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Clinical Oncological Society of Australia

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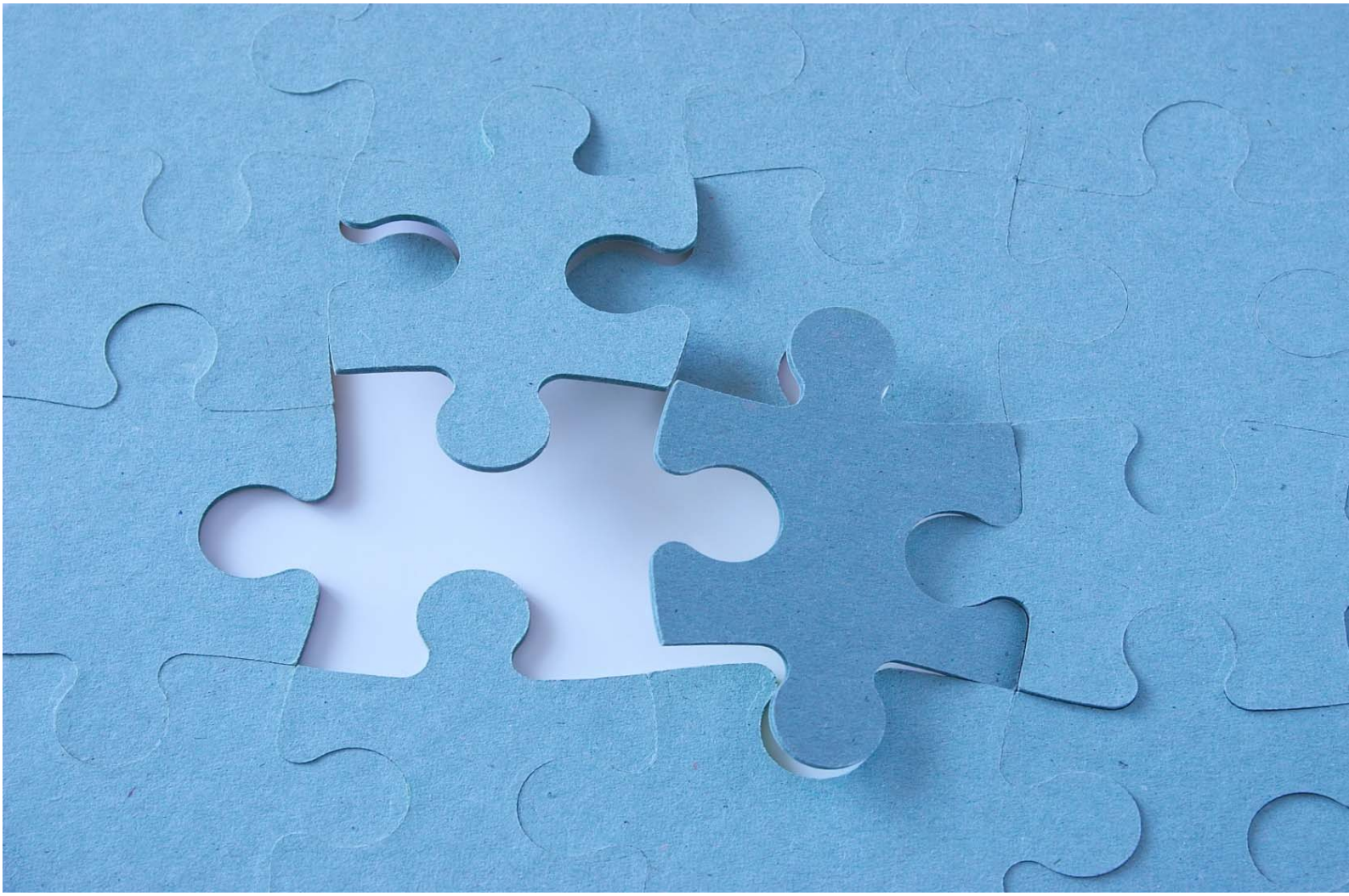
Developing a nationally coordinated approach to biobanking for Cancer Clinical Trials in Australia

22nd March 2010



Contents

Acknowledgements **ii**

Executive Summary **vi**

1 Biobanking in Australia: opportunities and challenges **1**

1.1 Biobanking infrastructure in Australia 1

1.2 Progress towards nationally coordinated biobanking 2

1.3 Continuing challenges to nationally coordinated biobanking in Australia 3

1.4 Rationale for a coordinated approach and linking infrastructure 4

2 Developing a national approach: research objectives and method **9**

2.1 Research background and objectives 9

2.2 Project methodology 9

2.3 The Initial Consultation Phase 10

2.4 The Solutions Workshop 13

3 The Recommended Model **14**

3.1 Key features of the Recommended Model 14

3.2 Operation of the Recommended Model 14

3.3 Governance 16

4 The way forward **18**

4.1 Next steps 18

4.2 The Working Group: recommended members 19

4.3 Proposed timeframes 20

Appendix A **21**

National Tissue Bank Forum Agenda 21

Appendix B **22**

Stakeholders invited to the Initial Consultation Phase 22

Appendix C **23**

Issues and Options Paper 23

Appendix D **27**

Participants in the Solutions Workshop 27

About the Clinical Oncological Society of Australia

The Clinical Oncological Society of Australia (COSA) is the peak national body representing health professionals whose main work is cancer control; being all actions reducing the impact of cancer on people.

COSA is a not-for-profit organisation, with a membership network that includes 22 professional groups and 13 cooperative cancer clinical trial groups across Australia. COSA promotes clinical innovation, advocacy, research, professional development, collaboration, networking and all notions supporting the encompassing goal of maximising cancer care outcomes for all Australians.

Our highly respected clinical and academic members keep us at the national and international cancer forefront and our proven history of working as a sincere independent continues with our work in this Tissue Banking project.

For more information please visit our website www.cosa.org.au

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Statement of Responsibility

This report was prepared by Deloitte for the Clinical Oncological Society of Australia for the purpose of informing their research into a solution for coordinating biobanking among cancer clinical trials groups in Australia.

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Consultations

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John Thompson	ANZ Melanoma Trial Group
John Seymour	Australasian Leukaemia & Lymphoma Group
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Megan Ellis	Australasian Leukaemia & Lymphoma Group
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Executive Summary

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 in order to maintain 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 and CCTG
- 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 in 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 1 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. Identification of 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

1 Biobanking in Australia: opportunities and challenges

The following chapter outlines the current status of biobanking for clinical trials in Australia. It considers the dimensions along which Cooperative Cancer Clinical Trial Groups and other research centres vary in this matter and the rationale for adopting a coordinated approach to biobanking for cancer clinical trials.

1.1 Biobanking and cancer clinical trials

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.

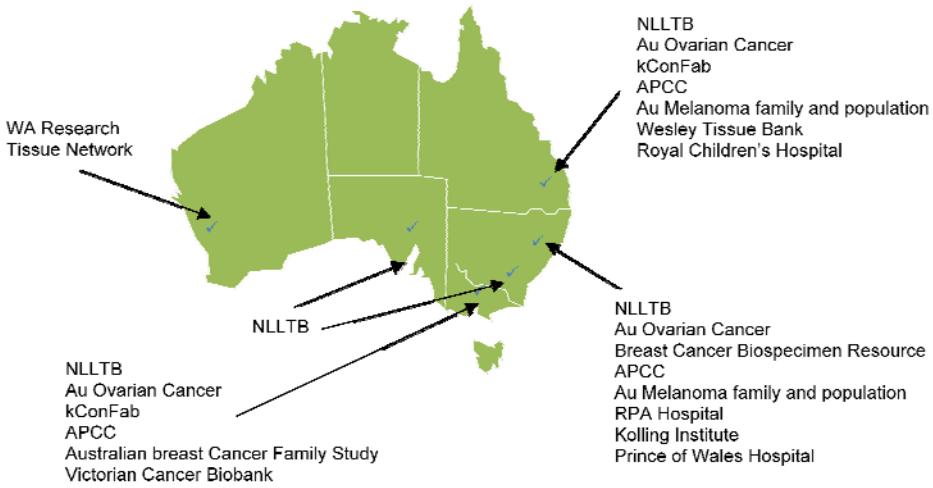
1.2 Biobanking infrastructure in Australia

Currently in Australia, biobanking of specimens from patients enrolled in cancer clinical trials is carried out predominantly by the pharmaceutical industry.

While tumour biobanks have been established at many sites in Australia (Figure 1), approaches to biobanking for cancer clinical trials are not standardised and there is currently no systematic approach to biobanking for multisite trials. Many of these biobanks have started to work in a cooperative fashion – most notably, the seven biobanks involved with the Australasian Biospecimen Network – Oncology (ABN), the National Leukaemia and Lymphoma Tissue Bank, the Breast Cancer Biospecimen Resource, the Australian Prostate Cancer Collaboration BioResource, the Victorian Cancer Biobank Consortium, and the Australian Ovarian Cancer Study.

These cooperatives are funded from a wide variety of sources including competitive grants from a number of different agencies, State governments and philanthropic groups.

Figure 1. Australian States with major biobanks (✓)



1.3 Progress towards nationally coordinated biobanking

There has been significant investment in biobanking infrastructure and efforts are underway to standardise processes and procedures for biobanking in cancer clinical trials. This includes the development the development of minimum datasets for cancer clinical trials and biospecimens, standards of practice for biospecimen collection and efforts to reduce administrative barriers to research that exist with multicentre clinical trials.

1.3.1 Minimum datasets for cancer clinical trials and biospecimens

The Framework for Specialist Minimum Dataset Development for Specific Cancers in Clinical Cancer Registration[1] has been developed by Professor David Roder on behalf of Cancer Australia. The minimum dataset is intended to be an ideal set of fields that all cancer biobanks should record wherever possible. Individual banks may wish to add their own relevant fields in their own database as required. National Minimum Dataset specifications are in the final stages of development both for trial data and biospecimen data.

1.3.2 Standards of practice

Existing biobanks typically have Standard Operating Procedures (SOPs) for the main aspects of the biobanking procedure, including patient consent, specimen collection and storage. However, SOPs are typically developed internally at each bank, resulting in considerable variation across biobanks. Despite this variation in practice, there are some examples of common SOPs across biobanks. In Victoria, for example, the Victorian Cancer Biobank Consortium has standardised procedures across all of its member banks based on the International Society for Biological and Environmental Repositories Best Practices for Repositories. The ABN also has a standard set of SOPs applied across its membership – the Australasian Biospecimen Network Biorepository Protocols.

[1] ISBN: 1-74186-792-4: online ISBN: 1-74186-793-Publications Number: P3-4769

1.3.3 Ethics harmonisation

Another challenge encountered by clinical trial groups seeking access to biospecimens relates to the lack of a standardised approach to ethics approval for clinical trial activity. Human Research Ethics Committees (HRECs) review research proposals involving human participants and approve their conformity with the requirements of the *National Statement on Ethical Conduct in Human Research*[2]. Currently over 250 HRECs exist in public and private organisations, hospitals and universities across Australia. For researchers planning multi-site and/or multi-centre research projects, the need to submit ethic review applications to multiple institutional HRECs can result in considerable delays and additional costs.[3]

In October 2006, the Australian Health Ministers' Advisory Council (AHMAC) agreed to implement a national system enabling the recognition of a single scientific and ethical review process within and across all Australian jurisdictions. In August 2007, the National Health and Medical Research Council (NHMRC) established the Harmonisation of Multi-centre Ethical Review (HoMER) Jurisdiction group to advise on the development and implementation of a national approach to single ethical review.[4]

In the 2007 Federal Budget, $5.6 million was allocated to the HoMER project over a period of 4 years. The allocation will fund costs for the consultation, development and implementation of a national approach for single ethical review. The process is currently entering into initial pilot stages.[5] Harmonisation of ethics processes will support the development of standardised patient consent processes and future access to biospecimens.

1.4 Continuing challenges to nationally coordinated biobanking in Australia

Although there has been significant progress towards a consistent approach to biobanking in Australia, a number of barriers remain. Key challenges include variation in practice between CCTGs and lack of infrastructure funding.

1.4.1 Variation in CCTG practices

Currently, significant variation exists between CCTGs in Australia, with groups ranging from large, well-established groups with well-documented procedures to newer, smaller groups that are still in early stages of development. Consequently, not all CCTGs have the same level of experience in biobanking. Even among those CCTGs that are currently undertaking biobanking activity, there is variation in the level of coordination of processes and in approaches to data collection and storage.

Clinical trials involving biospecimen collection generate patient-specific data, trial-specific data and sample-specific data. Some CCTGs store all three types of data centrally while others store data at each trial site.

The procedures and ease of biobanking can vary by tumour type, affecting CCTGs differently.

- *Tissue type* – the requirement for access to fresh tissue varies according to tumour type. There is also significant variation in the type of tissue that can be banked. Tissue may be fresh, frozen, formalin-fixed or paraffin-embedded; blood samples may include whole

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[2] (2007) http://nhmrc.gov.au/publications/synopses/e72syn.htm
3 NHMRC (2009) 'HoMER Background and History' accessed online: http://www.nhmrc.gov.au/health_ethics/homer/homer_history.htm , last accessed 27.11.09
4 Ibid.
5 Ibid.

blood, plasma, serum, buffy coat or clotted blood. DNA and RNA may also be extracted and stored.

- *Tumour availability* – Variation in tumour size means that the amount of tissue available for banking varies according to tumour type, with smaller tumours limiting the volume available for storage.
- *Tumour heterogeneity* – Some cancers have a greater variation in tumour type than others. This means that the benefits biobanking and subsequent biological studies will have varying payoffs for different groups.

Variation in SOPs across sites can compromise the quality and credibility of research data collected. An effective nationally coordinated approach to biobanking should offer solutions to address both of these matters.

1.4.2 Gaps in funding and infrastructure

As discussed by Carchpoole et al (2007)[6], the collection of samples and data from an adequately large number of cases is typically beyond the scope of any single institution. In the absence of a coordinated approach, researchers face significant costs in procuring sufficient samples and risk overlooking samples that could be of use to their work.

A number of activities and infrastructure critical to support a nationally coordinated approach to biobanking in cancer clinical trials are not currently funded or available.

- Collection of tissue beyond that required for diagnosis is not funded and collection of samples for biobanking relies on goodwill by the pathologist. This results in a smaller pool of biospecimens for translational research than would otherwise be available.
- Key personnel involved in the collection of biospecimens are often not trained in SOPs, which result in inconsistent sample collection and can affect the quality of biospecimens. This introduces unwanted elements of variability into research activity, compromising its quality and credibility.
- Given that samples are not systematically stored for research, information is not readily available about sample availability. This can result in a highly inefficient process for sourcing biospecimens and applying to individual sites for ethics approval/access. In some instances, collected samples may not actually be used because the research community is unaware of their availability. Both outcomes are a waste of already scarce time and money.

The result is the collection of biospecimens that are ultimately not used because they are not known to be available to the research community and have not been collected in a consistent manner. Moreover, in the absence of a standardised approach, unwanted elements of variability are introduced into research work, compromising its quality and credibility.

1.5 Rationale for a coordinated approach and linking infrastructure

Development of a nationally coordinated approach to biobanking as well as appropriate infrastructure to facilitate access to biospecimens would significantly increase the quality of cancer research undertaken in Australia. This would result in improved outcomes for patients, through the

[6] Carchpoole D., deFazio, A, Devereux L, Fleming M, Hof M, Schmidt C, Thourne, H, Zeps N (2007) The importance of biorepository networks: the Australian Biospecimen Network – Oncology. *Australian Journal of Medical Science*, 28(1): 16 - 20

development of more targeted cancer therapies, and would lead to economic benefits, through more targeted use of high-cost cancer medicines as well as the attraction of increased pre-clinical research dollars into Australia.

1.5.1 Higher quality research through better infrastructure

The benefits of a nationally coordinated approach to biospecimen collection and storage are:

- increased access to larger sample sizes for research
- increased researcher awareness of specimen availability
- increased quality and consistency of samples from standardised collection procedures
- increased economies of scale.

By accessing a larger pool of higher quality specimens, researchers will be able to draw more robust conclusions regarding the effectiveness of therapies in particular patient groups. This will drive benefits to the CCTGs and the broader research community in the form of:

- increased research productivity and efficiencies
- the potential to attract increased research grant funding to CCTGs
- the potential for a greater proportion of pre-clinical research to be located in Australia
- the potential to define new research directions
- more frequent publications in Tier 1 journals.

Box 1 provides two examples of how access to a larger sample of biospecimens has resulted in higher quality research activity in Australia. In the first example large number of specimens permitted the identification of a subgroup whose outcome exceeded expectations for the entire sample. A small but real difference in benefit was seen for the entire group when treated with the new drug compared to no treatment but the subgroup showed a much larger benefit, indeed the subgroup with no target had no benefit at all.

In the second example a rare tumour for which no one centre can accumulate experience was able to be studied through networking and collaboration to get a rapid answer

In both cases the clinical network is well established but more rapid biospecmen acquisition and access will transform the number and quality of such high impact studies

Box 1. Increasing research quality and productivity – the *K-ras* example

Increased publication of high-quality academic research in Tier 1 journals

Study: '*K-ras* Mutations and Benefit from Cetuximab in Advanced Colorectal Cancer' (2008), published in *The New England Journal of Medicine*

Background and method

Treatment with cetuximab, a monoclonal antibody directed against the epidermal growth factor receptor, improves overall and progression-free survival and preserves the quality of life in patients with colorectal cancer that has not responded to chemotherapy. The mutation status of the K-ras gene in the tumour may affect the response to cetuximab and have treatment-independent prognostic value.

The study analysed tumour samples, obtained from 394 of 572 patients (68.9%) with colorectal cancer who were randomly assigned to receive cetuximab plus best supportive care or best supportive care alone, to look for activating mutations in exon 2 of the K-ras gene. It assessed whether the mutation status of the K-ras gene was associated with survival in the cetuximab and supportive-care groups.

Conclusions

Patients with a colorectal tumour bearing mutated K-ras did not benefit from cetuximab, whereas patients with a tumour bearing wild-type K-ras did benefit from cetuximab. The mutation status of the K-ras gene had no influence on

survival among patients.

Involvement of biobanks

Karapetis *et al* (2008) used specimens from both Australia and Canada stored at a central tumour bank located at Queens University, Ontario. This is a Tumour/Tissue/Data bank maintained by the National Cancer Institute of Canada Clinical Trials Group Cooperative.

Increasing research productivity through increased efficiencies

Study: Denosumab Study targeting RANKL in giant cell tumor of bone *(in press)*

Background and method

Giant cell tumours (GCT) of bone is a primary osteolytic bone tumor with low metastatic potential and is associated with significant skeletal morbidity. GCT is rich in osteoclast-like giant cells and in cells that express RANK ligand, a key mediator of osteoclast activation. We investigated the potential therapeutic effect of denosumab, a fully human monoclonal antibody against RANKL, on tumor cell survival and growth in subjects with GCT.

In this single-arm, proof-of-concept study, 37 subjects with recurrent or unrespectable GCT were enrolled and received open-label, subcutaneous denosumab 120 mg monthly (q28 days), with loading doses on days 8 and 15 of month 1. The primary endpoint was tumor response, defined as elimination of ≥90% of giant cells or no radiologic progression of the target lesion for up to week 25.

Conclusion

In this proof-of-concept study, 86% of subjects with recurrent or unrespectable GCT met the response criteria with denosumab treatment. Further investigation of denosumab as a therapy for GCT is warranted.

Benefit from biobanking

The availability of appropriate biospecimens facilitated biomarker identification, and the subsequent measuring of response in this study using PET CT has enabled this work to be validated in a rapid timeframe as compared to the scenario whereby sufficient numbers of patient samples would need to be accumulated in such a relatively rare group.

Source: Karapetis, C., Khambata-Ford, S., Jonker, D, O'Callaghan, C., Tu, D., Tebbutt, N, Simes, J., Challchal, H., Shapiro, J., Robitallie, S., Price, T, Shepherd, L, Au, H., Langer, C., More, M, Zalcberg, J. (2008), 'K-ras Mutations and Benefit from Cetuximab in Advanced Colorectal Cancer', The New England Journal of Medicine, 359(17), pp 1757- 1766; Denosumab Study – in press: Correspondence with Thomas, D.

1.5.2 Patient benefits: access to more effective therapies sooner

The use of chemotherapeutic and biological agents has expanded rapidly over the past half century due to their strong contribution towards longer life expectancy and higher quality of life as well as their relative cost-effectiveness compared with other acute therapies. However their high cost has meant that there have been long delays to approval. Identifying the most sensitive subgroups with the greatest responses for the longest periods of time maximizes the cost efficacy and decreases approval time.

High rates of adverse drug reactions, poor responses by some patients, poor patient compliance and the high cost of cancer clinical trials support the need for more targeted approaches. Trials which include unselected populations are higher risk for showing only small differences and failing to identify those who will get a major benefit. Testing all of the relevant subgroups that biology might identify, requires a network of both clinicians and scientists who can effectively collaborate to move in new trial directions as they are identified in the laboratory.

Research into patient responses to high-cost cancer drugs based on their genomic profile offers the potential to radically improve the use of therapeutic agents by:

- improving the efficacy of therapies and the quality of care by targeting only the susceptible cohort
- avoiding wasted expenditure on ineffective drugs
- improving compliance through a greater risk-benefit balance.

Patients will benefit from the more rapid development of medicines (see Box 2) that are more targeted to their individual biochemistry.

Box 2. Patient benefits from better research – the K-Ras research example

Colorectal cancer, also called bowel cancer, includes cancerous growths in the colon, rectum and appendix. It is the third most common form of cancer, causing 655,000 deaths worldwide each year, and is the second leading cause of cancer-related death in the Western world.

Once diagnosed (by colonoscopy), patients are classified into one of four stages depending on how far the cancer has penetrated through the bowel wall. Stage I and II of the disease can be treated with surgery alone to remove the bowel and surrounding lymph nodes. Stage III of the disease requires surgery and additional chemotherapy to try to prevent recurrence. Widespread disease is currently treated with chemotherapy. Over the past decade significant advances in survival with newer chemotherapies have been seen both in the late advanced stages and in the application of that knowledge using adjuvant or prevention chemotherapy after surgery to higher risk earlier stages.

More recently, targeted therapies that utilise a specific understanding of the biology of the tumour under study have been trialled in addition to chemotherapy. They have been shown to enhance the effectiveness of chemotherapy both in increasing the number of patients who respond and the length of their survival.

Due to genetic variations, however, these drugs are not effective in all people. One example is the drug cetuximab. The previously described research released in 2008 (*see Box 1 – research conducted by Chris Karapetis based on research from biospemicens collected in Canada*) has shown that patients with colorectal cancer that have a mutated K-Ras biomarker will continue to provide growth signals to stimulate cancer cells in spite of using the blocking drug cetuximab as it relies on an intact signal pathway. It is estimated that 35 to 45 per cent of all patients have the mutated K-Ras and therefore will not respond to cetuximab.

The use of cetuximab in patients that have the mutated K-Ras biomarker has potentially serious health consequences for patients.

- Patients are delayed, potentially by months, from receiving alternative effective treatment, which can have very serious impacts on their survival rates. A patient taking cetuximab with the mutated K-Ras biomarker could otherwise be on a different targeted therapy bevacizumab. Its benefit is not limited by K-Ras expression and is likely to be a more appropriate treatment pathway
- At the same time, the patient is at risk of experiencing side effects from cetuximab (without receiving any benefit in terms of cancer therapy).

Source: Deloitte, 2008, Improving the Quality Use of Medicines in Australia: Realising the Potential of Pharmacogenomics, prepared for the Australian Centre for Health Research, October 2008.

1.5.3 Economic benefits: reduced expenditure on ineffective medicines

The production of high-quality, credible research has benefits for researchers, patients and the wider community. Such research has a clear link to the development of more targeted and effective therapies for patients. This in turn produces economic efficiencies by providing avenues for more cost-effective allocation of health funding to the most appropriate cancer therapy for each patient.

Taking the example of the mutated K-Ras gene again highlights the economic benefits to the community of more effective prescribing (Box 3).

Box 3. Economic benefits from better research – the K-Ras research example

From an economic perspective, expenditure is also wasted by providing patients with ineffective therapies. The drug Cetuximab is only effective in patients with an unmodified target expression that can be blocked. In 2007-08, 385 scripts for cetuximab were provided, if these had been subsidised the cost would have been more than $17 million to the government. Since between 35 and 45 per cent of patients did not possess the right target, then expenditure of between $6.1 million and $7.8 million could have been wasted.

There is a diagnostic test to identify if an individual patients tumour does express an intact pathway. It is available in the United States at US$450 and US$500 per test (2008 figures). Assuming a cost of A$500 per test, the total cost to test the 385 patients would have been $192,500 Testing patients to ensure the right medicine is used to treat patients would result in net economic savings of $5.9 to $7.6 million each year in drug costs alone.

Even more importantly, patients that have access to the test and are shown to be non-responsive may also begin treatment with alternative therapies.

Source: Deloitte, 2008, Improving the Quality Use of Medicines in Australia: Realising the Potential of Pharmacogenomics, prepared for the Australian Centre for Health Research, October 2008.

1.5.4 Economic benefits: attraction of more pre-clinical research to Australia

Australia's world class medical research base and infrastructure has been identified as a major factor contributing to Australia's competitiveness as a location for clinical trials[7] with participation in clinical trials being high by international standards, relative to population size. In 2006-07, for example, the pharmaceuticals industry invested more than $860 million in R&D in Australia (across all phases of research). The rapid increase in trial activity in our region requires a more strategic approach to maintaining and enhancing this funding stream.

Australia has an opportunity to capture a growing proportion of pre-clinical pharmaceuticals funding, which can only be achieved by academics (Clinical Trial Groups) and commercial/pharmaceutical sectors working together. Only by developing a national network of biospecimens for translational research can we significantly increase the volume of pre-clinical, translational research in Australia. It is this activity that will underpin the future of medicines development globally. Our contribution to this work can only continue if we can -

- create a unique research infrastructure that enables more effective cancer therapies to be developed in shorter timeframes
- reduce the costs of clinical trials in Australia through streamlined ethics approvals processes.

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[8].

The attraction of additional research dollars from the private sector that would have otherwise gone to another economy would be expected to increase the number of jobs in the economy and household income holding all else constant.[9]

[7] Pharmaceuticals Industry Strategy Group 2008. *Pharmaceuticals Industry Strategy Group Final Report.* December 2008.

[8] NSW Clinical Trials Business Development Centre 2009.

[9] This could be modelled, using a computable general equilibrium (CGE) model of the Australian economy, as part of a business case based on expected increases in expenditure by pharmaceutical companies. The CGE model can show the net increase in Gross Domestic Product, employment, investment and jobs as a result of new expenditure in the economy by pharmaceutical companies.

2 Developing a national approach: research objectives and method

The following chapter outlines the progress made by COSA towards developing a model for coordinating biobanking for cancer clinical trials. Deloitte's involvement in the project is described and the outcomes from discussions through this project are presented.

2.1 Research background and objectives

COSA is the peak national body representing health professionals whose main work is cancer control. Reflecting its understanding of the current barriers to nationally coordinated biobanking across CCTGs, and the potential benefits that would flow to patients, researchers and the community from a nationally coordinated approach, COSA has progressed research into the development of a national model that each of the major stakeholders in cancer clinical trials could support.

COSA formally began its research into the need for nationally coordinated biobanking and the barriers to biobanking in 2008 under the leadership of Dr Nik Zeps, Chair of the Cancer Research Group and Professor David Goldstein, past president of COSA, in partnership with the CCTGs and commercial firms involved in cancer clinical trials research.

COSA's work began in April 2008 with a short survey of CCTG biobanking activities, followed by a 1-day stakeholder workshop in October 2008. The national workshop identified the emerging need for a national coordinated approach to biospecimen collection and storage and included a discussion of the major barriers to such an approach in Australia.

Deloitte was engaged by COSA in August 2009 to help define a national model for coordinated biobanking for clinical trials, building on the work that had been undertaken in 2008.

2.2 Project methodology

The methodology undertaken by Deloitte included:

- a literature review of existing biobank infrastructure and national and international models for coordination of biobanking which concluded that adequate infrastructure already exists but is not well connected and that large scale unfocused stand alone biobanking was unlikely to be cost effective.
- an Initial Consultation Phase in which individual interviews were conducted with key stakeholders to gather their views on a preferred model for coordinated biobanking (supported by an 'Issues and Options Paper' (Appendix C) provided in advance of the consultation)

- a National Tissue Banking Forum held on 16 November 2009 (the 'Solutions Workshop') to obtain agreement on a proposed model for national coordination of biobanking with a view to informing a business case for funding.

2.3 The Initial Consultation Phase

Seventeen consultations were conducted with key stakeholders including CCTG Chairs, pathologists and other key bodies (see Appendix B).

2.3.1 Stakeholder perspectives on tissue and sample data storage options

Common views on many of the issues emerged from the consultations; these included:

- a strong preference for a 'centralised' model for sample data storage (Figure 2)
- a preference for a 'hybrid' model for tissue sample storage where existing infrastructure (biobanks) are maintained in individual states and used to collect, process and store local samples while feeding their inventory into a central repository (Figure 3).

Figure 2. Preferences, by number and strength, for different models of sample data storage

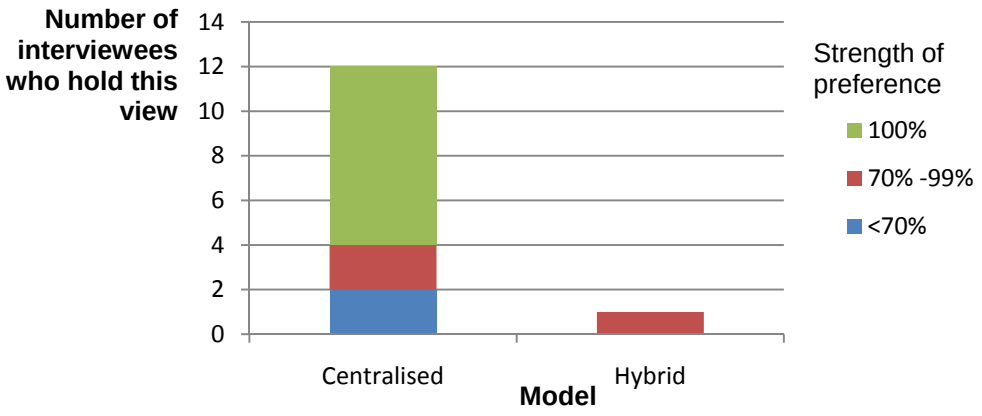
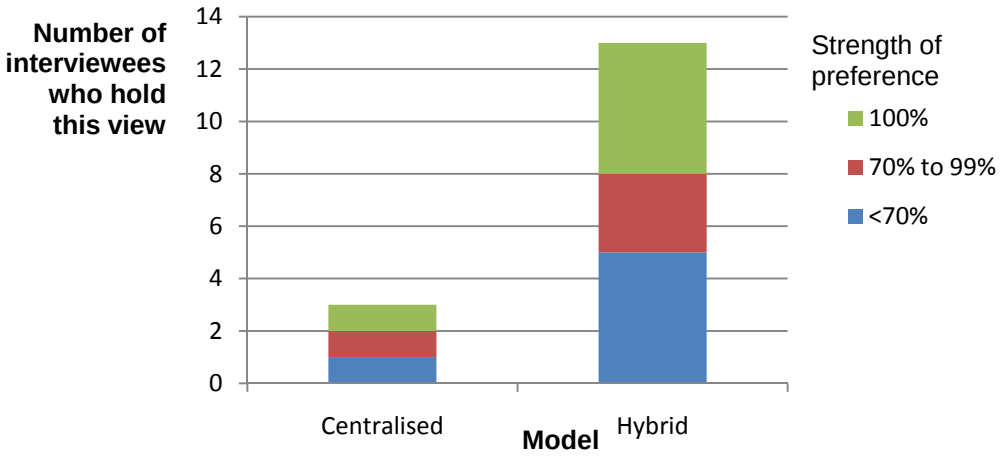


Figure 3. Preferences, by number and strength, for different models of tissue sample storage



2.3.2 Stakeholder perspectives on standardised patient consent procedures

A majority of stakeholders interviewed did not think that there would be significant barriers to creating and using a standardised patient consent form for biobanking. Key themes that emerged in relation to standardising patient consent forms are outlined below.

- Patients are generally quite amenable to signing generalised consent forms, recognising that they are benefiting from research and would like to help others as well.
- Pharmaceutical companies need to be involved to ensure that standard consent forms do not conflict significantly with their consent form requirements. Harmonising patient consent forms with key industry partners was seen as essential to avoiding unnecessary administrative costs that may act as a barrier to increased translational research activity in Australia.
- The use of standardised consent forms would be made easier following the implementation of the HoMER Model; however, there was significant uncertainty by stakeholders that mutual recognition could realistically be achieved.
- CCTGs need to be encourage to identify ways to create standardised consent form processes that can still meet their individual needs.

2.3.3 Stakeholder perspectives on standardised operating procedures for tissue collection

There was strong agreement that standardised processes for the collection of tissues and sample data needed to be implemented and funded nationally. Stakeholders reported significant variation in practice between sites, with many sites lacking training in new technologies, such as those required to collect fresh tissue.

It was emphasised that implementation of SOPs relating to tissue collection would need to have some degree of flexibility so as not to act as a barrier. For example, this may involve the specification of a ‘gold standard’ for tissue collection (collection of fresh tissue within a specified timeframe, for example) with the capacity to document where the gold standard had not been achieved (e.g., delay in freezing tissues within a specified timeframe).

2.3.4 Stakeholder perspectives on funding

Stakeholders identified a range of different funding options for each stage of cancer clinical trial biobanking, including:

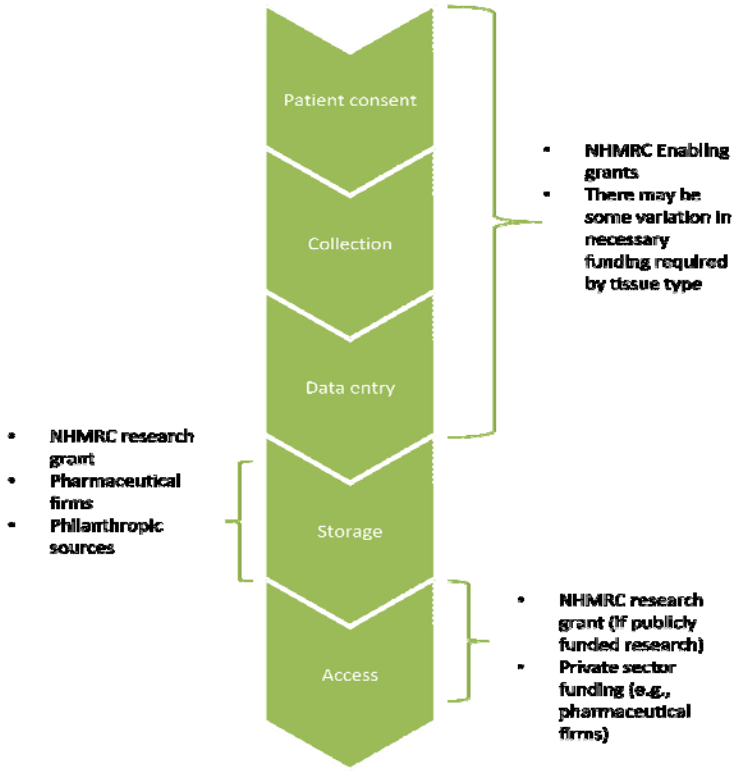
- NHMRC Enabling Grants
- NHMRC Research Grants (CCTG to build costs into grant applications)
- state and territory governments
- philanthropic sources
- pharmaceutical funding (may be subject to granting of preferential treatment of funding companies in tissue and data access terms).

The appropriate funding sources differed for each stage of banking (Figure 5). There was strong consensus that the appropriate funding sources for the collection of tissues should involve some combination of NHMRC Enabling Grants, industry and/or philanthropic sources. This view was founded on the fact that tissue collection contributes to the development of national research infrastructure that would have the potential to benefit both Australian communities and private organisations.

Stakeholders indicated that the costs of tissue storage should be funded through a mix of access charges, which researchers would be able to obtain through research grant applications, and government support. Where industry funds were used to support tissue storage facilities, it was recognised that the relevant firms would expect to obtain a reduced access charge compared with other pharmaceutical firms.

It was noted, however, that the NHMRC Enabling Grant was under review and may not be available in the future.

Figure 5. Funding options for each stage of biobanking model



2.4 The Solutions Workshop

The Solutions Workshop was attended by 29 individuals including CCTG members, other researchers, pathologists and representatives from key bodies engaged in the issues of biobanking in including existing biobanks and government agencies.

Deloitte facilitated the workshop and presented the findings from the Initial Consultation Phase together with a draft model for a national approach to biobanking in Australia.

The Recommended Model, as agreed by the Workshop participants, is presented in Chapter 3.

3 The Recommended Model

3.1 Key features of the Recommended Model

3.1.1 Objective

The Recommended Model focuses on value-adding to CCTGs by facilitating collection and access to tissue associated with cancer clinical trials while also enabling access to a larger pool of samples and sample data by the private sector and the broader research community.

3.1.2 Structure

The Recommended Model would be a 'hub and spoke' model where a 'Central Body' would support the development of and streamlined access to strategic translational research infrastructure, namely a 'virtual' national repository of biospecimens collected in cancer clinical trials and stored across an integrated network of member biobanks.

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.

3.2 Operation of the Recommended Model

The recommended approach to operation of the Recommended Model for biospecimen collection and storage agreed during the Solutions Workshop is identified below.

The Central Body would manage the national network and coordinate key activities involved in biobanking (see Table 1). The following sections describe how the Central Body would work in partnership with other bodies to deliver services at each key point of the biobanking process.

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

3.2.1 Obtaining patient consent for biospecimen collection

Standardised patient consent forms would be used to obtain patient consent. The Central Body would provide training to raise awareness and support a nationally coordinated approach to biobanking. Standardised patient consent forms would be developed in partnership with industry to ensure that the national approach maximises the potential for additional research and development by commercial stakeholders in Australia.

3.2.2 Collection of biospecimens

SOPs for biospecimen collection would be developed and distributed by the Central Body in collaboration with relevant stakeholders. Workshop participants agreed that development of national protocols should include input from both CCTGs and commercial stakeholders to maximise the potential economic benefits from increased pre-clinical research funding in Australia.

Biospecimens would be collected by existing biobanks in each state/territory as part of an integrated national network with information about available specimens held centrally. CCTG trial sites with available samples would contact the Central Body, which would locate the nearest biobank and organise for collection to be made. Biobanks would provide trained staff to visit the trial site and perform the collection in a standardised manner.

In all new clinical trials, researchers would be funded through an infrastructure enabling grant or government grant program to prospectively collect biospecimens for banking. The Central Body would also support the identification of archived tissues and sample data that could be added to the national network.

3.2.3 Data entry and storage

Data about biospecimens would be entered by pathologists at the trial site. The software used would be open-source and designed to negate any need for duplicate data entry by the pathologist. The data would be regularly and automatically uploaded to the central data server managed by the Central Body, at which point it would be cleaned and stored. The Central Body would maintain a

register of information on tissues/data that have been collected nationally. The Central Body would ensure that all member biobanks maintain an up-to-date inventory of stock to coordinate access to tissues. It was agreed that the Central Body may outsource the management of the national sample data repository.

3.2.4 Biospecimen storage

Biospecimens would be stored in the nationally integrated network of biobanks. Over time, the biobank network may develop protocols for the most efficient storage of tissues across the network, which may involve the consolidation of some tissue types at particular biobanks.

3.2.5 Access to biospecimens and sample data

CCTGs and other research groups would be able to identify what biospecimens are stored across the national network from the Central Body's website and request access to the biospecimens as needed. The Central Body would have a 'shop front' for researchers to submit their applications. CCTGs and other researchers, including industry, would be able to approach the Central Body with data and biospecimen requests. The Central Body would then conduct a search for available tissue and data.

Once the available biospecimens have been identified, the CCTG or researcher would submit a standardised ethics approval application to the Central Body. The Central Body would, if needed, assist the researcher to tailor this application for the relevant ethics committees and approach them for approval. Once approval was granted, the Central Body would arrange for the samples to be transported along with sample data to the researcher. The initial fee structure for these services would be decided upon by a Working Group to be convened by COSA, as explained below and outlined in Figure 7.

The Central Body would work with the CCTGs over time, in the context of the HoMER process, to allow for a streamlined process to be agreed. This feature was seen as integral to ensuring that the Recommended Model allows for gains from efficiencies to the research community.

3.3 Governance

During consultations it was suggested that no single organisation currently exists that could satisfactorily provide all of the functions required of the Central Body and that it may be appropriate for a partnership of existing bodies to deliver the Central Body functions.

As such, it was determined that the Central Body would be composed of several units that act together as a confederated body. The Central Body's governance arrangements would be comprised of a Board, CCTG Advisory Committee and a management team.

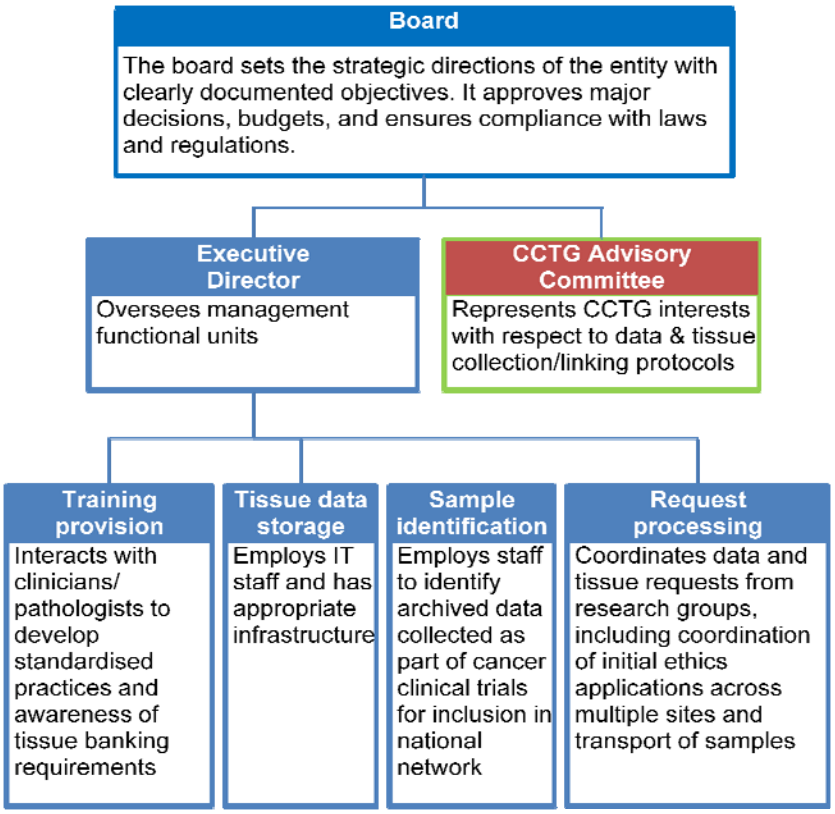
- The Board would be comprised of key stakeholders from the sector and would set the strategic direction of the organisation
- The CCTG Advisory Committee would ensure CCTG interests are represented with respect to national protocols
- An Executive Director would oversee the management of four functional units of the Central Body, providing the following services:
    - coordination of standardised procedures nationally in cancer clinical trials, including the provision of training services to standardise procedures and improve access nationally
    - identification of archived tissue and sample data that may have been collected

- hosting of centralised sample data storage, linked to an integrated national network of banked tissue samples
- a request-processing function that connects CCTGs to data/samples, including a centralised ethics approval 'shop front' which means that only one standard application needs to be made by the CCTG/researcher, with the Central body approaching individual ethics committees to obtain approval.

Provision of these services may be outsourced to another organisation on a contractual basis (e.g., an organisation with skills to host/manage the data repository, for example). Protocols and management functions for the Central Body would need to be developed in consultation with CCTG representatives, and where appropriate, industry and government stakeholders.

The structure of the proposed governance framework of the Central Body is illustrated in Figure 7.

Figure 7. Structure the proposed governance framework of the Central Body



4 The way forward

The following chapter lists the steps which were identified in the Solutions Workshop to further this project. The attributes of the Working Group that will drive progress in this project is described and a timeframe is proposed.

4.1 Next steps

The Solutions Workshop participants identified a list of key actions going forward, starting from the assembly of a Working Group through to the delivery of a business case (see Table 2).

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

Step	Agreed elements
1. Identification of 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 (see Section 4.2)
3. Formation of subcommittees	• To focus on progressing key aspects of the model requiring more detailed implementation planning, including: – Funding subcommittee: identify funding sources – Governance subcommittee: finalise governance structure of Central Body – Ethics subcommittee: work with stakeholders to progress ethics harmonisation such that there is a central 'shop front' for ethics approval procedures, including establishing procedures for streamlined access for access to clinical data within the context of the NHMRC's Harmonisation of Multi-centre Ethical Review (HoMER) process – Operations subcommittee: determine processes for the design and set up of the central data repository; determine processes for agreeing standard operating procedures, including patient consent; determine procedures and processes for storage and retrieval
4. Preparation of business case for funding	• To be progressed in parallel to other aspects of the implementation plan

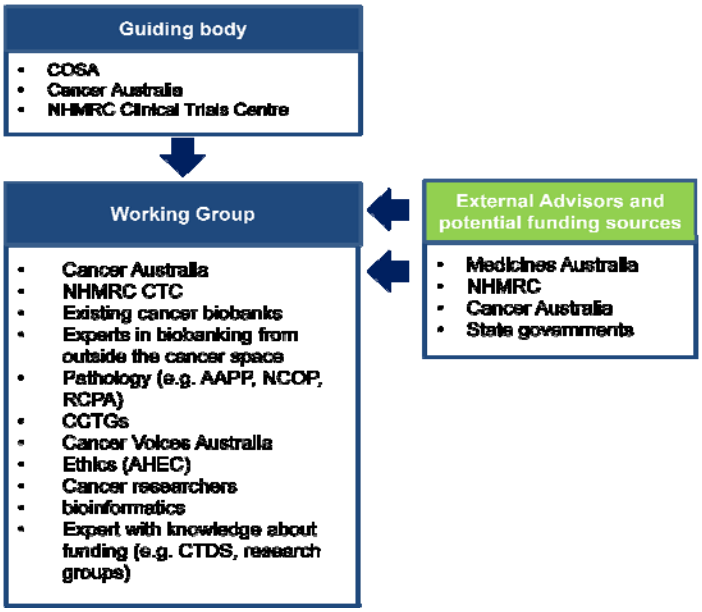
4.2 The Working Group: recommended members

At the workshop, the composition of a Working Group that would implement the Recommended Model was agreed (Figure 8).

It was seen as critical that the development of national protocols include input from both CCTGs and industry stakeholders to ensure potential economic benefits from increased pre-clinical research funding in Australia were able to be maximised. Thus the Working Group was charged with working in close partnership with key Government and industry stakeholders that may provide funding for the infrastructure and operations of the Central Body and national biobank network.

There was strong consensus that all members in the group should be prepared to work and *actively* contribute in a meaningful way to the actions going forward.

Figure 8. Proposed working group structure



4.2.1 Actions to be completed by the Working Group

The Working Group will need to put in place agendas and relevant subcommittees to design and progress the following items in the first half of the year:

1. Identify funding
2. Finalise the governance structure of Central Body including relevant subcommittees
3. Commission a business case to be developed.

In parallel, more detailed implementation planning was required, which was expected to be completed in partnership with government and industry as appropriate:

4. Determine standard operating procedures for biobanks
5. Determine standardised patient consent procedures
6. Document and communicate common dataset requirements for the network
7. Progress ethics harmonisation such that there is a central ‘shop front’ for ethics approval procedures.

4.3 Proposed timeframes

A timeframe of 1 year commencing from November 2009 was set for the completion of the tasks outlined in Table 2. It was agreed that the identification of funding sources should be completed by the first half of 2010.

It was agreed that with the right resources, steps 1 to 6 above would take at best 12 months to complete and no longer than 18 months. It was seen to be important that action commenced soon after the Solutions Workshop in order to sustain interest among key stakeholders.

Appendix A

National Tissue Bank Forum Agenda

Subject	WORKING TOWARDS A NATIONAL SOLUTIONS PAPER IN CLINICAL DATA MANAGEMENT & CANCER CONTROLS FOR CLINICAL TRIALS
Date:	Monday 16th November 2009
Time:	1.00p-4.00p
Venue	Meeting Room 4 Gold Coast Convention Centre, (Cnr Gold Coast Highway & TE Peters Drive) Broadbeach QLD 4218
Facilitators:	Duncan Buckeridge, Partner, Deloitte Melanie Kelly, Director, Deloitte
Objectives:	Review findings of consultations Gain consensus for a preferred model Develop implementation plan

Topic:	**Time**
1. Project overview: key findings of consultations & identification of the preferred model by CCTGs	1.00p-1.15p
2. Discussion of preferred model by group and agreement of broad approach to national coordination	1.15p-1.45p
Break for afternoon tea	1.45p-2.00p
3. Implementation of the national model a. Governance arrangements b. Funding sources c. Models for working with the private sector, other researchers d. Delivery roles	2.00p-3.30p
4. Confirmation of outcomes & identification of next steps	3.30p-4.00p

Appendix B

Stakeholders invited to participate in the Initial Consultation Phase

Bruce Mann	Current COSA President
Dan Thurley	Roche
David Currow	Cancer Australia
David Thomas	Australian Sarcoma Study Group
Geoff Lindeman	Victorian CBC
Glenn Francis	Royal College of Pathologists Australia
Ian Davis	ANZ Urogenital & Prostate Cancer Trials Group
John Forbes	ANZ Breast Cancer Trials Group
John Thompson	ANZ Melanoma Trial Group
John Zalcberg	Australasian Leukaemia & Lymphoma Group
Katherine McGrath	Australian Association of Pathology Practices
Katrina Vanin, Mitch Kirkman	Novartis
Lisa Devereux	Peter MacCallum
Michael Millward	Australasian Lung Trials Group
Michael Quinn	ANZ Gynaecology Oncology Group
Steve Ackland	Australian Gastrointestinal Trial Group,
Timothy Dyke	NHMRC

Appendix C

Issues and Options Paper

Consultation guide: Issues and options associated with a nationally coordinated approach to biobanking for clinical trials in Australia

15 September 2009

This paper

The Clinical Oncology Society of Australia is exploring options for a nationally coordinated approach to biobanking in cancer clinical trials. It is intended that the solution developed will be informed by the expressed needs and suggestions made by key stakeholders.

There is considerable interest in linking biological studies with cancer clinical trials and it is increasingly common for trial protocols to include a biological sub-study. Such trials have the potential to make a significant contribution to cancer care, providing the capacity for a targeted approach to treatment that is individualised to a patient's needs.

Deloitte has been engaged to conduct a series of consultations with key stakeholders to gather their views in defining the preferred options for coordinated biobanking for clinical trials. This paper sets out a structure to guide these discussions. The following sections outline key issues and options that have been previously identified; however, you are encouraged to raise topics beyond what is listed where you feel it is appropriate.

An initial background question

To begin the discussion, we would like to understand how your group operates in the absence of a coordinated approach to biobanking and how this may change following the introduction of such an approach. We are interested in understanding how a nationally coordinated approach to biobanking changes the nature of the work that you will engage in.

Considering, more broadly, cancer research in Australia, we would also like to discuss how and to what extent a nationally coordinated approach to biobanking would affect Australia's international competitiveness in research.

Issues and options associated with establishing a nationally coordinated approach to biobanking in Australia

The potential issues that may arise in establishing a nationally coordinated approach to biobanking fall into three categories:

1. Sample storage and access
2. Data storage and access
3. Standardised procedures that reduce uncertainty

To guide this discussion, we present five initial issues from these categories. Please feel free to raise issues that are not addressed below.

Theoretically, options for addressing each issue loosely fall into one of three models:

1. **Fully Centralised Model**: a central body provides storage for samples and data in a centralised location. Access to these facilities and the stored information is contingent on compliance with standards, and procedures set by the central body.

2. **Hybrid Model**: a central body coordinates the storage of samples in decentralised locations. They also act as either a central data repository or intermediary between those who store data and those who request it. They provide information on standards and procedures to increase transparency within the network.

3. **Fully Decentralised Model**: Standards and procedures are agreed upon between Clinical Cancer Trial Groups (CCTGs) and data/samples are shared through group-to-group communication.

Discussions preceding the production of this paper have suggested that either a Fully Centralised Model or a Fully Decentralised Model would be neither feasible nor optimal. For this reason, we have chosen to focus on canvassing options that exist within a broadly defined Hybrid Model

Category 1: Sample and storage access

Options	Potential benefits	Questions raised
Option 1. Central body provides information sheets and advice.	▪ Transparent process reduces uncertainty regarding sample quality ▪ Simple process may make Australia an attractive location for research projects ▪ Some uniformity through system ▪ Logistics are simpler than in fully centralised model	▪ Who will be the central body? ▪ If a central body is established, how will its activities be funded? ▪ Who will ensure that output addresses all requirements? ▪ Will the costs of implementation match or exceed benefits?
Option 2. Central information repository set up and maintained by a central body. CCTGs adhere to collection/storage requirements and submit data to virtual repository.		
Option 3. Central body organises access system to a register of those who can perform collection, processing and storage on behalf of a CCTG.		

Category 2: Data storage and access

Options	Potential benefits	Questions raised
Option 1. CCGTs maintain ownership over their own data. They are given capacity to upload their data to a central server under their name. A central body sets up and maintains the central server. Central body collects and processes standardised data requests. This approach assumes that there is a centralised data repository.	▪ Transparent process reduces administrative burden on researchers ▪ Some uniformity through system ▪ Potential for more efficient matching of data and researchers ▪ Simple process may make Australia an attractive location for research projects	▪ Who will be the central body? ▪ If a central body is established, how will its activities be funded? ▪ How easily can this model be implemented given the existing framework? ▪ Will the costs of implementation match or exceed the benefits?
Option 2. CCGTs maintain ownership over their own data. Central body acts as an intermediary between custodian of data and researcher requiring the data. This approach assumes that there is no centralised data repository.		

Option	Potential benefits	Questions raised
Central body sets up a register of information and then ensures that it is regularly maintained and updated.	▪ Transparent process reduces administrative burden on researchers ▪ Some uniformity through system ▪ Potential for more efficient matching of sample and researchers ▪ Simple process may make Australia an attractive location for research projects ▪ Logistics are simpler than in fully centralised model	▪ Who will be the central body? ▪ If a central body is established, how will its activities be funded? ▪ How easily can this model be implemented given the existing framework? ▪ Will the costs of implementation match or exceed the benefits?

Category 3: Standardisation procedures that reduce uncertainty

Option	Potential benefits	Questions raised
A central body sets out a list of necessary elements that must be covered in any information sheet and consent form.	▪ Groups will retain ability to tailor ethics forms to their own activities ▪ Some uniformity through system ▪ Simple process may make Australia an attractive location for research projects	▪ Who will be the central body? ▪ If a central body is established, how will its activities be funded? ▪ Who will ensure that output addresses all requirements? ▪ Will the costs of implementation match or exceed benefits?

Option	Potential benefits	Questions raised
A central body provides training in access and standard procedures. Clinicians opt into training programs.	▪ Increased and enhanced involvement potentially means that more samples are collected and that there will be greater use of samples ▪ Clinicians and pathologists given discretion over the extent of their involvement	▪ Who will be the central body? ▪ If a central body is established, how will its activities be funded? ▪ Will clinicians and pathologists have time to participate? ▪ Will the costs of implementation match or exceed benefits?

Appendix D

Participants in the Solutions Workshop

Albert Chetcuti	Children's Hospital Westmead Tumour Bank
Anna DeFazio	Westmead Gynae Tissue Bank
Anne Thompson	Victorian Cancer Biobank
Audrey Partenan	Wesley Research Institute QLD
Baden McMaster	National Health and Medical Research Council (NHMRC)
Candace Carter	Australia New Zealand (ANZ) Melanoma Trial Group
David Currow	Cancer Australia
David Goldstein	Australian Gastrointestinal Trial Group/COSA
David Thomas	Australian Sarcoma Study Group
Glenn Francis	Royal College of Pathologists of Australasia
Heather Thorne	kConFab, Peter Mac
Ian Davis	ANZ Urogenital & Prostate Cancer Trials Group
Jane Carpenter	National Breast Cancer Centre Tissue Bank
John Forbes	ANZ Breast Cancer Trials Group
John Seymour	ANZ Melanoma Trial Group
John Zalcberg	Australian Gastrointestinal Trial Group
Judith Clements	Australian Prostate Cancer Bioresource
Katherine McGrath	Australian Association of Pathology
Kerrie McDonald	Australian Brain Tumour Bank
Lisa Devereux	Peter MacCallum Cancer Institute
Megan Ellis	Australasian Leukaemia & Lymphoma Group
Michael Quinn	Australasian Lung Trials Group
Nik Zeps	Australian Gastrointestinal Trial Group, COSA
Paula Marlton	Australian Gastrointestinal Trial Group, COSA
Peter Downie	Australasian Leukaemia & Lymphoma Group
Sandro Porceddu	ANZ Children's Haematology & Oncology Group
Scott Williams	Trans Tasman Radiation Oncology Group
Sonia Yip	NHMRC Clinical Trials Centre
Steve Ackland	Enabling Grant Chair, COSA