Joint Submission to the Clinical Trials Action Group:

Enhancing Australia's position as a preferred destination for clinical trials

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Executive summary

This submission comprises an overview of the benefits of independent cancer clinical trials in the context of the review, as well as detailed answers to the review questions. These answers are briefly summarised/highlighted as follows; also following is a list of general recommendations for improving the international competitiveness of cancer clinical trials in Australia while ensuring patient outcomes are a priority.

Clinical trials roadmap

1. Key success factors for clinical trials in Australia?

- Improving timeliness of trial approval processes, accelerating the roll-out of e-Health and accelerating patient recruitment to trials
- Development of a strong institutional culture within hospitals which recognizes properly conducted clinical research as an important standard of care.
- Development of a strong independent clinical trials workforce, sharing of infrastructure and establishing resources such as collaborative national bio-banking.

2. Additional support initiatives?

- There are a number of initiatives, as discussed on page 12, however greater coordination and investment are required to ensure independent trials groups are better supported, thus improving Australia's competitiveness as a trials destination.

3. How else can government, industry, consumers etc. support trials?

- Allocate a fixed percentage of NHMRC research funds to clinical trials.
- Increase clinical trials capacity/culture in public hospitals (including performance indicators, benchmarks).
- Streamline ethics/governance review.
- Match government funding of independent cancer clinical trials groups to their growth.

4. Example, lessons, implications re international activities

- UK National Institute of Health Research Clinical Research Network Program.

Developing performance measures

1. Collection of clinical trials performance information?

- Measures should include number/type of trial activated by disease group, patient recruitment rates, adherence to timelines, impact of trials results on clinical practice, outcomes etc.
- Collection could occur through the TGA (Clinical Trials Notification Scheme) and the ANZ Clinical Trials Register; expenditure on hospitals-based research could be collected by the Australian Institute of Health and Welfare.

2. Using information to improve Australia's international attractiveness?

- Set targets for the performance measures and regularly publish data to monitor progress against targets; use the publication to also promote the highlights of clinical trials in Australia as described throughout this submission.

3. Scope for monitoring trials through hospital performance indicators?

- Yes. Clinical trials performance monitoring should also be included in overall hospital performance measures, using hospital accreditation processes.

Streamlining ethics, governance

1. Strategies for adopting HoMER

- Jurisdictions need to work towards greater consistency at their level if HoMER is to be effective; common application of the HoMER guidance resources would assist.

2. Do strategies change depending on sector?

- Essentially, the strategies remain the same. However, ethical review and research governance should be formally separated so ethical review can be coordinated broadly while governance is a local unit's responsibility.

3. The role of private funders?

- Private funders should harmonise or eliminate redundancy in processes and documentation.

4. The role of state/federal governments?

- State governments should encourage streamlining/harmonisation within their jurisdictions (documentation, standards, culture); federal government should articulate standards, develop sample documents etc.
- Trials institutions should be required to meet Section 5 of the National Statement.

8. Practical barriers to concurrent review?

- The main barrier is a false perception that governance review is unnecessary if a project is rejected on ethical grounds.

Strategies to improve patient recruitment

1. Effective patient recruitment mechanisms and their expansion

- The most common mechanisms for recruitment are the CCTGs and their state-based networks, which offer scope for expansion. Promotion of the benefits/availability of trials through wider clinical networks, general practice, health consumer groups etc. would also boost recruitment.
- The development of a comprehensive online register is essential.

2. Other recruitment options?

- Enhancing clinical collaborative networks to encourage patient referral; development of a comprehensive, national on-line clinical trials register with a consumer-friendly component; implementing a coordinated national approach to promoting the value of participation in clinical trials, targeted at both patients and clinicians; and supporting clinical research within the primary care sector.

3. Tailoring effective international mechanisms for Australia?

- Practice based research networks (PBRNs) provide a useful model, including the MRC General Practice Research Framework and the NIHR Primary Care Research Network.
- Further investment is required in Australia's formative PBRNs.

5. Mechanisms for patients to register interest in trials?

- See previous point re comprehensive online register.

Generic recommendations

- Australia must increase its clinical trial capacity to ensure that Australians continue to have access to world class evidence-based health care.
- Measures to enhance clinical trials activity in Australia need to support both a strong independent clinical research capacity through co-operative trials groups as well as increased pharmaceutical industry investment, as these sectors enhance and complement each other.
- Funding and infrastructure support for CCTGs, which is not covered by competitive funding sources, falls substantially short of requirements despite recent initiatives to enhance support in these areas. It is critical to the ongoing viability of these groups, the retention of independent research capacity and best clinical outcomes for patients.
- Critical measures in improving Australia's competitiveness as a location for clinical trials include improving the timeliness of trial approval processes, accelerating the roll-out of e-Health incorporating features to assist in managing clinical trials; and initiatives to increase and accelerate patient recruitment to trials.
- Other key factors include a strong institutional culture within hospitals which recognizes properly conducted clinical research as an important standard of care; the availability a strong independent clinical trials research sector as represented by the CCTGs; and of the availability of a skilled clinical trials workforce
- To encourage a pro-research culture in hospitals, clinical research should be included in hospital performance indicators and accreditation processes.
- Government can support clinical trials by: providing dedicated clinical research funding; improving support for clinical research within public hospitals; streamlining ethics and governance review processes for clinical trials; providing increased support for CCTG research; supporting training and education of staff.
- Comprehensive national data on clinical trials performance should be published regularly and be used to set targets for, drive and monitor improvements in performance as part of a clinical trials enhancement strategy. This strategy should also highlight the strengths of clinical research in Australia including: world class scientific and medical research expertise: translational research capacity and expertise in quality of life and cost-effectiveness research.
- Rapid uptake of streamlined ethics and governance review processes is critical and will require both national and jurisdictional action.
- State and territory governments can play a key role by mandating that hospitals under their control substantially overhaul their research governance and HREC processes to facilitate ethically sound research. This includes not charging fees for ethics and governance review processes.
- E-Health offers enormous potential to streamline data management for clinical trials and to enhance patient recruitment. An ICT strategy must: prioritise and enable a single electronic submission process for applications for multi-site clinical trials across all states; must allow remote monitoring of patient records and verification of source data for clinical trial subjects; and must also address the need for appropriate software and infrastructure to support CCTGs by enabling web-based patient registration/randomization, data entry, resolution of data queries, and long-term follow-up.

About the Clinical Oncological Society of Australia

The Clinical Oncological Society of Australia (COSA) is the peak multi-disciplinary organisation representing healthcare professionals working in cancer. COSA's mission is to develop and maintain high-quality clinical care of cancer patients in Australia; the promotion and facilitation of clinical research is a critical component of this mission.

COSA members are doctors, nurses, scientists and all types of allied health professionals and include all 13 national cancer Clinical Cooperative Trial Groups (CCTGs) which undertake independent, investigator-initiated cancer clinical trials in Australia.

COSA actively supports the development and maintenance of clinical research infrastructure and capacity. In 2001, COSA commissioned the Wall report to assess the capacity and contribution of the CCTGs which resulted in major government initiatives to support clinical trials infrastructure.

More recently COSA received an enabling grant from the NHMRC to enhance the capacity of CCTGs by facilitating networking and developing common resources to reduce costs and enhance operations. This project has led to a number of major efficiency gains in the areas of insurance, operating procedures and training for clinical research professionals with additional efficiencies identified in the areas of audit processes and information technology. COSA also supports networking and collaboration between the CCTGs at an operational level to enhance efficiency through sharing of information and resources.

Currently, COSA, in consultation with all major stakeholders, including researchers, pathologists, industry and government, is developing a national model for biobanking of specimens from participants in clinical trials that can be used for further research.

COSA is affiliated with Cancer Council Australia as its clinical partner.

About the Cancer Council

Cancer Council Australia is the nation's peak non-government cancer control organisation. Cancer Council Australia advises the Australian Government and other bodies on practices and policies to help prevent, detect and treat cancer and also advocates for the rights of cancer patients for best treatment and supportive care.

Cancer Council Australia acts nationally on behalf of its member organisations, the eight state and territory Cancer Councils.

Cancer Councils are the leading funders of independent cancer research and related activities in Australia, granting more than $47 million to cancer research, research scholarships and fellowships in 2009. Cancer Councils fund research aimed at unraveling the biological mechanisms behind cancer and improving prevention and early detection of cancer, cancer treatments and quality of life for people with cancer.

Most Cancer Councils also provide funding to support clinical trials infrastructure, including study nurses, data managers and clinical trial co-coordinators to improve access to cancer clinical trials for patients and health professionals.

Overview

The Clinical Oncological Society of Australia (COSA), together with the CCTGs and the Cancer Council Australia welcome the opportunity to provide feedback to the Clinical Trials Action Group about ways in which Australia can enhance its position as a preferred destination for clinical trials. We are pleased to see this important issue being addressed.

The conduct of clinical trials is an essential component of developing the evidence base for improving cancer treatments and care and the opportunity to conduct trials locally offers many benefits for Australia. Cancer survival rates in Australia are among the best in the world. This outcome can very reasonably be said to reflect the emphasis on participation in clinical research that has been a feature of cancer care in this country, with Australia's participation in clinical trials high by international standards, relative to its population size.[1]

In considering initiatives to enhance Australia's position as a preferred destination for clinical trials, COSA and CCA recognize the central importance of encouraging pharmaceutical industry investment in clinical trials in Australia. However, in order to optimize clinical trial outcomes, it is also important to maintain independent clinical research capacity through CCTGs. The independent research conducted by CCTGs complements pharmaceutical industry research and works to optimize outcomes for cancer patients and the health system by addressing clinically important questions regardless of the prospect of a commercial return.

Furthermore, one of the most important factors in retaining and enhancing pharmaceutical industry investment is the availability of a viable, thriving local research community. The CCTGs provide an essential mechanism for strengthening the local research community and developing the world class expertise that attracts pharmaceutical investment in clinical research in Australia.

Consequently measures to strengthen CCTGs are important both to enhance pharmaceutical industry investment in clinical research in Australia and to optimize outcomes for patients and the Australian health system.

Benefits of Clinical Trials

The capacity to conduct clinical trials in Australia offers a range of national benefits.

The average dollar invested in Australian health R&D returns $2.17 in health benefits.[2] In addition, economic and employment benefits arise from the financial investment required to conduct clinical trials. These benefits include spin-off developments in complementary sectors such as biotechnology which then further enhance the prospect of conducting additional trials within the country.

There are also major benefits in the form of development, maintenance and retention of world-standard local expertise in scientific and medical research and clinical care.

Most important are the benefits to patients which include:

- Early access to new therapies for patients participating in trials
- Improved outcomes for patients participating in clinical trials, even for those not given the treatment under investigation
- Improved quality of care leading to improved outcomes for all patients, even those not participating in a trial, as a result of clinicians involved in trials transferring the more rigorous care protocols required for trials into routine care.
- Faster uptake of proven new therapies due to the development of a pool of local clinician expertise arising from participation in trials.

For these reasons, it is essential that Australia maintains and increases its clinical trial capacity.

In doing so, however, it is important to implement measures to support the development of a strong independent clinical trials capacity through CCTGs as well as to encourage increased pharmaceutical investment in clinical trials. While industry-sponsored trials are important, the vast majority of advances in cancer care are made through clinical trials conducted by cooperative groups.[3]

Benefits of independent clinical trials research

In Australia, cancer clinical trials are coordinated under the auspices of two main sectors:

a) CCTGs which undertake investigator-initiated trials that are not primarily sponsored by industry. These groups are Australia-wide multidisciplinary networks of volunteer clinicians with an interest in a particular therapeutic area. Trials coordinated by national academic trials networks are designed to address clinically important questions, which are directly related to improving patient outcomes. They may involve collaborations with the pharmaceutical industry but also include trials of non-drug interventions e.g. surgery vs. radiotherapy and subsequent development of National Best Practice guidelines. A list of the national CCTGs is given in Appendix 1.

b) Pharmaceutical industry either directly or through the services of a Contract Research Organisation (CRO). The purpose of trials coordinated by the pharmaceutical industry is to develop new drugs and devices.

Additionally, some trials are done by individual hospitals/departments/units. Usually these are smaller trials representing proof of concept and are intended to inform the design of larger more advanced studies.

Both trial sectors (academic and commercial/pharmaceutical) contribute to the translational research agenda and to improving patient outcomes. In addition, strength in one sector enhances strength in the other.

The existence of CCTGs contributes to the development of a pool of skilled researchers and health professionals that the pharmaceutical industry can draw on to conduct the quality research required by local and international government regulatory bodies to approve new therapeutic options. Australia's world class medical research base and infrastructure have been identified as a major factor contributing to Australia's competitiveness as a location for clinical trials.[1] In addition investigator initiated clinical research utilizing therapeutic agents developed by the pharmaceutical industry can add value to drug development by ensuring that such trials address unmet clinical needs.

In turn the pharmaceutical industry is a significant source of funding for clinical trials in Australia. The benefits for investigators of participating in industry funded clinical research include, in addition to the opportunity to improve patient care: providing Australian health researchers with global recognition for their expertise; providing practical experience for Australian staff in conducting clinical trials; providing funds for academic research; and retaining researchers in the Australian health and hospital system.[4]

While the commercial focus of pharmaceutical companies is an essential driver of the research and development which leads to new therapeutic agents, it does not always address the most important issues from a patient's perspective. The independent research conducted by co-operative trials groups works to optimize outcomes for

cancer patients and the health system by addressing clinically important questions regardless of the prospect of a commercial return.

CCTGs conduct wide-ranging research that addresses issues such as:

- The best use of existing treatments, thus achieving optimum outcomes for patients making best use of already available resources;
- Appropriate introduction and use of high-cost drugs and technology for cancer care, based on evidence, including identifying which patients are most likely to benefit from expensive new therapies and technology and which are not, thereby reducing costs through more informed use of expensive treatments;
- Essential aspects of cancer care where expensive or new drugs and technology may not be involved, such as surgery, radiotherapy, and psychosocial, supportive and palliative care.

In addition CCTGs in Australia generally adopt high standards of quality assurance which provide a competitive advantage for Australia relative to developing countries. For example, clinical trials involving radiation therapy are largely managed by the Trans-Tasman Radiation Oncology Group which has an extremely high standard of quality assurance and consistency of technique. In a recent trial involving concurrent chemotherapy and radiation for head and neck cancer, it was found that the benefit of implementing improved quality assurance in radiation delivery technique as part of the trial far outweighed the benefit of the chemotherapy drug. Such quality assurance facilities are not readily available in developing countries.

There are many examples of research conducted by CCTG's that has changed the standard of care for patients, a number of which have resulted in substantially reduced costs to the health system, including:

- Studies in advanced breast cancer found that high-dose chemotherapy with bone marrow transplantation was no better than standard dose chemotherapy, despite initial enthusiasm for the high-dose treatment. In Australia up to 1,000 patients a year have avoided this toxic procedure (estimated cost saving $50,000 per patient; total savings approximately $50 million per annum).
- Studies in malignant melanoma have progressively shown that less extensive surgery is safe and effective. Recently, limited removal of lymph glands ("sentinel lymph node biopsy"), a minor procedure, has defined who needs the more radical operation ("extensive lymph node dissection"), thus saving patients many days in hospital and about $5,000 per patient (total savings approx. $10 million).
- An Australian trial in testicular cancer (the most common cancer in young men) found that one type of chemotherapy cured more patients and saved more lives than another. Before the trial, the two treatments were considered equally effective.[5]
- Aromatase inhibitors in adjuvant treatment for breast cancer (ANZBCTG)
- Chemoradiotherapy for oesophageal cancer (AGITG, TROG and CTC)
- Sentinel Node Biopsy Management for Breast Cancer (SNAC group) and for melanoma (MTG)

In summary, CCTG research provides new evidence about the most effective treatment regimens regardless of commercial value, raises care standards, facilitates the translation of research findings into clinical practice and reduces costs through more informed use of expensive treatments.

Challenges for independent clinical trials research:

Funding and Infrastructure support

CCTGs use a range of funding sources to support their research and activities:

- Competitive grants from research funding organisations such as the NHMRC, Cancer Australia, Cancer Councils and other groups
- Independent fundraising
- Clinical trials units in some hospitals may provide funding support for trials by providing infrastructure, paying researchers and absorbing the costs of some aspects of a trial (e.g. laboratory tests and consumables)
- The pharmaceutical sector may provide direct funding to clinical trials groups undertaking trials, funding for research staff, and/or may supply the therapeutic agents under study. Collaboration with the pharmaceutical sector helps provide some of the key infrastructure that enables CCTGs to remain viable.

Funding for trial group activities, particularly for infrastructure costs, which are not covered by most competitive funding sources, has long been an issue for CCTGs which typically run on very limited budgets and rely heavily on professionals volunteering their time to support the group's activities.

In 2001 COSA commissioned the Wall report to assess the activities of CCTGs, their contribution to cancer care and whether and how they should be strengthened.[3] This report confirmed the value and importance of CCTGs and identified a number of ways in which funding and infrastructure support for the groups could be improved. The executive summary of this report is provided at Appendix 2. The key areas identified for support included: the operational costs of the CCTGs themselves; local data management; central trial co-ordination, management and analysis of trials: and audit and quality assurance of trials.

Following this report two initiatives have been implemented to improve funding for supportive infrastructure to build the capacity of the CCTGs to conduct clinical trials:

- Cancer Australia's Support for Clinical Trials program provides some funding towards salaries for key trials development staff and administrative personnel, personnel training and development, IT and administrative support, central trial data management and travel for face-to-face collaborative group meetings
- An NHMRC Enabling Grant provided through COSA is designed to enhance the capacity of CCTGs to conduct high quality clinical research by developing and providing shared resources. The development of shared resources in protocol development, web-based randomization, data collection and quality assurance, improves procedures and generates savings through economies of scale. This project has led to a number of major efficiency gains in the areas of insurance, operating procedures and training for clinical research professionals with additional efficiencies identified in the areas of audit processes and information technology. In particular, an umbrella insurance scheme established under this project provides a valued cost effective means for the management of clinical trials insurance and provides certainty of cover for participating CCTGs.

Despite these initiatives, funding for CCTG activities continues to fall substantially short of requirements. For example the number of CCTGs has doubled since the Cancer Australia Support for Clinical Trials program was implemented, but the level of funding provided under the program has not increased.

Another critical factor in supporting research by CCTGs is the need for increased hospital support for research. Although some hospitals provide funding support for certain trial costs, many hospitals do not and often charge for associated services such as ethical review. There is a need to change the culture within hospitals to ensure that properly conducted clinical research is recognized and supported as an important standard of care.

Increased funding and support for CCTGs will be critical to the ongoing viability of these groups and the retention of the independent research capacity that is critical to ensuring the best clinical outcomes for patients. In addition, as many clinical trials are conducted over several years, longer term funding (current funding arrangements cover a three- to five-year span) is also important.

Working with the pharmaceutical industry

COSA conducted a Pharmaceutical Industry Forum in October 2009 in which health professionals and pharmacy/medical device companies met to discuss ways to improve the transparency of their working relationship. Recognition of the importance of this relationship was universally accepted. One area of action identified was the need to improve public perceptions relating to the relationship between health professionals and pharmaceutical companies, to reduce the challenges faced by the industry in supporting innovative research and by clinicians working in the area. This forum report is provided at Appendix 3.

Improving government support for clinical trials infrastructure and activity would also help to address this issue by decreasing the dependence of CCTGs on pharmaceutical industry funding and encouraging a strong independent research sector.

References

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2. Access Economics 2008. *Exceptional returns: The value of investing in Health R&D in Australia*
3. Oceania Health Consulting 2002. *Cooperative Clinical Trials in Cancer – the need for increased capacity.* January 2002
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Paper 1: Developing a Clinical Trials Roadmap

As identified in the discussion paper on this issue improving the timeliness of trial approval processes, accelerating the roll-out of e-Health incorporating features to assist in managing clinical trials and initiatives to increase and accelerate patient recruitment to trials, are critical factors in improving Australian clinical trials competitiveness.

Questions

1. Are there any other key success factors for clinical trials in Australia?

Other key success factors include:

- The development of a strong institutional culture within hospitals in support of research and innovation which recognizes properly conducted clinical research as an important standard of care.
- The availability and retention of a strong independent clinical trials research sector as represented by the CCTGs which enhances the skilled clinical trials workforce available to industry to conduct trials as well as providing networking and sharing of resources. A vibrant series of national academic co-operative groups in each of the disease groupings would be the ideal
- The availability and retention of a skilled clinical trials workforce including world class medical and scientific researchers, trial co-coordinators, data managers and biostatisticians.
- Collaborative development and sharing of key infrastructure and resources to support and enhance research in Australia. An example is the development of a national model for biobanking of specimens from participants in clinical trials that can be used for further research. COSA recently held a workshop of key stakeholders to develop a national collaborative model for biobanking: a summary of the outcomes of this workshop is provided at Appendix 4.

2. Are there any other initiatives that support clinical trials in Australia?

Funding and infrastructure support initiatives

Competitive research grant programs such as those provided by NHMRC and Cancer Australia make significant contributions by funding investigator initiated *non pharmaceutical* trials that answer important questions that pharmaceutical industry will not fund and directly help maintain the quality of the human capital required to make Australia a priority site for clinical trials.

As noted previously, Cancer Australia's *Support for Clinical Trials* program provides some funding for supportive infrastructure for CCTGs and COSA administers an NHMRC Enabling Grant to develop shared resources for CCTGs, with both initiatives designed to enhance the capacity of these groups to conduct high quality independent clinical trials.

Most Cancer Councils across Australia also provide active support for clinical trials, including:

- providing grants to hospitals to conduct clinical trials;
- providing funding for on-site data managers and clinical trial co-coordinators;
- facilitating collaborative research by working with specialist oncology health professionals to develop clinical trials

- providing information on clinical trials for patients
- providing online listings of clinical trials (e.g. The Victorian Cancer Trials Link) that can be used by both consumers and clinicians
- fostering clinical networks through state based co-operative oncology groups which promote and facilitate cooperative studies on cancer.

However the funding and infrastructure support initiatives that are available to CCTGs only meet a small part of the costs associated with conducting independent clinical trials. The type and level of support available across jurisdictions also varies considerably. In general, in addition to increasing support, there is a need to improve consistency across different agencies and jurisdictions in the funding and support provided for independent clinical trials.

This could be done by using successful state based initiatives to provide a template for action at a national level. For example, Cancer Council Queensland provides funding to hospitals for on-site data management on the basis of contributions to multi-centre phase II or phase III trials that are supported by a recognized national or international trials group. The Queensland government also contributes by matching Cancer Council funding. This model should be implemented at a national level.

The ClinicalTrialsNSW Initiative also provides a template for action at a national level. Under this initiative, the NSW Clinical Trials Business Development Centre (ClinicalTrialsNSW) promotes NSW's and Australia's capabilities as an ideal place for international sponsors to conduct their clinical trials, connects sponsors with the clinical research community and provides services to facilitate and improve capacity, quality and timeliness of clinical trials.

Australian Cancer Trials Online

Cancer Australia is working in partnership with the University of Sydney and the Australian and New Zealand Clinical Trials Registry to develop a website to provide consumer-friendly access to information about current cancer clinical trials. Australian Cancer Trials Online is due to be made available in early 2010 and will provide consumers with fast, easy to use information about open clinical trials, information about the pros and cons of clinical trial participation and decision support tools to facilitate the informed consent process.

3. What other ways can government, industry, consumers and other stakeholders support clinical trials?

Government

- ***Provide dedicated clinical research funding***

Funding for clinical research needs to be revitalized by ensuring that a *fixed percentage* of NHMRC project/program grants is devoted to clinical trials. Additionally, the current funding system of up to five years fails to acknowledge the fact that some studies may require 15-20 years follow up, so a more flexible case by case approach is required.

- ***Improve support for clinical research within public hospitals***

Fifty-six percent of clinical trials are based in public hospitals.[1] However, there is a need for state and territory departments of health to encourage a stronger institutional culture within public hospitals in support of research and innovation that recognizes well conducted clinical research as an important standard of care.

Public hospitals benefit from trials being conducted within their institution because they can provide subsidized care and free drugs to patients as well as the prestige of

being part of innovative research. However, more often than not; the culture within hospitals is not “pro research”, and at times is actually anti-research by requiring payment for trial related care such as pharmacy fees and investigations even when such care is part of standard treatment (ie would be paid for out of hospital operating budgets if the patient was not on trial). In addition, other hospital departments apply charges (eg. ethics approval fees) that are a major threat to the viability of CCTG trials.

Public hospitals should support clinical trials by

- Adopting a pro-research culture that recognizes properly conducted clinical research as an important standard of care.
- Providing appropriate infrastructure support.
- Providing protected time for research and related activities, such as participation in grant review panels, by funding pharmacy and clinical research fellowships and backfill for clinician researchers that are independent of fluctuating trial income. This would also ensure a clear career path that will retain high quality staff.
- Meeting treatment costs for patients on trial such as laboratory tests and consumables. The recognition that costs associated with running trials within each institution should be the responsibility of that institution (just as for standard care) is vital.
- Not charging for services associated with conducting trials, such as fees for ethics and governance approval.

A pro-research culture could be encouraged by including specific clinical research indicators (eg number of trials supported, funding provided, timeliness of research review processes etc) as a necessary part of hospital accreditation requirements and performance indicators.

The need for research to be valued and enabled as a normal part of providing health services was identified by the National Health and Hospitals Reform Commission in its final report on the Australian health system.

- ***Streamline ethics and governance review***

Our federated system poses challenges for conducting clinical trials across jurisdictional borders, most clearly in the area of ethics and governance approval processes where separate approvals are required for each site participating in a trial. The streamlining of these processes is critical to improving clinical trials efficiency in Australia. Consequently it is essential that the streamlining of trial approval and management processes across jurisdictions, such as under the HoMER initiative, becomes a national priority.

- ***Provide increased support for CCTG research***

As indicated previously, initiatives to increase support for independent clinical trials research through CCTGs would improve Australia’s competitiveness as a location for clinical trials by enhancing the local pool of medical and clinical research expertise. They would also ensure the retention of an independent clinical research capacity that is critical to ensuring the best clinical outcomes for patients in Australia.

Increasing Cancer Australia funding for CCTGs infrastructure under the *Support for Clinical Trials* program would be an important measure. The number of CCTGs has doubled since funding commenced but there has not been any increase in the overall level of funding allocated under the program. As a result the funds available per

group are falling at a time when the need to develop an enhanced infrastructure to attract international funding is increasing.

Government funding for clinical trials insurance would also provide valuable support for CCTGs and free up funding which could then be reallocated directly to research. Existing examples include the Treasury Managed Fund in NSW and the Victorian Managed Insurance Authority..

- ***Support training and education of clinical trials staff***

Training and education for clinical trials staff in the not-for-profit sector, such as trial coordinators and investigators, is a major area of unmet need and could be addressed by Government supported education programs run by collaborative organisations such as COSA.

All Parties

A coordinated national approach to promoting the value of clinical trials and of participation in clinical trials would assist in improving patient recruitment and potentially counter negative public perceptions of pharmaceutical companies. Consumers and consumer groups could contribute by participating in trial evaluation committees and raising awareness of the value of trial participation among their networks. Leading groups such as Cancer Councils are ideal advocates to promote clinical trial benefits to the community.

Industry

Industry can further support clinical trials activity by using their international research networks to foster collaborations between international and local researchers.

Other stakeholders

Private hospitals should take a more active role in supporting and participating in clinical research.

The development of practice based research networks to strengthen the capacity of general practitioners to participate in clinical research should also be encouraged. (see responses to questions 3 and 6 posed in the *Strategies to improve patient recruitment* paper)

4. What other examples are there (..Of international activities to improve operations) and what lessons or implications for Australia are there?

The National Institute of Health Research Clinical Research Network program in the UK, which provides government funding at hospital level and for trials groups, as referred to in Discussion Paper 1, has dramatically enhanced clinical recruitment to trials and a similar approach could be effective in Australia.

Paper 2: Developing Key Performance Measures for Clinical Trials

Questions

1. What clinical trial performance information should be collected? How, when and by whom?

Comprehensive national data on clinical trials performance should include indicators that measure changes in the clinical trials environment that will attract clinical trials to Australia. The following performance indicators could be included:

- Number of trials activated by disease group and type of trial
- Number of patients recruited to clinical trials and recruitment rate
- Number of trials achieving on time patient recruitment
- Clinical trial start-up times
- Time taken for ethical and governance approval processes
- Trained and accredited clinical trials workforce including number of data managers, trial co-coordinators, biostatisticians etc.
- Percentage of NHMRC budget allocated to clinical trials
- Inclusion of clinical research support in the criteria for public/private hospital accreditation processes and number of hospitals meeting the research criteria
- Public/private hospital expenditure on clinical research, including number of clinical research fellowships supported
- Number of published trial results/citations
- Translation of trials results into clinical practice.

Some data relating to the number and type of trials could be collected through the Therapeutic Goods Administration (through the Clinical Trials Notification scheme), although not all drug trials are covered by this scheme. More detailed data about trials could also be collected through the ANZ Clinical Trials Registry, although registration is voluntary at this stage, so the data is unlikely to be comprehensive. Mandatory clinical trial registration through the ANZ Clinical Trials Registry could assist in ensuring more comprehensive data was available on clinical trials activity in Australia.

Hospital expenditure on clinical research could be included in hospitals data collected by the Australian Institute of Health and Welfare. Data on support for clinical trials and time taken for ethical and governance review could also be collected and benchmarked as part of hospital accreditation processes.

Hospital accreditation and performance measures should also be linked directly to funding to encourage the removal of barriers between clinical trials research and provision of high quality care.

2. How should information be used to improve Australia's attractiveness as a destination for international clinical trial investment?

The data collected should be published regularly and be used to set targets for, drive and monitor improvements in performance as part of a clinical trials enhancement

strategy. The publication should also highlight the strengths of clinical research in Australia including: clinical research networks and expertise; the potential to value-add through the availability of infrastructure such as well-annotated tumour and blood banking; the availability of translational research capacity (pharmacokinetics, pharmacogenetics, pharmacogenomics); bioinformatics; and expertise in quality of life research and cost -effectiveness analysis.

3. What scope is there to include clinical trial performance information into the hospital and related care in health system performance indicators?

As clinical trials are critical to achieving improvements in health care, it is appropriate that clinical trial performance data are included in health system performance indicators and reporting.

Hospital accreditation processes, for both public and private hospitals, should include measures of support for clinical trials and should set benchmarks based on hospital size, resources, dominant health streams treated/areas of specialty and ethics committee processes. Hospitals should be able to demonstrate that they sponsor a culture that recognizes properly conducted clinical research as an important standard of care.

4. What other examples are there of clinical trials performance measures? What possible lessons or implications are there for the clinical trials environment in Australia?

See response to question 1.

Paper 3: Ensuring the Rapid Uptake of Streamlined Ethics, Scientific and Governance Review Process

Preamble

Streamlined ethics and governance processes are integral to Australia's competitiveness in clinical trials. The importance of clinical research in the NHMRC Strategic Plan (2010-12) and the development of HoMER reflect a government commitment to addressing these concerns. However, a number of additional practical steps must be urgently taken, particularly by state and federal governments, to improve competitiveness.

The objectives of HoMER will be easier to achieve if states have first developed their own centralised ethical review processes, which will be facilitated by the use of HoMER's resources to encourage consistency.

NSW is the first jurisdiction to have implemented single ethical review of multicentre trials, with demonstrated benefits.[1] However; the experience also highlighted a problem reported internationally[2] – that while ethical review can be centralised and streamlined, governance arrangements are likely to remain the responsibility of individual health units conducting trials. Separate targets are therefore essential for the ethical and governance review of each project; but these cannot be developed while ethics and governance are considered together. Timelines and standards must be applied to local governance review, in addition to the requirements of the ethics review. This will enable ethics committees to fulfil their oversight of research governance, without necessarily having direct input into local processes.

In addition, the NHMRC National Statement on Ethical Conduct in Human Research (2007) states in section 5.1.1 that:

"*Institutions must see that any human research they conduct or for which they are responsible is:*

> *(a) designed and conducted in accordance with the Australian code for the responsible conduct of research; and*
>
> *(b) ethically reviewed and monitored in accordance with this National Statement."*

This statement requires institutions, whether public, private, university, hospital or community-based, to provide adequate infrastructure to fulfil their obligations for responsible research governance. However, compliance varies widely across Australia's diverse mix of research institutions; there is neither national framework nor mandate to support and ensure compliance. Addressing this need is also integral to sustaining competitive clinical trials in Australia.

Questions

1. What strategies can be used to encourage the rapid adoption by institutions across Australia as the various elements of HoMER become ready for use?

The adoption of central ethical review of multicentre research should ideally be a top-down/bottom-up process. The establishment of HoMER is a positive development, providing resources that can facilitate centralised ethical review. However, HoMER's adoption will require:

- Each state accepting centralised ethics review, using resources developed through HoMER where applicable. Encouraging individual jurisdictions to

develop their own standard models builds trust in the system, a key element of the success of the Ontario experience of centralised ethical review, and is essential to establishing a single national ethics review process;[3]

- Well defined guidance and timeframes for local governance review, as well as for the central scientific and ethical review;
- Accreditation of independent and professional HRECs that can deliver timely and comprehensive ethical reviews. It could be mandatory that institutions use external and independent HRECs (an approach also supported by healthcare consumer groups);
- An implementation plan that includes training and accreditation for researchers, clinical trials staff, institutions, HRECs and other key stakeholders in the conduct of multi-centre research to clarify roles and responsibilities and to ensure consistency in interpretation and approach.

2. Do these strategies vary depending on whether the institution is a public hospital, university or research institute?

The strategies do not change. However, to avoid delays in processing applications and to support the research efforts of investigators, it will be essential to ensure adequate infrastructure to support research governance within institutions;

- A focus within the system on facilitating the research efforts of investigators, rather than just compliance with regulation;
- Research governance must be adequately financed, but a user pays system requiring excessive payments, often from private companies, will discourage investment in Australia-based research institutions and will also discourage investigator initiated research;
- Formal separation of the ethical review and the research governance processes, recognising that governance will remain a local health unit responsibility.

Charging researchers for the 'privilege' of conducting research sends the wrong message. Institutions should not be charging for ethics or governance review; if they conduct research, they should support adequate infrastructure to facilitate it.

In addition to public hospitals, universities and research institutes, private hospitals and general practitioner organisations should also be included in strategies to encourage the adoption of HoMER.

3. Do private funders of clinical research, such as pharmaceuticals and biotechnology sectors, have a role to play in streamlining ethics, scientific and governance review processes?

Private funders could contribute to streamlined processes by harmonising and eliminating redundancies in the clinical trials processes and documentation they require. This would include developing a consistent format/template for key documents that could be used across all trials/sites; using generic wording of sections of the patient information form, when produced by central ethics committees; and wording indemnity and other legal documents such as Clinical Trial Research Agreements according to Medicines Australia guidelines to facilitate ethics and governance review. A streamlined approach in these areas would reduce clinical trial start-up times and result in significant resource savings.

If private funders are expected to contribute to reasonable cost recovery of the ethics and governance review processes, this should be linked to performance outcomes in terms of timeliness and expertise shown in the review process.

4. What role do state and federal governments have to play in rapid adoption of a national streamlined approach?

The state governments' key role is to:

- Encourage central ethics review of multicentre research within their jurisdictions;
- Harmonise documentation, by working on acceptable wording of key documents for use by researchers in their applications for approval of research projects. The more such generic documents parallel federal government resource documents, the better.
- Develop and publish standard operating procedures for ethical and governance review in their jurisdiction
- Promote a pro-research culture across public hospitals

The federal government's key role is to:

- Articulate standards for both ethical and governance review, and provide sample documents for use by applicants for approval to conduct trials;
- Introduce a formal requirement and national framework for institutions to demonstrate how they will fulfil Section 5 of the national statement. This is not currently required and is an area of high need for ensuring Australia remains competitive in clinical research.

While state and federal governments must recognise the importance of nationally streamlining ethical processes, as stated in response to the question on HoMER, jurisdictions must work towards centralised review of multicentre research in their own states.

5. What strategies can be used to ensure the adoption of best practice processes for streamlined research governance across Australia?

See responses to questions 1-4.

6. What are the opportunities for appropriate standardisation of processes?

See responses to questions 1-4.

7. Is it feasible to gather benchmarking data across Australia to encourage improvements in research governance review?

Benchmarking is feasible and ideally coordinated by the federal government, if state jurisdictions would agree to release their data – even if de-identified – and share in a set of benchmarks that could be derived from it.

8. What are practical barriers to having concurrent reviews? Can these barriers be overcome and if so how?

The main barrier to concurrent ethical and governance review is a perception that, if a project was to be rejected on ethical grounds, governance review would be unnecessary. However, a simple examination of the outcomes of ethics committee reviews shows this is a rare event; there is no such barrier to concurrent review processes.

9. What strategies or measures are there to encourage concurrent review?

The best strategy to encourage concurrent review would be to set and agree upon timelines which could only be achieved by concurrent review. An audit of compliance with review standards would be additional incentive.

10. What other strategies are there to expedite approvals for clinical trials e.g. adequate resourcing and training of research governance officers?

One strategy is to eliminate the transfer of paper by creating secure electronic systems for all parts of the review process. The more generic the documentation for application etc., the more efficient the review process would be. Governance efficiency is not just about the training of governance officers, but also creating an environment where the urgency of review is recognised and prioritised accordingly.

There is also scope to adopt streamlined processes in compiling information for ethics and governance review: for example all Victorian hospitals could be advised by a single review of documents by the Victorian Managed Insurance Authority.

11. Who will drive improvements and coordinate the efforts of stakeholders in this system?

Each state government should drive and coordinate activities in its own jurisdiction, while the federal government takes responsibility for setting the standards and providing the documentation to harmonise the review processes.

12. What other examples are there of streamlined review processes? What are the lessons and/or implications for Australia?

There is a growing international literature base, particularly from Canada and Great Britain, reporting on the success and pitfalls of streamlining review processes that are relevant to the Australian system. In general, centralization of the ethics review process and possibly disease group specialisation seem to offer the greatest potential for speeding up review processes.[2-5]

13. Can Australia achieve best practice of streamlined review processes?

Australia, with a relatively small research community, is ideally placed to achieve a streamlined review process. Federal/state collaboration will be key, as will a commitment to rationalising ethics review and streamlining local governance review.

The NHMRC Strategic Plan (2010-12) places research as an integral part of healthcare delivery. Institutions wanting to work towards better health for Australians must stop treating research as an optional extra or a burden, as is currently the case.

We need a significant change in the philosophical approach to ethics and governance away from the present adversarial system, if Australia is to remain competitive and deliver on the NHMRC Strategic Plan. State and territory governments can play a key role in fostering and supporting clinical research, by mandating that hospitals under their control substantially overhaul their research governance and HREC processes to facilitate ethically sound research, rather than treat it as low-priority risk management.

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Paper 4: Strategies to Improve Patient Recruitment

Preamble:

With more than 90% of clinical trials experiencing recruitment delays and up to 50% of total trial duration being committed to recruitment, improving patient recruitment rates is an important way in which Australia's clinical trial competitiveness can be improved.

Randomised clinical trials (RCTs) have come to be regarded by many as the gold standard for treatment evaluation underpinning evidence-based medicine.[1-3] Surveys of the general public show widespread support for the concept of clinical trials as an important and ethical means of attaining superior medical care.[4,5] However, only a small proportion of eligible patients enter clinical trials in many of the institutions promoting clinical trial participation. A retrospective review of medical records at a major Sydney teaching hospital to determine the percentage of eligible patients enrolled in trials of adjuvant systemic therapy in early breast cancer found that approximately 23% of eligible patients are enrolled.[6.]

Slow trial accrual subsequently delays assessment and introduction of effective new treatments and the abandonment of less effective or dangerous ones. Selective refusal can also raise concerns about whether the trial findings can be generalized to the broader population. Thus the community as a whole is best served by assiduous attention to accrual in clinical trials.

A substantial proportion of non-trial-participation is explained by "patient refusal". Many eligible patients who are invited to participate in a trial, decline (estimates vary from 22-50%).[6,7,8] Reasons for trial refusal by eligible patients have been explored in several studies [9,10] and include concerns regarding experimentation and uncertainty and loss of control over treatment decisions. Many patients and the general community do not understand the role of randomization in avoiding bias in treatment selection.

There is a need to increase patient awareness and understanding of the value of participation in clinical trials both to themselves and to the broader community and to promote participation in trials as the avenue to the best possible health care, rather than as a risky experiment. There may also be a need to educate clinicians and trial staff in patient recruitment strategies that help them recognize patient sensitivities and identify appropriate opportunities for presenting trial information to patients to maximize recruitment.

Questions:

1. What are the effective patient recruitment mechanisms in Australia? Can they be expanded? What are the lessons to be learnt from existing patient referral networks?

Clinical research networks such as the national CCTGs and state based networks, such as the NSW Cancer Trials Network and co-operative oncology groups are the most common mechanisms used for patient recruitment to cancer clinical trials. However there is scope to expand and improve collaboration within and across these networks.

In addition more could be done to increase knowledge and awareness of clinical trials among treating clinicians, including allied health professionals and GP's as well as community and consumer organisations such as Cancer Voices Australia. Access to multidisciplinary care can also improve patient access to clinical trials and should be a major component of patient referral networks.

The use of existing clinical networks as patient referral networks for clinical trials would be enhanced by the development of a strong institutional culture within hospitals in support of clinical research. Better linkage of health record s would also assist in improving referral networks.

The availability of dedicated clinical trial co-ordinators also increases patient recruitment, highlighting the importance of providing adequate infrastructure support for clinical trials.

Clinical trials registry

Australia has no comprehensive register of clinical trials being conducted in the country that would assist interested clinicians or patients in locating potentially suitable trials. While a number of online clinical trial listings/registries are available none of these are comprehensive and there is scope to improve their accuracy and utility as an aid to patient recruitment.

The ANZ Clinical Trials Registry (ANZCTR) was established to provide a national register of clinical trials but registration of trials is voluntary, limiting its comprehensiveness. This registry could be enhanced by making trial registration mandatory and by including portals leading to appropriate information for investigators and patients. There is also scope to make the registry more consumer-friendly.

A number of state-based clinical trials listings/registries exist through Cancer Councils and state health agencies but these list mainly state based trials and a selection of national trials and are sometimes out of date. Resourcing and updating these sites is clearly an issue in managing multiple registries.

As mentioned previously, Cancer Australia is developing a consumer-friendly register of cancer clinical trials. Australian Cancer Trials Online (ACT-Online) is currently under evaluation and is due to become available in early 2010. ACT-Online automatically downloads information from ANZCTR and the clinicaltrials.gov <http://clinicaltrials.gov> database, with some additional cancer-specific fields requested from investigators. This information is presented in a consumer-friendly, searchable data base, with a glossary of terms, suggested questions to ask the doctor, a summary of the issues to be considered when deciding whether or not to join the trial and general information about the rationale for and design of trials.

The development of a comprehensive, national on-line clinical trials register with a linked consumer version such as ACT-Online, would be an ideal mechanism for promoting available clinical trials to both patients and treating clinicians and would reduce existing duplication of effort in this area.

2. Are there other ways to increase patient recruitment?

As noted previously, there is a need to increase patient awareness and understanding of the value of participation in clinical trials. A coordinated national approach to promoting the value of participation in clinical trials, targeted at both patients and clinicians, would assist in improving patient recruitment. This could include educational programs and materials for patients and consumer groups such as trial brochures in clinics and a national online clinical trials database with a consumer-friendly interface that can be used to identify available and relevant trials. There may also be some value in a broader public education campaign through the media to highlight the value of clinical trial participation.

Additional ways for improving patient recruitment could include:

- Enhancing collaboration and promotion of clinical trials within and between existing clinical networks, such as state-based tumour stream collaboratives,

and establishing clear communication streams/processes between clinicians regarding trial availability

- Improving networking and collaboration between clinical trials groups that work in the same therapeutic area to encourage and facilitate sharing of information relating to trials that are not disease specific, such as phase I, trials of side effects, etc)
- Promoting pro-active recruitment measures by clinical trials staff through enhanced education and training. Pro-active recruitment measures such as data managers actively surveying patient eligibility would be enhanced by e-health records once these are established and by improved record linkage
- Removing impediments to patients entering clinical trials. e.g. patients from rural and regional areas entering clinical trials are not eligible for Government travel reimbursement. Patients on clinical trials receiving standard of care should be eligible for normal cover under Medicare and via Private Health Insurance funds.
- Increased promotion of participation in both local and international trials to clinicians through co-operation between Australian and international trials groups, presentations at local and international meetings and workshops and support for international principal investigators to visit Australia and present trial data at local meetings.
- Establishing mechanisms for patients to register their interest for involvement in a clinical trial.
- Providing funding for centres to employ clinical research fellows – specialists early in their career whose task is specifically to promote patient recruitment to clinical trials.
- Encouraging participation of private hospitals and clinicians in clinical trials.

3. Are there effective international patient recruitment mechanisms that can be tailored for Australia?

Health care in Australia is overwhelmingly delivered in the community. A very small proportion of all Australians receiving health care at any one time access it via the hospital system. While the majority of cancer treatments occur in hospital, primary care plays an important role in cancer prevention, screening and early diagnosis, follow-up, survivorship, and palliative care. At the same time, the great majority of clinical research in Australia is conducted in hospitals by hospital-based clinicians. Community or practice-based research is logistically challenging and requires significant investment in research infrastructure to reduce the evidence gaps that exist for many clinical and health service research questions.

Internationally several governments have supported the development of practice based research networks (PBRNs) to strengthen the capacity of the primary health care sector to deliver practice and policy relevant research. PBRNs have often been likened to the 'laboratories' of primary health care research. Best understood as a piece of research infrastructure, practice-based research networks operate by bringing primary health care practitioners (GPs, practice nurses, community and allied health practitioners) together with academic GPs and other researchers in long-term research collaborations. They create the necessary infrastructure to conduct large scale clinical trials in primary care. Examples include the MRC General Practice Research Framework, which has run several internationally significant clinical trials in general practice, and more recently the NIHR Primary Care Research Network which interacts with disease specific networks including the UK Cancer

Research Network. There are similar national PBRNS in the US and Netherlands which have helped establish the necessary infrastructure to conduct clinical trials in the community.

While in Australia there exist a number of fledgling PBRNs (eg VicRen at the University of Melbourne), further investment is required to develop a national PBRN that could support large scale clinical trials in the Australian community.

4. Is it feasible to better link existing clinical trial sites from the same therapeutics area or capability?

See response to Question 1.

5. What are the effective mechanisms for patients to register their interest for involvement in a clinical trial? Do they exist in Australia?

At present there is no automatic mechanism for patients to register their interest for involvement in a clinical trial. However online clinical trial listings and registries, such as ANZCTR and CCTG websites usually provide contact details for individual trials that patients could follow-up if they are interested in participating.

Consumer groups, both state based and disease specific, can also provide information on trials of potential interest.

As noted in the response to question 1, the development of a comprehensive, national on-line clinical trials register, such as an enhanced version of the ANZCTR, could assist in patient recruitment. This registry could also include a mechanism to allow patients to register their interest in participating in trials.

See also the response to question 7 below.

6. Do general practitioners need to be better engaged in clinical trials? If so, how?

See response to Question 3.

An example of engaging primary care in research is the recently establish Primary Care Collaborative Cancer Clinical Trials Group funded by Cancer Australia to develop and conduct cancer research in primary care. This group aims to improve cancer outcomes in Australia by fostering collaboration between researchers, to build capacity and enable the development of a series of pre-trial studies that will lead to large-scale, multi-site studies.

There is also scope to improve clinical trials awareness among GPs through educational sessions on the value and benefits to patients of being involved in clinical trials and promotion of online trials registries. The Australian General Practice Network and the RACGP could provide avenues for promoting clinical trials to GPs.

The costs for general practices, which operate as small businesses, must be acknowledged and funding mechanisms developed to support general practice based patient recruitment.

7. What is the scope for improving patient recruitment through the introduction of e-Health?

E-Health has great potential to increase trial participation. One avenue for its use would be for people to self-nominate their “interest” in participating in a clinical trial or in receiving information about relevant clinical trial opportunities. This information could be used to generate lists of potential trial participants for active recruitment by clinical trials staff.

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Paper 5: Developing an Information and Communications Technology (ICT) Strategic Plan for Clinical Trials

Questions:

1. Are there any other benefits that e-health could bring to Australian clinical trials considering international approaches?

E-Health provides the opportunity for clinical trial data to be sourced, collected and verified directly from the primary originating source of that data (medical laboratory / imaging centre / patient electronic medical record) without requiring double entry. Such a process would have enormous advantages for time-efficiency and resource utilization for the conduct of clinical trials at all levels within Australia and removal of double entry will dramatically improve data accuracy.

COSA very strongly supports the proposed facilitation of systems and regulatory guidelines to enable remote monitoring of patient records and verification of source data for clinical trial subjects. This will have major cost-saving, efficiency and data accuracy advantages for the co-operative clinical trial groups as well as industry.

The development of a national ICT strategy for clinical trials must prioritise and enable the streamlining of a system for a single electronic submission of applications for multi-site clinical trials across all states to avoid the wasteful multiplication of effort currently required for approval and activation of multi-site trials across multiple states. This is covered in greater detail in section 3.

The ICT strategy must also address the need for appropriate software and infrastructure for both the central data centres of the Co-operative Trials Groups, and the public and private hospitals within Australia and New Zealand that are members of the CCTGs, to enable web-based patient registration / randomization, data entry, resolution of data queries, and long-term follow-up. There would need to be consensus on the preferred system to be supported amongst major sites and co-operative groups to ensure consistency and inter-operability between groups.

Although primarily a “recruitment aid”, any ICT strategy must support and enable a detailed, up-to-date, and searchable data base of currently available clinical trials meeting the distinct but partially overlapping needs of (1) clinicians to identify appropriate trials for their patients and enable clarification of eligibility and suitability, and facilitate referral to recruiting sites, (2) the pharmaceutical industry to better identify competing or overlapping studies, and (3) patients / consumers to empower them to seek and identify potentially appropriate trials and geographically accessible treating centres.

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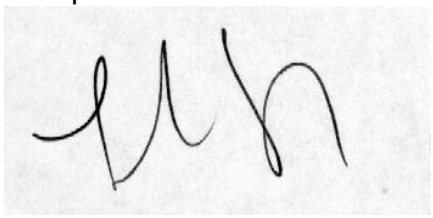

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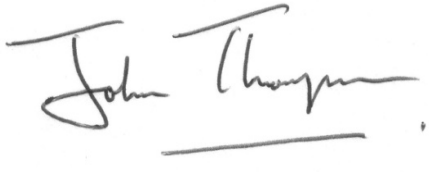

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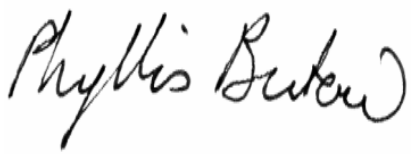

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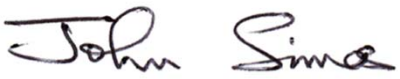

Appendix 1 –List of Cancer Clinical Co-operative Trials Groups

- The Australasian Sarcoma Study Group (ASSG) provides the infrastructure for collaboration between multi-disciplinary teams (MDT), which comprise specialist health professionals working together to discuss your case and how best to manage your treatment and care (for example, specialist cancer doctors and nurses and supportive care clinicians such as social workers, psychologists and physiotherapists).

- The Australasian Gastro Intestinal Trials Group (AGITG) mission is to improve outcomes for patients affected by GI cancer. Involving the community at all levels of the institute to raise awareness and funds for the prevention and treatment of GI cancer in Australia and New Zealand.

- The Australasian Leukaemia & Lymphoma Group (ALLG) is an independent non-profit organisation established by clinicians who care for patients with leukaemia, lymphoma and related blood diseases. It aims to improve the treatment of these patients and to foster collaboration with other relevant groups both national and international. It also aims to fund appropriate research and specific programs to reduce the burdon of such diseases for present and future generations, and to increase the understanding of such diseases by appropriate research including clinical trials.

- The Australasian Lung Trials Group (ALTG) is Australia and New Zealand's lung and thoracic cancer clinical research group. The ALTG is a multi-disciplinary organisation dedicated to reducing the incidence, morbidity and mortality of lung and thoracic cancer and improving the quality of life of lung and thoracic cancer patients in Australia and New Zealand through the coordination and facilitation of high quality clinical research.

- The Australian New Zealand Breast Cancer Trials Group (ANZBCTG) is dedicated to the control of breast cancer through quality research.

- The Australian and New Zealand Children's Haematology and Oncology Group (ANZ CHOG) aim is to encourage and support education and the advancement of knowledge in all aspects of treatment and childhood cancers. Emphasis is on advances in molecular biology, and the opportunities afforded by those advances for the improvement in diagnosis, treatment and prediction of outcomes of therapy.

- Australia New Zealand Gynaecology Oncology Group (ANZGOG) was established to foster and support collaborative research throughout Australia and New Zealand and improve outcomes of women with gynaecological malignancies through randomised clinical trials.

- The Australia New Zealand Melanoma Trials Group (ANZ MTG) was established in 1999. Its first project was to design and support randomised phase III trial in melanoma comparing adjuvant radiotherapy to observation in patients with resected nodal disease. Since then the ANZ MTG has successfully met the target patient recruitment for this trial and is in the process of developing 4 new clinical trial protocols. The ANZ MTG has recognised the need to centrally promote and support melanoma trials for investigators and consumers.

- The Australian and New Zealand Urogenital and Prostate Cancer Trials Group Ltd (ANZUP) Limited is a public company limited by guarantee and incorporates APUG (Australian Prostate & Urogenital cancers Group) and ANZGCTG (Australian & New Zealand Germ Cells Trial Group). The group is multidisciplinary in composition and is dedicated to best practice and innovation in urogenital and prostate cancer clinical trials.

- Co-operative Trial Group for Neuro-Oncology (COGNO) is a newly formed national neuro-oncology trial based group based at the NHMRC Clinical Trials Centre, located at the University of Sydney. COGNO's mission is: "The achievement of better health outcomes for patients and those affected by brain tumours through clinical trials research."

- Primary Care Collaborative Cancer Clinical Trials Group (PC4TG)

- The Psycho-oncology Cooperative Research Group (PoCoG) was established in 2005, in response to a recognised need to develop the capacity and co-ordinated collaboration to conduct large-scale, multi-centre psycho-oncology and supportive care research.

- The TransTasman Radiation Oncology Group (TROG) is Australia and New Zealand's specialist clinical research group for radiotherapy. TROG is a cooperative multidisciplinary organisation dedicated to the control of a wide range of cancers through quality multicentre research.

Appendix 2 –Executive Summary: Cooperative Clinical Trials in Cancer – the need for increased capacity (the "Wall report")

Executive Summary

In the clinical management of cancer, the practice of evidence based medicine is almost totally reliant on the findings of previous clinical trials. While industry-sponsored trials are important, the vast majority of advances in cancer care are made through clinical trials conducted by cooperative groups. This has long been recognised by the US Government, and more recently the UK Government. Both see that cancer clinical trials are a vital priority in improving patient outcomes and that there is a need for greater numbers of cooperative clinical trials in cancer. Both have further increased the funding for cooperative cancer trial groups.

Australia risks losing the capacity to continue "world's best practice" cancer treatment as comparable countries increase the role, standards and capacity of cooperative groups in conducting clinical trials in cancer. This outcome could retard the practice of evidence-based medicine in Australia as trials are integral to its practice. It could also compromise Australia's access to advanced therapies.

This project was commissioned to assess the current capacity of Australian cooperative groups to conduct clinical cancer research trials in Australia. Consultations were conducted with cooperative group chairs and members, other cancer researchers, cancer councils and consumers, and the relevant literature was reviewed.

Current status

The gold standard for clinical research is the randomised controlled trial (RCT). However, they are complex, difficult to conduct, require substantial infrastructure and expertise, and are therefore costly compared to other forms of research (although not when compared to the overall cost of clinical care). Due to the need for substantial numbers of recruits into such trials, they are mostly conducted on an multicentre basis, and the national cooperative groups (essentially large virtual networks) make this possible. Trials conducted by cooperative groups have substantially contributed to the spectacular progress in improving the survival of cancer patients. In children for example, leukaemia now has 75% long term survival (from 0% in 1970). Similarly, outcomes for patients with limited stage breast and bowel cancer have substantially improved as a result of large scale trials in these diseases. Australian groups have been an important part of this world-wide effort.

Relative to the costs of health care, the costs of clinical trials research are value for money, as they provide a highly cost-effective means of ensuring more effective and cost-effective cancer care for patients. This has been recognised overseas, where increased funding in other countries to enhance the capacity of cancer cooperative groups is helping them forge ahead while Australian trials groups continue to struggle to conduct high-quality research. There is a risk that we will lose the ability to conduct large local trials or participate in international trials, thereby losing the numerous benefits that arise from the conduct of such studies.

Benefits of clinical trials

Clinical trials are important for the benefits they provide. Benefits may be to the trial participant, to the general community and to science. Patients benefit from early access to new therapies; improved outcomes (on average) for patients who enter the trials, irrespective of which treatment they receive; improved quality of care from the patients' perspective; and improved therapies in future.

The broader community benefits from better health outcomes; a decrease in premature death and disability; improvement in the evidence behind cancer care; and a health system that is both cost-effective and "world's best practice".

Science and clinical scientists benefit from access to new therapies; improved clinical practice as a result of the discipline that a trial imposes; and a more rewarding professional life. Trials improve clinical practice in the institutions that conduct them, i.e. they improve the organisational culture through enhanced clinical rigour, which in turn benefits the patients.

Conduct of national cancer trials and participation in international cancer trials necessitates formation of national cooperative groups with substantial expertise and capacity. Australian groups treat around 2000 new cases in clinical trials in a year but could treat many more if there was funding to do so. Fewer than 3% of the new adult cases each year enter a clinical trial. This is in line with historical levels here and in many similar overseas countries but it is less than optimal. At least twice as many adult cancer sufferers that would benefit from trial entry are denied the opportunity.

Australia's cooperative groups

Australia is fortunate in having seven national cancer cooperative groups[1] all of which are conducting world class research, despite severe financial constraints. The groups have shown they can be sustainable and effective, the members are committed, their contributions provide substantial leverage on their existing but extremely limited funds, and the groups are flexible and efficient. The shortage of funding, however, means that there are some weaknesses in the cooperative group arrangements , e.g. there are areas for which there is not a cooperative group (such as lung and prostate cancer) and groups have different approaches based on what they can afford rather than what is optimal practice. More fundamentally, this shortage of funding is threatening the sustainability of the groups that do exist.

The number of new cancer therapies is growing rapidly, based on advances in molecular biology and pharmacology. This growth presents a great opportunity to improve cancer care, but all of the new therapies have to undergo trials to demonstrate their correct place in treating cancer. The objective of the cooperative groups, finding the correct place, differs fundamentally from that of industry trials. Australia's low cost base but high level of scientific expertise makes Australia an excellent place to conduct trials on these new therapies but a potential lack of capacity to conduct trials to contemporary international standards in future is a threat to this opportunity.

Gaps in capacity

This review has identified gaps that are developing as a result of the funding crisis. There is a risk that as the gaps continue to widen, the limited number of major Australian research centres will drop out of Australian trials groups and focus on participation in international trials or industry-sponsored trials that provide funding to meet costs. This would mean that in future even major regional centres and possibly the smaller capital cities will have no access to clinical trials and the modern treatment options to which they provide early access. Large sectors of the community will then miss out on the benefits of such access. Finally, this will greatly weaken the existing cooperative group structure in Australia, resulting in the potential loss of a valuable asset.

Gaps in capacity have been identified as:

1. ***Operational cost of the cooperative groups themselves;***

Cooperative groups are small businesses with expenses that include organising and attending meetings of the executive, other communication expenses, staff costs, insurance charges, legal agreements, etc. as well as the cost involved in the pursuit of the group's goal, i.e. identify suitable clinical questions, seek members'

[1] Five of the seven cancer cooperative groups are incorporated bodies.

involvement in the particular trials, and ensure they are conducted efficiently. A fixed annual payment (the same for each group) is proposed to assist in these fundamental requirements.

2. Local data management;

The ability to manage data and other aspects of the trial locally is key to trial recruitment and quality. Oncologists need trial nurses/data managers on hand if they are to be able to recruit subjects efficiently. Nearly all State cancer councils provide some support in this way, mostly in metropolitan teaching hospitals. Additional support for local data management is required if increased recruitment is to occur. It could also be targetted on sectors that have not been involved in trials before, e.g. the private and rural sectors.

3. Central trial coordination, management and analysis of trials;

The coordinating centres manage trials; provide input to trial design and protocol development, database design, etc; as well as trial management, data management, biostatistical analysis and reporting, education and training, and long term follow up of cases. They train and support study nurses, data managers and principal investigators.

Funding arrangements should reflect the actual cost of each of these activities by providing a cooperative group with a lump sum at activation of the protocol (around $100,000 for a national phase III trial with lesser amounts for phase II and international phase III trials) and a modest amount per case ($500) thereafter. A large payment per case as the sole funding mechanism does not reflect expenditure patterns or actual cash flow.

4. Audit and quality assurance of trials.

Triennial on-site audits of at least 10% of records is the de facto international standard. That is met by some groups in Australia but is unaffordable for others. All cooperative group trials need to be part of an audit/monitoring scheme that meets certain minimum standards. Data audits are one universal aspect of quality. Quality assessment of radiation, chemotherapy, surgery, pathology, etc. also needs consideration. Agreed minimum audit and quality standards for Australia need to be defined. An amount per trial site should be allocated for audit programs.

In addition to funding the four areas discussed above, consideration needs to be given to funding for coordination of the program, promotion of clinical trial enrolment to the public and health providers, establishment of a clinical trials register and program evaluation.

Funding mechanism

Departmental funding for an initial three year period, with a review of the whole program in the third year is recommended. The NHMRC is examining capacity issues in medical research but it will take some time yet, and there is no indication that disease-specific funding will be supported, although in other respects the NHMRC (Chalmers) Review of Clinical Research in Australia and this proposal are consistent and complementary.

Governance

It is assumed that the funder (the Commonwealth) would establish an oversighting committee possibly under the aegis of an existing organisation such as COSA. The Chair should have a good understanding of clinical research and preferably no affiliation with any of the cooperative groups. This committee would implement the program in line with the funder’s objectives and guidelines. Funding in the first instance should be for a three year period.

List of recommendations

1. That the Commonwealth enhance the capacity of Australian cancer cooperative groups by providing Department of Health and Ageing funding for a period of three years, with ongoing assessment and final review in the third year.
2. That the funding be applied to: .....**Error! Bookmark not defined.**
   a) develop and enhance the existing cooperative groups' organisational capacity, trial design/protocol preparation, local and central trial coordination, data management and analysis, and quality and audit programs, so that Australia retains its capacity to conduct world-class clinical cancer research;
   b) develop cooperative groups for common cancers where no such groups are established;
   c) provide for cancers that are too small to warrant a dedicated cooperative group in Australia.
3. That performance be continuously assessed, including measures of:
   a) the number of clinical trial protocols facilitated, and the quality, relevance and health priority of each;
   b) the number of positions funded, and the organisations supported through the funding;
   c) evidence of improved quality assurance activities including the establishment of uniform standards across groups and increase in audit activities undertaken;.....
   d) leverage of funding from other sources;
   e) other appropriate longer term measures. .....
4. That the review in the third year consider whether any future funding should remain with the Department of Health and Ageing or be rolled into NHMRC funding processes.....
5. That the Department of Health and Ageing fund a consumer awareness campaign as to the availability of, and benefits from participation in cancer clinical trials.....
6. That funding be conditional on appropriate consumer involvement in the operations of the cooperative groups. .....
7. That a Cooperative Cancer Clinical Trials Committee be established to oversee the implementation and management of any funding program that is provided.**Error! Bookmark not defined.**
8. That the Cooperative Cancer Clinical Trials Committee have the power to form an Executive Committee for day-to-day management, as well as such subcommittees as are necessary to its efficient and effective functioning.....
9. That the Cooperative Cancer Clinical Trials Committee be provided with the resources to access the services of an Executive Officer, and other financial resources as are necessary for its efficient operation.....
10. That the Cooperative Cancer Clinical Trials Committee be able to require such data as are necessary to assess the outcomes of the cooperative group trials program, but that the Committee be mindful of the administrative burden on the cooperative groups in setting the reporting requirements.....**Error! Bookmark not defined.**
11. That assessment and review of the program be funded as part of the program, the review commencing not later that nine months before the end of the initial funding period. .....
12. That funding be provided to establish of a Clinical Trials Register for cancer trials in Australia.

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Appendix 3 – COSA Industry Report – *Full report; www.cosa.org.au*

Interaction between cancer clinicians and pharmaceutical-medical device companies: Opportunities for enhancement

Background

There are growing concerns regarding the nature and level of interactions between pharmaceutical and medical device companies (industry) and clinicians; in media literature[2].

The 'contacts' between cancer clinicians and Industry are many and varied. Industry seeks interaction with cancer clinicians via educational events, participation in advisory boards, in facilitation of clinical trials and by way of individual 'detailing'.

Clinical professional organisations such as the Clinical Oncological Society of Australia (COSA) also have interaction with industry, through their provision of unrestricted grants to run scientific and educational meetings, projects and other initiatives.

Despite the development of codes of conduct or guidelines for the industry and for groups of clinicians in recent years, there is continuing consumer, media and community concern about the potential effect of such interaction on clinical decision-making.

COSA's Clinician and Industry Forum

Recognising these concerns, COSA convened a forum of medical and radiation oncologists, surgeons, cancer nurses, allied health and other professionals, consumer and industry representatives in Sydney on Friday 30 October 2009.

COSA is the peak national body representing health professionals whose work encompasses cancer care and control. COSA has more than 1300 members in 22 different professional groups, all involved in the clinical care of people affected by cancer.

One of the objectives of this forum was to determine if there is a role for professional bodies in facilitating interaction between cancer clinicians and the pharmaceutical industry to reduce the potential for conflict of interest. Is there a role for an organisation like COSA that will enable a win-win situation; that will facilitate interaction between clinicians and Industry to maintain the valued benefits but reduce actual or perceived conflict of interest?

COSA's aim is to facilitate and/or develop a new framework that will provide improved processes for and confidence in clinician-industry interaction.

'Perspectives' on the challenges and key issues in clinician-industry interaction were presented by the forum convenor, Associate Professor Eva Segelov, and the following forum participants:

Ethical and legal issues	Professor Ian Olver CEO, Cancer Council Australia
Practicing clinicians	Professor Stephen Clarke Medicine, Concord Clinical School ANZAC Research Institute
Industry	Ms Deborah Monk Director, Innovation and Industry Policy Medicines Australia
Medical oncologists	A/Prof Michael Michael

[2] Tattersall, MHN, Dimoska A and Gan K. "Patients expect transparency in doctors' relationships with the pharmaceutical industry." *MJA* 2009;190(2):65-68;

	Chair, Medical Oncology Group of Australia
Clinicians using devices	Associate Professor Sandro Porceddu Radiation oncologist
Nursing and allied health	Mr Keith Cox Oncology Nurse Practitioner
Pharmacy	Professor Andrew McLachlan Professor of Pharmacy (Aged Care), University of Sydney
Consumers	Mr John Stubbs Executive Officer, Cancer Voices Australia

This report collates the key issues, principles and recommendations from the presentations and group discussions at the Forum. It was written by communications consultant Lisa-Maree Herron on behalf of COSA.

Appendix 4: *Developing a nationally coordinated approach to biobanking for Cancer Clinical Trials in Australia: Executive Summary*

Executive Summary

The Clinical Oncological Society of Australia (COSA) is constantly searching for avenues to facilitate the Australian Clinical Research agenda towards improving outcomes for Australian Cancer patients. This biobanking solutions paper is the result of 2 years of consultations.

Background

Biological studies linked to clinical trials can generate significant improvements in patient outcomes by supporting targeted approaches to cancer treatment.

There is increasing interest nationally and internationally in linking biological studies with cancer clinical trials. Biological studies involve the analysis of tissue or blood samples and allow correlation of clinical outcomes with markers that can predict response to treatment or that have prognostic value. In addition, they can provide information about markers of underlying disease, such as serum markers used to detect malignancy in apparently disease-free patients.

Biological studies require the appropriate collection and storage of fixed or frozen tissue and blood samples as well as mechanisms to facilitate timely access to these biospecimens for analysis. This relies on the availability of tissue banks, or biobanks, which provide a central repository for biological samples, including malignant and benign tissue (fresh, frozen or formalin fixed), blood or other body fluids.

The need for a national approach

A nationally consistent and streamlined approach to biobanking linked to cancer clinical trials will be vital to maintaining Australia's standing as a country of choice for the conduct of cancer clinical trials in an increasingly competitive international market.

While tumour biobanks have been established at many sites in Australia, approaches to biobanking for cancer clinical trials are not standardised and there is currently no systematic approach to biobanking for multisite trials.

Identified drivers for a coordinated approach to biobanking include:

- improved research quality and efficiency through access to a larger pool of biospecimen samples, increased quality of samples and economies of scale
- attraction of increased research funding and cancer clinical trial activity to Australia as a result of improved infrastructure, research quality and infrastructure
- improved patient outcomes through targeted approaches to treatment
- economic benefits resulting from reduced expenditure on inefficient treatments and streamlined approaches to trial activity.

As the peak national body in Australia representing health professionals whose main work is cancer control, the Clinical Oncological Society of Australia (COSA) has taken a lead role in developing a national approach to biobanking in cancer clinical trials through a strategic consultation and planning process involving:

- a literature review to identify national and international approaches to biobanking
- stakeholder consultation to identify issues, barriers and solutions for a national approach to biobanking
- development of consensus on a recommended model and implementation plan for biobanking through a national Solutions Workshop held in November 2009.

The recommended model focuses on facilitating access to biospecimens collected during clinical trials undertaken by the 13 Cooperative Cancer Clinical Trial Groups (CCTGs). These groups conduct single- and multicentre cancer clinical trials across Australia with funding from a range of sources.

Facilitation of access to a larger pool of biospecimens and sample data by the private sector and the broader research community has also been considered.

A recommended model for biobanking in cancer clinical trials

COSA has facilitated the development of a recommended model for biobanking in which a central body would support and coordinate a national integrated network of biobanks in each state used to store biospecimens collected during cancer clinical trials.

Key features of the recommended model include:

- appointment of a central body to support coordination of a national network of existing biobanks, with appropriate governance, advisory and management arrangements and implementation of contractual agreements for outsourced components as required
- development and promotion of nationally-agreed protocols and procedures to guide the operation of the biobank network, including standard operating procedures, standardised documentation, minimum data set requirements and streamlined ethics processes
- centralised storage of data on the nature and location of samples in a national data repository accessible by each biobank
- implementation of a streamlined process to support access to biospecimens and sample data by CCTGs and other research groups
- continued storage of clinical data by individual CCTGs on CCTG servers.

Table 1: Overview of proposed roles for the biobank network central body

Role	Detail
Development of standardised procedures across all member biobanks	• Standardised patient consent forms • Standardised operating procedures for biospecimen collection • A minimum data set for biospecimens • Streamlined ethics processes
Awareness raising and training	• Promotion of nationally agreed protocols and procedures to ensure compliance
Coordination of access to biospecimens and data	• Centralised information repository about available biospecimens • Centralised approach to sample applications and access to biospecimens (subject to ethics and scientific approvals and CCTG agreements) • Centralised approach to access to data about biospecimens (subject to ethics and scientific approvals and CCTG agreements) • Assistance with identifying archived tissue and sample data collected before the establishment of the national network

Implementation of the recommended model

COSA will lead the next steps towards the implementation of a national approach to biobanking in cancer clinical trials with input from Cancer Australia and the NHMRC Clinical Trials Centre and a working party of relevant stakeholders.

Identified next steps to support the implementation of the recommended model for biobanking in Australia are outlined in Table 2. A timeframe of one year commencing from November 2009 has been set for the completion of these tasks, with identification of funding sources to be completed by the first half of 2010.

Table 2: Next steps in implementing the recommended model for biobanking

Step	Agreed elements
1. Announce a lead organisation	• COSA to continue to lead the process of implementing the recommendations • Cancer Australia and National Health and Medical Research Council (NHMRC) Clinical Trials Centre (CTC) to be involved in facilitating implementation
2. Establishment of Working Group	• To be convened by the lead organisation • To comprise key stakeholders including representatives from CCTGs and other research groups, biobanks, cancer organisations, consumer organisations, ethics and other relevant experts
3. Formation of subcommittees	• To focus on progressing key aspects of the model requiring more detailed implementation planning, including funding, governance issues, harmonisation of ethics, and central body operations
4. Preparation of business case for funding	• To be progressed in parallel to other aspects of the implementation plan