

PENINSULA CANCER RESEARCH NETWORK

PROGRESS REPORT

1 APRIL 2003 – 31 MARCH 2004



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Executive Summary

Achievements during the Year

- 15 staff in post (12.3 Wte) supported by PCRN funding.
- 18.7 % of incident patients entered into a trial during 2003-2004
- Overall accrual into NCRN portfolio studies increased 237% from baseline year of 2001-2002
- Year on year increased accrual to trials across 14 of 16 Cancer Site Specific Groups.
- 2nd best Network Nationally in overall recruitment (as % of incident cancer patients)
- Royal Cornwall Hospital increased growth in Research Infrastructure supporting an expanding trials portfolio.
- Royal Devon and Exeter attaining greatest overall numbers.
- Torbay supports a broad trials portfolio with increased support to haematological cancer trials.
- Barnstaple significant accrual to colorectal and lung trials.
- Plymouth increased support to lung, prostate and paediatric cancer research.
- 4th Cancer Research Symposia planned for 23/04/04 attracting year on year a wider and larger audience of Cancer Research Staff, Consumers and Gp's.
- 150 Peninsula Research staff trained in ICH/GCP on accredited
- A rolling training programme on Informed Consent To Clinical Trials and Communications training being delivered across all trusts,

Future Plans

- We appreciate that we have achieved well above the National 10% target for accrual and need to ensure that our expanded trials activity can be sustained.
- We should explore increasing trial activity to the less common malignancies.
- We need to audit the potential impact of future trial follow up on our Research workforce and ensure we are supporting a balanced trials portfolio.
- The Research Governance Agenda and EU directive require our continued support across the Peninsula to ensure that robust quality assurance can be achieved.
- Much remains to be done but we look forward to maintaining the Peninsula as a proven, successful, collaborative Network within the NCRN.

1. Organisation and Development of Network

1.1 NCRN appointments

All NCRN appointments, including indicative total annual costs for each post (salary plus oncosts) for 2003/4 are shown in Appendix 1a.

1.2 Staff in post

A list of all current employees within the Peninsula Cancer Research Network is provided in Appendix 1b. This only includes staff currently employed by the NCRN.

1.3 Overview of network staffing profile

At the time of compiling this report this Research Network employs 5.0 WTE Research Nurses who constitute the largest professional group within the workforce. Medical staffing funded by the PCRN amounts to 0.8 WTE which includes sessions provided by the Clinical Lead for Research (Dr. Nigel Bailey), Dr. Anne Hong (Clinical Oncologist based in Exeter) and Dr. Phillipa Bradbury an Oncology Research Fellow in Derriford Hospital.

The Peninsula Cancer Research Network also employs 2.0 WTE in administration, a Research Radiographer (Linda Welsh) at the Royal Devon and Exeter Hospital. Dr. Darren Beech and Mrs. Sophie Mephram remain in post as Research and Development Team Leader and Cancer Research and Development Facilitator at the Royal Cornwall Hospital in Truro. These two members of staff have a biological sciences background. Our staffing compliment supported by NCRN funding amounts to approximately 12.3 WTE.

All 5 hospitals within our network have access to NCRN research infrastructure support. Funding has been allocated largely reflecting catchment population of the hospitals and in reference to proposals Each Trust was asked via the Cancer Service Manager to bid for monies according to their projections. It was made clear that any funding would be performance managed according to trial accrual figures.

As the Research Network has matured since its inception in October, 2001 there has been development within staff roles. Support to Haematology trials across the Peninsula prior to the establishment of the NCRN was minimal and support largely provided by the goodwill of Cancer Nurse Specialists. Support for these complex trials is now provided in all 5 trusts .In Exeter this support is provided through the R & D Funding mechanism.

It is recognised that the success of the Peninsula Cancer Research Network has been due to the motivation and hard work of staff both directly employed on NCRN funding and those within the existing workforce who have embraced the goals and aspirations of the NCRN.

In respect of staff directly employed on NCRN funds, Dr. Darren Beech (Research and Development Team Leader) in Truro and Mrs. Sheila Bullard (Clinical Trials and MDT Liason Officer) in Plymouth have wider responsibilities working at a Clinical Trials Manager level and are responsible for leading, identifying and supporting clinicians within the core multidisciplinary teams to adopt relevant clinical trials and

facilitate recruitment into non-commercial trials and have proved very effective in these roles.

As an outcome of the annual review for 2002-2003 it was recognised that there was further potential to increase accrual by the provision of additional Research Nurse cover for the Royal Cornwall Hospital and additional administrative support for Torbay and the Royal Devon and Exeter. Additional fixed term funding for a period of 2 years was agreed by the co-ordinating centre.

An additional post for a fixed term 1.0 Wte G Grade Research Nurse has been advertised from the Royal Cornwall Hospital. This post has been appointed and is due to commence on 01/06/2004. The start date was delayed due to the seniority of the appointee and notice required from the previous post.

Originally a 0.5 Wte F Grade Haematology Research Nurse post was proposed for Torbay Hospital. It proved difficult to appoint to this post and it was revised to provide for a Haematology Data Manager 1.0 Wte A & C 4 Grade. There were major delays in appointing to this post due to funding issues within the trust, however candidates for this post has now been interviewed with the appointee due to take up post on 10/05/2004.

Due to an increase in activity suppressed during 2003-2004 and to ensure trials can be run under EU Directive regulations we have received proposals for a further 1.0 Wte F Grade Oncology Research Nurse and administrative support 0.5 Wte A & C 4. These posts would be supported initially by underspend from 2003-2004. It is proposed that the allocation to radiology as agreed in earlier funding bids be reduced but it is noted that as a relatively smaller trust with a large Cancer Trials Portfolio there are service pressures and that additional support may be required to support the pharmacy service with increased trials activity and the increased requirements to meet the EU Directive.

The Royal Devon and Exeter have contributed greatly to our increased accrual figures and have a broad trials portfolio and a significant incrementally increasing workload with follow up of patients entered into trials over previous years. It was proposed that additional administrative support would be required to maintain an increase in accrual. Angie Hope has been appointed as administrative assistant in January, 2003 and her hours have since increased. It has been proposed that this post be upgraded to a Clinical Trials Officer post with effect from 07/06/2004.

We have experienced some turnover of staff during 2003-2004 with 3 staff leaving the Research Network. Two members of staff having left due to family commitments one from North Devon Hospital and one from Royal Devon and Exeter Hospital. These posts have been reappointed. It was clear from termination interviews that family commitments were the cause for leaving. However, the impact of this particularly for North Devon Hospital is noted in respect of the small staffing establishment. We are pleased that the vacancies created have been filled.

Dr. Edwina Scott Oncology Research Fellow from Plymouth has also left the team but this post has been reappointed with Dr. Philippa Bradbury taking over providing continuity for this post. We appreciate that the nature of this post is such that we would expect reasonable turnover due to career development of postholder but that this should not be detrimental to the aims of the post.

Staff accommodation was initially a problem in four of our trusts however, this still remains a problem for North Devon Hospital with 4 staff sharing a small office. In the

short term accommodation has also been a problem in the Royal Cornwall Hospital with the Research Staff sharing limited office space within the Cancer Services Department however, we understand that larger office space will be available later this year within the newly built Oncology Centre.

1.4 Training and development

1.4.1 Induction

Line management of all staff employed within the Peninsula Cancer Research Network is devolved to line managers within the individual trusts. In general this is a shared process with day to day accountability to the local Clinical Trials Manager, but with professional accountability to a senior manager for nurses to the Lead Cancer Nurse and for non- nursing staff through the R & D Managers or Cancer Service Managers.

Staff appraisal systems already exist within all 5 trusts. Therefore, initially it was difficult to implement the NCRN Training and Education SOP fully, given that managers already have trust verified systems in place.

However, the NCRN training and education SOP has been explained fully to all line managers and copies given to all managers at site visits. All managers have been introduced to the relevant documentation and the copies of the proposed NCRN Induction Programme have been made available to all managers and new staff.

The Research Network Manager has proposed that NCRN training needs assessment form should be used as the basis for assessing the learning needs and skills of the individual staff members and as a template to inform any local appraisal system.

1.4.2 Training and education SOP

The role of Network Training Link has informally been shared between the Research Network Manager and Mrs. Claire Ridler (Cancer Trials Manager) at the Royal Devon and Exeter Hospital. Mrs. Ridler has a line management role for staff at the Royal Devon and Exeter Hospital and also provides support for Research staff at North Devon Hospital in Barnstaple. The Peninsula Cancer Research Network has agreed to support her in respect of her time to facilitate this role. She is also kindly facilitating the Communication Training Programme which is being rolled out across Networks having attended the training course in Brighton earlier this year.

Ideally all new staff are seen by the Research Network Manager or assistant training link within 3-6 week after appointment and the rationale for the NCRN training SOP discussed. All staff are provided with a staff training record and encouraged to keep it up to date. All staff both NCRN funded and non-NCRN funded staff working on trials within the NCRN trials portfolio are made aware of the training available and encourage to attend appropriate study days as agreed by their local line managers.

All line managers are kept up to date by e-mail of future training and education courses and of availability on these courses. All course bookings are arranged by the Peninsula Cancer Research Network Manager's secretary and where possible travel expenses are reimbursed or travel arranged directly through the Peninsula Cancer Network offices.

The provision of accessible education and training courses was recognised as a priority for the Research Network 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. We appreciate the commitment of our staff in attending the excellent training courses which have been provided and of their managers in releasing them from their clinical trials workload.

During years 1 and 2 the Research Network had prioritised regular site visits and probably achieved visits to new staff approximately 4 monthly and time with established staff at least twice a year in line with the NCRN training and education SOP. This was felt to be beneficial in respect of supporting new staff, increasing motivation and in helping to foster a team spirit and in developing local trials portfolio's. However, this has been increasingly more difficult to achieve given the development of links with Cancer site specific groups, and other National and regional meetings which place increasing demands on the Research Network Managers time.

Fortunately, many staff remain in post and have gained in experience but we are still aware of the need to support new staff as they come into post. We need to explore developing more robust peer support systems and to ensure that adequate local induction programmes are in place.

Copies of the NCRN suggested induction programme and training needs assessment forms are included in the appendices.

1.4.3 Local training

The frequency of local training provision has so far not been formalised recognising the geographical barriers within the Peninsula. The core research workforce is still relatively small and the cost of holding a regular timetabled induction programme would be prohibitive.

However, to maximise attendance we have held 3 annual Research Symposia at Plymouth, Exeter and Newquay. A fourth symposium is planned for Saunton Sands in North Devon on 23/04/2004.

Attendance has increased year on year with over 60 attendees in Newquay on 4th April, 2003 and an expected 130 attendees for the planned symposium at Saunton Sands in North Devon on 23/04/2004. The aim of the annual symposia is to update all local staff on Peninsula trial activity, to provide an opportunity for local investigators to present local Cancer Research Trials and an opportunity to invite national speakers.

The symposia have proved to be a growing success and attracting a wider audience and an opportunity to promote our work with the wider research community and to other important stakeholders such as consumers, general practitioners and Cancer Support Groups. PGME approval has been sought for the forthcoming symposium.

ICH/GCP and EU Directive Training

The potential impact of the EU Directive 2001/20/EC on GCP in Clinical Trials, which will make GCP a legal requirement for both industry-sponsored and publicly funded studies alike was recognised as a particular priority for local training for 2003-2004.

Although the core Research Staff particularly Research Nurses and Clinical Trials Managers have accessed national NCRN courses it was felt important to maximise attendance by Investigators, Clinicians and other research active staff within the Peninsula.

Two ICH/GCP Training courses were held on 1st December, 2003 in Truro and 2nd December, 2003 in Plymouth these courses were held in association with the local R and D managers and were directed to local research staff and Cancer Nurse Specialists similar to 2 previous courses. A further course funded by the NCRN Co-ordinating centre was held at a local venue in Exeter on 11th March, 2004. Clinicians were encouraged by the clinical lead for research to attend the later session.

Overall 60 staff attended local (one day) ICH/GCP training courses within the Peninsula during 2003-2004. A further 2 courses are planned for 2004-2005 on 1st April, 2004 in Plymouth and 27th April, 2004 in Truro we are expecting a further 62 staff to attend. All courses have been delivered by trainers accredited by the NCRN and all attendees have received certificates of attendance. On completion of these 2 further courses planned for 2004 a total of 150 staff will have received accredited ICH/GCP training with some staff having attended both introductory level and advanced courses.

Outlines of the courses delivered are included in the appendices.

1.4.3 Attendance on NCRN and local training courses

The table in Appendix 2 of this document shows which of our Network staff have attended both NCRN training courses in the past 12 months and also includes local training attended by NCRN staff in the period 1 April 2003 to 31 March 2004. The professional group / job title of each member of staff is shown where known.

The Research Network Manager has maintained a record of attendance of staff attending all courses held within the Peninsula since the inception of the Research Network.

1.4.5 Other network training and development initiatives

The provision of local ICH/GCP training has had an impact on other training initiatives during 2003-2004 and as a result only one further formal training event was held on 12th December, 2003 titled "Are we prepared to be legal". The emphasis of this day was to inform research staff of the requirement of an MHRA inspection and looking at quality control issues in research. A programme for this study day is attached in the appendices. 14 staff attended this event.

Informed Consent To Clinical Trials- A Workshop For Health Care Professionals-Communications Training

Mrs. Claire Ridler attended the training course in respect of the above training course and a programme of small group one day training sessions is being developed to deliver this training. The first session was held in Exeter on 24th February, 2004 with 2 further dates of 8th March, 2004 in Torbay and 11th May, 2004 in Plymouth planned. Due to the sensitive nature of the training material it is expected that attendance will be no more than 8-10 staff at each study day.

We would plan to hold to 2 further study days in Truro and Barnstaple to ensure coverage of all 5 trusts and then to evaluate the potential to roll this programme out to a wider professional audience.

Other Training and Education Initiatives

The success of our annual research symposia has been discussed in the previous section. However, we appreciate that the size and geography place limitations on arranging local training events. A series of meetings have been held with Research Network Managers of neighbouring networks which have included Avon, Somerset and Wiltshire, Three Counties, Dorset and Central South Coast to explore the possibility of combined meetings.

It is hoped that future initiatives may involve collaboration with research colleagues in our neighbouring networks which may enable us to provide a wider range of local training.

During 2003-2004, 5 staff from the Peninsula attended the BODMA/ NCRN Conference held in Nottingham on the 8th and 9th of September, 2003. 3 staff were supported to attend an advanced EU Directive training courses held by SCOPE in Bristol on 18th September, 2003.

Staff routinely attend NCRI National Study Days and National Trials Meetings, however feedback to colleagues within the network is limited and future plans are in place to improve this feedback to colleagues and relevant Cancer Site Specific Staff.

1.5 Structures and integration

• Representation Of PCRN within the Cancer Network management structures

The PCRN is part of the Peninsula Cancer Network (PCN) which serves Devon, Cornwall and the Isles of Scilly. The Network includes the 5 acute trusts, 13 primary care organisations and 5 hospices and serves a population of 1,599,665 (OPCS 1999). The PCN is led by an Executive Board which reports to the Strategic Health Authority. The Network Cancer Management Team is led by Mr Martin Cooper (Clinical Director) and by Sara Aspley (Director) to whom we report directly. Each Trust has a Cancer Services Lead and Cancer Services Manager who also report to the Management Team. Across the Peninsula there are 12 Cancer Site Specific Groups and 13 Generic Groups which includes an R & D group.

The 5 acute trusts are widely separated and the area covered includes large areas of sparse population together with major inner city conurbations. Whilst there are few ethnic minority groups in the Peninsula the population includes people from some of the most affluent groups in England as well as some of the most deprived in inner city Plymouth and Cornwall. Because of the wide geographical separation between

Trusts within the PCRN it was agreed at its inception that responsibility for managing PCRN funds be delegated to the Cancer Service Managers at each Trust.

Clinical research is recognised by the Peninsula Cancer Network as an important component of standard care. All cancer service managers are part of the Peninsula R & D group which meets quarterly at Lifton. This group is chaired by the PCRN Clinical Lead for Cancer Research and includes primary care, palliative care and patient representatives. Site specific groups are linked to this group by a named liaison member.

- **How our research network staff work together**

One of the greatest strengths of the PCRN has been its integration within the structures of the Cancer Service Network. The Cancer Service Managers within the individual trust have been actively involved in the financial planning underpinning the support of the research staff within their trusts and have a clear understanding of the aims and objectives of the NCRN.

Communication of the activities and progress of the PCRN and National objectives are disseminated through the Cancer Network Research and development group and its membership which includes Cancer Service Managers, Trials Managers, R & D Managers, Consumers and link staff with individual site specific groups.

Attendance at Site Specific Group meetings is a vital element to our communications regarding NCRN Cancer Trials but this is discussed in more detail later in this section.

The Research Network Manager communicates regularly with the individual trial managers within the trusts and all relevant new Research information, NCRN Newsletters, Training and Education events are forwarded as appropriate. Regular telephone contact is maintained between site visits.

The Research Network Manager is based within the Cancer Network Offices and has direct contact with Senior Managers within the Cancer Service Network and therefore good two way communications exist.

It was planned to invest in developing part of the existing Peninsula Cancer Network website to communicate more effectively with the Site Specific Groups and Research staff and to make Peninsula Specific data more easily available to stakeholders. The Research Manager met with Mr. David Ives (Dartington, Web Site Designer) and Mr. Richard Harpin from the NCRN Co-ordinating centre on 8th August, 2003 to formulate plans. This meeting was successful, however other work commitments of the Research Network Manager have prevented progress on this. It is hoped that this project can be completed within the forthcoming year.

- **How the PCRN is working with other research networks, both nationally and regionally**

The Research Network Manager has arranged meeting with colleagues from neighbouring Cancer Research Networks to explore areas where there is a potential for collaboration and sharing of expertise and resource. The membership of this group has included the Research Network Managers from the Peninsula, Avon, Somerset and Wiltshire, Three Counties, Dorset and Central South Coast. Staff from the South West Cancer Intelligence Service based in Bristol were also invited to these meetings. This group met on 5th June, 28th July and 28th November, 2003.

The meetings were informal by design but did explore variations in trials portfolio's and differences in management structures within networks. Common issues such as the impact of recruitment to trials in networks with a higher proportion of elderly residents were discussed. Whilst the UK proportion of individuals over 75 years of age is 7.4% in Devon and Cornwall this figure approaches 10%. This is reflected in 41% of incident cancer patients being over 75. The possibility of auditing entry into trials by age cohort was discussed as a future collaborative project.

After establishing these meeting there was a change of Research Network Manager in both Avon, Somerset and Wiltshire and Three Counties Research Networks. We have now agreed to meet as a larger group including other networks within Southern England and have met in London on 16th February, 2004.

The Peninsula Research Network Manager is working closely with Erica Denholm Research Network Manager for Avon, Somerset and Wiltshire. In particular we have been collaborating in respect of local education and training events with a view to developing wider links between research staff working on similar projects. We hope that over time this will encourage greater peer support for staff. Staff from the Peninsula attended the 2nd Research Teaching day in Taunton on 5th June, 2003 and reciprocal visits were made to the study day held on 12th December, 2003 in Okehampton.

- **How the research network is represented in Multidisciplinary Teams**

Outside of the Site Specific Groups and within the Multidisciplinary Teams within the individual trusts there is some variability in how the Research Network is presented, in most cases a member of the NCRN Research team is present, however, in some cases where there are highly research active clinicians there is direct referral of suitable volunteers to the research teams.

In Plymouth, Sheila Bullard attends the Breast, Lung, Gynaecology and Urology MDT's on a weekly basis. She also provides regular newsletters with information on all currently open trials which are updated when there are protocol amendments. A4 handouts are also provided for new studies for staff at MDT Meetings. She has also been involved in supporting the paediatrician within the trust with ensuring current protocols are available for trials which are co-ordinated from Bristol.

In North Devon Hospital the Research Nurses attend all local MDT Meetings with the exception of urology.

The Research Nurses and support team do not attend the MDT Meetings at the Royal Devon and Exeter, but they are well supported by Local Investigators and Clinicians and volunteers are referred to them. All the clinics are screened for possible trial patients, and there is a regular Research Team Meeting which involves the respective investigators. As shown by trial accrual this system obviously works well. The Haematology Research Nurse do however attend the weekly MDT meeting and histology and bone marrow meetings.

In Torbay the Research Nurses and Research Radiographer attend most of the MDT meetings. Katrina Greenfield covering Lung ,Colorectal and upper GI meetings, Ingrid Koehler attending the Breast and Gynaecology MDT's and Christine Rawlings attends the Urology MDT meeting.

At the Royal Cornwall Hospital Sophie Mepham attends MDT meetings for Haematology and Paediatric Oncology, with Darren Beech attending the Breast and Urology Meetings. Suitable patients for Colorectal and Upper GI trials are referred directly by Dr. Richard Ellis (Clinical Oncologist). All lung clinics are screened by the research staff.

- **How our research network is represented in Site Specific Groups**

The Research Network Manager regularly attends site specific group meetings to update them on trials specific to their group, accrual data and other relevant research updates, local training etc. A list of trials is agreed for the individual groups which is signed off by the Clinical Lead for Research, Research Network Manager and Chair of the Group. The site specific groups feedback to their trusts MDT's through the Clinical Leads for each trust.

To reduce the dependence on the Research Network Manager to attend these numerous meetings we are working with experience members of the Research team to report to individual site specific groups particularly where they have a site specific interest or experience. Relevant data and updates will be made available through the Research Network Manager for the group and the link person will report to the Research Network Manager. So far Sheila Bullard has offered to support the Breast and Lung Site specific groups, Christine Rawlings supports the Urological Cancer Group, and Sophie Mepham has agreed to support and liase with the Paediatric Oncology and Haematological Cancer Groups. It is planned that the link person will liase with the appropriate clinical leads and Research Staff within the individual trusts and the Research manager to follow up any actions arising from the meetings.

- **How primary care and palliative care are represented and involved in the research network.**

At the current time Primary Care and palliative care are not well represented in the research network. A member of the primary care and palliative care group does regularly attend our Cancer Network Research and Development Group meeting and is therefore able to report back to the respective groups. All general practitioners within the region have been invited to attend our forthcoming Research Symposium.

In formulating the bid for the use of funding for the Cancer Research Network key objectives were in developing infrastructure to increase accrual to Cancer Clinical trials and few trials were available for the palliative care and Primary care settings. However, within our local trials portfolio hospices within the Peninsula have been participating in a study looking at antifungal drug resistance which has been conducted by Dr. Andrew Leonard in collaboration with the Avon, Somerset and Wilts Cancer Research Network.

In the primary care setting there has been some activity with the BBC Study.

We appreciate that supporting trials in these setting is at present difficult in respect of the allocation of Research infrastructure and with current staff contracted to work within individual trusts.

Please highlight any changes/developments to the management structures described in the 2002/3 report.

There are no significant changes to the management structure described in the 2003/4 report.

The Network Site Specific Groups and generic groups which include the Research and Development Group report to the Cancer Network Executive Board via the Network Strategy Group annually for endorsement of Network referral and clinical guidelines, risk assessment and progress against meeting national targets and areas for service development. This process informs the development of Network strategy and in consequence both local and Network commissioning of cancer services.

The Network Strategy Board is chaired by the Chief Executive of the host Health PCT (Torbay) and meets quarterly. The Network Executive Board oversees and supports the Network Strategy Group in the development of strategy and implementation of the Network objectives. The Peninsula Cancer Research Network Clinical Lead is a member of the Network Strategy Board.

The Strategic Health Authority remains responsible for performance managing the Cancer Network and its constituent organisations in its implementation of the NHS Cancer Plan.

2. Accrual

Accrual data has been provided for the full 2003/4 year and has been obtained from the NCRN website.

2.1 Overall accrual into NCRN Portfolio studies

Overall accrual into NCRN Portfolio studies for the periods 1 April 2001 to 31 March 2002 (Year 1), 1 April 2002 to 31 March 2003 (Year 2), and 1 April 2003 to 31 March 2004 (Year 3) are shown graphically for each hospital in our network and for the network overall. (See Pg.)

Overall there has been a significant rise in accrual across the Network in four of the 5 trusts with overall accrual having increased by 237% from the baseline year of 2001-2002. This is a fantastic achievement considering the increase of 115% already achieved during 2002-2003. This has been achieved as a result of increased activity across the common cancer sites, expanded trials portfolio's across all trusts and the increase in infrastructure to support this activity. Torbay has not seen an increase in accrual during 2003-2004 but accrual has remained stable. However, a planned increase in infrastructure in respect of an additional Research Nurse and administrative support was not achieved due to recruitment and trust restrictions on staff appointments which has restricted growth in accrual. We hope this will be resolved in 2004-2005.

2.2 Accrual by cancer site into NCRN Portfolio studies

Overall accrual into NCRN Portfolio studies for the Network for the periods 1 April 2001 to 31 March 2002 (Year 1), 1 April 2002 to 31 March 2003 (Year 2) and 1 April 2003 to 31 March 2004 (Year 3) are shown graphically for each cancer site. (See Pg)

We have specifically concentrated on the common cancer sites namely Lung, Breast, Colorectal and Prostate. However, we have achieved a year on year increase in accrual in 14 of the 16 Cancer Sites. Our lowest recruitment being in Head and Neck Cancers, Melanoma and Sarcoma, and we will explore the feasibility of increasing activity in these rarer Cancer in the forthcoming year. We believe this is an excellent result and all staff involved should be recognised for this achievement.

2.3 Monthly accrual into NCRN Portfolio studies for Network

Total monthly accrual into NCRN Portfolio studies for the period 1 April 2002 to 31 March 2004 (Years 2 & 3) are shown graphically for the network. (See Pg)

Looking at the graph there is some fluctuation in the monthly accrual figures however when averaged over the individual years it is noted that average monthly accrual for 2001-2002 was 27 patients/ month, during 2002-2003 an average of 60 patients/ month with a further increase to an average to 93 patients/ month during 2003-2004. Therefore, the monthly accrual rate has tripled since inception. We appreciate the significance of this increase and appreciate that this must have a knock on effect in terms of workload for trial staff, increasing levels of follow up of patients and increased demand on services supporting these trials.

2.4 Monthly accrual into NCRN Portfolio studies by Hospital

Total monthly accrual into NCRN Portfolio studies for the period 1 April 2002 to 31 March 2004 (Years 2 and 3) are shown graphically for each hospital in our network. And we have also included the graphs for accrual by the hospices and general practice for completeness. These graphs are on Pgs.

North Devon District Hospital (Barnstaple)-Cancer Unit

During 2002-2003 there was accrual into only 6 studies which has increased to accrual into 18 studies during 2003-2004. The range of studies is affected by the level of Cancer Services within the trust with radiotherapy based in Exeter and consultants covering more than one hospital. Accrual reflects the smaller catchment population of the hospital. Nevertheless there has been significant accrual from the hospital with Dr.Mark Napier and Dr.Liz Toy who are very active trialists. Accrual to the GELCAPS and NSCCG studies have been very encouraging.

Derriford Hospital (Plymouth)-Cancer Centre

There has been accrual to approximately 27 trials over both years but an increase in accrual to Lung and Prostate studies . Sheila Bullard has supported these areas and a noticeable increase of accrual has occurred in these Cancer Sites. This is building on the existing strengths of the Oncology Trials Unit and ongoing accrual to colorectal and Upper GI Trials. Haematology and Lymphoma studies continue to accrue well and are well supported by Dr.Simon Rule and colleagues.

Royal Cornwall Hospital (Truro)-Cancer Unit

During 2002-3003 there was accrual to 11 studies with Oncology trials starting up in the Unit. This has increased to 26 studies accruing patients during 2003-2004

There has been significant accrual to the GELCAPS,TAPS, VICTOR and POSH studies. This has been matched with a continued expansion and involvement in a wider trials portfolio and particularly strong support to haematology trials.

Torbay Hospital –Cancer Unit

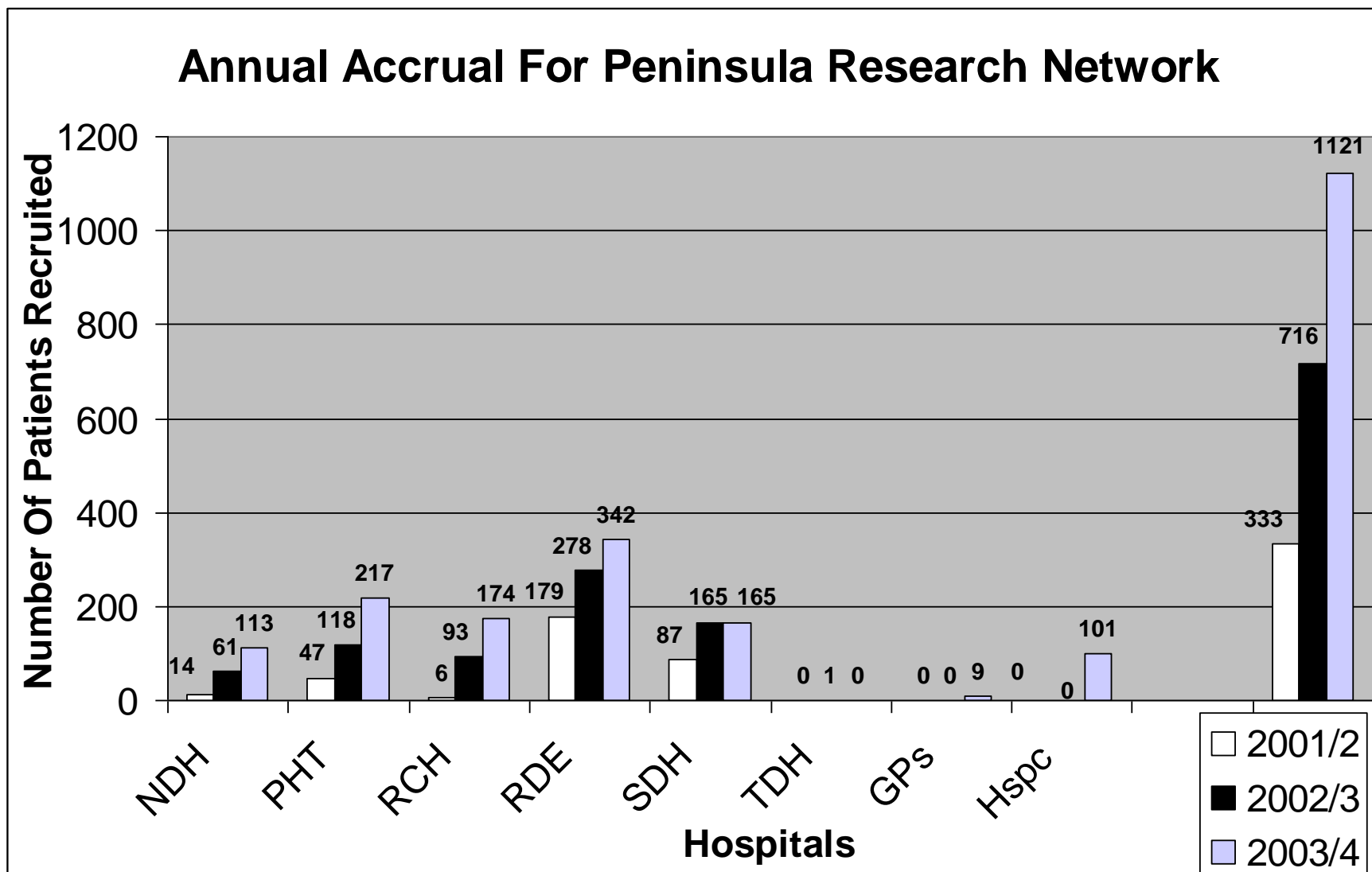
2002-2003 saw accrual to 24 NCRN studies with excellent accrual to the START, TACT and TANGO studies. Torbay maintains accrual to a good mix and some quite

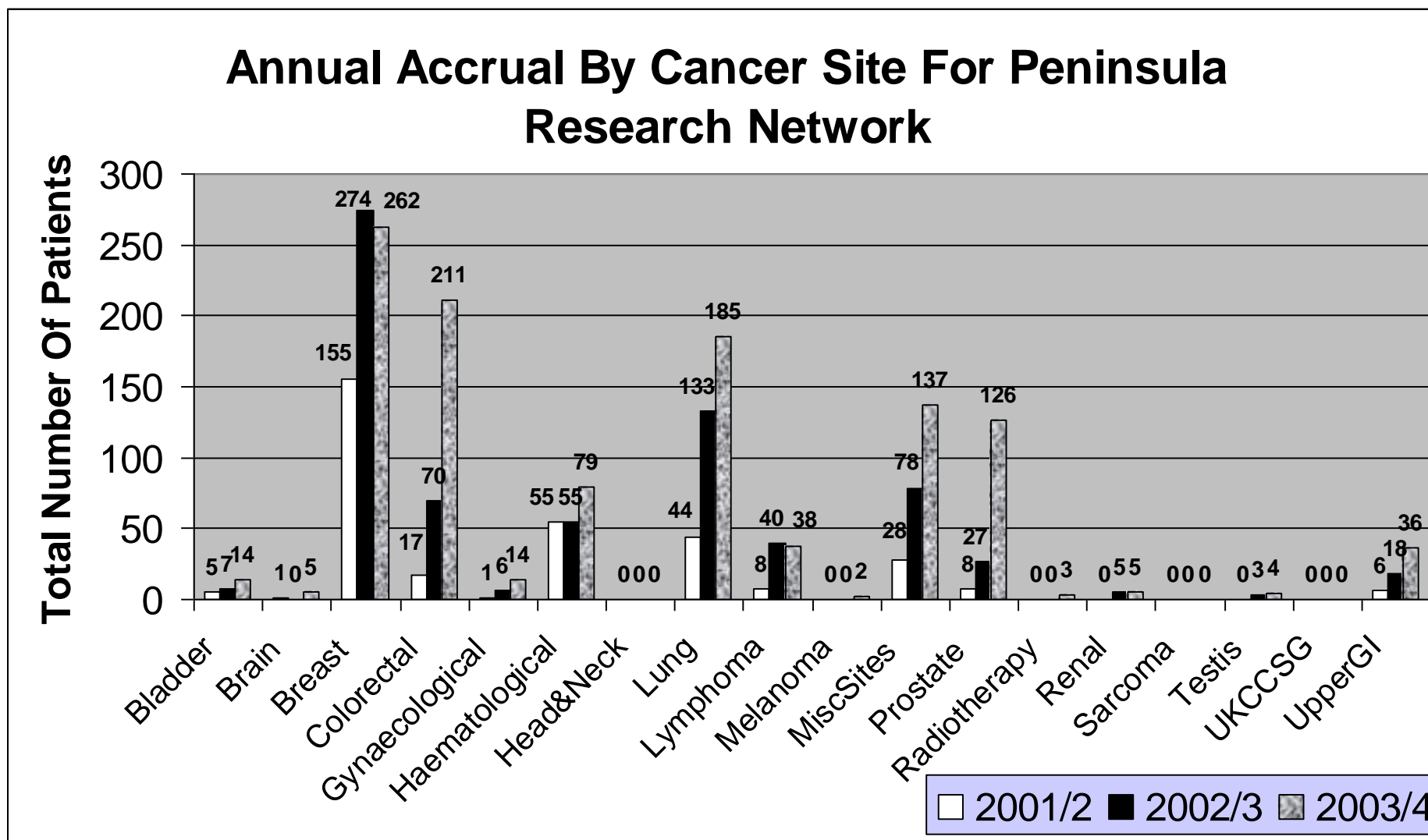
complex studies with a total of 34 NCRN studies currently accruing patients. Delays to staff appointments have without doubt had some impact on accrual but expect these to be resolved in the forthcoming financial year. We note a major dip in accrual for September 2003 but have no explanation for this other than perhaps annual leave of clinicians and staff.

Other Activity

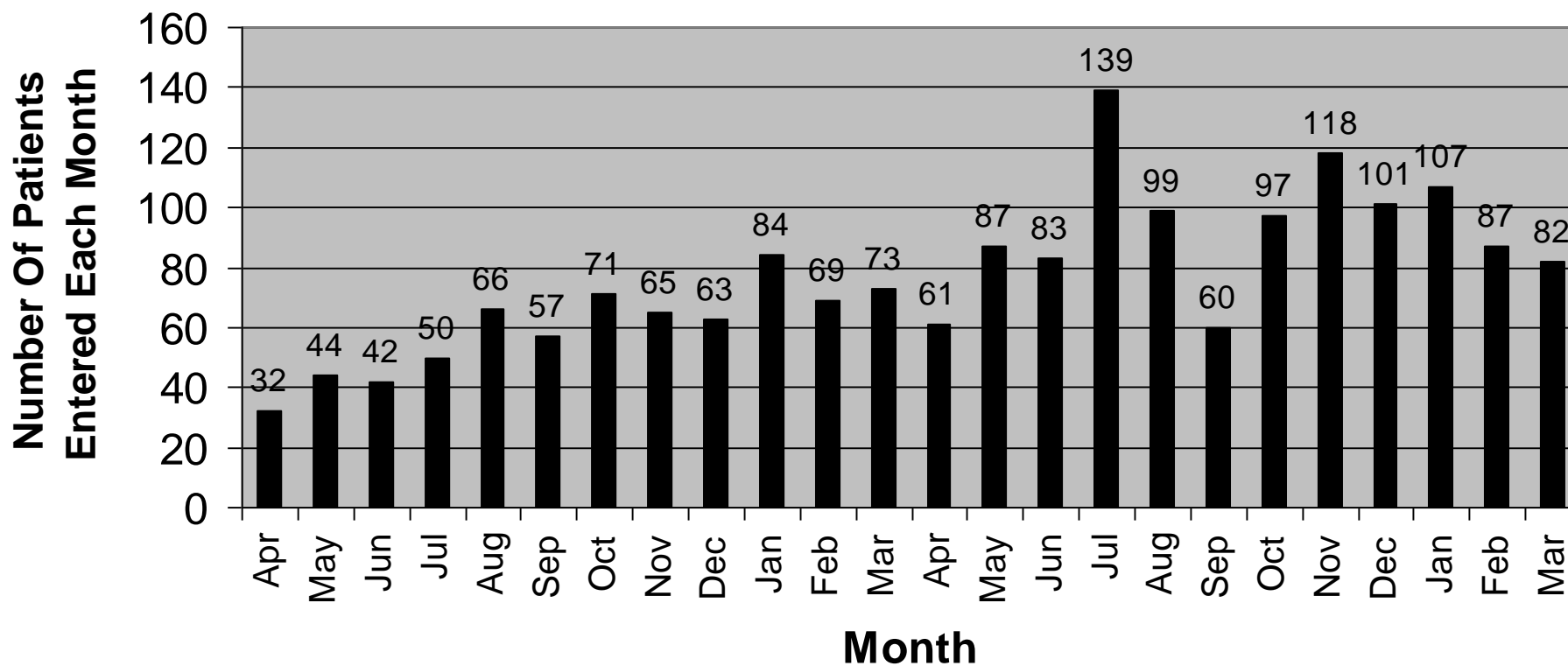
We have included the graphs representing additional accrual from studies which have involved both general practitioners and palliative care staff within the Peninsula noting the additional activity within the network and with thanks for their commitment to the Research agenda.

We appreciate that our infrastructure still does not offer the levels of support we would like to achieve in these areas and realise that further collaborative opportunities exist.

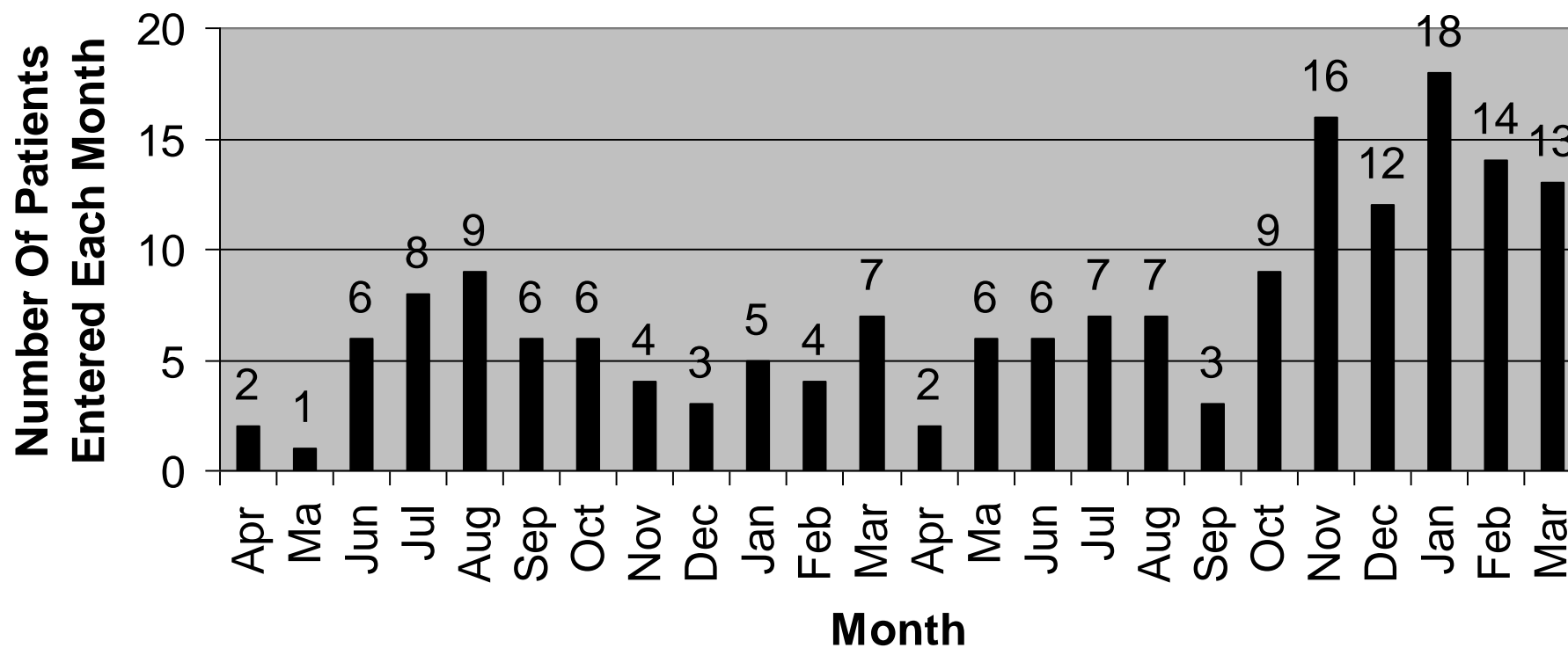




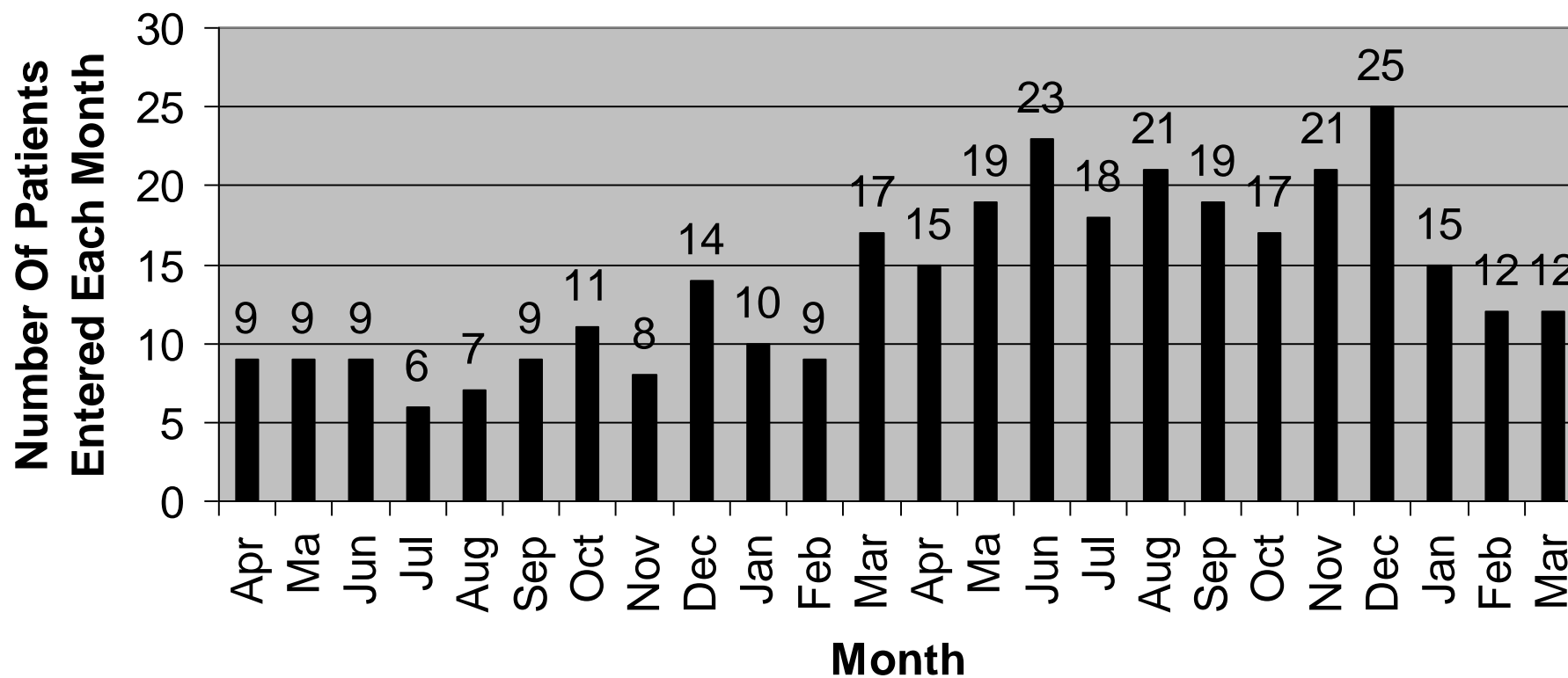
Monthly Accrual For Peninsula Research Network (Years 2 and 3)



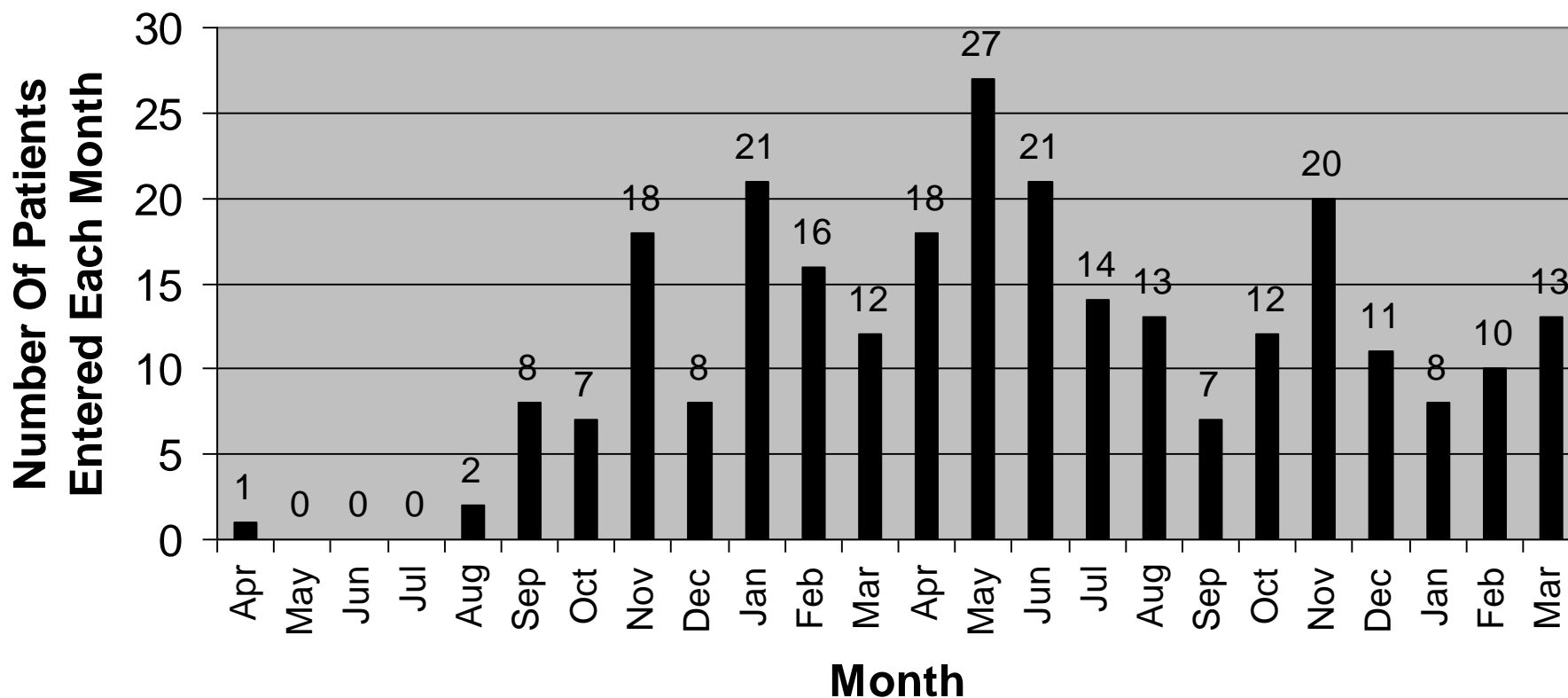
Monthly Accrual Into NCRN Portfolio Studies (NDH) (Years 2 and 3)



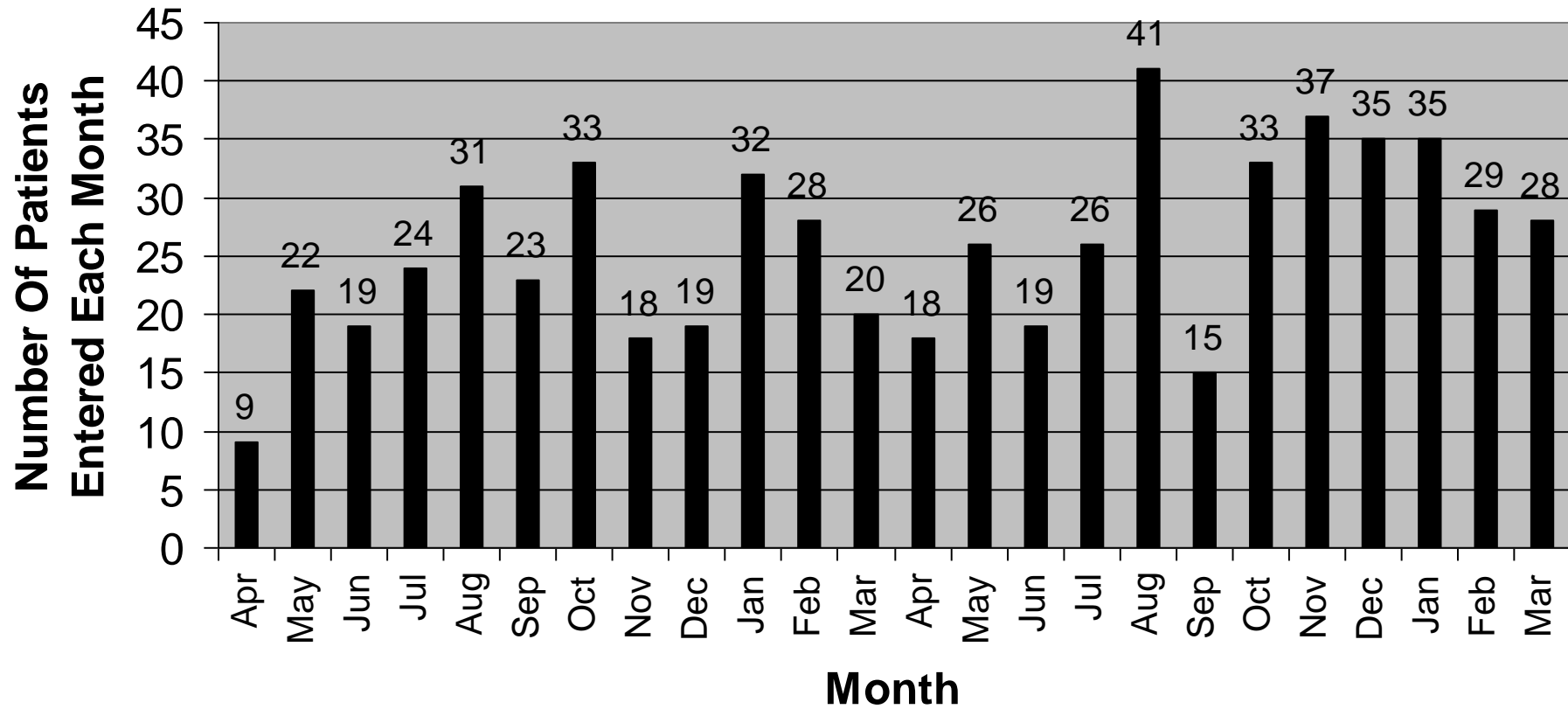
Monthly Accrual Into NCRN Portfolio Studies (PHT) (Years 2 and 3)



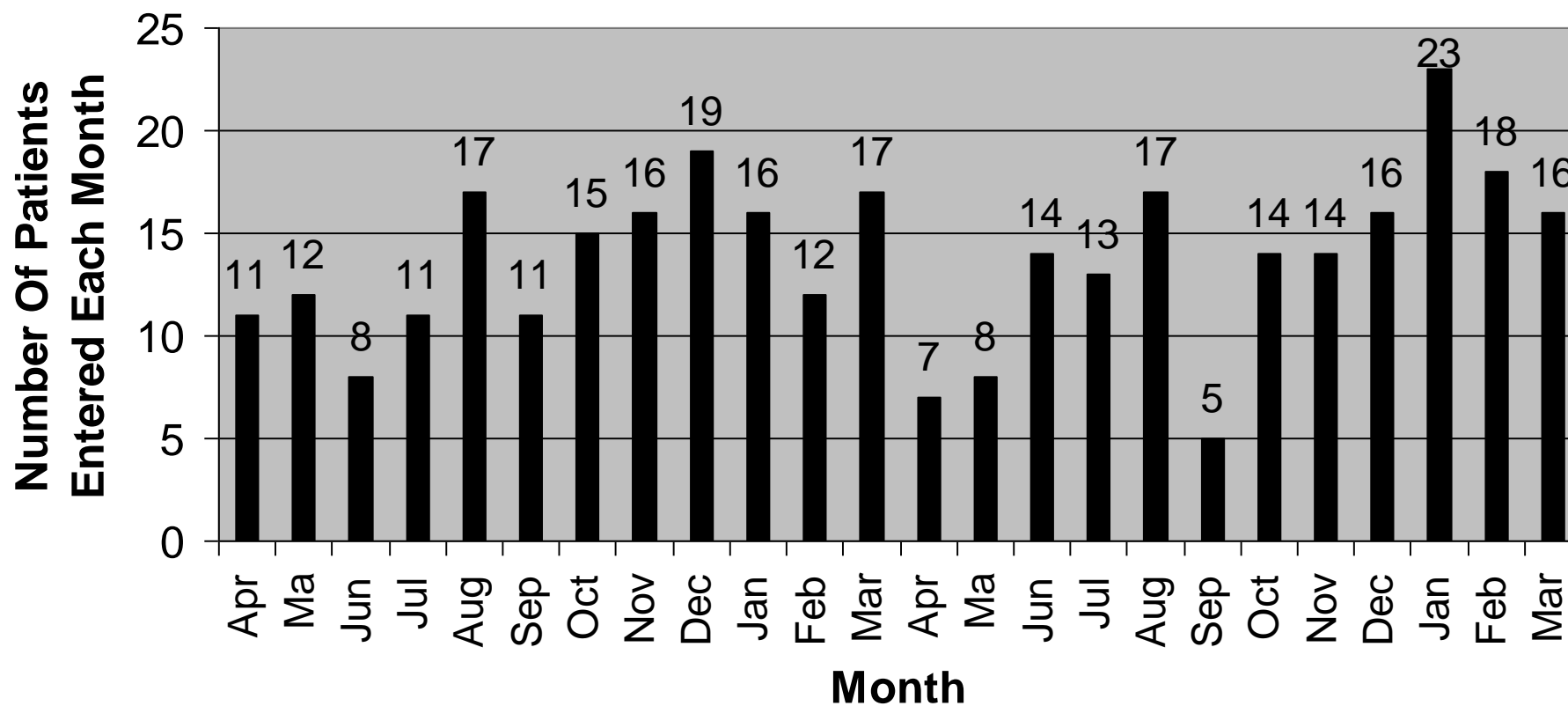
Monthly Accrual Into NCRN Studies (RCH) (Years 2 and 3)

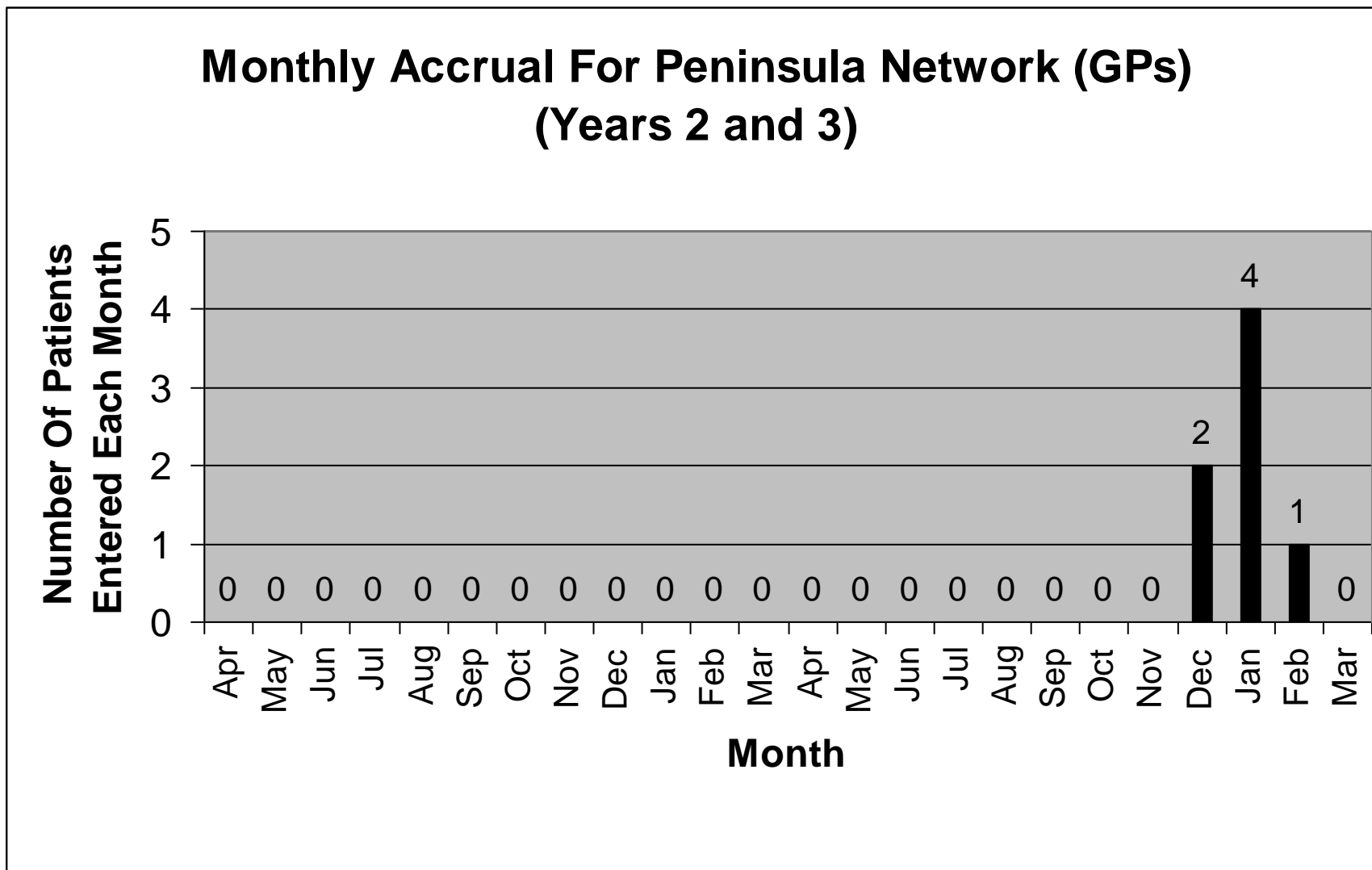


Monthly Accrual For Peninsula Research Network (RDE) (Years 2 and 3)

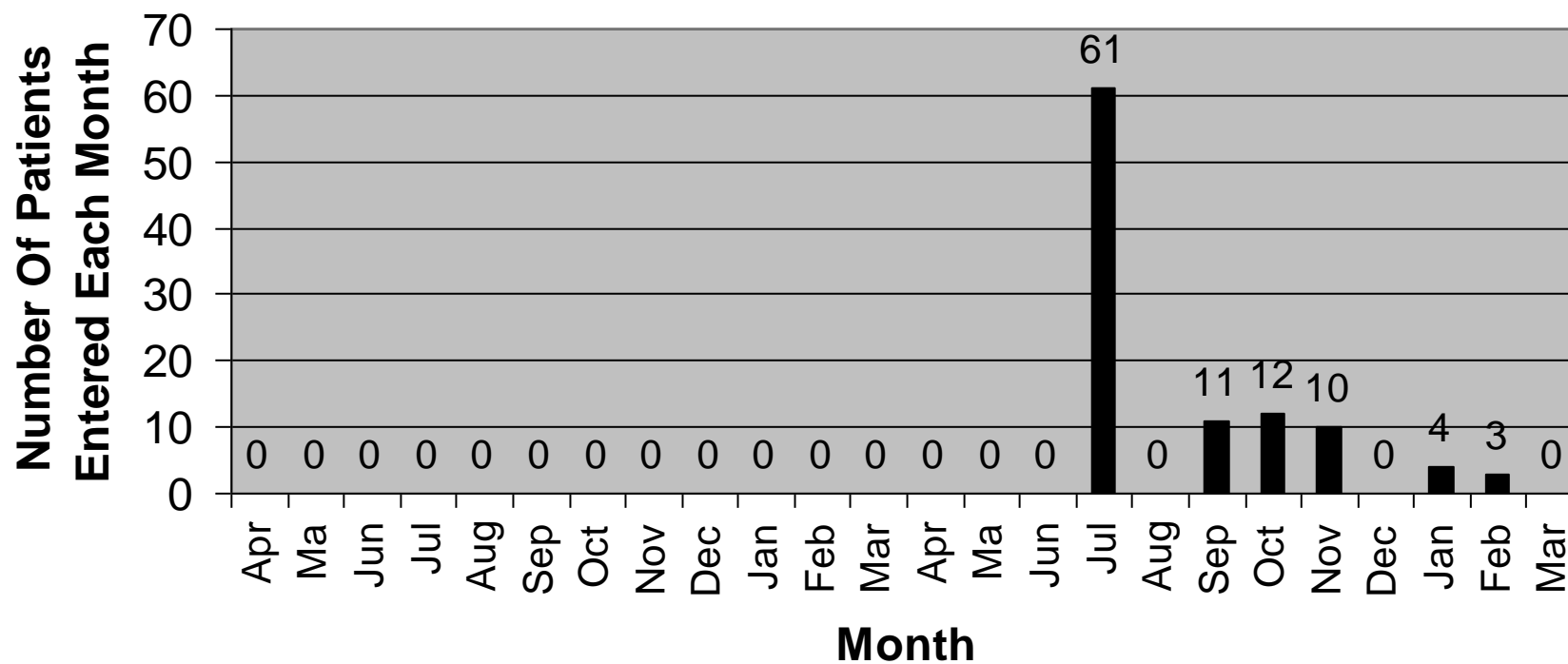


Monthly Accrual For Peninsula Network (SDH) (Years 2 and 3)





Monthly Accrual For Peninsula Network (Hospices) (Years 2 and 3)



Peninsula Cancer Research Network Accrual Data-2001-4

Hospital	NDH	PHT	RCH	RDE	SDH	TDH	GPs	Hspc	Overall
2001/2	14	47	6	179	87	0	0	0	333
2002/3	61	118	93	278	165	1	0	0	716
2003/4	113	217	174	342	165	0	9	89	1121

Annual Accrual Data By Cancer Site For 2001/2 and 2002/3

Cancer	Bladder	Brain	Breast	Colorectal	Gynaecological	Haematological	Head&Neck	Lung
2001/2	5	1	155	17	1	55	0	44
2002/3	7	0	274	70	6	55	0	133
2003/4	14	5	262	211	14	79	0	185

Cancer	Lymphoma	Melanoma	Misc Sites	Prostate	Radiotherapy	Renal	Sarcoma	Testis
2001/2	8	0	28	8	0	0	0	0
2002/3	40	0	78	27	0	5	0	3
2003/4	38	2	137	126	3	5	0	4

Cancer	UKCCSG	UpperGI	All Trials
2001/2	0	6	328
2002/3	0	18	716
2003/4	0	36	1121

Peninsula Cancer Research Network Raw Accrual Data

Monthly Accrual Data For Network For 2001/2 and 2002/3

Peninsula	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Total
2002/3	32	44	42	50	66	57	71	65	63	84	69	73	716
2003/4	61	87	83	139	99	60	97	118	101	107	87	82	1121

Monthly Accrual Data By Hospital For 2001/2 and 2002/3

Hospital	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Total
NDH	2	1	6	8	9	6	6	4	3	5	4	7	61
PHT	9	9	9	6	7	9	11	8	14	10	9	17	118
RCH	1	0	0	0	2	8	7	18	8	21	16	12	93
RDE	9	22	19	24	31	23	33	18	19	32	28	20	278
SDH	11	12	8	11	17	11	15	16	19	16	12	17	165
TDH	0	0	0	0	0	0	0	1	0	0	0	0	1

2.5. Accrual into Non-NCRN Portfolio Studies

Accrual data are not centrally collected for non-NCRN Portfolio studies within our network. At present there is only NCRN trial activity in North Devon. Data for Torbay is not currently available. Total known annual accrual for the network into each of the following types of trial/studies for 2003/4:

- Non-NCRN Portfolio non-commercial trials (Nationwide)-Total= 31 patients
Plymouth-12 patients
Truro- 19 patients
- Non-NCRN Portfolio non-commercial trials (Local/non-nationwide)-Total= 20 patients
Plymouth-17 patients
Exeter-3 patients
Truro-18 patients
- Commercial trials-Total= 53 patients
Plymouth- 34 patients
Exeter-19 patients
- Phase I/II studies.
No data available

2.6. Plans for achieving/maintaining accrual

We appreciate that we have achieved high levels of accrual across the network as a result of expanding trials portfolio within all 5 trusts. This has been possible due to the increased infrastructure, support from many active clinicians and a truly motivated workforce. Structures are in place within the site specific groups and participation in NCRN trials is recognised as an important part of the care package we offer our patients.

Expectations for support with clinical trials has been raised. We need to ensure that that individual trusts have a balanced trials portfolio. Overstretched support services such as pharmacy, chemotherapy staff and radiology could limit further growth in accrual. The impact of increasing follow up may also limit further growth.

2.7. Non-accrual trial activity data, including follow-up

The impact of follow up has already been discussed within this report. At present we do not have collective figures for numbers of patients on active follow-up but appreciate that this is vital for future planning and intend to work collaboratively to collect this data which is likely to be available within our individual clinical trials units.

We understand that the Wales Cancer Network has undertaken some valuable work in this area and would like to ask for some further guidance on the best method to collect this data.

Screening data is not collected in a uniform format within the PCRN at present and we were awaiting a template from the Respective Research Network Managers sub

group. We would appreciate further guidance on what data should be collected as soon as possible so that we can provide this data for future reporting

3. Local Portfolio of NCRN Studies

3.1 Current local portfolio

A copy of our current local trials portfolio is attached as **(Appendix 4)**

3.2 Adoption

Three local studies have been submitted/ considered for adoption and none of these applications have been successful. The main reasons for this being inadequate peer review and one lung study conflicted with another already being considered for adoption.

This has had a negative impact for our network, whilst encouraging our active clinicians to further develop their research ideas and protocols we did not have the support within our network to progress their applications and access to a robust peer review process. In respect of motivation of key staff has been detrimental.

3.3 R&D approval

R & D approval is currently managed within 4 of our trusts with North Devon receiving R & D support from Exeter. The Network has benefited from the support and commitment of our R & D Managers to the NCRN's objective and R & D approval has not been problematic.

The R & D Managers in general have been very effective in identifying appropriate service support costs and ad hoc funding and subvention funding has been applied for where appropriate to support the increased research activity.

Since, the R & D Management support has been effective we have not centrally documented the time taken, from completion of form to receipt of approval, and the amount of staff time involved in this process. This information may be available within the individual trusts.

3.4 Ethics approval

Ethics approval again has not been particularly problematic although some delays in the approval of the Gelcaps study were noted in Plymouth where the ethics committee had asked for some clarifications from the respective MREC. Ethics approval data has not been collected centrally.

3.5 Strategy for developing local NCRN portfolio

Our network's research priorities for cancer remain as of 2002-2003 with the intention of further exploring where further activity is possible with some of the trials in some of the rarer cancers. However, we appreciate we should look at this more strategically

to ensure that the mix of trials does not cause excessive burden on support services within individual trusts

The Research Network Manager and Clinical Lead for Research regularly review the NCRN portfolio and formally adopt those additional studies which we believe to be of interest to local investigators. Following the formal adoption of such trials we then discuss with the Site Specific groups the potential to set up these trials within individual trusts and seek their approval. and thereby encourage other investigators to enter patients. If any of the 5 acute hospital trusts are not partaking we inform the R & D team at that site to determine whether there are legitimate local reasons for non-participation.

Cancer service standards require site-specific groups to have a list of agreed clinical trials and most have used the PCRN adopted portfolio for this purpose. Currently 88 studies have been reviewed and formally adopted as the PCRN Portfolio.

NCRN studies are publicised via the site specific group meetings, local trust research departmental meetings and internal website. Future plans are to make the local portfolio available via our Cancer Network website using NCRN website links to view our local portfolio.

4. Consumer Involvement

- Consumer involvement. We currently have a lay representative Mr. Richard Thorpe as a member of our R & D Group. We plan to explore further ways of involving consumers locally and are looking to work with any volunteers identified by a questionnaire recently distributed by Pat Fairbrother (PCN User Group facilitator) to local users. We recognise that we will need to support our consumers in this process.

We have been purposely watchful of the pilot studies undertaken by the Consumer Liaison Officer of the NCRN in association with Macmillan and look forward to the feedback from these pilot sites prior to developing further consumer initiatives within the Peninsula. We are concerned that adequate support structures and training and education are available for interested consumers prior to developing this strategy further.

5. Examples of activities/initiatives developed in your network that have been particularly effective

We feel the integration of the PCRN with the Cancer Service Network has been very successful in raising the awareness of the multidisciplinary teams of NCRN objectives and trials. Their ownership of their individual trials portfolio's has been most positive.

As the Network has matured involvement of Research Staff in site specific group activities should increase communications and feedback.

The education and training programme provided by the NCRN and the addition local training initiatives and annual Research symposia have raised

the profile and awareness of NCRN activity across the Peninsula and have been most effective.

6. Finance

Department of Health Funding for the Peninsula Cancer Research Network allocated via the NCRN for 2003/2004 was £378,800. There was an underspend from 2002/2003 of £ 44,250.

The underspend for 2002/2003 was largely attributed to late appointment of posts agreed by the NCRN for part funding of a Clinical Research Fellow in Plymouth and delays in the appointment of the Clinical Trials Research Assistant Post also in Plymouth these posts have since been filled. This underspend amounted to £ 26,454. A further £ 6,700 underspend resulted from an initial allocation for radiology support for Torbay which had been allocated to support Radiology reporting to RECIST standards which was not achieved. A further £ 11,100 remained from funding initially allocated to the Core Team budget for planned IT support and office equipment.

The underspend has been used to provide additional Support in respect of 2 part time Research Nurses employed on a fixed term contract providing support to the Plymouth Oncology Unit during 2003-2004.

Therefore, the budget allocation for 2003-2004 was £423,050. Of this allocation £ 55,400 has been spent supporting the Core Network Staff (Clinical Lead, Research Network Manager and Research Network Secretary).-£ 276,300 has been spent on Staff contracted within the 5 trusts with £ 56,920 spent on non-staff costs.

It is planned that approximately a £ 34,000 underspend be carried forward to support agreed 2 year fixed term posts providing additional support of a Cancer Trials Facilitator in Truro, and administrative support in Torbay and Exeter. These posts are included in the staffing appendices attached to this report. Further support to these posts has been provided from external funding separate from the DOH budget allocation.

7. Future Plans

The future potential pressure points are likely to result from an increasing burden on chemotherapy Units and pharmacy . The workload of local chemotherapy Units appears to be increasing with increasing demands on staff. Our Network Pharmacy / Chemotherapy Group have raised concerns about the impact of clinical trials on the services. No definitive piece of work has been conducted to extrapolate the part that clinical trials have placed on these services.

This would be a valuable piece of collaborative work and important to the planning of future trials portfolio's. However, to complete this effectively would require additional administrative support to determine accurately, the impact of chemotherapy trials and identification of costings for trials particularly in respect of staff time where regimens are in addition to standard therapy.

There is ongoing pressure on pharmacy both in respect of additional administration to comply with the EU Directive in terms of paperwork and administrative support and similar pressure on chemotherapy preparation Units.

An analysis of the impact of trial follow up on Research Staff time is vital to predicting restriction on further increased accrual and again would require administrative support or collaboration from audit to complete effectively.

It would be valuable to conduct an audit of reasons for non accrual and we understand that similar work has been conducted in West Anglia Network at Addenbrooke's. A local audit would be useful to see if current screening processes are effective.

8. Additional Information

There is increasing pressure within the Cancer Service Network for information on studies nearing completion and we are being asked to identify the potential impact of positive trials on Cancer drug prescribing. This type of information is not readily accessible and often difficult to extrapolate.

The Cancer Service Network drugs and therapeutics committee had requested to be involved in the "sanctioning of new trials involving chemotherapy" but this has been resisted since it was felt that this process should occur locally within the trusts as part of the R & D approval process and that it would result in further delays to the setting up of trials if dependent on meetings schedules.

For a relatively small Research Network delivery of the education and training SOP has not been easy with the geography of the Peninsula and the increasing support of site specific groups. This is difficult to delegate with the current network structure and budget. Although effective training has been provided for existing staff it is important that a rolling training programme remains available for new staff allowing for staff turnover and that this is accessible for our more isolated network.

Finally, we would just like to congratulate all our staff for their enormous contribution to this fantastic achievement and to the NCRN Co-ordinating centre for their support in this process. We hope that the Peninsula Cancer Research Network will continue to grow from strength to strength and that we will be able to consolidate current achievements and ensure equitable access to clinical trials for all our Cancer patients who wish to take part.

9. Network Contact Information

9.1 Cancer Research Network Team

A table of Network Cancer Research Network team is included in this report as Appendix 3a.

9.2 Cancer Service Network Team (see Appendix 3b)

A table of Network Cancer Service Network Team is included in this report as Appendix 3b.

9.3 Network Research Leads in each cancer site (contact details not required)

A table of Network Site Specific Chair's is included in this report as Appendix 3c. Although we do have Research Leads for some of these groups we would prefer that communications should be through the Chair's of the groups whose details are updated on our local website :- www.pcn.nhs.uk

9.4 Hospitals and PCTs in the Network

Please find below provide contact details for each hospital and PCT in the network.

<p>North Devon Healthcare NHS Trust North Devon District Hospital Raleigh Park Barnstaple EX31 4JB Tel : 01271 322577</p>	<p>Plymouth Hospitals NHS Trust Derriford Hospital Derriford Road Plymouth PL6 8DH Tel : 01752 777111</p>
<p>Royal Cornwall Hospital NHS Trust Royal Cornwall Hospital Treliske Truro TR1 3LJ Tel : 01872 250000</p>	<p>Royal Devon & Exeter Foundation Trust Royal Devon & Exeter Hospital Barrack Road Exeter EX2 5DW Tel : 01392 411611</p>
<p>South Devon Healthcare NHS Trust Torbay Hospital Lawes Hospital Torquay TQ2 7AA Tel : 01803 614567</p>	
<p>South Hams & West Devon PCT Lescaze Offices Shinner's Bridge Dartington TQ9 6JE Tel : 01803 861814</p>	<p>Teignbridge PCT Bridge House Collett Way Brunel Industrial Estate Newton Abbot TQ12 4PH Tel : 01626 357000</p>
<p>Torbay PCT Rainbow House Avenue Road Torquay TQ2 5LS Tel : 01803 210910</p>	<p>Plymouth PCT Building 1 Derriford Business Park Plymouth PL6 5XP Tel : 01752 315315</p>
<p>Central Cornwall PCT John Keay House Tregonissey Road St. Austell PL25 4NQ Tel : 01726 777777</p>	<p>West of Cornwall PCT Head Office Foundary Road Camborne TR14 8DS Tel : 01209 888222</p>
<p>North Devon PCT Barstaple Health Centre Vicarage Street Barnstaple EX32 7BH Tel : 01271 327779</p>	<p>Exeter PCT Dean Clarke House Southernhay East Exeter EX1 1PQ Tel : 01392 205205</p>

9.4 Hospitals and PCTs in the Network (contd.)	
East Devon PCT Dean Clarke House Southernhay East Exeter EX1 1PQ Tel : 01392 207521	Mid Devon PCT Newcourt House Old Rydon Lane Exeter EX2 7JU Tel : 01392 449700
North & East Cornwall PCT Lamellion Hospital Station Road Liskeard Cornwall PC14 4DG Tel : 01208 256800	

9.4.1 Chief Executives of Trusts

Alan Tibbenham
 Chief Exec
South Hams & West Devon PCT
 Lescaze Offices
 Shinner's Bridge
 Dartington
 Devon TQ9 6JE
 01803 861814
alan.tibbenham@shandwd-pct.nhs.uk
pct.nhs.uk

Pam Smith
 Chief Exec
Teignbridge PCT
 Bridge House
 Collett Way
 Brunel Industrial Estate
 Newton Abbot TQ12 4PH
 01626 357000
pam.smith@teignbridge-pct.nhs.uk

Peter Colclough
 Chief Exec
Torbay PCT
 Rainbow House
 Avenue Road
 Torquay TQ2 5LS
 01803 210910
peter.colclough@torbay-pct.nhs.uk

Ann James
 Chief Exec
Plymouth PCT
 Building 1
 Derriford Business Park
 Plymouth PL6 5XP
 01752 315315
ann.james@pcs-tr.swest.nhs.uk

Lyn Manuell
 Chief Exec
Central Cornwall PCT
 John Keay House
 Tregonissey Road
 St Austell
 PL25 4NQ

 01872 354499
lyn.manuell@centralpct.cornwall.nhs.uk

Antek Lejk
 Chief Exec
West of Cornwall PCT
 Head Office
 Foundry Road
 Camborne TR14 8DS
 01209 888222
 Fax 01209 886572
antek.lejk@westprimcare.cornwall.nhs.uk

9.4.2 Chief Executives of Trusts-Contd.

Kate Tompkins
Chief Exec
North Devon PCT
Barnstaple Health Centre
Vicarage Street
Barnstaple EX32 7BH
01271 327779
kate.tompkins@ndevon.swest.nhs.uk

Iain Tulley
Chief Exec
East Devon PCT
Dean Clarke House
Southernhay East
Exeter EX1 1PQ
01392 207521
iain.tulley@eastdevon-pct.nhs.uk

Jill Ashton, Chief Exec
Exeter PCT
Dean Clarke House
Southernhay East
Exeter EX1 1PQ
01392 205205
jill.ashton@exeter-pct.nhs.uk

Lesley Dunaway, Chief Exec
Mid Devon PCT
Newcourt House
Old Rydon Lane
Exeter EX2 7JU
01392 449700
Lesley.dunaway@middevon-pct.nhs.uk

Ian Williams, Chief Exec
North & East Cornwall PCT
Lamellion Hospital
Station Road
Liskeard PL14 4DG
01579 335341
ian.williams@nepct.cornwall.nhs.uk

9.4.3 R&D Department

Names and contact details of R&D Contacts in each hospital are included in this report in **Appendix 3d**.

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Hospitals covered by post (base hosp first)	Post Title	Post Category	Tumour Site 1	Tumour Site 2	Tumour Site 3	Tumour Site 4	Tumour Site 5	Grade	WTE	Contract Length (mts)
PCRN	Clinical Lead for Research	CL	All						0.1	
PCRN	Research Network Manager	MG	All					H	1.0	
PCRN	Secretary	AD	All					A&C III	0.4	
RDE	Research Nurse	RN	All					F	1.0	
RDE	Research Nurse	RN	All					F	1.0	24
RDE	Research Radiographer	RR	All					Sup II	0.5	
RDE	Lead Clinician	CL	All					1 Session	0.1	
Torbay	Research Nurse	RN	All					E	1.0	
Torbay	Research Nurse	RN	All					F	0.7	
Torbay	Data Manager	DM	All					A & iV	1.0	24
PCRN	Research Nurse	RN	All					F	1.0	
NDH	Research Nurse	RN	All					E	0.5	18
NDH	Research Nurse	RN	All					E	0.6	6
NDH	Research Nurse	RN	All					F	0.5	18
NDH	Research Nurse	RN	All					F	0.2	18
NDH	Research Nurse	RN	All					F	0.6	18
NDH	Clerical Administrator	AD	All					A&C III	0.8	18
RCH	Research & Development Team Leader	MG	All					SMP 24	1.0	12
RCH	Research & Development Team Leader	MG	All					SMP 20	1.0	36
RCH	Cancer Research & Development Facilitator	CT	All					SMP 27	1.0	36
RCH	Cancer Research & Development Facilitator	RN	All					G	1.0	24
PHT	Clinical Trials & MDT Liason Officer	CT	All					G	0.6	
PHT	Clinical Trials & MDT Liason Officer	CT	All					G	0.6	
PHT	Research Fellow	CL	All					Junior Reg.	1.0	12
PHT	Research Fellow	CL	All					Junior Reg.	0.5	12
PHT	Clinical Trials Assistant	CT	All					E	0.2	
PHT	Research Nurse	RN	All					E	0.6	12
PHT	Research Nurse	RN	All					E	0.6	12
PHT	Research Sister	RN	All					E	0.3	
PHT	Research Sister	RN	All					E	0.3	
RDE	Clerical Administrator	AD	All					A & C 111	0.4	
RDE	Clerical Administrator	AD	All					A & C 111	0.6	

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Appendix 1a-NCRN Appointments (Peninsula Cancer Research Network)							
Hospitals covered by post (base hosp first)	Post Title	Surname	Forename	Salutation	Start Date	End Date	Comments
PCRN	Clinical Lead for Research	Bailey	Nigel	Dr	01/10/2001		
PCRN	Research Network Manager	Rees	Glyn	Mr	17/12/2002		
PCRN	Secretary	Williams	Suzanne	Ms	04/03/2002		
RDE	Research Nurse	O'Keefe	Michael	Mr	05/06/2002	08/10/2003	Postholder left
RDE	Research Nurse	Adams	Melissa	Ms	24/11/2003		New appointment to existing post
RDE	Research Radiographer	Welsh	Linda	Ms	01/04/2002		Increased Hours To Existing Post
RDE	Lead Clinician	Hong	Anne	Dr	01/04/2002		Clinician Session Only
Torbay	Research Nurse	Greenfield	Katrina	Ms	29/04/2002		Reduced Hours But Upgrade to Post
Torbay	Research Nurse	Greenfield	Katrina	Ms	01/07/2003		
Torbay	Data Manager						Vacant Post-Interviewed to start 10/05/2004
PCRN	Research Nurse	Diaper	Karen	Ms	07/05/2002	09/05/2003	Postholder Left & Post reviewed
NDH	Research Nurse	Wells	Beverley	Ms	20/01/2003	31/05/2003	Postholder Increased Hours
NDH	Research Nurse	Wells	Beverley	Ms	01/06/2003	30/04/2004	Postholder left-moved from area
NDH	Research Nurse	Averns	Caroline	Ms	03/11/2003		
NDH	Research Nurse	Van-Koutrick	Lyne	Ms	15/09/2003	06/06/2004	
NDH	Research Nurse	Van-Koutrick	Lyne	Ms	07/06/2004		Increase In Hours Planned
NDH	Clerical Administrator	Lay	Sam	Mrs	17/03/2003		
RCH	Research & Development Team Leader	Beech	Darren	Dr	13/05/2002	30/06/2003	G Grade Equivalent
RCH	Research & Development Team Leader	Beech	Darren	Dr	01/07/2003	01/09/2006	Post Upgraded H Grade Equivalent
RCH	Cancer Research & Development Facilitator	Scrivenor	Sophie	Ms	01/03/2003	31/03/2006	F Grade Equivalent-likely to be upgraded
RCH	Cancer Research & Development Facilitator				01/04/2004	31/03/2006	New Post-Currently Vacant-Fixed Term
PHT	Clinical Trials & MDT Liason Officer	Bullard	Sheila	Ms	05/01/2004		
PHT	Clinical Trials & MDT Liason	Bullard	Sheila	Ms	05/01/2004		

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	Officer						
PHT	Research Fellow	Scott	Edwina	Dr	14/10/2002	07/09/2003	Postholder left but post reappointed
PHT	Research Fellow	Bradbury	Phillipa	Dr	08/09/2003	08/09/2004	Fixed Term Contract-To be reviewed
PHT	Clinical Trials Assistant	York	Maxine	Ms	01/04/2003	01/04/2004	Fixed Term Contract-To be reviewed
PHT	Research Nurse	Pascoe	Julie	Ms	01/04/2003	01/04/2004	Fixed Term Contract-Unlikely To Continue
PHT	Research Nurse	Cogley	Lyne	Ms	01/04/2003	01/04/2004	Fixed Term Contract-Unlikely To Continue
PHT	Research Sister	Chetty	Sarah	Ms	01/04/2002		Support For Haematology Trials
PHT	Research Sister	Teasdale	Lesley	Ms	01/04/2002		Support For Haematology Trials
RDE	Clerical Administrator	Hope	Angie	Ms	16/01/2003	01/08/2003	Increased Admin Support-Increased Hours
RDE	Clerical Administrator	Hope	Angie	Ms	01/08/2003		

Appendix 1b: Staff in Post - Peninsula

Title	Salutation	Forename	Surname	WTE	Salary and Oncosts
Clinical Lead for Research	Dr	Nigel	Bailey	0.1	£17,500.00
Research Network Manager	Mr	Glyn	Rees	1	£33,500.00
Secretary	Ms	Suzanne	Williams	0.4	£4,600.00
Research Nurse	Ms	Katrina	Greenfield	1	£4,347.00
Research Nurse	Ms	Katrina	Greenfield	0.72	£13,915.00
Research Nurse	Ms	Melissa	Adams	1	£28,512.00
Research Radiographer	Ms	Linda	Welsh	0.5	£12,053.45
Lead Clinician	Dr	Anne	Hong	0.1	£7,663.00
Research Nurse	Ms	Beverley	Wells	0.6	£15,346.00
Research Nurse	Ms	Caroline	Averns	0.5	£14,460.00
Research Nurse	Ms	Lyne	Van-Koutrick	0.2	£5,783.00
Clerical Administrator	Mrs	Sam	Lay	0.75	£12,178.00
Research & Development Team Leader	Dr	Darren	Beech	1	£31,964.00
Cancer Research & Development Facilitator	Ms	Sophie	Scrivenor	1	£28,512.00
Clinical Trials & MDT Liason Officer	Ms	Sheila	Bullard	0.6	£23,039.00
Research Fellow	Dr	Phillipa	Bradbury	0.5	£17,876.00
Clinical Trials Assistant	Ms	Maxine	York	0.2	£3,153.00
Research Nurse	Ms	Julie	Pascoe	0.64	£10,433.50
Research Nurse	Ms	Lyne	Cogley	0.64	£10,433.50
Research Sister	Ms	Sarah	Chetty	0.3	£7,730.00
Research Sister	Ms	Lesley	Teasdale	0.3	£7,730.00
Clerical Administrator	Ms	Angie	Hope	0.6	£11,160.55

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1.4.3

Local Training

Appendix 1c

Delegate	Job Title	Hospital	Course(s) Attended
Dawn Astill	Oncology Research Nurse	RDE	Peninsula Symposium (04/04/2003) Developing Practice Based on Users Experiences (20/05/2003) Research Methodology (22/07/2003)
Melissa Adams	Oncology Research Nurse	RDE	ICH GCP Training (02/12/2003)
Kassie Andain	Research Nurse, Renal Unit	RCH	ICH GCP Training (01/12/2003)
Caroline Averbs	Clinical Research Nurse	NDH	ICH GCP Training (01/12/2003) Cancer Policy and Politics (02/12/2003)
Dr Nigel Bailey	Clinical Lead For Research	SDHT PHT	National Briefing (23/10/2003) EU Directive Training-SCOPE-Bristol-(18/09/2003)
Beverley Balin	Patient Experience Project Co-Ordinator	RCH	ICH GCP Training (01/12/2003)
Darren Beech	Cancer R&D Team Leader	RCH	ICH GCP Training (01/12/2003) Peninsula Symposium (04/04/2003) Are We Prepared to Be Legal? (12/12/2003)
Martin Blundell	Cancer Services Pharmacist	SDHT	Peninsula Symposium (04/04/2003)
Pippa Bradbury	Oncology Research Fellow	PHT	ICH GCP Training (02/12/2003)
Jacqueline Briggs	ASWCRN	ASWCRN	Are We Prepared to Be Legal? (12/12/2003)
Sheila Bullard	Cancer Clinical Trials Co-Ordinator	PHT	BODMA NCRN Conference 08/09/2003-09/09/2003) Advanced ICH-GCP (04/11/2003) ICH GCP Training (02/12/2003) Are We Prepared to Be Legal? (12/12/2003)
Sue Bulley	ASWCRN		Are We Prepared to Be Legal? (12/12/2003)
Anne Carroll	Nurse Specialist - Urology	SDHT	ICH GCP Training (02/12/2003)
Nick Carter	Technologist & Research Co-ordinator, Nuclear Medicine	PHT	ICH GCP Training (02/12/2003) Peninsula Symposium (04/04/2003)

Peninsula Cancer Research Network Annual Progress Report: 1 April 2003-31 March 2004-Appendix

Karole Champion	Orthopaedics Research Nurse	PHT	ICH GCP Training (02/12/2003)
Sarah Chetty	Haematology Research Sister	PHT	Are We Prepared to Be Legal? (12/12/2003) ICH Good Clinical Practice (GCP) (14/05/2003) Cancer Policy & Politics (02/12/2003)
Dr Ginny Chorghade	Clinical Research Associate	RCH	ICH GCP Training (01/12/2003)
Dr Tim Clifford	Research Associate	RCH	ICH GCP Training (01/12/2003)
Dr Matthew Collinson	Consultant Clinical Oncologist	RCH	Peninsula Symposium (04/04/2003)
Dr Mary Davies	Clinical Assistant	RDE	Advanced GCP and EU Directive (11/03/2003)
Dr Lee Dobson	Respiratory Consultant	SDH	Advanced GCP and EU Directive (11/03/2003)
Mr Peter Donnelly	Consultant Surgeon	SDH	Advanced GCP and EU Directive (11/03/2003)
Dr Nicole Dorey	Specialist Registrar	PHT	Advanced GCP and EU Directive (11/03/2003)
Dr Phillip Davies		PHT	ICH GCP Training (02/12/2003)
Richard Ellis	Consultant Clinical Oncologist	RCH	Peninsula Symposium (04/04/2003)
Jayne Elmes	Urology Research Nurse	PHT	ICH GCP Training (02/12/2003)
Paul Evans	Lead Pharmacist Cancer Services	RCH	Peninsula Symposium (04/04/2003)
Michelle Farley	R & D Administrative Assistant	RCH	ICH GCP Training (01/12/2003)
Clare Ferris	Clinical Nurse Specialist - Colorectal	RCH	ICH GCP Training (01/12/2003) Peninsula Symposium (04/04/2003)
Gill Fowler	Clinical Nurse Specialist	RCH	Peninsula Symposium (04/04/2003) ICH Good Clinical Practice (GCP) (13/11/2003)
Jenny Forrest	Specialist Registrar	PHT	Advanced GCP and EU Directive (11/03/2003)
Sue Golding-Cook	Research Governance Nurse	PHT	ICH GCP Training (02/12/2003)
Katrina Greenfield	Research Nurse	SDH	Communication – Talking about Randomised Clinical Trials (08/03/2004) ,Peninsula Symposium (04/04/2003) BODMA NCRN Conference 08/09/2003-09/09/2003) Advanced ICH GCP (14/11/2003)
Dr T. Gruning	Consultant in Nuclear Medicine	PHT	Peninsula Symposium (04/04/2003)
M. Halawa	Consultant Orthopaedic Surgeon	PHT	Peninsula Symposium (04/04/2003)
Caroline Harnett	Cancer Nurse Specialist	SDH	Communication – Talking about Randomised Clinical Trials (08/03/2004)

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Jane Hall	Haematology Research Nurse	RDE	Developing Practice Based on Users Experiences (04/08/2003) BODMA NCRN Conference 08/09/2003-09/09/2003)
Libby Hardy	Peninsula Network Pharmacist	RDE PCN	Are We Prepared to Be Legal? (12/12/2003) Advanced GCP and EU Directive (11/03/2003)
Rachel Harris	Superintendent Research Radiographer	PHT	Peninsula Symposium (04/04/2003)
Derek Hart	Urology Nurse Practitioner	PHT	ICH GCP Training (02/12/2003) Peninsula Symposium (04/04/2003)
Peter Helliwell		RCH	Peninsula Symposium (04/04/2003)
Anne Hogan	Aseptic Services Manager	RCH	Peninsula Symposium (04/04/2003)
Becky Holbrook	Research Manager	NDH	Peninsula Symposium (04/04/2003) Are We Prepared to Be Legal? (12/12/2003) Advanced GCP and EU Directive (11/03/2003) Advanced ICH-GCP (04/11/2003)
Dr Anne Hong	Consultant Clinical Oncologist	RDE	Peninsula Symposium (04/04/2003)
Angie Hope	Clerical Administrator	RDE	Peninsula Symposium (04/04/2003) Introduction to Cancer Course (04/09/2003)
Lisa Howell		PHT	ICH GCP Training (02/12/2003)
John Hyslop	Consultant Radiologist		Peninsula Symposium (04/04/2003)
Wendy Ingram	CAMS Trial	PHT	ICH GCP Training (02/12/2003)
Giles Jones			Peninsula Symposium (04/04/2003)
Ingrid Koehler	Research Nurse	SDH	Advanced GCP and EU Directive (11/03/2003) Peninsula Symposium (04/04/2003) Developing Practice Based on Users Experiences (04/08/2003) Research Methodology (23/10/2003) Cancer Policy & Politics (02/12/2003) Are We Prepared to Be Legal? (12/12/2003) Communication – Talking about Randomised Clinical Trials (08/03/2004)
Kate Lansdell	Lung Cancer Nurse Specialist	PHT	ICH GCP Training (02/12/2003)

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Jane Lee		SDH	Peninsula Symposium (04/04/2003)
Sam Ley	Secretary To Research Nurses	NDH	ICH GCP Training (01/12/2003) Introduction to Cancer Course (04/12/2003)
Cathryn Love-Rouse	R & D Senior Manager	RCH	ICH GCP Training (01/12/2003) Peninsula Symposium (04/04/2003)
Dr. Anna Lydon	Clinical Oncologist	SDH/RDE	Advanced GCP and EU Directive (11/03/2003)
Seamus MacDermott	Clinical Trials Pharmacist	RDE	Advanced GCP and EU Directive (11/03/2003)
Carolyn Medicle			ICH GCP Training (01/12/2003)
Jill Melhuish	Haematology Research Nurse	RDE	Developing Practice Based on Users Experiences (04/08/2003) Research Methodology (23/10/2003)
Katy Munro		RCH	Peninsula Symposium (04/04/2003)
S. Natale	Associate Specialist In Urology	PHT	Peninsula Symposium (04/04/2003)
Kate O'Connor	Pharmacist	RDE	Are We Prepared to Be Legal? (12/12/2003) Advanced GCP and EU Directive (11/03/2003)
Michael O'Keefe	Research Nurse	RDE	Peninsula Symposium (04/04/2003) Training Link Meeting (10/07/2003)
Dr Melanie Osborne	Clinical Oncologist	RDE	Advanced GCP and EU Directive (11/03/2003)
Louise Paetz		SDH	Peninsula Symposium (04/04/2003)
Julie Pascoe	Oncology Research Nurse	PHT	ICH GCP Training (02/12/2003)
Andrew Pye	PhD Student Dermatology	RCH	ICH GCP Training (01/12/2003)
Christine Rawlings	Research Radiographer	SDH	Communication – Talking about Randomised Clinical Trials (08/03/2004), Peninsula Symposium (04/04/2003) Are We Prepared to Be Legal? (12/12/2003) Advanced ICH GCP (04/11/2003) Cancer Policy & Politics (02/12/2003)
Glyn Rees	Peninsula Cancer Research Network Manager	PCN	Are We Prepared to Be Legal? (12/12/2003) BODMA NCRN Conference (08/09/2003 – 09/09/2003) NTL Forum (26/11/2003)

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			RNM Professional Development Programme 09/12/2003 – 10/12/2003 EU Directive Training-SCOPE-Bristol-(18/09/2003)
Eileen Reid	Theatre Practitioner	RCH	ICH GCP Training (01/12/2003)
Suzi Reilly	CAMS Trial	PHT	ICH GCP Training (02/12/2003)
Claire Ridler	Cancer Clinical Trials Manager	RDE	Communication – Talking about Randomised Clinical Trials (08/03/2004) Are We Prepared to Be Legal? (12/12/2003) Cancer Policy & Politics (03/06/2003) National Briefing (23/10/2003) Research Methodology (23/10/2003) NTL Forum (26/11/2003) Roll out of Communication Issues to NTLs (28/01/2004-29/01/2004) Advanced GCP and EU Directive (11/03/2003) EU Directive Training-SCOPE-Bristol-(18/09/2003)
Pat Rimmer	Cancer Service Information Lead	RCH	Peninsula Symposium (04/04/2003)
Ann Rigby-Jones		RCH	ICH GCP Training (02/12/2003)
Fiona Roberts	Research Co-ordinator	SDH	Peninsula Symposium (04/04/2003) BODMA NCRN Conference (08/09/2003 – 09/09/2003) Advanced ICH GCP (04/11/2003) Are We Prepared to Be Legal? (12/12/2003) Communication – Talking about Randomised Clinical Trials (08/03/2004)
Dr.Claudius Rudin	Consultant Haematologist	RDE	Advanced GCP and EU Directive (11/03/2003)
Dr Nick Ryley	Consultant Histopathologist	SDH	Peninsula Symposium (04/04/2003)
Dr S. Sardesai	Consultant Physicist	RCH	Peninsula Symposium (04/04/2003)
Sophie Scrivener	Cancer Clinical Trials Facilitator	RCH	Peninsula Symposium (04/04/2003)
Liz Shailes	Cancer Services	RCH	Peninsula Symposium (04/04/2003)
Dr.Denise Sheehan	Clinical Oncologist	RDE	Advanced GCP and EU Directive (11/03/2003)
Dr. Srinivasan	Specialist Oncology Registrar	PHT	Advanced GCP and EU Directive (11/03/2003)
Tony Shute	Macmillan Team Leader	PHT	ICH GCP Training (02/12/2003)

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Nicky Sinclair	Vascular Research Nurse	RCH	ICH GCP Training (01/12/2003)
Johanna Skewes	Pharmacist	RCH	ICH GCP Training (01/12/2003)
Vanessa Smart		SDH	Peninsula Symposium (04/04/2003)
Elizabeth Stanley	Medical Research Sister	RCH	ICH GCP Training (01/12/2003)
Ian Stanley		RCH	ICH GCP Training (01/12/2003)
Kerstin Stepp	Staff Grade	RCH	Peninsula Symposium (04/04/2003)
Nicola Stephens	Oncology Pharmacist	PHT	Peninsula Symposium (04/04/2003)
Rita Stoneman			ICH GCP Training (02/12/2003)
Gale Sutton		PHT	Peninsula Symposium (04/04/2003)
Jan Taplin	Nurse Specialist - Upper GI	RCH	Peninsula Symposium (04/04/2003)
Lesley Teasdale	Haematology Research Sister	PHT	ICH GCP Training (02/12/2003)
Dr.Liz Toy	Clinical Oncologist	RDE/NDH	Advanced GCP and EU Directive (11/03/2003)
Dale Travis	Cancer Services Manager	RCH	Peninsula Symposium (04/04/2003)
Siobhan Tulley	Breast Care Specialist Nurse	SDH	ICH GCP Training (02/12/2003)
Dr.Chris Tyrrell	Clinical Oncologist	PHT	Advanced GCP and EU Directive (11/03/2003)
Gina Twine	Cardiology Research Co-Ordinator	PHT	ICH GCP Training (02/12/2003)
Lynne Van-Koutrick	Research Nurse	NDH	Research Methodology (23/10/2003) ICH GCP Training (01/12/2003) Cancer Policy & Politics (02/12/2003)
Lisa Vickers	Research & Development Manager	PHT	ICH GCP Training (02/12/2003)
Jane Vickery	CAMS Trial	PHT	ICH GCP Training (02/12/2003)
Clare Webb	Oncology Research Nurse	RDE	ICH GCP Training (02/12/2003)
Beverley Wells	Research Nurse	NDH	Peninsula Symposium (04/04/2003) Cancer Policy & Politics (03/06/2003) Developing Practice Based on Users Experiences (04/08/2003) Research Methodology (23/10/2003) Advanced GCP and EU Directive (11/03/2003)
Linda Welsh	Research Radiographer	RDE	Peninsula Symposium (04/04/2003)

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			Developing Practice Based on Users Experiences (04/08/2003)
Dr Duncan Wheatley	Consultant Clinical Oncologist	RCH	Peninsula Symposium (04/04/2003)
Suzanne Williams	Peninsula Cancer Research Network Sec.	PCN	Peninsula Symposium (04/04/2003)
Jenny Wingham	Cardiac Rehabilitation Research	RCH	ICH GCP Training (01/12/2003)
Prof. Tony Woolf		RCH	ICH GCP Training (01/12/2003)
Dr.You Yone	Staff Grade In Oncology	SDH	Advanced GCP and EU Directive (11/03/2003)

Good Clinical Practice Training(01/12/2003 & 02/12/2003)
An Introduction to GCP for Study Site Personnel

- 09.15 **Aims and Objectives of the Day**
Ice Breaker session
- 09.35 **Fundamentals of Good Clinical Practice**
History and development of GCP and ICH GCP
EU Directive and its implications for site staff
- 10.20 **Principles of Good Clinical Practice**
Practical implementation of the principles of ICH
Group Workshop: 'GCP jargon buster' quiz
- 11.00 Break
- 11.15 **Research Governance**
- 11.30 **Roles and Responsibilities in Clinical Research**
Ethics Committee - COREC and the changes to the ethics approval process
The Investigator - Investigator responsibilities
The Sponsor - Monitoring, data-management, and pharmacovigilance
- 12.30 Lunch
- 13.30 **Informed Consent**
Elements of the patient information sheet & consent form
Procedure for obtaining consent
Vulnerable groups and consent
Group discussion - Scenarios in consent
- 14.15 **Adverse Events**
Definitions of AEs, ADRs, SAEs and SUSARs
Reporting requirements - Current and future
Group Workshop - SAE exercise
- 15.00 Break
- 15.15 **Documentation and Audit**
Essentials Documents
Typical audit questions
- 16.00 **Grand Quiz and Prize Giving**
- 16.30 **Close**

About This Training Course:

This course provides an informal but extremely comprehensive overview of the fundamentals of Good Clinical Practice (GCP) and its implementation at the trial site.

The training is based on ICH GCP guidelines but also introduces the Directive 2001/20/EC on GCP in Clinical Trials, which will make GCP a legal requirement for both industry-sponsored and publicly funded studies alike.

Key learning points from each session will be consolidated through quizzes, discussion and workshop groups, using oncology based examples, to make the day both interactive and enjoyable.

Course Objectives:

- Understand the history and development of GCP
- Formulate strategies for implementing the principles of GCP at the trial site
- Be aware of the components of the Dept. of Health Research Governance Framework for Health and Social Care
- Be aware of COREC and the new ethics application process
- Define the main roles and responsibilities in clinical research
- Understand the requirements for informed consent and safety reporting
- Define an Essential Document and develop systems to improve clinical trial documentation and data quality at the trial site
- Be aware of the type questions an auditor could ask on each aspect of the trial process

Prepared by Tanya Symons
Training Consultant - T Symons Associates
August 2003

Peninsula Cancer Research Network Annual Progress Report: 1 April 2003-31 March 2004-Appendix
Agenda- Are We Prepared To Be Legal ?

Date: 12th December, 2003

Time: 09:30 hrs- 13:00 hrs

Venue: The White Hart Hotel, Fore Street, Okehampton, Devon.

09.30 Registration /Coffee and welcome

09:45 Aims and Objectives of the Day & Update On: Dept of Health and the MRC joint project
-“The implementation of the EU Clinical Trials Directive in the UK”.
Mr.Glyn Rees-Peninsula Cancer Research Network Manager

10:00 Feedback From MHRA Voluntary Audit At Velindre Hospital, Cardiff
Lucy Branston -Manager, Wales Cancer Trials Network

10:45 Discussion

11:00 Coffee

11:15 Feedback From ISO 9001:2000 Standard Audit-Oncology Clinical Trials Unit, Royal
Devon & Exeter Hospital.
Claire Ridler -Manager, Oncology Clinical Trials Unit, Royal Devon & Exeter Hospital.

11.45 Discussion

12:00 Update On Pharmacovigilance Issues & Pharmacists Perspective
Libby Hardy-Lead Pharmacist-Peninsula Cancer Network

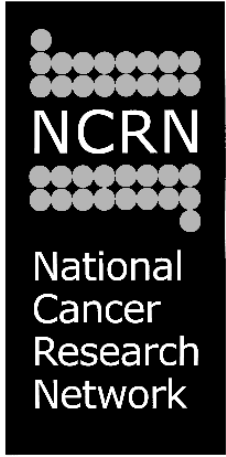
12:30 General Discussion-“The Way Forward”

13:00 Lunch

13.30 Close- (Nb.Peninsula Staff attending afternoon meeting R & D in Lifton will depart).

For Map Of Venue please see Website: www.okehamptondevon.co.uk/

Look in accommodation section under White Hart Hotel



NCRN Extended Programme: GCP and the EU Directive

Clinical Research Regulation

Date: 11th March 2004

Venue: Seminar Room,
RDSU,
Royal Devon & Exeter Hospital,
Barrack Road, Exeter

Aim: To provide the latest information on the new regulations contained within the EU Directive on GCP for Clinical Trials.

Course Objectives:

- To ensure delegates are familiar with the latest developments in Good Clinical Practice and understand the effects that EU Directive 2001/20/EC will have on current working practices within clinical research.
- To have an overview of the changes in the UK ethics review process (GAfREC) and look at the implications for investigators and sponsor companies.
- To understand the audit/inspection process and the importance of Mandatory Inspections that will commence in the UK at sponsor premises and investigational sites from May 2004.

NCRN courses are free of charge to all NCRN staff & members of the Clinical Research Team working on the NCRN portfolio of studies, however, late cancellation or failure to take up a pre-booked, confirmed place without giving the necessary notice (view Registration Procedure on www.ncrn.org.uk) will incur a charge to cover the NCRNs costs. Delegates will be personally liable

NCRN Extended Programme: GCP and the EU Directive: 11th March 2004	
Name:	Position:
	Tel:
Department:	
Contact	Fax:
Address:	Email:
Cancer Research Network:	
Your registration will be confirmed initially using the email address you provide.	
You will then receive further details by land mail to the contact address you provide above, about four weeks before the course PLEASE WRITE CLEARLY.	
Which NCRN trials are you working on?	
Authorised by Network Training Link (NTL)	
Signed:	Date:
Please return completed, NTL signed, registration forms ASAP to the address below: Registration forms returned by email will be accepted only from Network Training Links	or fax to 0113 392 4092

Alison Suckall, NCRN Coordinating Centre, Arthington House Cookridge Hospital, Leeds LS16 6QB

Peninsula Cancer Research Network Annual Progress Report: 1 April 2003-31 March 2004-Appendix Informed Consent To Clinical Trials-A Workshop For Health Care Professionals - NCRN Training Programme.

**09:15 Welcome & Introduction to the modules
Aims & Objectives of the day**

09:30 MODULE 1: COMMUNICATION ABOUT RCTS – COLLABORATION OR CONFLICT OF INTERESTS? (Suggested Session Time 1.5-2 hrs)

(This module deals with general issues surrounding the discussion and implementation of randomised clinical trials in the workplace. Clinicians, research nurses, trial managers and patients all make comments about the above with links between topic areas provided by Lesley Fallowfield.)

- Introduction To Module & Exercise 1
- Attitudes To Trials
- Uncertainty & The Doctor Patient Relationship

10:00 Pacing Information Giving & Exercise 2

-
- Describing Randomisation & Exercise 3

10:45 Coffee Break & Discussion

11:00 Time and Resource Issues

- Reasons Patients Take Part
- Patient Groups

12:00 Recap On Morning Session-General Discussion

12:30 **Lunch**

13:15 MODULE 2: DISCUSSING RCTS OF ADJUVANT THERAPY: DEALING WITH UNCERTAINTY (Suggested Session Time 1 hr)

This module illustrates some of the issues that may arise when discussing adjuvant treatment trials with essentially good prognosis patients. Both of the trials discussed in the module are “double blind” but the first scenario has the added difficulty of explaining a placebo arm.

Scenario ‘A’- The Victor Trial

- This first scenario provides an example of how the clinician and research nurse deal with uncertainty in a new patient who is suspicious and anxious about the reasons for being invited to participate in a trial.
-

Scenario ‘B’- The Intergroup Exemestance Trial

- In this second scenario we see a clinician handling the reintroduction of uncertainty in a patient 2 years post diagnosis who is well and getting on with her life.

14: 15 MODULE 4: DISCUSSING RCTS WITH PATIENTS WHO HAVE A PREFERENCE FOR ONE TREATMENT ARM (Suggested Session Time 1 hr)

Scenario ‘E’- The CLASICC Trial

- Scenario E concerns a trial involving a novel surgical technique.

14:45 **Afternoon Tea**

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15:00 Scenario 'F'- The MRC PRO7 Trial**

- Scenario F- shows a clinician handling a patient who has accumulated a great deal of information about his condition and possible treatment from the Internet and newspaper articles.

In this module, two patients who have clear preferences for specific treatment arms confront their clinicians

15:30 Recap Of Afternoon Session

15:45 Keypoints From The Day

16:00 Close

Alternative Schedule To Include Module 4

14: 15 MODULE 4: DISCUSSING RCTS WITH PATIENTS WHO HAVE A PREFERENCE FOR ONE TREATMENT ARM (Suggested Session Time 1 hr)

Scenario 'E'- The CLASICC Trial

- Scenario E concerns a trial involving a novel surgical technique.

14:45 **Afternoon Tea**

15:00 Scenario 'F'- The MRC PRO7 Trial

- Scenario F- shows a clinician handling a patient who has accumulated a great deal of information about his condition and possible treatment from the Internet and newspaper articles.

In this module, two patients who have clear preferences for specific treatment arms confront their clinicians

15:30 Recap Of Afternoon Session

15:45 Keypoints From The Day

16:00 Close

THE THIRD PENINSULA CANCER NETWORK

RESEARCH & DEVELOPMENT SYMPOSIUM
HEADLAND HOTEL, NEWQUAY, CORNWALL

4 APRIL 2003

Commences at 9.00 am – finishes at 3.30 pm

CME / PGEA approved

Dr Matthew Collinson Consultant Clinical Oncologist Royal Cornwall Hospitals Trust	- Introduction
Dr David Gould Consultant Dermatologist Royal Cornwall Hospitals Trust	- New lamps for old, arsenic, afternoon tea and old lace
Dr Darren Beech R&D/Trials Team Leader Royal Cornwall Hospitals Trust	- Current RCHT Cancer Clinical Trials
Dr Nigel Bailey Lead Clinician PCN Cancer Research Network	- Progress of the Peninsula Cancer Research Network
Ms Christine Rawlings Research Radiographer South Devon Healthcare Trust	- Current issues in BC 2001 Bladder Cancer Trial
Ms Erica Denholm Trial Co-ordinator Institute of Cancer Research	
Dr Ian Pedley Consultant Clinical Oncologist Newcastle General Hospital	- Recent Advances in Prostate Brachytherapy
Dr D Sharp Senior Lecturer in Behavioural Oncology Postgraduate Medical Institute University of Hull	- Behavioural Oncology: Psychosocial Factors in Cancer Treatment
Mr Tim Smit Chief Executive, Eden Project	- The Eden Project

This third Peninsula Cancer Research Symposium is open to all. Registration includes tea, coffee and lunch. **To register:** please send a cheque for £ 8.00 made payable to "Cancer Research Fund for Cornwall":

FAO: Suzanne Williams, Peninsula Cancer Network Secretary,
The Lescaze Office, Shinnars Bridge, Dartington, Totnes TQ9 6JE
Tel : 01803 861937 Fax : 01803 861853
e-mail suzanne.williams@sw-devon-ha.swest.nhs.uk

**THE 4TH PENINSULAR CANCER NETWORK
RESEARCH & DEVELOPMENT SYMPOSIUM (FINAL draft)
Friday 23RD APRIL 2004**

SAUNTON SANDS HOTEL, SAUNTON SANDS, NORTH DEVON

CME/PGEA approved

09.30	Coffee / Registration	
10.00	Dr Anne Hong Consultant Clinical Oncologist Royal Devon & Exeter Healthcare NHS Trust	Introduction & welcome
10.05	Dr Nigel Bailey Lead Clinician PCRN	Progress of the Peninsula Cancer Research Network
10.30	Professor Richard Begent NTRAC Lead Investigator Professor of Oncology, UCL	'On Track' - NTRAC National Translational Cancer Research Network
11.00	Coffee	
11.20	Dr Mark Napier Consultant Medical Oncologist Northern Devon & Royal Devon & Exeter Healthcare NHS Trusts	Colorectal Cancer – where we are now & where are we going?
11.45	Dr Peter Barrett-Lee Consultant Clinical Oncologist Velindre Hospital, Cardiff	Back to the future: the changing face of Breast Cancer treatment
12.15	Dr Phil Bryson Director, Hyperbaric Medical Centre DDRC, Plymouth	Research at the Diving Disease Research Centre
12.45	Lunch	
14.00	Jenny Day FORCE Cancer Support Specialist, Royal Devon & Exeter Healthcare Trust	Cancer patient support, information and Complementary therapies - your Centre
14.25	Dr Liz Toy Consultant Clinical Oncologist Royal Devon & Exeter & South Devon Healthcare Trusts	Lung Cancer Trials – where we are now & where are we going?
14.50	Dr Tim Habeshaw Senior Medical Adviser Roche	"A Message from the Dark-Side" - The Challenge of Oncology Trials – the role of Industry
15.15	Tea	
15.35	Gerry Gillespie, Cancer Support Specialist	'Out of Africa'
16.15	Close	

This 4th Peninsula Cancer Research Symposium is open to all. Registration includes tea, coffee and lunch. To register: please send a cheque for £8.00 made payable to 'FORCE' F.A.O: Suzanne Williams, Peninsula Cancer Network Secretary, The Lescaze Office, Shinnars Bridge, Dartington, Totnes TQ9 6JE Tel: 01803 861937 Fax: 01803 861853 e-mail: suzanne.williams@sw-devon-ha.swest.nhs.uk

**Peninsula Cancer Research Network Annual Progress Report: 1 April 2003-31 March 2004-
Appendix 3A & 3B**

Appendix 3A

<p>Dr. Nigel Bailey Clinical Lead for Cancer Research Torbay Hospital Lawes Bridge Torquay Tel : 01803 655052 (Sec – Helen) E-Mail : nigel.bailey@sdevonhc-tr.swest.nhs.uk</p> <p>Derriford Hospital Derriford Road Plymouth</p> <p>Tel : 01752 777111 (Sec – Charlotte) E-Mail : nigel.bailey@phnt.swest.nhs.uk</p>	<p>Glyn Rees Network Research Manager & Training Link Peninsula Cancer Network The Lescaze Offices Shinner's Bridge Dartington</p> <p>Tel : 01803 861980 Fax : 01803 861853 E-Mail : glyn.rees@sw-devon-ha.swest.nhs.uk</p>
<p>Suzanne Williams Peninsula Cancer Network Secretary Peninsula Cancer Network The Lescaze Offices Shinner's Bridge Dartington</p> <p>Tel : 01803 861937 Fax : 01803 861853 E-Mail : suzanne.williams@sw-devon-ha.swest.nhs.uk</p>	<p>Claire Ridler Clinical Research Manager & Training Link Rooms S142-144 Cherrybrook Unit Royal Devon & Exeter Healthcare NHS Trust Royal Devon & Exeter Hospital Barrack Road Exeter</p> <p>Tel : 01392 402867 Fax : 01392 402112 E-Mail : claire.ridler@rdehc-tr.swest.nhs.uk</p>

Appendix 3B

<p>Dr, Martin Cooper Cancer Network Lead Clinician Peninsula Cancer Network The Lescaze Offices Shinner's Bridge Dartington</p> <p>Tel : 01803 861840 Fax : 01803 861853 E-Mail : martin.cooper@rdehc-tr.swest.nhs.uk</p>	<p>Ms.Sara Aspley Cancer Network Manager Peninsula Cancer Network The Lescaze Offices Shinner's Bridge Dartington</p> <p>Tel : 01803 861980 Fax : 01803 861853 E-Mail : glyn.rees@sw-devon-ha.swest.nhs.uk</p>
<p>Mrs.Sue Bulley Cancer Network Nurse Director Peninsula Cancer Network The Lescaze Offices Shinner's Bridge Dartington</p> <p>Tel : 01803 861908 Fax : 01803 861853 E-Mail : sue.bulley@sw-devon-ha.swest.nhs.uk</p>	<p>Dr.Chris Bowman, Primary Care Cancer Lead C/O Chulmleigh Health Centre, Chulmleigh Devon</p> <p>Tel : 01769 580269 Fax : 01769 581045 E-Mail : Christopher.Bowman@gp-L83025.nhs.uk</p>

**Peninsula Cancer Research Network Annual Progress Report: 1 April 2003-31 March 2004-
Appendix**

Appendix 3C

Cancer Site/Area	Name	Hospital
Bladder Cancer	Mr.Richard Pocock	Royal Devon & Exeter Foundation Trust
Brain Cancer	Mr.Stephen Kelly	Plymouth Hospitals NHS Trust
Breast Cancer	Mr.Roger Watkins	Plymouth Hospitals NHS Trust
Colorectal Cancer	Mr.Rupert Pullan	South Devon Healthcare NHS Trust
Gynaecological Cancer	Mr.Tony Falconer	Plymouth Hospitals NHS Trust
Haematological Oncology	Dr.Simon Rule	Plymouth Hospitals NHS Trust
Head & Neck Cancer	Mr.Andrew Brightwell	Royal Devon & Exeter Foundation Trust
Lung Cancer	Mr.Michael Oliver	North Devon Healthcare NHS Trust
Lymphoma	Dr.Simon Rule	Plymouth Hospitals NHS Trust
Melanoma	Dr.Tom Lucke	Royal Cornwall Hospital NHS Trust
Prostate Cancer	Mr.Richard Pocock	Royal Devon & Exeter Foundation Trust
Renal Cancer	Mr.Richard Pocock	Royal Devon & Exeter Foundation Trust
Radiotherapy	Dr.Peter Bliss	Royal Devon & Exeter Foundation Trust
Sarcoma	Dr.Francis Daniel	Plymouth Hospitals NHS Trust
Testis Cancer	Mr.Richard Pocock	Royal Devon & Exeter Foundation Trust
Upper GI Cancer	Mr.Martin Cooper	Royal Devon & Exeter Foundation Trust
Primary Care Cancer	Dr Chris Bowman	North Devon PCT,C/o Chulmleigh Health Centre
Palliative Care	Dr Richard Scheffer	Rowcroft Hospice,Torquay
Psychosocial Oncology	Not Known	

Nb. The contacts given above are the Chair's of the respective site specific groups. Current contact details can be found on www.pcn.nhs.uk

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Appendix 3D

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<u>Clinical Studies Group</u>	<u>Trial Title</u>	Local Participation		
		In Setup	Open	In follow-Up
All Sites	Antifungal Drug Resistance Study An investigation into the relationship between antifungal drug use, salivary gland dysfunction and antifungal drug resistance in patients with advanced cancer - Phase 1 (Observational Study)		HHs HsCE LaHs MEHs NDHs RHsT SLHs TrHs	
All Sites	SIGNIFICANT A Randomised prospective double-blind, placebo controlled trial of prophylactic oral levofloxacin following chemotherapy for lymphoma and solid tumours.			PHT RCH RDE SDH
All Sites	WARP A multicentre, prospective, randomised, controlled trial of thrombosis prophylaxis with warfarin in cancer patients with central venous catheters		PHT NDH RDE	
Bladder	BA11 Randomised phase III study comparing Paclitaxel/Cisplatin/Gemcitabine and Cisplatin/Gemcitabine in patients with metastatic or locally advanced urothelial cancer without prior systemic therapy [EORTC 30987]	PHT	SDH	
Bladder	BC2001 2x2 Factorial Randomised Phase III Study comparing Standard versus Reduced Volume Radiotherapy with and without synchronous Chemotherapy in Muscle Invasive Bladder Cancer		RDE SDH	
Bladder	BS06 A Randomised Study of Radical Radiotherapy in the Management of pT1G3 NxM0 Transitional Cell Carcinoma of the Bladder			SDH
Bladder	EORTC 30994 Randomized phase III trial comparing immediate versus deferred chemotherapy after radical cystectomy in patients with pT3-pT4, and/or N+M0 transitional cell carcinoma (TCC) of the bladder	PHT		
Brain	BR12 Temozolomide vs PCV/BCNU in astrocytoma	PHT SDH	RCH RDE	
Breast	aTTom A Large, Uniquely Simple, Randomised Study to Assess Much More Reliably the Balance of Benefits and Risks of Prolonging Adjuvant Tamoxifen Treatment in Early Breast Cancer		PHT NDH RCH RDE SDH	
Breast	AZURE Does Adjuvant Zoledronic Acid Reduce Recurrence in Patients with High Risk Localised Breast Cancer	PHT NDH RDE SDH		
Breast	DEVA A multicentre randomised trial of sequential epirubicin and docetaxel vs epirubicin in node +ve postmenopausal breast cancer	RCH SDH	PHT	
Breast	FH01 - HTA Mammography Trial Evaluation of mammographic surveillance services in women under 50 with a family history of breast cancer	RCH		
Breast	HERA - recommended Trial of 1 vs 2 years of Herceptin vs no Herceptin in Women with HER2-positive primary breast cancer who have completed adjuvant chemotherapy		RDE SDH	

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Breast	HRT UK Randomised Trial of Hormone Replacement Therapy (HRT) in Women with a History of Early Stage Breast Cancer	SDH	RDE	
Breast	IBIS-II An international multicentre study of Anastrozole vs Placebo in Postmenopausal Women at Increased Risk of Breast Cancer. and also An international multicentre study of Anastrozole vs Tamoxifen in Postmenopausal Women with Ductal carcinoma in Situ (DCIS)		RCH	
Breast	MATCH Attitudes of Men with Breast Cancer in the United Kingdom			PHT RCH RDE
Breast	NEAT National Breast Cancer Study of Epirubicin plus CMF versus Classical CMF Adjuvant Therapy (NEAT)			NDH SDH
Breast	POSH Prospective study of Outcomes of treatment in Hereditary versus Sporadic breast cancer	SDH	NDH RCH RDE	
Breast	PRIME The PRIME breast cancer trial (postoperative radiotherapy in minimum-risk elderly)		PHT RDE SDH	
Breast	SECRAB Sequencing of Chemotherapy and Radiotherapy in Adjuvant Breast Cancer			RDE SDH
Breast	START Standardisation of Breast Radiotherapy (START) Trial			PHT RDE SDH
Breast	TACT A randomised trial of standard anthracycline-based chemotherapy with fluorouracil, epirubicin and cyclophosphamide (FEC) or Epirubicin and CMF (Epi-CMF) vs FEC followed by sequential docetaxel as adjuvant treatment for women with early breast cancer			PHT NDH RDE SDH
Breast	tAnGo A Phase III randomised trial of gemcitabine in paclitaxel-containing, epirubicin based adjuvant chemotherapy for women with early stage breast cancer.		PHT NDH RDE SDH	
Breast	TEAM An open label, randomised multicentre comparative trial of 5 years adjuvant Exemestane treatment versus 5 years adjuvant tamoxifen treatment in postmenopausal women with early breast cancer.			PHT NDH RCH RDE SDH
Breast	Will Weekly Win A randomised 2-arm, prospective, multi-centre, open-label Phase III trial comparing the activity and safety of a weekly versus a 3 weekly Paclitaxel treatment schedule in patients with advanced or metastatic breast cancer	RDE	RCH SDH	
Colorectal	ACT II A Second UK Phase III Anal Cancer Trial: A Trial of Chemoradiation and Maintenance Therapy for Patients with Anal Cancer	SDH	PHT RCH RDE	
Colorectal	CLOCC Randomised phase III study of the local treatment of liver metastases by radiofrequency combined with chemotherapy versus chemotherapy alone in patients with colorectal liver metastases.	RDE		
Colorectal	CR07 A Randomised Trial Comparing Pre-Operative Radiotherapy and Selective Post-Operative Chemoradiotherapy in Rectal Cancer		RDE	
Colorectal	FACS A randomised controlled trial to assess the cost-effectiveness of intensive versus no scheduled follow-up in patients who have undergone resection for colorectal cancer with curative intent		SDH	
Colorectal	FOCUS A randomised trial to assess the role of irinotecan and oxaliplatin in advanced colorectal cancer			PHT RCH

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				RDE SDH
Colorectal	FOCUS2 Drug treatment for bowel cancer: making the best choices when a milder treatment is needed.	SDH		
Colorectal	Genetic Factors in Colorectal Cancer The role of genetic factors in clinical outcome for colorectal cancer patients	RDE		
Colorectal	NSCCG National Study of Colorectal Cancer Genetics	SDH	NDH RCH RDE	
Colorectal	QUASAR Quick and Simple and Reliable A Study of Colorectal Cancer Treatment			RDE SDH
Colorectal	VICTOR Phase III randomised double-blind placebo controlled study of rofecoxib (VIOXX) in colorectal cancer patients following potentially curable therapy.		PHT NDH RCH RDE SDH	
Gynaecological	ASTECA A Randomised Trial of Lymphadenectomy and of adjuvant External beam Radiotherapy in the Treatment of Endometrial Cancer		PHT	
Gynaecological	ICON5 An international, 5-arm randomised trial of paclitaxel and carboplatin v triplet or sequential doublet combinations in patients with epithelial ovarian or primary peritoneal carcinoma.		PHT NDH RDE SDH	
Gynaecological	OV05 A Randomised Trial in Relapsed Ovarian Cancer: Early Treatment Based on CA 125 Levels Alone versus Delayed Treatment Based on Conventional Clinical Indicators.		SDH	
Gynaecological	UKFOCSS The UK Familial Ovarian Cancer Screening Study		SDH	
Haematological	AML 12 AD AML12 MEDICAL RESEARCH COUNCIL WORKING PARTY ON LEUKAEMIA IN ADULTS ACUTE MYELOID LEUKAEMIA TRIAL 12			PHT RCH RDE SDH
Haematological	AML 12 CH AML12 MEDICAL RESEARCH COUNCIL WORKING PARTY ON LEUKAEMIA IN CHILDHOOD ACUTE MYELOID LEUKAEMIA TRIAL 12			RDE
Haematological	AML 14 A Randomised Trial for Patients with Acute Myeloid Leukaemia or High Risk Myelodysplastic Syndrome Aged 60 or over.	RCH	PHT RDE SDH	
Haematological	AML 15 MEDICAL RESEARCH COUNCIL WORKING PARTIES ON LEUKAEMIA IN ADULTS AND CHILDREN. ACUTE MYELOID LEUKAEMIA TRIAL 15		PHT NDH RCH RDE SDH	
Haematological	LRF CLL4 (MRC Working party on Leukaemia in Adults) Chronic Lymphocytic Leukaemia trial 4: A Randomised Comparison of Chlorambucil ,Fludarabine and Fludarabine plus Cyclophosphamide		PHT NDH RCH RDE SDH	
Haematological	MRC AML-HR Protocol for patients with high risk (resistant, refractory, relapsed or adverse cytogenetic) AML			PHT RCH RDE SDH
Haematological	MRC CLL5 THE VALUE OF AUTOGRAFTING YOUNGER PATIENTS WITH HIGH RISK CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL). A		RCH SDH	

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	RANDOMISED PHASE III INTERGROUP TRIAL			
Haematological	MRC CML V A Medical Research Council Prospective Randomised Study to Compare Low-Dose Interferon-Alpha n1 (Welferon) Against High-Dose Interferon-Alpha n1 in Patients with Newly Diagnosed Chronic Phase Myeloid Leukaemia			SDH
Haematological	MRC Myeloma IX Myelomatosis therapy trial for patients of all ages. A randomised trial comparing second generation vs third generation bisphosphonates, induction chemotherapy regimens (CVAD vs CTD, and MP vs CTDa) and thalidomide maintenance vs no maintenance therapy.	RCH	RDE SDH	
Haematological	MRC PT1 A Medical Research Council Randomised Trial to Compare Aspirin versus Hydroxyurea/Aspirin in Intermediate Risk Primary Thrombocythaemia and Hydroxyurea/Aspirin versus Anagrelide/Aspirin in High Risk Primary Thrombocythaemia		PHT RCH RDE SDH	
Haematological	MRC UKALL XII Medical Research Council Trial for Adult Patients with Acute Lymphoblastic Leukaemia Under 56 years of Age. To compare related donor transplant versus autologous transplant versus chemotherapy.		PHT RCH RDE SDH	
Lung	BLT A randomised trial of cisplatin-based chemotherapy for patients with all stages of non-small cell lung cancer.			PHT NDH RDE SDH
Lung	GELCAPS Genetic Lung Cancer Predisposition Study: a molecular epidemiology study		PHT NDH RCH RDE SDH	
Lung	GRIN A Phase III Study of Radical Radiotherapy with or without Gemcitabine in Patients with T1-2 N0-1 M0 Non-Small Cell Lung Cancer		RDE SDH	
Lung	INCH A randomised phase II/III trial of induction chemotherapy followed by Continuous Hyperfractionated Accelerated Radiotherapy (CHART) versus CHART alone in patients with inoperable non-small cell lung cancer.	RDE SDH		
Lung	Julian Peto's Mesothelioma and Lung Cancer Study (MALCS) A POPULATION BASED CASE-CONTROL STUDY OF MESOTHELIOMA AND LUNG CANCER IN RELATION TO OCCUPATION AMONG BRITISH MEN AND WOMEN UNDER THE AGE OF 60		PHT NDH RCH RDE SDH	
Lung	LLCG Study 10 A Phase III randomised comparison of gemcitabine/carboplatin with cisplatin/etoposide in small cell lung cancer			NDH RDE SDH
Lung	LLCG Study 11 A Phase III randomised comparison of Gemcitabine/Carboplatin (GC) with Mitomycin/Ifosfamide/Cisplatin (MIC) in non-small cell lung cancer (NSCLC)			NDH RDE SDH
Lung	LLCG Study 12 Study 12 - A phase III Randomised, Double-blind, Placebo Controlled Trial of Carboplatin/Etoposide with or without Thalidomide in Small Cell Lung Cancer.		PHT NDH RDE SDH	
Lung	LLCG Study 14 A Phase II/III Randomised, Double Blind, Placebo Controlled Trial of Gemcitabine/ Carboplatin with or without Thalidomide in Advanced Non-Small Cell Lung Cancer .		NDH RDE SDH	
Lung	LU22 A Randomised Trial of Surgical Resection With or Without Pre-Operative Chemotherapy in Patients With Operable Non-Small Cell Lung Cancer (NSCLC) of any Stage		PHT NDH RCH RDE	

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			SDH	
Lung	MESO-1 Randomised feasibility study of active symptom control with or without chemotherapy in the treatment of patients with mesothelioma			PHT NDH RDE SDH
Lung	MS-01 A randomised controlled trial of active symptom control with or without chemotherapy in the treatment of patients with malignant pleural mesothelioma		PHT NDH RDE SDH	
Lymphoma	BNLI 60+ A phase III trial comparing CHOP to PMItCEBO with or without G-CSF in patients aged 60 plus with aggressive non-Hodgkin's lymphoma.		RDE SDH	
Lymphoma	BNLI MCD vs FMD BNLI RCT of MCD vs FMD in follicular NHL		PHT RCH RDE SDH	
Lymphoma	BNLI Radiation Dose BNLI Randomised trial of radiation dose in non-Hodgkin's lymphoma		RCH RDE SDH	
Lymphoma	BNLI Stanford V Protocol for a randomised phase III study of the Stanford V regimen, compared with ABVD for the treatment of advanced Hodgkin's disease		PHT RCH RDE SDH	
Lymphoma	EBMT-LYM1 Randomised Study of Rituximab (MabThera) in Patients with Relapsed or Resistant Follicular Lymphoma Prior to High Dose Therapy as in Vivo Purging and to Maintain Remission Following High Dose Therapy		RDE	
Lymphoma	EORTC 20981 Chimeric anti-CD20 monoclonal antibody (Mabthera*) in remission induction and maintenance treatment of relapsed follicular non-Hodgkin's lymphoma : a phase III randomised clinical trial - Intergroup Collaborative Study (EORTC 20981) Including Amendment 4		RDE SDH	
Lymphoma	LY10 A clinicopathological study in Burkitt's and Burkitt-like non-Hodgkin's Lymphoma.		PHT RCH RDE SDH	
Lymphoma	MISTRAL A randomised phase III trial of standard chemotherapy (CHOP regimen) versus sequential high-dose chemotherapy with autologous stem cell transplantation in patients with newly diagnosed aggressive Non-Hodgkin's lymphomas and poor prognostic factors		SDH	
Lymphoma	NCRI Mantle Cell Lymphoma Trial Phase II randomised study of fludarabine/ cyclophosphamide combinaton with or without Rituximab in patients with untreated mantle cell lymphoma		PHT NDH RCH RDE SDH	
Lymphoma	Waldenstrom's study Randomised trial of Chlorambucil vs Fludarabine as initial therapy of Waldenströms's macroglobulinaemia & splenic lymphoma with villous lymphocytes	RDE	PHT SDH	
Melanoma	EORTC 18991 TRIAL 18991 ADJUVANT PEG-INTRON TREATMENT IN STAGE III MELANOMA versus OBSERVATION AFTER REGIONAL LYMPH NODE DISSECTION A Multicenter Randomized Phase III trial			RDE
Prostate	Familial prostate cancer study Familial Prostate Cancer: Epidemiology and Molecular Studies. The Cancer Research UK/British Prostate Group UK Familial Prostate Cancer Study	NDH	PHT RCH RDE TDH SDH	

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Prostate	Intercontinental INTERmittent or CONTINuos ENdocrine Therapy After failure in Localised prostate cancer.	NDHs SDH		
Prostate	PR07 A Randomised trial of Hormone Therapy plus Radical radiotherapy versus Hormone Therapy alone in Non-Metastatic Prostate Cancer	PHT	RCH RDE SDH	
Prostate	TAPS Targeted PSA screening for familial prostate cancer	SDH	PHT NDH RCH RDE	
Radiotherapy	RIB A multicentre randomised trial of single dose Radiotherapy compared to Ibandronate for localised metastatic Bone pain	PHT	NDH RDE	
Renal	EORTC 30955 Adjuvant Interleukin-2, Interferon-Alpha and 5-Fluorouracil for Patients with high risk of relapse after surgical treatment for Renal Cell Carcinoma		RDE	
Renal	RE04 A randomised trial of interferon-alpha , interleukin-2 and 5-fluorouracil versus interferon-alpha alone in advanced renal cell cancer.		RDE SDH	
Sarcoma	EORTC 62931 Randomized phase III trial of adjuvant chemotherapy with high-dose doxorubicin, ifosfamide and lenograstim in high grade soft tissue sarcoma.			RDE
Testis	Familial TGCT Identification and molecular analyses of families with susceptibility to Testicular Germ Cell Tumour Cancer	RDE		
Testis	TE08 A randomised Trial of Two CT Scans Versus Five CT Scans in the Surveillance of Patients with Stage I Teratoma of the Testis			RDE
Testis	TE22 A study of 18-FDG PET in the prediction of relapse in patients with a clinical stage I non-seminomatous germ cell tumour		RDE	
Upper GI	ESPAC-3(v2) Phase III Adjuvant Trial in Pancreatic Cancer Comparing 5FU and D-L-Folinic Acid vs. Gemcitabine		PHT NDH RDE SDH	
Upper GI	GEMCAP A phase III multicentre randomised clinical trial comparing gemcitabine alone or in combination with capecitabine for the treatment of patients with advanced pancreatic cancer	SDH	PHT NDH RCH RDE	
Upper GI	MAGIC A Randomised, Controlled Trial of Pre- and Post-Operative Chemotherapy in Patients with Operable Gastric Cancer			PHT NDH
Upper GI	REAL 2 A phase II/III randomised trial coparing Epirubicin, Cisplatin & Protracted Venous Infusion (PVI) 5-Fluorouracil (ECF) with Epirubicin, Oxaliplatin & PVI 5-FU (EEF), Epirubicin, Cisplatin and Capecitabine (ECX) with Epirubicin, Oxaliplatin & Capecitabine		PHT NDH RCH RDE	