

Cancer Institute NSW Monograph

**Cancer Clinical Trials in New South Wales,
2004–2006**

May 2008

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The NSW Government agency dedicated to the control and cure of cancer
through prevention, detection, innovation, research and information.



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Foreword from the Minister

The NSW Government has made a substantial commitment to the control and cure of cancer in recognition of the burden this disease places on our community. The approach of the Government is to implement the *NSW Cancer Plan 2007–2010* and its comprehensive strategy to improve the results with cancer in the State.

Much of the improvement we expect to see in cancer results will be the direct impact of high-quality clinical trials that test innovative new treatments and approaches. Such activity is vital if we are to continually improve our clinical care based on the best, and most recent, cancer research.

This report shows that the cancer clinical trials program is successful in NSW, thanks to the patients who generously agree to participate and the dedicated staff who undertake this important work on behalf of us all. This report also highlights some cancers where more trials are to be encouraged. It provides a clear indication where more work is likely to have a substantial impact on better cancer outcomes in the future.

I commend this report to you.

The Hon. Verity Firth MP
Minister for Climate Change and the Environment
Minister for Women
Minister for Science and Medical Research
Minister Assisting the Minister for Health (Cancer)

I. Executive summary

This review of cancer clinical trials in NSW captured around 75% of the State's cancer trial activity. It revealed that there were 341 active trials during the period January 2004–December 2006, 4,381 patients were enrolled on trials in the three-year period and at the end of 2006, 5,290 patients were active on trials. In 2006 around 5.3% of newly diagnosed cancer patients were enrolled in clinical trials.

There was an increase of 31% in the number of active trials and 94% in enrolments to trials from 2004 to 2006. The clinical grouping with the most active trials was breast cancer, but melanoma had more enrolments in trials during this period. Most trials were multi-centred, around 60% were randomised controlled trials and 70% of enrolments were to investigator initiated or co-operative group trials.

Analysis of the number and types of trials open and new enrolments onto trials, compared with cancer incidence and mortality, provides insight into which patients are being offered trials and where more trials could be done for high-volume cancers. Correlation to the State's cancer mortality with trials available and enrolments to trials will assist future planning to promote more trials in clinical areas where improved survival through treatment advances is most needed. While more trials should be encouraged in all cancers, additional trials are particularly needed in respiratory cancers, urogenital cancers, upper gastrointestinal cancers, brain cancers, cancers of unknown primary site, bowel cancer and head and neck cancers.

A review of Human Research Ethics Committee (HREC) submissions demonstrated the high degree of duplication in administrative effort that occurred in 2004–2005, with 44% of cancer clinical trial submissions relating to trials that had already been submitted to an HREC elsewhere in NSW. The median time for approval of trials by an ethics committee was 60 days, with only 20% approved on first application, but only 1% of applications were ultimately rejected.

This review identified a high and increasing level of activity in cancer clinical trials in NSW. It highlights specific types of cancers where more trials are needed.

The NSW Cancer Trials Network aims to increase the quality and quantity of trials available to cancer patients and thus increase patient enrolment to clinical trials in NSW. This will be achieved by collaboration and partnerships within Area Health Service Networks. The NSW Cancer Trials Network provides a strategic, statewide approach to cancer clinical trials in NSW and will work the NSW Oncology Groups to encourage a high level of clinical trial activity in all clinical groupings.

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2. Introduction

There is considerable evidence that improved practices through clinical trial results have substantially reduced cancer mortality.

The case for cancer clinical trials

Clinical trials research is a standard method used to identify new treatments or approaches to improve patient care. Clinical trials are often a cancer patient's best treatment option,¹ and there is evidence to suggest that participation in a clinical trial may lead to better survival. For example, patients with non-small cell lung cancer treated within a clinical trial had improved survival, compared to non-participants and those with childhood leukaemias had similar results.^{2–4} However, not all studies show this advantage and there have been too few well-controlled studies to determine that there is a clear survival benefit for all trial participants.⁵

There are numerous other reasons why participation in a trial may benefit a cancer patient, including improved quality of life. Patients being treated within a clinical trial may get access to treatments that are not otherwise available and these treatments may be safer, or more effective, than standard treatment. Patients on trials may be more carefully monitored for changes in their condition and for side effects of their treatment as well as being offered a greater number of treatment options.⁶ A patient on a trial is generally being treated according to the best standard of care. However, the new treatment may not be effective. In such situations, early stopping rules and the careful monitoring of side effects offer most patients a high level of protection not often present outside a clinical trial. For some patients, being treated within such a structured setting may provide additional psycho-social support and many obtain comfort from the knowledge they are helping future cancer patients.

While the level of direct benefit for each clinical trial participant may be difficult to determine, it is critical for long-term improvements in cancer outcomes that a high level of trial participation is achieved. Higher participation will mean that trial recruitment targets are met sooner, leading to a faster attainment of results and a shorter time to translate promising therapies into better routine clinical practice. Ultimately there is value in encouraging the shortest timeframes for introducing successful approaches to the greatest number of cancer patients as the new treatment becomes the new routine standard of care.

Encouraging greater participation in research among doctors and other health professionals is also of benefit to future patients. The review by Wood et al into NSW health research, commissioned by the NSW Minister for Science and Medical Research in 2004, suggested that those involved in delivering care in a research-oriented environment are constantly exposed to the most recent evidence, and are constantly challenged to incorporate it into their practice.⁷ Direct benefits follow for patients in that environment.

This report also suggested that clinical trial research is a particular strength within NSW and that cancer research in general is both a National and a State priority area due to the large burden cancer imposes upon individuals and health systems.⁸ Consequently, the first statewide *NSW Cancer Plan 2004–2006* set an important research priority to develop and support a clinical trial program.⁹ The second plan, the *NSW Cancer Plan 2007–2010*, proposed to establish a statewide clinical trials network to support increased activity in cancer trials.¹⁰

There is considerable evidence that improved practices through the incorporation of clinical trial results have substantially reduced cancer mortality.¹¹ Cancer mortality has fallen by 16% in men and 11% in women over the past decade and five-year survival for all cancers has increased by 14% in NSW since 1980.^{12,13} In some cancers, such as breast cancer, improvements have been more dramatic, with a decrease of 18% mortality with five-year survival increasing from 73% in 1980 to 88% in 2004.^{12,13}



Mortality reduction in breast cancer appears to result equally from increased population screening and better treatment programs.¹¹ Both screening and treatment advances have been based on large randomised clinical trials. In haematological cancers, breakthrough treatments tested in clinical trials have not only improved survival, but have revolutionised the way patients are treated. For example, the availability of new therapeutic agents has meant that for some cancers, such as chronic myeloid leukaemia, more intense and invasive treatments, including stem cell transplantation, can now often be avoided in many patients by use of new targeted therapy.¹⁴

NSW Cancer Trials Network

The Cancer Institute NSW Clinical Trials Program commenced in late 2004 with grants provided to 20 clinical trial units to fund the employment of dedicated clinical trial nurses and data managers across NSW. The program was expanded during 2005 to include grants for nine sites to establish clinical trial units and employ a dedicated nurse or data manager. A clinical trials partnership grant was established with the NHMRC Clinical Trials Centre (CTC) to provide additional operational and statistical support for trial investigators.

From 1 July 2007, the program was further expanded as the NSW Cancer Trials Network. The Network now incorporates the clinical trials funding programs of the Cancer Institute NSW and The Cancer Council NSW. Across the State, this Network now supports the positions of more than 67 cancer trials nurses and data managers (47.5 full-time equivalent positions) across 44 individual clinical trial units.

The NSW Cancer Trials Network aims to increase the number of high quality trials available to cancer patients and thus increase patient enrolment to clinical trials in NSW. The *NSW Cancer Plan 2007–2010* sets a goal for the Network to increase participation to 10% of new cancer cases on trials by 2010.¹⁰

Local clinical trials networks have been formed within Area Health Services (AHS) supported by the appointment of a Director of Clinical Cancer Research and a Clinical Regulatory Affairs Officer. Each AHS network is encouraged to select trials strategically to ensure they are of the highest priority and quality, as well as feasible within the local environment. Information about trials from all AHS Networks will be collected and made publicly available in the NSW Cancer Trials Portfolio, providing an overview of key recruiting trials.

Streamlined ethical review

A possible obstacle to attracting more high-quality clinical trials to NSW and achieving higher recruitment is the administrative burden faced by investigators and staff at clinical trial units and the sponsoring companies seeking to initiate trials. Duplication of ethical review for multi-centre trials has been identified as one such obstacle that increases the administrative workload of ethics committees, trial units, co-operative cancer trials groups and sponsor company staff.

The Cancer Institute NSW, working within a broader framework of the NSW Department of Health for streamlined ethical review, established a Clinical Cancer Research Ethics Committee in October 2006. From 1 July 2007, this Committee has been accredited as a lead ethics committee by NSW Health, providing a single review of cancer clinical research in NSW. Key Performance Indicators have been established to ensure high-quality, timely single ethical reviews of Cancer Clinical Trials and, in turn, decrease duplication of effort both for ethics committees and trial personnel and increase the speed at which clinical research can commence in NSW.

The quality of cancer clinical trials

While efforts are being directed towards increasing the number of trials in NSW, it is also essential to ensure these trials are of increasingly high quality. For clinical research to have a positive impact on patient outcomes, trials need to address important questions and be designed to answer these questions effectively. High-quality design, treatment and data collection at each participating trial site is required to produce trial results that are meaningful for future patients.

Clinical trial activity reporting against a portfolio of trials is planned to encourage a high level of accountability for the trials being conducted in NSW. The Cancer Institute NSW has initiated measures to encourage high quality trials, including the formation of an interstate Medical and Scientific Review Panel to support the NSW Cancer Trials Network and Cancer Institute NSW Ethics Committees. Quality assurance practices within clinical trial units will be supported including the development of generic Standard Operating Procedures (SOPs).

Monitoring clinical trial activity

The level of clinical trial activity in NSW has been difficult to report, with many trial units operating in isolation. The main reason for this isolation lies in the fact that cancer trials are traditionally initiated through a variety of sources, including individual investigators, cancer co-operative research groups and pharmaceutical companies.

The establishment of a comprehensive Australian Clinical Trial Register has assisted reporting. In addition, the International Committee of Medical Journal Editors' (ICMJE) policy recommended compulsory registration of trials, with an aim to make clinical trials and the reporting of their results a more transparent process.¹⁵ Further, the establishment of the NSW Cancer Trials Network provides a framework for the ongoing monitoring of clinical trial activity across the State.

Other jurisdictions monitor clinical research activity by a number of methods. The National Cancer Institute in the United States supports a comprehensive web-based database of clinical trials and clinical trial results for trials registered within their PDQ (Physician Data Query) Cancer Trials database.¹⁶ This database includes all cancer trials registered within the more general 'clinicaltrials.gov' registry. More than 5,600 active cancer studies are registered on this site, as well as more than 16,000 studies that are now closed to recruitment. Of the 5,600 active trials, around 2,000 were located solely outside the USA, suggesting that this database has broader reporting potential than just trials in the USA.

The National Cancer Research Network (NCRN) in the UK also supports a portfolio of trials that is published in their online database.¹⁷ The NCRN portfolio was established in 2003 and initially included only government and charity-supported studies funded by member organisations. The NCRN is now developing a process for incorporating appropriate industry-sponsored studies. In June 2007, the NCRN database included 512 studies, of which 221 were open to recruitment. The NCRN have been monitoring accruals against this portfolio and have demonstrated a doubling in recruitment since commencement of the program.

Prior to the development of the NCRN, information on cancer trial activity in the UK was available from the UK Coordinating Committee for Cancer Research National Register of Clinical Trials.

An analysis of UK cancer randomised controlled trials from this register for trials initiated from 1971 to 2000 found an increasing number of trials until 1995 with a slight drop in number for 1995–2000.¹⁸ From 1971 to 2000, trials became larger, with a higher proportion of multiple sites. However, this register did not include a comprehensive list of pharmaceutical industry trials.

A recent survey of Cancer Research in Victoria shows that during 2005 there were 537 active trials and 6974 patients on trial in Victoria either receiving treatment or in follow-up.¹⁹ This provides some context and comparison for clinical trial activity within Australia.

Cancer clinical trials in NSW, 2004–2006

This report provides an overview of clinical trial activity in Cancer Institute NSW supported units during the period 2004–2006, which reflects the period covered by the first *NSW Cancer Plan 2004–2006*. Activity has been assessed by looking at information about the number of trials actively recruiting or in follow-up phase during this period, as well as enrolment numbers and the number of patients on trial.

This activity information was collected as part of routine reporting for clinical trial units supported through grants from the Cancer Institute NSW. It includes information about the broad clinical grouping of the trials, industry affiliation, trial design and phase of trials. Information is also presented regarding the duplication of ethical review across the state for multi-centre research studies. It represents a comprehensive overview of cancer trials conducted in NSW.

3. Methods

Clinical trial activity data

Information about trials and number of patients on trials was collected from sites funded through Cancer Institute NSW clinical trials nurses and data managers or clinical trial unit establishment grants. Data from additional trial units not supported through this funding stream was voluntarily supplied. For the purposes of this analysis, information was collected for the period January 2004–December 2006. This sample does not include data from the children's hospitals in NSW; therefore this report is limited to adult cancer clinical trials.

Information was collected on all trials conducted at each reporting site. The data items collected included: trial details (name, trial acronym or trial protocol number, disease type, sponsor and principal investigator) and recruitment details (recruitment start and end dates; new patients enrolled during 2004, 2005 and 2006; and patients active on study at 31 December for 2004, 2005 and 2006). Trials were defined as active if they were open to recruitment; or had patients on treatment; or being followed up. Patients were defined as active if they were enrolled, were receiving treatment or were being followed up.

Matching the trials

Trials were excluded for a particular site if they were closed to recruitment prior to January 2004 and had no patients on trial (either receiving treatment or in follow-up) from that date onwards. Using the trial title, sponsor and other identifiers reported (such as acronym/ trial code/ protocol number), each trial was then matched wherever possible to a Clinical Trial Registration Number to ensure unique trials were identified and reported. The following trial registration sites were searched:

<http://www.clinicaltrials.gov>

<http://www.actr.org.au>

<http://www.controlled-trials.com/isrctn/>

<http://www.umin.ac.jp/ctr/index.htm>

Each trial matched with a registration number was then included against a unique code in the NSW list of trials. Further information was recorded for each trial using data available on registration sites including: registration number; trial title, phase of trial, type of disease; stage of disease; and study design.

If no match was made, a further search of relevant databases or websites was conducted. These included sites from the US and UK:

<http://www.ncrn.org.uk> <http://www.cancerhelp.org.uk/trials/trials/> and <http://www.cancer.gov/clinicaltrials>.

For Australian Co-operative Group Trials, further information was obtained from:

<http://www.petermac.org/allg/>

<http://www.anzbctg.org/>

<http://www.ibcsg.org/>

<http://www.gicancertrials.org.au/>

<http://www.ranzcr.edu.au/affiliatedgroups/trog/index.cfm>

Once identified within one of these trial lists, the trial was included in the trials list against a unique code. Information was recorded as above. Where no registration number was available, other identifying codes or acronyms were recorded to ensure trials were included only once.

For smaller investigator initiated trials, additional information was requested directly from the site to ensure duplication of trials was avoided.

Data on submissions to Human Research Ethics Committees (HRECs)

A separate retrospective audit of HREC files was conducted on behalf of the Cancer Institute NSW for the period July 2004–June 2005. This audit identified the number of cancer research ethics committee submissions and the proportion of duplicate reviews that occurred in this period.



Twenty-one HRECs were approached and 14 consented to participate in the survey, of which two later indicated they did not review cancer studies. For the remaining 12 committees, the following information was collected on all cancer trials submitted for ethical review during the time period: name of study; principal investigator; sponsor; type of study (clinical trial, population health, biomedical); phase of trial (for clinical trials); date of submission; date of approval letter; and the number of amendments.

Data was either provided directly by HRECs using an electronic survey tool or collected by site visits. Studies were matched using trial name, sponsor and other identifiers to establish the number of unique trials and the number of duplicate reviews. The average number of submissions per HREC and the proportion of unique studies were used to estimate the number of submissions and unique trials across responding HREC committees. This was then used to extrapolate likely numbers of submissions for all of NSW.

Clinical groupings

Clinical groupings are categories based on professional treatment teams for that group of cancers.¹³ For example; a urologist would commonly treat cancers of the prostate, testis, bladder, kidney and other male genital cancers. Similarly, a gynaecologist would normally treat cancers of the cervix, uterus, ovary, and other female genital cancers. These groupings were developed by the Cancer Institute NSW and presented for discussion and endorsement at the Australian Association of Cancer Registers (AACR) Annual General Meeting in December 2004. Minor modifications of these groupings were requested and the AACR have now adopted these groupings for clinical and planning purposes and where appropriate as normal inclusions in state and national incidence and mortality reports.¹³

Definitions

Clinical trials are categorised into different phases depending on the aim of the study. Phase I trials are initially to test the safety of a particular new drug or treatment and are sometimes the first time a drug or treatment has been

used in humans. Phase I studies assess the side-effects and identify an optimal dose. Phase II trials generally aim to test how well an intervention works in a particular type of cancer. Phase III trials aim to test a new treatment compared against a standard treatment to assess which is better. This is usually compared in a randomised study design. Phase IV trials occur after a drug or device has been registered and it may assess the feasibility and safety of the intervention in a wider population.

Randomised controlled trial (RCT) was defined as a trial that involves an intervention and a control group. Allocation to the control or experimental group is randomly assigned. Treatment allocation may be blinded or non-blinded to patients participating and/or treating doctors.

Non-randomised trial was defined, for the purpose of this review, as either:

- an intervention (e.g. treatment or device) trial where the intervention is not randomly allocated; or
- a prospective study where patients are being followed over time but there is no comparison between groups. For example, within early phase dose-finding studies all participants may be given the active treatment, with no control group.

All studies reported by trial units that did not follow patients over time, such as retrospective audits and cross-sectional surveys were not included as 'trials' and were excluded from all analyses.

Matching clinical trial activity to cancer incidence and mortality

Trial activity was correlated with the cancer burden in our community to identify if trials were available for patients with the most common or most fatal cancers.¹³ The proportion of cancer incidence and deaths in for each clinical grouping in NSW was matched to the proportion of clinical trials or patients on trial in that grouping.

The most recent cancer incidence and mortality data was obtained from published data of the NSW Central Cancer Registry.¹³

4. Results

4.1 Summary of cancer clinical trial activity in NSW, 2004–2006

Overall, 1,258 separate trial listings were provided by 34 sites. After removing trials that were archived prior to 2004 or trials that could not be validated with an external source, 1,029 separate trial listings were identified and matched to 374 unique trial numbers. The 374 identified trials formed the NSW Trial Activity list. Seventy per cent of these trials were matched to a registration number from one of the four approved trial registration sites searched. Those that were not matched to a registration number tended to be older studies that pre-dated the IJMR registration requirements but still had patients on follow-up.

From January 2004 to December 2006, there were 341 active trials across Cancer Institute NSW supported clinical trial units (Table 1). Of these trials, 299 were recruiting during the reporting period with a total of 4,381 new enrolments to these trials (Figures 1 and 2). At the end of 2006, there were 5,290 active patients on trials in NSW (Figure 3).

There was a substantial increase in number of trials, enrolments and also active patients on trial since 2004. Patient enrolments increased by 94% since 2004 and there was a 30% increase in active patients on trials in that period.

Table 1: Summary of clinical trial activity: 2004–2006

Year	Number of recruiting trials	Number of active* trials	New enrolments to trials	Patients active** on trial
2004	175	219	926	4,094
2005	223	279	1,656	4,774
2006	234	286	1,799	5,290
Total 2004–2006	299	341	4,381	4,719[†]

* Trials that were open to recruitment or had patients on treatment or follow-up.

** On treatment or in follow-up at December 31.

[†] Average patients on trial over the period 2004 - 2006.

'Active trials' are defined as those trials either open to recruitment during this period or trials that still had patients in treatment or follow-up during this period. A small number of trials were reported that were not yet open to recruitment in 2006 and these were excluded.

Figure 1: Active trials: 2004–2006

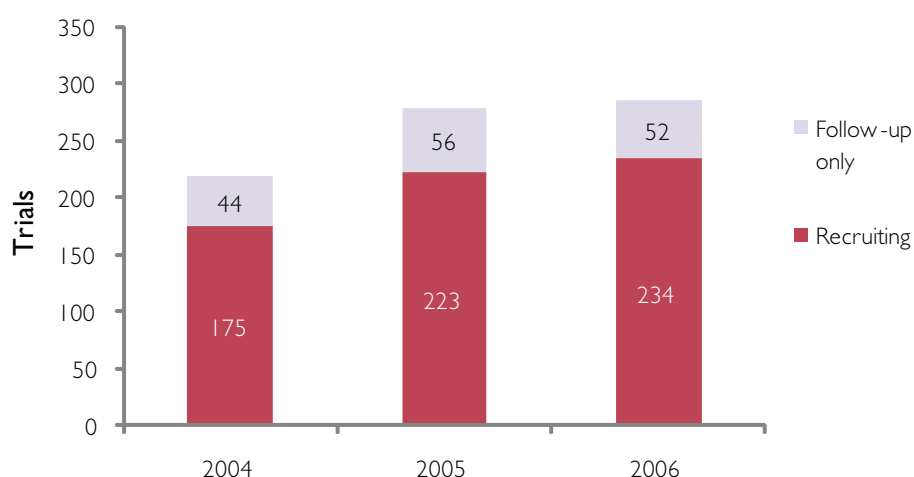


Figure 2: New enrolments 2004–2006

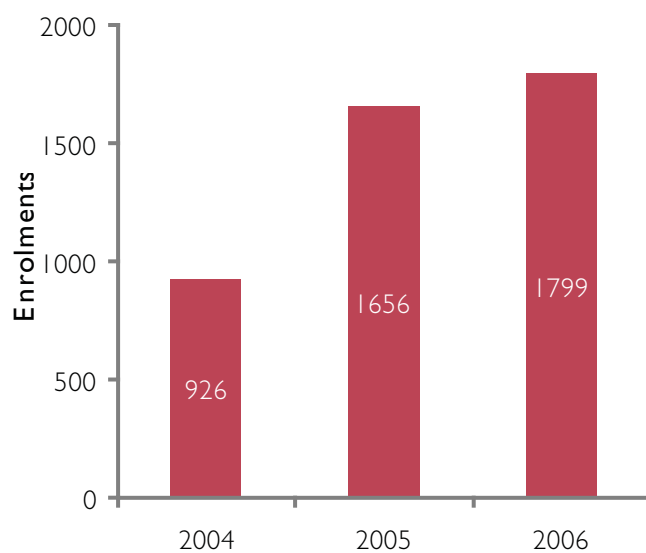
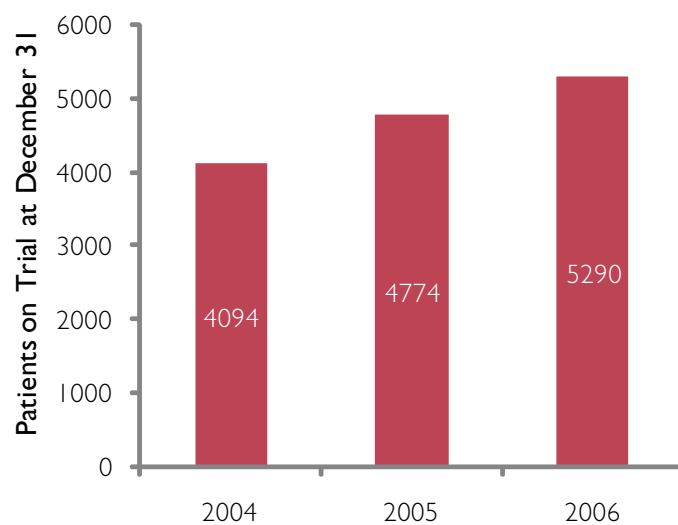


Figure 3: Active patients on trials 2004–2006



4.2 Area Health Services

The NSW Cancer Trials Network has established a framework for clinical trials researchers to work collaboratively within their Area Health Service and to select the trials most appropriate for their patients. Collaboration is further encouraged on a state wide basis through the NSW Cancer Trials Network and the establishment of an Executive Committee to support this Network. A goal has been set in the *NSW Cancer Plan 2007–2010* to reach a target of 10% of new cancer cases on cancer clinical trials by 2010.¹⁰

The establishment of new clinical trial units and increased support for existing units has enabled an increase in both the number of trials and enrolments to occur across the State since 2004 (Tables 2 and 3). All Area Health Services demonstrated increased activity between 2004 and 2006. During 2006, the total enrolments of patients on trials represented approximately 5.3% of new cancer cases. The total number of active patients on trials in December 2006 represented around 15% of new cancer patients diagnosed within 2006, but only 2.2% of prevalent cases.²³ Around 3.7% of new cancer cases were enrolled on randomised trials, with enrolment on these trials in 2006 varying from 1.2% to 8.0% across Area Health Services.

Sydney South West reported the most trials open to recruitment and the highest enrolment to trials, but with high activity also in Sydney West, South Eastern Sydney Illawarra and Hunter New England Area Health Services. The proportion of incident cancer cases per year reported within each area health service enrolled on clinical trials varied from less than 2% in some Area Health Services in 2004 to more than 10% in other Area Health Services by 2006.

Table 2: Number of clinical trials open to recruitment by design of trial and Area Health Service 2004–2006

Area Health Service	Year	RCT	Non-randomised trial	Total
Greater Southern	2004	41	13	54
	2005	55	15	70
	2006	57	15	72
Hunter New England	2004	54	17	71
	2005	68	25	93
	2006	70	26	96
North Coast	2004	22	5	27
	2005	28	9	37
	2006	39	10	49
Northern Sydney	2004	28	8	36
	2005	39	12	51
Central Coast	2006	50	15	65
	2004	47	25	72
South Eastern Sydney Illawarra	2005	57	30	87
	2006	51	29	80
Sydney South West	2004	62	30	92
	2005	87	40	127
	2006	87	42	129
Sydney West	2004	59	28	87
	2005	71	30	101
	2006	80	32	112
NSW Total	2004	114	61	175
	2005	148	75	223
	2006	157	77	234

RCT = randomised controlled trial. Non-randomised trial = any other intervention trial or prospective observation study.

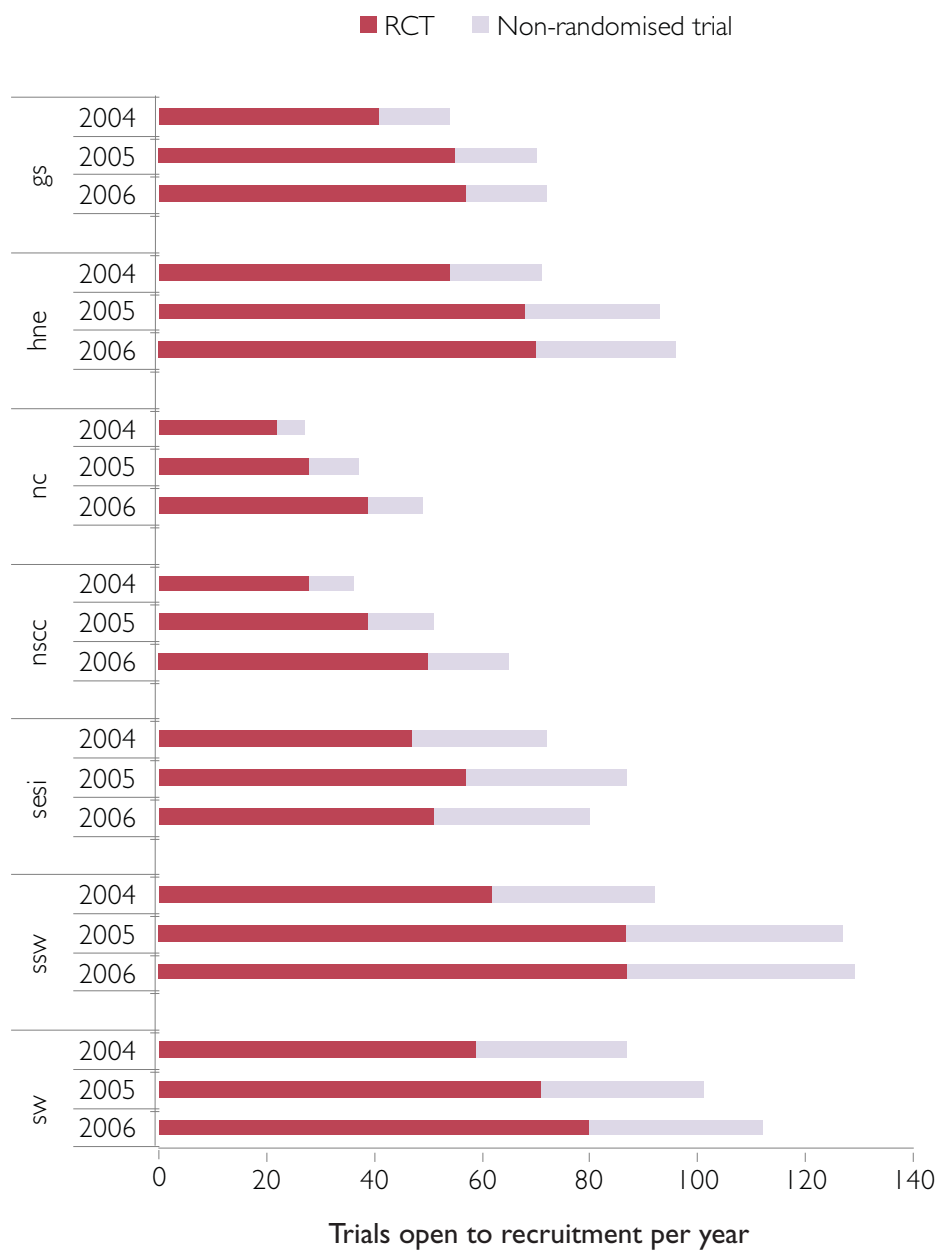
Table 3: Enrolment to active clinical trials by design of trial and Area Health Service, 2004–June 2006

Area Health Service	Year	RCT	Non-randomised trial	Total	Enrolment to RCTs Total enrolment		New cancer cases 2004 ¹³
					as a % of New Cancer Cases	as a % of new cancer cases	
Greater Southern	2004	39	18	57	1.6%	2.4%	2,411
	2005	62	13	75	2.6%	3.1%	
	2006	48	15	63	2.0%	2.6%	
Hunter New England	2004	131	26	157	3.0%	3.6%	4,388
	2005	183	54	237	4.2%	5.4%	
	2006	260	26	286	5.9%	6.5%	
North Coast	2004	39	18	57	1.4%	2.0%	2,870
	2005	92	22	114	3.2%	4.0%	
	2006	85	14	99	3.0%	3.4%	
Northern Sydney Central Coast	2004	89	17	106	1.5%	1.8%	5,776
	2005	53	32	85	0.9%	1.5%	
	2006	72	76	148	1.2%	2.6%	
South Eastern Sydney Illawarra	2004	158	57	215	2.7%	3.6%	5,916
	2005	222	226	448	3.8%	7.6%	
	2006	292	174	466	4.9%	7.9%	
Sydney South West	2004	161	70	231	3.2%	4.6%	5,024
	2005	364	138	502	7.2%	10.0%	
	2006	408	113	521	8.1%	10.4%	
Sydney West	2004	52	51	103	1.3%	2.6%	3,912
	2005	91	104	195	2.3%	5.0%	
	2006	84	132	216	2.1%	5.5%	
NSW Total	2004	669	257	926	2.0%	2.7%	34,092
	2005	1067	589	1656	3.1%	4.9%	
	2006	1249	550	1799	3.7%	5.3%	

RCT = randomised controlled trial.

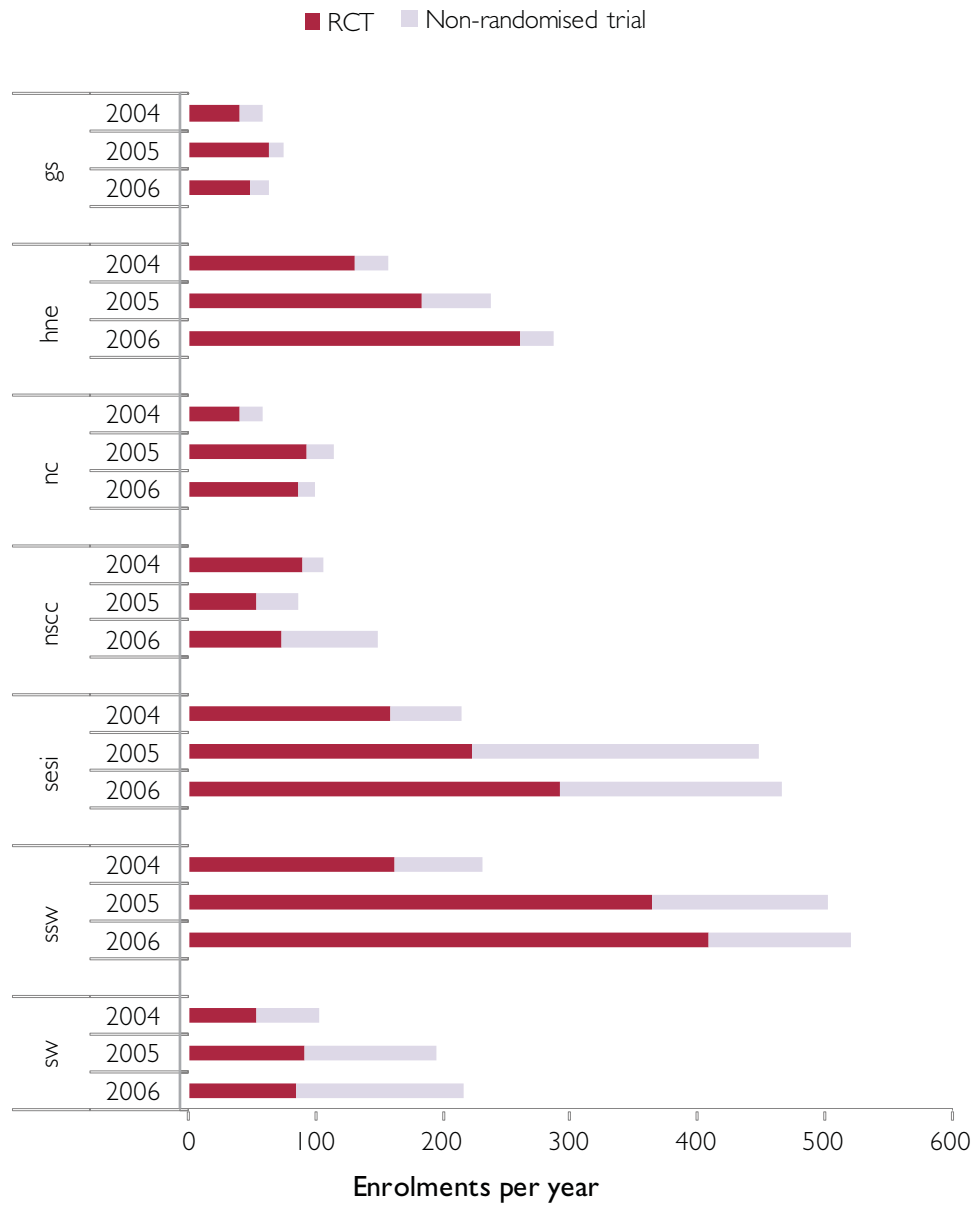
Non-randomised trial = any other intervention trial or prospective observation study.

Figure 4: Recruiting clinical trials by Area Health Service and trial design (2004–2006)



RCT = randomised controlled trial.
 Non-randomised trial = any other intervention trial.
 gs = Greater Southern AHS.
 hne = Hunter New England AHS.
 nc = North Coast AHS.
 nsc = North Sydney Central Coast AHS.
 sesi = South Eastern Sydney Illawarra AHS.
 ssw = Sydney South West AHS.
 sw = Sydney West AHS.

Figure 5: Patient enrolment by Area Health Service and trial design (2004–2006)



RCT = randomised controlled trial.

Non-randomised trial = any other intervention trial.

gs = Greater Southern AHS.

hne = Hunter New England AHS.

nc = North Coast AHS.

nsc = North Sydney Central Coast AHS.

sesi = South Eastern Sydney Illawarra AHS.

ssw = Sydney South West AHS.

sw = Sydney West AHS.

4.3 Clinical groupings

The clinical grouping with the largest number of active trials was breast cancer, followed by haematological malignancies (Table 4, Figure 6). However, the highest enrolment in trials occurred for melanoma (Figure 7). The latter was mainly due to two large melanoma trials that were recruiting during this period. Enrolments were also high for urogenital cancers and the category of trials open to many cancers or 'All types/various'. This latter grouping includes palliative care trials, pain control trials and early phase trials for advanced cancer. Other trials in this category include hereditary cancer trials or psycho-oncology trials that may apply to more than one cancer grouping.

The majority of trials are randomised controlled trials, but trials in haematological malignancies have a higher proportion of non-randomised trials than some other groupings (Figure 9). Haematology trials include a number of non-randomised trials of bone marrow transplantation.

The clinical grouping of breast cancer had the most active patients on trial, accounting for 50% of active patients in December 2006 followed by melanoma with 20% (Figure 8). Urogenital cancers (8%), colorectal cancers (6%) and haematological malignancies (5%) are the other major clinical groups with active patients on trial.

Table 4: Summary of clinical trial activity by clinical grouping: 2004–2006

Clinical Group	Number of Recruiting Trials 2004–2006	Number of Active* Trials 2004–2006	Enrolments to Trials 2004–2006	Patients Active** On Trial - Dec 2006
All types/various	16	17	453	32
Breast	69	74	871	2,677
Colorectal	31	37	452	334
Upper GI	15	20	168	135
Gynae	16	19	118	136
Haematology	54	65	372	269
Head and Neck	5	8	21	21
Melanoma	36	38	912	1,078
Neurological	5	5	19	11
Respiratory	27	28	451	166
Urogenital	25	30	544	431
All Trials	299	341	4,381	5,290

* Trials that were open to recruitment or had patients on treatment or follow-up.

** On treatment or in follow-up.

Figure 6: Active clinical trials by clinical grouping: 2004–2006



Figure 7: Enrolments by clinical grouping: 2004–2006

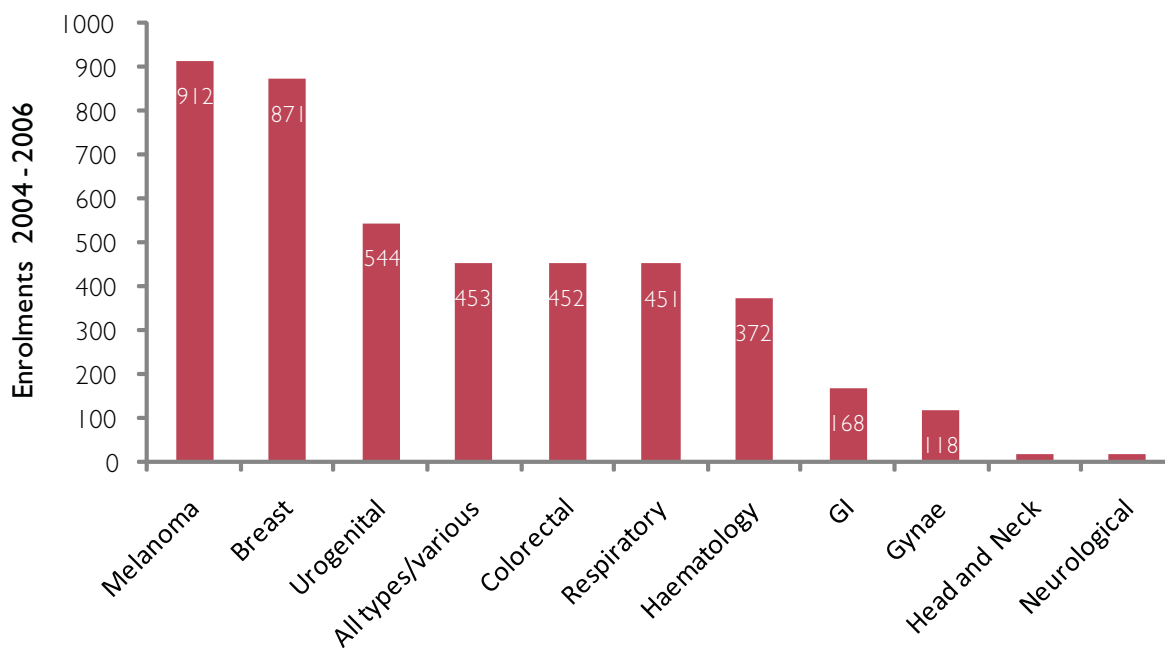


Figure 8: Active patients on trial by clinical grouping: 2004–2006

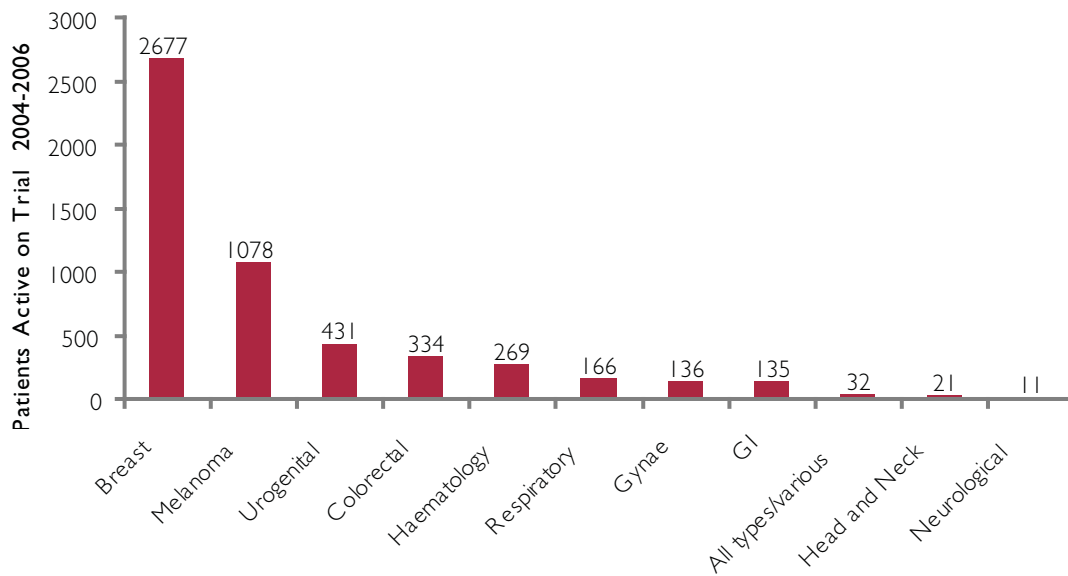
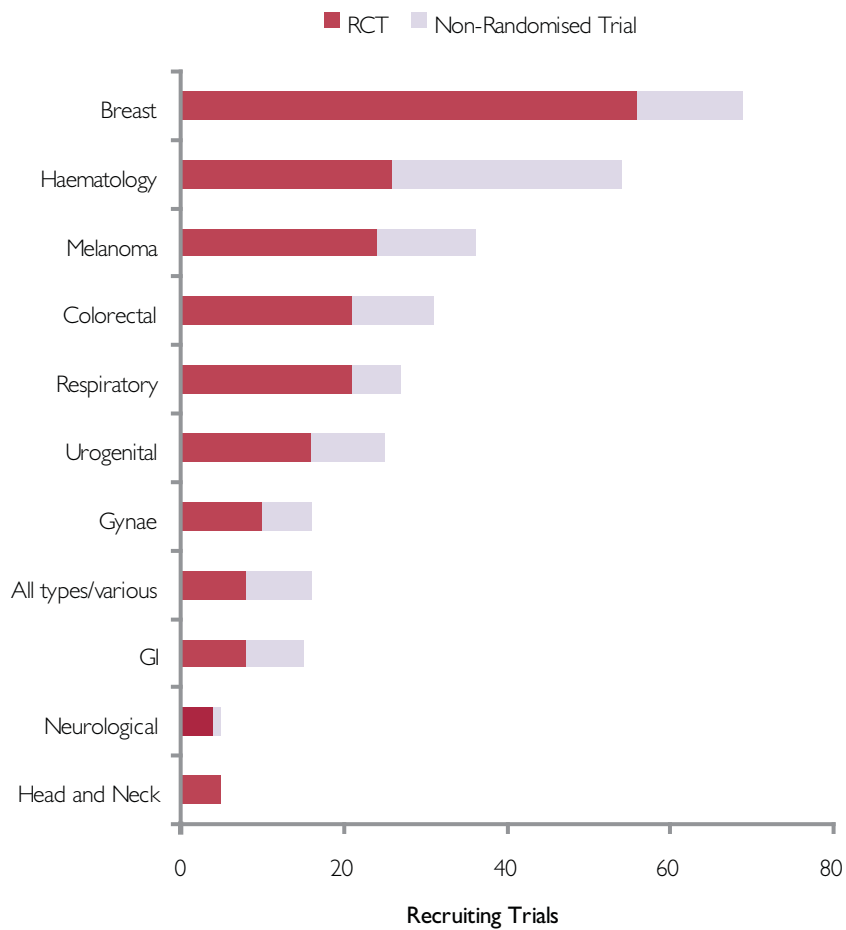


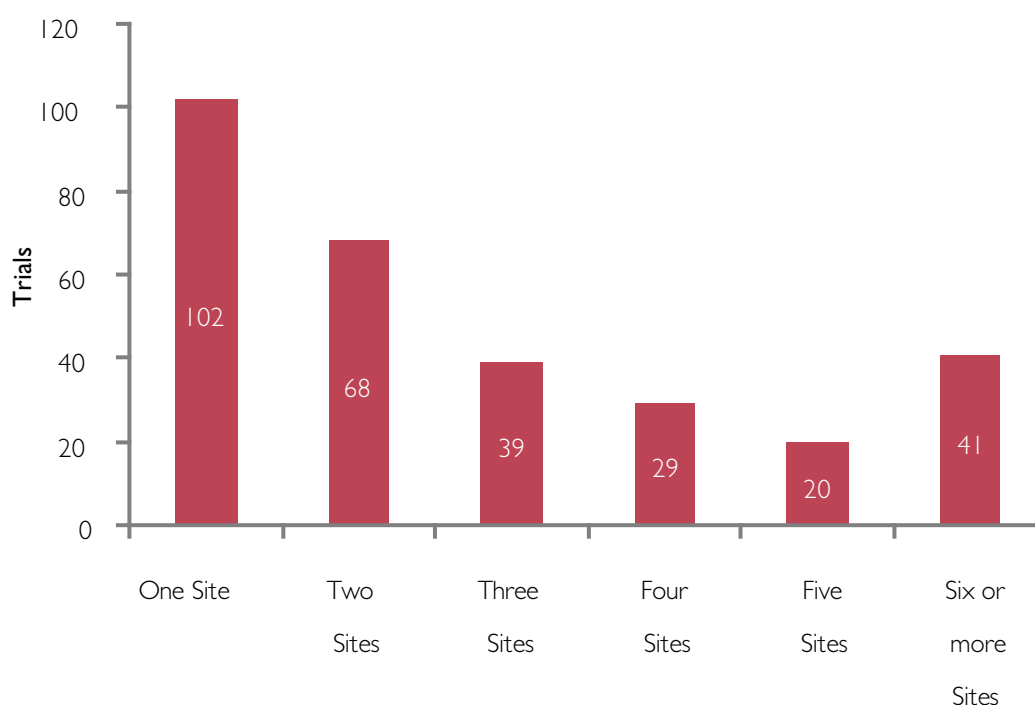
Figure 9: Recruiting trials: by clinical group and design of trial



4.4 Multi-centre research in NSW

The majority of trials were multi-centred trials (Figure 10). These trials may have also been open to recruitment outside NSW, elsewhere in Australia or internationally. Around 35% of trials were recruiting at only one site within the supported units in NSW with a further 45% recruiting at two to four units. Around 14% of trials were recruiting across six or more units. The trial with the most sites open to recruitment was an Australasian Gastro-intestinal Study Group colorectal cancer trial recruiting across 16 different units.

Figure 10: Number of sites per trial: recruiting studies (2004–2006)



Overall, the breast cancer clinical group had the highest number of large-scale, multi-site trials with 20 trials involving five or more participating sites in NSW (Figure 11). Haematological and melanoma trials tended to be active at less than four sites. However, at least two large specialised haematological trial units within NSW were not included in the current analysis. Melanoma trials tended to occur mostly at specialised units rather than general oncology trial units.

Around 90% of pharmaceutical industry sponsored trials were conducted at between one and four sites in NSW, with only 10% of these trials running at five or more sites (Figure 12). In contrast, around 30% of non-industry trials were conducted at five or more sites in NSW and 14% were conducted at eight or more sites (Figure 13).

Figure 11: Number of sites per trial by clinical grouping: recruiting trials 2004–2006

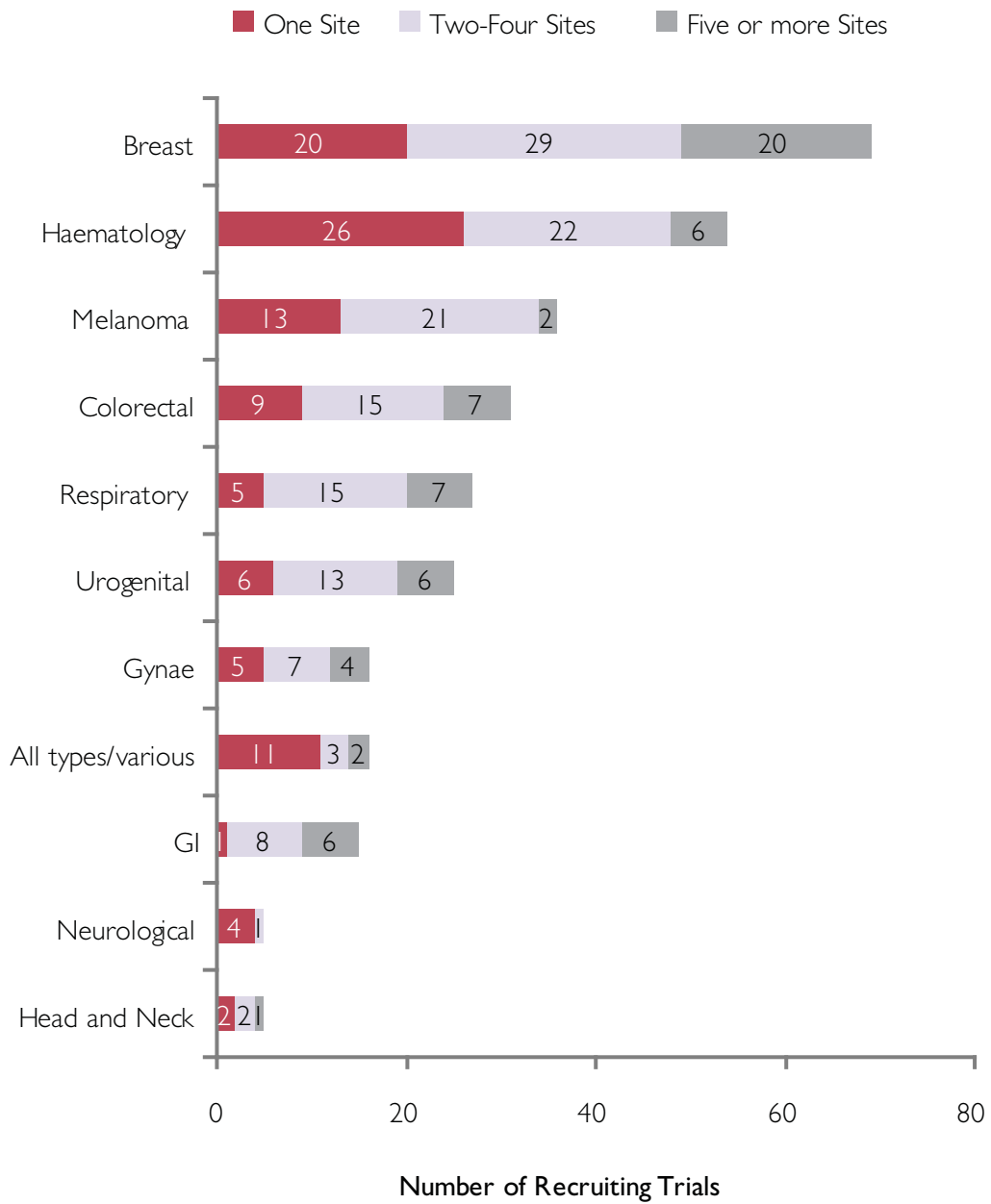


Figure 12: Number of sites per trial: recruiting trials 2004–2006. Pharmaceutical industry sponsored trials

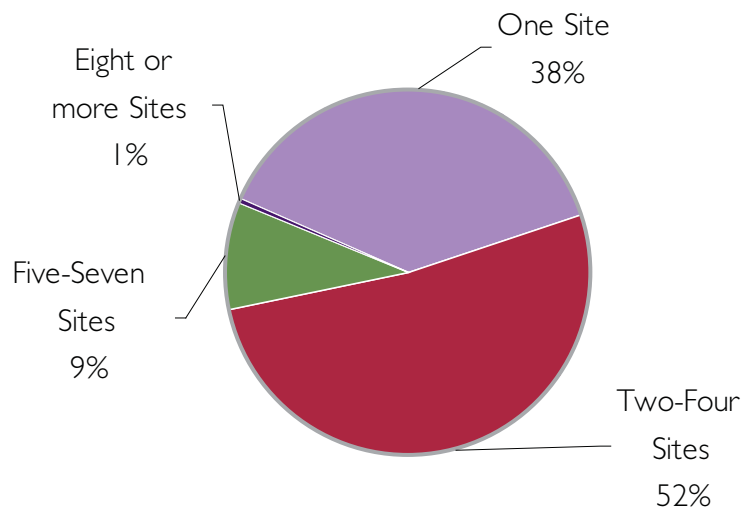
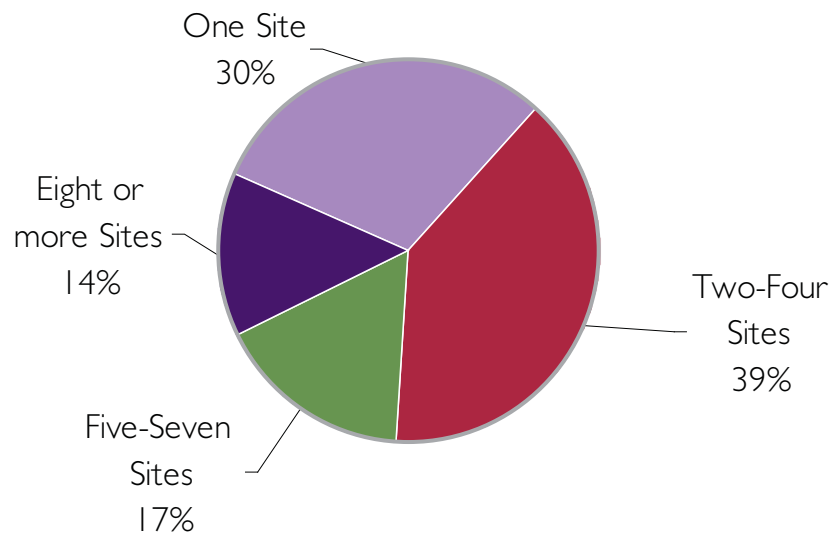


Figure 13: Number of sites per trial: recruiting trials 2004–2006. Non-pharmaceutical sponsored trials



4.5 Phase of clinical trials

For a small proportion of trials identified (6%), phase was not able to be assigned due to insufficient information available. These trials were excluded from the analysis below. Of those trials where phase was available, almost 60% were phase III and 27% were phase II (Table 5). A small proportion were phase I trials or phase IV trials. In a further 6% of studies phase was not applicable, as they were non-intervention prospective observation studies.

The clinical groupings with the greatest proportion of phase I trials reported were melanoma and 'all types/various'. The category of 'all types/various' includes advanced cancer trials and palliative care trials.

Some clinical groupings had a higher proportion of enrolments to phase III trials than the overall average of 59% across all clinical groupings (Table 6). These were breast cancer trials with 83% of enrolments for phase III trials and melanoma enrolments at 71%.

Table 5: Clinical trials recruiting 2004–2006 by phase of trial and clinical grouping

Clinical Group	Phase					Total	Proportion (%)
	I	II	III	IV	n/a*		
All types/ various	5	2	5	.	3	15	5.3
Breast	1	7	53	3	2	66	23.5
Colorectal	2	6	18	2	.	28	10.0
Upper GI	.	5	9	.	.	14	5.0
Gynae	.	5	8	.	3	16	5.7
Haematology	3	21	21	1	2	48	17.1
Head and Neck	.	.	5	.	.	5	1.8
Melanoma	6	13	13	.	3	35	12.5
Neurological	.	1	4	.	.	5	1.8
Respiratory	.	6	16	2	1	25	8.9
Urogenital	.	9	13	.	2	24	8.5
All Trials	17	75	165	8	16	281**	100.0
Proportion (%)	6.0	26.7	58.7	2.8	5.7	100.0	

* For some prospective observation studies of other trials, 'phase' was determined to be 'not applicable'.

** For a small percentage of trials, phase was not able to be assigned due to insufficient information available. These trials were excluded from this table.

Table 6: Clinical trial enrolments 2004–2006: phase of trial and clinical grouping

Clinical Group	Phase					Total	Proportion (%)
	I	II	III	IV	n/a*		
All types/various	54	16	108	.	274	452	11.0
Breast	4	74	716	66	10	870	21.3
Colorectal	2	139	199	71	.	411	10.0
GI	.	59	108	.	.	167	4.1
Gynae	.	16	49	.	53	118	2.9
Haematology	13	50	138	.	36	237	5.8
Head and Neck	.	.	20	.	.	20	0.5
Melanoma	118	120	625	.	18	881	21.5
Neurological	.	.	19	.	.	19	0.5
Respiratory	.	72	117	163	35	387	9.5
Urogenital	.	173	315	.	42	530	13.0
All	191	719	2,414	300	468	4,092**	100.0
Proportion (%)	4.7	17.6	59.0	7.3	11.4	100.0	

* For some prospective observation studies of other trials, 'phase' was determined to be 'not applicable'.

** For a small percentage of trials, phase was not able to be assigned due to insufficient information available. Enrolments to these trials were excluded from this table.

4.6 Industry and non-industry supported trials

There were approximately equal numbers of pharmaceutical industry and non-pharmaceutical industry supported trials that were recruiting patients during 2004–2006 (Table 7). However, non-industry trials, that were either investigator initiated or co-operative group-led trials, accounted for around 70% of new trial enrolments. The clinical groupings associated with a high proportion of non-industry trials included haematology, breast, upper GI and gynaecological trials (Figure 14). Melanoma and respiratory cancers had the highest proportion of industry sponsored trials open for recruitment. Neurological and respiratory cancer trials had the highest enrolment on industry sponsored trials (Figure 15).

Table 7: Number of recruiting trials and patient enrolments within clinical groupings by industry or non-industry sponsor

Clinical Grouping	Trials			Enrolments		
	Non-Industry	Industry	(N: Total Recruiting Trials)	Non-Industry	Industry	(N: Total Patients enrolled)
	%	%	N	%	%	N
All types/ various	56.3	43.8	16	91.8	8.2	453
Breast	66.7	33.3	69	82.0	18.0	871
Colorectal	32.3	67.7	31	51.8	48.2	452
Upper GI	60.0	40.0	15	73.8	26.2	168
Gynae	62.5	37.5	16	88.1	11.9	118
Haematology	70.4	29.6	54	92.7	7.3	372
Head and Neck	40.0	60.0	5	65.0	35.0	20
Melanoma	27.8	72.2	36	73.7	26.3	912
Neurological	40.0	60.0	5	5.3	94.7	19
Respiratory	18.5	81.5	27	22.4	77.6	451
Urogenital	36.0	64.0	25	68.4	31.6	544
Total	50.2	49.8	299	70.7	29.3	4380

Figure 14: Number of recruiting trials within clinical groupings by industry or non-industry sponsor

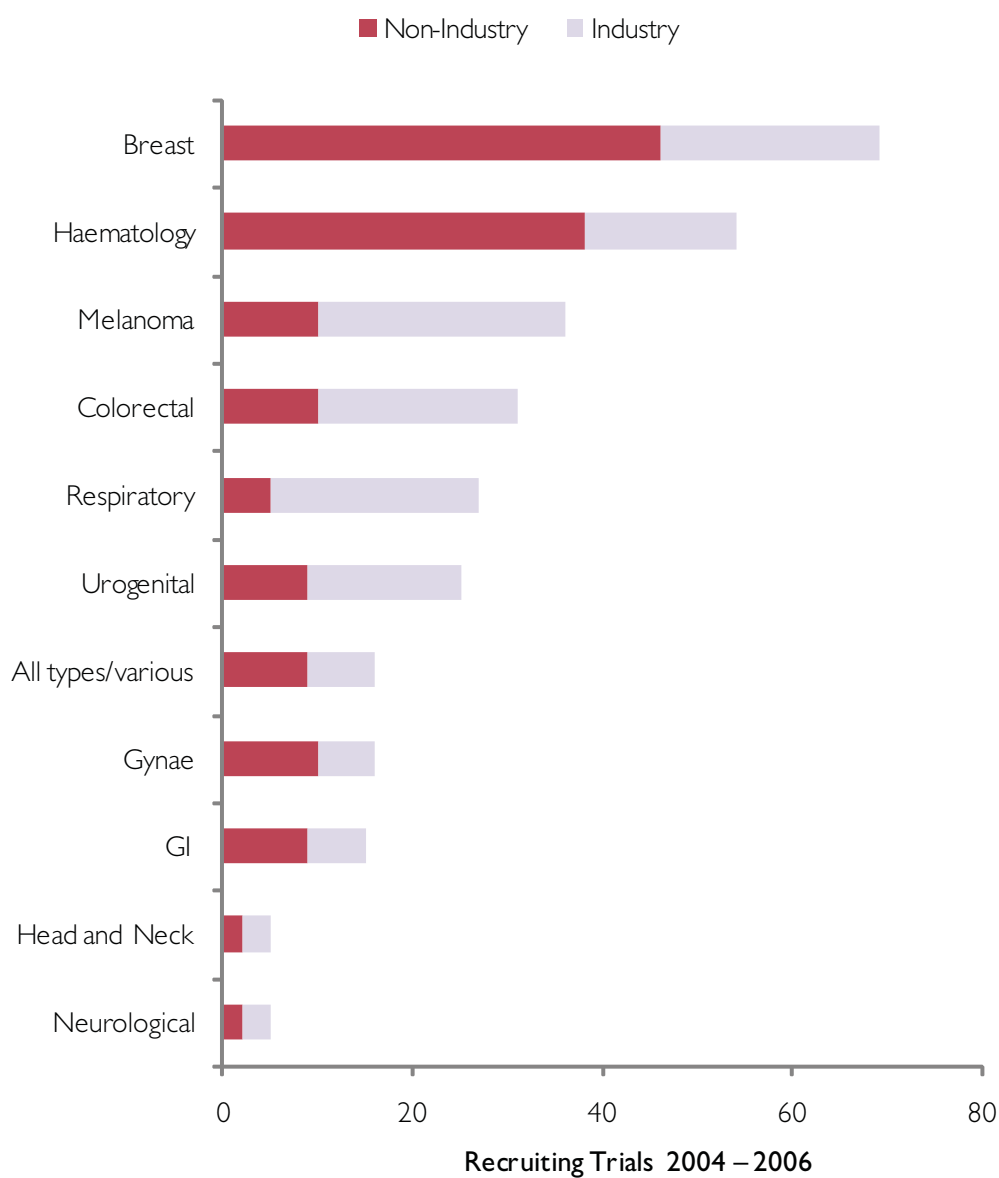
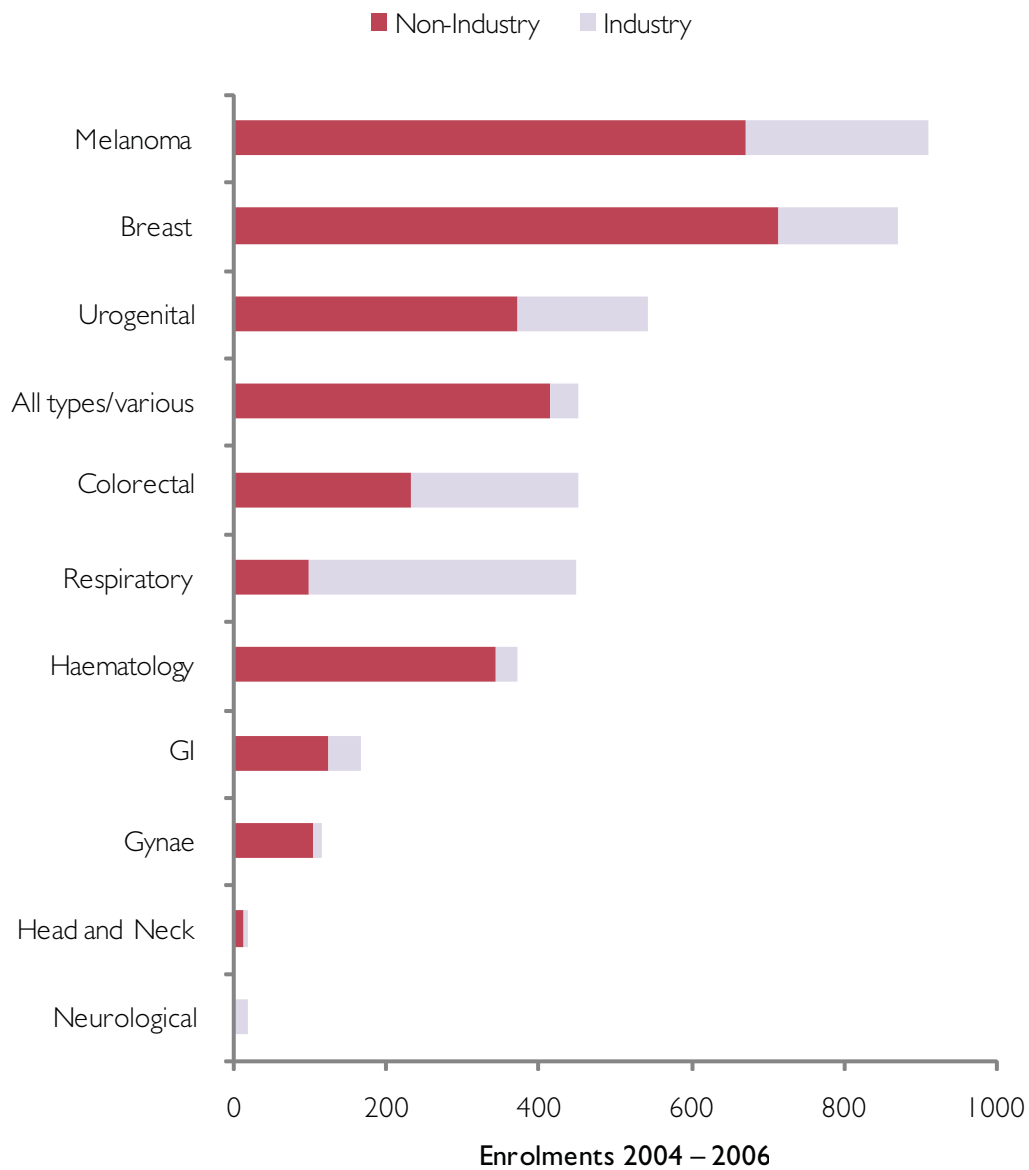


Figure 15: Trial enrolments within clinical groupings by industry or non-industry sponsors



Both industry and non-industry trials were mostly Phase III (Table 8). However, there were a higher proportion of industry-led trials that were early phase. Phase III non-industry studies enrolled the most patients, with around 45% of all enrolments on these types of trials (Table 9).

Table 8: Number of recruiting trials by phase and industry or non-industry sponsors

Sponsor	Phase					Total
	I	II	III	IV	n/a	
Non-industry	7	36	79	1	13	136
Industry	10	39	86	7	3	145
All	17	75	165	8	16	281

For a small percentage of trials, phase was not able to be assigned due to insufficient information available. These trials were excluded from this table.

Table 9: Number of enrolments by phase and industry or non-industry sponsor

Sponsor	Phase					Total
	I	II	III	IV	n/a	
Non-industry	117	384	1,851	64	408	2,824
Industry	74	335	563	236	60	1,268
All	191	719	2414	300	468	4092

For a small percentage of trials, phase was not able to be assigned due to insufficient information available. These trials were excluded from this table.

4.7 Matching clinical trial activity to cancer incidence and mortality

The most recent cancer incidence and mortality results were matched with available trials and enrolment on those trials.¹³ The proportion of trials open for recruitment and the proportion of clinical trial enrolments do not correlate well with cancer incidence or deaths for many clinical cancer groupings (Table 10).

High-incidence cancer groups, such as urogenital cancer, have relatively few trials open for enrolment (Figure 16). Similarly, enrolments in the trials are proportionally low for bowel, upper gastro-intestinal and head and neck cancers (Figure 17). There are no trials identified for the 8% of cancer patients who present each year with a carcinoma of unknown primary site.

The most fatal cancers, including respiratory, upper gastro-intestinal cancers, unknown primary and colorectal cancers, had a lower proportion of clinical trials open for recruitment within the group surveyed (Figure 18). This was also reflected in the average enrolments per year for those cancers (Figure 19). Conversely, cancers with excellent survival were well represented with large enrolments on breast and melanoma trials.

Table 10: Clinical trial activity compared to new cancer cases and deaths¹³ across top ten clinical groupings

Clinical Group	New Cancers 2004		Cancer Deaths 2004		Average Number of Recruiting Trials per year*		Average Enrolments to Trials per year**	
	n	%	n	%	n	%	n	%
Urogenital	7,421	22	1,588	13	17	8	181	12
Colorectal	4,517	13	1,610	13	19	9	151	10
Breast	4,124	12	935	7	49	23	290	20
Melanoma	3,654	11	401	3	23	11	304	21
Respiratory	3,245	10	2,618	21	19	9	150	10
Haematological	2,832	8	1,225	10	40	19	124	8
Upper GI	2,387	7	1,784	14	13	6	56	4
Unknown Primary	1,452	4	964	8	0	0	0	0
Gynaecology	1,384	4	514	4	10	5	39	3
Head and Neck	873	3	351	3	4	2	7	0
Neurological	467	1	346	3	3	2	6	0
Total								
All Cancers	34,092	100	12,686	100	211	100	1,460	100

*Average number of trials open for recruitment per year (2004–2006).

**Average number of patients enrolled to trials (2004–2006).

Figure 16: Relative proportions of new cancer cases and recruiting trials³

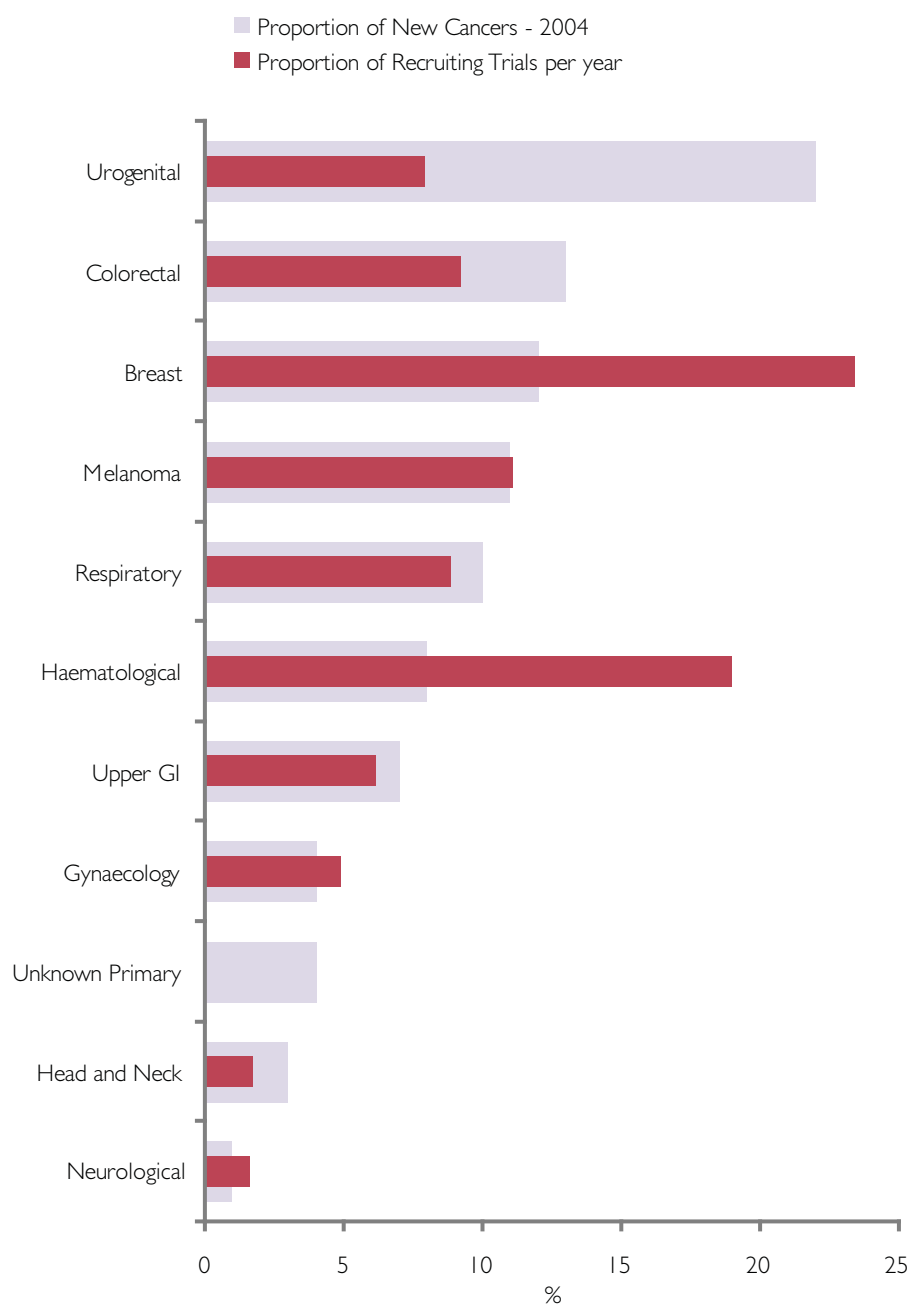


Figure 17: Relative proportions of new cancer cases and enrolment on clinical trials¹³

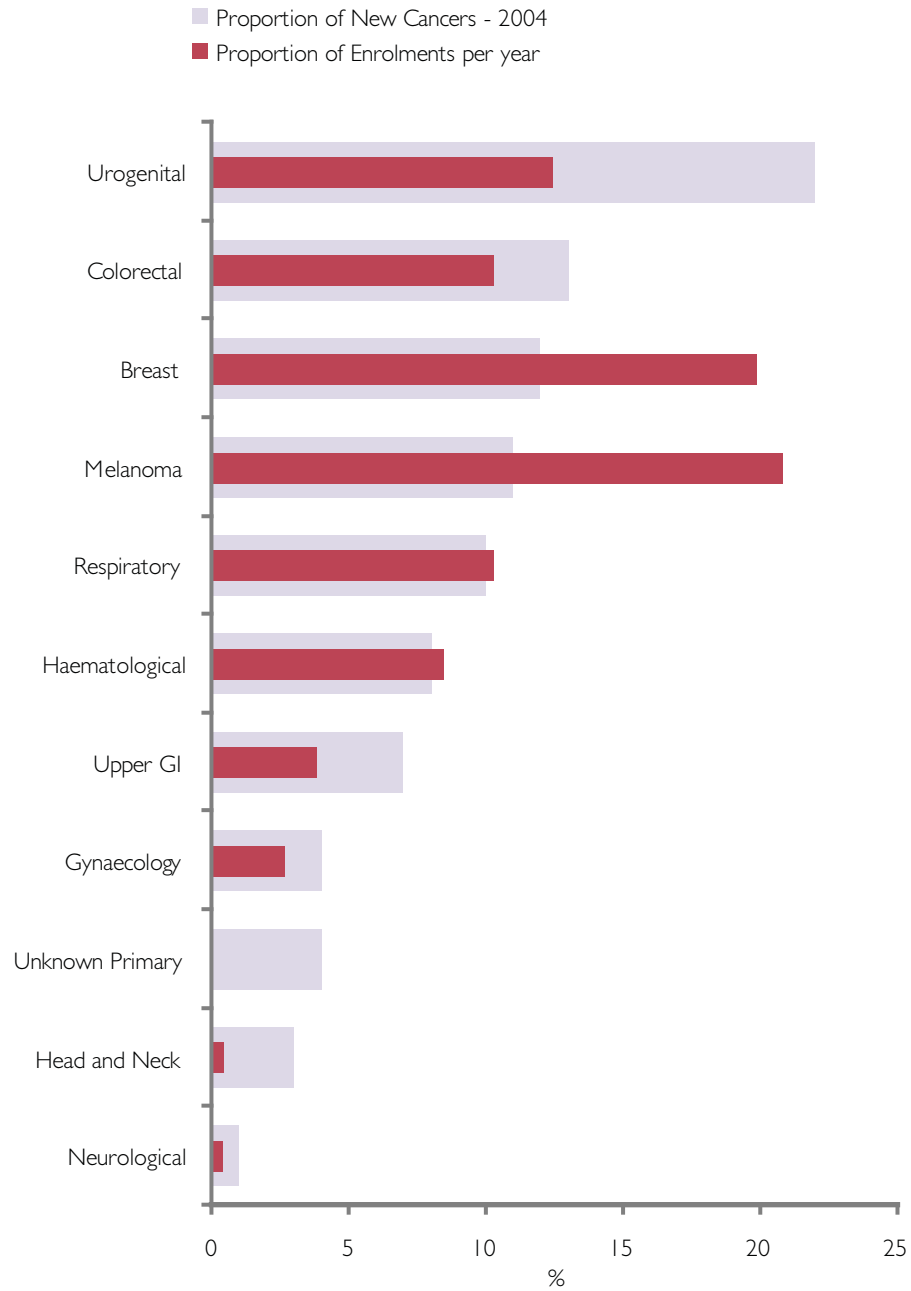


Figure 18: Relative proportion of cancer deaths and recruiting trials³

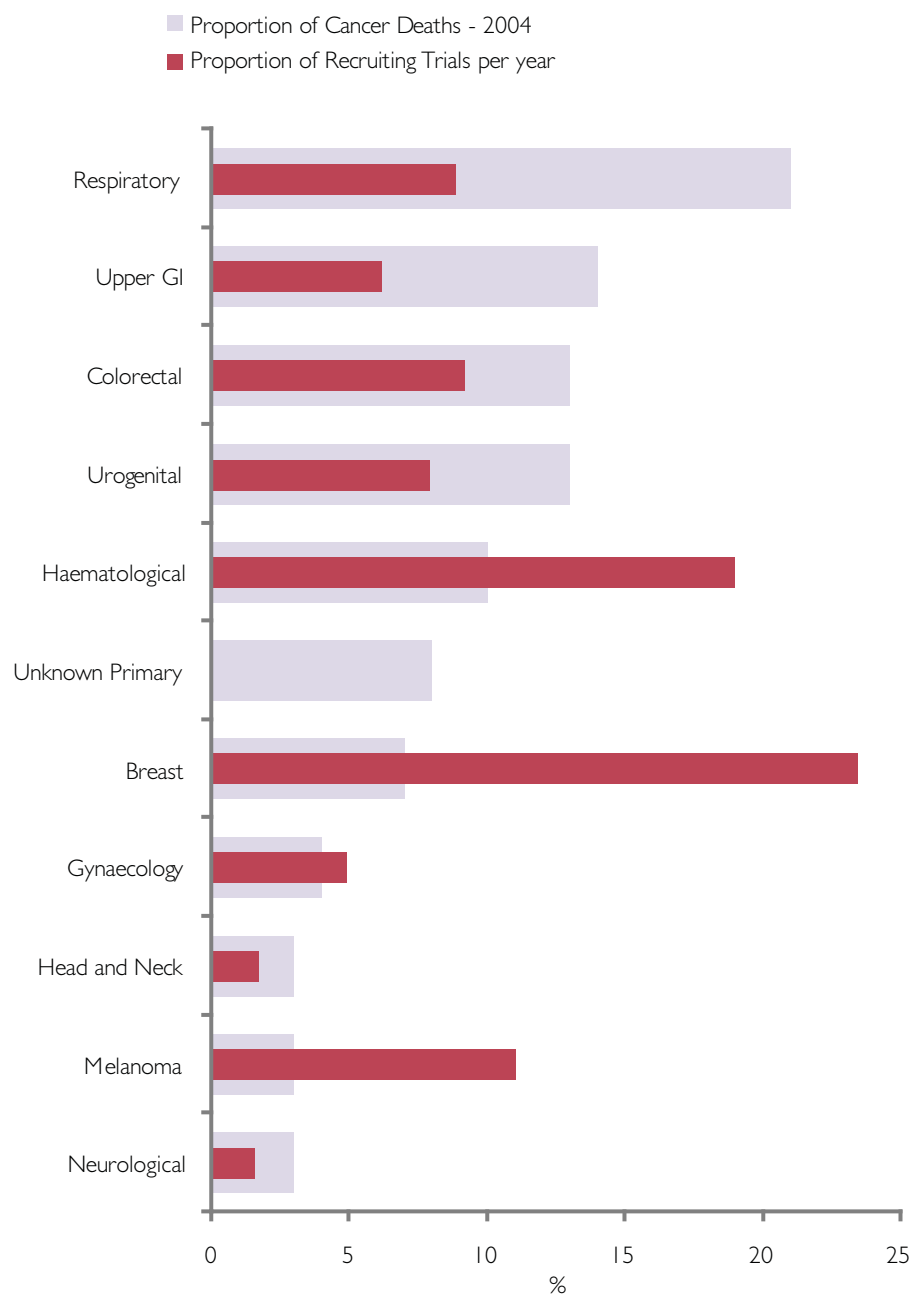
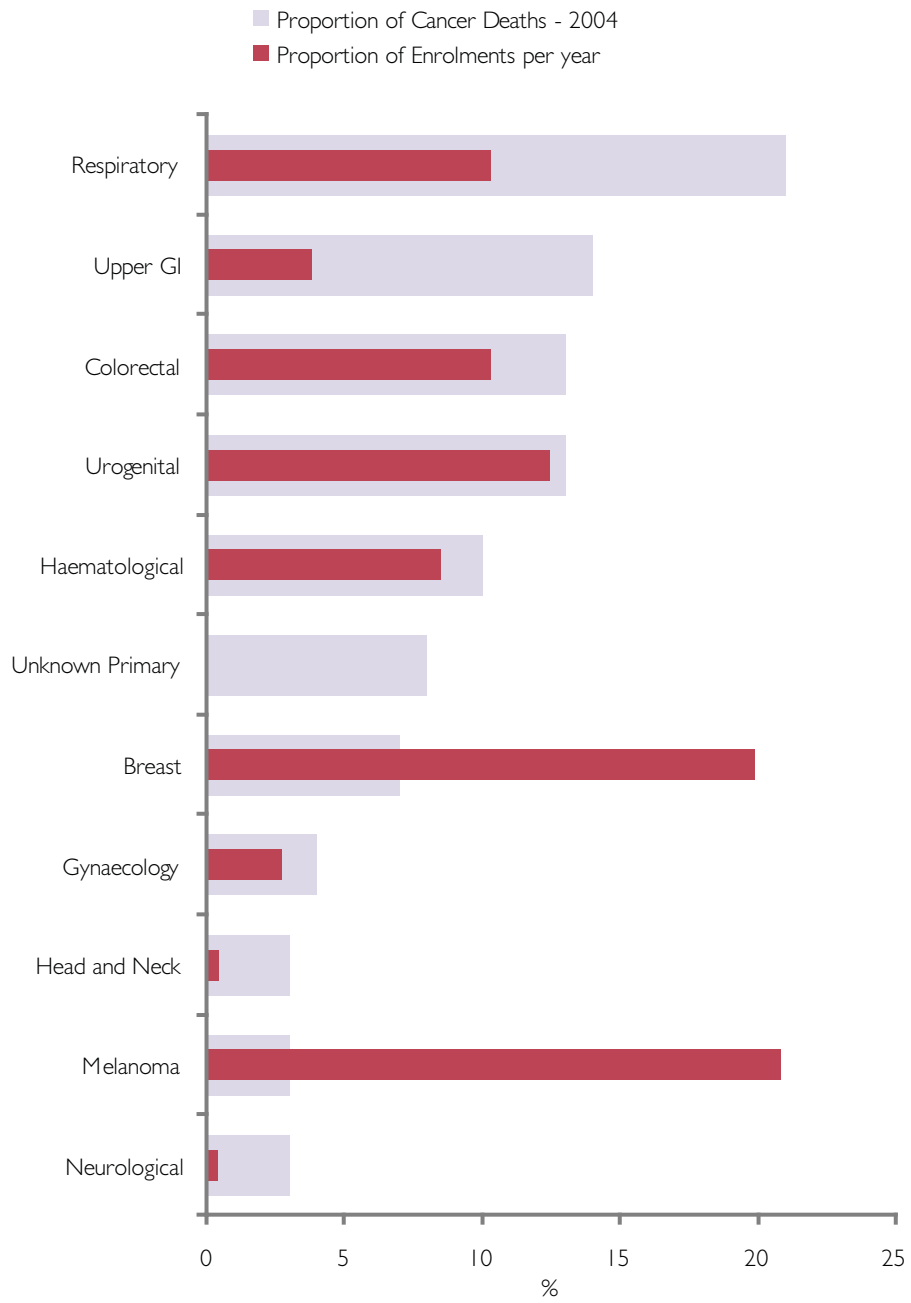


Figure 19: Relative proportions of cancer deaths and enrolments on clinical trials¹³



4.8 Review of ethics committee activities

The review of Human Research Ethics Committee (HREC) submissions for the period July 2004–June 2005 found that the majority of cancer-related studies reviewed were clinical trials (77%). A further 18% were epidemiological studies and 5% were biomedical studies.

During this period there were estimated to be 259 cancer-related clinical trial submissions made to the HRECs in NSW. These submissions related to only 144 unique trials, which means that 115 (44%) were duplicate submissions that had already been submitted to another HREC for review in NSW within the 12-month period under review. Only 20% of studies were approved at the first review and only 1% were ultimately rejected. Across NSW the average approval time was 80 days (median 63 days) from submission with a range of 28 to 548 days.

5. Discussion

This review has identified a high level of cancer clinical trial activity in NSW.

This review has identified a high level of cancer clinical trial activity in NSW, with 341 active clinical trials during the period 2004–2006 and 299 trials actively recruiting patients during this time. At the end of December 2006, there were 5,290 active patients on trials, with a total of 4,381 enrolments from 2004–2006. During 2006 it was estimated that new enrolments to clinical trials, within Cancer Institute NSW supported units, accounted for 5.3% of new cancer patients for that year. Given that this data collection was limited to clinical trial units supported by Cancer Institute NSW grants, not all clinical trial activity in NSW has been captured. It is estimated that up to 25% additional trials or active patients were not included in this survey which suggests that, at present, enrolments to cancer trials in NSW may represent up to 6.5% of new NSW cancer cases with around 6,600 active patients in NSW.

The increase in activity observed over the three-year period was marked, with an increase of 31% in active trials and 94% in enrolments comparing the year 2004 with 2006. This increase occurred across all Area Health Services (AHS), although to a greater extent in some areas. The National Cancer Research Network (NCRN) in the UK experienced similar differential patterns of increased activity across areas within the first few years of the NCRN.²⁰ Differing levels of activity across NSW is to be expected given the geographically dispersed nature of the non-metropolitan NSW population and the varying level of experience in

conducting trials across areas. The NSW Cancer Trials Network provides support to trial units across the state via a number of mechanisms. Funding for nurses and data managers are provided to units to support the workload involved in data management as well as recruiting, treating and maintaining follow-up of patients on trials. Funding is also provided to support a director of clinical cancer research in each AHS, along with a full time regulatory affairs officer. These positions assist in co-ordinating the administrative workload of trials, as well as encouraging a collaborative research network amongst clinical trial units in NSW.

While 35% of trials were recruiting at only one Cancer Institute NSW supported unit, the majority of trials were conducted at multiple sites in NSW. The findings from the review of Human Research Ethics Committees suggests that initiating a clinical trial across multiple sites in NSW has previously involved a considerable level of duplication of administrative effort, with 44% of cancer clinical trial submissions relating to trials that had already been submitted to an HREC elsewhere in the state.

The process has also been slow, with a median of 63 days for approval at a single HREC and around 80% of applications requiring protocol modification before final approval. For a multi-centre study, the entire timeframe between submission to first HREC and approval from final HREC has, in some instances, taken well over a year. The NSW Health model for a streamlined approach to ethical review, which commenced 1 July 2007, promises to alleviate a large share of administrative burden across the state relating to the initiation of clinical trials. This model also has the potential to improve HREC review timeframes for initiating multi-centre trials. Timeframes for review will be monitored under the NSW model of single ethical review and this ongoing monitoring of performance against the international benchmark of a 60-day turnaround will be used in future evaluation of this model.



Around 60% of cancer clinical trials identified in the current review were phase III trials. Phase III trials are generally testing promising new treatments against the standard best practice within a given indication and therefore positive findings within these trials can often be immediately applicable to standard clinical practice with the possibility of immediate clinical benefit. Around 17% of trials were phase I trials. These trials are generally testing new discoveries such as new molecules or new approaches to treatment and this level of activity demonstrates that NSW researchers are actively participating in cutting edge research that will attempt to translate scientific discoveries into clinical practice.

While around 50% of trials within this report are industry-led trials, 70% of patient enrolments were to non-industry-led trials. The difference between trials and enrolments can be explained by the finding that non-industry trials tended to include more sites in NSW per trial than industry trials. Both types of trial are essential. Pharmaceutical industry trials often play a vital role in the development of new treatments and in bringing promising new drugs into clinical practice. This provides an appropriate mix of the introduction of promising new drugs owned by industry and investigator initiated research aiming to fundamentally change practice using the best ideas from our leading cancer experts.

The clinical grouping with the most trials was breast cancer, followed by haematological malignancies. Clinical trials have driven major advances in both these disease groups and both groups have well-established co-operative research groups in Australia.^{12,14,21,22} Haematological malignancies represent many subtypes of cancer, each of which requires individual trials to study the best treatments for this large range of conditions. The largest enrolments of patients were in melanoma, breast and urological cancer trials including prostate cancer. All of these cancers have excellent five-year survivals of 88% or above. These survival rates have, in part, resulted from a long history of trials research in these tumour groups.¹²

This report has identified that there are many common cancers and cancers with unacceptably high death rates with low clinical trial activity for clinical groupings such as brain, head and neck and respiratory cancers and unknown primary cancer. To rapidly improve the outcome for these patients, additional clinical trials activity and more research generally needs to be further encouraged.

The NSW Cancer Trials Network allows a strategic approach to cancer clinical trials in NSW and will work with clinical trial researchers across the State, as well as the NSW Oncology Groups, to encourage a high level of clinical trial activity in all clinical groupings. The overall aim of the Network is to increase the quality and quantity of trials available to cancer patients and thus increase patient enrolment to clinical trials in NSW. This will be achieved through supporting and encouraging collaboration and partnerships within and between Area Health Service Networks, as well as continued commitment from the dedicated staff who undertake this important work on behalf of us all.

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7. Appendix

Clinical Trial Units that provided data included in this analysis

- Bankstown/Lidcombe Hospital – Oncology Unit
- Border Medical Oncology
- Breast Surgeons NSW
- Concord Repatriation General Hospital – Dept of Haematology, Sydney Cancer Centre
- Concord Repatriation General Hospital – Medical Oncology, Sydney Cancer Centre
- Lismore Base Hospital – Cancer Care and Haematology Unit
- Liverpool Hospital – Cancer Therapy Centre
- Nepean Hospital – Haematology, Cancer Care Centre
- Nepean Hospital – Nepean Cancer Care Centre
- Newcastle Mater Misericordiae Hospital – Department of Medical Oncology
- Newcastle Mater Misericordiae Hospital – Department of Radiation Oncology
- Newcastle Mater Misericordiae Hospital – Department of Surgical Oncology
- Newcastle Mater Misericordiae Hospital – Newcastle Melanoma Unit
- Port Macquarie Base Hospital – Oncology & Haematology Unit
- Prince of Wales Hospital – Department of Medical Oncology
- Riverina Cancer Care Centre – Clinical Trials Unit
- Royal North Shore Hospital – Department of Medical Oncology
- Royal North Shore Hospital – Department of Radiation Oncology
- Royal Prince Alfred Hospital – Institute of Haematology
- Royal Prince Alfred Hospital – Radiation Oncology Department, Sydney Cancer Care
- Royal Prince Alfred Hospital – Surgical Outcomes Research Centre (SOuRCe)
- Royal Prince Alfred Hospital – Sydney Cancer Centre – Medical Oncology
- Royal Prince Alfred Hospital – Sydney Cancer Centre – Radiation Oncology
- Royal Prince Alfred Hospital – Sydney Melanoma Unit
- Sacred Heart Hospice, St Vincent's Hospital
- Sacred Heart Hospice, St Vincent's Hospital – Palliative Care Clinical Trials Unit
- St George Hospital – Clinical Trials Unit, Cancer Care Centre
- St Vincent's Hospital – Medical Oncology Department
- Sydney Haematology and Oncology Centre – Sydney Haematology and Oncology Clinical Trials Unit
- Tamworth Base Hospital – Oncology Clinic
- The Tweed Hospital – Department of Medical Oncology
- Westmead Hospital – Haematology Department
- Westmead Hospital – Oncology Research Unit
- Wollongong Hospital – The Illawarra Cancer Care Centre

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