Tissue Banking for Cancer Clinical Trials

Clinical Oncological Society of Australia (COSA)

Stamford Hotel, Sydney Airport 24 October 2008
Summary report

Workshop report prepared by Alison Evans Consulting on behalf of COSA
December 2008

Workshop supported by unrestricted educational grants from Roche Products Pty Limited (Australia) (Gold Sponsor) and Novartis Pharmaceuticals Australia (Silver Sponsor)
BACKGROUND

Cancer clinical trials are research studies that test whether new or modified approaches to the prevention, diagnosis or treatment of cancer are safe and effective. Some trials may also explore aspects of supportive care such as quality of life.

Biological studies involve correlation of clinical outcomes with markers that predict response to treatment or that have prognostic value through analysis of tissue or blood samples. In addition, such studies can provide information about markers of underlying disease, such as serum markers used to detect occult malignancy in apparently disease-free patients. Such 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.

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. In many cases a biological question is already included as part of the trial, particularly in studies exploring combination use of ‘biological’ agents and conventional chemotherapy or radiation. 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.

Examples of biological studies with therapeutic relevance for cancer include:

- the development of therapies targeting HER2-positive breast cancer
- recent data about the influence of K-ras mutation status on response to cetuximab in advanced colorectal cancer.¹

COOPERATIVE CLINICAL TRIALS GROUPS

There are currently 13 Cooperative Cancer Clinical Trials Groups (CCTGs) in Australia (see Appendix I). These trials groups receive funding from a variety of sources including:

- National Health and Medical Research Council (NHMRC) Enabling Grants awarded through the Clinical Oncological Society of Australia (COSA)
- Cancer Australia’s Priority-driven Collaborative Cancer Research Scheme
- funding obtained through trial activity itself (mixture of philanthropic donations, competitive grants and industry support).

Trials overseen by these groups vary in size and complexity but are typically multicentre studies recruiting patients in several states and territories and in some cases New Zealand and other countries. Some studies are multinational, and these may be managed centrally by an overseas collaborating group or by the Australian CCTG.

CURRENT STATUS OF BIOBANKING IN AUSTRALIA

Biobanking of specimens from patients enrolled in cancer clinical trials in Australia is currently undertaken predominantly by the pharmaceutical industry. Most of this activity
involves collection of blood samples for pharmacogenomic\(^1\) or pharmacogenetic research\(^2\) conducted exclusively by/for the sponsor company, with specimens and data often sent overseas for analysis. While some CCTGs have been actively involved in biobanking, each group typically collects specimens only for a particular trial and there is currently no standardised or systematic approach to biobanking for multisite clinical trials.

Tumour biobanks have been established at many sites in Australia (see Appendix II). A number of these have started to work cooperatively – most notably the seven biobanks involved with the Australasian Biospecimen Network – Oncology (ABN), the National Leukaemia and Lymphoma Tissue Bank (NLLTB), the Breast Cancer Biospecimen Resource, the Australian Prostate Cancer Collaboration (APCC) BioResource, the Victorian Cancer Biobank (VCB), kConFab and the Australian Ovarian Cancer Study (AOCS).

These cooperatives are funded from a variety of sources, including competitive grants, State government and philanthropic donations. Funds are used not only for costs associated with specimen collection and storage, such as salaries and consumables, but also for the development of standard operating procedures to ensure consistency and quality assurance, and, in some cases, for database design, web-based cataloguing of specimens and education.

Tissue banks linked to cancer clinical trials clearly have a vital and growing role in improving patient outcomes, maintaining Australia’s international standing in medical research and enabling Australia to remain a country of choice for clinical trial conduct in an increasingly competitive international market.

COSA is ideally placed to facilitate a collaborative and coordinated approach to biobanking of specimens collected as part of cancer clinical trials conducted by CCTGs in Australia. A 1-day workshop of key stakeholders held in October 2008 represented an important first step in standardising and rationalising approaches and identifying future needs.

---

\(^1\)The study of the human genome to identify genes involved in the mechanism of action or metabolism of drugs

\(^2\)The study of a limited number of genes involved in the mechanism of action or metabolism of drugs
WORKSHOP OVERVIEW

COSA convened a 1-day workshop in October 2008 with the aim of exploring a coordinated approach to the collection, storage and efficient utilisation of clinical trial specimens as well as appropriate mechanisms for funding tissue banking and access within the CCTGs in Australia. The workshop program is provided as Appendix III.

The workshop was attended by 50 participants from biobanks, CCTGs and cancer registries as well as consumers and representatives from relevant cancer organisations such as Cancer Australia (see Appendix IV).

WORKSHOP INTRODUCTION

Professor David Goldstein, President of COSA, welcomed participants and highlighted the need for practical and collective strategies to enhance the relationship between cancer clinical trials and the collection, storage and distribution of tissue in Australia.

The workshop facilitator, Professor Ian Olver, CEO of the Cancer Council Australia, asked participants to focus particularly on the role that COSA could take in facilitating tissue banking for trials conducted by the CCTGs. He emphasised the importance of achievable outcomes that build on existing initiatives and avoid duplication of effort.

SUMMARY OF PRESENTATIONS

The workshop opened with a series of presentations providing context for the later group discussions. A brief outline of the key points covered in each presentation is provided below.

The statistical considerations

Professor John Simes (Director, NHMRC Clinical Trials Centre, University of Sydney) and Dr Chee Lee (Researcher, NHMRC Clinical Trials Centre, University of Sydney)

Professor Simes and Dr Lee described the importance of both prognostic and predictive biomarkers in defining therapeutic choices in order to ensure individualised treatment and avoid under or over treatment.

- A **prognostic marker** is a single trait or signature of traits that separates different populations with respect to the risk of an outcome of interest in absence of treatment or despite non targeted ‘standard’ treatment (identifies who needs treatment).

- A **predictive marker**: a single trait or signature of traits that separates different populations with respect to the outcome of interest in response to a particular (targeted) treatment (identifies which treatment is best).

The presenters highlighted key statistical considerations to be factored into the design of trials examining biomarkers, including:

- the potential impact of cancer heterogeneity on clinical trial outcomes if not accounted for in the trial design
- the importance of selecting the appropriate trial design based on the clinical question(s)
- the risks associated with discovery-based research and the potential for generating results by chance when using multivariate models.

The strengths and limitations of a number of different trial designs were described.

- **Enrichment design**: used when there is strong biological evidence that treatment efficacy is limited to biomarker-positive populations. This design has the benefit of
requiring only a small number of randomised patients because those who are unlikely
to benefit from treatment are excluded from the trial. However, this design only
establishes treatment effectiveness in a specific subgroup of patients and requires an
adequate definition of ‘positive’ and ‘negative’ and a validated method of biomarker
testing.

- **Unselected design**: used when the biological basis for selecting biomarker-positive
  patients is less than compelling. In such studies, both biomarker-positive and
  negative patients are included in the trial, with stratification used to test hypotheses in
  biomarker-positive and negative populations. This design permits testing of the utility
  of treatment and the biomarker test but requires a large sample size and adequate
  power calculations from the outset.

- **Retrospective design**: uses pre-existing randomised controlled trial data and
  archived tissue specimens to compare treatments for which a biomarker is proposed
to be predictive. This design has the benefit of being time and cost effective but
  requires the availability of adequate and representative archived specimens and the
  development of a prospective analysis plan prior to performing assays to avoid
  spurious outcomes.

Given the benefits of both prospective and retrospective studies, the presenters
recommended that tissue and blood collection is included as part of every trial protocol and
that patient consent includes the potential to use stored samples to test hypotheses that can
be validated in future trials.

**The importance of tissue banking in clinical trials**

**Professor Paul Waring** *(Professor of Pathology and Laboratory Medicine, University of
Western Australia)*

Professor Waring presented data from major US pharmaceutical companies illustrating the
escalating costs of drug development and the associated decline in new drug approvals over
the past 25 years. Noting the need for increased efficiency in the drug development process,
Professor Waring identified the following strategic imperatives for cancer clinical research in
relation to tissue banking:

- identify those indications in which the tumour is truly dependent upon the targeted
  pathway (indication selection)

- determine in phase I and II studies whether there is drug-induced modulation of the
  target pathway in the tumour (pharmacodynamic markers)

- choose the right patients for phase III trials using biomarkers that predict therapeutic
  benefit (prospective patient selection)

- ensure that each study is designed and powered to identify a responder subset in the
  event the trial fails in ‘all comers’ (retrospective subset analysis)

- understand the mechanism of primary and secondary resistance to help guide the
development of second-generation drugs (drug-resistance mechanism).

Professor Waring added to the previous presentation, describing the logistical and regulatory
implications of different trial designs, including:

- **prospective tumour biomarker validation** – may represent an accelerated path to
  regulatory approval but disincentives include enrolment delays, uncertainty about the
  biomarker’s predictive value and requirement for a validated assay to be available
  prior to commencement of the study
• **retrospective studies** – overcome enrolment delays but represent an uncertain route to regulatory approval, are dependent on prior approval for use of specimens for unspecified exploratory research and may be limited by the number and quality of available samples.

He described the following barriers to the conduct of biomarker studies:

- **lack of incentives** for pathology laboratories to provide archived samples from clinical trial participants
- **sub-optimal processing** of diagnostic samples for biomarker studies, precluding their use for pharmacodynamic biomarker studies and limiting predictive biomarker development
- **use of inappropriate samples** for validation and testing of biomarkers – for example use of diagnostic samples from primary tumours rather than the metastatic tumour being treated.

In closing, Professor Waring used an example from the US to illustrate the benefits of collaboration between diagnostic companies and cooperative tissue banks, with the generation of a validated and commercially available prognostic test for breast cancer.

**Overview of ALLG clinical trial collection**

*Dr Paula Marlton (Head of Leukaemia and Lymphoma Services, Princess Alexandra Hospital, QLD)*

Dr Marlton presented an overview of the development of the National Leukaemia and Lymphoma Tissue Bank, which was launched in 2002 following 3 years of planning. Dr Marlton indicated that philanthropic, funding together with a NHMRC Enabling Grant, has facilitated an increase in staffing and a steady increase in tissue sample activity. In 2007–2008, the Tissue Bank provided samples for 13 research studies in Australia and overseas, with an additional study currently under consideration.

Tissue requests, and strategic and policy decisions are made by a Tissue Bank Management Committee comprising investigators from the NHMRC Enabling Grant, representatives from each state, and a consumer representative. Key staffing roles include a Tissue Bank Manager, Tissue Bank Research Scientist, Tissue Bank Scientist, Sample Coordinator and Administrative support. An automated robot has recently been purchased to assist with extraction processes.

Dr Marlton described a number of new and proposed strategic initiatives for the Tissue Bank, including:

- a plan to include routine tissue banking as part of all ALLG trials (opt-out process)
- targeting of regional centres to encourage and support the conduct of research and participation in tissue banking
- approaches to collaboration and linkage, including other trial centres, paediatric trial groups and the Australian Biospecimen Network
- logistical initiatives, including development of a web-interfaced database to facilitate national access to information about specimen availability, improved integration with clinical trial data and development of minimum data sets for non-trial samples
- pro-active marketing of the availability of samples and tendering of priority-driven projects
- new approaches to sample collection, including collection of matched normal tissue, familial cancer samples and transplant donor recipient collections.
While providing an excellent example of what can be achieved through a strategic approach to planning and development, Dr Marlton’s presentation also highlighted the importance of long-term funding to ensure sustainability, particularly given the minimal income generated through cost-recovery from Tissue Bank activities.

**An update on current tissue banking in Australia**

*Ms Heather Thorne (kConFab Manager, Peter MacCallum Cancer Centre)*

Ms Thorne summarised the current status of tissue banking in Australia, describing the large number of oncology tissue banks across the country and the high degree of cooperation and collaboration that exists between them (see Appendix II). She summarised current guidelines and legislation that guides the collection and distribution of tissue samples as outlined below.

- **NHMRC National Statement on Ethical Conduct in Research Involving Humans** (developed in 1999 and updated in 2007): provides guidelines for researchers, Human Research Ethics Committees and Institutions for the ethical conduct of human research. There are specific sections on Tissue banks (Section 3.4) as well as genetic research (3.5) and Clinical Trials (3.3). In addition Sections 2.2 and 2.3 deal with general principles of consent.

- **Privacy Act (Commonwealth (1988) and Private (2001), which include Health Privacy Principles**: provide standards for the collection, handling and disposal of health information in Commonwealth and private domains at national level. Some States have enacted their own Privacy Acts, which operate alongside the federal legislation and fill the gap left by the Commonwealth and private acts not addressing state and territory public institutions.

Ms Thorne stated that there is currently no unified process for obtaining patient consent or ethics approval for multisite studies run in different states and territories involving the collection of biological specimens.

Other issues highlighted included the need for:

- improvements in database design and data linkage
- increased involvement of biobanks in clinical trials to facilitate translational oncology research
- greater unification to maximise use of funds and avoid duplication of effort
- consideration of commercial aspects and appropriate approaches for liaison with industry
- strategies to limit the bureaucratic load on the system that can delay the conduct of trials.

**Review of NSW tissue banks**

*Dr Parisa Glass (Research & Information Advisor, Cancer Institute NSW)*

Dr Glass described outcomes from a review of tissue banks in NSW undertaken by the Cancer Institute NSW with a view to consolidating effort, increasing access and improving the quality and consistency of specimens. Through a survey of 150 contacts across NSW, 17 formalised biobanks have been identified to date covering a range of tumour types. The majority of the biobanks identified combine multiple collection sites with single storage facilities. Common issues identified through the review included the inadequacy of funding to support tissue banks, and the lack of consistency in reporting and measures of success.
Barriers to specimen access identified by Dr Glass included:

- the dispersed nature of biobanks and specimen locations
- lack of a central register that would allow researchers to locate specimens or a single scientific advisory committee for submission of applications to access samples from multiple sites
- requirement by HREC for details of ethics approvals of biobanks to which the researcher is applying
- inadequacy of research funding to cover costs associated with biospecimen access other than freight costs.

Enablers to specimen access identified by Dr Glass included:

- a central register of specimen locations, ideally grouped by cancer type
- streamlined approval process for ethics at researcher institution and for scientific advisory committee approval and access to specimens at housing institutions
- minimising the costs associated with biospecimen access, unless covered by the grant.

Dr Glass summarised a range of issues to be considered as part of strategies to improve coordination and consistency of tissue banking, including governance issues, development of standard operating procedures, consent and ethics issues, approaches to funding and cost recovery and marketing strategies.

Potential models for clinical trials collections

Dr Nik Zeps (Research Manager, St John of God Pathology and Radiation Oncology, Sir Charles Gairdner Hospital; incoming Chair of the COSA Research Group)

Dr Zeps presented a range of questions and issues for consideration by workshop participants in relation to the role COSA could play in facilitating a more streamlined, uniform and cost-effective approach to tissue banking for oncology clinical trials conducted by the CCTGs in Australia.

Questions identified included:

- who should coordinate and run tissue banks (CCTGs/subcontractors)?
- what questions should be considered by the Trial Management Committee in relation to a biological study:
  - which samples and how should they be processed (issues for tissue/blood/DNA)?
  - who should collect samples (centralised or distributed)?
  - who should store/manage samples (how can access be improved)?
- what roles could COSA play in facilitating new approaches:
  - clearinghouse/information role (register of tissue banks/register of specimens/links to relevant protocols)?
  - tendering role?
  - facilitating partnerships/collaborations/linkages (RCPA/tissue banks/clinicians/researchers)?
• quality assurance role?
  • what are the potential barriers?
  • what are the likely costs and how can funds be sought?
  • what are the measures of success?

These questions provided a foundation for subsequent small group discussion in the remainder of the workshop.
WORKSHOP OUTCOMES

Participants were asked to consider four issues in relation to tissue banking for CCTGs in Australia:

1. minimum data elements
2. standardised consent/ethics
3. collection and storage of samples
4. distribution of samples and sustainability.

Issues and recommendations were identified through discussion by four self-appointed multidisciplinary groups. Time limitations precluded a full consensus approach and the outcomes reported below summarise key outcomes reported back to the plenary group.

All groups recognised the importance of avoiding duplication and building on existing national and international initiatives.

Minimum data elements for a tissue bank linked to cancer clinical trials

The minimum data elements identified for a tissue bank linked to cancer clinical trials related to demographic identification of the trial and specimen, with specific data elements identified for the trial and the specimen itself.

<table>
<thead>
<tr>
<th>Minimum data elements for the trial*</th>
<th>Minimum data elements for the specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary questions for the tissue sub-study</td>
<td>Trial name/identifier</td>
</tr>
<tr>
<td>Contact details of the trial group/principal investigator</td>
<td>Patient identifier</td>
</tr>
<tr>
<td>Type of specimen collected (as defined by the trial protocol)</td>
<td>Tumour type</td>
</tr>
<tr>
<td>Type of consent (generic or specific to the trial)</td>
<td>Type of tissue (tumour, blood, plasma, serum, DNA etc)</td>
</tr>
<tr>
<td>Potential availability for collaborative research (Y/N/qualified)</td>
<td>Collection method (fresh, frozen, paraffin-embedded etc)</td>
</tr>
<tr>
<td></td>
<td>Date of collection</td>
</tr>
<tr>
<td></td>
<td>Storage location</td>
</tr>
<tr>
<td></td>
<td>Type of consent</td>
</tr>
</tbody>
</table>

*To be based on the World Health Organisation minimum data set for clinical trials³

Standardised consent/ethics

Current issues identified in relation to consent and ethics approval for the collection and storage of tissue samples as part of cancer clinical trials included the need for:

- increased awareness and application of national guidelines for consent and ethics such as those developed by the Australian Health Ethics Committee (AHEC)² and issued by the NHMRC as well as the Harmonisation of Multi-centre Ethical Review (HoMER) project⁴
- public engagement about the benefits of tissue collection and the importance of information collected from specimens held in biobanks.
It was suggested that the ultimate goal in Australia should be to obtain consent for the collection and storage of tissue samples for the purposes of research from all patients at the point of diagnosis. One possibility would be an opt-out rather than an opt-in policy and would ideally include storage of samples for germ line sampling and assessment of somatic mutations. However, there are major health consumer concerns with such an approach and much would need to be done to gain wide acceptability. The need for a streamlined, efficient process that could be applied beyond cancer was identified.

Questions to be considered in developing a standardised approach to consent included:

- timing of obtaining consent (at diagnosis vs on entry to the clinical trial)
- who should obtain consent
- process for informing the patient or family members about the implications of the information obtained from sample analysis
- implications of use of tissue after death
- sampling considerations (for example, collection of normal tissue, blood samples and relapse tissue).

Possible roles for COSA in facilitating a standardised approach to consent and ethics included:

- lobbying for legislation around the process of consent for tissue banking (while raised as an option there was some debate about whether such an approach is appropriate)
- liaison with the Royal College of Pathologists of Australasia (RCPA)
- undertaking a review of international and national consent procedures
- development of common guidelines, templates and procedures
- public engagement about the altruistic benefits of tissue collection and storage.

Collection and storage of samples

The following obstacles to the collection and storage of tissue samples by CCTGs were identified:

- lack of pathology contact before trial initiation
- lack of standardisation in approaches to sampling and storage
- lack of financial incentives for pathologists to be involved in the collection, storage and release to third parties of tissue for research purposes
- quality issues associated with different sampling approaches – eg difficulties associated with obtaining frozen samples and limitations of paraffin-embedded samples
- lack of awareness by funders and policy makers of the complexities of tissue collection and storage.

Possible solutions to encourage a consistent approach to storage of tissue samples included:

- greater involvement of pathology from the trial outset, including inclusion of a pathologist on Trial Management Committees and, where possible at each participating site, and subsequent scientific acknowledgement of pathology input
• consideration of reimbursement options for pathologists involved in tissue sampling, including the option of a Medicare item number for collection and preparation of tissue by pathologists for the purposes of research
• pre-definition of a biological or translational research question with a clinical trial that has a clear clinical objective to promote clinician engagement and encourage the collection of a sufficient quantity of tissue of appropriate quality for testing
• creation of a virtual network to allow samples to be collected and stored locally but accessed nationally
• standard collection of a second block of tissue to be stored locally for future studies (aspirational goal).

Possible roles identified for COSA included:
• collaboration with the RCPA to centralise coordination of pathology input
• collaboration with appropriate partners to lobby government for a Medicare number to reimburse pathologists for collection of tissue for research purposes
• tendering for activities to support localised collection and storage of tissue samples.

Distribution of samples
The heterogeneity of existing tissue banks was identified as a key issue in limiting the distribution of tissue samples for the purposes of clinical research. It was suggested that additional tissue samples collected in relation to a specific clinical trial should be quarantined from translational research samples. Such clinical trial samples should remain under the governance of the Trial Management Committee. In contrast, access to ‘open collection’ samples for biomarker discovery, pre-clinical studies and translational research should be managed by the respective tissue bank.

The sustainability of tissue banks was considered to be dependent on:
• international best practice\(^5\) and standard operating procedures
• database management and clinical linkages
• long-term funding through a range of avenues, including federal and state government, grants and philanthropic groups
• amalgamation of consortiums to maximise efforts.

The potential role of COSA in advocating for funding was discussed.

OPPORTUNITIES FOR FUNDING
A range of potential sources of funding were identified to support the collection, storage and distribution of tissue for oncology clinical trials and translational research in Australia.

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government/government bodies</td>
<td>• Enabling grants/infrastructure grants (eg NHMRC, Cancer Australia)</td>
</tr>
<tr>
<td></td>
<td>• Tax revenue</td>
</tr>
<tr>
<td></td>
<td>• Medicare items for sample collection</td>
</tr>
<tr>
<td>Trial sponsors/commercial entities</td>
<td>• Pharmaceutical companies</td>
</tr>
<tr>
<td></td>
<td>• Health instrument/consumable suppliers</td>
</tr>
<tr>
<td>Category</td>
<td>Examples</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Philanthropic donations</td>
<td>• Banks</td>
</tr>
<tr>
<td></td>
<td>• Health insurance companies</td>
</tr>
<tr>
<td></td>
<td>• Disease-specific charitable foundations (eg Leukaemia Foundation)</td>
</tr>
<tr>
<td>Non-government organisations</td>
<td>• Cancer Councils</td>
</tr>
<tr>
<td></td>
<td>• Australian Cancer Research Foundation</td>
</tr>
<tr>
<td>Overseas funding sources</td>
<td>• National Institutes of Health (USA)</td>
</tr>
<tr>
<td></td>
<td>• National Cancer Institute (USA)</td>
</tr>
<tr>
<td></td>
<td>• Department of Defence (USA)</td>
</tr>
<tr>
<td>Other potential sources</td>
<td>• Private hospital associations</td>
</tr>
</tbody>
</table>

Questions to be considered in relation to funding of tissue banks included:

- who should receive funding – clinical investigators/tissue bank groups/research scientists/health departments/hospitals?
- who ‘owns’ the tissue/specimen?
- what is the long-term cost-effectiveness of targeted approaches to cancer treatment developed through analysis of biomarkers?

Options to be considered in ensuring long-term sustainability included:

- embedding value-added research in clinical trials and making clinical questions more cost-effective
- exploring the potential for commercial opportunities/partnerships (eg providing new pathology services to measure known biomarkers)
- prioritisation of translational research involving tissue banks, with priority given to collections from randomised controlled trials with linked high-quality clinical data that allow analysis of prognostic and predictive markers
- centralisation, standardisation and linking of approaches and knowledge to improve efficiency and maximise use of available funds
- conduct of a national audit of existing biobanks and processes to build and learn from existing initiatives
- consideration of cost-efficiencies in shared approaches to infrastructure
- engagement of consumer advocacy groups such as Cancer Voices Australia to assist in lobbying for change.

Specific actions to be considered by COSA in moving forward included:

- joint submission with the RCPA to government in relation to the creation of a Medicare item number for preparation of specimens for the purposes of research
- coordination of a committee to seek a 5-year funding grant from the Australian Cancer Research Foundation to support a tissue bank coordinating centre
- exploration of options for 7-year renewable funding for cancer clinical trial tissue banking
- building on the existing NHMRC enabling grant to facilitate new initiatives
• commissioning of an analysis of the cost-effectiveness of tissue banking activities, in partnership with the pharmaceutical industry and/or Pharmaceutical Benefits Advisory Committee
• appointment of a project officer to assist in building a business case and identifying and engaging relevant stakeholders
• consideration of approaches to capture and promote the international value of the Australian situation to international bodies such as the Wellcome Foundation.

WHERE TO FROM HERE?

Professor David Goldstein (President, COSA)

In closing, Professor Goldstein thanked the sponsors, speakers, participants, facilitator and Working Group members for their interest and participation. He outlined the following priorities for action:

• development of a health economic model to support the need for tissue banking
• scoping activities to identify options for tissue banking linked to cancer clinical trials and map existing initiatives
• identification and pursuit of potential funding sources.

Professor Goldstein indicated COSA’s commitment to building a business case for tissue banking linked to cancer clinical trials in Australia. COSA will employ a project officer to oversee commissioned projects and ensure that identified goals are achieved. He emphasised the importance of the meeting in setting a solid foundation and direction for future activities to guide a consolidated approach to tissue banking in Australia and encouraged ongoing dialogue and collaboration to facilitate progress in this important area.
ACKNOWLEDGEMENTS

The workshop was sponsored by unrestricted educational grants from Roche Products Pty. Ltd. (Australia) (Gold Sponsor) and Novartis Pharmaceuticals Australia (Silver Sponsor).

COSA gratefully acknowledges the input and support of the workshop facilitator, Professor Ian Olver, and the members of the Workshop Steering Committee:

- Professor David Goldstein (Chair)
- Professor Stephen Ackland
- Dr Anna deFazio
- Dr Anne Thompson
- Ms Heather Thorne
- Dr Nik Zeps
- Dr David Roder
- Margaret McJannett
- Kathy Ansell.

COSA would also like to thank the workshop presenters Professor John Simes, Dr Chee Lee, Dr Paul Waring, Dr Paula Marlton, Dr Heather Thorne, Dr Parisa Glass and Dr Nik Zeps.

The workshop report was developed by Dr Alison Evans from Alison Evans Consulting.
REFERENCES AND FURTHER READING


USEFUL WEBSITES

Australian Health Ethics Committee

Australian Government Health Privacy Principles

State and Territory Privacy Laws

International Society for Biological and Environmental Repositories
http://www.isber.org/

NHMRC Enabling Grants
APPENDIX I: COOPERATIVE CLINICAL TRIALS GROUPS IN AUSTRALIA

- Australia and New Zealand Melanoma Trials Group (ANZMTG) [http://www.anzmtg.org/](http://www.anzmtg.org/)
- Australian New Zealand Breast Cancer Trials Group (ANZBCTG) [http://www.anzbctg.org/](http://www.anzbctg.org/)
- Australian Prostate and Urogenital Cancer Group (APUG)
- Co-operative Trial Group for Neuro-Oncology (COGNO)
- Australia Sarcoma Study Group (ASSG).
<table>
<thead>
<tr>
<th>Title of project and granting agencies</th>
<th>Institute and participating sites</th>
</tr>
</thead>
</table>
| National Leukaemia and Lymphoma Tissue Bank (NLLTB) | Princess Alexandra Hospital with member sites:  
• Royal Melbourne Hospital  
• Mater Newcastle  
• Concord Hospital  
• Geelong Hospital  
• St Vincent’s Sydney  
• Nepean Hospital  
• Box Hill Hospital  
• Westmead Hospital  
• Mater Brisbane  
• Adelaide Hospital  
• Gosford Hospital  
• Canberra Hospital  
• Adelaide Hospital |
| Funding: NHMRC, Pricewaterhouse Cooper Foundation and the Leukaemia Foundation |  |
| Australian Ovarian Cancer Study: A multidisciplinary ovarian cancer resource for the genomic era | Peter MacCallum Cancer Centre  
• QIMR Royal Brisbane Hospital  
• Westmead Hospital  
• University of Melbourne  
• 21 Australian public and private hospital collection sites |
| Funding: US Department of Defence, NHMRC and state Cancer Councils. |  |
| kConFab - Kathleen Cuningham Foundation Consortium for Research into Familial Breast Cancer | Peter MacCallum Cancer Centre  
• QIMR Royal Brisbane Hospital  
• 32 Australian/NZ public hospitals and research institutions. |
| Funding: NHMRC and NBCF |  |
| The Western Australian DNA Bank *Not exclusively an oncology bank* | University of Western Australia |
| Funding: NHMRC |  |
| Australasian Biospecimen Network – Oncology (ABN) | Member banks:  
• Peter MacCallum Cancer Centre Tissue Bank  
• Gynaecological Oncology Tissue Bank, Westmead Hospital  
• kConFab, Peter MacCallum Cancer Centre  
• Australian Mesothelioma Tissue Bank, Perth  
• Western Australian Research Tissue Network, Perth  
• The Children’s Hospital at Westmead Tumour Bank  
• QIMR Royal Brisbane Hospital Cell Line Bank |
| Funding: NHMRC, state Cancer Councils/Institutes/Department of Health Services & philanthropic organisations, National Breast Cancer Foundation and local infrastructure funds |  |
### Title of project and granting agencies

**Breast Cancer Biospecimen Resource**

Funding: NHMRC, National Breast Cancer Foundation and Cancer Institute NSW

Institute and participating sites:
- The University of Sydney/Westmead Hospital with members sites:
  - Westmead Millennium Institute
  - Garvan Institute
  - Kolling Institute
  - Hunter Medical Research Institute
  - NSW Breast Cancer Institute
  - Newcastle Mater Hospital
  - Prince of Wales Hospital
  - Royal Prince Alfred
  - St Vincent’s Hospital
  - Australia New Zealand Breast Cancer Trials Group

**Australian Prostate Cancer Collaboration (APCC) BioResource**

Funding: NHMRC, Commonwealth Bank, Andrology Australia and the Prostate Cancer Foundation of Australia

Institute and participating sites:
- Queensland Institute of Technology and member sites:
  - Hanson Institute of Medical Research
  - Queensland University of Technology
  - Monash Medical Centre Melbourne
  - St Vincent's Hospital
  - Garvan Institute
  - Prince of Wales Hospital
  - Royal Prince Alfred Hospital Sydney

### Biobanks supported by non-NHMRC Enabling Grants

**The Australian Melanoma family and population consortia’s**

Funding: NHMRC, Cancer Councils in NSW, Qld and Vic, National Institutes of Health (USA)

Institute and participating sites:
- Queensland Institute for Medical Research and Westmead Hospital

**The Australian Breast Cancer Family Study (ABCFS)**

Funding: NHMRC, VicHealth, Cancer Council NSW and the National Institutes of Health (USA)

Institute and participating sites:
- The University of Melbourne

**Victorian Cancer Biobank (VCB)**

Funding: Cancer Council Victoria and the Victorian Government

Institute and participating sites:
- The Cancer Council of Victoria (lead agency)
- The Austin Hospital
- The Peter MacCallum Tissue Bank
- Melbourne Health Tissue Bank
- Southern Health Tissue Bank
- Plus 14 hospitals
<table>
<thead>
<tr>
<th>Title of project and granting agencies</th>
<th>Institute and participating sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Wesley Tissue Bank, Brisbane</td>
<td>• Wesley Hospital, Brisbane</td>
</tr>
<tr>
<td>Funding: Queensland Government</td>
<td></td>
</tr>
<tr>
<td>The Royal Prince Alfred Hospital Prince Sydney</td>
<td>• Sydney Breast Cancer Institute</td>
</tr>
<tr>
<td>Funding: In house</td>
<td>• Royal Prince Alfred Hospital, Sydney</td>
</tr>
<tr>
<td>The Royal Children’s Hospital Paediatric Tumour Bank Brisbane</td>
<td>• The Royal Children’s Hospital</td>
</tr>
<tr>
<td>Funding: In house and philanthropic</td>
<td></td>
</tr>
<tr>
<td>Kolling Institute Sydney Tumour Bank</td>
<td>• Kolling Institute Sydney</td>
</tr>
<tr>
<td>Funding: NHMRC, Cure Cancer Australia, Ramaciotti Foundation, Northern Sydney Health, Sydney University</td>
<td></td>
</tr>
<tr>
<td>Prince of Wales Hospital (formerly St Vincent’s Hospital Sydney)</td>
<td>• St Vincent’s Hospital Sydney</td>
</tr>
</tbody>
</table>
### APPENDIX III: WORKSHOP AGENDA

COSA Tissue Banking Forum  
Meeting the needs for clinical trials research  
Friday 24 October 2008  
Stamford Hotel, Sydney airport  
Facilitator: Professor Ian Olver, CEO, Cancer Council Australia

<table>
<thead>
<tr>
<th>Time</th>
<th>Session title</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:50</td>
<td>Welcome &amp; Introduction</td>
<td>Professor David Goldstein</td>
</tr>
<tr>
<td>09:00</td>
<td>Forum Objectives</td>
<td>Professor Ian Olver</td>
</tr>
<tr>
<td>09:10</td>
<td>The statistical considerations</td>
<td>Professor John Simes Dr Chee Lee</td>
</tr>
<tr>
<td>09:30</td>
<td>The importance of tissue banking in clinical trials</td>
<td>Professor Paul Waring</td>
</tr>
<tr>
<td>09:45</td>
<td>Overview of ALLG clinical trial collection</td>
<td>Dr Paula Marlton</td>
</tr>
<tr>
<td>10:00</td>
<td>An update on current tissue banking in Australia.</td>
<td>Ms Heather Thorne</td>
</tr>
<tr>
<td>10:15</td>
<td>Review of NSW Tissue Banks.</td>
<td>Dr Parisa Glass</td>
</tr>
<tr>
<td>10:20</td>
<td>MORNING TEA</td>
<td></td>
</tr>
<tr>
<td>10:35</td>
<td>Potential models for clinical trials collections</td>
<td>Dr Nik Zeps</td>
</tr>
<tr>
<td>10:50</td>
<td>Round table discussions on models for clinical trials collection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• minimum data elements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• standardised consent/ethics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• storage of samples (i.e. where)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• distribution of samples (who decides- i.e. governance) sustainability</td>
<td></td>
</tr>
<tr>
<td>12:15</td>
<td>LUNCH</td>
<td></td>
</tr>
<tr>
<td>13:00</td>
<td>Presentation of round table outcome</td>
<td></td>
</tr>
<tr>
<td>13:30</td>
<td>Opportunities for funding and how to go forward</td>
<td></td>
</tr>
<tr>
<td>14:30</td>
<td>BREAK</td>
<td></td>
</tr>
<tr>
<td>14:45</td>
<td>Presentations from round table discussions</td>
<td></td>
</tr>
<tr>
<td>15:30</td>
<td>Review of outcomes and recommendations</td>
<td>Professor Ian Olver</td>
</tr>
<tr>
<td>15:45</td>
<td>Where to from here?</td>
<td>Professor David Goldstein</td>
</tr>
<tr>
<td>16:00</td>
<td>MEETING CLOSE</td>
<td></td>
</tr>
</tbody>
</table>
# APPENDIX IV: LIST OF ATTENDEES

<table>
<thead>
<tr>
<th>Name</th>
<th>Discipline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Steve Ackland</td>
<td>Hunter New England Health Area Director of Clinical Cancer Research, NSW</td>
</tr>
<tr>
<td>Ms Kathy Ansell</td>
<td>Project Officer, COSA</td>
</tr>
<tr>
<td>Clinical Associate Professor Michael Bilous</td>
<td>Institute of Clinical Pathology &amp; Medical Research, University of Sydney, NSW</td>
</tr>
<tr>
<td>Associate Professor Fran Boyle</td>
<td>Director, Patricia Ritchie Centre, Mater Hospital, and Associate Professor of Medical Oncology, University of Sydney, NSW; representing ANZBCTG.</td>
</tr>
<tr>
<td>Ms Candace Carter</td>
<td>Melanoma Tumour Bank, Sydney University</td>
</tr>
<tr>
<td>Dr Daniel Catchpole</td>
<td>Head, Tumour Bank, Oncology Research Unit, The Children's Hospital, Westmead Hospital, NSW</td>
</tr>
<tr>
<td>Professor Christine Clarke</td>
<td>Department of Medicine, University of Sydney and NHMRC</td>
</tr>
<tr>
<td>Professor Judith Clements</td>
<td>Head of Hormone Dependent Cancer Program, Queensland University of Technology</td>
</tr>
<tr>
<td>Dr Michelle Cummins</td>
<td>Trial Coordinator, NHMRC Clinical Trials Centre</td>
</tr>
<tr>
<td>Professor David Currow</td>
<td>CEO Cancer Australia</td>
</tr>
<tr>
<td>Dr Anna deFazio</td>
<td>Senior Clinical Lecturer, Department of Obstetrics and Gynaecology, University of Sydney, and Director, Gynaecological Oncology Research Group, Westmead Institute for Cancer Research, NSW</td>
</tr>
<tr>
<td>Ms Lisa Devereux</td>
<td>Research Manager, Research Division, Peter MacCallum Cancer Centre, Vic</td>
</tr>
<tr>
<td>Professor Peter Downie</td>
<td>Royal Childrens Hospital, Melbourne, Vic; representing ANZCHOG</td>
</tr>
<tr>
<td>Dr Alison Evans</td>
<td>Alison Evans Consulting (report writer)</td>
</tr>
<tr>
<td>Professor Stephen Fox</td>
<td>Director Anatomical Pathology, Peter MacCallum Cancer Centre, Vic</td>
</tr>
<tr>
<td>Dr Parisa Glass</td>
<td>Research &amp; Information Advisor, Cancer Institute NSW</td>
</tr>
<tr>
<td>Professor David Goldstein</td>
<td>President COSA; Medical Oncologist, Prince of Wales Hospital, NSW</td>
</tr>
<tr>
<td>Professor Nick Hawkins</td>
<td>Pathologist, School of Medical Sciences, University of New South Wales, NSW</td>
</tr>
<tr>
<td>Associate Professor Joy Ho</td>
<td>Institute of Haematology, Royal Prince Alfred Hospital, Sydney, NSW; Chair of Laboratory Sciences Committee of ALLG</td>
</tr>
<tr>
<td>Associate Professor David Horsfall</td>
<td>National Project Manager, Australian Prostate Cancer BioResource and South Australia Oncology Tissue Bank, SA</td>
</tr>
<tr>
<td>Name</td>
<td>Discipline</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ms Amber Johns</td>
<td>Clinical Research Coordinator, Pancreatic Cancer, Garvan Institute, NSW</td>
</tr>
<tr>
<td>Dr Chee Lee</td>
<td>Medical Oncologist and Researcher, NHMRC Clinical Trials Centre, NSW</td>
</tr>
<tr>
<td>Dr Geoff Lindeman</td>
<td>Molecular Genetics of Cancer Division, Walter &amp; Eliza Hall Institute of Medical Research, Vic</td>
</tr>
<tr>
<td>Dr Marian Macnish</td>
<td>Manager, Western Australia DNA Bank, (WAIMR), WA</td>
</tr>
<tr>
<td>Dr Paula Marlton</td>
<td>Head of Leukaemia and Lymphoma Services at the Princess Alexandra Hospital, QLD; representing ALLG</td>
</tr>
<tr>
<td>Ms Kerrie McDonald</td>
<td>Cerebral Tumour Research Group, Kolling Institute, NSW</td>
</tr>
<tr>
<td>Ms Margaret McJannett</td>
<td>Executive Officer, COSA</td>
</tr>
<tr>
<td>Ms Wendy-Jane Murray</td>
<td>Tissue Bank Manager, Wesley Research Institute, QLD</td>
</tr>
<tr>
<td>Dr Paul Jelfs</td>
<td>Assistant Statistician, Social Analysis and Reporting Branch, Australian Bureau of Statistics, ACT</td>
</tr>
<tr>
<td>Associate Professor James Kench</td>
<td>Department of Anatomical Pathology, Royal Prince Alfred Hospital, Sydney, NSW</td>
</tr>
<tr>
<td>Professor Soon Lee</td>
<td>Chair of Pathology, University of Western Sydney and Royal Prince Alfred Hospital, NSW</td>
</tr>
<tr>
<td>Dr Huw Lewellyn</td>
<td>ACT Pathology; representative of National Cancer Data Strategies, ACT</td>
</tr>
<tr>
<td>Professor Ian Olver</td>
<td>CEO, Cancer Council Australia (meeting facilitator)</td>
</tr>
<tr>
<td>Professor Lyle Palmer</td>
<td>Director, Centre for Genetic Epidemiology and Biostatistics, University of Western Australia, WA</td>
</tr>
<tr>
<td>Dr Nick Pavlakis</td>
<td>Medical Oncologist, Royal North Shore Hospital, NSW; representing ALTG</td>
</tr>
<tr>
<td>Ms Rosemary Radovan</td>
<td>Account Manager, NSW Roche, Ventana</td>
</tr>
<tr>
<td>Associate Professor Danny Rischin</td>
<td>Medical Oncologist, Peter MacCallum Cancer Centre; representing ANZGOG</td>
</tr>
<tr>
<td>Ms Rachel Rowntree</td>
<td>Novartis</td>
</tr>
<tr>
<td>Professor Pamela Russell</td>
<td>Director, Oncology Research Centre, Prince of Wales Hospital, NSW</td>
</tr>
<tr>
<td>Professor John Simes</td>
<td>Director, NHMRC Clinical Trials Centre, NSW</td>
</tr>
<tr>
<td>Professor Bernard Stewart</td>
<td>Department Head, Cancer Control Program, South East Sydney Area Health Service Public Health Unit; outgoing Chair, COSA Research Professionals Group</td>
</tr>
<tr>
<td>Mr John Stubbs</td>
<td>Executive Officer, Cancer Voices Australia</td>
</tr>
<tr>
<td>Dr Ann Thompson</td>
<td>Executive Officer, Victorian Cancer BioBank, Vic</td>
</tr>
<tr>
<td>Ms Heather Thorne</td>
<td>kConFab Manager, Peter MacCallum Cancer Centre, Vic</td>
</tr>
<tr>
<td>Mr Dan Thurley</td>
<td>Associate Medical Director, Roche Products Pty Ltd</td>
</tr>
<tr>
<td>Name</td>
<td>Discipline</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ms Nadia Traficante</td>
<td>Project Manager, Australian Ovarian Cancer Study, Peter MacCallum Cancer Centre, Vic</td>
</tr>
<tr>
<td>Dr Katrina Vanin</td>
<td>Medical Scientific Liaison-Oncology, Novartis</td>
</tr>
<tr>
<td>Ms Alex Walther</td>
<td>Research Support Office, Prince of Wales Hospital, NSW</td>
</tr>
<tr>
<td>Professor Paul Waring</td>
<td>Dean, Pathology and Laboratory Medicine, University of Western Australia, WA</td>
</tr>
<tr>
<td>Dr Scott Williams</td>
<td>Researcher; representing APUG</td>
</tr>
<tr>
<td>Professor John Zalcberg</td>
<td>Director, Division of Haematology and Medical Oncology, Peter MacCallum Cancer Centre, Vic; representing AGITG</td>
</tr>
<tr>
<td>Dr Nik Zeps</td>
<td>Research Manager, St John of God Pathology and Radiation Oncology, Sir Charles Gairdner Hospital, WA; incoming Chair, COSA Research Professionals Group</td>
</tr>
</tbody>
</table>