Landscape of cancer clinical trials in Australia: using trial registries to guide future research

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ABSTRACT

Objective: To quantify and describe current cancer clinical trial activity in Australia and help guide future trials research using trial registries.

Design and setting: Data from cancer trials recruiting in Australia at 31 March 2009 were extracted from the Australian New Zealand Clinical Trials Registry and ClinicalTrials.gov. A regression model was used to identify factors associated with industry sponsorship.

Main outcome measures: The proportion of cancer trials compared with estimated burden of disease for each cancer.

Results: There were 368 interventional cancer trials open to recruitment. The most-researched cancer was breast cancer, accounting for 17% of trials. Only 7% of trials were in lung cancer, yet lung cancer is responsible for the greatest burden of disease. Industry was the primary sponsor in 43% of trials. Drug treatments were tested in most trials (69%). Trials were more likely to be industry sponsored if they tested systemic rather than local treatments (OR, 16.71; 95% CI, 4.70–59.43), included patients with advanced rather than early disease (OR, 3.76; 95% CI, 1.78–7.94) and used random rather than non-random allocation (OR, 1.78; 95% CI, 1.06–3.00).

Conclusion: There is variation in the number of trials according to cancer site, with some cancers being underrepresented relative to their burden of disease. Industry sponsorship is more likely for trials that investigate systemic therapy, recruit patients with advanced disease and are randomised.

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Clinical trial registries provide a comprehensive record of all trials commenced (with the aim of preventing publication bias). However, they may serve additional purposes. For example, data could be extracted and analysed to provide an overview of the amount and nature of current trial activity. This might enable researchers and funding agencies to explore whether certain types of cancer or types of trials are being disproportionately supported, and to identify gaps in research to guide new funding initiatives.

Furthermore, clinical trial registries are well placed to provide representative information about trial sponsorship and funding sources. A United Kingdom study[1] found that support for randomised trials from non-industry sources in the UK had fallen, suggesting that an increasing proportion of trials were funded by industry, raising concerns about the desirability of this trend and whether policy changes should address it. In the United States, funding from industry sources (pharmaceutical, biotechnology and medical device firms) increased each year from 2003 to 2008.[2] The concern is that studies suggest industry-funded trials tend to draw pro-industry conclusions.[3]

The largest trial registry, ClinicalTrials.gov (CT.gov),[4] was established in the US in 2000.[5] There is also a large European registry,[6] and smaller local registries are being established in several countries. The Australian New Zealand Clinical Trials Registry (ANZCTR),[7] a World Health Organization primary registry, was created in 2005, and 3668 trials were registered to the end of 2009.

Our aim was to explore whether we could use the data from the ANZCTR and CT.gov to quantify, describe and analyse current clinical trial activity in Australia. Cancer trials were chosen as the focus of this paper because we wanted to explore the implications for cancer-related research in Australia. Specifically, we aimed to explore whether trial activity reflected cancer burden of disease and might be associated with different sponsorship sources.

METHODS

Data were extracted from the ANZCTR and CT.gov for trials that fulfilled three criteria: cancer, interventional trials, and recruiting in Australia at 31 March 2009. Original data were retained wherever possible; however, some data items were collected differently by each registry and were recoded for consistency (details of recoding are provided at http://sydney.edu.au/science/psychology/cemped/research.shtml#patientcommunication).

The cancer types used in our report have been standardised to those used by the Australian Institute of Health and Welfare and refer to the primary site of the cancer.[8]

We used the WHO definition of primary sponsor: "The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study."[9] Primary sponsors' responsibilities include initiating and managing a study, appropriate conduct and reporting, and obtaining ethics approval to commence a study. We categorised primary sponsor as industry (pharmaceutical and device companies) or non-industry (universities, collaborative groups, charities and government organisations). The primary sponsor of a trial may or may not be its main funder. The main funder is defined as the "major source(s) of monetary or infrastructure support for the trial",[9] such as a funding agency, foundation, company, hospital or university.

Analysis

We described trials in terms of: cancer type, intervention tested, sponsorship and funding source, phase and design (randomised versus non-randomised), characteristics of enrolled subjects, trial registry (the ANZCTR or CT.gov) and location of recruitment (Australia only or Australia and overseas). For each cancer, we obtained data on disability-adjusted life-years (DALYs) for 2003.[10] DALYs are the sum of the years of life lost due to premature mortality in the population and the equivalent "healthy" years lost due to disability for incident cases. We tested whether the number of clinical trials for each cancer was proportional to the number of DALYs for that cancer using the χ^2 goodness-of-fit test. The following cancer types with small numbers of trials were grouped together for this analysis: prostate and testis; head and neck, eye and thyroid; pancreas, liver and gallbladder; and cervix and uterus. The cancer types of all/multiple, other, other haematological, mesothelioma and unknown primary sites were not

1 Cancer types ranked by number of clinical trials, burden of disease (as DALYs) and total target sample size

Cancer type	Trials		DALYs		Sample size	
	No.	Rank	No.	Rank	No.	Rank
Breast	62	1	60 654	3	74 247	1
Lymphoma	31	2	22 263	6	7923	8
Leukaemia	31	2	19 956	8	14 183	3
All/multiple*	31	2	na	na	9060	6
Lung	24	5	88 904	1	16 062	2
Colorectal	21	6	63 605	2	8636	7
Brain	21	6	19 792	9	4792	11
Melanoma	17	8	20 236	7	12 044	5
Kidney	15	9	12 487	13	5933	10
Myeloma	15	9	8925	16	3311	13
Sarcoma	15	9	5879	17	6423	9
Prostate	14	12	36 547	4	12 175	4
Head and neck	12	13	17 215	10	1428	19
Ovary	9	14	11 994	14	4076	12
Other haematological†	7	15	na	na	940	22
Oesophagus	6	16	14 163	12	670	25
Other‡	6	16	na	na	1400	18
Pancreas	5	18	22 680	5	1658	16
Stomach	5	18	15 218	11	2430	15
Cervix	5	18	5231	18	1600	17
Liver	3	21	4716	19	2650	14
Uterus	3	21	4663	20	1320	20
Bladder	2	23	10 077	15	990	21
Eye	2	23	952	22	690	24
Testis	2	23	862	23	326	26
Mesothelioma	2	23	na	na	870	23
Gallbladder	1	27	3549	21	45	28
Thyroid	1	27	762	24	100	27
Unknown primary	0	29	na	na	0	29
Total	368		471 330		195 982	

DALYs = disability-adjusted life-years. na = not available: the all/multiple, other, other haematological, mesothelioma and unknown primary sites were not reported in the source from which DALYs were obtained. * All/multiple category included because Phase 1 trials and trials investigating behavioural interventions may include patients with any type of cancer. † Bone marrow transplant, myelodysplastic syndromes, haemaglobinopathies. ‡ Non-melanoma skin cancer, bone, adrenocortical. ◆

included in this analysis as DALY information was not available.

Bivariate analyses (χ^2 test and logistic regression) were used to test whether the following prespecified variables were associated with primary sponsorship by industry: cancer type, intervention, allocation to intervention, and cancer extent. Their independent association was analysed by multivariable logistic regression.

SAS, version 9.2 (SAS Institute Inc, Cary, NC, USA) was used for statistical data analysis.

RESULTS

We identified 368 cancer trials that were recruiting in Australia at 31 March 2009. Of these, 131 trials (36%) were registered with the ANZCTR and 237 trials (64%) were registered with CT.gov. Fifty-seven per cent were randomised controlled trials.

Cancer type

Most trials were in breast cancer, followed by lymphoma and leukaemia, lung cancer, colorectal cancer, brain cancer and melanoma (Box 1). Breast cancer trials anticipated recruiting the largest number of patients: 74 247 patients (38%) out of an expected total sample size of 195 982 for all trials combined.

Many of the cancers with higher burdens of disease (measured by DALYs) were underrepresented (Box 1 and Box 2). This was most notable for lung, colorectal, prostate and pancreatic cancers. Conversely, leukaemia and lymphoma were overrepresented relative to their DALYs. There was a significant difference between the observed number of trials in each cancer type and the number of trials expected based on DALYs ($\chi^2 = 154.7$; $P = 0.001$). We found a similar pattern for the anticipated sample size relative to DALYs (http://sydney.edu.au/science/psychology/cemped/research.shtml#patientcommunication).

Primary sponsor and funding source

Industry sources were the primary sponsor in 43% of trials (Box 3). There was strong evidence of a difference in the primary sponsor between the cancer types ($\chi^2 = 26.7$; $P = 0.005$). Of 368 trials, there were 337 (92%) with the same funding source and primary sponsor. Industry funded 98% of industry-sponsored trials and 13% of non-industry-sponsored trials.

Most drug trials were sponsored or funded by industry (56% and 64%, respectively). For all other interventions analysed, non-industry was the main source of sponsorship (Box 4) and funding.

Bivariate analysis showed a relationship between primary sponsorship by industry and cancer group ($P = 0.001$), intervention type ($P < 0.001$) and cancer extent ($P < 0.001$) (Box 5).

In the multivariate analysis, the significant factors were intervention type ($P < 0.001$), cancer extent ($P = 0.001$) and allocation to intervention ($P = 0.030$) (Box 5). Trials of systemic interventions were more likely than local therapies to be sponsored by industry (OR, 16.71; 95% CI, 4.70–59.43). Trials that included patients with advanced disease were more likely to be sponsored by industry than trials that included patients with early disease (OR, 3.76; 95% CI, 1.78–7.94), and randomised controlled trials had higher odds than non-randomised trials of being sponsored by industry (OR, 1.78; 95% CI, 1.06–3.00).

Intervention

Drug treatments were the most commonly tested intervention (69%), followed by biological treatments, behavioural interventions, radiation, chemoradiation, surgery

and diagnosis (Box 6). The least common interventions tested included prevention, early detection and lifestyle (1% each).

Cervical cancer, melanoma and uterine cancer were the only cancer types for which drug treatment was not the main intervention.

Most trials investigating drugs, biological agents and radiation were registered with CT.gov and were open for recruitment internationally. In contrast, most trials investigating behaviour, lifestyle, diagnosis, early detection and prevention were registered with the ANZCTR and recruiting only in Australia (Box 6).

Results describing trials according to cancer extent, age restrictions and phase of trials can be found at http://sydney.edu.au/science/psychology/cemped/research.shtml#patient-communication.

Location of recruitment and place of registration

Most trials (60%) were recruiting both in Australia and overseas, while 40% of trials were recruiting only in Australia. In cancers of the gallbladder (100%), oesophagus (83%), cervix (80%), colorectum (67%), head and neck (58%) and breast (54%), there was a higher proportion of trials recruiting only in Australia compared with other cancer types. Of 222 trials open to recruitment both in Australia and overseas, 84% were registered with CT.gov.

Eighty per cent of the trials open to recruitment only in Australia had a non-industry primary sponsor and 62% were non-industry funded. In contrast, the majority of trials open to recruitment in Australia and overseas had an industry primary sponsor (58%, 129/222) and an industry funder (also 58%, 129/222).

Comparison with cancer trials internationally

We conducted a search of the WHO International Clinical Trial Registry Platform (ICTRP) for cancer trials recruiting at 31 March 2009.[11] We found a similar proportion of trials were recruiting for each cancer type as in our analysis (see http://sydney.edu.au/science/psychology/cemped/research.shtml#patient-communication), suggesting that our data are representative of cancer clinical trials internationally.

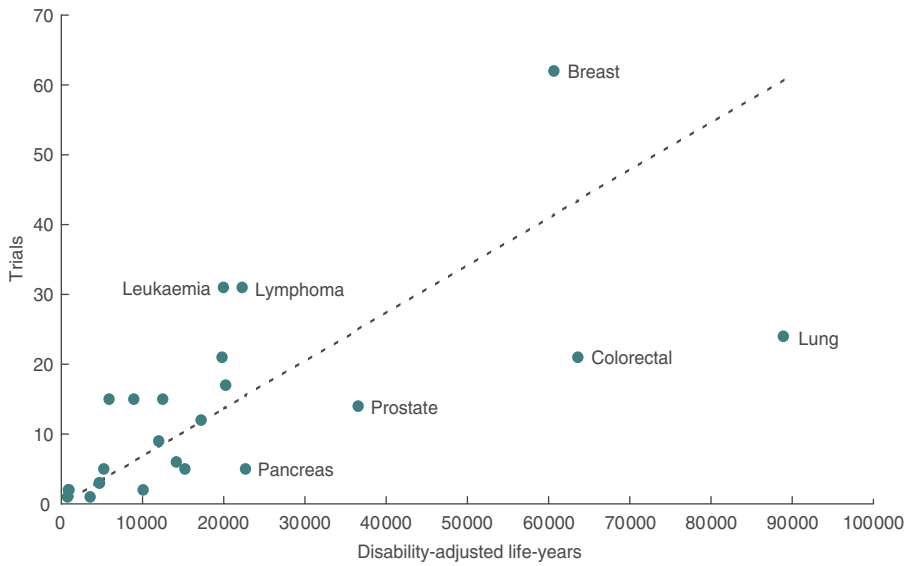
DISCUSSION

Our report uses clinical trial registry data to describe Australia's cancer trial activity. The development of publicly accessible, online, searchable registries has made this possible. We found that the number of trials for each cancer type did not always match the burden of disease caused by that cancer, thereby identifying gaps in cancer trials research. Four of the five cancers that result in the greatest burden of disease had relatively few clinical trials (lung, colorectal, prostate and pancreatic cancers). It is possible they are underrepresented because, until recently, there have been relatively few interventions worth testing for these cancers. Repeating this analysis in a few years may reveal that the distribution of cancer types being studied in clinical trials changes due to the increasing investigation of targeted therapies.

In contrast, there were more trials relative to burden of disease for breast, brain, kidney and haematological malignancies and sarcoma. The highest proportion of registered, open-to-recruitment, interventional trials were in breast cancer. Breast cancer was also notable because it anticipated recruiting a very large number of patients relative to its burden of disease. Our findings are consistent with reports comparing the number of trials with cancer incidence and mortality data.[12]

Trials in breast cancer differed in important ways. For all cancer types except breast cancer, most trials included people with advanced disease, whereas most breast cancer trials included women with early-stage disease. A large proportion of breast cancer trials were investigating non-drug interventions — all prevention trials, two-thirds of lifestyle trials and almost 30% of behavioural trials. Relatively, a higher proportion of breast cancer trials were non-industry sponsored and funded. These features might be a consequence of consumer influence on the research agenda. For example, the US National Breast Cancer Coalition, set up in 1991, has been

2 Number of cancer trials, by disability-adjusted life-years



3 Industry-sponsored trials, by cancer type*

Cancer type	No. of trials	No. of industry-sponsored trials
Haematological	84	36 (43%)
Breast	62	20 (32%)
All/various	40	17 (43%)
Urogenital	33	20 (61%)
Lung	26	20 (77%)
Colorectal	21	10 (48%)
Neurological	21	5 (24%)
Upper gastrointestinal	20	7 (35%)
Gynaecological	17	5 (29%)
Melanoma	17	9 (53%)
Sarcoma	15	7 (47%)
Head and neck	12	3 (25%)
Total	368	159 (43%)

* $\chi^2 = 26.7$; $P = 0.005$ for test of equal proportions across cancer type groups. Cancer type groups: all various = all/multiple, other, eye and thyroid; upper gastrointestinal = oesophagus, stomach, pancreas and liver; gynaecological = cervix, uterus and ovary; haematological = lymphoma, leukaemia, multiple myeloma and other haematological; lung = lung and mesothelioma; urogenital = kidney, bladder, prostate and testis. ◆

4 Primary sponsorship of intervention types used in cancer clinical trials

Intervention type	No. of trials	No. of industry-sponsored trials
Treatment: drugs	253	141 (56%)
Treatment: biological	31	12 (39%)
Behaviour	22	0
Treatment: radiation	18	2 (11%)
Treatment: chemoradiation	14	0
Treatment: surgery	9	0
Diagnosis	8	3
Prevention	4	0
Early detection	3	0
Lifestyle	3	0
Treatment: other*	3	1
Total	368	159 (43%)

* Acupuncture, nasopharyngeal humidification and enteral nutrition. ◆

5 Factors associated with industry primary sponsorship of cancer clinical trials

		Bivariate analysis			Multivariate analysis		
	No. of trials	χ^2	Odds ratio (95% CI)	*P*	χ^2	Odds ratio (95% CI)	*P*
Cancer type*							
Breast	62	24.2	1.00	0.001	18.8		0.064
Colorectal	21		1.91 (0.70–5.23)			2.04 (0.58–7.16)	
Gynaecological	17		0.88 (0.27–2.82)			0.83 (0.20–3.55)	
Haematological	84		1.58 (0.79–3.13)			0.69 (0.30–1.60)	
Head and neck	12		0.70 (0.17–2.87)			0.90 (0.18–4.60)	
Lung	26		7.00 (2.43–20.13)			4.58 (1.35–15.54)	
Melanoma	17		2.36 (0.79–7.04)			2.10 (0.60–7.42)	
Neurological	21		0.66 (0.21–2.04)			0.47 (0.13–1.68)	
Sarcoma	15		1.84 (0.58–5.78)			0.95 (0.27–3.42)	
Upper gastrointestinal	20		1.13 (0.39–3.27)			0.72 (0.22–2.40)	
Urogenital	33		3.23 (1.34–7.77)			2.14 (0.75–6.12)	
All/various	40		1.55 (0.68–3.53)			1.20 (0.44–3.23)	
Intervention type†							
Local	44	68.1	1.00	< 0.001	31.2		< 0.001
Systemic	284		15.96 (4.83–52.73)			16.71 (4.70–59.43)	
Other	40		1.11 (0.21–5.83)			0.56 (0.08–3.87)	
Cancer extent							
Early	74	27.5	1.00	< 0.001	13.7	1.00	0.001
Advanced‡	267		3.82 (2.09–6.98)			3.76 (1.78–7.94)	
Not applicable	27		1.04 (0.36–3.00)			7.93 (1.56–40.18)	
Allocation to intervention							
Non-randomised trial	159	1.5	1.00	0.226	4.7	1.00	0.030
Randomised controlled trial	209		1.30 (0.85–1.97)			1.78 (1.06–3.00)	

* Cancer type groups: all various = all/multiple, other, eye and thyroid; upper gastrointestinal = oesophagus, stomach, pancreas and liver; gynaecological = cervix, uterus and ovary; haematological = lymphoma, leukaemia, multiple myeloma and other haematological; lung = lung and mesothelioma; urogenital = kidney, bladder, prostate and testis. † Intervention categories: local = radiation, surgery, chemoradiation; systemic = drugs and biological; other = other, behaviour, lifestyle, diagnosis, early detection and prevention. ‡ Advanced and haematological cancers. ◆

instrumental in increasing federal funding for breast cancer research in the US.[13]

Drug and biological treatments were the most common interventions tested. The least common interventions investigated were cancer prevention, early detection and lifestyle trials. Non-drug interventions should be an important consideration for future cancer clinical trials.

There was strong evidence that intervention type, cancer extent and allocation to intervention were related to sponsorship by industry after allowing for cancer type. It was surprising that cancer type was not significantly associated with industry sponsorship; type of treatment rather than type of cancer was more strongly associated with industry sponsorship.

The number of trials and their associated sample sizes are easily derived measures of the resources allocated to a particular cancer. A more comprehensive enumeration of the resources involved in each trial may provide different results.

Our study might not include all interventional trials open for recruitment in Australia. Unlike in the US (where trial registration of drugs and devices is legally required, except for Phase 1 trials[14]), it is not a legal requirement to register clinical trials in Australia, although policies to increase registration rates have been implemented. In 2007, the revised *National statement on ethical conduct in human research*, which governs the conduct of human research ethics committees in Australia, recommended that clinical trials be registered before enrolment of the first patient.[15] As in other countries, we anticipate the majority of large, Phase 3 trials recruiting in Australia would be registered because proof of registration is increasingly required by institutional ethics committees. In addition, the *Australian code for the responsible conduct of research* states that "Researchers must register clinical trials with a recognised register to promote access to information about all clinical trials".[16] These policies have added to international initiatives, including the International Committee of Medical Journal Editors requirement for prospective trial registration[17] and the Declaration of Helsinki, which includes trial registration as a core ethical principle.[18] Unfortunately, the number of unregistered trials currently in progress in Australia remains unknown and is not estimable. Despite this limitation, we have observed some very strong associations in our data, and there would have to be a large number of unregistered trials with very different features from those described here to substantially alter the pattern of our results.

A search of the ICTRP found that 98% of registered trials open to recruitment in Australia were registered with the ANZCTR and CT.gov.[11] Given that only 2% were regis-

6 Intervention types, by trial registry and recruitment location

	No. of trials	CT.gov	ANZCTR	Australia only
Treatment: drugs	253 (69%)	187 (74%)	66 (26%)	71 (28%)
Treatment: biological	31 (8%)	20 (65%)	11 (35%)	15 (48%)
Behaviour	22 (6%)	2 (9%)	20 (91%)	21 (95%)
Treatment: radiation	18 (5%)	11 (61%)	7 (39%)	9 (50%)
Treatment: chemoradiation	14 (4%)	7 (50%)	7 (50%)	9 (64%)
Treatment: surgery	9 (2%)	4	5	2
Diagnosis	8 (2%)	2	6	8
Prevention	4 (1%)	1	3	3
Early detection	3 (1%)	0	3	3
Lifestyle	3 (1%)	1	2	3
Treatment: other*	3 (1%)	2	1	2
Total	368 (100%)	237 (64%)	131 (36%)	147 (40%)

ANZCTR = Australian New Zealand Clinical Trials Registry. CT.gov = ClinicalTrials.gov. * Acupuncture, nasopharyngeal humidification and enteral nutrition. ◆

tered with the other trial registries, it is unlikely that the exclusion of these trials would have affected our results.

Our findings demonstrate the potential of registry data to identify gaps in current trial activity and to guide future trials research. Recent studies[19,20] used CT.gov to describe cancer vaccine trials and ongoing clinical trials in non-small cell lung cancer but did not provide a national picture or a comprehensive analysis for cancer. Our description of the national clinical trial landscape in cancer is unique. This approach may provide a useful addition for setting future research priorities and provides a baseline against which to measure future trends.

Cancers causing the greatest burden of disease in Australia are underrepresented in recruiting trials, revealing gaps in current research activity. Industry sponsorship is associated with supporting randomised controlled trials of systemic therapies that include patients with advanced cancer but not with cancer type. Our analysis raises concerns about the direction of the research agenda and may be useful when designing and funding future cancer clinical trials. Clinical trial registries are a largely untapped resource to describe the clinical trial research landscape and guide future trial activity.

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COMPETING INTERESTS

Lisa Askie and John Simes are Manager and Director, respectively, of the ANZCTR.

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