Clinical Oncological Society of Australia

Models to improve efficiencies in Cancer Cooperative Trials Group activities

A Clinical Oncological Society of Australia workshop

8 November 2010

WORKSHOP SUMMARY

Workshop report prepared for COSA by ZEST Health Strategies

INTRODUCTION

Australia[1] currently has 14 Cancer Cooperative Trials Groups (CCTGs), operating predominantly on the Australian East Coast (Table 1). Entities that provide support for existing trials group operations include the National Health and Medical Research Council (NHMRC) Clinical Trials Centre (CTC) in Sydney and the Centre for Biostatistics and Clinical Trials (BaCT) at the Peter MacCallum Cancer Centre. These centres are key contributors to components of CCTG activity.

The Clinical Oncological Society of Australia (COSA) is the peak clinical body representing all providers of cancer care. The overarching mission of COSA is to develop and maintain high-quality clinical care for cancer patients in Australia. The COSA membership is involved in 22 cancer professional groups, 6 cross-disciplinary interest groups and the 14 national CCTGs.

In 2004, COSA and the existing CCTGs were successful in obtaining an NHMRC Enabling Grant to support measures of efficiencies across the CCTGs. COSA has played a key role in managing the Enabling Grant project and facilitating efficiencies across the groups. COSA's Executive Officers Network was formed in 2005 to enhance collaborations between the CCTGs through the operational managers and increase the efficiency of cancer cooperative research through sharing of information and use of resources. The current Enabling Project will expire in 2010.

The changing nature of cancer clinical trials and the competitive international research environment challenge the CCTGs to be dynamic, responsive to change and maximally efficient in order to deliver best-quality, cost-effective clinical trials to the Australian community. While considerable shared operational efficiencies have been made through the Enabling Project, the potential to gain further efficiencies through increased collaboration has been proposed.

In May 2010, COSA and the CCTGs submitted an expression of interest to the Australian Cancer Research Fund (ACRF) for infrastructure funding to support the CCTGs. The application was shortlisted for development of a full application. A COSA workshop in July 2010 provided the opportunity for CCTG representatives to discuss potential models to be considered in a full funding application. While there was in-principle support from workshop attendees for greater collaboration and consolidation of effort between the CCTGs, there was insufficient consensus on the ideal model to warrant submission of a full funding application. Instead, a further workshop was planned prior to the COSA's 37th Annual Scientific Meeting (ASM) to continue discussion about the benefits and risks to Australia's CCTGs of greater collaboration and to determine a strategic way forward.

Table 1: Australia's Cancer Cooperative Trials Groups

Abbreviation	Name
AGITG	Australasian Gastro-intestinal Trials Group
ALLG	Australasian Leukaemia & Lymphoma Group
ALTG	Australasian Lung Cancer Trials Group
ANZBCTG	Australian New Zealand Breast Cancer Trials Group
ANZCHOG	Australian and New Zealand Children's Haematology and Oncology Group
ANZGOG	Australia New Zealand Gynacological Oncology Group
ANZMTG	Australia and New Zealand Melanoma Trials Group

[1]This report refers to cancer cooperative trial group activity in Australia. It is acknowledged that for a number of CCTGs, activities also involve New Zealand.

Abbreviation	Name
ANZUP	Australian and New Zealand Urogenital and Prostate Cancer Trials Group
ASSG	Australasian Sarcoma Study Group
COGNO	Cooperative Trials Group for Neuro-oncology
PC4	Primary Care Collaborative Cancer Clinical Trials Group
PaCCSC	Palliative Care Clinical Studies Collaborative
PoCoG	Psycho-oncology Cooperative Research Group
TROG	Trans-Tasman Radiation Oncology Group

WORKSHOP OVERVIEW

COSA and the Enabling Project held a workshop on Monday 8 November 2010 at the Melbourne Exhibition and Convention Centre, prior to the 37th COSA ASM. The workshop was attended by Executive Officers and Chairs of 12 of the 14 CCTGs as well as representatives from the NHMRC CTC, COSA and the Enabling Project. The workshop was facilitated by an independent facilitator – Dr Norman Swan.

A pre-reading document circulated in advance of the workshop summarised a number of benefits and risks associated with different levels of CCTG collaboration (Table 2). Each CCTG was asked to critically appraise each model and identify areas in which increased collaboration could assist or improve their functions. A representative from each CCTG was invited to give a short presentation outlining: (i) how greater efficiencies could be achieved for their group; (ii) the benefits/efficiencies to be gained for the CCTG through the proposed model; (iii) and any risks/costs associated with such a model.

Table 2: Pros and cons of different levels of CCTG collaboration/integration

Model	Pros	Cons
1. Fully integrated, co-located CCTG centre (as per NCIC) *Central operations group with trial group- specific activity undertaken by member groups/committees*	• Would provide the ultimate level of efficiency/ consolidation of effort if starting from a zero trials base	• Difficult to implement given the geographic spread, varying organisational complexity and differing stage of development of CCTGs
2. Staged 'opt-in' integration *Co-location of administrative functions for smaller and newer CCTGs who opt in*	• Likely to create valuable efficiencies for smaller/ newer CCTGs • Option to involve more CCTGs over time	• May be difficult to gain agreement on location • Need to consider how likely integration with larger/more established CCTGs would be over time
3. 'Virtual' integration *Identification of some shared operational and administrative functions across all groups without the need for physical co-location*	• Supports better/more equitable use of limited resources, eg consumer advisors, health economics and biostatistics • Use of ICT would mean that shared functions are not dependent on one physical location	• Requires agreement on governance/responsibility for shared functions
4. No integration *Status quo – each CCTG maintains its own administrative, operational and governance functions*	• Allows for independence of decision making	• Question over long-term sustainability, particularly for newer and smaller groups • Potential for duplication of effort • May be detrimental in the longer term if Enabling Grant funding/functions cannot be maintained

WORKSHOP OUTCOMES

The workshop highlighted a broad range of views from the CCTGs about the benefits and risks associated with different levels of collaboration, and identified some common areas of agreement. that could form the basis of a strategic plan to drive improvements in cancer clinical research in Australia. Outcomes have been summarised below.

CURRENT STATUS OF COLLABORATION BETWEEN CCTGs

Presentations from CCTG representatives highlighted the variation that exists between trial groups in terms of duration of operation, organisational structure and size. It was apparent that there is already some degree of standardisation, collaboration and integration:

- Cancer Australia provides infrastructure funding to 13 groups through competitive grants
- the NHMRC CTC provides support for 7 of the CCTGs, through provision of common infrastructure, administrative and statistical support
- BaCT is the trial centre for the ALLG and ASSG and for some TROG trials
- ANZCHOG operates as a collaborative with the Children's Oncology Group in the USA
- some degree of collaboration occurs between CCTGs, particularly with those groups that do not have a disease-specific focus (PoCoG, PC4TG, TROG)
- the Enabling Project has already facilitated some important areas of standardisation, such as the umbrella insurance policy, templates for clinical trial agreements, education and training initiatives and platforms for communication between CCTGs, such as the Executive Officers Network.

DRIVERS FOR FURTHER COLLABORATION

Participants identified a number of common issues related to the conduct of cancer clinical research in Australia that highlight the importance of greater CCTG collaboration (Table 3).

Table 3: Key drivers for greater collaboration between CCTGs

Driver	Detail
International positioning	• Australia needs to position itself to compete with newer clinical research groups that are evolving within the Asia-Pacific region
Capacity	• Australia does not have sufficient patient numbers required for large-scale clinical trials; partnership with other countries is required • As therapies become more targeted, the sub-populations of patients available to test particular hypotheses are diminishing
Efficiency	• Australia is losing ground in clinical research because clinical trials take too long and are too expensive to conduct • Time to approve trials is a major barrier, due to delays in ethics and requirements for individual contractual agreements with sponsors, partners in other countries and individual sites
Changing landscape	• The cancer research landscape is evolving from tumour-/disease-specific trials to pathway-specific trials (eg molecule-specific or defect-specific research) • With the Enabling Project funding coming to an end, the position of 'status quo' will not necessarily mean no change from the current status
Innovation	• Australia does not have a central or common mechanism to generate cross-platform ideas and share approaches to addressing global questions relating to cancer research

Australia's strength in the conduct of well-designed trials that generate high-quality data was flagged, although it was noted that this would not always remain a point of difference within the Asia-Pacific region. Participants reflected on the considerable progress in coordination and collaboration that has been made over the past 6 years since the inception of the Enabling Project and emphasised the importance of building on rather than losing momentum.

It was suggested that a strategy should be formulated that identifies and addresses priorities for the next 10 years with the aim of cementing Australia's position as a centre for the conduct of innovative and high-quality cancer clinical research aimed at improving patient outcomes. It was agreed that opportunistic activities based on the availability of short-term grant funding would be insufficient as a long-term strategy to achieve this goal.

While it was agreed that issues of long-term funding and patient accrual would not be solved through greater collaboration alone, there was consensus that some commonality in approach would be beneficial, particularly in relation to providing a single platform for lobbying and advocacy activities.

OPTIONS FOR GREATER COLLABORATION

In discussing options to improve the efficiency of cancer clinical trial activity, participants noted international experience which suggests that the issues being faced in Australia are not unique but can be overcome through greater collaboration and facilitation and through shared infrastructure. There was broad agreement that the optimal structure to underpin collaborative clinical trial activities would be a central organisation rather than a disparate group of organisations with different corporate structures. However, it was recognised that given the history and broad range of CCTGs, such a structure is no longer possible in Australia.

In discussing potential options for greater collaboration, a range of questions were identified, that warrant further exploration, including:

- what is the true cost of undertaking collaborative clinical trials in Australia?
- where are the weak points/delays in the clinical trial process and where can efficiencies be achieved for each CCTG?
- can consolidation/coordination between CCTGs lead to greater efficiencies in the key aspects of trial set-up and implementation?
- what would a 'consolidated' model look like in practice?
- what is the role of the New Zealand component of the CCTGs in any integrated model?
- what impact, if any, will efficiencies have in terms of driving patient accrual?
- would a more collaborative structure make it easier to identify and recruit patients to trials at the coalface?

BENEFITS AND RISKS OF GREATER COLLABORATION

All CCTG representatives who presented during the workshop identified 'virtual integration' as an acceptable model to facilitate greater collaboration of effort. The benefits and risks of such an approach identified by the CCTGs are summarised in Table 4.

Table 4: Overview of CCTG views on models for greater collaboration

CCTG	Preferred model	Shared initiatives	Benefits	Risks/unanswered questions
COGNO	Virtual integration	Consumer networks Coordination of education/training Philanthropy/fundraising Communication links/networks	Better use of limited resources Shared knowledge/expertise Flexible approach that takes account of differing maturity/structures of CCTGs Allows maintenance of independence	Questions over: • costs • governance model • approach to developing/managing
AGITG	Virtual integration	Administrative efficiencies, eg meeting/conference coordination	Reduced need to outsource to Professional Conference Organisers Increased purchasing power Increased efficiencies	Requires staff with skills in meeting/event coordination Variable workload Requires fair allocation of costs across CCTGs
PoCoG	Some benefits to virtual integration	Shared consumer panel Shared data management/support Network of statisticians Health economics Common approaches to lobbying and advocacy Common approaches to education/training Common platforms for data management/health economics etc	Risk of losing the focus on psycho-oncology among the tumour-specific trial groups	Common approach to ethics would not be useful – PoCoG studies tend to be low-risk studies so ethics process is already streamlined
ANZMTG	Virtual model	Centralised pool of resources for setting up/running studies Shared electronic technologies and training Administrative support	Greater efficiencies and better use of resources Increased access to experience of staff in other groups when negotiating contracts	Risk to volunteerism and innovation Removes independence of decision-making Physical integration could remove benefits of co-location with the melanoma unit

CCTG	Preferred model	Shared initiatives	Benefits	Risks/unanswered questions
TROG	Virtual integration	Common approaches to education	More equitable use of resources Negates the need to change location or company structure Mitigates reduction in enabling grant funding	Requires a satisfactory governance model Potential alienation of small centre participation
ALTG	Virtual integration (in the absence of substantial funds available for a different approach)	Common approaches to education, funding, strategic directions, agreements, ethics	Increased educational opportunities for members Access to biobanking, ethics, psychosocial input Access to data safety and monitoring Consumer training Lobbying for trial funding Liaison with other CCTGs	Risk of loss of contact/interaction with the lung cancer community Reliance on external collaborations and interactions Question over future funding Risk of over-governance
ANZUP	Integration into a shared corporate structure	Finance Basic office functions Contract/compliance functions Communications Governance and reporting	Benefits in terms of lobbying, education, shared approaches and common platforms, although some shared activities do already exist through COSA and the Enabling Project and through the CTC and BaCT	Risk of loss of autonomy/identity Risk of dilution of smaller groups out of proportion to the importance of the disease Disproportionate use of resources Difficulty in attracting disease-specific funding
ALLG	Virtual integration/staged opt-in integration	Administrative functions – eg meeting coordination Information dissemination Professional education Centralised ethics function	Benefits considered for each of the four proposed models Virtual integration seen as a flexible, low-risk option Staged integration may have greater benefit for smaller/newer groups	Collaboration may dilute the focus on individual tumours and reduce passion/volunteerism A virtual approach may not be seen by funders/policy makers as a significant enough move towards collaboration

CCTG	Preferred model	Shared initiatives	Benefits	Risks/unanswered questions
ANZBCTG	Would want to be involved and contribute expertise but see the benefits more for smaller/less established groups Benefits more likely through collaboration than formal integration	Lobbying for research funding Professional development Cross trial activities (eg biobanking, data collection and management)	Benefits remain to be determined given mature systems and business structure of the group	Questions over level of work required to achieve integration and who will undertake the role of overseeing this process Risk of duplication of effort with existing activities through CTC and Cancer Australia Questions over whether more efficient administrative functions will assist with issues around managing scientific committees and management fatigue
ANZCHOG	Integration into a shared corporate structure	Integration of operations rather than Executive Independence in decision making to be maintained Important to remember New Zealand involvement	Better national integration Program management not state-dependent Greater sustainability	Already strong collaboration with COG in the US Questions over the benefits for ANZCHOG Risk to independence of decision making Centralised functions may make it difficult to access Chair for decision making

ROLE OF THE NHMRC CLINICAL TRIAL CENTRE

The NHMRC CTC provides support for 7 of the CCTGs (Table 5).

Table 5: Role of NHMRC CTC with the CCTGs

CCTG	CTC function
AGITG	Trial Coordinating Centre, Group Operations housed at CTC offices
ANZGOG	Trial Coordinating Centre, Group Operations housed at CTC offices
ALTG	Trial Coordinating Centre, Group Operations housed at Australian Lung Foundation in QLD
COGNO	Trial and Group Coordinating Centre (COGNO unincorporated)
ANZUP	Trial Coordinating Centre, Group Operations housed at CTC offices
ANZBCTG	Statistical & Randomisation Centre, Operations Office in Newcastle
PC4	Protocol Development & Stats Support, no centralised Trial Coordinating Centre

Identified benefits of consolidation of effort through the CTC included:

- shared infrastructure
- staffing efficiencies
- single point for formal collaborations with other groups and organisations, eg PC4, Cancer Australia.

Reflecting on these efficiencies, Professor John Simes identified additional benefits that could be achieved through greater collaboration across all of the CCTGs. These included:

- streamlined approach to education and training in clinical research
- efficiencies and cost savings through common approaches to outsourcing and contracts
- network of CCTG-affiliated consumers
- single data monitoring panel with rotating membership.

ROLE OF COSA

COSA has taken a leading role in facilitating the Enabling Project and in providing the impetus and infrastructure for CCTG collaboration to date. There was considerable discussion during the workshop about the role of COSA in overseeing a more collaborative approach between the CCTGs. Participants agreed that COSA's remit is to improve cancer care in Australia and that clinical research is an integral part of cancer care. It was generally agreed that COSA would be an appropriate group to continue to facilitate the CCTG collaborative and any steps towards virtual integration, given its overarching view across all groups and lack of a vested interest in one particular area.

ENDPOINT/GOALS OF ENHANCED COLLABORATION

A central question posed to all of the CCTGs represented at the workshop was the level of commitment from each group to a greater level of integration and collaboration. It was agreed that a key step in setting a strategic plan for future activity would be to clearly identify the aspiration and rationale for greater collaboration. It was agreed that the ultimate goal of CCTG activities is to improve outcomes for people affected by cancer through the identification and evaluation of new/improved approaches to diagnosis, treatment and care.

Achievement of this goal will require:

- efficient systems that make optimal use of limited resources (funds, human resources and infrastructure)
- efficient approaches that minimise the time to register and approve a clinical trial
- a culture in which clinical research is recognised as an integral part of healthcare and is embedded as a core component of health care delivery
- coordinated approaches that maximise accrual of suitable patient populations into research studies.

WORKSHOP OUTCOMES

Opportunities and model for collaboration

Key outcomes from the workshop are summarised below.

1. A common approach to some core functions across all of the CCTGs, including education and training of research staff and training of consumer panels, would be beneficial to maximise use of limited resources.
2. Sharing of some administrative functions, such as audit and compliance functions, data management and accounting, between some of the smaller and less well-established CCTGs, may be beneficial to drive efficiencies in operations
3. A unified approach to advocacy would present a more compelling national voice for driving improvements in clinical research and lobbying for increased funding and education.
4. Greater CCTG collaboration could be achieved without requiring CCTGs to change their individual corporate structures or lose their individual identities, potentially through an umbrella organisation.

Strategy for collaboration

It was agreed that a Collaborative Clinical Research Strategy should be developed that clearly outlines the purpose of greater CCTG collaboration and the actions required to achieve such collaboration. It was agreed that the Collaborative Clinical Research Strategy should:

1. document a pro-active, long-term approach that defines the agenda and advocates for what is needed to achieve this, rather than reacting to what is determined by government or other sponsors
2. include a costed business plan that identifies approaches to achieve incremental advances in cancer clinical research in Australia and New Zealand
3. involve the CCTGs, COSA, CTC and BaCT as well as key partners, such as Cancer Councils and professional colleges/bodies.

Next steps

It was agreed that development of the Collaborative Clinical Research Strategy will require commitment from each of the CCTGs, both in terms of contribution to strategic discussions, and a financial contribution to support the planning process (possibly pro-rated on the basis of CCTG size). Agreed next steps are outlined below.

1. Each CCTG will be asked to review the workshop outcomes and recommendations and identify their commitment to the strategic planning process and their willingness to make a financial contribution to support the process (ballpark of $10–15K for the first 2 years, possibly pro-rated according to CCTG size).

2. The Enabling Project Steering Committee will progress plans for development of a Collaborative Clinical Research Strategy, including identifying the costs and human resources required (ballpark estimate of 2 project officers employed over a 2-year period).
3. A report on progress will be delivered in the next 6–12 months.

APPENDIX I: WORKSHOP ATTENDEES

Name	Representing
Professor Stephen Ackland	Enabling Project, AGITG
Rowena Amin	TROG
Mari Bakker	COSA
Professor Bryan Burmeister	TROG
Wendy Carmichael	ANZBCTG
Jenny Chow	COGNO
Russell Conley	AGITG
Rhonda Cousins	COSA
Professor Ian Davis	ANZUP
Dr Haryana Dhillon	PoCoG, Enabling Project
Dr Peter Downie	ANZCHOG
Dr Alison Evans	ZEST Health Strategies (report writer)
Professor David Goldstein	AGITG, COSA
Dr Liz Hovey	COGNO
Professor Bruce Mann	COSA, ANZBCTG
Margaret McJannett	COSA
Professor Michael Millward	ALTG
Dr Dina Neiger	ASSG
Libby Paton	ANZMTG
Megan Sanders	ALLG
Associate Professor John Seymour	ALLG
Professor John Simes	NHMRC CTC
Associate Professor Martin Stockler	NHMRC CTC
Robyn Strong	ANZCHOG
Dr Norman Swan	Facilitator
Burcu Vachan	NHMRC CTC
Dr Sally Whyte	ASSG
Professor John Zalcberg	AGITG