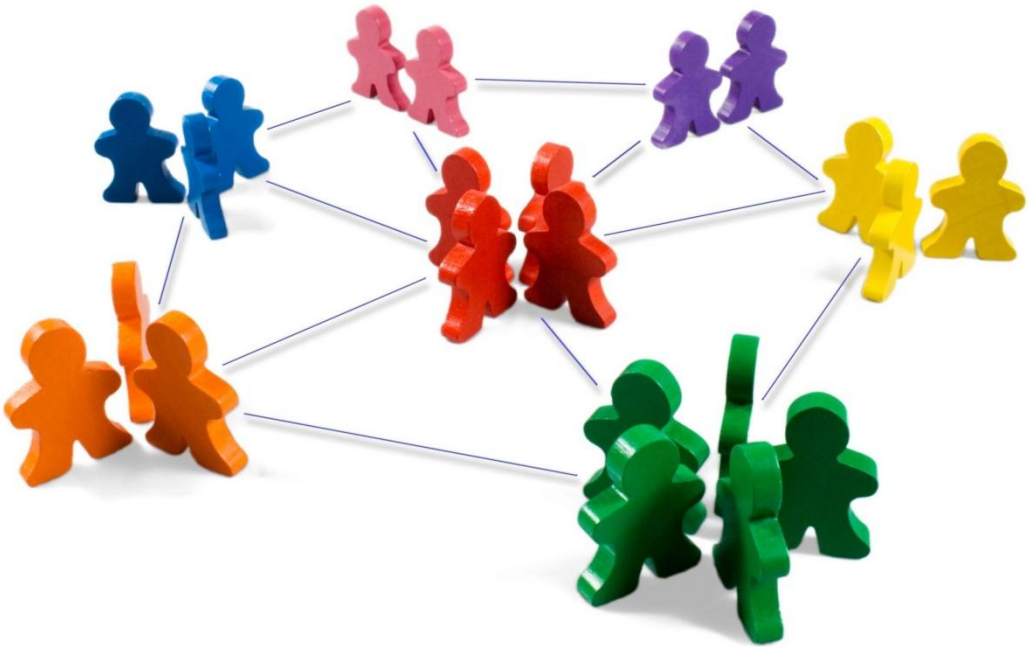
NORTHERN IRELAND
CLINICAL RESEARCH NETWORK



Annual Report
2010

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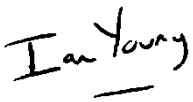
1 Director's Introduction

The aim of the Northern Ireland Clinical Research Network (NICRN) is to facilitate the delivery of clinical trials and other high quality clinical research in Health and Social Care. NICRN is one of the UK's clinical research networks, and its existence is essential to ensure that patients in Northern Ireland have access to new and experimental treatments in the same way as patients elsewhere in the UK.

Over calendar year 2010, a total of 95 studies have been adopted or run by NICRN staff, and 6876 patients accrued into these studies. There is copious evidence that participation in clinical research improves outcomes for patients and creates an environment which attracts and retains high quality healthcare staff. In addition, a strong clinical trials infrastructure helps to attract inward investment and assists the development of local enterprises. For all of these reasons, it is important that patients throughout Northern Ireland have the opportunity to participate in research studies and to benefit from the improvements in clinical care which result. The establishment and growth of NICRN helps to ensure that this is the case.

Many studies are ongoing, and will not have their full impact for some time, but already patients have been able to access treatments which would not otherwise have been available to them through participating in network research. Thanks are due to all of the staff whose hard work has contributed to this success, but above all to those patients who have agreed to take part in these studies.

While these figures above are impressive, the network is now running at close to saturation and further expansion will require the investment of additional income from commercial funders. This will be a significant goal for 2011.



Prof. Ian S.Young

Director, Northern Ireland Clinical Research Network

2 Background

2.1 The Northern Ireland Clinical Research Network

The Northern Ireland Clinical Research Network (NICRN) was established in 2008 to support the contribution of the clinical research community in NI to the work of the UK Clinical Research Collaboration (UKCRC) and the associated clinical research networks (CRNs).

NICRN MISSION

Our mission is to develop and enable a well resourced network of skilled staff which provides investigators and patients from throughout Northern Ireland with access to and help in developing high quality clinical research studies across all Health and Social Care (HSC) structures.

We aim to:

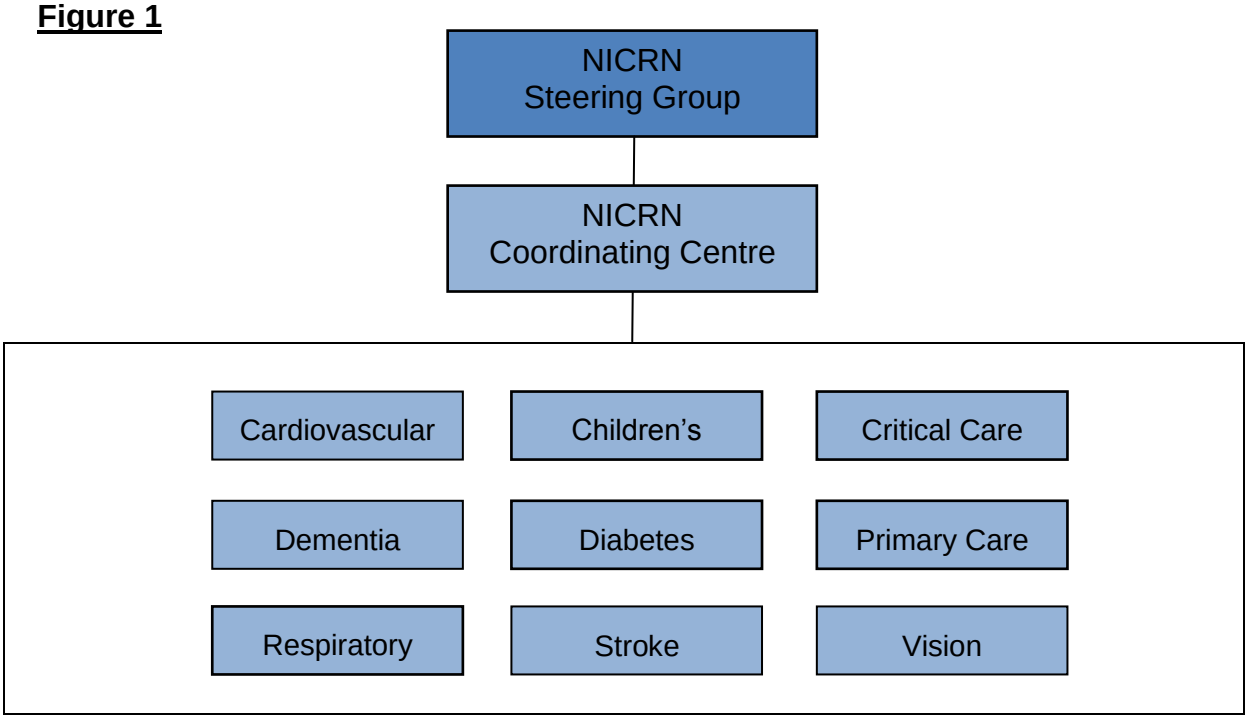
- Enhance the ability of patients and Health care professionals to participate in and benefit from clinical research
- Enhance the quality of clinical research undertaken within HSC
- Improve the speed of delivering research outcomes
- Enhance the regional coordination of clinical research across Trusts and academic organisations
- Improve local integration of clinical research within HSC structures and services

When NICRN was established, it was decided that the most efficient model for delivering this mission was via a managed thematic clinical research network. This brings together existing R&D structures and personnel with proven track records in disease areas of particular relevance to HSC. These groups also broadly map with the topic groups from other UK nations, therefore allowing easy integration of NI network structures into national models. This approach, along with the establishment of complementary NI R&D supporting structures such as the Northern Ireland Cancer Network, local accredited Clinical Trials Units (CTU's) and Clinical Research Facilities (CRF's), would aid NI researchers in their ability to design and conduct clinical research within the HSC environment to the highest national standards.

2.2 NICRN Components

The NICRN is composed of a strategic Steering Group, a central regional Coordinating Centre and nine disease-specific clinical Interest Groups. This thematic approach to support was adopted in line with established NI strengths in clinical research and to facilitate common UK wide working processes.

Figure 1



2.2.1 NICRN Steering Group

Overall strategic direction and oversight for NICRN are the responsibility of the NICRN Steering Group which meets on a biannual basis. This is made up of the clinical leads from each Interest Group and representation from other NI stakeholders such as the principal funder (Health and Social Care R&D Division; HSC R&D), NI cancer network, regional clinical trials pharmacist and other co-opted members from the NI clinical research community (Appendix 1).

NICRN Steering Group functions;

- To provide guidance, oversight and strategic direction to the NICRN
- To act as a regional platform enabling discussion of the continued development of NI research capabilities
- To highlight blocks to progress and provide direction on solutions
- To enable high level agreement on financial investment

2.2.2 NICRN Coordinating Centre (NICRN CC)

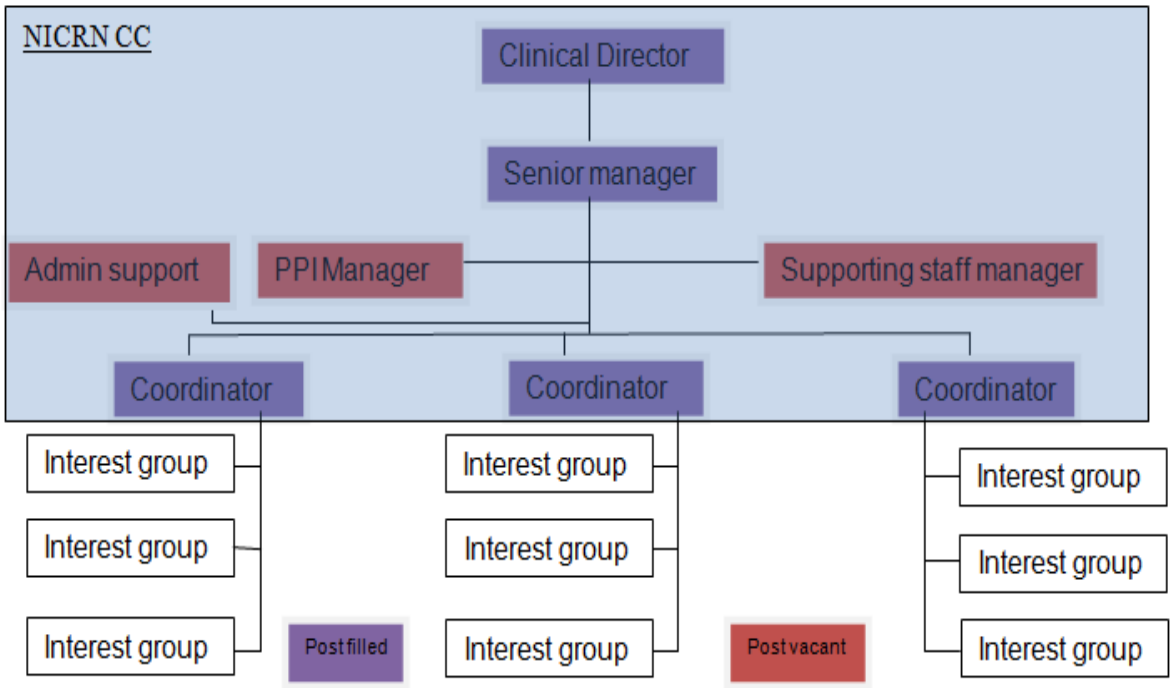
The Coordinating Centre provides support functions to the Interest Groups:

- Administration and support to help meet local portfolio management requirements
- Establishing and supporting links at UK wide level
- Enabling coordination of interest group activities, adoption of studies, collection and ongoing management of accrual data
- Recruitment and selection of staff
- Performance management of interest groups
- Financial management in line with agreed spending strategy

The NICRN CC is hosted by the Belfast Health and Social Care Trust (BHSCT), which as the largest research active trust within NI, places the coordinating centre within relatively easy reach of the majority of network staff, health care professionals interested in participating in clinical research and the patients/participants.

NICRN Coordinating Centre Organisational chart

Figure 2



2.2.3 NICRN Clinical Interest Groups

These are multidisciplinary groups of clinicians and other health care professionals with a critical mass of interest in research in a specific disease area and with access to a patient population of sufficient size to enable recruitment to local and national studies. Currently Interest Groups include:

1. Cardiovascular
2. Children's
3. Critical Care
4. Dementia
5. Diabetes
6. Primary Care
7. Respiratory
8. Stroke
9. Vision

Although this approach does limit access to network resources, investigators working in other disease areas are encouraged to participate using the existing managed network Interest Groups.

Each NICRN Interest Group has four main roles:

1. **To recruit and manage the care of patients enrolled on clinical studies**
2. **To provide scientific direction by choosing and / or designing studies that will be run by that group**
3. **To develop a balanced, skilled workforce capable of delivering group activities in line with objectives**
4. **To ensure equality of access to high quality research projects for all NI patients**

Where the NICRN Interest Groups overlap with those established in other UK nations, appropriate linkages are developed via clinical lead and senior management participation at national steering group level to ensure full NI participation and a UK wide approach. This includes contributing to the development and conduct of studies in the UK portfolio, training of research staff, development of common processes, and reporting of performance measures. At present, comparable structures do not exist on an all-Island basis, but it is hoped that these will be developed in the future.

Each Interest Group has its own Clinical Management Group (CMG, Appendix 2), and central to each group's objectives is that the CMG should have representation across all five HSC Trusts where possible. This inclusive approach supports research across the region and facilitates access to high quality research for all NI patients.

The CMG comprises a chair, who generally is a lead clinician or academic investigator within the specialty, representation from nursing and Allied Health Professions (AHP's), lay/Patient/Public involvement and NICRN Coordinating Centre representation.

2.3 NICRN Clinical Interest Group Performance Measures

To ensure a strong programme of activity and therefore efficient use of the core staffing resource, each Interest Group is set a series of annual objectives in line with UK CRN topic groups.

The metrics recorded are broadly indicative of the groups' responsibilities for the ongoing development of the overall network, including their relationship to commercial organisations in pharma and biotech industries, working relationships with the Coordinating Centre, developing a portfolio of high quality studies and a regional approach to undertaking research.

Performance measures are agreed with each group via meetings between the NICRN Clinical Director, the Coordinating Centre Senior Manager and the groups' clinical leads. The outcomes of these meeting are then cascaded to the relevant CMG members for discussion with any interested parties in HSC. The objectives for each group are based on activity, staffing levels, previous outcomes and planned developments for forthcoming year.

Table 1

Objective		Comment	Groups
1. Portfolio			
1.1	Number of studies adopted	3-6 per year. Ongoing levels of activity will be considered when setting target each year	All Groups
1.2	Percentage of commercial studies	Info gathering	All Groups
1.3	Percentage of studies at two or more clinical nodes	15% - 50% target.	Except Vision and Respiratory groups
1.4	Percentage of studies for each of five Trusts	Info gathering	All Groups
1.5	Percentage of RCT's	Info gathering for support on quality of portfolio	All groups
2. Accrual			
2.1	Percentage of studies meeting/exceeding target recruitment	50% target. Both the monthly and cumulative recruitment will be recorded.	All Groups
2.3	Numbers of people recruited to studies	Info gathering to be tied to annual increase	All Groups
3. Speed			
3.1	Completion of recruitment on or ahead of schedule	50% target	All Groups

Within HSC structures, the delivery mechanism for specialised services which exist as regional referring centres has made achievement of regional targets for Dementia, Respiratory and Vision Interest Groups problematic. In these areas, recruitment of patients from all five Trust areas is a more realistic goal. However, in the key areas of study adoption and subject accrual all groups are performing well.

2.4 NICRN Staffing Levels

During the development phase of the NICRN, each Interest Group proposed staffing levels in line with their projected activity. As the development of a clinical research network had been identified as a central strategic goal by HSC R&D, they have invested to support core staffing levels in line with those proposals.

Achieving a full complement of staff has been a focus for the NICRN over the past 12 months. This has broadly been achieved as can be seen from the table below.

Table 2

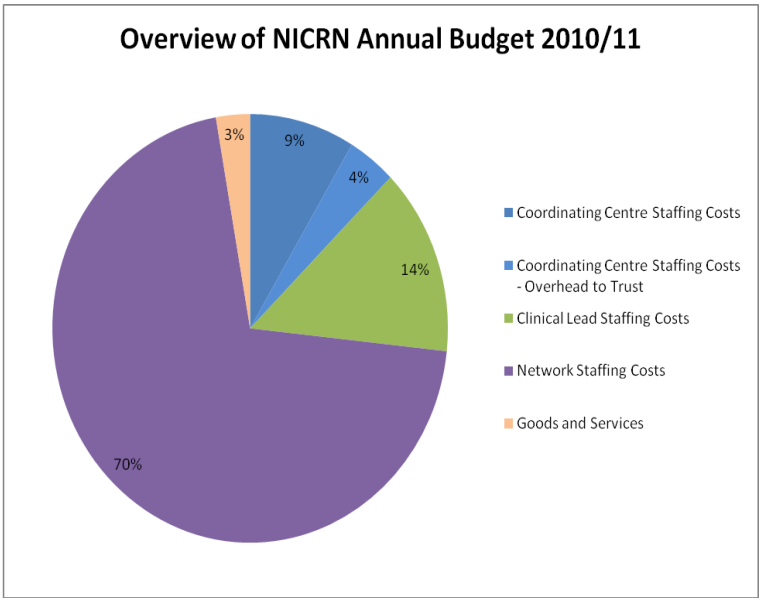
Interest group	Clinical PAs	I.G Staff Target	Staff in post
Cardiovascular	2	4.0	4.0
Children's	2	2.5	2.0
Critical Care	2	5.5	5.5
Dementia	2	2.0	2.0
Diabetes	2	4.0	3.6
Primary Care	2	2.0	2.0
Respiratory	2	4.0	4.0
Stroke	2	4.5	4.5
Vision	2	4.0	4.0
NICRN CC		4.0	3.5
TOTAL	**18**	**36.5**	**35.1**

2.5 NICRN Finance Overview

The NICRN is financially supported by HSC R&D. Along with the Coordinating Centre, HSC R&D funds a cadre of core staff, mainly nursing and AHPs, to allow each group's objectives to be achieved. They also support the clinical leads by funding protected time (programmed activities – PAs) to enable the development of their specific Interest Group activities and the NICRN Coordinating Centre.

Separately from the NICRN, HSC R&D also fund core staff in Trust R&D offices along with pharmacy and finance services across the 5 NI Trusts. This support enables the network to be embedded in a cohesive matrix of staff designed to facilitate study set up, approval and conduct throughout NI's HSC structures.

NICRN financial management is principally achieved through the Coordinating Centre. Budgets are agreed between the NICRN CC and HSC R&D. These are set in line with group objectives and requirements. The core staff are employed by host organisations but funded via HSC R&D, with the NICRN CC liaising between funder and Interest Group to justify expenditure for specific activities. The NICRN CC is also the processing body for costs incurred by Interest Groups such as essential travel, training, education and ICT. As the Coordinating Centre is hosted by BHSCT, an overhead of 46% is placed on all staff salaries within the Coordinating Centre.



As hosting organisations incur costs associated with this function, an 8% fee on all staff salaries is made available to employing Trusts to encourage clinical research and to offset any administration costs. This is agreed and funded by HSC R&D as part of overall Trust involvement in hosting NICRN staff.

A more detailed breakdown of HSC R&D spend on NICRN across each Trust is given in Appendix 3.

2.6 NICRN Portfolio and Accrual Data

Study portfolio and patient accrual are the key performance targets applied to clinical Interest Groups. Table 3 illustrates the overall NICRN portfolio and accrual as well as providing detail across Interest Groups. The highlights are that in calendar year 2010 a total of 95 studies were run by NICRN staff and 32 of those studies were newly adopted during the year. Of the 9850 patients accrued in total into these studies, 6876 of those patients were accrued during 2010. A more detailed listing of each group's portfolio is provided in Appendix 4

Table 3

Interest group	No. Studies Adopted (2010)	Total Patients Accrued (2010)
Cardiovascular	17 (3)	1123 (1058)
Children's	12 (4)	1136 (1007)
Critical Care	9 (3)	1344 (986)
Dementia	5 (1)	529 (199)
Diabetes	13 (6)	3540 (2231)
Primary Care	9 (0)	836 (294)
Respiratory	13 (5)	183 (149)
Stroke	10 (4)	289 (228)
Vision	7 (6)	870 (724)
TOTAL	**95 (32)**	**9850 (6876)**

2.7 NICRN Study Adoption Process

To ensure consistency and transparency, a formal adoption process for studies has been agreed by the NICRN Steering Group. This process, as illustrated in Appendices 5 and 6, first collects a data set which allows the relevant CMG to provide an initial response to the study proposal. In line with other national networks, the NICRN provides a 14 day turnaround time for commercial proposals. The data set collected in Section A, Appendix 6, also provides the relevant detail for inclusion of NI initiated studies on to the UK portfolio. If a CMG approves the proposal, then the clinical lead must provide the Coordinating Centre with a list of interested sites in NI (Section B). These sites then complete a local feasibility assessment including patient population, study intensity, and staffing capacity along with finance, accommodation, access to other support services such as pharmacy, labs, radiology etc (Section C).

If the study is judged as feasible by the CMG then the paperwork is signed off by the Clinical Director and formally adopted onto the NI portfolio (Section D). This process and the subsequent ongoing accrual activity is then managed by the relevant Interest Group Coordinator and administrated by the Coordinating Centre.

3 Clinical Interest Group Activity

In line with the other UK nations, the network as a managed structure sets targets for clinical Interest Groups. Within NICRN we have broadly accepted the initial NIHR CRN metrics and used these since 2008 to review progress and set new targets.

3.1 NICRN Cardiovascular Group Activity for 2010

The Cardiovascular Interest Group is led by Prof Frank Kee and Dr Donna Fitzsimons, and currently has 4.0 WTE staff spread across the WHSCT, NHSCT, SEHSCT and SHSCT with an additional study-specific 0.2 WTE in BHSCT, equating to an overall group staff spend, excluding Clinical Lead costs, for 2010 of £125,021. In 2010, the group was involved in 17 studies of which 5 were adopted during the year. These include the use of novel biomarkers in the rapid diagnosis of acute coronary syndrome, international collaborations examining the most effective treatment for unprotected left main stem stenosis and the use of novel techniques such as cardiac CT as a first line investigative tool for the assessment of patients with suspected coronary artery disease.

As can be seen from the following graphics, this group has essentially met its objectives for 2010. Five new studies were adopted during this period. Their portfolio is strongly weighted in favour of commercial activity with 71% being commercially sponsored and or funded. Almost 88% of the studies are Randomised Controlled Trials (RCT's) (82% Clinical Trials Investigational Medicinal Product, 6% CT OTHER) with 2 studies (12%) being observational. In 2010, 1058 patients were recruited into 17 studies.

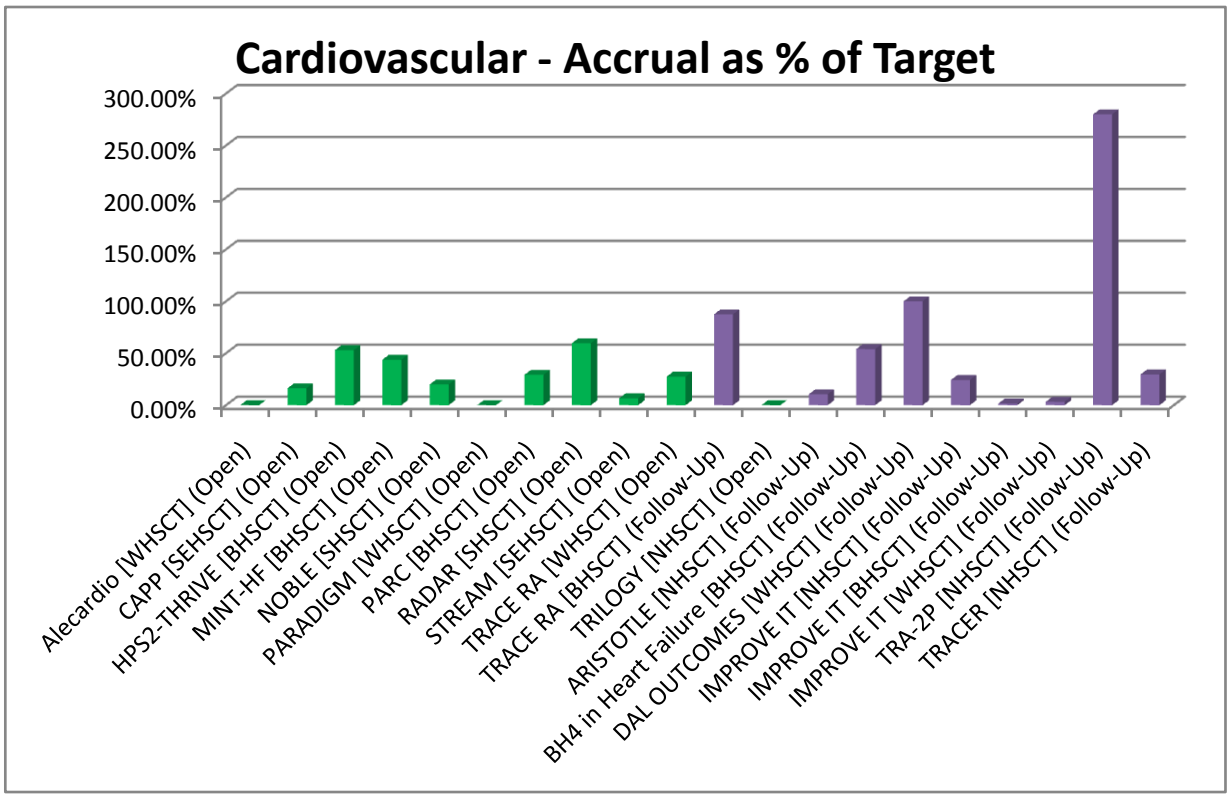
Cardiovascular Objectives

Table 4

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted	Agreed to adopt 2 studies in 2010		
1.2	Percentage of commercial studies	Agreed to maintain a 50% commercial portfolio		
1.3	Percentage of studies at two or more clinical nodes	Agreed to meet a 20% target for 2010.		Cardiovascular group achieved 35% of portfolio as multi centre studies.
1.4	Percentage of studies for each of five trusts	Info gathering	BHSCT=35% NHSCT=29% WHSCT=29% SEHSCT=12%	BHSCT did have research nurse resource over first 6 months of 2010; this resource has now left and will not be

			SHSCT=12%	replaced. SHSCT has only been in network since Nov 10
1.5	Percentage of RCT's	Info gathering	88%	
2. Accrual				
2.1	Percentage of studies meeting/exceeding target recruitment	Agreed to achieve 20% target in 2010.		
2.2	Numbers of people recruited to studies	Info gathering	1058	
3.0 Speed				
3.1	Completion of recruitment on or ahead of schedule	Agreed to remain at 50% target	All studies still actively recruiting or in follow up	

Figure 3



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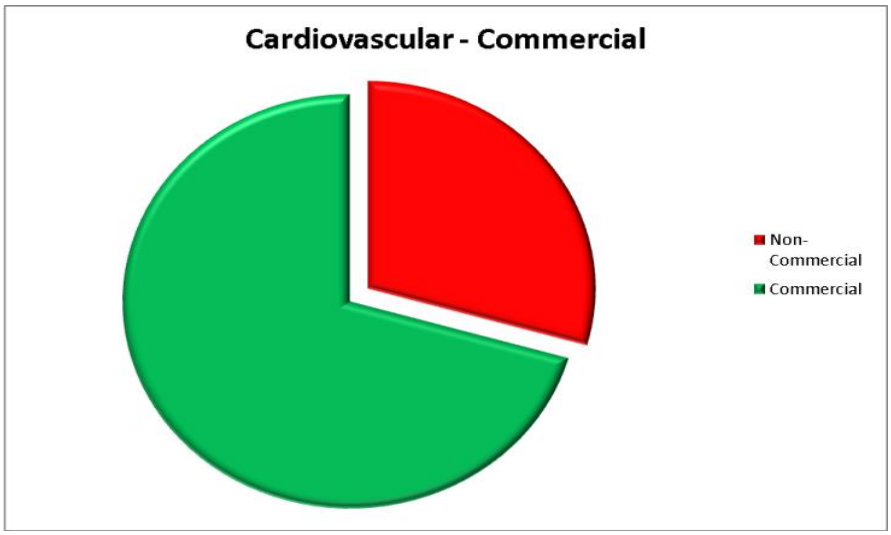

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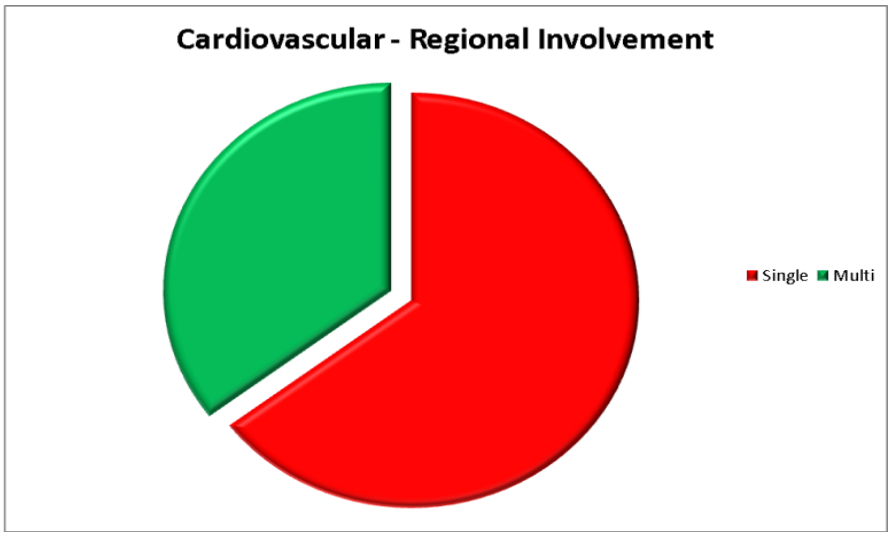

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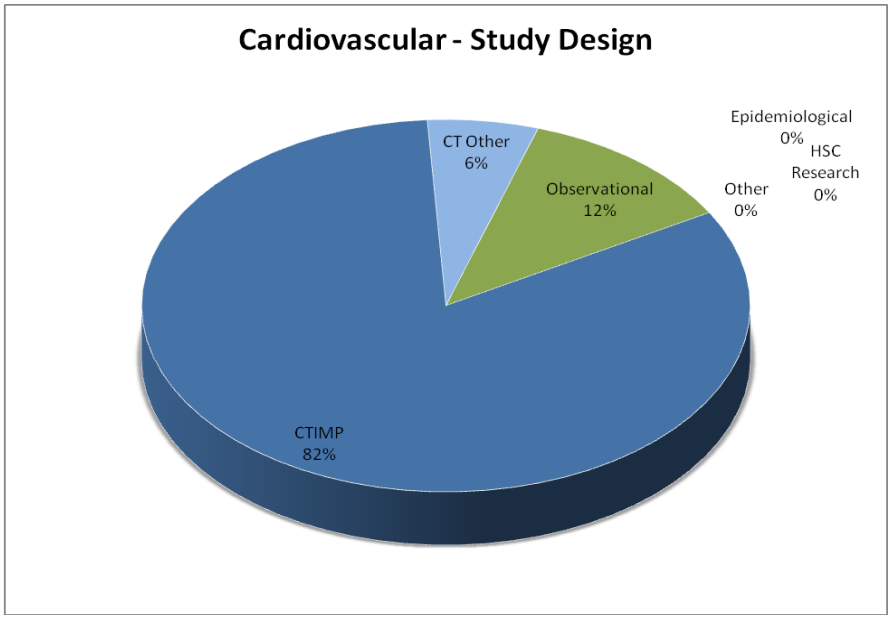


3.2 NICRN Children's Group Activity for 2010

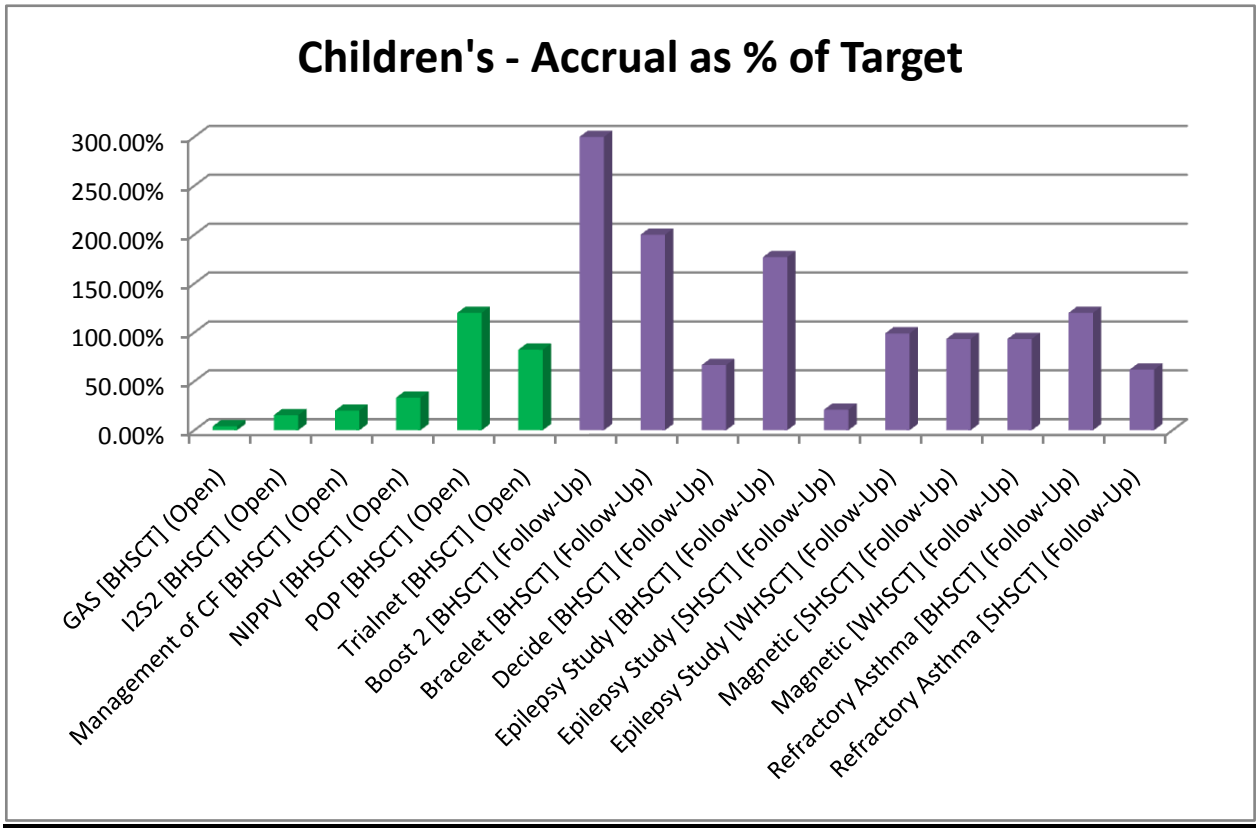
The Children's Interest Group is led by Dr Mike Smith, and currently has 3 staff spread across 3 Trusts (1.0 WTE in BHSCT and 2 x 0.5 WTE in WHSCT and SHSCT). This staffing level resulted in an overall spend of £73,034. In 2010, the group was involved in 12 studies of which 4 were adopted during the year. These include a number of studies which have investigated key research areas in collaboration with the national perinatal epidemiology unit in Oxford examining the effects of targeting arterial oxygen saturation levels on very preterm babies and the comparison of regional and general anaesthesia for effect on neurodevelopment outcome and apnoea in infants.

Children's Objectives

Table 5

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted	Agreed to adopt 4 studies		
1.2	Percentage of commercial studies	25%		
1.3	Percentage of studies at two or more clinical nodes	Info gathering due to staffing level		25%
1.4	Percentage of studies for each of five trusts	Info gathering	N/A	
1.5	Percentage of RCT's	Info gathering	67%	
2.0 Accrual				
2.1	Percentage of studies meeting/exceeding target recruitment	Agreed to raise target to 60%		From studies in follow up ie no longer recruiting then only 49% have accrued to target
2.2	Numbers of people recruited to studies	Info gathering	1007	This figure must be treated with caution as 71% is attributed to 1 study
3.0 Speed				
3.1	Completion of recruitment on or ahead of schedule	Agreed to raise target to 60%	No studies accruing in 2010 have ended therefore not applicable	Note objective 2.1 above

Figure 7



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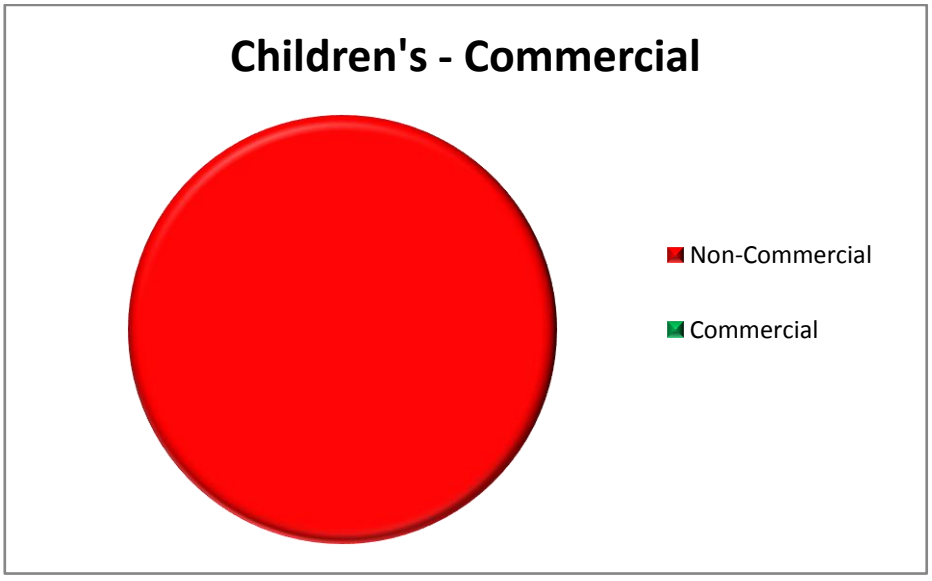

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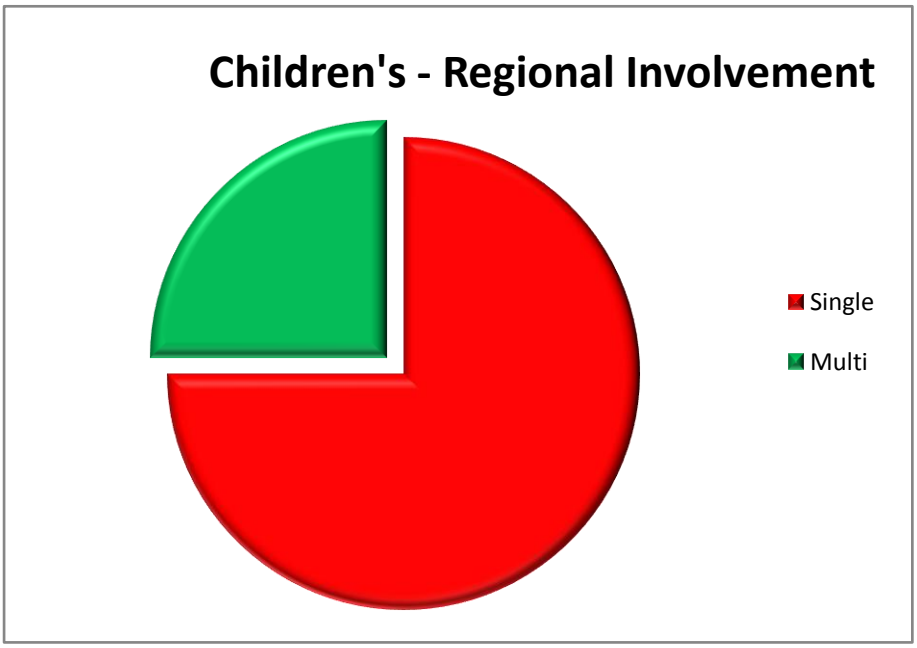
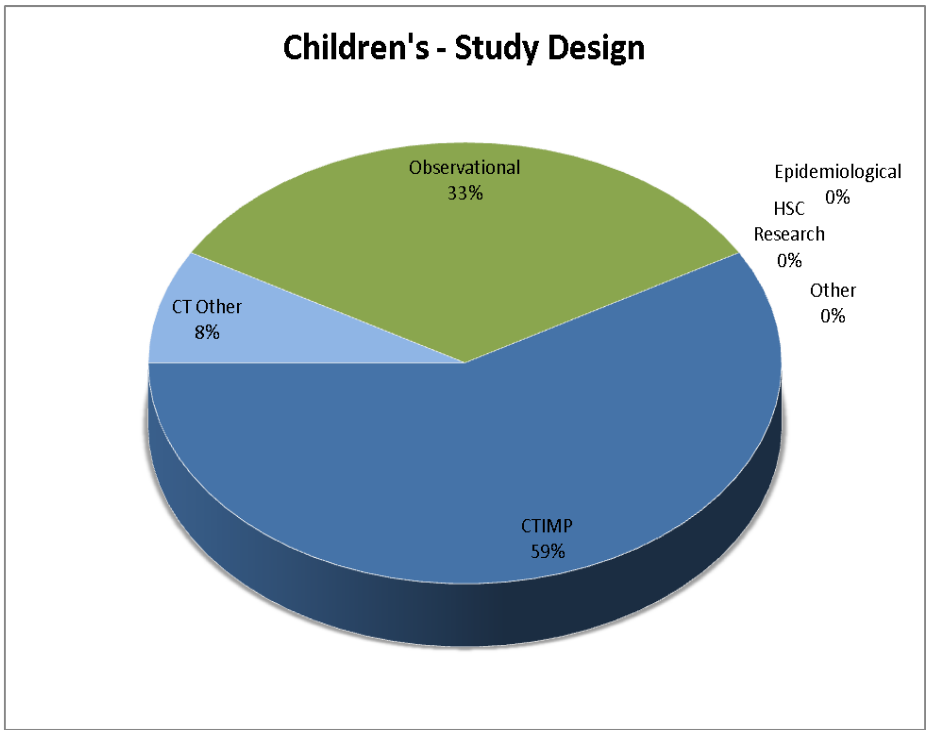


Figure 10



3.3 NICRN Critical Care Group Activity 2010

The Critical Care Interest Group is led by Prof Danny McAuley and over the majority of 2010 had 3 WTE staff spread across 4 HSC trusts. Due to the development of staff necessary for the delivery of a major national/international study successfully secured by Professor McAuley, this staffing level has been increased over last quarter of 2010 by a further 2.0 WTE over all 5 HSC trusts. This staffing level resulted in a spend across this group of £98,792

In 2010, the group was involved in 9 studies of which 3 were newly adopted during the year. These include studies which have investigated different methods of delivery and different formats for post operative analgesia, and evaluation of early warning systems and acute care training for early detection and management of deteriorating ward-based patients.

The critical care group has been successful in securing funding from the MRC Efficacy and Mechanism Evaluation (EME) programme for the HARP2 study. Leadership of a major UK/international study is an important achievement for the group and much of the group's focus has been on securing this funding and ensuring governance processes have been set up appropriately, which has taken up a significant proportion of all staff time. The study opened at the BHSCT in 2010 and will open at all NI sites early in 2011.

In total, the critical care group ran 9 studies over 2010. Of these, 3 were newly adopted in this period and 7 (77%) were RCT in design. For regional networking across Trusts, 3 studies (33%) took place at more than 1 centre. In total this group recruited 986 patients into clinical research protocols.

Critical Care Objectives

Table 6

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted	agreed to adopt at least 3 additional studies		
1.2	Percentage of commercial studies	agreed that 25% of studies should be commercial studies		Group has brought one study with a commercial partner forward for adoption, however rejected as no network involvement was required.
1.3	Percentage of studies at two or more clinical nodes	agreed to increase this target to 60%		
1.4	Percentage of studies for each of five Trusts	info gathering	BHSCT=88% WHSCT=11% SEHSCT=11%	
1.5	Percentage of RCT's	Info gathering	78%	

2.0	**Accrual**			
2.1	Percentage of studies meeting/exceeding target recruitment	increase to 60%		Of 5 studies(across 6 sites) 4 (80%) accrued to target
2.2	Numbers of people recruited to studies	info gathering	986	
3.0	**Speed**			
3.1	Completion of recruitment on or ahead of schedule	increase target to 60%		

Figure 11

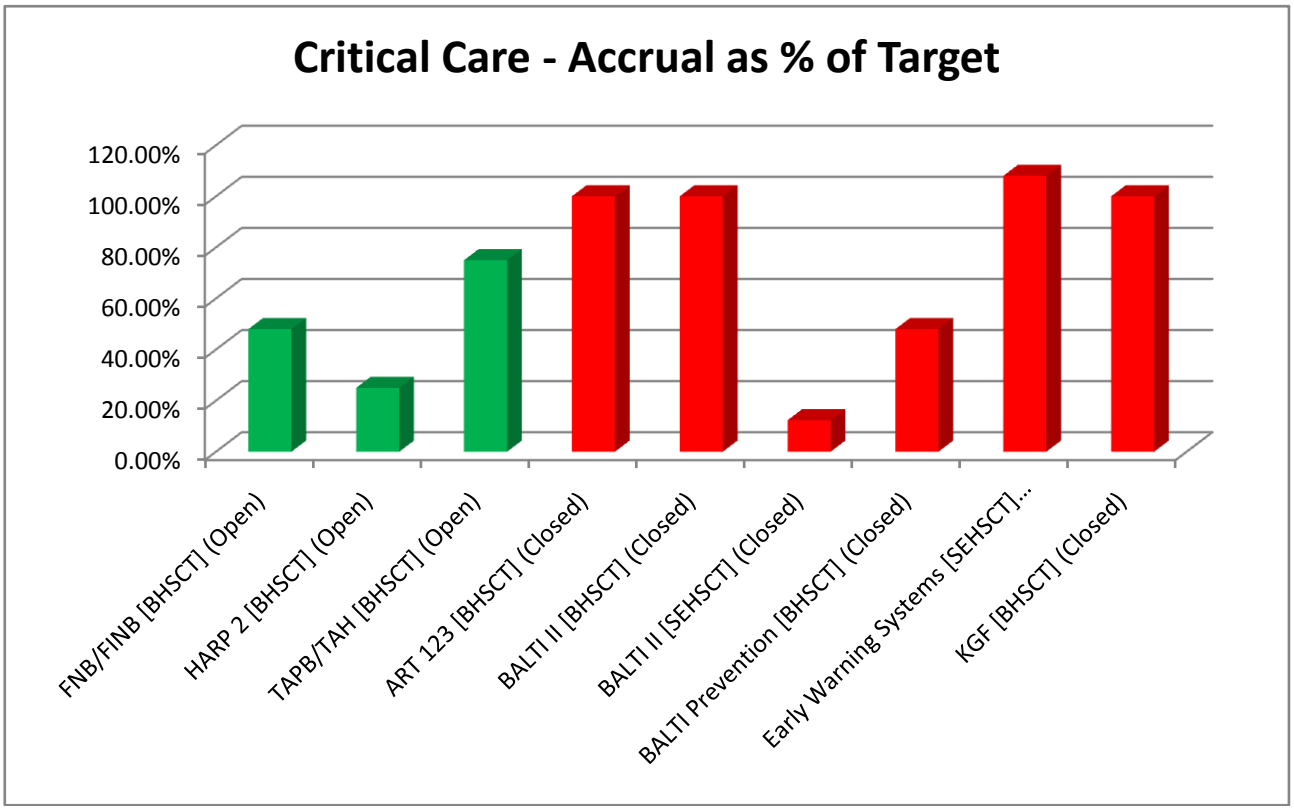


Figure 12

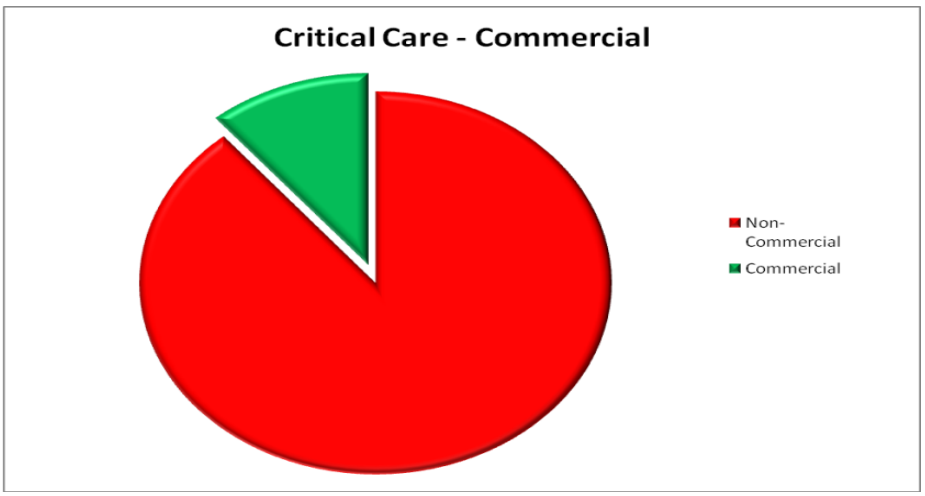


Figure 13

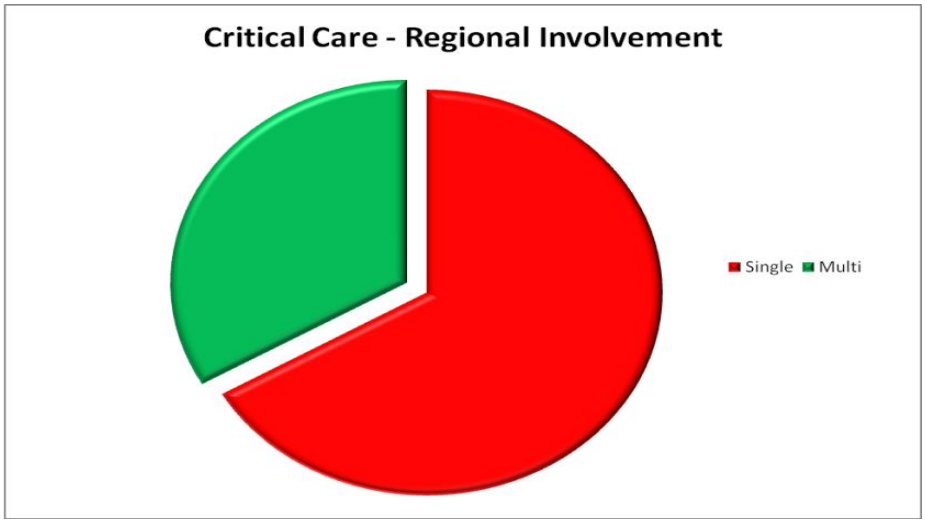
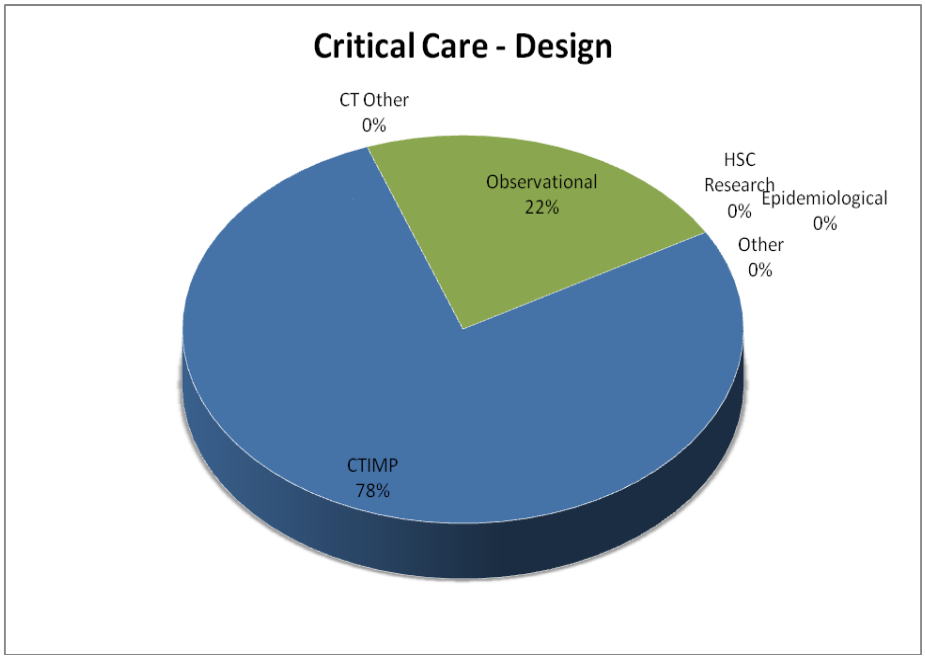


Figure 14



3.4 NICRN Dementia Group Activity for 2010

The Dementia Interest Group is led by Professor Peter Passmore and for most of 2010 Dr Bernadette McGuinness was co-clinical lead. The group currently has 3 staff solely within the BHSCT which is reflected in a staffing spend of £64,246. In 2010, the group was involved in 5 studies of which one was newly adopted during the year. These include the role of beta secretase in mild cognitive impairment and Alzheimer's disease as well as novel approaches such as the development, implementation and evaluation of a reminding system using mobile phone technology.

Dementia Objectives

Table 7

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted	Agreed to adopt 2 new studies in 2010		Group adopted 1 study over 2010
1.2	Percentage of commercial studies	Agreed that 1 of the 2 new studies would be commercial.		
1.3	Percentage of studies at two or more clinical nodes		NA	
1.4	Percentage of studies for each of five trusts	Info gathering	NA	
1.5	Percentage of RCT's	Info gathering	**20%**	
2.0 Accrual				
2.1	Percentage of studies meeting/exceeding target recruitment	Agreed to increase this to 60%		Of 2 studies which have completed accrual and are in follow up only 1 met target. Note other study did reach 80% of target.
2.2	Numbers of people recruited to studies	Info gathering	199	
3.0 Speed				
3.1	Completion of recruitment on or ahead of schedule	*50%*		

Figure15

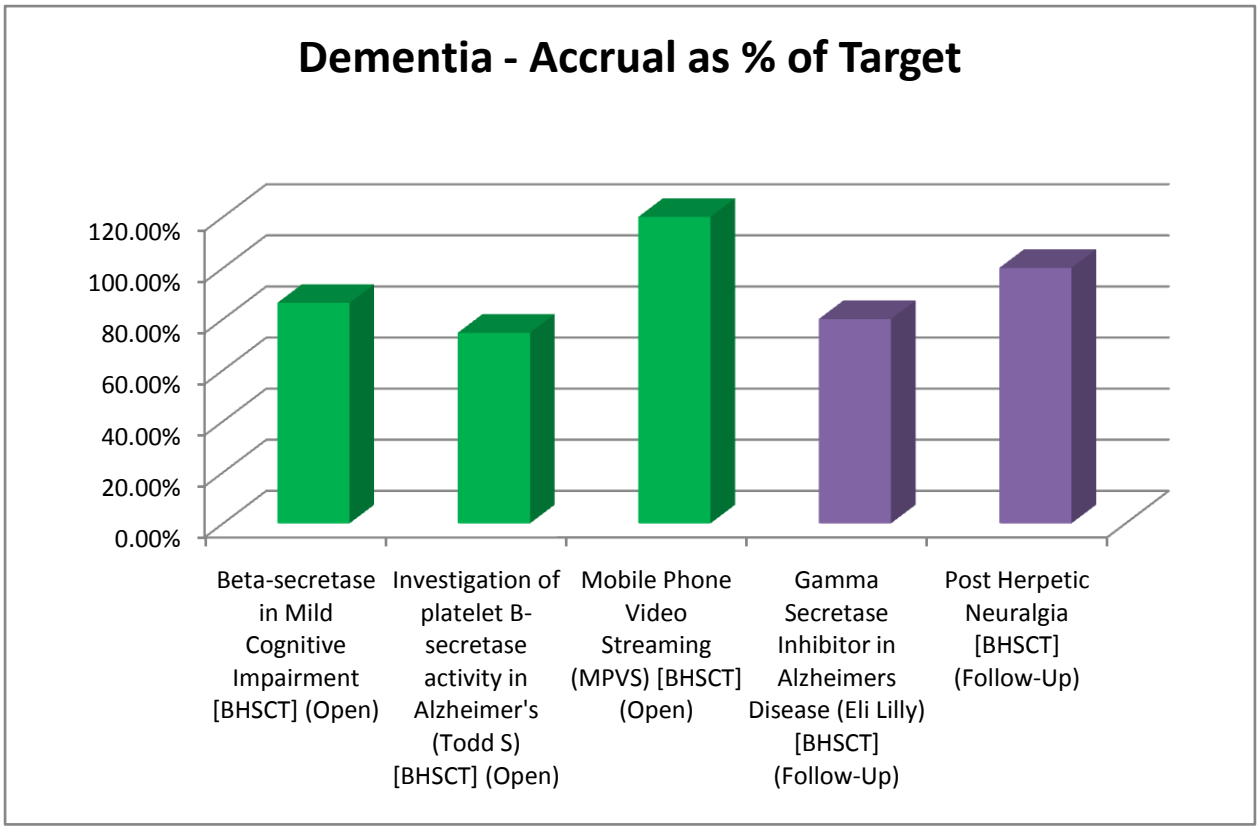


Figure 16

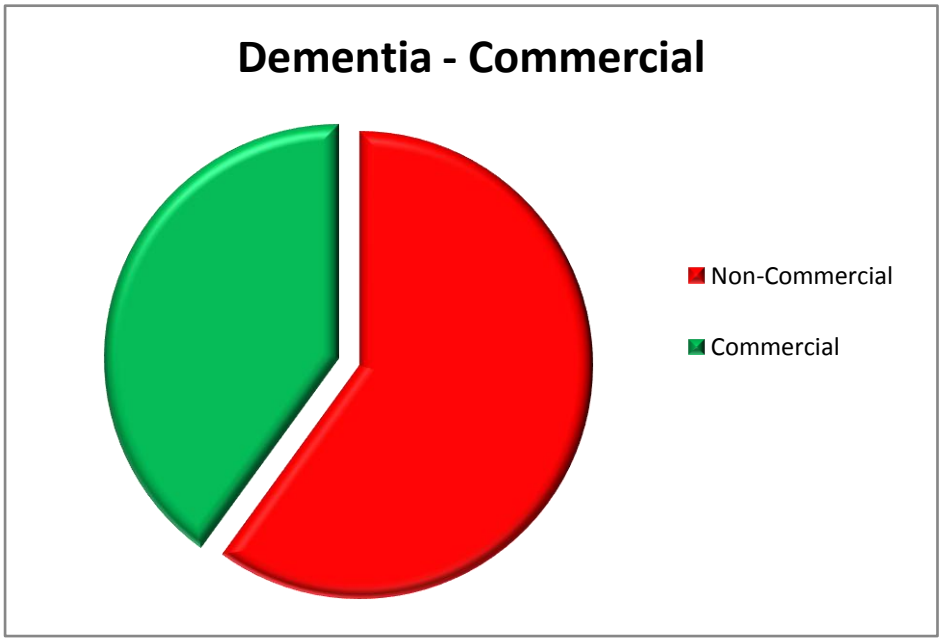
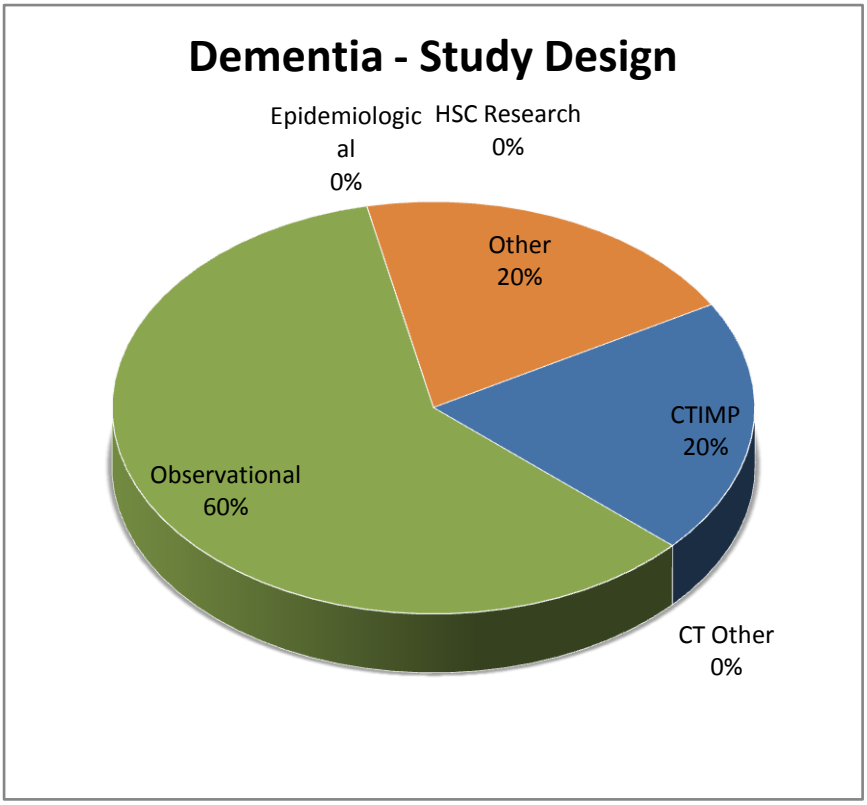


Figure 17


Dementia - Study Design
Epidemiologic al 0%
HSC Research 0%
Other 20%
CTIMP 20%
Observational 60%
CT Other 0%

3.5 NICRN Diabetes Group Activity for 2010

The Diabetes Interest Group is led by Professor Patrick Bell and currently has 3.6 WTE staff spread across 4 HSC trusts which equates to a staff spend of £131,716. In 2010, the group was involved in 13 studies of which 6 were newly adopted during the year. These include a long term study assessing the impact of intrauterine, postnatal, parental and environmental factors on obesity and cardiovascular risk factors in 6-7 year old offspring. The group has also been successful in developing ongoing relationships with several commercial pharmaceutical companies such as Johnston and Johnston and Novo Nordisk.

Of the total portfolio, 4 (30%) had commercial involvement and 7 (54%) were RCT's. In total this group recruited a total of 2231 patients; however, this was principally attributable to 2 studies over 3 centres which accounted for 1953 (87%) of total accrual.

Diabetes Objectives

Table 8

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted	agreed to adopt 4 new studies		
1.2	Percentage of commercial studies	agreed that 2 of the 4 new studies adopted would be commercial		
1.3	Percentage of studies at two or more clinical nodes	agreed that 25% of studies would take place at two or more clinical nodes		Overall 46% were at >2 sites. However for studies adopted in 2010 only 1 study (7%) occurred at>2 sites
1.4	Percentage of studies for each of five trusts	Info gathering Agreed to monitor this	BHSCT=46% WHSCT=38% SEHSCT=23% NHSCT=15%	
1.5	Percentage of RCT's	Info gathering	54%	
2.0 Accrual				
2.1	Percentage of studies meeting/exceeding target recruitment	agreed to increase this to 60%		63%
2.2	Numbers of participants recruited to studies	Info gathering	2231	
3.0 Speed				
3.1	Completion of recruitment on or ahead of schedule	agreed to remain at 50%		

Figure 18

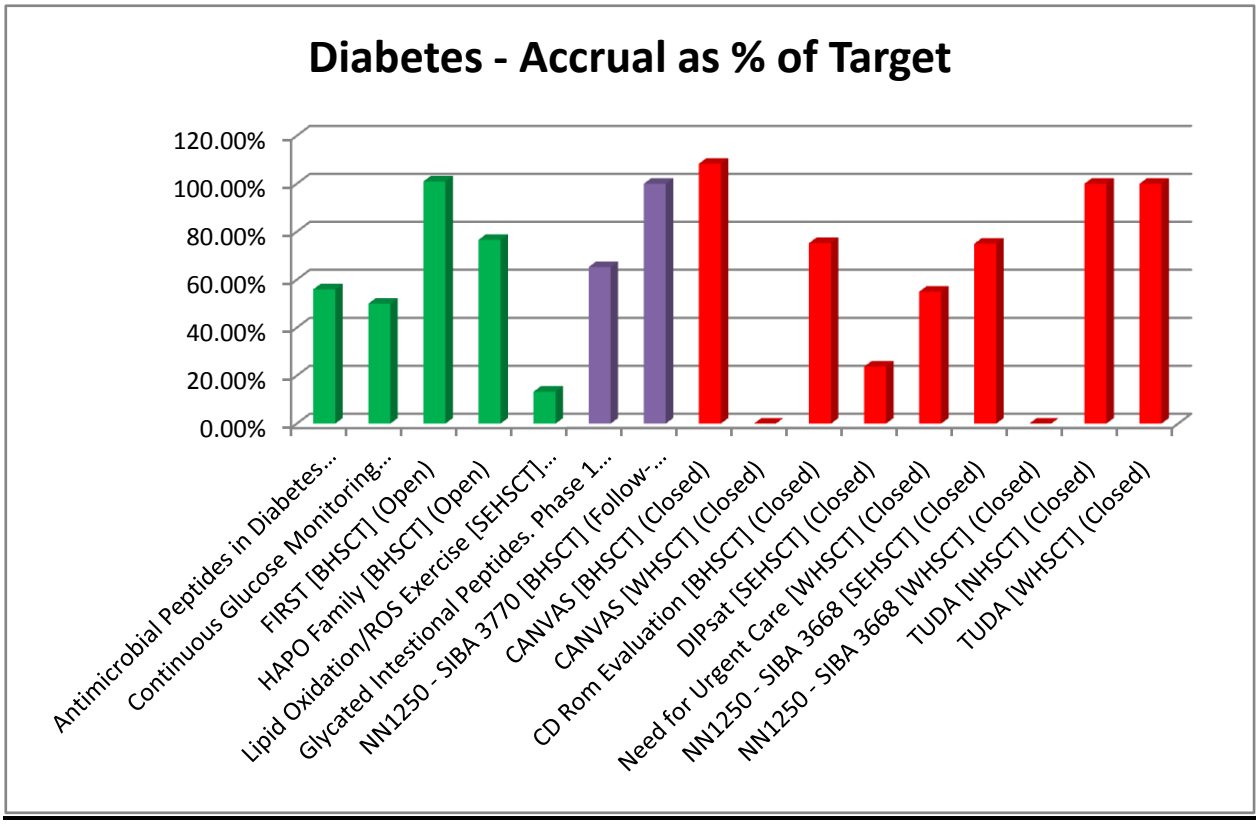


Figure 19

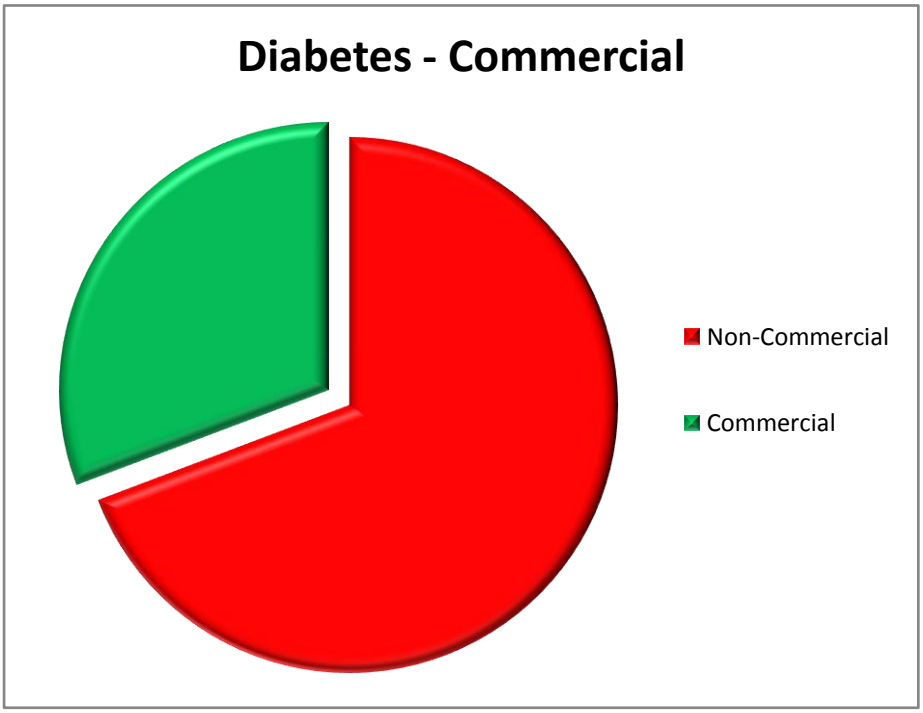


Figure 20

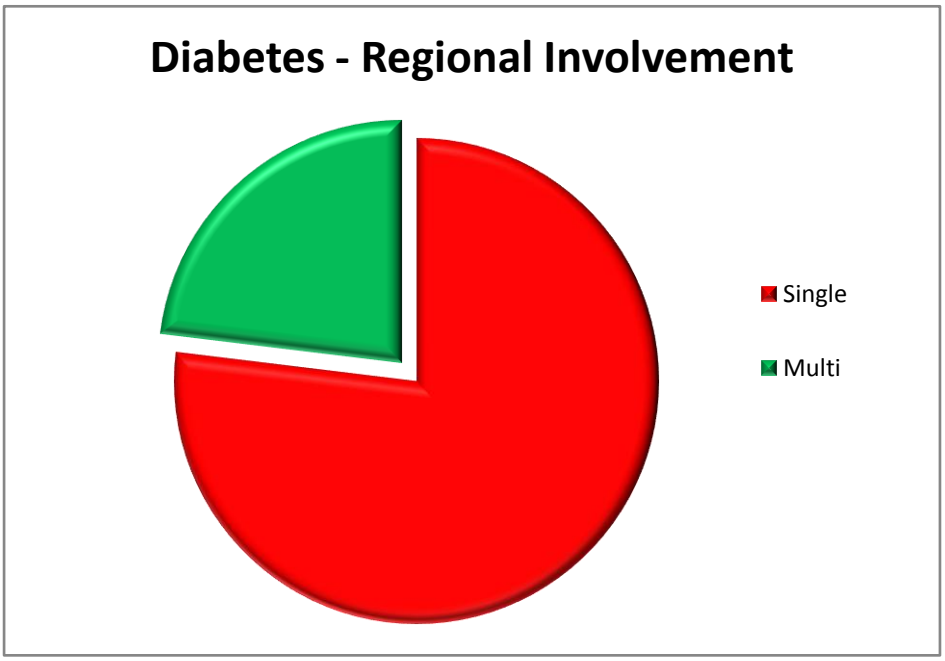
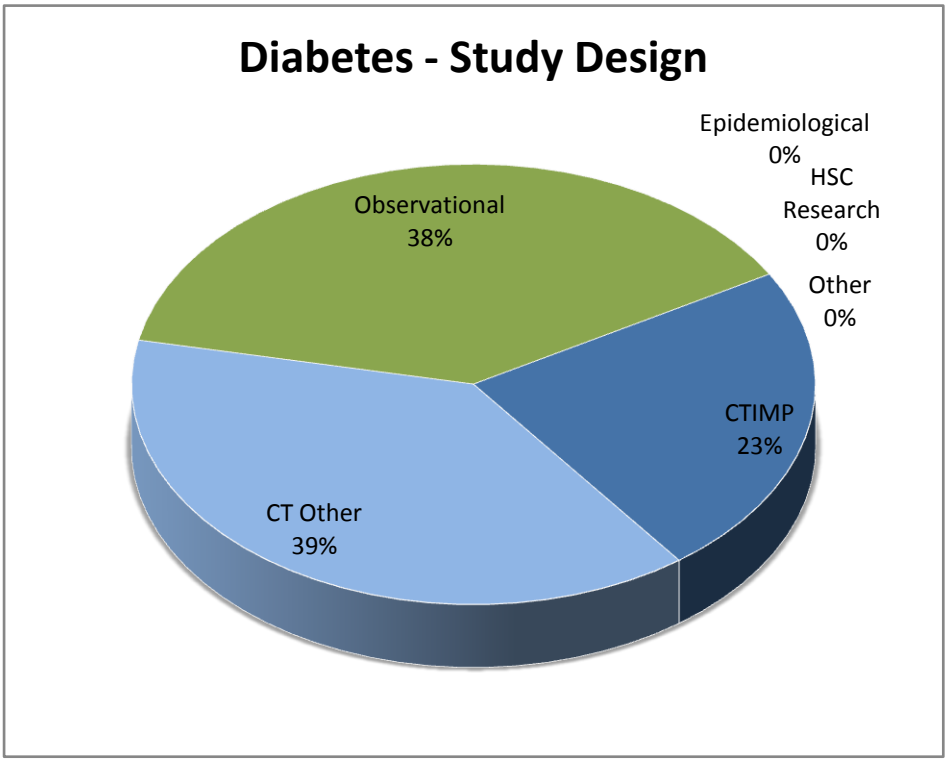


Figure 21



3.6 NICRN Primary Care Group Activity for 2010

The primary interest group is led by Professor Carmel Hughes and Dr Margaret Cupples and for the majority of 2010 was supported by 1.0 WTE clinical trials practitioner giving a total staff spend of £45, 948. In 2010, the group was involved in 9 studies. These include an RCT of surveillance for the early detection of cancer and a comparative research study investigating the construction and implementation of patient choice policies. During the seasonal surveillance period for H1N1 infection the primary care group were involved in the collection of regional data informing national databases.

The capacity of the primary care group to adopt new studies during 2010 was limited by access to nursing support. The group continued to support 5 studies opened from 2009 and a further 4 studies which closed during 2010. In December 2 X 0.5 WTE were recruited and so this will allow increased activity during 2011.

The group's portfolio included 5 studies; 3 (60%) were RCTs and all 5 were multi-centred with 1 having commercial involvement. In total this group recruited 294 patients to these studies over 2010. As can be seen from figure 21 the groups activity to target is very good with all 6 completed studies having achieved 100% accrual to target.

One of the key functions of this group has been to develop the primary care structure and outwith the objectives set for this group they have succeeded in developing practice involvement across NI, with more than 20 practices indicating interest in being involved in network activities. They have also been central to developing working relationships with local Contract Research Organisations and Association of British Pharmaceutical Industry (ABPI) members.

Primary Care Objectives

Table 9

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted	Ongoing studies to be continued and no objective set until staff in post	NA	New staff in post as of December 2010 and will need taken into account for 2011 objectives
1.2	Percentage of commercial studies	1 commercial		
1.3	Percentage of studies at two or more clinical nodes	50%		
1.4	Percentage of studies for each of five trusts	NA	NA	
1.5	Percentage of RCT's	Info gathering	44%	
2.0 Accrual				
2.1	Percentage of studies meeting/exceeding target recruitment	50%		
2.2	Numbers of people recruited to studies		294	
3.0 Speed				
3.1	Completion of recruitment on or ahead of schedule	50%		

Figure 22

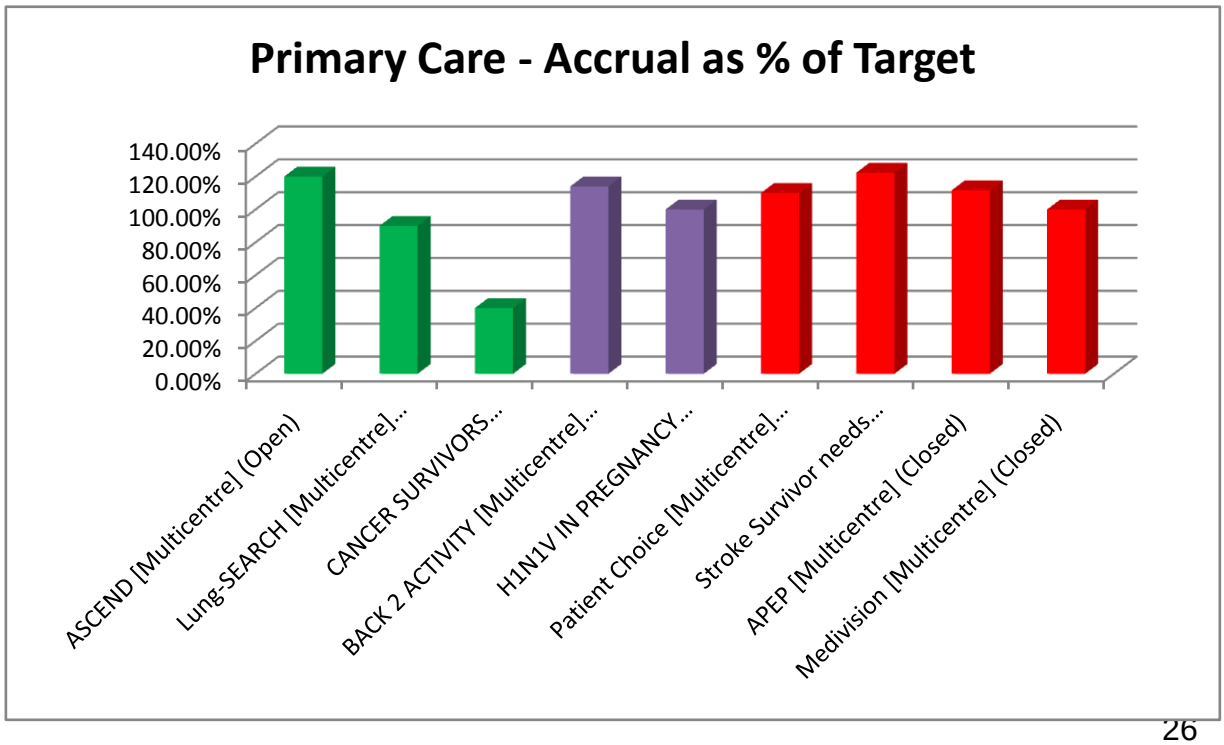


Figure 23

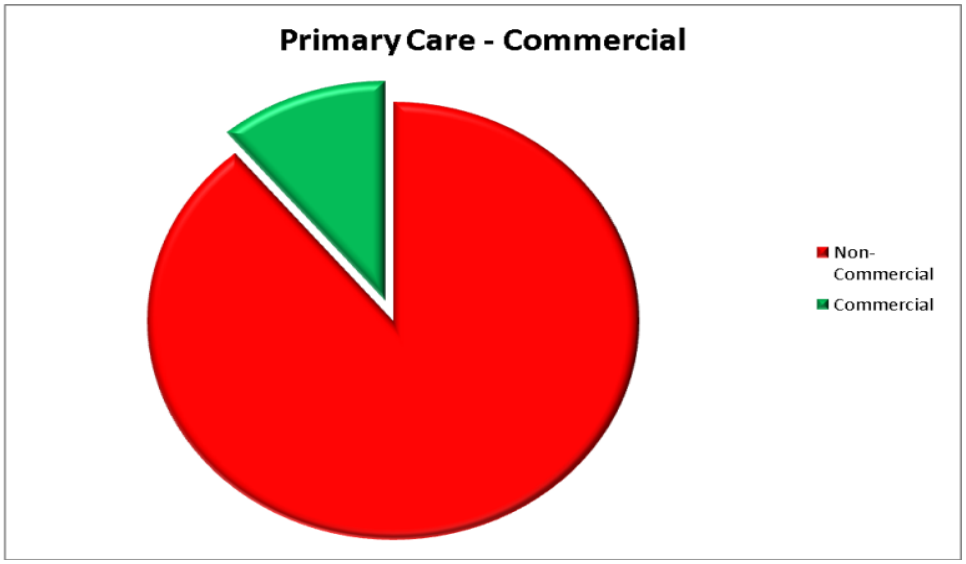
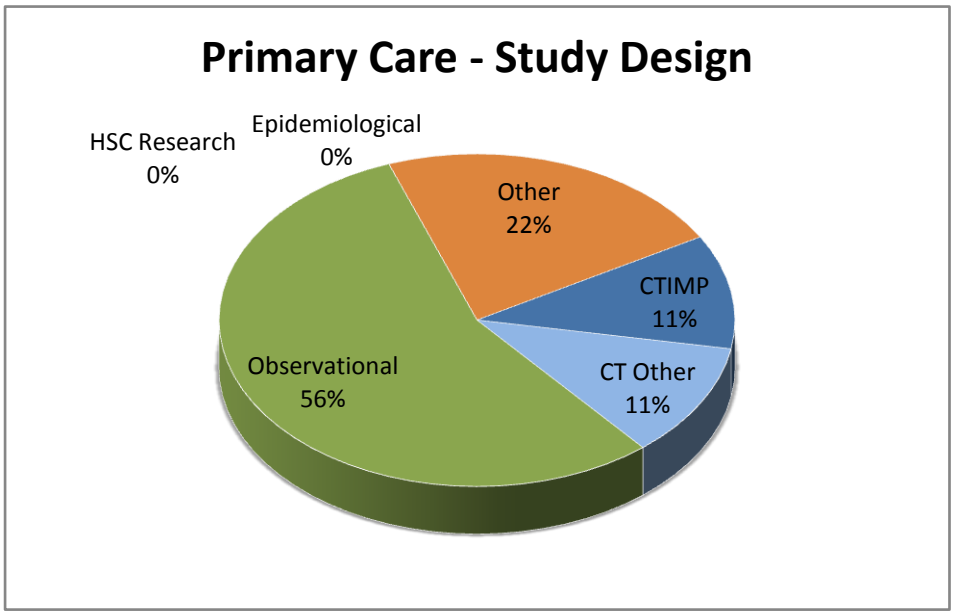


Figure 24



3.7 NICRN Respiratory Group Activity for 2010

The NICRN respiratory group had a particularly successful year over 2010. The group is led by joint clinical leads Dr Judy Bradley and Dr Lorcan McGarvey. Over 2010 the group has broadly maintained their 4.0 WTE posts throughout the year with a total staff spend of £149,822.

The respiratory group has been involved in 13 studies over 2010, with 5 new studies being adopted. Of the total 2010 portfolio 62% had commercial involvement and 77% of activity relates to RCTs. Nine studies (69%) of which were CTIMPS. This has allowed the group to reinvest residual income and over 2011 they have committed to using this income to develop administrative and clerical support, hence freeing up nurse time to support patient accrual. In total 149 patients have been recruited to trials, often of complex design, during the year.

Respiratory Objectives

Table 10

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted	Adopt sufficient studies to maintain portfolio		
1.2	Percentage of commercial studies	Agreed to maintain 50% commercial and to consider an observational study of good scientific quality.		
1.3	Percentage of studies at two or more clinical nodes	Agreed to try to increase the clinical nodes.		Due to the location of the regional respiratory centre in BHSCT, this objective has not been achieved. However through participation in CMG by non BHSCT clinicians and developing clinical links with both WHSCT and SHSCT, the group is endeavouring to address this target. If funding for support staff were available this would be met.
1.4	Percentage of studies for each of 5 Trusts	N/A		
1.5	Percentage of RCTs	Info gathering	77%	
2.0 Accrual				
2.1	Percentage of studies meeting/exceeding target recruitment	50%		
2.2	Numbers of people recruited to studies	Info gathering	149	
3.0 Speed				
3.1	Completion of recruitment on or ahead of schedule	50%		Current recruitment stands at 46% of target

Figure 25

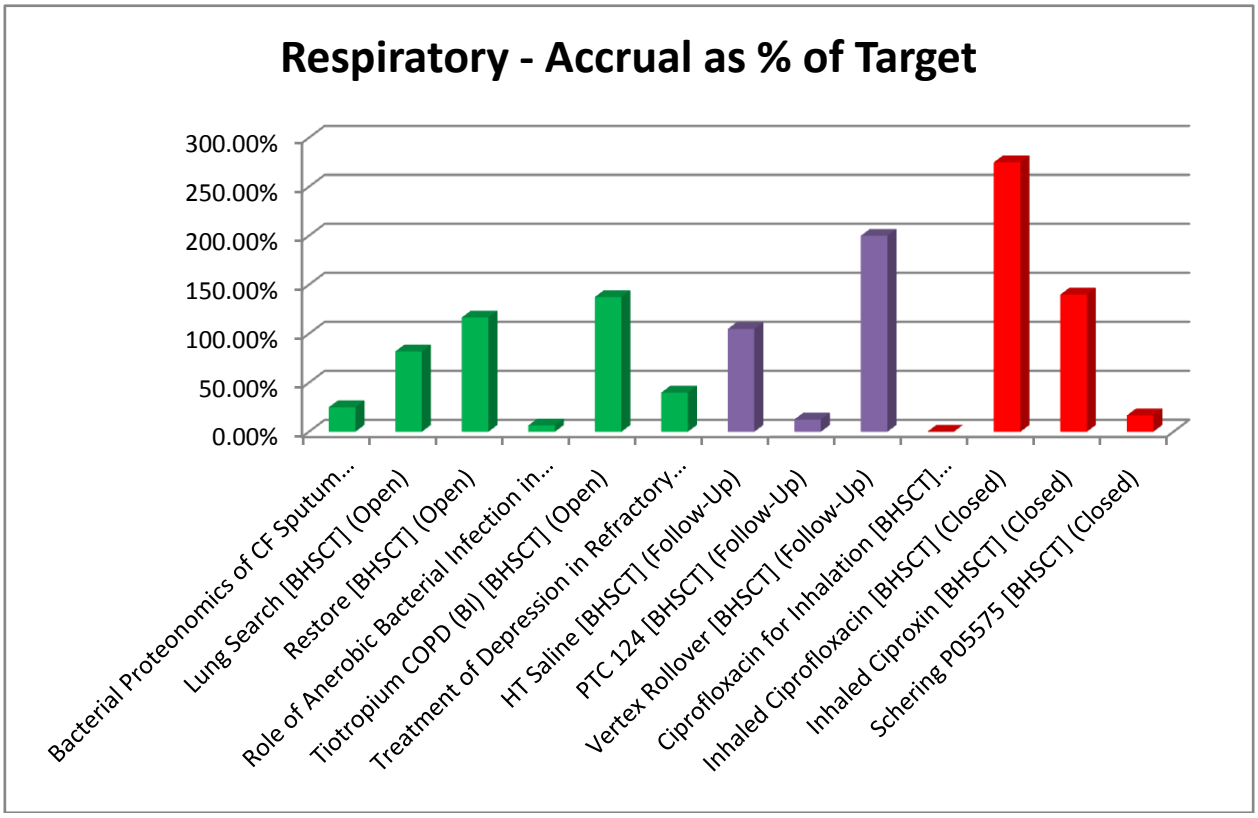


Figure 26

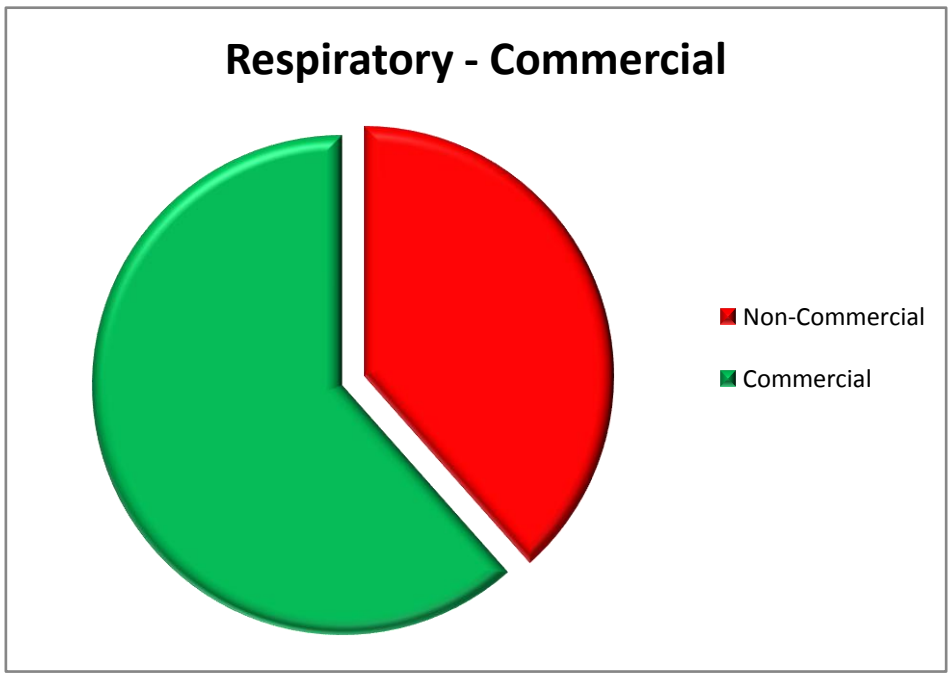
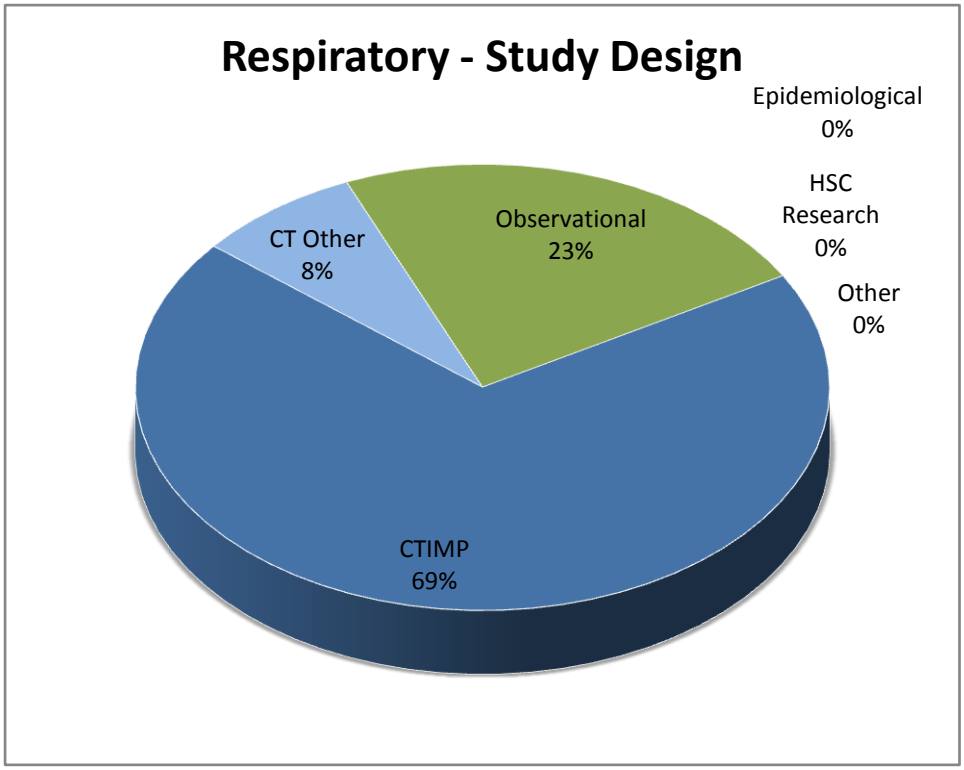


Figure 27


Respiratory - Study Design
Epidemiological 0%
HSC Research 0%
Other 0%
Observational 23%
CT Other 8%
CTIMP 69%

3.8 NICRN Stroke Group Activity for 2010

The NICRN stroke group is led by joint clinical leads Dr Michael Power and Dr Sheila Lennon-Fraser. This group has 4.5 WTE posts across all 5 of the HSC Trusts which equates to a spend of £180,976.

This group have been running 10 studies over 2010, 4 of which were newly adopted. Out of the total portfolio, 7 were multi-centred (2 or more sites) across NI and 60% were RCT's, with 1 of these involving an investigational medicinal product and have recruited a total of 228 patients over 2010.

This group's portfolio has included areas of research such as the treatment of acute ischaemic stroke via intravenous recombinant tissue plasminogen activator and areas of early rehabilitation on stroke outcomes.

Stroke objectives

Table 11

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted in current year.	agreed to adopt 2 new studies in 2010		
1.2	Percentage of commercial studies	50%		
1.3	Percentage of studies at two or more clinical nodes	60%		
1.4	Percentage of studies for each of five trusts.	Info Gathering	BHSCT=40% NHSCT=60% SEHSCT=70% SHSCT=30% WHSCT=30%	
1.5	Percentage of RCT's	Info gathering	60%	
2.0 Accrual				
2.1	Percentage of studies meeting/exceeding target recruitment	50%		Of studies closed (carers study phase 1&2) only 1 site met target in phase 1. However screening figures suggest (349 screened to get 10 participants) that this was an extremely difficult study to recruit to.
2.2	Numbers of people recruited to studies	Agreed to double recruitment figures for studies = target of 98.	228	
3.0 Speed				
3.1	Completion of recruitment on or ahead of schedule	50%		This is not met principally due to restriction in stroke care environment.

Figure 28

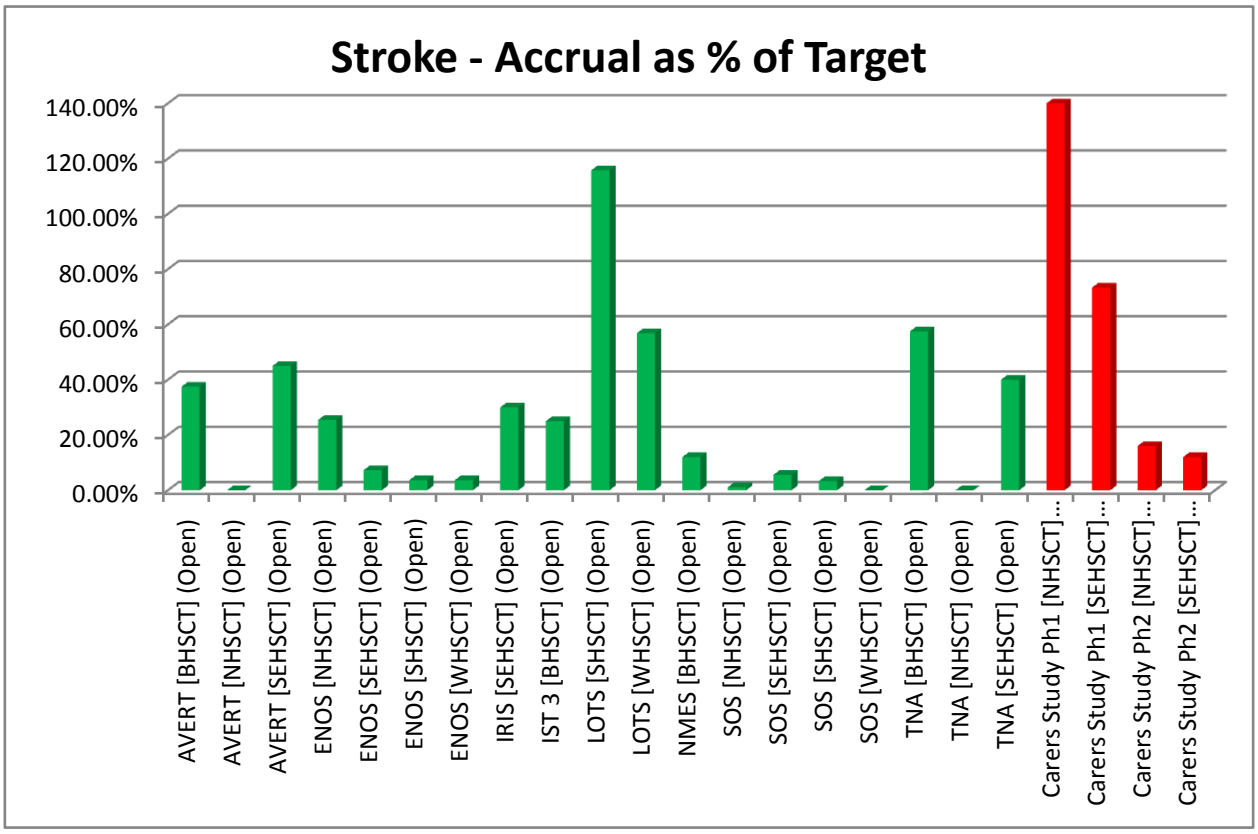


Figure 29

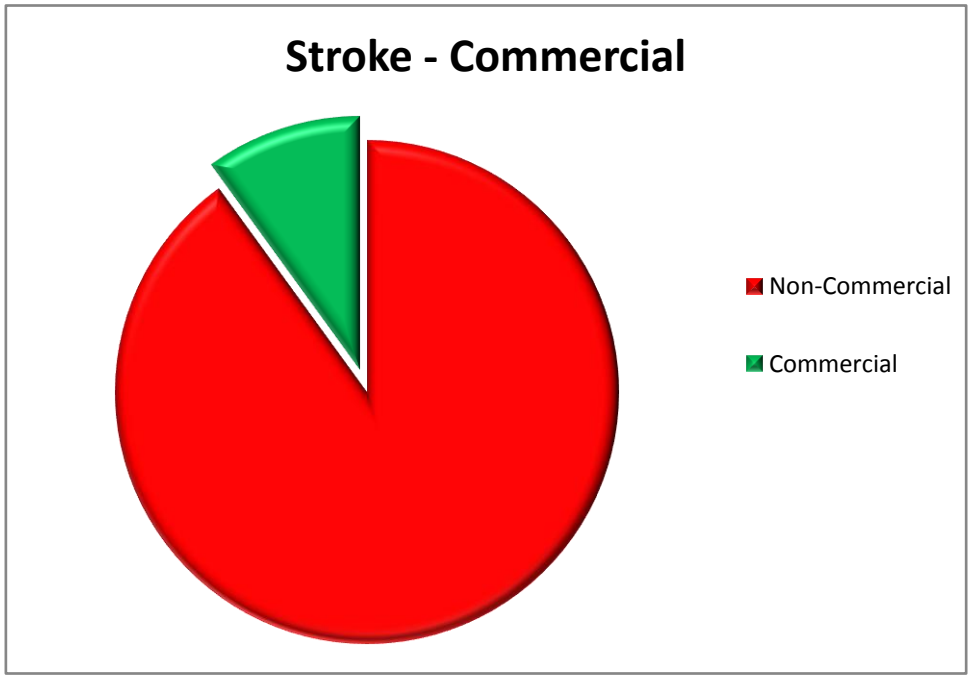


Figure 30

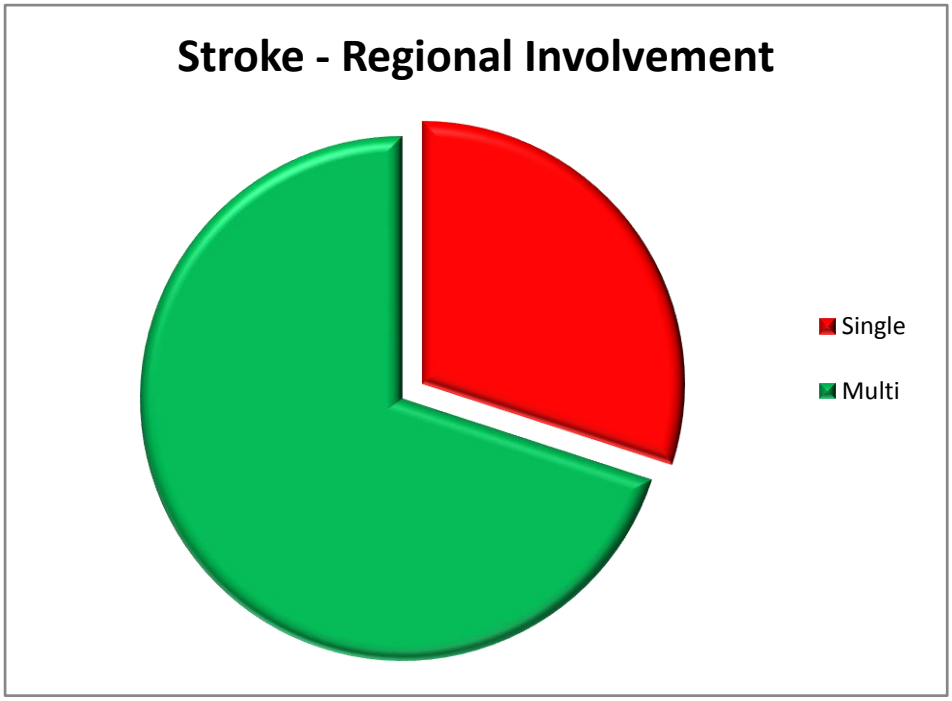
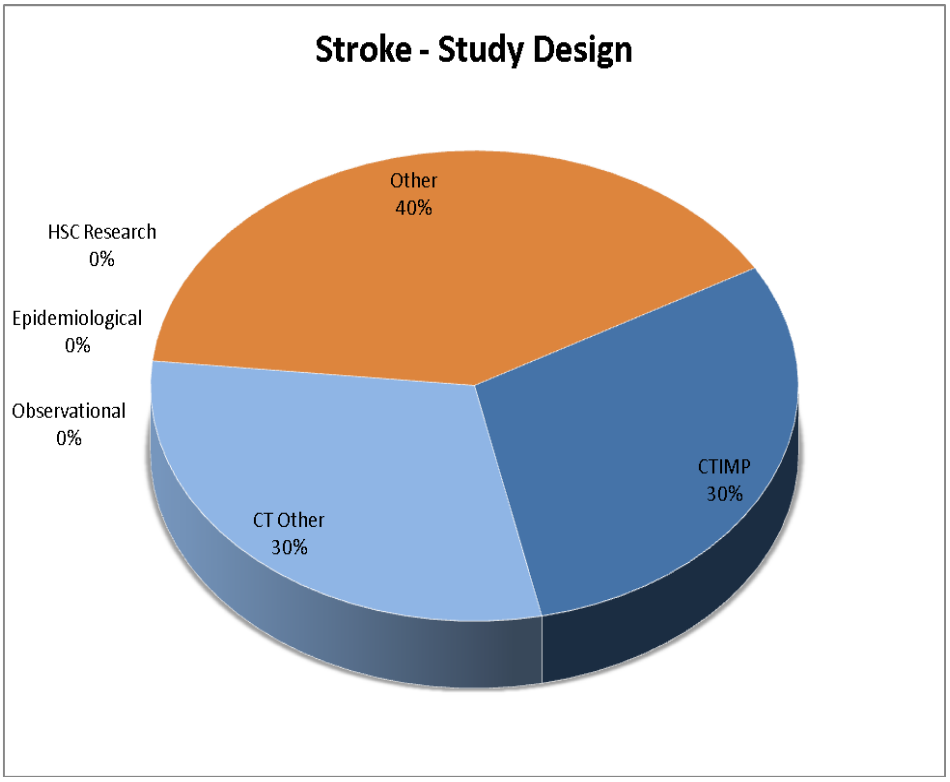


Figure 31



3.9 NICRN Vision Group Activity for 2010

The vision group is led by joint clinical leads Professor Jonathan Jackson and Dr Giuliana Silvestri. The staffing level throughout 2010 sat at 2.0 WTE research nurses, 1.0 WTE Vision Technician and 1.0 WTE optometrist. This equates to a staff spend for Vision of £138,343.

The group undertook 7 studies over 2010 and of these 6 (85%) were newly adopted, 29% were RCTs and 28% were involving commercial funders. This group's portfolio included large national multicentre studies such as IVAN and a particular area of interest for this team is macular degeneration with several studies investigating this disease area.

Vision objectives

Table 12

Objective		Target	2010	Comment
1.0 Portfolio				
1.1	Number of studies adopted	Agreed to adopt 3 studies for 2010.		
1.2	Percentage of commercial studies	30%		28% achieved
1.3	Percentage of studies at two or more clinical nodes	Agreed to try to increase the clinical nodes.	NA	Regional centre
1.4	Percentage of studies for each of fiveTrusts	Info gathering	NA	Regional centre
2.0 Accrual				
2.1	Percentage of studies meeting/exceeding target recruitment	60%		Only one study completed recruitment phase in 2010 and therefore met target
2.2	Numbers of people recruited to studies	Info gathering	724	
3.0 Speed				
3.1	Completion of recruitment on or ahead of schedule	50%		

Figure 32

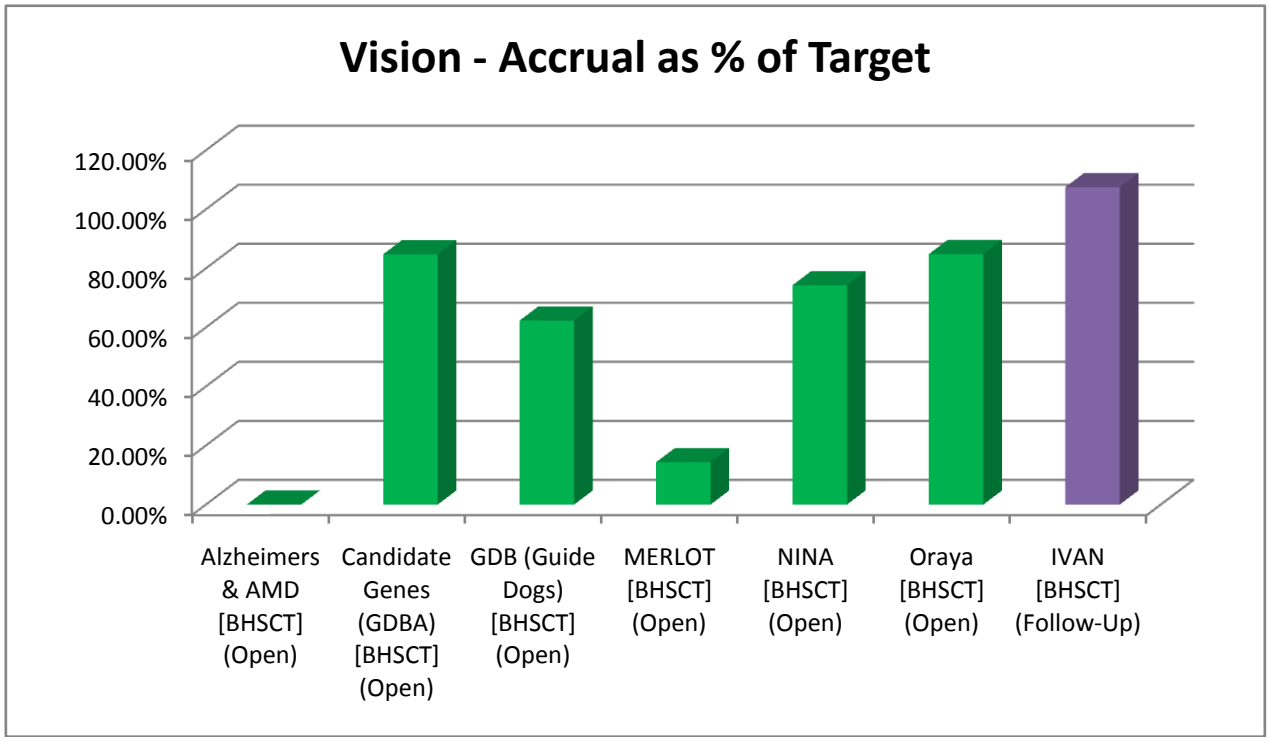


Figure 33

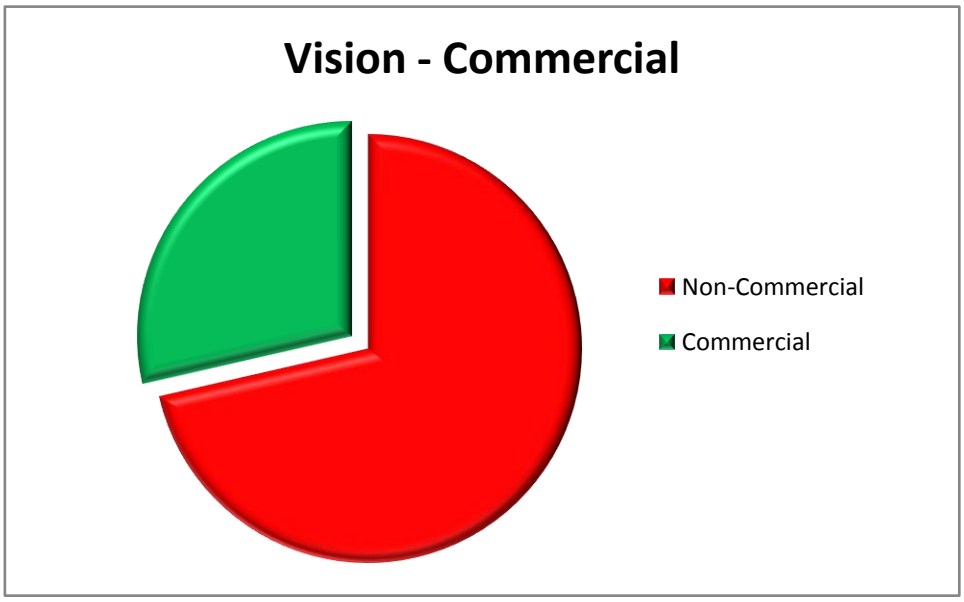
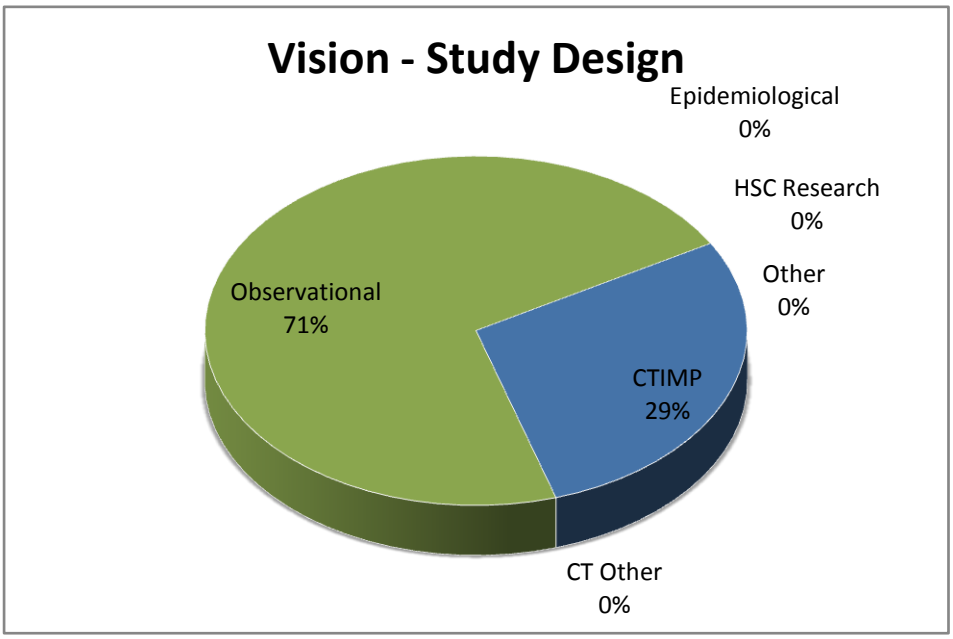


Figure 34


Vision - Study Design
Epidemiological
0%
HSC Research
0%
Other
0%
Observational
71%
CTIMP
29%
CT Other
0%

APPENDIX 1 – Steering Group Membership (as of March 2011)

Professor Ian Young (Chair)	Clinical Director NICRN
Dr Paul Biagioni	NICRN CC Manager
Dr Michael Neely	Operational Director RDD PHA
Dr Janice Bailie	Programme lead RDD PHA
Professor Frank Kee	Co-clinical lead Cardiovascular group
Dr Donna Fitzsimons	Co-clinical lead Cardiovascular group
Dr Mike Smith	Clinical lead Children's group
Professor Danny McAuley	Clinical lead Critical care group
Professor Peter Passmore	Co-clinical lead Dementia group
Dr Stephen Todd	Co-clinical lead Dementia group
Professor Patrick Bell	Clinical lead Diabetes group
Professor Carmel Hughes	Co-clinical lead Primary care group
Dr Margaret Cupples	Co-clinical lead Primary care group
Dr Judy Bradley	Co-clinical lead Respiratory group
Dr Lorcan McGarvey	Co-clinical lead Respiratory group
Dr Sheila Lennon-Fraser	Co-clinical lead Stroke group
Dr Michael Power	Co-clinical lead Stroke group
Professor Jonathan Jackson	Co-clinical lead Vision group
Dr Giuliana Silvestri	Co-clinical lead Vision group
Dr Melanie Morris	Operational Director NICN
Dr Richard Wilson	Clinical Director NICN
Mrs Margaret McFarland	Lead Clinical Trials Pharmacist BHSCT

APPENDIX 2 – Clinical Management Group Membership (as of April 2011)

Interest group	Membership	E-mail
NICRN Coordinating centre	Paul Biagioni (Manager) Ciara McKenna (Co-ordinator) Shane Jackson (Co-ordinator) Angelina O'Neill (Co-ordinator)	Paul.biagioni@belfasttrust.hscni.net Ciara.mckenna@belfasttrust.hscni.net Shaner.jackson@belfasttrust.hscni.net Angelina.O'Neill@belfasttrust.hscni.net
Cardiovascular	Donna Fitzsimons (Co-Clinical Lead) Frank Kee (Co-Clinical Lead) Virginia Anderson Michael Curran Mark Harbinson Dennis Harkin David Higginson Gillian McCorkell Pascal McKeown Ian Menown	donna.fitzsimons@belfasttrust.hscni.net F.Kee@qub.ac.uk
Children's	Michael Smith (Clinical Lead) Dennis Carson Henry Halliday James McElnay Mike Shields Naiomh White	mike.smith@southerntrust.hscni.net
Critical Care	Danny McAuley (Clinical Lead) Stephen Austin Ronald Bailie Bronagh Blackwood Chris Clarke Lynn Gilfeather Mark Jenkins Gavin Lavery Catherine Leonard Ronan McMullan Fidelma Moran Brian Mullan Mark Sheridan John Trinder	d.f.mcauley@qub.ac.uk
Dementia	Peter Passmore (Co-Clinical Lead) Stephen Todd (Co-Clinical Lead) Cathal Foy Gordon Kennedy (PPI) George Lyons (PPI) Mary McGrath Paul McMonagle Stephen Todd Jamil Vahidassr Maura Young	p.passmore@qub.ac.uk s.todd@qub.ac.uk
Diabetes	Patrick Bell (Clinical Lead) John Andrews Vivien Coates Iain Foster Roy Harper Alyson Hill Peter Maxwell David McCance Mae McConnell Kieran McGlade Gary McVeigh	patrick.bell@belfasttrust.hscni.net

Interest group	Membership	E-mail
	Maurice O'Kane Des Rooney	
Primary Care	Margaret Cupples (Co-Clinical Lead) Carmel Hughes (Co-Clinical Lead) Joe Brogan Paul Conn Helen Dolk Michael Donaldson Claire Leathem Tanya McCance Suzanne McDonough Trevor Spratt Robert Thompson	M.Cupples@qub.ac.uk c.hughes@qub.ac.uk
Respiratory	Judy Bradley (Co-Clinical Lead) Lorcan McGarvey (Co-Clinical Lead) Stuart Elborn Liam Heaney Martin Kelly Joe Kidney Anne Marie Marley Jacqui Megarry Brenda O'Neill	jm.bradley@ulster.ac.uk l.mcgarvey@qub.ac.uk
Stroke	Sheila Lennon (Co-Clinical Lead) Michael Power (Co-Clinical Lead) Sandra Aitcheson Bronagh Byrne Margaret Cupples Peter Deazley Andrew Dougal Peter Flynn Jim Kelly Anne Madden Maureen Matthews Patricia McCaffrey Mark McCarron Michael McCormick Carolee McLaughlin Philip Reilly Jamil Vahidassr Ivan Wiggam David Wilson John Yarnell	s.lennon@ulster.ac.uk michael.power@setrust.hscni.net
Vision	Jonathan Jackson (Co-Clinical Lead) Guiliana Silvestri (Co-Clinical Lead) Rosie Brennan Usha Chakravarthy Rosaleen Dempsey Olivia Earley Elinor Johnston Jennifer Lindsay Andrew Murdoch Liam Patton Barbara Pierscionek Brian Scotney Vittorio Silvestri	jonathan.jackson@belfasttrust.hscni.net G.Silvestri@qub.ac.uk

APPENDIX 3 – Financial Breakdown for NICRN Staff Costs

Financial Breakdown for NICRN Coordinating Centre

Group	Job Title	WTE Funded +46% Trust overhead	Overall Total
NICRN Office	Senior Manager	1.0	**78639**
NICRN Office	Coordinator (1)	1.0	**23753**
NICRN Office	Coordinator (2)	1.0	**46707**
NICRN Office	Coordinator (3)	1.0	**33540**
NICRN coordinating centre total =			**£182,639**

Financial Breakdown for NICRN Staffing Costs Incurred in SEHSCT

Group	Job Title	WTE Funded	Overall Total
Cardiovascular	Nurse	1.0	**25939**
Critical Care	Nurse	0.5	**4853**
Critical Care	Nurse	0.5	**21710**
Diabetes	Nurse	1.0	**37382**
Stroke	Nurse	1.0	**44041**
Stroke	CL	0.1	**14299**
SEHSCT total =			**£148,224**

Financial Breakdown for NICRN Staffing Costs Incurred in NHSCT

Group	Job Title	WTE Funded	Overall Total
Cardiovascular	Nurse	1.0	**44773**
Critical Care	Nurse (on maternity leave)	0.5	**7396**
Diabetes	Nurse	1.0	**20087**
Stroke	Nurse	0.5	**15265**
Stroke	Nurse	0.5	**20990**
NHSCT total=			**£108,511**

Financial Breakdown for NICRN Staffing Costs Incurred in SHSCT

Group	Job Title	WTE Funded	Overall Total
Cardiovascular	Nurse	1.0	**9409**
Children's	Nurse	0.5	**17505**
Children's	Clinical Lead		**24420**
Critical Care	Nurse	0.5	**11558**
Stroke	Nurse	1.0	**45195**
Total staffing cost including CL PA =			**£108,087**

Financial Breakdown for NICRN Staffing Costs Incurred in BHSCT

Group	Job Title	WTE Funded	Overall Total
Cardiovascular	Nurse	1.0	**11137**
Cardiovascular	Nurse	0.2	**7738**
Cardiovascular	Clinical Lead	0.1	**22491**
Cardiovascular	Clinical lead	0.1	**10268**
Children's	Nurse	1.0	**42882**
Critical Care	Nurse	0.5	**10393**
Critical Care	Nurse	1.0	**35591**
Critical Care	Clinical Lead	0.2	**17928**
Dementia	Nurse	1.0	**35090**
Dementia	Nurse	0.5	**14603**
Dementia	Nurse	0.5	**14553**
Dementia	clinical Lead	0.1	**11663**
Dementia	Clinical Lead	0.1	**4770**
Diabetes	Nurse	1.0	**34453**
Diabetes	Nurse	0.6	**21424**
Diabetes	Clinical Lead	0.2	**15697**
Primary Care	Clin. Trials Practitioner	1.0	**44983**
Primary Care	Nurse(<2month in post)	1.0	**965**
Primary Care	Clinical lead	0.1	**13152**
Primary Care	Clinical lead	0.1	**7520**
Respiratory	Nurse	1.0	**36678**
Respiratory	Physiotherapist	1.0	**17918**
Respiratory	Physiotherapist	1.0	**19513**
Respiratory	Physiologist	1.0	**44609**
Respiratory	Nurse	1.0	**31104**
Respiratory	Clinical Lead	0.1	**10268**
Respiratory	Clinical Lead	0.1	**10832**
Stroke	Nurse	1.0	**37115**
Stroke	Clinical lead	0.1	**9588**
Vision	Nurse	1.0	**44609**
Vision	Nurse	1.0	**18499**
Vision	Optometrist	1.0	**35555**
Vision	Technician	1.0	**39680**
Vision	Clinical Leads	0.1	**12552**
Vision	Clinical Lead	0.1	**6792**
Vision	Clinical Lead(speciality)		**13605**
Total staffing cost including CL PA's =			**£766,218**

Financial Breakdown for NICRN Staffing Costs Incurred in WHSCT

Group	Job Title	WTE Funded	Overall Total
Cardiovascular	Nurse	1.0	**26025**
Children's	Nurse	0.5	**12647**
Critical Care	Nurse	1.0	**25293**
Diabetes	Nurse	0.5	**18370**
Stroke	Nurse	0.5	**18370**
Total staffing cost including CL PA=			**£100,705**

This gives a staff annual spend against the NICRN of £40,417 for goods and services across all groups equating to a **total spend of £1,454,801**

APPENDIX 4 – Summary Tables for All Interest Groups

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Y/N)	RANDOMISED (Y/N)	NI MULTI CENTRE (Y/N)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Cardiovascular	Alecardio	Open	WHSCT	5	0	0	0	0	290	0	290	0	0.00%		Yes	Yes	No	Yes	CTIMP
Cardiovascular	CAPP	Open	SEHSCT	300	0	0	0	0	58	49	58	49	16.33%		No	Yes	No	No	CT Other
Cardiovascular	HPS2-THRIVE	Open	BHSCT	100	0	0	0	0	172	53	172	53	53.00%		Yes	Yes	No	Yes	CTIMP
Cardiovascular	MINT-HF	Open	BHSCT	112	0	0	181	21	366	28	547	49	43.75%		No	Yes	No	No	CTIMP
Cardiovascular	NOBLE	Open	SHSCT	40	-	-	-	-	0	8	0	8	20.00%		Yes	Yes	No	No	CTIMP
Cardiovascular	PARADIGM	Open	WHSCT	12	-	-	-	-	170	0	170	0	0.00%		Yes	Yes	No	No	CTIMP
Cardiovascular	PARC	Open	BHSCT	1900	0	0	0	0	316	556	316	556	29.26%		No	No	No	Yes	Observational
Cardiovascular	RADAR	Open	SHSCT	650	-	-	-	-	1416	388	1416	388	59.69%		Yes	No	Yes	No	Observational
Cardiovascular	STREAM	Open	SEHSCT	45	0	0	0	0	12	3	12	3	6.67%		Yes	Yes	Yes	No	CTIMP
Cardiovascular	TRACE RA	Open	WHSCT	40	0	0	0	0	220	11	220	11	27.50%		No	Yes	Yes	No	CTIMP
Cardiovascular	TRACE RA	Follow-Up	BHSCT	40	0	0	118	28	31	7	149	35	87.50%						
Cardiovascular	TRILOGY	Open	NHSCT	20	0	0	0	0	33	0	33	0	0.00%		Yes	Yes	No	No	CTIMP
Cardiovascular	ARISTOTLE	Follow-Up	NHSCT	19	0	0	156	1	4	1	160	2	10.53%		Yes	Yes	No	No	CTIMP
Cardiovascular	BH4 in Heart Failure	Follow-Up	BHSCT	50	0	0	0	0	250	27	250	27	54.00%		No	Yes	Yes	Yes	CTIMP
Cardiovascular	DAL OUTCOMES	Follow-Up	WHSCT	11	-	-	-	-	0	11	0	11	100.00%		Yes	Yes	No	No	CTIMP
Cardiovascular	IMPROVE IT	Follow-Up	NHSCT	62	0	0	368	5	81	10	449	15	24.32%		Yes	Yes	Yes	Yes	CTIMP
Cardiovascular	IMPROVE IT	Follow-Up	BHSCT	62	0	0	0	0	140	1	140	1	1.62%						
Cardiovascular	IMPROVE IT	Follow-Up	WHSCT	62	0	0	0	0	852	2	852	2	3.24%						
Cardiovascular	TRA-2P	Follow-Up	NHSCT	20	0	10	0	18	0	28	0	56	280.00%		Yes	Yes	No	No	CTIMP
Cardiovascular	TRACER	Follow-Up	NHSCT	27	0	1	205	2	68	5	273	8	29.63%		Yes	Yes	Yes	No	CTIMP
			TOTALS:	3059	0	11	847	54	3593	1058	4440	1123	36.71%						

Count Yes	12	15	6	3
Study Count	17	17	17	17
Percentage	70.59%	88.24%	35.29%	17.65%

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Y/N)	RANDOMISED (Y/N)	NI MULTICENTRE (Y/N)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Childrens	GAS	Open	BHSCT	25	0	0	0	0	5	1	5	1	4.00%		No	Yes	No	Yes	CTIMP
Childrens	I2S2	Open	BHSCT	130	0	0	0	0	not available	20	not available	20	15.38%		No	Yes	No	Yes	CTIMP
Childrens	Management of CF	Open	BHSCT	100	0	0	0	0	not available	20	not available	20	20.00%		No	No	No	Yes	Observational
Childrens	NIPPV	Open	BHSCT	42	0	0	not available	5	not available	9	not available	14	33.33%		No	Yes	No	No	CTIMP
Childrens	POP	Open	BHSCT	30	41	18	21	10	10	8	72	36	120.00%		No	Yes	No	No	CTIMP
Childrens	Trialnet	Open	BHSCT	900	not available	0	not available	20	not available	721	0	741	82.33%		No	No	No	No	CTIMP
Childrens	Boost 2	Follow-Up	BHSCT	20	not available	17	not available	3	not available	40	not available	60	300.00%		No	Yes	No	No	CTIMP
Childrens	Bracelet	Follow-Up	BHSCT	3	0	0	0	0	not available	6	not available	6	200.00%		No	Yes	No	No	Observational
Childrens	Decide	Follow-Up	BHSCT	30	0	0	not available	12	not available	8	not available	20	66.67%		No	Yes	No	No	CT Other
Childrens	Epilepsy Study	Follow-Up	BHSCT	33	0	0	0	0	191	59	191	59	177.00%		No	No	Yes	Yes	Observational
Childrens	Epilepsy Study	Follow-Up	SHSCT	33	0	0	0	0	31	7	31	7	21.00%						
Childrens	Epilepsy Study	Follow-Up	WHSCT	33	0	0	0	0	54	33	54	33	99.00%	Total is 99					
Childrens	Magnetic	Follow-Up	SHSCT	15	0	0	0	0	not available	14		14	93.33%		No	Yes	Yes	No	CTIMP
Childrens	Magnetic	Follow-Up	WHSCT	15	0	0	0	0	not available	14	not available	14	93.33%	Total is 28					
Childrens	Refractory Asthma	Follow-Up	BHSCT	50	not available	6	not available	17	not available	37	not available	60	120.00%		No	No	Yes	No	Observational
Childrens	Refractory Asthma	Follow-Up	SHSCT	50	not available	0	not available	21	not available	10	not available	31	62.00%	Total is 91					
			TOTALS:	1510	41	41	21	88	291	1007	353	1136	75.23%						

Count Yes	0	8	3	4
Study Count	12	12	12	12
Percentage	0.00%	66.67%	25.00%	33.33%

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Y/N)	RANDOMISED (Y/N)	NI MULTI CENTRE (Y/N)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Critical Care	FIRE	Open	BHSCT	NA	-	-	248	248	551	482	799	730	NA		No	No	Yes	No	Observational
Critical Care	FIRE	Open	WHSCT	NA	-	-	0	0	317	317	317	317	NA						
Critical Care	FINB/FINB	Open	BHSCT	120	-	-	-	-	60	58	60	58	48.00%		No	Yes	No	Yes	CTIMP
Critical Care	HARP 2	Open	BHSCT	12	-	-	-	-	10	4	10	4	25.00%		No	Yes	Yes	Yes	CTIMP
Critical Care	TAPB/TAH	Open	BHSCT	40	-	-	-	-	35	30	35	30	75.00%		No	Yes	No	Yes	CTIMP
Critical Care	ART 123	Closed	BHSCT	5	-	4	123	0	168	1	291	5	100.00%		Yes	Yes	No	No	CTIMP
Critical Care	BALTI II	Closed	BHSCT	73	-	50	174	19	168	4	342	73	100.00%		No	Yes	Yes	No	CTIMP
Critical Care	BALTI II	Closed	SEHSCT	73	-	-	91	8	102	1	193	9	12.33%						
Critical Care	BALTI Prevention	Closed	BHSCT	20	-	-	2	2	16	7	18	9	48.00%		No	Yes	No	No	CTIMP
Critical Care	Early Warning Systems	Closed	SEHSCT	67	-	-	-	-	-	73	-	73	108.00%		No	No	No	No	Observational
Critical Care	KGF	Closed	BHSCT	36	-	11	-	16	-	9	-	36	100.00%		No	Yes	No	No	CTIMP
			TOTALS:	446	0	65	638	293	1427	986	2065	1344	6	Count Yes	1	7	3	3	
														Study Count	9	9	9	9	
														Percentage	11.11%	77.78%	33.33%	33.33%	

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Y/N)	RANDOMISED (Y/N)	NI MULTICENTRE (Y/N)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Dementia	Beta-secretase in Mild Cognitive Impairment	Open	BHSCT	300	-	70	-	127	318	62	318	259	86.33%		No	No	No	No	Other
Dementia	Investigation of platelet B-secretase activity in Alzheimer's (Todd S)	Open	BHSCT	280	26	13	-	89	369	107	395	209	74.64%		No	No	No	No	Observational
Dementia	Mobile Phone Video Streaming (MPVS)	Open	BHSCT	40	-	9	-	18	7	21	7	48	120.00%		No	No	No	No	Observational
Dementia	Gamma Secretase Inhibitor in Alzheimers Disease (Eli Lilly)	Follow-Up	BHSCT	10	-	-	-	4	4	4	4	8	80.00%		Yes	Yes	No	No	CTIMP
Dementia	Post Herpetic Neuralgia	Follow-Up	BHSCT	5	-	-	-	-	20	5	20	5	100.00%		Yes	No	No	Yes	Observational
			TOTALS:	635	26	92	0	238	718	199	744	529	83.31%	Count Yes	2	1	0	1	
														Study Count	5	5	5	5	
														Percentage	40.00%	20.00%	0.00%	20.00%	

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Yes / No)	RANDOMISED (Yes /No)	NI MULTICENTRE (Yes / No)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Diabetes	Antimicrobial Peptides in Diabetes	Open	BHSCT	200	-	-	0	0	650	112	650	112	56.00%		No	No	No	Yes	Observational
Diabetes	Continuous Glucose Monitoring	Open	NHSCT	16	-	-	-	-	23	8	23	8	50.00%		No	Yes	No	Yes	CT Other
Diabetes	FIRST	Open	BHSCT	102	-	-	62	45	84	58	146	103	100.98%		No	Yes	No	No	CT Other
Diabetes	HAPO Family	Open	BHSCT	1450	0	273	101	382	635	456	736	1111	76.62%		No	No	No	No	Observational
Diabetes	Lipid Oxidation/ROS Exercise	Open	SEHSCT	30	-	-	-	-	14	4	14	4	13.33%		No	Yes	No	Yes	CT Other
Diabetes	Glycated Intestional Peptides. Phase	Follow-Up	WHSCT	72	-	-	0	13	799	34	799	47	65.28%		No	No	No	Yes	CT Other
Diabetes	NN1250 - SIBA 3770	Follow-Up	BHSCT	3	-	-	-	-	5	3	5	3	100.00%		Yes	Yes	No	Yes	CTIMP
Diabetes	CANVAS	Closed	BHSCT	12	-	-	-	-	316	13	316	13	108.33%		Yes	Yes	Yes	Yes	CTIMP
Diabetes	CANVAS	Closed	WHSCT	3	-	-	-	-	0	0	0	0	0.00%						
Diabetes	CD Rom Evaluation	Closed	BHSCT	101	-	-	80	56	21	20	101	76	75.25%		Yes	Yes	No	No	CT Other
Diabetes	DIPsat	Closed	SEHSCT	160	-	-	40	30	9	8	49	38	23.75%		No	No	No	No	Observational
Diabetes	Need for Urgent Care	Closed	WHSCT	40	-	-	8	5	15	17	23	22	55.00%		No	No	No	No	Observational
Diabetes	NN1250 - SIBA 3668	Closed	WHSCT	4	-	-	356	0	0	0	356	0	0.00%		Yes	Yes	Yes	No	CTIMP
Diabetes	NN1250 - SIBA 3668	Closed	SEHSCT	4	-	-	2	2	1	1	3	3	75.00%						
Diabetes	TUDA	Closed	NHSCT	800	-	-	-	-	1102	800	1102	800	100.00%		No	No	Yes	No	Observational
Diabetes	TUDA	Closed	WHSCT	1200	-	-	1575	503	960	697	2535	1200	100.00%						
			TOTALS:	4197	0	273	2224	1036	4635	2231	6859	3540	84.35%	Count Yes	4	7	3	6	
														Study Count	13	13	13	13	
														Percentage	30.77%	53.85%	23.08%	46.15%	

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Y/N)	RANDOMISED (Y/N)	NI MULTI CENTRE (Y/N)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Primary Care	ASCEND	Open	Multicentre	20	-	-	n/a	2	n/a	24	-	24	120.00%	MULTIPLE TRUSTS	No	Yes	Yes	No	CTIMP
Primary Care	Lung-SEARCH	Open	Multicentre	100	-	-	36	16	135	90	135	90	90.00%	MULTIPLE TRUSTS	No	Yes	Yes	No	CT Other
Primary Care	CANCER SURVIVORS	Open	Multicentre	270	-	-	-	-	-	108	-	108	40.00%	MULTIPLE TRUSTS	No	No	Yes	No	Observational
Primary Care	BACK 2 ACTIVITY	Follow-Up	Multicentre	50	-	-	-	-	79	57	79	57	114.00%	MULTIPLE TRUSTS	No	Yes	Yes	No	Observational
Primary Care	H1N1V IN PREGNANCY	Follow-Up	Multicentre	15	-	-	-	0	-	15	-	15	100.00%	MULTIPLE TRUSTS	Yes	No	Yes	No	Observational
Primary Care	Patient Choice	Closed	Multicentre	20	-	-	-	22	-	-	-	22	110.00%	MULTIPLE TRUSTS	No	No	Yes	No	Other
Primary Care	Stroke Survivor needs	Closed	Multicentre	125	-	-	-	153	-	-	0	153	122.40%	MULTIPLE TRUSTS	No	No	Yes	No	Observational
Primary Care	APEP	Closed	Multicentre	60	-	-	-	67	-	-	0	67	111.67%	MULTIPLE TRUSTS	No	Yes	Yes	No	Other
Primary Care	Medivision	Closed	Multicentre	300	-	-	-	300	-	-	0	300	100.00%	MULTIPLE TRUSTS	No	No	Yes	No	Observational
			TOTALS:	**960**	**0**	**0**	**36**	**560**	**214**	**294**	**214**	**836**	**87.08%**	**Count Yes**	1	4	9	0	
														Study Count	9	9	9	9	
														Percentage	**11.11%**	**44.44%**	**100.00%**	**0.00%**	

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Y/N)	RANDOMISED (Y/N)	NI MULTI CENTRE (Y/N)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Respiratory	Bacterial Proteonomics of CF Sputum	Open	BHSCT	40	-	-	-	-	10	10	10	10	25.00%		No	No	No	Yes	Observational
Respiratory	Lung Search	Open	BHSCT	100	-	-	not available	21	not available	61	0	82	82.00%		No	Yes	No	No	CT Other
Respiratory	Restore	Open	BHSCT	6	-	-	not available	1	not available	6	0	7	116.67%		Yes	Yes	No	No	CTIMP
Respiratory	Role of Anerobic Bacterial Infection in CF	Open	BHSCT	170	-	-	-	-	not available	11	0	11	6.47%		No	No	No	Yes	Observational
Respiratory	Tiotropium COPD (BI)	Open	BHSCT	8	-	-	not available	6	938	5	938	11	137.50%		Yes	Yes	No	No	CTIMP
Respiratory	Treatment of Depression in Refractory Asthma	Open	BHSCT	20	-	-	-	-	not available	8	0	8	40.00%		No	Yes	No	Yes	Observational
Respiratory	HT Saline	Follow-Up	BHSCT	20	-	-	-	-	401	21	401	21	105.00%		No	Yes	No	No	CTIMP
Respiratory	PTC 124	Follow-Up	BHSCT	8	-	-	-	-	1	1	1	1	12.50%		Yes	Yes	No	No	CTIMP
Respiratory	Vertex Rollover	Follow-Up	BHSCT	1	-	-	-	-	2	2	2	2	200.00%		Yes	No	No	Yes	CTIMP
Respiratory	Ciprofloxacin for Inhalation	Closed	BHSCT	3	-	-	-	-	45	0	45	0	0.00%		Yes	Yes	No	Yes	CTIMP
Respiratory	Inhaled Ciprofloxacin	Closed	BHSCT	8	-	-	not available	1	213	21	213	22	275.00%		Yes	Yes	No	No	CTIMP
Respiratory	Inhaled Ciproxin	Closed	BHSCT	5	-	-	not available	5	not available	2	0	7	140.00%		Yes	Yes	No	No	CTIMP
Respiratory	Schering P05575	Closed	BHSCT	6	-	-	0	0	626	1	626	1	16.67%		Yes	Yes	No	No	CTIMP
			TOTALS:	395	0	0	0	34	2236	149	2236	183	46.33%						

Count Yes	8	10	0	5
Study Count	13	13	13	13
Percentage	61.54%	76.92%	0.00%	38.46%

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Y/N)	RANDOMISED (Y/N)	NI MULTI CENTRE (Y/N)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Stroke	AVERT	Open	BHSCT	27	-	-	-	-	114	10	114	10	37.50%		No	Yes	Yes	Yes	CT Other
Stroke	AVERT	Open	NHSCT	27	-	-	-	-	69	0	69	0	0.00%						
Stroke	AVERT	Open	SEHSCT	27	-	-	-	-	447	12	447	12	45.00%						
Stroke	ENOS	Open	NHSCT	28	-	-	75	5	557	2	632	7	25.45%		No	Yes	Yes	No	CTIMP
Stroke	ENOS	Open	SEHSCT	28	-	-	8	0	421	2	429	2	7.27%						
Stroke	ENOS	Open	SHSCT	28	-	-	-	-	192	1	192	1	3.64%						
Stroke	ENOS	Open	WHSCT	28	-	-	22	0	6	1	28	1	3.64%						
Stroke	IRIS	Open	SEHSCT	10	-	-	-	-	231	3	231	3	30.00%		Yes	Yes	No	Yes	CTIMP
Stroke	IST 3	Open	BHSCT	12	-	-	-	-	65	3	65	3	25.00%		No	Yes	No	Yes	CTIMP
Stroke	LOTS	Open	SHSCT	48	-	-	-	-	365	55	365	55	115.79%		No	Yes	Yes	No	CT Other
Stroke	LOTS	Open	WHSCT	48	-	-	22	6	176	21	198	27	56.84%						
Stroke	NMES	Open	BHSCT	25	-	-	-	-	19	3	19	3	12.00%		No	No	No	Yes	Other
Stroke	SOS	Open	NHSCT	90	-	-	-	-	103	1	103	1	1.11%		No	Yes	Yes	No	CT Other
Stroke	SOS	Open	SEHSCT	90	-	-	-	-	175	5	175	5	5.56%						
Stroke	SOS	Open	SHSCT	90	-	-	-	-	103	3	103	3	3.33%						
Stroke	SOS	Open	WHSCT	90	-	-	-	-	6	0	6	0	0.00%						
Stroke	TNA	Open	BHSCT	120	-	-	23	21	123	48	146	69	57.50%		No	No	Yes	No	Other
Stroke	TNA	Open	NHSCT	120	-	-	-	-	16	0	16	0	0.00%						
Stroke	TNA	Open	SEHSCT	120	-	-	-	-	444	48	444	48	40.00%						
Stroke	Carers Study Ph1	Closed	NHSCT	15	-	4	75	14	82	3	157	21	140.00%		No	No	Yes	No	Other
Stroke	Carers Study Ph1	Closed	SEHSCT	15	-	1	0	10	7	0	7	11	73.33%						
Stroke	Carers Study Ph2	Closed	NHSCT	25	-	-	-	-	192	4	192	4	16.00%		No	No	Yes	No	Other
Stroke	Carers Study Ph2	Closed	SEHSCT	25	-	-	-	-	68	3	68	3	12.00%						
			TOTALS:	**970**	**0**	**5**	**225**	**56**	**3981**	**228**	**4206**	**289**	**29.81%**						

Count Yes	1	6	7	4
Study Count	10	10	10	10
Percentage	**10.00%**	**60.00%**	**70.00%**	**40.00%**

INTEREST GROUP	STUDY NAME / ACRONYM	ACCRUAL STATUS	TRUST	NI ACCRUAL TARGET	2008		2009		2010		TOTAL SCREENING	TOTAL PATIENTS ACCRUED	ACCRUAL AS % OF TARGET	COMMENT	COMMERCIAL (Y/N)	RANDOMISED (Y/N)	NI MULTI CENTRE (Y/N)	ADOPTED IN 2010 (Y/N)	DESIGN
					SCREENING	ACCRUAL	SCREENING	ACCRUAL	SCREENING	ACCRUAL									
Vision	Alzheimers & AMD	Open	BHSCT	40	0	0	0	0	0	0	0	0		study is yet to start - see emails in study folder	No	No	No	Yes	Observational
Vision	Candidate Genes (GDBA)	Open	BHSCT	500	0	0	105	105	319	319	424	424	84.80%		No	No	No	Yes	Observational
Vision	GDB (Guide Dogs)	Open	BHSCT	300	0	0	0	0	not available	187	0	187	62.33%		No	No	No	Yes	Observational
Vision	MERLOT	Open	BHSCT	363	0	0	0	0	100	52	100	52	14.33%	another CARF study - figures are not really accurate	Yes	Yes	No	Yes	CTIMP
Vision	NINA	Open	BHSCT	70	0	0	0	0	not available	52	0	52	74.29%		No	No	No	Yes	Observational
Vision	Orsya	Open	BHSCT	132	0	0	0	0	not available	112	0	112	84.85%		Yes	No	No	Yes	Observational
Vision	IVAN	Follow-Up	BHSCT	40	0	30	not available	11	not available	2	0	43	107.50%		No	Yes	No	No	CTIMP
			TOTALS:	**1445**	**0**	**30**	**105**	**116**	**419**	**724**	**524**	**870**	**60.21%**	**Count Yes**	2	2	0	6	
														Study Count	7	7	7	7	
														Percentage	**28.57%**	**28.57%**	**0.00%**	**85.71%**	

APPENDIX 5 – NICRN Study Adoption Process

Proposer contacts NICRN CC

↓

NICRN CC sends Adoption Forms with Guidance Notes

↓

Proposer completes Section A and returns with a copy of Protocol or Summary (if available)

↓

NICRN Coordinator contacts Clinical Lead and agrees if application should wait to CMG meeting or be e-mailed to members to be 'approved in principle'

↓

The CMG confirm interest (either at meeting or via e-mail)

↓

Clinical Lead fills in Section B at the meeting or in advance of the meeting if possible

↓

The Co-ordinator circulates the documentation (Adoption form, Section C, Protocol) to:

- any other listed sites to confirm interest – if interested the PI should complete and return Section C (request return of form within 2 weeks)
- R&D Manager
- Clinical Trial Pharmacist if relevant

↓

Co-ordinator collates documentation

↓

Review Section C and develop project breakdown in collaborate with PIs and Network Staff

↓

Submit final forms via e-mail to Clinical Lead

↓

Clinical Lead signs off on adoption

↓

Section D is signed by Paul Biagioni and Clinical Lead at next CMG meeting to complete process

↓

Co-ordinator sends confirmation of Adoption e-mail to all PIs,
Network Staff, R&D Manager using agreed template

↓

Original signed Adoption forms and copy of confirmation e-mail kept in NICRN Study File

APPENDIX 6 – NICRN Adoption Guidance

Section A (To be completed by Proposer)
PLEASE NOTE FIELDS MARKED WITH * MUST BE COMPLETED OR THE APPLICATIONCANNOT BE PROCESSED.

***Proposer**	
The person proposing the study for adoption to the Clinical Management Group e.g. Chief Investigator/Principal Investigator, Pharmaceutical company representative etc.	
***Acronym or Short Name**	
The short name for the study	
***Study Title**	
The full title of the study	
ISRCTN	**EudraCT No**
International Standard Randomised Controlled Standard Number (if available)	European Union Drug Regulating Authority Clinical Trials Number (if available)
MREC No	**MREC Date**
Multi Centre Research Ethics Committee number (if available)	The date MREC approved (if available)
***Randomised Study?**	
Choose between, Randomised/Non Randomised or Both	
***Primary Study Design**	
Interventional ☐	**Both** ☐
Observational ☐	**Not Specified** ☐
If the study design does not meet the selection above then choose 'not specified'.	
***Interventional**	
Treatment ☐	**Prevention** ☐
Screening ☐	**Process of Care** ☐
Diagnosis ☐	**Not Specified** ☐
If the study design is interventional please choose from the categories above, this does not need to be completed if the study is not interventional.	
***Phase**	
Pilot / Feasibility ☐	**II / III** ☐
Experimental Medicine ☐	**III** ☐
I ☐	**IV** ☐
I / II ☐	**N/A** ☐
II ☐	
Which phase is the study?	
***Main Objectives/Summary of Study (attach a copy of Protocol if available)**	
Give a brief summary of the study.	
***Main Inclusion & Exclusion Criteria**	
List the main inclusion and exclusion criteria from the protocol.	

***Funder**	**Sponsor**
Provide details of the funder of the study	Provide details of the sponsor of the study
***Degree of Commercial Participation**	
None ☐ **Industry supported, non-industry sponsored** ☐	**Industry supported, industry sponsored** ☐ **Not Specified** ☐

***Planned Start of Recruitment**	***Planned End of Recruitment**	**End of Study**
Provide the date of the start of recruitment for NI	Provide the planned date of the end of recruitment for NI	What date will the study complete follow-up and close?

***Open to New Centres**	
Yes, within lead country only ☐ **Yes, within & outside lead country** ☐ **Yes, outside lead country only** ☐	**No** ☐ **Unknown** ☐
Is the study open to other centres with NI/Outside NI or if not indicate "no"	
Estimated Accrual (NI)	
Please advise the estimated accrual figure for Northern Ireland	
***Chief Investigator Contact Details**	
Provide the CI contact details	
***Study Co-ordinator Contact Details**	
Provide the study co-ordinator contact details if there is a co-ordinator for the study or indicate that the CI is the co-ordinator	
***Accrual Contact Details**	
Provide the contact details of the person nominated to manage the accrual information and who will provide this to the NICRN co-ordinating centre on a monthly basis.	
Research Governance Status?	
Indicate whether the study has been submitted to a Trust research governance office and if so advise on the status of the application.	
Indicate NI sites involved or interested?	
Indicate what hospitals/sites in NI (if any) have expressed interest in participating in this study.	
Completed by	**Date**

Section B (To be completed by Clinical Lead)

Are there any competing or conflicting studies that would impact on patient recruitment?				
Based on the CMG portfolio consider whether there are conflicting studies which would affect recruitment to the study				
Could this study involve another NICRN group?				
If the study could involve other groups within the NICRN indicate which group(s)				
Table at Next CMG Meeting?				
Advise if the study is to be proposed at the next CMG meeting				
Circulate to other Sites?				
Site	PIs	Telephone No.	Email	
For potential participation in the study advise which PIs at which sites should this study be circulated to.				
Other Issues / Questions?				
Are there any other issues around the study which need to be addressed (these may have been discussed at the CMG)				

Section C (Separate Form – To be completed by PI at each site)

Section D (Office Use)

NICRN ID	**NIHR ID**
The NICRN ID should be detailed	If available to NIHR portfolio ID should be detailed
Target Accrual (NI)	
A summary of the accrual targets from the SSF forms will give an overview of the overall target accrual for NI sites.	
Adopted (and if not why)?	
Yes/if no then an explanation should be provided	
NICRN Clinical Lead(s)	**Date**
To be signed off by the clinical lead	
NICRN Director (Signature)	**Date**
To be signed off by the NICRN Director	

Study Name:
Group:

Section C (To be completed by PI at each site)

Site
The hospital/trust site where the PI is based.
PI
The principal investigators name at this site.
How will the potential patients be identified?
Advise how potential patients will be identified at the Trust site e.g. screening logs/clinics etc.
How many patients fulfilling the study inclusion/exclusion criteria attend your clinic per month/year?
Using the information above estimate how many patients attend the clinic/ward over a period of time that meet the inclusion/exclusion criteria.
How many patients per month can your site recruit
Give an accurate, conservative target of how many patients the site can recruit to the study *per month*, based on the information above.
How many hours a month do you require from the Network Research Staff to carry out this study? (Please liaise with Clinical Lead or Support staff to identify requirements)? ATTACH A PROJECT BREAKDOWN OF ACTIVITIES AND TIME THE NETWORK STAFF WOULD BE REQUIRED TO PERFORM ON STUDY
The NICRN has research staff at each Trust site who may be able to assist the PI at the site with this study. This decision is based on availability of the staff, the workload of the staff and the amount of time required at each site. It will be made by the clinical lead and the clinical management group along with the nursing staff & management. **Therefore it is important to consider the protocol and the study requirements and give an accurate figure for the amount of time you would require from the network staff in hours per month. If the study has a co-ordinator they may be able to provide you with further information to make this decision. This information should be discussed with the clinical lead & research staff at the site.**
Have you considered all the resources required for the study for eg. Location, labs, pharmacy
Considering the study protocol and requirements for the study ensure that each site is capable of carrying out the study requirements e.g. lab test/x-rays/patient accommodation/storage & distribution of study drug etc. **If these issues are not considered at the set up of the study this will delay the start of the study or may affect the sites ability to participate in the study.**
At what stage is your Trust Research Governance application?
The study has to be approved at each Trust site governance office. Advise on the progress of the application to the site's research governance office. **If not yet submitted then consider advising the office on the upcoming study and submitting the application within an adequate timeframe as a delay in gaining approval will affect the study start.**

Completed By	**Date**