



NHS
**National Institute for
Health Research**

**NORFOLK & SUFFOLK
COMPREHENSIVE LOCAL RESEARCH NETWORK**



ANNUAL REPORT 2010/11

29 July 2011

CLRN Annual Report 2010/11

Cover Sheet

CLRN:	Norfolk & Suffolk
Host Organisation:	Norfolk & Norwich University Hospitals NHS Foundation Trust
Member Organisations (please list):	<ul style="list-style-type: none"> • East of England Ambulance Service NHS Trust (EEAST) • Great Yarmouth and Waveney PCT (GY&W PCT) • Ipswich Hospital NHS Trust (IH) • James Paget University Hospitals NHS Foundation Trust (JPUH) • Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) • Norfolk and Waveney Mental Health NHS Foundation Trust (NWMHT) • Norfolk Community Health & Care NHS Trust • Norfolk PCT (NPCT) • Suffolk Mental Health Partnership Trust (SMHP) • Suffolk PCT (SPCT)
CLRN Population:	2.70%
2010/11 Final Budget Allocation	£5,597,384
Topic LRNs	Eastern England Diabetes Research Network East Anglia DeNDRoN East Anglia Mental Health Research Hub Anglia East Cancer Research Network East of England Primary Care Research Network

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To be completed by CLRN

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1. Executive Summary

This annual report covers the operation of Norfolk & Suffolk Comprehensive Local Research Network (N&S CLRN) for the period 1 April 2010 to 31 March 2011. The report is submitted to the National Institute for Health Research Clinical Research Network Co-ordinating Centre (NIHR CRN CC) and describes the key activity streams undertaken in 2010/11, working to the objectives set in the Business Plan 2010/11 submitted in March 2010.

N&S CLRN budget for 2010/11 was approx. £5.5m at the start of the financial year. A year end budget summary for 2010/11 is set out in Appendix 4, p. 20 at the end of this report.

Progress made in 2010/11 is summarised in the Annual Report as follows:

- **Participant recruitment in NIHR portfolio studies has increased by 33%** from the previous year in terms of raw recruitment figures (**13,416 recruited** against a target of 11,305). 7 out of 9 Member Trusts have achieved, or come within 1% of achieving, their Trust recruitment targets for the year.
- There has been an **expansion of the local portfolio** with the number of 'live' studies (open to recruitment or in follow-up) increasing from 165 in 2009/10 to 242 in 2010/11.
- Industry studies have featured more prominently in our local portfolio this year such that the target of 7% of the overall portfolio being industry studies was exceeded throughout the year. The overall average for the year was **10.2% of the portfolio being made up of industry sponsored studies**. Studies for Biosynexus and AMGEN at NNUH have been particular highlights with highest recruiting sites in the UK being achieved on these two studies.
- **2010/11 has been a year of change for clinical directorship at the N&S CLRN**. There was a period of transitional arrangements in Q2 & Q3. In January 2011 Dr Andoni Toms took over the role of Clinical Director from Prof. David GI Scott. There was also another change of personnel in the role of Lead RM&G Manager due to the extended secondment of the substantive post holder to the Co-ordinating Centre.
- Monitoring of R&D approval times through the **Centralised System for Gaining NHS Permission (CSP)** and identifying and resolving delays has been a high priority this year. 7 out of 10 Member Trusts were able to achieve a median of <50 days from Site Specific Information form validation to approval. 5 out of 10 Member Trusts achieved <=28 days.
- **Engagement activities with our NHS Member Organisations** has continued to be a high priority. 68% attendance has been achieved at Network Board meetings and all our Member Trusts are contributing to recruitment on the NIHR portfolio.
- **14 Local Specialty Groups** have been fully supported by a CLRN Support Manager and met on a regular basis. The concept of performance management of the portfolio, including **recruiting to time and target** has become a core agenda item for all groups. Work has already been done to ensure that there is appropriate cross-referencing going on between groups to ensure that the appropriate links are made between topic areas. The Public Health Research and Health Service Research LSG were both disbanded at the end of 2010/11. All LSGs were required to complete an Annual Report during 2010/11 and these were reviewed by the Executive Group as well as undergoing a peer review process by the LSG leads themselves.
- The CLRN supports **Patient & Public Involvement** in the implementation and delivery phases via the supply of funding of the Norfolk & Suffolk Patient and Public Involvement in Research (PPiRes) project. We continue to include PPI representation at Board level.
- **Training & Workforce Development** activities have been effectively delivered and well evaluated. Highlights have been the continued cross-network delivery of the **"Research In Practice"** modules for research nurses, and the roll out of the **NIHR Introduction to Good Clinical Practice** one-day training programme. Practice Nurse training in the primary care setting has also been delivered successfully.
- **N&S CLRN Annual Event took place during October 2010** in Ipswich was attended by 100 delegates and the keynote speaker was Louise Wood from the Department of Health.
- **Norfolk Community Health & Care NHS Trust**, established on 1 November 2010, became a Member Organisation of the network.

2. Overview and Management of CLRN

The following changes have taken place during 2010/11:

2.1 Member Organisations

2.1.1 **Norfolk Community Health & Care NHS Trust** was established on 1 November 2010.

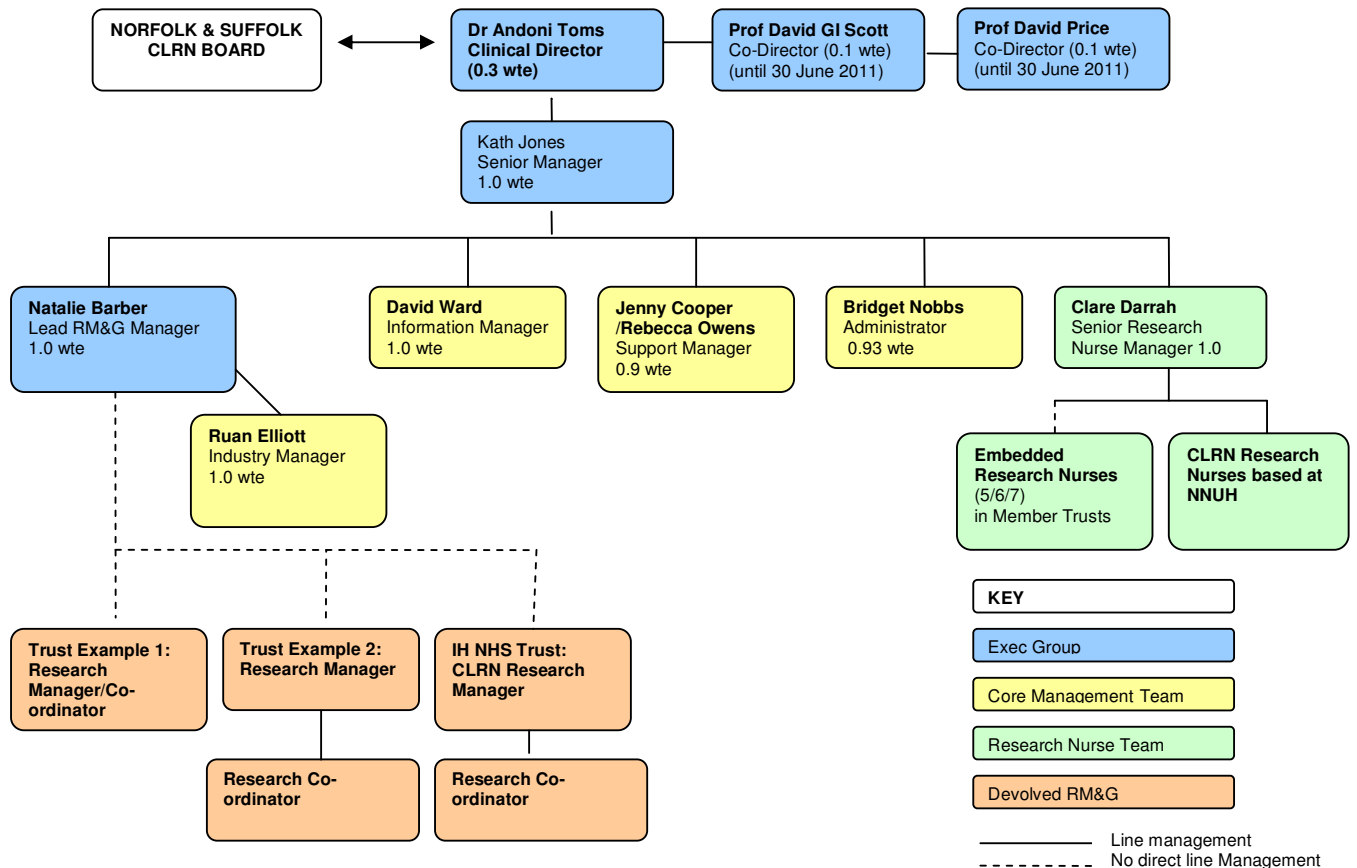
2.2 Topic Specific Research Networks

2.2.1 The Norfolk & Waveney Cancer Research Network was disestablished in Spring 2010 and the new Anglia East Cancer Research Network was set up in October 2010. The new network has added Ipswich Hospital NHS Trust as a Member Organisation.

2.3 Organisational Structure of Core Team

There have been a number of staff changes in the Core team during 2010/11 but no substantial changes to the organisational structure.

- Prof David Scott stepped down as Clinical Director on 30 June 2010 and became Co-director.
- Dr Andoni Toms became Co-director from 1 July 2010 and Clinical Director from 1 January 2011.
- Natalie Barber was seconded to the Lead RM&G Manager position in April 2010, taking over from David Hughes who left at the end of 2009/10.
- Ruan Elliott joined the Core Team as Industry Manager in August 2010.



3. National Performance Reports and Targets

3.1 Objective 1: Increase in the number of patients recruited into NIHR Portfolio studies by 12% from 2009/10 to 2010/11

	Month											
	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March
2008/9	1200	3491	4310	5344	5983	6411	7120	8196	8652	9357	9862	10360
2009/10	978	1933	2759	3660	4391	5263	6120	6909	8066	8940	9574	10121
2010/11	585	1506	2338	3121	3827	5795	7564	9419	10259	11245	12257	13416
Target 2010/11	942	1884	2826	3768	4710	5653	6595	7537	8479	9421	10363	11305

N&S CLRN recruited 13,416 patients to NIHR portfolio studies in 2010/11 against a target of 11,305. Therefore the network has achieved an increase in recruitment of approx 33% on the previous year recruitment total of 10,121.

It has been possible to reach this target due to a number of high recruiting studies such as FIRE and Respiratory Survey.

3.2 Objective 2: To deliver a balanced portfolio of clinical studies across all disease areas and from commercial and non-commercial funders. Measure: Increase in the proportion of industry studies on the Portfolio (a percentage of the network's overall portfolio by quarter)

N&S CLRN has achieved a marked and sustained increase throughout 2010-11 in the number of NIHR adopted Industry studies recruiting within the region, such that the target of 7% was exceeded in each of the four quarters. In fact, the Network met the stated objective of 10% for subsequent years with an average proportion over all four quarters of 10.2%.

	2008/09 Baseline				2009/10 Baseline				2010/11 (to date)			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Industry	5	4	3	3	2	6	5	7	13	11	14	20
Non-Industry	78	81	67	68	98	102	102	109	116	120	130	140
Total	83	85	70	71	100	108	107	116	129	131	144	160
Target proportion	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	6.0%	6.0%	7.0%	7.0%
Proportion	6.0%	4.7%	4.3%	4.2%	2.0%	5.6%	4.7%	6.0%	10.1%	8.4%	9.7%	12.5%

This rise in local participation in Industry studies was achieved against a background of steadily increasing numbers of non-commercial recruiting studies and so represents substantial growth in Industry-sponsored research that has outpaced the increase in academic studies.

3.3 Objective 5: Maximise engagement in NIHR Portfolio research

Measure: Increase in participants recruited into NIHR Portfolio studies by member organisations

	2008/9	2009/10	2010/11*	Target 2010/11	% Difference
East of England Ambulance Service NHS Trust	0	37	313	190	+65
Great Yarmouth & Waveney PCT	619	230	305 (195)	480	-37
Ipswich Hospital NHS Trust	556	1815	1791 (1884)	1190	+50
James Paget University Hospitals NHS FT	211	916	609 (719)	220	+277
Norfolk & Norwich University Hospitals NHS FT	1606	2719	2744 (3116)	2800	-1
Norfolk & Waveney Mental Health NHS Foundation Trust	334	335	542	550	-1
Norfolk PCT	6325	3341	4771 (4399)	4800	-1
Suffolk Mental Health Partnership NHS Trust	71	148	148	180	-18
Suffolk PCT	560	539	2153 (2060)	895	+241
Norfolk Community Health & Care NHS Trust	-	-	5	None Set	-
Private	50	41	27	None Set	-
University of East Anglia	16	0	8	None Set	-

4 Member Trusts have met and exceeded the target set and 4 have come very close to meeting very challenging targets. Great Yarmouth and Waveney PCT have not met target due to lack of supply of studies that are geographically compatible, e.g. studies that require patient travel into Norwich. Also inadequate travel costs have been a deterrent to recruitment in some studies open in the Great Yarmouth area.

* Recruitment for SEARCH study is manually reassigned to Primary Care from Secondary Care. Consent is by post from invitation sent from GP (names sent from study team to practice).

4. Local Performance measures

Measure title	Measure Definition	2010-11 Target	2010-11 Actual	Commentary
Increase in number of Portfolio studies	Number of 'live'* p/f studies that are being undertaken by N&S CLRN. *Live = actively accruing, open to recruitment, or in follow-up	165 recruiting studies	242 recruiting studies	119 of these studies recruited less than 10 participants, and of those, a relatively high proportion were commercial studies. The year-end snapshot of studies was 9 in set-up, 304 open to recruitment, 141 in follow-up.
Centralised System for Gaining NHS Permission – Approval times (days)	To monitor the efficiency of RM&G systems and processes in facilitating speedy set-up of studies. Time from SSI validation to completion of local governance checks	To complete local checks within 28 days of SSI form validation, with a maximum of 50 days	5 / 10 Trusts achieved <=28dy median 7/10Trust achieved <50 dys 3/10 Trust >50dy	Approval times are closely monitored within each Trust, identifying and resolving delays. Reports were issued monthly to R&D Offices, discussed at quarterly review meetings and presented at each CLRN Board meeting. The final quarter of 2010/11 has seen marked improvements in R&D approval times at the NNUH.
CLRN Board meeting attendance	Percentage membership attendance per Network Board meeting and achievement of quoracy.	All meetings to be quorate and minimum of 66% Member Trust Attendance at each Board meeting	May 2010 – 89% Oct 2010 – 56% Jan 2011 – 60% Average = 68%	Only 1 of 3 Board meetings was actually quorate. The Executive Group continued to communicate the benefits of attending these meetings to our Member Organisations and to impress upon them the importance of being quorate. It is noted that one Trust has not sent representation to any Board meetings in 2010/11 and this issue has been raised. However engagement with Board member for this Trust does occur at quarterly review meetings.
Participation in LSG meetings	Attendance levels at LSG meetings.	Expectation that meetings will be held quarterly.	Only 1 LSG out of 9 failed to run 4 meetings in 2010/11	Many of our LSGs run joint meetings, e.g. Injuries and Emergencies joins Musculoskeletal.
Attendance at LSG leads meetings	Percentage attendance per LSG Lead at LSG Leads meetings	Each LSG lead to attend or be represented by a deputy at least 3 of 4 LSG leads meetings	Only one full LSG leads meeting held in 2010/11. Attended by 10 out of 14 LSG	We are now trying to encourage LSG Leads to nominate a deputy to attend meetings when they are not able to. Other attempts were made during the year to run LSG leads meetings but failed because of inability to get a critical mass of LSG leads to attend. One small meeting was organised with a select group of LSG leads where there were cross-cutting themes. This was well attended.

5. Development Plans

5.1 Embedding and utilising the study delivery infrastructure

Our objective for 2010/11 was to use the current research nurse infrastructure efficiently and effectively in order to address study delivery needs. During this year the generic research nurse team has been expanded and is fully established as an effective service. To give just one example, the CLRN were able to act responsively by supplying generic research nurses to support the Amgen STARTT-Hip study in Trauma & Orthopaedics at the NNUH. As a result the original recruitment target has been exceeded by 50% and the NNUH is the top recruiting site in the UK.

The Senior Research Nurse Manager role has played a vital part in enabling the network to manage the delivery of portfolio research in secondary care through the management of the CLRN research nurse workforce. The network has taken on studies such as FEMCO (UKCRN: 5290 and Probiotic (UKCRN: 7582) that have been failing elsewhere and managed to get them recruiting locally.

The CLRN has recruited research nurses from “return to practice” schemes this year and used secondments to attract ‘new blood’ into the research nurse pool. Workload planning is being enhanced by the recent adoption of eRostering systems.

This year the CLRN has closely monitored the use of clinical sessions in secondary care and mental health. Where clinical sessions have not been embedded into job plans they have been used to fund alternative posts such as research nurses.

5.2 Maximising cross-network and cross-organisation opportunities

The East of England NIHR Local Research Network workshops were held biannually during 2010/11 with the January 2011 meeting organised by the N&S CLRN in collaboration with the East Anglia MHRN Hub. This is open to all the CLRNs, P/TCRNs in the region, and was also attended by the SHA East of England, with the aim of exploring common objectives such as recruiting to time and target.

Once again this year a Research Day for Suffolk Mental Health Partnership NHS Trust was delivered jointly by East Anglia DeNDRoN, East Anglia MHRN and N&S CLRN, which is an example of how the CLRN is working with and for one of our local Trusts to promote the Trust’s R&D agenda. The network has also been involved a number of Trust-based R&D events to promote research, e.g. NWMHT Ready for Research programme, and NNUH/CLRN Nurse Research Forum meetings.

Our relationships with the established TCRNs continue to mature. Quarterly progress meetings between CLRN/TCRN managers have now become a part of business as usual. Both DeNDRoN and MHRN join the CLRN with the quarterly review meetings that take place between the CLRN and the Mental Health Trusts. The PCRN and CLRN hold joint interface meetings on a quarterly basis with the Primary Care Trusts. There has been significant progress in collaboration with the MCRN in the network during 2010/11. The CLRN is now funding a 0.4wte Research Facilitator to support MCRN studies in the network which forms part of a joint initiative with WACLIN to provide MCRN coverage where there has been none previously.

The N&S CLRN has undergone another change of Management Lead during 2010/11 and it is suggested that NIHR CCRN and N&S CLRN could work more effectively together if these changes were kept to a minimum going forward. The Host Organisation’s current contract for CLRN terminates on 31 March 2013 which places a limitation on the fixed term contracts that can be issued and this is now restricting our ability to attract candidates to vacancies within the core management team. Support in the form of written communications to Trust CEOs and HR Directors, from the Coordinating Centre would be welcomed by the CLRN.

Going forward the CLRN/PCRNs would benefit from central CCRN support and engagement with the newly emerging primary care agenda and specifically how the Clinical Commissioning Groups and social enterprise groups will interact with the CLRNs and R&D issues.

5.3 Development of Local Specialty Groups

Significant progress has been made this year with the monitoring and performance management of the Local Specialty Groups. In January 2011 all LSG were asked to submit annual reports which were reviewed by the Executive Group. The information from these reports was also used to inform budget setting processes and business planning for 2011/12. These reports were also peer reviewed and RAG rated by the LSG leads. The Annual Report review aimed to identify ways in which the LSGs had made a difference to study delivery in 2010/11.

During 2010/11 the CLRN took the decision to discontinue the LSGs for Public Health Research and Health Services Research. As with the national groups, which have subsequently been disbanded, the cross-cutting and diverse nature of the portfolio meant that interest in this group could not be sustained. Members from these groups have been encouraged to join the membership of other LSGs.

The CLRN has endeavoured to improve the effectiveness of LSG meetings by improving accessibility to LSG meetings via video conferencing at all meetings. This is beginning to work well with 3-way conferences finally achieved in 2010, and is now becoming a regular feature. The CLRN provides management information for all meetings and the CLRN Information Manager attends all meetings to provide background and interpretation as required. The CLRN ensures that portfolio monitoring is on each agenda and recruiting to time and target is now supplied in all the standard reports, with RAG rating for each study.

The CLRN provides a 0.5wte Support Manager to provide administrative support for LSGs and is available to meet with all LSG leads before each planned LSG meeting to discuss agenda setting. The CLRN Support Manager has also supported one group (Metabolic & Endocrine) to run a half-day research showcase seminar in January 2010. This event successfully raised the profile for this research area and was very well attended and received.

5.4 Enhancing staff/management systems performance

5.4.1 Training and Workforce Development

The structures that were put in place by the CLRN following the Workforce Survey carried out in 2009 have become embedded in business as usual during 2010/11. For example, research nurse induction documentation is now standardised and have been refined and expanded during 2010/11 and now include opportunities for new staff to train in research teams across the network. This provides a chance to gain experience and exposure to other specialties and is also a development opportunity for the existing members of the research team.

The “Research in Practice” cross-network, cross-organisation training programme has gone from strength-to-strength during 2010/11. The credit for the success of this programme is due to the input and leadership provided by N&S CLRN Senior Research Nurse Manager, Clare Darrah. She has worked with the other nurse managers from the 3 CLRNs in East of England Region to deliver a modular training event for new research nurses in Autumn 2010. In Spring 2011 the CLRN delivered at 3-day residential course of “Research in Practice” at Belsey Bridge in Suffolk for 30 experienced research nurses from across all three CLRNs and other TCRNs.

During 2010/11 the CLRN have successfully delivered a rolling programme of NIHR Good Clinical Practice courses and have successfully trained 150 research staff across the Member Organisations. The CLRN have only 3 trained research facilitators, which is a limitation for our network, but there are now plans to work with other facilitators recently trained from Primary Care. There have also been reciprocal training arrangements with a facilitator from WACLIN. GCP training delivery has been adapted to be delivered on a modular basis where this is considered to be the best way to engage a particular staff cohort. All three facilitators have passed a written exam to gain their Certificate of Good Clinical Practice issued by the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians and the CLRN has adopted a policy of selecting facilitators who have a true depth of knowledge and experience in clinical research and understanding of pharmacovigilance. Consequently, feedback from the GCP sessions has been excellent and comments received suggest that the training is meeting the demands of clinical research practice in a more effective way than the ‘chalk and talk’ approaches.

The CLRN funded 3 Practice Nurse Workshops in autumn 2010 at both introductory and advanced level. These courses continue to provide accessible and relevant training for practice nurses (mainly) but also other members of practice staff. The introductory course is accredited by RCN. Nurses who attend may have completed their GCP or, following the course, usually see the benefits of doing so. The advanced course involves the nurses working from study protocols focusing on how they work to successfully deliver the recruitment strategies within their practice environment. There is also an opportunity to look in more detail at such areas as randomization and event reporting. The courses have been well evaluated.

In the area of RM&G training has been arranged in response to local needs.

- IRAS training has been provided free of charge to Member Organisations on 4 occasions during the year, delivered by Infonetica using local training facilities.

- CSP Reda training has been provided by existing license holders in the member organisations and is now part of 'business as usual'.
- Research Support Services development has been followed closely by the CLRN and a support role has been provided by the Lead RM&G Manager.
- Workshops to clarify the attribution of costs for research in the NHS have been organised by NNUH and UEA Research Offices and the Lead RM&G Manager has contributed to these sessions.

A full list of training provision by the N&S CLRN is provided in Appendix 1.

5.4.2 Information Systems

The following objectives have been met during the reporting period:

- The functionality of the CLRN Project Database has been further developed over the year to enable the R&D approval time metrics to be analysed and for regular reports to be automated.
- Significant progress has been made with the production of meaningful performance management data on recruiting to time and target at site level. Approx. 60% of local studies have accurate local recruitment targets against which RAG ratings are now attributed and used as part of performance review at LSG meetings and MO quarterly reviews.
- The N&S CLRN arranged for the appointment of a Business Cluster Lead for East of England on behalf of the 3 CLRN. This has enabled us to engage with the national RD MIS development. We have also been able to identify trainers in the 'train-the-trainer' scheme for RD-MIS CSP Module.
- Information is now sent out regularly to LSG leads on new studies that have been recently been added to their portfolio that may be open to recruitment in new host sites.
- Systems have been put into place to collect local information on costing templates information for portfolio commercial studies. This will require further systems development during 2011/12 in order that the CLRN can monitor income from commercial studies.

5.4.3 Communications

- Quarterly performance reports have been issued to each CEO/Board Chair of our Member Organisations since May 2010. This concise 4-page report, tailored for each Trust, has been identified as an exemplar of best practice at the NIHR Advisory Board which is chaired by Prof Dame Sally Davies.
- The N&S CLRN publishes a 12-page newsletter in January, April and October and uses this to raise awareness and disseminate news on successful portfolio research taking place locally and to share examples of best practice.
- In October 2010 the N&S CLRN hosted its Annual Event at the Trinity Park Conference Centre in Ipswich. This was attended by 100 delegates and received excellent feedback. The keynote speaker was Louise Wood from the Department of Health.
- N&S CLRN are working with Member Trusts to help to promote research activity in the area. For example we co-ordinated research stands in 5 NHS Trusts for International Clinical Trials Day in May 2010.

5.5 Initiatives to enhance relationships and engagement with R&D Community

The Senior Manager and the Lead RM&G Manager covered the attendance at a number of research governance meetings and Trust R&D Committees taking place in Member Organisations during 2010/11. The Lead RM&G Manager attended the monthly Research Managers meetings, comprising Trust and University R&D Managers and colleagues, which has provided good opportunities for collaboration and engagement between CLRN and R&D community.

In order to improve the level of NHS engagement with the Clinical Research Networks at Trust Board level the CLRN Clinical Director has written to all Trust Chief Executive to ask if they would consider establishing a nominated member of their Trust Board with a remit to cover research. However, this has not yielded one positive response and 3 out of 10 Trusts have declined this suggestion.

CLRN Clinical Director has had three meetings with the Chief Executive of NNUH to discuss network delivery at the Trust and also has regular dialogue with the Medical Director.

6. Research Management & Governance

Section 1						
Member Organisation	Are you aware of CRN portfolio studies not using NIHR CSP to gain NHS Permission?	Are your Member Organisations undertaking the NHS permission's process in a reasonable timely manner?	Are you assured that your MOs are working in line with the NIHR CSP Operating Guidelines?	Does your CLRN website have the RM&G contacts listed for the core and local R&D teams within your Member Organisations?	Are you confident that your Member Organisations have policy level commitment (or equivalent) for implementation of the HR Good Practice Guidance?	Does your CLRN website have the current Research Passport Lead's contact details listed?
Norfolk and Norwich University Hospital	Yes	No. 84% >28dy target. 60% >50 days target Median = 77 days	Yes	Yes	Yes	Yes
Ipswich Hospital	Yes	Yes. Median = 34.5 days	Yes	Yes	Yes	Yes
James Paget University Hospital	Yes	Yes. Median = 43.5 days	Yes	Yes	Yes	Yes
Norfolk and Waveney Mental Health	Yes	No. 83% > 28 day target 67% > 50 day target Median = 77 days	Yes	Yes	Yes	Yes
Suffolk Mental Health Partnership	Yes	No. (not caused by IH) 86% > 50 days Median = 85 days	Yes	Yes	Yes	Yes
Norfolk PCT	Yes	Yes. Combined PCT median = 33.5 days	Yes	Yes	Yes	Yes
Suffolk PCT	Yes	Yes. Combined PCT median = 33.5 days	Yes	Yes	Yes	Yes
Great Yarmouth & Waveney PCT	Yes	Yes. Combined PCT median = 33.5 days	Yes	Yes	Yes	Yes
Norfolk Community Health & Care	Yes	Yes. Combined PCT median = 33.5 days	Yes	Yes	Yes	Yes

Section 2
<p><i>Please comment or provide feedback (related to specific MOs) on steps taken or progress made to ensure that the 2010/11 targets set locally by the CLRN were met.</i></p> <p>Local performance metrics have been regularly produced by Trusts throughout the reporting year. These metrics included listings studies on a red (50+ days)/amber (29-50 days)/green (<28 days) basis for studies that are progressing NHS permission through CSP and graphical presentation of mean and median number of days by Month and Trust to gain NHS permission through CSP. This has helped Trusts to focus on clearing the red and amber studies and having a clear picture of what is coming up or approaching amber/red status. In addition to this the CLRN core team will also highlight priority studies for expedited approval, which the R&D offices have welcomed. Over the</p>

reporting year median approval times have shown a downward trend in the number of days to gain CSP approval across the CLRN. The peak in June 2010 of median 123 days has decreased steadily to April 2011 median of 42 days. The main driver for this reduction was the Trusts preparing to meet the new time lines that would be imposed in the next reporting year of <30 days to gain NHS permission. There will always be out-lying studies that could have an overall impact on a particular Trusts metrics where issues are seemingly insurmountable (e.g. approving of excess treatment costs) but the CLRN is encouraged that Trusts are working hard to achieve the targets set despite the individual challenges. Reducing these time lines presented a big challenge for NNUH, so additionally to these reports the Lead RM&G manager would meet regularly with the Trust R&D manager to review metrics and ascertain where the blocks may be for Red studies. Just highlighting the studies that are Red in this forum seemed to lead to these shortly gaining permission. These types of interactions appear to be beneficial and these exchanges have improved engagement from the Trust.

Section 3

Please provide an update on progress against the local RM&G objectives set in the 10/11 Business Plan

1. Improve approval times for studies using CSP – Addressed in section 2

2. Improve processes at host Trust to expedite study approvals – Addressed in section 2

3. Recruiting and retaining to CLRN-funded posts - Making working environment conducive to expediting study approval and set-up and establishing close working relationship with Research Study & Recruitment Facilitators.

The CLRN held a joint training sessions on 21/06/10 and 28/07/10 with all Research Study & Recruitment Facilitators from all 3 acute Trusts to set the scene from the CLRN and introduce the CLRN team to them. This was also as an opportunity for the facilitators to meet each other from across the region.

Retaining CLRN funded posts across the CLRN has proved not to be an issue across member Trusts except for the NNUH. They have had a period of turn over with their Study Recruitment and Facilitator posts due to no one specific reason. The Lead RM&G manager is involved in the recruitment of these posts at the NNUH to ensure the person understands the role in relation to the CLRN's objectives.

4. Research Passport implementation - Finalise embedding of the *Research in the NHS: HR Good Practice Pack* into policy documents within all member Trusts and UEA. Complete on 27/08/10. Policies have either been embedded or letter of assurances have been received from all member Trusts. During 2011/12 the CLRN will ask for a pro-forma to be returned to gauge continuing adherence to HR Good Practice and policies written by Trusts and UEA.

5. Lead CLRN proposal - To create an action plan for delivery

Action plan for delivery has been finalised. We have yet to be in a position to implement the policy to comment on how well or not it is working.

6. Provide access to training and national involvement for RM&G staff - Provide access to national or local training for any changes in working practice, e.g. RDMIS.

Encouraging involvement in local and national RM&G issues, e.g. RSS implementation.

RDMIS has been supported through our RDMIS Business Cluster Lead Dr David Hughes. Dissemination of developments on RDMIS CSP module is filtered through the Lead RM&G manager to member organisations. The Research Co-ordinator from JPUH volunteered to take part in the Train the trainer program for RDMIS CSP along with David Hughes. We also encouraged RM&G staff from across the region to get involved with the UAT of RDMIS and two representatives from different trusts are involved in this. RSS implementation has been supported through the CLRN via the Lead RM&G manager. The RSS champion is the R&D manager from the NNUH, and she has been the key to informing Trusts on the requirements for delivery of RSS. RSS implementation has been supported through the CLRN via the Lead RM&G manager who has been at the sessions held by the RSS champion to disseminate information. They can bring corroborative support through information that has been passed through them at national Lead RM&G Managers meetings.

7. IRAS training - To organise local delivery of Infonetica IRAS training course and to evaluate course and consider future provision

The CLRN has arranged and provided IRAS training on 4 occasions over the reporting period, 12/05/10, 11/10/10, 19/01/11, 17/02/11. These course are always well attended and often oversubscribed. Infonetica run these courses and they do not request formal feedback. However verbal feedback received by the Lead RM&G manager would suggest that these courses are useful. If the CLRN were to hold future training sessions for IRAS they would be filled easily, but these are expensive courses to put on, the Infonetica fee alone for ½ days training is around £1000. If training of this type could be delivered internally more courses could be run and at less cost to the CLRN.

It is suggested that perhaps something to link up RDMIS CSP and IRAS could be considered from the NIHR CRN CC.

7. Industry

7.1 Increasing engagement in commercial portfolio studies

A number of strategies have been employed to strengthen engagement in commercial portfolio studies across the Network. The Industry Manager has given a series of presentations at LSG meetings discussing:

- The scope for individual LSGs to participate in Industry studies based on the numbers of relevant studies NIHR adopted studies and on other factors, such as requirements for specialist facilities.
- The LSG's response and success rates with requests for pre-selected site reviews / expressions of interest.
- Strategies for improving success rates with expressions of interest.
- The importance of robust feasibility and realistic target setting for recruitment.

One of the outputs agreed from these discussions will be brief documents setting out the research interests, track record and local strengths of each LSG. This information will be included in expressions of interest to enhance their impact and should also provide a focus to help improve LSG's track record in Industry studies.

We also have had some significant success engaging with clinicians from certain specialties for which there is currently no local specialty group; most notably with local neurologists and cardiologists who have developed strong local portfolios of NIHR adopted Industry studies (5 Nervous System Disorders Industry studies opened within the Network in 2010/11; 1 Cardiovascular Industry study opened to recruitment, 1 currently in setup and 2 further expressions of interest submitted during 2010/11).

7.2 Efficient identification of sites

We have met the objective of expanding the Industry sponsored research at Ipswich and the James Paget University Hospitals. In fact, the number of Industry studies opened to recruitment at each of our acute Trusts was higher in 2010/11 than in the previous year, with the highest percentage increase at the James Paget University Hospital.

Acute Trust	Number of Industry studies opened	
	2009/10	2010/11
Ipswich Hospital	6	7
James Paget University Hospital	3	6
Norfolk and Norwich University Hospital	13	22

To date, the East of England Ambulance Trust and our newest Member Trust, Norwich Community Health and Care, have not had any realistic opportunities to participate in NIHR adopted Industry studies. However, we are currently in discussion with companies about one study that would involve the Ambulance Trust and two that would involve Norwich Community Health and Care.

7.3 Robust feasibility

Undertaking robust feasibility analysis and setting realistic recruitment targets remain major challenges, particularly for Industry studies where there is very limited time to prepare the expressions of interest. We continue to collate recruitment data for Industry studies led by all the investigators within the Network. This is expected to represent a valuable resource for future feasibility evaluation. However, several additional years of data are likely to be required before it can be used effectively.

In 2010/11 64 requests were received for expressions of interest in Industry studies. Expressions of interest were submitted on behalf of local investigators for 16 [25%] of these, compared with 19 of 48 [40%] in 2009/10. A significant factor in this decrease appears to have been more cautious feasibility evaluation leading to a higher number of studies for which a clear decision was made not to participate (20 studies [31%] rejected locally in 2010/11 compared with 9 studies [19%] in 2009/10). Reasons for choosing not to participate included:

- Incompatibility of protocol with local practice
- Insufficient patient numbers
- Requirements for specialist facilities that are not available within the Network
- Insufficient research capacity within specific departments due to expansion of their local portfolio.

7.4 Efficient site set-up

Although approval times for Industry studies within the region have improved (the median time from valid SSI validation to local approval has dropped from 55 days in 2009/10 to 43 days in 2010/11), more work is required to bring them down into the approval times achieved in the North West Exemplar project (31 day median) and, the NIHR CRN high level objective to achieve at least 80% of studies obtaining NHS permission within 40 days from receipt of a valid complete application. We also are increasingly turning our attention to improving times from local approval to start of recruitment with a view to the NIHR CRN high level objective to achieve 80% of commercial studies achieving first participant recruited within 30 days of NHS permission being issued.

7.5 Patient Identification Centre (PIC) work for Industry studies

The primary care teams in N&S CLRN have a track record of putting together packages for PIC work for academic and industry studies. On a large scale or studies requiring intense referral support (e.g. some of the industry studies) these can involve significant capacity in the primary care team.

It should also be noted in relation to industry portfolio activity that CLRN-funded staff in Suffolk PCT have made significant input through PIC work recruitment on DRN 222 SCALE, DRN 220 Lanscape and DRN 512 DUAL for West Suffolk Hospitals and Ipswich Hospital. More work needs to be done to enable the PIC work to be recognised and recorded by the network and to ensure that the resources associated with this activity can be managed effectively.

It is important going forward that an assessment is made at all levels of the feasibility process, including by the study PI, of the attractiveness/ acceptability of these studies as a key factor in influencing response rates to ensure that the effort is fully justified.

8. Patient and Public Involvement

8.1 Development of Local Partnerships to support local PPI activity

In 2010/11 N&S CLRN continued to provide funding support to the PPIRes project for the delivery phases of NIHR portfolio projects. This project has been running throughout Norfolk since 2004 and is now extended into Suffolk. The PPIRes team supports 35 volunteers on these portfolio studies, which involves organising, supporting and facilitating pre-steering group meetings, ensuring financial aspects of involvement are in order and offering training and support to volunteers and researchers. The funding is used to cover the salary of a PPIRes co-ordinator post. During 2010/11 PPIRes has been involved in 22 NIHR portfolio studies during implementation and delivery phases.

8.2 PPI representation on the N&S CLRN Board

There are two PPI representatives on the Network Board and they have attended Board meetings regularly during 2010/11.

8.3 PPI Activities

PPIRes has taken part in two national conferences, the Society for Academic Primary Care (SAPC) and Health Services Research & Pharmacy Practice (HSRPP). Volunteers were invited to be co-chairs for the abstract sessions (this is the first time this has been done at these conferences) and the PPIRes co-ordinator presented at the HSRPP conference.

In line with the new PPI requirements outlined in all the NIHR funding streams, PPIRes has developed and supported a series of five workshops called "Demystifying the World of Research" - a Programme for Community Representatives active in healthcare research. 20 volunteers from across the East of England attended the workshop where researchers and volunteers worked together to understand each others' perspectives. It was very well received on both sides and as a result the course of workshops has been funded by the WA CLRN to be held in Cambridge this year.

As a result of PPIRes work with UEA, Visiting Researcher Rights are now offered to all PPIRes volunteers actively involved in funded research projects.

PPIRes has now taken over the management of the PPI budget allocation for the implementation elements within research project grants on behalf of investigators.

In order to reflect the increased NIHR PPI requirements in research applications, PPIRes has enhanced the pre-application in portfolio studies to include focus groups to establish co-applicant and steering group volunteers for projects. PPIRes is developing training for volunteers and research on how to contribute effectively to research steering groups and what it means to be a co-applicant.

Work progressed locally on developing patient recruitment tools (PowerPoint presentation) for GP surgeries. The aim of the presentations is to increase the public's understanding of what it means to take part in research and to supply information on what studies they could potentially get involved in. Pilot work has been carried out involving the CLRN, PCRN, RDS and PPIRes locally as well as collaboration with the E&H CLRN.

In March 2011 the N&S CLRN, working with one of the LSG leads, facilitated the inclusion of wording in all outpatient letters at the NNUH to remind patients of opportunities to become involved in research. Other Member Trusts are now being encouraged to include similar messages in their outpatient letters.

8.4 PPI Partnerships

A joint call from HSR/INVOLE to evaluate public involvement in research lead to PPIRes contributing to one of those projects, The RAPPORT study (ReseArch with Patient and Public invOLvement: a Realist evaluation) This aims to look at PPI in research in four regions in England. This came about through our close partnership working with the Research Design Service.

Our collaborations with the UEA Pharmacy department lead to invitations to their national conference and PPIRes is now involved in three portfolio studies for this department.

Our involvement in stroke rehabilitation research with Prof Valerie Pomeroy, (Professor of Neurorehabilitation Director, Health and Social Sciences Research Institute, UEA) has lead PPIRes to contribute to the overall strategy for recruiting and retaining research participants in this area.

PPIRes works closely with the RDS to help researchers submit strong applications for funding, including work on participant recruitment.

9. Making an Impact

Listed below are 2 examples (supplied to the NIHR CRN CC separately in PowerPoint format) showing evidence of positive impact of the network on the development of clinical research, in particular the effects of increasing recruitment.

1) Industry study recruitment success for Injuries & Emergencies

- UKCRN 7731 CCRN189 (Hip Fracture)
- Prof Simon Donell, LSG lead for Injuries & Emergencies, took on the Chief Investigator role for this AMGEN study
- Recruitment on the study was fully supported by the CLRN Generic Research Nurse team, Senior Research Nurse Manager and CLRN Industry Manager
- 6 patients have been recruited against a local target of 4 and it hoped that even more patients will be recruited
- At 23/5/2011 the site (Norfolk & Norwich University Hospital) was the top recruiting site in UK

2) Industry study recruitment success for Neurology

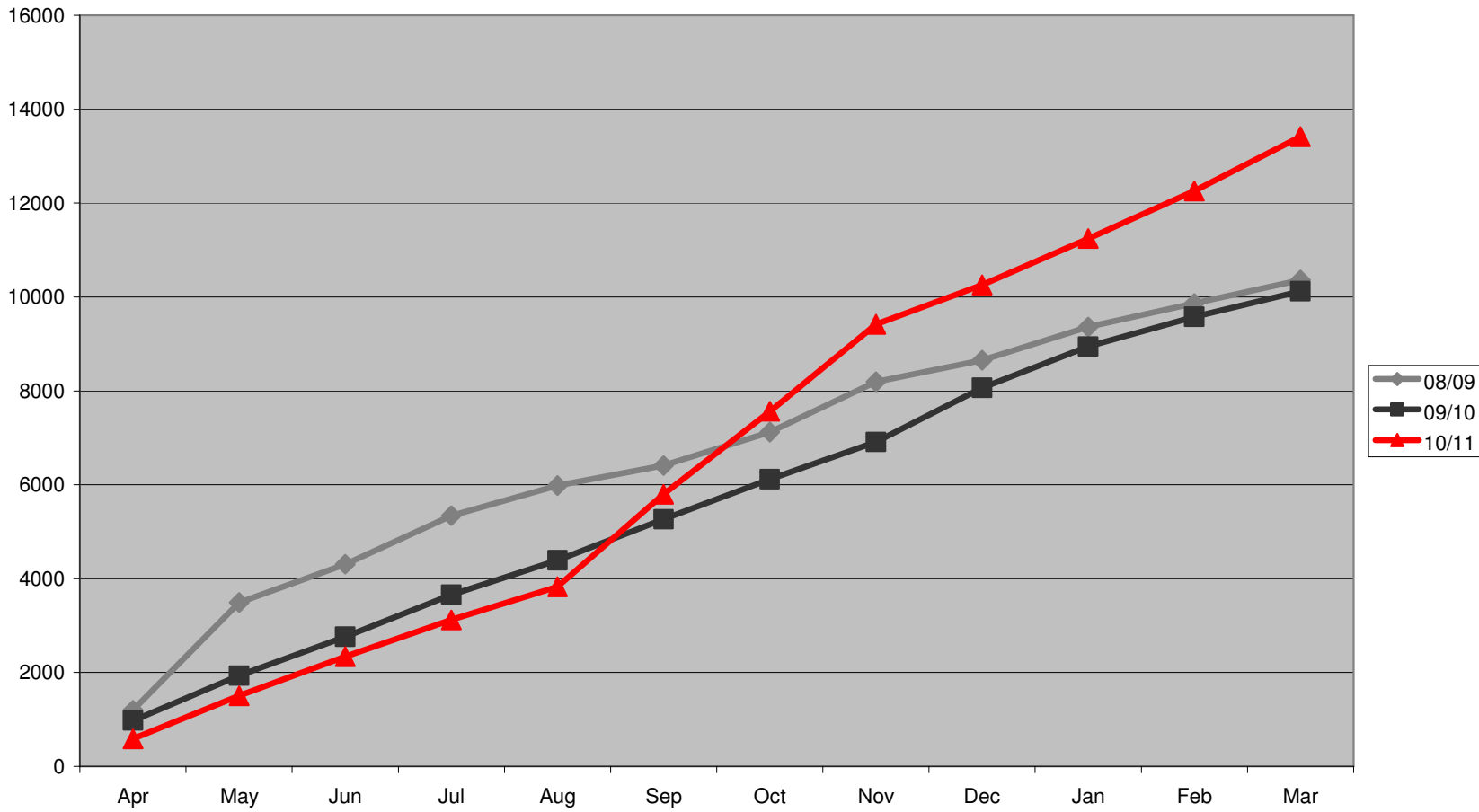
- UKCRN ID 8214: CCRN 249 (MS) – use of fingolimod in multiple sclerosis patients
- CLRN funded Research Nurses and Administrators have supported recruitment across 2 sites in the network, JPUH & NNUH
- Recruitment targets have been exceeded at both sites:
 - 8 patients recruited at NNUH against a target of 5
 - 8 patients recruited at JPUH against a target of 4

APPENDIX 1 Workforce Training 2010/11

Course	Provider	Dates in 2010/11	Number of trainees	Outcomes	Plans for 2011/12
IRAS training	Infonetica	12 May 2010 11 October 2010 19 January 2011 17 February 2011	11 9 12 7	Increase in quality submissions to R&D offices. Reduced submission times	May October January
Paediatric Informed Consent	Dr Margaret Fletcher, Co-Director, South West MCRN	July 2010	40 (across region)	Improved skills & expertise in Paediatrics and capacity to recruit effectively to these studies	To be considered
Commercial Contracts Training	Morgan Cole Solicitors	October 2010	17	R&D office more confident with commercial contracts and reduced processing times	None planned
NIHR Introduction to Good Clinical Practice	In house 8 February at JPUH 28 February at IH 22 March at UEA	15 June – NWMHT 27 Sept – NNUH (6) 12 October – JPUH 16 November - JPUH Nov to Dec – NICU, NNUH – (modular) 29 November - UEA 2 December – NCH&C	150 total	Increased number of trained staff to undertaken clinical research. Improves research capacity.	Monthly Also to run modules on GCP in paediatric setting
GCP for Pharmacists	London Pharmacy Education and Training (in partnership with James Lyddiard, UCL Hospitals NHS Foundation Trust)	October 2010	17 (across region)	Increased number of trained staff to undertaken clinical research. Improves research capacity.	None
Research in Practice	In house	April & May 2010 September 2010 October 2010 November 2010 December 2010	53 29 27 26 27	Increased number of trained staff to undertaken clinical research. Improves research capacity.	April 2011 Autumn 2011 (4 sessions) Spring 2012 (4 sessions)
Advanced Communication for recruiting participants with communication difficulties	Onion Communications	September 2010	24	Outcomes used directly for TOMAS study.	If required

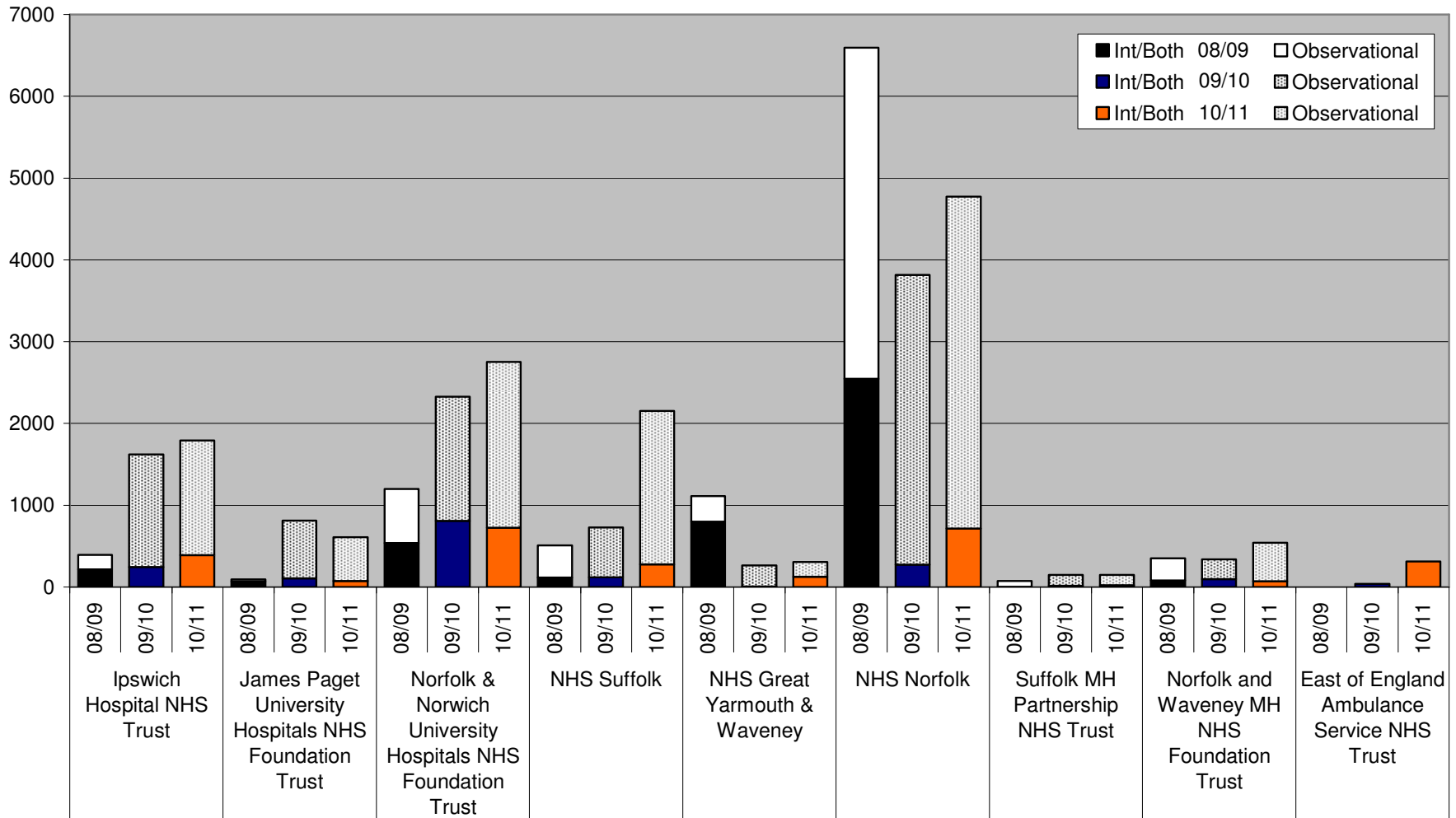
APPENDIX 2

Participants Recruited onto NIHR Portfolio Studies in N&S CLRN by Month and Year (Figures as at 30/6 After Year End)



APPENDIX 3

Recruitment onto Portfolio Studies by Trust and Year, Divided Between Observational Studies and Studies which are Interventional or Both, as at 20/6/11 (08/09 Figures as at 30/6/09, 09/10 as at 30/6/10)



APPENDIX 4**Financial Report at Year End 2010/11**

Income	
£	
Management & Host	445,360
Per Capita	1,505,245
Activity Based Funding	3,562,049
Mental Health ad hoc allocation	84,730
TOTAL	5,597,384

Expenditure												£
	CLRN Management	Clinical Staff/ Consultants	Clinical Staff/ Nursing	Non-Clinical (Delivery)	Service Support				RM&G	Work-force Devel.	Other	Total
					Other (Study based)	Radiology	Pharmacy	Pathology				
Norfolk & Norwich University Hospital	394,889	749,874	835,097	28,440	80,291	143,657	103,945	56,514	77,427			2,470,134
Ipswich Hospital		296,534	264,371	48,125	19,897	91,520	65,426	40,632	84,439			910,944
James Paget Hospital		176,347	153,767	11,376	8,124	28,990	35,250	30,952	25,224			470,030
NHS Suffolk		52,800	65,384		73,285				14,714	6,090		212,273
NHS Norfolk		294,065	93,103	28,501	302,181				54,420	20,226		792,496
NHS Great Yarmouth & Waveney		85,000		6,896	5,000				27,211	2,500		126,607
Norfolk & Waveney Mental Health		164,038		67,240	106,147		18,572		18,572			374,569
Suffolk Mental Health		55,169		30,214	18,161		12,381		6,306			122,231
East of England Ambulance Service		6,896			4,060				4,168			15,124
MHRN - East Anglia				46,400								46,400
DeNDRoN - East Anglia			23,151									23,151
Patient & Public Involvement											15,315	15,315
CLRN Wide Workforce Development										18,110		18,110
TOTAL EXPENDITURE	394,889	1,880,723	1,434,873	267,192	617,146	264,167	235,574	128,098	312,481	46,926	15,315	5,597,384
Over/ (Under) spend												(0)
Budget Allocation Split at Year End	7%	59%	5%		22%				6%	1%		100%
Recommended Range by CC	3-6%	55-75%	4-6%		20-27%				7-10%	4-6%		