



NHS
*National Institute for
Health Research*

Northumberland, Tyne and Wear

Comprehensive Local Research Network

ANNUAL REPORT 2009/10

Produced by;

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CLRN Annual Report 2009/10

Cover Sheet

CLRN:	Northumberland, Tyne and Wear	
Host Organisation:	The Newcastle upon Tyne Hospitals NHS FT	<i>Contact Details:</i> Wendy Jones (wendy.jones2@nuth.nhs.uk)
Member Organisations (please list):	City Hospitals Sunderland NHS Foundation Trust Gateshead Health NHS Foundation Trust The Newcastle-upon-Tyne Hospitals NHS Foundation Trust South Tyneside NHS Foundation Trust Northumbria Health Care NHS Foundation Trust Northumberland, Tyne and Wear NHS Trust Sunderland Teaching PCT South Tyneside PCT Northumberland Care Trust North Tyneside PCT Newcastle PCT Gateshead PCT North East Ambulance Service NHS Trust	
CLRN Population:	1.4 m	

Management Details		
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CLRN Overview	
Infrastructure model summary <i>(devolved/centralised/ mixed)</i>	Devolved
2009/10 Budget Allocation	£8,472,588
Topic LRNs <i>(please list)</i>	NCRN; DeNDRoN; SRN; DRN; MHRN; PCRN MCRN presence now established through joint representation with CDTV

To be completed by CCRN CC			
Date received:		Date of sign off:	
Received by:		Signed off by:	

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1 Executive Summary

This annual report for 2009/10 is presented, on behalf of the Executive and Board of NTW CLRN, to the Coordinating Centre for the National Institute of Health Research Clinical Research Networks (NIHR CRN CC). The report has three objectives:

- It offers a reflection on progress against our 2009/10 Business Plan: ***“Building the capacity and embedding the change required to double recruitment into portfolio trials”***
- It demonstrates the transition in NTW from implementation to delivery
- It provides, through the financial return, evidence that the funding deployed by NTW CLRN was used appropriately within member organisations in support of NIHR portfolio studies

The report describes the successful deployment of £8.47m within NHS Trusts in NTW to support portfolio studies. It also presents an 86% increase in recruitment and a 39% increase in the number of studies recruiting.

1.1 Progress against objectives set in 2009/10

Our strategic priorities in 2009/10 as set out in the Business Plan were to build capacity and to embed change in order to facilitate NIHR portfolio studies. Underpinning these strategic objectives were four goals:

1.1.1 To double, by April 2011, both recruitment to portfolio studies and the number of studies recruiting

The CLRN Blue Report of recruitment by member organisation (MO), Local Research Network (LRN) and Specialty Group (SG) continues to be distributed monthly. As well as helping influence the deployment of resource both between and within MOs, the Blue Report has become part of the MOs’ understanding and management of their activity. The final Blue Report for the year is presented in Appendix 1. The summary recruitment figures below are taken from it.

Total NTW Recruitment			Studies active in NTW		
2008/09	2009/10	% increase	2008/09	2009/10	% increase
10,703	19,943	86%	239	333	39%

If these trajectories can be maintained over 2010/11, we will achieve our recruitment objective and come very close to doubling the number of studies we offer to patients in the region.

1.1.2 To actively manage the CLRN funding in support of portfolio studies

The financial report that accompanies this document (a summary is presented in Appendix 2) shows how CLRN funding has been used in support of NIHR portfolio activity in NTW. The position returned by NTW CLRN for 2009/10 year-end was:

Total income to the CLRN	£8,472,588
Total expenditure through member organisations	£8,467,966
Underspend	£4,622

1.1.3 To establish and embed effective processes for research management and study delivery

The key research management processes in terms of NIHR priorities are CSP and research passports. **CSP performance targets** of 60 days for sign-off on commercial studies and 90 days for sign-off on non-commercial studies have been agreed with the R&D Clinical Directors of each MO and signed off by Chief Executives. Progress towards the targets on CSP is illustrated in the table below and it should be noted that the figures are from receipt of R&D form until permission is granted for the study to begin.

NIHR Co-ordinated System for gaining NHS Permission Approvals through NTW CLRN			
Figures as at 29 June 2010			
		% Within Target	
		Commercial (60 Days)	Non Commercial (90 Days)
2009	Q1	0%	6%
	Q2	7%	21%
	Q3	5%	53%
	Q4	15%	21%
2010 Q1		17%	48%

In 2009/10 all our member organisations committed to implementing **research passports**.

Progress on the **study delivery** aspect of this objective is central to demonstrating the transition from set-up to delivery. Case study 4, on work done in The Newcastle upon Tyne Hospitals NHS FT illustrates the engagement

and investment undertaken by our most research active member organisation. Though the scale of the undertaking is different in other MOs, all have invested in local RM&G and delivery teams in a similar manner.

1.1.4 To engage stakeholders through a sustained communications drive

Making the CLRN role and remit visible and understood was an area in which the CLRN Core Team invested a great deal of time and effort in 2009/10. Initiatives included:

- [Roadshows](#) – 12 events at MOs and University sites across the CLRN
- Clinical Director Meetings – two half-day strategy meetings for the R&D Clinical Directors of each MO and Local Research Network
- Quarterly managerial meetings with MOs and Networks with one, very constructive, half-day joint event to discuss resource allocation and deployment

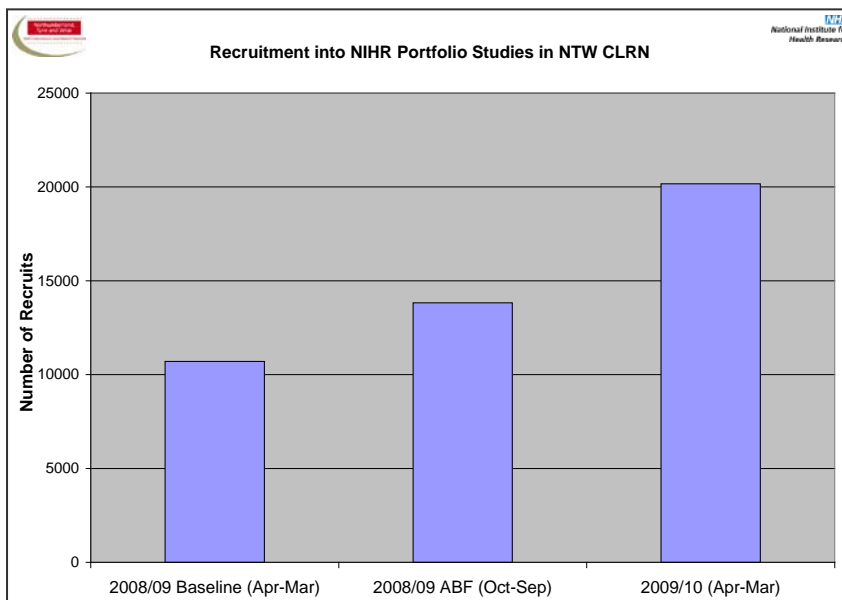
A variety of other approaches to improving engagement have also been taken such as: the four newsletters produced to highlight good practice and disseminate information; the extensive training programme (see section 8) which has time built in for networking and the conduct of an annual 360° review inviting feedback from our stakeholders on their perception of our performance.

2 Reflection on SWOT analysis

There were no material changes during 2009/10 to organisations or service patterns that impacted on our ability to achieve our plan. The themes identified in our SWOT analysis in the business plan (provided for ease of reference as appendix 4) remain relevant:

2.1 Building on strengths and realising opportunities

Our strong recruitment figures (identified as S1 in the 09/10 Business Plan) bode well for continuing improvements in activity-based funding to the region. However, most of the increase is from observational studies and we remain keen to increase the proportion of both interventional and industry studies. The figures do, however, demonstrate the **stable incremental progression** we have highlighted as a priority for CLRN development. In the graph below the CRN CC figures for the 08/09 Activity Based Funding (ABF) year



have been included to show the incremental progression.

CLRN governance structures continue to work well (S2) and member organisation buy-in (S3) is also still a strong feature of NTW CLRN. We believe that the continued emphasis on a transparent, fair and inclusive way of working (S4) contributes to this.

This approach has opened up a significant number of opportunities (O1, O2, O4) for effective collaborative working. The perception and position of the CLRN is enhanced by such behaviours and the feedback from our [annual 360° review](#) has again been positive. We continue to be viewed by MOs, LRNs and Specialty Groups as a partner not as an adversary. The resultant narrative within the CLRN of activity driving funding which is then made available to the researchers (O4) is evidence of the CLRN's remit becoming embedded.

2.2 Addressing weaknesses and mitigating threats

We have worked hard on communicating the remit of the CLRN (W1) and the opportunities that are available (e.g. section 1.1.4). We have ensured that we visited all MOs and that each MO has the capacity to contribute at the level to which they aspire (W2). Relative to other CLRNs we appear to be quite Chief Investigator (CI)-rich so W3 may have been more in perception than in reality. We continue to work with MOs to monitor and adjust support to service departments (W4).

We expressed concern that the national and local funding algorithms could lead to large sudden shifts in funding. The operation of the algorithms nationally has provided reassuring stability while allowing funding to follow activity. Our strong recruitment in 2009/10 may provide some protection against future reductions in funding and with time the funding will, hopefully be perceived by MOs as recurrent (T1 and T2).

T3 and T4 relate to the responsiveness of HR systems to the research agenda and the availability of staff. These risks continue to be managed through influencing within MOs' HR departments and through delivery of a high quality training programme. However, the responsiveness of HR Departments and the risk aversion in making long-term appointments on CLRN funding streams remain issues for us. The process of having posts approved and the time taken to appoint once they are approved significantly affects our ability to react to opportunities. It has also resulted in substantial underspends within some budget lines in 2009/10. These underspends were well managed by the MOs but they were indicative of delays in providing the necessary infrastructure.

Related to this, T5 cited as a threat uncertainties in the national funding environment for studies as a threat. If anything this is even less certain than it was when this was identified. As well as potentially reducing the number of studies funded there is a risk that uncertainty around NIHR funding streams could compound existing problems in establishing network posts.

3 Management and Infrastructure

3.1 Core Team, Executive & Board

Significant changes in personnel during 2009/10 included a change in CLRN **Board** Chair. Professor Oliver James took over from Professor Sir George Alberti. We also had one change to the **Executive** membership with Dr Alan Thomas replacing Dr Roger Paxton as Mental Health Representative. The only change to the **Core Team** is that Hilary Noone has replaced Mark Ryan-Daly as our administrator. Mark has moved to the delivery team and supports CSP. The management structure of the network has not changed.

There were three Board meetings in 2009/10 and eleven Executive meetings. Attendance at both is recorded in the [published minutes](#) and neither the Chair of the Board nor the Clinical Director has any concerns over levels of engagement. There has been no change to the composition of the Exec or Board although some of the personnel have changed as previously described. Our view is that the current structures provide appropriate and effective governance within the CLRN.

The CLRN senior management have no concerns in relation to the financial role played by our **Host Organisation**: on the contrary, in managing the CLRN finances they are both supportive of our role as a regional initiative and effective at separating the hosting duties from their activities as a MO.

3.2 Cross network-working

The 2010/11 Business Plan has described our close interactions and collaborative working with County Durham and Tees Valley CLRN. Throughout 2009/10 this joint working continued and included:

- Joint support for the North East Ambulance Service
- Strengthening of SG and Network links across CLRN boundaries (e.g. Reproductive Health)
- Agreement to jointly establish a MCRN presence in the North East with Dr Julian Thomas as the North East representative on the MCRN Board, with support from Dr Samir Gupta in CDTV.

Similarly, co-working with our Local NIHR Research Networks has flourished through:

- Close working with LRNs in budget setting and resource deployment within MOs
- Co-location of staff from NE DRN, PCRN N&Y and NTW CLRN at Network Central in the Centre for Life alongside the National Coordinating Centre for the Stroke Research Network.

Co-location of the NIHR networks has been a positive move: we share insights, information and support each other. Anna Lartey, LRN Manager for NE DRN commented “the move to the Centre for Life has allowed us to work much more closely with the CLRN and PCRN. Interactions with both are crucial to our development and we are well placed to capitalise on these opportunities.”

4 Portfolio Management (commercial and non-commercial)

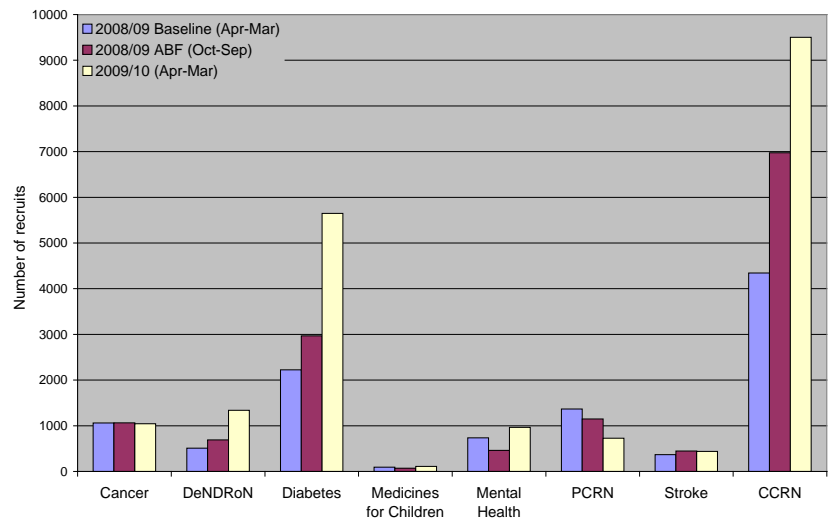
NTW CLRN's contribution to the recruitment goal within the NHS Operating Framework goal is clear from the increases in recruitment from 2008/09 to 2009/10.

4.1 Developing the NTW contribution to the national portfolio

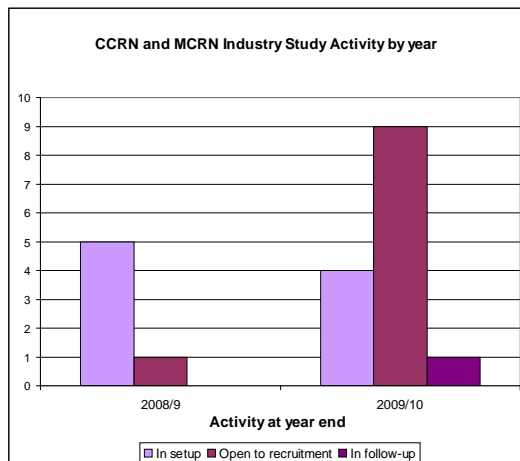
Our principal strategy for increasing recruitment into both commercial and non-commercial studies is to engage with MOs, SGs, LRNs and investigators to identify opportunities for contributing to portfolio studies. We then support the relevant MO in providing the required resource for the conduct of those studies. We measure the success of these interventions through monitoring recruitment



Recruitment into NIHR Portfolio Studies in NTW CLRN



levels by MO, SG and TCRN against the stated objectives. (Appendix 1, the Blue Report). Progress is assessed by the Exec and Board in terms of: total recruitment; relative complexity of the studies undertaken; and the number of new areas beginning to recruit (new MO sites for SGs and TCRNs and new disciplines becoming research active within MOs).



We continue to prioritise **industry studies**. Professor Richard Walker provides Exec level leadership on our Industry work programme. There has been a step change in the volume of CCRN and MCRN industry studies offered within NTW. Feasibility has been carried out on 93 CCRN industry studies and from a baseline of 20 CCRN studies offered in 2008/09 and the snapshot (left) of activity at year end illustrates the trajectory.

There is a high level of awareness within MOs as to the importance of all eligible studies being included on the portfolio. The CLRN RM&G team work closely with CLRN funded staff in MO R&D offices. The main driver for this level of awareness is activity-based-funding as, through the model employed in NTW, it provides incentivisation at both MO and investigator levels. Similarly, the CLRN Information Manager works with the Data Contact for each study run from NTW to ensure that they are supported in uploading recruitment each month.

4.2 Developing the lead network approach

Justine Smith, Lead RM&G Manager for NTW CLRN developed an implementation plan for the Lead Network proposal. Justine has briefed the Core Team on the impact of the proposal on their area of work and we will be appointing a Lead Network facilitator to assist CIs in understanding and negotiating their way through the national systems for securing service support for their studies.

Consistent with this ethos of supporting local CIs in delivering their studies we have developed a system to monitor and report on recruitment against target for all the CCRN portfolio studies where we are lead network. We will roll out this system in 2010/11 and use the information it provides to support CIs in using the national network systems and resource to deliver their studies to time and target.

5 Research Management and Governance

Within the development of CLRN-led RM&G provision, 2009/10 was a very busy time. We invested almost £1m in new or established RM&G posts within MOs and consolidated the relationships within the devolved model through which RM&G initiatives are delivered. Real challenges remain in delivering change on the scale of CSP, passports and the relationship management required to retain the engagement of MOs. However, Justine Smith, the Lead RM&G Manager for NTW and Dr Alan Thomas, Executive lead for RM&G can point to significant progress in the past year.

5.1 Facilitation of study feasibility, set-up and delivery

The devolved model of CLRN activity in NTW has three elements:

- RM&G posts within member organisations that are responsive to portfolio studies
- Embedded delivery teams and services within member organisation
- Coordination of this infrastructure by the core CLRN team

CLRN RM&G staff are available throughout study development, initiation and delivery to provide advice and support to researchers and research teams. Staff based within the CLRN core team actively support the wider, MO-based team in obtaining the information required to undertake governance checks and to resolve any issues they have. The MO-based RM&G team lead on providing support and advice to investigators during the R&D approval process and in signposting the researchers to the delivery support that is available to them through the delivery teams and service support embedded within each MO.

Karen Hutchinson, the CLRN Industry Manager provided, throughout 2009/10, dedicated support to investigators involved in commercial NIHR portfolio studies. Karen assisted with feasibility assessments for studies coming from the national Industry Team. This involved coordination of input from Specialty Groups, local PIs and R&D Managers. Karen remains proactive in contacting selected PIs and their teams, assisting them with submitting the documents required for R&D approval and supporting them during study set-up and delivery.

Establishing and embedding a delivery infrastructure for portfolio studies (commercial **and** non-commercial) was our main priority for 2009/10. That infrastructure relies on effective and efficient management and governance systems and also the availability of delivery teams and services. The NTW model for study delivering is also a devolved one. R&D Departments manage the service support resource in each MO. They fund and manage the teams and services required for delivery. The deployment of this resource and the right of portfolio studies to have access to it is managed locally but coordinated across the SGs and partner networks by the CLRN Core Team.

5.2 Embedding CSP and promoting the active management of the process

In early 2010 the CEOs of all MOs signed up to manage portfolio studies through CSP. Target times were agreed and additional staff were employed and trained during 2009/10 to manage the process. All MO-based staff were trained and supported in CSP by the CLRN Core Team.

We created a database to track studies going through CSP. This was used to provide reports to show progress at both CLRN and MO level for commercial and non-commercial studies. The reports were used by MOs, the CLRN Board and Exec and the RM&G working groups to assess progress and show areas for improvement.

NIHR Co-ordinated System for gaining NHS Permission Approvals through NTW CLRN

Figures as at 29 June 2010

		% Within Target	
		Commercial (60 Days)	Non Commercial (90 Days)
2009	Q1	0%	6%
	Q2	7%	21%
	Q3	5%	53%
	Q4	15%	21%
2010 Q1		17%	48%

Discussion with the Clinical Directors of R&D and RM&G staff resulted in the introduction of targets for CSP, with staff in the MOs being supported to change practice to align local practice more closely with CSP or to streamline internal processes.

Core CLRN RM&G staff were proactive in managing studies coming through CSP. Certain tasks continued to be retained centrally to ensure consistency and maintain the global view. Reports were provided to MO-based RM&G staff to show study progress and highlighting those over target and approaching the target (using a RAG status system). MOs reported delays to studies which were then actively managed by the central staff until resolution.

5.3 Local performance measures for CSP

Discussion in late 2009 with the Clinical Directors of R&D and RM&G staff led to the setting of targets for CSP turnaround times.

The target (from R&D form validation to approval) for a commercial study is 60 days and for a non-commercial study it is 90 days. The results are not yet as we or the MOs would like, but in keeping with the metrics-focused

Study approval times: NIHR Co-ordinated System for gaining NHS Permission - Approvals by Trust in 2009/10

The percentage of studies given NHS permission within the agreed targets for commercial and non-commercial studies

Trust	Time from R&D form submission to signed NHS permission letter							
	Commercial (Target 60 Days)				Non Commercial (Target 90 Days)			
	Q1/Q2		Q3/Q4		Q1/Q2		Q3/Q4	
	Requiring Approval	% Within Target*	Requiring Approval	% Within Target*	Requiring Approval	% Within Target*	Requiring Approval	% Within Target*
South Tyneside NHS FT	0	0%	1	0%	2	100%	4	75%
Northumberland, Tyne and Wear NHS FT	0	0%	0	0%	7	71%	8	75%
North Tyneside PCT	3	0%	0	0%	8	50%	7	71%
Newcastle PCT	4	0%	0	0%	8	50%	13	69%
Sunderland Teaching PCT	3	33%	4	50%	7	71%	3	67%
Gateshead PCT	2	0%	4	50%	8	63%	2	50%
Northumberland Care Trust	3	0%	0	0%	7	43%	6	50%
Gateshead Health NHS FT	2	0%	0	0%	10	20%	5	40%
Northumbria Healthcare NHS FT	1	0%	3	0%	8	50%	12	33%
Newcastle upon Tyne Hospitals NHS FT	15	7%	16	0%	30	10%	47	15%
City Hospitals Sunderland NHS FT	2	0%	2	0%	11	18%	7	0%
South Tyneside PCT	2	0%	2	50%	7	71%	1	0%
North East Ambulance Service NHS Trust	Managed through CDTV CLRN							
Summary Of Approvals for the CLRN	37	5%	32	16%	113	39%	115	37%

* The % within target figure includes studies not yet approved because at the time of this report they have, by definition, failed to meet the target. As 90 days of 2009/10 this report includes all the studies that came in during 2009/10.

approach we have established, we now have evidence on which to base our management decisions.

In consultation with the MO R&D Departments we are identifying and addressing the issues that delay set-up. In addition, our local CSP tracking database now includes information on time to first patient entered and as well as replicating, for non-commercial studies, the metric often used by commercial studies, this is providing valuable insights into the transition between governance and delivery components of the work system.

5.4 Embedding Research Passports and streamlined HR arrangements

All MOs and Universities in the CLRN have officially signed up to running to a standard policy which embeds the Research Passport Scheme. The policy was created in 2009 from discussions in a working group set up to implement the scheme. The working group includes R&D, HR and Occupational Health staff from member organisations and Universities and is used to disseminate updates.

This collegiate and inclusive model of working has allowed us to develop a shared understanding of the requirements and priorities. It has also allowed rapid communication on issues that arise. Justine Smith continues to act as a point of contact and facilitator for enquiries from R&D Departments, CIs and PIs when inter-organisational HR or patient access issues arise. As well as providing swift reactive interventions on behalf of studies, Justine has been proactive in delivering training and advice to HR departments. In particular, where changes in staff occurred within HR departments Justine provided one-to-one training so that continuity of understanding and service was possible.

5.5 Advice and support for researchers

As described above, the provision of an effective and seamless advice and support service to researchers is the *raison d'être* of the RM&G network. RM&G staff based within the MOs are the first port of call for regulatory and governance advice, as they have established relationships with research teams. If the RM&G staff at the sites cannot answer the questions raised, or have queries of their own, they seek advice from the CLRN Core Team. 2009/10 saw significant progress in establishing this understanding. The core CLRN team for RM&G now act primarily to coordinate activities regionally, monitor performance and provide expertise. Justine and her team within the CLRN office have often sought clarification from national agencies on behalf of the devolved RM&G staff within MOs and escalated their input and concerns when appropriate,

One area of intense activity and learning in 2009/10 was around the expedited set-up required for swine flu studies. In particular the swine flu in pregnancy study (CRN 7376) was intensively supported by CLRN staff to get it approved and recruiting nationally. This provided a valuable insight into the Lead Network role and the CLRN has since put in place a strategy for formal implementation of the Lead Network initiative.

6 Local Specialty Groups

Twenty one Specialty Groups have been established in NTW: these are highlighted in bold in the table (right).

While there is a low level of recruitment in areas outside of these specialties, all active portfolio studies are supported irrespective of whether there is an established SG locally.

6.1 SG Leadership

SG activity and development is led at Exec level by Professor Stephen Robson and an annual strategy review for each SG was introduced in early 2010 to look at the activity and intentions with a view to informing the prioritisation of resource allocation within and across MOs.

Stephen chairs 6-monthly meetings of local SG leads and represents the SG priorities within the Exec, Board and Clinical Directors' meetings. Other, informal contact between the CD or Core Team and the SG leads and SG membership help inform the support and performance management of the SGs and feed into the strategic direction and operational delivery of the CLRN.

6.2 SG resourcing

For a variety of reasons some SGs have been more successful than others in identifying studies to which they can recruit and resource allocations within MOs take account of this. The resource required to deliver the studies is provided through the MOs. In addition to this support for study delivery all local SG leads receive an allocation for travel to national meetings and to allow them to administer the local group.

6.3 SG engagement with the industry agenda

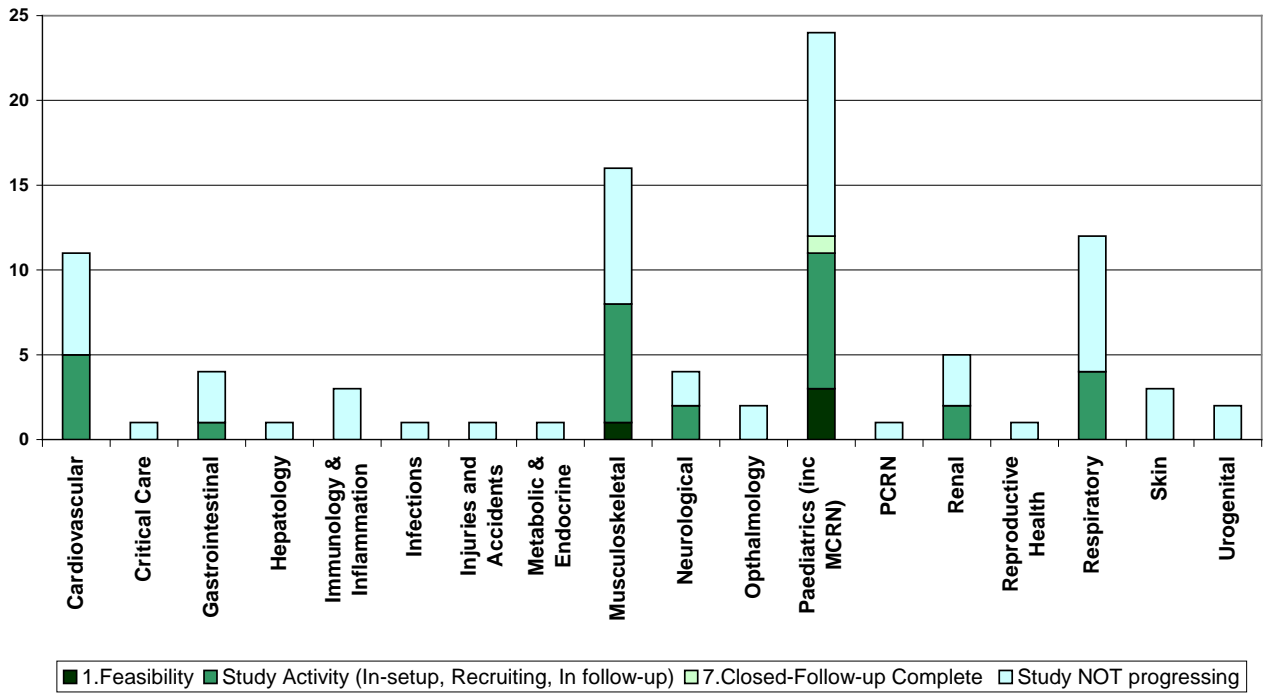
A number of NTW Specialty Groups are highly active in terms of the NIHR CCRN commercial studies. The bar chart below shows the volume of studies that Karen Hutchinson has offered to each SG. These data have been shared with the R&D Management teams in member organisations so that engagement can be encouraged and the devolved resource deployed in support of the industry agenda.

Respiratory and Renal are good examples of engagement between a local SG and the industry agenda. The Respiratory Group, led by Dr Tony deSoyza have carried out feasibility on twelve studies, they have been selected as a site for four of these and one of these studies is about to close having recruited to time and target. In Case study 3, Prof Neil Sheerin, the local lead for the Renal SG, sets out the factors that have supported that group in engaging with the NIHR priorities.

Recruitment by Specialty Group in NTW CLRN

Primary Specialty Group	2008/09 (Apr - Mar)	2009/10 (Apr - Mar)	
Age & Ageing	41	182	344%
Anaesthetics			
Cardiovascular	416	910	119%
Clinical Genetics	30	50	67%
Critical Care		108	
Dermatology	178	226	27%
ENT	56	9	-84%
Gastrointestinal	4	543	13475%
Health Services Research	16	345	2056%
Hepatology	269	96	-64%
Immunology and Inflammation	121	49	-60%
Infectious Diseases & Microbiology	285	13	-95%
Injuries & Accidents		7	
Metabolic & Endocrine	42	37	-12%
Musculoskeletal	795	1045	31%
Nervous System Disorders	3	58	1833%
Non Malignant Haematology		2	
Ophthalmology	8	86	975%
Oral & Dental	62	60	-3%
Paediatrics	6	259	4217%
Public Health Research	30	65	117%
Renal	128	742	480%
Reproductive Health & Childbirth	1665	2469	48%
Respiratory	33	536	1524%
Surgery	11		
Urogenital	145	1606	1008%
Total	4344	9503	119%

CCRN Industry Studies offered to NTW-CLRN from April 2009 - March 2010 (n=93)



The figure above illustrates the volume and spread of activity in NTW on CCRN industry studies at 2009/10 year-end. The light blue part of the bar illustrates the studies on which feasibility was done but the study did not progress in NTW. The green sections show where CCRN industry activity is now coming on-line. The black sections represent studies in the system that were undergoing feasibility at the end of March 2010.

7 Patient and Public Involvement

The PPI objectives set out in the 2009/10 Business Plan centred on understanding the PPI environment within NTW and planning our engagement accordingly.

The [scoping exercise](#) conducted for us by Dr Anna Jones and Dr Tina Cook of the University of Northumbria was received by the Board in September and the recommendations are being implemented. The work proposed is based on partnership with CDTV CLRN and the North East Research Design Service that is shared by the two CLRNs.

- The PPI Officer within the North East RDS, Andrew Robinson had been funded 3 days per week. The two CLRNs covered already by his work agreed to contribute the funding required to make the post full time. The result is that Andrew has been engaged to develop a programme of training and awareness-raising on PPI in the North East that is consistent with the remits of all three NIHR funded organisations. The initiative is managed through a joint working group.
- NTW CLRN, CDTV CLRN and the North East RDS have all engaged with the Action Learning Sets established by CRN CC to help CLRNs move forward with PPI in ways that add value to their work. CLRN Projects Officer, Mark Ryan-Daly has attended the action learning sets on behalf of NTW CLRN (along with Andrew Robinson). This has allowed us to integrate the approaches to PPI with CDTV and the North East RDS within a structured environment. We are confident that the approaches established in 2009/10 will both tie our approach to the national agenda and allow us to retain a local focus.
- In parallel, we have begun in NTW to pilot PPI input into SGs to see if recruitment can be enhanced through involvement of a patient perspective on trials to be undertaken. The Renal SG has been the first to do this and a patient representative is attending their SG meetings and providing input.

8 Training and Workforce Development

The NTW CLRN programme of training and workforce development is central to our ambition of making our region the destination of choice for high quality clinical research. It is understood¹ that a stable, motivated workforce is the single most significant success factor in the consistent delivery of studies. Access to high quality training is one important element of the research environment we wish to create.

We have conducted and published an extensive [workforce development review](#) and the work programme that has resulted is led at Exec level by the CLRN Senior Manager, Séamus O’Neill. Tom Wooldridge, the newly appointed lead nurse will has responsibility for delivery of the programme. Tom and Andrea Stutt have been trained on the national GCP facilitation scheme and will soon be our principal GCP trainers.

8.1 The nature of the NTW CLRN training programme

The features of our [training programme](#)² are:

- Delivery is by the experts: we buy in time from the best people we know
- Events are free to those involved with portfolio studies
- We actively seek feedback from participants to continually improve provision
- Events are delivered locally and have time built in for networking
- Courses are widely publicised and available to staff in any MO or Network
- Course outlines and booking facilities are provided online
- We put on additional courses and bespoke events where there is a need

8.2 Courses delivered, numbers trained and the feedback received

Overall Impression	Number Trained	Excellent	Good	Fairly Good	Poor	Very Poor
IRAS & CSP	66	42%	47%	11%	0%	0%
GCP	271	30%	52%	15%	3%	0%
Project Management	22	68%	32%	0%	0%	0%
Mental Capacity Act	63	63%	30%	7%	0%	0%
Human Tissue Act	49	29%	63 %	4%	4%	0%
Ethics & Informed Consent	85	42%	48%	8%	2%	0%

Management and leadership training is a developing element of the programme. We already provide change and project management training and we are adding events on: leadership and teams; developing and communicating strategy; and dealing with complexity. We are also providing courses on written and oral presentation skills.

Our experience, and that of the participants, is that the contacts made and the relationships built combine to add value over and above the training itself. The programme is valued and training events will continue to be powerful contributors to the effectiveness of the research network.

¹ <http://www2.warwick.ac.uk/fac/soc/wbs/research/ikon/research/clinicaltrials/>

² http://www.crncc.nihr.ac.uk/index/networks/comprehensive/clrns/northumberland/latest_news/mainColumnParagraphs/01119/document/Comprehensive%20Newsletter%20-%20Issue%207%20-%20April%202010.pdf

9 Information systems

As demonstrated in the preceding sections the collation and dissemination of high quality management information is integral to the operation of NTW CLRN. This section briefly draws together the main components of the management information systems we used in 2009/10 to describe the NIHR research landscape for our stakeholders. The financial management systems are not described in detail here as they are dealt with in the finance component of this report.

9.1 Recruitment

The Blue Report remains the primary means of communicating recruitment data within the CLRN. It is locally derived from national figures and has been instrumental in establishing a shared understanding of activity by member organisation, SG and Topic Network. We used the complexity adjusted figures to inform local allocations and the report is a standing item on all Exec and Board meetings. It is also, invariably, on the table during meetings with MOs, SG, TCRNs and other stakeholders.

9.2 CSP tracking database

As described in section 5 above, in 2009/10 the CSP tracking database and the reports it provides became embedded in the management processes of the CLRN. The collection and analysis of the time taken for studies to be signed off within member organisations and the identification of causes for delays has allowed the discussions with member organisations to move beyond focussing solely on the role of the R&D Departments. A routine RAG reports is run to show MOs which studies need attention as a priority.

The purple report and breakdown of sign-off times by member organisation are now well-established metrics within the system and are included alongside recruitment data in half-yearly reports to CEOs.

9.3 Metrics on Industry studies

As illustrated in section 6.3, data are collected, analysed and disseminated on the CCRN industry studies offered to each SG and member organisation. The reports on uptake of studies are shared with the Exec, Board and Clinical Directors of R&D in each member organisation. In 2009/10 we began to report to R&D CDs on instances where we have not been able to find a PI for a CCRN study. Information on involvement in NIHR Industry studies is used by the Executive to inform decision making in the allocation of clinical sessions

9.4 Other management information and communications approaches

As well as delivering the management information systems described above, Lestryne Clift, the NTW CLRN Information Manager has been highly proactive in promoting the use of interactive working within the network through Sharepoint and the NIHR portal workspaces. Lestryne has established and rolled out workspaces for the Core Team, the Exec, the Primary Care Delivery Group (led by PCRN) and also provided

The Newcastle upon Tyne NHS FT R&D Department with a workspace to facilitate document sharing for their approvals committee.

The evidence-based approach used within NTW CLRN and the information systems that underpin it were fundamental elements of achieving the stated objectives for 2009/10: “building capacity and embedding change”. Progress made in 2009/10 means that we can accurately describe capacity and performance in both RM&G and in study delivery; these are crucial elements of embedding the change we need to see.

The report to CEOs developed in 2009/10 is a key output of this approach and the management information that underpins it. The report, presented as appendix 3 is shared with the SHA and other Board members.

10 Making an Impact

2009/10 saw a noticeable shift in both perception and practice within NTW CLRN. It began with the CLRN budget having increased from £3.1m (in 2008/09) to £8.4m as the transitional arrangements for R&D funding ended. It ended with the funding having increased further to £9.4m and recruitment having risen by 86%.

In the intervening 12 months MOs deployed the funding allocated to them to establish RM&G and delivery infrastructures that are capable of delivering a world class platform for clinical research in NTW. The case studies highlighted here and in the appendices that follow are examples of that work. We, in the CLRN Core Team and Executive remain grateful to the staff in the MOs for their efforts in realising what one colleague referred to as *'a once in a generation opportunity for clinical research in the North East'*.

The case studies that follow are:

- Getting out of the House: how effective network/MO working helped deliver a stroke rehabilitation study
- Renal Specialty Group: how CLRN investment allowed expansion of recruitment in an established area of research activity
- Critical Care Specialty Group: how CLRN support for an emerging area enabled recruitment to become established at multiple sites in a discipline that previously had little portfolio activity
- RM&G and delivery capacity in NUTH: how the RM&G and delivery infrastructure in a large, highly research active teaching MO has been developed in partnership with the CLRN

10.1 Summary slides on case studies

Getting Out of the House: an example of cross-network and cross-MO working

Multi centre, randomised control trial led by Nottingham University and funded by HTA.

SRN-adopted study to test a novel rehabilitation technique delivered by a Rehabilitation Therapist in Primary Care

Patients identified and recruited in secondary care but intervention and support also required in primary care

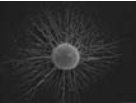
CLRN brokered agreement process to examine the patient pathway for the study to understand contributions required from all parties. SRN, Gateshead Health NHS FT and Sunderland Teaching PCT took part

Agreement was reached and Gateshead was the first site to be initiated and recruited the first patient into the trial in November 2009.

NTW Critical Care SG: the challenges of raising awareness and promoting activity

Critical Care research in NTW


- Starting from a low base
- Infrastructure and coordination required
- Effective and Enthusiastic leadership identified



Aspergillus - a target of the FIRE study

Investment through member organisations in 2009/10

- Sessional support to research leads
- 1.5 research nurse FTEs in large teaching trust
- Access to generic data management and CTO time within MOs
- Support from CLRN Core Team in establishing the SG

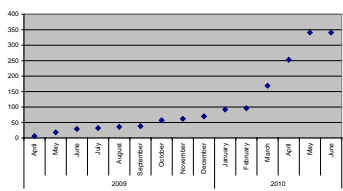


NTW Critical Care SG: the challenges of raising awareness and promoting activity

Resulting in:

- Significant levels of recruitment to Critical Care studies
- Broad engagement across Member Organisations - Recruitment reported by all ITUs in NTW
- SG actively screening the portfolio and opening studies

Total recruitment to Critical Care studies from NTW - Cumulative figures



Year	Studies	Sites
2008/09	0	0
2009/10	2	5

NTW Renal SG: Identifying and addressing barriers to recruitment

Renal research in NTW

- Significant historical activity but localised
- Infrastructure and resource required to increase participation
- Effective and enthusiastic leadership identified

Investment through member organisations in 2009/10

- Sessional support to research leads
- Full time research nurse at most active site
- Access to generic data management and CTO time within MOs
- Support from CLRN Core Team in establishing the SG

NTW Renal SG: the challenges of raising awareness and promoting activity

Resulting in:

- Substantial increases in recruitment to Renal studies
- SG actively screening the portfolio and opening studies
- SG actively seeking to involve new sites in the region
- Two CCRN industry studies now active

	Portfolio studies active		Total recruitment
	Non-commercial	Commercial	
2008/09	2	0	129
2009/10	3	2	742

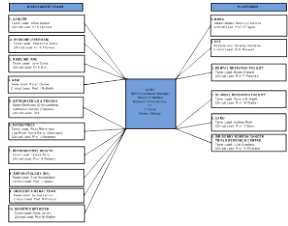
Delivering a world-class research infrastructure within The Newcastle upon Tyne Hospitals NHS FT

2009/10 delivery highlights in NUTH

- Delivery funding - £4.2m
- Recruited - 8000 patients
- Established a comprehensive and versatile delivery infrastructure

Multi disciplinary research platforms and teams

- Available to undertake commercial and non-commercial portfolio studies
- Staff mobility and cross-cover
- Professionalisation of the research workforce
- Security of tenure for research support staff
- Coordination of training and career development
- Links study management and performance to resource deployment



Resulting in:

A standing infrastructure of high quality as an easily communicated offering to industry and other partners as they seek to place studies

Appendix 1 - The Blue Report

2009/10



Recruitment into NIHR Portfolio Studies in NTW CLRN
April 2009 - March 2010

Primary Topic/SpG	City Hospitals Sunderland	Gateshead Health	North East Ambulance	Northumbria Healthcare	North of Tyne	Northland Tyne & Wear	Newcastle Hospitals	South of Tyne & Wear	South Tyneside	NULL	Total	%	Adjusted
Cancer	69	121		55	35		661	38	67		1046	5%	7%
DeNDRoN	1	4		35	604	298	392			5	1339	7%	5%
Diabetes	10	32		44	5260		80	30	23		5479	27%	19%
Medicines for Children	13						98				111	1%	1%
Mental Health		4			16	888	2	36	2		948	5%	5%
PCRN	48	8			248			409		11	724	4%	6%
Stroke	214	5		88			102		29		438	2%	3%
Age & Ageing					14		168				182	1%	1%
Anaesthetics													
Cardiovascular	17	8		77	293		504		1		900	5%	6%
Clinical Genetics	3						47				50	0%	0%
Critical Care	10	21		2			75		2		110	1%	0%
Dermatology					8		216				224	1%	2%
ENT							9				9	0%	0%
Gastrointestinal	1			49			406		84		540	3%	2%
Health Services Research	11		67	81	46	129	12				346	2%	1%
Hepatology	3			14			72		7		96	0%	0%
Immunology and Inflammation	1	2		3			43				49	0%	0%
Infectious Diseases & Microbiology	1						12				13	0%	0%
Injuries & Accidents	6						1				7	0%	0%
Metabolic & Endocrine							34				34	0%	0%
Musculoskeletal	11	35		482			492	9			1029	5%	4%
Nervous System Disorders					3		54	1			58	0%	0%
Non Malignant Haematology	2										2	0%	0%
Ophthalmology	49						37				86	0%	1%
Oral & Dental							63				63	0%	1%
Paediatrics	8	3		95	6	33	113	1			259	1%	1%
Public Health Research							65				65	0%	0%
Renal							741				741	4%	2%
Reproductive Health & Childbirth	42	18		115	44		2541	17	26		2803	14%	8%
Respiratory		9		382			140		2		533	3%	2%
Surgery													
Urogenital	43			432			1184				1659	8%	19%
Total	563	270	67	1954	6577	1348	8364	541	243	16	19943	100%	100%
%	3%	1%	0%	10%	33%	7%	42%	3%	1%	0%	100%		
Adjusted	4%	2%	0%	13%	24%	6%	45%	5%	2%	0%	100%		

Figures as at 30 June 2010

- Areas of new activity within MOs and across SG or LRNs have been monitored throughout the year against member organisations' strategies for expansion of activity
- Similarly, LRNs' levels of recruitment and their engagement with member organisations have also been monitored
- The complexity adjustment (in grey) is on the basis of the national banded weightings for recruitment. This remained a central tenet of the local funding algorithms
- This report was circulated monthly to the entire CLRN mailing list

2008/09 (for comparison)



Recruitment into NIHR Portfolio Studies in NTW CLRN April 2008 - March 2009

Primary Topic/SpG	City Hospitals Sunderland	Gateshead Health	North East Ambulance	Northumbria Healthcare	North of Tyne	Northland Tyne & Wear	Newcastle Hospitals	South of Tyne & Wear	South Tyneside	Total	%	Adjusted
Cancer	119	155		167	41		484	20	76	1062	10%	11%
DeNDRoN	5			113	29	94	267			508	5%	4%
Diabetes		182		116	1667		250	9		2224	21%	11%
Medicines for Children	43						50			93	1%	2%
Mental Health				134	5	160	302		136	737	7%	11%
PCRn					674		33	661		1368	13%	11%
Stroke	189	2		79			86		11	367	3%	4%
Age & Ageing					30		11			41	0%	0%
Anaesthetics												
Cardiovascular		1		52			363			416	4%	4%
Clinical Genetics	3	1					24		2	30	0%	0%
Critical Care												
Dermatology							178			178	2%	3%
ENT							56			56	1%	1%
Gastrointestinal				4						4	0%	0%
Health Services Research	1			1	1		2	11		16	0%	0%
Hepatology	2	1					266			269	3%	1%
Immunology and Inflammation							121			121	1%	1%
Infectious Diseases & Microbiology	3			9	7		266			285	3%	5%
Injuries & Accidents												
Metabolic & Endocrine							42			42	0%	0%
Musculoskeletal		54		4	4		733			795	7%	4%
Nervous System Disorders	1						2			3	0%	0%
Non Malignant Haematology												
Ophthalmology	5						3			8	0%	0%
Oral & Dental							62			62	1%	1%
Paediatrics							6			6	0%	0%
Public Health Research							30			30	0%	1%
Renal							128			128	1%	1%
Reproductive Health & Childbirth	7	18		129	15		1480		16	1665	16%	21%
Respiratory		1					31		1	33	0%	0%
Surgery							11			11	0%	0%
Urogenital							145			145	1%	1%
Total	378	415	0	808	2473	254	5432	701	242	10703	100%	100%
%	4%	4%	0%	8%	23%	2%	51%	7%	2%	100%		
Adjusted	3%	3%	0%	9%	13%	4%	59%	7%	3%	100%		

Appendix 2 – Financial returns for 2009/10

NIHR CCRN - YEAR END RETURN 2009/10

Sheet 1 - Summary

Complete green boxes only

CLRN:	Northumberland Tyne and Wear CLRN
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	£	£	
	ORIGINAL ALLOCATION	ALLOCATION AS AT YEAR END	Variance
CLRN initial allocation 2009/10	8,153,141	8,153,141	0
Inflation uplift 2009/10		122,297	122,297
Band 1a ABF allocation		54,321	54,321
Allocations from national contingency		105,829	105,829
Brought forward from previous year		37,000	37,000
Total CLRN allocation	8,153,141	8,472,588	319,447

RESOURCE CATEGORY

	OUR Planned Expenditure 2009/10	Actual Expenditure for Year (April 09 - March 10)	Variance
CLRN Management	435,570	455,762	20,192
Clinical Sessions	3,674,395	4,181,363	506,968
Key Service Support	425,500	428,755	3,255
Other Service Support	2,508,981	2,540,730	31,749
Research Management	855,106	714,924	(140,182)
Other Allocations*	257,390	66,936	(190,454)
ABF and Contingency	0	79,496	79,496

* Other allocations to include are such as PPI, T&E etc

TOTAL	8,156,942	8,467,966	311,024
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Under/(Over) spend (3,801) 4,622

2009/10 Year End Summary - Actual Expenditure April 09 - March 10

NHS Organisation / Provider of NHS Services	CLRN Management	Clinical Staff	Key Service Support	Other Service Support	Research Management	Other Allocations*	ABF & Contingency	TOTAL	OUR Planned Expenditure	Variance
Newcastle upon Tyne Hospitals NHS Foundation Trust	455,762	2,563,581	224,055	1,498,791	189,838	0	38,037	4,970,064	5,228,070	(258,006)
City Hospitals Sunderland NHS Foundation Trust		212,000	20,000	229,327	52,000	10,000	0	523,327	441,933	81,394
Gateshead Health NHS Foundation Trust		200,700	0	85,485	44,370	0	0	330,555	295,958	34,597
Gateshead Primary Care Trust		0	0	0	0	0	0	0	0	0
Newcastle Primary Care Trust		0	0	0	0	0	0	0	0	0
North East Ambulance Service NHS Trust		0	0	20,288	24,911	0	0	45,199	44,911	288
North Tyneside Primary Care Trust		135,681	68,000	195,476	107,686	22,250	41,459	570,552	510,483	60,069
Northumberland Care Trust		0	0	0	0	0	0	0	0	0
Northumberland Tyne & Wear NHS Trust		394,126	80,000	128,800	24,000	5,000	0	631,926	441,804	190,122
Northumbria Healthcare NHS Foundation Trust		430,678	16,700	124,308	127,814	5,000	0	704,500	604,179	100,321
South Tyneside NHS Foundation Trust		138,363	0	69,764	36,023	17,486	0	261,636	193,676	67,960
South Tyneside Primary Care Trust		0	0	0	0	0	0	0	0	0
Sunderland Teaching Primary Care Trust		106,234	20,000	188,491	108,282	7,200	0	430,207	395,928	34,279
Mixed Hospitals		0	0	0	0	0	0	0	0	0
Medicines for Children		0	0	0	0	0	0	0	0	0
PCRNI		0	0	0	0	0	0	0	0	0
Dendron		0	0	0	0	0	0	0	0	0
DRN		0	0	0	0	0	0	0	0	0
SRN		0	0	0	0	0	0	0	0	0
MHRN		0	0	0	0	0	0	0	0	0
CRN		0	0	0	0	0	0	0	0	0
CLRN wide		0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0
TOTAL FUNDING ALLOCATED TO MEMBER ORGANISATIONS	455,762	4,181,363	428,755	2,540,730	714,924	66,936	79,496	8,467,966	8,156,942	311,024

NIHR CCRN - Outline Use of Resources 2009/10

SHEET 2 - CLRN MANAGEMENT & HOST CORPORATE SERVICES

Complete green boxes only

	Name	e-mail address	Phone Number
CLRN:	Northumberland Tyne and Wear CLRN		
Clinical Director:	Professor Tim Goodship	T.H.J.Goodship@ncl.ac.uk	0191 241 8842
Senior Manager:	Dr Séamus O'Neill	Seamus.O'Neill@nuth.nhs.uk	0191 241 8842
Host Organisation:	Newcastle upon Tyne Hospitals NHS FT		
Host Finance Lead:	Ms Wendy Jones	Wendy.Jones2@nuth.nhs.uk	0191 213 7069

2009/10
£

FUNDING

2009/10 Funding for CLRN Management & Host Corporate Services
2009/10 Funding brought forward for CLRN Management

424,000
0

TOTAL

424,000

USE OF FUNDING

CLRN Management Pay Costs

Role	Name	Grade	WTE	Start Date	£ 2009/10 OUR Planned Expenditure	£ 2009/10 Forecast at mid year	£ 2009/10 Actual (April 09 to March 10)	£ Variance - mid year forecast to plan	£ Year End Variance (Actual to Plan)
Clinical Director	Tim Goodship		0.5	1st April 2009	51,168	51,166	51,168	(2)	0
Co-Director								0	0
Co-Director								0	0
Co-Director								0	0
Senior Manager	Séamus O'Neill	NHS 8c	1	1st April 2009	72,149	70,284	71,124	(1,865)	(1,025)
Lead RM&G Manager	Justine Smith	NHS 8b	1	1st April 2009	63,824	65,507	65,650	1,683	1,826
Industry Manager	Karen Hutchinson	NHS 7	1	1st April 2009	41,234	40,608	40,682	(626)	(552)
Information Manager	Lestryne Clift	NHS 6	1	1st April 2009	30,457	30,066	30,768	(391)	311
Administrator	New appointment	NHS 4	1	1st Nov 2009	22,238	15,000	9,097	(7,238)	(13,141)
Temp admin staff	Various	4	1	1st April 2009		15,000	9,016	15,000	9,016
Total					281,070	287,631	277,505	6,561	(3,565)

CLRN Management Non-Pay Costs

40,000 36,724 54,185 (3,276) 14,185

Host Pay Costs

Role	2009/10 OUR Planned Expenditure	2009/10 Forecast at mid year	2009/10 Actual (April 09 to March 10)	Variance - mid year forecast to plan	Year End Variance (Actual to Plan)
Human Resources	12,500	12,500	12,500	0	0
Finance	16,000	16,000	16,547	0	547
Information Systems	5,000	5,000	5,000	0	0
Total Host Staff Costs	33,500	33,500	34,047	0	547

Host Non-Pay Costs

Type of allocation	Cost per m ²	2009/10 OUR Planned Expenditure	2009/10 Forecast at mid year	2009/10 Actual (April 09 to March 10)	Variance - mid year forecast to plan	Year End Variance (Actual to Plan)
Estates	486	26,000	26,000	36,231	0	10,231
Facilities	Included in Estates				0	0
Other (give details)	General Management	5,000	5,000	3,794	0	(1,206)
Total Host Non-Staff Costs		31,000	31,000	40,025	0	9,025

Total Host Costs

64,500 64,500 74,072 0 9,572

Executive Group Members

Role	Name	WTE	2009/10 OUR Planned Expenditure	2009/10 Forecast at mid year	2009/10 Actual (April 09 to March 10)	Variance - mid year forecast to plan	Year End Variance (Actual to Plan)
Primary Care	Dr Scott Wilkes	0.1	12,000	12,000	12,000	0	0
Secondary Care	Dr Richard Walker	0.1	12,000	12,000	12,000	0	0
Tertiary Care	Professor Steve Robson	0.1	12,000	12,000	12,000	0	0
Mental Health	Dr Roger Paxton	0.1	12,000	12,000	12,000	0	0
						0	0
						0	0
						0	0
						0	0
						0	0
						0	0

Board Chairman Professor Sir George Alberti

2,000 2,000 2,000 0 0

Total Pay Costs

364,570 371,131 361,552 6,561 (3,018)

TOTAL

435,570 438,855 455,762 3,285 20,192

The detail of the expenditure within MOs is available on the [Documents and Reports](#) section of our website

Appendix 3 – Half-year CEO report

A pdf copy of the report sent to CEOs of each MO is available on the [Documents and Reports](#) section of our website



NORTHUMBERLAND, TYNE AND WEAR CLRN

HALF-YEAR REPORT TO CEOs

Q1 Q2 Q3 & Q4

IN THIS REPORT:

- THREE REPORTS** 1
- RECRUITMENT FIGURES** 2
- STUDY SET-UP TIMES** 3
- FUNDING FOR 2010/11** 4
- INFORMING TRUST QUALITY 4 ACCOUNTS**

ACHIEVEMENTS THIS YEAR!

- NTW CLRN recruitment in 2008/9 was 10,703 and in 2009/10 it was 20,370
- Income rose from £3.4m to £8.1m and then £9.4m in FYs 08, 09 and 10 respectively
- Standing research infrastructure now established in partnership with NHS Trusts

CLRN HALF-YEAR REPORTS TO CHIEF EXECUTIVES

This is the first in a series of 6-monthly reports to Chief Executives. We are producing the reports to keep you informed of NIHR portfolio activity within your organization.

The Comprehensive Local Research Networks (CLRNs) have a remit of establishing and actively managing a world-class research infrastructure within the NHS. We are part of the National Institute of Health Research (NIHR). We do this in partnership with the NHS Trusts which are our member organizations.

We have set out in the following pages reports on the crucial parameters of NIHR activity, namely: recruitment numbers; study approval times and funding per organisation.

We note that CEOs are now required to research in the Quality Accounts for their organizations and we hope you find these reports useful in this regard. We would welcome your feedback on how we can tailor them to help you.

Tim Goodship
CLRN Clinical Director

WHAT THIS REPORT COVERS


In terms of the metrics included in this report, we have concentrated on three aspects of our remit:

- **Recruitment to portfolio studies:** The NHS Operating framework sets a target of doubling recruitment within 5 years and, of more immediate concern, recruitment drives CLRN funding through a national algorithm for activity-based-funding.
- **Study approval times:** This really matters to pharma studies and the industry agenda is a major driver for the overall agenda and funding.
- **The funding we provide to Trusts:** As this facilitates the first two.

The time-period covered is quarters three and four of financial year 2009/10. This frequency of reporting provides sufficient time for trends in metrics like recruitment or study sign-off to become apparent.

There is a lag in reporting as we compile the figures for any given time period so we propose to report twice yearly at the end of quarters one and three.

Séamus O'Neill
CLRN Senior Manager



NORTHUMBERLAND, TYNE AND WEAR CLRN

HALF-YEAR REPORT TO CEOs

Q3 AND Q4 2009/10

TOWARDS 60 AND 90 DAY TARGETS FOR STUDY SIGN-OFF

Further to discussions in the R&D Director's Away Day in January on setting targets for NHS approval times, the following targets have been proposed for study sign-off:

- 60 days for commercial portfolio studies
- 90 days for non-commercial portfolio studies

The target times are from the receipt of a valid R&D form until the issuing of a letter of permission for the trust.

In support of these targets the CLRN provides approximately £1m per annum to R&D posts across Trusts in NTW.

Our aim is to make the region more competitive as a destination for high-quality clinical research through encouraging efficiencies in the processes. The CLRN Lead R&MG Manager, Justice Smith is working with the R&D Teams in each Trust to produce a Trust action plan to improve set-up times.

Innovative approaches to local issues are being developed as CLRN-funded staff within Trusts ensure that forms and documents are submitted to R&D in a timely manner and that issues are followed up and managed proactively.

It is understood that factors outside the control of R&D Departments can cause significant delays in study sign-off. The core CLRN team are working with Trust-based staff to identify and, where possible, address these issues.

National figures comparing performance between Trusts are imminent and we will share these with you as soon as we have them.

A central element of the CLRN offering to industry is rapid and predictable study set-up within the NHS. Much of the NIHR research infrastructure income is predicated on delivering this.


Study approval times: NIHR Co-ordinated System for gaining NHS Permission - Approvals by Trust in 2009/10

The percentage of studies given NHS permission within the agreed targets for commercial and non-commercial studies

Trust	Time from R&D form submission to signed NHS permission letter					
	Commercial (Target 60 Days)			Non Commercial (Target 90 Days)		
	Q1/02	% Within Target	Q3/04	Q1/02	% Within Target	Q3/04
South Tyneside NHS FT	0	0%	0	0%	0	0%
Northumberland, Tyne and Wear NHS FT	0	0%	0	0%	7	71%
North Tyneside PCT	3	0%	0	0%	8	50%
Newcastle PCT	4	0%	0	0%	8	50%
Sunderland Teaching PCT	3	33%	4	55%	7	71%
Gateshead PCT	2	0%	4	50%	8	50%
Northumberland Care Trust	3	0%	0	0%	7	43%
Gateshead Health NHS FT	2	0%	0	0%	10	20%
Northumbria Healthcare NHS FT	1	0%	3	0%	8	50%
Newcastle upon Tyne Hospitals NHS FT	15	7%	16	0%	30	10%
City Hospitals Sunderland NHS FT	2	0%	2	0%	11	18%
South Tyneside PCT	2	0%	2	50%	7	71%
North East Ambulance Service NHS Trust	Managed through COTY CLRN					
Summary Of Approvals for the CLRN	37	8%	32	16%	113	39%

* The % within target figure includes studies not yet approved because at the time of this report they have, by definition, failed to meet the target. As 90 days have passed since the end of Q4 of 2009/10 this report includes all the studies that came in during 2009/10

The target agreed with Trusts is that, by Q3/Q4 of 2010/11, at least 50% of commercial and non-commercial studies should be signed off within 60 and 90 days respectively



NORTHUMBERLAND, TYNE AND WEAR CLRN

HALF-YEAR REPORT TO CEOs

RECRUITMENT TO NIHR PORTFOLIO STUDIES

Trust	2008/09		2009/10	
	Q1/Q2	Q3/Q4	Q1/Q2	Q3/Q4
Newcastle upon Tyne Hospitals NHS FT	2858	2474	3062	5325
Newcastle PCT	589	1320	2916	3326
Northumberland, Tyne & Wear NHS FT	156	98	505	863
Northumbria Healthcare NHS FT	331	477	1279	675
City Hospitals Sunderland NHS FT	166	212	269	294
Sunderland Teaching PCT	150	205	46	174
Gateshead PCT	153	88	66	155
South Tyneside NHS FT	83	159	104	138
Gateshead Health NHS FT	153	262	139	131
Northumberland Care Trust	210	192	197	93
North Tyneside PCT	65	97	144	86
South Tyneside PCT	62	38	36	64
North East Ambulance Service NHS Trust	0	0	23	44
Null	0	0	11	5
Total	5081	5622	8797	11373
Grand Total	10703		20170	

Patent recruitment is the surrogate marker of research activity in NIHR portfolio studies. The figures above show a healthy increase in most Trusts and, as a result, a strong performance for the CLRN overall.


This is important at both CLRN and Trust level as the national funding algorithm is driven by recruitment volume and the local mechanisms for devolving funding to Trusts are also predicated on patient numbers.

Both the local and national funding processes include a weighting to correct for study complexity.

The Executive and Board of the CLRN are mindful that headline figures at Trust and CLRN level are vulnerable to change as high volume studies come and go. We will endeavor to protect organizations from rapid shifts in funding.

Activity-based funding is a core principle of CLRN funding at national and local levels.

NTW CLRN received over £7m in activity-related funding to be deployed in Trusts in 2010-11.



NORTHUMBERLAND, TYNE AND WEAR CLRN

HALF-YEAR REPORT TO CEOs

FUNDING TO

The CLRN's remit is to provide the service support necessary for NHS Trusts to contribute to NIHR Portfolio research.

The detail on how the funding allocations are derived, and the infrastructure each Trust is providing, is available in our business plan.

Through the CLRN Board, which includes representation from each Trust, we agree and implement an activity-related mechanism for local dispersal of the funding.

	2009/10	2010/11 (Projection)
Q3 + Q4	£2,184,598	£2,121,800
Newcastle upon Tyne Hospitals NHS FT	£352,250	£378,192
Northumbria Healthcare NHS FT	£315,963	£307,356
North Tyneside PCT	As Not Primary Care Consortium	
Northumberland Care Trust	£285,276	£285,904
Newcastle PCT	£261,664	£257,750
City Hospitals Sunderland NHS FT	£215,104	£184,658
Sunderland Teaching PCT	As Not Primary Care Consortium	
Gateshead PCT	£165,278	£188,212
South Tyneside PCT	£130,818	£135,392
Gateshead Health NHS FT	£22,600	£26,830
South Tyneside NHS FT		
North East Ambulance Service NHS Trust		
Funding still to be allocated (annual figure)		£827,639
CLRN Management through CLRN Host Trust (annual figure)		£445,590
Region-wide posts funded through CLRN Host Trust (annual figure)		£868,400

It is worth noting that the projected income for quarters 1 and 2 of 2010/11 is the minimum each Trust can expect. Once the unallocated funds are disseminated the figures will rise.

TRUST QUALITY ACCOUNTS AND RESEARCH

From 1st April 2010, [www.nhs.uk](#) will require Trusts to include a statement on research within their quality accounts. Trusts are encouraged to report on areas which demonstrate commitment to research as a driver for improving the quality of care and the patient experience in relation to research. An illustrative model statement is provided at <http://www.nhs.uk/QualityAccounts>

*** Commitment to research as a driver for improving the quality of care and patient experience**

The number of patients receiving NHS services provided or sub-contracted by (provide in the reporting period) that were recruited during that period to participate in research approved by a research ethics committee was (insert number)

(provide) was involved in conducting (insert number) clinical research studies. (provide) completed (insert percentage) of these studies as designed within the agreed time and to the agreed recruitment target. (provide) used national systems to manage the studies in proportion to risk. Of the (insert number) studies given permission to start, (insert percentage) were given permission by an authorised person less than 30 days from receipt of a valid complete application. (insert percentage) of the studies were established and managed under national model agreements and (insert percentage) of the (insert number) eligible research involved used a Research Prospect. (insert number) of these studies through its research networks.

In the last three years, (insert number) publications have resulted from our involvement in NIHR research, helping to improve patient outcomes and experience across the NHS. We would be very happy to work with Trust R&D Departments to provide information on NIHR Portfolio Research for your quality accounts.

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Appendix 4 – SWOT analysis from 2009/10 Business Plan

<p>Strengths</p> <p>S1 Strong recruitment in year 1 leading to a significant increase in funding</p> <p>S2 Effective Board, Executive and Core Team</p> <p>S3 Member Organisation buy-in and commitment within R&D Departments</p> <p>S4 Established values and ways of working which are, fair, transparent, inclusive and sustainable</p>	<p>Weaknesses</p> <p>W1 CLRN remit and opportunities not well understood outside of close circle of contacts</p> <p>W2 Research culture less strong outside major teaching hospital</p> <p>W3 Relatively few local CIs on portfolio studies, particularly within Topic Networks</p> <p>W4 Little insight into the actual workload encountered by service support departments</p>
<p>Opportunities</p> <p>O1 CLRN perceived as an honest broker, providing an impetus and opportunity for change</p> <p>O2 Collegiate attitude of interactions with colleagues in MOs gives excellent platform for delivering sustainable change</p> <p>O3 Increased funding allows the influence of the CLRN to be extended across specialties</p> <p>O4 Working with SGs locally and nationally allows CLRN to intervene to support effective delivery of studies and establish a culture of performance management.</p>	<p>Threats</p> <p>T1 Major changes in funding levels in future funding rounds could destabilise capacity-building initiatives established this year</p> <p>T2 The perception of CLRN funding as impermanent remains a barrier to effective long-term planning within MOs.</p> <p>T3 Responsiveness of key systems (eg time taken to recruit staff or grant patient access across organisational boundaries) remains a concern.</p> <p>T4 Loss of key staff or inability to recruit suitable personnel in key areas (such as Pharmacy and RM&G) could be damaging.</p> <p>T5 Doubling recruitment will require an increase in the number of studies available. This assumption which may be tested by the current economic downturn (particularly for industry studies)</p>

Case Study 1 - Getting Out of the House: an example of cross-network and cross-MO working

Contributors: Claire Kelly, Research Lead, and Linda Walker, Research Nurse, Gateshead PCT: Alison Harvey, R&D Manager, Gateshead Health NHS Foundation Trust: Penny Williams, North East Stroke Research Network Manager

Study Background

Clinicians and therapy staff from Gateshead PCT and Gateshead Health NHS Foundation Trust became one of nine sites nationally to take part in this multi centre, randomised control trial led by Nottingham University. The study was adopted by the Stroke Research Network in June 2009 and tests a novel rehabilitation technique delivered by a Rehabilitation Therapist in Primary Care. The technique, which takes into account not only physical mobility, but confidence, motivation and self belief, is aimed at improving outdoor mobility after stroke. The novel rehabilitation technique (intervention group) will be compared to a usual care group (control group). Participants randomised to the intervention group receive up to twelve visits in a four month period from the community Rehabilitation Therapist where the novel rehabilitation technique is delivered. The trial is funded through the NIHR Health Technology Assessment Programme.

Working Collaboratively

Unlike other trial sites where eligible patients are identified via GP practice databases, in Gateshead eligible patients are identified via the Stroke Register which is maintained by Gateshead Health NHS Foundation Trust. This change to the recruitment strategy has been a great opportunity for the PCT and Foundation Trust to work collaboratively supported by the Stroke Research Network. Following discussions, mediated by NTW CLRN Senior Manager and North East Stroke Research Network Manager, agreement was quickly established for determining how credit for recruitment and cost attribution would be divided so the contribution of both organisations was appropriately recognised. This involved examining the patient pathway for the study to understand contributions required from all parties. ***As a result Gateshead was the first site to be initiated and recruited the very first patient into the trial in November 2009.***

Locally, procedures for identifying eligible patients have been developed and the team at Gateshead Health NHS Foundation Trust and Gateshead PCT work closely to coordinate delivery of the study with support from the North East Stroke Research Network. The aim is to recruit approximately 90 participants from Gateshead over a 12 month period with follow up planned for twelve months after recruitment. As of March 2010 recruitment stands at 7, with the expectation that this will increase considerably over coming months as we move out of the winter period during which unprecedented poor weather conditions were experienced.

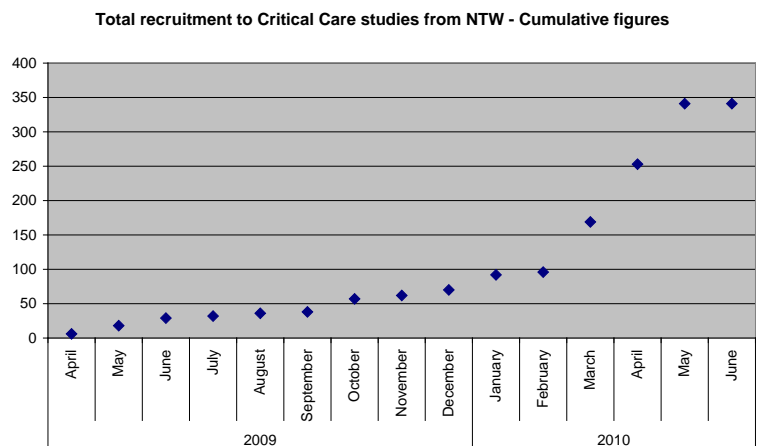
Case Study 2 - NTW Critical Care Specialty Group: A Q&A with Dr Stephen Wright

Tell us about your role with the NTW Critical Care SG

I am a Consultant in Anaesthesia and Critical Care at the Freeman Hospital, Newcastle upon Tyne. I am part of the Critical Care Specialty Group which is led by my colleague Dr Simon Baudouin. Simon and I have initiated regular SG meetings and negotiated with Trusts for access to support for NIHR portfolio studies. Crucially we have identified studies on the NIHR portfolio to which we can recruit and we are following through on getting them established within the CLRN.

The recruitment numbers in Critical Care seem to have risen significantly in 2009-10. What is making that possible?

It's down to a number of factors but, in short, the Specialty Group has managed to tap into the great interest in research that already existed within critical care but was lacking both in support and resources. Then, with CLRN funding and advice, we have succeeded in removing some of the barriers that prevented



recruitment and start recruiting to these important, multi-centre, portfolio studies.

As you and Simon established the group and the activity, what lessons have you learned along the way?

The most encouraging part of this has been the sense of opportunity and collaboration amongst the clinical community. This has been backed up by real help and support from the CLRN and the Trust R&D staff: this has really helped us overcome the barriers.

The challenge now is to maintain this momentum and develop a sustainable infrastructure for critical care research within our network. To raise awareness of portfolio research in critical care we presented at the winter meeting of the North of England Intensive Care Society. This provided access to the professionals involved with the ICU clinical network. This also had the benefit of introducing cross-CLRN interactions at the outset. We are pleased that we now have consultant representation on the SG from each of the 9 ICUs in the NTW CLRN.

We will continue to engage with colleagues through the regional critical care network and through dedicated SG meetings to explore portfolio and development opportunities. Substantive leadership of the initiative has been important in set-up and the sessions have allowed us to do that. Additional sessions for colleagues contributing to studies would be an effective way to provide practical assistance in engaging other colleagues and embedding research alongside service activity.

Our next SG meeting is in August, then every two months thereafter, our main aims are: to identify suitable portfolio studies; to facilitate study set-up and promote recruitment; and to develop our own portfolio studies.

What have been the important investments?

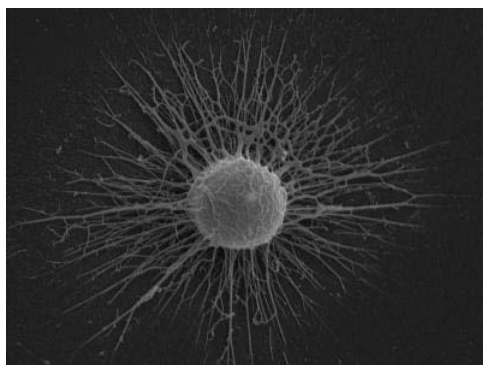
The new resource has been crucial. The availability of research nurse capacity (for example 1.5 FTE in my own Trust with the appointments of Micheala Allsop and Charley Higham) have allowed us to progress rapidly through study set-up and then recruit well to a number of studies. Allied to that, the two consultant sessions awarded to the Critical Care Group have allowed dedicated time for research to be included in Consultant job plans.



What is your strategy for targeting studies to which you might recruit?

We are trying to establish a balanced local portfolio – a combination of complex trials and simpler studies to provide opportunities for all units. For

example, we are currently recruiting approximately 30 patients per week to a study on fungal infection, the **FIRE** Study. Currently, this is open on ICUs at the Freeman and RVI sites and we hope to open soon on other units in the network.



***Cryptococcus neoformans* - a target of the FIRE study**

SWIFT, a swine flu triage study run through ICNARC (the Intensive Care Audit and Research Centre) is similar to FIRE in that it is a relatively low intensity study. This study, along with others, has allowed all Trusts in NTW CLRN that have ICUs to register recruitment. Hence, the Blue Report has returns for all possible sites under Critical Care.

PROMISE is at the other end of the complexity spectrum. It is a study of early goal-directed resuscitation in patients with septic shock and is a complex and high intensity study with 24-hour cover required. The Critical Care SG are seeking to roll this out CLRN-wide as part of the hub and spoke model envisaged within the study design. The group are hoping to be one of 8 national groups of 6 hospitals contributing to the study which will require close collaboration between critical care, acute medicine and emergency medicine departments. Local leads have been identified from these 3 areas in all 6 hospitals. Clearly the organisational advantage afforded by the SG will be important to the success of this trial. The study is currently awaiting ethical approval.

We are also looking to open a number of other studies including the **OSCAR** study - an interventional trial of high frequency ventilation in acute lung injury – which is already taking place in Gateshead is currently with the NUTH R&D office for site approval.

And have you had interactions with the National SG?

The National SG has rapidly established under the chair of Tim Walsh. We recently presented a progress report for our SG and we seem to be doing pretty well. One thing that my colleagues at national level are very impressed by was the Clinical Research Associate initiative, and we are absolutely delighted to have been awarded one of these posts. It will provide an excellent opportunity for a senior intensive care trainee will make a big difference to what we can do over the next year. With the of the support from the National SG, NTW CLRN, the local R&D departments, the hard work of our research team, and the enthusiasm of our clinical colleagues I am hopeful we can have a successful 2010-11.

Case Study 3 – NTW Renal SG: the impact of CLRN investment

	Portfolio studies active		Total recruitment
	Non-commercial	Commercial	
2008/09	2	0	129
2009/10	3	2	742

Professor Neil Sheerin is a consultant Renal Physician and the Renal SG lead for NTW. Below Neil has identified a number of factors that have contributed to the group’s ability to increase activity.

The fact that I, and consultant colleagues, have been able to spend time engaging with the portfolio and encouraging clinical teams to get involved has been an important component of the increased recruitment that we are now seeing. Dr Suren Kanagasundaram and I were awarded **PAs** by the CLRN and job-planning these have allowed us to provide leadership at both the strategic and study level.

Then the appointment of a dedicated renal **research nurse**, Mark Playford, added very significantly to our ability to recruit to portfolio studies through the renal clinics in NUTH.

The interactions through the CLRN have been helpful in allowing us access to studies that might not otherwise have come to Newcastle. The **visibility and accessibility of commercial trials** requiring additional sites has allowed willing clinicians to get involved in studies they might not otherwise have known about. The national system for dissemination of industry studies and Karen Hutchinson’s introduction of two CCRN industry studies have allowed the clinicians at the Freeman Hospital to engage with the national industry agenda.

The activity driven nature of the metrics and resourcing is something we are comfortable with and it is readily understood by colleagues. We keep a close eye on the metrics and we are encouraged by the trajectory. We have established and communicated a clear **SG strategy**. Our priority for 2009/10 was to get the people and processes in place and develop our levels of activity. We have done that and now we are seeking to press ahead. We are actively seeking to engage colleagues outside of The Newcastle upon Tyne Hospitals NHS FT. Have identified leaders at other sites, notably in City Hospitals Sunderland, opening studies there is the objective for 2010. We are also looking for ways to link our activity to sites in Teesside and Carlisle, so our efforts at cross-CLRN working are looking as though they will soon come to fruition.

We have developing **links with Primary Care** and Clare O’Loughlin, the CLRN-Funded R&D Manager within North Tyneside PCT has helped us to identify GPs with an interest in Renal research. These GPs are reviewing studies on our behalf in order to determine whether we could recruit through Primary Care practices or identify patients through screening the practice databases. Clare is coming along to our next SG meeting to discuss these issues.

Challenges remain however:

The sessional support has been an important intervention by the CLRNs, it sends out the right signals in terms of embedding research alongside clinical practice, but it is still exceptionally difficult to identify and secure backfill for clinical sessions even where funding is made available by the CLRN.

There is also a tactical issue around the deployment of sessions awarded. The benefits of concentrating the sessions in the job-plans of a few highly research active consultants needs to be balanced with the potential benefit of achieving wide-spread buy-in through a broader approach to distributing sessions that could result in engagement of colleagues across the specialty. But, overall, there is real enthusiasm amongst my colleagues for this and we need to find a way to address this balance. The preferred option of the College is that we find a way to embed research within the service delivery, so that both benefit. That has got to be the goal and is certainly consistent with the aspirations of the NHS.

Most frustratingly perhaps is the need for high levels of admin support for non-commercial portfolio studies. Commercial studies work well, but national non-commercial studies still require a lot of time and often have an overly complex approval process. There is still a risk of disenfranchising would-be investigators because of this.

Case Study 4 - Creating the infrastructure in a large research active teaching Trust

Background

The Newcastle upon Tyne Hospitals NHS FT (NUTH) is the most research active NHS Trust in NTW CLRN. NUTH is a large teaching Trust with a broad and complex portfolio of studies. Staff in the Trust recruited approximately 8000 patients to NIHR portfolio studies in 2009/10.

This section provides two perspectives on the 2009/10 activity in establishing and integrating CLRN research infrastructure within NUTH. The RM&G insights were provided by Amanda Tortice then Paddy Stevenson sets out the work undertaken to establish a comprehensive research infrastructure to support delivery and describes how this has been integrated with the already very active research environment.

Expanding RM&G capacity in NUTH

From Amanda Tortice: Research Operations Manager for the Joint Research Office

Developments in healthcare through translational medicine are key for the strategic direction of both the Trust and University and we are all passionate about our role in facilitating this. There is a clear and developing alignment of Trust research strategy activity and the NIHR objective of establishing research as a core component of NHS activity.

Effective and efficient RM&G provision for portfolio studies is central to the NIHR vision of a world-class research infrastructure in the NHS. We have viewed the transition from Culyer funding as an opportunity to rethink structures and provision. The 2009/10 period has therefore been a very busy time for us in terms of staff recruitment and training.

We have around 250 portfolio studies active at any given time and the complexity of the studies for which



we are responsible means that we see an intensity around study set-up and management that is matched in few organisations. We are sponsor for approximately 20 CTIMPs at the minute.

Within The Newcastle upon Tyne Hospitals NHS FT, RM&G is delivered by the Joint Research Office (see photo), a collaboration between the Trust and Faculty of Medical Science of the University of Newcastle.

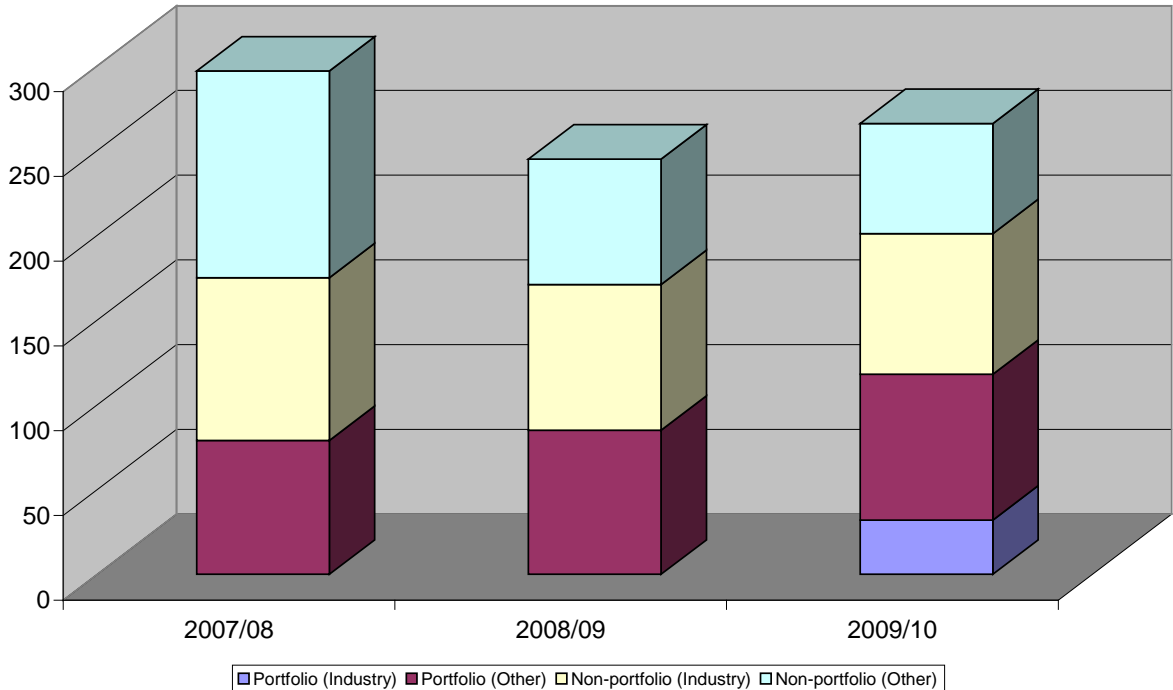
To deliver the NHS requirements, we have 7 staff in post (plus two vacancies) and plans to secure funding for an additional team of 3 have already been successful. This is a major expansion for us but one that we welcome. We recently had a successful MHRA inspection – their final report (unusually for them) commented that the team was smaller than in comparator institutions and they were reassured that there were plans in place to expand the team.

While we are very grateful for the funding, our relationship with the CLRN is more than that. We disagree sometimes but there is no doubt that there is a sense of a common purpose and of us 'being in this together'.

One interesting and encouraging trend is that we have seen a moderate increase in the number of commercial studies we have had in the last three years. This is counter to the national figures and we take this as evidence that the companies are happy with the service we provide throughout the project life-cycle.

The graph below gives a breakdown of the studies we have had over the last 3 years.

Newcastle upon Tyne Hospitals NHS FT studies by category



You will note that:

- Delivery of commercial portfolio studies is now a significant component of Trust research activity
- The numbers of non-commercial portfolio studies has remained static - at an already high level
- The 'Other' category – mainly own-account – has fallen following the introduction of an own account policy within the Trust. This prioritises high-quality, externally funded research. The Trust maintains its commitment to supporting high-quality own account research (such as Trustees' funding and local charity) as pump-priming vehicles for larger applications.

The infrastructure for delivery

From Paddy Stevenson: NIHR Operations Manager NUTH

This Trust has a long and proud tradition of clinical research and the changes over recent years to NIHR funding streams, and in particular the CLRN funding, has allowed us to put in place the infrastructure we believe is required to realise the vision of the NHS as a world-class research provider.

NUTH is the regional powerhouse for clinical research and the interaction between the University and NUTH is a key element of the research environment. One of the challenges was the need to merge the delivery infrastructures across a range of areas and to manage the separate funding streams within very different managerial environments.

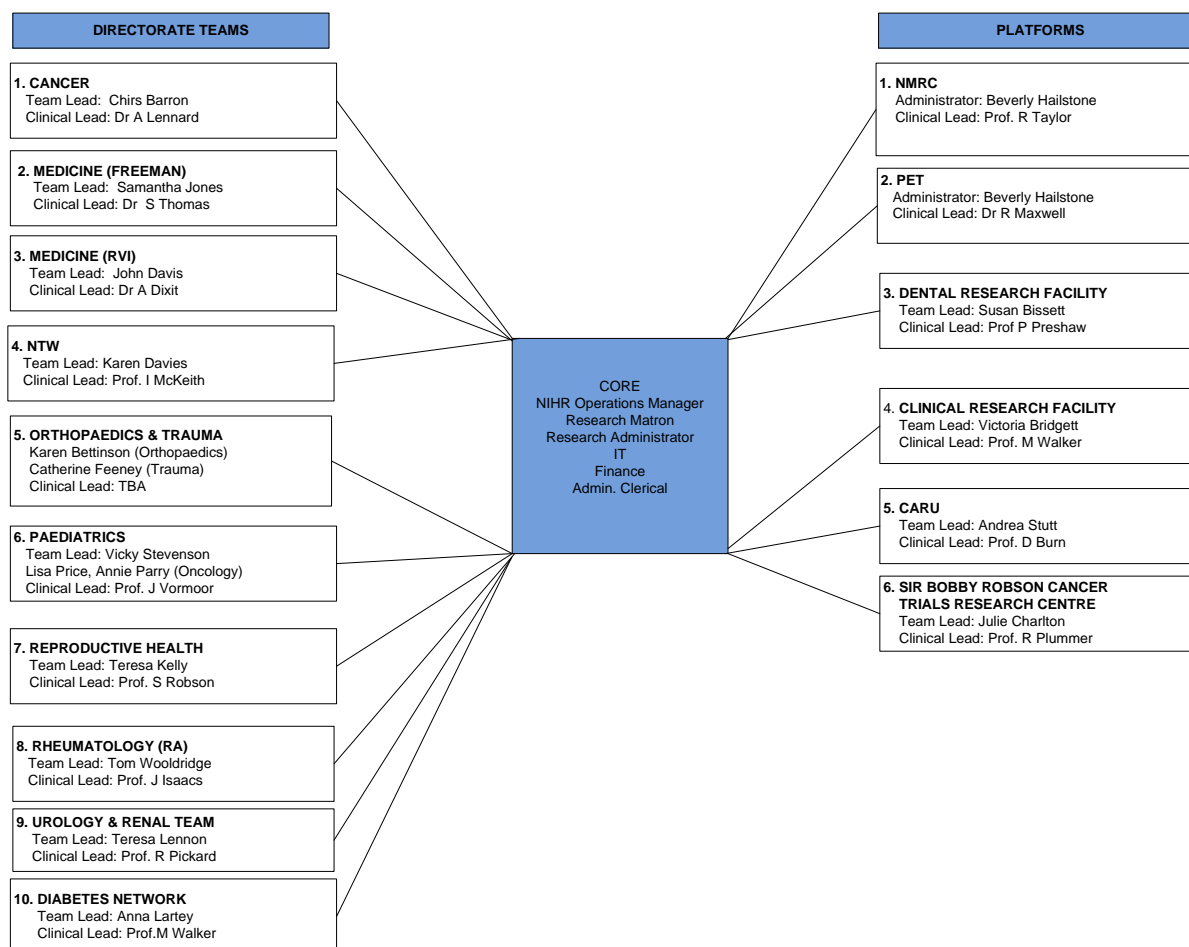
The work we have done in 2009/10 has embedded a number of **cultural changes** within the clinical research environment. For instance, the concept of investigators having access to service support as opposed to service support costs has been a fundamental shift. Service support is now embedded in the Trust; it is no longer a funding stream to PIs and CIs. The funding to teams and service departments is clearly identifiable and linked to activity. Delivery teams are multi-disciplinary and can now be properly supported and professionalised. The research nurses, CTOs and data managers can cross-cover and if necessary move between disciplines to meet the demands of fluctuating levels of activity. Service support requirements are assessed for each study within the Trust and advice is provided on best approach. Often the initial request for a research nurse may not necessarily be what is needed and we will consider with the investigator whether data-management or CTO time might be more appropriate.

The scale of the CLRN investment in NUTH and the number of posts to be established brought its own challenges but our strategy was clear from the outset. In line with the existing Trust strategy for support of clinical research we would invest in platforms and teams to flexibly support areas of research activity. Some of these areas have a clear physical presence such as the Clinical Aging Research Unit or the Sir Bobby Robson Cancer Unit. Other areas of activity such as Musculoskeletal, Respiratory and Cardiovascular are better supported by teams that are close to the PIs.

This concept of **professionally supported platforms and teams** has benefited greatly from the CLRN investment and it delivers:

- Mobility and cross-cover between and within teams
- Security of tenure for research support staff
- Clear communication channels for support and professionalisation of the research workforce within the Trust
- Coordination of training, development and career progression within Trust structures
- Ability to link study management and performance to resource deployment

- A standing infrastructure of high quality as an easily communicated offering to industry partners as they seek to place studies



The schematic above illustrates the infrastructure we have developed in 2009/10 with CLRN support. It is gratifying to see the teams now taking ownership of identifying portfolio studies, ensuring recruitment to time and target, and contribution to bids for funding (as well as being a credible mechanism for the delivery of these bids). 2009/10 has seen a huge amount of effort within NUTH to set up CLRN funded infrastructure and to integrate that with the existing structures and capacity. It has involved management of structural, organisational and cultural change, but ***the capacity created is a once in a generation opportunity for clinical research in the North East.***

Case Studies Submitted



Getting Out of the House: an example of cross-network and cross-MO working



Multi centre, randomised control trial led by Nottingham University and funded by HTA.

SRN-adopted study to test a novel rehabilitation technique delivered by a Rehabilitation Therapist in Primary Care

Patients identified and recruited in secondary care but intervention and support also required in primary care

CLRN brokered agreement process to examine the patient pathway for the study to understand contributions required from all parties. SRN, Gateshead Health NHS FT and Sunderland Teaching PCT took part

Agreement was reached and Gateshead was the first site to be initiated and recruited the first patient into the trial in November 2009.

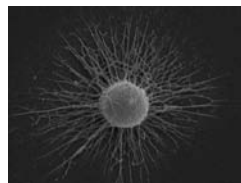


NTW Critical Care SG: the challenges of raising awareness and promoting activity



Critical Care research in NTW

- Starting from a low base
- Infrastructure and coordination required
- Effective and Enthusiastic leadership identified



Aspergillus - a target of the FIRE study



Investment through member organisations in 2009/10

- Sessional support to research leads
- 1.5 research nurse FTEs in large teaching trust
- Access to generic data management and CTO time within MOs
- Support from CLRN Core Team in establishing the SG

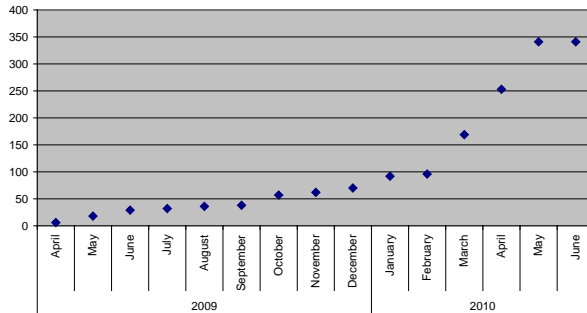


NTW Critical Care SG: the challenges of raising awareness and promoting activity

Resulting in:

- Significant levels of recruitment to Critical Care studies
- Broad engagement across Member Organisations - Recruitment reported by all ITUs in NTW
- SG actively screening the portfolio and opening studies

Total recruitment to Critical Care studies from NTW - Cumulative figures



	Studies	Sites
2008/09	0	0
2009/10	2	5



NTW Renal SG: Identifying and addressing barriers to recruitment

Renal research in NTW

- Significant historical activity but localised
- Infrastructure and resource required to increase participation
- Effective and enthusiastic leadership identified

Investment through member organisations in 2009/10

- Sessional support to research leads
- Full time research nurse at most active site
- Access to generic data management and CTO time within MOs
- Support from CLRN Core Team in establishing the SG



**NTW Renal SG:
the challenges of raising awareness and promoting activity**

Resulting in:

- Substantial increases in recruitment to Renal studies
- SG actively screening the portfolio and opening studies
- SG actively seeking to involve new sites in the region
- Two CCRN industry studies now active

	Portfolio studies active		Total recruitment
	Non-commercial	Commercial	
2008/09	2	0	129
2009/10	3	2	742



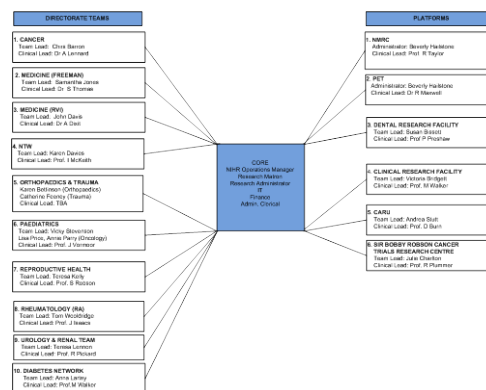
**Delivering a world-class research infrastructure
within The Newcastle upon Tyne Hospitals NHS FT**

2009/10 delivery highlights in NUTH

- Delivery funding - £4.2m
- Recruited - 8000 patients
- Established a comprehensive and versatile delivery infrastructure

**Multi-disciplinary research platforms
and teams**

- Available to undertake commercial and non-commercial portfolio studies
- Staff mobility and cross-cover
- Professionalisation of the research workforce
- Security of tenure for research support staff
- Coordination of training and career development
- Links study management and performance to resource deployment



Resulting in:

A standing infrastructure of high quality as an easily communicated offering to industry and other partners as they seek to place studies