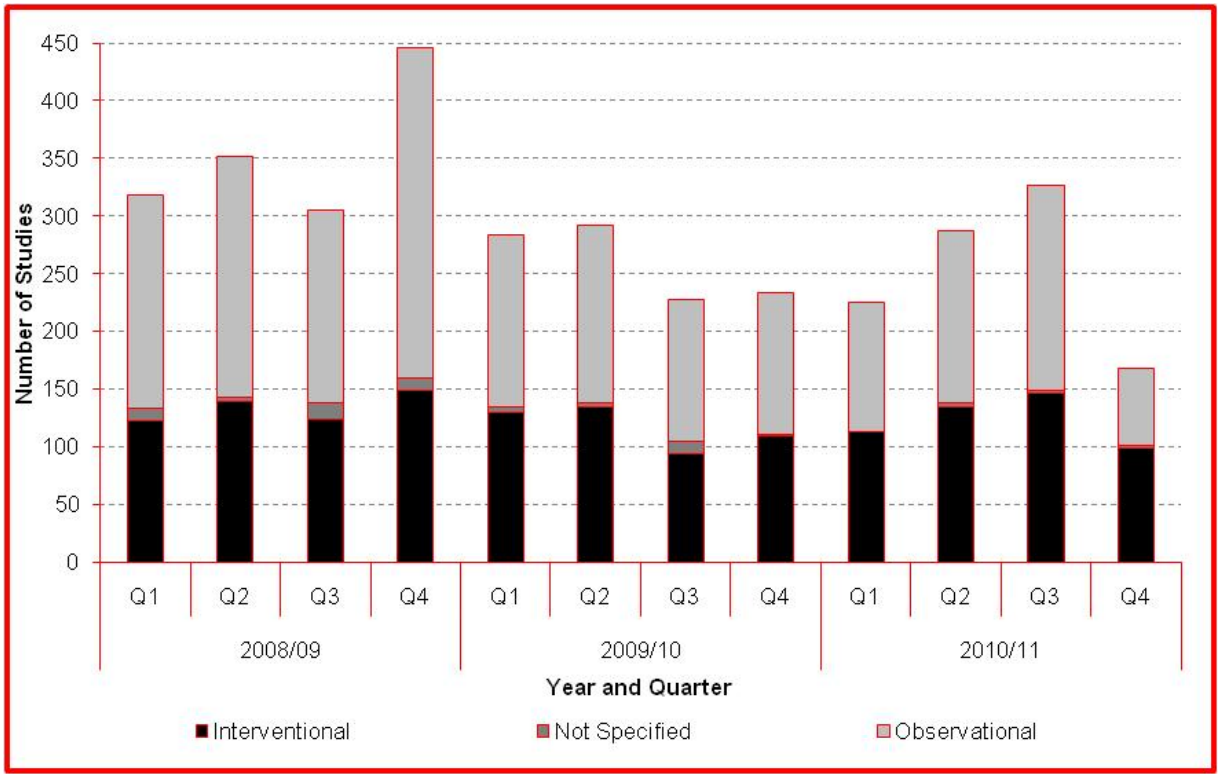



Figure 3.1 also gives an indication of the demand for support from the NIHR Clinical Research Network. It is expected that the Clinical Research Network should have the capacity to meet this demand with a reasonable balance of ongoing studies closing and new studies opening. Quarter 4 2010/11 has seen a decrease in the number of studies eligible for NIHR Clinical Research Network support in comparison to Quarter 4 in the previous year (2009/10); however when comparing full year data (2009/10 = 1037 studies, 2010/11 = 1006 studies) there does still appear to be stability in the system.

**Fig 3.2: Number of Studies Entered onto the Portfolio by Primary Study Design**




The NIHR Clinical Research Network supports a broad range of studies. Figure 3.2 provides the total number of interventional and observational studies deemed eligible for NIHR Clinical Research Network support in each quarter. As figure 3.2 illustrates there is a good split in each quarter between observational and interventional studies and this trend is maintained in Quarter 4 of 2010/11 demonstrating that the NIHR Clincal Research Network continues to support a balanced portfolio of research studies. Interestingly, in Quarter 4 the number of interventional studies (N=99) deemed eligible for the NIHR CRN Portfolio has surpassed the number of observational studies (N=67). This ratio of interventional to observation studies is not observed in previous quarters or years.

The number of new studies entered onto the Portfolio Database is limited by issues such as the levels of funding available to commission research and the number of high quality proposals developed and submitted for funding. Some of the NIHR Clinical Research Networks, i.e. the Topic–specific Clinical Research Networks, are to some extent able to influence this latter limitation by the investment the Topic Coordinating Centres are making in Clinical Studies Groups (or equivalent) whose purpose is to identify gaps in knowledge and develop research proposals to fill these gaps.

**Table 3.3: Number of Studies Open to Recruitment, Reporting Recruitment and Recruitment by Network**

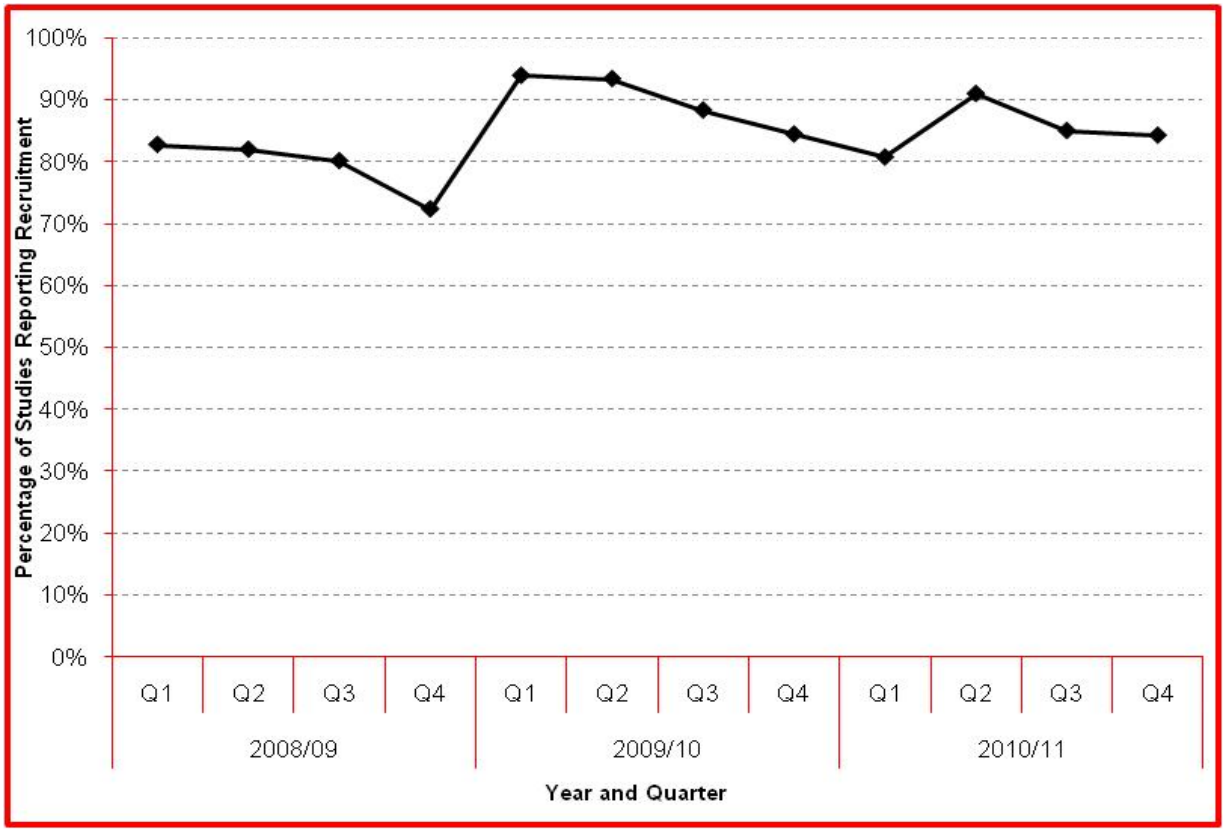
| Network | Number of Studies Open to Recruitment during Q4 2010/11 | Total Number of Studies Reporting Recruitment in Q4 2010/11 | Total Recruitment Q4 2010/11 |
|---|---|---|---|
| **Cancer** | 411 | 393 | 18,950 |
| **Comprehensive** | 1,422 | 1,192 | 63,807 |
| **Dementias & Neurodegenerative Diseases** | 103 | 87 | 4,342 |
| **Diabetes** | 160 | 107 | 10,229 |
| **Medicines for Children** | 101 | 91 | 1,470 |
| **Mental Health** | 223 | 163 | 5,845 |
| **Primary Care** | 135 | 113 | 16,656 |
| **Stroke** | 90 | 81 | 2,902 |
| **TOTAL** | **2,645** | **2,227** | **124,201** |

The number of studies open to recruitment (table 3.3) gives a broad indication of the scale of opportunities for participants to take part in clinical research in the NHS in England. In addition, it indicates the current level of recruitment-related work being carried out by the Clinical Research Network. In this quarter the number of studies open to recruitment has increased by 119 studies on Quarter 3 (2010/11) in which 2,526 studies were open to recruitment. The number of studies attributed to each of the Networks is also provided in table 3.3 illustrating a wide range in the number of studies being “led” by each of the Networks. Interestingly all Networks have seen an increase in the number of studies they have open to recruitment in Quarter 4 compared with Quarter 3 this year (2010/11).

The number of studies reporting recruitment data in Quarter 4 (2010/11) has also increased in comparison to Quarter 3 (2010/11) with 81 more studies reporting recruitment data in Quarter 4 than Quarter 3. In this quarter 84% of all open studies were reporting recruitment data (see figure 3.4). This is comparable to the percentage of studies reporting recruitment data in both Quarter 3 2010/11 (85%) and Quarter 4 2009/10 (83%).

It is important to note that the number of studies reporting recruitment data may be an under representation of the number of studies that have recruited participants as some studies may not yet have uploaded their recruitment data into the national Portfolio Database. Study teams are asked to report recruitment data on a monthly basis although for some studies this is not as practical as for others which results in delays in the inclusion of some recruitment data in reports.

**Fig 3.4: Percentage of Open Studies Reporting Recruitment**




In terms of total recruitment, 124,201 participants were recruited into NIHR CRN Portfolio studies this quarter (tables 3.3 and 3.5). This is an increase of 23,245 participants compared to the previous quarter (table 3.5). This is a large increase on the previous quarter and highest number of participants recruited in any one quarter this year. This is likely to be linked to the increase in the number of studies reporting recruitment data (table 3.3) which both may be the result of increased reporting around the year end to ensure the inclusion of recruitment data in 2010/11 data. In addition, this specifically large increase may also be a result of one or more high recruiting studies opening, or increasing recruitment in this quarter.

As with previous quarters this year (2010/11), the Comprehensive Clinical Research Network, which supports the greatest number of studies (table 3.3), also contributes the greatest number of recruits to the overall total. In addition, both the Diabetes Research Network and the Dementias and Neurodegenerative Diseases Research Network have large increases in their number of recruits in this quarter compared to Quarter 3 2010/11 (table 3.5). Not all Networks however have experienced an increase in recruitment this quarter compared to Quarter 3 2010/11 (table 3.5); this may be the result of one or more of a number of external limiting factors, including:

- The type of study - observational studies tend to recruit a larger number of participants (figure 3.6) 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 (figure 3.6) for the same time and effort invested
- The nature of the disease area - studies investigating rare conditions or hard to reach populations will by their nature recruit fewer participants
- Closure of one or more high recruiting studies in the previous quarter where Networks have experienced a decrease in recruitment this quarter. Or, alternatively for those Networks observing a significant increase this quarter, the opening of one or more high recruiting studies (figure 3.6)

**Table 3.5: Recruitment by Network**

| Network | 2008/09 | | | | 2009/10 | | | | 2010/11 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| **Cancer** | 19,932 | 19,995 | 18,336 | 12,690 | 10,996 | 12,866 | 15,015 | 15,281 | 17,080 | 16,703 | 15,127 | 18,950 |
| **Comprehensive** | 47,572 | 27,787 | 30,568 | 20,997 | 49,460 | 52,355 | 55,854 | 53,812 | 40,591 | 60,599 | 50,583 | 6,3807 |
| **Dementias & Neurodegenerative Diseases** | 1,789 | 1,366 | 1,473 | 1,534 | 1,619 | 2,134 | 2,024 | 2,273 | 2,134 | 2,276 | 2,931 | 4,342 |
| **Diabetes** | 4,620 | 9,106 | 7,260 | 5,023 | 6,703 | 13,333 | 10,492 | 6,492 | 8,455 | 7,231 | 5,407 | 10,229 |
| **Medicines for Children** | 849 | 768 | 1,005 | 1,141 | 1,259 | 1,444 | 2,768 | 1,738 | 1,842 | 1,696 | 1,666 | 1,470 |
| **Mental Health** | 4,745 | 3,203 | 3,672 | 2,926 | 11,233 | 12,396 | 15,506 | 12,546 | 12,478 | 9,242 | 6,840 | 5,845 |
| **Primary Care** | 19,899 | 23,637 | 16,174 | 16,164 | 17,168 | 15,797 | 23,629 | 20,310 | 8,135 | 10,353 | 15,929 | 16,656 |
| **Stroke** | 1,659 | 1,686 | 1,519 | 2,131 | 1,960 | 1,908 | 1,661 | 2,106 | 2,074 | 2,390 | 2,473 | 2,902 |
| **Total** | 101,065 | 87,548 | 80,007 | 62,606 | 100,398 | 112,233 | 126,949 | 114,558 | 92,789 | 110,490 | 100,956 | 124,201 |

**Fig 3.6: Recruitment by Primary Study Design**

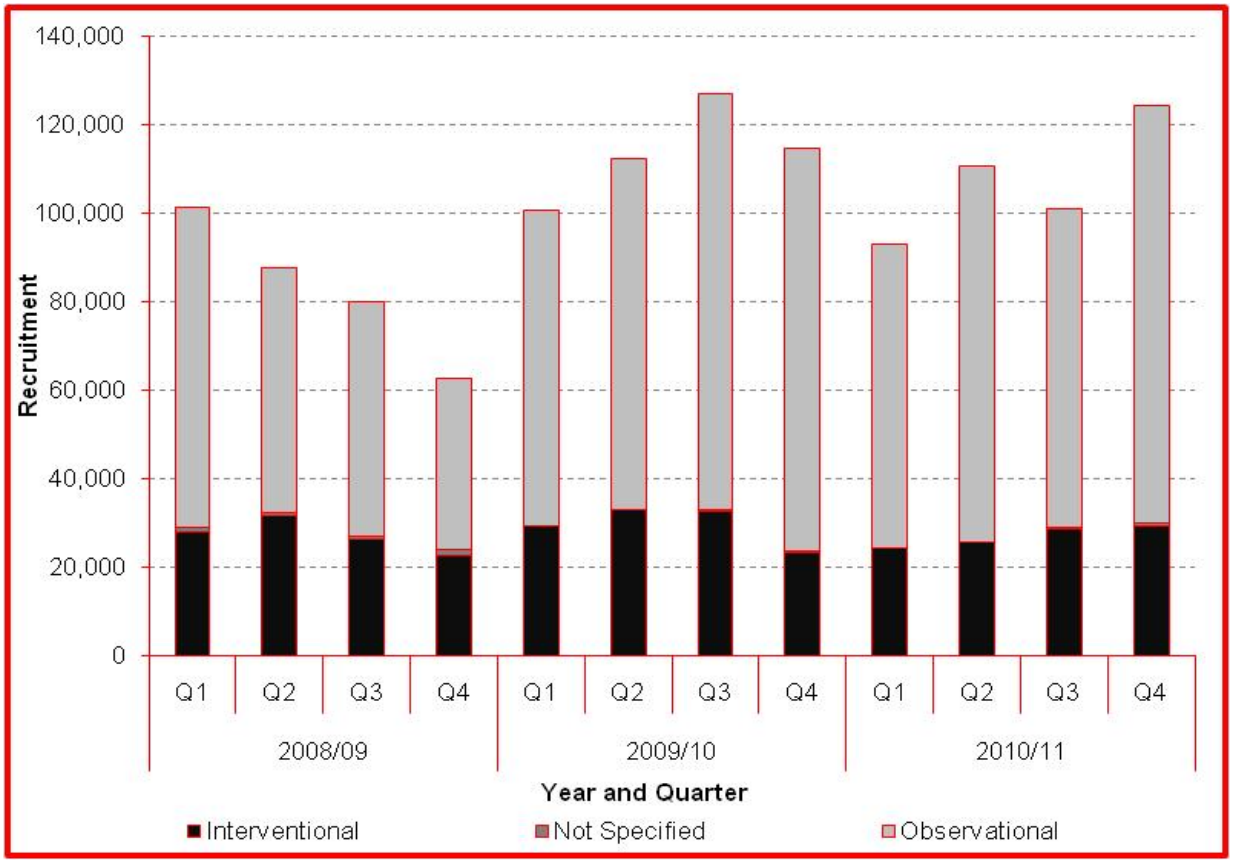



Figure 3.6 provides a breakdown of the total recruitment according to the primary study design. This illustrates that observational studies account for a greater proportion of total recruitment in comparison to interventional studies. This trend is maintained in this quarter despite a greater proportion of interventional studies than observational studies being added to the Portfolio Database this quarter. Interestingly, recruitment into interventional studies is more consistent over time than that in observational studies (figure 3.6), this is likely to be accounted for by recruitment into a small number of very large observational studies in specific quarters. This is clearly demonstrated in this quarter.

In Quarter 4 2010/11 there are 94,389 recruits into observational studies compared to 72,079 recruits into observational studies in Quarter 3 2010/11 and 29,318 recruits in interventional studies in Quarter 4 compared to 28,576 recruits in Quarter 3 2010/11. The overall increase in recruits seen in this quarter is therefore primarily a result of increased recruitment into observational studies, and more likely the specific result of the opening of or increased recruitment into one or more very large observational studies.

## 4. NHS RESEARCH MANAGEMENT AND GOVERNANCE ACTIVITY

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.

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. Figure 4.1 shows overall approval time, from receipt of a valid R&D form for the study, to the date of receiving NHS Permission. 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). This data therefore provides a picture of approval times as a whole, as they are experienced by researchers. However it is not an indicator of the Clinical Research Network’s ‘performance’ in relation to study approval.

Figure 4.1 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 median figure for the last three quarters has been relatively static.

This measure reflects all the sites for which an application has been made in a study. As sites may be set up at various times, the metrics need to reflect this variation in order to avoid double-counting or counting redundant time. In calculating the time to achieve NHS Permission, the following measures are used:

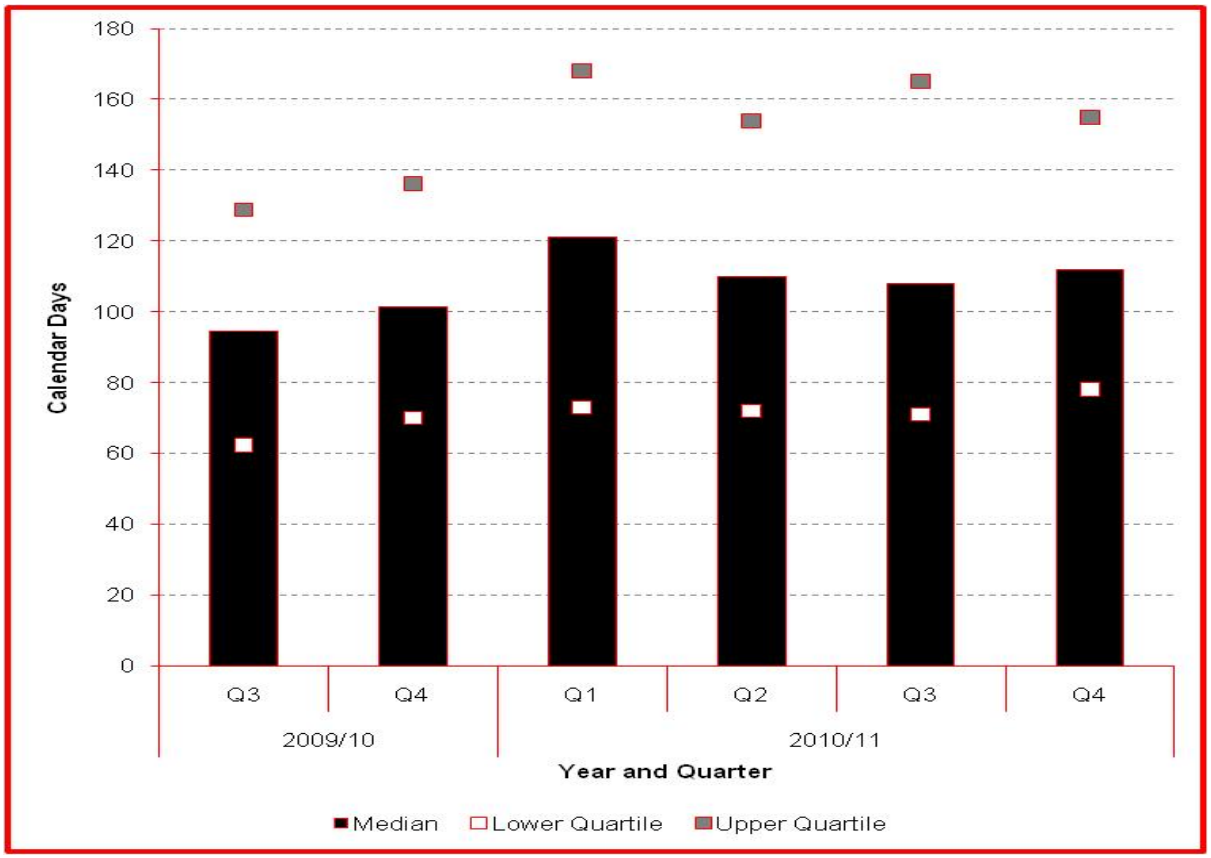
1. Where local permission takes place within the time taken for study-wide checks to be completed, the period measured is R&D form validation to study-wide checks completed
2. Where the SSI form is validated before study-wide checks are completed, but NHS permission is granted after study-wide checks are complete, the period measured is R&D form Validation to Date NHS Permission is granted
3. Where the SSI form is validated after the study-wide checks, the period measured is R&D form validation to study-wide checks completed plus SSI form validation to NHS permission

The CSP information systems used during Quarter 4 did not allow us to separate out the part of the process that was under the management of the Clinical Research Network (i.e. NHS Permission), therefore we cannot offer interpretative commentary on these data in respect of Clinical Research Network performance.

In the period examined, there were very limited situations in which the clock was 'stopped'. In these situations the time is deducted from the total time taken to achieve NHS Permission. In order to more accurately reflect the part of the process that is under the control of the Clinical Research Network, from April 2011 we have implemented new conditions for the situations in which the clock is stopped, to more accurately reflect elapsed time that is within the control of the Clinical Research Network. These data will begin to be available from next quarter.

The starting point for the measures in this quarter is the validation of the form. Forms are submitted electronically by applicants. However, the accompanying documents for the complete application are provided separately in hard copy or by email. The time between submitting the form and submitting the accompanying documents is included in the measures. The CSP information systems used during Quarter 4 did not allow us to measure from the time at which a complete application is received. As the time from submission of the form to submission of the documents is entirely under the control of the applicant, the measure does not accurately reflect the activities that are under the control of the Clinical Research Network. In order to more accurately reflect the part of the process that is under the control of the Clinical Research Network, we have implemented new arrangements from April 2011 to collect data on the date of validation of the complete application.

**Fig 4.1: Median Average Time to Achieve NHS Permission**




Figures 4.2 and 4.3 show a breakdown of the two components of CSP, the study-wide checks and the local checks. As noted above, these figures do not yet adequately reflect the time which is under the control of the Clinical Research Network. Lengthy times may therefore be affected by a range of external factors including waiting for responses from applicants and waiting for other parts of the approval system.

Figure 4.2 shows the time to complete study-wide checks. This is the time from R&D form validation to study-wide checks completed. The graph shows data by the quarter in which the study-wide checks were completed. These figures are showing an overall downward trend, which suggests that the arrangements being put in place across the Clinical Research Network to address lengthy timelines for study set-up are beginning to have an impact. To date, these arrangements have included a greater focus on performance management of studies through CSP by the CLRNs and supporting a more proportionate process to the review of studies. Further activities to improve the performance of CSP are in development and are intended to make an even greater impact on timelines.

**Fig 4.2: Median Average Time to Complete Study-Wide Checks**

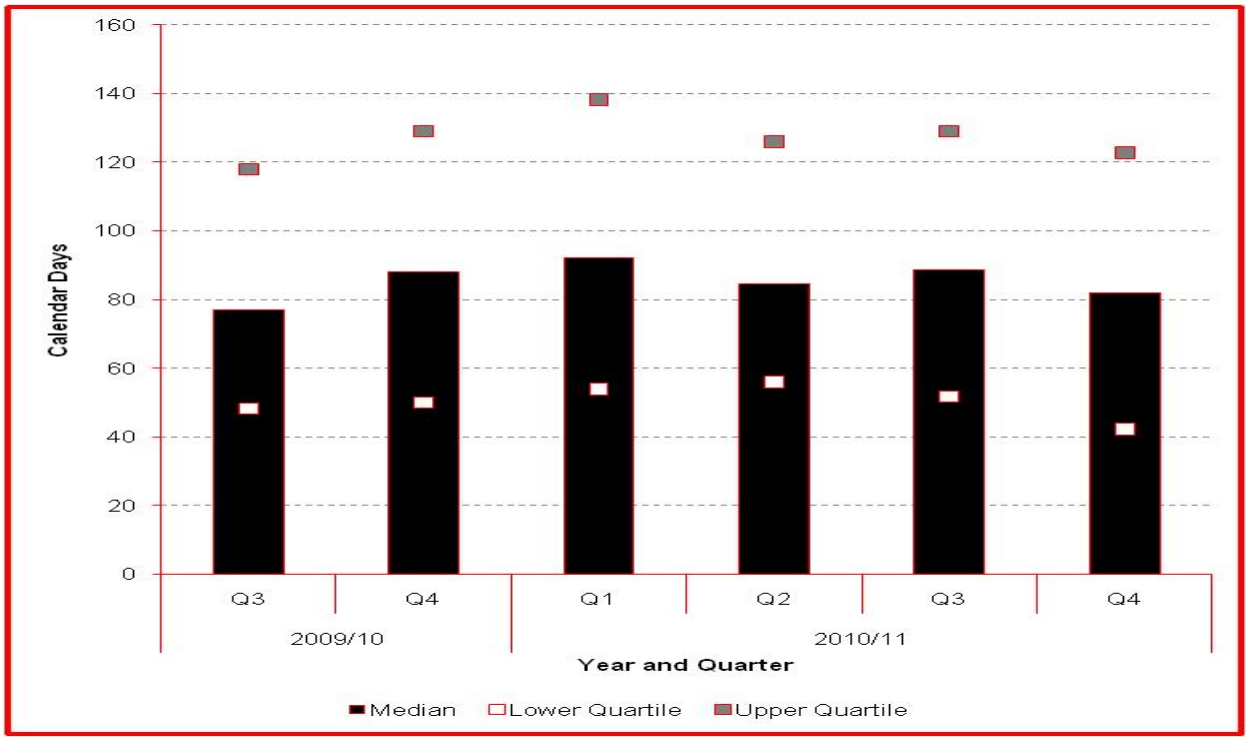


Figure 4.3 shows the time to complete local checks, by the quarter in which the local checks were completed. This is the time from SSI form validation to NHS permission. It should be noted that studies may be counted more than once as each study will have local reviews for each site.

These figures are showing an overall downward trend, which suggests that the arrangements being put in place across the Clinical Research Network to address lengthy timelines for study set-up are beginning to have an impact. The rate of improvement in the speed of local review appears to be greater than the rate of improvement in the study-wide review. It may be that this reflects the greater local control and ownership of local review that is being encouraged through the CLRNs.

**Fig 4.3: Median Average Time to Complete Local Checks**

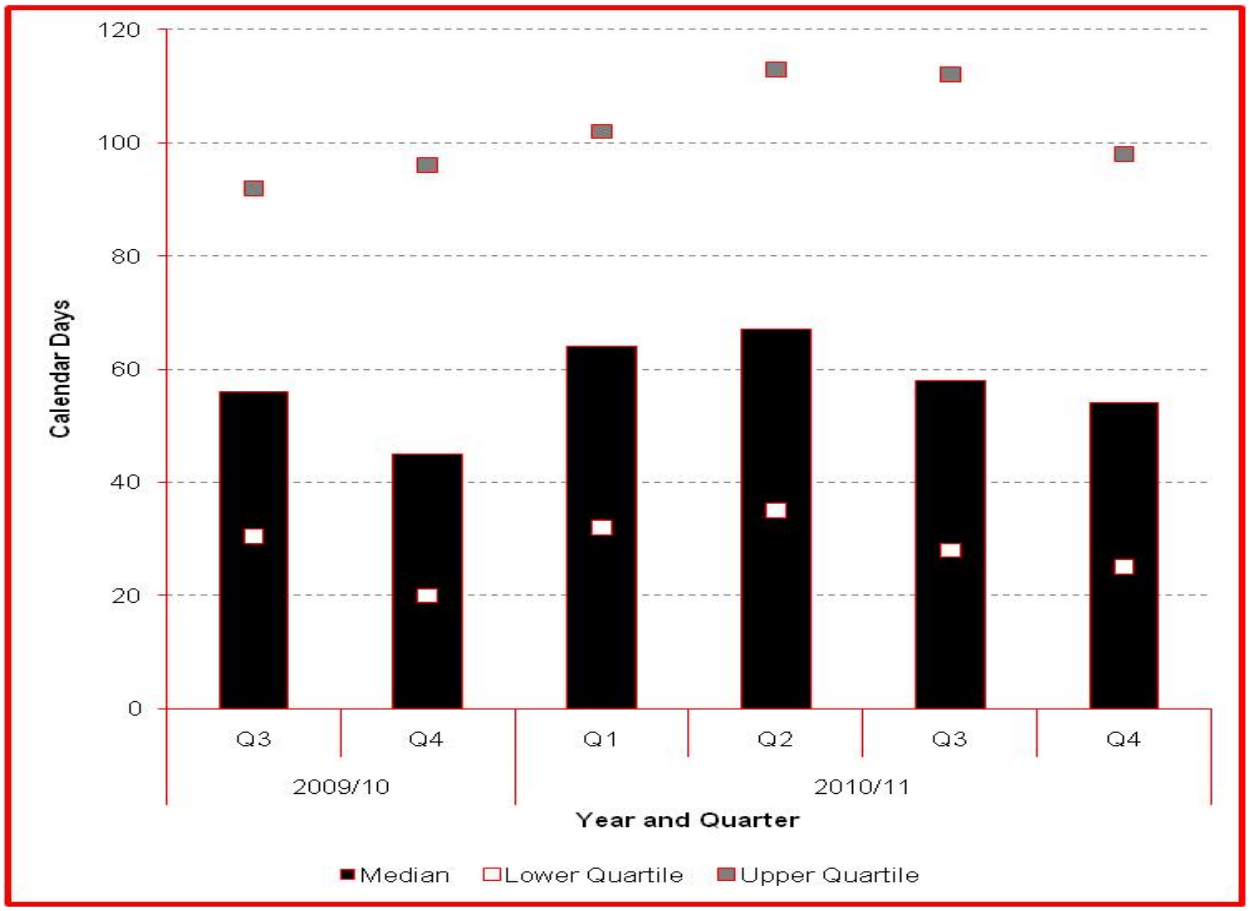
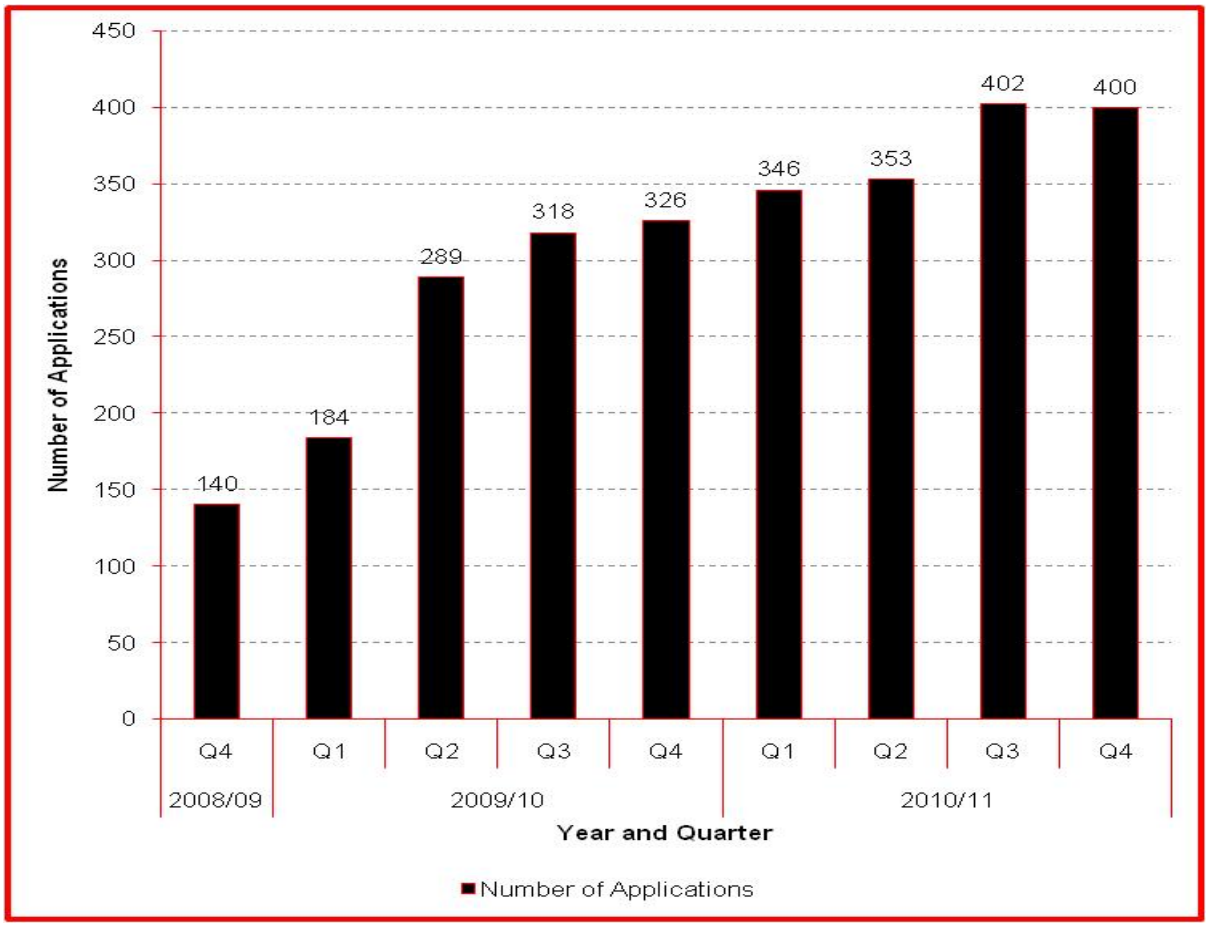


Figure 4.4 shows the number of studies accepted for processing through CSP per month. Some fluctuation month by month is expected, particularly in response to funding rounds and seasonal variations in academic activity. Quarter 3 showed an increase in applications due to a surge in applications in October, which is traditionally a peak time for submitting applications. The number of applications in Quarter 4 is similar to Quarter 3. The pattern does not mirror that in figure 3.1, as there is a lag between the study being registered on CSP and being deemed eligible for Clinical Research Network support and then added to the Portfolio Database. The Portfolio eligibility process takes a variable length of time and will not therefore reflect the rate of entry into CSP.

**Fig 4.4: Number of Applications via CSP**



## 5. LIFE-SCIENCES INDUSTRY STUDIES

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 Clinical Research Network 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 jointly supported which means that more than one Network is engaged in supporting the research. Where this is the case, a “Lead” Network is allocated. Table 5.1 shows this data. Benefits of joint support include 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 5.1.

Table 5.1 tabulates the number of commercial studies that apply for Network support but which are NOT adopted onto the NIHR Clinical Research Network 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. The proportion of studies not being adopted has remained almost static as compared to the last quarter and is consistently around 9 %.

**Table 5.1: Number of Industry Studies by Network as at 31 March 2011**

| Clinical Research Network | Total Number of Adopted Industry Studies by Lead Network | Total Number of Adopted Industry Studies by Jointly Supported Network | Number of Adopted Industry Studies by Network, Including Jointly Supported Studies | Number of Medical Device Studies Included in Total | No. of Studies Which Have NOT Been Adopted |
|---|---|---|---|---|---|
| **Cancer** | 180 | 1 | 181 | 1 | 25 |
| **Comprehensive** | 241 | 68 | 309 | 32 | 30 |
| **Dementias & Neurodegenerative Diseases** | 58 | 0 | 58 | 1 | 6 |
| **Diabetes** | 111 | 8 | 119 | 8 | 5 |
| **Medicines for Children** | 115 | 11 | 126 | 2 | 2 |
| **Mental Health** | 20 | 2 | 22 | 0 | 3 |
| **Primary Care** | 21 | 43 | 64 | 0 | 1 |
| **Stroke** | 13 | 2 | 15 | 1 | 2 |
| **TOTAL** | **759*** | **135** | **894** | **45** | **74** |

*Total number of unique studies

**Trend information:**

- The total number of unique life-sciences studies on the NIHR CRN Portfolio to date is 759, compared with 700 reported at the end of the second quarter of 2010/11. This represents continued growth for the Clinical Research Network commercial portfolio

- The number of jointly supported studies on the NIHR CRN Portfolio has increased by 16% (from 116 studies to 135 studies) compared with the last quarter. This increase is greater than the last quarter comparison. It demonstrates the increasing partnership and sharing of expertise by the different topic Networks when adopting and delivering studies

- The number of Med-tech studies adopted increased by 12% (from 40 to 45 studies) compared with the last quarter. This increase is not as high as the last quarter comparison but still demonstrates steady growth and the continued efforts made by the NIHR Clinical Research Network Industry team to engage with Med-tech companies and highlight the benefits of working with the Networks

**Fig 5.2: Recruitment into Industry Studies for each Operating Year**

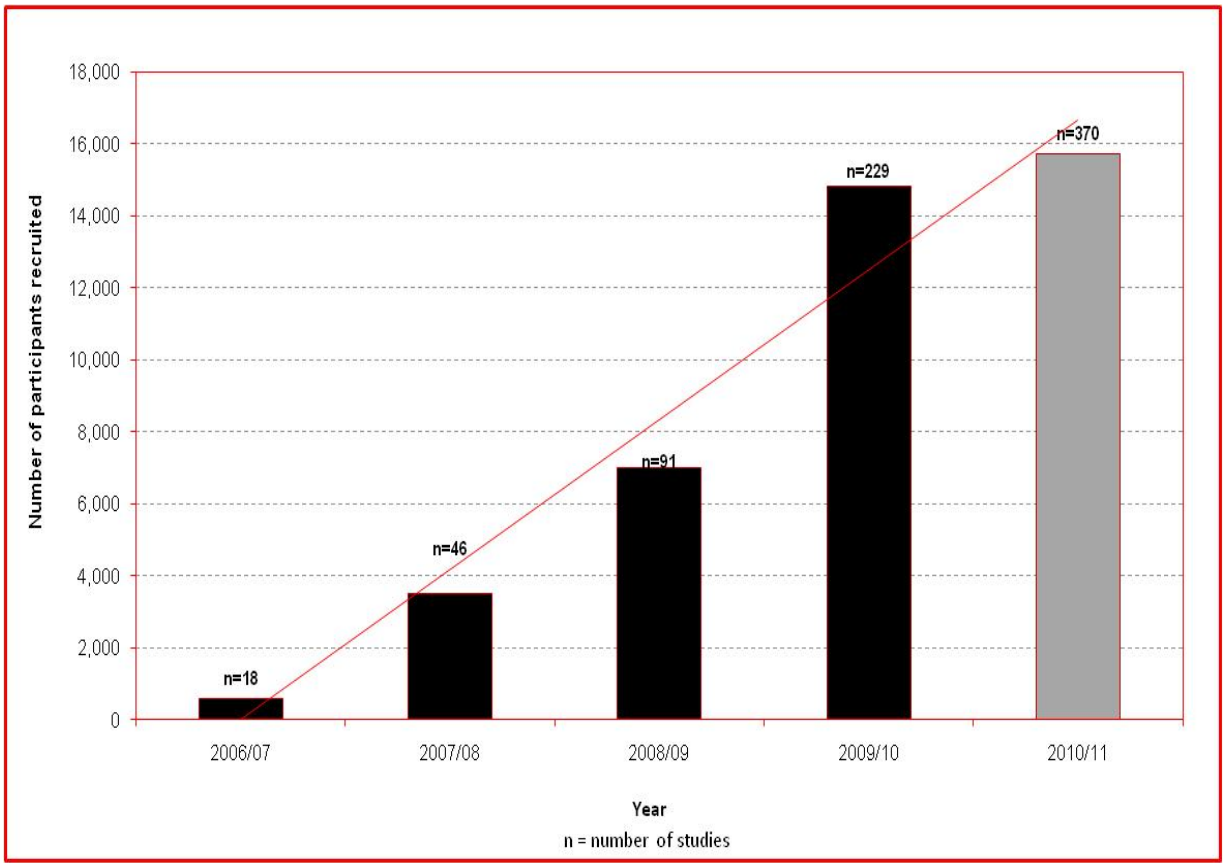
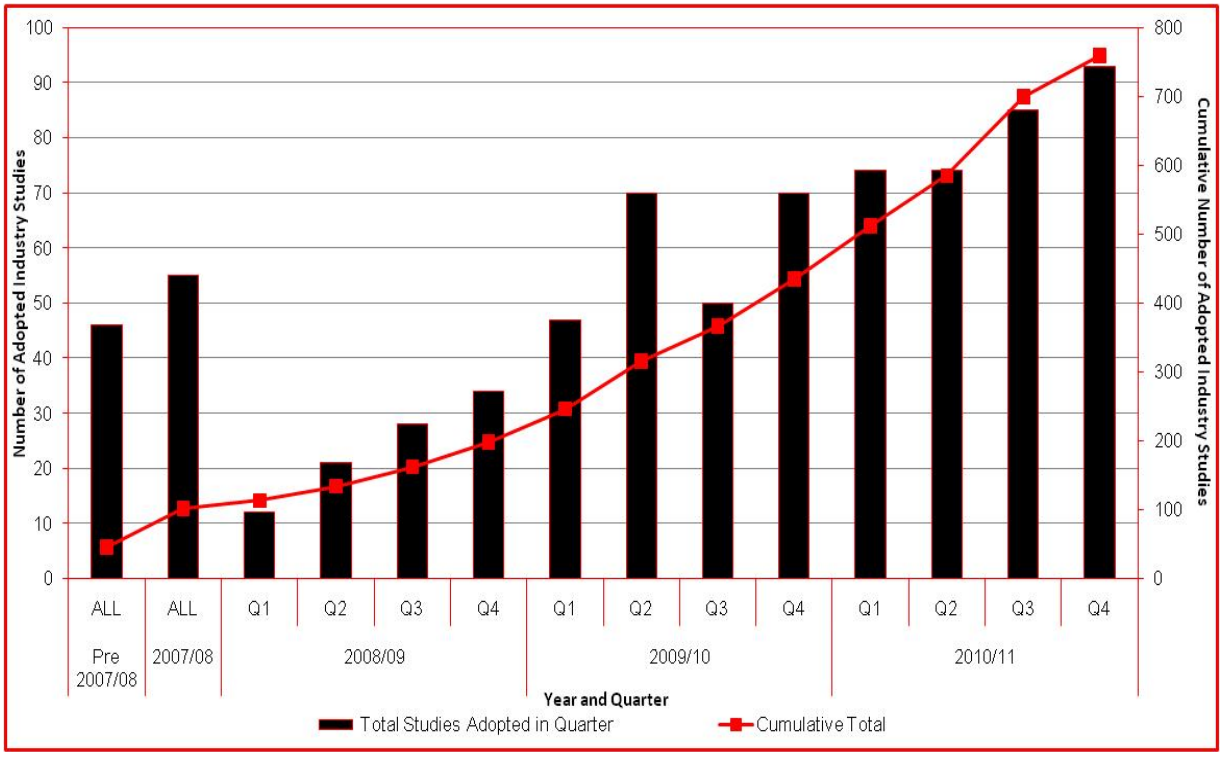



Figure 5.2 shows the level of participant recruitment into NIHR CRN Portfolio studies funded and sponsored by the life-sciences industry. This represents an increased number of participants recruited into studies running in the UK, which are actively supported and performance managed by the Networks.

**Trend information:**

- 2010/11 recruitment currently stands at 15,724 for the year to date, meaning the Networks are likely to exceed the trend for increased recruitment established over the last four years
- Cumulative recruitment has increased by 32% as compared to the last quarter
- 56 new studies have opened for recruitment since Quarter 3 2010/11. This represents an increase of 18% for Quarter 4 2010/11

**Fig 5.3: Number of Adopted Industry Studies over Time**




**Trend information:**

- Figure 5.3 illustrates the cumulative trend of continued and positive engagement with Industry as the number of commercial studies adopted continues to increase each year
- There was a 9% increase in the number of studies adopted in Quarter 4 (93 studies) as compared to Quarter 3 (85 studies) 2010/11

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