



# NIHR Pan Birmingham Cancer Research Network

## ANNUAL REPORT April 2009 – March 2010





## National Institute for Health Research

### Pan Birmingham Cancer Research Network

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Dear Reader

This Annual Report forms part of the performance management process by the National Cancer Research Network (NCRN) Coordinating Centre of the Pan Birmingham Cancer Research Network. It also serves a local purpose in keeping you, our stakeholders, up to date about the activities of the Cancer Research Network. The aim of the report is to evaluate the Network's progress and performance against the national requirements and local objectives and goals.

Together with our Work Programme and Constitution, it is also a tool for documenting our compliance with the standards laid down in the Manual of Cancer Standards for Research Networks and demonstrates:

- That we are a properly constituted and functioning cancer research network
- That we have effective processes in place for evaluating participation in clinical trials and other well designed studies across this network and identifying points for improvement
- That we have effective processes for engaging with our Cancer Network to highlight priorities and barriers/challenges to the delivery of good quality research

Copies of the Network Constitution and Work Programme are available from the Research Network Office or the Cancer Network website.

For the first time there has been recruitment to studies in every tumour site with recruitment to adult brain tumour studies. There was also recruitment into the palliative care portfolio for the first time.

Recruitment to randomised controlled trials has increased for the fourth year to 6.8% of cancer diagnoses equivalent. Overall recruitment increased significantly.

To date, the total number of people with cancer or a pre-malignancy who have given their consent to participate in NCRN portfolio studies since 2001 is 8237; a further 6500 volunteers have participated in screening and prevention studies.

For all Trusts in the Network the cancer portfolio forms a significant contribution towards their National Institute for Health Research (NIHR) activities. As such it forms an important part of ensuring that Trusts continue to receive R&D funding.

This report details the activities of the Trusts and the Network over the last 12 months which have contributed to the achievements above. Our plans for the coming years can be found in the separate Work Programme.

As always, we welcome your comments and, if you require any information, please do not hesitate to contact us.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Dan Ford'.

Dr. Daniel Ford  
Clinical Lead

A handwritten signature in black ink, appearing to read 'Gina Dutton'.

Mrs. Gina Dutton  
Manager

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## Executive Summary

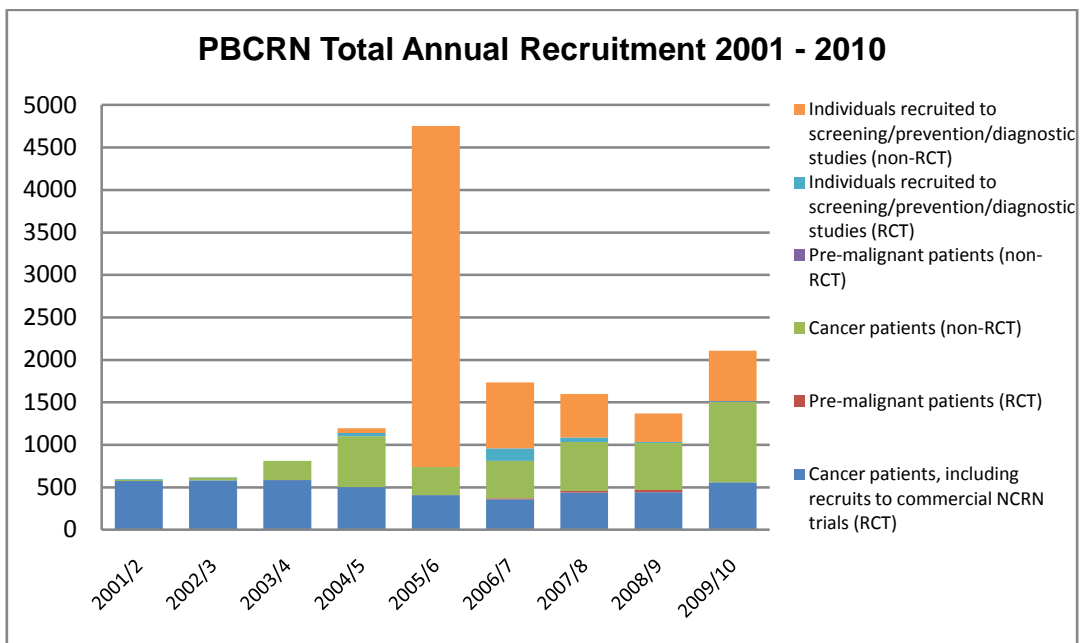
### Key achievements of the Network during 2009/10

Pan Birmingham Cancer Research Network (PBCRN) has, for the first time, recruited to studies within every tumour specific clinical studies group, which is a major achievement. There was recruitment of patients with cancer or a pre-malignant condition to 104 different studies. There were 11 National Institute for Health Research (NIHR) portfolio industry studies open to recruitment during the year. Recruitment occurred for the first time into the adult brain and palliative care portfolios. A further 27 studies were open to recruitment but did not recruit any patients. Many of these studies were in uncommon subgroups of patients or rare cancers where numbers of patients are expected to be small, such as paediatrics and haematology and, therefore, zero recruitment is not unexpected. These studies represent an important part of the portfolio.

To date more than 8230 patients with cancer or a pre-malignancy have been recruited into National Cancer Research Network (NCRN) portfolio clinical trials and other well designed studies since 2001 in Pan Birmingham Trusts. A further 6500 volunteers have also participated in screening and prevention studies. This represents a significant accomplishment for all of the staff that have contributed to this success.

Randomised controlled trial (RCT) recruitment of patients with cancer or a pre-malignancy, increased to 6.8% from 5.6% in the previous year with 560 patients agreeing to participate, including 36 participants in the NIHR commercial portfolio. This is the fourth consecutive increase in recruitment for the Network.

**Figure 1: Pan Birmingham Cancer Research Network Total Annual Recruitment to NIHR Portfolio studies 2001 - 2010**



Overall recruitment was 18.2% compared with 12.3% in the previous year. This significant increase was largely a result of a single study in the colorectal portfolio which has now closed. When adjustment is made to remove this study, recruitment to non-RCT studies has increased by 23%.

A total of 2047 participants were recruited into all NIHR cancer portfolio studies, including 537 participants recruited to screening, prevention and diagnostic studies. 59 patients with cancer were recruited into optional bolt-on studies to treatment trials.

At least 80 non-medical staff, 63.3 whole time equivalent (wte), support cancer research across Pan Birmingham; 29 individuals, 21 wte which receive PBCRN funding, including the core team. That is, approximately 33% of the workforce is PBCRN funded. The other funding sources are a mixture of Birmingham and Black Country Local Comprehensive Research Network (BBC CLRN), other NIHR funding streams, Childhood Cancer and Leukaemia Group (CCLG), research grants, charitable and commercial funds. BCC CLRN fund approximately 28% of the workforce.

All staff regardless of funding stream can attend PBCRN training events and access training by the Lead Nurse and/or Research Network Manager (RNM), as well as training delivered by Birmingham Research Training Collaborative.

Researchers can access the Pan Birmingham Cancer Network User Partnership via the RNM. During 2009/10 the User Partnership members provided valuable input into key documents for one study.

There have been a number of initiatives across the Network, many of which have been Trust instigated. These include the employment of Research Coordinators in the three big Trusts, who are now the point of contact for all studies involving imaging. This is particularly useful for NIHR industry trials, when the imaging schedule may be very different to standard UK practice and image transfer is required. At University Hospital Birmingham NHS Foundation Trust, the Cancer Research Facilitation Group, which is made up of research support teams and the service departments, is working well and significantly reducing the time taken to open studies, as well as providing a co-ordinated approach to the portfolio. At Heart of England NHS Foundation Trust a procedure has been established in Imaging to allow the cancer research nurses to request study protocol imaging examinations, including those covered by IR(ME)R. This has improved the quality of the requests and ensured that study specific tests and reports are completed in a timely manner. They are also piloting electronic alerts for trials patients to ensure that research staff are made aware of admissions and improve serious adverse event reporting. At Sandwell and West Birmingham Hospitals NHS Trust, the Cancer Management have ensured that research is embedded into their cancer strategy and MDTs are required to report their research activity as part of their regular report to the Trust Cancer Locality Executive Group meeting. Many more examples can be found in the Trust reports.

### **Key priorities for the Network for 2010/11 and beyond**

The key drivers for the next few years are portfolio balance and delivery, including recruitment performance, commercial trials and measuring impact. PBCRN will be appointing an Operations Manager to lead this work which will include supporting Trusts to initially collate forecasts, monitor against forecast and ultimately to improve forecasting and, therefore, improve feasibility information.

The other key priority is ensuring that Trusts have appropriate funding for their portfolios. this includes service support from both Pan Birmingham Cancer Research Network and Birmingham and Black Country Comprehensive Research Network, and that the funding allocated is used appropriately, affording value for money; as well as continuing to be able to access treatment and excess treatment costs via good relationships with the Commissioners.

## **1 Organisation and Development of Network**

Pan Birmingham Cancer Research Network (PBCRN) was established in 2002. It is a geographically small Network and serves a population of 1.94 million people in the Birmingham and Black Country Conurbation. It is an integral part of the Pan Birmingham Cancer (Service) Network, working closely with the Network Groups to integrate research into standard care.

The Network includes seven acute Trusts, four of which provide district general hospital (DGH) services to their local populations. One of these, University Hospital Birmingham NHS Foundation Trust (UHBFT) hosts the Cancer Centre which provides radiotherapy services for the Network and surrounding areas. University Hospital Birmingham NHS Foundation Trust and Heart of England NHS Foundation Trust (HEFT) provide tertiary level services for haematology and some surgical specialities.

The Network also has three specialist Trusts providing tertiary services in paediatrics, orthopaedics and obstetrics and gynaecology.

Trusts in Pan Birmingham have a long history of participation in cancer research pre-dating the NCRN, recruiting large numbers of patients into breast, colorectal, haematology and paediatric trials, in particular. There are two Experimental Cancer Medicine Centres (ECMC) based at University Hospital Birmingham NHS Foundation Trust and Birmingham Children's Hospital NHS Foundation Trust (BCHFT). Both institutions also have Wellcome Trust Clinical Research Facilities (WTCRF).

Although not coterminous with, Pan Birmingham Cancer Research Network is contained within Birmingham and the Black Country Comprehensive Local Research Network (BBC CLRN).

PBCRN predominantly operates a devolved model, whereby Trusts are allocated funding and have autonomy to employ the staffing that they think are most appropriate and have direct control over the portfolio which is open within their Trust. In most Trusts, staff are line managed within Cancer Services. In Heart of England NHS Foundation Trust, research nurses are employed and line managed by the Research and Development Department (R&D). At the end of March 2010, the solid tumour team at Sandwell and West Birmingham Hospital NHS Trust (SWBHT) moved line management from Cancer Services to R&D. Line management generally reflects initial decisions made by Trust Chief Executives regarding who would represent the Trust for the Network.

Each Trust has a Trust-nominated Cancer Research Lead, who is responsible for attending the Research Committee and meeting the requirements of the Service Level Agreement (SLA).

Appendix 1 provides a summary of Network information, recruitment and the abbreviations used for Trusts in the Network.

## **1.1 Overview of staffing profile**

Pan Birmingham Cancer Research Network has a small central core team who provide support for Trust based staff, Investigators, Multi-disciplinary Teams (MDTs) and Network Site Specific Groups (NSSGs). The total establishment of the core team is presently 3.78 whole time equivalent (wte). During 2009/10 a case was successfully made to the Research Committee for the expansion of the core team to include one whole time equivalent (wte) Operations and Development Manager. The post should be filled in the first half of 2010/11. Funding for this post will come from displacing two Trust based posts to be funded by BBC CLRN. Following the resignation of the Network Data Manager, the requirement for this post was re-evaluated, which is standard practice for all PBCRN funded posts. A decision was made to move the post into the core team's host organisation, South Birmingham PCT. The reason for this was largely to have greater control over appointment and obtaining honorary contracts/letters of access, which have been a problem in the past.

All Trusts within the Network receive funding from PBCRN. In quarter 3 of 2009/10, all Trusts were asked to provide information on all staff supporting cancer research regardless of funding stream. A total of 80 staff, 63.3 wte, support cancer research; 29 individuals, 21.0 wte which receive PBCRN funding, including the core team. This equates to 33 percent of the total wte. The other funding sources are a mixture of BBC CLRN, ECMC, Childhood Cancer and Leukaemia Group (CCLG), research grants, charitable and commercial funds. Trusts indicated that 25 individuals, approximately 18 wte or 28%, were wholly or in part funded by BBC CLRN. Nine posts were funded from Flexibility and Sustainability Funding (FSF) during 2009/10.

Several Trusts reported delays in replacing staff or making new appointments, these were predominantly for two reasons. Firstly, protracted HR processes exacerbated by the current financial climate; this was resolved by multiple letters from the Research Network Manager (RNM) to relevant senior management. A timeline expectation has also been written into Service Level Agreements (SLAs) to try and prevent this problem in the future. The second reason is the shortage of trained research nurses and the number of work opportunities across all diseases, not just cancer. The PBCRN Lead Nurse led a local initiative including senior nurses from the non-specialist Trusts to try and work to resolve this. This work is ongoing.

## **1.2 Workforce Development**

The Pan Birmingham Cancer Research Network Lead Nurse, Jackie Sears, is responsible for training and development and the post combines both clinical research and Network Training Link<sup>1</sup> responsibilities. All research staff, regardless of their funding stream, have access to training and support as required. This can involve one to one training sessions with the Network Training Link and/or Research Network Manager or attending events organised by the Cancer Research Network. PBCRN organises three events per year, which are a mixture of training and business meetings.

During 2009/10, PBCRN has revised its Induction Handbook, which will be available for distribution shortly.

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<sup>1</sup> The Training Link is a title given to the person with responsibility for training and development in Cancer Research Networks.

### *Birmingham Research Training Collaborative*

Pan Birmingham Cancer Research Network benefits from being part of the Birmingham Research Training Collaborative (BRTC), which was founded in 2004, and takes its membership from Research and Development personnel from all the acute NHS Trusts in Birmingham and Walsall; the Cancer Research UK Clinical Trials Unit, the School of Primary Care Clinical Sciences (University of Birmingham), the Wellcome Trust Clinical Research Facility (UHBFT), Birmingham Clinical Research Academy and the Birmingham and the Black Country Comprehensive Local Research Network, which includes a consortium of Primary Care Trusts in Birmingham and Solihull. The BRTC continues to provide regular training seminars for all researchers employed by the members of the Collaborative. As BBC CLRN serves a wider geographical area, including acute, primary care and mental health trusts in Dudley, access to BRTC courses has been widened to include staff from these organisations. Individual training courses receive CPD points from the Royal College of Physicians. More information about the courses run can be found on the BRTC website, [www.brtc.org.uk](http://www.brtc.org.uk). If there are a number of new starters or requests are received through the website for fresh topics to be covered, the BRTC can host a "Needs Led seminar", drawing on a wealth of knowledge and expertise within the Birmingham area.

Historically, Pan Birmingham was part of the Midlands Regional Group. During 2009/10 the regional group was reconfigured and Pan Birmingham now sits within the Central Regional Group. The Lead Nurse represents Pan Birmingham at both national and regional training and education meetings. The PBCRN NTL is one of the representatives for the Central Region at national meetings. Both the Lead Nurse and Research Network Manager were involved in the Central Region Training Strategy. Training meetings were stalled during the changeover of the groupings whilst Network Managers agreed the need for reconfiguration and priorities for the new group. In year, there was one meeting and a teleconference to agree the strategy, which were both attended by the Lead Nurse.

The Cancer Research Network Lead Nurse is working very closely with the two recently appointed Lead Research Nurses for Birmingham and Black Country Comprehensive Local Research Network.

### **1.3 Integration with Cancer Service**

Pan Birmingham Cancer Research Network is fully integrated into the Pan Birmingham Cancer Network (PBCN), with research forming one of the work streams of the Network. As well as the line management arrangements for the Research Network Manager and Clinical Lead being directly to the Network Director and Medical Director respectively, the Research Committee, which is the decision making group for the Research Network is a sub-group of the Network Board and, as such, the Research Network reports bi-annually to the Board, who take an active interest in the activities of the Network. The Research Committee Chair, Professor Khalid Khan, stepped down at the end of March 2010, as he left the Network to take up a post elsewhere. The Network is actively seeking a replacement.

During 2009/10, the Research Network was in addition required to make two reports to the PBCN Governance Committee regarding the length of time that it takes Trusts to obtain local Trust approval. The Research Network was able to use the directive by the Governance Committee to steer the Research Committee to insist on new reporting requirements within the SLA which took effect on the 1 April 2010. The PBCN Risk Register, which includes risks for the Cancer Research Network is submitted to the Governance Committee.

In addition to the annual reporting cycle to the NCRN, via the submission of the Annual Report and a performance review meeting, the Clinical Lead for the Research Network has an annual performance review by the Medical Director of the Pan Birmingham Cancer Network.

During 2009/10 there has continued to be a high level of engagement from PCT commissioners within the Network with members of the PBCN Commissioning Group continuing to agree all requests for excess treatment costs that were brought to them during the year.

The Cancer Network Medical Director has a place on the Research Committee, which is attended by Trust-nominated Cancer Research Leads, who are a mix of R&D and Cancer Leads and, as such, is able to influence the decisions made by the group and the strategic direction of the Network. The Research Network Manager attends Trust Cancer Research and Cancer (service) Steering Groups to support Trusts involvement of research within cancer services.

Detailed information about the role of the Research Committee and the Trust Nominated Cancer Research Leads can be found in the Network Constitution. Attendance at the meeting has been good, with most Trusts represented by their nominated lead or a deputy.

As part of the process for agreeing the Network Site Specific Group (NSSG) trials list, several groups have been actively mapping their portfolios to try and ensure that there is network coverage and referral for appropriate studies. Haematology, urology and lung groups actively refer patients between Trusts, although historically this has not been well recorded. Increasingly Trusts are recording this information, and where this has been received, it is included in the relevant Trust report. Centralisation of surgical services as a result of NICE Improving Outcomes Guidance is now largely complete within Pan Birmingham and referral pathways are now well established and the distribution of the portfolio reflects this. In keeping with the Cancer Reform Strategy, care in the appropriate setting, whenever possible studies will be opened as widely as possible, with recruitment and follow up taking place at a number of Trusts and treatment at a single site. This has particularly been the case for radiotherapy trials, where recruitment initially takes place only at UHBFT and widens to all Trusts over time. The research teams contact each other to share information about studies.

Pan Birmingham Cancer Research Network did not undergo a peer review visit in 2009/10 and all findings from the earlier peer review cycle had been resolved in year. Several NSSGs and MDTs underwent self assessment and full peer review during the year. Compliance was variable with some teams not meeting the research measures. PBCRN has provided NSSGs and MDTs with templates to complete. Completion of these was also variable. The templates will be reviewed and reissued with more advice about how to incorporate the research measures into the three documents produced by each team. Although these measures are not the responsibility of the Cancer Research Network, it is the role of the Network to support the process and provide assistance so that MDTs can undertake their remedial actions. Therefore, future Cancer Research Network Annual Reports will include a summary of compliance.

#### **1.4 Integration with Other Research Infrastructure**

Pan Birmingham Cancer Research Network although not coterminous with Birmingham and the Black Country Comprehensive Local Research Network, is wholly within it. PBCRN and BBC CLRN have good formal and informal links, which are working well. The Cancer Research Network Manager is a member of the BBC CLRN Board and the Clinical Lead attends the Priority Area Board meeting. The CLRN Senior Manager is a member of the PBCRN Research Committee. The Managers of the two Networks are in regular contact to discuss common issues and priorities. Other staff within the Networks also have frequent contact.

In 2009/10, 40% of the BBC CLRN budget was allocated to cancer studies via the constituent Trusts, which equates to £3.2 million. This included funding for posts previously funded by PBCRN from historic underspend, as well as posts identified by Trusts and general service support allocations. The PBCRN Manager provided information for most Trusts regarding staffing requirements. Cancer funding information is provided to the Research Committee by the BBC CLRN Senior Manager. The use of the funds will be closely reviewed by the CLRN management team, as initial review suggests a wide variation in costs per study between Trusts.

There is presently an agreement that feasibility and management of cancer industry studies are managed by the PBCRN Manager. The BBC CLRN Industry Manager immediately contacts PBCRN if a cancer study is flagged to her. Costings are undertaken by staff within the Trust R&D Departments.

As outlined earlier, the Lead Nurses for the two Networks are working closely to ensure harmonisation of activities.

The Topic, Primary Care and Comprehensive Clinical Research Networks in the West Midlands Strategic Health Authority and Leicestershire, Northamptonshire and Rutland CLRN area meet regularly. The four meetings held during 2009/10 were chaired by the PBCRN Manager. Informal communications occur outside of the meetings.

The Primary Care Research Network for Central England is based in the School of Primary Care Clinical Sciences in The University of Birmingham (UoB), with which the PBCRN has a long standing relationship, through the Birmingham Research Training Collaborative and the Research Committee membership. PBCRN has previously provided funding for a primary care study, where recruitment took place in secondary care. At present there are no co-funded posts. The RNM has been working closely with one of the study co-ordinators to ensure that a study designed and co-ordinated within a primary care trials unit environment, which will be recruiting in secondary care imaging departments, is practicable and will recruit well when it opens.

There is a wealth of research infrastructure based within Pan Birmingham including a Cancer Research UK Cancer Centre, Experimental Cancer Medicine Centre and three trials units. During the year clinical trials management for studies in the Children's Cancer and Leukaemia Group (CCLG) portfolio have transferred from the CCLG Data Centre in Leicester to the Cancer Research UK Clinical Trials Unit (Birmingham) with the establishment of the National Children's Cancer Clinical Trials Team.

Pan Birmingham Cancer Research Network was, until April 2010, based within the Cancer Research UK Clinical Trials Unit (Birmingham) in the School of Cancer Sciences at The University of Birmingham. Strong links between the two organisations have been built. Their hospitality and support during this time is appreciated.

There is an active West Midlands Region Haematology Research Group which meets regularly. It has a number of working sub-groups. The Research Network Manager periodically attends the regular main group meeting to provide support and advice, as requested.

## **2 Portfolio Development and Recruitment**

Pan Birmingham Cancer Research Network includes hospitals which are situated in more than one Network. These are Solihull Hospital, part of Heart of England NHS Foundation Trust, and, until March 2010, Walsall Hospitals NHS Trust. There are different arrangements with each Cancer Research Network as to how the recruitment is proportioned to the Networks. For graphs showing Network recruitment only activity which is attributed to PBCRN is used. For the Trust specific data, the entire patient recruitment activity is shown, in order to appropriately reflect the Trust activity. Unless otherwise stated, data is available up to and including March 2010.

National Cancer Research Network initial targets are based on numbers of patients with cancer participating in NCRN approved studies. Volunteers recruited into screening and prevention studies of the general population do not, at present, count towards this target. They do, however, form an important part of the portfolio and participants are recorded separately. Patients with a pre-malignant condition now contribute to the RCT recruitment target. The tables and graphs in this report have been produced demonstrating this differentiation.

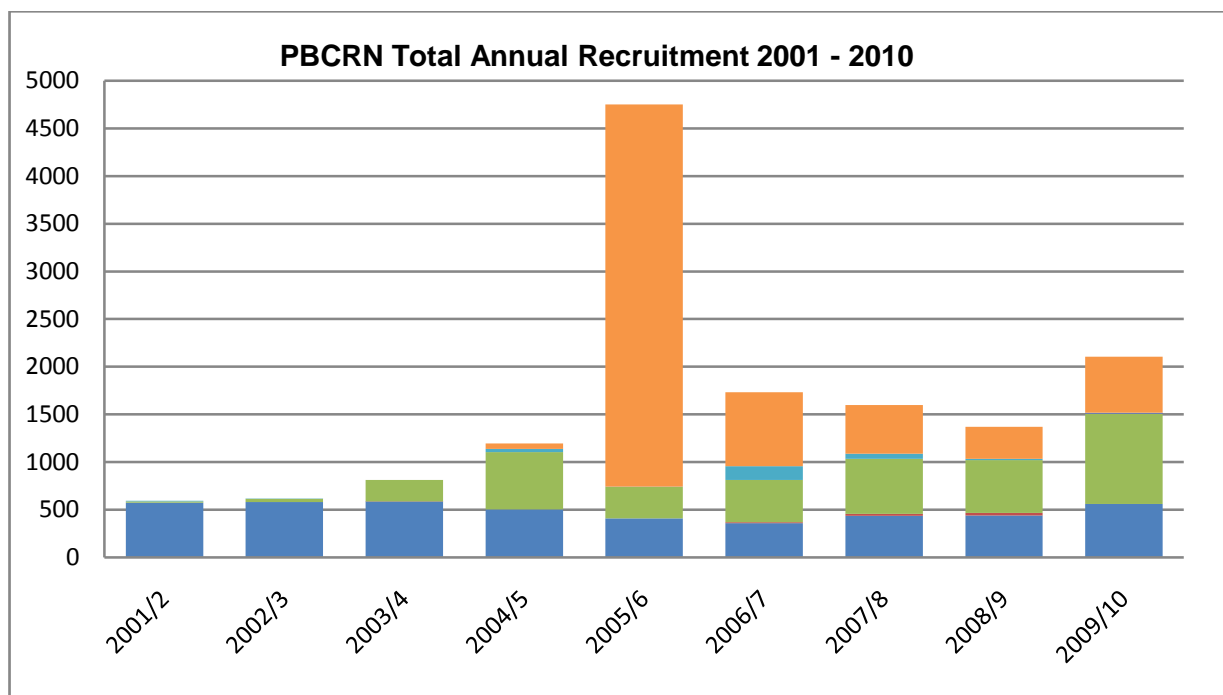
The percentage of patients recruited is calculated using the expected number of cancers for the Network population. The incidence used is 4600 new diagnoses per 1 million population. Pan Birmingham Cancer Research Network prior to 1 April 2010 received funding for 1.8 million population; the expected cancer incidence per year is, therefore, 8280.

With effect from 1 April 2010, the population for Walsall that historically fell within Greater Midlands Cancer Research Network has transferred to Pan Birmingham, along with its associated funding. All *future* reports will be adjusted to include all Walsall population and recruitment.

Information about the numbers of patients recruited by the Network is held on a central database at the National Institute for Health Research Clinical Research Network (NIHR CRN) Coordinating Centre. During 2006 a new database was created. The purpose of the new database is to improve the overall accuracy and enable a more detailed breakdown of the recruitment activity. One of the features of the database is that information about patients and controls can now be recorded separately in the database. In previous years some controls may have been erroneously recorded as patients. This may result in differences between data published in previous annual reports.

## 2.1 Overview of the Local Network Portfolio and 2009/10 Recruitment

**Figure 1: Pan Birmingham Cancer Research Network Total Annual Recruitment to NIHR Portfolio studies 2001 - 2010**



- Key**
- Individuals recruited to screening/prevention/diagnostic studies (non-RCT)
  - Individuals recruited to screening/prevention/diagnostic studies (RCT)
  - Pre-malignant patients (non-RCT)
  - Cancer patients (non-RCT)
  - Pre-malignant patients (RCT)
  - Cancer patients, including recruits to commercial NCRN trials (RCT)

Figure 1 above shows that PBCRN has increased the number of patients with cancer or a pre-malignant condition recruited to National Institute for Health Research (NIHR) portfolio clinical trials and other well designed studies. The percentage of cancer patients recruited to randomised controlled trials (RCTs) has increased to 6.8% from 5.6%, with a total of 560 patients recruited. Overall recruitment for patients with cancer or a pre-malignant condition has increased to 1510 or 18.2%. It should be noted that 38% of non-RCT recruitment are participants in just two non-treatment trials. There has been a steady consistent increase in RCT recruitment since 2006/7, when RCT recruitment was at its lowest. Non-RCT recruitment of cancer patients and studies in screening, prevention or diagnosis fluctuates year on year as some of the studies in these portfolios may recruit large numbers in a short period of time. Often these studies recruit using study specific staff. 537 participants were recruited to screening, prevention and diagnostic studies and 59 patients with cancer were recruited into optional bolt-on studies to treatment trials.

## 2.2 Cancer Research Network Portfolio 2009/10

During 2009/10 there were studies open and recruitment across every disease specific portfolio. This was the first year that it was achieved and demonstrates the breadth of the portfolio within Pan Birmingham Trusts. There was also recruitment to the Palliative Care portfolio for the first time. There was no recruitment to studies within the Primary Care,

Psychosocial Oncology and Teenager and Young Adults Clinical Studies Group (CSG) portfolios, this is in part a result of the paucity of studies within these portfolios. It should be noted that there are some studies which fit into multiple Clinical Studies Groups portfolios. Pan Birmingham attributes these studies to the CSG in which the NIHR recruitment database attributes the study, unless all recruitment is within a different disease site. As a result, recruitment to the radiotherapy portfolio is under reported. A total of 94 patients were recruited into 10 studies where radiotherapy is the treatment under investigation, either alone or with chemotherapy or where the radiotherapy department has been required to alter practice to meet the requirements of the protocol.

<b>Randomised Controlled Trials for Cancer &amp; Pre-malignant Patients</b>	<b>PBCRN Total</b>
No. of Open RCTs	80
No. of RCTs with Recruitment	59
No. of RCTs Opened In Year	33

<b>Non RCTs for Cancer and Pre-malignant Patients (including sub-studies)</b>	<b>PBCRN Total</b>
No. of open Non-RCTs	51
No. of Non-RCTs with recruitment	45
No. of Non-RCTs which opened in year	20

<b>All of Trials for patients without cancer</b>	<b>PBCRN Total</b>
No. of studies recruiting in year	8
No. of studies opening in year	3

There was recruitment in 104 different studies for patients with cancer or a pre-malignant condition, including separately identified sub-studies. A further 27 studies were open to recruitment but did not recruit any patients. Many of these studies were in uncommon subgroups of patients or rare cancers where numbers of patients are expected to be small, such as paediatrics and haematology and, therefore, zero recruitment is not unexpected. More information about these studies is found later in the report. 53 studies were opened in year.

There were 8 studies in the portfolio which recruited participants that do not have a cancer diagnosis.

Some of the recruitment which is attributed to Pan Birmingham is out-with the control of the Research Network. Recruitment data is regularly monitored to ensure that this recruitment is not masking decreases in recruitment to studies where the NIHR does provide resource via the Research Networks.

Detailed recruitment data by Clinical Studies Group can be found in Tables 2a and 2b on [pages 32 and 33](#).

### *Areas of Strength*

The urology portfolio is a major strength with recruitment into the portfolio of all four Clinical Studies Groups. Bladder Cancer Prognosis Programme and SELINIB, the associated RCT have continued to recruit well. Studies for patients with prostate cancer, including CHHiP, Stampede and TRAPEZE have contributed 14.5% of RCT recruitment, with recruitment for patients with renal, bladder and testicular cancer delivering almost 11% collectively.

Haematological oncology, including lymphoma, remains a significant strength for Pan Birmingham Cancer Research Network with 19% of RCT and 10% of all recruitment in the Network resulting from activity in this portfolio. This is despite the fact that the portfolio lacked a wide eligibility myeloma study and AML17 only opening in the latter half of the year. 75% of RCT recruitment takes place at BCHFT or HEFT.

Paediatric oncology research is another important area of strength with recruitment across a wide portfolio, including CCLG, sarcoma and haematology studies, with 10% of Network RCT recruitment taking place at BCHFT.

Breast recruitment has significantly improved with 15% of RCT recruitment being from studies in the breast portfolio, which has expanded significantly in recent years, with good recruitment to studies where patients are identified and recruited by the surgical teams.

The radiotherapy portfolio has been an area of continued growth with the appointment of a second radiographer and a dedicated research medical physicist. 16.3% of RCT recruitment is from studies involving radiotherapy. Patients are recruited both at the Cancer Centre and at the DGHs with treatment at the centre. The Radiotherapy Team at UHBFT recruited 111 patients including 41 to RAPPER, a radio-genomics study open to participants in CHHiP.

In 2009/10, recruitment has again increased to studies in the head and neck portfolio; this is due to the Determination of Quality of Life Instrument study. However, there has also been recruitment into HOPON, PET-NECK and COSTAR.

Sarcoma surgery is a regional specialist service based at The Royal Orthopaedic Hospital NHS Foundation Trust (ROHFT). In Pan Birmingham Cancer Research Network, sarcoma studies contribute 1.5% of RCT recruitment compared with 0.22% in the national portfolio.

Pan Birmingham Cancer Research Network is fortunate to have an active Primary Care academic department within its boundary. Many of its activities are centred on screening and early detection, which is not recorded in the cancer patient activity. The non-cancer patient recruitment is shown in Figure 3 on page 35. Recruitment to patients and controls for the large recruiting colorectal study, Patient Experience of ED, was coordinated by a team in the School of Primary Care Clinical Sciences.

#### *Areas of development*

Recruitment has taken place in the adult brain tumour portfolio for the first time with 11 patients recruited to NBT, a genetic epidemiology study. The Neuro-oncology Team at UHBFT has also opened a commercial trial and has a second in set up.

There has also been recruitment to a palliative care study for the first time with participation of 44 patients in EPAT at UHBFT.

#### *Gaps in the local portfolio*

As previously stated, Pan Birmingham was able to recruit patients within every disease site in 2009/10. Recruitment to some portfolios has been lower than previously, for example lung and melanoma. This reflects changes in the portfolios with the closure of BTOG2 and the delay in opening AVAST-M for the latter disease site.

At present, the portfolio is well balanced across disease sites. Further work will be carried out on it to determine whether there is good within disease site balance, such as a range of studies from diagnostics to end stage disease. However, at present clinicians are able to open almost all studies that they would like to, which would suggest that all areas of the portfolio which are of local interest are actually opened.

#### *Studies that could not be opened in year*

Several studies could not be opened in 2009/10 for a variety of reasons. Some of these had significant delays which resulted in them failing to open in year. At SWBH, RT3VIN, a study in the gynae-oncology portfolio was delayed due to pharmacy issues, delays in obtaining signatures and slow response from the coordinating centre. Likewise, CHHiP and COG experienced long delays with the R&D process at WHT, in particular signing of the CTA, but should open shortly.

Other studies which did not open in 2009/10 are unlikely to ever open. At HEFT, radiology could not approve SORCE as the PIS was not IR(ME)R<sup>2</sup> compliant for local practice. At UHBFT, ReACH and PAIRed were unable to be opened due to the large number of additional PET scans and an inability to internally resolve the funding of these. NCRN069 also has not been opened due to an inability to agree costs with the sponsor. WHT were unable to open IMPORT LOW due to funding issues. This was only latterly brought to the attention of the Network and R&D, by which time the study was too close to closure to progress.

### **2.3 Performance against forecast recruitment (academic) 2009/10**

One of the priorities for the Cancer Research Networks is to improve recruiting to time and target. Historically, Trusts within PBCRN have not recorded centrally individual trial targets for academic studies, nor have they monitored recruitment against target for these studies. The importance of this has been raised with Trusts and, in March 2010, the Research Committee agreed that this must be routinely recorded and monitored by Trusts in the Network. This has been written into the Service Level Agreement.

As part of the 2009/10 Annual Report, the National Cancer Research Network Co-ordinating Centre required Networks for the first time to include an individual study estimate. This was undertaken by the Research Network Manager taking into account, amongst other things, historic performance of the same or similar studies, expected closure and opening dates. Network performance against forecast can be found as Table 1 in Appendix 2A. This table shows the red, amber, green status as defined below.

Green if the study is recruiting to at least 95% target

Amber if the study is recruiting to 80-95% of target

Red if the study is recruiting to less than 80% target

It should be noted that although the colours used are the same, the percentage recruitment they represent is different to the convention used for commercial studies in section 2.4 and Appendix 2B.

The red, amber, green status should be viewed with caution for studies where expected and actual recruitment numbers are small, as variance of one patient impacts significantly on

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<sup>2</sup> The Ionising Radiation (Medical Exposure) Regulations

percentage of forecast. There were 25 studies in which the forecast was 5 or less patients per year and 10 where recruitment was estimated to be 2 or less. These studies are predominantly in the paediatric and haematology portfolios. The rarity of these cancers and sub-groups of patients makes it difficult to forecast precisely. These studies form an important part of the Trust/disease site portfolio, despite the small actual numbers recruited. It is recognised that workload to open and maintain these studies by the teams is substantial.

The forecast included in the Work Programme is also compiled by the RNM, with limited input from Trust data, but forecasts in future years will use information produced by Trusts.

For studies involving patients with cancer or a pre-malignancy, there were 33 studies for which no estimate of recruitment was made. For most of these studies the Research Network Core team was not aware that they were in set up.

For the remaining 88 studies, the summary of how well actual recruitment matched to predicted can be found in the table below. Only 44% of studies recruited above or within 20% of estimate. For studies where small numbers were estimated, this was only 30%. This demonstrates the difficulty in predicting recruitment and why there is a need for everyone in the trials process to become more sophisticated at it. Interestingly, the total numbers estimated were within 5% of actual recruitment.

	RCT	Non-RCT	RCT	Non-RCT
	Number of studies		Percentage of studies	
Actual ≥ 95% or above estimate	9	22	44%	43%
Actual ≥ 80% <95% below estimate	3	4		
Actual < 80% of estimate	15	35	56%	57%
Actual < 80% of estimate, estimate ≤ 4 patients	7	20	70%	69%

	Number of patients	
Total estimate	529	513
Total actual	498	534

A number of studies failed to recruit, as previously mentioned. For a number of these the number of expected eligible patients is very small and so zero recruitment is not unexpected. SPARE was unable to recruit any patients, although two patients had participated in the previous year. This was a common problem and the study closed to recruitment nationally.

Several studies significantly exceeded the estimate. For many of the studies this represents a conservative estimation as studies were either expected to start later in the year, close earlier or did not have a predecessor study on which to base an estimate. For example EPAT and HOPON. Three studies had already been high performing studies; BTOG2, Determination of Quality of Life Instrument and BCPP, which all further increased recruitment.

A number of studies which performed at less than 80% of estimated did so because they opened later in the year than predicted. This category includes PERSEPHONE, which is now recruiting well, particularly at WHT.

For several studies the estimate was based on previous year's actual recruitment. For DIETCOMPLYF, the previous high recruitment may have been as a result of being able to recruit a cohort of existing eligible patients when the study first opened.

HEFT identified two studies where their recruitment was lower than expected, with at least four patients who were deemed ineligible by screening tests undertaken at Good Hope Hospital, who subsequently had the same tests at Heartlands Hospital and the results would have made them eligible. The Upper GI team have raised this as a concern, as the test is also used for clinical management. SOCS has also recruited less than previous years, when patients were approached for the study by their CNS rather than a research nurse. The CNS team no longer have the capacity to identify and approach patients.

At SWBH, NeoExcel was identified as recruiting lower than expected numbers, although the Network recruitment exceeded estimate. This was a result of a member of the surgical team, who was interested in the study, being off long term and issues identifying patients at the MDT. BTOG2 failed to recruit at the same Trust due to a lack of histology at the MDT and, therefore, patients could not be identified ahead of clinic appointments.

The colorectal study FOxTROT recruited lower than expected. The study is open at three Trusts, one is able to recruit well, the other two have found that many patients are ineligible or decline.

#### **2.4 NIHR adopted commercial portfolio and performance 2009/10**

As shown in Table 2 in Appendix 2B, 11 commercial trials in the NCRN portfolio were open and recruiting during 2009/10, 5 of these at UHBFT, 5 at HEFT and 1 at SWBH.

Pan Birmingham Trusts recruited 36 patients into NCRN portfolio commercial trials during 2009/10, which represents 6.4% of RCT recruitment in the Network, which is higher than the national average of 5%.

Table 2 shows the red, amber, green status for each of the studies, the status is determined by actual recruitment compared to expected recruitment as determined by the overall recruitment target as set out in the site Clinical Trials Agreement, as shown below:

Green if the study is recruiting to at least 80% target (proportionate to time elapsed)

Amber if the study is recruiting to 66-79% of target (proportionate to time elapsed)

Red if the study is recruiting to less than 65% target (proportionate to time elapsed)

It should be noted that although the colours used are the same, the percentage recruitment they represent is different to the convention used for academic studies in section 2.3 and Appendix 2A.

As noted previously, the red, amber, green status should be viewed with caution for studies where expected and actual recruitment numbers are small, as variance of one patient impacts significantly on percentage of forecast.

Seven studies are recruiting at or above target, 4 studies are currently recruiting behind target. However, NCRN043 is only expected to recruit 4 patients in 2 years and patients are actively

being screened and, therefore, this red status is not cause for concern. Likewise, NCRN085 has only recently opened and did not recruit a patient in the period of the report, a patient has since been recruited. Of the remaining two studies, NCRN044 has recruited at only 56% of target. This study was delayed in set up and therefore treatment became available under NICE, which impacted on recruitment, as this had been forecast assuming that the study population would not have access to treatment as standard of care in some PCTs. Furthermore, half of all sites nationally recruited below target. NCRN078 is a study in a rare tumour, remedial actions are underway to improve recruitment, including contacting treating clinicians in neighbouring Networks to encourage referral for trial entry.

During 2009/10 a total of 27 studies were sent out to local clinicians for expressions of interest (Eoi). Five expressions of interest were submitted from Pan Birmingham clinicians in year. Of these, two Eoi resulted in the site being selected and two were not selected. The other study is an observational one, which is likely to apply for section 60 exemption<sup>3</sup> and, therefore, not recruit via hospital sites.

It is still much more common that sites will have been pre-selected prior to the study being adopted than for sites to be selected following an expression of interest via the NCRN. For these studies, the Cancer Research Network Manager is often unaware until after the study is opened and cannot influence study set up times or site target recruitment. In recent months, there have been more regular communications from the NCRN Industry Team including accrual reports, with earlier notification of pre-selected sites. There remains a problem with the use of multiple identifiers making it difficult to cross reference studies with the BBC CLRN Industry Manager and sites.

The Cancer Research Network Manager handles all feasibility requests from the NCRN Industry Team and management of any issues raised by the site or study co-ordinator. The BBC CLRN Industry Manager advises the Cancer Research Network Manager if any studies are highlighted to her via CSP<sup>4</sup>. Management of the industry portfolio will be one of the primary tasks for the Operations Manager, when appointed.

## **2.5 Trust Performance**

Table 3, showing recruitment by Trust for 2009/10 and the previous year by study category, can be found in Appendix 2C. Details about individual Trust performance, portfolio balance, local initiatives and good practice can be found on the following pages. Please note that the recruitment graphs for each Trust are produced on a different scale.

Each Trust has a Trust-nominated Cancer Research Lead who represents the Trust at Network Research Committee meetings. The Clinical Lead and Research Network Manager meet periodically with the Trust Leads. Meetings involve discussions about recruitment and portfolio. The frequency of these meetings is variable, depending on a variety of factors including whether there is a Trust Steering Group that the RNM attends. In the last few years, the frequency of these meetings has been reduced due to time constraints. It is expected that with the appointment of the Operations Manager that this frequency will increase and be less variable.

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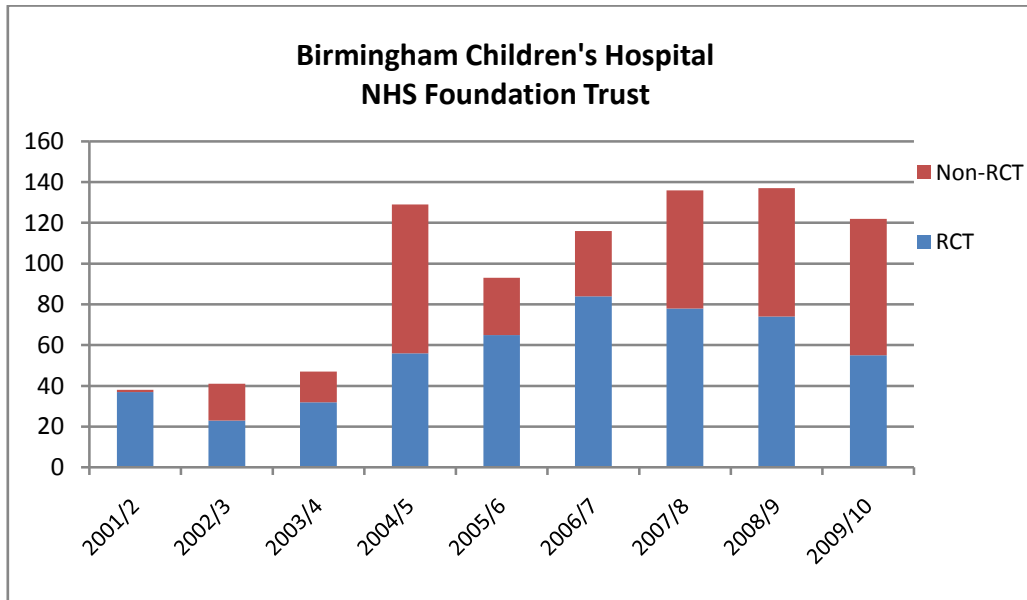
<sup>3</sup> Section 60 of the Health and Social Care Act 2001 enables the Secretary of State to support and regulate the use of confidential patient information in the interest of patients or the wider public good.

<sup>4</sup> NIHR Coordinated System for gaining NHS Permission

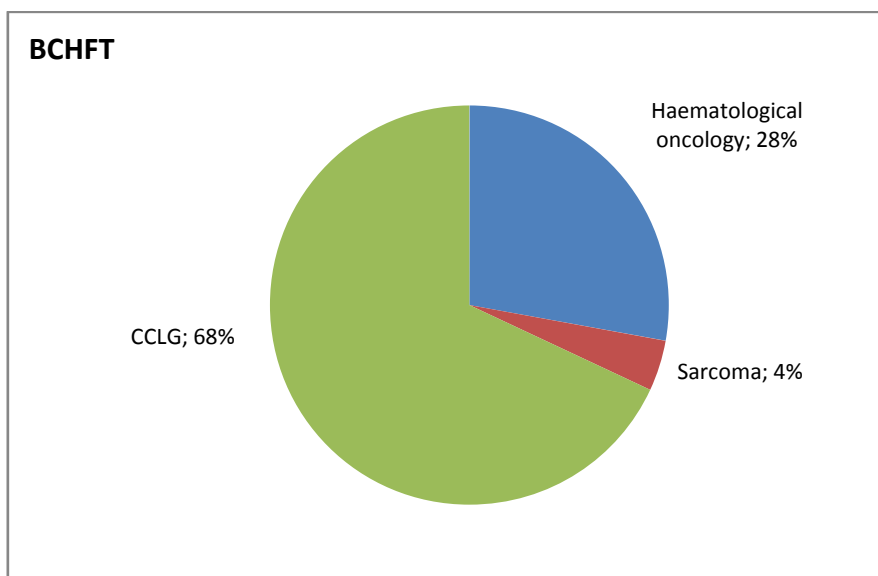
As described earlier Trusts will now be collating individual study recruitment targets which will enable them and the Network core team to review their target recruitment.

## Birmingham Children's Hospital NHS Foundation Trust

Figure 2a Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010 and portfolio by CSG for 2009/10



Pie Chart of recruitment by disease site by CSG for 2009/10



Birmingham Children's Hospital NHS Foundation Trust remains a significant contributor to recruitment in Pan Birmingham, with 10% of RCT recruitment of patients with cancer and a premalignant condition taking place at BCHFT. It performs well when compared to the other paediatric oncology centres, with more than 10% of all recruitment from the 20 centres occurring in Birmingham.

Recruitment continues across a broad spectrum of studies with recruitment to 30 different studies in the CCLG, sarcoma and haematology portfolios. Where recruitment into individual studies is small, this reflects the rarity of the tumour type.

### **Initiatives and Good Practice**

In paediatric practice trial entry has been the “norm” from many years. Most of the clinical services are, therefore, organised around the provision of research-standard care. During 2009/10, the research nurses moved to joint management between the Wellcome Trust Clinical Research Facility and cancer services, which should lead to greater flexibility and improved ability to recruit to early-phase clinical trials.

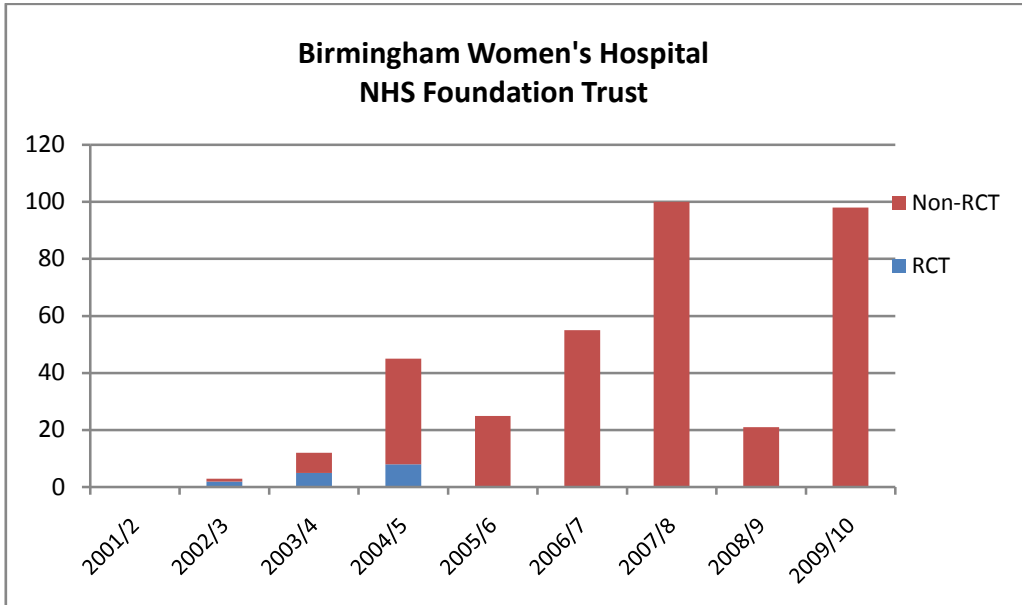
A robust model of shared care exists within the Paediatric Network as outlined in the NICE Improving Outcomes Guidance (IOG) document. In line with the IOG, all patients are recruited and registered on trial at BCH although treatment may be devolved to the shared care units across the wider West Midlands. During 2009/10, the Paediatric Oncology Supra-Network successfully bid for FSF to undertake a project looking at the data management requirements of the shared care units, where the data is largely completed by Consultant medical staff. The report will be distributed early in 2010/11.

The transfer of sponsorship of CCLG portfolio studies, when the clinical trials management transferred from the CCLG Data Centre in Leicester to the Cancer Research UK Clinical Trials Unit (Birmingham), has resulted in a significant workload for the Birmingham Children’s Hospital. Continuity of trials recruitment was maintained throughout this period.

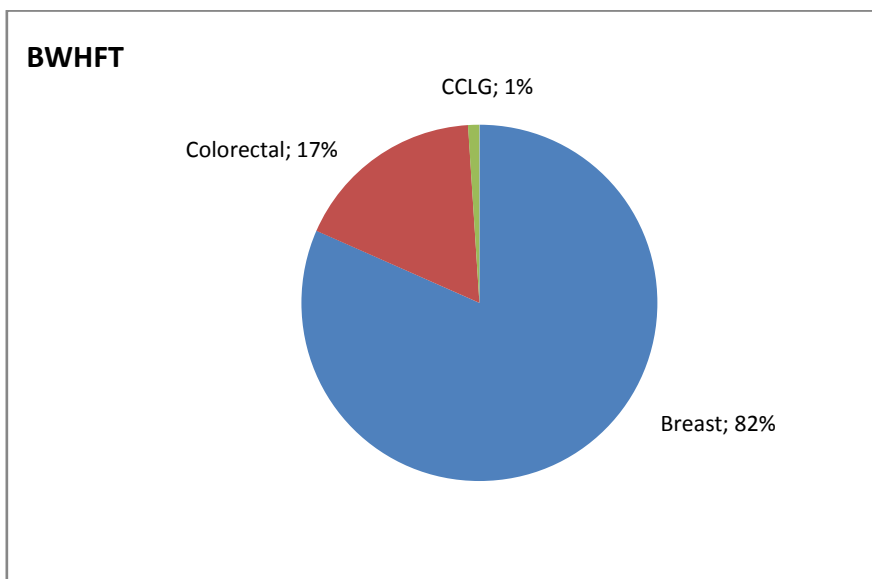
Birmingham Children’s Hospital NHS Foundation Trust has recently been awarded £3.7m NIHR capital funds for a 3T MRI scanner. This will allow the internationally recognised work in magnetic resonance spectroscopy to expand. Currently the focus has been looking at children with CNS tumours. The new scanner will allow work to be broadened to look at non-CNS tumours (biomarkers of response etc) as well as the metabolism of some non-oncology diseases (neurology/inherited metabolic disease etc).

## Birmingham Women's NHS Foundation Trust

**Figure 2b Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010 and portfolio by CSG for 2009/10.**



**Pie Chart of recruitment by disease site by CSG for 2009/10**



Birmingham Women's NHS Foundation Trust (BWFT) is a specialist hospital. Under NICE Improving Outcomes Guidance, gynae-oncology surgery, with the exception of early stage endometrial and cervical cancer, is centralised at City Hospital. There is no chemotherapy service at the Trust. As a result, the portfolio available to BWFT is limited.

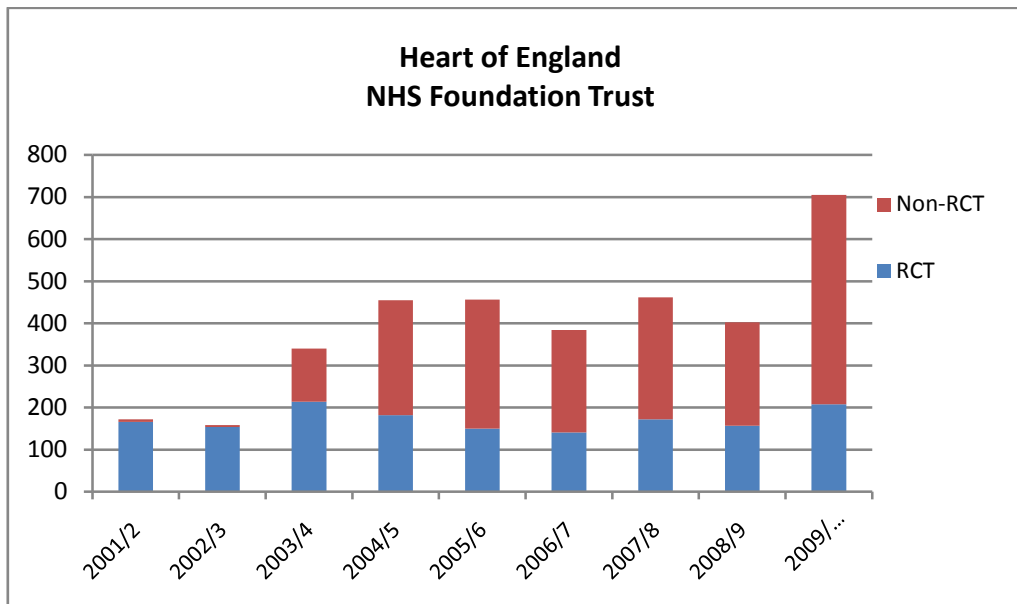
BWFT hosts the West Midlands Regional Clinical Genetics Service. Staff in the Genetics Service recruited all of the patients recruited at the Trust. The opening of FBCS, an observational study, increased recruitment back up to 2007/8 levels. It should be noted that

EMBRACE is open to women with breast or ovarian cancer, all recruitment data is attributed to the breast portfolio.

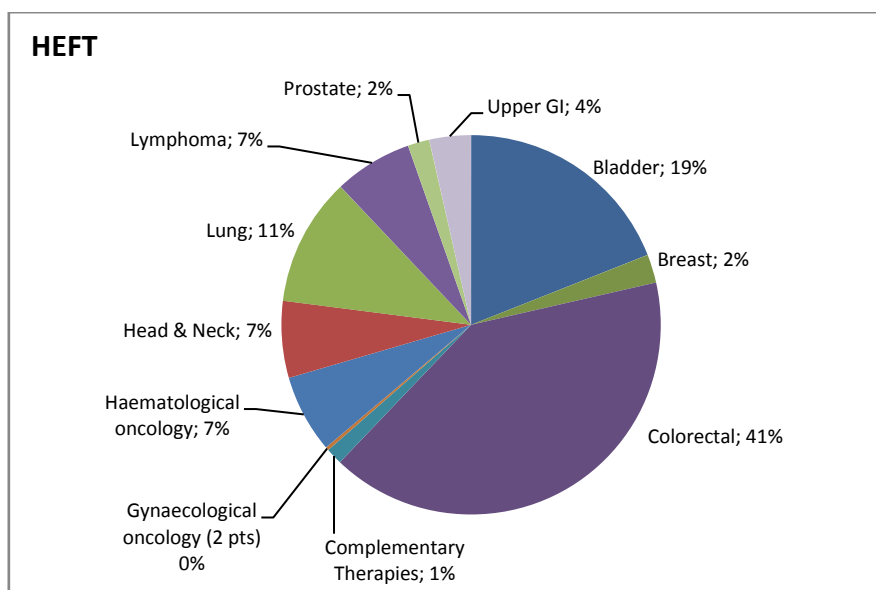
Histopathology services for the IOG compliant Gynae-oncology surgery centre at City Hospital are provided by BWFT. Several studies open at the centre impact on histopathology and have required a change in laboratory processing, for which the Trust has received funding from the CLRN.

## Heart of England NHS Foundation Trust

Figure 2c Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010 and portfolio by CSG for 2009/10.



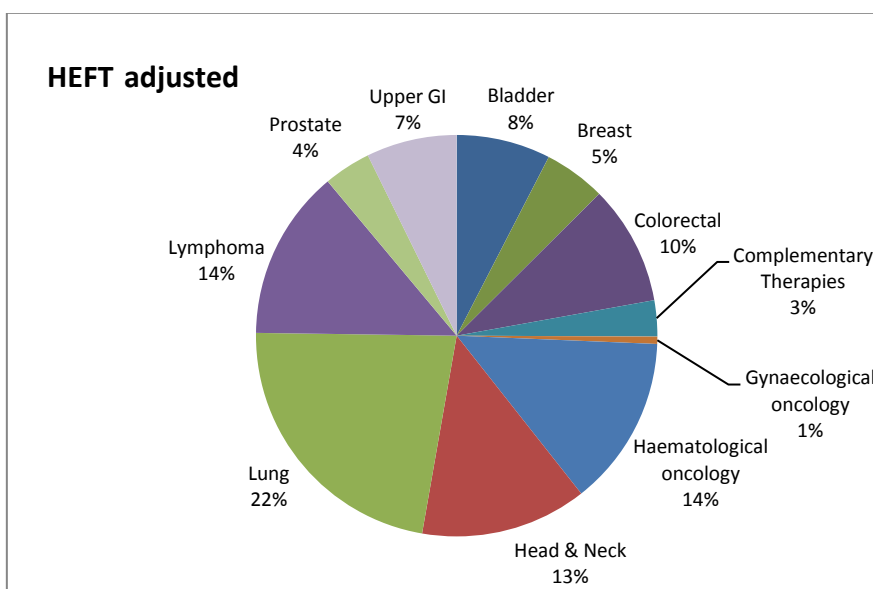
Pie Chart of recruitment by disease site by CSG for 2009/10



Heart of England NHS Foundation Trust includes Birmingham Heartlands Hospital, Good Hope Hospital and Solihull Hospital. Recruitment at Solihull may be counted in Arden or Pan Birmingham depending on the Network funding supporting the study. In 2009/10 recruitment from a single study at Solihull was attributed to Pan Birmingham with the remainder attributed to Arden Cancer Research Network. The Trust serves a population of more than 1 million people.

Recruitment into RCTs has been consistently good at HEFT, with recruitment being maintained year on year with small fluctuations. Non RCT recruitment has been boosted by a single study in the colorectal portfolio which recruited at all three hospital sites. If this is adjusted for, non-recruitment has been maintained.

HEFT has a wide portfolio with recruitment into more than 40 different studies across 11 clinical studies groups. The balance of recruitment is distorted by the colorectal study mentioned above and a bladder genetic study. If recruitment is adjusted to remove these two studies, recruitment is more evenly distributed as shown below, with good recruitment in a number of disease sites. Half of all recruitment is within the lung and haematology, including lymphoma, portfolios, which are particular areas of strength for the Trust.



HEFT had 5 NCRN commercial studies open and recruiting during 2009/10.

### Initiatives and Good Practice

Research is very much integrated into the patient pathway and plays a key role at MDT meetings when discussing possible treatments for patients. The clinicians have a wide portfolio to choose from and during these meetings, further studies are identified for inclusion onto the portfolio. The close working relationship between the research nurse team and the clinical service have enhanced the service, for example improved chemotherapy charts, medical safety alerts and nurse radiology requests procedures.

The Trust has established the Medical Innovation Development Research Unit (MIDRU) a purpose built, modern facility located on Heartlands Site. The research nurses and data managers are accommodated within the building, along with the main R&D Directorate. The building also houses a dedicated trial pharmacy and associated staff. The facility allows them to have dedicated space to work and, since the move into MIDRU, approval times for the opening of new trials has slowly started to decrease, with much of the backlog being cleared. The Trust is working towards a 56 day approval time for the opening of new studies and the R&D Directorate is working very closely with the support service teams, notably pharmacy, to achieve this target.

The Radiology Department has recently developed a protocol with the cancer research nurses to allow them to request all radiological tests, as required by research protocols. This

extended role will benefit the multi-disciplinary team involved in research as it will provide a more effective method of requesting tests for clinical trials. A Standard Operating Procedure has been generated and has already proven to be a more efficient way of ensuring patient's received the necessary tests or study specific reporting, for example RECIST<sup>5</sup>.

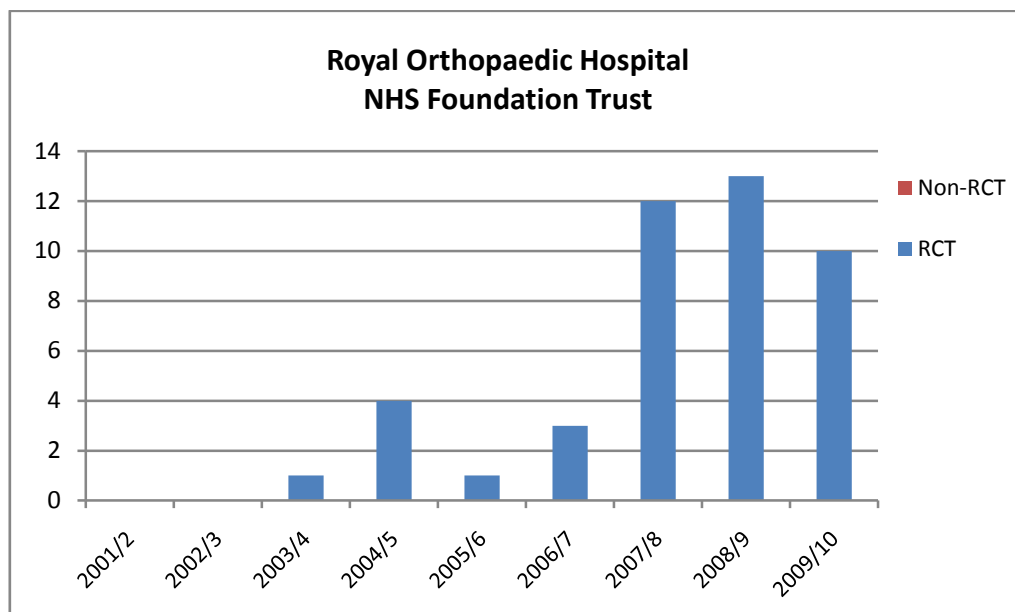
An initiative to encourage effective serious adverse event reporting for patients on clinical trials is currently being developed by the HEFT Cancer Research Team and will soon be piloted in the Oncology/Haematology Directorate. Any patients unexpectedly admitted into the hospital will have an electronic alert tagged to their electronic medical record which will notify the ward staff that this patient is on a clinical trial and detailing that they should contact the cancer research team. Work is still in progress and we are hoping to develop the alert further so that an electronic alert is sent to the cancer research team with minimal work involved for the ward staff. The implementation of this alert system will benefit both patients' safety and support safe reporting procedures. If successful, there is an intention to roll this system out to include patients taking part in clinical trials from all specialities across the Trust.

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<sup>5</sup> Response Evaluation Criteria In Solid Tumours

## Royal Orthopaedic Hospital NHS Foundation Trust

Figure 2d Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010 and portfolio by CSG for 2009/10.



The Royal Orthopaedic Hospital NHS Foundation Trust is a specialist orthopaedic hospital which has one of the largest referral practices for patients with bone and soft tissue sarcomas in the U.K. Surgical treatment is carried out at the ROHFT but patients receive chemotherapy and/or radiotherapy at their referring or local hospitals. All recruitment at ROHFT is into the sarcoma portfolio.

VORTEX, a randomised controlled trial in soft tissue sarcoma, has continued to recruit well. 10 patients were recruited into VORTEX with 9 patients agreeing to participate in the VORTEX BIOBANK. Patients have their surgery at ROHFT. However, radiotherapy is undertaken at the patients local hospital. Some potentially eligible patients have been unable to participate due to their local radiotherapy centres not opening the trial.

### Initiatives and Good Practice

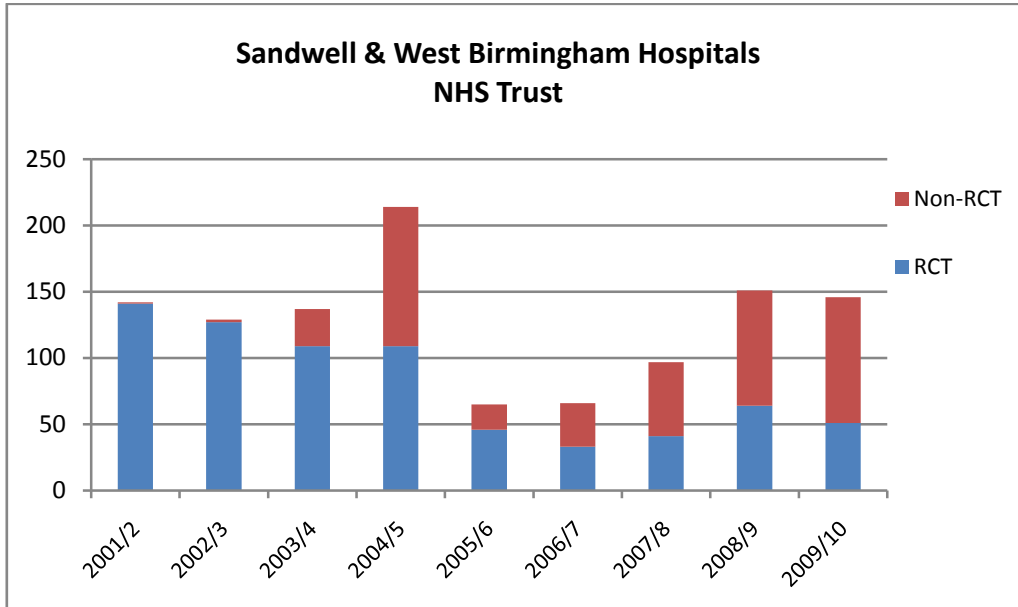
There are a significant number of sarcoma patients for whom ROHFT performs the surgery who are recruited into clinical trials at their local hospital. Staff at ROHFT provide surgical and pathological data. Following a project in 2008/9 looking at the patient flows and data management needs for this group of patients, the Royal Orthopaedic Hospital NHS Foundation Trust successfully bid for flexibility and sustainability funding to implement the recommendations of the project and provide data management support for these patients. The post holder is presently working to formalise written research pathways between Trusts.

The department has recently undertaken an audit to assess the timeliness of referral following diagnosis, as it had been suggested that the delay in referring patients had meant they had not been able to participate in clinical trials, this audit demonstrated that this was not the case.

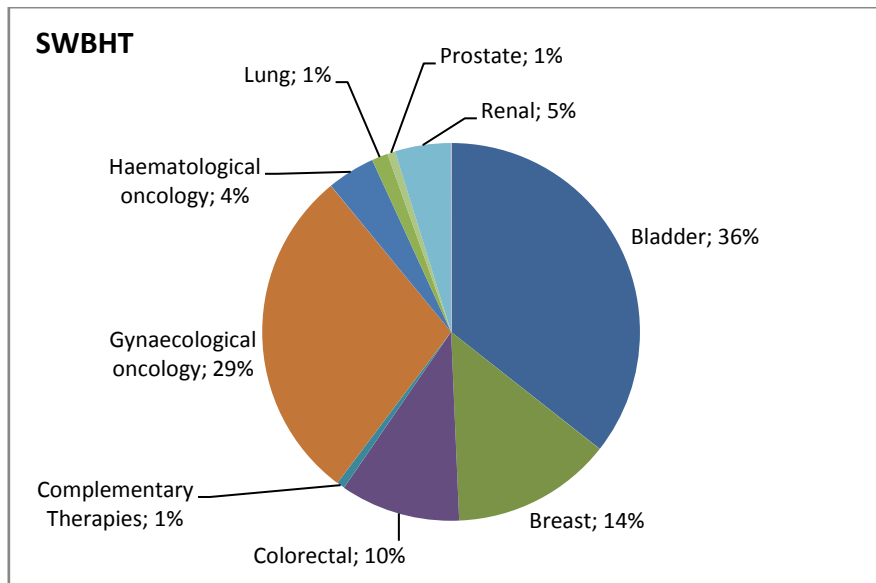
The Trust is also involved in other non-portfolio research both academic and commercial.

## Sandwell and West Birmingham Hospitals NHS Trust

Figure 2e Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010 and portfolio by CSG for 2009/10.



Pie Chart of recruitment by disease site by CSG for 2009/10



In 2009/10 Sandwell and West Birmingham Hospitals NHS Trust maintained its recruitment of cancer patients and the number of studies undertaken has expanded.

As described earlier, at the end of the year, the solid tumour team moved under the line management of the R&D Department, along with another non-cancer team within the Trust. It is expected that other teams will also move under a single line management structure to increase flexibility and ensure that both hospital sites have good support, which is difficult with a small team.

SWBHT also have a small team employed by The University of Birmingham, Cancer Research UK Clinical Trials Unit. The Trust and University teams are co-located and work collaboratively, with a senior trials co-ordinator providing oversight over the portfolio. This has proved to be effective and the relationship continues to grow.

RCT recruitment is still below the historic high levels. This is partly as a result of changes in study design. SWBHT clinicians historically recruited well into breast trials, which frequently were open to 'all women with breast cancer'. Newer studies are targeting smaller subgroups, thus requiring a greater number of studies to achieve the same recruitment levels.

There was one NCRN portfolio industry study open and recruiting at SWBHT during 2009/10.

### **Initiatives and Good Practice**

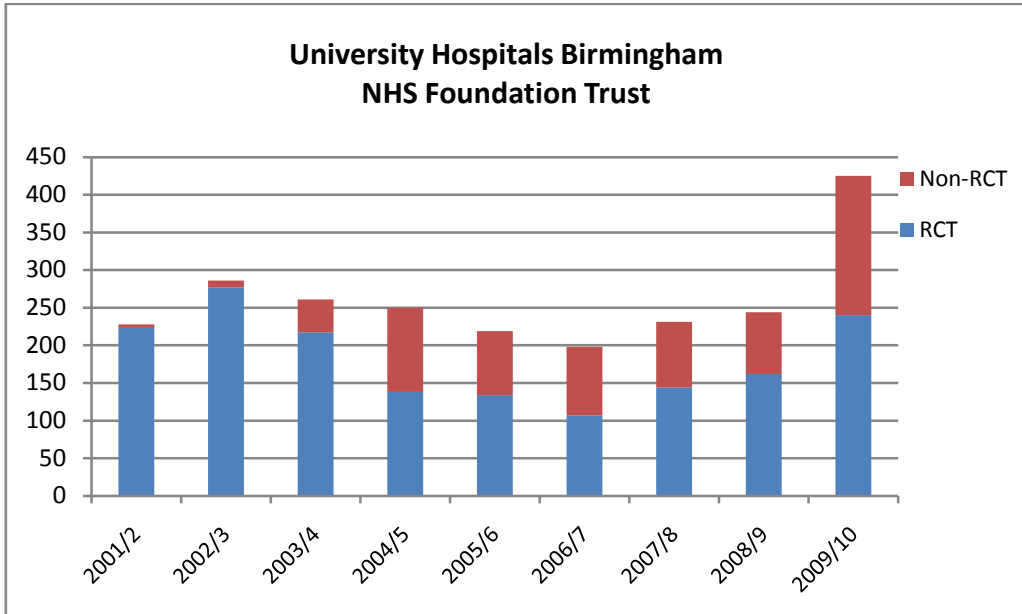
During 2009/10, the Cancer Research Steering Group at Sandwell and West Birmingham Hospitals NHS Trust has increased in strength and there is improved liaison between the group and the service support departments. The Trust has employed a part time Imaging Research Co-ordinator using FSF, who provides a single point of contact for studies involving imaging and has improved IR(ME)R compliance.

Midyear, the team at SWBH started to maintain a formal record of patients referred to other Trusts for trial entry. Eight patients were referred in total for entry into SCOPE, STAMPEDE and CHHiP. The Trust received patients referred for SORCE and BEATRICE.

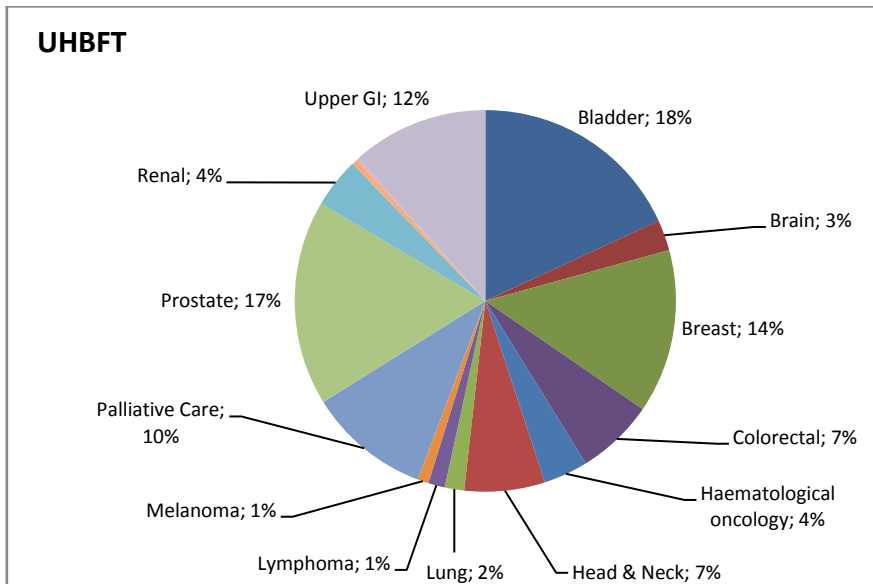
Research is embedded into the Trust Cancer Strategy and Multidisciplinary Teams are expected to report research activity in their reports to the Cancer Management at the Trust. Similarly, MDT Lead Clinicians attend the Management Meeting when the Trust-nominated Cancer Lead report. The Research Team has been involved in compiling MDT research reports. A number of MDTs have merged across the two hospitals sites to hold one meeting per week, this has made identifying patients easier.

**University Hospital Birmingham NHS Foundation Trust**

**Figure 2f Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010 and portfolio by CSG for 2009/10.**



**Pie Chart of recruitment by disease site by CSG for 2009/10**



Recruitment at University Hospital Birmingham NHS Foundation Trust has continued to rise with the changes implemented over the preceding two to three years taking effect. RCT recruitment increased in 2009/10 by 50% to 240 patients with cancer or pre-malignancy. The pie chart above demonstrates the breadth of the portfolio with recruitment across 13 Clinical Studies Groups and recruitment or trial treatment for all tumour sites. Recruitment has taken place for the first time in brain tumour and palliative care studies.

Co-ordination of the cancer research portfolio has significantly improved and although research staff may be employed by a number of departments and recruitment still takes place across a number of teams, including neuro-oncology, dermatology, solid tumour and haematology research teams, radiotherapy team, the Wellcome Trust Clinical Research Facility and the UoB Early Drug Development Team; the Cancer Research Facilitation Group (CRFG) ensures that there is a co-ordinated approach, with studies being placed with the most appropriate team.

There were 5 NCRN industry studies open and recruiting at UHBFT during 2009/10.

### **Initiatives and Good Practice**

The Trust has continued with its plans to better embed cancer research within cancer services. The Cancer Research Steering Group has continued to meet with senior management and clinical engagement to drive the whole research portfolio including NCRN, NCRN commercial and non-NCRN commercial activity within the Trust.

Over the last 12 months, the Cancer Research Facilitation Group (CRFG) has become firmly embedded as the principal mechanism for the presentation, discussion and subsequent approval of new trials. This has led to a more streamlined and transparent process for the setting up of trials and has ensured that all service departments are fully engaged from the outset. In general, this has meant a reduction in the time taken to open trials and, above all, it has established a collaborative approach to research overall.

UHBFT also appointed a Research Co-ordinator in the Imaging Department, who is the single point of contact for all studies involving imaging. The department has recently established a Cancer Trials Imaging Meeting which meets ahead of the CRFG to ensure that imaging issues are highlighted and responded to quickly. This is of particular importance for industry studies where the Imaging Manual is often American and, therefore, practice and radiation dose often differs from UK practice. The Research Co-ordinator has established systems to ensure that all patients who are identified as trial participants have RECIST reporting prospectively.

The Regional Haematology Research Nurse Group is co-ordinated by the UHBFT Haematology Senior Research Nurse. The group meets 6 weekly for education and sharing of good practice.

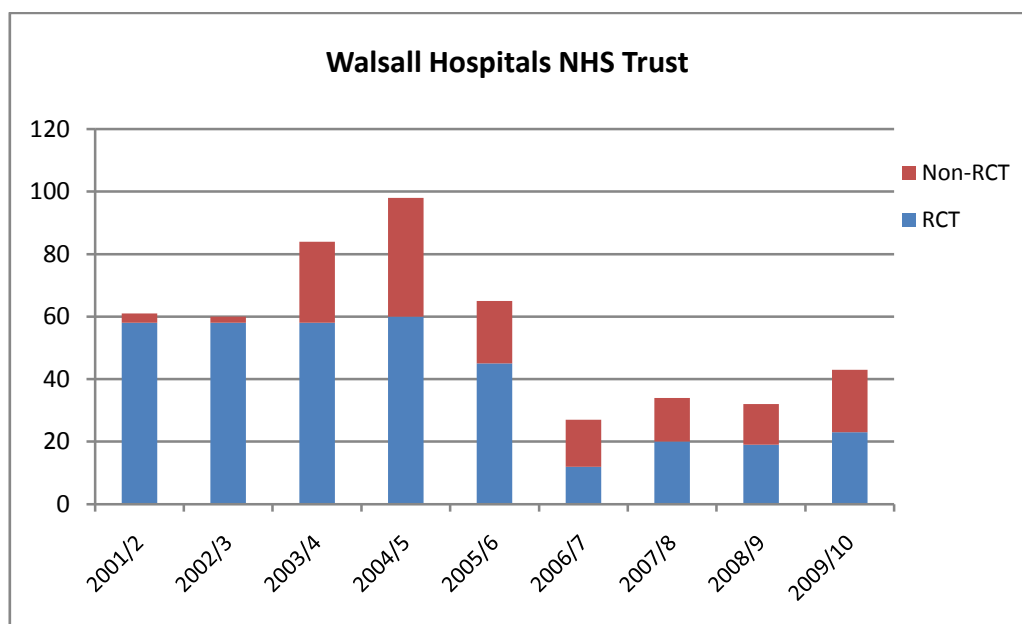
There have been a number of staff changes within UHBFT with the solid tumour and haematology teams both now having a senior research nurse. This ensures that the Research Nurse teams have direct line management support and leadership. Similarly a Senior Trials Coordinator was appointed in 2009 to provide essential line management support and leadership for the data management/administrative component of the team. The research nurse team has expanded in year, allowing a widening of the portfolio to include palliative care. The Trust has recently appointed a Trust Lead Research Nurse.

Another initiative that has recently occurred at the Trust, is the approval of a non-medical PI for a non IMP study. This is a model that is being encouraged at the CRFG. In addition, one of the Research Radiographers has been approved to receive consent from patients for radiotherapy studies, with the aim being that this will facilitate recruitment.

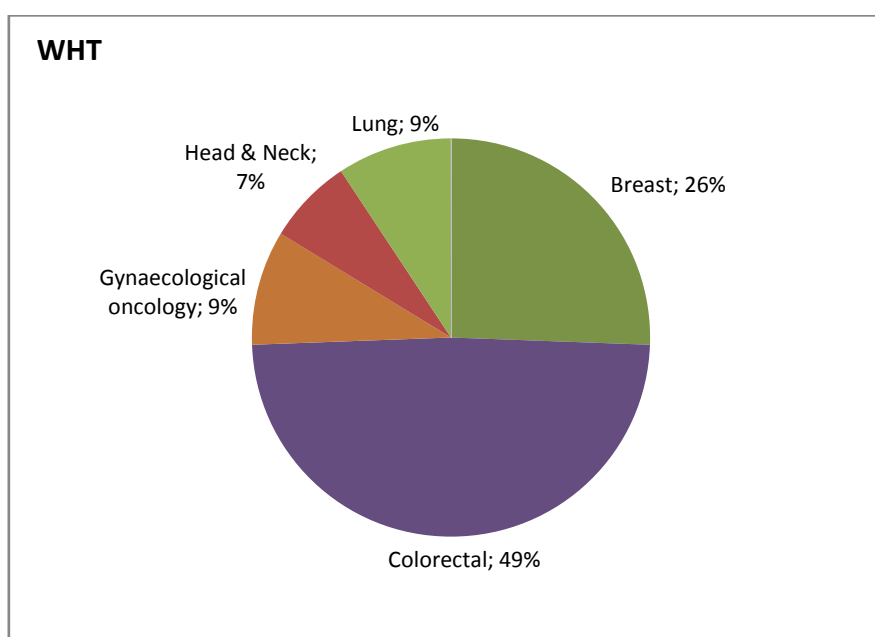
## Walsall Hospitals NHS Trust

Until March 2010, Walsall Hospital NHS Trust was situated in Pan Birmingham and Greater Midlands Cancer Research Networks. There is an agreement between the two Networks that recruitment is shared 1:2, as initially Pan Birmingham provided a 0.5 wte Research Nurse and Greater Midlands 1.0 wte.

**Figure 2g Recruitment of cancer patients and patients with a pre-malignancy to NCRN portfolio studies (including adopted commercial) 2001-2010 and portfolio by CSG for 2009/10.**



**Pie Chart of recruitment by disease site by CSG for 2009/10**



Recruitment at Walsall Hospitals NHS Trust has shown a small increase in both RCT and non-RCT recruitment. The delays in opening studies which were reported in 2008/9 persisted for some time into 2009/10. The portfolio has expanded this year to include 5 tumour sites, with patients recruited into 9 different studies. Three studies did not recruit patients as patients were ineligible or declined and there was no active screening for three urology studies due to staff changes in the urology team.

As a DGH with no specialist surgical services, the Trust is particularly impacted on by the change to more targeted therapies. The historic high levels of RCT recruitment was predominantly into breast trials, which frequently were open to 'all women with breast cancer'. Newer studies are targeting smaller subgroups, thus requiring a greater number of studies to achieve the same recruitment levels. The expansion of the portfolio to a greater number of disease sites will help to mitigate for this effect.

### **Initiatives and Good Practice**

There has been an increase and enhancement in the relationships and integration of the research team with other key stakeholder departments to ensure processes worked well for patients in clinical trials.

Two patients were referred for trial entry outside the Trust, one to UHBFT, the other to Royal Marsden.

During 2009/10, there was agreement that Walsall would transfer the population which resided within Greater Midlands to Pan Birmingham with effect from 1 April 2010. This was agreed by the Trust and the steering groups of both Cancer Research Networks and the National Cancer Research Network. The Research Network Managers for both Networks worked closely with the Trust management to ensure continuity of staffing, whilst the HR process was completed for the new Trust based posts.

## 2.6 Portfolio balance compared to national portfolio 2009/10

Section 2.2 details the balance and performance by clinical studies group within Pan Birmingham Cancer Research Network. As previously stated, there has been recruitment in every tumour site which is a major achievement.

Tables 4a and 4b, on the following pages, show recruitment by clinical studies group compared to the national average for that disease site. It should be noted that the national portfolio does not necessarily have the ideal spread of recruitment, but it is useful to be able to benchmark the Network's activity.

Recruitment into the national portfolio is dependent on the number of studies available, the incidence of the tumour type, the resources allocated across all Networks, as well as clinician interest.

The table has been colour-coded using the convention below.

Equal or greater than national average	Less than 80% of national average
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Again it should be noted that where the percentage of recruitment in the national portfolio is very low, the colour coding does not discriminate well between studies that Pan Birmingham recruits significantly or slightly below the national average.

The distribution of RCT to non-RCT recruitment in Pan Birmingham is very similar to the national portfolio as shown below.

	% of Total PBCRN Recruitment 09/10	% of Total National Recruitment 09/10
RCT	37	42
Non-RCT	63	58

As previously described in section 2.2, Pan Birmingham has a number of areas of strength. All of the disease sites identified recruitment above the national average either for RCTs or non-RCTs or both, with the exception of the breast portfolio, which is well below the national average for both RCT and non RCT recruitment. This, however, reflects that some Networks are unable to have the wide balance of portfolio and recruitment is concentrated in common tumour sites.

As previously noted, most radiotherapy recruitment is attributed to the disease site with which patients are diagnosed, the following tables, therefore, under-represent this recruitment, both nationally and locally.

Non-RCT colorectal recruitment is almost three times the national average due to a single local study, which has recently closed to recruitment. A local lung study also boosts non-RCT recruitment above the national average.

**Table 4a: Annual Network recruitment to RCTs (cancer, pre-malignant, commercial) by Clinical Studies Group from 2001-2010**

Recruitment of cancer, pre-malignant patients and recruitment to NCRN adopted commercial studies by CSG by year (by network)											
	Recruitment to RCTs									% of Total Local Network Recruitment 09/10	% of Total National Recruitment 09/10
	2001-2	2002-3	2003-4	2004-5	2005-6	2006-7	2007-8	2008-9	2009/10		
Bladder	18	14	6	5	8	5	22	38	40	2.6	0.5
Brain	0	0	0	0	0	0	0	0	0	0.0	0.1
Breast	245	225	199	126	49	4	27	46	82	5.4	9.1
Colorectal	28	45	69	36	25	48	74	29	34	2.3	4.9
Complementary Therapies	0	0	0	0	0	0	0	0	0	0.0	0.7
Gynaecological oncology	12	14	20	15	0	0	12	11	7	0.5	0.6
Haematological oncology	104	65	116	123	139	139	120	81	97	6.4	4.3
Head & Neck	0	0	0	0	0	0	0	58	76	5.0	1.7
Lung	17	6	8	26	29	19	33	36	28	1.9	3.1
Lymphoma	8	37	25	18	28	27	32	12	10	0.7	1.2
Miscellaneous	136	96	7	11	0	0	0	1	0	0.0	0.3
Melanoma	0	36	65	61	51	28	1	0	3	0.2	1.1
Palliative Care	0	0	0	0	0	0	0	0	0	0.0	1.6
Primary Care	0	0	0	0	0	0	0	0	0	0.0	0.4
Prostate	0	12	8	15	21	35	31	43	81	5.4	4.6
Psychosocial oncology	0	0	0	0	0	0	0	0	0	0.0	1.7
Renal	0	6	16	18	12	3	0	3	19	1.3	0.8
Radiotherapy	0	0	0	1	0	0	0	0	2	0.1	0.4
Sarcoma	2	0	0	1	1	2	13	15	15	1.0	0.4
Testis	3	5	0	0	0	0	5	3	1	0.1	0.3
CCLG	1	16	20	14	13	23	24	34	16	1.1	0.6
Upper GI	0	4	25	32	34	36	53	57	50	3.3	3.5

Equal or greater than national average

Less than 80% of national average

Note. Recruitment into radiotherapy studies is frequently attributed to the disease specific clinical studies group, rather than the Radiotherapy CSG, therefore, Tables 4a and 4b erroneously underestimate the level of radiotherapy research activity. This also affects other studies where participants may come from several disease sites.

**Table 4b: Annual Network recruitment to non- RCTs by Clinical Studies Group (cancer, premalignant, commercial) from 2001-2010**

Recruitment of cancer, pre-malignant patients and recruitment to NCRN adopted commercial studies by CSG by year (by network)												
	Recruitment to non-RCTs									% of Total Local Network Recruitment 09/10	% of Total National Recruitment 09/10	
	2001-2	2002-3	2003-4	2004-5	2005-6	2006-7	2007-8	2008-9	2009/10			
Bladder	0	0	0	1	37	100	162	173	223	14.8	0.9	
Brain	0	0	0	0	0	0	0	0	11	0.7	0.2	
Breast	0	0	12	131	104	104	135	93	88	5.8	26.4	
Colorectal	0	0	56	196	91	69	76	27	320	21.2	7.2	
Complementary Therapies	0	0	0	0	0	5	9	24	11	0.7	1.4	
Consumer Liaison Group	0	0	0	0	0	0	0	0	0	0.0	0	
Gynaecological oncology	0	0	0	0	0	0	18	57	38	2.5	1.8	
Haematological oncology	0	0	3	3	13	12	3	7	6	0.4	2.2	
Head & Neck	0	0	0	0	0	0	0	0	0	0.0	0.9	
Lung	11	2	110	154	38	50	58	71	59	3.9	1.6	
Lymphoma	1	4	2	2	4	0	0	0	43	2.8	0.5	
Miscellaneous	0	0	0	0	0	0	0	0	0	0.0	1	
Melanoma	0	0	10	6	0	0	0	3	1	0.1	0.8	
Palliative Care	0	0	0	0	0	0	0	0	44	2.9	0.7	
Primary Care	0	0	0	0	0	0	0	0	0	0.0	0.2	
Prostate	3	7	13	23	15	6	2	2	7	0.5	3.8	
Psychosocial oncology	0	0	0	0	1	0	0	0	0	0.0	3	
Renal	0	0	0	0	0	0	0	0	6	0.4	0.3	
Radiotherapy	0	0	0	0	0	0	0	0	0	0.0	0.1	
Sarcoma	0	0	0	0	0	0	0	0	0	0.0	0	
Testis	0	5	0	0	0	0	0	0	0	0.0	1.3	
CCLG	0	17	14	72	27	32	58	63	68	4.5	1.1	
Teenage & Young Adults	0	0	0	0	0	0	0	0	0	0.0	0	
Upper GI	0	0	6	11	0	64	57	34	24	1.6	2.8	

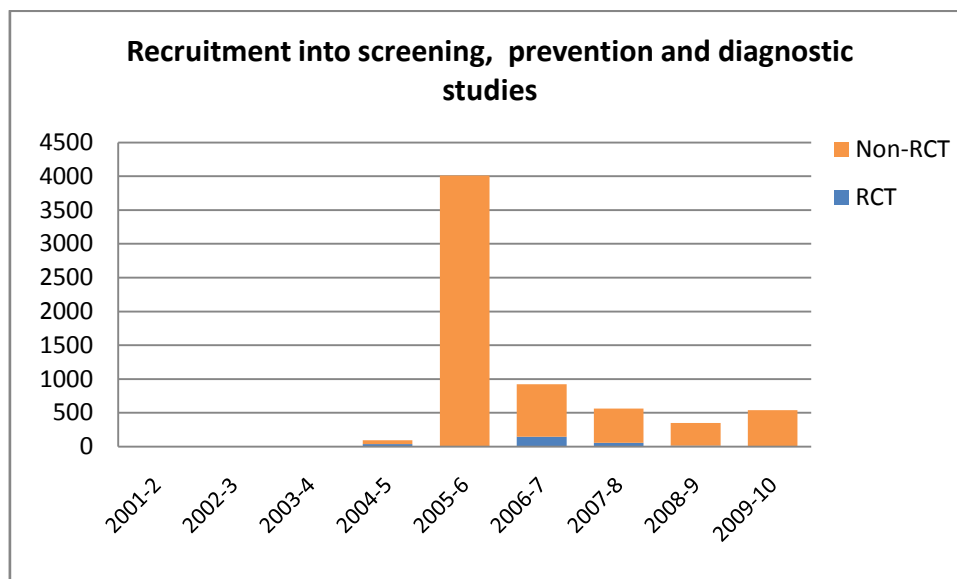
## Recruitment in Primary Care

Additional recruitment of cancer patients into the BBC study is undertaken by GPs and there was recruitment of 2 patients into this study in 2009/10 attributed to Pan Birmingham Cancer Research Network in the NIHR CRN database.

## Non-cancer Patients

As described earlier, there is active recruitment of volunteers into screening and prevention studies within Birmingham, much of this is coordinated and recruited by the University of Birmingham School of Primary Care Clinical Sciences. This is attributed to the disease specific CSG.

**Figure 3 Recruitment into screening, prevention and diagnostic studies 2001/2 - 2009/10**



## 2.7 Follow Up

Follow up of NCRN portfolio studies, including studies that pre-date the NCRN, remains a time consuming activity. Trusts in the Network historically recruited large numbers of patients into breast trials. With the high survival rates for the women entered into these clinical trials, the number of patients continuing to be followed up is substantial. As well as the burden of data returns, this has an impact on the follow up clinics as patients continue to attend hospital for appointments, which at the time the studies opened would not have been considered to be excess visits. Haematology also has a high follow up burden. Paediatric patients are followed up for life and with such high recruitment rates, this places a large burden of data collection on BCHFT and subsequently on UHBFT, when they transfer into adult care. For some organisations this is resulting in delays in returning data for patients who are post treatment.

Some Trusts keep robust records of patients in follow up, where this information is available it is recorded below.

### *BCHFT*

Closed studies – patients on follow-up: 304

Open studies – patients on follow up: 371

### *SWBHT*

Patients still raising queries/last follow ups 2009-2010: approx 700

Closed to recruitment, active follow up: 180

*WHT*

Studies closed to recruitment: 259 patients across 9 studies, including AZURE in which some patients are still on treatment

Open studies – patients on follow up: 12 patients across 4 studies.

The remaining Trusts are unable to give data on the numbers of patients in follow up at present.

## **2.8 Referral of Patients**

As outlined earlier, there is referral of patients between Trusts particularly in some disease sites. All NSSGs receive information about which study is open at which Trust. At present, only some tumour sites proactively encourage referrals for trial entry.

We are aware that some MDTs do make referrals to other Trusts for trial participation, for example the lung MDT at City Hospital make referrals to Birmingham Heartlands Hospital and skin MDTs routinely refer trial eligible patients to Selly Oak. Referrals are frequently made for trial consideration to the urology oncologists from outside of the Network. During 2008/9, the UHBFT-SWBHT Urology MDT agreed to open different studies at the two Trusts with cross referral between the organisations. Increasingly, NSSGs are reviewing their portfolio this way and are encouraging referrals between Trusts, where appropriate.

Where information is known about the numbers of patients referred between Trusts, this is included in the relevant Trust report.

## **2.9 Activity Out With the NCRN Portfolio**

Non-NCRN academic and commercially funded research is undertaken in several Pan Birmingham Trusts.

Heart of England NHS Foundation Trust and University Hospital Birmingham NHS Foundation Trust have staff funded from commercial income who provide support for these studies.

Commercial trials are also run through the Wellcome Clinical Research Facility at UHBFT.

The Cancer Research UK Clinical Trials Unit Early Drug Development Team undertake commercial and academic research at UHBFT. The team conducts a variety of studies, encompassing both solid tumour and haematological malignancies.

There is also a small team from the Trials Unit based at City Hospital, which is involved in commercial research. As described in the Trust report, the team are co-located and work closely with the Trust based team.

The Birmingham Children's Hospital team also work on non-portfolio as well as portfolio research.

A breakdown of recruitment by site is found overleaf.

**Table 5 Recruitment out with the NCRN portfolio**

		Studies Open	Recruitment
BCHFT - Haematology	Commercial	1	1
BCHFT - Solid Tumour	Commercial	6	2
HEFT - BHH Haematology		8	55
HEFT - BHH Solid Tumour		5	23
ROHFT - Solid Tumour	Commercial	2	2
SWBHT - Solid Tumour	Commercial	3	4
UHBFT - Haematology	Academic	2	17
UHBFT - Haematology	Commercial	2	4
UHBFT - Solid Tumour	Academic	3	39
UHBFT - Solid Tumour	Commercial	8	21

There is a research active Oncology Psychology Department at University Hospital Birmingham NHS Foundation Trust. At present, none of the research is within the NCRN portfolio.

### **3 Consumer Involvement**

#### **3.1 Summary of Consumer Involvement Activity**

A number of years ago, Pan Birmingham Cancer Research Network decided not to set up a separate Consumer Group. The Research Network Manager or Lead Nurse attends the Pan Birmingham Cancer Network User Partnership, which meets monthly and facilitates access to the group for researchers.

A member of the User Partnership attends the Research Committee and sits on the Flexibility and Sustainability Funding panel and the Minutes of the meetings are available to the general public via the Pan Birmingham Cancer Network website.

Copies of the PBCRN Newsletter and Annual Report are made available to members of the User Partnership and the Consumer Liaison Group member that resides in Pan Birmingham.

#### **3.2 Impact of Consumer Involvement Activity**

During 2009/10, one researcher accessed the User Partnership for comments. The User Partnership meeting which was attended by more than 10 patients and carers reviewed both the layout of a questionnaire and the wording of individual questions, as well as the wording of the Participant Information sheet and invitation letter for a NIHR School for Primary Care Research funded study. A number of helpful comments were received at the time and members of the group made a number of comments on paper copies of the documents and returned these direct to the researcher. The comments will be incorporated into updated versions of the documents prior to ethics submission.

#### **3.3 Contact Point for Further Examples of Consumer Involvement**

Enquiries about Consumer Involvement should be directed to the Cancer Research Network Manager.

#### **4 Network initiatives, good practice and impact**

One of the primary roles of the Research Network is to gather and share good practice, both within and between Networks. Highlighted below are several examples of initiatives and good practice within Pan Birmingham.

It is also important that the impact of delivering research through Research Networks can be highlighted and reported. Trusts were asked to give examples of this and these are given below. Additional examples are always welcome.

##### *Initiatives and good practice*

Pan Birmingham Cancer Research Network has provided funding through the flexibility and sustainability funding stream for Research Co-ordinators in the Imaging Departments at HEFT, UHBFT and SWBH. HEFT initiated the type of post and this was replicated by the other two Trusts. The purpose of the post is to have a single point of contact for studies involving imaging. The Research Co-ordinators have been meeting regularly to ensure consistency across the Network. They are involved in ensuring that IR(ME)R is complied with locally, RECIST reporting is undertaken and ensuring systems are in place to open studies quickly, for example, image transfer is required.

As detailed earlier in the report, Pan Birmingham Cancer Research Network is part of a well established training initiative, the Birmingham Research Training Collaborative, which has ensured that research staff have easy local access to relevant training. This continues to evaluate well amongst attendees.

The Research Network has continued to benefit from an excellent relationship with the Pan Birmingham Cancer Network Commissioning Group and has, therefore, continued to be able to access excess treatment costs.

The Research Committee agreed the inclusion of several more clauses to the Service Level Agreement which will support efforts to improve recruiting to time and target, when implemented.

The development of a process to allow research nurses at HEFT to request imaging, including those covered by IR(ME)R as per the study protocol has improved the quality of the request and, therefore, ensured that study specific tests and reports are completed in a timely manner.

The Cancer Research Facilitation Group at UHBFT, which is made up of all service departments and the research teams, has been highly successful at streamlining the set up process and ensuring engagement of the service leads as well as better integrating the multiple research teams.

HEFT are piloting electronic alerts for trials patients to ensure that research staff are aware of admissions and, therefore, improve serious adverse event reporting.

SWBH Cancer Management have ensured that research is embedded into their cancer strategy and MDTs are required to report their research activity as part of their regular report to the Trust Cancer Locality Executive Group meeting. MDT Leads are expected to attend the meeting at which the Research Lead reports.

More examples of initiatives and good practice within the Trusts have been highlighted in the relevant Trust reports.

### *Impact*

The ability of the Cancer Research Network to ensure that there is appropriate resource across the Network Trusts has ensured that, for the first time, there has been recruitment in every tumour site, thus enabling increased access to clinical research for more patients.

The Radiotherapy Department at UHBFT has been able to establish IMRT<sup>6</sup> and IGRT<sup>7</sup> in use for various patient groups as a result of opening several studies including CHHiP, IMPORT LOW and COSTAR. Being able to introduce this within the context of clinical research has ensured that the numbers of patients were controlled and the team were supported by the study team. Outside of trial entry, only a small number of head and neck patients presently have access to IMRT in Pan Birmingham.

The heightened awareness of research amongst the clinical teams and the necessity for KRAS testing for some colorectal trial patients has ensured that KRAS has been swiftly implemented into standard care.

A specific study that was given as an example of influencing local clinical guidelines is: Changes to adjuvant endocrine therapy approach as a result of TEAM trial 5 year analysis and translational Sub-protocol results.

The Research Network core team will be working with Trusts and local teams to ensure that impact is more readily identified and documented in future.

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<sup>6</sup> Intensity-Modulated Radiation Therapy

<sup>7</sup> Image-Guided Radiation Therapy

## Appendix 1 Summary Sheet

<b>Network</b>	Pan Birmingham
<b>Clinical Lead(s) for Research</b>	Dr Daniel Ford
<b>Research Network Manager(s)</b>	Mrs Gina Dutton
<b>Network Population</b>	1,940,000 (This includes the whole Walsall population from April 2010) (1,800,000 in 2009/10)
<b>Financial allocation (2009/10)</b>	£ 620,053 plus £161,423 Flexibility and Sustainability Funding

<b>Network organisation</b>	<b>Centralised/devolved/mixed</b>
Staff appointments	Core team – part of Cancer Network; Trust posts – employed by Trusts
Line management	Manager and Clinical Lead – Cancer Network; Trust posts – Trust Line Manager, mix of cancer services and R&D
Governance	Central completion of SSI forms available by Information Officer
Portfolio management	Trust decisions, with support and guidance from Core Team

Summary of NHS organisations within the network from which patients are recruited (or referred)				Nature of the institution:				Summary of staff resource (wte)		
Trust name	Trust acronym	Hospital site(s)	Hospital site acronym	University Teaching Hospital with Medical School (y/n)	ECMC centre (y/n)	Able to deliver radiotherapy? (y/n)	Able to deliver intravenous chemotherapy? (y/n)	NCRN-funded (wte)	CLRN funded (wte)	Non-NIHR funded (wte)
Birmingham Children's Hospital NHS Foundation Trust	BCHFT	Birmingham Children's Hospital	BCH		Y	N	Y	1.0	1.2	4.0
Birmingham Women's NHS Foundation Trust	BWHFT	Birmingham Women's Hospital	BWH		N	N	Y	0.2		
Heart of England NHS Foundation Trust	HEFT	Birmingham Heartlands Hospital	BHH		N	N	Y	4.9	8.3	3.2
		Solihull Hospital – also in Arden Network	SH							
		Good Hope Hospital	GHH							

## Appendix 1 Summary Sheet

Summary of NHS organisations within the network from which patients are recruited (or referred)				Nature of the institution:				Summary of staff resource (wte)		
Trust name	Trust acronym	Hospital site(s)	Hospital site acronym	University Teaching Hospital with Medical School (y/n)	ECMC centre (y/n)	Able to deliver radiotherapy? (y/n)	Able to deliver intravenous chemotherapy? (y/n)	NCRN-funded (wte)	CLRN funded (wte)	Non-NCRN funded (wte)
Royal Orthopaedic Hospital NHS Foundation Trust	ROHFT	Royal Orthopaedic Hospital	ROH		N	N	N	0.7		
Sandwell and West Birmingham NHS Trust	SWBHT	City Hospital Sandwell General Hospital	CH SGH		N	N	Y	4.8	2.2	0.8
University Hospital Birmingham NHS Foundation Trust	UHBFT	Queen Elizabeth Hospital Selly Oak Hospital	QEH SOH	Y	Y	Y	Y	4.4	6.9	10.7
Walsall Hospitals NHS Trust	WHT	Walsall Manor Hospital – also in Greater Midlands Network	WMH		N	N	Y	1.6* *0.5 funded by PBCRN 1.1 funded by GMCN		

## Appendix 1 Summary Sheet

### Summary of Activity in the NCRN Portfolio:

	Total numbers participants recruited/year (including NCRN Commercial Activity)								Recruitment as a % of cancer incidence (using a rate of 0.0046 cases/head of population)	
	Cancer patients		Patients with pre-malignant disease		Non-cancer pts (Screening & prevention studies)		Cancer patients recruited to Commercial NCRN trials (currently all RCTs)		RCT	Non-RCT
	RCT	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	No studies open	Recruitment		
2001-2	574	15	0	0	6	0			6.9	0.2
2002-3	581	35	0	0	3	0			7.0	0.4
2003-4	586	226	1	0	0	0			7.1	2.7
2004-5	504	599	0	0	35	58			6.1	7.2
2005-6	410	330	0	0	1	4011			5.0	4.0
2006-7	358	442	11	0	146	776			4.5	5.3
2007-8	428	578	19	0	54	510	2	9	5.5	7.0
2008-9	437	554	26	0	14	334	4	4	5.6	6.7
2009-10	524	948	0	2	7	589	9	36	6.8	11.5

### Summary of Activity in the Commercial NCRN Portfolio

NCRN ID	Agreed mCTA target (number by date)	Actual numbers of patients recruited to date	NCRN ID	Agreed mCTA target (number by date)	Actual numbers of patients recruited to date
BEATRICE	6	7	NCRN055	4	8
NCRN014	8	9	NCRN072	4	0
NCRN016	3	3	NCRN078	3	3
NCRN042	2	2	NCRN085	1	0
NCRN044	8	5	NCRN104	5	10

Other topic networks in your locality	
	West Midlands Medicines for Children Research Network
	West Midlands Stroke Research Network
	Heart of England Mental Health Research Hub
	Primary Care Research Network for Central England

Comprehensive Local Research Network(s)	Cancer Research Network Trust included
Birmingham and Black Country (BBC CLRN)	All of Pan Birmingham Cancer Research Network Trusts

## Appendix 2A Table 1: Pan Birmingham Cancer Research Network Forecast and Actual Recruitment 2009/10

This table shows red, amber, green status for actual recruitment compared to estimated recruitment. Please refer to body of Annual Report for information about method of estimating.

The red, amber, green status should be viewed with caution for studies where expected and actual recruitment numbers are small, as variance of one patient impacts significantly on percentage of forecast.

Green if the study is recruiting to at least 95% target
Amber if the study is recruiting to 80-95% of target
Red if the study is recruiting to less than 80% target
No estimate

Study Acronym	RCT/non-RCT	Study Category	Network Forecast Recruitment 2009/10	Network Actual Recruitment 2009/10
<b>Bladder Cancer Group</b>				
BCPP	Non-randomised	Cancer patients	180	223
SELENIB	Randomised	Cancer patients	50	40
SPARE	Randomised	Cancer patients	5	0
<b>Brain Cancer Group</b>				
NBT	Non-randomised	Cancer patients	20	11
<b>Breast Cancer Group</b>				
BBC Study	Non-randomised	Cancer patients	10	2
BBC-NCRN cohort	Non-randomised	Cancer patients	20	2
BEATRICE	Randomised	Cancer patients	10	3
EMBRACE	Non-randomised	Cancer patients	20	36
FBCS	Non-randomised	Cancer patients	36	44
FBCS	Non-randomised	Non-cancer patients		6
ICICLE	Non-randomised	Pre-malignant patients		2
IMPORT LOW	Randomised	Cancer patients	24	33
NeoExcel	Randomised	Cancer patients	18	24
PARP BRCA trial	Non-randomised	Cancer patients		2
Persephone	Randomised	Cancer patients	20	7
PG-SNPS - Bolt on study	Non-randomised	Cancer patients	0	0
POETIC	Randomised	Cancer patients	5	11
PRIME II	Randomised	Cancer patients	4	1
REACT	Randomised	Cancer patients		0
SoFEA	Randomised	Cancer patients	8	1
SUPREMO	Randomised	Cancer patients	3	2
TACT Trial Long Term QL (sub-study)	Randomised	Bolt on study	3	7

**Appendix 2A Table 1: Pan Birmingham Cancer Research Network Forecast and Actual Recruitment 2009/10**

Study Acronym	RCT/non-RCT	Study Category	Network Forecast Recruitment 2009/10	Network Actual Recruitment 2009/10
<b>Children's Cancer and Leukaemia Group</b>				
CLOUD	Non-randomised	Cancer patients		1
CNS 2004 03 (LOW GRADE GLIOMA 2 SIOP-LGG2 2003)	Randomised	Cancer patients	8	3
CNS 2004 10 (MRS Brain Tumours)	Non-randomised	Cancer patients	30	22
CNS 2004 11 (MRS Brain Stem Tumours)	Non-randomised	Cancer patients		0
CNS 2007 04 (BSG temozolomide)	Non-randomised	Cancer patients		1
CNS 2007 09 (Infant ependymoma observation study)	Non-randomised	Cancer patients	1	0
CRUK / CCLG AT9283 in Paediatric Patients	Non-randomised	Cancer patients		1
ET 2000 03 (EURO-E.W.I.N.G. 99)	Randomised	Cancer patients	4	2
FACT	Non-randomised	Non-cancer patients	10	4
FACT	Non-randomised	Cancer patients		1
GC 2005 04 (Germ Cell 3)	Non-randomised	Cancer patients	3	0
GC 2006 06 (Germ Cell survivors)	Non-randomised	Cancer patients	6	1
LEG 2004 06 (Wilms tumour survivors)	Non-randomised	Cancer patients	3	1
LT 2007 03 (SIOPEL 06)	Non-randomised	Cancer patients		0
MR based functional imaging for the enhanced management	Non-randomised	Cancer patients		31
NB 2002 06 (High Risk Neuroblastoma)	Randomised	Cancer patients	3	3
NHL 2000 06 (ALCL 99)	Randomised	Cancer patients	2	0
PK 2003 07 (13-cis RA in Neuroblastoma)	Non-randomised	Cancer patients	1	1
PK 2003 08 (Act D/Vincristine in Wilms Patients)	Non-randomised	Cancer patients	1	0
PK 2005 02	Non-randomised	Cancer patients	2	1
PK 2006 07	Non-randomised	Cancer patients		2
PK 2006 09	Non-randomised	Cancer patients		2
RB 2005 11 (Retinoblastoma)	Non-randomised	Cancer patients	9	3
STS 2006 03 (NRSTS)	Non-randomised	Cancer patients		0
STS 2006 04 RMS 2005 (ESSG1)	Randomised	Cancer patients	4	4
WT 2002 01 (SIOP Wilms)	Randomised	Cancer patients	6	4
<b>Colorectal Cancer Group</b>				
COIN B / CR11	Randomised	Cancer patients	3	0
CORGI	Non-randomised	Cancer patients		17
CORGI	Non-randomised	Non-cancer patients		59
CReST	Randomised	Cancer patients		1
FACS	Randomised	Cancer patients	8	7
FOXROT	Randomised	Cancer patients	16	8
NSCCG - Includes non-cancer recruits	Non-randomised	Cancer patients	25	31

**Appendix 2A Table 1: Pan Birmingham Cancer Research Network Forecast and Actual Recruitment 2009/10**

Study Acronym	RCT/non-RCT	Study Category	Network Forecast Recruitment 2009/10	Network Actual Recruitment 2009/10
<b>Colorectal Cancer Group (Continued)</b>				
Patient Experience of ED	Non-randomised	Cancer patients		272
Patient Experience of ED	Non-randomised	Non-cancer patients		179
QUASAR 2	Randomised	Cancer patients	4	5
SCOT	Randomised	Cancer patients	10	13
<b>Complementary Therapies Development Group</b>				
DietComplyf	Non-randomised	Cancer patients	24	11
<b>Gynaecological Cancer Group</b>				
CHORUS Main trial	Randomised	Cancer patients	2	1
GROINSS-V II	Non-randomised	Cancer patients		3
NEO-ESCAPE	Randomised	Cancer patients	8	6
NSECG	Non-randomised	Cancer patients	30	35
SCOTROC 4	Randomised	Cancer patients	3	0
UK FOCSS	Non-randomised	Non-cancer patients	15	33
<b>Haematological Oncology Group</b>				
ALLR3	Randomised	Cancer patients	5	0
AML 16	Randomised	Cancer patients	18	20
AML 17	Randomised	Cancer patients		18
ARCTIC	Randomised	Cancer patients		0
CLL207	Non-randomised	Cancer patients	4	0
EsPhALL	Randomised	Cancer patients	2	0
FCLL	Non-randomised	Cancer patients	8	0
MRC PT1	Randomised	Cancer patients	1	0
MRC UKALL 2003	Randomised	Cancer patients	30	37
Myeloma X Relapse (Intensive)	Randomised	Cancer patients	3	3
NCRN042	Randomised	Cancer patients	4	2
NCRN043	Randomised	Cancer patients	4	1
RICAZA	Non-randomised	Cancer patients	5	6
SPIRIT 2	Randomised	Cancer patients	6	3
TOPPS	Randomised	Cancer patients		13
UKATT/UK Amyloidosis Treatment Trial	Randomised	Cancer patients	1	0

**Appendix 2A Table 1: Pan Birmingham Cancer Research Network Forecast and Actual Recruitment 2009/10**

Study Acronym	RCT/non-RCT	Study Category	Network Forecast Recruitment 2009/10	Network Actual Recruitment 2009/10
<b>Head and Neck Cancer group</b>				
COSTAR	Randomised	Cancer patients	3	1
Determination of Quality of Life Instrument	Randomised	Cancer patients	40	60
HOPON	Randomised	Cancer patients	2	8
PET-NECK study	Randomised	Cancer patients	8	7
SEND	Randomised	Cancer patients	4	0
<b>Lung Cancer Group</b>				
BTOG2	Randomised	Cancer patients	8	15
CLUB	Non-randomised	Non-cancer patients	50	6
CLUB	Non-randomised	Cancer patients	50	47
FRAGMATIC	Randomised	Cancer patients	3	1
LungStar	Randomised	Cancer patients	15	10
MALCS (Mesothelioma and Lung Cancer Study)	Non-randomised	Cancer patients	4	5
NCRN014 - INDUSTRY STUDY	Randomised	Cancer patients	2	2
Qualitative interviews with lung cancer patients	Non-randomised	Cancer patients		7
QUARTZ	Randomised	Cancer patients	2	0
<b>Lymphoma Group</b>				
Mantle Cell P3	Randomised	Cancer patients	2	1
NCRN016 - MAIN	Randomised	Cancer patients	4	3
PET After 2 cycles in NHL	Non-randomised	Optional Sub Study Recruits		2
RATHL	Randomised	Cancer patients		4
R-CHOP 14 vs 21	Randomised	Cancer patients	Closed	2
R-CODOX-M/IVAC	Non-randomised	Cancer patients		1
SDO - Information for Choice	Non-randomised	Cancer patients		42
Waldenstrom's study	Randomised	Cancer patients	2	0
<b>Melanoma Group</b>				
AVAST-M	Randomised	Cancer patients	10	3
Melanoma Cohort Study	Non-randomised	Cancer patients		1
The Melanoma Lifestyle Study	Non-randomised	Cancer patients	3	0
<b>Palliative Care Group</b>				
EPAT©	Non-randomised	Cancer patients	8	44

**Appendix 2A Table 1: Pan Birmingham Cancer Research Network Forecast and Actual Recruitment 2009/10**

Study Acronym	RCT/non-RCT	Study Category	Network Forecast Recruitment 2009/10	Network Actual Recruitment 2009/10
<b>Prostate Cancer Group</b>				
BIPAS	Non-randomised	Non-cancer patients	250	209
CHHIP	Randomised	Cancer patients	25	37
NCRN078	Non-randomised	Cancer patients		3
RADICALS	Randomised	Cancer patients	5	3
RAPPER	Non-randomised	Optional Sub Study Recruits	25	41
Stampede	Randomised	Cancer patients	15	23
TRAPEZE	Randomised	Cancer patients	18	18
UK Genetic Prostate Cancer Study	Non-randomised	Cancer patients	5	4
<b>Radiotherapy Group</b>				
SCORAD	Randomised	Cancer patients		2
<b>Renal Cancer Group</b>				
European Trial of Free Light Chain Removal by Extended Haemodialysis in Cast Nephropathy	Non-randomised	Cancer patients		6
NCRN044 - INDUSTRY STUDY	Randomised	Cancer patients	5	4
NCRN055 - INDUSTRY STUDY	Randomised	Cancer patients		8
SORCE	Randomised	Cancer patients	5	7
<b>Sarcoma Group</b>				
EURAMOS 1	Randomised	Cancer patients	2	5
VORTEX	Randomised	Cancer patients	14	10
VORTEX BIOBANK	Non-randomised	Recruits to optional sub-study	14	9
<b>Testis Cancer Group</b>				
BEP 111	Non-randomised	Cancer patients		1
<b>Upper Gastro-Intestinal Cancer Group</b>				
NCRN104	Randomised	Cancer patients		10
BILCAP	Randomised	Cancer patients	3	5
ESPAC - Tplus	Non-randomised	Cancer patients		20
OE05	Randomised	Cancer patients	18	14
SCOPE 1	Randomised	Cancer patients	4	3
ST03	Randomised	Cancer patients	4	10
SOCS	Non-randomised	Cancer patients	5	4
COG	Randomised	Cancer patients	4	4
COUGAR	Randomised	Cancer patients		4
MOSES	Non-randomised	Non-cancer patients		41

## Appendix 2B Table 2: LNR NIHR-adopted commercial portfolio, agreed targets and performance 2009-10

The red, amber, green status should be viewed with caution for studies where expected and actual recruitment numbers are small, as variance of one patient impacts significantly on percentage of forecast.

Green if the study is recruiting to at least 80% target (proportionate to time elapsed)

Amber if the study is recruiting to 66-79% of target (proportionate to time elapsed)

Red if the study is recruiting to less than 65% target (proportionate to time elapsed)

Clinical Studies Group	NCRN Ref No.	Agreed mCTA target (Number by date)	Actual Number of patients recruited to date	Comments
Breast	BEATRICE	6	7	Closed
Lung	NCRN014	8	9	
Lymphoma	NCRN016	3	3	Closed
Haematology	NCRN042	2	2	
Haematology	NCRN043	2	1	Small numbers results in big steps in proportional recruitment
Renal	NCRN044	8	5	Delays in opening resulted in patients accessing treatment under NICE, which was not available when target agreed
Renal	NCRN055	4	8	Closed
Upper Gastro-Intestinal	NCRN072	4	0	Remedial actions underway
Prostate	NCRN078	3	3	
Brain	NCRN085	1	0	Study opened to recruitment 18 Jan 2010, although R&D approval and initiation in 2009.
Upper Gastro-Intestinal	NCRN104	5	10	

**Appendix 2C - Table 3: Recruitment by Trust for 2008/09 and 2009/10**

Study/Recruit type	RCT/non-RCT	BCHFT		BWHFT		HEFT		ROHFT	
		2008/09	2009/10	2008/09	2009/10	2008/09	2009/10	2008/09	2009/10
Cancer	RCT	74	55			155	200	13	10
	non-RCT	63	67	21	98	245	497		
Pre-Malignant	RCT								
	non-RCT								
Commercial	RCT					2	8		
	non-RCT								
Bolt-on	RCT								
	non-RCT							12	9
SEARCH	non-RCT								
Non-cancer	RCT					0			
	non-RCT		2		67	49	173		
<b>TOTAL</b>		<b>137</b>	<b>124</b>	<b>21</b>	<b>165</b>	<b>451</b>	<b>878</b>	<b>25</b>	<b>19</b>

Study/Recruit type	RCT/non-RCT	SWBHT		UHBFT		WHT		GP	
		2008/09	2009/10	2008/09	2009/10	2008/09	2009/10	2008/09	2009/10
Cancer	RCT	34	48	160	215	20	23		
	non-RCT	87	93	82	185	12	20	63	2
Pre-Malignant	RCT	26							
	non-RCT		2						
Commercial	RCT	4	3	2	25				
	non-RCT								
Bolt-on	RCT	10	1	4	6				
	non-RCT	8		0	43				
SEARCH	non-RCT								
Non-cancer	RCT	0		0					
	non-RCT	14	78	251	217				
<b>TOTAL</b>		<b>183</b>	<b>225</b>	<b>499</b>	<b>691</b>	<b>32</b>	<b>43</b>	<b>63</b>	<b>2</b>