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**Peninsula Cancer Research Network  
Annual Progress Report  
1<sup>st</sup> April 2009-31<sup>st</sup> March 2010**

**and**

**Peninsula Cancer Research Network  
Work Programme  
1<sup>st</sup> April 2010-31<sup>st</sup> March 2011**

**Compiled By**

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## Executive Summary

### Key achievements of the network during 2009-10

**Portfolio:** During 2009/10 the Peninsula overall has recruited 1,967 patients into 99 trials across 18 NCRI Clinical Studies Groups. Compared to 2008/9 this represents increased activity of 39% in RCTs, 105% in Non-RCTs and overall an 85% increase for all trials. Significant increased activity in Breast, Colorectal, Gynaecological, Primary Care and Upper GI (Non-RCTs) with general increased RCT activity particularly in Head and Neck, Lung, Haematological and Complementary Therapy trials.

**Recruitment:** The Network has recruited 8.7% (surpassing NCRN target of 6.5%) of incident cancer patients (including those with a pre-malignancy) into NIHR portfolio RCTs (commercial and non-commercial) during 2009-10.

The Network has recruited 24% of incident cancer patients (including those with a pre-malignancy) into all NIHR portfolio RCTs (commercial and non-commercial) during 2009-10.

Recruitment of 15 patients to 7 NIHR Commercial trials across 10 sites with 3 further trials opening soon and 3 trials now closed.

**Comparative Performance:** Overall 1,953 participants were recruited to NIHR cancer portfolio studies (i.e. patients and volunteers) during 2009-10 with a further 14 recruited to additional sub-studies and therefore 1,967 participants in total. Best performing year overall.

Overall the total number of cancer patients (cancer and pre-malignant) recruited since 2001 is 9,464 participants with a further 1,394 participants supporting screening and prevention studies (absolute total of 10,858 participants).

**Network resources:** Approximately 42.5 WTE individuals are now involved in recruiting or supporting recruitment to NIHR cancer portfolio studies across the network. The PCRN funds 17.4 WTE and therefore financially supports 40% of the workforce. This excludes the many supportive Clinicians, investigators and service staff.

**Staffing structure:** This year has seen the appointment of a Lead Oncology Research Nurse at PHNT and new Oncology Trials manager at RDEFT bringing much expertise and new ideas to the network. There has been significant restructuring of workforce and skill mix at PHNT to deliver a broader portfolio of trials supported by both trust and network. The Oncology research team at NDHT is now supporting Haematology trials, and increasing RCT trials and a new R&D Manager is driving forward policies, processes and performance management.

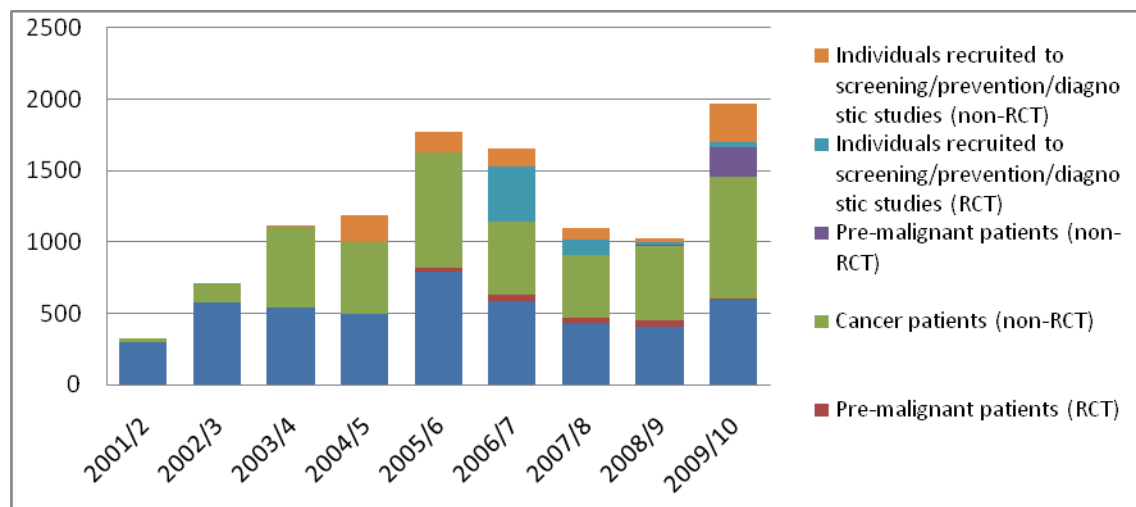
**Workforce development:** The RNM is leading Central region (12 NCRN Networks) training and education group. Focus is delivery of cancer specific training across the region and aims to improve equitable access to training.

**PHNT:** Lead Oncology & Trust Lead Research Nurses have delivered training on: ICH GCP, IRAS, Centrifuge, Dry Ice, CSP, Essential Skills for New Staff, Essential and Mandatory training, Research Network Forum, Archiving, KSF and Appraisal. To enhance skills, improve confidence, credibility and competence in delivering safe research to their patients. Proposal for a Student Nurse placement for 3 months in clinical research in collaboration with the Clinical Nurse Education Team

A Senior Research Practitioner was appointed at RDEFT in December 2009 (FSF funded) leading to the expansion of the surgical breast portfolio. This has led to some very innovative changes greatly enhancing the support to these trials, success both in delivery and changing research practice. Similar success at RCHT with Lung, Gynecological and surgical Breast and radiotherapy studies with a highly motivated team as evidenced by high recruitment activity.

**Consumer Involvement:** The PCRN has been well supported by two members on the Steering Committee and support on the FSF funding panel. An audit is planned looking at topics like patient information and awareness of trials in the region. The aim is to monitor the contributions from the clinical trial team; improve service delivery and identify areas for improvement.

**Annual Recruitment (2001/2 to 2009/10) inclusive:** RCT, non-RCT, cancer patients, patients with pre-malignancy, non-cancer patients.



### Key priorities for the network for 2010-2011 and beyond

- **Support to Site Specific Group (NSSG) Research Leads** to lead site portfolio development with better definition of roles and responsibilities. More frequent but simplified research reports.
- **Develop a more robust centralised approach for Peer Review Measures** - to fully integrate the multi disciplinary team (MDT) and Site Specific Group (NSSG) Research Peer Review measures so activity is reviewed annually and areas for potential growth /increased activity are developed and findings feed into the reporting process.
- **Ensure training provision reflects assessed training needs** The PCRN identified priorities for training via an online survey. To repeat this annually and build into the Central regional training strategy. Develop local delivery in tandem with this and other provision by Trusts and CLRN.
- **Maintain/increase recruitment** Build on successful achievements .e.g. Urology, Surgical Breast, Gynecology and Lung trials. To encourage new sites e.g. Palliative care and skin cancer. To work with CLRN to deliver more radiotherapy trials
- **Maximise potential participation in Industry trials** PCRN will pilot whether increased data manager support to commercial trial feasibility, costings and set up, results in increased Peninsula site selection and, facilitating recruitment of these trials to time and target.

## 1. Organisation and Development of Network

### 1.1 Overview of staffing profile

All research and support staff in the network who contribute to NIHR cancer portfolio (NCRN activity) are listed in **Appendix 2**.

The current staffing profile of the network supporting NIHR cancer portfolio activity is comprised of staff supported from a number of sources but predominantly through NCRN-core funding, through funds allocated by the Peninsula Comprehensive Local Research Network (PCLRN) funding via the new stream of “Flexibility and Sustainability funding” and through commercial income.

There are currently at least 67 staff who receive some funding to support NIHR cancer portfolio activity. The “total full strength” WTE staffing (regardless of funding source) is 43.25 WTE.

We estimate that 40% of the total staff are currently funded by NCRN Core Funding and NCRN FSF Funding, 54% by the Comprehensive Local Research Network (CLRN) and approximately 6% through Commercial funds and some grant funding.

A total of 8 posts received some support by the NIHR Flexibility and Sustainability and funding stream and these posts continue into 2010/11.

All acute Trusts within the Network receive access to both NCRN and CLRN research infrastructure support as shown in appendix 2. The level of overall support is largely commensurate with catchment populations and current activity levels

The Peninsula CLRN has been proactive in addressing indirect support to pharmacy, pathology and radiology which are fundamental to the delivery of the Cancer Trials Portfolio. Wide consultation to Pharmacy and radiology stakeholder in September, 2008 identified more specific needs.

The Imaging review identified the need for targeted administrative, medical physics and radiographer support, which has been reflected in the 2009/10 Key Service Support allocations (£40,000 for imaging administrators, £52,000 for Medical Physics Sessions and £70,000 for radiographer support). Within Pharmacy services it was identified more Pharmacist support was required (£165,000) was allocated for support at 8a or 8c level. Pathology was also identified as an area with potential blocks, funding similarly allocated for band 6 MLSO cover (£83,000) using recruitment into interventional cancer trials as a surrogate for activity.

The Peninsula Cancer Research Network welcomes this support which clearly recognises the necessity of these services to support our ability to engage in interventional studies. Whilst benefits of this directed support are beginning to be realised in some trusts we recognise that proactive monitoring of the performance of this support is vital. Shortages of staff with these specific skills are a national issue. Identifying and appointing skilled pharmacy and medical Physics staff remains challenging. This is however vital if increased activity in key interventional studies is to be achieved and in particular expansion of the radiotherapy trials portfolio.

North Devon District Hospital have no vacant posts, wish to upgrade the post of Research Secretary with increased duties to support trial set up. There have been some internal changes within the staffing structure.

Derriford Hospital has seen a significant positive restructuring and strengthening of staffing supported both by the FSF funding stream and supported by Trust R&D Management. The appointment of the Lead Oncology Research Nurse has been key to delivery of increased accrual to Oncology studies. A recent review of skill mix has led to the appointment of a Band 7 Research Nurse with a remit to set up Research Nurse led follow up clinics. In addition the Trust has supported 1.7 WTE Band 5 Research Nurse posts and a further 0.36 WTE administrative support. This builds on the improved administrative support provided by 2009/10 FSF. The Trust has recently advertised for additional Oncologists and it is hoped that appointments should provide additional much needed support with regard to colorectal trials.

Future plans through FSF bids include proposals for a Band 6 Research Nurse to support Surgical/Oncology Breast studies and an additional 0.5 WTE Band 4 data managers post.

The Royal Cornwall Hospital team has benefitted from further expansion with the addition of a 0.6 WTE Research Nurse supporting peri-surgical and genetic Breast studies, a 0.4 WTE Research Nurse developing the Lung and Melanoma portfolio. A further Research Radiographer Post currently has not been appointed although advertised twice. There has been a restructuring within the team with the Research and Development Facilitators taking over greater management responsibilities for respective trials portfolio's. The administrative support is now established. Plans for 2010/11 include a band 4 Research Healthcare assistant and 0.2 WTE Paediatric Oncology Research Nurse.

The Royal Devon and Exeter Hospital has seen the appointment of a new Manager, with a positive impact on the morale and support to the team, increased activity and addressing setting up new trials. There are no issues with regard to staff retention. There has been some pressure due to staff sickness during the year and an increased workload burden but now much improved and with no significant impact on activity. The appointment of a Senior Research Practitioner supporting Breast Surgical studies has been a very successful and innovative post. Support to Urology continues with a highly motivated clinical team and most recently appointment of a Research Officer should benefit delivery of Cancer Genetic Trials across the Peninsula. Future plans include a proposed Band 5 data Manager supporting both Commercial NCRN badged trials and radiotherapy studies. It is planned the post holder will work collaboratively in the support of setting up these trials with other Network Trusts in tandem with the Research Network Manager. Lack of office space is an issue for this team.

Torbay Hospital has needed to restructure its current team. One Research Nurse has recently been promoted to a team leader's position. However, due to clinical workload commitments the 2 Haematology Clinical Nurse Specialists who historically have led and managed all Haematology Cancer Trials is no longer viable. This work has been absorbed within the remaining team and at present the team lacks capacity to expand activity. This is recognised by the R & D Manager. Recent FSF bids proposing an additional Band 6 Research Nurse and Band 7 Research Radiographer were unsuccessful. The team have however continued to deliver stable activity and a high proportion of patients in RCT's to their credit. Core NCRN budget is committed with no immediate opportunity to provide additional support other than through discussion with the CLRN. The move of a highly trials active Oncologist from Torbay to Exeter may also have some impact. The Torbay team have moved into a new building "The Horizon Centre" with excellent facilities.

## 1.2 Workforce development<sup>1</sup>

The Research Network training link role is incorporated into the role of the Research Network Manager and realistically less than 0.1 WTE of the role can be allocated to this important aspect of the Research Network.

During 2009/10 additional specific local training provision facilitated by the Research Manager has been directed to the support of staff attending NIHR and NCRN training courses and courses specific to individual professional development.

NIHR/ NCRN Courses attended include:

- Communication regarding Randomised Controlled Trials - April 2009
- GCP & EU Directive New Staff - May 2009
- Valid Informed Consent - May 2009
- Cancer, Policy & Politics - June 2009
- GCP & EU Directive Experienced Staff - July 2009
- Essential for New Clinical Research - February 2010
- Inspection Readiness - March 2010

The Research and Development Manager in Exeter and CLRN Senior Manager have continued in the local delivery of the “Communications Training for RCT’s”.

A significant amount of time was spent by the Research Network Manager between January and April 2010 in setting up and leading the NCRN Central Regional Training and Education Group. **The following section is included particularly for the Peninsula readership of this report to provide an update on the developments of this group.**

### **This group:**

- Supports the national ambition that Cancer Research Staff are fully trained to the highest quality in research governance and processes; understand the complexities of the disease itself and treatments available to ensure patient safety.
- Aims to provide robust structures, processes, partnerships and communication links to facilitate the development and delivery of a regional programme of cancer-specific and generic training courses. This programme should be informed by and meet the needs of its workforce and delivered in association with partner organisations.
- Serves as a platform for discussion, sharing of good practice and expertise, creative thinking and developing new initiatives. It aspires to creating new courses, piloting and evaluating them locally with a view to sharing them nationally.

The group formally met on 21<sup>st</sup> January, 2010 in Birmingham and have subsequently agreed the following:

**Some of the key aims of the group** are to:

- Develop strong communication links between the 3 nominated regional “Leads” to ensure consistency of approach and reduce duplication of effort across the 3 regions.
- The group will prioritise the NIHR portal, NCRN Central Training Group web pages and online discussion forums to maintain good communications and ensure their respective managers and staff can access these resources.
- Work in collaboration across networks within the region, and across the 3 regional T&E working groups. The group will all contribute to produce a joint Central Regional calendar of training events prior to the start of 2010 financial year.
- To work in collaboration with the Clinical Trials Units and other partner organisations (including CLRN/TCRN/ PCRNs) to achieve its ambitions.
- Lead on the development of new course ideas and be willing to pilot, evaluate, feed back to the UK NCRN T&E Working Group and agree a mechanism for rolling out successful pilot courses across all 3 regions.
- To support national programmes of work including representation on an editorial group for the Staff Induction Handbook and to support the development of a Staff Induction Programme.

The Central T&E working group has agreed to meet on 3 occasions in the first year. The frequency will be reviewed at the end of Year 1 but the group will meet at least on 2 occasions in subsequent years.

## **Strategy & Plans for Central Region**

### **Geographical Influences**

In the delivery of all aspects of the training programmes identified below the group is aware that there are logistical challenges in achieving equitable access to courses for its staff in particular those Networks on the Eastern and South West fringes. The needs of the staff on the peripheries of the region need to be taken into account in the development of a sustainable long term programme. We acknowledge that staff will want to attend training in other regions and that the group must facilitate this by joint working with both Pan London/ South England and North regions and should similarly consider linking with training links in Wales.

### **Cancer-specific training courses – core programme**

The group agreed that it would prioritise the support of the four courses outlined below which are current developed, of high quality, well evaluated and should remain part of the region’s core cancer-specific training programme:

- **Introduction to Cancer: Biology & Anatomy:** This 2 day course is currently provided by an external provider (O’Halloran Consultancy) and was previously funded by NIHR. The course consistently receives the highest evaluation scores of all NIHR courses and there is a high demand for this

course. 2 courses are planned within the region / year with the first course provisionally planned for Exeter in September, 2010.

- **Cancer Policy & Politics**: The group are keen to establish links and support the two NCRN Research Network Managers (Heather Phillips and Kim Tye, Pan London & SE region) who have developed and delivered this 1-day course on behalf of the NIHR Workforce Development Team since 2007. We understand that they also support the NCRI Consumers Liaison Group by providing a similar course tailored to the needs of newly-recruited consumers, as and when required.

One course per year in the region should meet the demand (max 40 delegates per course). We would plan to review the options for local provision of this course as a longer term aim.

- **Biological Agents: Demystifying the Science**: this course has filled an important gap in the knowledge of experienced/senior research staff (nursing and data management) and should therefore continue as part of the core training programme.

This course was initially developed by an external provider in collaboration with NCRN (via the Pan London & SE region [Heather Phillips] and supported by the NCRN CC) the external provider has agreed to provide 2 1-day courses in the region for the next two years. We will scope actual demand, and initially plan to support 2 courses in the region per year (30 places per course). Should demand prove higher we could contract separately with the provider to deliver further courses

We understand that provisionally courses will be provided in the Central region in September 2010, March and September 2011 and March, 2012.

- **Fallowfield “Communicating RCTs” Course**: the group agree that this course has continued to be a pivotal part of the local network training programme over several years.

The training is aimed at professionals involved in the informed consent process. The training package consists of various modules with video taped scenarios and interactive exercises the aim being to assist professionals in exploring their own practice.

There are currently 13 trainers delivering this training package across the region.

In order to further support these trainers the group will provide a shared database of contact details of all trainers to assist both Peer support of the trainers and to help plan the delivery of sessions. A one day catch up session is planned for the summer of 2010 to gather trainers together to discuss progress in rolling out the programme, share best practice, gain valuable feedback from the developers of the programme and from the feedback of delegates.

With a fully supported group of trainers the aim is to provide monthly sessions within the region, these will be open to any-one wishing to attend from the NCRN Central Region group.

## **Other Work Streams and Initiatives**

**Review of NCRN CC Induction Handbook** – Representatives from the central group will feedback and assist in development and encourage any potential improvements to the handbook.

### **Communications: Updating the Central Regions Information on the NCRN CC website**

The central group aspires to create an up-to-date events calendar on the NCRN webpage to keep all members of the group abreast of locally available training and to maximise awareness of local training.

The group will update the web pages to include:

Who we are? What are our aims? What are we working towards? Insert a link to view current central groups? Sign posting to generic courses e.g. GCP at more local level with links to courses.

The region already benefits from the existing **Birmingham Research Training Collaborative (BRTC)**. The web address is: <http://www.brtc.westmidlands.nhs.uk>

**Training needs analysis** – A training needs analysis project has been conducted in the South West of the Central region. This is a Western Comprehensive Local Research Network led initiative with Avon, Somerset and Wilts Cancer Research Network and Peninsula Cancer Research Network involvement.

The objective of the online training needs analysis is to inform those involved on local training priorities and requirements. The plan is to use the analysis to inform priority and assess demand for future training and plan to review this on an annual basis.

**Trial pathway planning** This evolved out of the NCRN Road Show Workshops in 2008 and was developed by RNMs across several networks/regions. There is potential to develop this as a course that could be rolled out via a 'train the trainer' programme.

Staffs in Pan Birmingham have kindly agreed to develop the materials with a view to delivering the course in the region. The content is of great value to NCRN Networks and Trials Units alike.

**Shadowing and mentoring – network/CTU cross-working** The group will explore the possibility of developing shadowing and/or mentoring projects between trials unit and networks. We will also conduct some exploration of the benefit of the use of shared tools such as trial summaries (in PowerPoint) and training summaries to empower networks to better promote trials involvement/participation.

**Engaging with Industry** - The central group will also engage with its links in Industry to look at the potential value in working with Pharmaceutical companies to deliver specific training course (Roche, Pfizer and Astra Zeneca). The central group will liaise with the NCRN CC's Industry lead, Jenny Gray, to explore this further.

**QoL and Statistics** – The Lead Research Nurse (CRUK-Birmingham) is in the early stages of designing a one-day conference looking at basic statistics and use of quality of life assessment forms in clinical practice. The day will take place in

September 2010 and the evaluation of this day will help to design a one day course that can be piloted in the region.

### **Data Managers Study Day**

The Greater Midland CRN have developed a Data Managers Study Day, scheduled for April, to train and educate data managers/ coordinators on some of the basics of chemotherapy, radiotherapy, understanding histology reports etc. There will be a combination of presentations and workshops/ demonstrations. The day will be evaluated with a view to rolling out across the region.

### **Course for New Consumers**

In consideration of the needs of consumers the group considered that these may be best met by providing short, local courses to small groups which may be just 1 or 2 delegates at a time. It is planned to develop a 1 day (portable) course that can be delivered locally to small groups of consumers. These courses should help meet the requirements of consumers for information on issues relating to clinical trials.

Content would include information on types of trials, our trials portfolio, how a patient is selected to participate, what information is provided & how they are supported, the patients experience, etc. Course material could be developed and piloted by the work stream and in consultation with the NCRI Consumers Liaison Group to utilise existing course material available.

### **Professional Development Training**

The group aims to compile a directory of training courses available in the region/nationally. The list will include courses/training undertaken in the past by group members or their colleagues that have been found to be beneficial. The possibility of running courses regionally will also be explored and the predicted uptake for such courses ascertained.

The provision of accessible education and training courses remains an issue particularly in respect of the geography of the region. Travelling time to attend courses outside of the network is especially prohibitive particularly for staff with child care commitments. The hope is that in the longer term learning materials and local trainers will develop to provide a more sustainable and robust training programme locally within the Peninsula.

Staff in Exeter have attended the "Essentials for New Clinical Staff course, local GCP update courses. The trust R&D department are developing workshops on research.

The manager is developing a structured and varied training and education programme for staff and is working with the medical team to incorporate clinical trials in the medical teaching sessions for Oncology staff. This will allow greater participation, knowledge of trials and allows the nursing staff to present trials to the medical team. It will also engage (hopefully) new staff to participate in research and to discuss issues surrounding trials and in particular, those not recruiting which will enable an action plan to be put in place for those having difficulties.

The T&E programme will primarily be for the cancer clinical trials team, especially in its immediate infancy but the aim is to reach out to service departments and other key staff involved in research and more importantly, engaging staff who have an interest in research.

Plans are in place to develop workshops in various aspects of research (such as financial costings, setting up a trial and breaking down barriers to research).

Developing nurse led areas which will enable them to remain updated in current practice and awareness of changes to policies/ guidelines in undertaking research.

**Content Will Include:**

Informed Consent  
Research & Clinical Governance  
Clinical Skills  
Formulations and Administration  
SOPs  
Ethics  
Consumer Involvement  
Audit & Clinical Trial Management  
Regulatory Approvals

One of the Research Nurses is to undertake a module in clinical trial management through the Oxford Brookes University to expand clinical trial knowledge.

During 2008/9 the Research Network Manager has remained a member of the NCRN Training and Education working group to ensure the issues faced by the region are raised to NCRN/ NIHR. The tangible benefits have been in maintaining awareness of the provision of national courses, understanding the direction of training provision. This information has been shared through reports circulated to the network steering group. It is planned that the forthcoming development of a more comprehensive Research Network website will help further raise awareness of training opportunities to wider network stakeholders.

**In Plymouth** there has been local training encompassing the following topics: ICH GCP, IRAS, Centrifuge, Dry Ice, CSP, Essential Skills for New Staff, Essential and Mandatory PHNT training, Research Network Forum, Archiving, KSF and Appraisal.

Some of the courses mentioned earlier are run by the Macmillan education team at PHNT & they are excellent foundation courses for people new to cancer & free to trust staff.

Members have staff have also accessed training for their own professional and personal development. For example, the Lead Oncology Research Nurse was released to undertake NURB 292 and NURB 360 – ‘Care / Enhanced Care of the Patient Requiring Chemotherapy’, Academic Partnership Modules between SDHFT and the University of Plymouth.

This demonstrates that the PHNT research workforce actively seek to develop and enhance their skills. Keeping them updated and appropriately trained enables the staff to be confident, credible and competent in delivering safe research to their patients, ensuring that the care and research they deliver are of the highest standard.

Going forward, the education and training strategy will take a twin approach – a programme of research related training covering a range of generic research knowledge and skills together with a more systematic approach to addressing the education and training needs of individuals as identified through the appraisal process.

The appropriate mechanisms to address the education and training needs of individuals will be reviewed through the appraisal/ KSF process. Additionally, the R&D Lead Research Nurse and the Lead Oncology Research Nurse will consider the overall picture of education and training needs that emerges from the appraisal process to identify potential topics/skills which may require education/training to be delivered in a more co-ordinated way e.g. organising a training event rather than sending individuals on courses.

From a trust wide perspective, and looking to the future, the R&D Lead Research Nurse and Lead Oncology Research Nurse are in collaboration with the Clinical Nurse Education Team to consider having a Student Nurse placement for 3 months in clinical research.

This placement will focus on the many clinical skills needed to be a research nurse whilst at the same time giving the opportunity for the Student nurse to view Research nursing as a credible, viable and interesting career option. These student nurses will be our workforce of the future.

The provision of high quality Good Clinical Practice (GCP) training to support the delivery of NIHR Portfolio studies is progressing in the Network with the roll out of 'Introduction to Good Clinical Practice (GCP)'.

The aim of this development is to provide the networks with the opportunity to have named individuals from the locality who are trained in the delivery of high quality GCP materials that can be delivered over one day or in modular form. These individuals are offered ongoing support both with training and with resources. This is progressing with several trainers now delivering this training and others undergoing the "train the trainer" programme.

### **Network Cancer Research Education Events.**

The 9<sup>th</sup> Annual Peninsula Cancer Research Symposium held on 15<sup>th</sup> May, 2009 was held at the Saunton Sands Hotel in North Devon. The programme was organised by Dr Anne Hong and the event was co-hosted by Dr. Katie Cross, Consultant Surgeon & Director of Cancer Services, North Devon District Hospital. It attracted around 110 attendees again from trusts, primary care, partners and other stakeholders across the Peninsula. It included presentations from Peninsula Investigators and included a talk by Dr Ming-Lee with an update on NCRI Lung Cancer Studies and included a Research Fellows/Scientists Forum. We received excellent presentations from all our local presenters. A full programme is included in the appendices.

The fourth Annual Haematology Research day was held on 14<sup>th</sup> January, 2010 in Totnes. This event is primarily attended by Haematology and affiliated Research Staff from across the Peninsula and focuses on developments in Haematological and Lymphoma studies. It was well attended and remains an annual event.

The 10<sup>th</sup> Annual Peninsula Cancer Research Symposium held on 7<sup>th</sup> May, 2009 was held at Dartington Hall, Totnes. The programme was organised by Mr Peter Donnelly, Consultant Surgeon & Research & Development Director, South Devon Healthcare Trust. It attracted around 130 attendees again from trusts, primary care, partners and other stakeholders across the Peninsula. It included presentations from both Peninsula Investigators and national speakers. It included the "Stuart Gibson Award" a Research Fellows/Scientists Forum encouraging new researchers to present their research. We received excellent presentations from all our local presenters. A full programme is included in the appendices.

These events provide excellent learning, a forum to share best Research practice but are occasions when there are real networking opportunities and thus are key events in the Peninsula Cancer Research Network calendar. The events are fully funded by support from commercial sponsors.

Torbay Hospital continues to host an annual “Riviera Research Day” in November which focuses on Research in South Devon and Cancer Research has been well represented at such events. There is also an annual “Cornwall Research Forum” event in December each year. The Research Network has used such events to promote and raise awareness of Cancer Research within the Network and more recently collaborated with other topic networks to promote NIHR Research studies.

Staff are encouraged to attend relevant national meetings such as NCRl Study Group Meetings, NCRl Conference, AML meetings, BNLI training days and Myeloma forums etc

### **1.3 Integration with Cancer Services**

#### **Cancer Network Organisation**

The Peninsula Cancer Research Network (PCRN) which was established in 2001 is now fully integrated into the Cancer Network organisation and has joint responsibility to NCRN and the Network Board. One of the agreed aims of the Peninsula Cancer Network is overseeing implementation of the NHS Cancer Plan and more recently the Cancer Reform Strategy. The Strategic Health Authority remains responsible for performance managing the Cancer Network and its constituent organisations in its implementation of these strategies.

The structure of the Peninsula Cancer Network remains similar to that reported in the 2008/9 report excepting additional workforce and work streams to meet the objectives of the Cancer Reform Strategy. However, for completeness is included again in this years report.

The Network Executive Board is made up of the Chief Executive, or Medical Director of the SW Strategic Health Authority, Chief Executives, or their representatives from the five Acute Trusts (5), Network Management Team (5), Patient representatives (2), Lead PCT Chief Executives from the four Health Communities in the Peninsula (4) and Chair of Network Specialist Palliative Care Group (representing Voluntary Sector).

The Network has set up 12 site-specific groups and 12 generic and working groups. Representatives from each of the tumour site specific Multi Disciplinary Teams are invited to Network meetings to ensure inclusiveness in decision making and agreement across the Peninsula. These Network Groups and the Network Research and Development Steering group report to the Executive Board through a clinical advisory group and progress against meeting national targets is included in the remit.

The Peninsula Cancer Network currently includes the South West Strategic Health Authority, five Acute Trusts, four Primary Care Trusts, and six providers of specialist palliative care services in Devon and Cornwall. The constituent organisations are listed below.

## **Trusts**

Northern Devon Healthcare NHS Trust  
Plymouth Hospitals NHS Trust  
Royal Cornwall Hospitals NHS Trust  
Royal Devon & Exeter NHS Foundation Trust  
South Devon Healthcare NHS Trust

## **Primary Care Organisations**

Cornwall and Isles of Scilly Primary Care Trust  
Devon Primary Care Trust  
Plymouth Teaching Primary Care Trust  
Torbay Care Trust

## **Hospices**

Hospicecare, Exeter  
Mount Edgcumbe Hospice, Cornwall  
North Devon Hospice  
Rowcroft Hospice, Torquay  
St Julia's Hospice, Cornwall  
St Luke's Hospice, Plymouth

The development of cancer services at centre/unit level is achieved through effective and explicit management arrangements under a lead clinician. His/her role is to ensure that cancer services are managed and organized effectively to support high quality care and in supporting the Lead Nurse and Cancer Services Manager. All 5 Acute Trusts within the Peninsula have a management team in place who link into Network management through the Network Strategy Group.

## **Geography and Demographics**

The Peninsula Cancer Research Network covers the counties of Devon & Cornwall. It is included in the South West Strategic Health Authority whose boundary encompasses the Peninsula, Dorset, Avon Somerset & Wilts (most) and the Gloucestershire part of the Three Counties Cancer Networks.

The Peninsula includes four [Primary Care Trusts](#) Cornwall, Devon, Plymouth (Teaching) and Torbay (Care). The population of the Network is approximately 1.668 million (source: Open Exeter System); 531,000 in Cornwall; 730,000 in Devon; 264,000 in the Plymouth Unitary Authority; and 143,000 in the Torbay Unitary Authority area.

The five Acute hospitals in Truro, Plymouth, Torquay, Exeter and Barnstaple overlap the four Primary Care Trusts thus the catchment population of each acute hospital can vary depending on the cancer being referred and the complexity of the disease.

The geography of the Network (Devon 2591 square miles, Cornwall 1357 square miles) and difficult travel especially in summer due to tourism has been recognised by the Cancer Action Team who monitor the Cancer Plan. They have agreed that for some cancers we can have more than one centre than that recommended per head of population by the Improving Outcomes Guidance.

The incidence of many cancers increases with age, and for some cancers age may be one of the most useful discriminating factors with 64% of cases diagnosed in people aged 65 and over. Less than 1% of all cases occur in children (0-14 years). Using the population profiles from the 2001 Census the impact of an elderly

population in the Peninsula is evident. 17.19% of the population is over 70 in Torbay compared with 11.51 (England), 13.75 (South West), 14.73 (Cornwall), 11.61 (Plymouth) and 15.56 (Devon).

### **1.3 Integration with Cancer Services**

**Network as a network** – The PCRN functions as a network on several different levels to ensure that managers, clinicians and researchers are involved as part of a wider network organisation.

The Peninsula Cancer Network-Research Steering Committee's membership was reviewed again in 2009/10 to ensure the inclusion of appropriate individuals, in light of falling attendance at meetings and with a view to synchronising with more recent Peer Review Research measure i.e. to encourage input from MDT Research Leads. However, we are well aware that attendance is predominantly those most involved operationally.

The group currently meets 3 times per year and has been chaired by the Research and development Manager from Torbay; meetings have been planned in tandem with the annual reporting and finance cycle. A sub-group of the steering group have volunteered to support the review of FSF bids received and includes members from the core steering group, Consumer representation with 2 co-opted reviewers from the CLRN and other topic networks. A central bidding process was agreed in association with the Western and Peninsula CLRN's and appeared to work effectively during 2008/10. However, with the change in application process for 2010/11 with review of bids centrally and a short application period of one month this process could not be used for this years allocations.

The intention was that decisions about the use of PCRN resources should be made by the Research Steering Committee on behalf of the Network. Such that changes in posts and spending of FSF monies are discussed and approved by the Research Steering Committee.

Trials activity across the Network and review of Clinical Studies Groups/ NSSGs and their respective MDT's contributing to activity are routinely discussed, updates provided on strategic national developments and trusts given an opportunity to report back on any local issues including service support which may affect activity or trial set up.

The Research Leads for each of the PCRN Site Specific Groups have been invited to attend the meeting .However attendance has been minimal. This has been brought to the attention of the Cancer Network Management team. It is planned that the June, 2010 meeting will focus on how to improve the "group's fitness for purpose". Suggestions on how to move forward include the possibility of more frequent meeting perhaps every 2 months of a more operation group (this has already been instigated). Wider engagement of stakeholders could be encouraged either by e-mail correspondence and feedback proformas. In addition one or two meetings per year could be opened up to the wider stakeholders. Distribution of more frequent performance / development updates may also improve engagement.

The attendance summaries for the Research Steering Group Meeting are provided in **Appendix 3A** (In support of Measure 10-5A-107).

The Research Leads and RNM have been keen to promote the 'network' of research activity at PCRN NSSG meetings and the ambition would be that the NSSG

research leads would encourage clinicians/ researchers to take an overview of the network activity as opposed to a more Trust based focus. However, further support for the Research Leads is required to assist them in their role at NSSG meetings. The cycle of Research reports has been more disjointed in 2009/10 due to Research Network Manager workload however, it is planned to improve this for 2010/11 and the manager aims to visit the Research Leads individually (time permitting). (Please note attendance at the Research Steering Committee meeting can be found in Appendix 3A).

Feedback from individual MDT's on activity and issues remains scanty and of varying quality. A revised and more simplified format will be used for 2010/11 NSSG/MDT Research Reports noting good practice in other networks.

A recently formed Cancer Research Operational Management Group has been re-established. This is a smaller operational group comprised of key managers from the 5 Trusts. The group serves to promote integration and collaboration across the Network and a forum for sharing good practice and support in delivering the research agenda.

It is hoped that a "Wider Research Forum " will grow from this group to promote cross-site networking by asking researchers to work together across the network to provide feedback sessions and improve peer support, share issues with regard to trials. Given the geography the use of NIHR portal, discussion forums would be encouraged.

In general cross-network facilitation of studies reflects established clinical working patterns. In several trusts there is cross cover by visiting Oncologists in particular between North Devon and Exeter but also between Torbay and Exeter. Where shared care arrangements are already in place this works reasonably well. However, further work needs to be done to provide clearer trial referral pathways particularly for trials in rarer tumours and to ensure that staffing and recruitment arrangements do not lead to the participating trusts being economically disadvantaged.

Research teams that contribute to the NIHR cancer portfolio activity across the network, who are not directly funded by NCRN monies, are integrated into the ASWCRN structures at a number of different levels. For instance, representatives from the Children's Hospital and the Bristol Royal Infirmary Urology and Upper GI teams are kept up-to-date with ASWCRN developments via inclusion on the main updates mailing list. All non-NCRN funded staff contributing to the portfolio are invited to partake in all Network events (which includes training events as well as the Research Forum and Annual Conference).

The network also has one annual report that summarises network activity from the previous year and is distributed across the network (Please note distribution of the annual report is shown in **Appendix 3B**)

### **Integration into the Cancer Service Network**

The PCRN is an integral part of the Peninsula Cancer Network Team and both are co-hosted by Torbay Care Trust. The RNM is line managed by the Cancer Network Director and the work plan of the RNM was reviewed by the Director for integrated into the overall work plan of the Cancer Service Network.

The RNM is an active member of the PCN team attending team meetings and management meetings, offering support to the PCN ensuring research is embedded within service.

The RNM has worked with the Cancer Network Meetings Manager and more recently Peer Review Manager to ensure trials are a standing item on NSSGs agendas; the RNM regularly attends the Site Specific Group meetings (ideally once a year) to facilitate discussions on trial portfolio and research and working with Research Leads to encourage presentations/ discussion on key trials at alternate meetings.

The RNM plans to meet with all NSSG Research Leads in 2010/11 to discuss their role in the group, to ensure they are fully aware of their role as a network Research Representative and to review challenges within their disease site.

Whilst the RNM has worked with the Trust Cancer Service Managers and Research Leads to ensure the NSSGs and MDT are prepared for the Research Measures of Peer Reviews ensuring trials are adequately discussed at MDT level is very labour intensive and not always fruitful.

The Network Clinical Lead reports directly to the Service Network's Clinical Lead and the Clinical Lead and network performance is reviewed by the Service Network Clinical Lead annually (Please see **Appendix 3C** for evidence of this meeting).

The current outcome for each Network Site Specific Group regarding measures 10-1C-2 and 10-1C-3 and MDT responses to the approved list of clinical trials and identified remedial actions (Measures 10-2-2 and 10-2-3) is provided in **Appendix 3D**.

**Response to Peer Review** – The PCRN received a favourable Peer Review in 2006/07.

Two specific issues were raised at that time and have been addressed. The Clinical Lead for Research was not at that time a member of the Network Board. Dr. Duncan Wheatley has since been included in the Board membership and has presented to the board on several occasions during 2009/10 to raise the profile of the Research Network and its agenda.

Service Level Agreements have also been agreed between the Cancer Research Network and the respective Trusts as advised by the Peer Review feedback to improve governance arrangements.

#### **1.4 Integration with other research infrastructure**

##### **Integration with Comprehensive Local Research Network**

The Clinical Lead for Research is a member of the Peninsula CRN Board and has attended meetings in 2009/10.

Meetings continue 3-4 times a year bringing together all topic Research Managers in the South West and the Senior CLRN Manager with the aim of Peer Support, greater understanding of potential future collaborations and sharing of resources where appropriate for generic Research events, training, staffing etc. The inclusion of the PCLRN Manager has been a natural development and clearly most valuable.

This managers' Group meets 3 times a year, i.e. January, May, and September. The Group was formed to help co-ordinate/facilitate research activities across the South West. The primary aim where possible, is to share learning, streamline processes, and to be a united, coordinated group in order to promote research activities across the whole of the South West. It aims to develop procedures/policy on activities that occur across multiple Networks with an opportunity to use resources in an optimal way. Activities may include e.g. FSF process, PPI activities etc.

Trust R&D managers have been requested to work with Topic managers to report activity in the business plan. It was anticipated that R&D departments would return their business plans by mid-late February. At the time of writing this report the final CLRN business plan has not been confirmed. However the CLRN anticipate that funding levels will remain similar for 2010-11 to keep stability within the networks.

In general CLRN funding for cancer research through direct Trust allocation has been supportive and worked synchronously in support of our own developments plans. This has so far enabled continued growth, FSF funded posts from 2008/9 and 2009/10 have been sustained. Support to key services has also been productive and the CLRN have recognised the needs of Cancer trials. We are pleased that this has been matched by the increased activity seen in 2009/10. There is potential for further activity in radiotherapy trials across the Network and discussions are planned regarding the possibility of additional support particularly for medical physics to facilitate these studies.

A joint application process had been established for FSF funding to allow transparency in funding awards and to enable more strategic and targeted support. The NCRN change to FSF application process means that this no longer fits with this process. It does still provide open access for Researchers to forward applications and the RNM keeps the CLRN informed of both funded and unfunded applications.

It is hoped that additional collaborations will develop. The South West Topic Research Managers have also more formally linked with the existing South West Research and Development Managers Forum which has been established for some time. A Primary Care Incentive Scheme Launch Meeting was held in Saltash as an opportunity to engage with the Primary investigators.

Regular meetings are held between managers of both Peninsula and Western CLRN's and information shared across the networks.

The RNM has met with the CLRN industry manager to discuss ways of working together. The industry manager is included in relevant communications regarding NIHR Commercial Cancer Trials and alerted to those in planned set up. However, the devolved structure of the Network requiring set up processes in respective trusts makes it difficult to identify the role that the industry manager can provide for Cancer. The Cancer Research Network holds the intelligence of which sites and investigators to approach. Staff have been identified in the trusts to support the costing process however this also requires the support and clinical knowledge of the investigators and research team when advising on complex cancer trials. A significant number of expressions of interest are placed by Peninsula Trusts but on the whole the majority of sites selected are in the larger national centres. Most success has been achieved with Breast studies in Cornwall and Haematology / Lymphoma studies across the Network.

The Peninsula CLRN Industry Manager is available to assist with Investigator identification when looking for sites within the comprehensive area. Topic Managers

are under increasing pressure to improve on set-up times of studies but do not have access to CSP. It is proposed the CSP report will now be circulated to Topic Managers. The inability to carry forward commercial income into the following financial year was raised as a block to commercial research.

### **Integration with Other Research Infrastructure–**

The PCRN is part of Cluster Group D (a grouping of similar NCRN Networks) and the Central Regional RNM group (meeting 3 times per year) and the RNM has collaborated across both these groups in the previous 12 months.

The Cancer Research Network Managers from the Peninsula, Avon, Somerset and Wiltshire and Dorset liaise where appropriate regarding research issues relevant to the region and meet face to face 3 times a year. One example of collaboration has been in the sharing of a joint training and education needs analysis which was conducted jointly across the Networks

There is ongoing collaboration to support shared care network governance issues with regard to Paediatric Oncology Trials overseen by the South West Paediatric Oncology Research Management Group (SWPORMG) initiated following the request of the Peninsula Research Manager some years ago. The group still meet 3 times a year. Meetings are well attended and provide a forum for network clinicians and R & D staff to share ideas. In addition it is an opportunity to develop the governance structure required to run clinical trials across a large shared care network.

The model of research governance adopted within our shared care network has been at odds with other UK Principal Treatment Centres since all our shared care centres obtain SSI approval for open phase III trials. We, together with other network colleagues and R& D members, believe that this method provides full GCP compliance particularly since many patients receive the majority of their trial related care at remote sites. Consent is largely undertaken in the Primary Treatment Centre (Bristol).

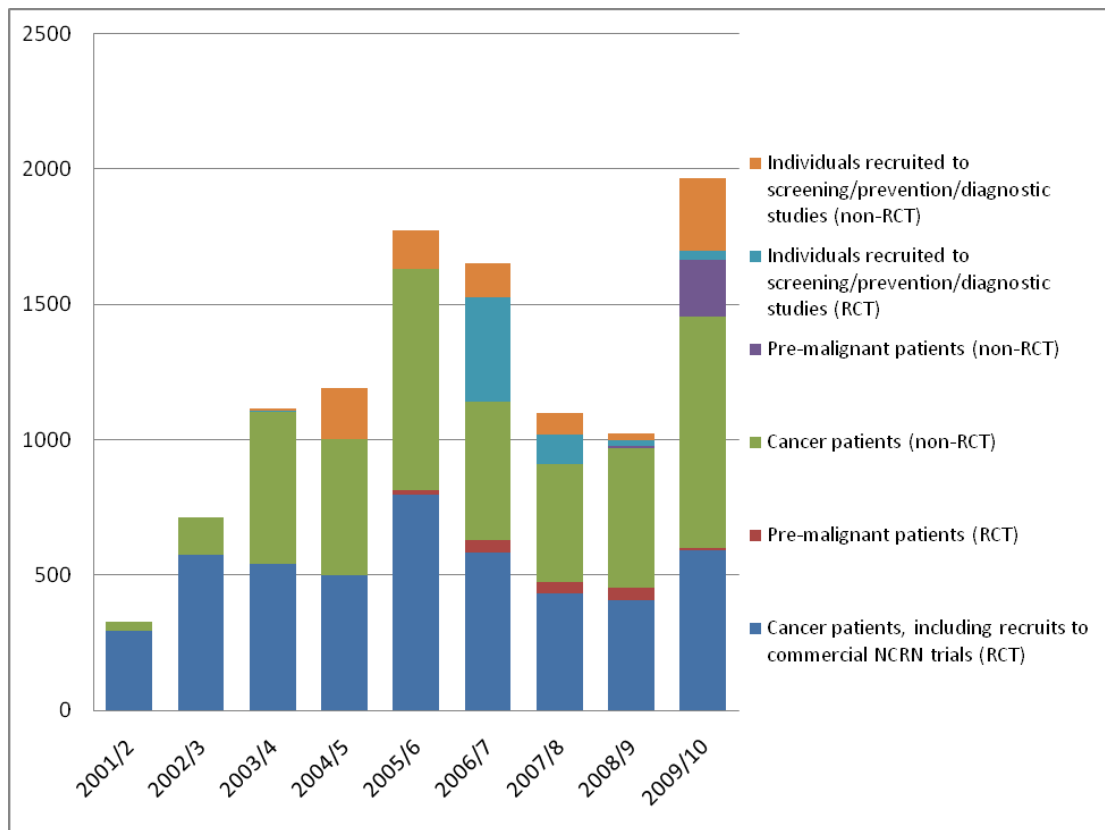
Each shared care centre has a designated document controller and the Bristol Trial Co-ordinator is responsible for distributing information to these individuals. Data flows from the network have been a challenge that will require further work in 2009. However, the Peninsula CLRN have provided additional funds for data management support within the Peninsula network and posts are now in place. A further FSF application has been agreed for the Royal Cornwall Hospital for 2010/11 increasing support to these trials.

## **2. Portfolio Development and Recruitment**

Detailed accrual information has been provided via the online reporting tool provided by the NIHR CRN Portfolio database. This has been discussed and shared with the trust trials managers. No significant discrepancies have been reported.

### **2.1 Overall LRN performance 2001-2010**

**Figure 1:** Peninsula Annual Recruitment to NIHR portfolio studies 2001 to 2010



### Increase in recruitment to randomised studies –

As illustrated above the Peninsula recruited 635 cancer patients to RCTs in 2009/10 not the highest number of cancer pts recruited to RCTs (with a peak in 2005/6 when some large Breast trials were open) however much improved from the dip in the last 2 years. Trials units are aware the emphasis on interventional rather than observational studies. However, there has been an increase in 2009/10 of % cancer patients recruited to RCTs at 8.7% of the estimated population (1.5 million using NCRN population statistics) – this puts the PCRN as one of the top recruiting networks nationally and surpassing the NCRN target of 6.5% set for 2009/10.

There has been a general increase in accrual of most categories (types of trial patients) and in particular cancer patients in non-RCTs.

During 2009/10 the Peninsula overall has recruited 1,967 patients into 99 trials across 18 NCRI Clinical Studies Groups. Compared to 2008/9 this represents increased activity of 39% in RCTs, 105% in Non-RCTs and overall an 85% increase for all trials. Significant increased activity in Breast, Colorectal, Gynaecological, Primary Care and Upper GI (Non-RCT's) with general increased RCT activity particularly in Head and Neck, Lung, Haematological and Complementary Therapy trials.

### 2.2 Peninsula Portfolio 2009-10

The Peninsula recruited to 99 NCRN portfolio trials from 1<sup>st</sup> April 2009 to 31<sup>st</sup> March 2010. This included 64 RCTs and 35 non-RCTs recruiting patients with cancer (and pre-malignancy) of these 7 non-RCT studies recruited some non cancer patients and 2 sub-studies.

**Table 1** is included as **Appendix 4A** and shows the actual recruitment by study for 2009/10. At the time of compiling the 2008/9 report there was insufficient time and feedback from the respective Trusts to predict 2009/10 accrual. However, table 1 is included which shows recruitment to studies that were open in 2008/9 compared to those which remained open in 2009/10 (rather than an actual prediction of 2009/10 recruitment). Overall 82 % of studies have recruited better than in the previous year. Those performing less well were either studies where the cohort of patients had already been approached or those closing in year accounting for 17% of studies.

During 2009/10 36 new studies opened with 8 closing in year. At the end of 2008/9 there were potentially 59 trials in which Peninsula Trusts had anticipated opening in 2009/10 of which 36 (61%) have opened. Overall the network has seen significant increased activity in Breast, Colorectal, Gynaecological, Primary Care and Upper GI (Non-RCT's) with general increased RCT activity particularly in Head and Neck, Lung, Haematological and Complementary Therapy trials.

Historically, the Peninsula has focussed on support to trials in the more common tumour sites (by incidence) namely Breast, Haemato-Oncology (with a long standing track record), Upper GI, Colorectal and Prostate Cancer. These are areas generally with a strong portfolio of trials and consistent support by clinicians. Activity remains strong in these sites.

The key factors to expanding the breadth in the portfolio are the strength of the site portfolios and availability of trials to this network, keen investigators and sufficient underpinning infrastructure to manage any increased workload. Growth in our portfolio has generally been due to these factors.

In 2008/9 the areas identified for development were to expand the surgical trials portfolio particularly with Breast trials in Exeter and North Devon, to increase Lung cancer and Gynaecological trials particularly at Royal Cornwall Hospital, to generally strengthen the breadth of the portfolio in Plymouth. These ambitions have seen achievements and the developments were supported by FSF funding. In addition 2 further areas were identified during 2009/10 which to increase support to Network wide Cancer Genetics studies and increased support to radiotherapy studies in Cornwall which are yet to deliver with new posts agreed in the latter part of the year.

One further area where there is both interest and potential for increased activity is with radiotherapy trials. 2009/10 has seen additional financial support for radiotherapy departments (medical physics and radiographer time). The recruitment of medical physicists has however remained an issue. Plans remain in place to pursue increased support to these trials which account for the larger proportion of trials which failed to open in 2009/10.

The Peninsula recognises that there are still gaps in the breadth of the portfolio with some rarer disease sites less well represented such as Melanoma (despite high incidence in the network), Sarcoma and Palliative Care. However, this is partly due to the availability of trials and in the case of sarcoma with referral to regional services.

The Research Network does seek direction from the 12 different NSSG in terms of network priorities and local trial endorsement. The portfolio is driven largely by clinicians particularly the Oncologists and efforts have been made in the past 12 months to ensure that the NSSGs are able to drive their local portfolio as appropriate.

In line with the Peer Review objectives each NSSG has a named clinical Research Lead the expectation being that they will be champions in supporting discussions

regarding research with their peers. This is working well with some groups but the Research Network Manager is aware that further work needs to be done in 2010/11 to support and engage with all Research Leads to help them in their role.

The Research Network core team produces a Research Report for at least one NSSG Meeting per year to highlight the portfolio, recruitment and notifies the group of any other open NCRN trials that could be conducted by the network. Most NSSG's meet bi-annually and the aim would be for the Research Lead for the NSSG to receive an updated report to review in advance of the meeting and to be encouraged to amend or add additional information as required. The Research Lead then to lead the NSSG through the report and the reports thereby generates discussion and promotes awareness of the portfolio at the NSSG meetings.

Although this is our ambition we recognise that we do not always achieve this outcome. Workload does not always permit timely production of reports, other meetings conflict and Research Leads do not always attend all meetings. However, we strive to improve in 2010/11.

Researchers within the network are responsible for encouraging clinicians into adopting trials or providing feasibility feedback for industry studies and thus are also crucial to the development of the portfolio. Feedback is not always forthcoming and the Research Network understands that general MDT meetings including annual meetings do not always lend themselves to allow in depth discussion particularly where large trials portfolios exist.

However, there are indications that progress is being made with increased activity and trials now more widely available in Gynaecological, Primary Care, Head and Neck, Lung, and Complementary Therapy trials. Other groups including Supportive and Palliative Care and Skin Cancer have expressed an interest to participate in trials.

The Network recognises the National ambition to increase activity in Industry trials. All expressions of interest are forwarded to the relevant teams and clinicians and in turn back to NCRN. However, despite a large number of positive responses few trials (11) have been set up by industry in the Peninsula. Most success has been achieved at the Royal Cornwall Hospital particularly Breast Trials no doubt helped by the support of the Clinical Lead for Research, but with trials in Haemato-Oncology also across a number of sites. We appreciate the success of such studies depends on establishing a track record, in speedy set up and recruitment to target. The network plans to further address these issues in 2010/11.

At a network level the Peninsula has maintained and expanded its portfolio, increased activity and is making steps to increase trial activity in surgical, radiotherapy trials, Genetics studies and industry whilst looking to open trials in rarer tumour sites where appropriate.

Other 'gaps' have been identified at a Trust level and individual Trusts have identified key areas for development and growth over the next 12 months.

Trust specific priorities and goals for 2010/ are likely to include:

**NDHT**-The main new area of development is haematology wherein one new trial was given R&D approval by the Trust in the financial year and two underwent feasibility and were signed off in April 2010. The remainder of new studies continue to reflect

the patient population in North Devon: that is, prostate, pancreatic, colorectal, lung, lymphoma, and Upper GI.

**PHNT**-There is a renewed enthusiasm within Oncology to expand the portfolio and increase recruitment of patients into studies with expressions of interest undertaken in Melanoma, Palliative care and Gynaecology. An area with potential for a large increase in recruitment is Breast studies including two new portfolio badged commercial studies in this area.

Already a major player internationally in haematology research, accrual to haematology trials is probably nearly at its maximum potential. It is anticipated that the appointment of another Oncologist, later this year, specialising in colorectal cancer, will enable increased recruitment in this area building on existing support from colorectal surgery. The trust is committed to supporting recruitment into radiotherapy trials and plan to expand this portfolio of trials.

Progress is being made to set up an innovative new research nurse led clinic service to manage the follow-up burden of many of the existing portfolio studies.

**RDEFT**- Are keen to develop the portfolio overall and achieve a balance by disease site. Plans are to prioritise key areas such as colorectal, surgical breast trials and gynaecology whilst maintaining a strong portfolio of breast trials. Plan to enhance links with medical physics/radiotherapy with a goal to increasing participating in radiotherapy trials.

To develop nurse led clinics. To focus support to continue expansion of the Urology portfolio in view of proposed trials due to open in next 12 months with an extremely motivated clinical team. To focus on recruitment to genetics trials now additional support is in place. A Senior Research Practitioner was appointed in December 2009 to develop the surgical breast portfolio and now has POETIC, ICICLE, IBIS II and GLACIER recruiting with FH02 in the set-up phase

**RCHT**-Recruitment vastly increased in Urology and Lung trials. Dermatology trial (AVAST-M) set-up started. Gynaecology trials increased recruitment with more trials due to open. Many non-oncology/haematology studies set-up started – BOXIT, BOSS etc

For an overview on network recruitment please review Table 1, Appendix 4A.

## **2.2 LRN Performance against forecast recruitment (academic) 2009-10**

As noted in section 2.2 at the time of compiling the 2008/9 report there was insufficient time and feedback from the respective Trusts to predict 2009/10 accrual.

However, table 1 is included below which shows recruitment to studies that were open in 2008/9 compared to those which remained open in 2009/10 (rather than an actual prediction of 2009/10 recruitment). Overall 82 % of studies have recruited better than in the previous year. Those performing less well were either studies where the cohort of patients had already been approached or those closing in year accounting for 17% of studies.

Feedback has been included in the table noting any comments received from the trusts regarding any difficulties with recruitment.

Similarly comments are provided where recruitment has been successful and exceed expectations/forecast.

In general the main issue experience has been the difficulty in opening radiotherapy trials as discussed previously. There is interest from the oncologists to participate in a number of these trials currently Lung ART and SCALOP in set up. Of those open nationally there is interest from Peninsula sites to support CHHIP, CONVERT, GROINSS V11, IMPORT HIGH, IMPORT LOW, PORTEC 3, RADICALS, SC20, SCOPE 1, SPARE and VORTEX and FAST-FORWARD (In set up).

Similarly FOXFIRE needs interventional radiology input/training.

Work Programme Appendix 1: Table WP1: Full list of NIHR academic and commercial portfolio studies and forecast recruitment for 2009-10

Study Acronym	Academic/ Commerical	RCT/ non-RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
<b>All Clinical Studies Groups</b>					
PENILE TPF	Academic	non-RCT	0	2	
<b>Bladder Cancer Group</b>					
BOXIT	Academic	RCT	0	7	
<b>Brain Cancer Group</b>					
BR13	Academic	RCT	0	0	PHNT-Unable to open BR13, due to lack of Med Physicists. By the time staff were in place the study had closed to recruitment
NBT	Academic	non-RCT	0	1	
<b>Breast Cancer Group</b>					
ALTTO	Academic	RCT	3	3	
BBC Study	Academic	non-RCT	5	1	
BBC-NCRN cohort	Academic	non-RCT	127	109	NDHT-criteria has changed and more difficult to recruit to however-2009-10 – forecasted 30 patients, 315 recruited over whole recruitment period.
BEATRICE	Commercial	RCT	2	5	
EMBRACE	Academic	RCT	28	33	
FBCS	Academic	non-RCT	0	100	
GLACIER	Academic	non-RCT	17	38	NDHT-patient pool already exhausted and criteria has changed can screen retrospectively.Higher Recruitment in 09/10 in some trusts due to retrospective screening

Study Acronym	Academic/ Commerical	RCT/ non-RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
IBIS-II DCIS	Academic	RCT	0	6	
IBIS-II Prevention	Academic	RCT	8	3	
ICICLE	Academic	non-RCT	4	205	NDHT-rare condition to recruit to (less than predicted due to cancer [pure DCIS] and potentials have to be under 60 years).RCHT-Higher Recruitment in 09/10 in some trusts due to retrospective screening
IMPORT LOW	Academic	RCT	40	59	RCHT-Recruited well-enthusiastic clinical lead & team
LATTE	Academic	non-RCT	0	16	
NCRN024 - INDUSTRY STUDY	Commercial	RCT	5	1	Due to close
NCRN089	Commercial	RCT	0	1	
PARP BRCA trial	Academic	non-RCT	0	2	NDH-Small numbers - happy to refer to PHT
Persephone	Academic	RCT	9	6	NDHT-PERSEPHONE – patients have been screened and approached, but are reluctant to consent since they would receive less treatment
POETIC	Academic	RCT	2	16	
PRIME II	Academic	RCT	14	15	NDHT-CLOSED PNHT-Exceeded expected accrual- 33 vs 10 overall
SoFEA	Academic	RCT	1	5	
SUPREMO	Academic	RCT	1	4	RDE-Delay in opening due to medical physics capacity.
TACT Trial Long Term QL (sub-study)	Academic	RCT	18	7	Presume eligible patients already considered-pool from closed studies
ZICE	Academic	RCT	17	18	

Study Acronym	Academic/ Commerical	RCT/ non-RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
<b>Colorectal Cancer Group</b>					
CORGI	Academic	non-RCT	0	52	
CReST	Academic	RCT	0	3	RCHT-Team encouraged to continue identifying patients for randomising. Only successful stent trial running so enthusiastic about increasing numbers recruited.
FACS	Academic	RCT	19	1	Trial Closed
FOxTROT	Academic	RCT	2	2	RCHT-Low numbers recruited initially, difficulty finding potential patients due to radiological criteria and logistics of starting chemo/delaying surgery to keep in with cancer targets.. Radiological criteria looks to be relaxing which should lead to a rise in recruitment
NSCCG	Academic	non-RCT	56	102	
Public perceptions of bowel cancer screening (Sep-09)	Academic	non-RCT	0	27	
PICCOLO	Academic	RCT	1	21	RCHT-Almost completed. Std arm is not optimal treatment
QUASAR 2	Academic	RCT	7	4	NDHT-looking to close study as shorter treatment available in SCOT trial-patients not keen
SCOT	Academic	RCT	15	26	RCHT-36 patients randomised (2nd in UK)
<b>Complimentary Therapies Group</b>					
Acupressure CINV	Academic	RCT	0	55	

Study Acronym	Academic/ Commerical	RCT/ non-RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
DietCompLyf	Academic	non-RCT	88	61	NDHT-115 patients recruited over whole recruitment period. Forecast was approx 20 at set up. Patients interested in their own lifestyle and contributing to research for best practice-CLOSED to recruitment in end of May 2010, still in FU
<b>Gynaecological Cancer Group</b>					
CHORUS Main trial	Academic	RCT	0	5	Due to close end 2010 -concerns due to poor recruitment to feasibility study
DNA Methylation Study	Academic	non-RCT	3	13	
ICON 6	Academic	RCT	0	0	Not open yet-difficult to predict
NEO-ESCAPE	Academic	RCT	0	2	
NSECG	Academic	non-RCT	0	42	NDHT-20 letters sent, 16 agreed - could potentially be a good recruiter
PORTEC-3	Academic	RCT	0	0	RDE-Delay in opening due to medical physics capacity.
UKFOCCS	Academic	non-RCT	3	50	
<b>Haematological Cancer Group</b>					
ADMIRE	Academic	RCT	0	5	SDHFT- In set-up – but small no patients eligible
AML 16	Academic	RCT	19	27	
AML 17	Academic	RCT	0	21	
EBV associated NK/T cell malignancies	Academic	non-RCT	0	4	
FCLL	Academic	non-RCT	3	4	

Study Acronym	Academic/ Commerical	RCT/ non-RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
MDSBio1	Academic	non-RCT	27	27	NDHT-there was a degree of confusion between consultants and protocol as to the patient pool. Problem was sorted and recruitment started in March 2010.
Myeloma X Relapse (Intensive)	Academic	RCT	4	4	
NCRN042	Commercial	RCT	0	1	
NCRN043	Commercial	RCT	0	2	Rde-No eligible patients
SPIRIT 2	Academic	RCT	0	8	
TOPPS	Academic	RCT	28	19	RDE-Exceeded expectation ie 32 vs 10 overall
<b>Head &amp; Neck Cancer Group</b>					
Determination of Quality of Life Instrument	Academic	RCT	0	32	
HiLo	Academic	RCT	3	3	
HOPON	Academic	RCT	0	2	
PET-NECK study	Academic	RCT	0	8	
TCUK IN	Academic	non-RCT	0	20	
<b>Lung Cancer Group</b>					
BTOG2	Academic	RCT	6	3	Trial closed
CONVERT	Academic	RCT	0	0	RDE-Delay in opening due to medical physics capacity.
ET Trial	Academic	RCT	0	4	
FRAGMATIC	Academic	RCT	12	24	

Study Acronym	Academic/ Commerical	RCT/ non-RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
LungStar	Academic	non-RCT	5	9	NDHT-: not many small cell patients plus potential recruits have had previous statin treatment
MALCS (Mesothelioma and Lung Cancer Study)	Academic	non-RCT	12	27	
TACTIC	Academic	RCT	0	1	
<b>Lymphoma Group</b>					
18-30	Academic	non-RCT	0	1	
AITL	Academic	non-RCT	1	1	
Bortezomib Study	Academic	RCT	3	2	
Mantle Cell P3	Academic	RCT	0	8	
PACIFICO	Academic	RCT	0	1	
RAPID (formerly PET Trial in Hodgkin's Disease)	Academic	RCT	3	7	NDHT-CLOSING soon, also rare disease, approx 4-5 diagnosed a year and would need to meet criteria
RATHL	Academic	RCT	2	14	
R-CODOX-M/IVAC	Academic	non-RCT	0	2	
RGCVP	Academic	non-RCT	1	2	
Waldenstrom's study	Academic	RCT	2	6	
Watch and Wait	Academic	RCT	0	1	
<b>Melanoma Group</b>					
AVAST-M	Academic	RCT	7	5	Long delays in opening at Peninsula sites outside local control
The Melanoma Lifestyle Study	Academic	non-RCT	1	1	

Study Acronym	Academic/ Commerical	RCT/ non-RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
<b>Primary Care Development Group</b>					
Clinical Features Of Metastatic Cancer	Academic		43	203	
<b>Prostate Cancer Group</b>					
CHHIP	Academic	RCT	0	2	
Matched pair QoL/Toxicity Study in Advanced Prostate Cancer	Academic	non-RCT	42	37	
NCRN018 - INDUSTRY STUDY	Commercial	RCT	4	2	
ProSTART	Academic	RCT	0	1	Was open in PHNT & SDHFT but problems recruiting-Closed nationally
			2	10	NDHT-recruited 1 patient. Eligibility criteria has recently been reviewed and changed to make recruitment more straight forward and hopefully easier to recruit to.
RADICALS (MRC PR10)	Academic	RCT			
Stampede	Academic	RCT	29	29	
UK Genetic Prostate Cancer Study	Academic	non-RCT	34	42	
<b>Renal Cancer Group</b>					
SORCE	Academic	RCT	5	12	
TRANSORCE (sub-study of SORCE)	Academic	non-RCT	6	15	
<b>Sarcoma Group</b>					
VORTEX	Academic	RCT	0	2	
<b>Testis Cancer Group</b>					
TE23	Academic	RCT	0	0	RDE-Trial on hold-? Previous safety issues

Study Acronym	Academic/ Commerical	RCT/ non-RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
The UK Genetics of Testicular Cancer Study	Academic	non-RCT	35	4	
<b>Upper GI Cancer Group</b>					
<b>BEST- BARRETT'S</b>	Academic	non-RCT	23	23	
BILCAP	Academic	RCT	4	2	Only open in Plymouth where PARP treatment available-but referrals accepted from within Peninsula
<b>BOSS</b>	Academic	RCT	0	28	
<b>ChOPIN</b>	Academic	non-RCT	0	33	
<b>COG</b>	Academic	RCT	0	2	
<b>ESPAC -Tplus</b>	Academic	non-RCT	0	18	NDHT-no further patients to recruit
ESPAC-4	Academic	RCT	0	3	
OE05	Academic	RCT	3	4	
SOCS	Academic	non-RCT	16	41	
ST03	Academic	RCT	2	2	
TeloVac	Academic	RCT	10	17	
<b>TOTAL</b>			<b>892</b>	<b>1,967</b>	

### 2.3 Peninsula NIHR adopted commercial portfolio and performance 2009-10

In 2009/10 the Peninsula recruited 15 patients into NIHR adopted commercial trials; this represents only 0.9 % of the total recruitment of cancer patients and pre-malignant patients into RCTs during this time frame. Nationally recruitment to NCRN Industry trials accounts for 5% of recruitment to RCTs, the Peninsula is therefore recruiting to commercial trials at a level below the national average.

Full feedback on the Peninsula recruitment to commercial studies can be viewed in Appendix 4B of this document however with reference to the agreed mCTA targets the following summary of Peninsula activity with respect to commercial trials in 2009/10 can be noted:

7 NIHR Commercial Trials have recruited patients during 2009/10

#### Closed trials -

- Three completed commercial trials achieved their mCTA targets;
- BEATRICE trial was open RDEFT and RCHT with a target of 8 patients at each site and achieving 4 and 3 patients respectively. This was below target but comparable to the experience nationally.
- AVEREL (NCRN010) although not recruiting in 2009/10 had successfully recruited to above target ie 3 patients contrary to the RAG report indicating 2 patients in RDEFT.
- VENICE-NCRN018 recruited 6 of target 10 patients at RDEFT-60% to target.
- ALLTO we understand is now closed to recruitment in the UK. This was open in RDEFT and PHNT with a target of 9 patients at each site. It recruited 2 patients at RDEFT (35%) and 70% at PHNT. Compared to 59% to target in UK.

#### On-going trials –

- NCRN024 is open at RCHT having recruited 6 patients with a target of 5 (RAG rating 151.3%)
- NCRN042 is open at RCHT having recruited 1 patient of target of 2 patients (128.3%).
- NCRN043 is open at RCHT, PHNT and RDEFT with a target of 4 patients at each site. It has achieved recruitment of 1 (50.2%), 1(50.2%), and 0 patients respectively. We understand this is proving difficult to recruit to nationally (16.3%), requires high screening levels as patients are put off since one trial treatment is given IV in trial whilst given orally in standard care.
- NCRN089 is open at RCHT having recruited 1 of target (2) patients-169.8% well above the national achievement rate.
- PCRN currently has seven trials that are open the 4 above which have recruited in 2009/10 and 3 below which have only recently opened and expected to recruit further in 2010/11.

#### Trials Only recently/about to Open

- NCRN098 BOLERO II – trial just recently opened in RCHT – target 4 patients. Just not had suitable/ willing patients but 1 patient to be entered 10/11.
- NCRN103- RCHT-Target 5 patients-RAG data incorrect .1 patient recruited March, 2010. The first patient into the study in UK. Since had 1 screening failure.
- NCRN138-RCHT-Target 20 patients- not open yet

In general the amount of screening required to randomise a patient in these studies is extremely high

### Expressions of Interest (EOIs) for Industry trials

The Peninsula has tried to improve its process for processing and monitoring EOIs within the network. Expressions of interest have been offered to all Trusts for 38 trials with 31 positive responses known to the RNM. This is probably an underestimate of the returned expressions of interest.

**Table 1:** Trusts registering interest in adopted commercial studies for 2009/10

<b>Site</b>	<b>Trial</b>	<b>Date Sent</b>	<b>NDHT</b>	<b>PHNT</b>	<b>RCHT</b>	<b>RDEFT</b>	<b>SDHFT</b>
All Sites	NCRN 151	01/03/2010	No	No	No	No	Yes
Breast	UKCRN099 Industry trials		No	No	Yes	No	No
Breast	NCRN096	16/10/2009	No	No	Yes	No	No
Breast	NCRN103 Bolero 1	02/02/2010	Yes	No	Yes	No	No
Breast	MARIANNE - formerly NCRN150	12/02/2010	No	No	Yes	No	No
Breast	NCRN115	12/03/2010	No	No		No	No
Breast	NCRN098-Bolero II		No	No	Yes	No	No
Breast	NCRN122 (Novartis)		No	No	Yes	No	No
Colorectal	NCRN140	04/12/2009	No	No	No	No	No
Colorectal	NCRN156	09/03/2010	No	No	No	No	No
Colorectal	NCRN159 (Gist)	16/04/2010	No	No	No	No	Yes
Endocrine	NCRN157 (Carcinoid)	26/03/2010	No	No	No	No	No
Gynae ?	Abdominal Surgery Feasibility - Feedback	16/10/2009	No	No	Yes	No	No
Haem	NCRN-042-OMB110913		No	No	Yes	Yes	Yes
Haem	NCRN-043-OMB110911		No	Yes	Yes	Yes	Yes
Haem	NCRN124	22/10/2009	No	No	Yes	No	No
Haematological	NCRN132	29/04/2010	No	No	Yes	Yes	No
Haematological	NCRN163	28/05/2010	No	No	Yes	Yes	No
Haematological	NCRN166	28/05/2010	No	No	No	No	No
Head & Neck	NCRN153	13/04/2010	No	No	No	Yes	No
Lung	NCRN095 (FORTIS-M)		No	No	No	No	No
Lung	NCRN073	11/09/2009	No	No	No	No	No
Lung ?	RADIANT	09/11/2009	No	No	No	No	Yes
Lymphoma	NCRN069		No	No	No	No	Yes
Lymphoma	ABC GCB	08/12/2009	No	No	No	No	No
Lymphoma	diffuse large B-cell NHL	08/12/2009	Yes	No	No	No	No
Lymphoma	NCRN160	29/04/2010	No	No	No	No	No
Melanoma	NCRN108	02/12/2009	No	No	Yes	No	Yes
Prostate	NCRN Industry Metastatic Castrate Resistant Prostate Cancer Study		No	No	Yes	No	No
Prostate	NCRN102		No	No	Yes	No	No
Prostate	NCRN 146 BMS prostate cancer study	25/02/2010	No	No	No	Yes	
Renal	NCRN Industry Renal Cancer Study		No	No	No	No	Yes
Sarcoma	NCRN-061-PALATTE	20/11/2009	No	No	No	No	No
Upper GI	NCRN079		No	No	No	No	No

<b>Site</b>	<b>Trial</b>	<b>Date Sent</b>	<b>NDHT</b>	<b>PHNT</b>	<b>RCHT</b>	<b>RDEFT</b>	<b>SDHFT</b>
Upper GI	Hepatocellular Carcinoma (NCRN104)	16/11/2009	No	No	No	No	No
Other	CCRN59- now on hold		No	No	No	No	No
Other	NCRN 090 - on hold 01/03/10		No	No	No	No	No
Other	UKCRN094 Industry trials		No	No	Yes	No	No

**Nb. Those in green represent trials which have progressed to set up.**

There are several challenges that the network has experienced with regard to NCRN commercial trials:

**Problems within a devolved network** - The PCRN is a very devolved network such that responsibility for recruiting and trial set up is devolved to the managers of individual Trust teams and their respective R & D Management. To achieve the recruitment to time and target for Industry trials and effectively manage the large volume of e-mails within the short turn around times is a significant additional burden on the RNM work time. There is also a high degree of duplication of work that is already being done by management within Trusts.

**Naming of Industry trials** – There is an inconsistent use of names and numbering systems for NCRN Industry trials which causes confusion.

**Costing template** – The costing template does not take into account adequate time to complete e-CRF's as opposed to paper forms, data clarifications or SAE reporting. Early requests for costing sense checks for trials which may not progress is very time consuming for trust staff particularly where trials are complex with multiple treatments arms. This is particularly noted in a devolved network where although R & D staff are nominated to assist, this often requires both clinician and research team advice and significant time.

**Challenges with monitoring Industry adopted trials activity** - Although several of the Industry trials come through the NCRN Co-ordinating Centre (NCRN CC) EOI process certain sites are pre-selected without the PCRN core team being aware of this. Often Trusts have not been aware an Industry trial is NCRN badged prior to opening the trial. However this is improving with more frequent updates via the NCRN industry manager and the recent RAG reports are helpful.

**Feedback on EOIs and sites selected** – The PCRN would be keen to see more rapid and detailed feedback on EOIs that are completed by Trusts. The PCRN are acutely aware that there will be attrition to the level of expressions of interests returned by trust teams which are constantly not considered as sites.

It would seem sensible to consider further collaboration with industry to signpost sites which have a strong track record in delivery of academic studies. Some pump priming investment/ resource to trusts which otherwise have the infrastructures to deliver such studies. Otherwise a catch 22 situation will remain whereby trials will continue to go to those sites with a track record but eventually will struggle to deliver due to capacity.

## Engagement with the CLRN Industry Manager

The issues are similar to those noted above in respect of a devolved Network. The initial feasibility and expression of interest notification best sits with the cancer RNM who has the appropriate contacts and needs to monitor interest. Site feasibility particularly for complex Cancer Trials rests with the Trust R & D and Cancer Research Teams. It would be unreasonable to expect the CLRN Industry Manager to advise on complex trials and to know standard chemotherapy regimes for example.

The PenCLR Industry Manager is keen to offer support but at present it is hard to define what tangible support would help in this setting. One area of potential support is that the RNM as common to other topics in the region does not have access to CSP and the regular distribution of CSP reports would help in monitoring any delays in trial set up.

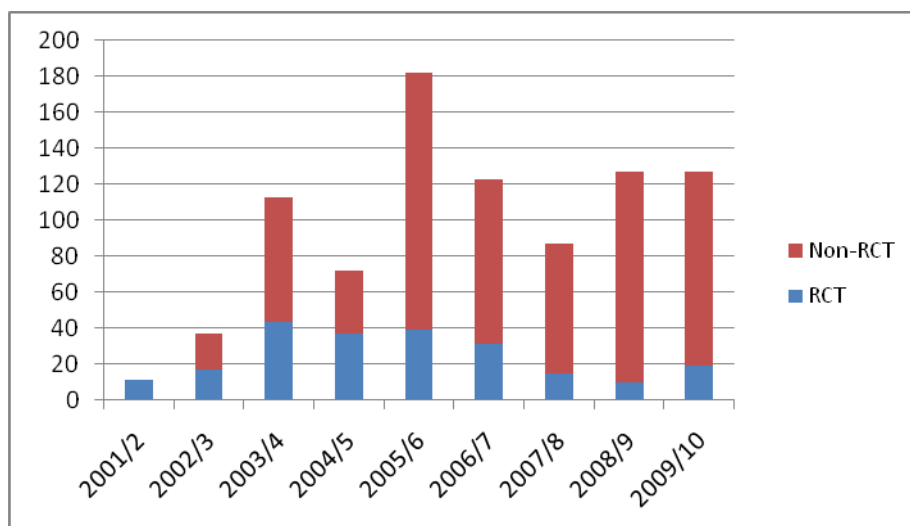
The RNM is however in regular contact with the CLRN industry manager and will continue to explore options for mutual support.

## 2.4 Trust Performance

**Appendix 4C, Table 3:** Shows Recruitment by Trust for 2008/09 and 2009/10 by RCT and non-RCT and by study recruitment type ie Cancer, Pre-Malignant, Commercial and non-cancer groupings.

A series of graphs are provided below which show the breakdown of trials activity by RCT vs non-RCT for each year since the initiation of NCRN (2001-10) and the proportion of recruitment for 2009-10 for each trust by disease site.

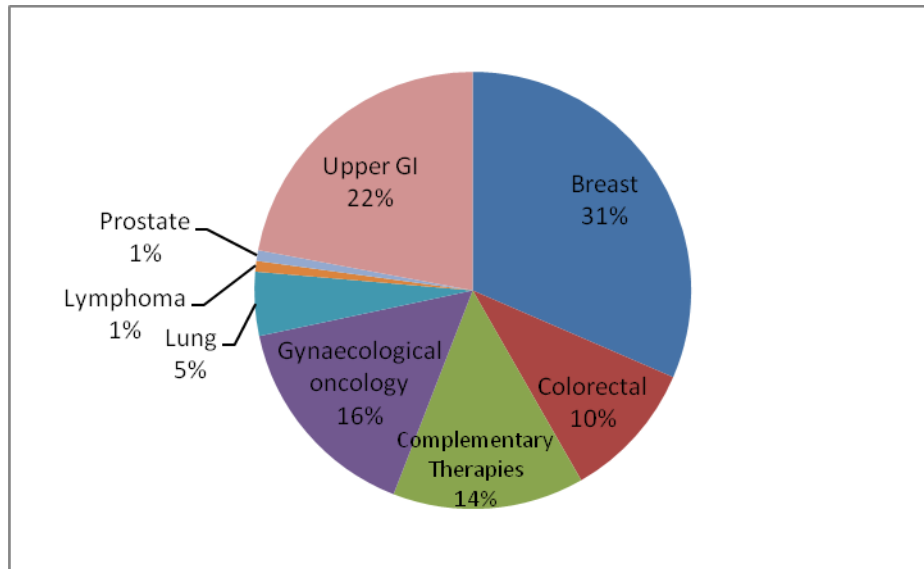
**Figure 2.4a.1: NDHT** Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010



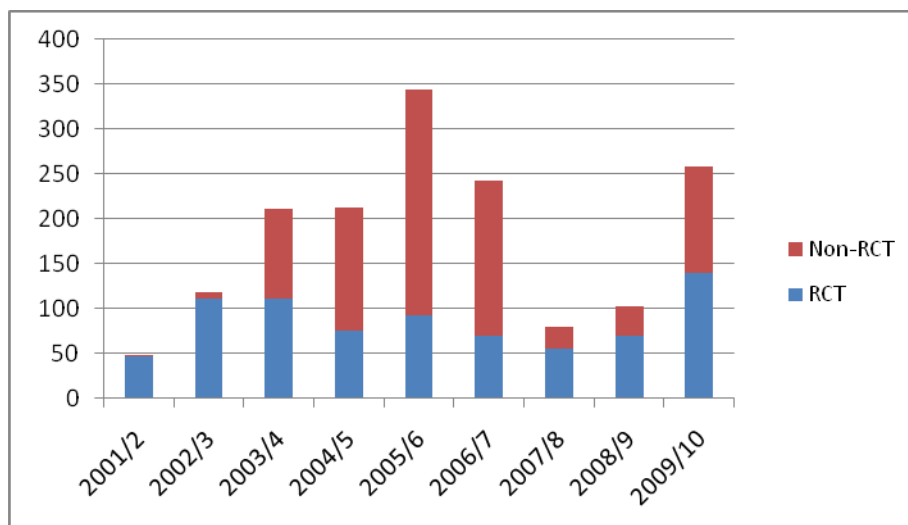
**NDHT-** has recruited to 17 trials, 8 RCT's and 9 Non-RCTs. A new area of development is haematology wherein one new trial was given R&D approval by the Trust in the financial year and two underwent feasibility and were signed off in April 2010. The remainder of new studies continue to reflect the patient population in North Devon: that is, prostate, pancreatic, colorectal, lung, lymphoma, and Upper GI. Considerable efforts have been made to increase RCTs with POETIC, PRIME 11, QUASAR ii, SCOT, ET, LUNGSTAR, RAPID & RADICALS all open and recruiting

The trust provides follow up for at least trials at where patients were entered in RDEFT. This enables North Devon patients the same opportunities and to be treated near home.

- **Figure 2.4a.II: NDHT** distribution of recruitment by CSG for 2009-10. (Cancer patients and patients with a pre-malignancy)

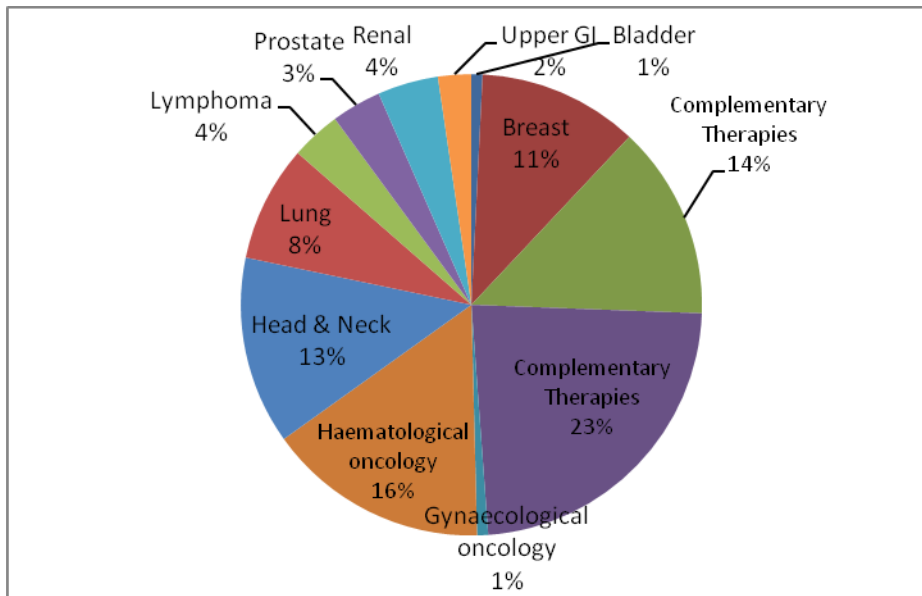


**Figure 2.4b.1: PHNT** Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010

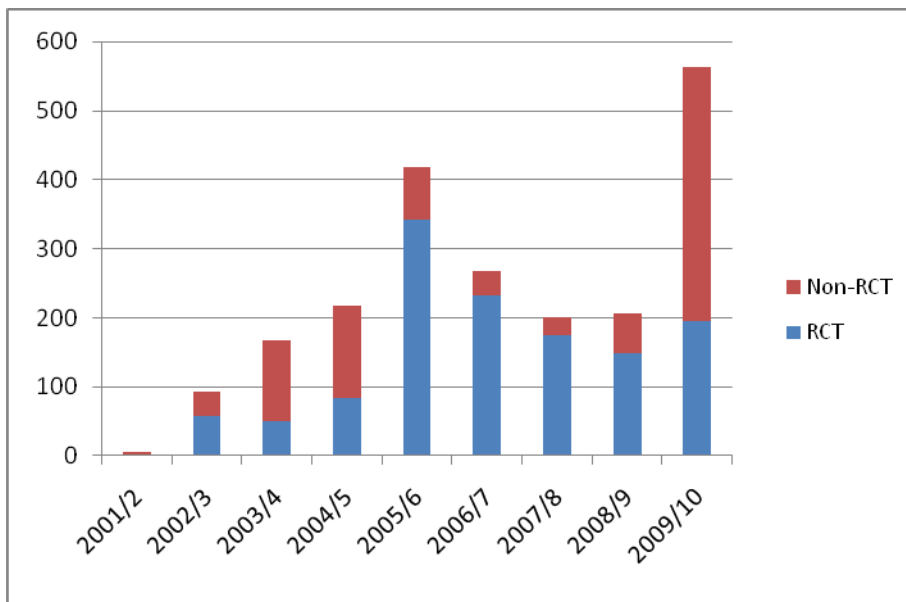


**PHNT** has made huge improvement in 2009/10 with overall accrual figure up 130%. There has been recruitment to 40 trials of which 25 are RCT's covering 12 disease sites. Haematological Trials activity remains strong but a much broader portfolio is evident. Further portfolio expansion is planned for 2010/11 in Oncology and Palliative care. In particular plans to expand the Breast trials portfolio (7 trials) including surgical trials (ICICLE, GLACIER & POETIC), Endocrine & Thyroid, Gynaecology (5 trials), Lung (4 trials) and AVAST-M in melanoma. Future plans also include increased activity in Colorectal and radiotherapy trials. The trust is to be commended for addressing the difficulties of the last 2 years and re-establishing a flourishing trials portfolio.

- **Figure 2.4a.II: PHNT** distribution of recruitment by CSG for 2009-10. (Cancer patients and patients with a pre-malignancy)

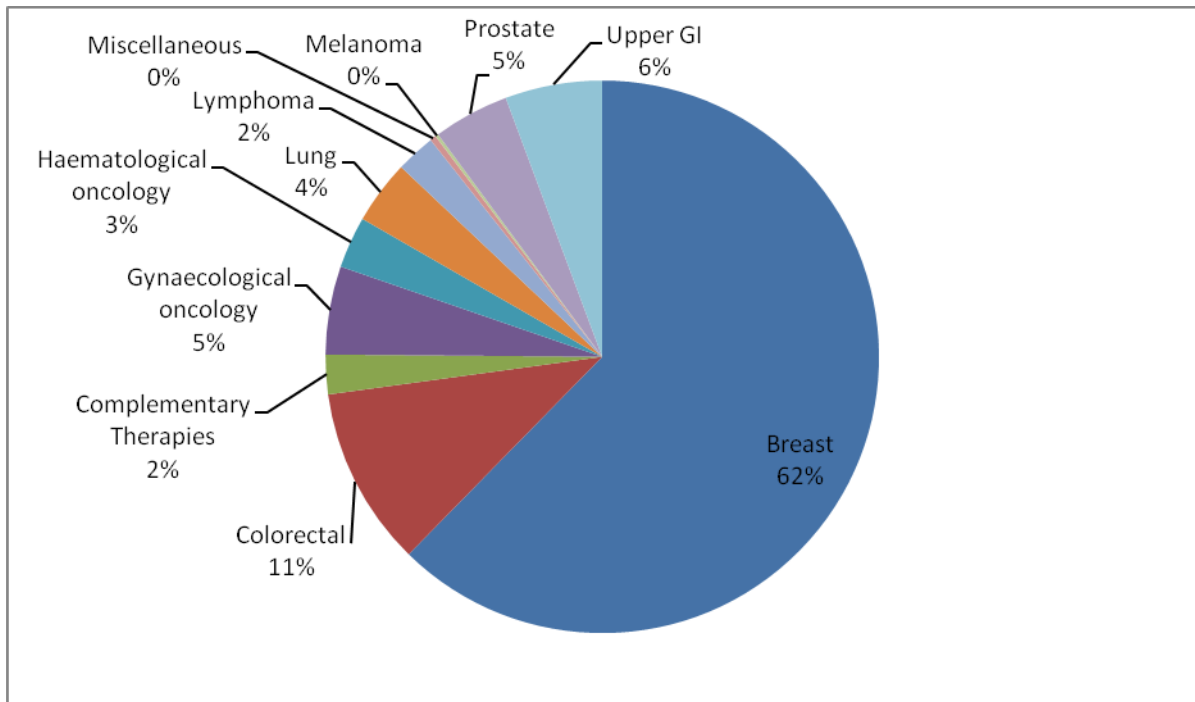


**Figure 2.4c.1: RCHT-** Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010

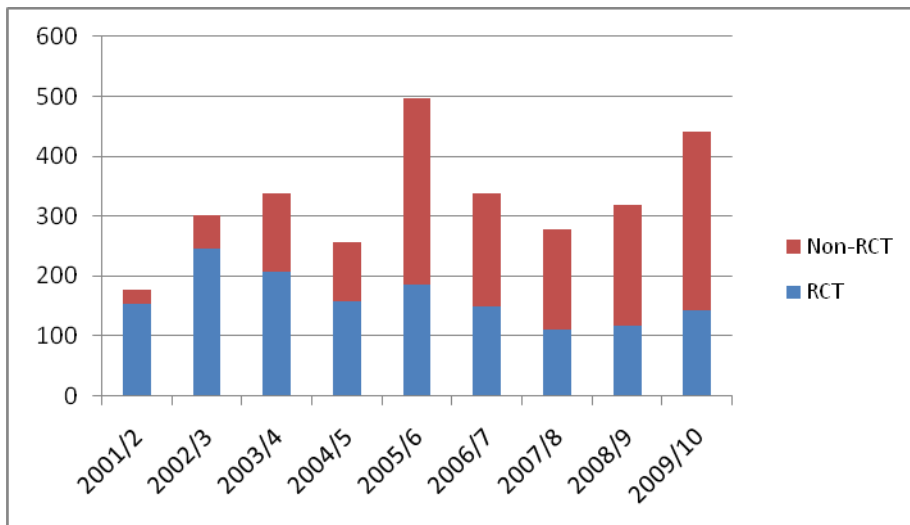


**RCHT-**The highest recruiting Trust in the Network this year and best year of activity for this trust. No doubt drive by the clinical Lead for Research but with a strong underpinning team. Building up the Gynaecology , Lung trials portfolio whilst maintaining strong Haematological, Colorectal and Upper GI trials. Overall recruiting to 44 trials of which 27 are RCT's. Dedicated support to the surgical Breast trials has seen a huge recruitment of 202 patients to ICICLE and 29 to Glacier with POETIC study also open. The most successful trust in terms of opening NCRN Commercial Trials (6 open/ about to open during the year). Future plans to increase radiotherapy trials such as FAST-FORWARD and IMPORT HIGH. Potential future activity with further surgical trials such as MINDACT and NEOCENT.

- **Figure 2.4c.II: RCHT** distribution of recruitment by CSG for 2009-10. (Cancer patients and patients with a pre-malignancy)

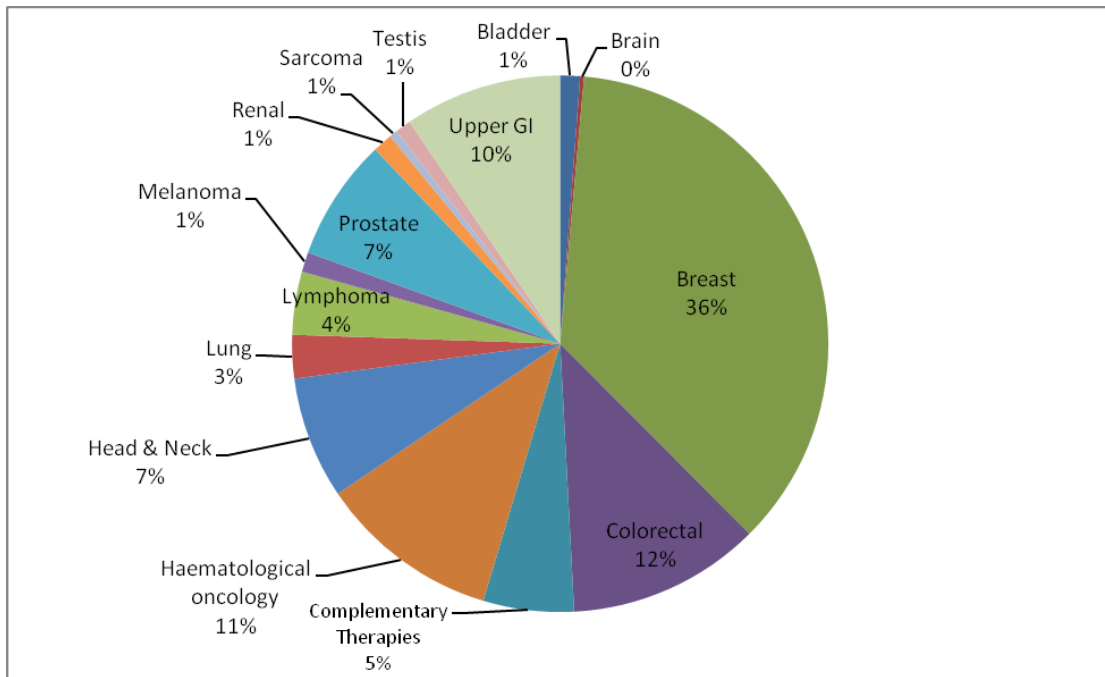


**Figure 2.4d.1: RDEFT-** Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010

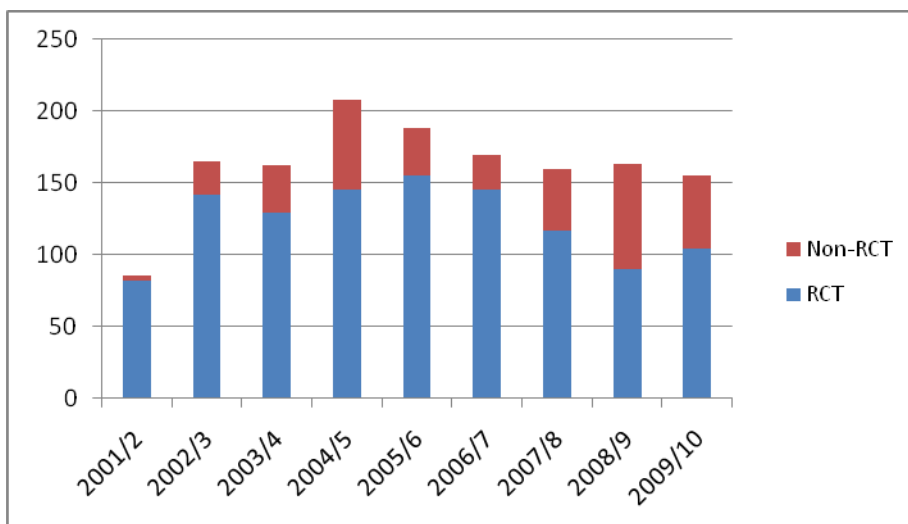


**RDEFT-** with overall recruitment of 504 patients. 61 trials open in year and recruitment to 48 trials (37 RCT's). Recognise pace of trial set up has dropped but is being addressed.. Activity across 15 disease sites. Continues strong in Haematological Trials, Lung, Upper GI and prostate. New trials have opened in Head and Neck, Thyroid, Sarcoma and Prostate. Future plans to increase portfolio overall and to show a balance by disease site. Prioritising key areas, colorectal, surgical breast trials and gynaecology. To re-establish a strong record of breast trials. Breast surgical trials POETIC, ICICLE, IBIS II and GLACIER recruiting with FH02 in the set-up phase. Good recruitment to prostate trials and evidence of thorough and effective screening for patients for a range of non-RCT trials. Developments for 2010/11 include plans to support commercial trials set up and radiotherapy trials.

- **Figure 2.4d.II: RDEFT** distribution of recruitment by CSG for 2009-10. (Cancer patients and patients with a pre-malignancy)

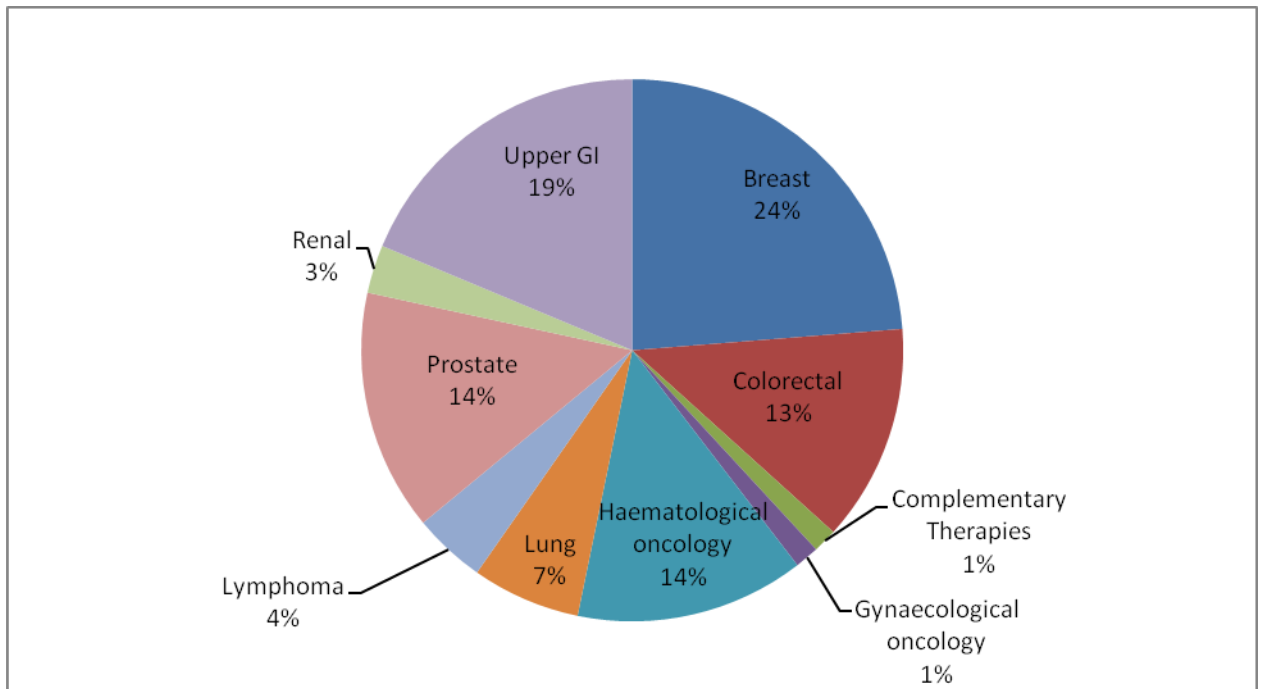


**Figure 2.4e.1: SDHFT-** Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010

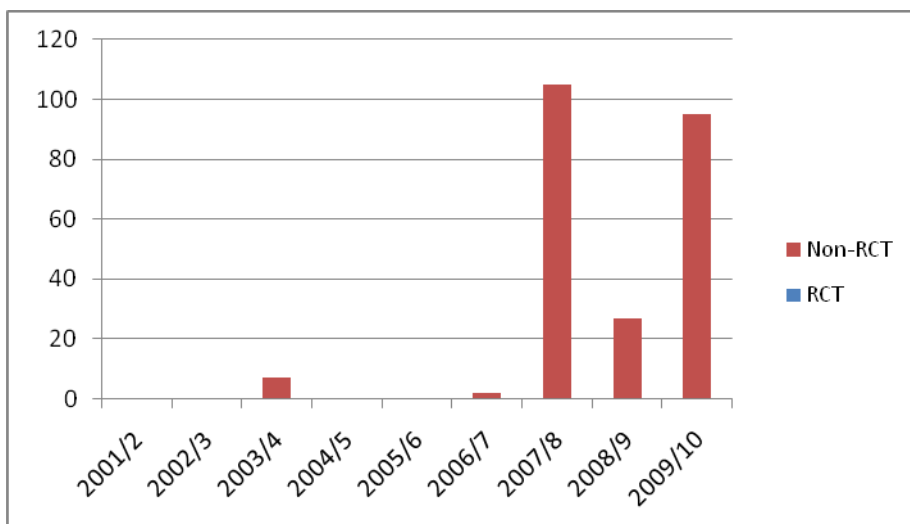


**SDHFT-** Despite the necessary re-structuring of the Research team and reduced capacity the trust has maintained strong recruitment to over 36 trials and in 28 RCT's (increased activity from 2008/9) with 163 patients in total recruited across 12 clinical studies groups. Maintaining good activity in Haematological Trials, prostate and upper GI trials. Recruiting 13 patients to the PICCOLO colorectal trial. Plans are to increase support to the recruitment to cancer portfolio studies; primarily in oncology and haematology, but also to offer support to surgical based trials. There is also potential to support further recruitment to radiotherapy trials. However, these developments will be dependent on securing additional funding.

- **Figure 2.4e.II: SDHFT** distribution of recruitment by CSG for 2009-10. (Cancer patients and patients with a pre-malignancy)

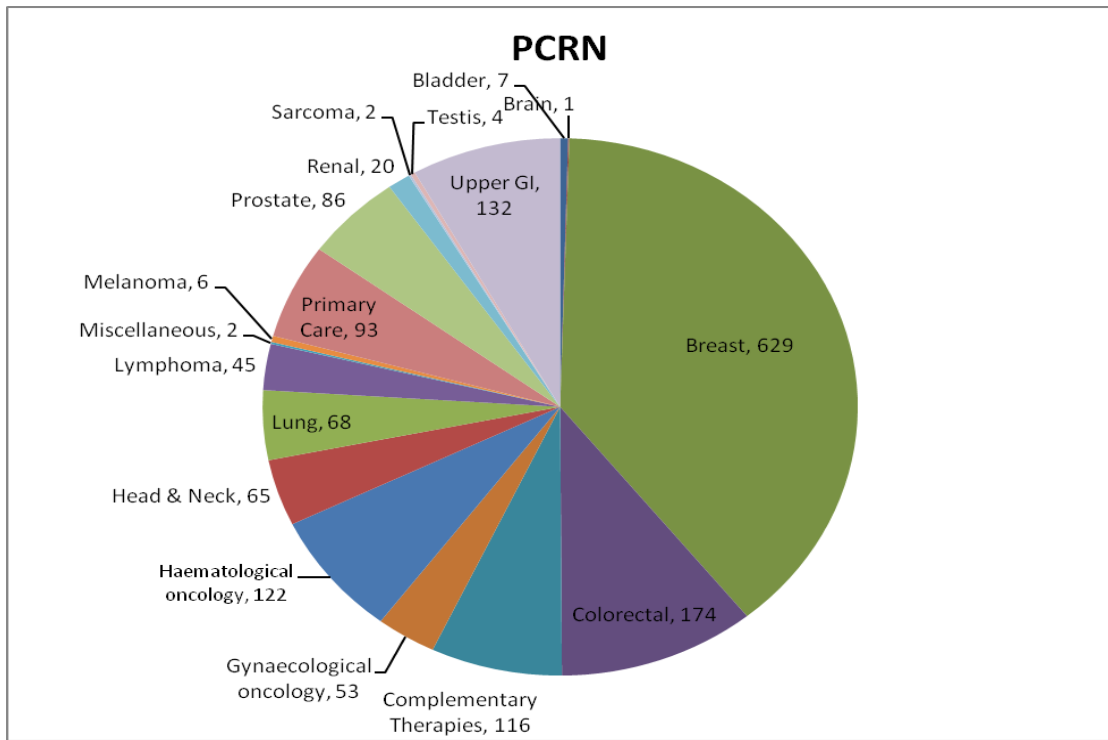


**Figure 2.4f.1: Gp's-** Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010



We also need to give thanks to the contribution of at least 10 GP practices across the Network which have recruited over 257 patients (95 cancer patients) into 5 non-RCT trials. These include BBC study, FBSC, Public perceptions of bowel cancer, Clinical features in metastatic cancer (Ide Lane Surgery) and BEST BARRETT'S (Spinney Surgery).

- **Figure 2.4g.II: Peninsula** distribution of recruitment by CSG for 2009-10. (Cancer patients and patients with a pre-malignancy)



The previous chart simply provides an over view of the current distribution and disease site where trials have been open across the Peninsula as a whole in 2009/10. Nb. This includes 1625 of the total (1967) patients and excludes those in prevention, screening and sub-studies.

## 2.5 Peninsula portfolio balance compared to national portfolio 2009-10

**Table 4a: Annual Network recruitment to RCTs (cancer, pre-malignant, commercial) by CSG from 2005 to 2010**

Recruitment of cancer, pre-malignant patients and recruitment to NCRN adopted commercial studies by CSG by year (by network)							
	2005-6	2006-7	2007-8	2008-9	2009-10	% of Total Local Network Recruitment 09/10	% of Total National Recruitment 09/10
Bladder	14	2	4	0	7	0.4	0.5
Brain	6	4	4	0	0	0.0	0.1
Breast	292	332	147	140	142	8.5	9.1
Colorectal	270	61	89	50	57	3.4	4.9
Complementary Therapies	0	0	0	0	55	3.3	0.7
Gynaecological oncology	2	3	7	7	7	0.4	0.6
Haematological oncology	109	103	59	59	87	5.2	4.3
Head & Neck	0	0	0	3	45	2.7	1.7
Lung	29	13	23	29	41	2.5	3.1
Lymphoma	50	43	53	41	39	2.3	1.2
Miscellaneous	0	0	0	0	0	0.0	0.3
Melanoma	0	0	0	7	5	0.3	1.1
Palliative Care	0	0	0	0	0	0.0	1.6
Primary Care	0	0	0	0	0	0.0	0.4
Prostate	5	15	23	37	44	2.6	4.6
Psychosocial oncology	0	0	0	0	0	0.0	1.7
Renal	4	1	2	5	12	0.7	0.8
Radiotherapy	5	0	4	0	0	0.0	0.4
Sarcoma	0	0	0	0	2	0.1	0.4
Testis	0	1	0	1	0	0.0	0.3
CCLG	0	0	0	0	0	0.0	0.6
Upper GI	11	10	15	54	58	3.5	3.5
<b>Total All Groups</b>	<b>797</b>	<b>588</b>	<b>430</b>	<b>433</b>	<b>601</b>		

Despite overall high accrual to RCTs and an increase on the previous 3 years it is interesting that the Peninsula only exceeds the national average in 4 sites ie Haematology, Lymphoma, Complementary Therapies and Head and Neck Trials and close to the average for Bladder, Breast, Renal and Upper GI. However, perhaps the data is skewed by both Networks with specialist services and availability of some of the trials in less common diseases. A comparison with networks of a similar size / set up would be interesting.

**Table 4b: Annual Network recruitment to non-RCTs (cancer, pre-malignant, commercial) by CSG from 2005 to 2010**

**Table 4b**

Recruitment of cancer, pre-malignant patients and recruitment to NCRN adopted commercial studies by CSG by year (by network)							
	2005-6	2006-7	2007-8	2008-9	2009-10	% of Total Local Network Recruitment 09/10	% of Total National Recruitment 09/10
Bladder	0	0	0	0	0	0.0	0.9
Brain	0	0	0	0	1	0.1	0.2
Breast	530	365	291	194	487	29.3	26.4
Colorectal	192	78	21	52	117	7.0	7.2
Complementary Therapies	40	45	95	87	61	3.7	1.4
Consumer Liaison Group	0	0	0	0	0	0.0	0
Gynaecological oncology	1	3	0	0	46	2.8	1.8
Haematological oncology	0	3	4	28	35	2.1	2.2
Head & Neck	0	0	0	0	20	1.2	0.9
Lung	0	5	3	12	27	1.6	1.6
Lymphoma	0	0	2	3	6	0.4	0.5
Miscellaneous	0	0	0	0	2	0.1	1
Melanoma	0	0	0	1	1	0.1	0.8
Palliative Care	0	0	0	0	0	0.0	0.7
Primary Care	0	0	0	0	93	5.6	0.2
Prostate	40	11	19	76	79	4.8	3.8
Psychosocial oncology	11	0	0	0	0	0.0	3
Renal	0	0	0	3	8	0.5	0.3
Radiotherapy	0	0	0	0	0	0.0	0.1
Sarcoma	0	0	0	0	0	0.0	0
Testis	1	0	1	23	4	0.2	1.3
CCLG						0.0	1.1
Teenage & Young Adults	0	0	0	0	0	0.0	0
Upper GI	0	4	2	39	74	4.5	2.8
<b>Totals</b>	<b>815</b>	<b>514</b>	<b>438</b>	<b>518</b>	<b>1061</b>		

In non-RCT recruitment it is interesting to note that recruitment to non-RCT breast trials makes up on average 26.4% of the national recruitment. The Peninsula fairs better than the average in 14 sites. However, this does identify those areas where there is further potential.

## **Portfolio Focus for 2010/11**

The Peninsula has previously focused on the common tumors but has in recent years through FSF funding been able to address some areas of weakness within trusts in tandem with new enthusiastic investigators a key ingredient to success i.e. a clinical drive with underpinning research support. This is already delivering results in Lung, Gynecological, Head and Neck, surgical breast trials and Urological trials. We anticipate an increase in Genetics trials activity following investments in 2009/10.

Over the next 12 months the network expects to see further activity in the above areas. As a network with a high incidence of Melanoma there is clearly potential for further activity. There is a network drive to provide a broader portfolio of trials in the areas of surgery and radiotherapy (providing both funding and Medical Physicists/Radiographers can be recruited).

Equity of access to trials across the network may benefit from review/ mapping in terms of improving network referrals particularly to offer access to trials in rarer tumour sites, industry trials etc. This may require the support of the service Network to ensure such referrals are possible and that trusts offering such trials are not financially disadvantaged.

There is interest from Palliative Care Clinician's to participate in trials and may be an area for consideration providing suitable trials are available.

New approaches to trials follow up are being developed in Exeter and Plymouth which in turn may free up existing trials staff to focus on trial recruitment in new areas. This is discussed further below.

### **2.6 Follow-up**

The level of follow-up activity being undertaken across the network is hard to quantify and different Trusts have different mechanisms for reporting follow-up. The following information provided by some Trusts gives an indication of the extent of the work load/ burden that follow-up currently represents.

	<b>NDHT</b>	<b>RDEFT Onc.</b>	<b>RDEFT Haem.</b>	<b>PHNT Onc.</b>	<b>SDHFT</b>	<b>RCHT</b>
Number of NIHR cancer studies closed with pts on active follow-up	19	60	11	20	Nk	Nk
Number of patients that are in "follow-up" stage of protocol-closed studies	145	752	114	317	Nk	Nk
Number of NIHR cancer studies open with pts on active follow-up	3	39	23	12	Nk	Nk
Number of patients that are in "follow-up" stage of protocol-open studies	126	398 (guestimate)	112	53	Nk	Nk

The data provided above are really an indication of levels of follow based on quick estimates and clearly the complexity of follow up will vary between trials. RDEFT has a significant burden of additional work with at least 25% of all trial patients seen since 2001 still in trials follow up.

Similar proportions are evident for PNNT and NDHT. So it would be reasonable to assume that at least 25-30% of patients are still in follow up. This is likely to rise where Breast Cancer trials are a larger proportion of the portfolio.

The figures below show :

All Patients Recruited 2001-10 (include cancer, commercial and pre-malignant recruitment).

	<b>RCT</b>	<b>Non-RCT</b>	<b>Total</b>
NDHT	222	657	879
PHNT	769	845	1614
RCHT	1286	854	2140
RDEFT	1468	1479	2947
SDHFT	1109	346	1455
GPs	0	236	236
Hspc.	0	120	120
PCGS	0	22	22
<b>Total</b>	<b>4854</b>	<b>4559</b>	<b>9413</b>
<b>%</b>	<b>51.6</b>	<b>48.4</b>	

This is helpful in identifying the overall like follow up burden for each of the trusts.

The table below shows follow up number by disease site for RDEFT which show that predominantly Breast , Haematology/ Lymphoma and Colorectal trials having most impact.

<b>RDEFT</b>	<b>Follow Up</b>
Breast	588
Colorectal	63
Lung	25
Gynae.	2
Haem	114
	<b>792</b>

Figures available from PHNT are also give below.

<b>Trial</b>	<b>No. in F/U</b>	<b>Died</b>	<b>Ongoing - Open to Recruitment</b>	<b>In FU</b>	<b>Died</b>	<b>Active Treatment</b>
Closed - in Follow UP						
ActII	4	2	Bilcap	7	0	0
Aspect	12	1	Chorus	1	0	0
ATTOM	7	2	DNA Methylation	11	2	0
AZURE	22	7	Foxtrot	2	0	0
Coin	3	1	Fragmatic	5	12	4
DCISII	2	0	IBIS II (DCIS)	5	0	0
Icon 7	2	0	IBIS II (Prevention)	4	0	0
Posh	20	1	OE05	4	2	0

Prime	9	1	PARP	1	1	0
Prime II	31	1	QUASAR II	9	1	0
START	42	4	ESPAC4	2	1	0
TACT	27	7	ST03	2	0	0
TANGO	5	2	<b>TOTAL</b>	<b>53</b>	<b>19</b>	<b>4</b>
BLT	1	5	<b>OVERALL TOTAL</b>	<b>53</b>	<b>19</b>	
FACS	8	0				

Trial	No. in F/U	
UKFOCCS	73	0
ALTTO	3	0
ATAC/LATTE	16	0
SCOTROC	11	6
Dietcomplyf	19	1
<b>TOTAL</b>	<b>317</b>	<b>41</b>

### New Approaches To Follow Up

**RDEFT** The manager has discussed with the Lead Oncology Clinician, CLRN Manager and Oncology Directorate the set up of nurse led research clinics. They aim to submit this to the Primary Care Trust for inclusion in their plan for 2010/2011. The manager is working with the Directorate in order to have this submission ready by the autumn. However, need to think about nursing implications and need further discussion/ input from lead oncology nurse.

**PHNT** Following a recent review the trust plan to set up an innovative new research nurse led clinic service to manage the follow-up burden of many of the portfolio studies. This has led to a review of the infrastructure of the department.

The addition of a Band 7 nurse has been agreed to support the set up and overseeing of the research nurse led follow up clinics. Feedback from other NCRN and devolved Cancer Research Networks has been sought, Standard Operating Procedures / protocol developed and this work is already underway. The plan is to start running research nurse led clinics to support initially the long term follow up of patients in Breast studies; then to audit the Service as a whole, by looking at patient satisfaction.

### 2.7 Referral of patients

All NSSGs are provided with information regarding trials open across the network to facilitate the referral of patients across the network and maximise recruitment into trials.

Patient referral pathways are in place for some trials where cross-site working is required and already exists within the clinical service this is largely where clinicians already work between sites or where specialist referral pathways have been implemented as part of the Improving Outcomes Guidance. However documented patient referral pathways are not currently available within the network.

There is clearly an excellent opportunity to include trials referral opportunities within the map of medicine which has been well developed in the Peninsula through the Cancer Service Improvement Facilitators.

Most Peninsula patients are treated in the Peninsula apart from in the very rare tumours.

**NDHT** has collaboration with RDEFT in Oncology and Haematology. There are numerous studies in follow-up where recruitment was taken in Exeter, but the follow-up data is collected and recorded in North Devon – shared care. Patient's preference to be followed up near home e.g. FAST, TEAM, AML-12, Tango, Prime Phase II, AML-15, AML-16, and LY09. There have been the same trials opened in both sites and this continues to be true of new studies to ensure North Devon patients can be given the same opportunities as Exeter and treated near home, such as Myeloma XI. Similarly, with radiotherapy studies, for which treatment NDHT patients would ordinarily travel to Exeter.

There are already known referrals for Paediatric Oncology trials through the shared care service with children referred to Bristol for treatment and then back to the Peninsula sites of NDHT, PHNT, RDEFT and RCHT for both clinical and trials follow up.

The current genetic service based in Exeter will have patients referred from all trusts within the Peninsula but has similarly been dependant on additional data management support to collect this data by referring trust.

The gynae-oncology surgeon in Torbay has been referring patients to the RD&E at Exeter for enrolment into UKFOCCS. No information about patient numbers available. Similarly there are referrals for trials undertaken in Urology in Exeter from Torbay where there is already cross site working between Oncologists.

One example has been provided by PHT

- 1) Trial acronym                    BILCAP,
- 2) Recruiting site                PNHT
- 3) Referring site                 Birmingham x 3, 1 x Torbay, 1 x Exeter, 1 x Truro
- 4) Number of patients referred
- 5) Number of referred patients subsequently recruited    x 3 recruited, x 3 refused due to geography

More recently a patient from Exeter has also been recruited into the PARP BRCA Trial in Plymouth.

Clearly further work needs to be done to map trial provision in patient pathways.

## **2.8 Activity outside the NCRN Portfolio**

The Research Network do not centrally collate reliable information about this activity.

The Research Network had a strong history of participating in commercial trials outside of the NCRN portfolio particularly in PHNT this has declined in recent years but still remains strong in Haematology where there are also a number of locally led studies. This information is not routinely collected. There are at least 4 Commercial Haematology Trials open at present. There is also one Commercial study in Prostate and one in Lung open.

RDEFT have participated in: Commercial trials-1 Breast study and 2 Lung studies. In addition there are 2 local investigator led Haematology studies.

RCHT have noted 1 Commercial Breast study in Oncology in addition to those NCRN Commercial badged studies noted earlier in the report. They also have 6 other Commercial Haematology studies currently open with one opening shortly. There are 5 further Haematology studies in early stage feasibility.

We are not aware of any non-NIHR activity in NDHT and do not have information from SDHT.

The situation regarding Consumer involvement is essentially unchanged from 2008/9.

We are pleased to have the support of two Consumers who are members of our Research Network Steering Group and who have provided excellent support during our previous Cancer Peer review and have been supportive to our steering group and in giving opinion as part of our FSF panel..Both members have experience having been involved with the Cancer Network Partnership Group and working with other Consumer Groups locally.

One of our consumers has undertaken training through the NCRN. We are also aware we have a local consumer has been a member of the national NCRI Renal Studies Group who until recently has been an active member of the Cancer Network Partnership Group

Few Cancer Research Studies have been developed in the Peninsula and therefore we have not focussed so far on developing a Cancer Consumer Advisory panel for Researchers

At present our immediate priority would be for the support and advice from consumers in how to best promote and disseminate information on local Cancer trials. We anticipate the much awaited re-development of the Peninsula Cancer Network website which will include a Research section to raise awareness of trials available within our Network. We hope that this will make our work better known to both local stakeholder and consumers alike.

We anticipate that a more regional/national approach using a network of Consumers and carers with experience of Cancer may be the way forward for our Network

We are aware that there are successful consumer Research groups supporting our colleagues in Diabetes and Stroke Research in the South West and the work of FOLK.US who are based in Exeter.

We understand that there are valuable resources and training available to support any interested Consumers and we would be more than happy to facilitate access to such training with the support of NCRN. The recently formed NCRN Central training group also has plans to develop a portable one day small group training package to better support consumers interested to support our agenda. Travel to national training provided outside the region has previously been raised as an issue discouraging involvement.

Consumers are invited to our Network Annual Research Symposium and other events such as the Riviera Research Day held in Torbay annually.

We are aware that a Haematology Consultant in Exeter has set-up a Haematology Consumer research advisory group. This is not meeting at present but has influenced activities in the past. This group has influenced design and content of patient information sheets.

**Access to patient representation via NSSG Consumer Representatives** Each network Site Specific Group has user representation and the Peninsula RNM plans to establish better links with these representatives in 2010/11 (pending agreement from the Consumer Liaison Lead to ensure they have a better understanding of research reports produced for these meetings and that they may support/ advocate greater involvement in research within the groups.

**Stakeholder in the South West Scoping Study on PPI** There was a South West 'Public Involvement in Research' Scoping Study involving 14 SW stakeholders led by North Bristol Trust and the University of the West of England. This looked at opportunities for users (Research Partners) to get involved in research in the South West.

Although, the Peninsula RNM was unable to attend this event it was attended by the ASWCRN RNM. Following this event and the outcomes of the project it has been decided that funding will be applied for to continue collaboration by employing a central resource to focus on information sharing.

We hope that the Peninsula CRN (RNM) will be able to attend such meetings in the future and can benefit from shared learning and decisions that will hopefully drive a consistent South West approach to user involvement in research.

### **3 Consumer Involvement**

#### **3.1 Summary of consumer involvement activity**

This has largely been restricted to input into our steering group and support with Peer Review.

#### **3.2 Impact of consumer involvement activity**

Our current consumers are interested to do some work looking at how Cancer Trials and Research trials in general are made known to prospective patients within the Peninsula and in respect of patient information and increasing the awareness of trials conducted in the region.

In line with these interests we would also welcome feedback from our Consumers regarding information they wish available via the planned website discussed above.

**RDEFT**- Keen to develop a Consumer Involvement strategy and the manager is working on a draft protocol to involve consumers on participating in trials and how we can improve on accrual. Proposals include an audit questionnaire to be rolled out to patients to assess impact/service delivery this can also be rolled out to clinicians/staff for their comments on impact of trials etc.

This audit will aim to monitor the contributions from the clinical trial team; improve service delivery; facilitates service support and identify areas for improvement within the unit

There are also plans to have a DVD made to raise the profile of clinical trials. This can be used in the hospital clinical waiting area and will include input from physicians, research nurses and importantly patient input on participating on clinical trials. The manager is meeting with an external company on 14<sup>th</sup> June to discuss further (with Trust R & D Management) and this could potentially be used in any setting (GP practices, other Trust's in the Network and other waiting areas in RDEFT..

We plan to include this as a work stream for collaboration within our operational managers group.

#### **4. Network Initiatives, good practice and impact**

Work of a Senior Research Practitioner in Breast Cancer Surgery from RDEFT

Initial tasks were to forge strong contacts with people, ascertain what trials were already running at the trust, carry out a simple SWOT analysis of each trial to ascertain the work still to be done, ascertain the clinics relevant to the trials, attend local meetings pertinent to clinical trials in order to ascertain the departmental needs.

**Results:** A lack of information, communication and support for the surgical team was identified. A new Trials Specific notice board was set up in the breast clinic waiting area. Attendance at weekly MDT meetings to promote trials proved to be beneficial and encourages enthusiasm. Networking with Peers in other Trusts to share good practice and learning. E.G. recognise Mammographers could help in identifying potential patients for biopsy.

In the future a more modern, responsive service is envisaged where trials data is incorporated with clinical data (via MDTs) to provide better insight into the reasons why patients do not always wish to participate in a clinical trial, e.g. style of trial, drugs treatment.

The Department has voiced thoughts of starting a Journal club and a Logo specific to our team to promote an image of excellence through learning and pride in identity.

It is important to give feed-back to the team and to highlight areas where we are failing to progress or succeed to ensure that the team is aware what people need and want.

An in depth piece of work has been carried out showing the overall numbers of patients screened, including pre-screening for a number of surgical breast studies.

#### **Examples of NCRN trials that have influenced local guidelines include:**

**AML15** Standard care for treatment of APL patients has changed to reflect the findings of AML 15 trial and subsequent recommendations. This has led to a reduction of inpatient stay for individual patients, improved quality of life and a reduction in associated hospital costs.

**Myeloma IX** As a result of the Myeloma IX trial, induction treatment for myeloma patients has changed from infusional treatment to oral treatment for younger patients with an improvement in quality of life. The reduced impact on chemotherapy services has allowed this service to absorb the increased demands of other tumour group chemotherapy requirements.

**IMPORT LOW** Participation in the IMPORT LOW trial has encouraged breast surgeons to put in clips at the tumour bed for all patients (not just those eligible for the trial). This is improving radiotherapy planning.

**START** results were published, in March 2008, reducing the then five-week regimen to a three-week schedule for most breast cancer patients. The same regimen is currently prescribed to the majority of British women, and the trial is likely to influence practices overseas.

**FAST** was set up by Professor John Yarnold and the ICR-CTSU between 2004 and 2007 to test a five-fraction regimen (treating once a week) against the international

standard 50 Gy in 25 fractions. The first analyses of the 900 women on follow up is awaited. Duncan Wheatley will be leading the FAST-FORWARD study in the Peninsula.

A general benefit in participation of the NIHR Radiotherapy trials has been the improvement in quality Assurance for Radiotherapy, planning and dosimetry.

Participation in recent Colorectal trials has proved the additional benefits of adding Cetuximab to the chemotherapy treatment for colorectal patients.

NIHR breast cancer trials have seen the addition of Taxanes to improve outcomes for breast cancer patients

The addition of Alimpta in the treatment of small cell lung cancer has produced better outcomes for these patients.

## 7. Work Programme for 2009-10

**Work Programme** for 2009-10; note that agreement of an annual Work Programme is a requirement of research network peer review – see measure 5A-104.

Activity/Task	2009-2010 "Peninsula" Cancer Research Network Work Programme											
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Review Of Network Staffing/ Skill Mix												
Trust Visits												
Review Of NCRN/ CLRN Funding Status/ Operational Plans												
Review FSF BIDS												
Review Trials Status												
Review Trials Activity												
Support and Reporting to NSSG's												
Workforce Development/Training and Education												
Annual Research Symposium												
Haematology Research Event												
Website Development												
Website Updates												
Collaboration With Other Stakeholders/ Networks												

## **Workplan 2009/ 2010 Narrative**

1. A more frequent review of Network Staffing and skill mix is required to ensure the staff funded via the combined funding stream through NCRN/ PCLRN and FSF are both supported and directed to relevant training and development opportunities.
2. There is ongoing need for more frequent trust/ site visits to ensure exchange of information, to assist in staff support, advise on national and regional developments. To engage with new staff and investigators, and meet with both team members and Research and Development staff and other stakeholders.
3. More frequent review of funding and changes to operational plans since the change in funding streams to ensure a seamless service regardless of funding streams.
4. FSF bids need to be developed appropriately, stakeholder need to know how to apply, bid need reviewing agreeing and planning strategic planning when funding expires. Performance reviewed on resultant activity.
5. Review of both trial status nationally and within Network to inform NSSG's, MDT Research Leads and all interested stakeholder.
6. Trials activity although in part available via EPS reporting is not universal and additional amalgamation for reporting is required for stakeholders and performance management.
7. Formal reporting to NSSG's requires a combination of the above to provide an overview and to assist in portfolio development and compliance with Peer Review Measures.
8. Workforce development and training is ongoing and requires collaboration and planning, managing attendees, funding, organising travel, promotion and assessing outcomes.
9. The Annual Research Symposium provides a significant workload for the Network Secretary but also involves much liason with speakers, sponsors, attendees and those involved in the programme development.
- 10, The planned website development is a significant piece of work which will require a bringing together of much information about the activities of the Research Network not only the need to ensure all information is current but in producing databases for trials activity, status, training events etc.
- 11 The collaboration with stakeholders is a significant workload with a wide range of meetings to arrange, prepare and attend. There is much work to be done to establish effective working with PCLRN, Cancer Network Groups, Managers, NCRN CC, other topic Networks etc

This list is by no means fully representative of the workload of either the Network Core Team or the wider Research Network Teams.

## Appendix 1

<b>Network</b>	Peninsula Cancer Research Network
<b>Clinical Lead(s) for Research</b>	Dr. Duncan Wheatley
<b>Research Network Manager(s)</b>	Mr Glyn Rees
<b>Network Population (NCRN)</b>	1.5 Million
<b>Financial allocation (2009/10)</b>	£ (Comprised of £ 522,312 Core Funding and £ 137,235 Fixed Term Flexibility & Sustainability Funding)

<b>Network organisation</b>	<b>Centralised/devolved/mixed</b>
Staff appointments	All staff are employed by trusts in a devolved model except Clinical Lead, Research Network Manager and Research Network Secretary.
Line management	Devolved model of line management.
Governance	Devolved model of governance with individual trust teams submitting regulatory submissions.
Portfolio management	Mixed model of Portfolio management driven by Research Network Management team, prioritised in Consultation with Site Specific Groups but finalised by local Research Teams and multidisciplinary teams.

Summary of NHS organisations within the network from which patients are recruited (or referred)			Nature of the institution:				Summary of staff resource (wte)		
Trust name	Trust acronym	Hospital site(s) Hospital site acronym	University Teaching Hospital with Medical School (y/n)	ECMC centre (y/n)	Able to deliver radiotherapy? (y/n)	Able to deliver intravenous chemotherapy? (y/n)	NCRN-funded (wte)	CLRN funded (wte)	Non-NCRN funded (wte)
Northern Devon Healthcare NHS Trust	NDHT	North Devon District Hospital		No	No	Yes	2.03	0.8	
Plymouth Hospitals NHS Trust	PHNT	Derriford Hospital	Yes	No	Yes	Yes	4	6.5	0.5
Royal Cornwall Hospitals NHS Trust	RCHT	Royal Cornwall Hospital	Yes	No	Yes	Yes	2.68	5.89	1.5
Royal Devon & Exeter NHS Foundation Trust	RDEFT	Royal Devon & Exeter Hospital (Wonford)	Yes	No	Yes	Yes	4.82	6.61	0.56
South Devon Healthcare NHS Foundation Trust	SDHFT	Torbay Hospital		No	Yes	Yes	1.96	3.4	

### Summary of Activity in the NCRN Portfolio:

	TOTAL NUMBER OF PARTICIPANTS RECRUITED/YEAR (INCLUDING NCRN COMMERCIAL ACTIVITY)								ACCRUAL AS % OF CANCER INCIDENCE <sup>1</sup> (CANCER & PRE-MALIGNANT, COMMERCIAL)	
	Cancer patients		Patients with pre-malignant disease		Non-cancer participants (Screening & prevention studies)		Cancer patients recruited to Commercial NCRN trials (currently all RCTs)		RCT	Non-RCT
	RCT	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	Number of open studies	Recruitment		
2001-2	295	32	0	0	0	0	0	0	4.3	0.5
2002-3	573	141	0	0	0	0	0	0	8.3	2.0
2003-4	539	563	2	0	2	10	0	0	7.8	8.2
2004-5	498	503	0	0	0	190	0	0	7.2	7.3
2005-6	795	815	19	0	0	144	0	0	11.8	11.8
2006-7	583	514	44	0	385	126	0	0	9.1	7.4
2007-8	432	438	39	0	108	82	1	1	6.8	6.3
2008-9	403	518	44	6	21	27	2	5	6.6	7.6
2009-10	577	855	9	206	34	271	7	15	8.7	15.4

<sup>1</sup> Using a UK incidence rate of **0.0046** cases/head of population

### Summary of Activity in the Commercial NCRN Portfolio

NCRN ID	Agreed mCTA target (number by date)	Actual numbers of patients recruited to date	NCRN ID	Agreed mCTA target (number by date)	Actual numbers of patients recruited to date
ALTTO	18 patients by 30/09/11	6 ( Open in 2 Trusts)	NCRN098 (BOLERO 11)	4 patients by 31/12/10	0 (Open in 1 Trust)
BEATRICE	16 patients by 02/11/09	7 (Closed in 2 Trusts)	NCRN103 (BOLERO 1)	5 patients by 30/11/11	0 (Open in 1 Trust)
NCRN010 (AVEREL)	2 patients by 05/01/10	2 (Closed in 1 Trust)	NCRN138	20 patients by 01/06/11	0 (Open in 1 Trust)
NCRN024	5 patients by 30/09/10	6 (Open in 1 Trust)	NCRN018	10 patients by 28/02/10	6 (Closed in 1 Trust)
NCRN089	2 patients by 30/04/11	1 (Open in 1 Trust)	NCRN042	2 patients by 31/08/11	1 (Open in 1 Trust)
			NCRN043	12 patients by 28/02/11	2 (Open in 3 Trusts)

### Other topic networks in your locality

Stroke Network, Diabetes Network, Medicines for Children Network, DeNDRoN, Mental Health Network and Primary Care.

Comprehensive Local Research Network(s)	Cancer Research Network Trust included
Peninsula Comprehensive Local Research Network	Northern Devon Healthcare NHS Trust
	Plymouth Hospitals NHS Trust
	Royal Cornwall Hospitals NHS Trust
	Royal Devon & Exeter NHS Foundation Trust
	South Devon Healthcare NHS Foundation Trust

## Appendix 2 – Staffing List

Trust	Role	WTE	% Time spent On Cancer Trials	Funding Source	NCRN	CLRN	FSF	COM
RCHT	Clinical Lead for Cancer Research	0.20	20%	NCRN	0.20			
PCN	Network Research Manager	1.00	100%	NCRN	1.00			
PCN	Research Secretary	0.55	55%	NCRN	0.55			
PCN		<b><u>1.75</u></b>			<b><u>1.75</u></b>			
NDH	Oncology Research Nurse	0.40	100%	CLRN		0.40		
NDH	Oncology Research Nurse	0.60	100%	NCRN	0.60			
NDH	Oncology Research Secretary	0.60	100%	NCRN	0.60			
NDH	Oncology Research Nurse	0.43	100%	NCRN	0.43			
NDH	Oncology Research Nurse	0.40	100%	NCRN/CLRN	0.40	0.40		
NDH		<b><u>2.43</u></b>			<b><u>2.03</u></b>	<b><u>0.80</u></b>	<b><u>0.00</u></b>	<b><u>0.00</u></b>
PHNT	Haematology Research Nurse	0.80		NCRN/CLRN	0.30	0.5		
PHNT	Haematology Research Nurse	1.00		NCRN/CLRN	0.30	0.7		
PHNT	Trials Administrator	1.00	100%	CLRN		1.00		
PHNT	Lead Oncology Research Nurse	1.00		CLRN-70%, NCRN-30%	0.30	0.7		
PHNT	Senior Oncology Research Nurse	1.00	100%	NCRN/CLRN	0.95	0.05		
PHNT	Oncology Research Nurse	0.80		NCRN	0.80			
PHNT	Oncology Research Nurse	1.00		CLRN/Commercial		0.5		0.5
PHNT	Oncology Research Nurse	1.00		CLRN		1.00		
PHNT	Oncology Research Nurse	0.53		CLRN		0.53		
PHNT	Oncology Trials Administrator	1.00		FSF-75% & CLRN 25%		0.25	0.75	
PHNT	Oncology Trials Administrator	0.50	100%	FSF			0.50	
PHNT	Oncology Trials Unit Receptionist	0.67	100%	CLRN		0.67		
PHNT	Research Nurse (urology)	0.60		CLRN		0.60		
		<b><u>10.90</u></b>			<b><u>2.65</u></b>	<b><u>6.50</u></b>	<b><u>1.25</u></b>	<b><u>0.50</u></b>

Trust	Role	WTE	% Time spent On Cancer Trials	Funding Source	NCRN	CLRN	FSF	COM
RCHT	Cancer R&D Team Leader	1.00	0.80	NCRN	1.00			
RCHT	Cancer R&D Facilitator	1.00	0.80	CLRN		1.00		
RCHT	Cancer R&D Facilitator	1.00	0.80	Commercial				1.00
RCHT	Cancer R&D Facilitator	1.00	1.00	Commercial & CLRN		0.5		0.50
RCHT	Cancer R&D Nurse	0.80	0.64	CLRN		0.80		
RCHT	Cancer R&D Nurse	1.00	0.80	CLRN		1.00		
RCHT	Cancer R&D Nurse	0.60	0.60	NCRN	0.60			
RCHT	Cancer R&D Nurse	0.40	0.40	CLRN		0.40		
RCHT	Cancer R&D Nurse	0.68	0.54	NCRN	0.68			
RCHT	Cancer R&D Nurse	0.53	0.42	CLRN		0.53		
RCHT	Cancer R&D Nurse	0.40	0.32	FSF			0.40	
RCHT	Cancer R&D Administrator	0.40	0.32	CLRN		0.40		
RCHT	Cancer R&D Administrator	1.00	0.80	CLRN		1.00		
RCHT	Cancer R&D Administrator	0.26	0.21	CLRN		0.26		
		<b>10.07</b>	<b>8.46</b>		<b>2.28</b>	<b>5.89</b>	<b>0.40</b>	<b>1.50</b>
RDEFT	Cons Clinical Oncologist / Clinical Research Lead	0.13		NCRN (1 session); CLRN (1/4 session)	0.10	0.03		
RDEFT	Cancer Clinical Research Manager	1.00		CLRN 80%; commercial income 20%		0.8		0.20
RDEFT	Senior Research Practitioner	1.00		FSF			1.00	
RDEFT	Research Nurse	0.40		CLRN 80%; commercial income 20%		0.32		0.08
RDEFT	Research Officer	0.80		CLRN 60%; NCRN 40%	0.32	0.48		
RDEFT	Research Nurse	0.40		CLRN 80%; commercial income 20%		0.32		0.08
RDEFT	Research Nurse	1.00		NCRN	1.00			
RDEFT	Research Nurse	0.40		CLRN		0.40		

Trust	Role	WTE	% Time spent On Cancer Trials	Funding Source	NCRN	CLRN	FSF	COM
RDEFT	Research Nurse	0.80		CLRN		0.80		
RDEFT	Research Nurse	1.00		NCRN 60%; CLRN 40%	0.60	0.4		
RDEFT	Research Nurse	0.40		CLRN 50%; commercial 50%		0.2		0.20
RDEFT	Research Nurse			Job share with above post				
RDEFT	Research Nurse	0.60		CLRN		0.60		
RDEFT	Research Nurse	0.60		CLRN		0.60		
RDEFT	Research Officer	1.00		FSF			1.00	
RDEFT	Research Officer (Genetics)	0.40		FSF			0.40	
RDEFT	Genetics Nurse Counsellor	0.40		FSF			0.40	
RDEFT	Clinical Trials Administrator	1.00		CLRN		1.00		
RDEFT	Clinical Trials Administrator	0.40		CLRN		0.40		
RDEFT	Clinical Trials Administrator	0.26		CLRN		0.26		
		<b>11.99</b>			<b>2.02</b>	<b>6.61</b>	<b>2.80</b>	<b>0.56</b>
SDHFT	Research & Development Manager and Cancer Trials Unit Manager	0.20		CLRN		0.2		
SDHFT	Research Nurse	0.80		CLRN		0.80		
SDHFT	Oncology Research Nurse	0.86		NCRN	0.86			
SDHFT	Oncology Research Nurse	0.80		CLRN		0.80		
SDHFT	Research Nurse (Gastro Enterology)	0.10		NCRN	0.10			
SDHFT	Research Nurse (Urology)	0.10		CLRN		0.1		
SDHFT	Oncology Clinical Trials Administrator,	1.00		CLRN		1.00		
SDHFT	Haematology Clinical Trials Administrator	1.00		NCRN	1.00			
SDHFT	Research Radiographer	0.50		CLRN		0.5		
		<b>5.36</b>			<b>1.96</b>	<b>3.40</b>	<b>0.00</b>	<b>0.00</b>

Trust	Role	WTE	% Time spent On Cancer Trials	Funding Source	NCRN	CLRN	FSF	COM
PCN		1.75			1.75	0	0.00	0.00
NDH		2.43			2.03	0.8	0.00	0.00
PHT		10.90			2.65	6.5	1.25	0.50
RCH		10.07	8.456		2.28	5.89	0.40	1.50
RDEFT		11.99			2.02	6.61	2.80	0.56
SDHFT		5.36			1.96	3.4	0.00	0.00
		<b><u>42.50</u></b>			<b><u>12.69</u></b>	<b><u>23.20</u></b>	<b><u>4.45</u></b>	<b><u>2.56</u></b>

### Appendix 3a – Attendance Summary for LRN Single Group (Research Steering Group)

Name	Job Title	Trust	Attended R&D Meetings from April 2009 to March 2010		
			23/06/09	22/10/09	18/03/10
Clare Adams	Consultant Surgeon	PHT			√
Nigel Bailey	Consultant Medical Oncologist	RCHT			
Darren Beech	Cancer R&D Team Leader	RCHT	√		
Carole Brewer	Consultant Clinical Geneticist	RDE			
Shelia Bullard	Cancer Clinical Trials Coordinator	PHT			
Peter Cant	Consultant Surgeon	PHT			
Ann Courtman	Research Administrator	PCN	√	√	√
Ian Daniels	Consultant Colorectal Surgeon	RDE			
Peter Donnelly	Consultant Surgeon	SDH			
Nicola Donlin	Lead Oncology Research Nurse	PHT			√
Dawn Edwards	Oncology Research Nurse	RDE			
Richard Ellis	Consultant Clinical Oncologist	RCHT			√
Claire Fairfax	Oncology Clinical Trials Administrator	SDH			
Mary Figg	Patient Representative				
Mezzi Franklin	Hospital Macmillan CNS	NDDH			
Andy Goodman	Consultant Clinical Oncologist	RDE			
Caroline Harnett	Haematology Advanced CNS	SDH			
Martin Highley	Consultant Medical Oncologist	PHT			
Becky Holbrook	Research Nurse	NDDH		√	
Anne Hong	Consultant Clinical Oncologist	RDE			
Jackie Kraska	Cancer R&D Manager	NDDH	√		
Cathryn Love-Rouse	Research Management & Governance Lead	PLCRN			
Anna Lydon	Consultant Clinical Oncologist	SDH			√
Lynne Van-Koutrick	Research Nurse	NDDH		√	
Jackie Kraska	R&D Manager	NDDH			
Sophie Mepham	Cancer R&D Facilitator	RCHT			
Nick Morley	Cancer R&D Facilitator	RCHT			
Mark Napier	Consultant Medical Oncologist	NDDH			
Sarah Pascoe	Consultant Clinical Oncologist	PHT			
Cathie Peters	Clinical Nurse Specialist Chemotherapy	NDDH			
Glyn Rees	Network Research Manager	PCN	√	√	√
Claire Ridler	CLRN Research Management & Governance Manager	RDE			
Fiona Roberts	Research & Development Manager and Cancer Trials Unit Manager	SDH	√		√
Amy Roy	Consultant Clinical Oncologist	PHT			
Simon Rule	Network Medical Director, Consultant Haematologist	PHT			
Denise Sheehan	Consultant Clinical Oncologist	RDE			
Suzy Tasker	Research Officer	RDE			
Lorraine Thornton	Haematology Clinical Trials Administrator	SDH			
Richard Thorpe	Patient Representative		√		
Deborah Turner	Consultant Haematologist	SDH			
Paula Underhill	Cancer Clinical Research Manager	RDE			√
Lisa Vickers	R&D Manager	PHT			
Gill Vivian	Consultant in Nuclear Medicine	PHT			
Saj Wajed	Consultant Upper GI & General Surgeon	RDE			
Sophie Warren	Trials Administrator	RDE			
Duncan Wheatley	Clinical Lead for Cancer Research	RCHT	√	√	√

### **Appendix 3B - Distribution of Annual Report**

The 2008/09 PCRN Annual Report was distributed via email to all members of the Research Steering Group, MDT and NSSG Research Leads. The Annual Report for 2009/10 will be made available on the PCRN pages of the PCN website for download when the 'new website' is launched shortly.

The 2009/10 report will be distributed to all highlighted groups via email once it is ratified by the Research Steering Group. The next meeting of the Research Steering Group is on Thursday the 24<sup>th</sup> of June 2010.

### **Appendix 3C – Review of meeting of Clinical Lead for Research and Network Lead Clinician**

The Clinical Lead of the PCN, Dr Simon Rule, and the Clinical Lead of the PCRN, Dr Duncan Wheatley discussed and confirmed the key objectives for the network in 2010/11 are as follows. They met in person on the 26<sup>th</sup> of November 2009 to confirm and further discuss these objectives.

#### **Objectives for PCN NCRN for year 2010-11**

1. Maintenance of comprehensive clinical trials portfolio and current recruitment levels into NIHR portfolio studies, however, reviewing funding of any clinical teams with minimal activity.
2. Work with individual site specific groups to establish which trials they wish to do and in particular prioritise trials that are widely supported but not open.
3. To identify whether the blocks to opening trials are largely administrative or due to service support capacity.
4. Review processes of trials set up in Trusts, to identify areas of good practice and where further improvements may be achieved.
5. To ensure research remains a commissioning priority within the service network by raising awareness of the benefits of research, e.g. savings to be made on pass through drug costs with local commissioners.
6. To arrange more local Trust meetings with interested Principal Investigators. To identify any specific local issues with regard to the setting up trials.
7. To simplify the trials reporting process to NSSGs and to rationalise attendance at these meetings.
8. Robust performance management of all posts and organisations to ensure that PCN NCRN delivers value
9. Lead work relating to supporting recruiting studies to time and target

Duncan Wheatley

Clinical lead PCRN NCRN

Agreed on behalf of PCN Network

Simon Rule

Medical Director

(Please note a signed copy of this document is available on request)

**Appendix 3D Collation of outcomes of NSSG and MDT Peer Review Research Measure**

To be included once information is provided by NCRN/CQuINS team.

**Appendix 4a – Table 1 Local Research Network Portfolio Forecast & Actual Recruitment 2009/10 (Please note accrual was not forecast in previous Annual Report, table is provided as an indication of trials which have performed better than in the previous year)**

<b>Work Programme Appendix 1: Table WP1: Full list of NIHR academic and commercial portfolio studies and forecast recruitment for 2009-10</b>					
<b>Study Acronym</b>	<b>Academic/ Commercial</b>	<b>RCT/ non- RCT</b>	<b>Network Recruitment 2008-9</b>	<b>Network Actual Recruitment 2009-10</b>	<b>Comments</b>
<b>All Clinical Studies Groups</b>					
PENILE TPF	Academic	non-RCT	0	2	
<b>Bladder Cancer Group</b>					
BOXIT	Academic	RCT	0	7	
<b>Brain Cancer Group</b>					
BR13	Academic	RCT	0	0	PHNT-Unable to open BR13, due to lack of Med Physicists. By the time staff were in place the study had closed to recruitment
NBT	Academic	non-RCT	0	1	
<b>Breast Cancer Group</b>					
ALTTO	Academic	RCT	3	3	
BBC Study	Academic	non-RCT	5	1	
BBC-NCRN cohort	Academic	non-RCT	127	109	NDHT-criteria has changed and more difficult to recruit to however-2009-10 – forecasted 30 patients, 315 recruited over whole recruitment period.
BEATRICE	Commercial	RCT	2	5	
EMBRACE	Academic	RCT	28	33	
FBCS	Academic	non-RCT	0	100	
GLACIER	Academic	non-RCT	17	38	NDHT-patient pool already exhausted and criteria has changed can screen retrospectively.Higher Recruitment in 09/10 in some trusts due to retrospective screening
IBIS-II DCIS	Academic	RCT	0	6	
IBIS-II Prevention	Academic	RCT	8	3	
ICICLE	Academic	non-RCT	4	205	NDHT-rare condition to recruit to (less than predicted due to cancer [pure DCIS] and potentials have to be under 60 years).RCHT-Higher Recruitment in 09/10 in some trusts due to retrospective screening

Study Acronym	Academic/ Commercial	RCT/ non- RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
IMPORT LOW	Academic	RCT	40	59	RCHT-Recruited well-enthusiastic clinical lead & team, SDHFT-due to close to recruitment in July 2010 - never recruited due to issues regarding visualising the surgical clips (for RT planning)
LATTE	Academic	non- RCT	0	16	
NCRN024 - INDUSTRY STUDY	Commercial	RCT	5	1	Due to close
NCRN089	Commercial	RCT	0	1	
PARP BRCA trial	Academic	non- RCT	0	2	NDH-Small numbers - happy to refer to PHT
Persephone	Academic	RCT	9	6	NDHT-PERSEPHONE – patients have been screened and approached, but are reluctant to consent since they would receive less treatment
POETIC	Academic	RCT	2	16	
PRIME II	Academic	RCT	14	15	NDHT-CLOSED PNHT-Exceeded expected accrual- 33 vs 10 overall
SoFEA	Academic	RCT	1	5	
SUPREMO	Academic	RCT	1	4	RDE-Delay in opening due to medical physics capacity.
TACT Trial Long Term QL (sub-study)	Academic	RCT	18	7	Presume eligible patients already considered-pool from closed studies
ZICE	Academic	RCT	17	18	
<b>Colorectal Cancer Group</b>					
CORGI	Academic	non- RCT	0	52	
CReST	Academic	RCT	0	3	RCHT-Team encouraged to continue identifying patients for randomising. Only successful stent trial running so enthusiastic about increasing numbers recruited.
FACS	Academic	RCT	19	1	Trial Closed
FOxTROT	Academic	RCT	2	2	RCHT-Low numbers recruited initially, difficulty finding potential patients due to radiological criteria and logistics of starting chemo/delaying surgery to keep in with cancer targets.. Radiological criteria looks to be relaxing which should lead to a rise in recruitment

Study Acronym	Academic/ Commercial	RCT/ non- RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
NSCCG	Academic	non- RCT	56	102	SDHFT-This 'dropped off the radar' over the past months but it is anticipated recruitment will now pick-up
Public perceptions of bowel cancer screening (Sep-09)	Academic	non- RCT	0	27	
PICCOLO	Academic	RCT	1	21	RCHT-Almost completed. Std arm is not optimal treatment. SDHFT-Registration line closed 2nd June - due to close completely at the end of August 2010. Only 1 more potential patient to be entered.
QUASAR 2	Academic	RCT	7	4	NDHT-looking to close study as shorter treatment available in SCOT trial-patients not keen, SDHFT-XELOX now standard treatment for this group of patients. Control arm of trial is Cap alone. Clinicians will only therefore approach patients who may not tolerate Oxaliplatin
SCOT	Academic	RCT	15	26	RCHT-36 patients randomised (2nd in UK), SDHFT-Lower recruitment than expected - due to a combination of tighter eligibility criteria than originally thought and also, due to nature of the study, patients not keen on receiving shorter/less treatment.
<b>Complimentary Therapies Group</b>					
Acupressure CINV	Academic	RCT	0	55	
DietCompLyf	Academic	non- RCT	88	61	NDHT-115 patients recruited over whole recruitment period. Forecast was approx 20 at set up. Patients interested in their own lifestyle and contributing to research for best practice-CLOSED to recruitment in end of May 2010, still in FU
<b>Gynaecological Cancer Group</b>					
CHORUS Main trial	Academic	RCT	0	5	Due to close end 2010 -concerns due to poor recruitment to feasibility study
DNA Methylation Study	Academic	non- RCT	3	13	
ICON 6	Academic	RCT	0	0	Not open yet-difficult to predict
NEO-ESCAPE	Academic	RCT	0	2	
NSECG	Academic	non- RCT	0	42	NDHT-20 letters sent, 16 agreed - could potentially be a good recruiter

Study Acronym	Academic/ Commercial	RCT/ non- RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
PORTEC-3	Academic	RCT	0	0	RDE-Delay in opening due to medical physics capacity.
UKFOCCS	Academic	non- RCT	3	50	
<b>Haematological Cancer Group</b>					
ADMIRE	Academic	RCT	0	5	SDHFT0 In set-up – but small no patients eligible
AML 16	Academic	RCT	19	27	
AML 17	Academic	RCT	0	21	
EBV associated NK/T cell malignancies	Academic	non- RCT	0	4	
FCLL	Academic	non- RCT	3	4	
MDSBio1	Academic	non- RCT	27	27	NDHT-there was a degree of confusion between consultants and protocol as to the patient pool. Problem was sorted and recruitment started in March 2010.
Myeloma X Relapse (Intensive)	Academic	RCT	4	4	
NCRN042	Commercial	RCT	0	1	
NCRN043	Commercial	RCT	0	2	Rde-No eligible patients
SPIRIT 2	Academic	RCT	0	8	
TOPPS	Academic	RCT	28	19	RDE-Exceeded expectation ie 32 vs 10 overall
<b>Head &amp; Neck Cancer Group</b>					
Determination of Quality of Life Instrument	Academic	RCT	0	32	
HiLo	Academic	RCT	3	3	
HOPON	Academic	RCT	0	2	
PET-NECK study	Academic	RCT	0	8	
TCUK IN	Academic	non- RCT	0	20	
<b>Lung Cancer Group</b>					
BTOG2	Academic	RCT	6	3	Trial closed
CONVERT	Academic	RCT	0	0	RDE-Delay in opening due to medical physics capacity.
ET Trial	Academic	RCT	0	4	
FRAGMATIC	Academic	RCT	12	24	SDHFT-Patient's not keen - mainly due to problems with self-injecting - needle phobia quite common.
LungStar	Academic	non- RCT	5	9	NDHT-: not many small cell patients plus potential recruits have had previous statin treatment

Study Acronym	Academic/ Commercial	RCT/ non- RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
MALCS (Mesothelioma and Lung Cancer Study)	Academic	non-RCT	12	27	
QUARTZ	Academic	RCT	0	0	SDHFT-Difficult study to recruit to - eligible patients are few and far between and when a eligible patients are identified they are not keen on entering the study.
TACTIC	Academic	RCT	0	1	SDHFT-25/05/10 - Temporary suspension of recruitment until further notice - during interim analysis
<b>Lymphoma Group</b>					
18-30	Academic	non-RCT	0	1	
AITL	Academic	non-RCT	1	1	
Bortezomib Study	Academic	RCT	3	2	
Mantle Cell P3	Academic	RCT	0	8	
PACIFICO	Academic	RCT	0	1	
RAPID (formerly PET Trial in Hodgkin's Disease)	Academic	RCT	3	7	NDHT-CLOSING soon, also rare disease, approx 4-5 diagnosed a year and would need to meet criteria
RATHL	Academic	RCT	2	14	
R-CODOX-M/IVAC	Academic	non-RCT	0	2	
RGCVP	Academic	non-RCT	1	2	
Waldenstrom's study	Academic	RCT	2	6	
Watch and Wait	Academic	RCT	0	1	
<b>Melanoma Group</b>					
AVAST-M	Academic	RCT	7	5	Long delays in opening at Peninsula sites outside local control
The Melanoma Lifestyle Study	Academic	non-RCT	1	1	
<b>Palliative Care Group</b>					
<b>Primary Care Development Group</b>					
Clinical Features Of Metastatic Cancer	Academic		43	203	
<b>Prostate Cancer Group</b>					
CHHIP	Academic	RCT	0	2	
Matched pair QoL/Toxicity Study in Advanced Prostate Cancer	Academic	non-RCT	42	37	
NCRN018 - INDUSTRY STUDY	Commercial	RCT	4	2	

Study Acronym	Academic/ Commercial	RCT/ non- RCT	Network Recruitment 2008-9	Network Actual Recruitment 2009-10	Comments
ProSTART	Academic	RCT	0	1	Was open in PHNT & SDHFT but problems recruiting-Closed nationally
RADICALS (MRC PR10)	Academic	RCT	2	10	NDHT-recruited 1 patient. Eligibility criteria has recently been reviewed and changed to make recruitment more straight forward and hopefully easier to recruit to.
Stampede	Academic	RCT	29	29	
UK Genetic Prostate Cancer Study	Academic	non-RCT	34	42	
<b>Renal Cancer Group</b>					
SORCE	Academic	RCT	5	12	
TRANSORCE (sub-study of SORCE)	Academic	non-RCT	6	15	
<b>Sarcoma Group</b>					
VORTEX	Academic	RCT	0	2	
<b>Testis Cancer Group</b>					
TE23	Academic	RCT	0	0	RDE-Trial on hold-? Previous safety issues
The UK Genetics of Testicular Cancer Study	Academic	non-RCT	35	4	
<b>Upper GI Cancer Group</b>					
BEST- BARRETT'S	Academic	non-RCT	23	23	
BILCAP	Academic	RCT	4	2	
BOSS	Academic	RCT	0	28	
ChOPIN	Academic	non-RCT	0	33	
COG	Academic	RCT	0	2	
ESPAC -Tplus	Academic	non-RCT	0	18	NDHT-no further patients to recruit
ESPAC-4	Academic	RCT	0	3	
OE05	Academic	RCT	3	4	Clinicians prefer ECX as standard treatment now
SOCS	Academic	non-RCT	16	41	
ST03	Academic	RCT	2	2	
TeloVac	Academic	RCT	10	17	
<b>TOTAL</b>			<b>892</b>	<b>1,967</b>	

## Appendix 4b - LRN NIHR-adopted commercial portfolio, agreed targets and performance 2009-10

Table 2: LRN NIHR-adopted commercial portfolio, agreed targets and performance 2009-10

Clinical Studies Group	NCRN Ref No.		Agreed mCTA target (Number by date)	Actual Number of patients recruited to date	Comments
Breast	ALTTO	RDEFT	9 Patients by 30/09/2011	2	Open-National accrual = 59% to Target
Breast	ALTTO	PHNT	9 Patients by 30/09/2011	4	Open-National accrual = 59% to Target
Breast	BEATRICE	RCHT	8 Patients by 02/11/2009	4	Closed/In Follow Up-National accrual = 68% to Target
Breast	BEATRICE	RDEFT	8 Patients by 02/11/2009	3	Closed/In Follow Up-National accrual = 68% to Target
Breast	NCRN010 (AVEREL)	RDEFT	2 Patients by 05/01/2010	2	Closed/In Follow Up-National accrual = 102% to Target
Breast	NCRN089	RCHT	2 Patients by 30/04/2011	1	Open-National accrual = 26.7 % to Target
Breast	NCRN098 - BOLERO II	RCHT	4 patients by 31/12/2010	0	Open-National accrual = 0 % to Target
Breast	NCRN103 - BOLERO I	RCHT	5 Patients by 30/11/2011	0	Open-National accrual = 0 % to Target
Gynaecological	NCRN138	RCHT	20 Patients by 01/06/2011	0	Open-National accrual = 0 % to Target
Prostate	NCRN018 - INDUSTRY STUDY	RDEFT	10 Patients by 28/02/2010	6	Closed/In Follow Up-National accrual = 114.4% to Target
Breast	NCRN024 - INDUSTRY STUDY	RCHT	5 Patients by 30/09/2010	6	Open-National accrual = 85.5% to Target
Haematological	NCRN042	RCHT	2 Patients by 31/08/2011	1	Open-National accrual = 25.0 % to Target
Haematological	NCRN043	RCHT	4 Patients by 28/02/2011	1	Open-National accrual = 16.3 % to Target
Haematological	NCRN043	RDEFT	4 Patients by 28/02/2011	0	Open-National accrual = 16.3 % to Target
Haematological	NCRN043	PHNT	4 Patients by 28/02/2011	1	Open-National accrual = 16.3 % to Target
Green if the study is recruiting to at least 80% target (proportionate to time elapsed)					
Amber if the study is recruiting to 66-79% of target (proportionate to time elapsed)					
Red if the study is recruiting to less than 65% target (proportionate to time elapsed)					

**Appendix 4C, Table 3: Recruitment by Trust for 2008/09 and 2009/10**

Study/Recruit type	RCT/non-RCT	NDHT		PHNT		RCHT		RDEFT		SDHFT		GP's		PCGS	
		2008/09	2009/10	2008/09	2009/10	2008/09	2009/10	2008/09	2009/10	2008/09	2009/10	2008/09	2009/10	2008/09	2009/10
Cancer	RCT	10	19	56	135	134	184	111	135	79	104	0	0	0	0
	non-RCT	118	106	35	118	62	165	202	298	75	51	28	95	0	22
Pre-Malignant	RCT	0	0	3	3	6	3	0	3	0	0	0	0	0	0
	non-RCT	6	2	0	0	0	203	0	1	0	0	0	0	0	0
Commercial	RCT	0	0	3	2	5	8	6	5	0	0	0	0	0	0
	non-RCT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Bolt-on	RCT	0	0	0	5	0	0	0	0	0	2	0	0	0	0
	non-RCT	0	2	2	18	0	0	0	0	4	5	0	0	0	0
SEARCH	non-RCT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Non-cancer	RCT	0	0	21	0	11	0	2	0	18	0	0	27	0	0
	non-RCT	1	2	2	32	0	14	18	64	0	1	43	133	0	0
<b>TOTAL</b>		<b>135</b>	<b>131</b>	<b>122</b>	<b>313</b>	<b>218</b>	<b>577</b>	<b>339</b>	<b>506</b>	<b>176</b>	<b>163</b>	<b>71</b>	<b>255</b>	<b>0</b>	<b>22</b>