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CASE FOR ACTION- PROPOSAL TO NHMRC

Post market surveillance and research into new cancer therapies

Cancer treatments are expensive. Do the cancer treatments we give work as they should?

Authors:

Professor David Roder
Professor Kwun Fong
Professor Michael Brown
Professor Michael Barton
Professor John Zalcberg
Professor Helen Zorbas
Professor Gail Risbridger
Associate Professor Mary Haines
Professor Richard Kefford

Submitted by the Research Translation Faculty Cancer Control Steering Group (September 2014)

CANCER CONTROL

The National Health and Medical Research Council (NHMRC) Research Translation Faculty (the Faculty) was established as a key advisory forum in 2012. The primary work of the Faculty for the 2013-15 Triennium has been to help NHMRC accelerate the translation of research by identifying the most significant gaps between research evidence and health policy and practice in each of the major health areas in the NHMRC Strategic Plan, and to propose to NHMRC possible action it could consider taking to address that gap – these are called Cases for Action. In April and May 2013, fourteen Faculty steering groups were established as NHMRC working committees to each oversee the development of a Case for Action.

The Faculty's Cancer Control Steering Group is comprised of a range of experts and includes primary (1˚) and secondary (2˚) representatives of NHMRC Health Care Committee (HCC), Prevention and Community Health Committee (PCHC) and Research Committee (RC). Further information is available at: www.nhmrc.gov.au/research/research-translation/research-translation-faculty/research-translation-faculty-steering-groups.

NHMRC Research Translation Faculty Cancer Control Steering Group - Membership

Professor Kwun Fong (Chair)

Professor David Roder (PCHC 1˚)

Professor Michael Brown

Professor Michael Barton

Professor John Zalcberg

Professor Helen Zorbas (HCC 1˚)

Professor Gail Risbridger

Associate Professor Mary Haines

Professor Richard Kefford

Professor Warren Alexander (RC)

Professor Guy Maddern (HCC 1˚)

Professor Melanie Wakefield (PCHC 2˚)

Research Translation Faculty Steering Group Secretariat

faculty@nhmrc.gov.au

Declaration of interests

The declarations of interests of Steering Group members, authors and contributors are available at Appendix 1.

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NHMRC Research Translation Faculty

Cancer Control Steering Group Case for Action

Title: Post market surveillance and research into new cancer therapies. *Cancer treatments are expensive. Do the cancer treatments we give work as they should.*

Submitted to NHMRC for consideration: September 2014

Steering Group Members:

Name	Position/Affiliation
Prof Kwun Fong (Chair)	Thoracic and Sleep Physician, University of Queensland Thoracic Research Centre, Prince Charles Hospital
Prof Michael Barton	Professor of Radiation Oncology, University of New South Wales, Research Director Collaboration for Cancer Outcomes Research and Evaluation, Ingham Institute for Applied Medical Research
Prof Michael Brown	Director, Cancer Clinical Trials Unit, Royal Adelaide Hospital Cancer Centre, Centre for Cancer Biology, SA Pathology and University of South Australia, Discipline of Medicine, University of Adelaide
A/Prof Mary Haines	Director Strategic Research Investment, Cancer Institute NSW
Prof Richard Kefford	Professor of Cancer Medicine, Macquarie University, Sydney
Prof Gail Risbridger	Prostate Cancer Research Program, Deputy Dean Strategic Projects, MCCC Research Director Monash University
Prof John Zalcberg	Professor of Cancer Research, Monash University
Prof Warren Alexander (RC contact)	Joint Head, Division of Cancer and Haematology, The Walter and Eliza Hall Institute of Medical Research
Prof David Roder (PCHC contact)	Chair of Cancer Epidemiology and Population Health, University of South Australia
Prof Helen Zorbas (HCC contact)	Chief Executive Officer, Cancer Australia
Prof Guy Maddern (HCC contact)	RP Jepson Professor of Surgery, Clinical Director Surgical Services, Central Adelaide Local Health Network
Prof Melanie Wakefield (PCHC secondary contact)	Director of Centre for Behavioural Research in Cancer, Cancer Council Victoria

RC-Research Committee; HCC-Health Care Committee; PCHC-Prevention and Community Health Committee

Authors (Positions and affiliations as described above):

Prof David Roder
Prof Kwun Fong (Chair)
Prof Michael Brown
Prof Michael Barton
Prof John Zalcberg
Prof Helen Zorbas
Prof Gail Risbridger
A/Prof Mary Haines
Prof Richard Kefford

RESEARCH TRANSLATION FACULTY

CANCER CONTROL STEERING GROUP

Case for Action

Post market surveillance and research into new cancer therapies

Cancer treatments are expensive.

Do the cancer treatments we give work as they should?

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Abstract

Australia's health system is challenged by rapidly rising costs and competing, growing demands from its' people. The 2014 *Australia's Health* report found that chronic diseases including cancer were the leading cause of illness, disability and death in Australia, accounting for 90 per cent of all deaths in 2011.

Costs of cancer services are increasing markedly in Australia due to population growth and ageing, increased survivals of cancer patients who still require ongoing monitoring and care, and the advent of new and expensive pharmaceuticals.

Case complexity is increasing as increasing proportions of cases present in the older age groups where there is often frailty and multiple co-morbidities. The translation of clinical trial evidence from the younger healthier patients generally included in trials to the older patients presenting in routine health service environments is uncertain. Side effects of treatment in these older patients and in the longer term are difficult to predict.

The ***Case for Action*** is to promote a data system for post market surveillance that will indicate whether new treatments are being used as intended, whether anticipated benefits are occurring, and the prevalence of side effects. This will enable health authorities to evaluate outcomes and direct limited health resources so as to maximize health benefits and efficiency. Most of the required data already exist but are scattered across multiple databases.

The proposal is to link these data together using well-established privacy-protecting mechanisms.

Australia has the skills, the experience, the data linkage facilities and the governance structures to integrate these data for post marketing surveillance in the public interest. It is proposed that this be done to help learn how we can best afford to continue to deliver quality cancer care for the 1 in 2 males and 1 in 3 females who will be diagnosed with cancer before their 85th birthday.

A. Evidence-practice gap and rationale for action:

General background:

Australian health expenditure on cancer and other neoplasms, excluding national screening programs, was $4.5 billion in 2008-9.[1]This expenditure had been increasing annually (e.g., by almost 6% annually in 2008-09 prices in 2000-5). Approximately $540 million were spent on cancer prescription pharmaceuticals in 2008-9.[1]

Despite this expenditure, Australian research has shown an under-utilization of systemic therapies for optimal cancer outcomes.[2] If this were rectified, health outcome improvements would be expected but pharmaceutical expenditure likely would increase. A recent NSW study indicated that 51% of cancer cases overall should receive chemotherapy for optimal effect, based on the best scientific evidence available.[2] By comparison, studies show that much lower utilizations have applied (e.g., between 29% and 49% by NSW Area Health Service in 1999).[2] Unfortunately recent population-based chemotherapy data are lacking, limiting opportunities to identify national trends and sub-groups of the population with the largest deficits who may warrant special targeting.

Attempts are being made to increase chemotherapy utilization in Australia through promotion of evidence-based guidelines and protocols, [3,4] and by increasing service access through newly established regional treatment centres.[5] Unfortunately the success of these initiatives cannot be assessed adequately due to the lack of population-based data on chemotherapy utilization. [27,28]

Cancer therapy is imposing a large and growing burden on the health budget. Over 340,000 Australians are now living with a recent cancer diagnosis (i.e., within 5 years) (non-melanoma skin cancer excluded) and most of these cases would require ongoing medical attention.[6]This number is increasing rapidly due to population growth and ageing. In the 20 years to 2010, numbers of new cancers diagnosed per annum increased by 85%, mostly due to demographic change.[7]For people aged 75 years or more, the increase was 102%.[7] Cancer deaths also increased, by 97% in this older age range.[7] These trends are expected to continue over the next 30 years, with numbers of cancer diagnoses projected to increase 2-3 times faster than population growth, due to ageing.[7, 8] Corresponding numbers of cancer deaths are projected to increase 3-4 times faster than population growth.[7, 8]

Apart from increases in numbers of cancers, cancer case complexity is also expected to rise due to the increase in proportion of cancers affecting the aged.[9] Age is associated with greater frailty and co-morbidity which can complicate care.[9] Treatment outcomes are also more uncertain because of a lack of direct scientific evidence of effectiveness (note: clinical trial evidence generally comes from younger healthier subjects and may not be relevant to many older patients).[10] Managing older patients is further complicated by an increasing plethora of treatment options, many of which have not been directly compared. The inability to determine relative impacts of these treatments in the Australian health service delivery environment, due to a

lack of comparative effectiveness testing,[11] increases the reliance that must be placed on conjecture and guess work in decision making, rather than evidence.

This lack of evidence is especially important, given the rapid introduction of new expensive treatments. Numbers of cancer survivors are increasing, many of whom would require ongoing care.[12] Research is increasing survivals through breakthroughs in molecular biology, genetics, immunology and other basic and clinical sciences. Survivals are also increasing through screening, earlier diagnoses from advances in imaging and other diagnostic technologies, and from better therapeutic outcomes in response to health system improvements. Thirty years ago, 40% of Australian cancer patients survived their cancers 10 years or more, but over 60% of today's patients do so.[12] Survival is increasing, both from time of initial diagnosis and subsequent to cancer recurrence, due to therapeutic advances.[12, 13] These trends contribute to longevity but they also bring cost pressures as people live longer with their cancers and often are in need of further novel therapies to counter clinical side effects and to combat recurrent cancer.

Measuring the impact of modern cancer interventions:

Australia needs to manage its limited health resources for cancer control carefully, given cost pressures. It needs evidence of treatment effectiveness, cost-effectiveness and population reach and impact to do this. Pharmaceutical and other industries are investing heavily in R&D to produce new products and the demand for access to new chemical and physical treatment entities will increase over time. This will increase claims for listing on the MBS/PBS. MSAC and PBAC will receive increasing numbers of commercial applications. They will base their decisions on the front-end research evidence available to them on comparative safety, effectiveness and cost-effectiveness, [14] but subsequent data on "real-world" outcomes following service applications, and the appropriateness or otherwise of these service applications, will also be important.

Post marketing surveillance:

The relevance to assessing new drugs of tracking outcomes in service settings is exemplified by a recent melanoma example. In this instance, the PBAC negotiated with the manufacturer entry of a high-cost novel melanoma immunotherapy drug, ipilimumab, onto the PBS.[15]The agreement included collection of basic demographic and staging data together with prospective 1 and 2 year survival data to enable comparison of trial-based outcomes used for drug approval with subsequent 'real-world' outcomes. This mechanism, which is likely to be applied to other such drugs, is a useful model for managing cost pressures of high-cost oncology drugs but it needs to be supplemented with data on longer term outcomes and late effects from linked cancer registry and administrative data.

The potential role for data integration for cancer outcome evaluation:

Linked data will be a powerful tool to help understand clinical management practices across the population in order to estimate likely uptake of new products, associated costs and population benefits.[16] Much of these data already exist in Australia but they are difficult to assemble and integrate due to their dispersion across agencies and barriers to data flow both within and across jurisdictions.[16] Australia's federated structure has served to disperse data governance and control, which has complicated data integration. Yet Australia has the skills and newly developed data linkage facilities and governance structures to undertake this integration. [17-20]Many data linkage precedents now exist as "proof of concept".[16, 19, 20]

Data linkage/integration facilities exist at both a State/Territory and Commonwealth level with histories of effective operation of up to 18 years.[17, 18] Remote data access facilities exist such that data can be accessed and analyzed in secure environments without release of unit record files to researchers, thereby maximizing data security.[21] Well established privacy protecting linkage protocols exist that are supported by Commonwealth and State/Territory privacy bodies and the Australian Health Ethics Committee. [16-18]

In summary: monitoring data will be important following the introduction of new products, to compare their use against the use intended, to determine whether expected health benefits are occurring, and to assess whether there are unexpected side effects (especially in the longer term). Post-market surveillance and research are fundamentally important for showing the outcomes of research translation that underpin product development and therapeutic advances. Without data for this purpose, there is inadequate feedback and accountability, and there are not the data to guide corrective action for inappropriate use of new therapies or unexpected side effects, nor indeed the data that may identify additional benefits not necessarily appreciated at the time of approval by the regulator or health technology assessment agency.

Other outputs:

The present proposal addresses evidence needs for control of cancer, which is a National Health Priority area. It also aligns with other components of the 2013-5 NHMRC Strategic Plan. [22] In the cancer area:

- It will provide evidence on the equitable use of new and expensive pharmaceuticals by socially disadvantaged groups, such as Aboriginal and Torres Strait Islander populations who experience particularly poor cancer treatment outcomes, lower socioeconomic groups, and rural and remote populations who live at some distance from specialist centres.
- It will provide real-world evidence of the effectiveness of new and expensive pharmaceuticals produced through the "omics" revolution and other new technologies.

- It aligns with NHMRC directions in improving the care of patients with multiple and complex chronic diseases (where cancer is one of these diseases).
- It will enable evidence-based decision-making post marketing of relevance for all cancer cases treated with designated therapies, but this evidence will have added value for older patients and other sub-groups poorly represented in clinical trials where the pre-marketing evidence is "thinner". Evidence from trials is generally acknowledged to be the "gold standard" but relevance of this evidence to elderly cases is often uncertain, especially for those with significant concurrent illnesses. The proposed data model will provide fundamentally important ancillary evidence to trial data.
- The piloted model is expected to be an exemplar for cancer control but may also have relevance for post marketing surveillance strategies in other fields of medicine.

In summary: The proposed data model will be fundamentally important for post-marketing surveillance and research into the use and outcomes of new cancer therapies. It would also have broader health monitoring and population health, health services and clinical research applications. Decisions on governance arrangements would be a matter for the Department of Health and other relevant authorities to decide, but the AIHW could well be custodian of the linked cancer database, supported by a steering committee of relevant stakeholders.

B. Proposed action:

What it is:

The action is for Australia to develop, maintain and operate a dynamic de-identified linked database as an information technology solution: for post market surveillance of new cancer therapies; for providing data feedback on therapy utilization across the population, outcomes and side-effects (including late effects); and for research into the use and outcomes of these new therapies. The proposed data will be of central importance for comparative effectiveness research which is so critical for defining the role of new drugs or devices in complex treatment algorithms. It is clearly a legitimate NHMRC research interest as the data would have a broad range of population health, health-service and clinical research applications, in addition to ongoing health monitoring functions.

Initially a pilot project is proposed to test the feasibility of this model for the follow-up of nominated targeted therapies (including new therapies requiring co-dependent assessment by MSAC and PBAC). The therapy or therapies for inclusion in the pilot will be chosen as part of the proposed methodology. Potentially one high-cost cancer drug could be chosen in the first instance.

Enablers and barriers:

A key enabler is promotion by Cancer Australia of: (1) the collection of cancer stage and potentially allied prognostic indicators by cancer registries for national purposes; and (2) the linking of these data with treatment and recurrence data.[23] The present proposal will act in tandem with the Cancer Australia initiative and strengthen considerably the data available for post-marketing surveillance of targeted pharmaceuticals.

Other enablers include the establishment of national data integration authorities (i.e., at the AIHW & ABS) with established legally and ethically approved linkage processes for undertaking linkage work. State/Territory based data linkage systems also exist that could contribute.[17, 18, 24, 25]There is Commonwealth support for analyzing linked data, ethically compiled through data linkage of this type, by remote access through the SURE system. [Secure Unified Research Environment].[21] There is also support from Commonwealth policies that encourage the use of publicly funded registry and administrative data for the public good, as reflected in the Australian Public Service Big Data Strategy.[26]

The proposal is feasible in that the source data exist, together with the data linkage/integration facilities to link data extracts from these sources together.[16] Privacy-protecting linkage protocols are well-established and are now an accepted means for undertaking this work.[16] The following data sources would be relevant:

- Australian Cancer Database (ACD): this covers the Australian population. It needs augmentation with stage and related prognostic data. This is being addressed through the Cancer Australia initiative, which

in turn is being facilitated by the extension of structured pathology reporting by RCPA. The ACD can provide the data spine around which other data can be linked to create the surveillance database.

- PBS/MBS data: these data cover services funded through Medicare. Relevant data extracts would be linked to ACD extracts.

  For example, valuable data is visible from routine PBS and MBS claims for cancer targeted therapies, eg for EGFR testing and mutation directed therapy; MBS item 73337 is claimed for "A test of tumour tissue from a patient diagnosed with non-small cell lung cancer, shown to have non-squamous histology or histology not otherwise specified, requested by, or on behalf of, a specialist or consultant physician, to determine if the requirements relating to epidermal growth factor receptor (EGFR) gene status for access to erlotinib or gefitinib under the Pharmaceutical Benefits Scheme (PBS) are fulfilled."

  EGFR TKI Erlotinib PBS approval :- Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC). The treatment must be as monotherapy, AND Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, AND Patient must not have progressive disease. Population criteria: Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

- DVA data: these data cover services funded through the Department of Veterans' Affairs. Again, relevant data extracts will be linked to ACD extracts.

- Australian hospital inpatient data: these include treatment statistics on surgery types and in-hospital provisions of systemic therapies. Relevant extracts will be linked to the ACD data spine. Probabilistic linkage without names may be needed initially, depending on data access, but use of named data would be more accurate for establishing the linkge keys. Hospital inpatient data will also be used with PBS data to develop co-morbidity indices, implementing NZ methodologies as a platform [Safarti D, et al.].

- Population-based radiotherapy data: these data are available, or can be rapidly obtained from modern radiotherapy machines. Data on radiotherapy type, fractions, doses, and target sites would be linked to the ACD, plus thinner MBS data on the fact of radiotherapy and dates.

It should be noted that "proof of concept" has already been achieved for each of these data linkage processes at jurisdictional level, although prior to the recent development of a cross-jurisdictional data linkage/integration mechanism, the work was piecemeal due to impediments to cross-jurisdictional data flow.

As part of the pilot we will attempt to evaluate the opportunity cost of not having any information on the net benefit or safety of these drugs when used in the real world post regulatory approval and funded following the HTA process.

Similar linked data, to those proposed here, but excluding MBS/PBS data, exist in a number of jurisdictions. In some instances, specialized clinical cancer registries/databases are imbedded in these linked systems to provide data of high quality for "drill down" investigation of sub-sets of cases. In the longer term,

this could be part of the proposed linkage system of data for post-marketing surveillance and research. These specialized clinical data could focus on priority issues (e.g., the use and outcomes of high-cost chemotherapies).

Potential barriers to this proposal may include:

- A lack of support from data custodian organizations, depending on their work programs, policies and priorities.
- Possible privacy concerns. The proposal would entail the use of privacy-protecting data linkage which is well established in Australia for developing de-identified datasets for analysis.[16] These matters will be discussed at workshops with data custodians and other custodians.

NHMRC role:

This would be to:

1. Recommend to the Commonwealth that the feasibility and value of this post marketing surveillance strategy be tested at a national level.
2. Establish a multidisciplinary group, including involvement from the Commonwealth Department of Health, for work-shopping the linked cancer treatment-outcomes data paradigm, focusing on a targeted therapy as the test therapy. Stakeholders included in the workshop would include the AIHW, AACR, MSAC, PBAC, TGA, DHA, ANZCR, CV and CHF.
3. Provide administrative support (e.g., HR, meeting, and travel support) for the workgroup to undertake its work.
4. Establish a timeline to develop a value proposal for the pilot model in response to the workshop (e.g., 6 months).
5. Undertake focus group assessments of the value of a proposed model to end-users, industry and consumers and confirm the focus of the pilot (e.g., whether all cancers with targeted agents, the top 10 cancers, or other targets). It would be important to involve the Commonwealth Department of Health in this process.
6. Invite the Commonwealth Department of Health to develop a business case for the establishment and maintenance of the proposed surveillance test system.
7. Identify funds for a 3-5 year pilot study, including an end of project audit to identify feasibility and barriers to future broader implementation across all cancer treatment modalities and ultimately extension to other disease groups.

8. Obtain national buy-in/approval via AHMAC auspicing of meetings.

9. Oversee governance and administration.

C. Impact of action:

Health-related outcomes:

This proposal will enable: informed post-marketing surveillance; research into uptake of new therapies, appropriateness of uptakes, and survival and other outcomes of uptake; identification of side effects of new therapies, including late effects (through data linkage); and better informed health administrations. Feasibility and utility of this surveillance system will be tested in the proposed pilot.

Number of people affected:

All Australians with cancer who receive designated new cancer therapies would be included in a fully developed monitoring system, plus other cases as comparators.

Economic impact:

We cannot quantify this impact exactly but potentially it would be very large, given the opportunities to positively influence the directions of large investments in drugs in Australia.

Time frame:

Up to five years to establish and test data utility.

Evaluation:

This would be process evaluation. Example questions would include: Did the processes work? What would be the utility of the data model for addressing key research questions and for ongoing surveillance?

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Cancer Control Case for Action - Declarations of Interests

The declarations of interests of Steering Group members, authors and contributors to this Case for Action are listed below.

Name and Role(s)	Interest(s) declared
Prof Kwun Fong • Steering Group Chair • Author	**Relationships** • Research Collaborations (University of Queensland, QIMR Berghofer Medical Research Institute, and others) • Medical Services Advisory Committee (MSAC) and its Protocol Advisory Sub-Committee (PASC) and Evaluation Sub-Committee (ESC) • Lung Foundation Australia • Collaborations - Cancer Australia • Member, Medical and Scientific Advisory Committee, Cancer Council QLD. **Consultancy fees/honorarium** • Honorariums for marking thesis, editorials, reviewing grant applications. **Grants** • Awarded competitive grants for research including NHMRC, Cancer Council, Cancer Australia. **Travel/accommodation support** • Reimbursement for participation/speaking at meetings including societies, industry, International Association for the Study of Lung Cancer (IASLC) Board, NGO meetings • Spouse (Rheumatologist) receives invitations to participate/speak at educational meetings including industry sponsored. **Meals/beverages** • Provided as delegate at various meetings including industry sponsored, IASLC Board, NGO meetings • Spouse – provided as delegate at various meetings including industry sponsored. **Gifts or gratuities** • Occasionally provided pens, pads and minor stationery at meetings. **Other** • Former Board member for IASLC • Other (e.g. unpaid advisory roles) o Chair, Lung Cancer Consultative Group, Lung Foundation of Australia o Past-Chair, Cancer Australia Lung Cancer Advisory Group o Past-Chair, Australasian Lung cancer Trials Group (ALTG).
A/Prof Mary Haines • Steering Group member • Author	**Relationships** • Board member, Research Australia. **Grants** • NHMRC Partnership Grants.
Prof John Zalcberg • Steering Group member • Author	**Consultancy fees/honorarium** • Amgen, Bayer, Ispen, Novartis, Roche, Sanofi, Specialised Therapeutics Australia. **Grants/research support** • Amgen, Bayer, Bristol-Myers Squibb, MerckSerono, Novartis, Roche, Specialised Therapeutics Australia. **Travel/accommodation support** • Travel support – Bayer, MerckSerono, Roche. **Meals/beverages -** Not specified. **Expert testimony** • Bayer • HeraldSun editorial: by virtue of being co-Chair and Board member of the Cancer Drugs Alliance.

Name and Role(s)	Interest(s) declared
Prof Richard Kefford • Steering Group member • Author	**Relationships** • Advisory Boards on drug development: Institutional reimbursement from Merck, BMS, Roche, GSK, Novartis. **Consultancy fees/honorarium** • Advisory Board Drug Development: Institutional reimbursement from Merck, BMS, Roche, GSK, Novartis. Institutional Honoraria for Educational Symposia: Merck, GSK, BMS. **Travel/accommodation support** • Travel to Advisory Board meetings and Steering Committees for Clinical Trials, Institutional reimbursement for unconditional educational grant: BMS. **Meals/beverages** • Received – in relation to above.
Prof Gail Risbridger • Steering Group member • Author	**Consultancy Fees/honorarium** • Engaged as an external speaker by Astellas Pharma Inc to present at following events (January 2011): Astellas Educational Seminar, Sapporo Medical University Public Hall, Sapporo, Japan. (Event cancelled); UTP (uridine 5'triphosphate) Symposium, Tokyo, Japan (Sponsored by Astellas). **Grants** • Holds NHMRC grants and may apply for further NHMRC grants throughout the period during which I am a member of this Steering Group. **Speeches/lectures** • Frequent and ongoing international and national invitations to speak on diagnosis and therapy on prostate cancer. **Expert testimony** • Invitation to appear as an expert witness at the Commonwealth of Australia Senate Select Committee on Men's Health in 2009.
Prof Michael Barton • Steering Group member • Author	**Grants** • NHMRC Program Grant – Scientific Title: The Australian MRI-Linac Program: Improving cancer treatment through real-time image guided adaptive radiotherapy. **Speeches/lectures** • Estimation of optimal chemotherapy and radiotherapy utilisation rates for cancer. Collaboration for Cancer Outcomes Research and Evaluation, Sydney, Australia.
Prof Michael Brown • Steering Group member • Author	**Consultancy fees/honorarium** • Glaxo-Smith-Kline, Novartis, Roche, Bristol-Myers-Squibb, Amgen, Bayer, Merck, Sharp & Dohme. **Grants/research support** • Amgen, Novartis, Roche. **Support for travel, accommodation, meals/beverages** • Received – in relation to above. **NHMRC Grant Support:** • 2011-2015. NHMRC Project Grant. CARPETS: A Phase I Open Label Study of the Safety and Immune effects of an Escalating Dose of Autologous GD2 Chimeric Antigen Receptor-Expressing Peripheral Blood T Cells in Patients with Metastatic BRAF-Mutant and GD2-Positive Melanoma.
Prof David Roder • Steering Group member • Prevention and Community Health Committee (PCHC) primary contact • Author	**Grants** • Chief Investigator (CID) on NHMRC Program Grant "Improving chronic disease outcomes for Indigenous Australians: causes, intervention system change" • Chief Investigator (CIF) on Australia Prostate Cancer Collaboration Bio-Resource NHMRC Enabling Grant • Chief Investigator on NHMRC Project Grants • Chief Investigator on Partnership Grant.

Name and Role(s)	Interest(s) declared
Prof Helen Zorbas • Steering Group member • HCC primary contact • Author	Nil to declare.
Prof Warren Alexander • Steering Group member • Research Committee contact	**Board membership** • Member of the American Society of Hematology Scientific Committee on Hematopoiesis (2014-2016) • Member of the Children's Cancer Institute Australia Scientific Advisory Committee • Member of the 2014 Peter MacCallum Cancer Institute Research Division Promotion Committee. **Employment** • Active researcher, Joint Head of the Cancer and Haematology Division of the Walter and Eliza Hall Institute of Medical Research. **Activities** • Holds an honorary Professorial position at the University of Melbourne • Member of NHMRC Research Committee and sub-committees thereof • Chair of NHMRC Research Fellowships peer review panel in 2014/15 • Member in 2014/15 of the Australian Society for Biochemistry and Molecular Biology (ASBMB), the Australian Society for Medical Research (ASMR), the American Society of Hematology, the International Society for Stem Cell Research (ISSCR) and the Society for Hematology and Stem Cells (ISEH). **Grants** • Chief Investigator on NHMRC Program and Project grants and holds an NHMRC Fellowship • Research funding and/or benefit from grants from other funding sources, currently including the US National Institutes of Health, the Science and Industry Endowment Fund (SIEF), Stem Cells Australia, the CRC program and from private philanthropy. **Direct or indirect pecuniary interest** • Holds shares in and is co-chair of the Scientific Advisory Board of Murigen Therapeutics.
Prof Guy Maddern • Steering Group member • Health Care Committee (HCC) primary contact	Nil to declare.
Prof Melanie Wakefield • Steering Group member • PCHC secondary contact	**Employment** • Since 2002 - Director, Centre for Behavioural Research in Cancer at Cancer Council Victoria. **Grants** • Chief Investigator or Associate Investigator on two NHMRC Project grants, three NHMRC Partnership grants, three National Institutes of Health (NIIH)/National Cancer Institute (NCI) grants and one Australian National Preventive Health Agency (ANPHA) grant pertaining to tobacco control, skin cancer prevention, obesity prevention or alcohol harm prevention.