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This is my last year as TROG President and consequently this will be my final President’s report. I described 2011 as being busy, 2012 has been tumultuous with ups and downs for the organisation. It has been a year of decisions for TROG with the economic slowdown finally catching up with clinical research which in turn has forced TROG to restructure, become more efficient and focus its attention on services to its members and maintaining the output of high quality clinical trials in radiation oncology. A summary of the year’s highlights are described below:

**ANROTAT**

The Assessment of New Radiation Oncology Technology and Treatments (ANROTAT) project was finally completed in July 2012 and the report on its finding submitted to the Department of Health and Aging (DoHA). The outcome of the project is a great testament to the many hours of work performed by all of the team involved and is bound to be the platform for many presentations and publications that will recognise this unique achievement. TROG is hopeful that an application submitted to the Medical and Scientific Advisory Committee (MSAC) will result in better funding for the use of new technologies such as intensity modulated radiation therapy (IMRT) and image guided radiation therapy (IGRT) which in turn will not disadvantage patients who require these forms of therapy and who are being managed at institutions where resources associated with these therapies may be constrained. A very useful “add on” to the project was the Australian Radiation Oncology Register Pilot (ARORP) in which we were able to register the details of a portion of the ANROTAT patients and this may form the pillar for a future radiation oncology register on a much larger scale. My sincere thanks again go to Gill Duchesne, Rowena Amin, Mel Grand, Michelle Hall, Deidre Cornes, Joan Torony, Rebecca Montgomery, Tomas Kron, Annette Haworth, Michael Jackson, Michael Ng, June Corry, Val Gebski, Deborah Schofield, Andrew Martin and Hannah Verry for all the work done in 2012 on this project.
Staffing

On the TROG Board we were very sad to lose the services of Gill Duchesne. Gill has not only been the TSC chair since 2007 but has been a spearhead as the chair of the Expert Advisory Group on the ANROTAT project. Having done the TSC Chair job myself, I have always believed it a much tougher assignment than being President and Gill has done a magnificent job in getting protocols and trials developed, activated and managed to completion. She will be taking over from Chris Milross as Dean of the Faculty of Radiation Oncology and we wish her luck in this venture. Sandro Porceddu has taken the position of interim TSC Chair and President-elect, whilst Farshad Foroudi has been elected as TSC Chair from 2013. Ian Roos our consumer on the Board has agreed to stay on for another year and we will welcome his continuing expertise. Bruce Judson from Auckland has taken over from Tomas Kron as the affiliate member on the Board.

During the year, there have also been a number of changes to staffing at the TROG Central Office (TCOO). Rowena Amin, the TROG CEO resigned in August to further her career in NSW Health. Deidre Cornes the QA Manager has taken up a secondment offer for 12 months to assist with the introduction of a radiation oncology service at Tamworth. Joan Torony has therefore taken up the dual role of both Central Operations Manager and Research Manager. Mel Crain has become the Acting QA Manager and we welcome her enthusiasm undertaking this role. TROG also lost the services of Mel Grand (Special Projects Officer) who returned to Sydney to work for the RANZCR. Mark Rembish has added the role of Company Secretary to his duties as Financial Controller. TROG has appointed a Clinical Liaison Officer (Jarad Martin) who will assist the Central Office in clinical matters. There have been additional changes to the staff in the QA team which will continue to improve efficiency and give a better service to TROG members.

Funding

Funding of TROG activities, particularly in regard to infrastructure costs associated with the TCOO continues to be a major issue. The NHMRC Enabling Grant expired at the end of 2011 and despite some efforts we have been unable to secure any further funding from that body. We have tried to secure some further funding through “Better Access to Radiation Oncology” (BARO) on the basis of its interest in a registry but this was unsuccessful. More recently we did get some good news from Cancer Institute NSW with a successful grant application, securing funding of $300,000 over three years for the Central Operations Manager role. Cancer Australia has and will hopefully continue to support TROG in its endeavour to ensure trials are available to the Australian public, particularly those in remote areas.
TROG’s Goals

TROG has developed and implemented a Strategic Plan for the 2011–2013 triennium. These goals are being achieved within the timelines and are on track to be delivered by the end of 2013. A special strategic planning workshop was held in November, which was facilitated by Alison Evans from ZEST Health Strategies. Representatives from the Board, Scientific Committee (TSC), TROG Central Operations Office (TCOO), TROG member representatives and independent representatives attended. The aim of the workshop was to develop creative approaches to address current challenges and contextual issues with a view to ensuring the longevity of the organisation.

The meeting was a great success with clear pathways established for ways of increasing sustainable funding and improving its quality of service to our members. In 2013 there will be ongoing attempts for grant applications however a longer term partnership with industry is in TROG’s long term aims. As in the previous Strategic Plan the selection of objectives for particular strategic focus during 2011-2013 will provide active, targeted objectives for TROG. Additionally, continued performance against a (revised) set of goals identified to support achievement of the objectives in the 2008-2010 Strategic Plan will also be reported.

The Annual Scientific Meeting

In 2012, TROG held its Annual Scientific Meeting at the Darwin Convention Centre. The meeting was convened by Dr Sid Baxi from the Alan Walker Cancer Centre in Darwin. The attendance was excellent and the social entertainment was in true Darwin style, with a crocodile encounter, harbour cruise and a night at the famous Mindil Beach markets. The ASM was the first to hold a Statistical and Research workshop for trainees in conjunction with the Faculty of Radiation Oncology, attracting 42 delegates. The technical and clinical trial management workshops offered excellent topics and speakers attracting good numbers. The invited international radiation oncologist was Peter Hoskin from Mount Vernon Cancer Centre in London. He gave several interesting presentations on Quality of Life and integrated well into the workshops. Other notable speakers were Dale Bailey from Royal North Shore Hospital, who addressed the role of functional imaging with PET scans, John Condon (a Darwin local) who spoke about HPV infection in Arnhem Land and Marion Hass from CREST who spoke about health economics in radiotherapy trials. Prizes were presented to Jim Denham (Trial Excellence Award) for the publication of TROG 96.01 in Lancet Oncology and to Sidney Davis (Outstanding Contribution to TROG) for his involvement in the incorporation of TROG and services on the TROG Board.

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**Sponsorship**

In parallel with the global financial crisis (GFC) there has been a notable reduction in sponsorship for TROG from industry. Our major supporters have remained committed to TROG although there has been reduction in the amount of support. We thank Varian particularly for their ongoing support of TROG. We hope this will pick up in coming years. TROG in the future will endeavour to make efforts to diversify its sponsorship efforts and involve industry that has been less affected by the GFC.

**In Conclusion**

In concluding, this being my final report, I would just like to thank my colleagues on the TROG Board. A very special thanks to all the staff based at the TROG Central Operations Office in Newcastle for the time and effort put into making this trials group the envy of many. My association with TROG goes back to 1991 when I attended the 3rd ASM held in Queenstown. Since then I have only missed two ASMs, convened 5 (including the 2014 meeting), had 3 terms as President, been TSC Chair for 5 years and chaired 3 randomised and one single arm TROG trials. Through TROG I have met and collaborated with a great variety of radiation oncology health professionals at all levels. We have had some wonderful times together at some exotic locations, all of which will remain in my memory. May you once again as readers enjoy this Annual Report and feel proud of our achievements and any contribution however small that you might have made.
The past 12 months has been a watershed period for TROG, with the decline in funding for clinical trials and trials groups, a fall in TROG’s income, the departure of staff from Central Office and the stepping down of Professor Gillian Duchesne as Chair of the TSC. While this has caused some trepidation it should also be viewed as an opportunity to review our structure and rethink how TROG and the TSC does business, and engages with our membership and key stakeholders. In this rapidly changing research and economic environment this attitude will allow us to strategically reposition ourselves and maintain our status as one of the pre-eminent international clinical trials groups.

We are very grateful of Gill’s work as the Chair of the TSC over a number of years. She provided great leadership in her personable and collegial style, akin to the nature of the organisation. Gill’s approach of being firm but fair always made the task of reviewing trials less onerous. She is a great ambassador for our specialty and we wish her well as Dean of the RANZCR Faculty of Radiation Oncology.

After many years at the helm, Professor Bryan Burmeister steps down as President. I cannot think of anyone else who has been more committed to TROG consistently over so many years. He has literally been involved with the organisation since its inception. Through his leadership TROG has experienced great success in terms of number of trials completed and publications. He has always been a strong advocate of ensuring all TROG trials are subsequently published. Bryan has great corporate knowledge of this organisation and therefore it is vital we retain his services in some capacity.

Sadly one of our TSC members, Professor Ming Wang, fell ill last year. We hear he is making a slow but steady recovery. We wish him, his wife and family all the best during this difficult period and look forward to seeing him back at TROG.

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The core business of the TSC remains the same as it always has; to facilitate the development of robust clinical studies involving radiotherapy, monitor the integrity, conduct and quality of the trials, and ensure timely publication.

To achieve this we acknowledge that it is important we communicate effectively and quickly with our members and investigators. Over the recent past we have been monitoring our response times with queries and working toward rapid turnaround times. We hope that some of you may have already noticed an improvement. We have also created a Clinical Liaison Leader (CLL) position to help provide advice to Central Office staff with matters relating to clinical issues, providing helpful insight from a clinician’s perspective.

To maintain the viability of the organisation during these current times of fiscal constraint it is important for TROG to recoup the costs involved in developing and monitoring trials. In the past TROG has been able to absorb many of these costs through various infrastructure grants. The available funding is now limited and we have to respond to this. The costs will need to be passed onto investigators and we are currently performing a costing of services, having produced a draft document with a list of costs for various TROG services. The plan is to develop a “Schedule of Fees”. Investigators will be able to individualise the services required from TROG and pay accordingly. This will provide a transparent process and allow investigators to prepare budgets for grant applications in collaboration with Central Office. We strongly encourage investigators to liaise with Central Office as early as possible in the development phase with respect to preparing a budget for grant submissions. However, TROG appreciates the difficulty investigators have in acquiring full funding and we will continue to seek grants and sponsorship money from other sources to help subsidise trials.

Quality Assurance has been the pillar to TROG’s success and what we have built our reputation on. It distinguishes us from many other trials groups. However with increasing technology this task has become more complex, time consuming and expensive. This is an area of great importance and we need to develop innovative models that ensure we maintain high-level QA processes but in a more cost-effective manner. Work in this area has already begun. We are looking at developing a tiered process whereby the intensity of the QA relates to the nature of the trial (palliative vs radical vs technical). Once again TROG Central Office hopes to work with investigators using a proforma where various QA activities are chosen during the development phase.
TROG TSC continues to take the initiative in strengthening the quality of our trials, having formed a Quality of Life working party, ongoing engagement with health economics experts through CREST, and consumer representation on the committee.

I would like to take this opportunity to thank the efforts of all the TSC members, publications committee, investigators and central office. I would like to wish Farshad Foroudi well in his new role as TSC Chair.

Congratulations also to all those investigators who achieved great success through publications or awarding of grants in 2012 (over the page).

**Sandro V Porceddu**  
Chair TROG Scientific Committee
Research Funding
During 2012, funding was obtained for the following trials:

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<thead>
<tr>
<th>Source</th>
<th>Title</th>
<th>Total Grant</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHMRC</td>
<td>TROG 08.08 - Randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer (TOPGEAR).</td>
<td>$806,175</td>
<td>3 years</td>
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<tr>
<td>Cancer Council Queensland</td>
<td>TROG 11.02 - A randomised phase III trial of single fraction radiotherapy compared to multifraction radiotherapy in patients with metastatic spinal cord compression (SCORAD III).</td>
<td>$164,000</td>
<td>2 years</td>
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<tr>
<td>NHMRC</td>
<td>TROG 08.08 - Randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer (TOPGEAR).</td>
<td>$1,974,558</td>
<td>4 years</td>
</tr>
<tr>
<td>NHMRC</td>
<td>TROG 12.01 - A randomized phase III trial of weekly Cetuximab and radiation versus weekly Cisplatin and radiation in locoregionally advanced HPV associated oropharyngeal cancer (HPV Oropharynx).</td>
<td>$1,097,932</td>
<td>4 years</td>
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<tr>
<td>NZ Lotteries Health Research</td>
<td>Trial in Development_RAVES DA - Evaluating the utility of a Patient Decision Aid for prospective participants in the TROG RAVES prostate cancer trial (Substudy of TROG 08.03).</td>
<td>$5,280</td>
<td>2 years</td>
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<tr>
<td>RANZCR</td>
<td>Trial in Development_RAVES DA - Evaluating the utility of a Patient Decision Aid for prospective participants in the TROG RAVES Prostate Cancer trial (Substudy of TROG 08.03).</td>
<td>$24,970</td>
<td>1 year</td>
</tr>
</tbody>
</table>

TROG Publications
The following articles have been published in peer-reviewed journals during 2012:


TROG Central Operations Office

Joan Torony
TROG Central Operations and Research Manager

We are all aware the TROG Central Operations Office has undergone major changes in the past 12 month with staff changes required under the restructure. As a result, the Central Operations Office is now staffed to 9.0 FTE positions.

A Communications Officer position was identified as an essential position for the Central Operations Office; this has now been filled on a part-time basis by Candice Ward, who is already working on a list of activities to increase the TROG profile and brand. I believe the reduced staffing capacity has not had an effect on the Central Operations Office day-to-day activities.

The current staff are dedicated and continue to offer an exceptional service to our membership in:

- Trial development
- Review of TROG Policy Statements, SOPs and procedures to assist with standardisation across all trials
- Protocol review and amendments
- Progress reports
- Study Start Up – Site Activation Pack
- Quality Assurance (QA)
- Organisation of meetings; ASM, TSC, Board and TPC
- Introduction of new committees; QoL and Health Economics
- Development of contractual agreements
- Annual report coordination and production
- On-going education and training

The Management Team along with the Board have had to seek new ways of diversifying our services to ensure long term sustainability. With funding becoming increasingly hard to secure we have now offered the services of Central Office for Trial Co-ordination Centre (TCC) activities. Four quotations have been provided for TCC and these have been accepted by the Trial Chairs pending grant outcomes.
Melissa Crain and I have completed site visits to St. George and Liverpool Hospitals. We hope to continue these visits to allow better communication with our sites and an understanding of their needs.

The role of Clinical Liaison Leader (CLL) has been taken up by Jarad Martin and is proving to be of great benefit at the Central Office for day-to-day clinical matters.

Following on from our strategic workshop held in Sydney in November 2012 a working party was developed and we have met several times to develop tasks, actions and timelines arising from the workshop. A grants calendar has been completed and we will be continuing to identify and prioritise suitable opportunities for funding. We have been successful with a Cancer NSW Institute grant of $300k over 3 years to support staffing at the Central Operations Office.

The Central Operations Office is determined to improve and continue support to the membership. I would like to take this opportunity to thank my Management Team Melissa Crain and Mark Rembish for their hard work and on-going support.

The team at Central Operations Office are dedicated and amazing, TROG are a fortunate organisation to have this team. Finally, thank you to the Board for their continued support.
TROG has a long standing commitment to the provision of Quality Assurance (QA) services in radiotherapy (RT) clinical trials. The aim of the central QA service is to support TROG’s vision of substantially improving patient care and outcomes as a world leader in clinical cancer research by ensuring the radiation oncology research community has access to relevant quality assurance infrastructure and technical expertise. TROG is fortunate to have the support of the radiation oncology workforce, of whom a significant number continue their active participation in the research program.

Standardised procedures, highly skilled staff and purpose-designed IT infrastructure mean that TROG can provide a unique and essential QA service. The Central Quality Management System (CQMS) is now a critical component of the TROG facility with over 400 registered users. The system enables treatment centres to upload RT plans and supporting documentation electronically and has demonstrated the ability to conduct ‘real-time’ QA case reviews in clinical trials where pre-RT review is warranted (such as use of a new technique or dose escalation design). TROG IT systems utilise independent external ‘real-time’ back-up and disaster recovery management to ensure the protection of data repositories and continuity of service in the event of a large-scale disaster. The experienced multi-disciplinary central QA team provide helpdesk support in addition to training through e-learning and presentations at TROG Technical Research Workshops. The widespread participation in TROG clinical trials provides the service with an ideal opportunity to demonstrate the user-friendly facilities to international treatment centres and CQMS is now being utilised in 5 trials internationally.

TROG QA activities provide opportunities for quality improvement of clinical practice through centre credentialing and benchmarking of treatment plans. The central QA service provides detailed QA case review reports to the treatment centre, and summative (grouped and anonymised results) QA progress reports to the Trial Management Committees. Through participation in QA Review Teams, Technical QA Working Parties, Trial Management Committees and the TROG Scientific Committee, there are opportunities for continued professional development for TROG members.
Relationships with industry partners (manufacturers of radiation oncology equipment and technical software) are extremely rewarding and essential, as they provide TROG’s Central QA Services with access to state-of-the-art resources. TROG is extremely fortunate to continue their partnership with Varian Medical Systems who have provided support to the QA service for the last 12 years. Technical resources are often generously provided on loan for the duration of specific projects or at a negotiated rate as part of QA sponsorship. Elekta has provided the central QA team with access to a research version of FocalPro, Insight Oceania offered TROG the opportunity to test the Velocity software in the clinical research environment, Mim Software has provided access to the MimCloud for testing in the TROG review setting, and the developers of the SWAN software collaborated with TROG to facilitate an inaugural users meeting to discuss future requirements. (February 2012).

The TROG central QA service continues to facilitate the development of a set of dosimetric resources, to be available for clinical trials if required for credentialing activities. A new anthropomorphic phantom CHARLIE (CIRS Model 801-P customised to TROG specifications) is now available and was developed in collaboration with CIRS, with funding by a NSW Cancer Institute Equipment Grant. CHARLIE has been utilised for IGRT credentialing activities with 4 site visits made throughout 2012.

The central QA team played an integral part in the Assessment of the New Radiation Oncology Technology and Treatments (ANROTAT) project, particularly in the design and delivery of the QA program, and the conduct of the TROG ANROTAT Project Dosimetric Anal Canal IMRT Evaluation (TAP DANCE) dosimetric site audits. The Quality Assurance Development Group (QADG) continues to provide strategic and policy advice for the development of the central QA service, and last met in August 2012. The QADG identified VMAT credentialing as a priority for future developments of radiotherapy QA in TROG clinical research. Procedures for credentialing of this technique will be piloted in the TROG 12.01 trial.

TROG keenly explores opportunities for collaboration, particularly with allied facilities such as the International Harmonisation Committee for RT QA in Clinical Trials and the Australian Clinical Dosimetry Service (ACDS) and look forward to building on these relationships with collaborative projects in the future. TROG is strategically planning for the future to ensure the ongoing provision of a high level centralised RT QA facility that is responsive to technological change. The central QA team looks forward to continuing to develop our QA management services and to supporting our members as the TROG research program continues to make a significant contribution to improvements in cancer care.
TROG COMMITTEE MEMBERS - 2012

TROG Board

President
Professor Bryan Burmeister
Princess Alexandra Hospital, Australia

Scientific Committee Chair
(to May 2012)
Professor Gillian Duchesne
Peter MacCallum Cancer Centre, Australia

Acting Scientific Committee Chair (from May 2012)
Australian Ordinary Member
Associate Professor
Sandro Porceddu
Princess Alexandra Hospital, Australia

New Zealand Ordinary Member
Dr Scott Babington
Christchurch Hospital, New Zealand

Affiliate Member
Mr Bruce Judson
Auckland City Hospital, New Zealand

Independent Consumer Representative
Dr Ian Roos OAM
Chair, Cancer Voices Australia

Independent Director
Mr Tom Denny
Worley Parsons
Brisbane, Australia

Chief Executive Officer
(to August 2012)
Ms Rowena Amin
TROG Central Operations Office
Newcastle, Australia

Company Secretary
(from August 2012)
Mr Mark Rembish
TROG Central Operations Office
Newcastle, Australia
TROG Scientific Committee

Scientific Committee Chair (to May 2012)
Professor Gillian Duchesne
Peter MacCallum Cancer Centre, Australia

Acting Scientific Committee Chair (from May 2012)
Radiation Oncologist - Trial Development/Grants Portfolio
Associate Professor Sandro Porceddu
Princess Alexandra Hospital, Australia

President
Professor Bryan Burmeister
Princess Alexandra Hospital, Australia

Radiation Oncologist
Dr Farshad Foroudi
Peter MacCallum Cancer Centre, Australia

Radiation Oncologist - Publications Portfolio
Associate Professor June Corry
Peter MacCallum Cancer Centre, Australia

Radiation Oncologist - Accrual Portfolio
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Auckland Hospital, New Zealand

Discipline Representative - Statistics
Professor Val Gebski
Biostatistics and Research Methodology
NHMRC Clinical Trials Centre, Australia

Discipline Representative - Diagnostic Imaging
Professor Ming Wang
Westmead Hospital, Australia

Discipline Representative - Radiation Therapy
Mrs Bronwyn Hilder
WP Holman Clinic
Royal Hobart Hospital, Australia
TROG Scientific Committee (cont)

Discipline Representative - Medical Oncology
**Associate Professor Danny Rischin**  
Peter MacCallum Cancer Centre, Australia

Discipline Representative - Physics
**Mr Michael Bailey**  
Illawarra Cancer Care Centre, Australia

Discipline Representative - Quality of Life
**Professor Madeleine King**  
Quality of Life Office, Psycho-oncology Co-operative Research Group (PoCoG)  
University of Sydney, Australia

Discipline Representative - Health Economist
**Professor Marion Haas**  
CHERE, University of Technology, Sydney, Australia

Independent Consumer Representative
**Mr Wallace Crellin**  
Melbourne, Australia

Special Advisor
**Associate Professor Tomas Kron**  
Peter MacCallum Cancer Centre, Australia

TROG Central Operations Office Scientific Advisor
**Dr Chris Wratten**  
Calvary Mater Newcastle, Australia

TROG Central Operations and Research Manager (from November 2012)  
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TROG Quality Assurance Manager (to November 2012)  
**Ms Deidre Cornes**  
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Acting TROG Quality Assurance Manager (from November 2012)  
**Mrs Melissa Crain**  
TROG Central Operations Office  
Newcastle, Australia

**Special Advisor**
**Professor Gillian Duchesne**  
Peter MacCallum Cancer Centre, Australia
Publications Committee

Chairperson
**Associate Professor June Corry**  
Peter MacCallum Cancer Centre, Australia

Scientific Committee Chair  
(to May 2012)
**Professor Gillian Duchesne**  
Peter MacCallum Cancer Centre, Australia

Acting Scientific Committee Chair  
(from May 2012)
**Associate Professor Sandro Porceddu**  
Princess Alexandra Hospital, Australia

Statistician
**Professor Val Gebski**  
Biostatistics and Research Methodology  
NHMRC Clinical Trials Centre, Australia

Radiation Oncologist
**Associate Professor David Christie**  
Premion, The John Flynn Hospital, Australia

TROG Central Operations and Research Manager
**Ms Joan Torony**  
TROG Central Operations Office  
Newcastle, Australia

Secretary
**Ms Louise Prosser**  
TROG Central Operations Office  
Newcastle, Australia
2012 COMMITTEE MEMBERS

Bryan Burmeister  Sandro Porceddu  Rowena Amin  Scott Babington

Michael Bailey  David Christie  Deidre Cornes  June Corry

Melissa Crain  Wal Crellin  Tom Denny  Gill Duchesne
TROG COMMITTEE ATTENDANCE - 2012

Committee attendance during 2012 was as follows:

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<td>Prof Gill Duchesne</td>
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<td>Ms Mel Grand</td>
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</table>
TROG CENTRAL
OPERATIONS OFFICE STAFF

Central Operations and Research Manager
Joan Torony (From November 2012, Research Manager to October 2012)
Ph: +61 2 401 43913
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Deidre Cornes (to November 2012)
On secondment 12 months

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Rowena Amin (to August 2012)
Deidre Cornes (Acting from August to November 2012)

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Daniela Rossetti (to February 2012)

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Claudia Koller (to November 2012)
Breearna Pickles (to January 2012)

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Erin Ginty (to May 2012)
Policy, Procedures and Special Projects Officer

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Breearna Pickles (to January 2012)

Administrative Officer

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Email: flora.reitsma@trog.com.au

TROG Information Officer
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Email: louise.macgregor@trog.com.au

New Zealand TROG Coordinator
Janfrey Doak
Ph: +64 3 378 6291
Email: Janfrey.Doak@cdhb.health.nz

Special Projects: ANROTAT and ARORP

Special Projects Manager
Melissa Grand (to September 2012)

Special Projects Officers (Senior)
Michelle Hall (to June 2012)
Rebecca Montgomery (to July 2012)

Special Projects Administrative Assistant
Jyoti Young (to June 2012)
Left to right, back row: Michelle Hall, Alisha Moore, Melissa Crain, Joan Torony, Conor Iles, Mark Rembish, Flora Reitsma. Front row: Louise Prosser, Rebecca Montgomery, Joan Hatton.

Janfrey Doak  Olga Kovacev  Louise MacGregor
Definitions

**New Proposal:**
*Definition:* A new trial concept, protocol synopsis or full protocol submitted to the TROG Scientific Committee (TSC) for consideration of presentation and subsequent voting by the TROG Membership at the TROG Annual Scientific Meeting (ASM).
*Start:* New proposal application form received at TCOO
*End:* New proposal approved for development

**Approved for Development:**
*Definition:* This phase commences when a new proposal received the endorsement of TROG Membership at the TROG ASM and is approved for development by the TSC.
*Start:* New proposal approved for development
*End:* Trial approved for site activation to commence

**Approved for Activation:**
*Definition:* This phase commences when a trial in development has met the ten TROG trial development milestones to the satisfaction of the TSC and given permission to commence Site Activation Processes. A TROG number will be allocated at the commencement of this phase.
*Start:* Trial approved for site activation to commence
*End:* Activation of first trial site

**Open to Accrual:**
*Definition:* A trial is considered as open (to accrual) when the first trial site has submitted all required regulatory and ethical documentation and has been approved for activation by the Trial Coordinating Centre.
*Start:* Activation of first trial site
*End:* Accrual of last patient
Closed to Accrual:
Definition: A trial is considered closed to accrual after the last patient has been recruited. During the closed phase, patients will complete follow up, the main analysis will occur and processes implemented to complete the trial.
Start: Accrual of last patient
End: Official notification from the TSC indicating that trial is considered to be complete

Completed:
Definition: A trial is considered to be completed when the final follow up has occurred, the main analysis has been performed and published, the trial database has been locked, trial sites have been closed and records archived.

Trials Portfolio by Disease Site
This table provides an overview of all TROG trials (both TROG initiated and collaborations) by disease site to 31st December 2012. TROG encourages a broad range of disease sites as well as new areas/fields of research which may be potentially valuable to TROG’s portfolio.

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<tr>
<th>Disease Site</th>
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<th>Approved for Activation</th>
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## TRIALS APPROVED FOR DEVELOPMENT

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<td>ERBC</td>
<td>A prospective study of conservative surgery and targeted systemic therapy for early breast cancer - molecular profiling for prognostication of local recurrence.</td>
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<td>PSA Dot Com</td>
<td>Post prostatectomy salvage radiotherapy dose and technique comparison.</td>
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<td>RAVES DA</td>
<td>Evaluating the utility of a patient decision aid for prospective participants in the TROG RAVES prostate cancer trial (A substudy of TROG 08.03).</td>
<td>Genitourinary</td>
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<td>NeBo2</td>
<td>A randomised phase II palliative radiotherapy trial of 30/10 versus either 8/1 or 20/5 for the relief of neuropathic pain caused by bone metastases.</td>
<td>Symptom Management</td>
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<td>SEINSATION</td>
<td>TROG SEINSATION occult breast cancer study: A prospective, observational database.</td>
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<td>REFORM</td>
<td>Radiotherapy followed by selective nodal dissection for bulky and/or inoperable nodal melanoma.</td>
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<td>SAFRON II</td>
<td>Stereotactic ablative fractionated radiotherapy versus radiosurgery for oligometastatic neoplasia to the lung: A randomised phase II trial.</td>
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<td>LIGHT</td>
<td>Stereotactic body radiotherapy for liver metastases.</td>
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<tr>
<td>12.02</td>
<td>A phase II study of the feasibility of breast conservation for locally advanced breast cancer using breast MRI and PET scanning to predict conservability, local control and disease free survival.</td>
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<td>12.01</td>
<td>A randomised phase III trial of cetuximab and radiation versus weekly cisplatin and radiation in locoregionally advanced HPV associated oropharyngeal cancer.</td>
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## OPEN TRIALS

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<tr>
<td>12.03</td>
<td>EAT</td>
<td>Eating As Treatment (EAT): An RCT of psychological training for dieticians to reduce malnutrition and depression in head and neck cancer patients undergoing radiotherapy.</td>
<td>Head &amp; Neck</td>
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<td>11.03</td>
<td>P_LUNG GP</td>
<td>A randomised phase III trial of high dose palliative radiotherapy (HDPRT) versus concurrent chemotherapy and HDPRT (C-HDPRT) in patients with good performance status, locally advanced/small volume metastatic NSCLC not suitable for radical chemo-radiotherapy.</td>
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<td>SCORAD III</td>
<td>A randomised phase III study of single fraction radiotherapy compared to multifraction radiotherapy in patients with metastatic spinal cord compression.</td>
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<td>SUPREMO</td>
<td>A phase III randomised trial to assess the role of adjuvant chest wall irradiation in ‘intermediate risk’ operable breast cancer following mastectomy. SUPREMO (Selective Use of Postoperative Radiotherapy after Mastectomy) BIG 2-04.</td>
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<td>A phase II efficacy study of synchronous weekly carboplatin and radiation in merkel cell carcinoma of the skin.</td>
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<td>CHISEL</td>
<td>A randomised phase III trial of highly conformal hypofractionated image guided (“Stereotactic”) radiotherapy (HypoRT) versus conventionally fractionated radiotherapy (ConRT) for inoperable early stage I non small cell lung cancer.</td>
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<td>RTN2</td>
<td>A randomised trial of post operative radiation therapy following wide excision of neurotropic melanoma of the head and neck.</td>
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<td>TOPGEAR</td>
<td>A randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemo therapy for resectable gastric cancer.</td>
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<td>STARS</td>
<td>A randomised comparison of anastrozole commenced before and continuing during adjuvant radiotherapy for breast cancer versus anastrozole and subsequent anti-oestrogen therapy delayed until after radiotherapy.</td>
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<td>WBRT</td>
<td>Whole brain radiotherapy following local treatment of intracranial metastases of melanoma - A randomised phase III trial.</td>
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<td>08.04</td>
<td>PORTEC - 3</td>
<td>Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma.</td>
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<td>08.03</td>
<td>RAVES</td>
<td>A phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) with early salvage RT in patients with positive margins or extraprostatic disease following radical prostatectomy.</td>
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<td>GBM in elderly patients</td>
<td>A randomised phase III study of temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients.</td>
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<td>DCIS</td>
<td>A randomised phase III study of radiation doses and fractionation schedules in non-low risk ductal carcinoma in-situ (DCIS) of the breast.</td>
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<td>05.02</td>
<td>MALT</td>
<td>A prospective single arm trial of involved field radiotherapy alone for stage I-II low grade non-gastric marginal zone lymphoma.</td>
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<td>05.01</td>
<td>POST</td>
<td>Post operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck.</td>
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## CLOSED TRIALS

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<td>A multicentre feasibility study of online adaptive image guided radiotherapy for muscle invasive bladder cancer.</td>
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<td>PROArCT</td>
<td>A phase II trial of integrated preoperative radiotherapy and chemotherapy with oxaliplatin 5-FU and folinic acid in patients with locally advanced rectal cancer</td>
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<td>08.01</td>
<td>PROFIT</td>
<td>A randomised trial of shorter radiation fractionation schedule for the treatment of localised prostate cancer (Prostate Fractionated Irradiation Trial).</td>
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<td>Cetuximab</td>
<td>A phase I/II trial of cetuximab, carboplatin and radiotherapy for patients with locally advanced head and neck squamous cell carcinoma.</td>
<td>Head &amp; Neck</td>
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<td>07.02</td>
<td>QUARTZ</td>
<td>A phase III multi-centre randomised controlled trial to assess whether optimal supportive care alone (including dexamethasone) is as effective as optimal supportive care (including dexamethasone) plus whole brain radiotherapy in the treatment of patients with inoperable brain metastases from non-small cell lung cancer.</td>
<td>CNS</td>
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<td>06.02</td>
<td>APBI</td>
<td>A multicentre feasibility study of accelerated partial breast irradiation using three-dimensional conformal radiation therapy for early breast cancer.</td>
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<td>06.01</td>
<td>GLIOMA</td>
<td>Primary chemotherapy with temozolomide vs. radiotherapy in patients with low grade gliomas after stratification for genetic 1p loss: a phase III study.</td>
<td>CNS</td>
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<tr>
<td>04.02</td>
<td>Cervical (FIGO Stage &amp; Tumour Volume)</td>
<td>Prospective study to determine the relationships between survival and FIGO stage, tumour volume and corpus invasion in cervical cancer.</td>
<td>Gynaecological</td>
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<tr>
<td>04.01</td>
<td>Cavilon Breast</td>
<td>A paired double blind randomised comparison of Cavilon Durable Barrier Cream (CDBC) to 10% Glycerine (“Sorbolene”) Cream in the prophylactic management of post-mastectomy irradiation skin care.</td>
<td>Symptom Management</td>
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<td>03.08</td>
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<td>Symptom Management</td>
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<td>03.06</td>
<td>TOAD</td>
<td>A collaborative randomised phase III trial: The timing of intervention with androgen deprivation in prostate cancer patients with a rising PSA.</td>
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<td>03.05</td>
<td>Breast (MA20)</td>
<td>A phase III study of regional radiation therapy in early breast cancer.</td>
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<td>03.04</td>
<td>RADAR</td>
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<td>03.03</td>
<td>Transplant &amp; IFRT (HDNHL04)</td>
<td>An ALLG/TROG prospective multicentre study of involved-field radiotherapy with transplantation for patients with Hodgkin’s disease and non-Hodgkin’s lymphoma.</td>
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<td>03.02</td>
<td>Gastric</td>
<td>A feasibility study to evaluate adjuvant chemoradiotherapy for gastric cancer.</td>
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<tr>
<td>03.01</td>
<td>Oesophagus (Dysphagia)</td>
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<td>02.03</td>
<td>Bladder (Phase III)</td>
<td>Multicentre phase III study comparing radical synchronous chemo-radiation vs radical radiation alone in the definitive management of muscle invasive TCC of the urinary bladder following maximal TUR.</td>
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<td>Melanoma (Phase III)</td>
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<tr>
<td>01.04</td>
<td>Rectal (Phase III)</td>
<td>A randomised trial of preoperative radiotherapy for stage T3 adenocarcinoma of the rectum.</td>
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<td>01.02</td>
<td>Primary CNS Lymphoma (PCNSL)</td>
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<tr>
<td>99.03</td>
<td>Follicular Lymphoma</td>
<td>A randomised multicentre trial of involved field radiotherapy versus involved field radiotherapy plus chemotherapy in combination with Rituximab (Mabthera®) for stage I – II low grade follicular lymphoma.</td>
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<td>96.01</td>
<td>Prostate (Androgen Deprivation)</td>
<td>A randomised trial investigating the effectiveness of different durations of maximal androgen deprivation prior to and during definitive radiation therapy for locally advanced carcinoma of the prostate.</td>
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**TROG COLLABORATIVE RESEARCH PROJECTS**

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<tr>
<td>Intensity modulated radiotherapy (IMRT) phantom and associated dosimetry equipment</td>
<td>Completed</td>
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<td>Equipment to assess the accuracy of image-guided and advanced technology used in multi-centre radiotherapy trials</td>
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## COMPLETED TRIALS

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<tr>
<td>08.07</td>
<td>The DECO Study: A randomised phase III trial of weekly docetaxel (Taxotere®) chemoradiotherapy +/- cetuximab (Erbitux®) in the treatment of localised resectable cancer of the oesophagus</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>03.07</td>
<td>A randomised phase II study of two regimens of palliative chemoradiation therapy in the management of locally advanced non small cell lung cancer.</td>
<td>Lung</td>
</tr>
<tr>
<td>02.02</td>
<td>A phase III randomised trial of concomitant radiation, cisplatin, and tirapazamine vs concomitant radiation and cisplatin in patients with advanced head and neck cancer.</td>
<td>Head &amp; Neck</td>
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<tr>
<td>01.05</td>
<td>A pilot randomised controlled trial of dexamethasone 96mg versus 16mg per day for malignant spinal cord compression treated by radiotherapy – TROG SuperDex Pilot.</td>
<td>Symptom Management</td>
</tr>
<tr>
<td>01.03</td>
<td>Concomitant and adjuvant temozolomide and radiotherapy for newly diagnosed glioblastoma multiforme (EORTC 26981/22981).</td>
<td>CNS</td>
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<tr>
<td>01.01</td>
<td>A phase III double-blind, randomised, placebo-controlled study of erythropoietin when used as an adjuvant to radiation therapy in patients with head and neck squamous cell carcinoma (EORTC 22996).</td>
<td>Head &amp; Neck</td>
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<tr>
<td>99.06</td>
<td>A phase I/II study of trans-urethral resection followed by modified synchronous chemo-radiation in the definitive management of localised invasive TCC of the urinary bladder.</td>
<td>Genitourinary</td>
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<tr>
<td>99.05</td>
<td>Tumour volume as an independent prognostic factor in patients with non-small cell lung cancer: A protocol for a prospective database.</td>
<td>Lung</td>
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<tr>
<td>99.04</td>
<td>A prospective, non-randomised study of chemotherapy and radiotherapy for osteolymphoma (OL).</td>
<td>Lymphoma</td>
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<tr>
<td>99.02</td>
<td>A prospective single arm non randomised study of concurrent radiation and chemotherapy for the organ conserving treatment of early anal canal cancer.</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>99.01</td>
<td>An ANZLG / TROG prospective study of limited chemotherapy and involved field radiotherapy for patients with clinical stage I – II Hodgkins disease.</td>
<td>Lymphoma</td>
</tr>
<tr>
<td>98.06</td>
<td>Concurrent radiotherapy and chemotherapy for oesophageal cancer patients.</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>98.05</td>
<td>A randomised trial of immediate versus delayed whole brain irradiation following surgery and/or radiosurgery for patients with one or two brain metastases.</td>
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<tr>
<td>98.04</td>
<td>A phase II study examining the efficacy of short fractionation radiotherapy for the palliation of liver metastases.</td>
<td>Symptom Management</td>
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<tr>
<td>98.03</td>
<td>A randomised trial to compare rates of disease-free survival in margin-positive patients after radical prostatectomy for carcinoma of the prostate with or without adjuvant post-operative radiotherapy.</td>
<td>Genitourinary</td>
</tr>
<tr>
<td>98.02</td>
<td>A randomised phase II study of two different strategies for chemoradiotherapy of advanced squamous cell carcinoma of the head and neck.</td>
<td>Head &amp; Neck</td>
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<tr>
<td>98.01</td>
<td>A phase II trial of preoperative radiotherapy with protracted infusion 5-fluorouracil for resectable adenocarcinoma of rectum.</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>97.01</td>
<td>A phase II study of trans-urethral resection followed by synchronous chemo-radiation in the definitive treatment of localised TCC of the urinary bladder.</td>
<td>Genitourinary</td>
</tr>
<tr>
<td>96.07</td>
<td>A phase II study of synchronous carboplatin/etopside and radiation in Merkel cell carcinoma of the skin.</td>
<td>Skin</td>
</tr>
<tr>
<td>96.06</td>
<td>A phase II study of radiation therapy following nodal surgery in malignant melanoma.</td>
<td>Skin</td>
</tr>
<tr>
<td>96.05</td>
<td>A prospective randomised trial of single fraction versus fractionated radiotherapy for neuropathic pain due to bone metastases.</td>
<td>Symptom Management</td>
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<tr>
<td>96.04</td>
<td>Phase III comparison of radiotherapy with glucocorticoid steroid support for the palliation of liver metastases.</td>
<td>Symptom Management</td>
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<tr>
<td>96.03</td>
<td>Concomitant accelerated radiotherapy boost for good prognosis oesophageal patients.</td>
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<tr>
<td>96.02</td>
<td>Standard radio-chemotherapy for oesophageal cancer patients.</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>95.03</td>
<td>A phase III double blind study of pentosan polysulphate sodium (PPS) in the treatment of late (chronic) radiation proctitis.</td>
<td>Genitourinary</td>
</tr>
<tr>
<td>95.02</td>
<td>A phase III double-blind randomised trial of rectal sucralfate suspension in the treatment of radiation proctitis.</td>
<td>Symptom Management</td>
</tr>
<tr>
<td>95.01</td>
<td>A randomised trial comparing adjuvant protracted venous infusion and bolus 5FU/leucovorin with either early or late radiotherapy in rectal cancer.</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>94.01</td>
<td>A randomised phase III clinical trial comparing surgery alone with concurrent preoperative chemotherapy and radiation followed by surgery for localised resectable carcinoma of the oesophagus.</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>92.01</td>
<td>A phase II study of intravenous methotrexate and cranial irradiation in the treatment of primary central nervous system lymphoma (PCNSL).</td>
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</tr>
<tr>
<td>TROG No.</td>
<td>Protocol Title</td>
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<tr>
<td>91.01</td>
<td>A phase III prospective randomised clinical trial of accelerated radiotherapy (ART) for stage III and IV squamous carcinoma of the upper aerodigestive tract.</td>
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</tr>
<tr>
<td>89.04</td>
<td>Synchronous radiotherapy and chemotherapy in oesophageal cancer.</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>89.03</td>
<td>A phase II study of accelerated fractionation radiotherapy for stage III squamous carcinoma of the upper aero-digestive tract.</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>89.02</td>
<td>Simultaneous adjuvant radiation and CMF chemotherapy following surgery for breast cancer.</td>
<td>Breast</td>
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03 RESEARCH UPDATES
BREAST CANCER

Breast Cancer Open Trials

TROG: 11.01

A phase III randomised trial to assess the role of adjuvant chest wall irradiation in ‘intermediate risk’ operable breast cancer following mastectomy.

SUPREMO (Selective Use of Postoperative Radiotherapy after Mastectomy) BIG 2-04

Lead Group: UK Medical Research Council

Accrual Target: 1600 (International)

Accrual Total: 1592 (International); 10 (TROG)

First Participant Accrued: 10 June 2008 (International) 28 December 2011 (TROG)

Anticipated Accrual End Date: April 2013

Primary Objective:
The primary objective of this trial is to determine the effect of Ipsilateral chest wall irradiation following mastectomy and axillary surgical staging for women with operable breast cancer at ‘intermediate risk’ of loco-regional recurrence.

Primary Endpoint:
The primary endpoint of this trial is overall survival.

Summary of Trial Activity for 2012
Six TROG sites were activated in 2012. Site accreditation and credentialing of radiation oncologists are coordinated by the Mount Vernon Centre for Cancer Treatment, UK.

Funding: Cancer Australia Research Grant - $510,000 (2011-2013)

TROG Trial Management Committee

Trial Chairperson:

Assoc Prof Boon H Chua
Peter MacCallum Cancer Centre, VIC

TROG Representatives:
Dr Scott Carruthers, Royal Adelaide Hospital, SA
Assoc Prof David Christie, Premion, QLD
Dr Steven David, Peter MacCallum Cancer Care Centre, VIC
Prof Geoff Delaney, Liverpool Hospital, NSW
Prof David Joseph, Sir Charles Gairdner, WA
Dr George Papadatos, Campbelltown Hospital, NSW
Dr Graham Pitson, Barwon Health, VIC
Dr Jonathan Ramsey, Radiation Oncology Services – Mater Centre, QLD & Oncology Research Australia, QLD
Dr Kandeepan Thuraisingam, Riverina Cancer Care Centre NSW

**TROG Trial Coordinator:**
Rebecca Montgomery, TROG Central Operations Office (Rebecca.Montgomery@trog.com.au)

**Collaborating Groups:**
Trans Tasman Radiation Oncology Group (TROG)
Breast International Group (BIG)
Scottish Cancer Trials Breast Group
European Organization for Research and Treatment of Cancer (EORTC)

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**TROG: 08.06**
A randomised comparison of anastrozole commenced before and continuing during adjuvant radiotherapy for breast cancer versus anastrozole and subsequent anti-oestrogen therapy delayed until after radiotherapy (STARS)

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 2000
**Accrual Total:** 656

**First Participant Accrued:** 16 September 2009
**Anticipated Accrual End Date:** December 2014

**Primary Objective:**
The primary objective of the study is to determine if commencement of anastrozole prior to radiotherapy results in improved local control compared to anastrozole commenced after radiotherapy. Post-irradiation initiation of anastrozole is considered to be the standard arm.

**Primary Endpoint:**
The primary endpoint is in-field recurrence of breast cancer. Clinical or radiological detection is preferably confirmed by cytology or biopsy.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
Copies of de-identified consent forms, histopathology reports and other relevant documents are requested for all patients before being registered onto this trial. Eligibility reviews are conducted by the trial coordinating centre at the time of randomisation and sent on to the TROG Central Operations Office. All sites wishing to participate in the trial are required to complete two benchmarking activities, which cover the full range of volumes being treated. To date, 22 sites have successfully completed both benchmarking activities and 5 sites are currently undergoing the activities. Radiotherapy reviews are conducted on the first 5 cases from each site and then on 1-in-5 random sampling basis thereafter. Radiotherapy data for all cases are collected and the site is not informed of the patients review status prior to review. To date 514 cases have submitted radiotherapy data, of which 175 have been selected for review. Sixty nine full radiotherapy reviews have been completed, demonstrating an acceptability rate of 92.3%. Major variations, minor variations and missing/inevaluable information has been reported at 1.5%, 5.4% and 0.8%, respectively.

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Toxicity:
Twenty five Serious Adverse Events (SAEs) (all hospitalisations) have been reported among 656 patients (3.8%), and 5 patients have died since enrolment. Twenty SAEs during the “trial period” (from randomisation to approx. 4 months post RT): 2 for radiotherapy complications, 6 for surgical wound complications, 2 with progressive breast cancer complications, 10 concurrent disorders. Remaining 5 SAE reports were due to treatment/progression of new cancers (at any time in follow-up). There has been one report of recurrence within the radiation fields (extensive subcutaneous metastases outside and within chest wall and SCF fields).

Funding:
2009 – AstraZeneca, $560,000
2010 – Cancer Australia, $600,000 (2010-2012)

Trial Management Committee
Trial Chairperson:
Assoc Prof Peter Graham
St George Hospital, NSW

Radiation Oncologists:
Assoc Prof Geoff Delaney, Liverpool Hospital, NSW
Dr George Papadatos, Campbelltown Hospital, NSW
Dr Chris Fox, Wollongong Hospital, NSW
Dr Susan Carroll, Royal Prince Alfred Hospital, NSW
Dr Jennifer Harvey, Princess Alexandra Hospital, QLD
Dr Susan Hewitt, Townsville, QLD
Dr Yvonne Zissiadis, Perth Radiation Oncology Centre, WA
Dr Michael Francis, Geelong Hospital, VIC

Medical Oncologists:
Dr Jodi Lynch, St George Hospital, NSW
Dr Craig Lewis, Prince of Wales Hospital, NSW

Radiation Therapy QA:
Laurel Schmidt, St George Hospital, NSW
Dr Regina Tse, Royal Prince Alfred Hospital, NSW
Dr Anne Capp, Calvary Mater Hospital Newcastle, NSW

Tissue Micro-array Committee/Pathology:
Dr Ewan Millar, St George Hospital, NSW

Statistician:
Dr Lois Browne, St George Hospital, NSW

Trial Coordinator:
Helen Cox, St George Clinical Trials Unit, NSW (Helen.Cox2@SESIAHS.HEALTH.NSW.GOV.AU)
A randomised phase III study of radiation doses and fractionation schedules in low-risk ductal carcinoma in situ (DCIS) of the breast

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Accrual Target: 1600
Accrual Total: 914
First Participant Accrued: 23 June 2007
Anticipated Accrual End Date: November 2015

Primary Objective:
To improve the outcome of women with DCIS treated with breast conserving therapy and to individualise treatment selection for women with DCIS to achieve long term disease control with minimal toxicity.

Primary Endpoint:
Time to local recurrence defined as the time from randomisation to the time of recurrent invasive or intraductal disease in any soft tissue of the ipsilateral breast.

Summary of Trial Activity for 2012
Quality Assurance:
Of the 88 radiotherapy QA reviews undertaken in 2012, 9 major deviations were identified in 6 cases. Since activation, 376 case reviews had been undertaken which showed a total of 77 major deviations in 51 cases. For specific information on major deviations please contact the Trial Manager.

Toxicity:
Seventeen Serious Adverse Events were reported, all of which were unrelated to protocol therapy and resolved.

Interim Analysis:
An interim analysis of the study endpoints (excluding overall survival) is planned to take place after 50% of the expected local recurrences have occurred, estimated to occur at approximately one year after the end of accrual. At this stage the significance criterion will be set at P < 0.001.
The main analysis of study endpoints (excluding overall survival) will take place 5 years after the end of accrual, with the significance criterion set at P < 0.05. Patients will then be followed yearly for a further 5 years, at the end of which the analysis of overall survival will take place together with an updated analysis of the other study endpoints.

Funding:
2008 – EORTC Trial Specific Funding, 150,000 (2009-2010)
2009 – Dutch Cancer Foundation, 275,495
2010 – IBCSG: Krebsforschung CH, CHF150,000
2012 – Susan G. Komen for the Cure®. US$349,900

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TROG Trial Management Committee

**Trial Chairperson:**

Assoc Prof Boon H Chua  
Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**

Prof Geoff Delaney, Liverpool Hospital, NSW  
Assoc Prof Peter Graham, St George Hospital, NSW  
Dr Jennifer Harvey, Princess Alexandra Hospital, QLD  
Assoc Prof David Christie, Premier Cancer Care, QLD  
Dr Scott Carruthers, Royal Adelaide Hospital, SA  
Dr David Byram, Launceston Hospital, TAS  
Dr David Blakey, Radiation Oncology VIC  
Prof David Joseph, Sir Charles Gardiner Hospital, WA  
Dr Margaret Latham, Royal Perth Hospital, WA  
Dr Scott Babington, Christchurch Hospital, NZ  
Dr Christine Elder, Auckland Hospital, NZ

**Radiotherapy Quality Assurance:**

Ms Brigid Moran & Dr Mary Dwyer, Peter MacCallum Cancer Centre, VIC

**Physics:**

Dr Matthew Williams, Wollongong, NSW

**Translational Research:**

Prof Stephen Fox, Prof Ian Campbell, Peter MacCallum Cancer Centre, VIC

**Pathology:**

Prof Stephen Fox, Peter MacCallum Cancer Centre, VIC

**Quality of Life Research:**

Assoc Prof Penelope Schofield, Peter MacCallum Cancer Centre, VIC

**Statistician:**

Dr Emma Link, Peter MacCallum Cancer Centre, VIC

**Trial Manager:**

Christopher Griffiths, Peter MacCallum Cancer Centre, VIC (christopher.griffiths@petermac.org)

**Collaborating Groups:**

Breast International Group (BIG) BIG 3-07  
Australia and New Zealand Breast Cancer Trials Group (ANZBCTG)  
National Cancer Institute of Canada Clinical Trials Group (NCIC CTG) MA33  
European Organisation for Research and Treatment of Cancer (EORTC) Trial 22086-10083  
International Breast Cancer Studies Group (IBCSG) 38-10  
Scottish Cancer Trials Breast Group (SCTBG)  
All-Ireland Cooperative Oncology Research Group (ICORG)
Breast Cancer Closed Trials

**TROG: 10.02** Randomised trial of accelerated partial breast irradiation (RAPID)

**Lead Group:** Ontario Clinical Oncology Group (OCOG)

**Accrual Target:** 2128 International
**Final Accrual:** 2135 (Internationally), 27 (TROG)

**Number of Participants in Follow-up:** 27 (TROG)
**Projected Closed to Follow-up Date:** August 2021

**Primary Objective:**
To determine if accelerated partial breast irradiation (APBI) using three dimensional conformal radiation therapy is as effective as whole breast irradiation following breast conserving surgery in women with a new histological diagnosis of ductal carcinoma in situ (DCIS) only or invasive breast cancer without evidence of metastatic disease (TROG sites recruited patients with invasive breast cancer only). Effectiveness will be determined by the rate of ipsilateral breast tumour recurrence. An important secondary outcome will be adverse cosmetic outcome as a measure of late radiation morbidity.

**Primary Endpoint:**
The primary outcome measure is ipsilateral breast tumour recurrence (IBTR). IBTR is defined as recurrent invasive or in situ cancer in the ipsilateral breast including the axillary tail. Histological evidence of local recurrence will be required. IBTR will be described as a true/marginal recurrence if it occurs within 1-2 cm of the surgical cavity or otherwise as an elsewhere recurrence. All recurrences will be reviewed by a central adjudication committee unaware of treatment allocation including a review of the location of the recurrence in the ipsilateral breast.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
The Data Safety Monitoring Committee endorsed release of results of the interim toxicity analysis to all investigators in October 2012. The Committee recommended that patients on the study should be made aware of these findings, and that the trial should continue with the follow-up plan as defined in the protocol. The rationale for this recommendation is that all patients have completed protocol therapy and it remains an important objective to follow patients for the primary efficacy outcome and any other associated toxicity that may emerge with longer follow-up.

**Toxicity:**
The planned interim toxicity analysis was undertaken in August 2012 and the results were released to all Investigators at the ASTRO Annual Meeting on 29 October 2012. The trial observed an increase in adverse cosmesis (fair or poor) at three years but there was no observed increased in grade 3 or 4 toxicity.

**Analysis:**
The first efficacy analysis will be conducted after 124 recurrences have been observed. This is estimated to occur about 8 years after the start of accrual (OCOG central activation 2006), at which time patients will have been followed for just over a median of 5 years. A second efficacy analysis is planned at a median follow up of 10 years.

*continues on next page*
Publication:

Funding:
OCOG funding for data management and tumour block banking.

**TROG Trial Management Committee**

**TROG Trial Chairperson:**

[Image: Assoc Prof Boon H Chua
Peter MacCallum Cancer Centre, VIC]

**Radiation Oncologists:**
Dr Claire Phillips, Peter MacCallum Cancer Centre, VIC
Dr Margot Lehman, Princess Alexandra Hospital, QLD
Dr Glenys Round, Waikato Hospital, New Zealand
Dr Gill Campbell / Dr G Sasso, Auckland Hospital, New Zealand
Dr Yvonne Zissiadis, Perth Radiation Oncology, WA

**Radiation Therapist:**
David Willis, Peter MacCallum Cancer Centre, VIC

**Trial Coordinator:**
Rebecca Montgomery, TROG Central Operations Office, NSW. (Rebecca.Montgomery@trog.com.au)

**Collaborating Group:**
Trans Tasman Radiation Oncology Group (TROG)
A multicentre feasibility study of accelerated partial breast irradiation using three-dimensional conformal radiation therapy for early breast cancer

**Lead Group**: Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target**: 48  
**Final Accrual**: 48  
**Number of Participants in Follow-up**: 47  
**Projected Closed to Follow-up Date**: 15 June 2018

**Primary Objective**:
To evaluate the technical feasibility and reproducibility of accelerated partial breast irradiation (APBI) limited to the region of the tumour bed using 3D conformal radiotherapy following breast conserving surgery.

**Primary Endpoint**:
Feasibility rate of APBI using 3D conformal radiotherapy defined as the proportion of eligible patients treated without a major protocol deviation.

**Summary of Trial Activity for 2012**

**Toxicity**:
Three grade 3 adverse events (AEs) were reported at 12 month post protocol therapy (breast pain, infection-axilla and dyspnea). At two years, 6 AEs were reported, 4 of which were probably related to treatment (breast pain, fatigue and induration/fibrosis). At three years and four years, 1 grade 3 induration/fibrosis was reported. No grade 4 AE or serious adverse event (SAE) had been reported.

**Analysis**:
Results of an analysis of the predictors of plan quality for external beam partial breast irradiation were presented at the TROG Annual Meeting 2012. The main analysis of time to ipsilateral breast recurrence, disease free survival, toxicity, cosmetic outcome and quality of life will take place 5 years after the completion of accrual. Patients will then be followed for a further 5 years at the end of which the analysis of overall survival will take place together with an updated analysis of time to ipsilateral breast recurrence, disease free survival, toxicity and quality of life.

**Publications**:
- Manuscript entitled “Can we predict plan quality for external beam partial breast irradiation: Results of a multicenter feasibility study of Trans Tasman Radiation Oncology Group (TROG) Study 06.02” is under editorial review.
Funding:
NHMRC Project Grant $150,000 (2007-2009)

TROG Trial Management Committee

TROG Trial Chairpersons:

Assoc Prof Boon H Chua
Peter MacCallum Cancer Centre, VIC

Prof Tomas Kron
Peter MacCallum Cancer Centre, VIC

Multidisciplinary Members:
Assoc Prof Graeme Morgan, Royal North Shore Hospital, NSW
Dr Penelope Schofield, Peter MacCallum Cancer Centre, VIC
Mr David Willis, Peter MacCallum Cancer Centre, VIC
Dr Gillian Campbell, Auckland Hospital, NZ
Mr Ian Campbell, Waikato Hospital, NZ
Assoc Prof John Collins, Melbourne Health, VIC
Assoc Prof Michael Henderson, Peter MacCallum Cancer Centre & St. Vincent’s Hospital, VIC
Dr Margot Lehman, Princess Alexandra Hospital, QLD
Prof Bruce Mann, Melbourne Health, VIC
Ms Jane O’Brien, Epworth Hospital & Peter MacCallum Cancer Centre, VIC
Dr Peter O’Brien, Calvary Mater Newcastle, NSW
Dr Ian Porter, William Buckland Radiotherapy Centre, VIC
Dr Glenys Round, Waikato Hospital, NZ
Mr David Speakman, Epworth Hospital & Peter MacCallum Cancer Centre, VIC
Ms Judith Martland, Royal North Shore Hospital, NSW

Statistician:
Dr Emma Link, BaCT, Peter MacCallum Cancer Centre, VIC

Trial Coordinator:
Teresa Morgan, BaCT, Peter MacCallum Cancer Centre, VIC (teresa.morgan@petermac.org)
International Lead Group: National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)

Accrual Target: 1832 Internationally
Final Accrual: 1832 Internationally (180 TROG)

Number of Participants in Follow-up: 151
Projected Closed to Follow-up Date: 2016

Primary Objective:
The primary objective is to improve the outcome of women with early breast cancer treated with breast conserving therapy and adjuvant systemic therapy (currently accepted chemotherapy and/or hormonal therapy). Specifically, it investigates if regional nodal radiotherapy in addition to breast irradiation prolongs survival compared to breast irradiation alone.

Primary Endpoint:
The primary endpoint is overall survival. It is estimated that the actuarial 5-year survival of patients in the control arm (breast radiotherapy) will be 80% with a clinically significant 5% increase in 5-year survival in the experimental arm (breast and regional nodal radiotherapy).

Summary of Trial Activity for 2012
Quality Assurance:
As per 2007 audit report, all TROG patients entered complied with the eligibility criteria. Real-time and final radiotherapy QA reviews showed that there were 31 major protocol deviations for TROG centres, 22 of which were reversed. Internationally, audit of the first 1289 patients randomised showed that 98.4% of patients completed RT as per randomisation.

Toxicity:
The NCIC CTG Data Safety Monitoring Committee (DSMC) reviewed this trial with respect to safety, trial conduct, including accrual, and where applicable, efficacy. In addition to trial related data, where applicable, relevant data from external sources (e.g. recently published literature) were also considered. There were no concerns raised by the DSMC.

Analysis:
The number of events required for the interim analysis was met on April 6, 2010. The database was locked and the interim analysis was performed. Based on the DSMC recommendations, the results were presented at ASCO Scientific Meeting in 2011 (LBA1003). Follow-up continues as per protocol.

Publication:
The full manuscript has been prepared and is under editorial review.

Funding:
TROG Trial Management Committee (Australia and New Zealand)

**TROG Trial Chairperson:**

Assoc Prof Boon H Chua  
Peter MacCallum Cancer Centre, VIC

**Trial Coordinator:**

Teresa Morgan, BaCT, Peter MacCallum Cancer Centre, VIC (teresa.morgan@petermac.org)

**Collaborating Groups:**

- Trans Tasman Radiation Oncology Group (TROG)  
- Radiation Therapy Oncology Group (RTOG)  
- National Surgical Adjuvant Breast and Bowel Project (NSABP)  
- Southwest Oncology Group (SWOG)  
- North Central Cancer Treatment Group (NCCTG)
Breast Cancer Trials
Approved for Development

TROG: 12.02

A phase II study of the feasibility of breast conservation for locally advanced breast cancer using breast MRI and PET scanning to predict conservability, local control and disease free survival (PET LABRADOR).

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Primary Objective:
The primary objective of the study is to demonstrate a local recurrence (LR) rate of \( \leq 20\% \) at three years in patients who undergo BCS based on histopathology, MRI and PET-CT scans. (LR <10% is expected).

Primary Endpoint:
The primary endpoint is local recurrence rates for all patients at 3 years and 5 years post registration.

Summary of Trial Activity for 2012

Trial Development:
In August 2012 the TROG Scientific Committee was satisfied that the development and content of the protocol met the requirements to be allocated a TROG number (12.02). The development of Case Report Forms and the trial database are underway and Clinical Trial Agreements have been drafted. Trial Activation and ethics submission are planned for early 2013. Additional funding is being sought.

Funding:
Seed funding from the Radiation Oncology Network Trust Fund - Crown Princess Mary Cancer Centre Westmead, $50K.

Trial Management Committee

Trial Chairperson:

Dr Verity Ahern
Westmead Hospital, NSW

Radiation Oncologists:
Dr Timothy Wang, Westmead Hospital, NSW
Dr Michelle Grogan, Royal Brisbane Hospital, QLD
Dr Jennifer Harvey, Princess Alexandra Hospital, QLD
Dr Martin Borg, Adelaide Radiotherapy Centre, SA

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**Medical Oncologists:**
Dr Rina Hui, Westmead Hospital, NSW  
Prof Francis Boyle, POCHE Centre, Mater Hospital, NSW

**Nuclear Medicine Physician:**
Dr Catherine Saunders, Westmead Hospital, NSW

**Surgical Oncologist:**
Assoc Prof Owen Ung, Royal Brisbane Hospital, QLD

**Radiologist:**
Shih-Chang Wang, Westmead Hospital, NSW

**Radiation Therapy:**
Christopher Kelly, Westmead Hospital, NSW  
Drew Latty, Westmead Hospital, NSW

**Physics:**
Edgar Estoesta, Westmead Hospital, NSW  
Jacqueline Foo, Westmead Hospital, NSW

**Translational Research:**
Rosemary Balleine, Westmead Hospital, NSW

**Quality of Life:**
Prof Madeleine King, Psycho-oncology Co-operative Research Group, USyd, NSW

**Cosmesis:**
Dr Eric Hau, St George Hospital, NSW  
A/Prof Peter Graham, St George Hospital, NSW

**Pathology:**
Raghwa Sharma, Westmead Hospital, NSW  
Nirmala Pathmanathan, Westmead Hospital, NSW

**Statistician:**
Prof Val Gebski, Clinical Trial Centre, USyd, NSW

**Consumer:**
Carol Whiteside, ANZ Breast Cancer Trials Group, NSW

**Trial Co-ordinator:**
Tracy Pearl-Larson, Westmead Hospital, NSW (Tracy.Pearl-Larson@swahs.health.nsw.gov.au)
A prospective study of conservative surgery and targeted systemic therapy for early breast cancer – Molecular profiling for prognostication of local recurrence (ERBC).

**Lead Group:** ANZ Breast Cancer Trials Group (ANZBCTG)

**Date Approved for Development:** 14 July 2010

**Current Status:** Development on hold - discussions regarding trial design underway at ANZBCTG

**Trial Chairperson:**
Assoc Prof Boon H Chua
Peter MacCallum Cancer Centre, Melbourne VIC
Boon.Chua@petermac.org

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An Occult Breast Cancer Study – A prospective, observational database (SEINSATION).

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Date Approved for Development:** 28 June 2012

**Current Status:** Development on hold - trial is surgeon dependent. Trial Chair in process of generating interest amongst surgeons.

**Trial Chairperson:**
Assoc Prof Peter Graham
St George Hospital, Kogarah NSW
peter.graham@sesihs.health.nsw.gov.au
CENTRAL NERVOUS SYSTEM (CNS)

CNS Open Trials

| TROG: 08.05 | Whole brain radiotherapy following local treatment of intracranial metastases of melanoma - A randomised phase III trial. (ANZMTG 01.07 WBRT post local treatment in melanoma) |

**Lead Group:** Australia and New Zealand Melanoma Trials Group (ANZMTG)

**Accrual Target:** 200

**Accrual Total:** 105 (Internationally), 69 (TROG)

**First Participant Accrued:** 30 April 2009

**Anticipated Accrual End Date:** As per protocol but subject to change

**Primary Objective:**
The primary objective is to assess the effect of whole brain radiotherapy (WBRT) (after complete localised treatment for melanoma brain metastases) on distant intracranial control, as assessed by MRI scanning.

**Primary Endpoint:**
The primary endpoint of the study will be the proportion of patients with distant intracranial failure (as determined through MRI assessment) after 12 months of follow-up. Distant intracranial failure is defined as new lesions appearing 1cm or more from a previous index metastases.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
TROG is responsible for the coordination of Radiotherapy Quality Assurance reviews and the reviewer is Dr George Hruby. Twenty one cases have been reviewed to date. The reviews have demonstrated acceptable compliance of 94.24%. The rate of major and minor variations is well within acceptable limits at 2.37% and 1.69% respectively. The rate of missing/inevaluable information has been reported at 1.69%.

Radiological audits of magnetic resonance imaging (MRI) scans are performed by Dr Catherine Mandel on the first 5 patients at each site and then on one randomly selected patient from each subsequent 5 patients. MRI audits have been performed for 22 patients.

Scoring of all neurocognitive function (NCF) assessments is performed centrally by Haryana Dhillon. A total of 116 individual NCF assessments have been scored across 29 individual participants who have completed baseline NCF assessments.

In-house review of CRF data is performed as CRFs are received at ANZMTG and data queries are issued as required. A comprehensive data entry audit was performed in September 2012.

Site monitoring visits were performed at 4 sites in July-November 2012.

**Toxicity:**
Nineteen Grade 3 and above adverse events (11 events in the WBRT arm and 8 events in the Observation arm) have been reported to date. All events were Grade 3 in intensity except for one Grade 4 adverse event for fatigue.
in the observation arm. This was not a protocol defined serious adverse event (SAE).

No protocol defined serious adverse events have been reported to date. One serious adverse event has been reported to ethics by Melanoma Institute Australia. The patient was randomized to the Observation arm but underwent further surgical excision and salvage WBRT after developing a local intracranial recurrence. The patient died from sepsis secondary to cerebral abscess. This event did not meet the protocol defined criteria for SAE as it occurred over 90 days after randomization.

**Interim Analysis:**
An interim analysis will be performed 12 months after the 100th patient randomisation and is scheduled to be performed in December 2013.

**Publications:**

**Funding:**
2007 – Cancer Australia, $281,019, 2008-2009 for the first 60 patients as part of a feasibility study.
2010 – Cancer Australia – Application for 12 month extension until 30 June 2011 granted.
2010 - Cancer Australia, $591,000 (excluding GST), 3 years, commencing 1 July 2011.

**Trial Management Committee**

**Trial Chairperson:**

![Dr Gerald Fogarty](image)

Dr Gerald Fogarty  
Director Mater Sydney  
Radiation Oncology, NSW

**Radiation Oncologists:**

Prof Bryan Burmeister, Princess Alexandra Hospital, QLD  
Assoc Prof Angela Hong, Melanoma Institute Australia, NSW

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Surgical Oncologists:
Prof John Thompson, Melanoma Institute Australia, NSW
Assoc Prof Kate Drummond, Royal Melbourne Hospital, VIC

Radiation Therapy Quality Assurance:
Dr George Hruby, Royal Prince Alfred Hospital, NSW

Quality of Life and Medical Oncology:
Prof Anna Nowak, Sir Charles Gairdner Hospital, WA

Pathology:
Prof Richard Scolyer, Royal Prince Alfred Hospital, NSW

Statistician:
Lauren Haydu, Melanoma Institute Australia, NSW

Health Economics:
Rachael Morton, University of Sydney, NSW

MRI QA:
Catherine Mandel, Peter MacCallum Cancer Centre, VIC

Neurocognitive QA:
Janette Vardy, University of Sydney, NSW

ANZMTG:
Elizabeth Paton, ANZMTG, NSW

OCTO:
Mark Middleton, University of Oxford, UK

Trial Coordinator:
Enmoore Lin, ANZMTG Project Officer, NSW (Enmoore.Lin@melanoma.org.au)

Collaborating Groups:
Sydney Neuro-Oncology Group (SNOG)
National Health and Medical Research Council (NHMRC) Clinical Trial Centre
Trans Tasman Radiation Oncology Group (TROG)
University of Oxford Oncology Clinical Trials Office (OCTO), United Kingdom
**Lead Group:** National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)

**Accrual Target:** 560 (internationally), 100-150 (TROG)

**Accrual Total:** 486 (Internationally), 79 (TROG)

**First Participant Accrued:** 20 February 2009

**Anticipated Accrual End Date:** 30 June 2013

**Primary Objective:**
To compare the overall survival rates between short-course radiation therapy alone and short-course radiation therapy given together with concurrent and adjuvant temozolomide, in elderly (>65 years) patients with newly diagnosed glioblastoma multiforme (GBM, WHO grade IV), who have had prior surgery/biopsy at diagnosis and who are not deemed suitable by their treating physician to receive the standard radiotherapy regimen (60Gy/30 fractions over 6 weeks) in combination with temozolomide.

**Primary Endpoint:**
The primary endpoint of this study is overall survival defined as the time from randomization to the time of death from any cause.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
Radiotherapy review is conducted by NCIC CTG as is outlined in the main protocol. Trial Centres must complete a dry-run before enrolment of 5th patient. Central pathology review: The TROG-associated pathologist will be prompted to send the required slides +/- block by the NCIC CTG after the patient has been randomised but not for real-time review.

**Toxicity:**
No SAEs have been reported. All AEs that have been experienced as part of this trial are expected.

**Interim Analysis:**
A planned futility analysis was conducted by the independent data safety monitoring after 120 events and resulted in a recommendation that the trial continue (Reported April 2011).

**Publication:**
Perry J, O’Callaghan C, Ding k et al, A phase III randomized controlled trial of short-course radiotherapy with or without concomitant and adjuvant temozolomide in elderly patients with glioblastoma (NCIC CTG CE.6, EORTC 26062-22061, TROG 08.02, NCT00482677). J Clin Oncol 30, 2012 (suppl; abstr TPS2104)

**Funding:**
2007 – Department of Health and Aging, Strengthening Cancer Care Grant - TROG Seed funding $20,000
2008 – NCIC CTG funding, $AUD2000 per patient, $AUD200 per centre for pathology processing.

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**Trial Management Committee**
The following TROG TMC has been formed in addition to the NCIC CTG TMC:

**Trial Chairperson:**

**Dr Claire Phillips**  
Peter MacCallum Cancer Centre, VIC

**Dr Mike Fay**  
Royal Brisbane Hospital, QLD

**Radiation Oncologists:**  
Dr Melissa James, Christchurch Hospital, NZ

**Medical Oncologists:**  
Dr Anna Nowak, Sir Charles Gardner Hospital, WA

**Neurosurgeon:**  
Dr Sarah Olsen, Princess Alexandra Hospital, QLD

**Trial Coordinator:**  
Laura Galletta, BaCT, Peter MacCallum Cancer Centre, VIC (laura.galletta@petermac.org)

**Collaborating Groups:**  
Trans Tasman Radiation Oncology Group (TROG)  
European Organisation for Research and Treatment of Cancer (EORTC)
CNS Closed Trials

TROG 2012 ~ A Phase III multi-centre randomised controlled trial to assess whether optimal supportive care alone (including dexamethasone) is as effective as optimal supportive care (including dexamethasone) plus whole brain radiotherapy in the treatment of patients with inoperable brain metastases from non-small cell lung cancer. (QUARTZ)

Lead Group: Medical Research Council, United Kingdom (MRC UK)

Accrual Target: 534 Internationally
Accrual Total: 359 Internationally (9 TROG)

Number of Participants in Follow-up: 0 (TROG)
Actual Closed to Follow-up Date: 20 June 2012 (TROG) – International accrual continuing

Primary Objective:
To determine whether optimal supportive care (OSC) (including dexamethasone) alone is as effective as OSC (including dexamethasone) plus WBRT, in terms of Patient Assessed Quality Adjusted Life Years in patients with NSCLC and inoperable brain metastases.

Summary of Trial Activity for 2012:
At the TROG Scientific Committee (TSC) Meeting held in May 2012 the TSC concluded that they are unable to support the ongoing conduct of this trial due to slow recruitment and that the trial be closed to accrual in Australia and New Zealand. The MRC Trial Management Committee are of this decision and are awaiting acknowledgement of closure of the Australian and New Zealand Trial Sites. All data queries have been finalised and sent to the MRC UK. This trial shall be considered completed when the final Trial Site closeout letter has been received by TROG from the MRC UK. This is expected to occur during early 2013.

Funding:
2007 – NHMRC $63,000, 2008-2010, this will provide capitation of $1000 per participant enrolled.
2007 – Department of Health and Aging, Strengthening Cancer Care Grant - TROG Seed funding, $18,000 over 1 year.

TROG Trial Chairperson (Australia and New Zealand):

Dr Tanya Holt
Radiation Oncology Services
Mater Centre, QLD

Trial Coordinator (Australia and New Zealand):
Kacy Baumann, Radiation Oncology Services - Mater Centre, QLD (kacy_baumann@health.qld.gov.au)

Collaborating Group:
Trans Tasman Radiation Oncology Group (TROG)
TROG 06.01  EORTC 22033-26033 – Primary chemotherapy with temozolomide vs radiotherapy in patients with low grade gliomas after stratification for genetic 1p loss: a phase III study.

**Lead Group:** European Organisation for Research and Treatment of Cancer (EORTC)

**Accrual Target:** 699 Internationally  
**Accrual Total:** 707 Internationally (69 TROG)

**Number of Participants in Follow-up:** 477  
**Actual Closed to Follow-up Date:** TBA

**Primary Objective:**  
To assess whether progression free survival (PFS) and overall survival can be prolonged by primary chemotherapy with temozolomide (TMZ), whether the incidence of late toxicity can be decreased by using primary chemotherapy, the toxicity profile of the two treatments and the quality of life of trial participants in both treatment arms.  
The impact of 1p deletions in low-grade gliomas (LGGs) will also be studied to assess the prognostic effect of the deletion on PFS overall and by treatment group, the benefit for patients with LGGs and deletions treated with TMZ compared to radiotherapy alone with respect to survival, and any interaction between treatment and cytogenetic features.

**Primary Endpoint:**  
The primary endpoint is progression-free survival.

**Summary of Trial Activity for 2012**  
Of the 707 patients accrued internationally, 477 patients have been randomised to date and are currently in follow-up. The remaining patients are yet to undergo the randomisation process. The Australia and New Zealand Trial Management Committee are awaiting confirmation from the EORTC regarding the close of the patients randomisation process and the projected closed to follow-up date. The final analysis will occur following 2.5 years of post-accrual follow up. No interim analyses are planned.

**Funding:**
2007 – COSA Enabling Grant $18,000  
2007 – NHMRC $385,000, 2008-2012

**Trial Management Committee (Australia and New Zealand)**  
**TROG Trial Chairperson:**  
Dr Gail Ryan, Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**
Dr Margot Lehman, Princess Alexandra Hospital, QLD  
Dr Andrew Pullar, Radiation Oncology Services – Mater Centre, QLD  
Dr Michael Fay, Royal Brisbane Hospital, QLD  
Dr Michael Back, Royal North Shore Hospital, NSW  
Prof. David Joseph, Sir Charles Gardiner Hospital, WA  
Dr Michael Barton, Liverpool Hospital, NSW  
Dr Mori Wada, Austin and Repatriation Medical Centre, VIC  
Dr Johann Tang, National University Hospital, Singapore
**Medical Oncologists:**
Dr Elizabeth Hovey, Prince of Wales Hospital, NSW
Dr Mark Rosenthal, Royal Melbourne Hospital, VIC

**Neuro-Oncologist:**
Dr Lawrence Cher, Austin and Repatriation Medical Centre, VIC

**Neurosurgeon:**
Dr David Walker, Royal Brisbane Hospital (Neurosurgeon), QLD

**Trial Coordinator:**
Anetta Matera, BaCT, Peter MacCallum Cancer Centre, VIC (anetta.matera@petermac.org)

**Collaborating Groups:**
Trans Tasman Radiation Oncology Group (TROG)
Brain Tumour Group, National Cancer Institute of Canada – Clinical Trials Group (NCIC CTG)
Medical Research Council – National Cancer Research Institute (MRC-NCRI)
GASTROINTESTINAL CANCER

Gastrointestinal Cancer Open Trials

TROG: 08.08

AG0407GR - A randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer (TOPGEAR).

**Lead Group:** Australasian Gastro-Intestinal Trials Group (AGITG)

**Accrual Target:** 752

**Accrual Total:** 64

**First Participant Accrued:** 30 September 2009

**Anticipated Accrual End Date:** 2018

**Primary Objective:**
The primary trial objective is to investigate whether preoperative chemoradiotherapy leads to improved survival in comparison with preoperative chemotherapy in patients undergoing adequate surgery (D1+) dissection for resectable gastric cancer.

**Primary Endpoint:**
The primary endpoint is pathological complete response rate.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
This trial includes a comprehensive radiotherapy quality assurance program, developed and coordinated by TROG, to ensure patient safety, appropriate trial conduct and data quality. Case reviews are conducted to evaluate source data for verification of protocol compliance and data accuracy in regard to radiotherapy treatment delivery and include pre-treatment review. To date, 26 patients have been reviewed prior to commencement of treatment with 97.7% of variables classified as acceptable. A major variation rate of 0.94% has been recorded. Seven cases have been required to re-submit after initial review. Resubmission of these plans resulted in the reversal of 13 major variations.

**Interim Analysis:**
The first safety review by the AGITG Independent Data and Safety Monitoring Committee (IDSMC) was completed on March 1st, 2012 with treatment data from the first 36 patients. This review did not detect any signals to indicate that the safety of the experimental arm was any different to that of the control arm. In particular, the committee did not identify any concerns with respect to (a) surgical morbidity; (b) feasibility of treatment delivery i.e. chemotherapy/chemoradiation completion and toxicity rates; and (c) treatment delays (including patients not receiving surgery). The IDSMC recommended that the study should continue as planned.
Publication:

Funding:
2008 – Cancer Council Australia and Cancer Australia funding $596,625 (2009-2012)
2009 – Health Research Council (HRC) New Zealand funding $NZ137,250 (2009-2011)
2010 – Cancer Society of New Zealand, $NZ 55,000 (2010-2012)
2011 – NHMRC $806,175 (2012-2014)

Other Relevant Information:
This trial is supported by the NSW Clinical Trials Partnership (Cancer Institute NSW and NHMRC Clinical Trials Centre)

Trial Management Committee
Trial Chairperson:
Assoc Prof Trevor Leong
Peter MacCallum Cancer Centre, VIC

Radiation Oncologists:
Assoc Prof Andrew Kneebone, Liverpool Hospital, NSW
Dr Daryl Lim Joon, Austin Health, VIC
Prof Nigel Spry, Sir Charles Gairdner Hospital, WA
Dr Kirsty Wiltshire, Royal North Shore Hospital, NSW
Mr David Willis, Peter MacCallum Cancer Centre, VIC
Prof Tomas Kron, Peter MacCallum Cancer Centre, VIC

Medical Oncologists:
Assoc Prof Michael Michael, Peter MacCallum Cancer Centre, VIC
Prof Michael Findlay, University of Auckland, New Zealand
Assoc Prof Niall Tebbutt, Austin Health, VIC

Surgical Oncologists:
Assoc Prof Mark Smithers, Princess Alexandra Hospital, QLD
Assoc Prof Peter Cosman, NHMRC Clinical Trials Centre, NSW

Translational Research:
Assoc Prof Alex Boussioutas, Peter MacCallum Cancer Centre, VIC

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Quality of Life:
Assoc Prof Michael Jefford, Peter MacCallum Cancer Centre, VIC
Assoc Prof Martin Stockler, NHMRC CTC, NSW

Statistician:
Prof Val Gebski, NHMRC CTC, NSW

Trial Coordinator:
Sarah Chinchen, NHMRC Clinical Trials Centre, NSW (topgear@ctc.usyd.edu.au)

Project Manager:
Danielle Miller, NHMRC Clinical Trials Centre, NSW

Collaborating Groups:
Trans Tasman Radiation Oncology Group (TROG)
National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)
European Organization for Research and Treatment of Cancer (EORTC)
Gastrointestinal Cancer Closed Trials

**TROG: 09.01**  
A phase II trial of integrated preoperative radiotherapy and chemotherapy with oxaliplatin 5-FU and folinic acid in patients with locally advanced rectal cancer (PROArCT)

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 40  
**Final Accrual:** 41  
**Number of Participants in Follow-up:** N/A – No Follow-Up

**Primary Objective:**  
To determine the tolerability rate in the setting of a multi-centre TROG study in patients with locally advanced rectal cancer that are treated with an integrated preoperative radiotherapy with FOLFOX chemotherapy regimen.

**Primary Endpoint:**  
The primary endpoint is the Tolerability Rate defined as the percentage of patients who are able to complete the planned treatment program and do not require a treatment break for toxicity.

**Summary of Trial Activity for 2012**

**Quality Assurance:**  
The QA program is coordinated by the TROG Central Operations Office (TCOO) QA team. Eligibility, radiotherapy and chemotherapy will be reviewed through TCOO. Of the 41 patients registered on to the trial, 29 have been reviewed for eligibility. To date, the QA reviews have indicated high protocol compliance with an acceptability rate of 96.1%, and only one major variation reported. Missing data is reported at 3.66%. Radiotherapy reviews, conducted by Dr Raphael Chee, are underway. Two have been completed, reporting an acceptability rate of 82.5%. Major and minor variations have been reported at 7.5% and 10.0%, respectively. No missing/inevaluable information has been reported. Chemotherapy reviews are yet to commence. Pathology reviews are conducted by Dr Bill Murray.

**Toxicity:**  
A planned interim analysis of grade 4 toxicity experienced by the first 16 consecutive patients, who had completed treatment, was undertaken in April 2012. The independent reviewer recommended the trial continue unchanged.

**Main Analysis:**  
The main analysis of tolerability, efficacy and toxicity endpoints will be undertaken in the first half of 2013.

**Funding:**  
2007 – Strengthening Cancer Care Enabling Grant - TROG Seed Funding, $40,000, 1 year  
2009 – Cancer Australia Priority Driven Collaborative Cancer Research Scheme, co-funded by Radiation Oncology Section (DOHA); $215,000 (2010–2012, with extension to June 2013)

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**Trial Management Committee**

**Trial Chairperson:**
Assoc Prof Sam Ngan
Peter MacCallum Cancer Centre, VIC

**Trial Co-Chairperson:**
Assoc Prof Michael Michael, Peter MacCallum Cancer Centre, VIC (Medical Oncologist)

**Surgery:**
Assoc Prof Alexander Heriot, Peter MacCallum Cancer Centre, VIC

**Pathology:**
Dr William Murray, Peter MacCallum Cancer Centre, VIC

**Trial Statistician:**
Assoc Prof Richard Fisher, BaCT, Peter MacCallum Cancer Centre, VIC

**Trial Coordinator:**
Bev McClure, BaCT, Peter MacCallum Cancer Centre, VIC (bev.mcclure@petermac.org)

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**TROG: 03.02**

A feasibility study to evaluate adjuvant chemoradiotherapy for gastric cancer.

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 52

**Final Accrual:** 56

**Closed to Follow-up:** 26 February 2012

**Analysis/Manuscript:**
The final analysis has been performed and the manuscript is pending.
Trial Chairperson:

Assoc Prof Trevor Leong
Peter MacCallum Cancer Centre, VIC

Trial Coordinator:
Dr Juliana Di Iulio, BaCT, Peter MacCallum Cancer Centre, VIC (Juliana.DiIulio@petermac.org)

Lead Group: National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)

Accrual Target: 220
Final Accrual: 220

Number of Participants in Follow-up: 1
Projected Closed to Follow-Up Date: 20 March 2013

Primary Objective:
To test the hypotheses that the addition of chemotherapy to a short course of radiation treatment improves the proportion of patients who achieve relief of dysphagia and improves quality of life compared to radiation alone in patients with advanced oesophageal cancer.

Primary Endpoint:
The primary study endpoint is relief of dysphagia, defined as improvement of at least one point on the Mellow scale. This will be measured at nine weeks after the start of radiotherapy and must be maintained at the next review 4 weeks thereafter. Radiation treatment must start within 2 weeks of randomisation.

Summary of Trial Activity for 2012
Quality Assurance:
QA reviews were conducted for initial ethics submission, annual renewal of ethics approval, eligibility, radiotherapy, chemotherapy and quality of life return compliance. All QA reviews have now been completed. Eligibility reviews demonstrated a high level of protocol compliance with an acceptability rate of 95.41%. Major variations and missing/invaluable information were reported at 0.81% and 3.78%, respectively, well within acceptable limits. Post-treatment radiotherapy reviews have demonstrated an acceptability rate of 92.41%, with major variations, minor variations and missing/invaluable information reported at 1.03%, 2.89% and 3.66%, respectively. The chemotherapy reviews demonstrated that 92.81% of variables reviewed were deemed as acceptable. Major variations were reported at 0.84%, minor variations at 2.84% and missing/invaluable information was reported at 3.51%. Overall, these reviews have demonstrated a high level of protocol compliance across eligibility, radiotherapy and chemotherapy.

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Given that QoL is a secondary end point for this trial, rate of return compliance of the QoL CRFs at baseline, week 9 and week 13 has been assessed. This will be used to determine whether sufficient data is available for analysis now that the trial has closed and all assessment time points for each patient have elapsed. The final QoL return compliance report is soon to be released.

**Funding:**
2003 - NHMRC grant $232,000, 2004 - 2007
2006 - TROG infrastructure Support, Strengthening Cancer Care Enabling Grant, TROG Seed funding $30,000.
2009 - Cancer Australia Priority Driven Collaborative Cancer Research Scheme (in conjunction with the NHMRC), $254,375, 2010 - 2012.
The NCIC provide funding for Canadian centres, and the trial is endorsed by Cancer Trials NSW.

**Trial Management Committee**

**TROG Trial Chairperson:**

![Dr Michael Penniment](image)

Dr Michael Penniment  
Royal Adelaide Hospital, SA

**Program Coordinator:**
Dr Chris O’Callaghan, NCIC Clinical Trials Group, Canada

**Radiation Oncologists:**
Dr Jennifer Harvey, Princess Alexandra Hospital, QLD  
Dr Euan Walpole, Princess Alexandra Hospital, QLD  
Dr Sam Ngan, Peter MacCallum Cancer Centre, VIC  
Dr Andrew Kneebone, Royal North Shore Hospital, NSW  
Dr Rebecca Wong, Princess Margaret Hospital, Canada  
Dr Yvonne Zissiadis, Royal Perth Hospital, WA  
Dr Iain Ward, Christchurch Hospital, NZ  
Dr Rajashi Roy, Princess Royal Hospital, United Kingdom

**Quality of Life:**
Dr Heather-Jane Au, Cancer Cross Institute, Canada

**Statistician:**
Prof. Phillip Ryan and Thomas Sullivan Data Management & Analysis Centre Discipline of Public Health University of Adelaide, SA

**Trial Coordinator:**
Sonya Stephens, Royal Adelaide Hospital, SA (Sonya.Stephens@health.sa.gov.au)

**Collaborating Group:**
Trans Tasman Radiation Oncology Group (TROG)
TROG 01.04

A randomised trial of preoperative radiotherapy for stage T3 adenocarcinoma of rectum.

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Accrual Target: 310
Final Accrual: 326

Closed to Follow-up Date: 22 May 2012

Analyses/Manuscript:
The main analyses was performed in February 2010 and published during 2012. The final analysis and final manuscript are pending. Trial Sites will remain open for at least another 12 months to ensure that data is available at site level in case any queries arise during the writing of the final manuscript.

Publication:

Trial Chairperson:
Assoc Prof Sam Ngan
Peter MacCallum Cancer Centre, VIC

Trial Coordinator:
Marijana Vanevski, BaCT, Peter MacCallum Cancer Centre, VIC (marijana.vanevski@petermac.org)

Collaborating Groups:
Australasian Gastro-Intestinal Trials Group (AGITG)
Colorectal Surgical Society of Australia and New Zealand
Section of Colon and Rectal Surgery: Royal Australasian College of Surgeons
Gastrointestinal Cancer Trials
Approved for Development

Liver Image Guided High Dose Radiation Therapy (LIGHT)

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Date Approved for Development: 16 February 2012


Trial Chairperson:
Dr Mark Lee
Liverpool Hospital, NSW

Trial Coordinator:
Rebecca Montgomery
rebecca.montgomery@trog.com.au
GENITOURINARY CANCER

Genitourinary Cancer Open Trials

**TROG: 08.03**

A phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) with early salvage RT in patients with positive margins or extraprostatic disease following radical prostatectomy (Radiotherapy – Adjuvant Versus Early Salvage – RAVES)

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 470

**Final Accrual:** 223

**First Participant Accrued:** 30 March 2009

**Anticipated Accrual End Date:** 28 February 2014

**Primary Objective:**
To test the hypothesis that active surveillance with early salvage radiotherapy can be considered non-inferior to standard treatment with adjuvant (immediate) radiotherapy with respect to risk of biochemical failure in patients with extraprostatic (pT3) disease and/or positive margins following radical prostatectomy.

**Primary Endpoint:**
Biochemical failure rate, defined as a Prostate Specific Antigen level ≥ 0.40 ng/mL and rising following radiotherapy.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
Each participating clinician is required to complete a dry run contouring exercise before recruiting patients. Sites who wish to treat patients with intensity-modulated radiation therapy (IMRT) must complete a separate IMRT Credentialing Program. To date, 32 sites have been activated, and a total of 78 investigators have successfully completed the Benchmarking Exercise. Nine sites have become credentialed to treat patients with IMRT.

The Peter MacCallum Cancer Centre provides technical radiotherapy (RT) review for the Benchmarking Exercise and the RT planning data for each trial patient who receives RT. TROG provides Quality Assurance (QA) review of eligibility and post-treatment RT data. Sites are required to submit planning QA data within one week prior to the RT start date to facilitate timely reviews. The RAVES trial uses TROG’s Central Quality Management System (CQMS) for electronic submission of QA materials.

Central Pathology Reviews are conducted for all patients. Professor Warwick Delprado of Douglass Hanly Moir Pathology (Sydney) and Dr Ronnie Cohen of Uropath (Perth) have developed the guidelines and will perform the reviews.

**Toxicity:**
Adverse events are a key component of the secondary endpoints. Therefore these events will be reported as part of trial analyses. No patient safety issues have been identified.

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**Interim Analysis:**
The first planned interim analysis was completed in 2012. The final report is pending.

**Funding:**
2006 – TROG infrastructure Support, Strengthening Cancer Care Enabling Grant, TROG Seed funding $20,000 over 1 year
2007 – RANZCR Research Grant $5000, 1 year
2007 – Auckland Hospital Charitable Trust NZD $20,000, 1 year
2007 – Cancer Council VIC $296,000, 2008-2011
2007 – Cancer Council NSW $177,000, 2008-2011
2007 – Health and Research Council (NZ) $NZ169,103, 2008-2012
2008 – Genesis Professional Development Award $NZ 3,000, 1 year
2008 – NHMRC project grant, $775,000, 2009-2013
2009 – Cancer Institute NSW $10,000 for Informed Consent Workshop
2009 – Prostate Cancer Foundation of Australia, $3,500 for patient outreach publications

**Trial Management Committee**

**Trial Chairpersons:**

<table>
<thead>
<tr>
<th>Dr Maria Pearse</th>
<th>Assoc Prof Andrew Kneebone</th>
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<tbody>
<tr>
<td>Auckland City Hospital, New Zealand</td>
<td>Royal North Shore Hospital, NSW</td>
</tr>
</tbody>
</table>

**Executive Committee:**
Prof Gillian Duchesne, Peter MacCallum Cancer Centre, VIC
Assoc Prof Richard Fisher, BaCT, Peter MacCallum Cancer Centre, VIC
Mr Mark Frydenberg, Monash Medical Centre, VIC
Dr Scott Williams, Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**
Assoc Prof Chris Atkinson, Christchurch Hospital, New Zealand
Dr Chakiath Jose, Auckland Hospital, New Zealand
Prof David Joseph, Sir Charles Gardiner Hospital, WA
Dr Liz Kenny, ORI, Royal Brisbane Hospital, QLD
Dr John Matthews, Auckland Hospital, New Zealand
Dr Jeremy Millar, WBRC, The Alfred Hospital, VIC
Prof Nigel Smy, Sir Charles Gardiner Hospital, WA
Dr Sandra Turner, Westmead Hospital, NSW
Dr Kirsty Wiltshire, Peter MacCallum Cancer Centre, VIC

**Urologists:**
Mr Tom Shannon, Hollywood Private Hospital, WA
Mr Manish Patel, Westmead Hospital, NSW
Dr John Yaxley, Brisbane Private Hospital, QLD
Mr Peter Swindle, Mater Private Hospital, QLD
Mr Michael Rice, Auckland Hospital, New Zealand
Mr Henry Woo, Westmead Hospital, NSW
Trial Physicist:
Assoc Prof Annette Haworth, Peter MacCallum Cancer Centre, VIC

Central Pathology Review:
Dr Warick Delprado, Douglass Hanly Moir Pathology, Sydney, NSW
Dr Ronnie Cohen, Uropath, Perth, WA

Translational Research:
Dr Julie Marsh, Centre for Genetic Epidemiology, University of Western Australia

Pathology:
Assoc Prof Warick Delprado, Douglass Hanly Moir Pathology, Sydney, NSW
Dr Ronnie Cohen, Uropath, Perth, WA

Statistician:
Assoc Prof Richard Fisher, BaCT, Peter MacCallum Cancer Centre, VIC

Consumer Representatives:
David Farley and Ross Gomersall

Trial Coordinator:
Carol Fraser-Browne, Trial Coordinating Centre, Auckland Hospital, NZ (CarolFB@adhb.govt.nz)

Collaborating Groups:
Urological Society of Australia and New Zealand (USANZ)
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
Psycho-oncology Cooperative Research Group (PoCoG)

Acknowledgements:
Medical Research Council Clinical Trials Unit (MRCCU) - The RADICALS trial (Radiotherapy and Androgen Deprivation in Combination after Local Surgery)
Australian Prostate Cancer Bio-resource (APCB)
Genitourinary Cancer Closed Trials

**TROG: 10.01** A multicentre feasibility study of online adaptive image guided radiotherapy for muscle invasive bladder cancer (BOLART)

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 50
**Final Accrual:** 54 (4 patients did not proceed to have protocol treatment)
**Number of Participants in Follow-up:** 43
**Projected Closed to Follow-up Date:** Approximately 7 patients have completed follow up.

**Primary Objective:**
The overall objective is to determine whether online adaptive image guided radiotherapy is feasible in multiple radiation oncology centers of varying size in Australia and New Zealand.

**Primary Endpoint:**
The primary endpoint is compliance with the Online Adaptive Radiation Therapy process, in which a patient is considered to be compliant with Online Adaptive Process for Online Adaptive Image Guided Radiotherapy for muscle invasive bladder cancer. Compliance is defined as completion of adaptive treatment without a major protocol deviation.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
The QA program for this trial is managed and coordinated by the TROG Central Operations Office (TCOO) QA team. Site visits and QA credentialing for all 15 sites have been completed. Real time-RT QA is conducted on the first 2 patients from each site either by Dr Colin Tang (Newcastle), Dr Farshad Foroudi (Peter Mac) or Dr Alex Tan (Townsville) with Daniel Pham reviewing the dose sections. To date, 29 patients have been reviewed in real time with 99.72% of variables classified as acceptable. A major variation has been recorded for 1 variable (0.05%). Thirty-six patients have also been reviewed for eligibility compliance with 100% of variables classified as acceptable.

**Toxicity:**
Eleven Serious Adverse Events (SAEs) have been reported and all were considered as expected. There has been no unexpected SAE reported to date. Nine Grade 3 Adverse Events (AEs) have been reported to date for patients under treatment out of which 3 were probably related to the protocol treatment (Dysuria, Cystitis non infective and Nausea) and 2 were definitely related to the protocol treatment (Diarrhea). During the follow up period, 7 grade 3 AEs have been reported to date out of which 1 AE (urinary inconsistency) at 15 month post radiotherapy was reported being definitely related to the protocol treatment and 2 being possibly related to the protocol treatment (proctitis at 3 month post radiotherapy and Cystitis non infective at 6 month post radiotherapy). No grade 4 AEs have been reported on the trial.

**Funding:**
- 2009 – NHMRC Project Grant $560,000, 2010-2012
- 2011 – Cancer Society of New Zealand Research Grant $NZ 84 696 (2011-2014)
Trial Management Committee

Trial Chairpersons:

Dr Farshad Foroudi
Peter MacCallum Cancer Centre, VIC

Prof Tomas Kron
Peter MacCallum Cancer Centre, VIC

Radiation Oncologists:
Prof Gillian Duchesne, Peter MacCallum Cancer Centre, VIC
Dr Kumar Gogna, Radiation Oncology Services – Mater Centre, QLD
Dr Margot Lehman, Princess Alexandra Hospital, QLD
Assoc Prof Jeremy Millar, The Alfred Hospital, VIC
Dr Marketa Skala, Royal Hobart Hospital, TAS
Dr Keen Hun Tai, Peter MacCallum Cancer Centre, VIC
Dr Alex Tan, Townsville Hospital, QLD
Dr Colin Tang, Calvary Mater Newcastle, NSW
Assoc Prof Sandra Turner, Westmead Hospital, NSW
Dr Leanne Tyrie, Waikato Hospital, New Zealand
Dr Steve Williams, Christchurch Hospital, New Zealand

Physicist:
Mr John Doody, Princess Alexandra Hospital, QLD

Urological Surgery:
Prof Dickon Hayne, Fremantle Hospital, WA

Translational Research:
Assoc Prof Christopher Hovens, University of Melbourne, VIC

Quality of Life:
Prof Jeffery Richardson and Angelo Lozzi, Monash University, VIC

Health Economists:
Sandra Younie, Deakin University, VIC
Robert Carter, Deakin University, VIC

Consumer:
Mr David Connah, NSW

Trial Statistician:
Mathias Bressel, Peter MacCallum Cancer Centre, VIC

Trial Coordinator:
Lavanya Gupta, BaCT, Peter MacCallum Cancer Centre, VIC (Lavanya.Gupta@petermac.org)
**TROG: 08.01**

**OCOG ~ A randomised trial of shorter radiation fractionation schedule for the treatment of localised prostate cancer (Prostate Fractionated Irradiation Trial) (PROFIT)**

**Lead Group:** Ontario Clinical Oncology Group (OCOG)

**Accrual Target:** 1206 internationally

**Final Accrual:** 1206 internationally (207 TROG)

**Number of Participants in Follow-up:** 930 (199 TROG)

**Projected Closed to Follow-up Date:** November 2020

**Primary Objective:**
To compare the efficacy of a shorter course of radiotherapy (60Gy in 20 fractions over 4 weeks) with a conventional fractionation course (78Gy in 39 Fractions over 8 weeks). The primary outcome is biochemical (PSA) failure defined by the American Society of Therapeutic Radiology and Oncology (ASTRO) consensus definition at the time of analysis.

**Primary Endpoint:**
The primary endpoint is biochemical-clinical failure (BCF) defined by a cluster of events including PSA failure based on the ASTRO definition, clinical evidence of local or metastatic progression (nodal or distant), post-treatment initiation of hormonal therapy by the treating physician, or prostate cancer related death. Secondary outcomes include BCF with PSA failure based on the Phoenix definition, mortality from cancer, toxicity and health-related quality of life.

**Summary of Trial Activity for 2012**
Patients will continue to be followed as per the trial schedule for at least the next 9 years. Sites will continue to complete online remote collection and entry of Case Report Forms (CRFs). Data cleaning has begun with a focus on baseline assessments and radiotherapy CRFs. At this stage the majority of baselines forms have been verified. Data entry and queries will continue to be managed by OCOG utilising the ORCCID system.

**Toxicity:**
Acute and late toxicity will continue to be assessed by the RTOG toxicity score. We have chosen this toxicity scale because it is widely recognized and investigators across the country have experience with its use. This scale is administered by the physician or clinical designate.

**Analysis:**
The PROFIT Data Safety Monitoring Board (DSMB) has reviewed the first and only formal interim analysis of the primary efficacy outcomes and safety outcomes planned for the PROFIT trial. The report covered the period up to July 13, 2012 and presented median follow-up of 2.5 years and a maximum follow-up of 5.8 years. The DSMB evaluated the information provided regarding biochemical and clinical failure, PSA failure, and serious GI and GU toxicity by group and found no cause to stop the study. The main analysis will be conducted in 2021.

**Publications:**
- Martin J, Frantzis J, Eade T, Chung P. Clinician’s guide to prostate IMRT plan assessment and optimization. JMIRO 2010
Funding:
2007 - Strengthening Cancer Care Enabling Grant - TROG Seed Funding $20,000, 1 year
2008 - Prostate Cancer Foundation of Australia $100,000
2009 - Cancer Australia $443,500, 2009-2011 (In addition to the CAN$1300 from OCOG per each patient randomised and followed for 3 years, sites will receive an additional $AUS1000 paid by the coordinating trial centre. There is also $AUS2000 for each site at the time of activation to offset the costs associated with credentialing and HREC processing.)

Trial Management Committee
The following TROG TMC has been formed in addition to the OCOG TMC:

**Trial Chairperson:**

Dr Jarad Martin  
(Participant on OCOG TMC),  
Calvary Mater Newcastle, NSW

**Radiation Oncologists:**

Dr Sandra Turner, Westmead Hospital, NSW  
Dr Keen Hun Tai, Peter MacCallum Cancer Centre, VIC  
Dr Andrew See, Ballarat Austin Radiation Oncology Centre, VIC  
Dr Thomas Eade, Royal North Shore Hospital, NSW

**Medical Physicists:**

Assoc Prof Tomas Kron, Peter MacCallum Cancer Centre, VIC  
Dr Brendon Healy, Radiation Oncology Queensland, QLD

**Radiation Therapist:**

Mr Jim Frantzis, Radiation Oncology Queensland, QLD

**Trial Coordinator:**

Clare Butters, Oncology Research Australia, Toowoomba QLD (clare.butters@roq.net.au)

**Collaborating Group:**

Trans Tasman Radiation Oncology Group (TROG)
**Lead Group:** Victorian Cooperative Oncology Group (VCOG)

**Accrual Target:** 450  
**Final Accrual:** 293  
**Number of Participants in Ongoing Follow-up:** 255  
**Projected Closed to Follow-up Date:** 15 January 2014

**Primary Objective:**  
To test the hypothesis that early intervention with androgen deprivation therapy (ADT) in patients with prostate cancer suffering a PSA relapse (Study 1), or considered unsuitable for curative treatment (Study 2), improves overall survival while maintaining an acceptable quality of life, when compared to delayed intervention.

**Primary Endpoint:**  
The primary endpoint for this trial is overall survival.

**Summary of Trial Activity for 2012**

**Toxicity:**  
Continued monitoring of reported adverse events such as hospitalisations. No change has been required to protocol.

**Analysis:**  
Data cleaning will occur in later 2013 in preparation for the main analysis planned for 2014. No analyses will occur in the interim.

**Funding:**  
2004 - A NHMRC project grant of $627,000 was awarded for 3 years in 2004 for commencement 2005. As of December 2007, NHMRC granted the trial an extension on this funding until December 2008.  
2005 - Mayne Pharma (now known as Hospira) contributes $200 per patient towards patient recruitment.

**Trial Management Committee (Australia and New Zealand)**  
**Trial Chairpersons:**  
Assoc Prof Henry Woo, Clinical Associate Professor, University of Sydney, NSW

**Prof Gillian Duchesne**  
Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**  
Mr Mark Frydenberg, Monash Medical Centre, VIC  
A/Prof Frank Gardiner, University of Queensland, QLD  
Dr Jeremy Millar, WBRC, The Alfred Hospital, VIC  
Dr Nigel Spry, Sir Charles Gairdner Hospital, WA
Dr Keen Hun Tai, Peter MacCallum Cancer Centre, VIC
Dr Sandra Turner, Westmead Hospital, NSW
Dr Viet Do, Westmead Hospital, NSW

Clinical Epidemiologist:
Dr Martin Stockler, NHMRC Clinical Trials Centre, NSW

Urologist:
Mr Justin Vivian, Hollywood Private Hospital, WA

Trial Statistician:
Prof Cate D’Este, University of Newcastle, NSW

Trial Coordinator:
Khoa Truong, Cancer Council Victoria, VIC (Khoa.Truong@cancervic.org.au)

Consumer:
Mr Leo Ledwich, Consumer, VIC

Collaborating Group:
Trans Tasman Radiation Oncology Group (TROG)

TROG: 03.04
Randomised trial investigating the effect of survival and PSA control of different durations of adjuvant androgen deprivation in association with definitive radiation treatment for localised carcinoma of the prostate (RADAR).

Lead Group: Trans Tasman Radiation Oncology Group (TROG)
Accrual Target: 1000
Final Accrual: 1071
Number of Participants in Follow-up: 844
Projected Closed to Follow-up Date: 28 February 2019

Primary Objective:
The primary objective of the trial is to test the hypothesis that 12 months adjuvant androgen deprivation using Leuprolelin acetate starting immediately after standard therapy (ie 6 months of Leuprorelin acetate before and during radiotherapy) will reduce prostate cancer-specific mortality (PCSM) when compared with standard therapy alone.

Primary Endpoint:
The primary endpoint of the trial is prostate cancer-specific mortality.

Summary of Trial Activity for 2012
Quality Assurance:
Site Data Monitoring: 10 monitoring visits were conducted during 2012.
Radiotherapy Technical Review: QA review is complete.
Histopathology: The central review of all diagnostic pathology has now been completed by Trial Pathologist,
Professor Brett Delahunt in Wellington, New Zealand with the assistance of Ms Judy Murray (New Zealand RADAR Trial Co-ordinator). Pathology slides of 997 patients were acceptable for review. Tissue from Western Australian patients are being assessed for neuro-endocrine differentiation by Dr Ronnie Cohen in Perth.

TLX/DEXA Audit: Central review of x-rays (electronic and film) and DEXA reports was completed in 2012.

Analyses:
Analyses of quality of life, rectal and urinary toxicity, and cardiac events have been completed and results published. The impact of treatment on bone mineral density and fractures has also been analysed and submitted for publication.

Publications:

Funding:
2003 - NHMRC funding of $1.75 million over 3 years, 2004-2006. This grant was originally provided for five years; however it was completed in 2006 as a result of rapid accrual.
2003 - HRC and Cancer Society of New Zealand funding of $NZ706,105 over 3 years, 2004-2006
2003 - HMRI funding of $20,000 over 1 year
2006 - NHMRC funding of $2,423,890 over 5 years, 2007-2011
2006 - Cancer Society of New Zealand funding of $NZ486,492, 1st October 2007-30th September 2010
2010 - Cancer Society of New Zealand funding of $NZ455,120, 1st October 2010-30th September 2013
2012 - Cancer Society of New Zealand funding of $NZ360,000, 2012-2014

Trial Management Committee

Trial Executives:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Institution</th>
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<tbody>
<tr>
<td><strong>Prof Jim Denham</strong></td>
<td>Trial Director</td>
<td>Calvary Mater Newcastle, NSW</td>
</tr>
<tr>
<td><strong>Clinical Prof</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>David Joseph</td>
<td>Australian Trial Chair</td>
<td>Sir Charles Gairdner Hospital, WA</td>
</tr>
<tr>
<td><strong>Prof David Lamb</strong></td>
<td>New Zealand Trial Chair</td>
<td>Wellington Hospital, NZ</td>
</tr>
<tr>
<td><strong>Prof Gillian Duchesne</strong></td>
<td></td>
<td>Peter MacCallum Cancer Centre, VIC</td>
</tr>
</tbody>
</table>
Radiation Oncologists:
Assoc Prof Chris Atkinson, St George’s Cancer Centre, Christchurch NZ
Dr Lizbeth Kenny, QRI Royal Brisbane Hospital, QLD
Dr Kumar Gogna, QRI Mater Hospital, QLD
Dr John Matthews, Auckland Hospital, NZ
Dr Nigel Spry, Sir Charles Gairdner Hospital, Perth, WA
Dr Keen-Hun Tai, Peter MacCallum Cancer Centre, Melbourne, VIC
Dr Sandra Turner, Westmead Hospital, NSW

Physics:
Dr Annette Haworth, Peter MacCallum Cancer Centre, Melbourne, VIC

Pathologist:
Professor Brett Delahunt, Wellington Hospital, NZ

Endocrinologist:
Dr Terry Diamond, St George Hospital, NSW

Statisticians:
Dr Patrick McElduff, University of Newcastle, NSW
Prof Cate D’Este, University of Newcastle, NSW

Consumer:
Dr Barry Clarke, Nelson Bay, NSW

Trial Coordinator:
Mrs Allison Steigler, University of Newcastle, NSW (allison.steigler@newcastle.edu.au)

Multicentre phase III study comparing radical synchronous chemo-radiation vs radical radiation alone in the definitive management of muscle invasive TCC of the urinary bladder following maximal TUR

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Accrual Target: 150
Final Accrual: 68

Actual Closed to Follow-up Date: February 2010

Analysis/Manuscript:
The final analysis has been performed and the manuscript is in draft format.

continues on next page
Trial Chairperson:

Dr Kumar Gogna
Radiation Oncology Services
Mater Centre, QLD

Trial Coordinator:

Kacy Baumann, Radiation Oncology Services - Mater Centre, QLD (kacy_baumann@health.qld.gov.au)

Collaborating Group:

Urological Society of Australia

TROG: 96.01

A randomised trial investigating the effectiveness of different durations of maximal androgen deprivation prior to and during definitive radiation therapy for locally advanced carcinoma of the prostate.

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Accrual Target: 800
Final Accrual: 818

Actual Closed to Follow-up Date: 31 August 2010

Summary of Trial Activity for 2012

Publications:


Trial Chairperson:

Prof Jim Denham
Calvary Mater Newcastle,
NSW

Central Trial Coordinator:

Allison Steigler, University of Newcastle, NSW (allison.steigler@newcastle.edu.au)
Genitourinary Cancer Trials
Approved for Development

Post prostatectomy salvage radiotherapy dose and technique comparison (PSa Dot Com)

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Date Approved for Development:** 14 July 2010

**Current Status:** Development on hold until funding is secured.

**Trial Chairperson:**
Dr Scott Williams
Peter MacCallum Cancer Centre, VIC
scott.williams@petermac.org

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TROG: 08.03
Substudy

**Evaluating the utility of a patient decision aid for prospective participants in the TROG 08.03 (RAVES) prostate cancer trial (RAVES DA)**

**Lead Group:** Psycho-Oncology Cooperative Research Group (PoCoG)

**Date Approved for Development:** 27 March 2010

**Current Status:** Development underway, nearing activation.

**Trial Chairperson:**
Dr Phyllis Butow
University of Sydney, NSW

**Trial Coordinator**
Esther Davis
esther.davis@sydney.edu.au
GYNAECOLOGICAL CANCER

Gynaecological Cancer Open Trials

**TROG: 08.04**

Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma (PORTEC-3)

**International Lead Groups:** Dutch Cooperative Gynecologic Oncology Group
  UK National Cancer Research Institute

**ANZ Lead Group:** Australia New Zealand Gynaecological Oncology Group (ANZGOG)

**Accrual Target:** 670 Internationally
**Accrual Total:** 554 (International), 101 (TROG)

**First Participant Accrued:** 7 November 2008 (TROG)
**Anticipated Accrual End Date:** 31 December 2013

**Primary Objective:**
Establish overall survival and failure-free survival of patients with high-risk and advanced stage endometrial carcinoma, treated after surgery with concurrent radiotherapy and chemotherapy, followed by adjuvant chemotherapy, in comparison with patients treated with pelvic radiation alone.

**Primary Endpoint:**
The primary endpoint of this trial is overall survival.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
The radiotherapy Quality Assurance (QA) program is co-ordinated by the TROG Central Operations Office (TCOO) QA team. The QA program for this trial involves the completion of a radiotherapy benchmarking exercise by all TROG investigators. All benchmarking submissions have been passed with 32 investigators from 17 participating sites completing the benchmarking exercise. There is only 1 pending site that still needs to complete the benchmarking exercise. Radiotherapy reviews have been completed on 53 cases. Of these reviews, 94% of variables were deemed as acceptable. Major variations were reported at 0.6%, minor variations at 5.4% and no missing /inevaluable information was reported.

**Funding:**
2008 – NHMRC Project Grant, $443,125, 2009-2011
2011 – Cancer Australia Priority-driven Collaborative Cancer Research Scheme, $300,778 (excl GST), (2012-2015)

**Trial Management Committee**
The following ANZGOG/TROG TMC has been formed in addition to the Dutch Cooperative Gynecologic Oncology Group and UK National Cancer Research Institute TMC.
TROG Trial Chairperson:

**Dr Pearly Khaw**  
Peter MacCallum  
Cancer Centre, VIC

**Radiation Oncologists:**  
Dr Viet Do, Westmead Hospital, NSW  
Dr Kerwyn Foo, Royal Prince Alfred/Sydney Cancer Centre, NSW  
Dr Carol Johnson, Wellington, NZ  
Dr Karen Lim, Liverpool Hospital, NSW

**Medical Oncologist:**  
Dr Linda Mileshkin, Peter MacCallum Cancer Centre, VIC (ANZGOG PI)

**Gynaecologic Oncologists:**  
Prof Michael Quinn, Royal Women’s Hospital, VIC  
Dr Alison Brand, Westmead Hospital, NSW

**Physicist:**  
Mr Michael Bailey, Illawarra Cancer Centre, Wollongong, NSW

**Radiation Therapists:**  
Ms Jennie Vassie, Peter MacCallum Cancer Centre, VIC  
Ms Jodie Cunningham, Peter MacCallum Cancer Centre, VIC  
Mr Justin Dixon, Illawarra Cancer Centre, Wollongong, NSW  
Ms Celia Gordon, Wellington, NZ

**Data Manager:**  
Dr Jessica Faggian, Peter MacCallum Cancer Centre, VIC

**ANZGOG Coordinating Centre:**  
Ilka Kolodziej (PORTEC-3@ctc.usyd.edu.au)

**Collaborating Groups:**  
National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)  
MaNGO Group (Italy)  
FNCLCC (FEDEGYN Group) (France)  
Trans Tasman Radiation Oncology Group (TROG)
Gynaecological Cancer Closed Trials

| TROG: 04.02 | Prospective study to determine the relationship between survival and FIGO stage, tumour volume and corpus invasion in cervical cancer |

**Lead Groups:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 280

**Accrual Total:** 108

**Number of Participants in Follow-up:** 0

**Actual Closed to Follow-up Date:** Trial suspended in 2009

**Principle Objective:**
The principle aim of the study is to assess the independent prognostic significance, with respect to overall survival, of the factors, FIGO stage, tumour volume and corpus invasion, in radically treated cervical cancer patients.

**Summary of Trial Activity for 2012**
During Nov 2009 the TSC supported the Trial Chairs recommendation to close this trial due to difficulties with accrual and funding. The TSC recommended that the Trial Chair obtain a comprehensive quote and continue to source funding for the purpose of collating, analysing and reporting data. Since then, no funding opportunities have come to fruition and in November 2012 the TSC recommended that a Senior Registrar or Fellow would be suitable to complete the outstanding issues for trial to be analysed. Advertisement of this position and recruitment is planned to commence in early 2013.

**Funding:**
Nil

**TROG Trial Chairperson:**
Contact the TROG Central Operations Office for all enquiries regarding this trial (trog@trog.com.au)
HEAD AND NECK CANCER (H&N)

H&N Cancer Open Trials

TROG: 12.03
An RCT of psychological training for dieticians to reduce malnutrition and depression in head and neck cancer patients undergoing radiotherapy (Eating As Treatment: EAT).

Lead Group: University of Newcastle
Accrual Target: 400
Accrual Total: 0
First Participant Accrued: Recruitment is expected to commence in March 2013.
Anticipated Accrual End Date: December 2015

Primary Objective:
The current study aims to test the effectiveness of a dietitian delivered behaviour change counselling intervention (EAT) to reduce malnutrition in Head and Neck Cancer (HNC) patients undergoing radiotherapy in six Australian sites.
The primary objective of the trial is to improve nutrition in HNC patients undergoing radiotherapy.

Primary Endpoint:
The primary endpoint of this trial is the nutritional status as measured by the PG-SGA.

Summary of Trial Activity for 2012
Six trial sites have been confirmed for participation in this trial. Ethics and governance approval has been confirmed for the lead site (University of Newcastle). Site specific approvals are underway.
The trial was presented at the following meetings:

- International Psycho-oncology Society [IPOS]: Joint Meeting of IPOS 14th World Congress and COSA's 39th Annual Scientific Meeting, Brisbane, Nov 2012.
- Clinical Oncological Society of Australia [COSA]: Joint Meeting of IPOS 14th World Congress and COSA's 39th Annual Scientific Meeting, Brisbane, Nov 2012.

Funding:
2012 – NHMRC project grant for $1,117,558.00

Trial Management Committee
Trial Chairpersons:
Dr Ben Britton
Centre for Translational Neuroscience & Mental Health, University of Newcastle, NSW

Dr Chris Wratten
Calvary Mater Newcastle Hospital, NSW
Multidisciplinary Members:
Prof Amanda Baker, University of Newcastle, NSW
Prof Gregory Carter, Calvary Mater Newcastle Hospital, NSW
Assoc Prof Judy Bauer, University of Queensland, QLD
Dr Luke Wolfenden, University of Newcastle, NSW

Statistician:
Dr Patrick McElduff, University of Newcastle, NSW

Trial Coordinator:
Dr Alison Beck, University of Newcastle, NSW (Alison.Beck@newcastle.edu.au)

Collaborating Group:
Trans Tasman Radiation Oncology Group (TROG)

H&N Cancer Closed Trials

TROG: 07.04 A Phase I/II trial of cetuximab, carboplatin and radiotherapy for patients with locally advanced head and neck squamous cell carcinoma.

Lead Group: Trans Tasman Radiation Oncology Group (TROG)
Accrual Target: 60
Accrual Total: 60
Number of Participants in Follow-up: 59
Projected Closed to Follow-up Date: 30 August 2017

Primary Objective:
To show the feasibility and safety profile of the combination of cetuximab, carboplatin and RT in treatment of patients with locally advanced head and neck cancer who are unfit for cisplatin.

Primary Endpoint:
Safety and feasibility as measured by the satisfactory completion of the treatment regimen.

Summary of Trial Activity for 2012
Quality Assurance:
The QA program is coordinated by the TROG Central Operations Office (TCOO) QA team. Trial sites are required to complete a radiotherapy benchmarking activity for this trial to verify compliance with the protocol’s treatment planning requirements. Five sites have passed the benchmarking activity (using conformal RT). Sites may use intensity modulated radiotherapy (IMRT) if they have successfully completed the TROG IMRT (head and neck) credentialing process. Case reviews are conducted to evaluate source data for verification of protocol compliance and data accuracy in regard to eligibility, radiotherapy treatment delivery, Cetuximab treatment delivery and reporting of sites of local and/or regional failure. Eligibility reviews are conducted by the Trial Coordinator, Dr Teresa Morgan. RT case reviews will be performed by
reviewers who were not involved with the treatment of the patient. Chemotherapy reviewers are in the process of being appointed. QA Radiotherapy and Chemotherapy case review documentation has been received for 49 patients.

**Toxicity:**
Interim analysis after 6 and 30 patients were undertaken. There were no unexpected toxicities and the study was given the all clear to continue to recruit. 60 patients have now been recruited.

**Analysis:**
Two interim analyses have been carried out; one was conducted when the 6th patient finished treatment. The second was performed after the accrual of 30 patients. Both analyses confirmed no unexpected toxicities. The main analysis of the secondary endpoints will be conducted when all 60 patients have a minimum of two years follow-up. The final analysis will be performed when all 60 patients have completed 4 years follow-up.

**Funding:**
2007 - MERCK Oncology Pty Ltd funding of $350,000, 2008-2012, plus provision of study drug cetuximab over the duration of the trial.

**Trial Management Committee**

**Trial Chairpersons:**
- **Assoc Prof June Corry**
Peter MacCallum Cancer Centre, VIC
- **Assoc Prof Danny Rishin**
Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**
- Dr Chris Wratten, Calvary Mater Newcastle, NSW
- Assoc Prof Sandro Porceddu, Princess Alexandra Hospital, QLD
- Dr Hedley Krawitz, Auckland Hospital, NZ

**Radiation Therapist:**
Mr Michael Ruemelin, Peter MacCallum Cancer Centre, VIC

**Translational Research:**
- Assoc Prof Ben Solomon, Peter MacCallum Cancer Centre, VIC

**Statistician:**
Marnie Collins, BaCT, Peter MacCallum Cancer Centre, VIC

**Trial Coordinator:**
Dr Teresa Morgan, BaCT, Peter MacCallum Cancer Centre, VIC (teresa.morgan@petermac.org)
Radiotherapy with Humidification in Head and Neck Cancer: A randomised phase III trial of the Trans Tasman Radiation Oncology Group in collaboration with Fisher and Paykel Healthcare (RadioHUM)

**Lead Group:** A collaboration between Trans Tasman Radiation Oncology Group (TROG) and Fisher & Paykel Healthcare (FPH)

**Accrual Target:** 210  
**Accrual Total:** 210  
**Number of Participants in Follow-up:** 45  
**Projected Closed to Follow-up Date:** 4 August 2013

**Primary Hypothesis:**  
Humidification will modulate the natural history of mucositis resulting in a clinically significant reduction in the intensity of severe acute mucositis as a function of time for CTCAE grade > 1 mucositis (e.g. grade 2 or higher), measured as the area under the time curve (AUC) of the plot expressing grade of acute reactions versus weeks for observed CTCAE mucosal reactions > 1.

**Primary Endpoint:**  
Intensity of mucositis as a function of time for CTCAE grade > 1 mucositis (e.g. grade 2 or higher) measured as the area under the time curve (AUC) of the plot expressing grade of acute reactions vs. weeks for observed CTCAE mucosal reactions > 1.

**Summary of Trial Activity for 2012**

**Quality Assurance:**  
The QA program is coordinated by the TROG Central Operations Office (TCOO) QA team and reviews are conducted to verify protocol compliance and data accuracy for eligibility, radiotherapy delivery and humidification compliance. Sites wishing to use Intensity Modulated Radiation Therapy (IMRT) were required to undergo credentialling consisting of a facility questionnaire, a de-identified typical IMRT plan relevant to the trial and de-identified results of a patient’s QA dosimetric study. When the trial closed to recruitment, 4 sites had completed credentialling and 1 site was pending. Eligibility reviews have been conducted for 186 cases. These reviews have demonstrated that 97.9% of variables reviews were deemed as acceptable. Major variations and missing/inevaluable information was reported at 0.08% and 2.0% respectively. Radiotherapy review variables and audit forms are under review after pilot reviews were conducted. Chemotherapy reviews consisted of source data verification only and protocol compliance will not be reported as there are no mandatory requirements for chemotherapy. A central review of humidifier compliance is conducted by the Trial Coordinating Centre (TCC) for all patients randomised to the investigational arm. Humidifier use is assessed using the Compliance Maximiser™ software to evaluate protocol compliance.

**Toxicity:**  
Grade 3 adverse events are key components or primary and secondary endpoints. Therefore these events will be reported as part of the trial analysis.

**Analysis:**  
The primary analysis is underway and results are anticipated to be reported in 2013.
Funding:
2006 - New Zealand's Foundation for Research, Science & Technology (FRST) $AUD 794,799. ($NZ 928,000)
2006 - Baxter Healthcare Ltd will provide the sterilised water required to operate the humidifiers free of charge
2011 - Auckland Hospital Charitable Trust: to supplement trial centre costs $25,266, July 2011 to June 2012

Trial Management Committee
Trial Chairperson: Dr Andrew Macann
Auckland Regional Cancer and Blood Service, NZ

Radiation Oncologists:
Assoc Prof Christopher Milross, Sydney Cancer Centre, NSW
Assoc Prof Sandro Porceddu, Princess Alexandra Hospital, QLD
Dr Michael Penniment, Royal Adelaide Hospital, SA
Dr Tsien Fua, Peter MacCallum Cancer Centre, VIC

Head and Neck Surgeon:
Assoc Prof Randall Morton, Counties Manukau District Health Board, NZ

Oral Medicine:
Dr David Hay, Auckland District Health Board, NZ

Oncology Nursing:
Vicki Thompson, Auckland City Hospital, NZ

Fisher and Paykel Healthcare:
Michelle Eccleston

Quality of Life:
Prof Madeleine King, Psycho-Oncology Co-operative Research Group, University of Sydney, NSW
Dr Melanie Bell, Psycho-Oncology Co-operative Research Group, University of Sydney, NSW

Statistician:
Hans Hockey, Biometrics Matters Ltd

Trial Coordinator:
Carol Fraser-Browne, Auckland Regional Cancer and Blood Service, NZ (CarolFB@adhb.govt.nz)
H&N Trials Approved for Development

<table>
<thead>
<tr>
<th>TROG:</th>
<th>A randomized phase III trial of weekly cetuximab and radiation versus weekly cisplatin and radiation in locoregionally advanced HPV associated oropharyngeal cancer (HPV Oropharynx).</th>
</tr>
</thead>
</table>

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Primary Objective:**
To compare symptom severity between weekly cisplatin and RT versus weekly cetuximab and RT from baseline to week 20 (13 weeks post-completion of radiotherapy).

**Primary Endpoint:**
The primary endpoint is the area under the curve of symptom severity as measured by MDASI-HN Symptom Severity Score (average of MDASI-HN items 1-22) from baseline to week 20 (13 weeks post-completion RT).

**Summary of Trial Activity for 2012**

**Trial Development:**
In June 2012 the TROG Scientific Committee was satisfied that the development and content of the protocol met the requirements to be allocated a TROG number (12.01). The successful outcome of the NHMRC funding application submitted for this trial in 2012 was announced in October 2012. Further to this the finalisation of the protocol continued with the aim obtaining final approval from the TSC during early 2013 in preparation for the ethics submission. Trial activation is planned for early 2013.

**Funding:**
2012 - NHMRC $1,097,932 for 5 years (2013 – 2017)

**Trial Management Committee**

**Trial Chairpersons:**

- **Assoc Prof Danny Rishin**
  Peter MacCallum Cancer Centre, VIC

- **Assoc Prof June Corry**
  Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**
Dr Chris Wratten, Calvary Mater Newcastle, NSW
Assoc Prof Sandro Porceddu, Princess Alexandra Hospital, QLD
Dr Liz Kenny, Royal Brisbane Hospital, QLD
Dr Andrew Macann, Auckland Regional Cancer and Blood Service, NZ

**Medical Oncologist:**
Prof Danny Rischin, Peter MacCallum Cancer Centre, VIC
Surgical Oncology/Audiometry:
Ben Dixon, Peter MacCallum Cancer Centre, VIC

Radiation Therapy:
Michael Ruemelin, Peter MacCallum Cancer Centre, VIC

Translational Research:
Mr Ben Solomon, Peter MacCallum Cancer Centre, VIC

Quality of Life:
Prof Madeleine King, PoCoG, University of Sydney, NSW

Pathology:
Stephen Fox, Peter MacCallum Cancer Centre, VIC

Statistician:
Prof Richard Fisher, BaCT, Peter MacCallum Cancer Centre, VIC

Health Economist:
Prof Jon Karnon, University of Adelaide, SA

Consumer:
Carl James, VIC

Depression Substudy:
Jeremy Couper, Peter MacCallum Cancer Centre, VIC

Trial Coordinator:
Janani Sivasuthan, BaCT, Peter MacCallum Cancer Centre, VIC (Janani.Sivasuthan@petermac.org)
LUNG CANCER

Lung Cancer Open Trials

**TROG: 11.03**
A randomised phase III trial of high dose palliative radiotherapy (HDPRT) versus concurrent chemotherapy and HDPRT (C-HDPRT) in patients with good performance status, locally advanced/small volume metastatic NSCLC not suitable for radical chemo-radiotherapy. (P_LUNG GP)

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 130
**Accrual Total:** 3

**First Participant Accrued:** 19 December 2012
**Anticipated Accrual End Date:** 19 December 2017

**Primary Objective:**
To compare the intrathoracic symptom response rate for each of dyspnoea, cough haemoptysis and chest pain achieved by high dose palliative radiotherapy (HDPRT) versus concurrent chemotherapy and HDPRT (C-HDPRT), as assessed six weeks after the completion of treatment, in this cohort of patients.

**Primary Endpoint:**
Change from baseline at 6 weeks after treatment in the Intrathoracic Symptom Burden Index and in each of the component symptoms, dyspnoea, cough, haemoptysis and chest pain.

**Summary of Trial Activity for 2012:**
**Quality Assurance:**
The QA program for this trial has been developed and will be managed by the TROG Central Operations Office (TCOO) QA team.

**Funding:**
Cancer Australia (Priority Driven Collaborative Cancer Research Scheme) $327,215 (2011-2013)

**Trial Management Committee**
**Trial Chairperson:**
Dr Margot Lehman
Princess Alexandra Hospital, QLD

**Trial Co-Chairperson:**
Assoc Prof Michael Michael, Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**
The primary objective of the study is to test whether highly conformal hypofractionated image guided radiotherapy (HypoRT) results in superior time to local failure in patients with inoperable stage I (T1, T2a) non-small cell lung cancer compared with standard care consisting of conventionally fractionated radiotherapy (ConRT).
Primary Endpoint:
The primary endpoint for this trial is time to local failure from the date of randomisation.

Summary of Trial Activity for 2012

Quality Assurance:
The QA program for this trial is managed and coordinated by the TROG Central Operations Office (TCOO) QA team. Credentialing of participating sites involves the completion of a facility questionnaire, approval of 2 benchmarking cases treated according to the hypofractionated arm and the demonstration that the site can deliver the prescribed hypofractionated treatment to a dynamic phantom. A total of 8 hospitals have now been credentialed and activated to the study.

All HypoRT arm patients are reviewed prior to treatment commencement. Pre-treatment radiotherapy review of 15 cases has demonstrated a high level of compliance with 93.98% of variables deemed as acceptable after final review. Three patients (20%) have been required to be re-submitted after the initial plan was deemed not to meet protocol requirements. Initial pre-treatment review determined that one patient could not proceed with hypo-fractionated treatment and the patient was switched to the conventional arm of the trial. The high proportion of cases requiring re-submission prior to treatment commencement demonstrates the value of a pre-treatment QA review program in this trial.

Publication:

Funding:
2008 – Cancer Australia funding $260,000, 2009-2013

Trial Management Committee

Trial Chairperson:
Prof David Ball
Peter MacCallum Cancer Centre, VIC

Radiation Oncologists:
Dr Thomas Eade, Royal North Shore Hospital, NSW
Assoc Prof Shalini Vinod, Liverpool Hospital, NSW
Dr Jane Ludbrook, Calvary Mater Newcastle, NSW
Dr Michael Fay, Royal Brisbane and Women’s Hospital, QLD
Dr Brigid Hickey, Radiation Oncology Services – Mater Centre, QLD
Dr Tao Mai, Princess Alexandra Hospital, QLD
Dr Marketa Skala, Royal Hobart Hospital, TAS
Dr Mark Bell, Launceston Hospital, TAS
Assoc Prof Michael MacManus, Peter MacCallum Cancer Centre, VIC
Dr Greg Wheeler, Peter MacCallum Cancer Centre, Moorabbin, VIC
Assoc Prof Andrew Wirth, Peter MacCallum Cancer Centre, Box Hill, VIC
Dr Daisy Mak, Peter MacCallum Cancer Centre, Bendigo, VIC
Dr Jeremy Ruben, The Alfred Hospital, VIC
Prof Sean Bydder, Sir Charles Gairdner Hospital, WA
Dr Scott Babington, Christchurch Hospital, NZ
Dr Nik Nedev, Palmerston North Hospital, NZ
Medical Oncologist:
Dr Ben Solomon, Peter MacCallum Cancer Centre, VIC

Surgeon:
Mr Morgan Windsor, Prince Charles Hospital, QLD

Physicist:
Assoc Prof Tomas Kron, Peter MacCallum Cancer Centre, VIC

Radiation Therapist:
Brent Chesson, Peter MacCallum Cancer Centre, VIC

Translational Research:
Dr Ben Solomon, Peter MacCallum Cancer Centre, VIC

Quality of Life:
Assoc Prof Penny Schofield, Peter MacCallum Cancer Centre, VIC

Consumer:
David Wenzel, Consumer Register, Peter MacCallum Cancer Centre, VIC

Trial Statistician:
Mr Alan Herschtal, Peter MacCallum Cancer Centre, VIC

Trial Coordinator:
Marijana Vanevski, BaCT, Peter MacCallum Cancer Centre, VIC (marijana.vanevski@petermac.org)

Lung Cancer Trials Approved for Development

Stereotactic ablative fractionated radiotherapy versus radiosurgery for oligometastatic neoplasia to the lung: A randomised phase II trial (SAFRON II).

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Date Approved for Development: 28 June 2012

Current Status: Development underway. Protocol nearing completion. NHMRC funding application to be submitted in 2013.

Trial Chairperson:
Dr Shankar Siva
Peter MacCallum Cancer Centre, VIC

Trial Coordinator:
Rebecca Montgomery
rebecca.montgomery@trog.com.au
LYMPHOMAS

Lymphoma Open Trials

TROG: 05.02
ALLG (NHL15) – A prospective single arm trial of involved field radiotherapy alone for stage I-II low grade non-gastric marginal zone lymphoma (MALT Lymphoma).

Lead Group: Trans Tasman Radiation Oncology Group (TROG)
Accrual Target: 100
Accrual Total: 48
First Participant Accrued: 8 June 2007
Anticipated Accrual End Date: 31 December 2013

Primary Objectives:
This prospective study will test the following hypothesis in patients with stage I-II low grade marginal zone (MZ) lymphoma:
- Involved Field Radiotherapy will produce a complete response rate of > 90%
- Radiotherapy will be associated with a locoregional progression of < 20% after 10 years
- Death from Marginal Zone lymphoma will occur in < 40% of patients within 10 years of radiotherapy

Primary Endpoints:
- Freedom from locoregional progression (FFLRP)
- Complete Response Rate
- Cancer-specific survival (CSS)

Summary of Trial Activity for 2012

Quality Assurance:
QA reviews are conducted for initial ethics submission and annual renewal of ethics approval, eligibility, radiotherapy and response. QA reviews to date have demonstrated a high level of protocol compliance. Over all, across eligibility, radiotherapy and response, an acceptability rate of 96.88% has been reported. The eligibility reviews demonstrated acceptable compliance of 99.49%, with no minor variations reported and major variations reported at 0.26%. Missing/invaluable data has been reported at 0.26%. Radiotherapy reviews have demonstrated that 94.34% of variables reviewed are deemed as acceptable. Major variations, minor variations and miss/invaluable information has been reported at 1.13%, 1.36% and 3.17% respectively. Response QA reviews have demonstrated 98.48% compliance, with 1 minor variation reported. Timeliness and completeness of CRF return will also be monitored.

Funding:
2006 - NHMRC project grant for $342,250, 2007-2011
2006 - Department of Health Strengthening Cancer Care Infrastructure Support for Clinical Trials, Data Management Infrastructure Support for TROG trials: 99.03, 99.05, 01.04, 02.01, 03.02, 04.02, 05.02, $30,000
Trial Management Committee

**Trial Chairpersons:**
Assoc Prof John Seymour, Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**
Assoc Prof Daniel Roos, Royal Adelaide Hospital, SA
Dr Peter O’Brien, Calvary Mater Newcastle, NSW
Dr Richard Tsang, Princess Margaret Hospital, Canada

**Statistician:**
Assoc Prof Richard Fisher, BaCT, Peter MacCallum Cancer Centre, VIC

**Trial Coordinator:**
Dr Bereha Khodr, BaCT, Peter MacCallum Cancer Centre, VIC (Bereha.Khodr@petermac.org)

**Collaborating Group:**
Australasian Leukemia & Lymphoma Group (ALLG)
Lymphoma Closed Trials

**TROG: 03.03**

**ALLG (HDNHL04) – An ALLG/TROG prospective multicentre study of involved-field radiotherapy with transplantation for patients with Hodgkin’s disease and non-Hodgkin’s lymphoma.**

**Lead Group:** Australasian Leukemia & Lymphoma Group (ALLG)

**Accrual Target:** 100

**Final Accrual:** 45

**Number of Participants in Follow-up:** 31

**Projected Closed to Follow-Up Date:** 31 December 2014

**Primary Objective:**
Determine the cumulative incidence of progression in irradiated pre-transplant sites of failure 3 years following commencement of treatment.

**Primary Endpoint:**
The cumulative incidence of progression in pre-transplant relapse sites at 3 years.

**Funding:**
- 2002 - ALLG $42,458 over 7 years (2002-2008)
- 2002 - RANZCR $10,000
- 2003 - Amgen Australia $10,000
- 2004 - Baxter Healthcare $20,000
- 2005 - Amgen Australia $10,000

**Trial Management Committee (Australia and New Zealand)**

**Trial Chairpersons:**
Dr Miles Prince, Haematology, Peter MacCallum Cancer Centre, VIC

**Radiation Oncologists:**
Assoc Prof Daniel Roos, Royal Adelaide Hospital, SA
Dr Peter O’Brien, Calvary Mater Newcastle, NSW

**Haematologists:**
Dr Mark Hertzberg, Westmead Hospital, NSW
Assoc Prof John Gibson, Royal Prince Alfred Hospital, NSW

**Statistician:**
Mathias Bressel, BaCT, Peter MacCallum Cancer Centre, VIC

*Dr Andrew Wirth*
Peter MacCallum
Cancer Centre, VIC

*Dr Andrew Wirth*
Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Final Accrual: 20
Number of Participants in Follow-up: 2
Projected Closed to Follow-Up Date: July 2013

Primary Objectives:
- To estimate the median and 2 year overall survival
- To estimate the risk of late neurotoxicity relative to results achieved in TROG 92.01.

Primary Endpoints:
- Kaplan-Meier estimate of survival at 2 years
- Median survival
- Kaplan-Meier estimate of survival at 5 years.

Trial Chairperson: Dr Peter O’Brien
Calvary Mater Newcastle, NSW

Collaborating Group: Australasian Leukemia & Lymphoma Group (ALLG)
TROG: ALLG (NHLLOW5) – A randomised multicentre trial of involved field radiotherapy versus involved field radiotherapy plus chemotherapy in combination with rituximab (Mabthera®) for stage I – II low grade follicular lymphoma

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Accrual Target: 150
Final Accrual: 150
Number of Participants in Follow-up: 141
Projected Closed to Follow-Up Date: 30 October 2022

Primary Objective:
To test the hypothesis that the addition of six cycles of systemic therapy as specified in the protocol will improve progression-free survival for patients with stage I and II low-grade follicular lymphoma treated with involved-field radiotherapy (IFRT).

Primary Endpoint:
Progression-free survival (PFS) defined as from the date of randomisation to first progression of disease or death from any cause.

Summary of Trial Activities for 2012

Quality Assurance:
The radiotherapy reviews are coordinated by the TROG Central Operations Office (TCOO) QA team. The radiotherapy technical reviews have now been completed with the exception of one patient. These reviews have demonstrated a high level of protocol compliance throughout the trial, with an acceptability rate of 92.78%. The rate of major and minor protocol variations have been reported at 1.59% and 1.19% respectively. Missing/invaluable information was reported as 4.1%.

Toxicity:
Toxicity has been greater in the chemotherapy arm but within expected limits.

Analysis:
Following the end of accrual and after all patients have finished their treatment, analyses of outcomes, without breaking the treatment assignment codes, will be performed in order to identify factors associated with better outcomes. As patient accrual was completed in July 2012, this interim analysis will be performed in 2013.

Funding:
1998 - The Cancer Council Victoria - $150,000 for the first 3 years, 1999-2001
2000 - AMGEN - $30,000
2011 - Peter MacCallum Cancer Centre, Department of Radiation Oncology - $20,000
2011 - ALLG - $20,000

Trial Management Committee

Trial Chairpersons:
Prof John Seymour, Peter MacCallum Cancer Centre, VIC
Radiation Oncologists:
Assoc Prof Daniel Roos, Royal Adelaide Hospital, SA
Clin Prof David Joseph, Sir Charles Gairdner Hospital, WA
Dr Peter O’Brien, Calvary Mater Newcastle, NSW
Assoc Prof David Christie, East Coast Cancer Centre, QLD
Dr Sid Davis, Alfred Hospital, VIC
Dr Andrew Macann, Auckland Hospital, NZ
Dr Richard Tsang, Princess Margaret Hospital, Toronto, Canada

Statistician:
Assoc Prof Richard Fisher, BaCT, Peter MacCallum Cancer Centre, VIC

Translational Researcher:
Prof Maher Gandhi, QIMR

Trial Coordinator:
Marijana Vanevski, BaCT, Peter MacCallum Cancer Centre, VIC (marijana.vanevski@petermac.org)

Collaborating Groups:
Australasian Leukemia and Lymphoma Group (ALLG)
Princess Margaret Hospital, Toronto Canada
SKIN CANCER

Skin Cancer Open Trials

**TROG: 09.03**  
A phase II efficacy study of synchronous weekly carboplatin and radiation in merkel cell carcinoma of the skin (MP3)

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 50  
**Accrual Total:** 21

**First Participant Accrued:** 2 June 2010  
**Anticipated Accrual End Date:** December 2016

**Primary Objective:**  
The primary endpoint of this trial is to investigate the efficacy and toxicity of a chemo-radiotherapy regimen of weekly carboplatin during radiation followed by adjuvant chemotherapy in Stage II-III MCC.

**Primary Endpoint:**  
The primary endpoints of this trial are time to loco-regional failure curve, incidence of grade 3 and 4 toxicity and incidence of febrile neutropenia.

**Summary of Trial Activity for 2012**

**Quality Assurance:**  
The QA program is coordinated by the TROG Central Operations Office (TCOO) QA team. Radiotherapy, chemotherapy and relapse will be reviewed through TCOO. Before registering a patient to the trial, the Trial Coordinating Centre (TCC) reviews the CRFs, source documents and consent forms to conduct eligibility reviews based on inclusion and exclusion criteria. Eligibility review of 18 cases has demonstrated a high level of compliance with 97.3% of variables deemed as acceptable. Major variations and missing/inevaluable information have been reported at 1.9% and 0.8% respectively. Pathology reviews are co-ordinated by the TCC and will be conducted by Assoc Prof Jane Armes located at the Mater Pathology Services. To date, 11 patients have been reviewed for radiotherapy treatment compliance. These reviews have demonstrated an acceptability rate of 85.5%, with major and minor variations reported at 9.0% and 5.5% respectively. No missing/inevaluable information has been reported. The chemotherapy and relapse reviews have not yet begun.

**Toxicity:**

<table>
<thead>
<tr>
<th>Toxicity (Acute)</th>
<th>Grade 3 (# of patients)</th>
<th>Grade 4 (# of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatitis</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Decreased Neutrophil Count</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Febrile Neutropenia</td>
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<td></td>
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<tr>
<td>Decreased WCC</td>
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<tr>
<td>Lymphocytopenia</td>
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</tr>
</tbody>
</table>
Funding:
2008 – Cancer Australia funding $185,000, 2009-2015

**Trial Management Committee**

**Trial Chairperson:**

Assoc Prof **Michael Poulsen**
Radiation Oncology
Mater Centre, QLD

**Radiation Oncologist:**
Assoc Prof Michael Veness, Westmead Hospital, NSW

**Medical Oncologist:**
Assoc Prof Danny Rischin, Peter MacCallum Cancer Centre, VIC

**Radiation Therapist:**
Narelle Wallace, Radiation Oncology – Mater Centre, QLD

**Physicist:**
Adrian Gibbs, Radiation Oncology Services – Mater Centre, QLD

**Nuclear Medicine:**
David MacFarlance, Royal Brisbane and Women’s Hospital, QLD

**Pathology:**
Assoc Prof Jane Armes, Mater Pathology, QLD

**Consumer:**
Lance Brooks, Cancer Voices

**Statistician:**
Lee Tripcony, Royal Brisbane and Women’s Hospital, QLD

**Trial Coordinator:**
Adrienne See, Radiation Oncology Services – Mater Centre, QLD (adrienne_see@health.qld.gov.au)

<table>
<thead>
<tr>
<th>Toxicity (Acute)</th>
<th>Grade 3 (# of patients)</th>
<th>Grade 4 (# of patients)</th>
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<tbody>
<tr>
<td>Pneumonia</td>
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<td>Fever</td>
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<tr>
<td>Wound Infection</td>
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<table>
<thead>
<tr>
<th>Toxicity (Late)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Jaundice</td>
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</tbody>
</table>
**TROG: 08.09**

ANZMTG 01.09 – A randomised trial of post operative Radiation Therapy following wide excision of neurotropic melanoma of the head and neck (RTN2)

**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 100
**Accrual Total:** 15

**First Participant Accrued:** 9 September 2009
**Anticipated Accrual End Date:** 9 September 2017

**Primary Objective:**
The primary objective of the trial is to determine, in patients who have undergone surgery with curative intent for neurotropic melanoma, whether there is a difference in the rate and timing of local (in field) recurrence between patients who are treated with post-operative radiation therapy and those that are initially observed.

**Primary Endpoint:**
The primary endpoint for this trial is time to local relapse: This refers to the time from randomisation to the time of diagnosis of the local relapse.

**Summary of Trial Activity for 2012**

**Quality Assurance:**
The QA program is coordinated by the TROG Central Operations Office (TCOO) QA team. Eligibility, radiotherapy treatment and relapse will be reviewed through TCOO. A protocol amendment in January 2012 was approved permitting the use of IMRT. Sites wishing to participate in the trial and use IMRT for treatment of patients must successfully undertake IMRT credentialing activities. To date no sites have expressed interest in using IMRT. There have been 4 eligibility reviews conducted, demonstrating an acceptability rate of 100%. No radiotherapy reviews have been conducted to date and no relapses have been reported.

**Funding:**
- 2007 - TROG Seed Funding Grant/Department of Health Strengthening Cancer Care Support for Clinical Trials, $20,000 over 1 year
- 2007 - Princess Alexandra Hospital Provisional Funding
- Ongoing - In kind support provided by TROG and ANZMTG

**Trial Management Committee**

**Trial Chairperson:**

**Dr Matthew Foote**
Princess Alexandra Hospital, QLD

**Radiation Oncologists:**
- Assoc Prof Bryan Burmeister, Princess Alexandra Hospital, QLD
- Dr George Hruby, Royal Prince Alfred Hospital, NSW
Dr Scott Carruthers, Royal Adelaide Hospital, SA
Assoc. Prof Angela Hong, Royal Prince Alfred Hospital, NSW / Melanoma Institute Australia
Dr Gerald Fogarty, Mater Hospital, NSW / Melanoma Institute Australia

Surgeons:
Prof John Thompson, Royal Prince Alfred Hospital, NSW / Melanoma Institute Australia
Dr Mark Smithers, Princess Alexandra Hospital, QLD
Dr Michael Quinn, Sydney Melanoma Unit, NSW / Melanoma Institute Australia
Dr Michael Henderson, Peter MacCallum Cancer Centre, VIC

Radiation Therapist:
Michelle Mauro, Princess Alexandra Hospital, QLD

Pathologist:
Richard Scolyer, Royal Prince Alfred Hospital, NSW / Melanoma Institute Australia

Statistician:
Elizabeth Burmeister, Princess Alexandra Hospital, QLD

Physicist:
Mrs Catherine Jones, Princess Alexandra Hospital, QLD

Trial Coordinator:
Janelle Meakin, Princess Alexandra Hospital, QLD (Janelle_Meakin@health.qld.gov.au)

Collaborating Group:
Australia and New Zealand Melanoma Trials Group (ANZMTG)

---

Post operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck (POST).

Lead Group: Trans Tasman Radiation Oncology Group (TROG)
Accrual Target: 350
Accrual Total: 300
First Participant Accrued: 20 April 2005
Anticipated Accrual End Date: 31 December 2013

Primary Objective:
To determine, in patients who have undergone surgery with curative intent for high-risk cutaneous squamous cell carcinoma of the head and neck, whether there is a difference in time to loco-regional relapse between patients treated with post-operative concurrent chemo-radiotherapy and post-operative radiotherapy alone.

Primary Endpoint:
The primary outcome is time to loco-regional relapse, measured from the date of randomisation.

continues on next page
Summary of Trial Activity for 2012

Quality Assurance:
The QA program is managed and coordinated by the TROG Central Operations Office (TCOO) QA team. To date, 100% of eligibility QA data received has been reviewed and 91.72% of RT data submitted has been reviewed. Eligibility reviews concluded that 98.91% of the variables can be classified as acceptable, 0.76% as major variations and 0.34% as missing/invaluable data. Radiotherapy review results are currently being analysed. Chemotherapy reviews still need to be conducted.

Toxicity:
The Independent Data Safety Monitoring Committee reviewed 150 patients for unacceptable radiotherapy and chemotherapy toxicity, the accrual rate and the relevance of the protocol if more effective therapy was now available. The committee determined that the toxicities observed were acceptable and that the accrual rate was satisfactory, and that the trial continue without modification.

Interim Analysis:
Following review by the Independent Data Safety Monitoring Committee it was recommended that the trial accrual be extended to 350 patients in order to adequately address the hypothesis. This amendment was approved by the TROG TSC, pending further funding. The trial received NHMRC funding for the 2012 round to complete accrual.

Funding:
- 2005 - RANZCR $7,500
- 2005 - Princess Alexandra Hospital Foundation $8,000
- 2005 - PAH Cancer Collaborative Group $10,000
- 2006 - 2007 - Cancer Council Queensland $150,000
- 2006 - 2007 - Department of Health Strengthening Cancer Care Infrastructure Support for Clinical Trials $15,000
- 2006 - Health Research Council of New Zealand Grant $123,562
- 2007 - 2011 - Queensland Government Smart State Grant $324,000
- 2012 - 2015 - NHMRC Research Grant $252,000

Trial Management Committee

Trial Chairpersons:

Assoc Prof Danny Rishin
Peter MacCallum Cancer Centre, VIC

Assoc Prof Sandro Porceddu
Princess Alexandra Hospital, QLD

Radiation Oncologists:
Dr Gerald Fogarty, St Vincent’s Hospital, NSW
Dr Andrew Macann, Auckland Hospital, NZ
Assoc Prof Chris Milross, Royal Prince Alfred Hospital, NSW
Dr Michael Penniment, Royal Adelaide Hospital, SA
Assoc Prof Michael Poulsen, Radiation Oncology Mater Centre, QLD
Dr Michael Veness, Westmead Hospital, NSW

Surgical Oncologist:
Dr Ben Panizza, Princess Alexandra Hospital, QLD
Skin Cancer Closed Trials

**TROG: 02.01**


**Lead Group:** Trans Tasman Radiation Oncology Group (TROG)

**Accrual Target:** 250

**Final Accrual:** 250

**Closed to Follow-Up Date:** November 2011

**Analysis/Manuscript:**
The main analysis of the primary endpoint was performed during 2009 and an updated analysis was performed in 2010 and published in 2012. The final analysis featuring updated information on the regional control and survival, as well as late toxicity and lymphoedema will be available early in 2013. Trial Sites will remain open until the final analysis has been completed and the manuscript published.

**Publication:**

**Trial Chairpersons:**
Prof John Thompson, Melanoma Institute of Australia, Sydney, NSW
Assoc Prof Michael Henderson, Peter MacCallum Cancer Centre, VIC

**Prof Bryan Burmeister**
Princess Alexandra Hospital, QLD

continues on next page
Skin Cancer Trials Approved for Development

Radiotherapy followed by selective nodal dissection for bulky and/or inoperable nodal melanoma (REFORM).

**Lead Group:** ANZMTG
**Date Approved for Development:** 28 June 2012
**Current Status:** Development being coordinated by ANZMTG

**Trial Chairperson:**
Dr Matthew Foote
Princess Alexandra Hospital, QLD
matthew_foote@health.qld.gov.au
SYMPTOM MANAGEMENT

Symptom Management Open Trials

TROG: 11.02 A randomised phase III study of single fraction radiotherapy compared to multifraction radiotherapy in patients with metastatic spinal cord compression (UCL/NCRI) - SCORAD III

International Lead Group: University College London/National Cancer Research Institute (UCL/NCRI)
Accrual Target: 700 Internationally
Accrual Total: 328 (Internationally), 0 (TROG)
First Participant Accrued: July 2010 (Internationally), TBA (TROG)
Anticipated Accrual End Date: December 2016

Primary Objective:
The objectives of this trial are to evaluate multifraction radiotherapy against single fraction radiotherapy in terms of ambulatory status, function, quality of life, adverse events and survival. The trial will be a multicentre, randomised (1:1) phase III trial. The patients will be randomised to receive either Arm 1: 20Gy over 5 fractions, or Arm 2: 8GY in a single fraction.

Primary Endpoint:
Ambulatory status at 8 weeks from day 1 of treatment compared to randomisation.

Summary of Trial Activity for 2012

Quality Assurance:
A QA program has been developed to review consent, confirmation of diagnosis of spinal cord compression and radiotherapy prescribed and delivered. Quality assurance reviews will be managed by the Trial Coordinating Centre utilising TROGs Central Quality Management System (CQMS) with summative QA results reported periodically to the TROG Trial Chair, the TROG Central Operations Office and UCL.

Site Activation:
One Australian trial site (The Canberra Hospital) has received ethics approval and has been activated to accrue participants. It is anticipated that TROG accrual will commence in 2013.

Funding:
Cancer Council Queensland funding $124,000 (2012-2013)

Trial Management Committee (Australia and New Zealand)
TROG Trial Chairperson:

Dr Tanya Holt
Radiation Oncology Services,
Mater Centre, Brisbane, QLD

continues on next page
TROG Trial Coordinator:
Kacy Baumann, Radiation Oncology Services – Mater Centre, Brisbane, QLD (Kacy_Baumann@health.qld.gov.au)

Collaborating Groups:
Trans Tasman Radiation Oncology Group (TROG)
National Cancer Research Institute Norway

Symptom Management Closed Trials

TROG: 04.01
A paired double blind randomised comparison of Cavilon Durable Barrier Cream (CDBC) to 10% Glycerine (“Sorbolene”) Cream in the prophylactic management of post-mastectomy irradiation skin care.

Lead Group: Trans Tasman Radiation Oncology Group (TROG)

Accrual Target: 330
Final Accrual: 333

Closed to Follow-up: 10 September 2007

Analysis/Manuscript:
The final analyses was completed in 2008 and published during 2012.

Publications:

• Graham P A paired double blind randomised comparison of a moisturising durable barrier cream (MDBC) to 10% glycerine (“Sorbolene”) cream in the prophylactic management of post-mastectomy irradiation skin care. TROG 04.01. (In Press December 2012: International Journal of Radiation Oncology, Biology, Physics)

Trial Completion:
In addition to the final analysis being accepted for publication, the TROG Central Operations Office received confirmation in December 2012 of the trial database lock, the closure of all Trial Sites and archiving of records. Official notification of trial completion has subsequently been provided to the Trial Chairperson.

Trial Chairperson:
Assoc Prof Peter Graham
St George Hospital, NSW

Trial Coordinator:
Helen Cox, St George Hospital, NSW (helen.cox2@sesiahs.health.nsw.gov.au)
International Lead Group: National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)

Accrual Target: 850 internationally

Final Accrual: 850 internationally (114 TROG)

Closed to Follow-up Date: 15 September 2012

Primary Objective:
To compare pain relief after re-irradiation of symptomatic bone metastases with 8 Gy or 20 Gy.

Primary Endpoint:
Overall response rates (complete response and partial response) at 2 months from the start of treatment.

Summary of Trial Activity for 2012

Analysis:
The clinical cut-off date was deemed as 15 September 2012 with no further follow-up required. All patient assessments and outstanding queries were submitted during 2012. Data has been cleaned and the final analysis will occur during early 2013.

Funding:
2004 – Cancer Council Australia $40,000
2004 – Royal Adelaide Hospital $25,000 to fund TROG centres
2010 – Royal Adelaide Hospital $10,000 to cover increase in accrual target

Trial Management Committee (Australia and New Zealand)

TROG Trial Chairperson:

Assoc Prof Daniel Roos
Royal Adelaide Hospital, SA

Trial Coordinator:
Julie Butters, Royal Adelaide Hospital, SA (julie.butters@health.sa.gov.au)

Collaborating Group:
Trans Tasman Radiation Oncology Group (TROG)
Symptom Management Trials Approved for Development

A randomised phase II palliative radiotherapy trial of 30/10 versus either 8/1 or 20/5 for the relief of neuropathic pain caused by bone metastases (NeBo2).

Lead Group: Prof Kristopher Dennis (Ottawa)

Date Approved for Development: 22 June 2011

Current Status: Development on hold whilst funding is being sought by Prof Dennis

ANZ Trial Chairperson:
Dr Daniel Roos
Royal Adelaide Hospital, SA
daniel.roos@health.sa.gov.au
TROG COLLABORATIVE RESEARCH PROJECTS

In Progress

Inter-Comparison of Australian Radiotherapy IMRT Systems (ICARIS)

Primary Contact Person:

Dr Matthew Williams
Radiation Oncology Medical Physicist,
Illawarra Cancer Care Centre,
Wollongong Hospital.

Brief Summary:
The reliability of the outcome of a randomised controlled trial in radiotherapy is dependent on the consistency of the radiation dose delivered across multiple institutions. A new type of radiotherapy technique, known as intensity modulated radiation therapy (IMRT), has been included in several clinical trials that are being conducted in Australia.

The main aim of this project is to verify and improve the accuracy of radiation dose delivered using IMRT to cancer patients.

Objectives:

1. To establish a robust methodology for the measurement of absorbed dose delivered using IMRT in a multi-institutional setting.
2. To use radiobiological models to simulate the impact of variations in the absorbed dose on the primary and/or secondary endpoints of clinical trials that allow the use of IMRT.
3. To measure the accuracy of absorbed dose delivered with IMRT at Australian radiotherapy centres.
4. To determine the achievable level of accuracy for the absorbed dose delivered using IMRT in a multi-institutional setting:
   a. Sensitivity and uncertainty analysis of the measurement technique (part of objective 1).
   b. Perform statistical analysis on the accuracy of dose measured for Australian radiotherapy centres (part of objective 3).
5. Report an accuracy threshold and the corresponding measurement technique for use in clinical trials for verifying the absorbed dose delivered using IMRT.

Summary of Activities for 2012:
This study has now closed. Twenty site visits were conducted with twenty-two IMRT plans audited. The analysis of site visit data is being prepared for publication.

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Funding:
$270,925 project grant from the Cancer Council NSW (2009-2011)

TROG Role:
TROG endorses this project and has provided a Quality Assurance representative to take part on the research team.

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Intensity Modulated Radiotherapy (IMRT) Quality Assurance Working Party

IMRT (and VMAT) Working Party Membership:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annette Haworth</td>
<td>Chairperson, Physicist, Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>Regina Bromley</td>
<td>Physicist, Auckland City Hospital Auckland, New Zealand</td>
</tr>
<tr>
<td>Deidre Comes</td>
<td>QA Manager, Radiation Therapist, TROG Central Operations Office, NSW</td>
</tr>
<tr>
<td>Jim Cramb</td>
<td>Physicist, Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>Thomas Eade</td>
<td>Radiation Oncologist, Royal North Shore Hospital, NSW</td>
</tr>
<tr>
<td>Martin Ebert</td>
<td>Physicist, Sir Charles Gairdner Hospital, WA</td>
</tr>
<tr>
<td>Craig Everitt</td>
<td>Radiation Therapist, Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>William Hackworth</td>
<td>Physicist, Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>Joan Hatton</td>
<td>Physicist, TROG Central Operations Office, NSW</td>
</tr>
<tr>
<td>John Kenny</td>
<td>Physicist, ACDS (Vic) &amp; ROQ, Toowoomba, QLD</td>
</tr>
<tr>
<td>Tomas Kron</td>
<td>Physicist, Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>Melissa Crain</td>
<td>Assistant QA Manager, TROG Central Operations Office, NSW</td>
</tr>
<tr>
<td>Peter Metcalfe</td>
<td>Physicist, University of Wollongong, NSW</td>
</tr>
<tr>
<td>Alisha Moore</td>
<td>QA Radiation Therapist, TROG Central Operations Office, NSW</td>
</tr>
<tr>
<td>Richard Short</td>
<td>Physicist, Macarthur and Liverpool Cancer Care Centres, NSW</td>
</tr>
</tbody>
</table>
Objectives:
The IMRT Quality Assurance Working Party (IMRT QAWP) is a specialist committee with members providing expertise in clinical implementation of IMRT and clinical trials quality assurance (QA). The group includes medical physicists, radiation therapists and radiation oncologists. The IMRT QAWP was established at the recommendation of the TROG Quality Assurance Development Group (QADG) to develop the TROG IMRT QA standard resources for TROG radiation oncology clinical trial quality assurance programs. To provide a framework for the development of these resources, the IMRT QAWP has developed ‘TROG Guidelines for the Use of IMRT in Clinical Trials’ which is available from the TROG Central Operations Office (TCOO).

Progress:
The IMRT QAWP continues to work with international groups (international trial groups and the Global Harmonisation Group) to ensure TROG trials meet international standards for quality assurance. Guidelines for incorporating IMRT techniques may be obtained from the TROG TCOO. Investigators wishing to use IMRT planning and treatment delivery techniques are reminded that TROG trials require a Radiation Therapist and Medical Physicist with IMRT experience on the Trial Management Committee (TMC) and that centres shall be credentialed for use of IMRT for each specific trial. Credentialing requires completion of a facility questionnaire, participation in an external IMRT specific dosimetry audit and completion of a trial specific benchmarking exercise to demonstrate the ability to plan and deliver the radiation treatment within the trial protocol guidelines. An appropriate level of treatment accuracy using IGRT techniques shall be demonstrated. Access to external phantom dosimetry audits has been a barrier for some sites, however, through the PROFIT, RAVES and ANROTAT project, many centres have now completed this requirement. The ASTRO (IJROBP 2009) and ICRU 83 recommendations for prescribing, recording and reporting are currently being incorporated into the TROG protocol template, and the IMRT QAWP will provide recommendations on how the content of these publications can be incorporated into clinical trials. It should be noted that the current TROG IMRT guidelines are specific to fixed gantry IMRT and are not applicable to rotating gantry IMRT (commonly called VMAT – volumetric modulated arc therapy). Tomotherapy credentialing has been piloted at the Royal Brisbane Hospital. The IMRT/VMAT sub-group is currently developing guidelines so these techniques can be incorporated into new and existing trials. This group is currently working with international trial groups to develop procedures aligned with international standards. Virtual phantom piloting is expected to commence early in 2013 to be followed by limited phantom auditing through loan of a phantom from a commercial provider. We are delighted to have John Kenny and Wil Hackworth managing this part of the project bringing together their considerable experience in external dosimetry audits and international clinical trial participation respectively.

Funding:
Limited funding is available to perform the phantom studies so trial investigators should consult with TCOO to discuss arrangements to secure funding within their trial budgets to audit centres that have not participated in an approved IMRT dosimetry audit.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morikatsu Wada</td>
<td>Radiation Oncologist, Austin Repatriation Cancer Centre, VIC</td>
</tr>
<tr>
<td>Matthew Williams</td>
<td>Physicist, Illawarra Cancer Care Centre, NSW</td>
</tr>
<tr>
<td>David Willis</td>
<td>Radiation Therapist, North West Cancer Centre, NSW</td>
</tr>
<tr>
<td>Philip Vial</td>
<td>Physicist, Liverpool Cancer Therapy Centre, NSW</td>
</tr>
</tbody>
</table>
Objectives:
The Image Guided Radiation Therapy (IGRT) QA working party was established at the recommendation of the TROG Quality Assurance Development Group (QADG) in early 2009. The aim of the group is to develop guidelines for the use of Image Guidance in TROG clinical trials and provide advice on quality assurance issues related with the use of image guidance in TROG clinical trials. It has membership from three professional groups (Radiation Oncologists, Radiation Therapists, Radiation Oncology Medical Physicists) with the additional stipulation to provide regional representation and ensure that the group has expertise on all major technologies for IGRT. The IGRT QAWP is required to report to the TROG QADG.
Summary of Activities for 2012:
As many group members were involved in work for the IGRT expert group in the Assessment of New Radiation Oncology Techniques and Technologies (ANROTAT) project not much progress has been made specifically by the group. The development of QA fact sheets for a range of image guidance options is continuing and it is anticipated that the group will be reconvened after the TROG AGM in April 2013.

Closed Collaborative Research Projects


Chairperson: Prof Gill Duchesne, Peter MacCallum Cancer Centre, VIC

Lead Group: Trans Tasman Radiation Oncology Group (TROG)
ANROTAT Accrual Target: 120
ANROTAT Final Accrual: 138
ARORP Accrual Target: 90
ARORP Final Accrual: 61

Primary Objectives:

a) To develop a robust and responsive Generic Research Framework capable of collecting and generating information to substantiate the safety, clinical efficacy and cost effectiveness of new technologies and treatments in radiation oncology.

b) The draft framework was piloted to assess its capacity to assess the effectiveness of Intensity Modulated Radiation Therapy (IMRT) and Image Guided Radiation Therapy (IGRT) in four tumour site-specific projects:
   1. Nasopharynx (IMRT)
   2. Anal Canal (IMRT)
   3. Post-Prostatectomy (IMRT)
   4. Intact prostate (IGRT)

The primary objectives for these projects was to synthesise the Dosimetric and Quality of Life data with information from previous studies and expert opinion, into a decision analytic model to estimate the safety, clinical efficacy and cost effectiveness of the new technologies compared to the conventional standards.

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c) Project work also included the development of the ANROTAT Radiation Oncology Register Pilot (ARROP – TRP11.B). The primary objective of this project was to assess the completeness and accuracy of the data collected using the system.

**Primary Endpoints:**

a) Establishment of the generic research framework structure and demonstrate that this model is suitable for adaption for a number of clinical scenarios.

b) The primary endpoint of the four tumour site-specific projects was quantifying the incremental effectiveness, and the incremental cost-effectiveness, of the four planned evaluations were Quality Adjusted Life Years (QALY) gained and cost-per-QALY gained.

c) The endpoint of the ARORP was data completeness quantified for each patient in terms of the number of fields completed divided by the number of expected fields (80% completion rate was considered satisfactory).

**Summary of Trial Activities for 2012:**

**Quality Assurance:**
The QA program was coordinated by TROG Central Operations and consisted of credentialing requirements for applicable sites in each tumour group, benchmarking of all applicable participating centres in each tumour group, individual Case Reviews of Treatment Plans uploaded into CQMS.

**Toxicity:**
SAEs and SUSARs were not collected as part of this study. QoL data, hospital admissions and toxicities were collected for analysis of cost per patient associated with treatment planning and delivery to determine cost effectiveness of the modality.

**Analysis:**
Main Analysis was completed in June 2012. Secondary Analysis will take place in 2013 prior to further publications.

**Publication:**
The ANROTAT Final Report was submitted to the Australian Government Department of Health and Ageing (DoHA) on 10th August 2012. Further publications are planned for 2013.

**Funding:**
$2,992,550 from the Australian Government Department of Health and Ageing (DoHA) over 3 years (2010-2012).

**Executive Advisory Group (EAG):**

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof Gill Duchesne</td>
<td>Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>Prof Bryan Burmeister</td>
<td>Princess Alexandra Hospital, QLD</td>
</tr>
<tr>
<td>Prof Tomas Kron</td>
<td>Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>A/Prof Annette Haworth</td>
<td>Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>Mel Grand</td>
<td>TROG Central Operations Office, NSW</td>
</tr>
<tr>
<td>Deidre Cornes</td>
<td>TROG Central Operations Office, NSW</td>
</tr>
</tbody>
</table>
Joan Torony | TROG Central Operations Office, NSW
Rowena Amin | TROG Central Operations Office, NSW (member until Aug 2012)
Olga Kovacev | TROG Central Operations Office, NSW (member Jun 2011-Sept 2011)
Kathy Hall | TROG Central Operations Office, NSW (member until Jun 2011)

**Expert Group Leaders/Invited EAG members:**

<table>
<thead>
<tr>
<th>Expert Group</th>
<th>Contact Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGRT</td>
<td>Prof Tomas Kron, Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>IMRT</td>
<td>A/Prof Annette Haworth, Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>IMRT PP/Invited EAG</td>
<td>Dr Michael Jackson, Prince of Wales Hospital, NSW</td>
</tr>
<tr>
<td>IMRT AC/Invited EAG</td>
<td>Dr Michael Ng, Radiation Oncology Victoria, VIC</td>
</tr>
<tr>
<td>IMRT NPC/ Invited EAG</td>
<td>Dr June Corry, Peter MacCallum Cancer Centre, VIC</td>
</tr>
<tr>
<td>Invited EAG Member</td>
<td>Prof Val Gebski, NHMRC Clinical Trials Centre, NSW</td>
</tr>
<tr>
<td>Invited EAG Member</td>
<td>A/Prof Deborah Schofield, NHMRC Clinical Trials Centre, NSW</td>
</tr>
<tr>
<td>Senior Project Officer/ Invited EAG member</td>
<td>Michelle Hall, TROG Central Operations Office, NSW</td>
</tr>
</tbody>
</table>

**Trial Statistician:**
Dr Andrew Martin, NHMRC Clinical Trials Centre, NSW

**Special Projects Officer:**
Rebecca Montgomery, TROG COO, NSW (rebecca.montgomery@trog.com.au)

---

**Completed Collaborative Research Projects**

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Primary Contact Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Level III Dosimetry Program Lead-In Project</td>
<td>Dr Martin Ebert</td>
</tr>
<tr>
<td>Intensity modulated radiotherapy (IMRT) phantom and associated dosimetry equipment</td>
<td>Dr Matthew Williams</td>
</tr>
<tr>
<td>Equipment to assess the accuracy of image-guided and advanced technology used in multi-centre radiotherapy trials</td>
<td>Assoc Prof Peter Greer</td>
</tr>
</tbody>
</table>
# TROG Total Accrual (Open and Closed Trials)

Total by Centre from Inception to 31st December 2012:

<table>
<thead>
<tr>
<th>Centre</th>
<th>Total</th>
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<td>Canberra, ACT</td>
<td>8</td>
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<tr>
<td>Albury, NSW</td>
<td>3</td>
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<tr>
<td>Calvary Mater Newcastle, NSW</td>
<td>1064</td>
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<tr>
<td>Campbelltown, NSW</td>
<td>37</td>
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<tr>
<td>Concord Repatriation General, NSW</td>
<td>2</td>
</tr>
<tr>
<td>Gosford, NSW</td>
<td>4</td>
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<tr>
<td>Illawarra Cancer Care Centre, Wollongong, NSW</td>
<td>136</td>
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<tr>
<td>Liverpool, NSW</td>
<td>189</td>
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<tr>
<td>Mater, Nth Sydney, NSW</td>
<td>2</td>
</tr>
<tr>
<td>North Coast Cancer Institute (Coffs Harbour), NSW</td>
<td>0</td>
</tr>
<tr>
<td>North Coast Cancer Institute (Port Macquarie), NSW</td>
<td>6</td>
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<tr>
<td>Nepean, NSW</td>
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<tr>
<td>Prince of Wales, NSW</td>
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<tr>
<td>Riverina Cancer Centre, NSW</td>
<td>46</td>
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<tr>
<td>Royal Prince Alfred, NSW</td>
<td>270</td>
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<tr>
<td>St George, NSW</td>
<td>491</td>
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<tr>
<td>St Vincent’s, Sydney, NSW</td>
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<tr>
<td>Westmead, NSW</td>
<td>458</td>
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<td>Mater Centre, QLD</td>
<td>939</td>
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<td>Mater Private, QLD</td>
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<tr>
<td>Oncology Research Australia (St Andrew’s Cancer Care Centre), QLD</td>
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<tr>
<td>Premion - Nambour, QLD</td>
<td>0</td>
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<tr>
<td>Premion - Tugun, QLD</td>
<td>112</td>
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<tr>
<td>Premion-Wesley Medical Centre, QLD</td>
<td>10</td>
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<tr>
<td>Princess Alexandra, QLD</td>
<td>689</td>
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<tr>
<td>Royal Brisbane and Women’s, QLD</td>
<td>468</td>
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<tr>
<td>Townsville, QLD</td>
<td>119</td>
</tr>
<tr>
<td>Centre</td>
<td>Total</td>
</tr>
<tr>
<td>------------------------------------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Allan Walker Cancer Centre, NT</td>
<td>22</td>
</tr>
<tr>
<td>Andrew Love Cancer Centre, Barwon Health, VIC</td>
<td>306</td>
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<tr>
<td>Austin Health, VIC</td>
<td>102</td>
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<td>Ballarat, VIC</td>
<td>8</td>
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<td>Epworth Freemasons Hospital, VIC</td>
<td>5</td>
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<tr>
<td>Frankston Private Hospital, VIC</td>
<td>21</td>
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<tr>
<td>Monash Medical Centre, VIC</td>
<td>54</td>
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<tr>
<td>Murray Valley Private, VIC</td>
<td>9</td>
</tr>
<tr>
<td>Peter MacCallum Cancer Centre – Bendigo, VIC</td>
<td>25</td>
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<tr>
<td>Peter MacCallum Cancer Centre - Box Hill, VIC</td>
<td>106</td>
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<tr>
<td>Peter MacCallum Cancer Centre - East Melbourne, VIC</td>
<td>1419</td>
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<tr>
<td>Peter MacCallum Cancer Centre – Moorabbin, VIC</td>
<td>62</td>
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<tr>
<td>Ringwood Private, VIC</td>
<td>0</td>
</tr>
<tr>
<td>Royal Melbourne, VIC</td>
<td>8</td>
</tr>
<tr>
<td>St Vincent’s, Melbourne, VIC</td>
<td>10</td>
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- The Alfred, VIC
- Royal Adelaide, SA
- St Andrew’s, SA
- WP Holman Clinic, Hobart, TAS
- WP Holman Clinic, Launceston, TAS
- Royal Perth, WA
- Sir Charles Gairdner Hospital, WA
- Perth Radiation Oncology Centre, WA
- Auckland, NZ
- Christchurch, NZ
- Dunedin, NZ
- Hamilton, Waikato, NZ
- Palmerston, NZ
- Wellington, NZ
- International

| TOTAL | 32 | 21 | 10 | 0 | 3 |
TIME SERIES ACCRUAL CHARTS

Figure 1: Cumulative Participant Accrual to TROG Trials by Geography 2001 to 2012

Figure 2: Annual Participant Accrual to TROG Trials by Geography 2001 to 2012
Figure 3: Percentage Contribution to Participant Accrual by Geography 2001 to 2012

Figure 4: Percentage Contribution to Participant Accrual by Geography 2001 to 2012 (Population weighted)
PUBLICATIONS SINCE 1990

Full Manuscripts

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<td>96.05</td>
<td>38. Roos DE, Davis SR, Turner SL, O’Brien PC, Spry NA, Burmeister BH, Hoskin PJ and Ball DL. Quality assurance experience with the randomised neuropathic bone pain trial (Trans-Tasman Radiation Oncology Group, 96.05). Radiother Oncol.2003;67:207–212.</td>
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<td>96.05</td>
<td>44. D.E. Roos, S.L. Turner, P.C. O’Brien, J.G. Smith, N.A. Spry, B.H. Burmeister, P.J. Hoskin, D.L. Ball Randomized trial of 8 Gy in 1 versus 20 Gy in 5 fractions of radiotherapy for neuropathic pain due to bone metastases (Trans-Tasman Radiation Oncology Group, TROG 96.05). Radiother Oncol 2005; 75: 54-63.</td>
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<td>54. O’Brien PC, Roos DE, Pratt G, Liew K-H, Barton MB, Poulsen MG, Olver IA, Trotter GE. Combined-modality Therapy for Primary Central Nervous System Lymphoma: Long-term Data from a Phase II Multi-center Study (Trans-Tasman Radiation Oncology Group). Int J Radiat Oncol Biol Phys. 2006; 64 (2), 408-413.</td>
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<td>59. Roos D, Wirth A, Burmeister B, Spry N, Drummond K, Beresford J and McClure B. Whole brain irradiation following surgery or radiosurgery for solitary brain metastases: Mature results of a prematurely closed randomized Trans-Tasman Radiation Oncology Group trial (TROG 98.05). Radiother Oncol. 2006; 80: 316-322.</td>
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<td>70. Capp A, Inostroza-Ponta M, Bill D, et al. Is there more than one proctitis syndrome? A revisitation using data from the TROG 96.01 trial. Radiother Oncol. 2009; 90 (3): 400-407.</td>
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<td>82. Kumar M, Steigler A and Denham JW. The value of combined androgen blockade in the neo-adjuvant treatment of localised prostate cancer – the jury must remain out. (Letter to the Editor) J Clin Oncol. 2010; 28 (25): e445-e446.</td>
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<td>83. Delahunt B, Lamb DS, Srigley JR, et al. Gleason scoring: a comparison of classical and modified (International Society of Urological Pathology) criteria using nadir PSA as a clinical end point. Pathology 2010; 42 (4), 339-343</td>
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<td>85. Roos D. Response to “Determining the incidence of pain flare following palliative radiotherapy for symptomatic bone metastases: results from three Canadian centers”. Int. J Rad Onc Biol Phys 2010; 78 (2): 637-637.</td>
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<td>98. Sundaresan P, Turner S, Kneebone A, Pearse M, Butow P. Evaluating the utility of a patient decision aid for potential participants of a prostate cancer trial (RAVES-TROG 08.03). Radiother Oncol. 2011; 101 (3): 521-524.</td>
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<td>103. Young R, Rischin D; Fisher R; et al. Relationship between Epidermal Growth Factor Receptor Status, p16(NK4A), and Outcome in Head and Neck Squamous Cell Carcinoma. Cancer Epidemiol Biomarkers Prev. 2011, 20 (6): 1230-1237 Doi: 10.1158/1055-9965. EPI-10-1262</td>
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**TOTAL CITATIONS FOR FULL MANUSCRIPTS** 2735
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<td>02.01</td>
<td>35. Henderson MA, Burmeister B, Thompson JF, J. Di Iulio J, Fisher R, Hong A, Scolyer R, Shannon K, Hoekstra H, and Ainslie J. Adjuvant radiotherapy and regional lymph node field control in melanoma patients after lymphadenectomy: Results of an intergroup randomized trial (ANZMTG 01.02/TROG 02.01) J Clin Oncol (Meeting Abstracts) 2009 27: 18S. 27</td>
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<td>45. A phase III randomized controlled trial of short-course radiotherapy with or without concomitant and adjuvant temozolomide in elderly patients with glioblastoma (NCIC CTG CE.6, EORTC 26062-22061, TROG 08.02, NCT00482677). J Clin Oncol 30, 2012 (suppl; abstr TPS2104)</td>
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**TOTAL CITATIONS FOR MEETING ABSTRACTS**: 151
# Summary of Total Citations

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06 ABOUT TROG
ABOUT TROG

Purpose of the Trans Tasman Radiation Oncology Group

TROG is a charitable body whose role is to act in the public interest. As such it does not seek to profit, or generate profit for allied parties, from its activities.

Objectives of the Trans Tasman Radiation Oncology Group

The objectives of TROG are to:
(a) carry out investigator-driven research in oncology, primarily clinical trials involving radiation therapy designed to improve the outcomes of cancer treatment.
(b) foster optimal patient care through maintenance of standards and through independent clinical research including trials.
(c) foster regional cooperation between all radiation oncologists in the Australian and New Zealand regions, and specifically to promote coordinated multi-institution research endeavours.
(d) promote the highest ethical standard of care and research including quality assurance.

Membership

Full Membership
Full Membership will be open to all Radiation Oncologists who have an interest in research in the practice of radiation oncology, and who accept the objects of the Company. An annual subscription is payable.

Affiliate Membership
Trial Coordinators, Data Managers, Radiation Therapists, Medical Physicists, Statisticians, Registrars, Medical Oncologists, Surgeons, Nurses and Radiologists or professions involved in another clinical discipline that relates to TROG’s clinical trials may be admitted as an Affiliate Member of the association without any annual subscription being payable. To be eligible as an Affiliate Member, the person must also be involved or have expressed an interest in becoming involved in TROG trials. Affiliate members do not hold voting rights.

Life Membership
In special circumstances, with the approval of the voting members of TROG, the Board will recommend that persons will be eligible for life membership. An annual subscription is not payable. Life members hold voting rights.
TROG Meetings

Annual Scientific Meeting

This meeting is held in the first half of the calendar year (in the February to May period) over a four day program at a venue in Australia or New Zealand. The TROG Clinical Trial Management and Technical Research Workshops are held on the day prior to the Annual Meeting.

New proposals for clinical trials are evaluated and ongoing trials are reviewed at this meeting. Clinical trial education is also an important feature. The Annual Meeting is open to radiation oncologists, trial coordinators, radiation therapists, physicists, industry partners and others interested.

The Annual General Meeting (AGM) is held during the four-day Annual Meeting program and is open to full TROG members only. The agenda includes voting on new clinical trial proposals, election of Board members and other administrative matters. The TROG Board, Scientific Committee, Publications Committee and individual Trial Management Committees also take the opportunity to meet during the Annual Meeting program.

TROG Milestones

1989 TROG established at Taupo, NZ meeting
1989 First TROG trial activated
1990 First TROG policy written leading to start of Policy & Procedure Manual (Red Book)
1990 First TROG publication
1991 First randomised trial (TROG 91.01 locally advanced H&N cancer)
1992 First competitive funding obtained for a trial (TROG 91.01)
1994 Part-time TROG Secretariat established at Newcastle Mater Hospital
1995 TROG’s incorporation as an association
1996 Trials Review Meetings initiated
1996 First employee appointed (Senior Operations Manager) at Newcastle Mater Hospital
1997 TROG Scientific Committee formed
1997 Annual Research Report initiated
1997 First NHMRC (Australia) funding obtained (TROG 94.01 phase III oesophagus trial)
1998 TROG website launched (sub site of RANZCR)
1999 First administrative assistant employed (part-time)
2001 QA Manager appointed
2001 First international trial group collaboration (EORTC)
2001 Membership expanded to Affiliate members (Data Managers, Radiation Therapists, Physicists etc)
2002 First Strategic Planning Meeting held
2003 TROG Publications Committee formed
2004 Business Development Manager appointed (part-time)
2004 Second Strategic Planning Meeting held
2004 First HRC (New Zealand) funding obtained (TROG 03.04 RADAR)
2005 NZ Planning Meeting held
2005 New TROG logo launched
2005 First infrastructure grants obtained (ie. not trial specific)
2005 QA Officer appointed
2005 Quarterly TROG Newsletter launched
2006 Consumers participate in TROG meetings

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2006 Appointment of Research Assistant, QA Research Assistant and QA Radiation Therapist
2006 Appointment of NSW Project Officer (based at RANZCR office)
2007 Launch of stand alone TROG web portal
2007 Clinical trials insurance cover obtained for TROG trials
2007 TROG becomes a member of the Breast International Group
2007 TROG 07.01 study to become the first global breast cancer trial led by TROG following endorsement by
the Breast International Group (BIG 3-07)
2008 Appointment of NZ Project Officer
2008 Appointment of TROG Trial Development Coordinator, Accountant, Policy & Procedures Officers,
Communications Officer, Information Officer and QA Research Assistant
2008 TROG approved as NHMRC Administering Institution for grant applications
2008 TROG transfers business status to Company Limited by Guarantee
2008 Nine (9) new trials approved for activation in one year
2008 8000 participants entered onto TROG trials to date
2009 QA Medical Physicist appointed
2009 100 publications (full publications and meeting abstracts) achieved
2010 QOL expert and Health Economics positions appointed to Scientific Committee
2010 9000 participants onto TROG trials to date
2010 Achievement of goals set in the 2008-2010 Strategic Plan:
  • 10 additional competitive grants and 100 publications (achieved one year ahead of schedule)
  • capacity to process trial development within 12 months from concept approval to activation
    achieved, although heavily dependent on the level of engagement by the Trial Chairperson
2010 TROG recognised by Australian Government Department of Health and Ageing (DOHA) as the peak body
for radiation oncology research and awarded a multimillion dollar contract to address barriers around
conducting research, and collecting associated evidence related to the safety, effectiveness and cost-
effectiveness of new radiation oncology technologies and treatments
2010 Significant increase in Consumer involvement with TROG
2011 10 000 participants entered onto TROG trials to date
2011 NHMRC Enabling Grant (ID 351217) project completed 31 December 2011 having met the primary aims
  of strengthening the quality and safety of RT trials by enabling rapid review and checking of treatment
  by electronic means and improving trial design
2012 11 000 participants entered onto TROG trials to date
2012 Completion of the ‘Assessment of New Radiation Oncology Technology and Treatments’ (ANROTAT) and
ANROTAT Radiation Oncology Register Pilot (ARORP) Projects
TROG History & Honour Roll

TROG President
TROG was incorporated in 1995, with the formation of a Board including the President’s position. Prior to this, the role was known as the TROG Chairperson.

1989-1990 Chris Atkinson, Christchurch Hospital, NZ
1990-1991 David Lamb, Wellington Hospital, NZ
1991-1992 Jim Denham, Newcastle Mater Hospital, NSW
1992-1993 Bryan Burmeister, Mater QRI, Brisbane, QLD
1993-1994 David Joseph, Geelong Hospital, VIC
1994-1995 Nigel Spry, Wellington Hospital, NZ
1995-2001 Jim Denham, Newcastle Mater Hospital, NSW
2001-2007 David Ball, Peter MacCallum Cancer Centre, Melbourne, VIC
2007-2013 Bryan Burmeister, Princess Alexandra Hospital, Brisbane, QLD

TROG Secretary
1989-1990 David Lamb, Wellington Hospital, NZ
1990-1991 Nigel Spry, Wellington Hospital, NZ
1991-1992 Chris Hamilton, Newcastle Mater Hospital, NSW
1992-1993 Quenten Walker, QRI Royal Brisbane, QLD
1993-1994 David Lamb, Wellington Hospital, NZ
1994-2000 Sid Davis, Alfred Hospital, Melbourne, VIC
2000-2005 Daniel Roos, Royal Adelaide Hospital, SA
2005-2008 David Christie, The John Flynn Hospital, QLD
2008-2009 Kim Reeves, TROG Central Operations Office, NSW
2009-2012 Rowena Amin, TROG Central Operations Office, NSW
2012-2013 Mark Rembish, TROG Central Operations Office, NSW

TROG Scientific Committee Chair
1997-2002 David Lamb, Wellington Hospital, NZ
2002-2007 Bryan Burmeister, Princess Alexandra Hospital, QLD
2007-2012 Gill Duchesne, Peter MacCallum Cancer Centre, Melbourne, VIC
2012-2013 Sandro Porceddu, Princess Alexandra Hospital, QLD

TROG Annual Meeting Convenor
1989 David Lamb, Wellington Hospital, NZ (Taupo)
1990 Chris Wynne, Christchurch Hospital, NZ (Akaroa)
1991 Perce Bydder, Palmerston North, NZ (Queenstown)
1992 Jim Denham, Newcastle Mater Hospital, NSW (Cairns, QLD)
1993 John Matthews, Auckland Hospital, NZ (Taupo)
1994 Bryan Burmeister, Mater QRI, Brisbane, QLD (Coffs Harbour, NSW)
1995 Sid Davis, Alfred Hospital, Melbourne (Launceston, TAS)
1996 John Matthews, Auckland Hospital, NZ (Coromandel)
1997 Daniel Roos, Royal Adelaide Hospital, SA (Adelaide, SA)
1998 David Lamb, Wellington Hospital, NZ (Methven)
1999 David Joseph, Sir Charles Gairdner Hospital, Perth (Perth, WA)
2000 Gail Ryan, Peter MacCallum Cancer Centre, Melbourne (Marysville, VIC)
2001 Andrew Macann, Auckland Hospital, NZ (Taupo)

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2002 Bryan Burmeister, Princess Alexandra Hospital, QLD (Couran Cove, QLD)
2003 Sandra Turner, Westmead Hospital, NSW (Canberra, ACT)
2004 John North, Dunedin Hospital, NZ (Queenstown)
2005 Bryan Burmeister, Princess Alexandra Hospital, QLD (Darwin, NT)
2006 David Christie, The John Flynn Hospital, QLD (Lindeman Island, QLD)
2007 Scott Babington, Christchurch Hospital, NZ (Rotorua)
2008 Sid Davis, Alfred Hospital, VIC (Alice Springs, NT)
2009 Bryan Burmeister, Princess Alexandra Hospital, QLD (Shoal Bay, NSW)
2010 Scott Babington & Maria Pearse, Auckland Hospital, NZ (Queenstown)
2011 Scott Carruthers, Royal Adelaide Hospital, SA (Glenelg, SA)
2012 Sid Baxi, Alan Walker Cancer Care Centre, NT (Darwin, NT)

TROG Awards

TROG New Trial Proposal Award (“The Orchids”)
Awarded for the new trial proposal with the largest number of votes for further development by the membership
at the Annual Meeting. Sponsored by Novartis.

2000 – Jill Ainslie, Peter MacCallum Cancer Centre, VIC
TROG 02.01 - Randomised clinical trial of surgery versus surgery plus adjuvant radiotherapy for regional control
in patients with completely resected macroscopic nodal metastatic melanoma.

2001 – Kumar Gogna, QRI, Mater Centre, QLD
TROG 02.03 - Multicentre phase III study comparing radical synchronous chemo-radiation vs radical radiation
alone in the definitive management of muscle invasive TCC of the urinary bladder following maximal TUR.

2002 – Michael MacManus, Peter MacCallum Cancer Centre, VIC
TROG 05.02 - A prospective single arm trial of involved field radiotherapy alone for stage I-II low grade non-gastric
marginal zone lymphoma

2003 – Gail Ryan, Peter MacCallum Cancer Centre, VIC
Temozolomide vs Radiotherapy for Newly Diagnosed Glioblastoma Multiforme in the elderly. A randomized
phase III study

2004 – Danny Rischin and David Ball, Peter MacCallum Cancer Centre, VIC
Randomised phase III trial of chemoradiation versus chemoradiation and concurrent gefitinib (Iressa) in patients
with locally advanced NSCLC

2005 – Sean Bydder, Sir Charles Gairdner Hospital, WA
A multicentre trial of the use of Sentinel Lymph Node Biopsy (SLNB) to determine the Radiotherapy (RT) volumes
for treatment of cN0-1 Squamous Cell Cancer (SCC) of the anus

2006 – Maria Pearse, Auckland Hospital, NZ
TROG 08.03 - RAVES: Radiotherapy – Adjuvant Versus Early Salvage in prostate cancer

2007 – Jarad Martin, St Andrews Cancer Care Centre Toowoomba, QLD
TROG 08.01/OCOG - A Randomised Trial of shorter radiation fractionation schedule for the treatment of localised
prostate cancer (Prostate fractionated Irradiation Trial) (PROFIT)
Trial Excellence Award
The TROG Trial Excellence Award was inaugurated in 2007.

2007 – Associate Professor Sam Ngan. The TROG 01.04 study led by Sam, was the first multimodality randomised trial in rectal cancer to be performed in Australia and New Zealand that involved all 3 modalities of cancer treatment (surgery, radiation therapy and chemotherapy). It is a landmark study that will influence the management of rectal cancer when results are available.

2008 – Associate Professor Boon Chua. The TROG 07.01 trial presents another milestone in the history of TROG by becoming the first global breast cancer trial led by TROG and endorsed by the Breast International Group (BIG 3-07).

2009 – Dr Trevor Leong. TROG 03.02 ~ A feasibility study to evaluate adjuvant chemo-radiotherapy for gastric cancer. This trial was a complex technologically challenging trial with good quality assurance and a solid accrual rate.

2010 – Dr Maria Pearse and Dr Andrew Kneebone. TROG 08.03 ~ A Phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) with early salvage RT in patients with positive margins or extraprostatic disease following radical prostatectomy. (RAVES – Radiotherapy Adjuvant Versus Early Salvage).

2011 – Professor Lester Peters and Professor Danny Rischin. TROG 02.02 ~ A phase III randomised trial of concomitant radiation, cisplatin, and tirapazamine vs concomitant radiation and cisplatin in patients with advanced head and neck cancer.

2012 – Professor Jim Denham TROG 96.01 ~ A randomised trial investigating the effectiveness of different durations of maximal androgen deprivation prior to and during definitive radiation therapy for locally advanced carcinoma of the prostate.

Outstanding Contribution to TROG
2007 – An award for Outstanding Contribution to TROG was inaugurated in 2007, with Annette Haworth being the first to receive the award. Annette has long served as medical physics advisor on the TROG Scientific Committee and been active in promoting TROG to physicists and RTs both in Australia & New Zealand and internationally. She has also been instrumental in developing the SWAN software, which was a key part of the TROG Central Quality Management System (CQMS) being developed as the cornerstone of TROG’s Quality Assurance program. Annette’s attention to detail has been a driving force for TROG trials in embracing quality assurance through medical physics and dosimetry programs.

2008 – Dr Peter O’Brien ~ Activities in relation to the role of TROG Group Coordinator and TROG Scientific Advisor. Peter has provided enormous support to the TROG Central Operations Office and has been a driving force behind the activities and successes that have placed TROG in the position it is in today.

2009 – Associate Professor Richard Fisher ~ Activities in relation to the role of TROG Statistician. Richard has played a key role on the TROG Scientific Committee and TROG Publications Committee.

2010 – Professor David Ball ~ In recognition of his committee representation, trial development and specialist expertise provided to the TROG Program.
2011 – Associate Professor Daniel Roos – In recognition of his services on the TROG Board and his achievement in conducting and completing a randomised trial involving palliative radiotherapy.

2012 – Associate Professor Sidney Davis – In recognition of his contribution to the TROG through membership of the Board and convenor of Annual Scientific and Trials Review Meetings.

Life Members of TROG
With the approval of voting members of TROG, the Board appointed the following members as Life Members in recognition of their outstanding support of TROG:

2001 – Professor Jim Denham
2010 – Professor Lester Peters and Dr Peter O’Brien
2011 – Professor David Ball

TROG Website - www.trog.com.au

Visit the TROG website for:

- Information on TROG trials for patients and members
- TROG history, structure and activities
- TROG policies and procedures
- TROG meetings and events
- TROG research program
- Trial specific contact details
- Trial publications and abstracts
- TROG Annual Research Reports
- TROG membership
- Sponsors and granting body acknowledgments
- Online membership applications
- Payment gateway for memberships
- Member forum for collaborative discussion groups

Additional ‘Members Only’ resources include:

- TROG templates and resources
- Trials directory
- Trial protocols
- Trial newsletters
- Members directory
- Minutes and presentations of TROG meetings
FINANCIAL HIGHLIGHTS

The audited financial statements for the year ended 31 December 2012 are included in this report. These financial highlights are intended to provide clarity by way of commentary to the financial statements and to highlight matters of interest. They are not intended to replace or modify the content of the separate audited financial statements.

Income (Profit/Loss)
TROG’s accounting policy recognises its revenue from grants when TROG obtains control of the grant (See Note 1). These grant funds are usually committed for specific purposes and are often expensed in the year(s) following their receipt. These committed funds have been disclosed as contingent liabilities (See Note 14). At 31 December 2012, TROG’s contingent liabilities were $1,204,642 (2011: $2,288,712), a $1,084,070 decrease from the prior year. Thus, during the 2012 year TROG essentially expended $1,084,070 in grant funding it had received in prior years. $713,379 of this decrease can be solely attributed to the conclusion of the ANROTAT project. The ANROTAT project consisted of a $3,000,000 DOHA grant over a 3 year period that required a significant escalation of TROG’s normal operational activities.

The decrease in contingent liabilities is directly reflected in TROG’s income statement. In 2012, TROG’s audited financial statements recorded a net loss for the year of $1,027,679. However, after adjustment for the change in contingent liabilities, TROG essentially posted a net profit for the 2012 year of $56,391 (2011: $268,872).
Directors’ Report

Your directors present their report on Trans Tasman Radiation Oncology Group Limited (the Company) for the year ended 31 December 2012.

Directors:
The following persons were directors of the Company during the financial year and to the date of this report:

<table>
<thead>
<tr>
<th>Director</th>
<th>Appointed/Resigned</th>
<th>Special Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>B Burmeister</td>
<td></td>
<td>President</td>
</tr>
<tr>
<td>S Porceddu</td>
<td></td>
<td>TSC Chair/ President Elect</td>
</tr>
<tr>
<td>T Denny</td>
<td></td>
<td>Independent Director</td>
</tr>
<tr>
<td>S Babington</td>
<td></td>
<td>Director</td>
</tr>
<tr>
<td>I Roos</td>
<td></td>
<td>Independent Consumer Representative Director</td>
</tr>
<tr>
<td>B Judson</td>
<td>Appointed in May 2012.</td>
<td>Director</td>
</tr>
<tr>
<td>G Duchesne</td>
<td>Resigned in May 2012.</td>
<td></td>
</tr>
<tr>
<td>T Kron</td>
<td>Resigned in May 2012.</td>
<td></td>
</tr>
<tr>
<td>R Amin</td>
<td>Resigned in September 2012.</td>
<td></td>
</tr>
</tbody>
</table>

Directors have been in office since the start of the financial year to the date of this report unless otherwise stated.

Company Secretary:
Mark Rembish held the position of company secretary at the end of the financial year. He was appointed company secretary on 27 September 2012.

Principal activities:
During the year the principal continuing activities of the Company consists of:

(i) carrying out investigator-driven research in oncology,
(ii) fostering optimal patient care through maintenance of standards and through independent clinical research including trials,
(iii) fostering regional co-operation between all radiation oncologists in the Australia and New Zealand regions, and specifically to promote co-ordinated multi-institution research endeavours,and
(iv) promoting highest ethical standard of care and research including quality assurance.

There were no significant changes in the nature of these activities during the year.
Significant Changes in the State of Affairs:
There were no significant changes in the Company’s state of affairs during the year.

Matters Subsequent to the End of the Financial Year:
No matter or circumstances have arisen since 31 December 2012 that have significantly affected, or may significantly affect:

(a) the Company’s operations in future financial years, or
(b) the results of those operations in future financial years, or
(c) the Company’s state of affairs in future financial years.

Environmental regulation:
No significant environmental regulations apply to the Company.

Meetings of Directors:
The number of meetings of the Company’s board of directors and of each board committee held during the year ended 31 December 2012, and the number of meetings attended by each director were:

<table>
<thead>
<tr>
<th>Directors Meetings Attended</th>
<th>Eligible to Attend</th>
<th>Number Attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>B Burmeister</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>S Porceddu</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>T Denny</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>S Babington</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>I Roos</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>B Judson</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>G Duchesne</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>T Kron</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>R Amin</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Members’ Guarantee:
The company is incorporated under the Corporations Act 2001 and is an entity limited by guarantee. If the company is wound up, the constitution states that each member is required to contribute a maximum of $10 each towards meeting any outstanding obligations of the company. At 31 December 2012 the total amount that members of the company are liable to contribute if the entity is wound up is $9,860 (2011: $9,210).
Auditor’s Independence Declaration:
The lead auditor’s independence declaration for the year ended 31 December 2012 has been received and can be found on page 193 of the report.

This report is signed in accordance with a resolution of the Board of Directors.

__________________
Associate Professor S Porceddu
Director

___________________
T Denny
Director

Newcastle
28 February 2013

Income Statement

<table>
<thead>
<tr>
<th>For the year ended 31 December 2012</th>
<th>Notes</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue from continuing operations</td>
<td>2</td>
<td>1,981,343</td>
<td>3,195,509</td>
</tr>
<tr>
<td>Other expenses from continuing operations</td>
<td></td>
<td>(3,009,022)</td>
<td>(2,698,831)</td>
</tr>
<tr>
<td>Net profit (loss) from continuing operations before income tax expense</td>
<td></td>
<td>(1,027,679)</td>
<td>496,678</td>
</tr>
<tr>
<td>Income tax expense</td>
<td></td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Net profit (loss)</td>
<td></td>
<td>(1,027,679)</td>
<td>496,678</td>
</tr>
<tr>
<td>Total changes in equity</td>
<td></td>
<td>(1,027,679)</td>
<td>496,678</td>
</tr>
</tbody>
</table>

The above income statement should be read in conjunction with the accompanying notes.
### Balance Sheet

<table>
<thead>
<tr>
<th>For the year ended 31 December 2012</th>
<th>Notes</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Current assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>3</td>
<td>2,321,158</td>
<td>3,330,182</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>4</td>
<td>257,929</td>
<td>309,362</td>
</tr>
<tr>
<td>Other assets</td>
<td>5</td>
<td>100,726</td>
<td>60,073</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td></td>
<td>2,679,813</td>
<td>3,699,617</td>
</tr>
<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plant and equipment</td>
<td>6</td>
<td>38,698</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total non-current assets</strong></td>
<td></td>
<td>38,698</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td></td>
<td>2,718,511</td>
<td>3,699,617</td>
</tr>
<tr>
<td><strong>Current Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>7</td>
<td>336,854</td>
<td>271,358</td>
</tr>
<tr>
<td>Provisions</td>
<td>8</td>
<td>123,896</td>
<td>148,698</td>
</tr>
<tr>
<td>Other liabilities</td>
<td>9</td>
<td>160</td>
<td>2,000</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td></td>
<td>460,910</td>
<td>422,056</td>
</tr>
<tr>
<td><strong>Non-current liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provisions</td>
<td>10</td>
<td>35,496</td>
<td>27,777</td>
</tr>
<tr>
<td><strong>Total non-current liabilities</strong></td>
<td></td>
<td>35,496</td>
<td>27,777</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td></td>
<td>496,406</td>
<td>449,833</td>
</tr>
<tr>
<td><strong>Net assets</strong></td>
<td></td>
<td>2,222,105</td>
<td>3,249,784</td>
</tr>
<tr>
<td><strong>Equity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retained earnings</td>
<td>11</td>
<td>2,222,105</td>
<td>3,249,784</td>
</tr>
<tr>
<td><strong>Total equity</strong></td>
<td></td>
<td>2,222,105</td>
<td>3,249,784</td>
</tr>
</tbody>
</table>

The above balance sheet should be read in conjunction with the accompanying notes.
Statement of Changes in Equity

<table>
<thead>
<tr>
<th>For the year ended 31 December 2012</th>
<th>Notes</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total equity at the beginning of the financial year</td>
<td></td>
<td>3,249,784</td>
<td>2,753,106</td>
</tr>
<tr>
<td>Total recognised income and expense for the year</td>
<td>11</td>
<td>(1,027,679)</td>
<td>496,678</td>
</tr>
<tr>
<td>Total equity at the end of the financial year</td>
<td>11</td>
<td>2,222,105</td>
<td>3,249,784</td>
</tr>
</tbody>
</table>

The above statement of changes in equity should be read in conjunction with the accompanying notes.

Cash Flow Statement

<table>
<thead>
<tr>
<th>For the year ended 31 December 2012</th>
<th>Notes</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cash flows from operating activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receipts from grants and other income (inclusive of goods and services tax)</td>
<td></td>
<td>2,196,209</td>
<td>3,257,335</td>
</tr>
<tr>
<td>Payments to suppliers and employees (inclusive of goods and services tax)</td>
<td>(3,258,019)</td>
<td>(3,116,879)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1,061,810)</td>
<td>140,456</td>
</tr>
<tr>
<td>Interest received</td>
<td></td>
<td>99,635</td>
<td>149,433</td>
</tr>
<tr>
<td><strong>Net cash inflow from operating activities</strong></td>
<td>12</td>
<td>(962,175)</td>
<td>289,889</td>
</tr>
<tr>
<td><strong>Cash flows from investing activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payments for property, plant and equipment</td>
<td>(46,849)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Net cash inflow (outflow) from investing activities</strong></td>
<td></td>
<td>(46,849)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Net increase (decrease) in cash held</strong></td>
<td>(1,009,024)</td>
<td></td>
<td>289,889</td>
</tr>
<tr>
<td>Cash at the beginning of the financial year</td>
<td>3,330,182</td>
<td>3,040,293</td>
<td></td>
</tr>
<tr>
<td><strong>Cash at the end of the financial year</strong></td>
<td>2,321,158</td>
<td>3,330,182</td>
<td></td>
</tr>
</tbody>
</table>

The above cash flow statement should be read in conjunction with the accompanying notes.
Notes to the Financial Statements

31 December 2012

Note 1.
Summary of Significant Accounting Policies

The financial statements are for Trans Tasman Radiation Oncology Group Limited as an individual entity, incorporated and domiciled in Australia. Trans Tasman Radiation Oncology Group Limited is a company limited by guarantee.

Basis of Preparation:
The financial statements are general purpose financial statements that have been prepared in accordance with Australian Accounting Standards – Reduced Disclosure Requirements of the Australian Accounting Standards Board (AASB) and the Corporations Act 2001. Australian Accounting Standards set out accounting policies that the AASB has concluded would result in financial statements containing relevant and reliable information about transactions, events and conditions. Material accounting policies adopted in the preparation of these financial statements are presented below and have been consistently applied unless otherwise stated. The financial statements, except for the cash flow information, have been prepared on an accruals basis and are based on historical costs, modified, where applicable by the measurement at fair value of selected non-current assets, financial assets and financial liabilities.

(a) Income tax
The company is exempt from income tax under Australian taxation laws in accordance with Division 50 of the Income Tax Assessment Act 1997. The Company is not liable for income tax therefore no provision is made.

(b) Revenue
Grant revenue is recognised in the income statement when the entity obtains control of the grant and it is probable that the economic benefits gained from the grant will flow to the entity and the amount of the grant can be measured reliably.
If conditions are attached to the grant which must be satisfied before it is eligible to receive the contribution, the recognition of the grant as revenue will be deferred until those conditions are satisfied.

When grant revenue is received whereby the entity incurs an obligation to deliver economic value directly back to the contributor, this is considered a reciprocal transaction and the grant revenue is recognised in the balance sheet as a liability until the service has been delivered to the contributor, otherwise the grant is recognised as income on receipt.
Donations and bequests are recognised as revenue when received.
Interest revenue is recognised using the effective interest rate method, which for floating rate financial assets is the rate inherent in the instrument.
Revenue from the rendering of a service is recognised upon the delivery of the service to the customers.
All revenue is stated net of the amount of goods and services tax (GST).

(c) Property, Plant and Equipment
Each class of property, plant and equipment is carried at cost or fair values as indicated, less, where applicable, accumulated depreciation and impairment losses.
Plant and equipment are measured on the cost basis less depreciation and impairment losses.
The carrying amount of plant and equipment is reviewed annually by directors to ensure it is not in excess of the recoverable amount from these assets. The recoverable amount is assessed on the basis of the expected net cash flows that will be received from the assets employment and subsequent disposal. The expected net cash flows have been discounted to their present values in determining recoverable amounts.
Plant and equipment that have been contributed at no cost or for nominal cost are valued and recognised at the fair value of the asset at the date it is acquired.
Depreciation
Depreciation is calculated on either a diminishing value basis or straight-line basis to write off the net cost of each item of property, plant and equipment (excluding land) over its expected useful life to the Company. Estimates of remaining useful lives are made on a
regular basis for all assets, with annual reassessments for major items. The expected useful lives are as follows:
Plant and equipment: 2-10 years
The assets' residual values and useful lives are reviewed, & adjusted if appropriate, at the end of each reporting period.
Asset classes carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.
Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains or losses are included in the statement of comprehensive income. When revalued assets are sold, amounts included in the revaluation reserve relating to that asset are transferred to retained earnings.

(d) Financial Instruments
Initial recognition and measurement
Financial assets and financial liabilities are recognised when the entity becomes a party to the contractual provisions to the instrument. For financial assets, this is equivalent to the date that the company commits itself to either purchase or sell the asset (i.e. trade date accounting is adopted). Financial instruments are initially measured at fair value plus transactions costs except where the instrument is classified ‘at fair value through profit or loss’ in which case transaction costs are expensed to profit or loss immediately.
Classification and subsequent measurement
Financial instruments are subsequently measured at fair value, amortised cost using the effective interest rate method or cost.
(i) Loans and receivables
Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market and are subsequently measured at amortised cost.
(ii) Financial liabilities
Non-derivative financial liabilities (excluding financial guarantees) are subsequently measured at amortised cost.
Fair Value
Fair value is determined based on current bid prices for all quoted investments. Valuation techniques are applied to determine the fair value for all unlisted securities, including recent arm’s length transactions, reference to similar instruments and option pricing models.
Impairment
At each reporting date, the entity assesses whether there is objective evidence that a financial instrument has been impaired. In the case of available-for-sale financial instruments, a prolonged decline in the value of the instrument is considered to determine whether impairment has arisen. Impairment losses are recognised in the Income Statement.

Derecognition
Financial assets are derecognised where the contractual rights to receipt of cash flows expires or the asset is transferred to another party whereby the entity no longer has any significant continuing involvement in the risks and benefits associated with the asset. Financial liabilities are derecognised where the related obligations are either discharged, cancelled or expired. The difference between the carrying value of the financial liability, which is extinguished or transferred to another party and the fair value of consideration paid, including the transfer of non-cash assets or liabilities assumed, is recognised in profit or loss.

(e) Impairment of Assets
At the end of each reporting period, the entity assesses whether there is any indication that an asset may be impaired. If such an indication exists, an impairment test is carried out on the asset by comparing the recoverable amount of the asset, being the higher of the asset's fair value less costs to sell and value in use, to the asset's carrying amount. Any excess of the asset's carrying amount over its recoverable amount is recognised immediately in profit or loss, unless the asset is carried at a revalued amount in accordance with another Standard (e.g. in accordance with the revaluation model in AASB 116). Any impairment loss of a revalued asset is treated as a revaluation decrease in accordance with that other Standard.
Where it is not possible to estimate the recoverable amount of an individual asset, the entity estimates the recoverable amount of the cash-generating unit to which the asset belongs. Impairment testing is performed annually for goodwill and intangible assets with indefinite lives.

(f) Employee Benefits
Provision is made for the company’s liability for employee benefits arising from services rendered by employees to the end of the reporting period. Employee benefits that are expected to be settled within one year have been measured at the amounts expected to be paid when the liability is settled. Employee benefits continues on next page
payable later than one year have been measured at the present value of the estimated future cash outflows to be made for those benefits. In determining the liability, consideration is given to employee wage increases and the probability that the employee may not satisfy vesting requirements. Those cash outflows are discounted using market yields on national government bonds with terms to maturity that match the expected timing of cash flows.

(g) Cash and Cash Equivalents
Cash and cash equivalents include cash on hand, deposits held at-call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts.

(h) Goods and services tax (GST)
Revenues, expenses and assets are recognised net of the amount of GST, except where the amount of GST incurred is not recoverable from the Australian Taxation Office. In these circumstances the GST is recognised as part of the cost of acquisition of the asset or as part of an item of expense. Receivables and payables in the Balance Sheet are shown inclusive of GST. Cash flows are presented in the Cash Flow Statement on a gross basis, except for the GST component of investing and financing activities, which are disclosed as operating cash flows.

(i) Comparative Figures
Where required by Accounting Standards comparative figures have been adjusted to conform to changes in presentation for the current financial year.

(j) Trade and Other Payables
Trade and other payables represent the liability outstanding at the end of the reporting period for goods and services received by the company during the reporting period which remain unpaid. The balance is recognised as a current liability with the amounts normally paid within 30 days of recognition of the liability.

(k) Critical Accounting Estimates and Judgments
The directors evaluate estimates and judgments incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the company.
## Note 2.
### Revenue

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue from continuing operations</strong></td>
<td>1,981,343</td>
<td>3,195,509</td>
</tr>
<tr>
<td>Donations</td>
<td>10,000</td>
<td>2</td>
</tr>
<tr>
<td>Facility fees</td>
<td>194,700</td>
<td>-</td>
</tr>
<tr>
<td>Fundraising</td>
<td>50</td>
<td>421</td>
</tr>
<tr>
<td>Grants</td>
<td>1,043,184</td>
<td>2,289,491</td>
</tr>
<tr>
<td>Meeting registrations</td>
<td>153,890</td>
<td>219,873</td>
</tr>
<tr>
<td>Membership subscriptions</td>
<td>29,249</td>
<td>17,588</td>
</tr>
<tr>
<td>Reimbursed expenses</td>
<td>37,500</td>
<td>-</td>
</tr>
<tr>
<td>Research services</td>
<td>203,352</td>
<td>287,509</td>
</tr>
<tr>
<td>Sponsorship of meetings</td>
<td>26,046</td>
<td>103,491</td>
</tr>
<tr>
<td>Sponsorship – general</td>
<td>-</td>
<td>126,143</td>
</tr>
<tr>
<td><strong>Total Revenue from continuing operations</strong></td>
<td>1,697,971</td>
<td>3,044,518</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue from outside the continuing operations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest</td>
<td>99,635</td>
<td>149,433</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>183,737</td>
<td>1,558</td>
</tr>
<tr>
<td><strong>Total Revenue from outside the continuing operations</strong></td>
<td>283,372</td>
<td>150,991</td>
</tr>
</tbody>
</table>

**Total Revenue**

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue from continuing operations</strong></td>
<td>1,981,343</td>
<td>3,195,509</td>
</tr>
<tr>
<td><strong>Revenue from outside the continuing operations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Revenue</strong></td>
<td>1,981,343</td>
<td>3,195,509</td>
</tr>
</tbody>
</table>

## Note 3.
### Current assets – Cash and cash equivalents

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash at bank and on hand</td>
<td>2,321,158</td>
<td>3,330,182</td>
</tr>
<tr>
<td>Balance as per cash flow statement</td>
<td>2,321,158</td>
<td>3,330,182</td>
</tr>
</tbody>
</table>
### Note 4. Current assets – Trade and other receivables

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade debtors</td>
<td>138,233</td>
<td>204,346</td>
</tr>
<tr>
<td>Accrued grant income</td>
<td>41,644</td>
<td>40,973</td>
</tr>
<tr>
<td>Sundry debtors</td>
<td>78,052</td>
<td>-</td>
</tr>
<tr>
<td>Net GST receivable</td>
<td>-</td>
<td>64,043</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>257,929</strong></td>
<td><strong>309,362</strong></td>
</tr>
</tbody>
</table>

### Note 5. Current assets – Other assets

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepayments</td>
<td>100,726</td>
<td>60,073</td>
</tr>
</tbody>
</table>

### Note 6. Non-current assets – Plant and equipment

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plant and equipment</strong></td>
<td>138,233</td>
<td>204,346</td>
</tr>
<tr>
<td>At cost</td>
<td>48,811</td>
<td>1,962</td>
</tr>
<tr>
<td>Less: Accumulated depreciation</td>
<td>10,113</td>
<td>1,962</td>
</tr>
<tr>
<td><strong>Total plant and equipment</strong></td>
<td><strong>38,698</strong></td>
<td>-</td>
</tr>
</tbody>
</table>
### Note 7. Current liabilities – Trade and other payables

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade creditors</td>
<td>74,841</td>
<td>198,317</td>
</tr>
<tr>
<td>Accruals</td>
<td>246,386</td>
<td>73,041</td>
</tr>
<tr>
<td>Sundry creditors</td>
<td>7,920</td>
<td>-</td>
</tr>
<tr>
<td>Net GST liability</td>
<td>7,707</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>336,854</td>
<td>271,358</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee entitlements</td>
<td>123,896</td>
<td>148,698</td>
</tr>
</tbody>
</table>

### Note 9. Current liabilities – Other liabilities

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income in advance – Membership fees</td>
<td>160</td>
<td>2,000</td>
</tr>
<tr>
<td>Quality assurance fees</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Note 10. Non-current liabilities - Provisions

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee entitlements</td>
<td>35,496</td>
<td>27,777</td>
</tr>
</tbody>
</table>
### Note 11. Retained earnings

<table>
<thead>
<tr>
<th>Retained earnings</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>at the beginning</td>
<td>3,249,784</td>
<td>2,753,106</td>
</tr>
<tr>
<td>of the financial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net profit (loss)</td>
<td>(1,027,679)</td>
<td>496,678</td>
</tr>
<tr>
<td>Retained earnings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>at the end of the</td>
<td>2,222,105</td>
<td>3,249,784</td>
</tr>
<tr>
<td>financial year</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Note 12. Reconciliation of profit (loss) from continuing operations after income tax to net cash inflow from operating activities

<table>
<thead>
<tr>
<th>Change in operating assets and liabilities:</th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease (increase) in trade and other receivables</td>
<td>51,433</td>
<td>(200,261)</td>
</tr>
<tr>
<td>Decrease (increase) in other assets</td>
<td>(40,653)</td>
<td>9,915</td>
</tr>
<tr>
<td>(Decrease) increase in trade and other payables</td>
<td>65,496</td>
<td>32,222</td>
</tr>
<tr>
<td>(Decrease) increase in provisions</td>
<td>(17,083)</td>
<td>(20,439)</td>
</tr>
<tr>
<td>(Decrease) increase in other liabilities</td>
<td>(1,840)</td>
<td>(28,638)</td>
</tr>
<tr>
<td><strong>Net cash inflow (outflow) from operating activities</strong></td>
<td>(962,175)</td>
<td>289,889</td>
</tr>
</tbody>
</table>
Note 13. Financial instruments

(a) Interest rate risk exposures:
The entity’s exposure to interest rate risk and the effective weighted average interest rate by maturity periods is set out in the following table. For interest rates applicable to each class of asset or liability refer to individual notes to the financial statements. Exposures arise predominantly from assets and liabilities bearing variable interest rates as the entity intends to hold fixed rate assets and liabilities to maturity.

<table>
<thead>
<tr>
<th>Notes</th>
<th>Floating Interest Rate</th>
<th>1 year or less</th>
<th>Over 1 to 5 years</th>
<th>More than 5 years</th>
<th>Non-Interest Bearing</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Financial assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>3</td>
<td>2,321,068</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>90</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>257,929</td>
</tr>
<tr>
<td></td>
<td><strong>2,321,068</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>258,019</strong></td>
</tr>
<tr>
<td><strong>Weighted average interest rate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>2.96%</strong></td>
</tr>
<tr>
<td><strong>Financial liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Credit cards</td>
<td>7</td>
<td>4,150</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>332,704</td>
</tr>
<tr>
<td></td>
<td><strong>4,150</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>-</strong></td>
<td><strong>332,704</strong></td>
</tr>
<tr>
<td><strong>Weighted average interest rate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>18.19%</strong></td>
</tr>
<tr>
<td><strong>Net financial assets (liabilities)</strong></td>
<td>2,316,918</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>(74,685)</td>
<td><strong>2,242,233</strong></td>
</tr>
</tbody>
</table>
### 2011

<table>
<thead>
<tr>
<th>Notes</th>
<th>Floating Interest Rate</th>
<th>1 year or less</th>
<th>Over 1 to 5 years</th>
<th>More than 5 years</th>
<th>Non-Interest Bearing</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Financial assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>3</td>
<td>3,330,136</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>46</td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>4</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>309,362</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3,330,136</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>309,408</td>
</tr>
<tr>
<td><strong>Weighted average interest rate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.97%</td>
</tr>
<tr>
<td><strong>Financial liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Credit cards</td>
<td>7</td>
<td>16,071</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>255,287</td>
</tr>
<tr>
<td></td>
<td></td>
<td>16,071</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>255,287</td>
</tr>
<tr>
<td><strong>Weighted average interest rate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>18.59%</td>
</tr>
<tr>
<td><strong>Net financial assets (liabilities)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3,314,065</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>54,121</td>
<td>3,368,186</td>
</tr>
</tbody>
</table>

(b) Net fair value of financial assets and liabilities

(i) On-balance sheet

The net fair value of cash and cash equivalents and non-interest bearing monetary financial assets and financial liabilities of the entity approximates their carrying amounts.
The net fair value of other monetary financial assets and financial liabilities is based upon market prices where a market exists or by discounting the expected future cash flows by the current interest rates for assets and liabilities with similar risk profiles.

**Note 14. Contingent liabilities**

The entity has entered into contracts for trials with institutions and commits to the completion of those trials. The extent of funds sourced by the entity for trials that have not been completed by 31 December 2012, the directors commit these funds for the purpose of completion of these trials in the future periods. As at 31 December 2012 the value of such funds was $1,204,642 (2011: $2,288,712).

**Directors’ Declaration**

Your directors present their report on Trans Tasman Radiation Oncology Group Limited (the Company) for the year ended 31 December 2012.

The directors of the entity declare that:
1. The financial statements and notes, as set out on pages 179 to 191, are in accordance with the Corporations Act 2001 and:
   (a) comply with Australian Accounting Standards; and
   (b) give a true and fair view of the financial position as at 31 December 2012 and of the performance for the year ended on that date of the entity.
2. In the directors’ opinion there are reasonable grounds to believe that the entity will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors.

___________________  
Associate Professor S Porceddu  
Director

___________________  
T Denny  
Director

Newcastle  
28 February 2013
Independent Audit Report to the Members of Trans Tasman Radiation Oncology Group Limited

Report on the Financial Report:
We have audited the accompanying financial report of Trans Tasman Radiation Oncology Group Limited (the Company) as set out on pages 179 to 191, which comprises the balance sheet as at 31 December 2012 and the income statement, statement of changes in equity and cash flow statement for the year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information and the directors’ declaration.

Directors’ Responsibility for the Financial Report:
The directors of the company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards – Reduced Disclosure Requirements (including the Australian Accounting Interpretations) and the Corporations Act 2001 and for such internal control as the directors determine is necessary to enable the preparation of the financial report that is free from material misstatement, whether due to fraud or error.

Auditor’s Responsibility:
Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. Those standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement.
An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor’s judgment, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity’s preparation of the financial report that gives a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.
We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Independence:
In conducting our audit, we have complied with the independence requirements of the Corporations Act 2001. We confirm that the independence declaration required by the Corporations Act 2001, which has been given to the directors of Trans Tasman Radiation Oncology Group Limited, would be in the same terms if given to the directors as at the time of this auditor’s report.

Auditor’s Opinion:
In our opinion, the financial report of the Company is in accordance with the Corporations Act 2001, including:
(i) giving a true and fair view of the Company’s financial position as at 31 December 2012 and of its performance for the financial year ended on that date; and
(ii) complying with Australian Accounting Standards – Reduced Disclosure Requirements and the Corporations Regulations 2001.

IE McEwan
Newcastle, 28 February 2013
McEwan and Partners Chartered Accountants
**Auditor’s Independence Declaration**

As auditor for the Trans Tasman Radiation Oncology Group Limited for the year ended 31 December 2012, I declare that to the best of my knowledge and belief, there have been:

(i) no contraventions of the auditor independence requirements as set out in the Corporations Act 2001 in relation to the audit; and
(ii) no contraventions of any applicable code of professional conduct in relation to the audit.

IE McEwan

Newcastle
28 February 2013
McEwan and Partners
Chartered Accountants

**Disclaimer of Opinion on Additional Financial Data of Trans Tasman Radiation Oncology Group Limited**

The additional financial data set out on page 194 is in accordance with the books and records of Trans Tasman Radiation Oncology Group Limited (the Company) and is made subject to the auditing procedures applied in the statutory audit of the Company for the year ended 31 December 2012. It will be appreciated that the statutory audit did not cover all details of the additional financial data. Accordingly, we do not express an opinion on such financial data and no warranty of accuracy or reliability is given. Neither the firm nor any member or employee of the firm undertakes responsibility in any way whatsoever to any person (other than the Company) in respect of the additional financial data, including any errors or omissions therein however caused.

IE McEwan

Newcastle
28 February 2013
McEwan and Partners
Chartered Accountants
## Operating Statement

**31 December 2012**

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donation</td>
<td>10,000</td>
<td>2</td>
</tr>
<tr>
<td>Facility fees</td>
<td>194,700</td>
<td>-</td>
</tr>
<tr>
<td>Fundraising</td>
<td>50</td>
<td>421</td>
</tr>
<tr>
<td>Grants</td>
<td>1,043,184</td>
<td>2,289,491</td>
</tr>
<tr>
<td>Interest</td>
<td>99,635</td>
<td>149,433</td>
</tr>
<tr>
<td>Meeting registration</td>
<td>153,890</td>
<td>219,873</td>
</tr>
<tr>
<td>Membership subscriptions</td>
<td>29,249</td>
<td>17,588</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>183,737</td>
<td>1,558</td>
</tr>
<tr>
<td>Reimbursed expenses</td>
<td>37,500</td>
<td>-</td>
</tr>
<tr>
<td>Research services</td>
<td>203,352</td>
<td>287,509</td>
</tr>
<tr>
<td>Sponsorship of meetings</td>
<td>26,046</td>
<td>103,491</td>
</tr>
<tr>
<td>Sponsorship – general</td>
<td>-</td>
<td>126,143</td>
</tr>
<tr>
<td></td>
<td><strong>1,981,343</strong></td>
<td><strong>3,195,509</strong></td>
</tr>
<tr>
<td><strong>Expenses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accommodation</td>
<td>15,520</td>
<td>7,041</td>
</tr>
<tr>
<td>Advertising</td>
<td>400</td>
<td>177</td>
</tr>
<tr>
<td>Annual meeting</td>
<td>-</td>
<td>166,108</td>
</tr>
<tr>
<td>Audit fees</td>
<td>9,500</td>
<td>11,000</td>
</tr>
<tr>
<td>Bank charges</td>
<td>2,349</td>
<td>1,706</td>
</tr>
<tr>
<td>Central operations staff (Mater contracts)</td>
<td><strong>1,090,330</strong></td>
<td><strong>915,207</strong></td>
</tr>
<tr>
<td>Computer &amp; IT services</td>
<td>22,555</td>
<td>10,096</td>
</tr>
<tr>
<td>Consultancy fees</td>
<td>46,538</td>
<td>15,000</td>
</tr>
<tr>
<td>Currency exchange loss</td>
<td>619</td>
<td>2,096</td>
</tr>
<tr>
<td>Depreciation</td>
<td>8,151</td>
<td>412</td>
</tr>
<tr>
<td>DOHA trial expenses</td>
<td>978,124</td>
<td>1,023,655</td>
</tr>
<tr>
<td></td>
<td>2012</td>
<td>2011</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>Donation</td>
<td>-</td>
<td>250</td>
</tr>
<tr>
<td>Equipment</td>
<td>46,550</td>
<td>10,950</td>
</tr>
<tr>
<td>Fees and licenses</td>
<td>394</td>
<td>491</td>
</tr>
<tr>
<td>Graphic designer</td>
<td>-</td>
<td>4,595</td>
</tr>
<tr>
<td>Insurance</td>
<td>52,787</td>
<td>44,301</td>
</tr>
<tr>
<td>Legal fees</td>
<td>2,820</td>
<td>1,903</td>
</tr>
<tr>
<td>Marketing</td>
<td>12,127</td>
<td>-</td>
</tr>
<tr>
<td>Meeting expenses (Other)</td>
<td>41,281</td>
<td>18,538</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>5,939</td>
<td>2,968</td>
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### Net profit (loss) from continuing operations before income tax expense

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<td>(1,027,679)</td>
<td>496,678</td>
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The above operating statement has not been subject to audit – refer to the Disclaimer.
**TROG GRANTS FROM COMPETITIVE SOURCES**

**Trial and Infrastructure**

<table>
<thead>
<tr>
<th>Funding Body</th>
<th>Year Granted</th>
<th>Title</th>
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<th>Duration</th>
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<tr>
<td>Queensland Cancer Foundation</td>
<td>1992</td>
<td>TROG 91.01 - Prospective randomised trial of accelerated radiotherapy for locally advanced SCC of the upper aerodigestive tract.</td>
<td>$33,650</td>
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<td>NHMRC</td>
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<td>TROG 94.01 - Randomised trial of preoperative radiation and chemotherapy for resectable carcinoma of the oesophagus</td>
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<td>NHMRC</td>
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<td>TROG 96.05 - Radiotherapy for neuropathic pain due to bone metastases - a randomised trial</td>
<td>$172,000</td>
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<td>ACCV</td>
<td>1998 (to start 1999)</td>
<td>TROG 99.03 - A randomised multicentre trial of IFRT vs IFRT plus chemotherapy for stage I-II low grade follicular lymphoma</td>
<td>$150,000</td>
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<td>TROG 96.01 - A randomised trial of optimal duration of neoadjuvant androgen deprivation in localised prostate cancer</td>
<td>$214,227</td>
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<td>RANZCR</td>
<td>1999</td>
<td>Dosimetric intercomparison study: Physics Quality Assurance Central Operations Office</td>
<td>$5,000</td>
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<td>RANZCR</td>
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<td>Temporary Clerical Support: Central Operations Office</td>
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<td>ACCV</td>
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<td>TROG 99.05 - Tumour volume as an independent prognostic factor in patients with non-small cell lung cancer: a protocol for a prospective database</td>
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<td>TROG 01.04 - A randomised trial of preoperative radiotherapy for stage T3 adenocarcinoma of rectum</td>
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<td>TROG 01.04 - A randomised trial of preoperative radiotherapy for stage T3 adenocarcinoma of rectum</td>
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<td>ACCV</td>
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<td>NHMRC</td>
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<td>TROG 96.01 - Optimal duration of neoadjuvant androgen deprivation therapy in localised prostate cancer (renewal grant)</td>
<td>$275,000</td>
<td>5 years</td>
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<td>NHMRC</td>
<td>2002 (to start 2003)</td>
<td>TROG 02.03 - Phase III study comparing radical synchronous chemo-radiation vs radical radiation alone in the definitive management of muscle invasive TCC of the urinary bladder following maximal TUR</td>
<td>$190,000</td>
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<td>NHMRC</td>
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<td>TROG 02.01 - Randomised clinical trial of surgery versus surgery plus adjuvant radiotherapy for regional control in patients with completely resected macroscopic nodal metastatic malignant melanoma</td>
<td>$305,000</td>
<td>3 years</td>
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<td>Cancer Council SA</td>
<td>2002 (to start 2003)</td>
<td>TROG 02.01 - Randomised clinical trial of surgery versus surgery plus adjuvant radiotherapy for regional control in patients with completely resected macroscopic nodal metastatic malignant melanoma</td>
<td>$10,000</td>
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<td>NHMRC</td>
<td>2003 (to start 2004)</td>
<td>TROG 03.04 - Randomised trial investigating the effect of biochemical (PSA) control and survival of different durations of adjuvant androgen deprivation in association with definitive radiation treatment for localised carcinoma of the prostate</td>
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<td>NHMRC</td>
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<td>TROG 03.01 - A randomised phase III study in advanced oesophageal carcinoma to compare dysphagia in patients treated with radiotherapy versus chemo-radiotherapy</td>
<td>$232,000</td>
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<td>Cancer Council Tas</td>
<td>2003 (to start 2004)</td>
<td>TROG 03.01 - A randomised phase III study in advanced oesophageal carcinoma to compare dysphagia in patients treated with radiotherapy versus chemo-radiotherapy</td>
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<td>RANZCR</td>
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<td>TROG 03.02 - A feasibility study to evaluate adjuvant chemo-radiotherapy for gastric cancer</td>
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<td>Multistate Cancer Council (VIC, NSW, SA, QLD)</td>
<td>2003 (to start 2004)</td>
<td>TROG 03.05 - A phase III study of regional RT in early breast cancer. (NCIC MA20)</td>
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<td>TROG 03.04 - Infrastructure funding: Randomised trial investigating the effect of biochemical (PSA) control and survival of different durations of adjuvant androgen deprivation in association with definitive radiation treatment for localised carcinoma of the prostate (RADAR)</td>
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<td>NHMRC</td>
<td>2004 (to start 2005)</td>
<td>TROG 03.06 - A collaborative randomised phase III trial: The timing of intervention with androgen deprivation in prostate cancer patients with a rising PSA</td>
<td>$627,000</td>
<td>3 years</td>
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<tr>
<th>Funding Body</th>
<th>Year Granted</th>
<th>Title</th>
<th>Total Grant</th>
<th>Duration</th>
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<tr>
<td>HRC (New Zealand) and Cancer Society of NZ</td>
<td>2004</td>
<td>TROG 03.04 - Randomised trial investigating the effect of biochemical (PSA) control and survival of different durations of adjuvant androgen deprivation in association with definitive radiation treatment for localised carcinoma of the prostate (NZ$706,105)</td>
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<td>Multistate Cancer Council (Vic, QLD)</td>
<td>2004 (to start 2005)</td>
<td>TROG 03.07 - A randomised phase II study of two regimens of palliative chemoradiation therapy in the management of locally advanced non small cell lung cancer</td>
<td>$49,613</td>
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<td>Cancer Council Australia</td>
<td>2004</td>
<td>TROG 03.08 - A phase III international randomized trial of single versus multiple fractions for re-irradiation of painful bone metastases. (NCIC CTG SC.20)</td>
<td>$40,000</td>
<td>1 year</td>
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<tr>
<td>Cancer Council Queensland</td>
<td>2005 (to start 2006)</td>
<td>TROG 05.01 - POST: Post-operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck. Post-Operative Skin Trial</td>
<td>$150,000</td>
<td>2 years</td>
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<tr>
<td>Multistate Cancer Council (Vic, NSW, SA, QLD)</td>
<td>2005</td>
<td>TROG 03.06 - A collaborative randomised phase III trial: The timing of intervention with androgen deprivation in prostate cancer patients with a rising PSA.</td>
<td>$106,000</td>
<td>3 years</td>
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<td>RANZCR</td>
<td>2005</td>
<td>TROG 05.01 - POST: Post-operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck. Post-Operative Skin Trial</td>
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<td>Dept of Health &amp; Aging, Aust</td>
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<td>Strengthening Cancer Care - Infrastructure Support for Clinical Trials Program</td>
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<td>2006</td>
<td>TROG 05.01 - POST: Post-operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck. Post-Operative Skin Trial</td>
<td>$323,075</td>
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<td>TROG 06.02 - A multicentre feasibility study of accelerated partial breast irradiation using 3D conformal radiation therapy for early breast cancer (APBI)</td>
<td>$154,910</td>
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<td>NHMRC</td>
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<td>TROG 07.01 DCIS - A randomised phase III study of radiation doses and fractionation schedules in non-low risk DCIS of the breast</td>
<td>$1,730,329</td>
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<td>TROG 05.02 - A prospective single arm trial of involved field radiotherapy alone for stage I-II low grade non-gastric marginal zone lymphoma</td>
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<td>TROG 96.01 - Optimal duration of neoadjuvant androgen deprivation therapy in localised prostate cancer treated by radiotherapy</td>
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<td>NHMRC</td>
<td>2006 (to start 2007)</td>
<td>TROG 03.04 - RADAR: Value of androgen deprivation and bisphosphonate in patients treated by radiotherapy in localised prostate cancer</td>
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<td>HRC, NZ and Cancer Society of NZ</td>
<td>2006 (to start 2007)</td>
<td>TROG 03.04 - RADAR: Value of androgen deprivation and bisphosphonate in patients treated by radiotherapy in localised prostate cancer (NZ$486,492)</td>
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<td>TROG 05.01 - POST: Post-operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck. Post-Operative Skin Trial (NZ$123,562)</td>
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<td>COSA</td>
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<td>TROG 06.01: Primary chemotherapy with temozolomide vs radiotherapy in patients with low grade glioma after stratification for genetic 1p loss: a phase III study. Protocol Development Grant</td>
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<td>TROG 07.02 – QUARTZ: Quality of life after radiotherapy and/or steroids (funding extended to 2012)</td>
<td>$63,000</td>
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<td>NHMRC</td>
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<td>TROG 06.01 - Primary chemotherapy with temozolomide vs radiotherapy in patients with low grade gliomas after stratification for genetic 1p loss: A phase III study (EORTC 22033-26033)</td>
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<td>Victorian Cancer Council</td>
<td>2007 (to start 2008)</td>
<td>TROG 08.03 - RAVES: Radiotherapy – Adjuvant Versus Early Salvage</td>
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<th>Total Grant</th>
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<td>NSW Cancer Council</td>
<td>2007 (to start 2008)</td>
<td>TROG 08.03 - RAVES: Radiotherapy – Adjuvant Versus Early Salvage</td>
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<td>Research Infrastructure Grant: Trans Tasman Radiation Oncology Group – Central Operations Office</td>
<td>$718,514</td>
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<td>Prostate Cancer Foundation of Australia</td>
<td>2007 (to start 2008)</td>
<td>TROG 08.01 - PROFIT: A Randomized Trial of a Shorter Radiation Fractionation Schedule for the Treatment of Localized Prostate Cancer (PROFIT: Prostate Fractionated Irradiation Trial)</td>
<td>$100,000</td>
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<td>Cancer Australia</td>
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<td>Support for Cancer Clinical Trials Program</td>
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<td>TROG 08.05 - WBRT: Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma-A randomised phase III trial (extended to June 2011).</td>
<td>$281,019</td>
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<td>TROG 08.03 - RAVES: Radiotherapy – Adjuvant Versus Early Salvage NZ$1,169,103</td>
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<td>COSA</td>
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<td>Protocol Development Grant</td>
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<td>Cancer Council Australia and Cancer Australia</td>
<td>2008 (to start 2009)</td>
<td>TROG 08.08 - Randomised phase II/III study of preoperative chemoradiotherapy versus chemotherapy for resectable gastric cancer. T Leong</td>
<td>$596,625</td>
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<td>Cancer Australia</td>
<td>2008 (to start 2009)</td>
<td>TROG 09.02 - CHISEL Lung - A randomised phase III trial of highly conformal stereotactic radiotherapy vs conventionally fractionated radiotherapy for inoperable early stage I non-small cell lung cancer. (extended to Dec 2013)</td>
<td>$260,000</td>
<td>4 years</td>
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<tr>
<td>Cancer Council Australia and Cancer Australia</td>
<td>2008 (to start 2009)</td>
<td>TROG 09.03 - MP3: Phase II efficacy study of synchronous weekly carboplatin and radiation in Merkel Cell Carcinoma of the skin.</td>
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<td>TROG 08.03 - RAVES: Radiotherapy - Adjuvant Versus Early Salvage</td>
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<td>Prostate Cancer Foundation of Australia</td>
<td>2008</td>
<td>TROG 08.03 - RAVES: Radiotherapy - Adjuvant Versus Early Salvage. Development of printed resources.</td>
<td>$3,900</td>
<td>1 year</td>
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<td>Genesis Oncology Research Trust</td>
<td>2008</td>
<td>TROG 08.03 - RAVES: Radiotherapy - Adjuvant Versus Early Salvage. Development of printed resources. NZ$3,000</td>
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<td>Duration</td>
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<tr>
<td>Cancer Australia</td>
<td>2008 (to start 2009)</td>
<td>TROG 08.01 - PROFIT: A Randomized Trial of a Shorter Radiation Fractionation Schedule for the Treatment of Localized Prostate Cancer (PROFIT: Prostate Fractionated Irradiation Trial).</td>
<td>$443,500</td>
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<td>2008 (to start 2009)</td>
<td>TROG 08.04 - PORTEC-3: Randomized phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma</td>
<td>$443,125</td>
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<td>Cancer Institute NSW - Research Equipment Grant</td>
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<td>IMRT phantom and associated dosimetry equipment</td>
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<td>Cancer Institute NSW</td>
<td>2009</td>
<td>TROG 08.03 - RAVES: Radiotherapy - Adjuvant Versus Early Salvage. Patient Information and Consent Workshop</td>
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<tr>
<td>NHMRC Project Grant</td>
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<td>TROG 10.01 - BOLART - A multi centre feasibility study of online adaptive image guided Radiotherapy for muscle invasive Bladder Cancer (2010-2012)</td>
<td>$560,000</td>
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<tr>
<td>NHMRC Project Grant</td>
<td>2009</td>
<td>TROG 10.01 - BOLART - A multi centre feasibility study of online adaptive image guided Radiotherapy for muscle invasive Bladder Cancer: e-learning</td>
<td>$434,000</td>
<td>5 years</td>
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<tr>
<td>Cancer Institute NSW</td>
<td>2009</td>
<td>Research Infrastructure Grant - TROG Central Operations Office</td>
<td>$657,000</td>
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<td>2009</td>
<td>NHMRC Enabling Grant 18mth Extension</td>
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<td>Cancer Australia &amp; Radiation Oncology Section (DOHA)</td>
<td>2009</td>
<td>TROG 09.01 – PROArCT: A phase II trial of integrated preoperative radiotherapy and chemotherapy with Oxaliplatin 5-FU and Folinic Acid in patients with locally advanced rectal cancer</td>
<td>$215,000</td>
<td>2 years</td>
</tr>
<tr>
<td>Cancer Australia &amp; Radiation Oncology Section (DOHA)</td>
<td>2009</td>
<td>TROG 03.01 - A randomised phase III study in advanced oesophageal carcinoma to compare dysphagia in patients with radiotherapy versus chemo-radiotherapy</td>
<td>$254,375</td>
<td>3 years</td>
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<tr>
<td>HRC, NZ</td>
<td>2009</td>
<td>TROG 08.08 – TOPGEAR: Randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer (NZ$137,250)</td>
<td>$106,656</td>
<td>2 years</td>
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<tr>
<td>Cancer Australia</td>
<td>2010</td>
<td>TROG 08.06 – STARS: A Randomised comparison of anastrozole commenced before and continued during radiotherapy for breast cancer versus anastrozole and subsequent anti-oestrogen therapy delayed until after radiotherapy</td>
<td>$600,000</td>
<td>3 years</td>
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<tr>
<td>Cancer Society New Zealand</td>
<td>2010</td>
<td>TROG 08.08 – TOPGEAR: Randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer (NZ$55,000)</td>
<td>$42,740</td>
<td>3 years</td>
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<td>Cancer Institute NSW - Equipment Grant</td>
<td>2010</td>
<td>Equipment to assess the accuracy of image guided and advanced technology used in multi-centre radiotherapy clinical trials. [Peter Greer]</td>
<td>$94,058</td>
<td>2 years</td>
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<tr>
<td>HRC, NZ and Cancer Society of NZ</td>
<td>2010</td>
<td>TROG 03.04 – RADAR: Value of androgen deprivation and bisphosphonate in patients treated by radiotherapy in localised prostate cancer ($NZ455,120).</td>
<td>$353,670</td>
<td>3 years</td>
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<tr>
<td>Cancer Australia</td>
<td>2010</td>
<td>TROG 11.01 – SUPREMO: A phase III randomised trial to assess the role of adjuvant chest wall irradiation in intermediate risk operable breast cancer following mastectomy</td>
<td>$510,000</td>
<td>3 years</td>
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<tr>
<td>DOHA</td>
<td>2010</td>
<td>Project to Assess New Radiation Oncology Treatments and Techniques (ANROTAT)</td>
<td>$2,992,550</td>
<td>2 years</td>
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<tr>
<td>NHMRC</td>
<td>2010</td>
<td>TCOO Enabling Grant Extension</td>
<td>$375,000</td>
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<tr>
<td>Cancer Australia</td>
<td>2010</td>
<td>Support for Cancer Clinical Trials Program</td>
<td>$1,408,452</td>
<td>3 years</td>
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<tr>
<td>Cancer Australia and Cancer Councils</td>
<td>2010</td>
<td>TROG 08.05 - WBRT post local treatment in Melanoma: Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma-A randomised phase III trial</td>
<td>$591,000</td>
<td>3 years</td>
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<tr>
<td>Victorian Breast Cancer Research Consortium</td>
<td>2010</td>
<td>TROG 07.01 - A randomised phase III study of radiation doses and fractionation schedules in non-low risk DCIS of the breast</td>
<td>$250,000</td>
<td>3 years</td>
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<td>NHMRC</td>
<td>2011</td>
<td>TROG 05.01 – POST: Post-operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck. Post-Operative Skin Trial</td>
<td>$252,000</td>
<td>3 years</td>
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<tr>
<td>Cancer Australia</td>
<td>2011</td>
<td>TROG 08.04 – PORTEC: Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage Endometrial Carcinoma</td>
<td>$300,778</td>
<td>3 years</td>
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<tr>
<td>Organisation</td>
<td>Grant Number</td>
<td>Description</td>
<td>Year</td>
<td>Funding Amount</td>
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<td>--------------</td>
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<td>-------------</td>
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<tr>
<td>Cancer Australia (Priority Driven Collaborative Cancer Research Scheme)</td>
<td>TROG 11.03</td>
<td>PLUNG: A randomised phase III trial of high dose palliative radiotherapy (HDPRT) versus concurrent chemotherapy and HDPRT (C-HDPRT) in patients with good performance status, locally advanced/small volume metastatic NSCLC not suitable for radical chemo-radiotherapy.</td>
<td>2011</td>
<td>$327,215</td>
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<tr>
<td>Cancer Society of New Zealand</td>
<td>TROG 10.01</td>
<td>BOLART: A multicentre study of on-line adaptive image guided radiotherapy for bladder cancer (NZ$84,696).</td>
<td>2011</td>
<td>$64,717</td>
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<tr>
<td>Genesis Oncology Research Trust</td>
<td></td>
<td>DEV_RAVES DA - Evaluating the utility of a Patient Decision Aid for prospective participants in the TROG RAVES Prostate Cancer trial (TROG 08.03)</td>
<td>2011</td>
<td>$13,924</td>
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<td>RANZCR</td>
<td>DEV_RAVES DA - Evaluating the utility of a Patient Decision Aid for prospective participants in the TROG RAVES Prostate Cancer trial (TROG 08.03)</td>
<td>2011</td>
<td>$10,000</td>
<td>1 year</td>
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<tr>
<td>NHMRC</td>
<td>TROG 08.08</td>
<td>TOPGEAR: Randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer</td>
<td>2012</td>
<td>$806,175</td>
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<tr>
<td>Cancer Council Queensland</td>
<td>TROG 11.02</td>
<td>SCORAD III: A randomised phase III trial of single fraction radiotherapy compared to multifraction radiotherapy in patients with metastatic spinal cord compression</td>
<td>2012</td>
<td>$164,000</td>
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<tr>
<td>NHMRC</td>
<td>TROG 08.08</td>
<td>TOPGEAR: Randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer</td>
<td>2012</td>
<td>$1,974,558</td>
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<tr>
<td>NHMRC</td>
<td>TROG 12.01</td>
<td>HPV Oropharynx: A randomised phase III trial of cetuximab and radiation versus weekly cisplatin and radiation in locoregionally advanced HPV associated oropharyngeal cancer.</td>
<td>2012</td>
<td>$1,097,932</td>
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<tr>
<td>NZ Lotteries Health Research</td>
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<td>Trial in Development - RAVES DA: Evaluating the utility of a Patient Decision Aid for prospective participants in the TROG RAVES Prostate Cancer trial (Substudy of TROG 08.03).</td>
<td>2012</td>
<td>$5,280</td>
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<td>RANZCR</td>
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<td>Trial in Development - RAVES DA: Evaluating the utility of a Patient Decision Aid for prospective participants in the TROG RAVES Prostate Cancer trial (Substudy of TROG 08.03)</td>
<td>2012</td>
<td>$24,970</td>
</tr>
</tbody>
</table>

**TOTAL** | | | | **$36,720,967** |
2012 SPONSORS & ACKNOWLEDGEMENTS

TROG gratefully acknowledges our sponsors and other important contributors for their support during 2012, including:

Corporate Partners

TROG’s Corporate Partners are industry members who provide additional support for TROG’s infrastructure and annual scientific meeting.

Varian once again partnered with TROG during 2012 providing support for the
• 2012 TROG Annual Scientific Meeting (Major Sponsor)
• 2012 Technical Research Workshop
• Quality Assurance Program

2012 Annual Meeting Major Sponsor

Varian Medical Systems
Merck Serono Australia Pty Ltd
Department of Health and Ageing

2012 Annual Meeting Minor Sponsors

Abbott Australasia
AstraZeneca Pty Ltd
Brainlab Australia Pty Ltd
Elekta Pty Ltd
Hospira
Merck Sharpe Dohme
Oncura
Industry Support for Individual TROG Trials

Pharmaceutical and other companies provide substantial support of a number of individual TROG trials. Support for open TROG trials in 2012 was provided by:

<table>
<thead>
<tr>
<th>Company</th>
<th>Support</th>
</tr>
</thead>
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<tr>
<td>Amgen</td>
<td>Grant ($30,000) for TROG 99.03</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Grant ($580,000) for TROG 08.06</td>
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<tr>
<td>Baxter Healthcare</td>
<td>Sterilised water for TROG 07.03</td>
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<tr>
<td>Fisher &amp; Paykel Healthcare</td>
<td>Humidifiers for TROG 07.03</td>
</tr>
<tr>
<td>Hospira</td>
<td>Grant ($100,000) for TROG 03.06</td>
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<tr>
<td>Merck Serono Australia</td>
<td>Product (Erbitux) and grant ($350,000) for TROG 07.04 Funding for TROG 08.07</td>
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<tr>
<td>Roche Products</td>
<td>Product (Mabthera) for TROG 99.03</td>
</tr>
<tr>
<td>Schering-Plough Australia</td>
<td>Product (Temozolomide) for TROG 06.01</td>
</tr>
</tbody>
</table>

External Funding Bodies

External funding bodies are the primary source of financial support for TROG trials and TROG Central Operations infrastructure. Our research program would not be possible without their support. Grants from the following external bodies have supported TROG:

- Australian Government Department of Health and Ageing (DoHA)
- National Health and Medical Research Council of Australia (NHMRC)
- Cancer Institute NSW
- Cancer Australia
- Cancer Council NSW
- Cancer Council Queensland
- Cancer Council Tasmania
- Cancer Council Victoria
- Cancer Society New Zealand
- Clinical Oncology Society of Australia (COSA)
- Foundation for Research Science and Technology (FRST), New Zealand
- Genesis Oncology Research Trust
- Health Research Council (HRC), New Zealand
- Hunter Medical Research Institute (HMRI), Newcastle
- NZ Lotteries Health Research
- Prostate Cancer Foundation of Australia (PCFA)
- Queensland Cancer Fund
- Royal Australian and New Zealand College of Radiologists
- Smart State, QLD Government
- Victorian Breast Cancer Research Consortium
Other Acknowledgements

TROG Facility Alliance

TROG acknowledges the centres listed below for their support through payment of the Facility Alliance fee implemented in 2012 to assist the functions of the Central Operations Office.

Auckland Regional Cancer & Blood Service
Christchurch Hospital
Dunedin Hospital
Epworth Freemasons Hospital (Epworth & Richmond)
Liverpool Hospital - South West Sydney District
Mid-North Coast Local Health District
(Lismore, Coffs Harbour, Port Macquarie)
Nepean Hospital
Newcastle Calvary Mater Hospital
Palmerston North Hospital
Peter MacCallum Cancer Institute
Princess Alexandria Hospital
Royal North Shore Hospital
Royal Prince Alfred Hospital
St Andrew’s Cancer Care Centre
St George Hospital
The Alfred Hospital
The Canberra Hospital
Townsville General Hospital
Waikato Hospital
Wellington Hospital
Westmead Hospital

TROG gratefully acknowledges the support of the Calvary Mater Newcastle, in particular the Department of Radiation Oncology, for provision of the physical infrastructure for the TROG Central Operations Office.

TROG also wishes to thank the institutions in the higher education sector who provide support through administration of research grants and research infrastructure, including the University of Newcastle, Melbourne University and the University of Otago.

Special thanks also to each of the institutions involved in support of TROG trials as trial coordinating centres and participating sites, as well as all the clinical staff, administrators and patients who make the TROG research program possible and thereby contribute to the vision of better patient care and outcomes.

Thank you to our generous private donors for their contributions during 2012.