NHS
National Institute for Health Research

Clinical Research Network

# Activity Report

## Quarter 3 2011/12 (October to December 2011)

**Issued: 14 March 2012**

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# 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, including the provision of streamlined research management and governance activities for NIHR supported studies
- Enhancing NHS resources by funding the people and facilities needed to carry out research "on the ground"
- 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.

## 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 a study's 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 October 2011 to 31 December 2011, which is Quarter 3 of the 2011/12 financial year.

Where figures are given for "year to date", this refers to the Clinical Research Network financial year, which is 01 April 2011 to 31 March 2012.

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 are 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 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 have been rolled out in a phased way, with full reporting on all High Level Objectives having commenced 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 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 | 2010/11 | 2011/12 | | | |
|---|---|---|---|---|---|---|
| | | | Q1 | Q2 | Q3 | Q4 |
| 1 | 125,000 | 141,175 [1] | 120,585 | 143,711 | 139,738 | |
| 2A | 80% | 21% | 17% | 37% | 44% | |
| 2B | 80% | 100% | 50% | 25% | 33% | |
| 2C | 80% | 38% | 44% | 35% | 22% | |
| 3 | 60% | 58% | 60% | 67% | 59% | |
| 4 | 80% | 8% | 11% | 24%[2] | 19%[2] | |
| 5A | 80% | 52% | 44% | 33%[2] | 38%[2] | |
| 5B | 80% | 22% | 17% | 24%[2] | 26%[2] | |
| 5C | 80% | 38% | 40% | 18%[2] | 15%[2] | |
| 6 | 98% | 97% | 97% | 98% | 98% | |

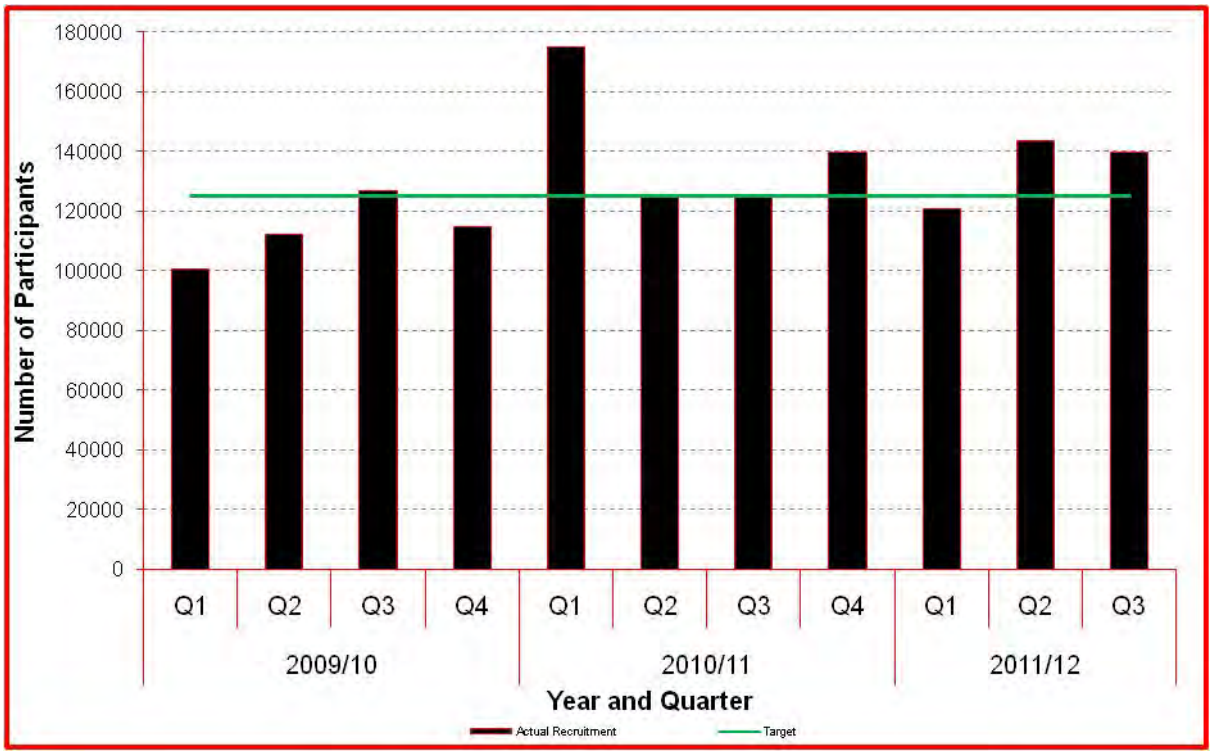
[1] Quarterly average

2 The previous report for Quarter 2 highlighted caveats about the data for that quarter due to known problems with data quality for migrated data. Those problems have now been addressed and we can therefore be confident that the data shown up to Quarter 2 2011/12 reflects the data from the legacy systems. The data for Quarter 3 are known to be affected by problems in recording activity in the CSP Module. Further data cleansing is likely to be undertaken but these data should be interpreted with caution.

## 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**




This objective was achieved in the financial year 2010/11, in which average quarterly recruitment to Clinical Research Network (CRN) Portfolio studies reached 141,000 participants (see table 2.2), surpassing the target of 125,000. The CRN now aims for consistent attainment of the target recruitment level, as a minimum.

A total of 139,738 participants were recruited into CRN Portfolio studies in this quarter, a decrease when compared to Quarter 2 2011/12 (n =143,711) but an increase on the Quarter 3 figure from the previous year (n =124,668 participants; see table 3.3). Despite this decrease compared to Quarter 2 figures, recruitment to CRN Portfolio studies surpassed the quarterly target of 125,000 for the second quarter this year. The quarterly average for 2011/12 is now 134,678, which is well above the 125,000 target.

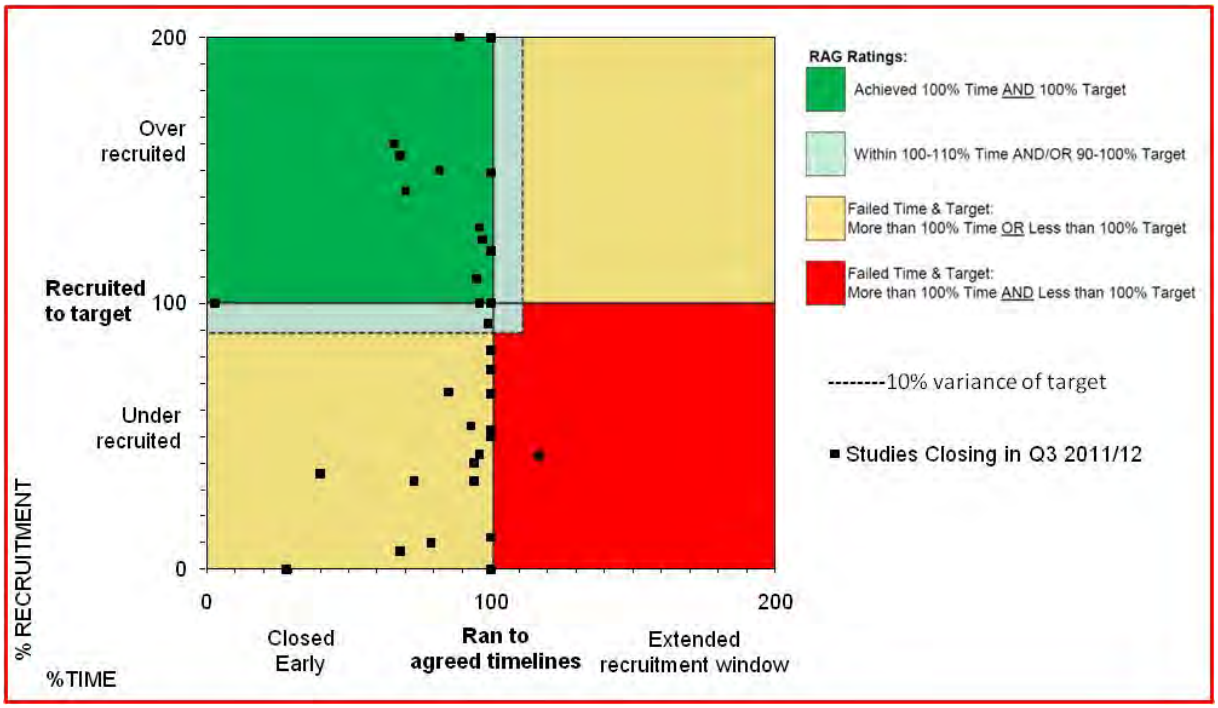
Bearing in mind the present CRN Portfolio recruitment reporting process (see section 1) and experience of data upload in 2010/11, we are content that the current data represent good progress towards consistent attainment of the target recruitment level.

## 2.4 High Level Objective 2

**Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time**

**High Level Objective 2A: Proportion of commercial contract studies achieving or surpassing their recruitment target during their planned recruitment period, at confirmed Network sites**

**Fig 2.4: Commercial contract studies, recruitment to time and target**




In Quarter 3 2011/12, 34 studies fulfilled the criteria to be included in this objective. This included one study that was closed prematurely by the company due to safety reasons.

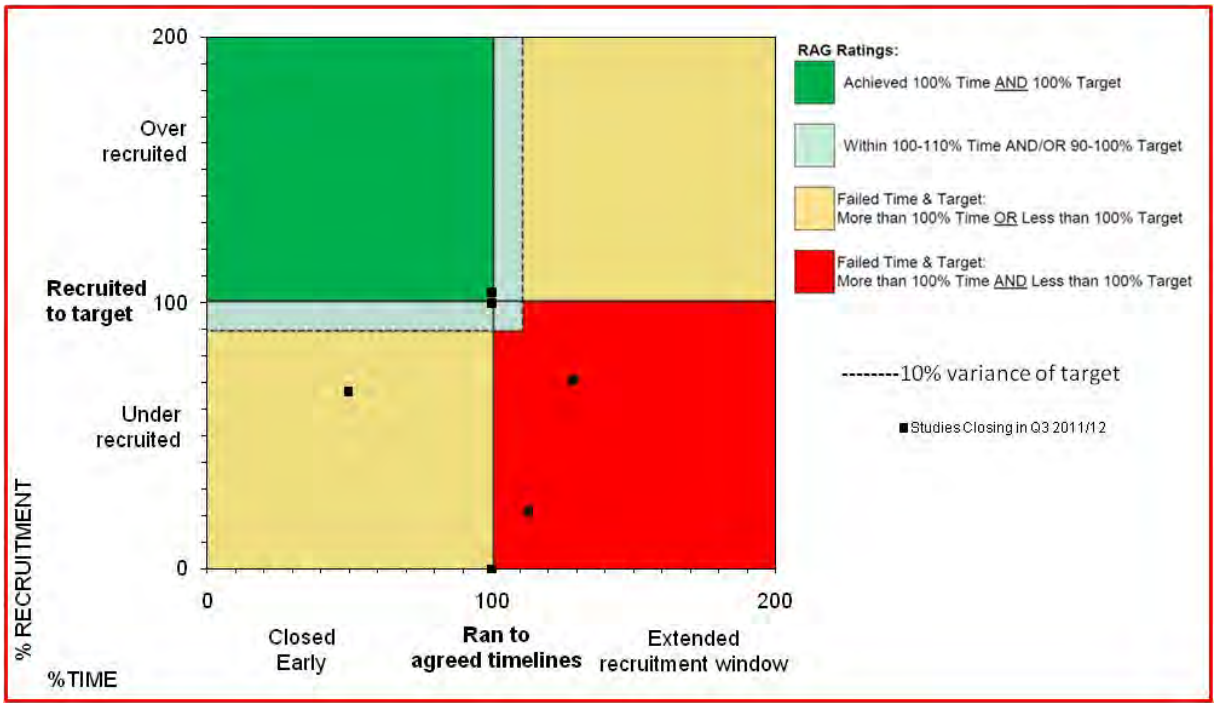
Figure 2.4 illustrates that in this quarter 44% (n=15) of studies achieved or surpassed their recruitment target during their planned recruitment period. Of which eight studies successfully managed to exceed their original recruitment targets in a shorter period of time than originally planned.

This moderate improvement since Quarter 2 2011/12 (37%) continues the trend of an increasing proportion of commercial contract research studies, supported by the Clinical Research Network, being delivered successfully. It does, however, still remain lower than our target of 80% of studies successfully recruiting to time and target by the end of March 2012. Initiatives and process reviews to improve delivery to time and target are continuing and we expect to see improved performance in 2012/13.

Some studies continue to close early before reaching their agreed recruitment target due to the study recruitment target being reached globally. Therefore rapid study set-up remains a vital component of successful study delivery as it supports an extended period of time to actively identify and recruit participants.

**High Level Objective 2B: Proportion of non-commercial studies managed by Registered CTUs achieving or surpassing their recruitment target during their planned recruitment period**

**Fig 2.5: Non-commercial studies managed by Registered CTUs, recruitment to time and target**



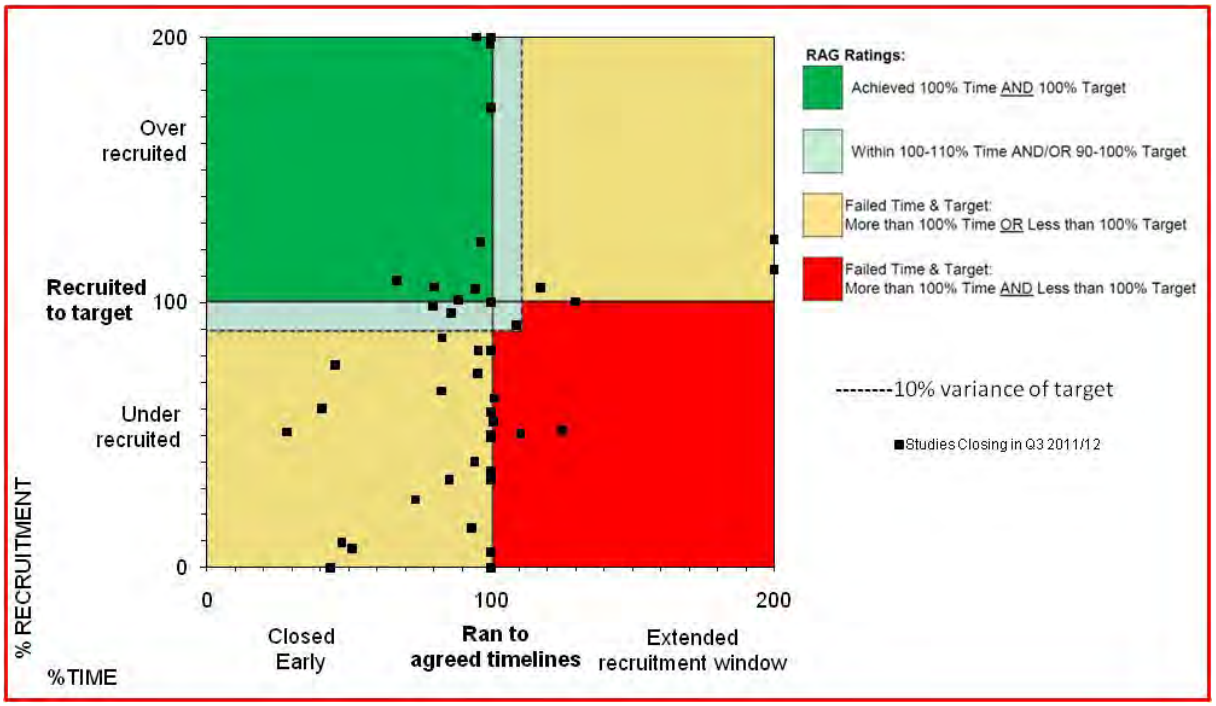

In Quarter 3 2011/12 six studies fulfilled the criteria for inclusion in this objective, compared with four studies for Quarter 2.

Figure 2.5 illustrates that two of these six (33%) successfully recruited their target number of patients within the planned recruitment period. The small number of studies means that it is not possible to assess meaningful trends in our performance.

The number of studies managed by Registered Clinical Trials Units (CTUs) remains very small. This is perhaps due to the tendency for studies managed by Registered CTUs to be larger and longer than those not managed by Registered CTUs. This means that there are very few studies which started on or after 1 April 2010 and have already closed (and hence are measured in this objective). As the year progresses we expect increasing numbers of studies to fulfil the criteria for inclusion in this objective.

**High Level Objective 2C: Proportion of non-commercial studies not managed by Registered CTUs achieving or surpassing their recruitment target during their planned recruitment period**

**Fig 2.6: Non-commercial studies not managed by Registered CTUs, recruitment to time and target**




In Quarter 3, 10 of the 45 studies (22%) eligible for inclusion in this objective achieved or surpassed their recruitment target during their planned recruitment period. This is a drop of 13% from Quarter 2, and is also some way below our success rate in 2010/11 (38%).

A further two studies were “near misses” – those which exceeded the planned recruitment time by up to 10% or under-recruited by up to 10%.

Our overall target is for 80% of non-commercial studies not managed by Registered CTUs to meet this objective by March 2015; with an interim target of 60% for next year 2012/13. The Clinical Research Network has processes in place to spot poorly performing studies and to take action when required. We are confident that significant progress will be made towards meeting this interim target over the coming year.

## 2.5 High Level Objective 3

**Increase the percentage of commercial contract studies delivered through the NIHR CRN**

**Fig 2.7: NIHR CRN adopted studies as a proportion of MHRA CTA approvals**

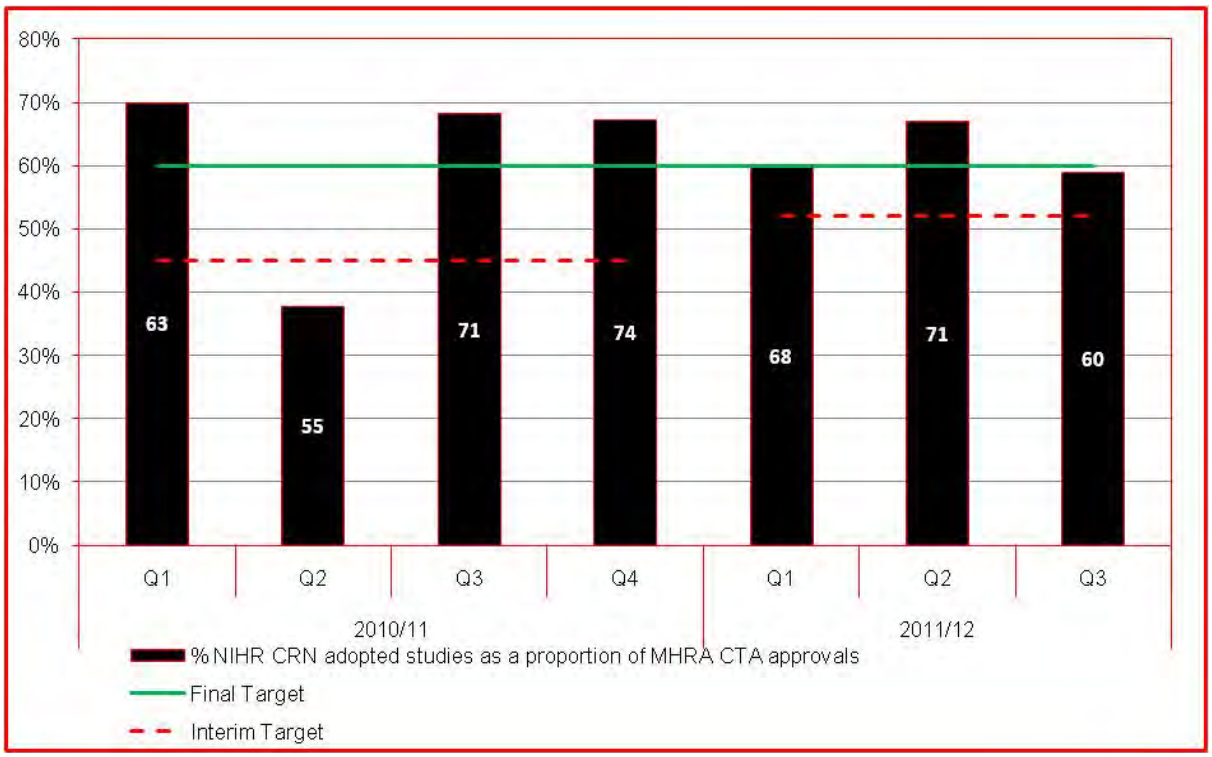



Figure 2.7 demonstrates the number of commercial contract studies on the NIHR CRN Portfolio as a percentage of the total commercial Medicines and Healthcare products Regulatory Agency (MHRA) Clinical Trial Authorisation (CTA) approvals for phase II to IV studies of investigational medicinal products. In Quarter 3 2011/12 the NIHR CRN was supporting the delivery of 59% (n=60) of studies approved by the MHRA during the same time period. This illustrates the continuing positive engagement of the Life-sciences Industry with the NIHR CRN. This is a slight reduction when compared to Quarter 2 2011/12 (67%). However, currently we are exceeding our interim target of 52% and we are progressing well against our final target of 60% by the end of December 2013.

## 2.6 High Level Objective 4

**Reduce the time taken to achieve NHS Permission through CSP for NIHR studies**

**Fig 2.8: Proportion of studies obtaining NHS Permission within 40 days**

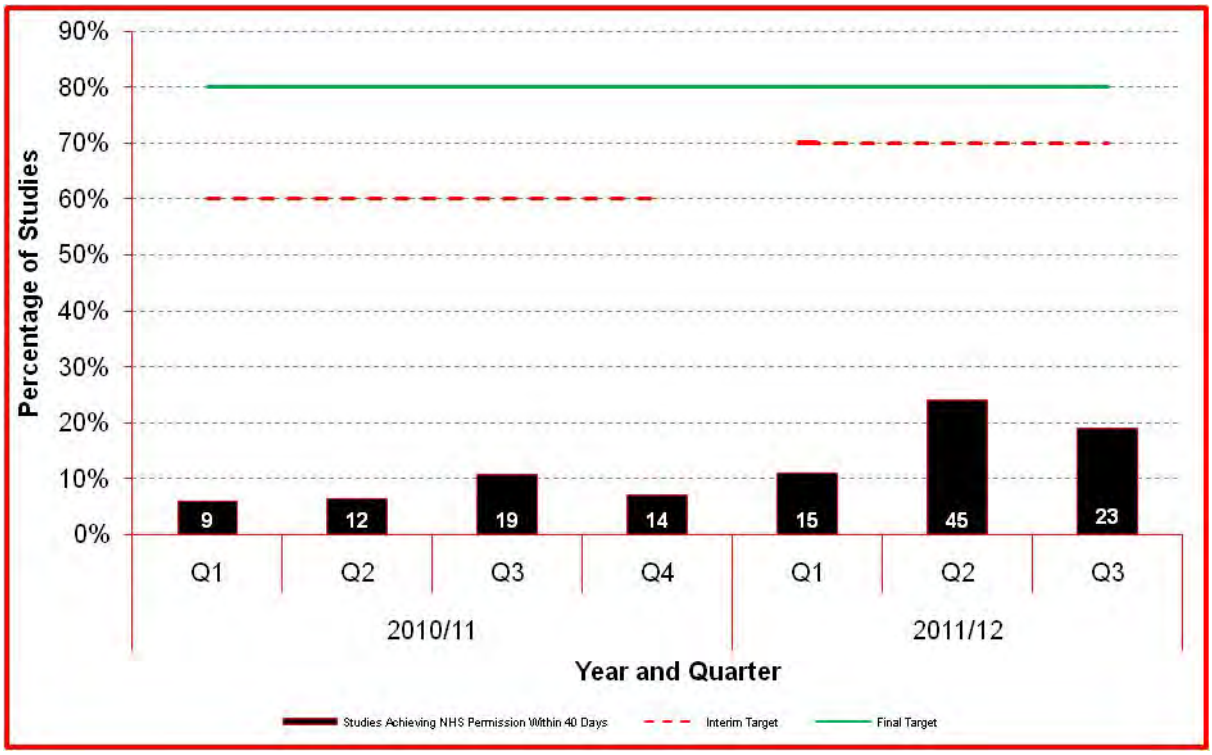



Figure 2.8 shows the percentage of studies achieving permission within 40 days within each quarter. These data are drawn from the CSP Module. This system was released in July 2011, with data from legacy systems migrated over in October 2011. A number of technical problems has affected both the migrated data and CSP activity since October 2011.

The previous report for Quarter 2 highlighted caveats about the data for that quarter due to known problems with data quality for migrated data. Those problems have now been addressed and we can therefore be confident that the data shown up to Quarter 2 2011/12 reflect the data from the legacy systems. This data, up to Quarter 2, show a significant improvement in the percentage of studies achieving the 40 day target, which reflects the considerable activity to address delays in NHS Permission as well as the impact of the new definitions for the metrics that were introduced in April 2011.

This measure reflects all the sites included in the application for a study and sites are often set up over a considerable time period. There is, therefore, an expected lag time of many months from the start of study set-up at the first site to completion of study set-up at the last site and inclusion in these metrics. These data suggest that some of the improvement in study-wide and local review times noted previously is now translating into impact on completed studies.

Since October 2011, the technical problems have affected the ability of Research and Development (R&D) staff to record activity in the CSP Module in real time. The data for Quarter 3 must therefore be interpreted with caution. Some activity will have been recorded late giving apparent delays; other activity will have been put through the system quickly, retrospectively, which will appear as very quick permission times. It is not clear yet how much the activity for Quarter 3 is affected by these different problems.

However, it should be noted that since the studies reported here only include those where all sites have issued permission, only some sites within the studies reported in Quarter 3 will have been affected by the technical problems since October 2011. The figures relating to Quarter 3 may be subject to change as further data cleansing is undertaken (see page 5 footnote 2).

## 2.7 High Level Objective 5

**Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies**

**High Level Objective 5A**: **Proportion of commercial contract studies achieving first participant recruited within 30 calendar days of NHS Permission being issued, at confirmed Network sites**

**Fig 2.9: Proportion of commercial contract studies, by the number of calendar days from NHS Permission issued to first participant recruited**

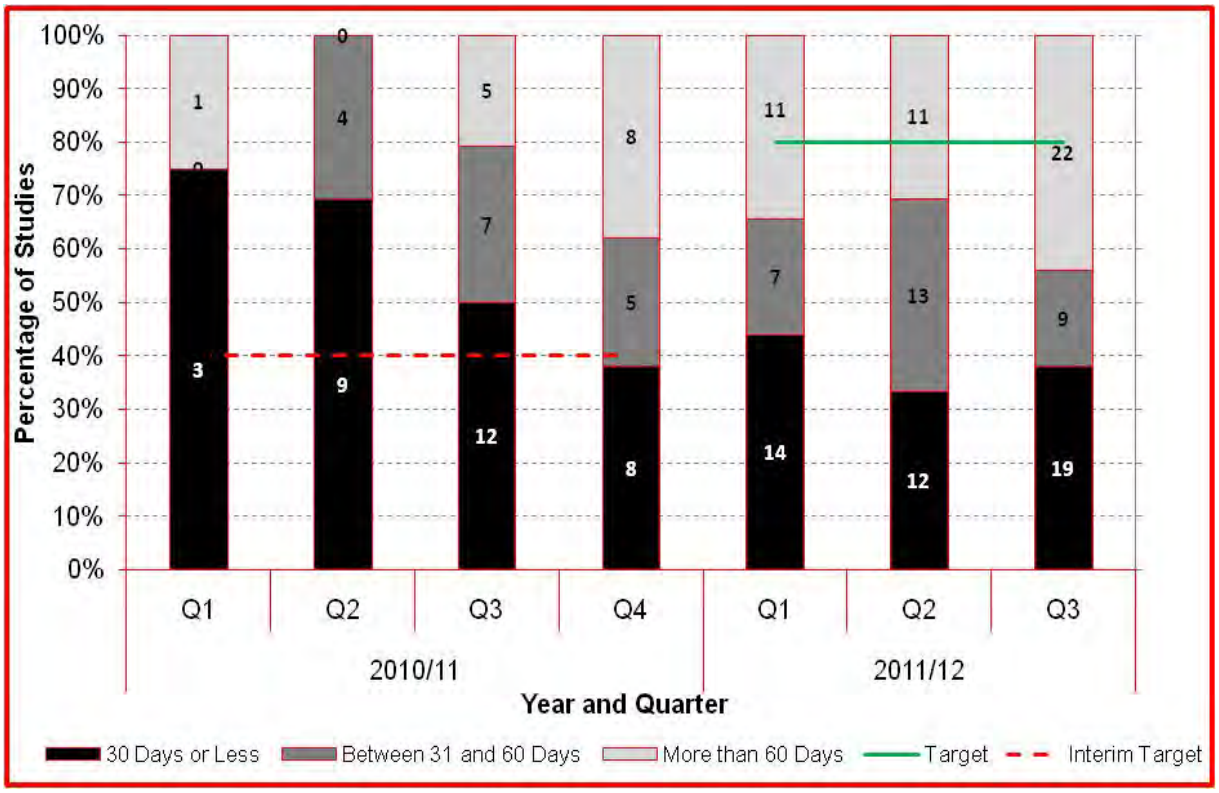
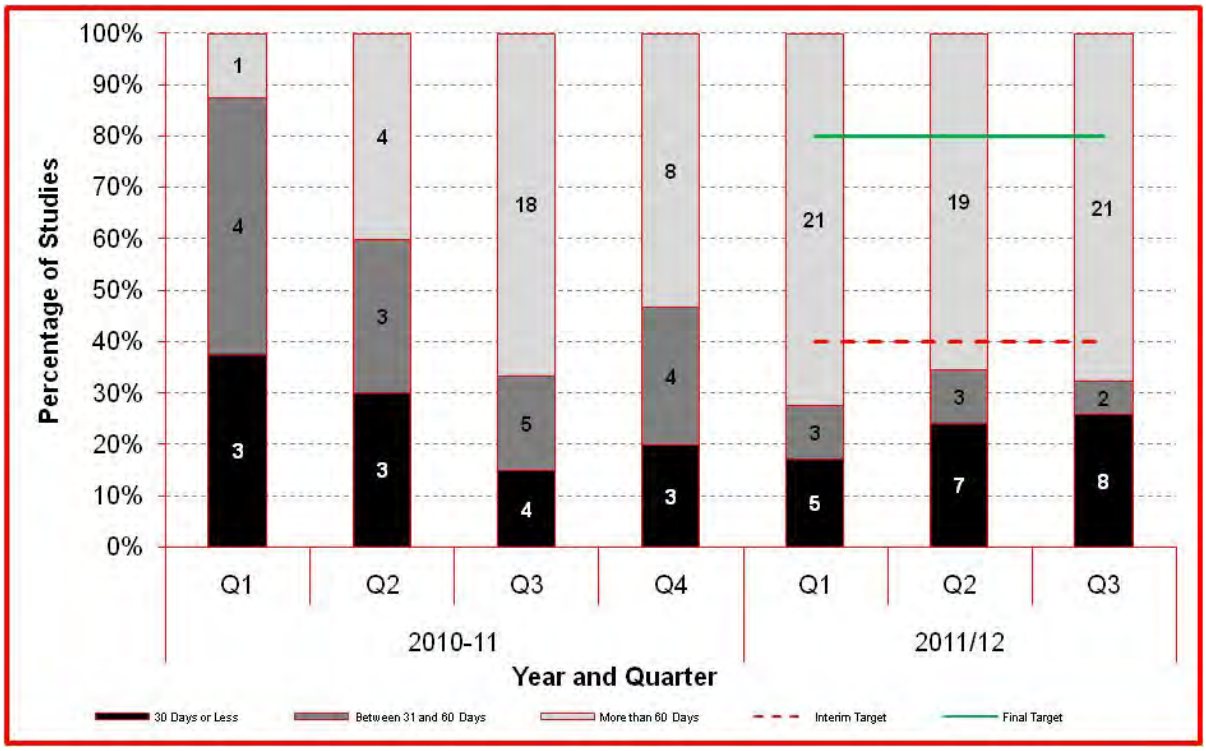



Figure 2.9 demonstrates that the proportion of commercial contract studies recruiting their first participant within 30 days of receipt of NHS Permissions has risen slightly in Quarter 3 2011/12 to 38% compared to 33% in Quarter 2 2011/12. This rise is encouraging, but the numbers of studies included in this measure remains small, and the nature of the disease area under investigation can impact on this objective. There is, however, a considerable way to go to achieving our target of 80% of studies recruiting their first participant within 30 days of receipt of NHS Permissions. Work continues to identify and address the issues that are preventing recruitment of the first participant within 30 days of NHS Permission being issued, and we expect that performance will continue to improve during the last quarter of 2011/12.

It should also be noted that the figures for this objective may be subject to change as further data cleansing may need to be undertaken (see page 5 footnote 2).

**High Level Objective 5B: Proportion of non-commercial studies managed by Registered CTUs achieving first participant recruited within 30 calendar days of NHS Permission being issued**

**Fig 2.10: Proportion of non-commercial studies by Registered CTUs, by the number of calendar days from NHS Permission issued to first participant recruited**




31 studies recruited their first participant in Quarter 3, a slight increase from Quarter 2 (29 studies).

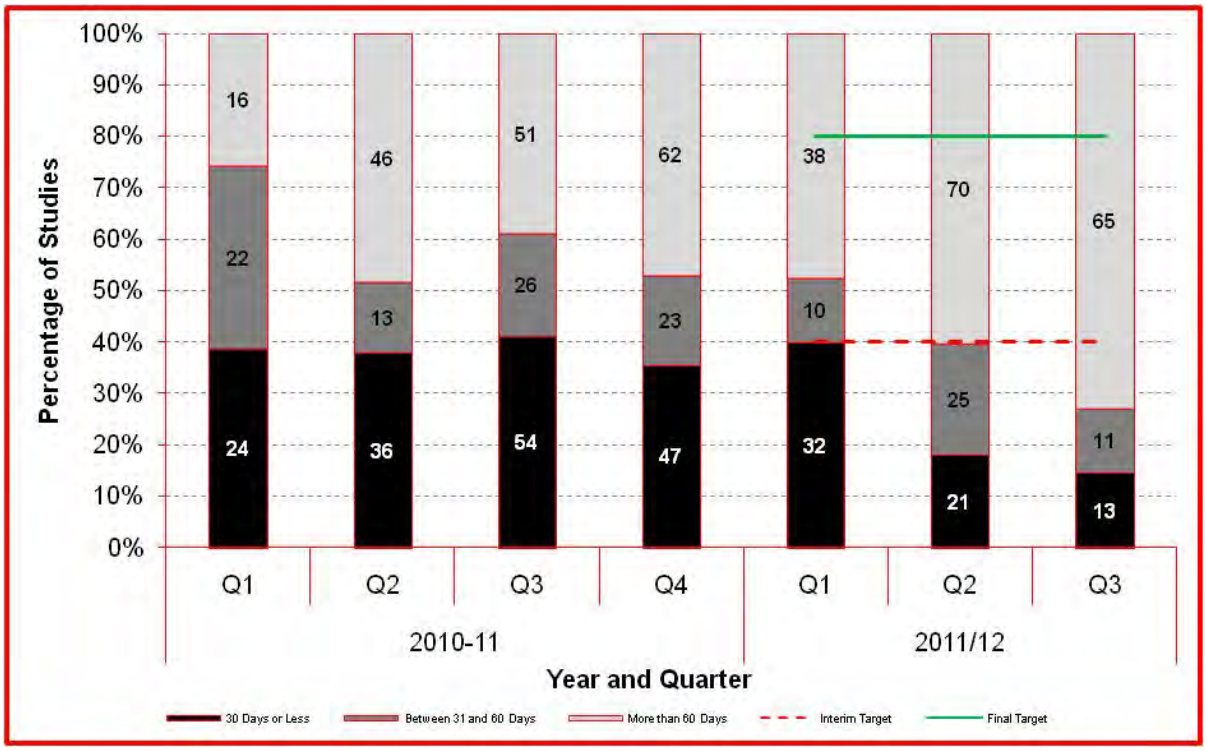
As figure 2.10 illustrates, the trend in performance on this objective looks positive: the percentage of studies recruiting their first participant within 30 days of NHS Permission being issued has risen slightly quarter by quarter in 2011/12, with 26% of studies achieving this objective in Quarter 3. We should note that the number of studies measured here is small, so the analysis should be treated with caution.

We are still falling short of our 2011/12 interim target on this objective (40%). However, further analysis indicates that during 2011/12 there are several studies which have not met this objective, but which would not have been expected to recruit a participant within 30 days given their planned recruitment rates; for instance, certain studies in rare diseases where the planned recruitment rate is less than 12 participants per year.

It should also be noted that the figures for this objective may be subject to change as further data cleansing may need to be undertaken (see page 5 footnote 2).

**High Level Objective 5C: Proportion of non-commercial studies not managed by Registered CTUs achieving first participant recruited within 30 calendar days of NHS Permission being issued**

**Fig 2.11: Proportion of non-commercial studies non managed by Registered CTUs, by the number of calendar days from NHS Permission issued to first participant recruited**




During this quarter 89 studies recruited their first participant and are therefore included in this measure.

Whilst the trend during 2010/11 and Quarter 1 2011/12 was relatively consistent, with performance broadly in line with our interim target for 2011/12 (40%), Quarters 2 and 3 have seen a drop in performance. In Quarter 3, the data show that 15% of studies recruited their first participant within 30 days, slightly lower than the percentage in Quarter 2 (18%).

As for High Level Objective 5B above, performance on this objective does not exclude those studies whose planned recruitment rate is less than 12 participants per year, ie studies which would not necessarily expect to recruit their first participant within 30 days.

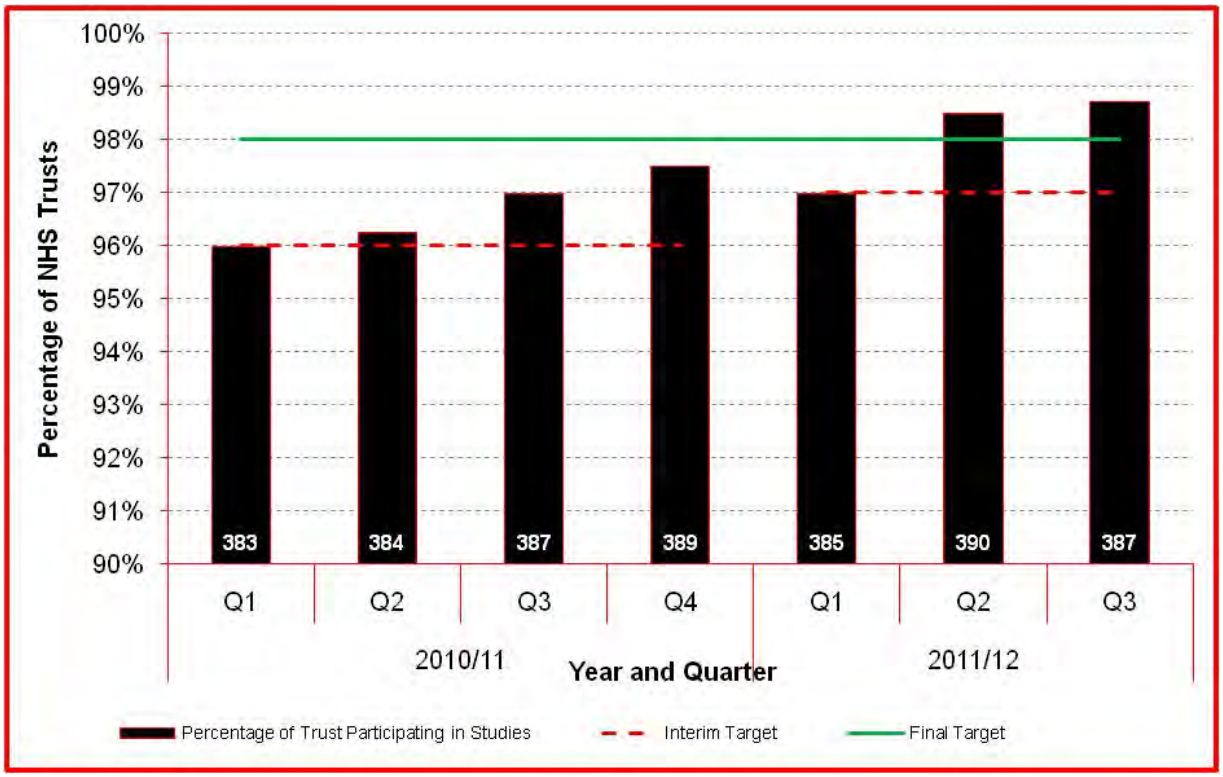
Work continues to identify and actively address the issues that are preventing studies from recruiting their first participant within 30 days of NHS Permission being issued.

It is important to note that the figures for this objective may be subject to change as further data cleansing may need to be undertaken (see page 5 footnote 2).

## 2.4 High Level Objective 6

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

**Fig 2.12: Percentage of NHS Trusts participating in NIHR Clinical Research Network Portfolio studies within the past 12 months**




The proportion of NHS Trusts actively recruiting to NIHR CRN Portfolio studies within the past 12 months increased to 98.7% this quarter, which means that the target for this High Level Objective has been achieved for a second consecutive quarter.

Of the 387 local NHS Trusts in England that are currently operational,[3] 382 actively recruited participants to NIHR CRN Portfolio studies in the 12-month period 01/01/2011 to 31/12/2011. Table 2.14 shows that of the five organisations that did not recruit to Portfolio studies in this period, three are care trusts and two ambulance trusts.

Table 2.13 shows recruitment activity in Quarter 3 2011/12 for each type of NHS Trust. All NHS Acute Trusts in England recruited patients in this quarter, as did 96% of mental health trusts, and 93% of primary care trusts. Research activity has been maintained in 9 of 11 ambulance trusts, and we are beginning to see progress in research recruitment in the community/care trust sector.

Overall these data show excellent progress in this objective to expand the reach of NIHR CRN to all sectors of the NHS, and to engage all NHS organisations in England in NIHR CRN research.

[3] The NHS website is used as the information source:
http://www.nhs.uk/NHSEngland/thenhs/about/Pages/authoritiesandtrusts.aspx

**Table 2.13: Number and percentage of active NHS organisations this quarter, for each NHS organisation type**

| Organisation type | Number of Organisations | Number of Active Organisations | Percentage of Active Organisations |
|---|---|---|---|
| Acute | 164 | 164 | 100.00% |
| Ambulance | 11 | 9 | 81.82% |
| Care | 15 | 9 | 60.00% |
| Mental Health | 55 | 53 | 96.36% |
| Mental Health/Care | 1 | 0 | 0.00% |
| Primary Care | 145 | 135 | 93.10% |
| Not currently categorised | 1 | 1 | 100.00% |
| **Total** | **392** | **371** | **94.64%** |

**Table 2.14: List of NHS organisations that have not reported recruitment activity in one or more of the past four quarters**

| Name | Organisation Type | Activity in past four quarters | | | |
|---|---|---|---|---|---|
| | | 2010/11 Q4 | 2011/12 Q1 | 2011/12 Q2 | 2011/12 Q3 |
| BASSETLAW PCT | Primary Care | ✓ | ✓ | × | × |
| BEXLEY CARE TRUST | Care | ✓ | × | ✓ | ✓ |
| BLACK COUNTRY PARTNERSHIP NHS FOUNDATION TRUST | Mental Health/Care | ✓ | ✓ | ✓ | × |
| BLACKBURN WITH DARWEN TEACHING CARE TRUST PLUS | Care | ✓ | ✓ | ✓ | × |
| BRIDGEWATER COMMUNITY HEALTHCARE NHS TRUST | Care | × | × | × | × |
| BRIGHTON AND HOVE CITY PCT | Primary Care | ✓ | × | ✓ | ✓ |
| BRIGHTON AND SUSSEX UNIVERSITY HOSPITALS NHS TRUST | Acute | × | × | ✓ | ✓ |
| CALDERSTONES PARTNERSHIP NHS FOUNDATION TRUST | Mental Health | × | ✓ | × | × |

| Name | Organisation Type | Activity in past four quarters | | | |
|---|---|---|---|---|---|
| | | 2010/11 Q4 | 2011/12 Q1 | 2011/12 Q2 | 2011/12 Q3 |
| CENTRAL LONDON COMMUNITY HEALTHCARE NHS TRUST | Care | × | × | × | × |
| CITY AND HACKNEY TEACHING PCT | Primary Care | ✓ | × | ✓ | ✓ |
| EAST LANCASHIRE HOSPITALS NHS TRUST | Acute | × | ✓ | ✓ | ✓ |
| EAST OF ENGLAND AMBULANCE SERVICE NHS TRUST | Ambulance | × | ✓ | ✓ | ✓ |
| EAST SUSSEX DOWNS AND WEALD PCT | Primary Care | ✓ | × | ✓ | ✓ |
| GREAT WESTERN AMBULANCE SERVICE NHS TRUST | Ambulance | × | × | × | × |
| GREENWICH TEACHING PCT | Primary Care | ✓ | ✓ | ✓ | × |
| HARROW PCT | Primary Care | ✓ | ✓ | ✓ | × |
| HARTLEPOOL PCT | Primary Care | ✓ | ✓ | ✓ | × |
| HAVERING PCT | Primary Care | ✓ | ✓ | ✓ | × |
| HERTFORDSHIRE COMMUNITY NHS TRUST | Care | × | × | ✓ | × |
| HILLINGDON PCT | Primary Care | ✓ | × | ✓ | ✓ |
| ISLE OF WIGHT NHS PCT | Primary Care | × | ✓ | ✓ | ✓ |
| KENT COMMUNITY HEALTH NHS TRUST | Care | ✓ | ✓ | × | ✓ |
| KINGSTON PCT | Primary Care | ✓ | × | ✓ | ✓ |
| KIRKLEES PCT | Primary Care | ✓ | ✓ | ✓ | × |
| KNOWSLEY PCT | Primary Care | ✓ | ✓ | × | × |
| LEEDS COMMUNITY HEALTHCARE NHS TRUST | Care | × | × | × | × |
| NEWHAM PCT | Primary Care | ✓ | ✓ | ✓ | × |
| NORTH EAST LINCOLNSHIRE CARE TRUST PLUS | Care | ✓ | ✓ | × | × |

| Name | Organisation Type | Activity in past four quarters | | | |
|---|---|---|---|---|---|
| | | 2010/11 Q4 | 2011/12 Q1 | 2011/12 Q2 | 2011/12 Q3 |
| NORTH WEST AMBULANCE SERVICE NHS TRUST | Ambulance | × | × | × | × |
| OXFORDSHIRE LEARNING DISABILITY NHS TRUST | Mental Health | × | ✓ | × | × |
| RICHMOND AND TWICKENHAM PCT | Primary Care | ✓ | ✓ | ✓ | × |
| ROYAL NATIONAL ORTHOPAEDIC HOSPITAL NHS TRUST | Acute | × | ✓ | ✓ | ✓ |
| SOUTH CENTRAL AMBULANCE SERVICE NHS TRUST | Ambulance | ✓ | × | ✓ | ✓ |
| SOUTH EAST COAST AMBULANCE SERVICE NHS FOUNDATION TRUST | Ambulance | × | × | ✓ | ✓ |
| SOUTH WESTERN AMBULANCE SERVICE NHS FOUNDATION TRUST | Ambulance | × | ✓ | ✓ | ✓ |
| TAMESIDE AND GLOSSOP PCT | Primary Care | ✓ | ✓ | ✓ | × |
| UNIVERSITY HOSPITALS OF MORECAMBE BAY NHS FOUNDATION TRUST | Acute | × | ✓ | ✓ | ✓ |
| WALSALL HEALTHCARE NHS TRUST | Acute | ✓ | × | × | ✓ |
| YORKSHIRE AMBULANCE SERVICE NHS TRUST | Ambulance | ✓ | × | ✓ | ✓ |

**Table 2.15: Recruitment per million resident population in each NHS Strategic Health Authority area [4]**

| SHA | Total Recruitment Q3 2011/12 | Population (million) | Total Recruitment Q3 2011/12 per million population |
|---|---|---|---|
| North West | 39,604 | 6.970 | 5,682 |
| South West | 15,341 | 5.279 | 2,906 |
| West Midlands | 15,248 | 5.455 | 2,795 |
| North East | 7,207 | 2.607 | 2,764 |
| South Central | 10,664 | 4.145 | 2,573 |
| London | 18,321 | 7.825 | 2,341 |
| East of England | 12,112 | 5.832 | 2,077 |
| Yorkshire and Humber | 10,857 | 5.299 | 2,049 |
| East Midlands | 6,094 | 4.450 | 1,369 |
| South East Coast | 4,290 | 4.372 | 981 |
| **TOTAL** | **139,738** | **52.234** | **2,675** |

[4] SHA resident population based on Office of National Statistics mid-2010 Resident Population Estimates

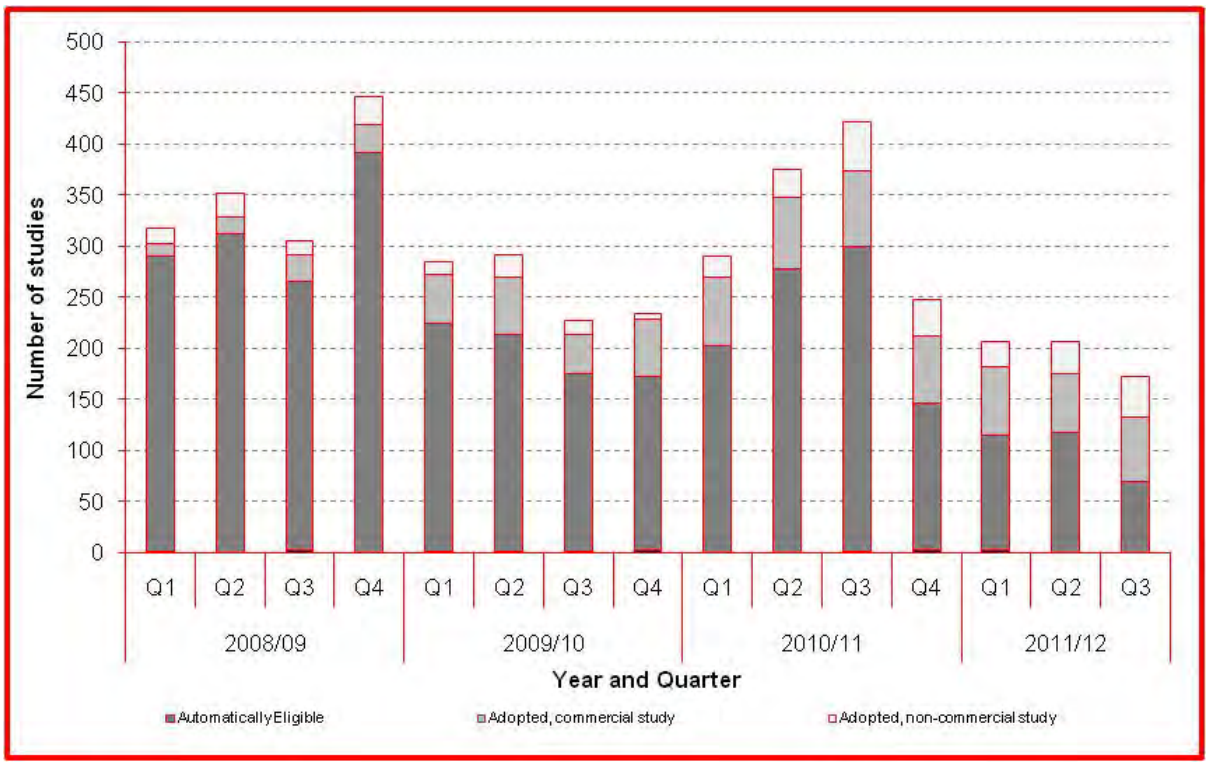
## 3. CLINICAL RESEARCH NETWORK PORTFOLIO ACTIVITY

The NIHR Clinical Research Network Portfolio is a collection of high quality clinical research studies that are eligible for consideration for Clinical Research Network support. Some studies may receive support from more than one of the eight 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 consideration for NIHR Clinical Research Network support entered onto the Portfolio database in each quarter is illustrated in figure 3.1. Non-commercial studies, including those that are automatically eligible and those that are required to go through the non-commercial adoption process, make up the greatest proportion of studies on the CRN Portfolio. This is a trend observed across all quarters since 2008/9 which is maintained in Quarter 3 of 2011/12.

The number of studies eligible for consideration for NIHR Clinical Research Network support has decreased in Quarter 3 when compared to the first two quarters of this year. The number of eligible studies added to the Portfolio database in the first three quarters of 2011/12 is markedly reduced when compared to the number of eligible studies added in the first three quarters of 2010/11 (n=586 studies in 2011/12 compared to n=1086 studies in 2010/11).

**Fig 3.1: Number of studies entered onto the Portfolio by eligibility type**

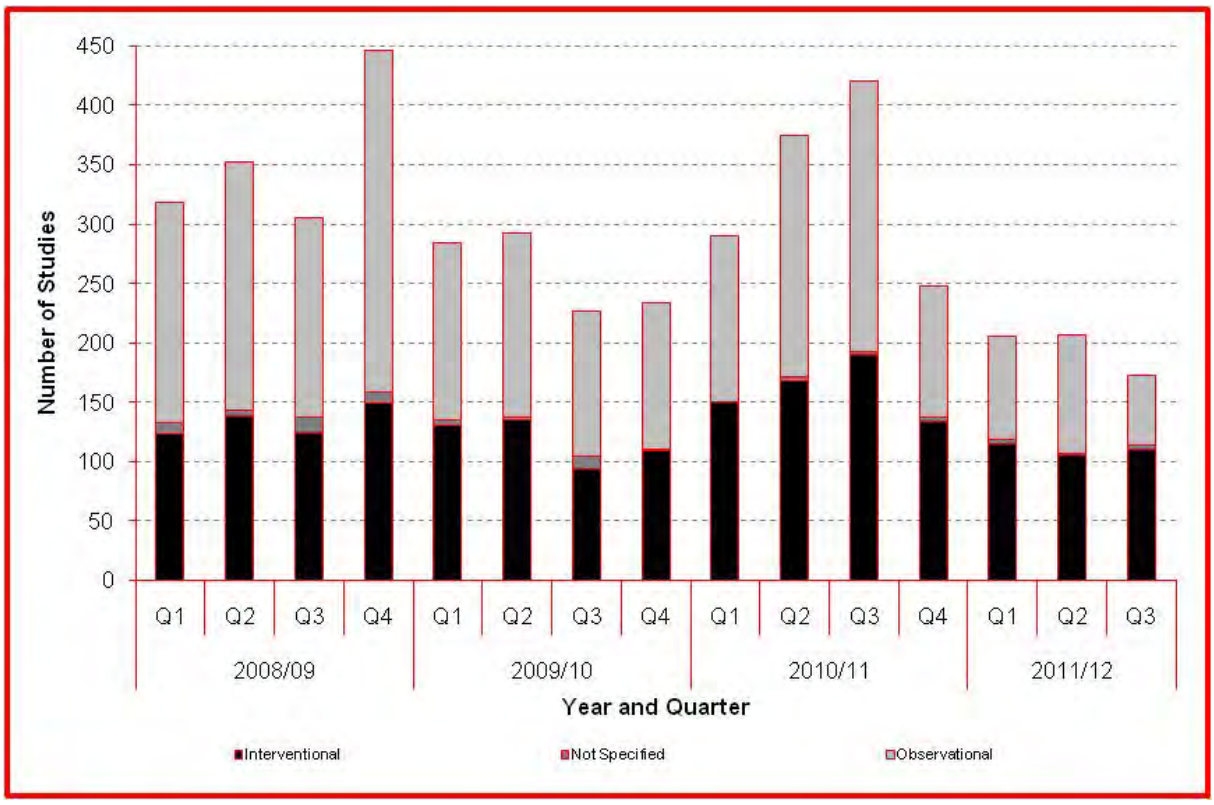



Interestingly, this quarter has seen a marked reduction in the number of automatically eligible studies added to the Portfolio database when compared to the previous two quarters this year. Even more noticable is the reduction in the number of automatically eligible studies this quarter (n=70 studies) when compared to Quarter 3 2010/11 (n=299 studies) when more than three times the number of automatically eligible studies were added to the Portfolio database.

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 research proposals developed and submitted for funding. The decrease in the number of studies deemed eligible for consideration for CRN support in the first three quarters of 2011/12, when compared to the first three quarters of 2010/11, may therefore be a result of a reduction in the amount of research grant funding available; hence a reduction in the overall number of clinical research studies being funded. Similarly, a reduction in the number of clinical research studies being funded could also be a result of government and charity funders supporting larger, more complex studies.

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 consideration for 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 3 2011/12, demonstrating that the NIHR Clinical Research Network continues to support a balanced portfolio of clinical research studies.

**Fig 3.2: Number of studies entered onto the Portfolio by primary study design**




In Quarter 3 2011/12 the number of interventional studies eligible for consideration for CRN support (n=111) increased in comparison to Quarter 2 (n=106) despite the overall reduction in the number of studies deemed eligible in this quarter compared to the previous. The number of observational studies eligible for consideration for CRN support (n=59) decreased in Quarter 3 when compared to the previous quarter (n=100) and all other quarters since 2008/9 (see figure 3.2). As with the last three quarters (Q4 2010/11, Q1 and Q2 2011/12) a greater number of interventional studies (n=332, 57%) have been added to the Portfolio database in Quarter 3 when compared to observational studies (n=246; 42%[5]).

[5] 1% of studies are reported as “not specified” in terms of their primary study design

This data continue to support the hypothesis that the reduction in the number of studies deemed eligible for consideration for CRN support in 2011/12 could be a result of research funders supporting more complex studies.

**Table 3.3: Summary trend data**

| | 2009/10 | | | | 2010/11 | | | | 2011/12 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 |
| **Number of Studies Entered onto the Portfolio** | 284 | 292 | 227 | 234 | 290 | 375 | 421 | 248 | 206 | 207 | 173 |
| **Number of Studies Open to Recruitment** | 2,091 | 2,183 | 2,268 | 2,305 | 2,417 | 2,476 | 2,577 | 2,679 | 2,761 | 2,815 | 2,896 |
| **Number of Studies Reporting Recruitment** | 1,963 | 2,038 | 2,002 | 1,945 | 2,186 | 2,229 | 2,257 | 2,264 | 2,217 | 2,379 | 2,397 |
| **Number of (NIHR CRN) Participants** | 100,398 | 112,233 | 126,949 | 114,558 | 174,820 | 125,410 | 124,668 | 139,800 | 120,585 | 143,711 | 139,738 |

Table 3.3 provides summary trend data which 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. The number of eligible studies added to the Portfolio database in the first three quarters of 2011/12 is markedly reduced when compared to the number of eligible studies added in the first three quarters of 2010/11 (n=586 studies in 2011/12 compared to n=1086 studies in 2010/11). Despite this reduction in the number of eligible studies added to the Portfolio database in 2011/12 compared with other quarters in other years, the Clinical Research Network was still supporting some 2,896 open studies in Quarter 3 2011/12 (table 3.3).

The number of studies open to recruitment (tables 3.3 and 3.4) gives a broad indication of the scale of opportunities for participants to take part in NIHR 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 81 studies on Quarter 2 2011/12, in which 2,815 studies were open to recruitment (table 3.3).

The number of studies attributed to each of the Networks is provided in table 3.4, illustrating a wide range in the number of studies being “led” by each Network.

**Table 3.4: Number of studies open to recruitment and number of studies reporting recruitment by Network**

| Network | Number of Studies Open to Recruitment during Q3 2011/12 | Total Number of Studies Reporting Recruitment in Q3 2011/12 |
|---|---|---|
| Cancer | 503 | 429 |
| Comprehensive | 1,527 | 1,222 |
| Dementias & Neurodegenerative Diseases | 115 | 91 |
| Diabetes | 168 | 126 |
| Medicines for Children | 114 | 107 |
| Mental Health | 231 | 211 |
| Primary Care | 154 | 128 |
| Stroke | 84 | 83 |
| **TOTAL** | **2,896** | **2,397** |

There has been a small increase (n=18) in the number of studies reporting recruitment data in Quarter 3 2011/12 (n=2,397) when compared to the Quarter 2 2011/12 (n=2,379; see table 3.3). In this quarter 83% of all open studies were reporting recruitment data (see figure 3.5); a small reduction when compared to the number reporting in Quarter 2 2011/12.

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 have yet to upload their recruitment data onto the national Portfolio database. Study teams are asked to report (ie upload) 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.

In terms of total recruitment, 139,738 participants were recruited into CRN Portfolio studies in this quarter (table 3.3). This is a decrease of 3,973 participants compared to Quarter 2 2011/12 but is an increase of 15,070 participants when compared to the same quarter in the previous year (see table 3.3). 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 result in fewer participants for the same time and effort invested (figure 3.6).

- The nature of the disease area – studies investigating rare conditions or hard to reach populations – will recruit fewer participants

**Fig 3.5: Percentage of open studies reporting recruitment**

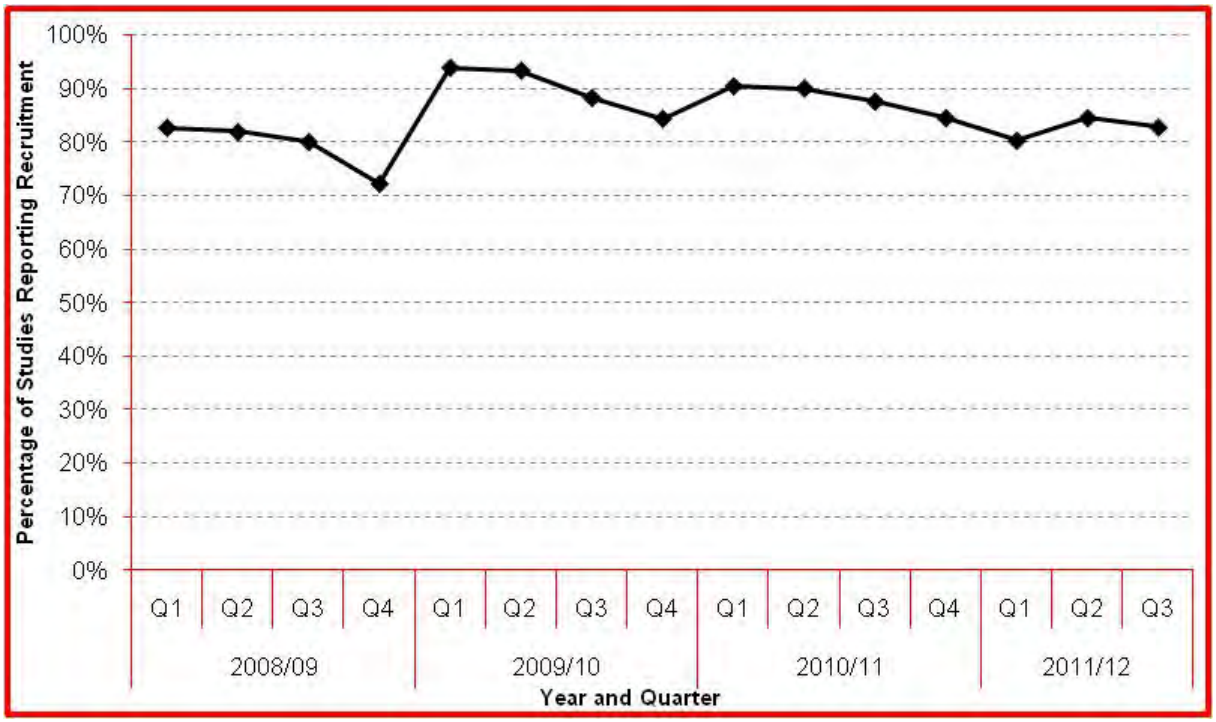



**Fig 3.6: Recruitment by primary study design**

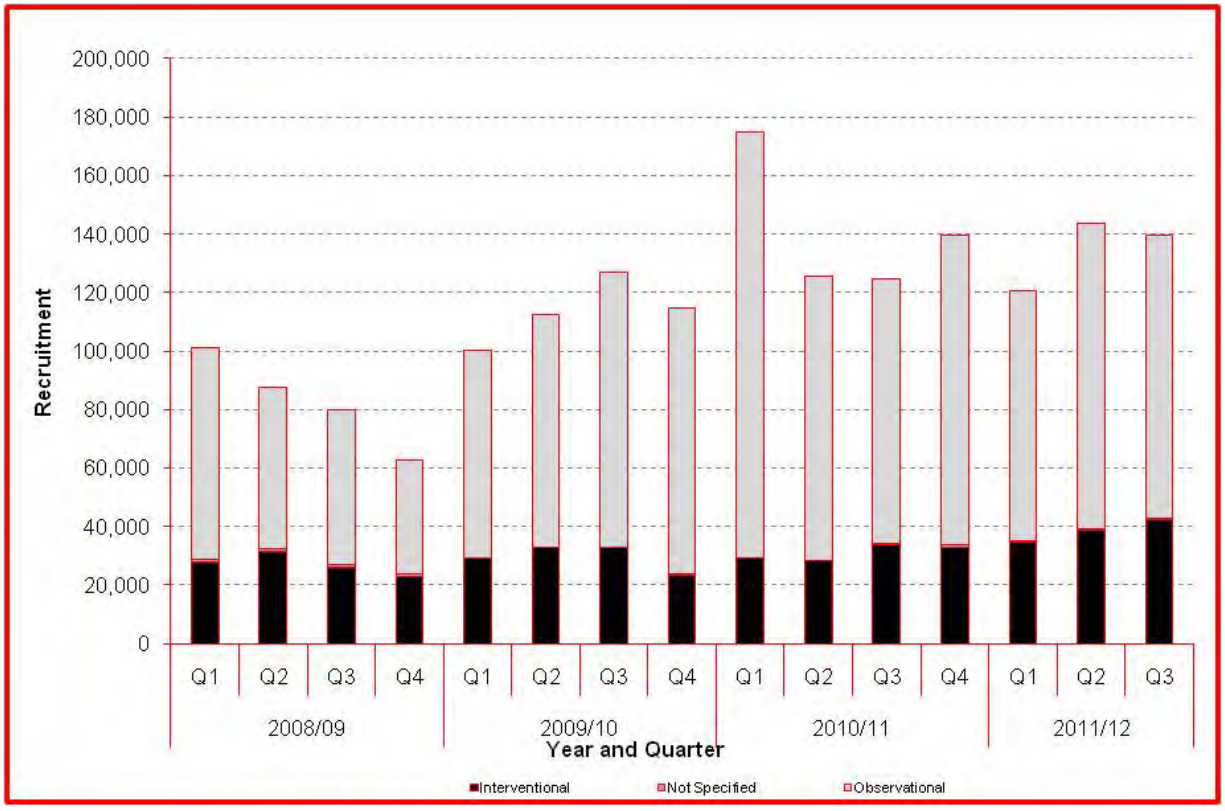



Figure 3.6 provides a breakdown of the total recruitment according to primary study design. This illustrates that observational studies account for a greater proportion of total recruitment in comparison to interventional studies. This trend is maintained in this quarter.

Interestingly, recruitment into interventional studies is more consistent over time than that into 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.

In Quarter 3 2011/12 there were 96,923 participants recruited into observational studies compared to 104,365 participants in the previous quarter. 42,106 participants were recruited into interventional studies in Quarter 3 2011/12 compared to 38,813 participants in Quarter 2 2011/12. The overall decrease in recruitment in this quarter is, therefore, primarily a result of decreased recruitment into observational studies.

**Fig 3.7: Recruitment by Network and study design**

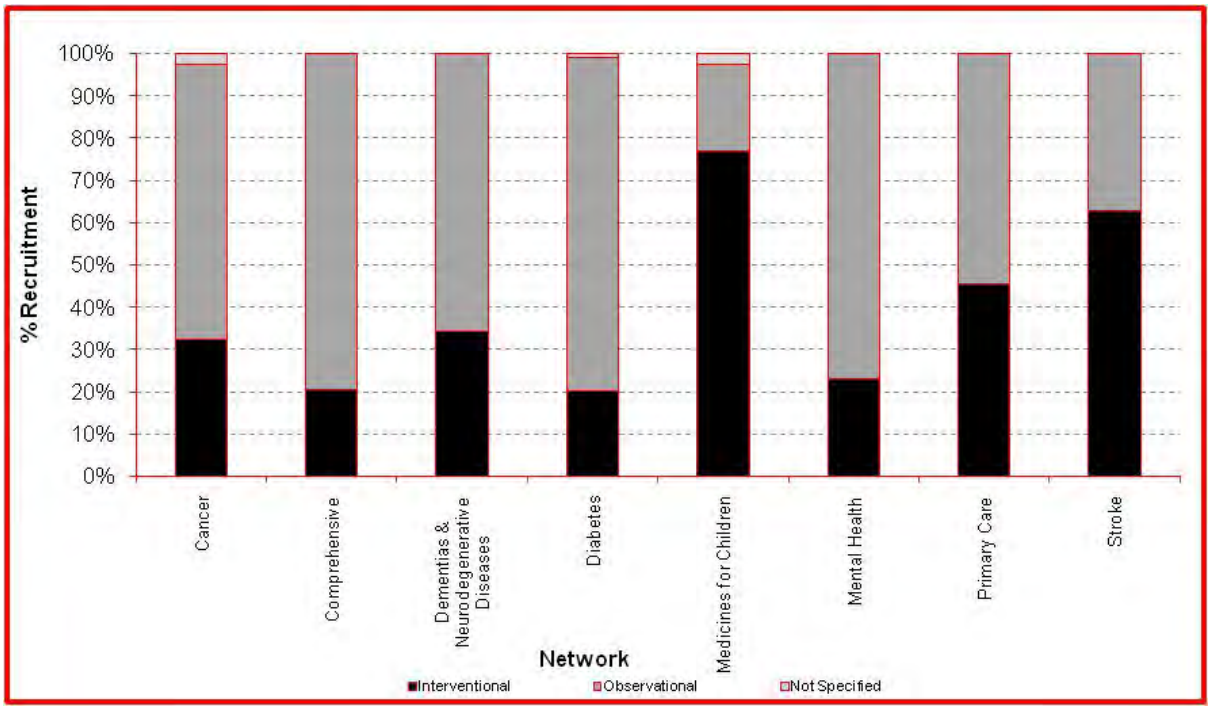



Figure 3.7 illustrates the breakdown of recruitment in each Network by primary study design. Whilst overall recruitment into observational studies surpasses that into interventional studies in Quarter 2 2011/12 (figure 3.6), two Networks (Medicines for Children and Stroke) again bucked this trend and recruited more participants to interventional studies than observational studies. Both of these Networks had this same pattern of recruitment in the previous quarters of 2011/12, demonstrating a trend for these Networks.

## 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. The CSP system tracks the beginning of the study set-up process 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 provide a picture of approval times as a whole, as they are experienced by researchers. However, it is not a direct indicator of the Clinical Research Network's 'performance' in relation to study approval only.

**Fig 4.1: Median average time to achieve NHS Permission**

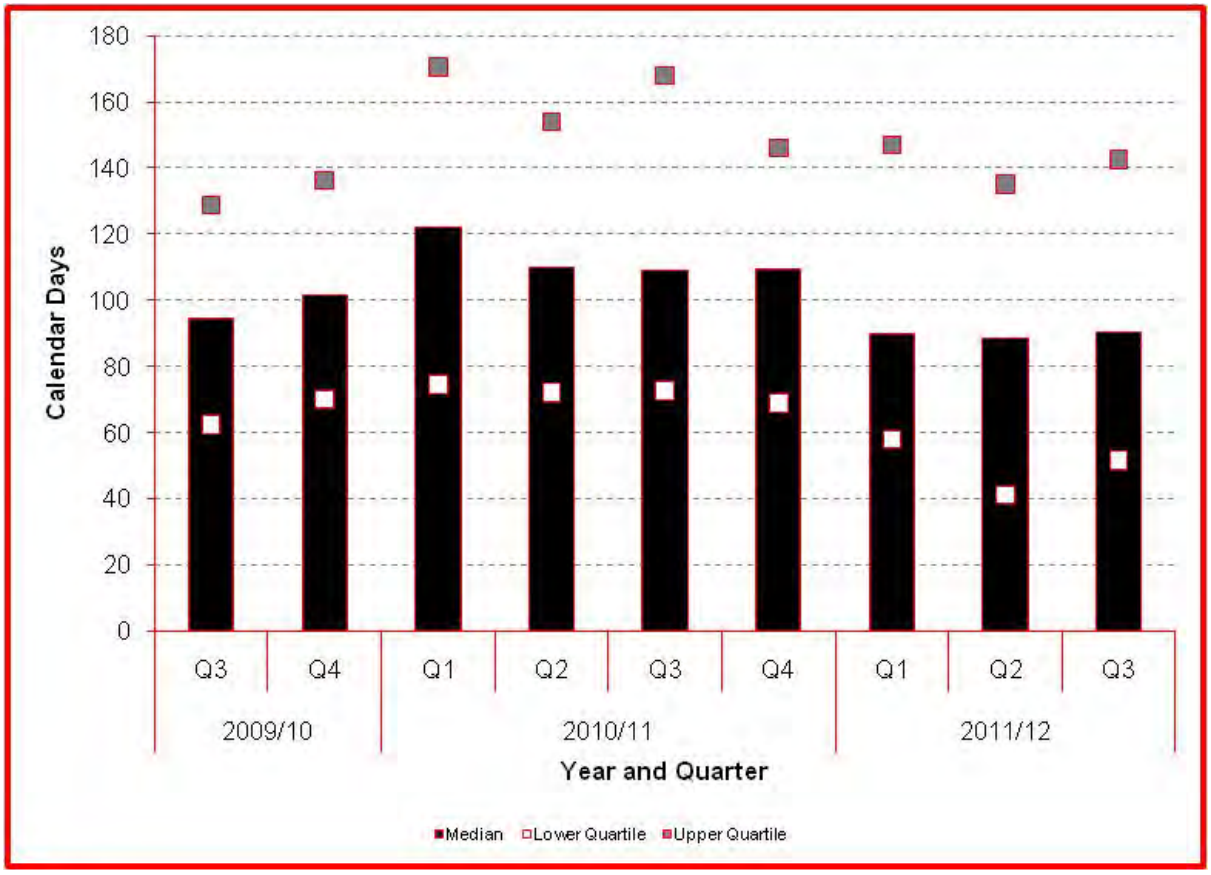
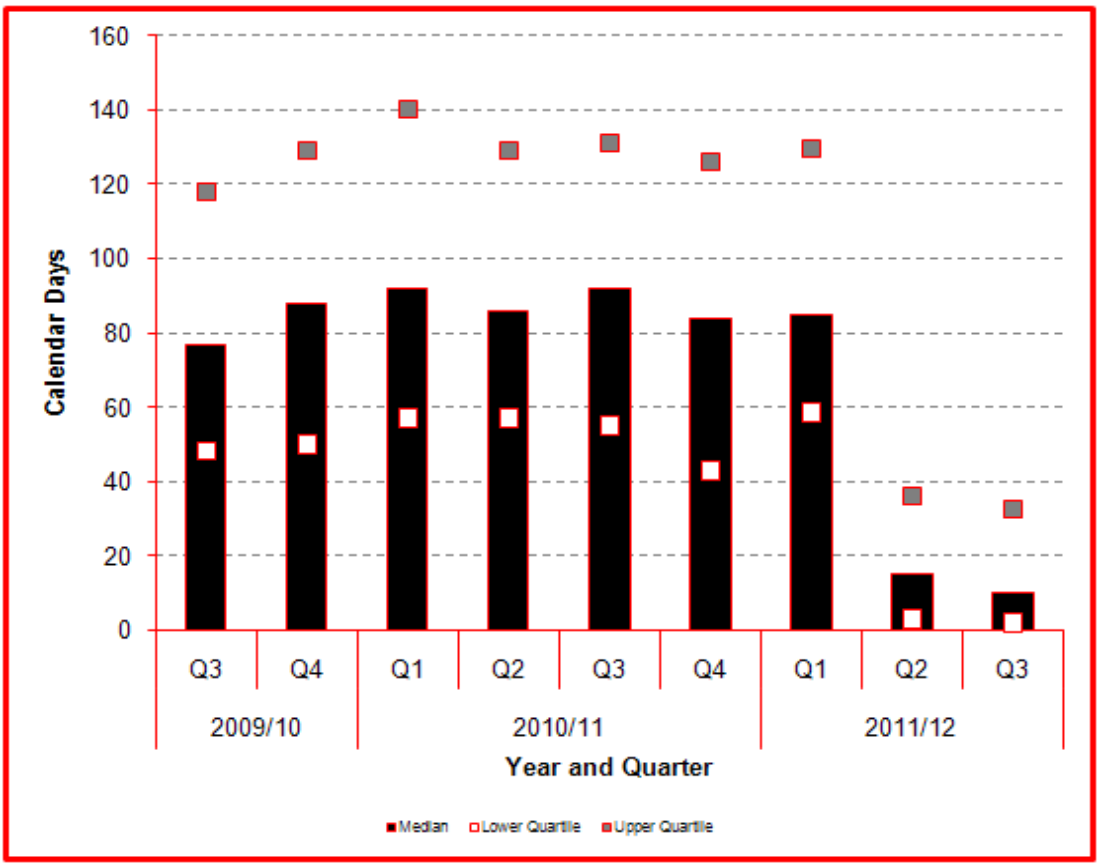



Figure 4.1 shows the (median) average time to permission for studies per quarter, ie the median time for the approvals process for those studies for which NHS Permission was issued in that quarter. This shows a downward trend in median time to permission through CSP up to Quarter 2 2011/12 compared with the peak figure in Quarter 1 2010/11.
These data are drawn from the CSP Module. This system was released in July 2011, with data from legacy systems migrated over in October 2011. A number of technical problems have affected both the migrated data and CSP activity since October 2011. The previous report for Quarter 2 highlighted caveats about the data for that quarter due to known problems with data quality for migrated data.

Those problems have now been addressed and we can therefore be confident that the data shown up to Quarter 2 2011/12 reflect the data from the legacy systems.

The data for Quarter 3 should be interpreted with caution. The technical problems have affected the recording of data in the system as well as causing real delays in some cases to the processing of studies. The figures relating to Quarter 3 may be subject to change as data cleansing is being undertaken.

**Fig 4.2: Median average time to complete study-wide review**




Figures 4.2 and 4.3 show a breakdown of the two components of CSP, the study-wide review and the local review.

Figure 4.2 shows the time to complete the study-wide review. This is the time from R&D validation to study-wide review completed. Prior to April 2011, the starting point was validation of the R&D form, whereas for studies starting after April 2011 the starting point is the validation of the R&D application package. The graph shows data by the quarter in which the study-wide checks were completed. A significant drop in study-wide review times was noted in Quarter 2. The median study-wide review time for Quarter 2 is below the target time of 30 days. As anticipated, the change in metrics in April 2011 has begun to have an impact on the timelines, reflecting the time previously taken for applicants to provide a valid application package. Arrangements are being put in place across the CRN to address lengthy timelines for study set-up, and clearly already having an impact by Quarter 2. Further activities to improve the performance of CSP are in development and are intended to make an even greater impact on timelines.

It is recognised that the implementation of the CSP Module will have had an impact on review. As noted above (section 2.6) the data for Quarter 3 is affected by incorrect data and, as the impact of the data quality issues is not yet clear, the data for this quarter should be interpreted with caution.

**Fig 4.3: Median average time to complete local review**

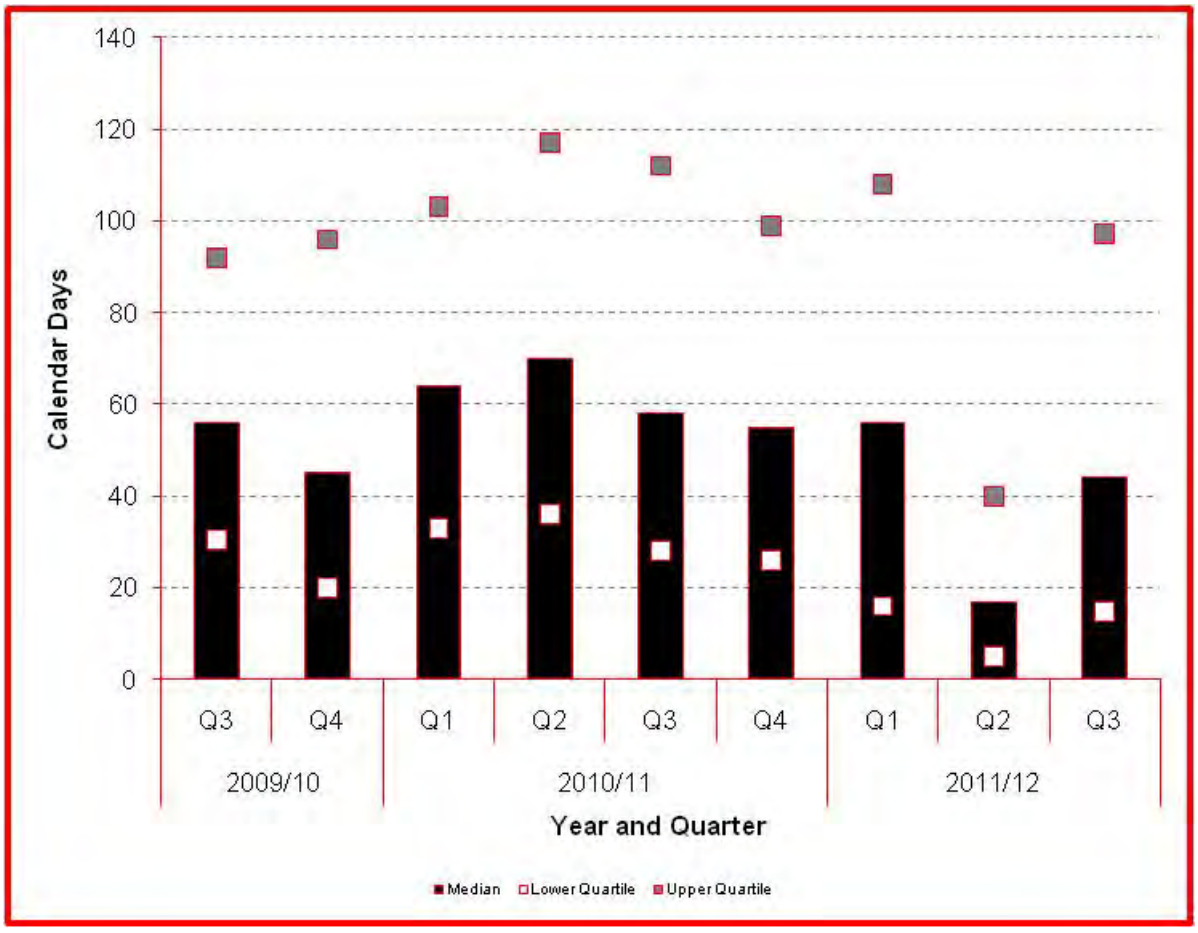



Figure 4.3 shows the time to complete the local review by the quarter in which the local reviews were completed. This is the time from Site Specific Information (SSI) form to NHS Permission for reviews started prior to April 2011 and from SSI application for reviews started after April 2011. It should be noted that studies may be counted more than once as each study will have local reviews for each site.

These figures are showing a significant downward trend to Quarter 2 2011/12, which suggests that the arrangements being put in place across the CRN to address lengthy timelines for study set-up have been having an impact. The impact of the change in metrics is also noticeable. 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. The median local review time for Quarter 2 is below the target time of 30 days.

As noted above (section 2.6) the data for Quarter 3 is affected by incorrect data and, as the impact of the data quality issues is not yet clear, the data for this quarter should be interpreted with caution. It is expected from anecdotal information that the local level data is particularly affected by retrospective reporting of activity into the system.

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

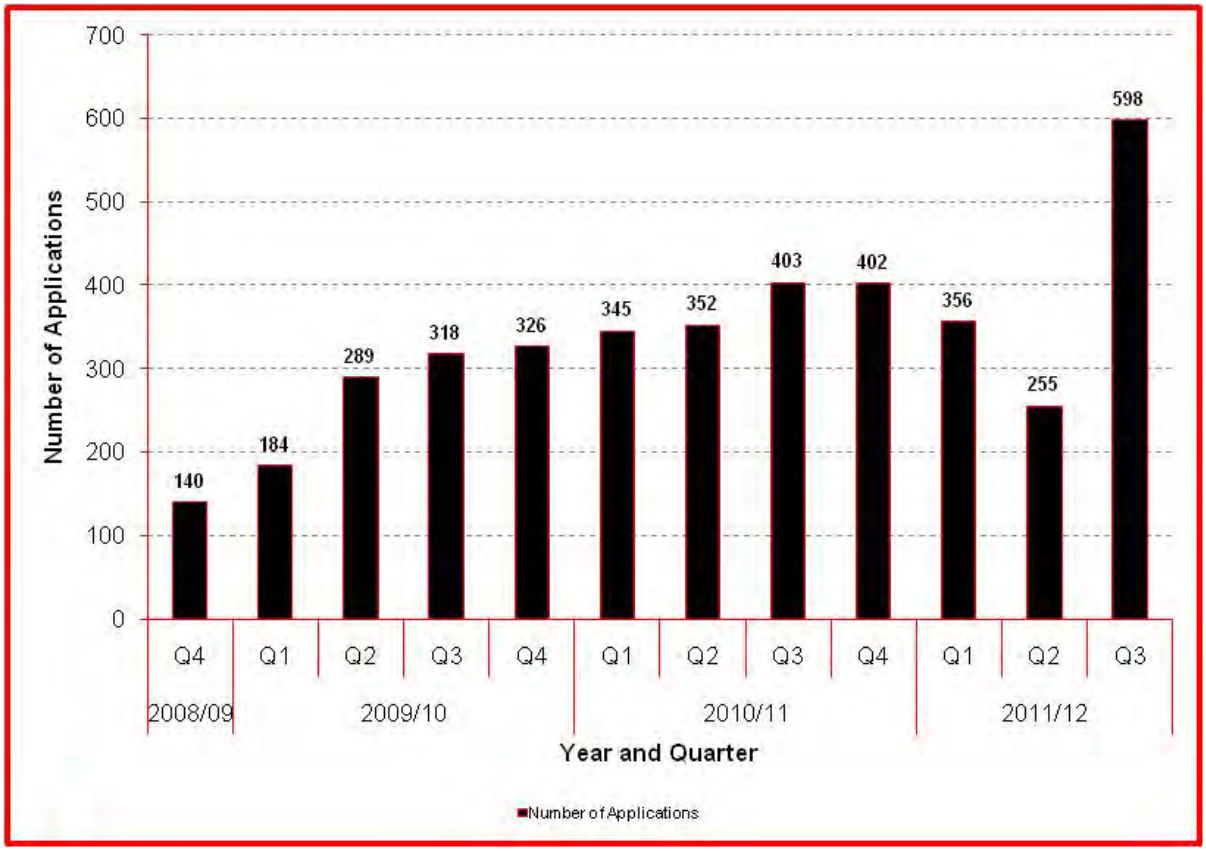



Figure 4.4 shows the number of studies accepted for processing through CSP per month. Some fluctuation month by month is expected, particularly in response to funding rounds and seasonal variations in academic activity.

However, there is a particularly noticeable drop in applications in Quarter 2 and a substantial increase in applications in Quarter 3. A similar drop is not noted in Quarter 2 in previous years although this quarter covers the summer holiday period. During Quarter 2 the legacy systems were still active so any impact of the release of the CSP Module would have been expected to be only partial. However, the subsequent rise in applications in Quarter 3 may mean that some of the reduction in Quarter 2 was due to applications being held back. There are no known problems with the accuracy of the number of applications recorded for Quarter 2 or Quarter 3 and the reason for the variation is unknown. It should be noted that the large volume in Quarter 3 exacerbated the impact of the technical difficulties resulting from the CSP Module.

## 5. LIFE-SCIENCES INDUSTRY STUDIES

The CRN activity report provides key activity data from the NIHR Clinical Research Network and provides information about the progress being made against the Clinical Research Network High Level Objectives described in section 2. To complement the CRN Activity Report an additional 'Industry Metrics' report is currently produced on a quarterly basis. The 'Industry Metrics' report includes two main sections, one detailing study performance for all commercial contract studies closing in a particular quarter and one reviewing overall study characteristics, recruitment and Industry engagement. Studies included in this 'Industry Metrics' report may not fulfil the criteria for inclusion in our High Level Objectives. For example, a study that opened to recruitment prior to April 2010 will not be included in our High Level Objectives. However, it would be included in 'Industry Metrics' report. Therefore when reviewed together the two reports reflect our past and present performance.

The following section describes the current status of the overall NIHR CRN commercial contract studies portfolio and the following tables and figures are the same as those contained in the 'Industry Metrics' report Quarter 3 2011/12.

**Table 5.1: Number of Industry studies by Network**

| 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 | Number of Studies Which Have NOT Been Adopted |
|---|---|---|---|---|---|
| **Cancer** | 227 | 0 | 227 | 1 | 28 |
| **Comprehensive** | 375 | 91 | 466 | 40 | 34 |
| **Dementias & Neurodegenerative Diseases** | 65 | 1 | 66 | 1 | 8 |
| **Diabetes** | 113 | 7 | 120 | 10 | 12 |
| **Medicines for Children** | 149 | 11 | 160 | 2 | 7 |
| **Mental Health** | 21 | 1 | 22 | 0 | 3 |
| **Primary Care** | 28 | 46 | 74 | 1 | 2 |
| **Stroke** | 14 | 1 | 15 | 3 | 2 |
| **TOTAL** | **992*** | **158** | **1,150** | **58** | **96** |

* This is the total number of unique studies

The NIHR Clinical Research Network Portfolio includes a collection of commercial contract studies that has been deemed eligible for Clinical Research Network support following a commercial adoption process. Table 5.1 describes the number and type of commercial contract studies supported by the eight Clinical Research Networks. In total 1,088 studies have been assessed, of which 992 have been deemed eligible for NIHR CRN support. Just under 9% (n=96) of studies were found not to be eligible and 17% (n=158) were jointly supported by more than one Network. This illustrates the continued partnership between Networks optimising recruitment opportunities within different care settings to support study delivery. The number of Medical Device studies being supported by the NIHR CRN continues to steadily increase. However, they represent a small proportion of overall number of commercial contract studies (6%). Many medical technology companies are small in size and have limited experience of conducting clinical research. With recent regulatory changes placing a greater emphasis upon the need for clinical research to support product development and continued effort by the NIHR CRN to engage with this key stakeholder group, it is hoped that this trend continues.

The number of studies attributed to each Network demonstrates a wide range in both the number of studies being 'led' or 'supported' by each one. The size of each Network's portfolio of studies is influenced by several factors, including therapeutic area, current focus for drug and product development, and availability of suitable patient populations.

**Fig 5.2: Recruitment into Industry studies for each operating year**

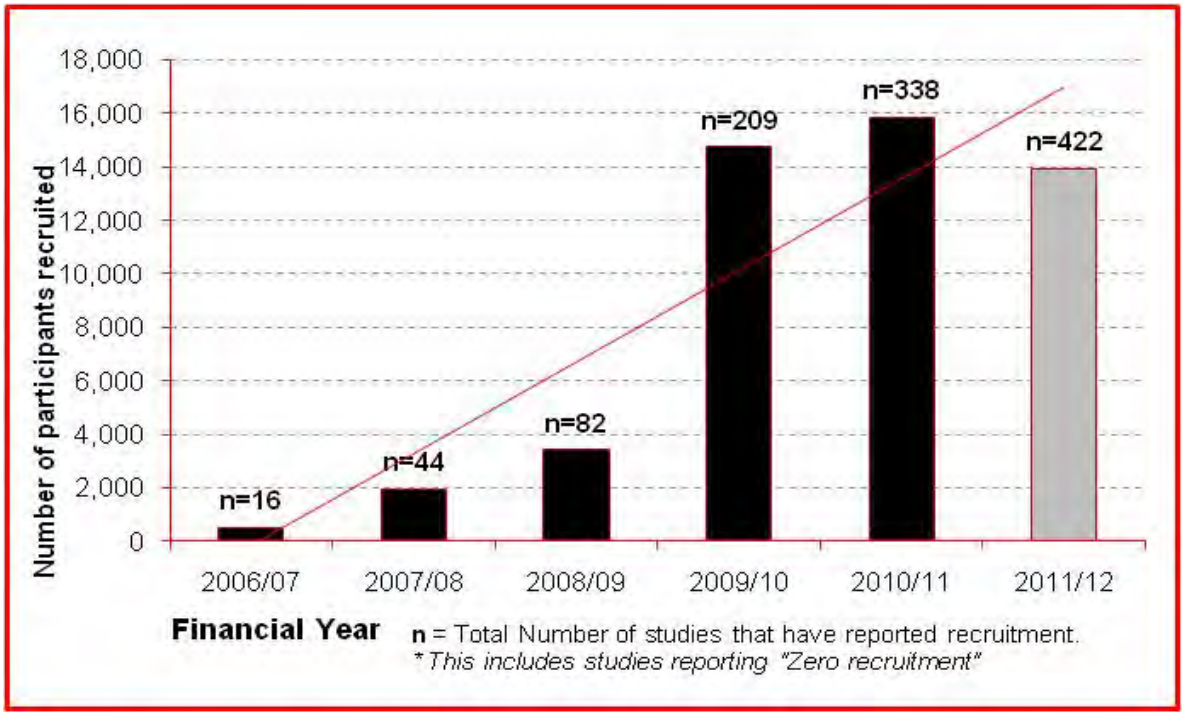



Figure 5.2 represents the total number of participants recruited to commercial contract studies in each financial year. Quarter 3 2011/12 data represent a considerable increase in the number of studies that have reported recruitment (n=422) from Quarter 2 2011/12. The increasing number of studies reporting recruitment gives an indication of opportunity for participants to participate in commercial contract research in the NHS in England.

Recruitment to date stands at 13,914 and if this continues to increase during the last quarter of this year at a similar rate, the overall recruitment of participants to commercial contract research will exceed the 2010/11 total of 15,827.

**Fig 5.3: Number of adopted Industry studies over time**

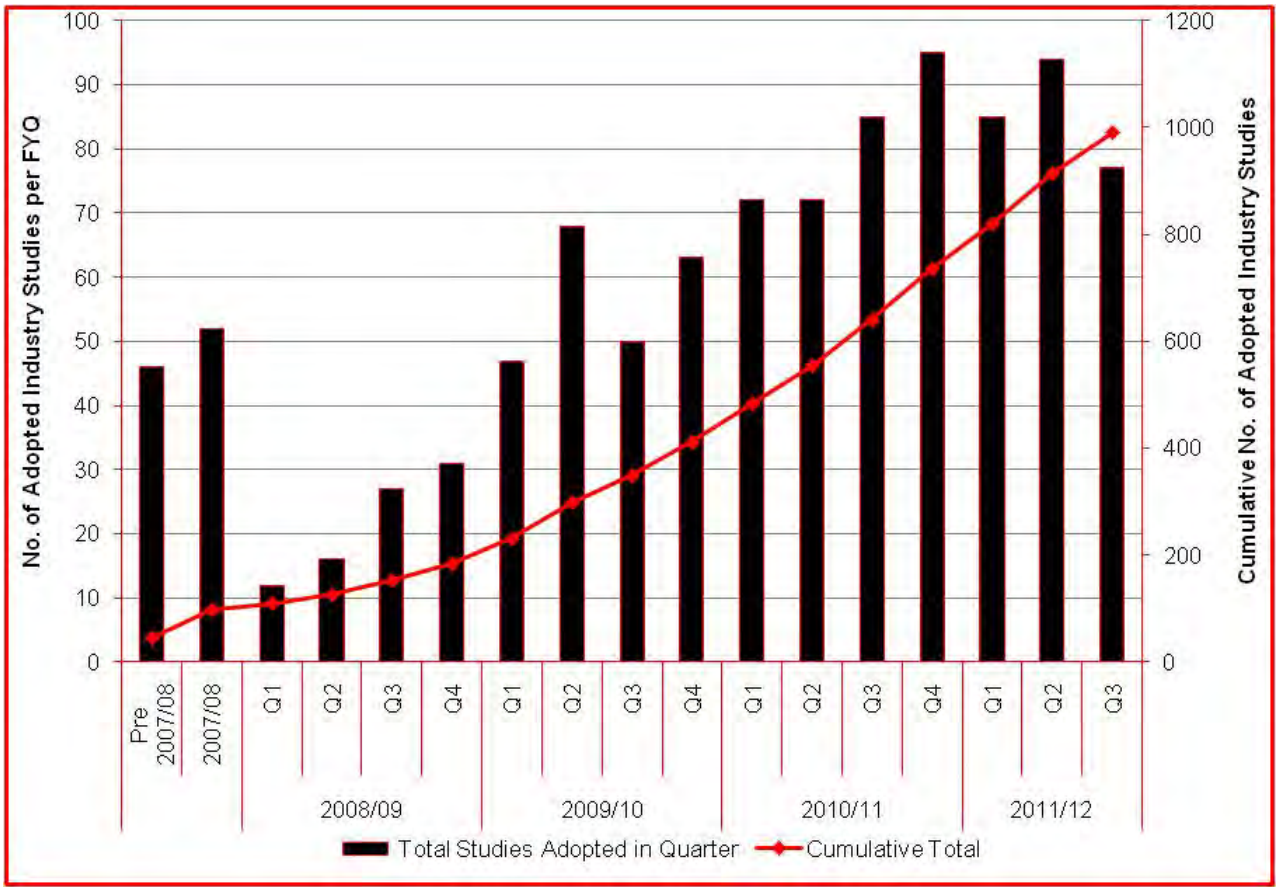



Figure 5.3 describes the number of commercial contract studies deemed eligible for NIHR CRN support ('adopted') each quarter and as a cumulative total.

In Quarter 3 2011/12, 77 studies were 'adopted'. This represents a small decrease since Quarter 2 2011/12. However, the overall trend of steadily increasing number of studies being adopted each quarter remains.

Figure 3.1 in section 3 supports further the increasing size and importance of the commercial contract studies portfolio. The number of studies eligible for NIHR Clinical Research Network support entered onto the Portfolio database in each quarter is illustrated in figure 3.1. This reflects the increasing size of the commercial contract studies portfolio. It demonstrates that commercial contract studies account for an increasing proportion of the overall NIHR CRN Portfolio each quarter. In Quarter 3 2011/12 35.8% of the NIHR CRN Portfolio was commercial contract research and this represents a moderate increase from Quarter 2 2011/12 (27.5%) and a considerable increase when compared with Quarter 3 2010/11 (17.6%). This, in part, reflects the decreasing numbers of non-commercial studies. However, it does emphasise the importance being placed upon the successful delivery of commercial contract studies in the NHS supported by the NIHR CRN.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