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# ACRN



Caring for the future

Arden Cancer Research Network

**Arden Cancer Research Network**

**Incorporating**

**Alexandra Hospital – Redditch**

**George Eliot Hospital – Nuneaton**

**Solihull Hospital – Solihull**

**Warwick Hospital – Warwick**

**University Hospital - Coventry**

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# Annual Report

## 2007/08

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<b>Network</b>	Arden
<b>Clinical Lead(s) for Research</b>	Professor Robert Grieve
<b>Research Network Manager(s)</b>	Judith Lake and Donna Halliman
<b>Network Population</b>	1 million

<b>Network organisation</b>	<b>Centralised/devolved/mixed</b>
Staff appointments	Centralised
Line management	Mixed
Governance	Centralised
Portfolio management	Centralised

<b>Summary of NHS organisations within the network from which patients are recruited (or referred)</b>				<b>Nature of the institution:</b>		
<b>Trust name</b>	<b>Trust acronym</b>	<b>Hospital site(s)</b>	<b>Hospital site acronym</b>	<b>University Teaching Hospital with Medical School (y/n)</b>	<b>Able to deliver radiotherapy? (y/n)</b>	<b>Able to deliver intravenous chemotherapy ? (y/n)</b>
University Hospitals Coventry and Warwickshire NHS Trust	UHCW	University Hospital, Coventry	UHCW	Yes	Yes	Yes
Worcestershire Acute Hospitals NHS Trust	WHNT	Alexandra Hospital, Redditch	AHR	No	No	Yes
George Eliot Hospital NHS Trust	GEH	George Eliot, Nuneaton	GEH	No	No	Yes
Heart Of England NHS Foundation Trust	BHST	Solihull Hospital	SHH	No	No	Yes
South Warwickshire General Hospitals NHS Trust	SWH	Warwick Hospital	SWH	No	No	Yes

	ACCRUAL						ACCRUAL AS % OF CANCER INCIDENCE (Cancer & pre-malignant)			
	Cancer pts		Pts with pre-malignant disease		Non-cancer pts (Screening & prevention studies)		Historic NCRN incidence rate		Updated UK incidence rate	
	RCT	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	RCT	Non-RCT
2001-2	232	5	0	0	0	0	5.8	0.1	5.0	0.1
2002-3	300	8	0	0	0	0	7.5	0.2	6.5	0.2
2003-4	354	55	0	0	0	0	8.9	1.4	7.7	1.2
2004-5	313	335	0	0	0	65	7.8	8.4	6.8	7.3
2005-6	203	1084	8	0	0	170	5.3	27.1	4.6	23.6
2006-7	153	364	18	0	5313	154	4.3	9.1	3.7	7.9
2007-8	240	402	23	0	0	87	6.6	10.1	5.7	8.7

<b>Other topic networks in your locality</b>	West Midlands Stroke Research Network Heart of England Mental Health Research Hub Thames Valley Diabetes Research Network West Midlands Medicines for Children Research Network Central England Primary Care and General Practice
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<b>Comprehensive Local Research Network(s)</b>	<b>Cancer Research Network Trust included</b>
West Midlands (South)	

## Executive Summary

The Arden Cancer Research Network was a third wave network receiving its funding in August 2002 and became fully staffed and operational in March 2003. The Network covers a population of one million spread between five hospitals, consisting of one cancer centre and four cancer units.

Before the establishment of the NCRN, there was only modest funding for cancer research within Warwickshire. There were two cancer research nurses and one secretary and the research conducted was a mixture of academic and commercial randomised controlled studies. Since the ACRN has become established, the emphasis has been on conducting studies from the NCRN portfolio, although there has been a more recent development of commercial studies, which will help supplement NCRN income. Before the establishment of the ACRN, up to 80% of trial activity was carried out in the Cancer Centre. There was very little research activity at the cancer units due to the lack of resources, however since the advent of the NCRN this has changed to an almost equal split of recruitment between the centre and the units, thereby providing a greater equity of access to trials across the Network.

The ACRN is a centralised network with all of the staff employed at the Cancer Centre (UHCW) and working at the cancer units. In 2007 InHANSE (Institute of Head and Neck Studies and Education) was created, this is a new initiative led by Hisham Mehanna (Head and Neck surgeon) to lead head and neck cancer research, a new senior research nurse was employed, and she works closely with the ACRN on both NCRN portfolio studies and also commercial studies. This post is partly funded by the pet-neck grant and commercial income.

The Arden Cancer Research Network has had a successful year, entering 6.6% (cancer and pre-malignant) into RCTs, (network target 4.5%) and recruiting 665 into all studies resulting in an overall 16.6 % of patients recruited into trials. These figures represent an improvement on last year. There are 49 studies open spanning most cancer sites. Trial entry still remains predictably very dependent on breast and colorectal studies, but there has been significant progress in the urology and head and neck groups. Brain, lung, lymphoma and gynaecology are still areas that need improvement for despite open studies, trial activity remains low. The UHCW is top equal recruiter to ZICE and second in PRIME II.

There have been important developments this year: Professor Poole has been appointed as a Professor of Medical Oncology and takes up his position in April 2008; he will energise the gynaecology group and further develop the breast portfolio. The ACRN were delighted to be awarded funding from the NCRN redistribution exercise for a clinical fellow to help address recruitment to those research areas where committed clinicians found it difficult to recruit to studies because of their heavy clinical workloads.

In common with other research networks, pharmacy has been an area under great service pressure and this has resulted in trials being particularly slow to be initiated. The South Midlands Comprehensive Network has now funded two pharmacy technicians to help solve this. Similar pressures on pathology time have restricted entry to some studies and funding has been provided to address this.

There are currently over 5000 cases entered on the database and follow up has become a pressing issue in common with other Networks. Upon the retirement of a previous manager the existing posts have been reconfigured and three staff are now in post (1.46 WTEs) responsible for this and also ethics and R&D applications. A one year fixed term contract for another data clerk was appointed from the NCRN redistribution exercise.

In April 2008 The Cancer Ward Appeal Charity agreed to release £600,000 to fund a new research area in University Hospitals Coventry and Warwickshire which will house the ACRN and Professor Poole's team. This will result in even greater collaboration with Warwick University and will incorporate a dedicated chemotherapy research area.

Next year will see the RCT target for the Network rise to 5.5%. The measures put in place will, we anticipate, enable this to be achieved, whilst increased recruitment to the weaker areas of activity and broadening the portfolio remain ongoing goals for the year ahead.

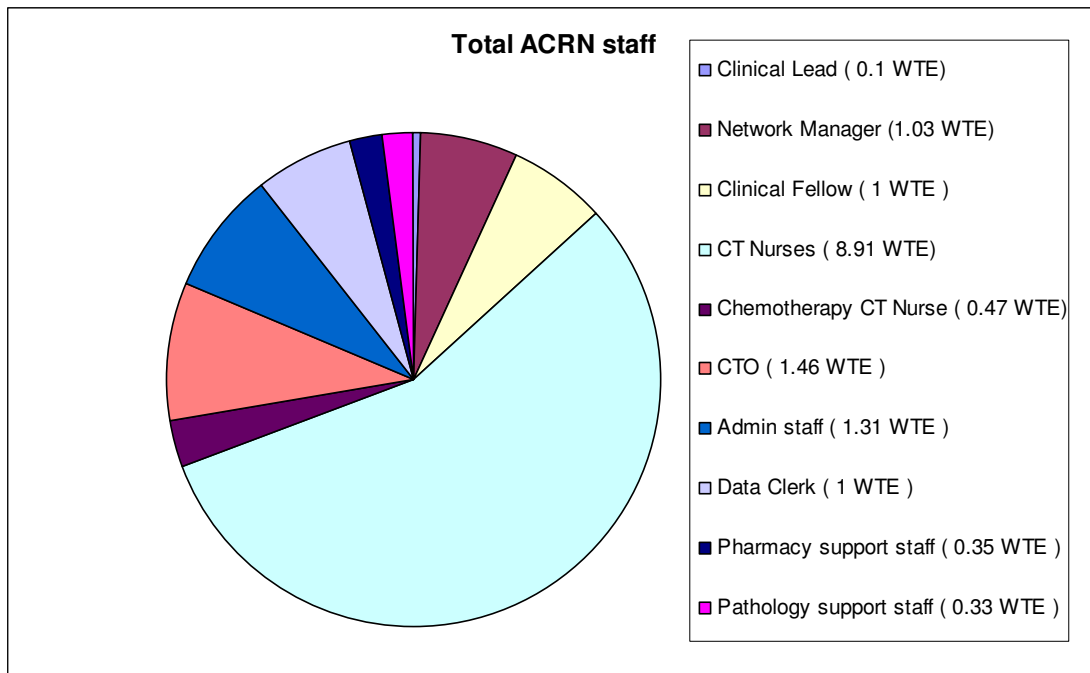
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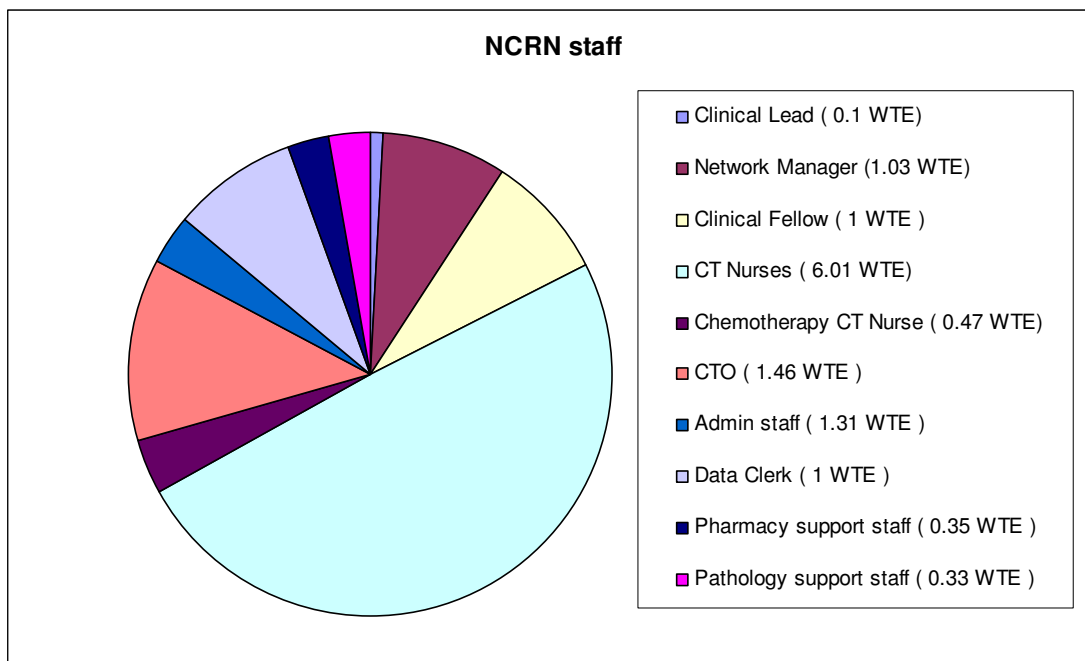
# 1 Organisation and Development of Network

## 1.1 Overview of research support infrastructure; including staffing and services.

The ACRN network team consists of 23 filled posts and one vacancy, all of whom support the NIHR portfolio. This is made up of 15.96 WTE. NCRN-funding provides virtually all of the total resource available supporting recruitment to NIHR cancer portfolio studies, with a few exceptions: the study MOSES is funded separately and the PET-NECK study is funded by the PET-NECK grant.

Research sisters make up the largest proportion of the research team, 56% of the total staff (8.91 WTE); the remainder of the staff are divided amongst the different disciplines as shown in the pie chart below. All hospitals within the Arden Network have access to the NCRN infrastructure, either directly with trials sisters based at the individual hospital, or by referral into the Centre.





The roles of all the posts within the ACRN have remained unchanged throughout the year; however three new posts have been created. A full time Senior Research Sister post for head and neck studies was created, funded by commercial income and with the Pet-Neck grant. Two further posts have been created, due to the NCRN redistribution exercise: a full time data clerk whose sole role is to complete follow up for all open studies, thereby releasing Research Sisters to concentrate on recruiting new patients into studies and a Clinical Fellow who was appointed in May 2008 to support entry of patients into study.

The ACRN has not experienced any issues with staff retention, career development or staff appointments over the past year.

The CLRN have made funding available to support 2 WTE pharmacy technicians, one for cancer and one for other research within the UHCW. These members of staff were appointed in April with an anticipation that they will help reduce delays in trial activation caused by low staffing levels in the Cancer Centre.

## 1.2 Training and Development

Approximately 0.1 WTE of a Senior Research Nurse's time is dedicated to the Network Training Link role, which is devoted to creating induction packages for new starters, delivering and supporting training within the research department, and facilitating appropriate training within the parameters and requirements of the research team. Over the past year this has included induction and objective packages for a range of new and existing NCRN staff. Time has also been spent with the clinical trial facilitators for the newly established Paediatric and Diabetes networks, and help and advice offered and best practice ideas shared.

The NTL facilitates monthly clinical trial surgeries for the research nurses, which involves formal teaching sessions with invited speakers, and clinical supervision; this is ongoing with the nurses requesting specific speakers which cover areas of special interest.

The training required for each individual is identified during the KSF appraisal and the NTL facilitates the individual's personal training objectives, with the most appropriate and cost effective training available.

Time restraints and a heavy clinical case load has prevented the NTL from becoming involved at a national level and indeed to an extent within neighbouring networks. There is some contact with the neighbouring networks through local managers meetings. Contact with the national networks is mainly via the UKCRN's jisk mail system, which has been useful in informing networks of training events, for example our own ICH/GCP updates have been advertised nationally via the jisk mail and also via our local Research and Development department.

The ACRN has established half day GCP updates bi monthly at a local venue to encourage clinician and other research staff within the Network to be regularly updated. To engender good will and to encourage research links within the Network, individuals who are outside the UKCRN's umbrella of research studies have been invited to attend if there have been spaces available on the course, and have not been charged to attend this study day.

In January 2008, with the collaboration and support of Coventry's Research Development department, a Data Protection study day for Research Nurses, Data Managers, Officers and Clerical staff was delivered at Coventry.

With the continuing good links with the Research and Development department at Coventry, it is the aim of the Arden Cancer Research Network to collaborate and liaise over the next year to develop local study days for local research personnel at a local level. This is shortly to include a "preparation for audit and MHRA inspection" study day.

With the development of the South Midlands Comprehensive Research Network, it is our aim to increase and expand our links locally and in future amalgamate training with the development of a training forum devoted to local training, to prevent duplication and improve cost effectiveness. The NTL has been invited to actively participate in this development and monitor its progress.

The NTL and Network Research Nursing Staff deliver overviews of our roles at Coventry University for the six monthly Network Chemotherapy training courses, and also update new staff and students at their local Trusts. The NTL contributes to the training annual updates for Network chemotherapy trained nurses, which are held locally at Coventry; these are delivered once a month.

The NTL supports new departmental staff, which includes students, with an explanation and overview of the research nurses role.

Within the ACRN, link nurses are identified who are interested in a specific nursing subject to deliver an update of their topic to the research nursing team after Team Brief, also updated clinical guidelines for the treatment of specific cancer tumour types are delivered as an integral part of the Team Brief.

## **1.3 Structures and Integration**

### **1.3.1 General Organisation of the Network**

All hospitals within the Network have access to clinical trial staff and support. The core team is based centrally at the Clinical Trial Office in the Arden Cancer Centre, UHCW, and support the clinical trial activity which occurs across the Network. Nursing staff co-ordinate clinical trial activity in the peripheral units and have bases within their respective trusts, from which they co-ordinate their clinical trial activity. All unit staff have line management within their units, who assist in the development of the clinical trial service within the unit. The Research Manager links in with the identified line manager in the Units regarding clinical trial activity within their respective Trust. All network research staff are employed by the Cancer Centre, University Hospitals Coventry and Warwickshire NHS Trust.

Key decisions, such as the distribution of network resources, are taken by the Network Lead and Manager and ratified by the Steering Committee. Other important decisions relating to portfolio development are taken in conjunction with the appropriate NSSG's.

### **1.3.2 Integration with Cancer Services**

Wherever possible, trials are opened at both the Cancer Centre and all cancer units within the Arden Network, when this is not possible, then if at all feasible, mechanisms are put into place to refer patients from one hospital to another e.g. it was only possible to open OE05 at two of the sites within the ACRN due to oesophageal oncology support not being available for patients at all of the sites. Oesophageal patients presenting at sites without the specialist care are referred to the Cancer Centre so that they are not denied access to this study.

As far as is possible, oncology research is integrated into the cancer services within the network, with the research nurses overseeing the care. Patients in studies which require treatment extra to standard care receive their treatment in the clinical trials centre, which is staffed by a trials nurse.

The ACRN was peer reviewed in February 2008, and the following paragraph has been extracted from the draft report (as yet a final report has not been issued):

“This is an effective cancer research network with a well-functioning central team. The research network is highly dependent on the central team for all

trials. The central team provides good direction and management and there are good working relationships within the team. The Steering Group is incorporated into the network board which ensures good senior Trust representation (although has less clinical research representative attendance).”

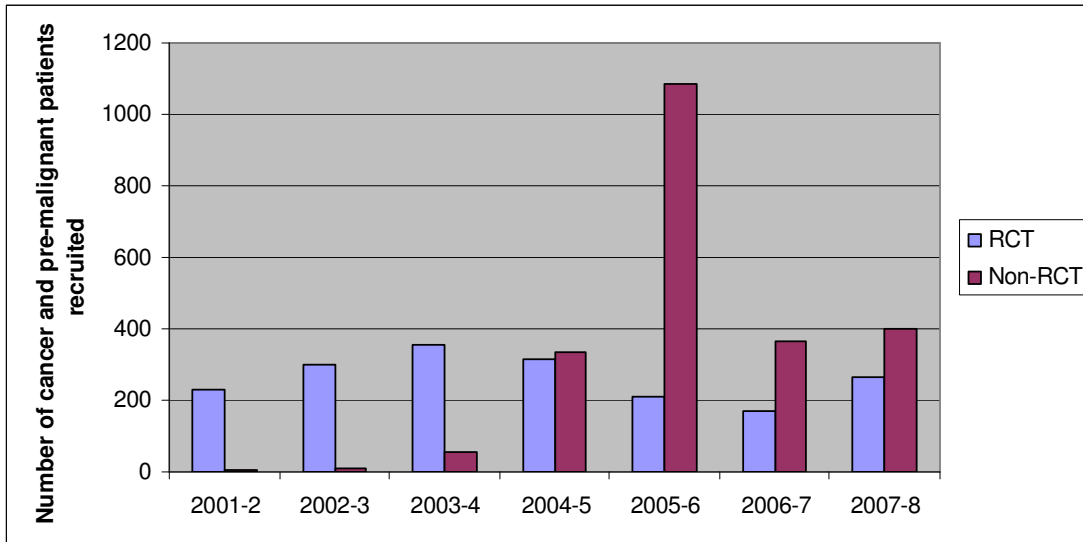
### **1.3.3 Integration with other research infrastructure**

The ACRN Network Manager meets with other local Managers both NCRN and TCRNs. Local NCRN meetings have been established for some years now and are a valuable tool for both peer support and sharing of ideas and initiatives; these meetings are usually held about three times a year. In between meetings, telephone and e-mail contact provides support and sharing of information and best practice. The local TCRNs are now developing and beginning to have collaborative meetings; it is anticipated that these will also become a valuable forum for discussion and to address shared difficulties faced by the different topic networks.

## 2 Portfolio Development and Accrual

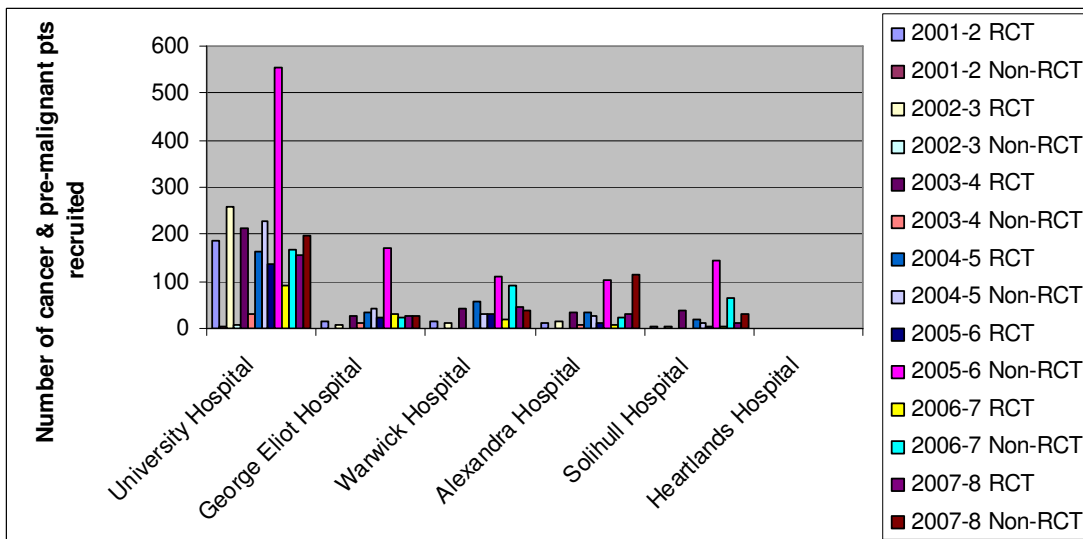
### 2.1 Portfolio and Accrual

Figure 1: Annual Accrual by Network



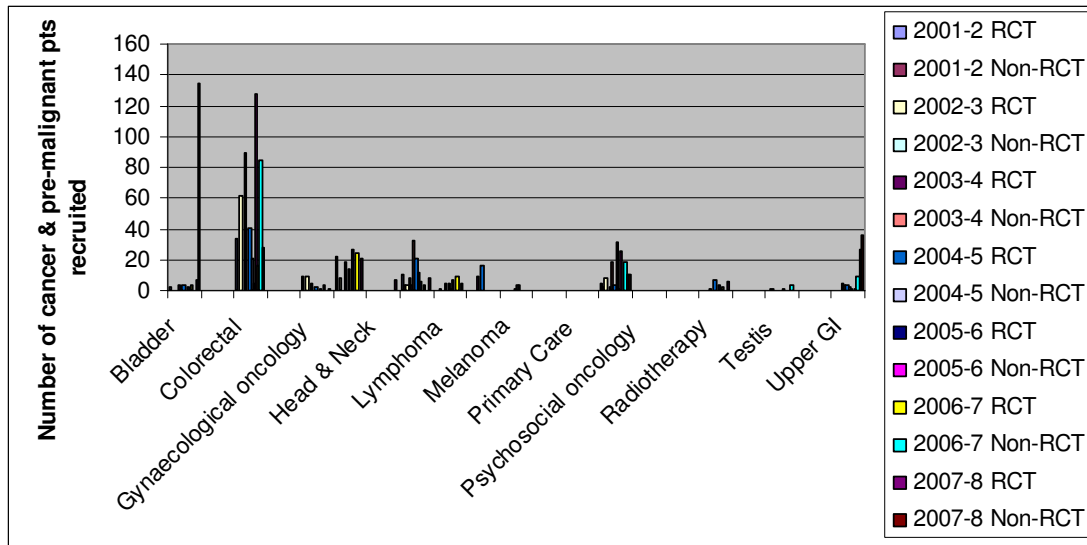
This year has seen a pleasing rise in recruitment to RCTs for cancer patients with 6% of patients being recruited against a recruitment target of 4.5%. If pre-malignant studies are included, this rises to 6.6%. Overall recruitment also rose this year resulting in a total recruitment of 16.7%.

Figure 2: Annual Accrual by Hospital Site



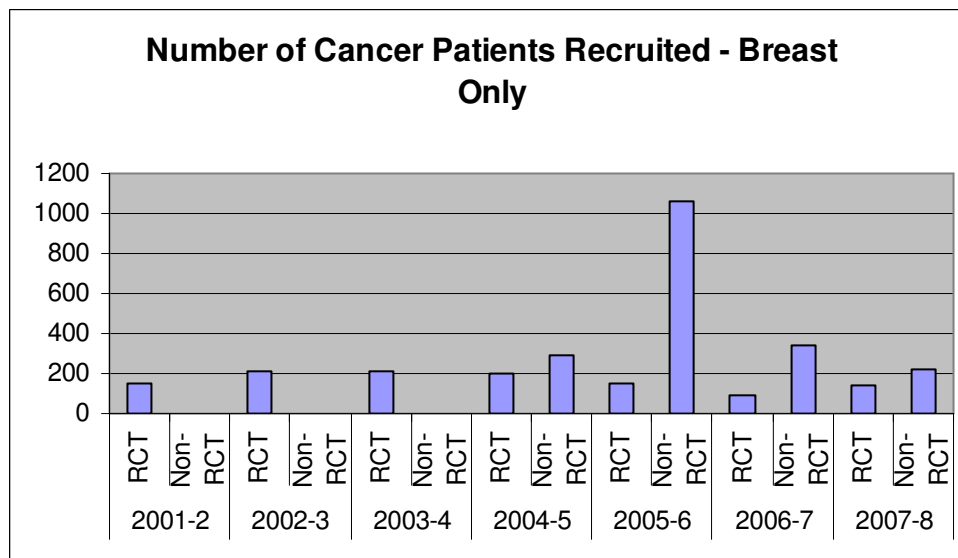
The distribution of trial activity reflects that of the catchment area of the Network with all hospitals contributing numbers appropriate to their population.

Figure 3a: Annual Accrual by Clinical Studies Group by Network (except Breast)



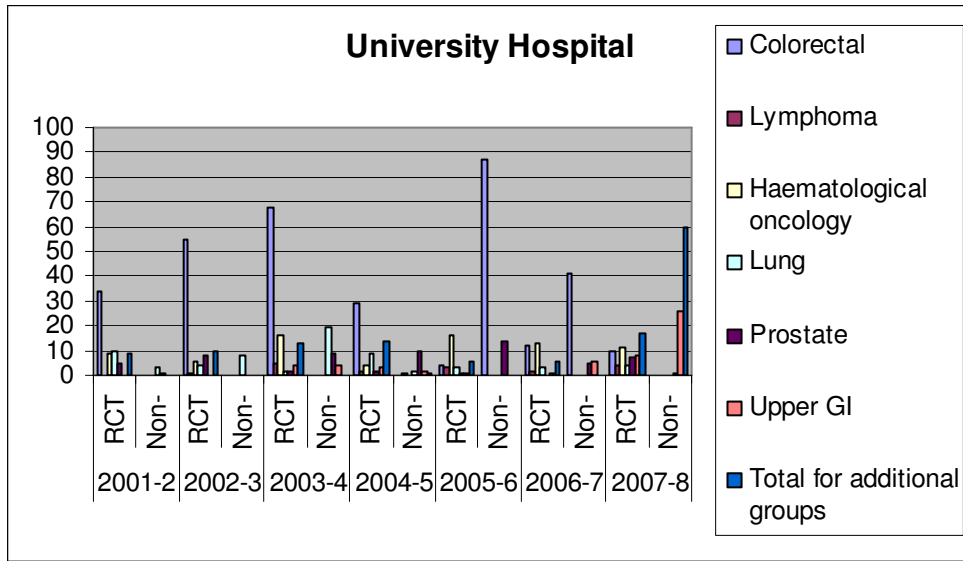
There has been greater recruitment to urology and head and neck trials this year. Gynaecology and CNS remain areas for concern.

Figure 3b: Annual Accrual by Clinical Studies Group: Breast Accrual Only



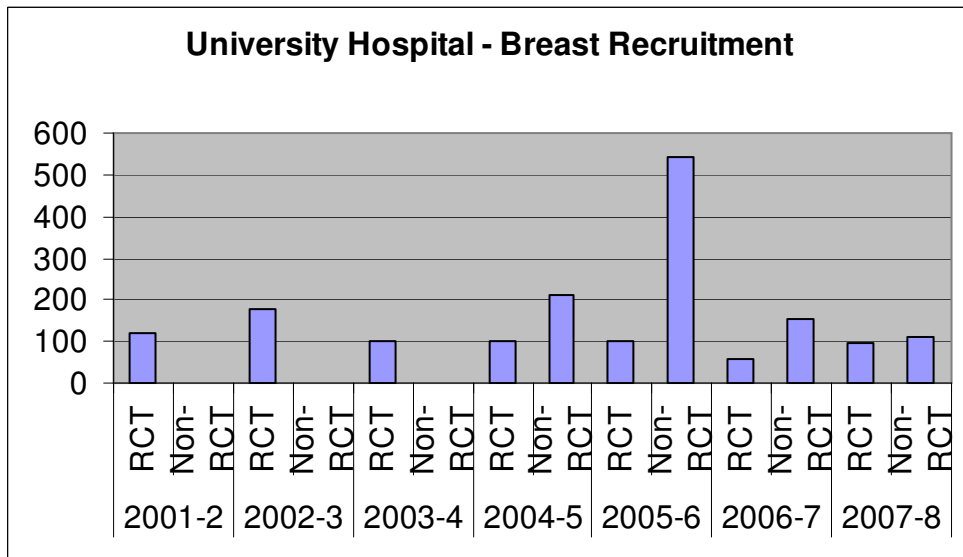
The ACRN continues to recruit very well to breast trials both randomised and non-randomised.

Figure 4ai: Annual Accrual by Clinical Studies Group except Breast: University Hospital



Colorectal studies recruit well but with a very heavy dependency on the NSCCG study. Urology has shown a pleasing upturn in recruitment this year. Leukaemia treatments are to be centralised in the Cancer Centre in 2008 which may help stimulate recruitment in haematological oncology.

Figure 4aii: Annual Accrual by Clinical Studies Group – Breast Recruitment Only – University Hospital



Breast recruitment in the centre remains a cornerstone of the Networks overall activity in both randomised and non randomised studies. UHCW is joint top recruiter nationally to ZICE and second in PRIME II.

Figure 4bi: Annual Accrual by Clinical Studies Group except Breast: George Eliot Hospital

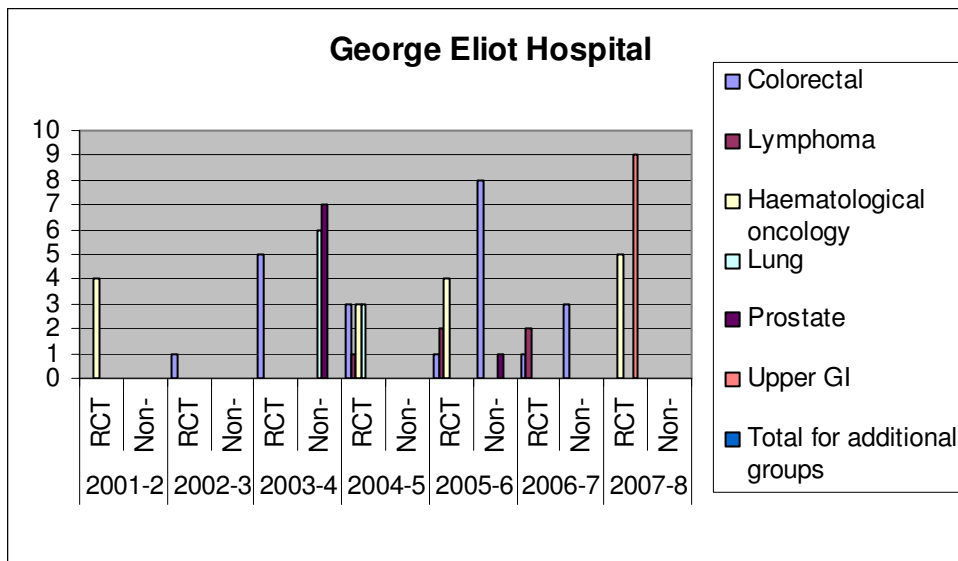
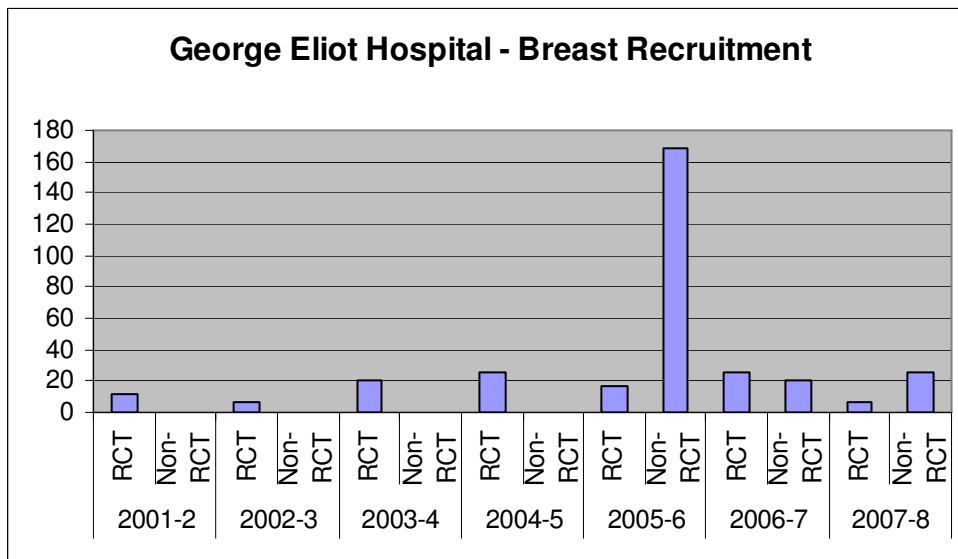


Figure 4bii: Annual Accrual by Clinical Studies Group – Breast Only: George Eliot Hospital



George Eliot Hospital has had a significant turnover of consultants in recent years with retirements and maternity leave but current indications have shown an increase in trial activity at the start of 2008. It does however have a low RCT recruitment activity. Breast studies, especially BBC, account for a large percentage of this Cancer Unit's activity.

Figure 4ci: Annual Accrual by Clinical Studies Group except Breast: Warwick Hospital

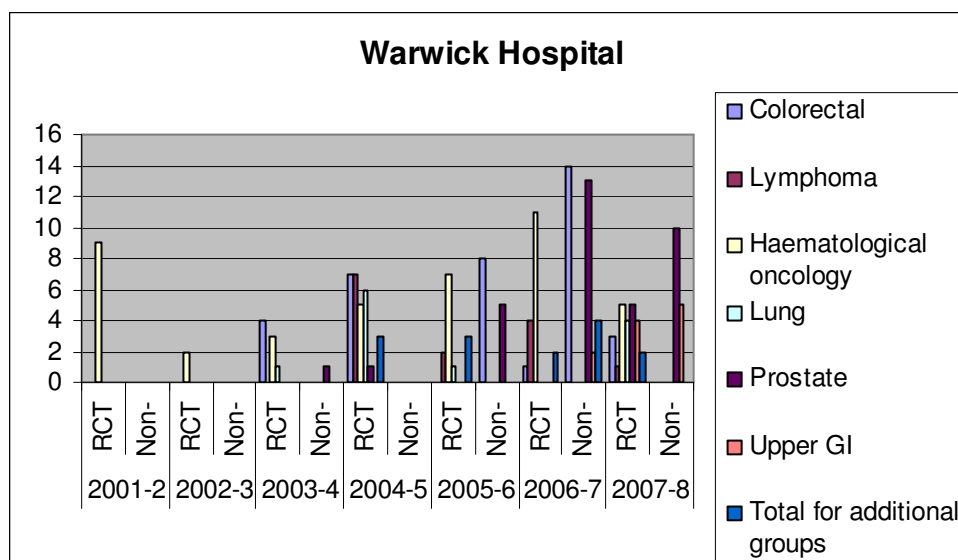
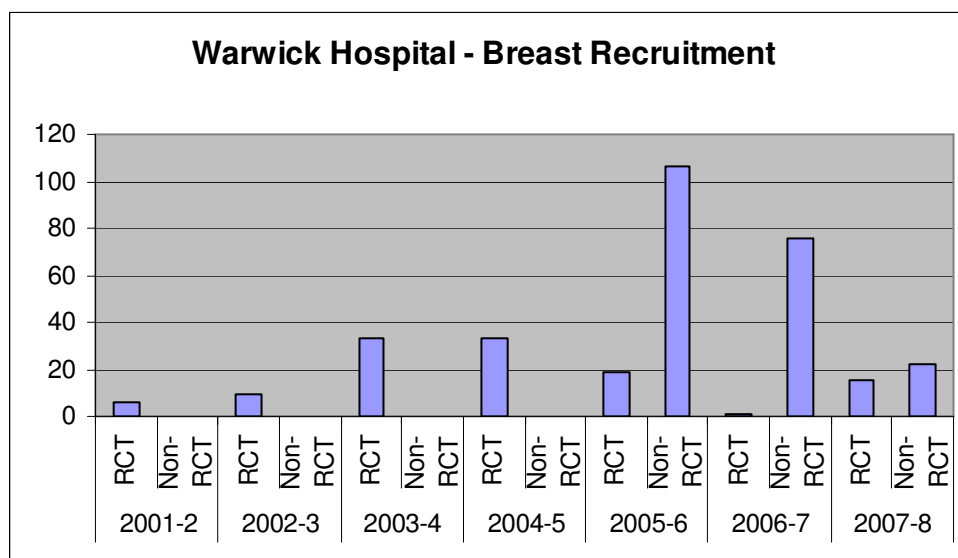


Figure 4cii: Annual Accrual by Clinical Studies Group – Breast Only: Warwick Hospital



Warwick Hospital recruits well from its population base with moderate numbers in RCTs. A new chemotherapy unit has opened this year, which should encourage recruitment to RCTs that had previously been difficult to open because of capacity issues in the Cancer Centre.

Figure 4di: Annual Accrual by Clinical Studies Group except Breast: Alexandra Hospital

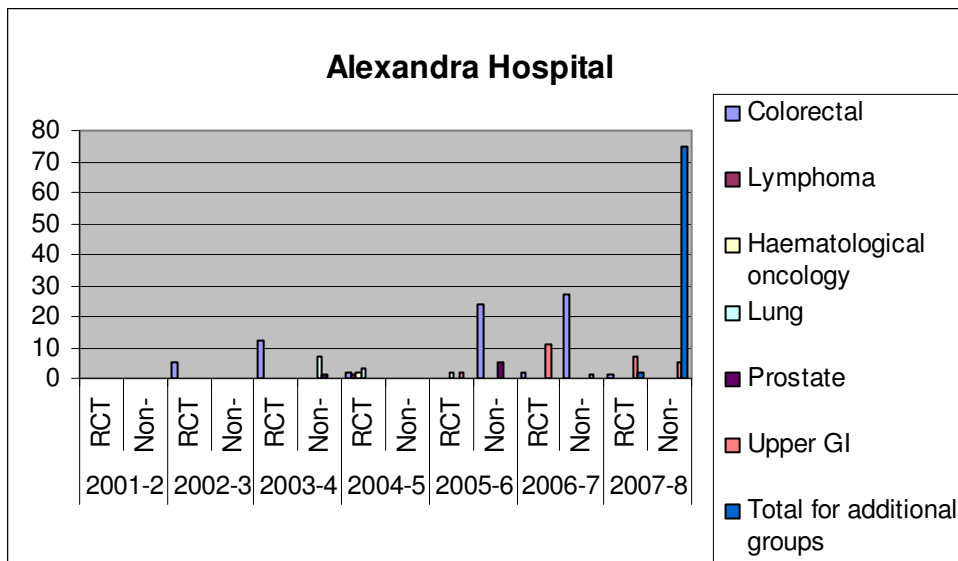
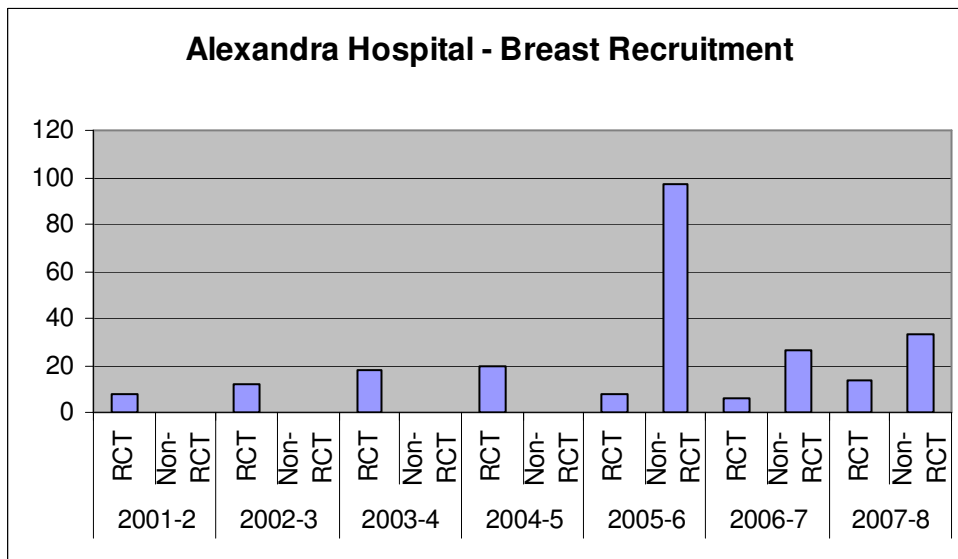
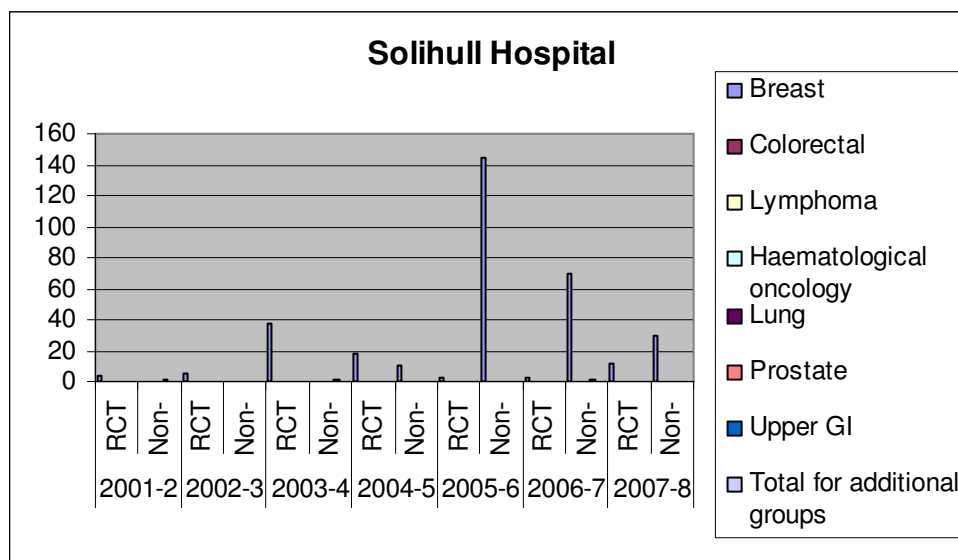


Figure 4dii: Annual Accrual by Clinical Studies Group – Breast Only: Alexandra Hospital



This has been Alexandra Hospital's most successful year but does remain heavily dependent on non RCTs for its overall research activity.

Figure 4e: Annual Accrual by Clinical Studies Group: Solihull



Solihull Hospital only provides breast work to the Arden Research Network because of historical access problems for radiotherapy treatment and has a limited portfolio due to chemotherapy service pressures. However it does actively recruit to non RCTs.

### 2.1.1 Overview of the local network portfolio and 2007- 08 accrual

All Consultants are invited to put forward new studies to the ACRN for consideration of entry into the trials portfolio, and at each NSSG meeting all relevant studies from the NCRN portfolio are presented to the group and if the consensus is that these studies should be opened, then these are taken forward to be looked at by the RNM and Clinical Lead. Factors determining acceptance onto the portfolio include competition with existing studies, the necessary resources available to conduct the study and the number of potential patients likely to be recruited.

Over the past year, the ACRN has concentrated on expanding the portfolio in some of our weaker areas. The urology portfolio now has four open studies, three of which are RCTs. We need to expand our gynaecology recruitment which historically has been very poor; to this end one new RCT has been opened during the past year (ICON 7) and there is a non-RCT about to be activated. Professor Poole's appointment will help drive this group forwards.

A considerable amount of physics development has allowed the introduction of IMRT. This enabled the Network to open CHHIP, to which we are actively recruiting.

The Head and Neck portfolio has been very limited until recently and UHCW has not recruited well in the past to this area of cancer medicine. Hisham Mehenna is a new consultant at the UHCW and the Chief Investigator of PET-

NECK study which is now open and has recruited seven patients in the first few months. The appointment of the NCRN funded clinical fellow will speed this process up the introduction of IMRT, particularly with COSTAR in mind.

The NRCN set the ACRN a target of recruiting 4.5% of patients into RCTs which has been achieved and indeed exceeded.

### **2.1.2 Network activity in the NCRN adopted commercial portfolio**

The ACRN has applied to participate in several NCRN adopted commercial studies in the past and has now been accepted to take part in a breast study. At present, it is only the Cancer Centre which has the facilities and resources to be able to consider participation, however, once a study was open at the Centre, patients could be referred in from the cancer units. The main cancer sites to consider commercial studies would be breast, colorectal, haematology and lymphoma; however, all sites are interested and potentially could participate, particularly gynaecology now that Professor Poole, who has a significant track record in this area, is in post.

## **2.2 Follow up**

Over 40% of each research nurse's time is spent on completing follow-up, in addition to this, a full time data clerk has been employed from the NCRN redistribution exercise to help support this work. As a percentage of the whole ACRN workforce this works out to be approximately 5.5 WTE of nurse time.

The total number of patients currently being followed up is 1406; further detail can be seen in Appendix 4.

## **2.3 Referral of patients**

The majority of studies are open at all sites within the ACRN, however, there are a few exceptions to this rule and in these cases patients are referred from the cancer units into the centre. The following list summarises the trials which do refer patients:

- OE05 – 1 patient referred and recruited from SWH to UHCW
- PICCOLO –open at UHCW, only opened Feb 08 but able to accept patients from rest of Network.
- ICON 7 – open at UHCW and will accept referrals from SWH, GEH and AHR.
- TE23 – currently patients are referred to Nottingham if randomised to receive the trial arm, however, ACRN is in the process of opening the entire study at UHCW and will accept patients from the rest of the Network.
- PET-NECK - open at UHCW, able to accept patients from GEH and SWH.

## **2.4 Activity out with the NCRN portfolio**

The ACRN is taking part in four commercial studies, all of which have recently opened. To date no patients have been recruited. A further two palliative care studies had just been opened but the manufacturing company had some technical problems, so those studies have been put on hold for a temporary period.

## **3 Consumer Involvement**

### **3.1 Summary of Activity**

- The network steering group has now combined its meeting with the Cancer Network board meetings. This provides the opportunity for consumer members on the board to be involved in the steering group meetings.
- In February of this year the Cancer Network partnerships facilitator and a number of representatives from the Cancer Network User group were invited to a meeting in the clinical trials offices. The focus of the meeting was to familiarise the user group with the function and the objectives of the research network and to invite them to make suggestions about how the research network could involve users in a more constructive manner.
- A meeting was held with the staff of the local Health Information Centre within the University Hospital in order to promote the function of the research network and to discuss opportunities to use the centres facilities to promote access to the research network.
- The cancer network user group have been invited to comment on the construction of the patient satisfaction questionnaire and other patient based information.

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

Due to the fact that consumer involvement has been limited, it is recognised by the network that there has been little impact on research activities. However, the network user group and the Health Information Officer came up with some useful ideas with regard to promotional activities which it is hoped may stimulate access to the trials unit from the general public.

### **3.3 Contact Point**

Judith Lake  
Arden Cancer Research Network Manager  
Clinical Trials Office  
Arden Cancer Centre  
University Hospital  
Coventry  
CV2 2DX  
Tel: 02476 967151

### **3.4 Future Consumer Involvement Activities**

The research network intends to:

- Promote cancer trials within the Health Information Centre
- Hold another open day in the main entrance to the University Hospital
- Review the patient satisfaction survey and undertake this in a more scientific manner.
- Liaise with the Cancer Network User Group and support them in promoting cancer clinical trials within the community.

## **4 Information Systems**

The ACRN does not employ any Information Systems staff, although within the role of the clinical trials officers they do monitor and record the accrual into Dendrite Clinical Systems which is part of the Patient Analysis and Tracking Systems, based on Cache technology.

The ACRN is currently working with a website designer to develop an ACRN website, which is expected to be open to the public by the summer of this year.

## **5 Network initiatives and good practice**

### **5.1 Joint working with R&D**

The clinical trials department have been working with the Research and Development office to provide ICH GCP and other relevant training to staff in order that they are fully prepared and updated with regard to the responsibilities relating to clinical trials. The joint working initiative has reached more staff members this year than any other and has facilitated speedier working processes between relevant departments having a positive impact on activity.

### **5.2 Head and Neck Clinical Trials Nurse post**

The recent appointment of a full time member of staff working between UHCW and The Heart of England NHS Trust solely for the recruitment and support of patients into head and neck trials has been a great success. Recruitment has risen and in the last 6 months three more new trials have opened with the expectation that these will recruit just as successfully.

### **5.3 Central England Haemato-oncology Research Bank and Regional Research Nurse Initiative**

The Arden Cancer Network is supporting this initiative which is being co-ordinated via Professor Craddock at the University Hospital in Birmingham. Nurses from the Arden Cancer Network will work in collaboration with Birmingham to raise the profile of NCRN Haematology Trials and also be able to offer patients in Coventry access to phase II haematology studies that are currently only accessible at Birmingham University.

### **5.4 Approval of PET scanner**

The University Hospital in Coventry has recently received approval as a PET scanner site for the PET in Hodgkin's study and the R-CHOP 14 v 21 study. This now means that patients can be offered entry into these studies and will not face the prospect of having to travel to another hospital for this essential investigation. It is hoped that this will have a positive impact on recruitment since refusal to travel to another PET centre has been an issue in Coventry.

### **5.5 Appointment of Data Clerk**

A data clerk whose main purpose is to be responsible for the management of clinical trials follow-up and recruitment of patients into non-randomised studies was appointed in March of this year. This should free up nursing time and improve recruitment.

## **5.6 Re-defined roles for Pharmacy technician and Clinical Trial Officers**

The pharmacy technician's role has been re-defined meaning that the pharmacist has more time to spend in the trials office offering direct personal support to the trials nurses with regard to pharmacy queries. Three new part – time clinical trials officers have made a similarly constructive impact on the trials application and amendment processes leaving the clinical staff with more time to concentrate on patient accrual.

## **5.7 Pathology Technicians post**

With dedicated personnel to deal with the pathology obligations of clinical trials it is now possible to undertake studies where this would have been unmanageable in the past.

## **5.8 Clinical Lead Communication**

The network clinical lead has put a considerable amount of effort into communicating the importance of clinical trial entry to all consultants. Regular updates of tumour site performance are presented at the two monthly Cancer Centre Audit meetings and this has resulted in improved trial recruitment in recent months. Individual Consultants are given their research activity update for their annual appraisals and an overview to the Clinical Director with the purpose of stimulating a research ethos.

## 6 Future strategic plans

2007/8 saw a rise in RCTs to 6% against a target of 4.5% for this year. This reflects a significantly increased activity due to the initiation of TACT2 and the continuing good recruitment to ZICE. In order to achieve the RCT percentage recruitment targets of 5.5% 2008/9, 6.5% 2009/10 and 7.5% 2010/11 it will be essential for the NCRN portfolio to continue to have attractive RCTs in the main tumour sites.

A key problem in the ACRN has been the slow initiation of studies caused by pharmacy costing issues and service capacity. The CRN recognises this and is to employ a new generic network pharmacist and pharmacy technicians. This should address the first problem. The development of the chemotherapy unit in Warwick and the research chemotherapy bay at the Cancer Centre will help improve the capacity problems and improve the ability of the network to expand its RCT portfolio.

The introduction of Medical Oncology with an anticipated expansion of consultant numbers, alongside a new Consultant Clinical Oncologist in 2008, will allow existing consultants more time to recruit to studies and add extra support to weaker performing tumour sites notably gynaecology, lymphoma and CNS.

In 2008 the NCRN funded a Clinical Fellow with the specific intention of addressing the low recruitment in these areas and developing IMRT to support the COSTAR trial.

These developments should allow the ACRN to consolidate on this year's progress and achieve or exceed next year's target of 5.5% RCT entry. This remains the first and key target in common with other networks and therefore large volume trials are inevitably prioritised.

When addressing the issues of rarer tumour types potential numbers and facilities still play a key determining role in opening such studies. The UHCW has a Betatron which provided Total Skin Electron Therapy for the West Midlands and beyond (3-5 cases per year are seen). The ACRN will open the Gem-Bex study once extra treatment costs are resolved. There are only 50 cases of MF each year in the UK and only a modest number of these will be suitable for this trial. Vortex is currently on the list of studies the ACRN wish to introduce but due to the low numbers of appropriate cases, realistically 2-3 / year would be entered into the study. A second neuro – oncology consultant to be appointed in 2008 should address weakness in this part of the portfolio.

As the network continues to develop it will be necessary to expand core staff. In order to sustain increasing trial work there will be a need to increase commercial trial activity. These new NCRN strategies will allow the network an opportunity to demonstrate its ability to provide good quality data in a timely manner and establish itself as an effective site for such work.

Links continue to develop with the Clinical Trials Unit at Warwick University and Professor Janet Dunn. At this time the research ethos is becoming embedded into the Cancer Centre and the Research Network now has a secure and effective base from which to expand and collaborate with the fresh impetus that the introduction of medical oncology will provide.

## **7 Signatures**

**Prof R. J. Grieve (Clinical Lead for Research)**

**Mrs Judith Lake (Research Network Manager)**

## **8 Appendix 1 – Staff listing**

[NB this Appendix has been removed for data protection purposes]

## 9 Appendix 2

9.1 Table 1: studies in the current network portfolio with 2007- 8 accrual per study listed by hospital site

CSG	Study acronym	RCT/non-RCT	Study category	UHCW	AHR	GEH	SWH	SHH
Breast	BISMARK	RCT	Cancer study	2	3	2	3	0
Breast	PRIME II	RCT	Cancer study	15	2	0	5	2
Breast	REACT	RCT	Cancer study	7	0	0	0	0
Breast	TACT 2	RCT	Cancer study	46	4	2	0	2
Breast	ZICE	RCT	Cancer study	23	0	1	0	2
Breast	BBC - NCRN Cohort	Non-RCT	Cancer study	105	31	26	22	30
Breast	POSH	RCT	Cancer study	0	5	2	7	5
Breast	PG-SNPS	Non-RCT	Bolt-on Study	4	2	0	0	0
Breast	SOFEA	RCT	Cancer study	1	0	0	0	0
Colorectal	QUASAR 2	RCT	Cancer study	8	5	4	5	0
Colorectal	NSCCG	Non-RCT	Includes non-cancer patients	29	12	1	17	0
Colorectal	ACT II	RCT	Cancer study	1	0	0	3	0
Colorectal	PICCOLO	RCT	Cancer study	1	0	0	0	0
Colorectal	CHRONICLE	RCT	Cancer study	0	1	0	0	0
Upper GI	ESPAC 3	RCT	Cancer study	1	0	0	0	0
Upper GI	OE05	RCT	Cancer study	4	0	0	0	0
Upper GI	ASPECT	RCT	Pre-malignant Study	3	7	9	4	0
Upper GI	MOSES	Non-RCT	Cancer study	26	5	0	5	0
Lung	BTOG2	RCT	Cancer study	3	0	0	1	0
Lung	FRAGMATIC	RCT	Cancer study	1	0	0	2	0
Lung	TOPICAL	RCT	Cancer study	0	0	0	1	0
Bladder	BC2001	RCT	Cancer study	1	0	0	0	0
Bladder	SELINIB	RCT	Cancer study	4	2	0	0	0
Bladder	BCPP	Non-RCT	Cancer study	60	75	0	0	0
Prostate	DA Vs DAS	RCT	Cancer study	1	0	0	5	0

Prostate	PATCH	RCT	Cancer study	5	0	0	0	0
Prostate	UKGPCS	Non-RCT	Cancer study	1	0	0	10	0
<b>CSG</b>	<b>Study acronym</b>	<b>RCT/non-RCT</b>	<b>Study category</b>	<b>UHCW</b>	<b>AHR</b>	<b>GEH</b>	<b>SWH</b>	<b>SHH</b>
Testis	UK Genetics of Testicular Cancer Study	Non-RCT	Includes non-cancer patients	28	0	0	0	0
Testis	Familial TGCT	Non-RCT	Includes non-cancer patients	0	0	0	0	0
Haematology	AML 15	RCT	Cancer study	2	0	1	3	0
Haematology	AML 16	RCT	Cancer study	1	0	0	2	0
Haematology	Myeloma IX	RCT	Cancer study	2	0	1	0	0
Haematology	PT1	RCT	Cancer study	2	0	2	0	0
Haematology	UKALL 2003	RCT	Cancer study	1	0	0	0	0
Haematology	SPIRIT	RCT	Cancer study	1	0	1	0	0
Haematology	MERIT	RCT	Cancer study	1	0	0	0	0
Haematology	UKALL 12	RCT	Cancer study	1	0	0	0	0
Lymphoma	FORT	RCT	Cancer study	2	0	0	0	0
Lymphoma	R-CHOP 14 Vs 21	RCT	Cancer study	2	0	0	1	0
Head & Neck	PET-NECK	RCT	Cancer study	7	0	0	0	0
Gynaecology	CHORUS	RCT	Cancer study	1	0	0	0	0
Radiotherapy	RIB	RCT	Cancer study	4	0	0	2	0

**9.2 Table 2: Accrual by hospital site to the following categories of trial/study**

	Accrual						Accrual as % of cancer incidence (Cancer & pre-malignant)			
	Cancer pts		Pts with pre-malignant disease		Non-cancer pts (Screening & prevention studies)		Historic NCRN incidence rate		Updated UK incidence rate	
	RCT	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	RCT	Non-RCT	RCT	Non-RCT
2001-2	232	5	0	0	0	0	5.8	0.1	5.0	0.1
2002-3	300	8	0	0	0	0	7.5	0.2	6.5	0.2
2003-4	354	55	0	0	0	0	8.9	1.4	7.7	1.2
2004-5	313	335	0	0	0	65	7.8	8.4	6.8	7.3
2005-6	203	1084	8	0	0	170	5.3	27.1	4.6	23.6
2006-7	153	364	18	0	5313	154	4.3	9.1	3.7	7.9
2007-8	240	402	23	0	0	87	6.6	10.1	5.7	8.7

## 10 Appendix 3 - Follow up (with detailed tables)

Recruitment prior to 31 <sup>st</sup> March 2002	University Hospital	Warwick Hospital	George Eliot Hospital	Alexandra Hospital	Solihull Hospital	Total
Breast	1001	6	2	6	5	1020
Colorectal	221	0	0	0	0	221
Gynae	22	0	0	0	0	22
Haematology excl Lymphoma	13	0	0	0	0	13
Head and neck	5	0	0	0	0	5
Lung	21	0	0	0	0	21
Other	19	0	0	0	0	19
Lymphoma	12	0	0	0	0	12
Urology	26	0	0	0	0	26
Others	7	0	0	0	0	7
<b>Total</b>	<b>1347</b>	<b>6</b>	<b>2</b>	<b>6</b>	<b>5</b>	<b>1366</b>
Recruitment 1 <sup>st</sup> April 2002 to 31 <sup>st</sup> March 2008	University Hospital	Warwick Hospital	George Eliot Hospital	Alexandra Hospital	Solihull Hospital	Total
Breast	552	113	113	60	80	918
Colorectal	140	25	18	24	0	207
Gynae	18	0	0	0	0	18
Haematology excl Lymphoma	39	29	16	0	0	84
Lung	10	4	0	0	0	14
Other	13	5	0	12	0	30
Lymphoma	17	9	5	0	0	31
Skin	4	0	0	0	0	4
Upper GI	24	4	8	19	0	55
Urology	26	17	1	1	0	45
<b>Total</b>	<b>843</b>	<b>206</b>	<b>161</b>	<b>116</b>	<b>80</b>	<b>1406</b>

		1 <sup>s</sup> April 2002 to 31 <sup>st</sup> March 2008					Total
		University Hospital	Warwick Hospital	George Eliot Hospital	Alexandra Hospital	Solihull Hospital	
Breast	ATTOM	95	38	25	22	17	197
	AZURE	68	35	30	17	10	160
	BISMARCK	2	3	2	3		10
	COMICE	12		11			23
	POSH	12	14	27	5	14	72
	PRIME	52	17	5	3	6	83
	REACT	9					9
	SECRAB	89			2	24	115
	SOFEA	1	1			4	6
	TACT	39	5	1			45
	TACT 2	46		2	4	2	54
	TANGO	1		1	1		3
	TEAM	89		1			90
	WARP				1		1
	WWW	3		4	2	1	10
	ZICE	34		4		2	40
	<b>Subtotal</b>	<b>552</b>	<b>113</b>	<b>113</b>	<b>60</b>	<b>80</b>	<b>918</b>
Colorectal	ACTII	7	6	1	1		15
	CHRONICLE				1		1
	CR07	53		4			57
	PICCOLO	1					1
	QUASAR 2	18	7	5	7		37
	QUASAR1	19	1	3	1		24
	VICTOR	42	11	5	14		72
	<b>Subtotal</b>	<b>140</b>	<b>25</b>	<b>18</b>	<b>24</b>	<b>0</b>	<b>207</b>
Gynae	ASTEC	13					13
	CHORUS	4					4
	SCOTROC 4	1					1
	<b>Subtotal</b>	<b>18</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>18</b>
Haematology	AML14	1	2	2			5
excl Lymphoma	AML15	13	14	3			30
	AML16	1	3	1			5
	MERIT	2					2
	Myeloma IX	8	10	5			23
	PT1	3		2			5
	SPIRIT	1		1			2
	UKALL12	9		2			11
	UKALL 2003	1					1
	<b>Subtotal</b>	<b>39</b>	<b>29</b>	<b>16</b>	<b>0</b>	<b>0</b>	<b>84</b>

		University Hospital	Warwick Hospital	George Eliot Hospital	Alexandra Hospital	Solihull Hospital	Total
Lung	BTOG2	4	1				5
	FRAGMATIC	1	2				3
	MS01	3					3
	TOPICAL	2	1				3
	Subtotal	10	4	0	0	0	14
Other	PET NECK	4					4
	RIB	5	5		2		12
	WARP	4			10		14
	Subtotal	13	5	0	12	0	30
Lymphoma	FORT	3	1				4
	LY10	1					1
	MCD vs. FMD	5		3			8
	PET1:PET	1		1			2
	PmitCEBO	1					1
	R-CHOP 14 vs. 21	2	5				7
	STANFORDV	4	3	1			8
	Subtotal	17	9	5	0	0	31
Skin	EORTC18961	4					4
	Subtotal	4	0	0	0	0	4
Upper GI	ASPECT	16	4	8	19		47
	ESPAC3	3					3
	GEMCAP	1					1
	OE05	4					4
	Subtotal	24	4	8	19	0	55
Urology	BC2001	7	4	1			12
	DA v DAS	1	5				6
	Familial TGCT		4				4
	ODMITC	1	2				3
	PATCH	5					5
	PRO7	11	2		1		14
	TE08	1					1
	Subtotal	26	17	1	1	0	45
	<b>Total</b>	<b>843</b>	<b>206</b>	<b>161</b>	<b>116</b>	<b>80</b>	<b>1406</b>

## **11 Appendix 4: Contact Information**

[NB this Appendix has been removed for data protection purposes]