

Trognews

Issue 11 / September 2009

New Leadership at TROG COO

Inside this issue:

CEO Introduction	1 - 2
TROG Funding	2
TROG Meeting Highlights	3 - 6
TROG QA Update	7
TROG Committee	8
Recent Trial News	9 - 17
TROG Staff Introduction	18 - 19
TROG COO Contacts	20 - 21
Upcoming Events	22



Rowena Amin, newly appointed CEO, TROG

TROG's new CEO Rowena Amin commenced her role with the TROG Central Operation Office (TCOO) during July 2009. In her previous role as Executive Officer of RANZCR Faculty of Radiation Oncology she has gained a good understanding of the radiotherapy environment. Rowena has had significant management experience within the healthcare sector and a nursing background has provided her with a 'hands-on, can do' approach to her work.

Commenting on her appointment, Rowena said "It is indeed a pleasure and a privilege to be leading such a professional and well respected organisation and I look forward to leading the

(Continued on page 2)

New Leadership at TCOO

(Continued from page 1)

TROG team into a new phase of growth and building sustainability."

To date Rowena has spent time gaining an understanding of the business environment and strategic issues facing TROG. Rowena said "I have spent time talking and listening to our staff and key stakeholders and the one thing that has struck me is the incredible dedication and professionalism of our staff and the high regard with which TROG is held. It is a tribute to the leadership and hard work of the TROG team over the past two decades."

Over the next year Rowena will be leading strategic planning to ensure that the next triennium's plan will position TROG well for future challenges. She said, "In development of the 2011-2013 Strategic Plan we'll be focussing hard on our Vision and Mission and during this entire process the most important question will be "How will this decision help TROG to achieve its aims and improve patient care and outcomes?"

Rowena is looking forward to hearing your feedback and ideas. Rowena contact details are E-mail: rowena.amin@trog.com.au or Phone: +61 2 49 211 719

TROG Receives Cancer Institute NSW Funding

Delivering improvements in cancer treatment through high quality cooperative group clinical trials. Trans Tasman Radiation Oncology Group Ltd - Infrastructure

On 29th June 2009 we received confirmation that the above titled grant application submitted to Cancer Institute NSW was successful. Dr Peter O'Brien, Staff Specialist in Radiation Oncology at Calvary Mater Newcastle and Chief Investigator of the grant, received \$657,000 for infrastructure funding which will ensure that essential TROG Operations Central Office activities and support for researchers continues. This funding will provide support to retain key TROG staff positions in research and administration for the next three years.

Thanks to all those involved in making this a successful application.

Highlights of 2009 Annual Scientific Meeting

2009 is an exciting year for TROG Cancer Research, marking 20 years since its establishment in New Zealand in 1989. The excitement commenced with the TROG 21st Annual Scientific Meeting held 25 - 28 March at the beautiful Port Stephens, and once again was bigger with a total of 245 delegates attending which is a reflection of the ongoing growth and increasing profile of our organisation.

The ASM Technical Research and Clinical Trial Management Workshops were both well attended and stimulated a good deal of productive discussion. Special thanks to the major sponsors of the ASM (Varian, AstraZeneca and Hospira).

The TROG 2008 Annual Research Report was launched at the Welcome Reception and Hawaiian Themed dinner on Wednesday 25 March 2009, with many of the delegates choosing to wear fancy dress. Thank you once again to Abbott Australasia for their sponsorship of the report. The evening was rounded off nicely with the TROG Piano Bar, many thanks to Danny Roos.

Delegates actively participated in the meeting and responded to the ASM presentations with questions and constructive feedback for the new proposal presentations in particular. Our invited speakers contributed additional expertise, variety and interest to the program with presentations from Assoc. Prof Geoff Ibbott (USA), Prof. Jim Hayman (Melbourne), Ms Karen Morano (USA) and Prof. Peter Wejborra (Cancer Institute NSW).

TROG 20th Anniversary Dinner was held on Friday evening in a marquee at Le Meillieur Horizons Golf Resort. Pre dinner drinks were served next to the marquee, which had clear walls and roof, with fairy lights. Two flat screens TVs provided a moving slide show of past TROG conferences. Many of the delegates commented on the marquee setup as being spectacular.

On the night TROG awards were presented, followed by a short presentation by Chris Atkinson on TROG Achievements. Entertainment for the evening was provided firstly by TROG's very own ABBA Band, performers Gail Ryan, Sandra Turner,



Performers Gail Ryan, Sandra Turner, Deborah Cruickshank and Jan Kilmurray.

Jan Kilmurray and Deborah Cruickshank. The night would not have been complete without the traditional TROG movie which was directed by David Willis, the lead actors were Boon Chua, Andrew Kneebone, Andrew Macann, Peter O'Brien and Jarad Martin. Dancing and music by Jungle Kings completed the evening.

Highlights of 2009 Annual Scientific Meeting

TROG Awards

The TROG Trial Excellence Award was presented to Associate Professor Trevor Leong for TROG 03.02: A feasibility study to evaluate adjuvant chemo-radiotherapy for gastric cancer.

Associate Professor Richard Fisher received the award for Outstanding Contribution to TROG in recognition of his committee representation, substantial input and statistical expertise provided to the TROG Research Program.



Trial in Excellence Award being presented to the 2009 winner Trevor Leong, by last years winner Boon Chua & President Bryan Burmeister.



Outstanding Contributions Award being presented to the 2009 winner Richard Fisher, by last years winner Peter O'Brien & Bryan Burmeister.

Clinical Trial Management Workshop Report

The 2009 Clinical Trial Management Workshop (previously called the Data Management Workshop) was held the day prior to the Annual Scientific Meeting in Port Stephens and was extremely popular with 78 delegates.

The workshop was designed to address specific issues involved in the running of clinical trials. The day started with presentations by the Trial Coordinators on various data management issues. These were followed by educational topics such as Central Trial Coordination (Janelle Meakin, PAH QLD), BaCT Update (Marianne Hundling), RT Information (Prof Chris Hamilton, Austin Hospital & Erin Nolan, TROG), and Budgeting & Grants (Judy Murray, Wellington Hospital & Carol Fraser-Browne, Auckland Hospital).

The afternoon session was devoted to a Good Clinical Practice (GCP) Workshop facilitated by Prof. Joe Badolato from ARCS Australia. This interactive workshop was designed to also include investigators with eight clinicians attending.

Feedback received indicated that the day was very informative and successful with many delegates requesting further GCP training and interest in numerous other educational topics. The presentations are available on the TROG website (members section/ meeting presentations).

TROG would like to thank the Clinical Trial Management Workshop (CTMW) Committee (Chair: Kacy Baumann, Judy Murray, Carol Fraser-Browne, Robin Smith, Erin Nolan & Olga Kovacev) for all their hard work in making the workshop so successful.

Planning has begun for the next CTMW so please contact Kacy Baumann on 07 3840 3219 or (Kacy_Baumann@health.qld.gov) if you would like any further information.

Highlights of 2009 Annual Scientific Meeting

Technical Research Workshop Report

The Technical Research Workshop (TRW) was conducted on the day prior to the Annual Meeting and attracted the highest number of delegates of the four workshops held to date with 77 members in attendance. Of particular note is the increase in attendance by medical physicists and radiation oncologists.

The aim of the TRW is to encourage participation of Radiation Therapists and Medical Physicists from Australia and New Zealand in clinical trials and to promote the use of new technology and equipment in clinical research.

Each year, guest speakers are invited to facilitate discussion around clinical trial conduct and participation. The workshop this year was fortunate to have three guest speakers, Geoff Ibbott, Karen Morano and Jim Hayman who all have particular expertise and experience in quality assurance in clinical trials and more broadly within radiation oncology treatment planning and delivery.

The TRW gives radiation therapists and medical physicists the forum to discuss their participation in current trials and to look at future trials and the opportunities that exist within them for involvement. To aid discussion three of the new trial proponents presented the synopsis of their study and received feedback on any technical issues that should be considered in the development of the trial.

The TRW is made possible by the support of Varian Medical Systems in providing funding to run the workshop and support the attendance of the guest speakers. TROG would like to acknowledge the contribution of all members involved in the TRW organising committee (Chair: Melissa Crain, Physics Convenor: Fiona Bignell, RT Convenor: Bronwyn Hilder, Craig Everitt, Peter Greer, Joan Hatton, Annette

Haworth, Rachel Kearvell, Kathryn Neilson, Shivani Prasad, Paula Tallon, Hannah Thompson, Matthew Williams and Dave Willis).

The continuing growth in attendance at the TRW confirms the commitment from radiation therapist and medical physicists to active contribution and involvement in TROG trials. Information provided from the feedback sheets and online survey indicated that the majority of the participants found the workshop to be valuable and effective.

Planning has begun for the next TRW so please contact Melissa Crain (melissa.crain@trog.com.au) if you would like any further information.

2009 Trials Review Meeting Incorporating Quality of Life Workshop

The 2009 Trials Review Meeting was held at the Stamford Plaza – Brisbane from 10 September to 11 September 2009. The local convenor of this year's meeting, Sandro Porceddu, chose a wonderful venue and certainly made sure that we were wined and dined in style over the course of the meeting!

The meeting kicked off on Thursday morning with a Quality of Life (QoL) Workshop facilitated by Prof Madeleine King who holds the Cancer Australia Chair in Cancer Quality of Life. The 29 delegates who attended the Workshop were unanimous in their praise of Madeleine as an extremely effective facilitator who managed to introduce a wide range of QoL measures with a very practical and useful approach. Overall the workshop was excellent, very necessary and very worthwhile. QoL is incredibly important and there is little understanding / appreciation of the various measures, which one to select and when to apply them. A number of participants commented that QoL education should become a regular feature at the Annual Meeting to capture a wider audience.

The Trials Review Meeting commenced on Thursday afternoon and the 36 delegates who attended the Thursday session, and the 39 who attended Friday session provided some extremely positive feedback. An excellent venue provided a comfortable environment for delegates to receive relevant, specific and useful information. The program allowed good time for discussion and a great opportunity to meet and discuss issues with experienced PIs.

Some members pondered that as this meeting is one of only a few opportunities for contribution towards trial development and conduct, future meetings may be even more valuable if other investigators (TROG members) are given the opportunity to attend - food for thought?

Thanks to the Organising Committee for their hard work in planning a successful meeting, and special thanks to Alyson Segrott for all her work behind the scenes to ensure that the event ran so smoothly.

Funding from our 2010 TRM Major sponsors (Hospira and Cancer Institute NSW) and our minor sponsors (Abbott Australasia, AstraZeneca Novartis,

Pfizer, Varian) made this meeting possible and we are extremely grateful to our industry partners for their continued support of TROG.

Implementation of CQMS in TROG Trials



The TROG Central Quality Management System (CQMS) is a purpose designed information technology system for the management and administration of clinical trials with an emphasis on quality assurance (QA). CQMS is now being piloted in the QA programs for five TROG trials

- TROG 07.01 (DCIS)
- TROG 08.01 (PROFIT)
- TROG 08.03 (RAVES)
- TROG 08.04 (PORTEC-3)
- TROG 08.06 (STARS)

Access by members may occur in two different roles as part of the QA program for a trial.

Site User

Members may upload requested source data using a patient-specific 'checklist form' within CQMS. The checklist form is allocated to a single person from each site so it is important that one person is nominated for each trial for the management of patient data at each site and works with other members from their site to coordinate the data upload. To date, some sites have

nominated their local data manager/ trial coordinator as this person who then liaises with the radiation therapists for the upload of the RTP (radiotherapy treatment planning) files into CQMS. At other sites, access and allocation of the checklist has been directed solely to the radiation therapists for completion and upload. During this implementation phase, sites are being requested to only upload RTP files into CQMS and continue submitting other requested documentation via email or post. New CQMS users will be notified of their access details once they have been nominated as the site user for a specific trial.

Reviewer

Members may access CQMS as a reviewer for a specified trial. Full reviews of patient treatment data have been conducted using CQMS. The system is designed for reviewers to log-in and access a patient's dataset for review using the SWAN software program (3-d review software developed at Sir Charles Gairdner Hospital, Perth). Reviewers can then complete an 'audit form' online in CQMS with automated reporting capability built-in according to defined variation classification. In contrast to the previous system of posting out paper copies of treatment plans, completion of a paper copy of the audit form and posting back

to the TCOO for analysis and reporting, we can now simply click a button within CQMS to produce a comprehensive report for feedback to sites. This is extremely important in trials where the use of 'real-time' or 'rapid' review has been deemed necessary to allow feedback to sites and enable impact and change to a patient's treatment prior to their treatment start date. We have achieved a turn-around time of less than one day from patient dataset upload into CQMS to issuing a detailed case report to the site, increasing the quality of the data produced and the compliance with the defined protocol treatment.

Members can now access an e-learning package for both CQMS and SWAN online at www.trog.com.au. A dedicated CQMS Helpdesk is available to assist members with any issues they encounter whilst using the system.

TROG Committee's

Board under Constitution ACT

Year of Service (AGM to AGM)	2008/9	2009/10	2010/11	2011/12	2012/13
President (Chair Of Board)	Bryan Burmeister	Bryan Burmeister			
Scientific Committee Chair	Gillian Duchesne	Gillian Duchesne			
Ordinary Member (Australia)	June Corry	June Corry			
Ordinary Member (NZ)	Andrew Macann	Andrew Macann	Andrew Macann		
Affiliate Member	Tomas Kron	Tomas Kron	Tomas Kron	Tomas Kron	
Managing Director (TCOO)	Gavin Rose	Rowena Amin			
Consumer Representative	Sally Hodgkinson	Sally Hodgkinson	Sally Hodgkinson		
Independent Director	TBA	TBA			

TROG Scientific Committee

Position	Appointed
Scientific Chair	Gillian Duchesne
TROG President	Bryan Burmeister
Trial Development Portfolio	Sandro Porceddu
Publications Portfolio	June Corry
Accrual Portfolio	Sidney Davis
Grants Portfolio	Andrew Macann / Gillian Duchesne
Statistician	Richard Fisher
Medical Oncologist	Danny Rischin
Radiation Therapist	Kathryn Neilson
Medical Physicist	Tomas Kron
Diagnostic Imaging Specialist	Ming Wang
Research Coordination	Kathy Hall
Quality Assurance	Deidre Cornes
Consumer Representative	Sally Hodgkinson
TCOO Scientific Advisor	TBA

TROG Publications Committee

Position	Appointed
Chair Person	June Corry
Scientific Chair	Gillian Duchesne
Statistician	Richard Fisher
Radiation Oncologist	David Christie
Secretary	Kathy Hall

GRANT APPLICATION ASSISTANCE PACKAGE (GAAP)

In December 2008 the TROG Central Operations Office (TCOO) initiated the Grant Application Assistance Package (GAAP) to assist trials in development with the completion and submission of NHMRC Project Grant applications and other applications associated with the Priority Driven Collaborative Cancer Research Scheme (PDCCRS) such as Cancer Australia and Cancer Council Australia.

The aim of developing the GAAP was to improve the ongoing scientific processes of TROG, with the main objective keeping with the Strategic Plan – 10 new competitive grants by 2010. By implementing the GAAP we are hoping to improve the success of TROG trials applying for funding, assist new Investigators, and hence, open trials to accrual earlier than they may have been able to previously.

The process began with an Expression of Interest (EOI) which was sent out to all Trial Chairpersons of trials under development. There were a total of five EOIs submitted; however only two trials were able to be supported due to the limited amount of resources at the TCOO. One FTE TCOO staff member was allocated to each trial. The following criteria were used to select two trials: scientific merit; TROG led trial; investigator grant experience; disease site identified as gap in TROG portfolio; trial development status and agreement to use TROG as the Administering Institution. The two trials selected to receive the GAAP were:

- 1) TROG 08.06 STARS Breast trial – Peter Graham
- 2) TROG 09.01 PROArCT (Rectal) trial – Sam Ngan

The GAAP was then distributed to both Trial Chairs, TCOO staff entered all grant application information into the informed filler, requested & collated required information from Chief Investigators (CIs), checked all applications for consistency & adherence to guidelines, and organised scientific expert review by the TSC

Grant Portfolio representatives (Gill Duchesne & Andrew Macann).

In order to gauge the level of assistance, TCOO sent out a quality survey to the two Trial Chairs that received the GAAP, and to the TSC Grant Portfolio representatives. The overall response was very positive, with the recommendation to continue the GAAP. Comments and suggestions were also taken on board and will be used to improve the application process in 2010.

This year TROG is offering the GAAP again to those Trial Chairs with trials in development; however the process began earlier with EOIs requested in August 2009. .

Overall, the GAAP has improved the application process for Trial Chairs and we anticipate that it will also improve the outcomes of the applications that are submitted.

TROG as NHMRC Administering Institution:

TROG is now an NHMRC Administering Institution which brings additional responsibilities and commitment of TROG staff, both at the TCOO and in the broader TROG community, in terms of application review and submission. In addition to GAAP, TROG also offers to all those trials that are submitting their grant application through TROG, full or partial review of all documents (depending on when the final draft application is provided to TROG). This review process involves TCOO staff and the Grant Portfolio members of the TSC, with the option of sourcing a review from external reviewers in the broader TROG community. This process needs to be formalised and the reviewers will need to be sourced.

Prepared by: Erin Nolan, Olga Kovacev, Michelle Hall

TROG Policy and Procedures Review

TROG's very first policy statement was written in 1990 leading to the formation of TROG's Policy and Procedure Manual, formally known as the "Red Book". A total of twelve policy statements were developed over the coming years, all of which set the required Good Clinical Practice standards for the development and conduct of TROG Clinical trials.

The expansion, development and reorganisation of TROG over the past 20 years has necessitated the review and update of all TROG policy statements and in some cases the development of new policy statements. During 2008 TROG's policy statements were reviewed and updated and, where necessary, new policy statements such as the TROG Glossary were developed. All new and updated policy statements approved by the TROG Scientific Committee (TSC) have since been implemented and are available on the TROG Website.

A new identification system has superseded the old numbering system of the Redbook i.e. TTP (TROG Policy and Procedures) E or C (External or Corporate) and then the policy number. See detailed list provided.

Further to the initial review process, 2009 will now see the commencement of an annual review process for TROG Policy Statements and TROG templates. This annual review process will ensure that policy statements and accompanying templates will continue to meet current regulatory requirements and reflect the constant evolution and improvement of TROG's processes. TPP E3 *Guidelines for the Development and Conduct of Clinical Trials* and all related resources, such as the TROG Protocol and PIC templates, are currently under review.

On a final note, the much used term "Red Book" which has been part of TROG's vocabulary for the past 20 years will be phased out due to hard copies of the policies being no longer distributed to TROG members. Alternatively, TROG members are encouraged to view TROG's policies on-line in order to ensure that the most current version is being utilised. Available at: <http://www.trog.com.au/Default.aspx?tabid=114>

Please note that TROG's Statistical Guidelines have recently undergone a major update with thanks to Associate Professor Richard Fisher.

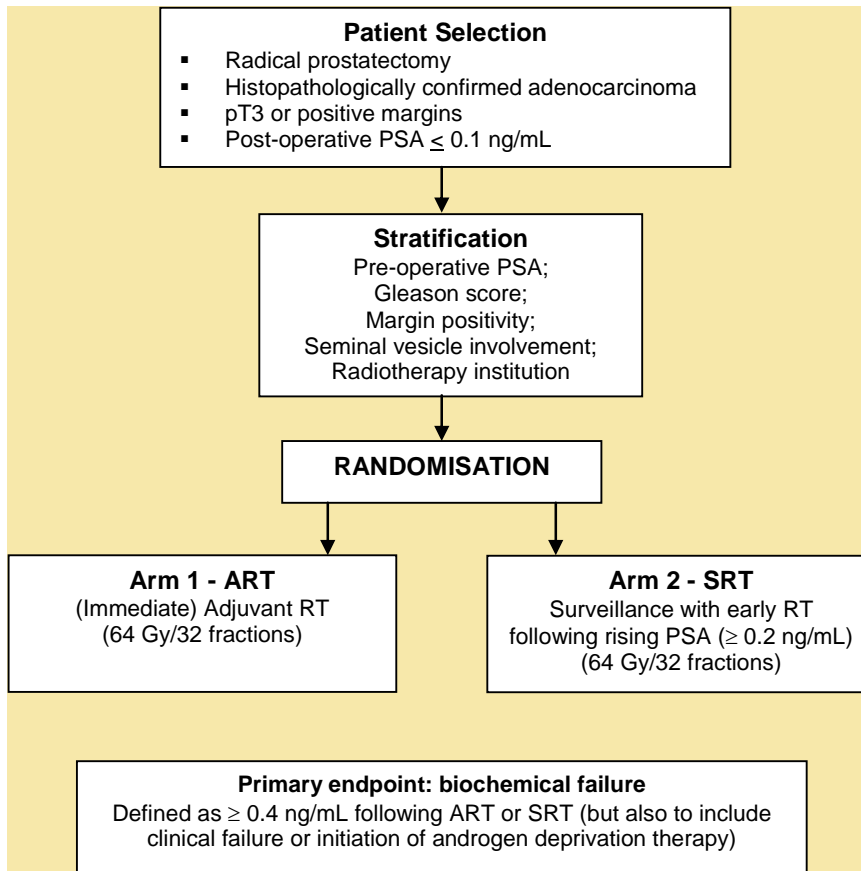
TROG Policy Index

- TPP E1** Glossary
- TPP E2** Ethical Principles
- TPP E3** Guidelines for the Development and Conduct of Clinical Trials
 - TPP E3 Resources**
 1. TROG New Proposal Synopsis Form
 2. TROG Feasibility Survey
 3. TROG Trial Development Resources
 - 3.1. Group Specific Appendix
 4. TROG Protocol template
 5. TROG Participant Information Sheet and Consent Form (PIC) template
 6. TROG Case Report Form template (*under development*)
 7. TROG Progress Report (Trials in development)
 8. TROG Progress Report (Trials in follow-up)
 9. TROG Progress Report (Open trials)
- TPP E4** Adverse Event Definitions, Scoring and Reporting
 - TPP E4 Resources**
 1. TROG Serious Adverse Event Report Form (S1)
 2. TROG Serious Adverse Event Report Form (S2)
- TPP E5** Statistical Guidelines
- TPP E6** Quality Assurance Guidelines
- TPP E7** Assessing Health Related QOL in Cancer Patients
- TPP E8** Responsibilities of Trial Management Committees
- TPP E9** Data Monitoring Committee Guidelines
- TPP E10** Authorship, Publication and Spokesmanship Guidelines

Trial in Profile

~ TROG 08.03 RAVES ~

RAVES: Radiotherapy—Adjuvant versus Early Salvage



The RAVES prostate cancer trial is gaining momentum following its launch at the March 2009 TROG Annual Scientific Meeting. This trial aims to determine whether surveillance with early salvage radiotherapy results in equivalent biochemical control and improved Quality of Life when compared with adjuvant radiotherapy.

Since the launch, nine sites have been activated and eight patients have been recruited. Active sites include:

- Auckland Hospital (4 patients)
- Calvary Mater Newcastle (1 patient)
- Radiation Oncology Mater Centre (ROMC)
- Peter MacCallum Cancer Centre (2 patients)
- Royal North Shore Hospital
- Royal Perth Hospital
- St George Hospital
- Sir Charles Gairdner Hospital (1 patient)
- Toowoomba Cancer Research Centre

This number is expected to increase significantly as an additional 24 sites throughout Australia and New Zealand come on board during the next few months. Thanks you to everyone who has been working on the Benchmarking Exercise, Ethics applications and contracts.

It is fantastic to be moving from fundraising and trial development to randomising patients. Now that the trial is underway, we're looking at practical solutions to the multi-disciplinary challenges of this trial:

- As anticipated, the support of Urologists is critical to the success of RAVES. A brochure and presentation are available for liaising with your local Urology departments. Please contact the RAVES Trial Centre if you need these materials. Thank you to all who have been working to build RAVES' profile with Urologists.
- Several sites have started screening patients from their local pathology databases prior to the patient seeing his Urologist. The Trial Coordinator then places RAVES information in the patient file, along with a referral form in case the Urologist decides the patient could be suitable for RAVES. This system has been

(Continued on page 12)

Trial in Profile ~ TROG 08.03 RAVES ~

(Continued from page 11)

working well at initial sites.

Two local initiatives have provided additional resources:

- The Prostate Cancer Foundation of Australia generously funded an Informed Consent Workshop for clinicians in New South Wales, held on 8 April 2009. Thanks to Mel Grand, TROG Project Officer, for organising this event, which served as a pilot project for future TROG initiatives. In particular, this workshop provided useful discussion about explaining trials to patients and clarifying RAVES protocol requirements.
- Thank you to the Radiation Oncologists at Christchurch Hospital for securing funding for a RAVES Technical Workshop for New Zealand investigators. At least one Radiation Oncologist and one Radiation Therapist from each site in New Zealand attended a half-day meeting in Christchurch to discuss the technical requirements of the trial and the common challenges sites had in completing the Benchmarking Exercise.

If you are interested in participating in RAVES, please contact the Trial Centre.

RAVES Co-Chairs:

Dr Maria Pearse: mariap@adhb.govt.nz

Dr Andrew Kneebone: AKneebone@nscchahs.health.nsw.gov.au

RAVES Trial Coordinator: Carol Fraser-Browne: carolfb@adhb.govt.nz

Consumer Advocacy

In February this year Cancer Australia launched new consumer resources that are now available on the Cancer Australia website

www.canceraustralia.gov.au

Two of the resources - Cancer support groups: A guide to setting up peer facilitated supports and Cancer support groups: Skills resource for peer facilitators - focus on establishing and maintaining support groups for people living with cancer.

The other two resources - “Consumer participation guide” and “Consumer training and mentoring guide” will help people build their skills to provide insight into the health system and national cancer policy and programs, as well as increase their ability to mentor other consumers to participate at a national level.

NHMRC Project Grant and Cancer Council and Cancer Australia Funding Outcomes 2009

Congratulations to the following TROG trials in attaining funding through a NHMRC Project Grant, Cancer Council or Cancer Australia.

NHMRC Grants

NHMRC ID	Investigators	Trial	Funding Amount	Comment
570894	Prof Michael Quinn Prof Michael Friedlander Dr Mary Gainford Dr Linda Mileskin Dr Pearly Khaw Dr Carien Creutzberg	PORTEC-3	\$443,125 over 3 years	ANZGOG lead group for ANZ University of Sydney
569293	Dr Andrew Kneebone Prof Gillian Duchesne A/Pr Mark Frydenberg A/Pr Richard Fisher Dr Scott Williams Dr Lizbeth Kenny	RAVES: A phase III trial comparing adjuvant versus salvage radiotherapy for high risk patients post radical prostatectomy	\$775,000 over 5 years	University of Newcastle

Cancer Council and Cancer Australia Grants

Funding Body	Investigator	Title	Amount
Cancer Council and Cancer Australia	Trevor Leong	TROG 08.08 - TOP-GEAR	\$596,625 over 3 years
Cancer Australia	David Ball	CHISEL Lung	\$260,000 over 3 years
Cancer Council and Cancer Australia	Michael Poulsen	MP3 – In Development	\$185,000 over 3 years
Cancer Australia	Jarad Martin	TROG 08.01 - PROFIT	\$443,500 over 3 years

Trials Recently Open for Accrual:

Trial Title	Trial Chair	Activation Date	Lead Group (s)	Collaborating Group(s)
TROG 08.01 - A randomized trial of a shorter radiation fractionation schedule for the treatment of localized prostate cancer (PROFIT: Prostate Fractionated Irradiation Trial)	Jarad Martin	5 th August 2008	OCOG	TROG
TROG 08.02 – 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 (NCIC CTG)	Claire Philip Mike Fay	23 rd July 2008	NCIC CTG	TROG
TROG 08.03 - RAVES – Radiotherapy Adjuvant Versus Early Salvage. A phase III multi-centre randomized trial comparing adjuvant radiotherapy (RT) with early salvage RT in patients with positive margins or extraprostatic disease following radical prostatectomy.	Maria Pearse (NZ), Andrew Kneebone (AUS)	25 th August 2008	TROG	USANZ
TROG 08.04 – A randomized Phase III Trial Comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in High Risk and Advanced Stage Endometrial Carcinoma. PORTEC-3	Pearly Khaw	6 th November 2008	Int'l: DutchCooperative Oncology Group, UK NCRI AUS: ANZGOG	NCIC CTG, MaNGO (Italy) and TROG
TROG 08.05 – Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma – a randomized phase III trial	Gerald Fogarty	6 th November 2008	ANZMTG	TROG and SNOG
TROG 08.07 – The DECO study: A randomized phase II trial of weekly Docetaxel (Taxotere®) chemoradiotherapy +/- cetuximab (Erbix®) in the treatment of localized respectable Cancer of the Oesophagus.	Michael Michael	24 th November 2008	AGITG	TROG

Trials Approved for Activation

Trial Title	Trial Chair	Activation Date	Lead Group (s)	Collaborating Group(s)
TROG 08.06 – 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 (STARS)	Peter Graham	19 th November 2008	TROG	N/A
TROG 08.08 – TOPGEAR: A randomized phase III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer.	Trevor Leong	24 th November 2008	AGITG	TROG
TROG 08.09 - A randomized phase III trial of post operative radiation therapy following excision of desmoplastic melanoma of the head and neck (RTN2)	Bryan Burmeister	17 th December 2008	TROG	ANZMTG
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)	Sam Ngan	15 th January 2009	TROG	AGITG
TROG 09.02 – A Randomised phase III trial of hypofractionated stereotactic radiotherapy versus conventional chemoradiation for inoperable stage I non-small cell lung cancer (NSCLC)	David Ball	16 th July 2009	TROG	N/A
TROG 09.03 – Phase II Efficacy Study of Synchronous Weekly Carboplatin and Radiation in Merkel Cell Carcinoma of the Skin	Michael Poulsen	13 th August 2009	TROG	N/A

Congratulations to everyone involved in the development of these trials. Keep up the good work throughout the accrual phase of your trials!

If you would like any further information about these or any TROG trials, please visit our website www.trog.com.au where you will find updated protocols, contact details and trial related information.

2009 TROG Trials

Approved for development

The following trials are currently in development with many in the final stages of that process. Updates in the changing status will be provided.

SUPREMO – Selective Use of Postoperative Radiotherapy after Mastectomy (BIG 2-04). (Boon Chua)

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

RAPID - Randomised trial of Accelerated Partial Breast Irradiation. (Boon Chua)

Multi-Centre Feasibility study of Online Adaptive Radiotherapy for Muscle Invasive Bladder Cancer. (Farshad Foroudi)

The effect of “Mepilex Lite” dressings on the management of radiation-induced skin reactions in patients with malignancies in Breast, Head & Neck. (Patricia Herst)

2009 TROG Trials

Approved on Scientific Merit

If you would like further information please contact Jan Kilmurray E-Mail jan.kilmurray@trog.com.au or

Phone +61 2 49 211 647

Randomised Phase III high dose palliative radiotherapy versus concurrent chemotherapy & high dose palliative radiotherapy in good performance status patient with locally advanced or small volume metastatic non-small cell lung cancer (NSCLC) - not suitable for radical chemo/radiotherapy. (Margot Lehman)

Randomised Phase II weekly Cetuximab + RT and weekly Cisplatin + RT in locoregionally advanced HPV-associated Oropharyngeal Cancer. (Danny Rischin)

A prospective study of the relationship between the radiotherapy planning target volume and sites of relapse in patients with Glioblastoma Multiforme treated with the Stupp protocol. (Gail Ryan)

A randomised Phase III study of the effects of radiotherapy for older women with endocrine-responsive stage I breast cancer. (Boon Chua)

Optimal radiation fractionation in the treatment of malignant spinal cord compression – a prognosis and performance status adapted approach. (Sid Baxi)

2009 TROG Publications Update

Congratulations to all of these authors and their respective research teams for all their hard work. If your publication has been left off this list, please let us know and we will update our files immediately. Keep up the good work!

Denham JW, Steigler A, Wilcox C, Lamb D, Joseph D, Atkinson C, Matthews J, Tai K, Spry N, Christie D, Gleeson P, Greer PB, D'Este C, on behalf of the Trans-Tasman Radiation Oncology Group 96.01 Trial lists. **Time to biochemical failure and prostate-specific antigen doubling time as surrogates for prostate cancer-specific mortality: evidence from the TROG 96.01 randomised controlled trial.** The Lancet Oncology, 2008, 9, 11, 1058 – 1068

Haworth A, Kearvell R, Greer PB, Hooton B, Denham JW, Lamb D, Duchesne G, Murray J, Joseph D. **Assuring high quality treatment delivery in clinical trials – Results from the Trans-Tasman Radiation Oncology Group (TROG) study 03.04 “RADAR” set-up accuracy study.** Radiotherapy and Oncology 90 (2009) 299-306.

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2010 Australia and Asia Pacific Clinical Oncology Research Development (ACORD) Workshop

On 7 December 2009, applications open for the 2010 Australia and Asia Pacific Clinical Oncology Research Development (ACORD) Workshop, running 12-18 September 2010, on Australia's Sunshine Coast. Presented by the Medical Oncology Group of Australia, this unique regional Workshop maintains a substantial position in oncology education due to its international focus, provision of hands-on collaboration and guidance by a world renowned faculty. Participants are selected based on a competitive process, including submission of a clinical trial protocol to be developed over the course of the Workshop. At this time, candidates with training in medical, radiation, surgical and psycho-oncology, palliative care, pharmacology, oncology research and allied health disciplines are encouraged to begin preparations for the ACORD application process by considering potential protocols and seeking supervisor support. Fellowships are available, which include travel expenses, accommodation and meals. Applications will be accepted online at www.acordworkshop.org.au until 26 February 2010.

Congratulations it's a

Congratulations to the following ladies on their new addition.

Mel Grand, TROG NSW Project Officer and her husband Mark, on their baby boy, Luke Grand born on 4/4/09; baby was 7lb or 3.1kgs

Martin Ebert, Medical Physicist, Sir Charles Gairdner Hospital, and his partner, on their daughter Beth Violet Ebert who was born on 20/10/08 weighing 9lb 7 oz.

Claire Phillips, TROG 08.02 Trial Chair, and her partner on their arrival of Matilda Claire Ross born on 5/8/08, weighing 2.61kg (5lb 12oz for those who like the 'old' way). Small but healthy just as were her two siblings were; Lucy 3 and James 22 months.

Tanya Holt, TROG 07.02 Trial Chair, and her husband David, on their arrival of Lila Rose Mudge born on the 27/8/08; Lila weighed 3.1kg. A sister for Ruby.



TROG New Staff

TROG QA Research Assistant



Claudia Koller,
TROG QA Research Assistant
TCOO

Hello,
I joined the TROG Central Operations Office at the Calvary Mater Newcastle in June as a QA Research Assistant. Prior to that I did research for many years at Newcastle University on the effects of pollutants

on vegetation. So, although I have a strong background in research, I have a limited knowledge of clinical trials, human disease and cancer treatment.

My introduction to the TROG office and more specifically to QA and RT has been very interesting, and what I have learned has been fascinating. I am very much enjoying these new aspects of my job and also the company of the lovely team in the TROG office.

To date I have done some work on eligibility checks and case reports which has been very educational. I am not up to speed yet, but look

forward to working with you all and eventually being able to provide more and more assistance with any queries you might have on trial-specific quality assurance programs, submission of eligibility and treatment information, as well as case and progress reports.

TROG Information Officer



Louise MacGregor
TROG Information Officer, TCOO

Claudia Koller
Hi Everyone

My name is Louise MacGregor, I joined the TROG team in November 2008 at the Calvary Mater Hospital Newcastle. I have been working in the TROG Central Operations Office as the Information Officer for the newly setup Central Quality

Management System or CQMS database. In this role I will continue to update and produce reports for all areas of the TROG clinical trials group.

(Continued on page 19)

TROG New Staff

(Continued on page 18)

Previous to joining TROG I was working for the Hunter New England Area Health Service located at John Hunter Hospital in the Respiratory Unit as a Co-ordinator for the Home Oxygen Service and for the Upper and Lower Hunter Clusters.

Clinical Trials is a totally new area for me and I welcome the challenge and look forward to gaining new knowledge and experience in this area of healthcare. The TROG team have been very welcoming and I look forward to a bright future with TROG.

Lou

TROG Accountant



Kim Reeves

TROG Accountant, TCOO

In July 2008 I joined TROG as internal accountant. My duties include preparing financial reports for funding bodies and the TROG Board preparing budgets for meetings and trials, invoicing granting bodies and paying supplier invoices. Other duties include preparing the

quarterly BAS return and generally processing all transactions related to the Annual Meeting, Trials Review Meetings and daily operations.

During my time with TROG I've worked as part of the team who created the "Trial budget template". This is now available for use by anyone wishing to submit a project grant application in the future. I'm happy to modify this template if required for each trial chair submitting a project grant application.

Recently my Newcastle colleagues and I have prepared the finance section of the Standard Operating Procedures manual. This will formally document the internal controls over finances & procurement. It also formally documents the delegations within TROG for approving expenditure.

Over the past six months I have worked with the Managing Director and the TROG Board

preparing successful applications for charitable collection licenses from each Australian State and New Zealand. TROG is now in the position to make an Australian and New Zealand fundraising appeal to the general public.

For further information regarding finance please do not hesitate to contact me.

Kim Reeves

What's new @

www.trog.com.au

TROG Annual Meeting 2009

The 2009 Annual Meeting marked TROG's 20th Anniversary. As those who attended the meeting all know, the presentation sessions were jam packed with interesting and educational information on TROG trials and related topics from the main scientific meeting, and the very successful Technical and Clinical Trial Management Workshops. Presentations from these meetings are now available on the TROG website in the members section under "Minutes and Presentations".

TROG TRM Presentations 2009

Presentations from the Trials Review Meeting are now available on the TROG website in the members section under "Minutes and Presentations".

TROG 08.02 GBM study Media Release

On May 13 2009, Dr Rosie Harrup, Principal Investigator from the Royal Hobart Hospital was interviewed in regards to the TROG 08.02 GBM in the elderly trial. This is great news for Claire Banks, Mike Fay and the whole team who are working on this trial. The media release can be found in the What's New? Section of the TROG website.

Please visit www.trog.com.au for a preview of what is to come and to note the dates into your diaries!

TROG Member Contact Details:

Have you recently changed your email address or contact details? If so please visit the TROG website, login to the members section and update your details!

TROG Central Operations Office

The following is a guide to the staff available to assist you with enquires regarding TROG membership and services. We look forward to talking to you!

RESEARCH STAFF

Research Manager:

Kathy Hall

Kathy.Hall@trog.com.au

Ph: +61 2 4921 1466

The key function areas that Kathy has overall responsibility for include: Trial Management and Conduct; TROG committees co-ordination and participation, TROG meeting organisation; communication with TROG members and others; any other research related issues that may arise.

Research Assistant:

Erin Nolan

Erin.Nolan@trog.com.au

Ph: +61 2 4921 1685

Please contact Erin with any questions or suggestions relating to the TROG website or clinical trial registration. Erin is also responsible for trial directory updates, progress reports and a number of other specific projects.

Policy, Procedures & Special Project Officer:

Michelle Hall

Michelle.Hall@trog.com.au

Ph: +61 2 4921 1648 Wed/Thurs/Friday

Michelle has responsibility for updating the TROG Policy and Procedures Manual as well as projects that provide resources to better assist and improve researchers capacity to be involved in TROG Clinical Trials.

Policy, Procedures & Special Project Officer:

Olga Kovacev

Olga.Kovacev@trog.com.au

Ph: +61 2 4921 1648 Tues/Wed

Olga has responsibility for updating the TROG Policy and Procedures Manual as well as projects that provide resources to better assist and improve researchers capacity to be involved in TROG Clinical Trials.

Trial Development Coordinator:

Jan Kilmurray

Jan.Kilmurray@trog.com.au

Ph: +61 2 4921 1647

Jan's role will be to develop processes which facilitate and streamline the trials development/activation process. Once your trial receives the "green light" at the ASM, Jan will work with you and your team to ensure the steps which are involved in trials development are met in a timely manner, and resulting in the earliest possible activation of that trial

Information Officer

Lou MacGregor

Louise.MacGregor@trog.com.au

Ph: + 61 2 4921 1764

Lou has the responsibility for updating the CQMS database at the TROG COO and can be contacted in regards to queries relating to specific trial contracts.

QUALITY ASSURANCE STAFF

Quality Assurance Manager:

Deidre Cornes

Deidre.Cornes@trog.com.au

Ph: +61 2 4921 1453

Please contact Deidre for any enquiries regarding quality assurance, particularly to discuss the design and development of procedures and resources for new trials. Deidre is responsible for policy development and strategic planning in relation to QA and facilitating the ongoing development of central QA infrastructure for TROG. This includes management of the QA projects relating to the NHRMC Enabling Grant. Deidre leads the central QA team and is also the chair of the Quality Assurance Development Group (QADG) and the QA representative on the TROG Scientific Committee (TSC).

Assistant Quality Assurance Manager:

Melissa Crain

Melissa.Crain@trog.com.au

Ph: + 61 2 4921 1546

Please contact Melissa for any enquiries regarding quality assurance, particularly to discuss procedures and resources for new trials. Melissa is facilitating the implementation of CQMS in the TROG research program and is also involved in organising the Technical Research Workshop.

Quality Assurance Radiation Oncologist:

Anne Capp

Anne.Capp@mater.health.nsw.gov.au

Ph: + 61 2 4921 1881

Anne is an advisor to the QA Office, provides assistance in protocol development, QA program design, and conducts central review of radiotherapy trial treatment.

Quality Assurance Research Assistant:

Claudia Koller

Claudia.Koller@trog.com.au

Ph: +61 2 4921 1548

Claudia is responsible for the administration of QA program in several trials. Please contact Claudia for any queries regarding quality assurance.

(Continued on page 21)

TROG Central Operations Office

The following is a guide to the staff available to assist you with enquires regarding TROG membership and services. We look forward to talking to you!

(Continued from page 20)

BUSINESS SERVICES STAFF

Chief Executive Officer:

Rowena Amin

Rowena.Amin@trog.com.au

Ph: +61 2 4921 1719

Rowena manages the day to day operations of TROG, its people and resources with responsibility for developing and implementing strategic, operational and business plans approved by the TROG Board. Rowena is responsible for ensuring the company's compliance with legal and regulatory obligations.

Administration Assistant:

Alyson Segrott

Alyson.Segrott@trog.com.au

Ph: +61 2 4921 1684

Please contact Alyson in relation to organisation of events and registrations for Annual Meeting and TRM meeting, teleconferences and administration assistance.

Accountant:

Kim Reeves

Kim.Reeves@trog.com.au

Ph: +61 2 4921 1549

Please contact Kim in relation to all membership, financial and budget queries or assistance in preparing a budget for your trial.

PROJECT OFFICERS

NZ Project Officers:

Kathryn Neilson and Janfrey Doak

trognz@trog.com.au

Ph: +64 3 378 6291

Kathryn and JD are responsible for investigating TROG's role in the New Zealand (NZ) research environment. Please contact us with any queries specific to NZ research activities.

TROG Central Operations Office
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Building 7, Level 5
Locked Bag 7
HRMC NSW 2310

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Fax: +61 2 4921 1465



TROG would like to acknowledge the support of our sponsors in 2009

**If you would like to sponsor TROG
please contact**

Rowena Amin
CEO
Phone: +61 2 4921 1719
Email: Rowena.Amin@trog.com.au

UPCOMING EVENTS

2009 - 2010

18— 20 October

COSA Scientific Meeting
Gold Coast, QLD

21— 24 October

RANZCR/FRO/AIR/ACPSEM
Annual Scientific Meeting

Brisbane, QLD

www.ranzcr.edu.au

1— 5 November

ASTRO Annual Meeting
Chicago, USA

12 November

Data Managers & ALLG
Investigators Meeting
Brisbane, QLD

24— 27 March 2010

TROG Annual Scientific
Meeting,
Queenstown, New Zealand

2009 Corporate Partners

