



TRIOG

CANCER RESEARCH

Trial Portfolio Update

Annual Scientific Meeting

17-19 March 2020

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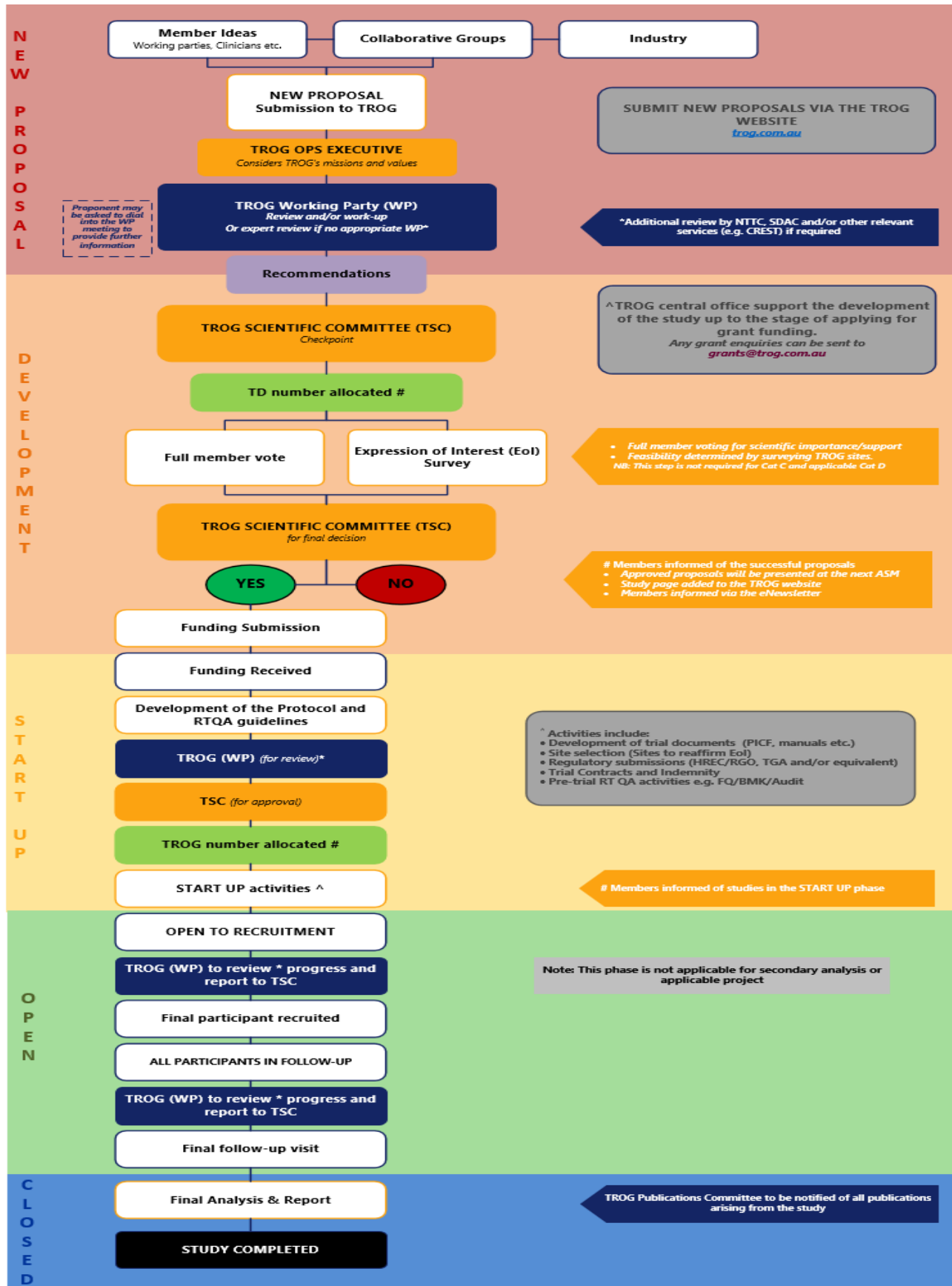
Acknowledgements

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

Glossary of Terms

Term or Abbreviation	Definition
Budget	Outline of the funds required to conduct the study
Database	The development of the trial database, an organised collection of structured information, or data, typically stored electronically in a computer system
Eoi	Expression of Interest. This survey is circulated to TROG sites to assess the feasibility of the new proposal
Funding	Securing the funds to conduct the study
Funding submission	Application to a funding body to obtain the funds needed to conduct the study
HREC	Human Research Ethics Committee
Ops Exec	TROG Operations Executive committee. This committee reviews each new proposal to ensure that it meets TROG's mission and values.
Protocol	The development of the trial protocol, a document describing the background, rationale, objectives, design, methodology, statistical considerations, and organisation of a clinical research project.
RTQA	Development of the Radiation Therapy Quality Assurance program
Summary of trial activity	Outline of the status of the key milestones in the new proposal, development and start up phases Not started, In Progress, Completed, Not applicable
TD	TROG Development (number); this is a tracking number given to proposals in the development phase of the TROG study pathway.
Trial Development Plan	Initial document to collect information for the development of the study, such as background, study rationale and objectives, outline methodology and initial statistical considerations
TSC	TROG Scientific Committee
Vote	Conduction of the TROG Full Members vote to determine the scientific merit of the new proposal
Working Party/ Expert	Review of the proposal by the subspecialty Working Party and/or other TROG committees and/or independent experts and/or national technical services

TROG Cancer Research Study Pathway



Note: This pathway was updated in 2019;

- The OPEN stage has been extended to be a study that has any participant activity. Therefore, a study is now considered open between activation of the first site (so active patient screening can start) to the completion of all follow-up visits (i.e. last patient, last visits).
- Once all patient activity has completed on a study, it is considered Closed. Activities in this stage would be the final data cleaning, final analysis and subsequent publications, closing out of sites, HREC etc., ensuring a copy of the database is held at TROG Central Operations Office and archiving the study documents.

Brain & Central Nervous System

Trial in Development

TD 17.04	NEURONE: Intracranial stereotactic radiosurgery with or without memantine
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Trial Chairperson:

Eric Hau

Organisation: Westmead Hospital

Email address: eric.hau@health.nsw.gov.au

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Phase: II

Category: A

Primary aim: To test the hypothesis that the addition of memantine will reduce the cognitive decline in patients treated with SRS for up to 10 metastases (each metastasis <3cm and total cumulate volume of BM ≤15ml)

Trial Update (2019): Funding not secured in 2019. Further funding applications to be submitted in 2020.

Summary of Trial Activity:

Vote

Eol

Trial Development
Plan

Budget

Funding
Submission

Trial in Start-up

TROG 18.06	FIG: Prospective, multicentre trial evaluating FET-PET in Glioblastoma (FET-PET in Glioblastoma)
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Trial Chairpersons:

Andrew Scott | Eng-Siew Koh

Organisation: ONJCRI; The Austin | Liverpool Hospital

Email address: andrew.scott@onjcricri.org.au | engsiew.koh@health.nsw.gov.au

Contact:

TROG Development/Patrick Wheeler

Organisation: TROG Cancer Research

Email address: FIG@trog.com.au

Phase: II

Category: A

Primary Aim: To investigate how the addition of FET-PET imaging to standard MRI imaging affects radiation target volume delineation and treatment planning for GBM and to determine the accuracy and management impact of FET-PET in distinguishing pseudoprogression from true tumour progression and / or tumour recurrence.

Trial Update (2019): In 2019 the protocol, RTQA manual, imaging guideline, radiopharmacy manual, laboratory manual and the PICF were finalised and the study was registered on the ANZCTR. Site selection was undertaken, with 10 sites invited to participate. Ethical approval was granted 02 January 2020. Currently, the team are working on developing the database, credentialing activities and imaging workflows.

Summary of Trial Activity:

Protocol

HREC

Funding

RTQA

Database

Open Trial	
TROG 15.02	ROAM: Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial

<p>Trial Chairperson: Gail Ryan Organisation: Peter MacCallum Cancer Centre Email address: gail.ryan@petermac.org</p>	<p>Contact: Tamica Humby Organisation: TROG Cancer Research Email address: ROAM@trog.com.au</p>
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Phase: III

Category: B (Lead Group – the Walton Centre NHS Foundation Trust)

Primary aim: Time to MRI evidence of tumour recurrence or death due to any cause

Accrual (Current / Target): 113/190 Intl (Total) | **9/30 TROG**

Site status: All 12 sites activated

Projected accrual end date: 01/09/2020

Publications (2019): Nil

Trial Update (2019): In 2019, TROG sites had the highest recruitment numbers in Australia since the trial opened.

Open Trial (accrual completed)	
TROG 6.01	Primary chemotherapy with temozolomide vs. radiotherapy in patients with low grade gliomas after stratification for genetic 1p loss: a phase III study

<p>Trial Chairperson: Gail Ryan Organisation: Peter MacCallum Cancer Centre Email address: gail.ryan@petermac.org</p>	<p>Contact: Patrick Wheeler Organisation: TROG Cancer Research Email address: patrick.wheeler@trog.com.au</p>
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Phase: III

Category: B (lead Group – EORTC)

Primary Aim: The aim of this study is to demonstrate a difference in progression-free survival (PFS) for primary treatment with temozolomide versus primary irradiation

Final accrual: 707 Int | 69 TROG
 (EORTC 707 registered/ TROG 69 registered, EORTC 473 rand/ TROG 47 rand)

No of patients in f/up: 17 (TROG)

Projected f/up end date: 30/09/2020

Publications (2019): Nil

Trial Update (2019): Follow-up continues. The possibility of extending the follow-up period is being explored. TROG will contact the sites in 2020 to gauge interest and availability of resources.

Breast

Trial in Development

TD 17.08	TAILOR RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer
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Trial Chairpersons:

Boon Chua

Organisation: Prince of Wales Hospital

Email address: boon.chua@health.nsw.gov.au

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Category: B (Lead group – NCIC/CCTG)

Primary Aim: To determine if omitting regional RT following breast-conserving surgery (BCS) or mastectomy is not inferior to its use in women with 1-3 positive axillary nodes and ER-positive (ER+) biomarker low risk breast cancer.

**Summary of Trial
Activity:**

Vote

EOI

Trial
Development Plan

Budget

Funding
Submission

Open Trial

TROG 16.02	LOCAL HER-0: A phase II study of local therapy only (stereotactic and or surgery) for treatment of up to 5 brain metastases from HER2+ breast cancer
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Trial Chairperson:

Claire Phillips

Organisation: Peter MacCallum Cancer Centre

Email address: claire.phillips@petermac.org.au

Contact:

Kassandra Wagenfuehr

Organisation: TROG Cancer Research

Email address: LocalHERO@trog.com.au

Phase: II

Category: A

Primary Aim: To assess the percentage of participants treated with whole brain radiotherapy within 12 months after completion of local therapy only for 1-5 previously untreated brain metastases from MHBC in women with metastatic HER2+ breast cancer who have good performance status and absent, controlled or treatable extracranial disease and are receiving HER2-targeted systemic therapy.

Accrual (Current / Target): 16/50

Site status: 7 activated / 2 pending

Projected accrual end date: Q4 2020

Publications (2019): Nil

Trial Update (2019): In 2019, an additional 2 sites were opened and 9 participants were recruited. 4 patients completed their 12 month follow-up.

Open Trial

TROG 12.02	PET LABRADOR: PET Scans for Locally Advanced Breast cancer and Diagnostic MRI to determine the extent of Operation and Radiotherapy
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Trial Chairperson:

Verity AhernOrganisation: The Crown Princess Mary Cancer Centre,
Westmead HospitalEmail address: verity.ahern@health.nsw.gov.au

Contact:

Tracy Pearl-LarsonOrganisation: The Crown Princess Mary Cancer Centre,
Westmead HospitalEmail address: Tracy.Pearl-Larson@health.nsw.gov.au**Phase:** II**Category:** A**Primary Aim:** The primary objective of the study is to demonstrate a LR rate of $\leq 20\%$ at three years in patients who undergo BCS based on histopathology, MRI and PET-CT scans. (LR $<10\%$ is expected).**Accrual (Current / Target):** 23/220**Site status:** 1 activated / 1 pending / 2 withdrawn**Projected accrual end date:** Q2 2021**Publications (2019):** Nil**Trial Update (2019):** Reviewed by the TROG IDSMC due to the slow recruitment.

2 sites withdrawn due to the inability to recruit patients and lack of staff resourcing.

Open Trial (Patients in follow up)

TROG 11.01	SUPREMO: Radiation Therapy or Standard Therapy in Treating Women With Stage II Breast Cancer Who Have Undergone Mastectomy
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TROG Trial Chairperson:

Boon Chua

Organisation: Prince of Wales Hospital

Email address: boon.chua@health.nsw.gov.au

Trial Contact:

Rebecca Montgomery

Organisation: TROG Cancer Research

Email address: Rebecca.Montgomery@trog.com.au**Phase:** III**Category:** B (Lead Group - UK Medical Research Council)**Primary aim:** To assess the role of adjuvant chest wall irradiation in 'intermediate risk' operable breast cancer following mastectomy**Final accrual:** 1688 Intl | **24 TROG****No of patients in f/up:** 122 Intl | 17 TROG**Projected f/up end date:** 30/04/2023**Publications (2019):** Nil**Trial Update (2019):** Follow-up continuing. The expected interim analysis is yet to be completed.

Open Trial (Patients in follow up)

TROG 8.06 STARS: A randomised comparison of anastrozole commenced before and continued during adjuvant radiotherapy for breast cancer versus anastrozole and subsequent anti-oestrogen therapy delayed

Trial Chairperson:

Peter Graham

Organisation: St George Hospital

Email address: peter.graham@health.nsw.gov.au

Trial Contact:

Helen Cox

Organisation: St George Hospital

Email address: SESLHDSTARStrial@health.nsw.gov.au

Phase: III

Category: A

Primary Aim: 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.

Final Accrual: 2023

No of patients in f/up: 1904

Projected f/up end date: 31/12/2026

Publications (2019): Nil

Trial Update (2019): Follow-up continuing. Data cleaning is continuing to publish cohort details and initial treatment data.

Open Trial (Patients in follow up)

TROG 7.01 DCIS: A randomised phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast

Trial Chairperson:

Boon Chua

Organisation: Prince of Wales Hospital

Email address: boon.chua@health.nsw.gov.au

Trial Contact:

Tamica Humby

Organisation: TROG Cancer Research

Email address: DCIS@trog.com.au

Phase: III

Category: A

Primary Aim: To assess if the addition of tumour bed boost after breast conserving surgery in women with non-low risk DCIS reduces the risk of local recurrence and if the risk of local recurrence in the shorter fractionation arm is not worse than that for the standard fractionation arm.

Final Accrual: 1608

No of patients in f/up: 1333 as of 31/12/2019

Projected f/up end date: 29/08/2024

Publications (2019): Olivotto I, Link E, Phillips C, Whelan T, Bryant G, Kunkler I, Westenberg A, Purohit K, Ahern V, Graham P, Akra M, McArdle O, Ludbrook J, Harvey J, Maduro J, Kirkove C, Gruber G, Martin J, Campbell I, Delaney G, Chua BH; BIG 03-07/TROG 07.01 trial investigators. International comparison of cosmetic outcomes of breast conserving surgery and radiation therapy for women with ductal carcinoma in situ of the breast. Radiother Oncol. 2020 Jan; 142: 180-5.

Trial Update (2019): An article on TROG and 07.04 DCIS was published in the Breast International Group (BIG) magazine early in the year.
DSMC and SC meeting in July 2019. Sites have been contacted frequently to obtain outstanding data for the main analysis.
The 3-year cosmesis manuscript was published in Radiotherapy and Oncology journal on 19 Jul 2019.
The 2 year QoL/PRO manuscript was submitted to Lancet on 28 June 2019 and after 4 rounds of revisions was accepted on 5th Feb 2020

Closed Trials		
TROG N ^o	TITLE	CAT
14.04	<p>HART: Deep Inhalation Breath Hold for reduction of cardiac toxicity in patients with left sided breast cancer undergoing radiotherapy</p> <p>Trial Chairperson: Tomas Kron</p> <p>Study update (2019): Study analysis completed in 2019. The study confirmed that DIBH reduces the radiation dose to the heart for left sided breast cancer patients receiving radiotherapy. There was a slightly higher anxiety scores among DIBH patients suggesting the act of breath hold, or knowledge of the purpose of DIBH, may increase patient anxiety.</p>	A
6.02	<p>APBI: A Multicentre Feasibility Study of Accelerated Partial Breast Irradiation Using Three-Dimensional Conformal Radiation Therapy for Early Breast Cancer 2019 Update: Awaiting on analysis.</p> <p>Trial Chairperson: Boon Chua</p> <p>Study update (2019): Awaiting final analysis</p>	A

Gastrointestinal

Trial in Development

TD 19.02 SIROCCO: Sir-spheres implanted with and without Occlusafe balloon micro catheter (Interventional Oncology)

Trial Chairpersons:

Nicholas Brown

Organisation: Wesley Hospital

Email address: nibrown@tpg.com.au

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Category: A

Primary Aim: Assess whether the use of a balloon micro catheter can significantly increase the amount of radiation implanted inside liver tumours (primary and secondary), and decrease the radiation dose delivered to background liver parenchyma.

Summary of Trial Activity:

Vote

EOI

Trial Development Plan

Budget

Funding Submission

Open

TROG 17.03 LARK: Liver Ablative Radiotherapy utilizing Kilovoltage intrafraction monitoring (KIM)

Trial Chairperson:

Dominique Lee | Tim Wang

Organisation: Princess Alexandra Hospital | Westmead Hospital

Email address: yooyoung.lee@health.qld.gov.au

tim.wang1@health.nsw.gov.au

Contact:

Annette Dempsey

Organisation: TROG Cancer Research

Email address: LARK@trog.com.au

Phase: II

Category: A (Sponsor USyd)

Primary Aim: Quantify accumulated patient dose distribution with the KIM intervention compared to dose distribution estimated without the KIM intervention.

Accrual (Actual/Target): 1/46

Site Status: 1 opened, 7 pending

Projected accrual end date: Q1 2023

Publications (2019): Nil

Trial Update (2019): The LARK Protocol and RTQA Guidelines were amended and received HREC approval.

The study opened to accrual in October 2019, with the Crown Princess Mary Cancer Centre Westmead activated as the first study site. Further clarifications to be made to the protocol in 2020 prior to activation of other sites.

Genitourinary (Bladder, Kidney & Prostate)

New Proposals

NP 19L	PACE C: Prostate Advances in Comparative Evidence International randomised study of conventional radiotherapy vs SBRT for organ-confined prostate cancer
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Trial Chairperson:

Giuseppe Sasso

Organisation: Auckland City Hospital

Email address: gsasso@adhb.govt.nz

Phase: II

Category: A

Primary Aim: In the primary management of organ-confined prostate cancer, to assess whether hypofractionated stereotactic body radiotherapy (SBRT) offers benefit over prostatectomy or conventional radiotherapy.

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Summary of Trial Activity:

Ops Exec

Working Party/ Expert

TSC

Trials in Start Up

TD 19.06	DECREASE: Darolutamide + Consolidation Radiotherapy in Advanced prostate cancer detected by PSMA
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Trial Chairperson:

Shankar Siva | Arun Azad

Organisation: Peter MacCallum Cancer Centre

Email address: shankar.siva@petermac.org

arun.azad@petermac.org

Phase: II

Category: A

Primary Aim: The M0 population in CRPC as reported in the ARAMIS trial is based on conventional imaging such as whole body bone scan and CT staging. In the era of PET imaging, many sites of disease that are occult on conventional imaging will be found on PSMA (prostate specific membrane antigen) PET. This is a randomised phase II study proposal investigating the use of darolutamide +/- local consolidation radiotherapy in a group of patients who are M0 on conventional imaging but who can also undergo PSMA PET.

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: DECREASE@trog.com.au

Summary of Trial Activity:

Vote

EOI

Trial
Development Plan

Budget

Funding
application

Protocol

HREC

Funding

RTQA

Database

Open Trial	
TROG 18.01	NINJA: Novel Integration of New prostate radiation schedules with adjuvant Androgen deprivation

Trial Chairperson:

Jarad Martin | Mark Sidhom

Organisation: Calvary Mater Newcastle | Liverpool Hospital

Email address: jarad.martin@calvarymater.org.au | mark.sidhom@sswahs.nsw.gov.au

Contact:

Jo Smart | Tess Vuong

Organisation: Calvary Mater Newcastle |

Liverpool Hospital

Email address: NinjaTrial@calvarymater.org.au

Phase: II-III

Category: A

Primary Aim: Prostate cancer biochemical control measured by Phoenix definition of nadir + 2ng/mL and/or detection of metastases or initiation of salvage intervention by the 5 year time point

Accrual (Actual/target) : 41/150 (Ph II)

Publications (2019): Martin J, Keall P, Siva S, et al. TROG 18.01 phase III randomised clinical trial of the Novel Integration of New prostate radiation schedules with adjuvant Androgen deprivation: NINJA study protocol. *BMJ Open* 2019;9:e030731.

Trial Update (2019): In 2019, 7 sites opened to recruitment, with an additional 7 sites pending activation and in process of completing RGO and RTQA credentialing requirements. 31 participants have been randomised to the trial and 20 participants are currently in follow up. 2 sites have implemented MRI only planning, and KBP feedback was successfully implemented as part of real-time review in August.

- Recruitment rate higher than projected
- Site activation for 7 out of the 14 selected sites this year
- 1 site progressing to phase 3 of MRI only sub-study

Open Trial	
TROG 15.03	FASTRACK II: Focal Ablative Stereotactic Radiosurgery for Cancers of the Kidney, a Phase II Clinical Trial

Trial Chairperson:

Shankar Siva

Organisation: Peter MacCallum Cancer Centre

Email address: shankar.siva@petermac.org

Contact:

Annette Dempsey

Organisation: TROG Cancer Research

Email address: FASTRACKII@trog.com.au

Phase: II

Category: A

Primary Aim: To estimate the efficacy of SABR for primary Renal Cell Carcinoma

Accrual (Current / Target): 71/71

Accrual end date: 2/3/2020

Publications (2019): Siva S, Chesson B, Pryor D, Higgs B, Reynolds H, Hardcastle N, Montgomery R, Vanneste B, Khoo V, Ruben J, Lau E, Hofman M, De Abreu Lourenco R, Sridharan S, Brook N, Martin J, Lawrentschuk N, Kron T, Foroudi F. TROG 15.03 phase II clinical trial of Focal Ablative STereotactic Radiosurgery for Cancers of the Kidney - FASTRACK II. *BMC Cancer*. 2018 Oct. 18:1030

Trial Update (2019): The trial is progressing as would be expected, however, recruitment was slightly behind expected accrual. 1 patient was enrolled in the study but the clinician decided to withdraw the patient before commencing any study treatment. As per protocol this patient will be replaced, overall accrual has therefore been increased to 71.

The first international site Maastricht was opened in July 2019 and recruited their first participant in November.

Accrual completed 02 March 2020.

Open Trial	
TROG 15.01	SPARK: Stereotactic Prostate Adaptive Radiotherapy utilising KIM (Kilovoltage Intrafraction Monitoring)

Trial Chairpersons:

Jarad Martin | Paul Keall

Organisation: Calvary Mater Newcastle | University of Sydney

Email address: jarad.martin@calvarymater.org.au | paul.keall@sydney.edu.au

Phase: II

Category: A (Sponsor USyd)

Primary Aim: Quantify accumulated patient dose distributions with the KIM intervention compared to dose distributions estimated without the KIM intervention.

Final Accrual : 49/ 48 Treated

Projected f/up end date: 29/03/2020

Publications (2019):

1. E Hewson, D Nguyen, R O'Brien, P Poulsen, J Booth, P Greer, T Eade, A Kneebone, G Hruby, T Moodie, A Hayden, S Turner, N Hardcastle, S Siva, K Tai, J Martin, P Keall. Is MLC Tracking Or Gating a Better Real-Time Correction Strategy? An Analysis of the TROG 15.01 Stereotactic Prostate Ablative Radiotherapy with KIM (SPARK) Trial. Med Phys. 2019 Jun; 46(6): E283-E283.
2. Wolf J, Nicholls J, Hunter P, Nguyen D, Keall P, Martin J. Dosimetric impact of intrafraction rotations in stereotactic prostate radiotherapy: A subset analysis of the TROG 15.01 SPARK trial. Radiother Oncol. 2019 Jul; 136:143-7.
3. Hewson E, Nguyen D, O'Brien R, Kim J, Montanaro T, Moodie T, Greer P, Hardcastle N, Eade T, Kneebone A, Hruby G, Hayden A, Turner S, Siva S, Tai K, Hunter P, Sams J, Poulsen P, Booth J, Martin J, Keall P. The accuracy and precision of the KIM motion monitoring system used in the multi-institutional TROG 15.01 Stereotactic Prostate Ablative Radiotherapy with KIM (SPARK) trial. Med Phys. 2019 Nov; 46(11): 4725-37.

Trial Update (2019): Current Publication Status: 6 papers in-press or published, 1 paper under review, 3 papers in draft, 6 abstracts in-press or published.

Primary outcome paper: Dosimetric analysis with UROBP (review)

Open Trial	
TROG 14.02	RAIDER: A randomised phase III trial of adaptive image guided standard or dose escalated radiotherapy in the treatment of transitional cell carcinoma of the bladder

Trial Chairperson:

Farshad Foroudi

Organisation: The Austin

Email address: farshad.foroudi@austin.org.au

Phase: III

Category: B (Lead Group - ICR)

Primary Aim: Stage I: The primary objective of stage I is to ensure that the dose escalated (DART) treatment can be planned and delivered at multiple centres within safe dose constraints

Stage II: Stage II aims to ensure the proportion of patients experiencing severe or medically significant late toxicity as a result of DART treatment is within acceptable limits.

Accrual (Current / Target): 279/240 Intl | 30/30 TROG | Total= 309

Projected accrual end date: March 202

Publications (2019): Nil

Trial Update (2019): The trial continues to get closer to recruitment targets.

The Austin recruited their first trial participant.

Two abstracts accepted for presentation in 2020.

Contact:

Patrick Wheeler

Organisation: TROG Cancer Research

Email address: RAIDER@trog.com.au

Open Trial	
TROG 8.03	RAVES: A phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) with early salvage RT in patients with positive margins or extraprostatic disease following radical prostatectomy

Trial Chairperson:

Maria Pearce

Organisation: Auckland City Hospital

Email address: mariap@adhb.govt.nz

Contact:

Carol Fraser-Browne

Organisation: Auckland City Hospital

Email address: carolFB@adhb.govt.nz

Phase: III

Category: A

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

Final Accrual (target): 333 (470)

No of patients in f/up: 298

Projected f/up end date: 30/06/2022

Publications (2019):

1. Cloak K, Jameson M, Paneghel A, Wiltshire K, Kneebone A, Pearce M, Sidhom M, Tang C, Fraser-Browne C, Holloway L, Haworth A. Contour variation is a primary source of error when delivering post prostatectomy radiotherapy: Results of the Trans Tasman Radiation Oncology Group 08.03 Radiotherapy Adjuvant Versus Early Salvage (RAVES) benchmarking exercise. J Med Imaging Radiat Oncol. 2019 Jun; 63(3):390-8.
2. Kneebone A, Fraser-Browne C, Delprado W, Duchesne G, Fisher R, Frydenberg M, Haworth A, Herschtal A, Joseph D, Lim T, Martin J, Millar J, Sidhom M, Spry N, Tang C, Turner S, Williams S, Wiltshire K, Woo H, Pearce M. A Phase III Multi-Centre Randomised Trial comparing adjuvant versus early salvage Radiotherapy following a Radical Prostatectomy: Results of the TROG 08.03 and ANZUP "RAVES" Trial. International Journal of Radiation Oncology Biology Physics. 2019 Sep; 1(1): S37-8.

Trial Update (2019): The primary analysis was completed in February 2019. An abstract of primary results was presented at the ASTRO 2019 Annual Scientific Meeting. A sub-study abstract was submitted to the TROG 2020 ASM, and accepted for oral presentation. Additional manuscripts of toxicity and Quality of Life results are in preparation.

Ongoing patient follow-up continued and has transitioned to an Annual Patient Status form including only survival, PSA, and relapse status.

An abstract of the primary analysis results was accepted for oral presentation at the ASTRO Annual Scientific Meeting in September 2019. It was deemed one of the top four genito-urinary presentations at the meeting and was presented again at the Best of ASTRO meeting in Washington D.C. in November 2019.

Closed Trials		
TROG N°	TITLE	CAT
3.04	<p>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</p> <p>Trial Chairperson: Jim Denham</p> <p>Publications (2019): Denham J, Joseph D, Lamb D, Spry N, Duchesne G, Matthews J, Atkinson C, Tai K, Christie D, Kenny L, Turner S, Gogna K, Diamond T, Delahunt B, Oldmeadow C, Attia J, Steigler A. Short-term androgen suppression and radiotherapy versus intermediate-term androgen suppression and radiotherapy, with or without zoledronic acid, in men with locally advanced prostate cancer (TROG 03.04 RADAR): 10-year results from a randomised, phase 3, factorial trial. Lancet Oncol. 2019 Feb; 20(2):267-81.</p>	A

Head Neck and Skin

Trial in Development

TD 18.03	Atezolizumab in low risk HPV oropharyngeal squamous cell carcinoma (OPSCC)
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Trial Chairperson:

Danny Rischin

Organisation: Peter MacCallum Cancer Centre

Email address: danny.rischin@petermac.org

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Phase: III

Category: A

Primary Aim: To determine the efficacy and toxicity profile of reduced dose radiation with atezolizumab in patients with HPVOPSCC with $\geq 5\%$ PDL1 positive intraepithelial immune cells

Trial Update (2019): Still negotiating contracts to access the De-ESCALaTE trial samples to validate the findings. CD103 data from the Peter MacCallum cohort and validated in Princess Alexandra cohort was published online in 2019 in the Annals of Oncology, which showed that the cohort of patients treated predominately with chemoradiation had 100% survival irrespective of stage. The data is of interest and proceeding cautiously.

**Summary of Trial
Activity:**

Vote

EOI

Trial
Development Plan

Budget

Funding
Submission

Trial in Development

TD 19.07	UTILITY: Unilateral Treatment In all Well-Lateralized Tonsillar Primary Tumours
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Trial Chairpersons:

Lachlan McDowell

Organisation: Peter MacCallum Cancer Centre

Email address: lachlan.mcdowell@petermac.org

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Category: A

Primary Aim: To determine the safety of unilateral treatment in all well-lateralised tonsillar tumours

**Summary of Trial
Activity:**

Vote

EOI

Trial
Development Plan

Budget

Funding
Submission

Open	
TROG 14.03	EORTC1219: 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

Trial Chairpersons:

Sandro Porceddu

Organisation: Princess Alexandra Hospital

Email address: sandro.porceddu@health.qld.gov.au

Contact:

Patrick Wheeler

Organisation: TROG Cancer Research

Email address: EORTC1219@trog.com.au

Phase: III

Category: B (lead Group-EORTC)

Primary Aim: To evaluate whether the hypoxic cell radio sensitizer nimorazole can improve the effect of primary curative accelerated fractionated concomitant chemo-radiotherapy with cisplatin and to investigate if patients who may have such benefit can be predicted by the use of a hypoxic gene profile.

Final Accrual: 194 of 240 (Int Total) / 12 of 60 (TROG)

Projected f/up end date: 31/12/2020

Publications (2019): Nil

Trial Update (2019): Sites were informed in October 2019 that the study had met the protocol definition of end of trial;

a) Ninety days after all patients have stopped protocol treatment

b) The trial is mature for the analysis of the primary endpoint as defined in the protocol

c) The database has been fully cleaned and frozen for this analysis

The results of the analysis of the primary endpoint are still be announced.

Sites are to continue to follow patients as per protocol.

Open	
TROG 12.01	HPV OROPHANYX: A Randomised Trial of Weekly Cetuximab and Radiation versus Weekly Cisplatin and Radiation in Good Prognosis Locoregionally Advanced HPV-Associated Oropharyngeal Squamous Cell Carcinoma

Trial Chairpersons:

Danny Rischin | June Corry

Organisation: Peter MacCallum Cancer Centre |

Genesis Cancer Care

Email address: danny.rischin@petermac.org |

june.corry@genesiscare.com.au

Phase: III

Category: A

Primary Aim: To compare symptom severity and distress between weekly cisplatin and RT versus weekly cetuximab and RT from baseline to 13 weeks post-completion of radiotherapy

Final Accrual: 189

No of patients in f/up: 147

Projected f/up end date: 23/08/2023

Publications (2019): Nil

Trial Update (2019): Protocol amendment version 3.2 (dated 2nd December 2019) was submitted to TROG Scientific Committee and Merck for review and approval. Currently waiting for the response before submitting to the HREC

Contact:

Ania Matera

Organisation: BaCT

Email address: anetta.matera@petermac.org

Open (Patients in follow-up)

TROG 09.03	A phase II efficacy study of chemo-radiotherapy in PET stage II and III Merkel cell carcinoma of the skin (MP3)
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Trial Chairpersons:

Michael Poulson

Organisation: Radiation Oncology Services - Mater Centre

Email address: michael.poulsen@health.qld.gov.au

Contact:

Narelle Wallace

Organisation: Radiation Oncology Mater Centre (ROMC)

Email address: Narelle.Wallace@health.qld.gov.au**Phase:** II**Category:** A**Primary Aim:** To investigate the efficacy and toxicity of a chemo-radiotherapy regimen of weekly carboplatin during radiation followed by adjuvant chemotherapy in Stage II-III MCC.**Final Accrual:** 58**No of patients in f/up:** 7**Projected f/up end date:** 28/02/ 2021**Publications (2019):** Nil**Trial Update (2019):** Participants remain in follow-up.**Category D Trials**

TROG N°	TITLE
17.10	<p>reHUM: Re-analysis of the TROG 07.03 RadioHUM study using deformable image registration to predict patterns of failure in head and neck cancer patients undergoing treatment with IMRT or 3DCRT</p> <p>Secondary Analysis: To determine the patterns of failure in head and neck cancer patients receiving either 3DCRT or IMRT relative to specified target volumes and doses using post-recurrence imaging co-registered to the delivered treatment plan.</p> <p>Trial Chairperson: Noel Ahern</p>

Lung

New Proposals

NP 20A	CHEST RT: Chemotherapy Immunotherapy in Extensive Stage Small cell with Thoracic Radiotherapy 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
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Trial Chairperson:

Eric Hau

Organisation: Westmead Hospital

Email address: eric.hau@health.nsw.gov.au

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Phase: II

Category: A

Primary Aim: Assess safety and feasibility, and describe efficacy in ES-SCLC treated with chemotherapy, immunotherapy and concurrent thoracic radiotherapy.

Summary of Trial Activity:

Ops Exec

Working Party/ Expert

TSC

Trial in Development

TD 19.08	SARON: Stereotactic Ablative Radiotherapy for Oligometastatic Non-small cell lung cancer
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Trial Chairpersons:

Gerry Hanna

Organisation: Peter MacCallum Cancer Centre

Email address: gerry.hanna@petermac.org

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Category: B

Lead Group: UCL- University College of London

Primary Aim: To investigate the impact on overall survival of the addition of conventional RT and SABR/SRS to standard systemic therapy in the first line treatment of non-small cell lung cancer patients with one to three metastatic lesions.

Summary of Trial Activity:

Vote

EOI

Budget

Funding Submission

Open Trial	
TROG 17.02	OUTRUN: A randomised phase II trial of Osimertinib with or without stereotactic radiosurgery for EGFR mutated NSCLC with brain metastases

Trial Chairpersons:

Fiona Hegi-Johnson | Chee Lee | Yu Yang Soon

Organisation: Peter MacCallum Cancer Centre | St George Hospital |

National University Hospital Singapore

Email address: fiona.hegi-johnson@petermac.org |

chee.lee@ctc.usyd.edu.au | yu_yang_soon@nuhs.edu.sg

Contact:

Patrick Wheeler

Organisation: TROG Cancer Research

Email address: OUTRUN@trog.com.au

Phase: II

Category: A

Accrual (Current / Target): 10/80

Projected accrual end date: 2022

Primary Aim: To assess the efficacy of Osimertinib with deferred local brain metastases directed therapies compared with upfront SRS followed by Osimertinib by assessment of intracranial progression free survival at 12 months

Publications (2019): Nil

Trial Update (2019): The first patient was recruited to the study in August 2019, and 5 participants recruited by year-end. Actively pushing additional sites to open in Q1 2020, including 2 Singapore sites. Currently on track recruitment wise, need to open additional sites to stay on target. The delays with Singapore arise from the contractual agreement required between TROG (Sponsor) and National University Hospital, Singapore and National Cancer Centre, Singapore and we are actively seeking to have this resolved as soon as possible. Additional delays have also arisen from the RTQA credentialing requirements from sites, an important aspect of the trial activation, and are working closely with sites and the ACDS to ensure timely completion and TROG approval of site credentialing. In 2020, we will be aiming to open the trial to a new cohort of patients (T790M negative) via a protocol amendment but await approval from AstraZeneca before being able to implement. We expect a positive outcome from this amendment as we have had 7 screen failures due to patients being T790M negative.

Open Trial	
TROG 13.01	SAFRON II: Stereotactic Ablative fractionated radiotherapy versus radiosurgery for oligometastatic neoplasia to the lung: A randomised Phase II trial

Trial Chairperson:

Shankar Siva

Organisation: Peter MacCallum Cancer Centre

Email address: shankar.siva@petermac.org

Contact:

Kassandra Waggenfuehr

Organisation: TROG Cancer Research

Email address: SAFRONII@trog.com.au

Phase: II

Category: A

Primary Aim: To assess multi fraction versus single fraction SABR in lung metastases

Final Accrual: 90

Projected f/up end date: 31/07/2020

Publications (2019): Nil

Trial Update (2019): Primary analysis at 1 –year completed and submitted for presentation in 2020. Follow up is continuing and data cleaning ongoing and the analysis of secondary endpoints planned for late 2020. The possibility of extending the follow-up period is being explored.

Closed Trials		
TROG N°	TITLE	CAT
11.03	<p>PLUNG_GP: A Randomised Phase III trial of high dose palliative radiotherapy (HDPRT) vs Concurrent chemotherapy + HDPRT (C-HDPRT) in patients with good performance status, locally advanced or metastatic NSCLC with symptoms predominantly due to intrathoracic disease who are not suitable for radical chemo-radiotherapy</p> <p>Trial Chairperson: Margot Lehman</p> <p>Primary Aim: To compare, in this group of patients, high dose palliative radiotherapy (HDPRT) versus concurrent chemotherapy and HDPRT (C-HDPRT), with respect to The relief of dyspnoea, cough, haemoptysis and chest pain as assessed by change in total symptom burden from baseline to six weeks after the completion of treatment. Response for each component symptom separately (dyspnoea, cough, haemoptysis, chest pain)</p> <p>Final Accrual: 76/130</p> <p>Trial Update (2019): Data analysis completed. Primary and Secondary analysis report completed Oct 2019</p>	A
9.02	<p>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</p> <p>Trial Chairperson: David Ball</p> <p>Publication (2019): Ball D. Quality of life in the CHISEL randomized trial of stereotactic ablative radiotherapy (SABR) versus standard radiotherapy for stage I non-small cell lung cancer (Trans Tasman Radiation Oncology Group 09.02). Ann Oncol. 2018 Nov; 29(S9)</p>	A

Lymphoma

Trials in Development

TD 19.01	FOLSTART: A multicentre randomized controlled trial of investigator's choice systemic therapy compared with the same systemic therapy plus low dose involved-field radiation therapy in stage IIIA low grade follicular lymphoma
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Trial Chairperson:

Michael MacManus

Organisation: Peter MacCallum Cancer Centre

Email address: michael.macmanus@petermac.org

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Phase: II

Category: A

Primary Aim: To assess the effect of involved site radiotherapy after standard of care systemic therapy on short term disease control as measured by CR30 and POD24 in patients with stage IIIA follicular lymphoma.

Summary of Trial Activity:

Vote

EOI

Trial
Development Plan

Budget

Funding
Submission

Closed Trials

TROG N°	TITLE	CAT
5.02	MALT Lymphoma: A prospective single arm trial of involved field radiotherapy alone for stage I-II low grade non-gastric marginal zone lymphoma Trial Chairperson: Michael MacManus Publications (2019): MacManus M, Roos D, O'Brien P, Tsang R, Wirth A, Capp A, Bressel M, Seymour J. Results of a Multicentre phase 2 trial of involved field radiotherapy alone for localized non-gastric marginal zone lymphoma: TROG 05.02. Hematol. Oncol. 2019 Jun; 37(Suppl. 2):221-2.	A
99.03	Follicular Lymphoma: A Randomised Multicentre Trial of Involved Field Radiotherapy Versus Involved Field Radiotherapy Plus Chemotherapy in combination with Rituximab (MabThera®) For Stage I – II Low Grade Follicular Lymphoma Trial Chairperson: Michael MacManus Publications (2019): MacManus M, Fisher R, Roos D, O'Brien P, Macann A, Tsang A, David S, Christie D, McClure B, Joseph D, Seymour J. Systemic therapy after Radiation Therapy in stage I-II follicular lymphoma: Final results of an International Randomized Trial TROG 99.03. Hematol. Oncol. 2019 Jun; 37(Suppl. 2):220-1.	A

Completed Trials

TROG N°	TITLE	CAT
99.04	Osteolymphoma (OL): A Prospective, Non-Randomised Study of Chemotherapy and Radiotherapy for Osteolymphoma (OL) Trial Chairperson: David Christie Publications: Tan M, Ball D, Fisher R. Is higher institutional patient accrual volume related to longer overall survival (OS) in patients with stage III non-small cell lung cancer (NSCLC) receiving radical (chemo) radiation – using the data from the multicenter TROG 99.05 study. J Med Imaging Radiat Oncol. 2018 Oct; 62(S2):143-74.	A

Multiple Tumour Sites

Trials in Development

TD 18.07 The Australian Particle Therapy Evidence Generating Network for Rare and Difficult-to-treat cancers (Registry)

Trial Chairperson:

Verity Ahern

Organisation: Westmead

Email address: verity.ahern@health.nsw.gov.au

Contact:

TROG development

Organisation: TROG Cancer Research

Email address: Trials@trog.com.au

Phase: NA

Category: D -Registry

Primary Aim: To establish a registry for patients with rare tumours suitable for treatment by particle therapy

Summary of Trial Activity:

Vote

Eol

Trial
Development Plan

Budget

Funding
application

Open Trial

TROG 16.03 CORE: A randomised trial of Conventional care versus Radioablation (stereotactic body radiotherapy) for Extracranial oligometastases

Trial Chairpersons:

Farshad Foroudi | David Pryor

Organisation: The Austin | Princess Alexandra

Email address: farshad.foroudi@austin.org | david.pryor@health.qld.gov.au

Central Trial Coordinator:

Patrick Wheeler

Organisation: TROG Cancer Research

Email address: CORE@trog.com.au

Phase: II

Category: B (Lead Group - ICR)

Primary Aim: To evaluate if the addition of SBRT to standard therapy improves progression free survival outcomes in patients with limited burden of oligometastatic disease

Accrual (Actual / Target): 235/230 (Int) | **18/36 (TROG)**

Site status: 9 activated / 6 pending

Accrual end date: 28/02/2019

Publications (2019): Nil

Trial Update (2019): Rapid recruitment to the prostate arm, allowed the trial to close faster than anticipated (Feb 2019).

The study team has successfully negotiated a one-year extension to the Cancer Australia funding to support the trial in its transition into a phase III trial in the prostate cohort, whilst they are actively seeking further funding to support the phase III trial. However recruitment is currently on hold.

Analysis of primary endpoint is planned for Q3 2020 – timing dependent on event rate.

Symptom Management

Trials in Development

TD 18.02	PPRISM: Paediatric Palliative Radiotherapy in Single or Multiple fractions
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Trial Chairperson:
Greg Wheeler
Organisation: Peter MacCallum Cancer Centre

Contact:
TROG development
Organisation: TROG Cancer Research
Email address: Trials@trog.com.au

Phase: II
Category: A
Primary Aim: To show that single fraction treatment is as effective as multiple fractions in the palliation of paediatric malignancies.

Open Trial

TROG 17.06	SC.24: A Phase III Randomized Feasibility Study Comparing Stereotactic Body Radiotherapy (SBRT) Versus Conventional Palliative Radiotherapy (CRT) For Patients With Spinal Metastases
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Trial Chairperson:
Shankar Siva | Matthew Foote
Organisation: Peter MacCallum Cancer Centre | Princess Alexandra Hospital
Email address: shankar.siva@petermac.org | matthew.foote@health.qld.gov.au

Contact:
Rebecca Montgomery
Organisation: TROG Cancer Research
email address: SC24@trog.com.au

Phase: II
Category: B (Lead group - CCTG)
Primary Aim: To assess complete pain response in the treatment area at 3 months post-radiation.
Accrual (Current/Target): 229/228 (Intl) | 24/35 (TROG)
Projected end date: 30/04/2020
Site status: 3 pending / 1 withdrawn (Nepean)
Trial Update (2019): The remaining 5 sites were activated in 2019 and 19 participants were recruited. International accrual closed on 27/09/2019 (229/228 participants randomised), which was earlier than expected. DSMC was held on 26/11/2019 – no concerns were raised. Of the 44 patients put on study in 2019, 19 came from Australian centres (total AUS pt: 24). 2 TROG sites were in the top 10 best-recruiting centres overall; Peter Mac (3rd) and PAH (6th).

Closed Trials

TROG N°	TITLE	CAT
11.02	SCORAD III: A randomised phase III study of single fraction radiotherapy compared to multifraction radiotherapy in patients with metastatic spinal cord compression Trial Chairperson: Tanya Holt Publications (2019): Hoskin P.J, Hopkins K., Misra V, Holt T, Mcmenemin R, Dubois D, Mckinna F, Foran B, Madhavan K, Macgregor C, Bates A, O'rouke N, Lester J.F, Sevitt T, Roos D, Dixit S, Brown G, Arnott S, Thomas S.S, Forsyth S, Beare S, Reczko K, Hackshaw A, Lopes A. Effect of Single-Fraction vs Multifraction Radiotherapy on Ambulatory Status among Patients with Spinal Canal Compression from Metastatic Cancer: The SCORAD Randomized Clinical Trial. JAMA. 2019 Dec; 322(21):2084-94.	B

Category C Trials

Breast

Nº	TITLE	LEAD GROUP
NP19K	AVATAR: Stereotactic Ablative Body Radiotherapy for Oligoprogressive Luminal Breast Cancer Trial Chairperson: Steven David	VCC
TROG 17.05 NCT03464942	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 Trial Chairperson: Steven David Website: https://trials.cancervic.org.au/details.aspx?ID=vctl_nct03464942	PMCC
TROG 16.04 ANZ 1601 BIG 16-02	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 (BCT 16.01) Trial Chairperson: Boon Chua Website: www.breastcancertrials.org.au/current-clinical-trials/expert	BCT

Gastrointestinal

Nº	TITLE	LEAD GROUP
TROG 18.04 AGO118PS	MASTERPLAN: Mfolirinox And Stereotactic Radiotherapy for Pancreatic cancer with Locally Advanced disease (MASTERPLAN): randomised study from the Australian Gastrointestinal trials Group (AGITG) Trial Chairperson: Dr Andrew Oar Publication (2019): Oar A, Lee M, Le H, Hruby G, Dalfsen R, Pryor D, Lee D, Chu J, Holloway L, Briggs A, Barbour A, Chander S, Ng S, Samra J, Shakeshaft J, Goldstein D, Nguyen N, Goodman K, Chang DT, Kneebone A. Australasian Gastrointestinal Trials Group (AGITG) and Trans-Tasman Radiation Oncology Group (TROG) Guidelines for Pancreatic Stereotactic Body Radiotherapy (SBRT). Pract Radiat Oncol. Article in press. Website: https://gicancer.org.au/clinical-trial/masterplan/	AGITG
TROG 8.08 AGO0407GR	TOPGEAR: A randomised phase II/III trial of preoperative chemoradiotherapy Versus preoperative chemotherapy for resectable gastric cancer. Trial Chairperson: Trevor Leong Website: https://gicancer.org.au/clinical-trial/topgear/	AGITG

Genitourinary (Bladder, Kidney & Prostate)

Nº	TITLE	LEAD GROUP
TROG 14.01 ANZUP 1303	ENZARAD: Randomised phase III trial of radiation plus androgen deprivation therapy with or without enzalutamide for high risk, clinically localised prostate cancer (ANZUP1303) Trial Chairperson: Scott Williams & Paul Nguyen Website: https://www.anzup.org.au/content.aspx?page=trials-enzarad	ANZUP

Gynaecological

Nº	TITLE	LEAD GROUP
TROG 08.04	<p>PORTEC-3: Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma</p> <p>Trial Chairperson: Dr Pearly Khaw</p> <p>Publication (2019): de Boer S, Powell M, Mileskin L, Katsaros D, Bessette P, Haie-Meder C, Ottevanger P, Ledermann J, Khaw P, Colombo A, Fyles A, Baron M, Kitchener H, Nijman H, Kruitwagen R, Nout R, Verhoeven-Adema K, Smit V, Putter H, Creutzberg C; PORTEC study group. Adjuvant chemoradiotherapy versus radiotherapy alone in women with high-risk endometrial cancer (PORTEC-3): patterns of recurrence and post-hoc survival analysis of a randomised phase 3 trial. <i>Lancet Oncol.</i> 2019 Jul; 20(9):1273-85.</p> <p>Website: http://www.anzgog.org.au/endometrial-cancer-portec3/</p>	<p>Dutch Cooperative Gynaecologic Oncology Group</p> <p>ANZGOG</p>

Head Neck and Skin

Nº	TITLE	LEAD GROUP
TROG 17.11 R2810-ONC-1788/	<p>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</p> <p>Trial Chairperson: Danny Rischin & Sandro Porceddu</p>	REGENERON
TROG 8.09	<p>RTN2: A randomised trial of post-operative radiation therapy following wide excision of neurotropic melanoma of the head and neck</p> <p>Trial Chairperson: Matthew Foote</p> <p>Website: https://www.masc.org.au/trials.aspx?cat=1</p>	MASC Trials
TROG 12.03	<p>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.</p> <p>Trial Chairperson: Chris Wratten and Ben Britton</p> <p>Publications (2019): Britton B, Baker A, Wolfenden L, Wratten C, Bauer J, Beck A, McCarter K, Harrowfield J, Isenring E, Tang C, Oldmeadow C, Carter G. Eating As Treatment (EAT): a stepped-wedge, randomised controlled trial of a health behaviour change intervention provided by dietitians to improve nutrition in patients with head and neck cancer undergoing radiotherapy (TROG 12.03). <i>Int J Radiat Oncol Biol Phys.</i> 2019 Feb; 103(2):353-62.</p>	Newcastle University
TROG 8.05 ANZMTG 0107	<p>WBRTMel: Whole Brain Radiotherapy following local treatment of intracranial metastases of melanoma-A randomised phase III trial</p> <p>Trial Chairperson: Gerald Fogarty</p> <p>Publications (2019):</p> <ol style="list-style-type: none"> Hong A, Fogarty G, Dolven-Jacobsen K, Burmeister B, Lo S, Haydu L, Vardy J, Nowak A, Dhillon H, Ahmed T, Shivalingam B, Long G, Menxies A, Hruby G, Drummond K, Mandel C, Middleton M, Reisse C, Paton E, Steel V, Williams N, Scolyer R, Morton R, Thompson J. Adjuvant Whole-Brain Radiation Therapy Compared With Observation After Local Treatment of Melanoma Brain Metastases: A Multicenter, Randomized Phase III Trial. <i>J Clin Oncol.</i> 2019 Nov; 37(33): 3132-41. Fogarty G, Dolven-Jacobsen K, Morton R, Hruby G, Nowak A, Vardy J, Drummond K, Dhillon H, Mandel C, Scolyer R, Shivalingam B, Middleton M, Burmeister B, Lo S, Reisse C, Paton E, Steel V, Williams N, Thompson J, Hong A. Phase 3 international trial of adjuvant whole brain radiotherapy (WBRT) or observation (OBS) following local treatment of 1-3 melanoma brain metastases (MBMs). <i>J Clin Oncol</i> 37, 2019 May (suppl; abstr 9500) <p>Website: https://www.masc.org.au/trialdetails.aspx?trialno=5</p>	ANZMTG

Lung

Nº	TITLE	LEAD GROUP
TROG 16.01 ALTG 14/002	<p>NIVORAD: Randomised phase 2 trial of nivolumab and radiotherapy versus nivolumab alone in advanced non-small cell lung cancer progressing after first line chemotherapy</p> <p>Trial Chairperson: Shankar Siva</p> <p>Publications (2019): Hardcastle N, Cook O, Mitchel P, Siva S. Credentialing of spine stereotactic ablative body radiotherapy in a multi-centre trial. Radiother and Oncol. 2019 Apr; 133. S320-S21.</p> <p>Website: https://altg.com.au/altg-14002/</p>	ALTG

Lymphoma

Nº	TITLE	LEAD GROUP
TROG 3.03 ALLG HDNLHL04	<p>HDNHL04: An ALLG/TROG Prospective Multicentre Study of Involved-Field Radiotherapy with Transplantation for Patients with Hodgkin's Disease and non-Hodgkin's Lymphoma</p> <p>Trial Chairperson: A/Prof Andrew Wirth</p> <p>Publications (2019): Wirth A, Prince H, Roos D, Gibson J, O'Brien P, Zannino D, Khodr B, Stone J, Davis S, Hertzberg M. A Prospective, Multicenter Study of Involved-Field Radiation Therapy With Autologous Stem Cell Transplantation for Patients With Hodgkin Lymphoma and Aggressive Non-Hodgkin Lymphoma (ALLG HDNHL04/TROG 03.03). Int J Radiat Oncol Biol Phys. 2019 Apr; 103(5):1158-1166</p>	ALLG