



Trial Portfolio Update

Trans Tasman Radiation Oncology Group (TROC)

Annual Scientific Meeting

12-15 March 2024

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ABOUT TROG CANCER RESEARCH

TROG Cancer Research is dedicated to improving the way radiation therapy is delivered to cancer patients with ongoing scientific research, clinical trials, and cutting-edge technology. TROG focuses on radiation medicine technology for all types of cancers that can be treated with radiation therapy which, like chemotherapy and surgery, is widely used for cancer treatment. In fact, one-in-two patients diagnosed with cancer could benefit from radiation therapy.

TROG conducts world-class research involving an international network of >1,500 health professionals and >100 sites globally. Our trial portfolio encompasses research into all radiation-treatable tumour sites. Research outcomes have led to changed clinical practice with new and improved radiation medicine techniques that can enhance outcomes for cancer patients. Over three decades, TROG has facilitated >115 clinical trials that contributed to improving outcomes and quality of life for >15,350 cancer patients globally. Over that time, the prognosis of cancer patients has improved from a cancer survival rate of less than 50 percent in the 1980s to survival rates for some cancers being as high as 90 percent.

The TROG working parties are vital in shaping the research priorities of TROG by identifying gaps in research, developing new research concepts, reviewing the scientific merit of research proposals, and providing expert advice. Our tumour stream Working Parties are comprised of members from many craft groups and disciplines, with a focus on Breast; Central Nervous System (CNS); Genitourinary (GU); Head, Neck & Skin (HNS); and Lung cancers.

The working parties are complimented by several committees and special interest groups, who guide the TROG Scientific Committee (TSC),

- Secondary Data Analysis Committee (SDAC): Oversees the development of guidelines and procedures for secondary analysis of TROG clinical trials data.
- New Technologies and Techniques Committee (NTTC): Ensures that up-to-date guidelines and procedures are available for implementing new and complex technologies in TROG clinical trials.
- Independent Data and Safety Monitoring Committee (IDSMC): Monitors progress of all TROG phase III and late phase II clinical trials in relation to quality processes and procedures and ensures the safety of patients and that, wherever possible, each trial meets its primary objectives.
- TROG Publications Committee (TPC): Provides peer review in the form of independent scientific review of material and timelines, helping to maintain high standards and encouraging accurate, thorough and credible research reporting of TROG clinical trials.
- TROG Special Interest Groups (SIG): Composed of TROG members who have an interest in clinical trial research involving specific technology or techniques in radiation oncology, current groups include Particle Therapy SIG, MR in Radiation Therapy SIG and Interventional Oncology SIG.

The participation of our members via these working parties, SIG's and committees brings incredible expertise, new ideas, partnerships and collaborations in support of advancing radiation medicine research to improve outcomes for those affected by cancer.

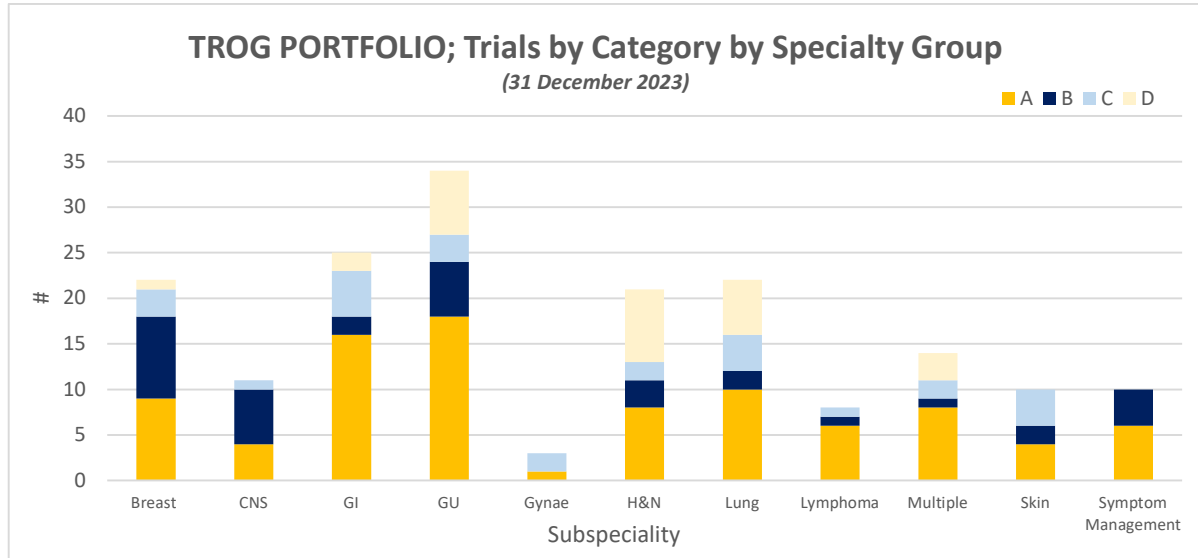
If you would like to join a TROG committee, go to www.surveymonkey.com/r/TROG_Join_a_Committee to express your interest.

TRIALS BY CATEGORY AND SUBSPECIALTY GROUP

Projects within TROG are split into 4 categories;

- **Category A:** An investigator-initiated new proposal which will be carried out under the auspices of TROG.
- **Category B:** An existing trial or new trial concept lead by an international trials organisation and where TROG would fulfil the role of the ANZ sponsor. The trial is carried out under the joint auspices of TROG and the group concerned.
- **Category C:** A trial initiated and sponsored by other trials organisation and is for collaboration or endorsement with TROG.
- **Category D:** An investigator-initiated project that involves data mining or secondary analysis.

Figure 1: Trials by Category by Specialty Group



Status definitions;

- **New Proposal;** Review period of a proposal, prior to being accepted by the TROG Scientific Committee for development.
- **Development;** Period between when the TSC accepts proposal for development and Start-up activities can begin.
 - Includes funding application, protocol development, development of RTQA program etc.
- **Start Up;** Period when start-up activities are undertaken until activation of the study (with first site opened for accrual)
 - Includes applying for ethics and regulatory approvals, development of patient information sheets, study manuals & essential documents, site selection and contracts, RTQA credentialing activities undertaken, selection of third party vendors, site training etc.
- **Open;** Period when there is participant activity (i.e. date first trial site is activated, the accrual period, the follow-up period and end of the date of last patient/last visit).
- **Closed;** When all participant activity has completed until study has been closed out and archived.
 - Includes data cleaning, main/final analysis, closing out all sites, ethics and regulatory, final report and archiving.
- **Completed;** When all close out activities have been completed, the trial results published, and all documents archived, the trial is then considered completed.
- **Data Requests;** Project requests submitted to TROG for access to trial data for data mining or secondary analysis projects, from people outside of the original trial team.

Table 1: Trials by Subspecialty and status

	Breast	CNS	GI	GU	Gynae	H&N	Lung	Lymphoma	Multiple	Skin	Symptom Management	TOTALS
New Proposal	0	1	0	0	0	0	1	0	0	1	0	3
Development	0	2	1	4	0	0	2	0	3	0	0	12
Start Up	0	0	1	0	0	0	0	0	0	0	0	1
Open	5	3	4	6	2	2	2	0	3	2	0	29
Closed	7	0	2	5	0	3	3	4	1	2	1	28
Completed	1	4	12	7	1	5	2	3	2	4	8	49
Data Requests	0	0	2	7	0	8	6	0	2	0	0	25
TOTAL	13	10	22	29	3	18	16	7	11	9	9	147

*As of 31 Dec 2023

BREAST WORKING PARTY (BWP) & TRIALS

BWP Members

Farshad Foroudi (Chair)
Tomas Kron (Deputy Chair)
Boon Chua

Chia May Wong
Jenna Dean
Joerg Lehmann

Kylie Jung
Melissa James
Robyn Cheuk

Steven David
Janice Yeh
Vikash Patel

Anelyn Chui
Rebecca Montgomery
Jessica Piotrowski

BWP Portfolio Summary

Identifiers	LEAD ORGANISATION (Local lead)	STUDY ACRONYM	STUDY TITLE	CHAIR (TROG PROPONENT)	CAT	Status	EMAIL	STUDY UPDATE
TROG 12.02	TROG	PET LABRADOR	PET scans for locally advanced breast cancer and diagnostic MRI to determine the extent of operation and radiotherapy	Verity Ahern	A	Open (FU)	Tracy.Pearl-Larson@health.nsw.gov.au	Accrual: 24 11/24 in follow-up Sites: 1 Open Data cleaning is underway with analysis of the primary objective (to be presented at TROG 2024 ASM).
TROG 08.06	TROG	STARS	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.	Peter Graham	A	Open (FU)	SESLLHD-STARSTrial@health.nsw.gov.au	Accrual: 2023 462/2023 in follow-up Sites: 33 Open 1 Closed This study compares the effectiveness of treatment with the drug anastrozole before and during adjuvant radiotherapy to anastrozole therapy delayed until after radiotherapy for women who have had a mastectomy or lumpectomy for breast cancer. Aim to publish cohort details and initial treatment data 2024
TROG 07.01/BIG 3-07	TROG	DCIS	A randomised phase III study of radiation doses and fractionation schedules in non-low risk ductal carcinoma in-situ (DCIS) of the breast	Boon Chua	A	Open (FU)	DCIS@trog.com.au	Accrual: 1608 462/1608 in follow-up Sites: 121 Open 17 Closed Main analysis conclusion - women with non-low risk DCIS treated with breast conserving surgery, the addition of tumour bed boost following conventional or hypofractionated WBI reduced local recurrence rates. There was no difference in local recurrence rates between conventional WBI and hypofractionated WBI.
MRC/BIG 2-04/TROG 11.01	MRC (TROG)	SUPREMO	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	(Boon Chua)	B	Closed	trials@trog.com.au	Follow Up completed 2023. Final data cleaning underway with the aim to lock database in Q2 2024.
TROG 16.02	TROG	Local HER-O	A phase II study of local therapy only (stereotactic radiosurgery and or surgery) for treatment of up to 5 brain metastases from HER2+ breast cancer	Claire Phillips	A	Closed	trials@trog.com.au	Latest publications/presentations; <ul style="list-style-type: none"> Poster Presentation; Local HERO: A Phase II study of local therapy only (stereotactic radiosurgery and / or surgery) for treatment of up to 5 brain metastases from HER2+ breast cancer. (TROG study 16.02) Advanced Breast Cancer Seventh International Consensus Conference 9-11 November 2023, Lisbon, Portugal Phillips C, Pinkham MB, Moore A, Sia J, Jeffree RL, Khasraw M, Kam A, Bressel M, Haworth A. Local hero: A phase II study of local therapy only (stereotactic radiosurgery and / or surgery) for treatment of up to five brain metastases from HER2+ breast cancer. (TROG study 16.02). Breast. 2024 Feb 5;74:103675. doi: 10.1016/j.breast.2024.103675. Epub ahead of print. PMID: 38340685.
TROG 14.04	TROG	HART	Deep Inhalation Breath Hold for reduction of cardiac toxicity in patients with left sided breast cancer undergoing radiotherapy	Tomas Kron	A	Closed / completed	trials@trog.com.au	
OCOG/TROG 10.02	OCOG	RAPID	Randomized trial of accelerated partial breast irradiation	(Boon Chua)	B	Closed / completed	trials@trog.com.au	
TROG 06.02	TROG	-	A Multicentre Feasibility Study of Accelerated Partial Breast Irradiation Using Three-Dimensional Conformal Radiation Therapy for Early Breast Cancer	Boon Chua	A	Closed / completed	trials@trog.com.au	
MA.20/NCIC CTG/ TROG 03.05	CCTG (TROG)	-	A Phase III Study of Regional Radiation Therapy in Early Breast Cancer	(Boon Chua)	B	Closed / completed	trials@trog.com.au	
TROG 04.01	TROG	Cavilon Breast	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.	Peter Graham	A	Closed / completed	trials@trog.com.au	<i>Symptom management study</i>
TROG 89.02	TROG	-	Simultaneous Adjuvant Radiation and CMF Chemotherapy Following Surgery for Breast Cancer	Jim Deham	A	Closed / completed	trials@trog.com.au	

CENTRAL NERVOUS SYSTEM WORKING PARTY (CNSWP) & TRIALS

CNSWP Members

Mark Pinkham (Chair)
Kylie Jung (Deputy Chair)
Alexandre Santos
Andrew Scott

Claire Phillips
Dionee Liefman
Eng-Siew Koh
Frank Saran

Hien Le
John Ryan
John Shakeshaft
Joseph Sia

Senthilkumar Gandhidasan
Shona Edwards
Sagun Parakh
Wee Loon Ong

Peter Gorayski
Peter Kerstens
Rebecca Montgomery
Jessica Piotrowski

CNSWP Portfolio Summary

IDENTIFIERS	LEAD ORGANISATION (LOCAL LEAD)	STUDY ACRONYM	STUDY TITLE	CHAIR (TROG PROPONENT)	CAT	STATUS	EMAIL	STUDY UPDATE
NP 22F	TROG	TAILOR-BEV	Tailored Bevacizumab dose for symptomatic radiation necrosis after stereotactic radiosurgery for brain metastases	Kylie Jung	A	New Proposal	TSC@trog.com.au	Development of study continues. RANZCR grant awarded to gather pilot data at Canberra hospital.
TD 23.02	TROG	-	Multi-fraction preoperative radiosurgery (Pre-SRS) for patients with brain metastases requiring surgery.	Neda Haghighi	A	Development	TSC@trog.com.au	EOI circulated; https://www.surveymonkey.com/r/MultifractionPreoperativeRadiosurgery_NHaghighi Development of study continues
MASC 05.21 / TROG 22.02	MASC	BETTER	Bevacizumab and immune checkpoint inhibitors plus hypofractionated stereotactic radiotherapy for the treatment of symptomatic melanoma brain metastases	Tim Wang	C	Development	hello@masc.org.au	Ethics approval received, and activation of first site pending.
TROG 22.01	PoCoG	RT Prepare Mask	RT Prepare Mask: development and testing of a psycho education intervention for people requiring immobilisation masks during radiotherapy	Georgia Halkett	C	Development	g.halkett@curtin.edu.au	Development of study continues. Application for funding submitted – waiting on outcomes.
TROG 18.06	TROG	FIG	Prospective, multicentre trial evaluating FET-PET in Glioblastoma	Eng-Siew Koh & Andrew Scott	A	Open (Recruiting)	FIG@trog.com.au	<p>Accrual: 175/210 (01 March 2024) Sites: 11/11 - 113 Group 1 63 Group 2</p> <p>Latest publications/presentations;</p> <ul style="list-style-type: none"> Publication; Barry N et al. Delineation and agreement of FET PET biological volumes in glioblastoma: results of the nuclear medicine credentialing program from the prospective, multi-centre trial evaluating FET PET in Glioblastoma (FIG) study-TROG 18.06. Eur J Nucl Med Mol Imaging. 2023 Aug 11. Publication; Koh ES et al. [18F]-fluoroethyl-L-tyrosine (FET) in glioblastoma (FIG) TROG 18.06 study: protocol for a prospective, multicentre PET/CT trial. BMJ Open. 2023 Aug 4;13(8):e071327. Publication; Langen KJ, Galliks N, Lohmann P, Mottaghy FM. Boosting the acceptance of 18F-FET PET for image-guided treatment planning with a multi-centric prospective trial. Eur J Nucl Med Mol Imaging. 2023 Nov;50(13):3817-3819. Poster Presentation; Preliminary findings from the MRI quality assurance programme for the prospective multi-site Australian FIG (FET-PET in Glioblastoma) TROG 18.06 study EANO, September 21-24, 2023 Rotterdam, Netherlands Poster Presentation; Evaluating inter-observer and intra-observer variability in radiotherapy target volume delineation: credentialing programme results from the FET-PET in Glioblastoma (FIG) trial. RANZCR ASM, 19-21 October 2023, Brisbane, Australia Poster Presentation; A prospective, multi-centre trial of FET-PET in Glioblastoma (FIG) patients (TROG 18.06): trial in progress. COGNO, 8-10 October 2023, Sydney, Australia Poster Presentation; Learnings and Opportunities from the multi-centre prospective FET-PET in Glioblastoma (FIG) TROG 18.06 study SIGA Workshop, Nov 16 2023, Melbourne, Australia
EORTC 1308/ TROG 15.02	EORTC (TROG)	ROAM	Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial (The ROAM trial)	(Neda Haghighi)	B	Open (FU)	ROAM@trog.com.au	<p>TROG Accrual: 15 (157 internationally) 11/42 in follow-up Sites: 6 Open 6 Closed Follow-up continuing and expected to be completed October 2025.</p> <p>Latest publications/presentations;</p> <ul style="list-style-type: none"> Poster Presentation; ROAM (EORTC 1308) trial – impact of prospective trial reviews on protocol adherence ESTRO, 12 May 2023 - 16 May 2023, Vienna, Austria
EORTC 22033-26033/ TROG 06.01	EORTC (TROG)	Low Grade Glioma	Primary chemotherapy with temozolomide vs. radiotherapy in patients with low grade gliomas after stratification for genetic 1p loss: a phase III study	(Claire Phillips)	B	Open (FU)	trials@trog.com.au	<p>TROG Accrual: 42 (478 internationally) 14/42 in follow-up Follow-up continuing and expected to be completed 2030.</p>
UCL / TROG 11.02	UCL (TROG)	SCORAD III	A randomised phase III study of single fraction radiotherapy compared to multifraction radiotherapy in patients with metastatic spinal cord compression	(Tanya Holt)	B	Closed / completed	trials@trog.com.au	<i>Symptom management study</i>
CCTG SC.24/ TROG 17.06	CCTG (TROG)	SC.24	A Phase III Randomized Feasibility Study Comparing Stereotactic Body Radiotherapy (SBRT) Versus Conventional Palliative Radiotherapy (CRT) For Patients with Spinal Metastases	(Shankar Siva and Matthew Foote)	B	Closed / completed	trials@trog.com.au	<i>Symptom management study</i>
CE.6 / TROG 08.02	NCIC CTG (TROG)	GBM in elderly patients	A Randomised Phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the	(Claire Phillips)	B	Closed / completed	trials@trog.com.au	

			treatment of newly diagnosed glioblastoma multiforme in elderly patients.					
MRC LU24 / TROG 07.02	MRC UK (TROG)	QUARTZ	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.	(Tanya Holt)	B	Closed / completed	trials@trog.com.au	<i>Symptom management study</i>
TROG 01.05	TROG	TROG SUPERDEX PILOT	A Pilot Randomised Controlled Trial of Dexamethasone 96mg Versus 16mg Per Day for Malignant Spinal Cord Compression Treated by Radiotherapy	Peter Graham	A	Closed / completed	trials@trog.com.au	<i>Symptom management study</i>
26981/22981 / TROG 01.03	EORTC (TROG)	-	Concomitant and Adjuvant Temozolomide and Radiotherapy for Newly Diagnosed Glioblastoma Multiforme. A Randomized Phase III Study	(Gail Ryan)	B	Closed / completed	trials@trog.com.au	
TROG 98.05	TROG	-	A Randomised Trial of Immediate Versus Delayed Whole Brain Irradiation Following Surgery and/or Radiosurgery for patients with one or two brain metastases.	Andrew Wirth	A	Closed / completed	trials@trog.com.au	

GENITOURINARY WORKING PARTY (GUWP) & TRIALS

GUWP Members

Wee Loon Ong (Chair from May 2023)
 Niluja Thiru (Deputy Chair from May 2023)
 Shankar Siva (Chair until May 2023)
 Stephen Chin (Deputy Chair until May 2023)

Alison Brown
 Charles Lin
 David Pryor
 Farshad Foroudi

Michael Huo
 Muhammad Ali
 Paul Keall
 Robyn Cheuk

Eric Wegener
 Suki Gill
 Shreya Armstrong
 Rebecca Montgomery

Jessica Piotrowski

GUWP Portfolio Summary

Identifiers	LEAD ORGANISATION (Local lead)	STUDY ACRONYM	STUDY TITLE	CHAIR (TROG PROPONENT)	CAT	Status	EMAIL	STUDY UPDATE
TD 23.04	ICR (TROG)	PEARLS	A phase II/III trial of Primary radiotherapy for Androgen sensitive prostate cancer patients with Lymph nodes	(Niluja Thiru)	B	Development	TSC@trog.com.au	EOI: https://www.surveymonkey.com/r/PEARLS_InitialFeasibility Grant funding applied for (MRFF ICTC) – waiting on outcomes.
TD 23.03	TROG	2SHOTS	2-fraction Stereotactic radiotherapy Of The prostate	Wee Loon Ong	A	Development	TSC@trog.com.au	Development of study continues. Application for seed funding applied for – waiting on outcomes.
TD 23.01	TROG	REMASTER	REDuced MArGin STEReotactic body radiotherapy for prostate cancer: A phase III randomised trial	Muhammad Ali	A	Development	TSC@trog.com.au	EOI: https://www.surveymonkey.com/r/REMASTER_InitialFeasibility Development of study continues
TD 21.11	CCTG (TROG)	ASCENDE-SABR	Androgen suppression combined with elective nodal and dose escalation with stereotactic body radiation therapy or brachytherapy	(Wee Loon Ong)	B	Development	TSC@trog.com.au	EOI: https://www.surveymonkey.com/r/TROG_EOI_2111ASCENDESBR Negotiations with CCTG (international lead organisation) continues. Local funding required.
TROG 19.06	TROG	DECREASE	Darolutamide + Consolidation Radiotherapy in Advanced prostate cancer detected by PSMA	Shankar Siva & Arun Azad	A	Open (Recruiting)	DECREASE@trog.com.au	Accrual: 53/87 (01 March 2024) Sites: 17/17 In this study, the study doctors are comparing the treatment outcomes of men taking Darolutamide with or without treating the small metastasis seen on the PSMA PET scan with radiation therapy. They aim to determine that the combination (Darolutamide + RT) is better than Darolutamide alone at controlling PSA levels and further spread of prostate cancer.
TROG 18.01	TROG	NINJA	Novel Integration of New prostate radiation schedules with adjuvant Androgen deprivation	Jarad Martin & Mark Sidhom	A	Open (Recruiting)	NinjaTrial@calvarymater.org.au	Accrual: 314 / 472 (01 March 2024) Sites: 20 / 21 The NINJA trial is comparing two emerging advanced techniques for the treatment of intermediate and high risk prostate cancer. The trial will assess the tolerability and efficacy of each technique. To date, the NINJA trial has been recruiting strongly, is ahead of schedule and has now officially converted to the Phase III trial.
TROG 15.03/ANZUP 16.001	TROG	FASTRACK II	Focal Ablative Stereotactic Radiotherapy for Cancers of the Kidney - a Phase II Clinical Trial	Shankar Siva	A	Open (FU)	FASTRACKII@trog.com.au	Accrual: 71 39/71 in follow-up Sites: 8 Open 3 Closed Latest publications/presentations; <ul style="list-style-type: none"> Oral presentation; TROG 15.03/ANZUP international multicentre phase II trial of Focal Ablative Stereotactic Radiotherapy for Cancers of the Kidney (FASTRACK II) ASTRO 65th Annual Meeting, October 1 - 4, 2023, San Diego, USA Siva S et al; FASTRACK II Investigator Group. Stereotactic ablative body radiotherapy for primary kidney cancer (TROG 15.03 FASTRACK II): a non-randomised phase 2 trial. <i>Lancet Oncol.</i> 2024 Mar;25(3):308-316 Summary of results: 100% of treated kidney cancers showed no signs of recurrence, even in cases with an average tumour size of 4.6cm. Only 10% of participants experienced significant treatment-related side effects, marking a noteworthy milestone in cancer care. The FASTRACK II signifies a turning point in progress for treatment of kidney cancer, presenting a compelling avenue for future advancements in radiation oncology.
ICR-CTSU/2015/10052/TROG 16.03	ICR (TROG)	CORE	A randomised trial of Conventional care versus Radioablation (stereotactic body radiotherapy) for Extracranial oligometastases	(Farshad Foroudi & David Pryor)	B	Open (FU)	CORE@trog.com.au	TROG Accrual: 18 (242 internationally) 2/18 in follow-up TROG sites: 6 Open 9 Closed Latest publications/presentations; <ul style="list-style-type: none"> Presentation: ESTRO 15/05/2023; Khoo, V. OC-0761 CORE - Standard of care +/- stereotactic body radiotherapy for oligometastases - primary results. May 2023. <i>Radiation Therapy and Oncology</i> 182:S627 Summary of results: The CORE trial showed that the addition of SABR to standard of care can help delay progression for patients with cancer relapsing in 3 or less metastatic sites. There was no significant increase in side effects. Accrual to the prostate arm of the study was strong, however, accrual to the breast and lung cohorts proved challenging. These results provide some additional information for patients with oligometastatic breast and lung cancer and justifies evaluating SABR in a larger trial in men with prostate cancer to measure the impact on survival and quality of life. No further analysis to date.
ICR-CTSU/2014/10049/TROG 14.02	ICR (TROG)	RAIDER	A randomised phase II trial of adaptive image guided standard or dose escalated radiotherapy in the treatment of transitional cell carcinoma of the bladder	(Farshad Foroudi)	B	Open (FU)	RAIDER@trog.com.au	TROG Accrual: 31 (345 internationally) 4/31 in follow-up TROG sites: 6 Open 3 Closed Latest publications/presentations; <ul style="list-style-type: none"> Huddart R, Hafeez S, Omar A, Alonzi R, Birtle A, Cheung KC, Choudhury A, Foroudi F, Gribble H, Henry A, Hilman S, Hindson B, Lewis R, Muthukumar D, McLaren DB, McNair H, Nikapota A, Olorunfemi A, Parikh O, Philipps L, Rimmer Y, Syndikus I, Tolentino A, Varughese M, Vassallo-Bonner C, Webster A, Griffin C, Hall E. Acute Toxicity of Hypofractionated and Conventionally Fractionated (Chemo)Radiotherapy Regimens for Bladder Cancer: An Exploratory Analysis from the RAIDER Trial. <i>Clin Oncol (R Coll Radiol).</i> 2023 Sep;35(9):586-597. doi: 10.1016/j.clon.2023.05.002. Epub 2023 May 9. PMID: 37225552.
TROG 08.03	TROG	RAVES	A phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) with early salvage RT in patients with positive margins or	Andrew Kneebone and Maria Pearse	A	Closed	CarolFB@adhb.govt.nz	333 participants recruited to the study over 32 centres. Follow up completed on 31 December 2022. Data cleaning is in progress prior to final analysis. Summary of primary results: TROG08.03 RAVES trial has shown surveillance with early salvage radiotherapy has similar rates of controlling cancer to adjuvant radiotherapy and is associated with fewer urinary problems.

			extra prostatic disease following radical prostatectomy.					After 5 years of follow-up, 86% of patients in the adjuvant radiotherapy arm were free from relapse measured by PSA tests, compared with 87% in the salvage radiotherapy arm. Primary analysis results were published in the <i>Lancet Oncology</i> in September 2020.
TROG 10.01	TROG	BOLART	A multicentre feasibility study of online adaptive image guided radiotherapy for muscle invasive bladder cancer.	Farshad Foroudi	A	Closed / completed	trials@trog.com.au	
OCOG/ TROG 08.01	CCTG (TROG)	PROFIT	A randomised trial of shorter radiation fractionation schedule for the treatment of localised prostate cancer (Prostate Fractionated Irradiation Trial)	(Jarad Martin)	B	Closed / completed	trials@trog.com.au	
TROG 03.04	TROG	RADAR	A Randomised Trial Investigating the Effect on Biochemical (PSA) Control and Survival of Different Durations of Adjuvant Androgen Deprivation in Association With Definitive Radiation Treatment for Localised Carcinoma of the Prostate	Jim Denham	A	Closed / completed	trials@trog.com.au	<p>Latest publications/presentations/Secondary analysis;</p> <ul style="list-style-type: none"> Ong, W. L., Nikitas, J., Joseph, D. J., Steigler, A., Denham, J. W., Millar, J. L., . . . Kishan, A. U. (2023). Patient-Reported Urinary and Bowel Quality of Life Outcomes Following External Beam Radiotherapy with or without High-Dose-Rate Brachytherapy Boost: Post-Hoc Analyses of TROG 03.04 (RADAR).. <i>Int J Radiat Oncol Biol Phys</i>, 117(2S), S93-S94. doi:10.1016/j.ijrobp.2023.06.424 Ong, W. L., Nikitas, J., Joseph, D., Steigler, A., Millar, J., Valle, L., . . . Kishan, A. U. (2023). Long-Term Quality-of-Life Outcomes After Prostate Radiation Therapy With or Without High-Dose-Rate Brachytherapy Boost: Post Hoc Analysis of TROG 03.04 RADAR. <i>International Journal of Radiation Oncology Biology Physics</i>. doi:10.1016/j.ijrobp.2023.09.051
TROG 02.03	TROG	-	Randomised phase III trial of radical chemo/radiotherapy vs radiotherapy alone in the definitive management of localised muscle invasive TCC of the urinary bladder	Kumar Gogna	A	Closed / completed	trials@trog.com.au	

HEAD NECK AND SKIN WORKING PARTY (HNSWP) & TRIALS

HNSWP Members

Charles Lin (Chair)
Lachlan McDowell (Deputy Chair)
Albert Tiong
Andrew Macann
Annette Lim
Anzela Anzela
Brett Hughes

Chris Wratten
Clare Bajraszewski
Daniel Xing
Danny Rischin
Dionee Liefman
Farhannah Aly
Howard Liu

James Sandison
Joe Chang
June Corry
Liz Kenny
Margaret Chua
Rahul Ladwa
Sandro Porceddu

Sweet Ping Ng
Thanuja Thachil
Tsien Fua
Lessandra Yan Shan Chee
Rathan Subramaniam
Eric Wegener
Puma Sundaresan

Bruce Ashford
Rebecca Montgomery
Jessica Piotrowski

HNSWP Portfolio Summary

IDENTIFIERS	LEAD ORGANISATION (LOCAL LEAD)	STUDY ACRONYM	STUDY TITLE	CHAIR (TROG PROPONENT)	CAT	STATUS	EMAIL	STUDY UPDATE
NRG CNRG-HN2316 / TD 24.02	NRG		Randomized Phase III Trial of Immunotherapy with Response-Adapted treatment versus Standard-of-Care Treatment for Resectable Stage III/IV Cutaneous Squamous Cell Carcinoma	(Danny Rischin)	B	Development	TSC@trog.com.au	NRG developing the study and expected to be open in US sites Q3 2024. Will be open to NRG member sites.
EORTC-1219 RCG-HNCG/ TROG 14.03	EORTC (TROG)	EORTC 1219	A blind randomized multicentre study of accelerated fractionated chemo-radiotherapy with or without the hypoxic cell radiosensitizer nimorazole (Nimoral), using a 15-gene signature for hypoxia in the treatment of squamous cell carcinoma of the head and neck.	(Howard Liu)	B	Open	eortc1219@trog.com.au	TROG Accrual: 13 (240 internationally) 6/13 in follow-up TROG sites: 3 Open 3 Closed Long term follow-up continues.
TROG 12.01	TROG	HPV OROPHARYNX	A randomised trial of weekly cetuximab and radiation versus weekly cisplatin and radiation in good prognosis loco regionally advanced HPV-associated oropharyngeal squamous cell carcinoma	Danny Rischin & June Corry	A	Closed	Juliana.Dilulio@petermac.org	Trial follow-up of the 189 participants completed 06 October 2023. Final report issued. Latest publications/presentations/Secondary analysis; <ul style="list-style-type: none"> McDowell L et al. Patient-Reported Symptom Severity, Health-Related Quality of Life, and Emotional Distress Trajectories During and After Radiation Therapy for Human Papillomavirus-Associated Oropharyngeal Cancer: A TROG 12.01 Secondary Analysis. Int J Radiat Oncol Biol Phys. 2023 Mar 1:S0360-3016(23)00199-2.
TROG 07.04	TROG	-	A Phase I/II trial of Cetuximab, Carboplatin and Radiotherapy for patients with locally advanced Head and Neck Squamous Cell Carcinoma.	Danny Rischin & June Corry	A	Closed / completed	trials@trog.com.au	
TROG 07.03	TROG	RadioHUM	Radiotherapy with humidification in head and neck cancer. A randomized phase III trial of the Trans Tasman Radiation Oncology Group	Andrew Macann	A	Closed / completed	trials@trog.com.au	
TROG 05.01	TROG	POST	Post operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck.	Sandro Porceddu	A	Closed / completed	trials@trog.com.au	
TROG 98.02	TROG	-	Randomised Phase II Study of Two Different Strategies for Chemoradiotherapy in Advanced Squamous Cell Carcinoma of the Head and Neck	Danny Rischin	A	Closed / completed	trials@trog.com.au	
TROG 96.07	TROG	-	A Phase II Study of Synchronous Carboplatin/Etoposide And Radiation In Merkel Cell Carcinoma Of The Skin	Michael Poulsen	A	Closed / completed	trials@trog.com.au	
TROG 96.06	TROG	-	A Phase II Study of Radiation Therapy Following Nodal Surgery in Malignant Melanoma	Bryan Burmeister	A	Closed / completed	trials@trog.com.au	
TROG 91.01	TROG	-	A Phase III Prospective Randomised Clinical Trial of Accelerated Radiotherapy (ART) for Stage III and IV Squamous Carcinoma of the Upper Aerodigestive Tract	-Michael Pulsen	A	Closed / completed	trials@trog.com.au	
TROG 12.03	UoN	EAT	Eating As Treatment (EAT): An RCT of psychological training for dieticians to reduce malnutrition and depression in head and neck cancer patients undergoing radiotherapy.	Ben Britton (C Wratten)	C	Closed / completed	trials@trog.com.au	
TROG 09.03	TROG	MP3	A phase II efficacy study of chemo-radiotherapy in PET stage II and III Merkel cell carcinoma of the skin.	Mike Poulsen / Andrew Pullar	A	Closed / completed	trials@trog.com.au	
TROG 02.02	TROG	HeadSTART	Phase III Randomized Trial of Concomitant Radiation, Cisplatin, and Tirapazamine (SR259075) Versus Concomitant Radiation and Cisplatin in Patients With Advanced Head and Neck Cancer	Lester Peters and Danny Rischin	A	Closed / completed	trials@trog.com.au	
TROG 02.01	TROG	-	A Randomised Clinical Trial of Surgery Versus Surgery Plus Adjuvant Radiotherapy for Regional Control in Patients With Completely Resected Nodal Metastatic Melanoma	Bryan Burmeister John Thompson and Michael Henderson	A	Closed / completed	trials@trog.com.au	
EORTC 22996 TROG 01.01	EORTC (TROG)	-	A Phase III Double-Blind, Randomized, Placebo-Controlled Study of Erythropoietin When Used as an Adjuvant to Radiation Therapy in Patients With Head & Neck Squamous Cell Carcinoma	Jim Denham	B	Closed / completed	trials@trog.com.au	

LUNG WORKING PARTY (LWP) & TRIALS

LWP Members

Fiona Hegi-Johnson (Chair)
Yu Yang Soon (Deputy Chair)
Brett Hughes
Chris Brown

Eric Hau
Jane Ludbrook
Margot Lehmann
Mark Pinkham

Michael Macmanus
Sagun Parakh
Shalini Vinod
Susan Ann McCullough

Tao Mai
Tomas Kron
Wen Xu
Rebecca Montgomery

Jessica Piotrowski

LWP Portfolio Summary

IDENTIFIERS	LEAD ORGANISATION (LOCAL LEAD)	STUDY ACRONYM	STUDY TITLE (SDA - SECONDARY DATA ANALYSIS REQUEST)	CHAIR (TROG PROPONENT)	CAT	STATUS	EMAIL	STUDY UPDATE
TD 24.01	TROG	MODERN-LUNG	Moderately hypofractionated chemoradiation followed by immunotherapy for inoperable Stage 3 Non-Small Cell Lung Cancer given with radical intent in older adults (MODERN-LUNG): a randomised phase 3 trial	Jane Ludbrook	A	Development	TSC@trog.com.au	Accepted for development in February 2024. EOI to be circulated Q2 2024
TOGA 20/005 TROG 21.10	TOGA	PRIME_LUNG	A randomised phase 2 trial of up-front stereotactic radiotherapy before standard-of-care systemic therapy in advanced lung cancer	Shankar Siva	C	Development	TSC@trog.com.au	Development of study continues. Funding required.
TD 21.09	Usyd (GCCTI)	OCTAVO	A phase II study of consolidation radiation for induced oligo-persistent disease following initial immunotherapy	Eric Hau	C	Development	TSC@trog.com.au	EOI: https://www.surveymonkey.com/r/EOI_TD2109 Development of study continues. Funding required.
TD 21.08	TROG	VITaL	The Ventilation Imaging for Thoracic Lung cancer radiation therapy trial	Paul Keall	A	Development	TSC@trog.com.au	EOI: https://www.surveymonkey.com/r/TD2108_VITaL_Eoi Development of study continues. Funding required.
TROG 20.01	TROG	CHEST RT	A phase II study of carboplatin and etoposide chemotherapy, durvalumab with or without thoracic radiotherapy in the first line treatment of patients with extensive-stage small-cell lung cancer	Eric Hau & Sagun Parakh	A	Open (Recruiting)	CHESTRT@trog.com.au	Accrual: 28/35 (01 March 2024) Sites: 8/8 This study is investigating the safety and effectiveness of combining chemotherapy and immunotherapy with chest radiation therapy for the treatment of extensive stage small cell lung cancer (ES-SCLC).
TROG 17.02	TROG	OUTRUN	Randomised phase II trial of Osimertinib with or without stereotactic radiosurgery for EGFR mutated NSCLC with brain metastases	Yu Yang Soon, Chee Lee & Fiona Hegi-Johnson	A	Open (FU)	OUTRUN@trog.com.au	Accrual: 40 13/40 in follow-up Sites: 12 Open 0 Closed Follow up is continuing and expected to be completed 30 November 2024 Latest publications/presentations; <ul style="list-style-type: none"> Oral Presentation; Changes in Cognition after osimertinib with or without SRS, in EGFRm NSCLC with Brain Metastases: a Pooled Analysis of RCTs WCLC, September 9-12 2023, Singapore
TROG 13.01/ALTG 13.001	TROG	SAFRON II	Stereotactic ablative fractionated radiotherapy versus radiosurgery for oligometastatic neoplasia to the lung: A randomised phase II trial	Shankar Siva	A	Closed / completed	SAFRONII@trog.com.au	Latest publications/presentations/Secondary analysis; <ul style="list-style-type: none"> ESTRO, 12 May 2023 - 16 May 2023, Vienna, Austria; Oral Presentation; Long-term outcomes of TROG 13.01 SAFRON II: Single vs multi-fraction SABR for pulmonary oligometastases to lung. Bucknell NW, Hardcastle N, Bressel M, Moore A, Montgomery R, Murnane A, Mai GT, Ball D, Kron T, Siva S; Stereotactic Ablative Fractionated Radiotherapy Versus Radiosurgery for Oligometastatic Neoplasia to the Lung (SAFRON) II Study Investigators. Impact on Pulmonary Function in a Randomized Trial of Single-Fraction and Multifraction Stereotactic Body Radiation Therapy for Pulmonary Oligometastatic Disease: An Analysis of TROG 13.01 (SAFRON II). Int J Radiat Oncol Biol Phys. 2023 Oct 21;50360-3016(23)08005-7. doi: 10.1016/j.ijrobp.2023.09.052. Epub ahead of print. PMID: 37871885.
TROG 11.03 /ALTG	TROG	PLUNG_GP	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.	Margot Lehmann	A	Closed / completed	trials@trog.com.au	
TROG 09.02	TROG	CHISEL	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.	David Ball	A	Closed / completed	trials@trog.com.au	Latest publications/presentations/Secondary analysis; <ul style="list-style-type: none"> Bucknell NW, et al. CHISEL coauthors. Comparison of Changes in Pulmonary Function After Stereotactic Body Radiation Therapy Versus Conventional 3-Dimensional Conformal Radiation Therapy for Stage I and IIA Non-Small Cell Lung Cancer: An Analysis of the TROG 09.02 (CHISEL) Phase 3 Trial. Int J Radiat Oncol Biol Phys. 2023 Oct 1;117(2):378-386.
TROG 99.05	TROG	-	Tumour Volume as an Independent Prognosis Factor in Patients with Non-Small Cell Lung Cancer: A Protocol for a Progressive Database	David Ball	A	Closed / completed	trials@trog.com.au	
TROG 03.07	TROG	-	A Randomised Phase II Study of Two Regimens of Palliative Chemoradiation Therapy in the Management of Locally Advanced Non Small Cell Lung Cancer	Bryan Burmeister and Michael Michael	A	Closed / completed	trials@trog.com.au	

OTHER SUBSPECIALITY TRIALS

SUBSPECIALITY	IDENTIFIERS	LEAD ORGANISATION	STUDY ACRONYM	STUDY TITLE	CHAIR (TROG PROPONENT)	CAT	STATUS	EMAIL	STUDY UPDATE
Gastrointestinal	AGITG TD 21.013	AGITG	NEEDS	Neoadjuvant chemoradiotherapy for Esophageal squamous cell carcinoma versus Definitive chemoradiotherapy with salvage Surgery as needed	Trevor Leong	C	Development	qa@trog.com.au	In development under AGITG.
Multiple	TD 18.07	TROG	ACCELERATE	TROG ACCELERATE Project: ACCELERating cancEr theRapy research via a nAational collaTed data assEt	TROG PT SIG	A	Development	trials@trog.com.au	Development on hold
Gastrointestinal	AGITG TD 21.06	AGITG	MRL SABR	MRI-Guided Stereotactic Ablative Radiotherapy for Abdominal Malignancies	Trang Pham	C	Start-up	trials@trog.com.au	Awarded the AGITG Innovations grant. Expected to open in 2024.
Gastrointestinal	TD 21.07	TROG	SOCRATES HCC	A randomised controlled trial of Standard Of Care versus RadioAblation in Early Stage HCC	David Pryor & Alan Wigg	A	Open (Recruiting)	SOCRATES_HCC@trog.com.au	Accrual: 38/218 (01 March 2024) Sites: 16/20 This study will investigate whether a radiotherapy technique (called SABR) can treat early stage liver cancer more effectively than current treatments which use heating probes directly inserted into the tumour or chemotherapy or radioactive particles injected into the blood supply of the tumour.
Multiple	TROG 21.12	TROG	ASPIRE	Australian Proton Therapy Clinical Quality Registry (APTCQR)	Hien Le	C	Open (Recruiting)	kelly.skelton@sahmri.com	Accrual: 58 Sites: 1 Open / 5 in start-up ASPIRE was showcased at the National Particle Therapy Symposium – poster presentation and the SAHMRI Registry Centre ASM – oral presentation. . In October 2023 ASPIRE featured in “The Benchmark” – a collaborative publication between Monash University, the South Australian Health and Medical Research Institute and the Australian Clinical Trials Alliance. The registry also featured extensively in a recent publication in the Journal of Medical Imaging and Radiation Oncology. Latest publications/presentations <ul style="list-style-type: none"> Khong J, Tee H et al. Proton beam therapy in paediatric cancer: Anticipating the opening of the Australian Bragg Centre for Proton Therapy and Research. J Med Imaging Radiat Oncol. 2023 Dec 25 https://www.protontherapy.sahmri.org.au/about-aptcqr/
Multiple	USYD/ TROG 17.03	TROG	LARK	Liver Ablative Radiotherapy utilising Kilovoltage intrafraction monitoring (KIM)	Dominique Lee & Tim Wang	C	Open (Recruiting)	LARK@trog.com.au	Accrual: 32/46 Sites: 7/7 To evaluate the accuracy of treatment delivery in patients receiving liver radiation with and without Kilovoltage Intrafraction Monitoring (KIM). It is hoped that this information will improve cancer targeting accuracy for all patients in the future. Latest publications/presentations <ul style="list-style-type: none"> Sengupta C, et al. The first clinical implementation of real-time 6 degree-of-freedom image-guided radiotherapy for liver SABR patients. Radiother Oncol. 2023 Nov 24;190:110031.
Gastrointestinal	TROG 09.01	TROG	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.	Sam Ng	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 03.01	TROG		A randomised phase III study in advanced oesophageal carcinoma to compare dysphagia in patients treated with radiotherapy versus chemo-radiotherapy.	Michael Penniment	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 99.02	TROG		A Prospective Single Arm Non Randomised Study of Concurrent Radiation and Chemotherapy For the Organ Conserving Treatment of Early Anal Canal Cancer	john Matthews	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 98.06	TROG		Concurrent Radiotherapy and Chemotherapy for Oesophageal Cancer Patients	Jim Denham	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 98.01	TROG		A Phase II Trial Of Preoperative Radiotherapy With Protracted Infusion 5-Fluorouracil For Resectable Adenocarcinoma Of Rectum	Sam Ngan	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 96.03	TROG		Concomitant Accelerated Radiotherapy Boost for Good Prognosis Oesophageal Patients	Jim Denham	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 96.02	TROG		Standard Radio-Chemotherapy for Oesophageal Cancer Patients	Jim Denham	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 95.01	TROG		A Randomised Trial Comparing Adjuvant Protracted Venous Infusion and Bolus 5FU/Leucovorin with Either Early or Late Radiotherapy in Rectal Cancer	Jim Denham	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 94.01	TROG		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	Bryan Burmeister	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 89.04	TROG		Synchronous Radiotherapy and Chemotherapy in Oesophageal Cancer	Jim Denham	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 89.03	TROG		Upper Aero-Digestive Track (Accelerated RT)	David Lamb	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 8.07	AGITG	DECO	The DECO Study: A Randomised Phase II Trial of Weekly Docetaxel (Taxotere) Chemoradiotherapy +/- Cetuximab	Michael Michael	B	Closed / completed	trials@trog.com.au	

				(Erbix) in the Treatment of Localised Resectable Cancer of the Oesophagus.					
Gastrointestinal	TROG 3.02	TROG		A Feasibility Study to Evaluate Adjuvant chemo-radiotherapy for Gastric Cancer	Trevor Leong	A	Closed / completed	trials@trog.com.au	
Gastrointestinal	TROG 1.04	TROG		A Randomised Trial of Preoperative Radiotherapy for Stage T3 Adenocarcinoma of the Rectum	Sam Ngan	A	Closed / completed	trials@trog.com.au	
Gynaecological	TROG 04.02	TROG		Prospective Study to Determine the Relationships Between Survival and FIGO Stage, Tumour Volume and Corpus Invasion in Cervical Cancer.	Kailash Narayan	A	Closed / completed	trials@trog.com.au	
Lymphoma	TROG 99.03	TROG		A Prospective, Non-Randomised Study of Chemotherapy and Radiotherapy for Osteolymphoma (OL)	Michael MacManus and John Seymour	A	Closed / completed	trials@trog.com.au	Latest publications/presentations <ul style="list-style-type: none"> Poster Presentation; Rituximab-Containing Combined Modality Therapy in Limited Stage Follicular Lymphoma: Mature Follow Up and derivation of a novel prognostic score from the TROG99.03 Phase III Trial ESTRO, 12 May 2023 - 16 May 2023, Vienna, Austria
Lymphoma	TROG 5.02	TROG		An ANZLG / TROG Prospective Study of Limited Chemotherapy and Involved Field Radiotherapy for Patients With Clinical Stage I-II Hodgkin's Disease	Michael MacManus and Andrew Wirth	A	Closed / completed	trials@trog.com.au	
Lymphoma	TROG 01.02	TROG		A Phase II Study of Intravenous Methotrexate and Cranial Irradiation in the Treatment of Primary Central Nervous System Lymphoma (PCNSL)	Peter O'Brien	A	Closed / completed	trials@trog.com.au	
Lymphoma	TROG 99.04	TROG		A Prospective, Non-Randomised Study of Chemotherapy and Radiotherapy for Osteolymphoma (OL)	David Christie	A	Closed / completed	trials@trog.com.au	
Lymphoma	TROG 99.01	ANZLG		An ANZLG / TROG Prospective Study of Limited Chemotherapy and Involved Field Radiotherapy for Patients With Clinical Stage I-II Hodgkin's Disease	Andrew Wirth	C	Closed / completed	trials@trog.com.au	
Multiple	TRP 11.B	TROG	ARORP	ANROTAT Radiation Oncology Register Pilot	Bryan Burmeister	A	Closed / completed	trials@trog.com.au	
Multiple	TRP 11.A -	TROG	ANROTAT	The Assessment of New Radiation Oncology Technologies and Treatment	Bryan Burmeister	A	Closed / completed	trials@trog.com.au	
Symptom Management	TROG 98.04	TROG		Phase II Study Examining the Efficacy of Short Fractionation Radiotherapy for the Palliation of Liver Metastases	Nigel Spry	A	Closed / completed	trials@trog.com.au	
Symptom Management	TROG 96.05	TROG		A Prospective Randomised Trial of Single Fraction Verses Fractionated Radiotherapy of Neuropathic Pain Due to Bone Metastases	Daniel Roos	A	Closed / completed	trials@trog.com.au	
Symptom Management	TROG 96.04	TROG		Phase III Comparison of Radiotherapy with Glucocorticoid Steroid Support for the Palliation of Liver Metastases	Nigel Spry	A	Closed / completed	trials@trog.com.au	
Symptom Management	TROG 95.02	TROG		A Phase III Double-Blind Randomised Trial of Rectal Sucralfate Suspension in the Treatment of Radiation Proctitis	Peter O'Brien	A	Closed / completed	trials@trog.com.au	
Symptom Management	TROG 3.08	NCI CTG (TROG)	BONEMETS	A phase III international randomized trial of single versus multiple fractions for re-irradiation of painful bone metastases.	(Daniel Roos)	B	Closed / completed	trials@trog.com.au	

TRIALS LED BY OTHER ORGANISATIONS (TROG collaboration, involvement or support)

PRIMARY SPONSOR	TRIAL NUMBER (TROG TRACKING NUMBER)	STUDY ACRONYM	STUDY TITLE	TRIAL CHAIR (TROG PROPONENT)	SUBSPECIALTY	STATUS
Breast Cancer Trials (BCT)	ANZ 1601/ BIG 16-02 (16.04)	EXPERT	A randomised phase III trial of adjuvant radiotherapy versus observation following breast conserving surgery and endocrine therapy in patients with molecularly characterised low-risk luminal A early breast cancer Website: www.breastcancertrials.org.au/current-clinical-trials/expert	Boon Chua	Breast	Recruiting
Australasian Gastro-Intestinal Trials Group (AGITG)	(21.03)	RESOLUTE	Randomised Phase II Trial to Evaluate the Strategy of Integrating Local Ablative Therapy with First-Line Systemic Treatment for Unresectable Oligometastatic Colorectal Cancer Website: https://gicancer.org.au/clinical-trial/resolute/	Jeanne Tie & Julie Chu	Gastrointestinal	Recruiting
	CTC 0245/AGITG AG0118PS (18.04)	MASTERPLAN	Randomised phase II study from the AGITG Mfolifirinox And Stereotactic Radiotherapy for Pancreatic cancer with Locally Advanced disease Website: https://gicancer.org.au/clinical-trial/masterplan/	Andrew Oar & Andrew Kneebone	Gastrointestinal	Recruiting
	AGITG AG0407GR (08.08)	TOPGEAR	A randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemo therapy for resectable gastric cancer. Website: https://gicancer.org.au/clinical-trial/topgear/	Trevor Leong	Gastrointestinal	In follow-up
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)	ANZUP 1801 (21.02)	Dasl-HiCaP	Darolutamide Augments Standard Therapy for Localised Very High-Risk Cancer of the Prostate (ANZUP1801). A randomised phase 3 double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high risk, clinically localised prostate cancer. Website: https://anzup.org.au/clinical-trial/dasl-hicap-trial/	Christopher Sweeney and Tamim Niazi	Genitourinary	Recruiting
	ANZUP 1303 (14.01)	ENZARAD	Randomised phase 3 trial of radiation plus androgen deprivation therapy with or without enzalutamide for high risk, clinically localised, prostate cancer Website: https://www.anzup.org.au/content.aspx?page=trials-enzarad	Scott Williams & Paul Nguyen	Genitourinary	In follow-up
Australia New Zealand Gynaecological Oncology Group (ANZGOG)	ANZGOG 1910/2020 (21.04)	ADELE	ADjuvant tislelizumab plus chemotherapy after post-operative pelvic chemoradiation in high risk Endometrial cancer: a randomised phase 2 trial Website: https://www.anzgog.org.au/research/trials/	Linda Mileschkin and Yeh Chen Lee (Pearly Khaw)	Gynaecological	Recruiting
	CKTO 2006-04 / CME P06.031 (08.04)	PORTEC-3	Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma Website: http://www.anzgog.org.au/endometrial-cancer-portec3/	(Pearly Khaw)	Gynaecological	In follow-up
Melanoma and Skin Cancer Trials (MASC)	MASC 03.18 (21.01)	I-MAT	Immunotherapy Merkel Adjuvant Trial Website: https://www.masc.org.au/i-mat/	Wen Xu	Skin	Recruiting
Regeneron Pharmaceuticals	R2810-ONC-1788 (17.11)	CPOST	A randomised, placebo-controlled, double-blind study of adjuvant Cemiplimab versus placebo after surgery and radiation therapy in patients with high risk cutaneous squamous cell carcinoma	Danny Rischin & Sandro Porceddu	Skin	Recruiting
Peter MacCallum Cancer Centre	PMC 20/54 (20.03)	AVATAR	Stereotactic radiotherapy for oligoprogressive ER-positive breast cancer Website: https://trials.cancervic.org.au/details.aspx?ID=vcvtl_pending	Steven David & Michelle White	Breast	In follow-up
	PMC 17/013 (17.05)	AZTEC	A randomised phase II trial comparing the efficacy of single fraction or multi-fraction SABR (Stereotactic ablative body radiotherapy) with Atezolizumab in patients with advanced Triple negative breast Cancer Website: https://trials.cancervic.org.au/details.aspx?ID=vcvtl_nct03464942	Sharine Loi & Steven David	Breast	Closed

Acknowledgements

The TROG Central Operations Office would like to thank the trial chairs and the central coordinators for submitting the bi-annual progress reports.