TROG CANCER RESEARCH

2021 ANNUAL RESEARCH REPORT

Together, we can defeat cancer.

trog.com.au

ABOUT TROG

CANCER RESEARCH

TROG Cancer Research has been improving the way in which radiation therapy is delivered to cancer patients for over 30 years. We are one of the largest clinical cancer trial groups in Australia and New Zealand, specialising in radiation medicine clinical trials, and are renowned internationally.

All cancers, one treatment.

Our mission at TROG is to conduct world-class research in radiation medicine that leads the global effort to better control and cure cancer. We are helping improve outcomes for people affected by cancer, through the conduct of high quality, practice changing clinical trials.

OUR VALUES

COLLABORATION

We work with key stakeholders, organisations and community groups who share our aim of defeating cancer.

QUALITY & EXCELLENCE

Our research is guided by rigour, accuracy and innovative methodology.

CARE

We provide the utmost care and consideration to clinical trial participants, TROG members, staff and the general community.

EQUITY

We strive to improve access and participation in clinical trials.

INNOVATION

By being innovative in our research and embracing new technologies, we aim to be a leader in radiation medicine research.

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2021 ANNUAL RESEARCH REPORT

2021 FACTS & FIGURES

TROG Cancer Research continues to maintain a large and diverse portfolio of clinical trials across varied tumour groups. In 2021, there were **13** trials in development, **2** in start-up and **29** open. A further **70** trials were either closed or completed.

114 TRIALS CONDUCTED

190 INTERNATIONAL CANCER CENTRES

14,945
TRIAL PARTICIPANTS TO DATE

13
TRIALS UNDER DEVELOPMENT

31
ACTIVE TRIALS

70
CLOSED / COMPLETED TRIALS

UP TO **90%**
POTENTIAL CANCER SURVIVAL RATE

TROG Tumour Group Working Parties

The TROG Cancer Research Tumour Group Working Parties play a key role in the development of the TROG clinical research portfolio via horizon scanning, concept development and the working up of concepts into clinical trial protocols.

PUBLICATIONS & DISSEMINATION

246
PEER-REVIEWED MANUSCRIPTS PUBLISHED

33 ANNUAL SCIENTIFIC MEETINGS HOSTED

128 ABSTRACT PUBLICATIONS

Our team collaborates with many cancer treatment facilities. In Australia and New Zealand we have collaborated with over **100** cancer centres and hospitals.

In addition, TROG Cancer Research has collaborated with just under **90** different cancer centres and hospitals internationally, excluding Australia and New Zealand.

TROG TRIAL SPOTLIGHT: 2021

TROG 12.01 (HPV OROPHARYNX)

Randomised Trial of Radiation Therapy with Weekly Cisplatin or Cetuximab in Low-Risk HPV-Associated Oropharyngeal Cancer.

Trial Chairs: Prof Danny Rischin and Prof June Corry

Trial Management Committee: Danny Rischin, June Corry, Madeleine King, Lizbeth Kenny, Sandro Porceddu, Christopher Wratten, Andrew Macann, Ben Dixon, Ben Solomon, Stephen Fox, Alan Herschtal, Anetta Matera, Jonathan Karnon, Carl James, Jeremy Coupler.

Acknowledgements: James Jackson, Mathias Bressel, Richard Fisher, Tsien Fua, Charles Lin, Chen Liu, Brett Hughes, Margaret McGrath, Lachlan McDowell.

The main results for the TROG 12.01 trial were published in 2021. In this randomised trial, 70 Gy radiation therapy with weekly cisplatin or cetuximab was investigated in low risk human papilloma virus (HPV) associated oropharyngeal cancer (HPV-OPSCC). The results were first presented at the Annual Meeting of the American Society of Clinical Oncology in June 2021 and the manuscript was later published in the Red Journal (Int J Radiat Oncol Biol Phys. 2021 Nov 15;111(4):876-886).

The underlying hypothesis for this trial was that the two regimens would achieve similar efficacy, but that the cetuximab arm would be associated with a decrease in symptom burden and toxicity.

The trial had a novel primary endpoint of symptom severity as assessed by the MD Anderson Symptom Inventory Head and Neck (MDASI-HN) Symptom Severity Scale from baseline to 13 weeks post completion of radiation therapy using the area under the curve (AUC).

A total of 189 patients were enrolled from 15 TROG sites, with 182 being included in the main analysis. The median follow up was 4.1 years. Local laboratory p16 results were confirmed in the central laboratory in 172/172 evaluable cases and confirmed to be in situ hybridisation for human papillomavirus (HPV) messenger RNA (HPV RNA ISH) positive in 155/155 evaluable cases as previously reported (Young et al Oral Oncol. 2020 Nov;110:104988).

There was comprehensive RTQA review performed on 65 patients (65/182, 36%). There were 9 major violations in either contour or dosimetry in 8 patients, 12.3% of the RTQA population. Compliance with completion of patient reported outcomes was excellent. For the 13 timepoints where the MDASI-HN for the primary endpoint was required to be completed between baseline and week 20 (13 weeks post RT), the median completion rates were 95.7% (range 88.0 – 100%) and 97.8% (range 87.8 – 99.8%) for the cisplatin and cetuximab arms respectively.

There was no significant difference in the primary endpoint of MDASI-HN symptom severity AUC (from baseline to week 20) between the arms; difference in AUC cetuximab –cisplatin was 0.05 (95%CI: -0.19, 0.30), p= 0.66. There were also no significant differences in MDASI-HN secondary endpoints of modified symptom severity, symptom interference score, mucositis symptoms or common symptoms. There were no significant differences between the arms in the Functional Assessment of Cancer Therapy - Head and Neck (FACT-HN) total score AUC (from baseline to week 33) nor for any of the FACT-HN subscales.

Failure-free survival was superior in the cisplatin arm; the 3-year failure-free survival rates were 93% (95% CI: 86-97%) in the cisplatin arm and 80% (95% CI: 70-87%) in the cetuximab arm (HR = 3.0 (95% CI: 1.2-7.7); p=0.015. There was no significant difference in overall survival.

Patterns of first failure revealed that the increase in failures in the cetuximab arm was approximately evenly split between distant and locoregional failures. There was more radiation dermatitis and acneiform rash in the cetuximab arm and more febrile neutropenia, emesis, dry mouth and fatigue in the cisplatin arm.

Our results are consistent with two trials that compared three-weekly high dose cisplatin to cetuximab. Both RTOG 1016 and the De-ESCALaTE trials demonstrated inferior overall and progression-free survival with the cetuximab regimen, without major gains in tolerability.

These three trials have confirmed that cisplatin and radiation therapy remains the standard of care. Furthermore, these results have raised concerns about the criteria used to define low risk patients for de-escalation trials, and reinforced that caution is required in the design of future trials.

SUB-STUDIES AND FUTURE WORK

There are several TROG 12.01 substudies being conducted, including an analysis of the CD103 biomarker in the combined TROG 12.01 and De-ESCALaTE cohorts.

In this study we found that CD103 expression separates CETUX/RT treated low risk HPV-OPSCC into excellent and poor prognosis subgroups. This was an oral presentation at a Clinical Science Symposium at ASCO 2021, and the manuscript is under review.

There is a study of unilateral versus bilateral radiation therapy led by Lachlan McDowell, a radiation therapy Quality Assurance study led by June Corry, an analysis of symptom severity and quality of life trajectories led by Lachlan McDowell and a hearing outcome study led by Laurelie Wishart and Sandro Porceddu.

CANCER TRIAL PARTICIPANT HOPING TO HELP

The TROG 08.03 RAVES Trial treating prostate cancer

Participating in a clinical trial, like the TROG 08.03 RAVES Trial, often means more than just accessing new technology that could change treatment and improve quality of life outcomes.

For people like James, it's about using an understandably challenging situation to help others.

"The way it was put to me is that I could potentially help another person in a similar situation by participating and that is why I did it. If you can help your fellow human beings, why don't you?" James said.

Having not long turned 50, James thought it a good idea to see his GP for a general check-up. A round of blood tests revealed an elevated prostate-specific antigen (PSA) level. This prompted his doctor to send James for another test.

"I had a second blood test and I thought that if there was a problem, they would follow up with me," he recalls. "Nine months later when I was at the GP, I happened to mention the follow-up test results but there was nothing in my file."

With no records to be found, another follow-up test was taken which confirmed James' PSA levels remained elevated and treatment was required.

A biopsy conducted by his Urologist detected cancer in nine out of 12 needle biopsies of James' prostate.

> *With his father having previously been treated for prostate cancer, James felt confident he knew what he was facing. Unfortunately, that wasn't so.*

"Dad's prostate cancer was treated with brachytherapy and seeded gold, so I asked if that treatment option was available. My Urologist said 'No'.

"'So, I need radiation therapy or surgery?' He said yes. The advice he gave was if you have surgery you can clean up [any remaining tumours] with radiation. But by doing it the other way around and starting radiation first, it is very hard to clean up with surgery."

PROSTATE CANCER SURGERY AND THE PATH TO RAVES

"Hunter Prostate Cancer Alliance (HPCA) chatted me through the process. They put me onto a naturopath and holistic health professional to put my life back into balance and to promote a better mindset before surgery and treatment."

The surgery went ahead but the news from the Urologist during the follow-up consultation was not as positive as they had hoped. The cancer had progressed through the prostate wall. It was at this time the Urologist told James he had discussed his case with TROG Cancer Research and that he was an ideal candidate to participate in the TROG 08.03 RAVES Trial.

ABOUT THE TROG 08.03 RAVES TRIAL

The 08.03 Radiation Therapy - Adjuvant Versus Early Salvage (RAVES) clinical trial focused on two treatment methods for men who have needed a radical prostatectomy following a diagnosis of prostate cancer.

Dr Anne Capp, who was once a Radiation Oncologist recruiting patients for the RAVES trial at the Newcastle Calvary Mater Hospital, explains:

"The first option is to give radiation therapy immediately after surgery. Known as adjuvant radiation therapy, research had already shown that treating everyone immediately after surgery halved the risk of the PSA rising again.

"The second treatment option is to monitor patients' PSA levels closely and only begin radiation therapy if their PSA began to rise.

"What we wanted to know, and the ultimate aim of RAVES, was whether patients treated with active surveillance and given radiation therapy as soon as their PSA rose had the same effectiveness as a treatment compared to immediate radiation therapy given to all patients at risk of a rising PSA."

James said the TROG Cancer Research team were great to work with.

"I had the treatment over six weeks at 12:30 PM, five days a week. I left the office, had the treatment, and was able to come back to work afterwards.

> *"The team were incredibly supportive. They allowed me to be a cancer patient without compromise – I could still have a life and live it."*

TROG 08.03 RAVES TRIAL RESULTS

Between March 2009 and December 2015 TROG Cancer Research conducted a phase III, randomised, controlled, non-inferiority trial across 32 oncology centres in Australia and New Zealand.

In total, 333 patients were randomly assigned (166 to adjuvant radiation therapy; 167 to salvage radiation therapy).

"Data from the RAVES trial supports the use of salvage radiation therapy," Dr Capp said.

"It results in similar biochemical control to adjuvant radiation therapy, sparing around half of all at risk men from pelvic radiation, and is associated with significantly lower genitourinary toxicity."

A FINAL WORD FROM JAMES

James, now aged 59, had his final round of radiation therapy in July 2013 and his most recent PSA check returned a reading of 0.01 compared to a reading of 11 pre-prostatectomy.

"I never said the word 'cancer' until probably five years ago. My mindset was to stay strong-willed with everything I was going through and what everyone was helping with – I needed to stay mentally strong myself.

"A strong mental fortitude is not going to do any harm in the process of going through something like this."

A MESSAGE FROM

PRESIDENT & BOARD CHAIR

Prof Trevor Leong

Despite the challenges imposed by the COVID-19 pandemic, the past twelve months have been busy for TROG Cancer Research.

I was appointed as TROG President at the Annual General Meeting held on 14 April 2021, and although I continue to serve on the TROG Scientific Committee (TSC), the role of TSC Chair has now passed to the capable hands of A/Prof Sashendra (Sasha) Senthi.

Having served on the TSC for the past six years, Sasha is very familiar with our clinical trial portfolio, and has already implemented changes to ensure that TROG responds appropriately to the ever changing research environment.

For the TROG Board, 2021 has been particularly eventful and we welcomed several new members. Sasha Senthi joined the Board of Directors as Chair of the TSC and Dr Melissa James joined the Board as our Elected Director in New Zealand. Melissa is a Senior Consultant Radiation Oncologist at Christchurch Hospital, and with her guidance and advocacy, we aim to strengthen our engagement with New Zealand members.

Dr Keen Hun Tai joined the Board as the Royal Australian and New Zealand College of Radiologists Faculty of Radiation Oncology (RANZCR FRO) representative, and in a reciprocal arrangement, I have joined RANZCR Council as the TROG representative. Dr Hun and I know each other very well through our mutual employment at Peter MacCallum Cancer Centre, and these joint appointments will serve to strengthen collaborations between TROG and the "College". One example of this collaborative effort is the inaugural RANZCR -TROG Research Grant that was awarded for the first time in 2021. Lastly, the Board appointed Sue Naeyaert as a new Independent Director in November 2021. Sue has had an impressive career in pharma and clinical trials and we look forward to her many contributions throughout her time with us.

On 28 April, we convened the Annual Board Strategic Planning Workshop. This new initiative was implemented to monitor our performance against the TROG 2020-2023 Strategic Plan, and enable the Board to respond to changes in the clinical research environment.

Items discussed at the workshop included; relevancy of the current Strategic Plan, opportunities and threats, membership and stakeholder engagement, and succession planning. Ideas and actions

developed during the workshop formed the basis of our 'Strategic Plan Roadmap', which has been used to inform subsequent Board discussions.

At a special AGM held on 7 July, members voted to pass a Special Resolution to amend the TROG Cancer Research Constitution, which was originally drawn up in 2014. The Board felt that the rapid pace of change in business and society had resulted in sections of the TROG Constitution becoming obsolete and outdated. Furthermore, the original Constitution did not promote the level of flexibility required for TROG to respond and adapt to changing external factors. The new Constitution will improve the operational efficiency of the organisation by removing outdated references and clauses in the Constitution, and providing for a more diverse Board of Directors, including an increased number of Elected and Independent Directors. TROG has enjoyed a very productive year and I am very proud of all our staff for their many significant achievements, which will be described in greater detail in the CEO, TSC Chair, and FARM Chair reports. Some of the 2021 highlights include:

- **Successful virtual ASM;**
- **Continuing trial activity with two trials reaching accrual, 12 new clinical trial proposals submitted, and 124 participants recruited;**
- **New investigator-initiated trials developed collaboratively with other Cancer Collaborative Trials Groups;**
- **Implementing new processes for financial reporting enabling more detailed and timely reporting to the Board;**
- **Submission of Cancer Australia 'Support for Cancer Clinical Trials Program Grant'.**

On behalf of the Board of Directors, I would like to express my sincere thanks to all TROG staff, members, friends, supporters and collaborative partners for their hard work and support in 2021. I would also like to personally thank my fellow Board Directors for their guidance and perseverance during my first year as President. TROG will continue to serve its members and the cancer community.

We remain focused on conducting high quality clinically important research that responds to, and is reflective of: patient needs, changes in cancer treatments, new technologies, the research environment, and our membership.

I look forward to seeing you face to face in 2022!

A MESSAGE FROM

CHIEF EXECUTIVE OFFICER

Susan Goode

TROG Cancer Research have continued to engage in a wide range of radiation medicine clinical research despite the on-going challenges of the pandemic.

With the support of our >1500 multidisciplinary members in 2021 we were able to deliver on the majority of activities in our strategic plan.

With travel and face to face meetings limited in 2021 due to the COVID pandemic TROG Central Operations Office continued business in the "new normal" and invested considerable time and effort to refine essential information technology infrastructure. We developed a new TROG website and member portal, implemented our new member database and commenced development of an internal trial management database.

In addition, we conducted a detailed review and needs analysis to future proof our Radiation Therapy Quality Assurance platform, processes and tools.

> *This review highlighted some great opportunities to integrate and expand our research infrastructure to create a data pipeline to support data ingest from a wider range of sources such as clinical registries.*

A proposal has been developed with a team of expert TROG Cancer Research investigators to seek funding for this infrastructure with several grant submissions in process.

Our 2021 Annual Scientific Meeting (ASM) was once again held as a fully virtual meeting due to the limitations of the COVID pandemic, however with advanced planning the virtual meeting was a great success. Thanks to our ASM co-convenors (Dr Renee Finnigan and Dr John Shakeshaft), the Encanta Event Management team and the ASM Program Committee we had more than 70 speakers, upwards of 260 delegates and 10 sponsors/exhibitors.

As we continue to work from home most of the time and meet virtually, TROG took the opportunity to host our inaugural TROG Concept Development Workshop in December 2021. The virtual platform enabled participation from all over Australia and Singapore with 13 new concepts workshopped by over 20 participants.

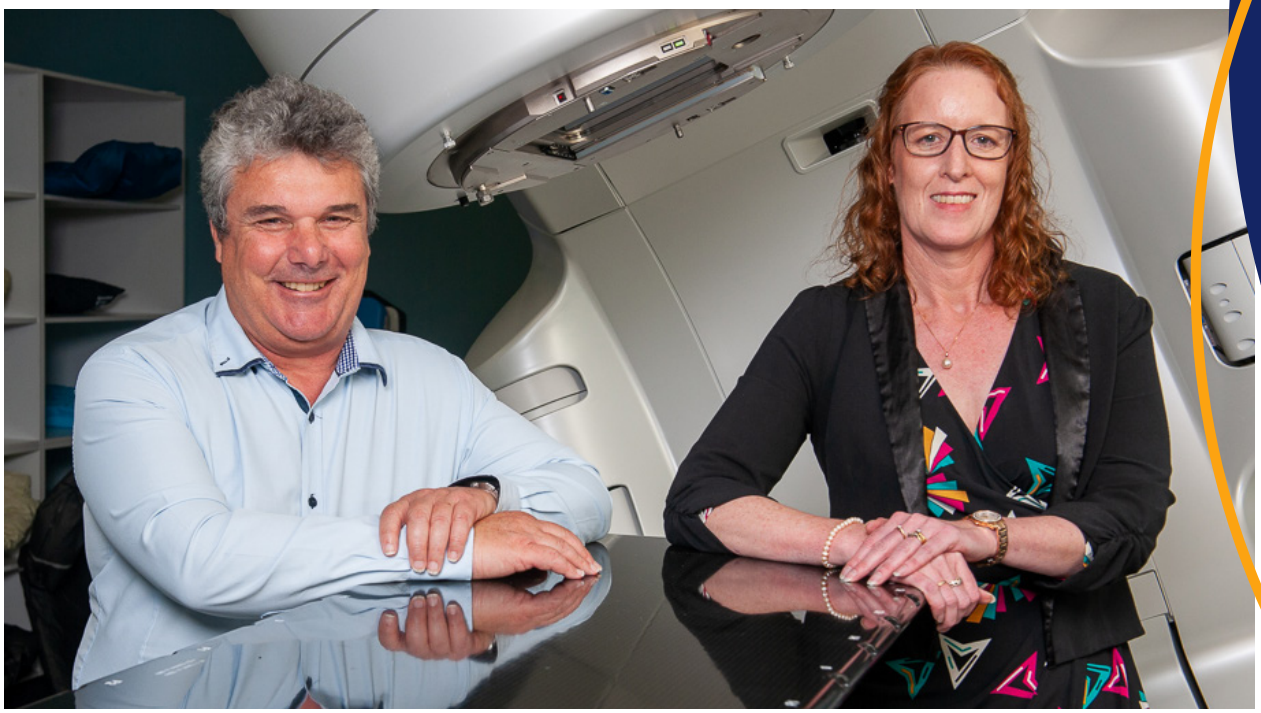
A special thanks to Chris Brown who guided participants through the clinical trial development process and to our wonderful team of TROG expert mentors (A/Prof Puma Sundaresan, Prof Trevor Leong, A/Prof Sasha Senthi, Prof Farshad Foroudi and Dr Yu Yang Soon).

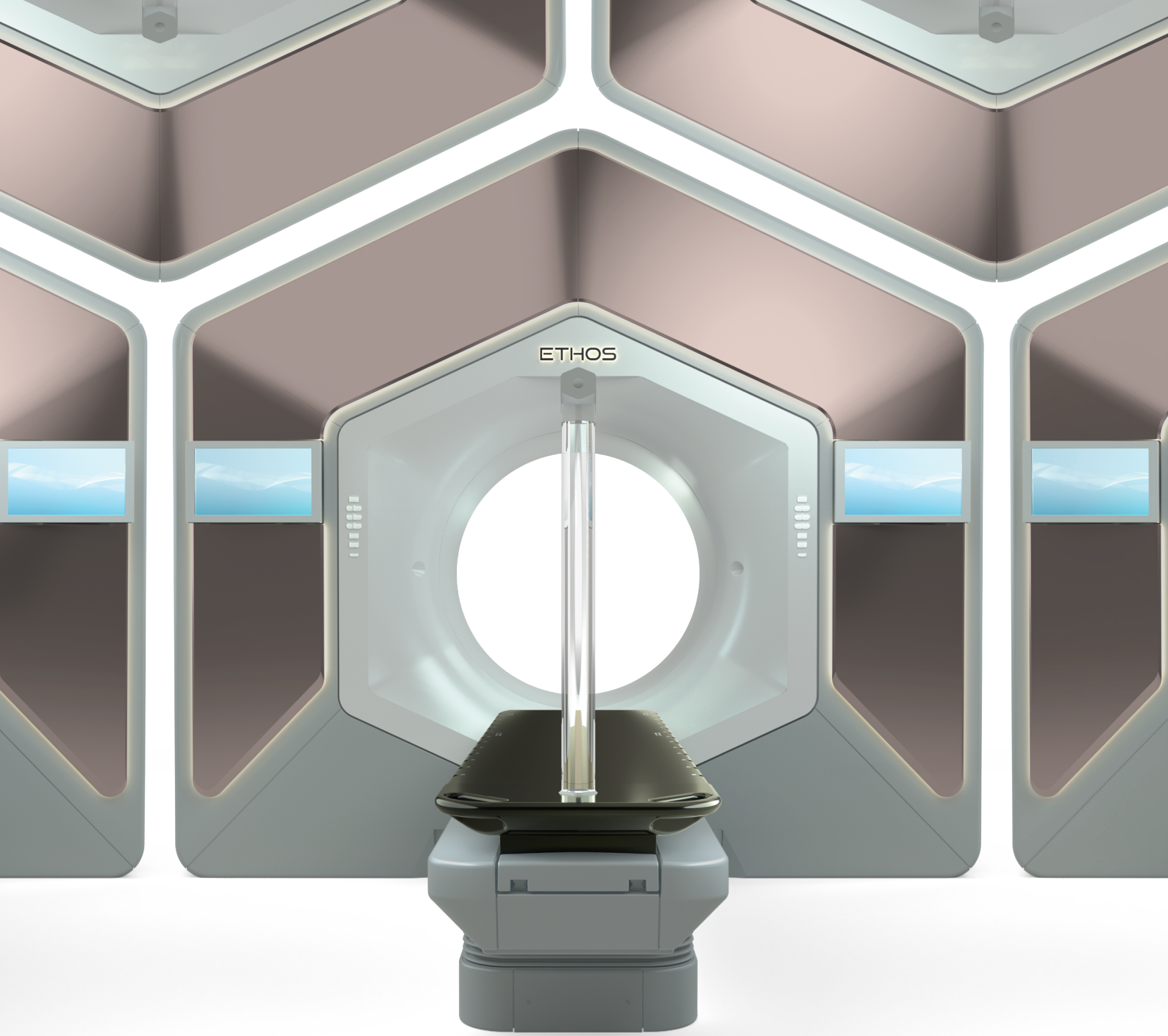
TROG is pleased to receive clinical trial support grant funding from Cancer Australia which provides TROG with essential infrastructure to support the development of investigator initiated clinical trials.

The current funding cycle finished in December 2021. In October 2021, TROG made a submission to Cancer Australia for a new clinical trial support grant which was successful and will be implemented the following year.

I am very pleased at the strong research collaborations that TROG continues to grow both nationally and internationally. We are actively collaborating on clinical trials with a number of Australian Cancer Collaborative Trials Groups including AGITG, ANZGOG, ANZUP, BCT, MASC, and TOGA. Internationally we continue to partner with a number of aligned organisations including the Breast International Group, Global Harmonisation Group, International Atomic Energy Agency and the Head and Neck Cancer International Group.

Once again, I am indebted to the amazing commitment and talents of our TROG team, including our expanding team of TROG staff, investigators, site staff, members and trial participants, all of which contribute to our success as a whole and help us to achieve our mission of improving outcomes for those affected by cancer.





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RADIATION THERAPY QUALITY ASSURANCE 2021 PROJECTS UPDATE

TROG's Radiation Therapy Quality Assurance (RTQA) program provides the framework to monitor radiation therapy protocol compliance and clinical trial data quality.

Advanced techniques and technology in radiation oncology continue to evolve, which in turn requires the TROG RTQA team to remain dynamic and nimble. The RTQA team collaborate on a range of special projects. Some highlights from 2021 include:

CQMS REDEVELOPMENT

TROG is pleased to announce that the Central Quality Management System (CQMS) is undergoing a major redevelopment to improve functionality and user experience. The TROG Central Quality Management System (CQMS) is a custom-built web based application developed for TROG over 10 years ago. It is used to manage and coordinate TROG's radiation therapy quality assurance and imaging activities. Radiation oncology techniques and technology has evolved significantly over this period and the application needs re-development to keep pace with these changes.

Future (and current) trials require significant infrastructure to support:

- **Large and complex imaging datasets**
- **Better integration and automation with TROG's 3D QA review software**
- **The incorporation of artificial intelligence and machine learning**
- **Improved efficiency of centralised reviews and analysis.**

A new responsive web application is being created to provide a far better user experience in both speed and functionality. TROG is investing in this important infrastructure. Initial scoping and gap analysis has been performed this year. 2022 will see this critical redevelopment continue to progress.

AusCAT (FORMERLY OzCAT)

Australian Cancer Data Network: distributed learning from clinical data

After receiving funding through the Australian Research and Data Commons (ARDC) Data Platforms grant round in 2020, the AusCAT team have continued to work on establishing a nationally agreed capability to link regular treatment (clinical practice) data and clinical trial data, for machine learning analysis. The data analysis is performed wherever the data resides, allowing learning across jurisdictions.

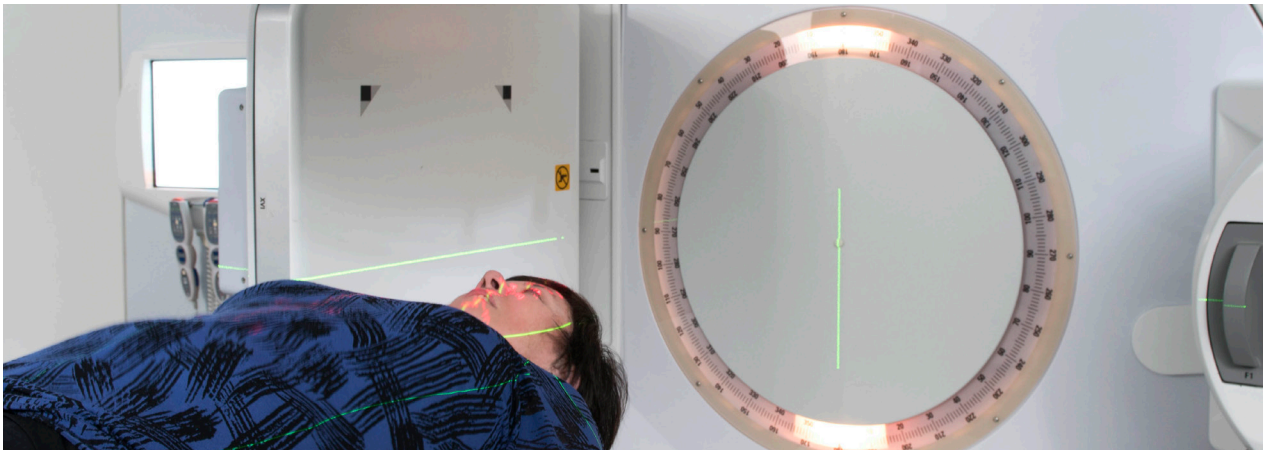
In 2021, a new server was installed at TROG, where an AusCAT node is being established. TROG will continue to work with the AusCAT team in 2022 and beyond to fully realise this important resource, which will improve the findability, accessibility, interoperability and reusability of TROG Cancer Research clinical trial data.

TROG STANDARDISED NAMING AND CONTOURING GUIDELINES

The Global Harmonisation Group (GHG) is a collaborative effort between the major clinical trial quality assurance offices worldwide to harmonise and improve radiation therapy quality assurance for multi-institutional cooperative clinical trials. Currently five organisations make up the core of the Harmonisation Group. They are EORTC, IROC, TROG, JCOG and RTTQA. TROG was delighted to have Prof Joerg Lehmann Chair the group in 2020/2021. In 2020, the GHG worked collaboratively to publish organ at risk delineation for radiation therapy clinical trials: Global Harmonisation Group consensus guidelines.

In 2021, TROG integrated these consensus guidelines (along with the American Association if Physicists in Medicine [AAPM] Task Group 263 report) into our clinical trial templates and procedures: TROG Standardised Naming and Contouring Guidelines. These guidelines form an important part of TROG clinical trials, promoting standardisation, facilitating data pooling and quality assurance activities.

Acknowledgements: We extend a sincere thanks to the efforts of the TROG New Techniques and Technologies Committee in the development of this document.



SOFTWARE

Software plays a huge role at TROG, particularly in TROG's radiation therapy and imaging quality assurance program.

Some highlights from 2021 include:

MIM Software: MIM has been a long-time supporter and software partner for TROG. MIM software continues to be used as TROG's primary 3D QA review software platform. In 2021, TROG increased the number of MIM licenses in support of the TROG 18.06 FIG trial, which has significantly bolstered overall infrastructure.

Elekta ProKnow: In 2021, TROG welcomed ProKnow software. ProKnow is a cloud-based platform, which allows TROG to store and interrogate large cohorts of data. TROG was successful in obtaining a $10,000 grant through Tour de Cure to facilitate the import of radiation therapy planning and imaging data into the platform. As well as being an important and powerful data warehouse, TROG continues to host Plan and Contour Accuracy Challenge via the ProKnow platform as part of the Technical Research Workshop (held in conjunction with the Annual Scientific Meeting).

Varian RapidPlan: Knowledge-based Planning (KBP) A novel approach to TROG RTQA methods was ongoing in 2021 using Varian's RapidPlan software. Knowledge-Based Planning (KBP) is being used to provide a systematic method for patient-specific qualitative feedback. TROG trials in the pilot program include: TROG 15.01 SPARK, TROG 15.03 FASTRACK II, TROG 17.03 LARK and TROG 18.01 NINJA. In 2021, initial findings from the use of knowledge based planning in the TROG 15.03 FASTRACK II trial were published. We expect the full outcome of this project to be reported on in 2022/2023.

Radformation ClearCheck: ClearCheck is a plugin to Eclipse and functions as automated plan evaluation software. In 2021, we implemented ClearCheck for customised reporting as part of the KBP qualitative feedback project.

VIRTUAL EPID STANDARD PHANTOM AUDIT (VESPA)

Principal Investigator (PI): Prof Peter Greer

In 2021, VESPA critically underpinned TROG's credentialing program, particularly for participating international centres. VESPA is a novel remote method for external dosimetric Treatment Planning System (TPS)-planned auditing of intensity modulated radiation therapy (IMRT) and volumetric modulated arc therapy (VMAT) using an electronic portal imaging device (EPID).

Evidence of an independent dosimetric audit is an essential requirement for participation in TROG trials. Many centres struggle to meet this requirement (particularly outside of Australia) due to a range of factors including availability, cost and time. In 2021, VESPA supported the participation of multiple international centres across a range of trials and countries. TROG greatly appreciates the continued efforts and support of Prof Peter Greer in the provision of this service.

TROG SCIENTIFIC COMMITTEE

A MESSAGE FROM THE TSC CHAIR

A/Prof Sashendra (Sasha) Senthi

Despite the continuation of the pandemic with more lockdowns and strains on the healthcare system, 2021 saw a record year for TROG and the TSC with;

1. 17 proposals submitted, reviewed, and accepted (5 Category A, 2 Category B, 5 Category C and 5 Category D (Secondary analysis)
2. The formation of the Central Nervous System Working Party (under the guidance of the Chair A/Prof Mark Pinkham and A/Prof Eng-Siew Koh)
3. The inaugural TROG Concept Development Workshop was held on 4th December 2021. 16 participants from a range of disciplines (Scientists, Interventional Radiologists, Radiation Therapists, Physicists and Radiation Oncologists) worked up 13 ideas with guidance from TROG faculty members. We look forward to running more development workshops with an even better format, to support new proposal development in 2022.
4. More than 3 million dollars awarded in funding. Congratulations to:

- Dr Eric Hau & A/Prof Paul Mitchell for being awarded Astra Zeneca Externally Funded Scientific Research funding and support for TROG 20.01 CHEST RT.
- Prof Trevor Leong and Susan Goode for the Cancer Australia Support for Cancer Clinical Trials Program – provided for capacity building support to develop cancer clinical trial protocols.
- Alisha Moore and the TROG RTQA department for being awarded Tour-De-Cure funding for a National Cancer Imaging Databank.

OTHER 2021 HIGHLIGHTS

TROG 18.01 NINJA

Novel Integration of New prostate radiation therapy schedules with adJuvant Androgen deprivation - has seamlessly transitioned from phase II to phase III trial, reaching over 150 participants. (Trial Chairs: Prof Jarad Martin, Calvary Mater Hospital, NSW and Dr Mark Sidhom, Liverpool Hospital, NSW).

TROG 12.01 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 - was published and presented at ASCO (Trial Chairs: Prof Danny Rischin, Peter MacCallum Cancer Centre, VIC and Prof June Corry, GenesisCare St Vincent's Hospital, VIC)

For patients with low risk HPV associated oropharyngeal cancer, radiation therapy and cetuximab had inferior failure-free survival without improvement in symptom burden or toxicity compared to radiation therapy and weekly cisplatin. Radiation therapy and cisplatin remains the standard of care.

TROG 13.01 SAFRON II

Stereotactic Ablative Fractionated Radiation Therapy versus Radiosurgery for Oligometastatic Neoplasia to the Lung – was published and presented at ESTRO (Trial Chair: A/Prof Shankar Siva, Peter MacCallum Cancer Centre, VIC).

For patients with pulmonary oligometastases, treating with Single Fraction (28Gy) or Multi Fraction (48Gy/4#) was both safe, effective, and didn't impact of quality of life. Single fraction SABR is more efficient to deliver, therefore may be preferred from a resource and patient perspective.

TROG 20.01 CHEST RT

A trial of Chemotherapy and Immunotherapy in Extensive-Stage Small-Cell Lung Cancer with Thoracic Radiation Therapy.

The trial was activated at three hospitals in 2021 (Trial Chairs: Dr Eric Hau, Westmead Hospital, NSW and A/Prof Paul Mitchell, Austin Hospital, VIC).

TROG 19.06 DECREASE

Darolutamide + Consolidation Radiation Therapy in Advanced prostate Cancer Detected by PSMA, was opened at five centres, and enrolled 10 participants in 2021 (Trial Chairs: A/Prof Shankar Siva and A/Prof Arun Azad, Peter MacCallum Cancer Centre, VIC).

See pages 45 - 46.

TROG 09.03 MP3

A phase II efficacy study of chemo-radiation therapy in PET stage II and III Merkel cell carcinoma of the skin – achieved completion of follow up for all participants (Trial Chairs: Prof Michael Poulsen, ICON North Lakes, QLD and Dr Andrew Pullar, Princess Alexandra Hospital, QLD).

TROG 16.02 Local HER-O

A Phase II study of local therapy only (stereotactic radiosurgery and/or surgery) for treatment of up to five brain metastases from HER2 positive Breast Cancer – achieved completion of follow up for all participants (Trial Chair: Dr Claire Phillips, Peter MacCallum Cancer Centre, VIC).

EORTC 1308 | TROG 15.03 ROAM

Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial.

This international trial completed accrual of 157 participants in Q2 2021. 10% of the participants were recruited from TROG sites (TROG Chairs: Dr Gail Ryan and Dr Neda Haghighi, Peter MacCallum Cancer Centre, VIC).

See page 47 for a breakdown of TROG's research portfolio as of 31 December 2021.

TROG SCIENTIFIC COMMITTEE MEMBERSHIP

I was appointed TSC Chair by the TROG Board in June 2021 when Prof Trevor Leong stepped down as the TSC Chair. Trevor joined the TSC in October 2013 as a representative for radiation oncology and was the TSC Chair from March 2018 - June 2021. I would like to thank him for his leadership and guidance.

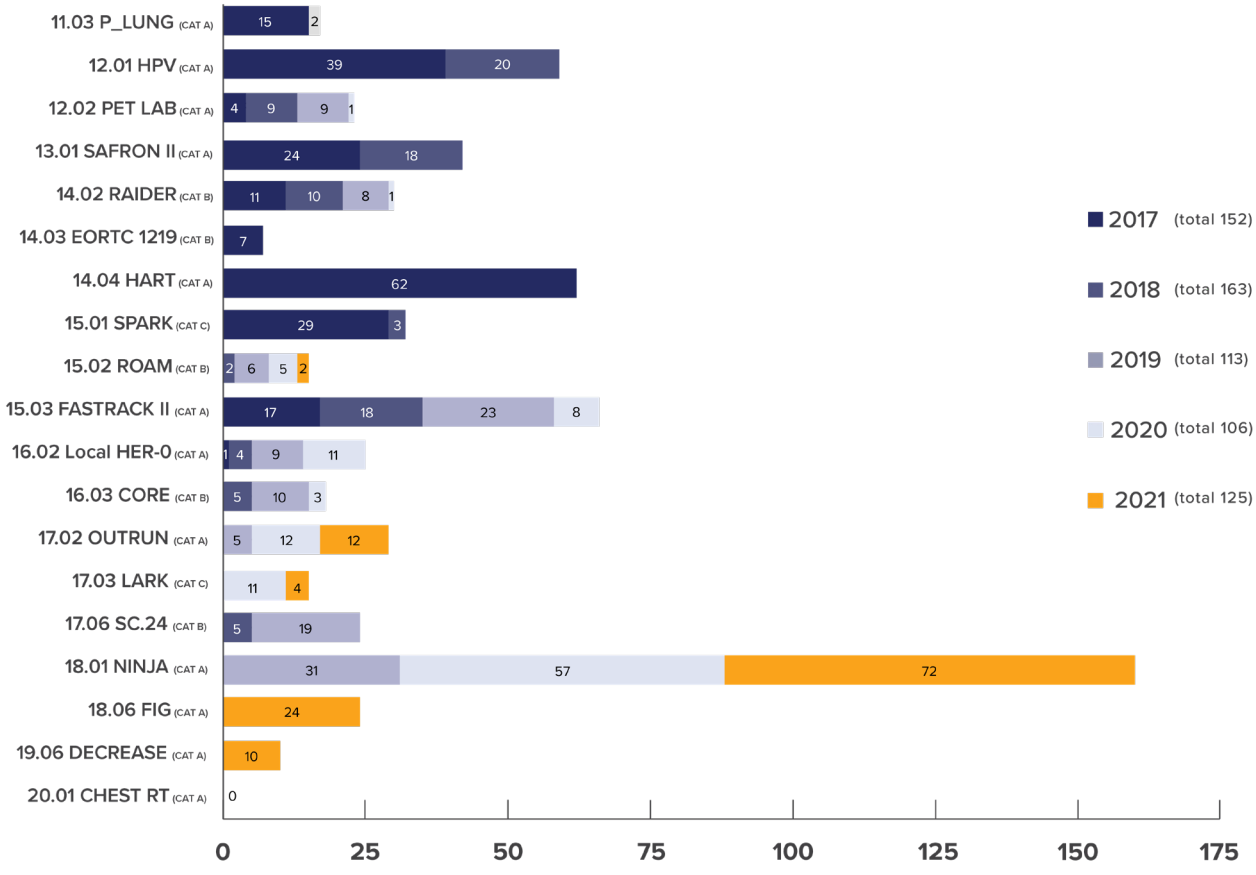
The TSC welcomed Dr Yoo Young (Dominique) Lee in September as the new discipline representative for radiation oncology. She has a strong interest in clinical research with a particular focus on stereotactic ablative radiation therapy (SABR) and represents RANZCR in Cancer Australia's National Pancreatic Cancer Roadmap Steering Group. Her specialty areas include lymphoma, gastrointestinal, hepatobiliary, skin cancers, and palliative care.

I would like to thank all members of the TSC for their enormous efforts during the year, particularly as much of this work is performed on a voluntary basis. My thanks also extend to the members of the various subcommittees that report to the TSC including the five TROG Working Parties (Breast, Central Nervous System, Genitourinary, Head, Neck and Skin and Lung), New Techniques and Technologies Committee, Independent Data and Safety Monitoring Committee, TROG Publications Committee, and the Secondary Data Analysis Committee.

Finally, I would like to extend my thanks to the entire TROG central office team for their unwavering commitment to this cause despite all the challenges this year brought.

TROG ACCRUAL OVER THE LAST 5 YEARS (2017-2021)

Over the last 5 years, 659 participants have joined a TROG lead trial. This graph shows the breakdown of participation each year per trial between 01/01/2017 – 31/12/2021



A MESSAGE FROM THE

FINANCE AUDIT & RISK MANAGEMENT COMMITTEE

Dr Tim Kuypers

The impact of COVID-19 on TROG remained a key focus of the Finance Audit & Risk Management Committee (FARM) in 2021.

The FARM, a sub-committee of the Board, increased its oversight of financial performance and forecasting to ensure the financial impacts of the unfolding pandemic were well understood and mitigated where possible.

Despite the financial impacts of slower clinical trial activation, slower patient accrual, and a reduced ASM programme due to the pandemic; the overall financial outcomes for 2021 were strong.

The results were underpinned by a continued focus by TROG Management on sensible cost control, and revenue support from the Government and bequests.

Outside of the pandemic impacts, the FARM was focused on appropriate cost recovery for Central Trial Coordination Services and Radiation Therapy Quality Assurance Services.

TROG has made significant improvements in measuring and monitoring financial performance at an individual trial level, and it is anticipated that this will provide a solid basis for improving fee for service financial performance in coming years.

I would like to thank the TROG central office team for their efforts and hard work during another difficult and challenging year.

I would also like to acknowledge my fellow FARM members and particularly thank the retiring members, Rob Ferguson and Denis Byron for their support and insights over a number of years.

FINANCE REPORT

TROG 2021

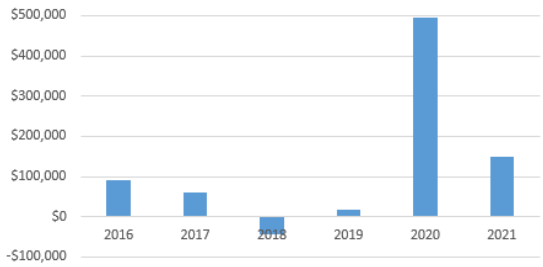
TROG delivered a surplus of $149,133 for 2021, which was a strong result given the challenges of the COVID-19 pandemic.

Revenue was $2.5m which is 16% lower than the previous year. The decline was mainly due to a reduction in Government pandemic support. Underlying revenue was again constrained by the impact of the pandemic on new clinical trial activity and patient accrual, although there was an encouraging increase in the income from Radiation Therapy Quality Assurance Services.

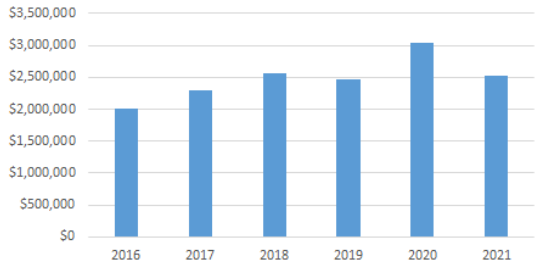
2021 total revenue benefited from continued Government pandemic support and a significant bequest of $163,000.

Cost management remained a focus for TROG, and there was a 6% reduction in total expenditure with employee expenses remaining flat, and a 13% reduction in administration expenses.

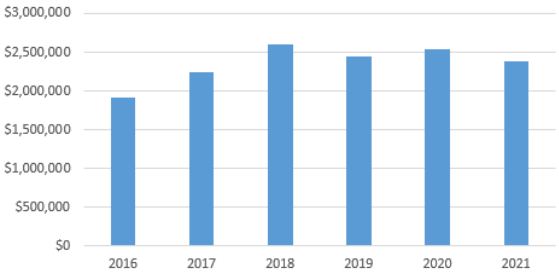
The surplus generated in 2021 adds to TROG's accumulated surplus (reserves for meeting future obligations and challenges). This is welcome given the ongoing challenges created by the pandemic and as government support is reduced there is potential for these reserves to be partially expended.



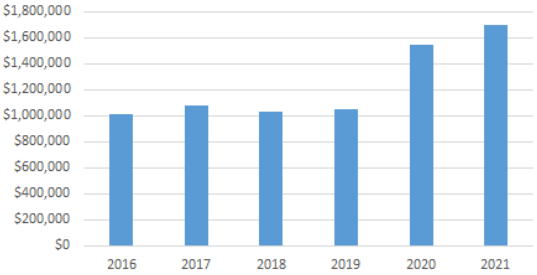
ANNUAL SURPLUS



TOTAL REVENUE



TOTAL EXPENDITURE



ACCUMULATED SURPLUS

BOARD OF DIRECTORS

TROG 2021

Prof Trevor Leong

Board Chair

Prof Trevor Leong is the President and Chair of TROG's Board and is a past Director of Radiation Oncology at Peter MacCallum Cancer Centre in Melbourne. As a Consultant Radiation Oncologist he is internationally recognised as a leader in the management and research of gastrointestinal cancers, and is an active clinician researcher engaged in both translational research programs and clinical research. Trevor holds Professorial appointments at the University of Melbourne and Monash University.

Trevor has been involved with TROG activities for almost 20 years in the positions of Trial Chair, member and Chair of the TROG Scientific Committee and Board Director, as well as being a key contributor to clinical trial radiation therapy quality assurance.

A/Prof Sashendra (Sasha) Senthi

Scientific Committee Chair

A/Prof Sashendra (Sasha) Senthi is a Radiation Oncologist with both public and private appointments at Alfred Health in Melbourne and ICON Cancer Care respectively. He has a PhD in the use of Stereotactic Radioation Therapy and a Masters in Public Health from Harvard University.

As an A/Prof at Monash University he started a biobank and co-supervises a laboratory looking for biomarkers of response and toxicity to radiation therapy and immunotherapy combinations. As Chair of the TROG Scientific Committee he strives to make it easier than ever for investigators to initiate trials and gain funding for radiation therapy research.

Dr Fiona Hegi-Johnson

Full Member Director

Dr Fiona Hegi-Johnson is a Radiation Oncologist at the Peter MacCallum Cancer Centre in Melbourne and a Senior Research Fellow at the University of Melbourne. Fiona specialises in the treatment of patients with lung, breast, and head and neck cancer and is an active clinical trial investigator. She is Chair of the TROG Lung Subspecialty Working Party and a current member of the TROG Finance, Audit, and Risk Management Committee.

A/Prof Puma Sundaresan

Full Member Director

A/Prof Puma Sundaresan is a Consultant Radiation Oncologist at Western Sydney Local Health District and a clinical academic with the University of Sydney. Puma has sub-specialty interests in head and neck, lower gastrointestinal and haematological malignancies, and research interest in clinical trials, survivorship, treatment-related decision making and quality indicators in cancer care.

She is the Board Chair of Head and Neck Cancer Australia, a Council Member for COSA, and a Management Advisory Board Member for CST. In addition, she is Associate Editor for JMIRO, the official journal of the RANZCR, and is a current member of the TROG Scientific Committee.

Prof Annette Haworth

Full Member Director

Prof Annette Haworth specialises in field of Medical Physics and is the Director of the Institute of Medical Physics at the University of Sydney.

She has over 20 years of hospital-based clinical experience and has been involved in TROG Cancer Research activities for over 15 years.

Annette has been a member of the New Techniques and Technologies Committee, the TROG Scientific Committee, the Radiation Therapy Quality Assurance Team, a representative on the Global Harmonisation Group, and a member of multiple Trial Management Committees. Annette received a Life Member Award from TROG in 2018 in recognition of her contribution to the organisation.

Dr Keen Hun Tai

RANZCR Representative

Dr Keen Hun Tai is a Consultant Radiation Oncologist at Peter MacCallum Cancer Centre in Melbourne. He specialises in the management of genito-urinary cancer and has been involved in many collaborative efforts in clinical trials. Keen Hun is Dean of the Faculty of Radiation Oncology, Royal Australian and New Zealand College of Radiologists (RANZCR), also serving on RANZCR's Board of Directors. In addition, Keen Hun is a member of the Australian Institute of Company Directors (AICD).

Dr Tim Kuypers

Independent Director

Dr Tim Kuypers is an experienced economic regulatory professional and senior executive with significant expertise in the highly regulated industries of transport and telecommunications. Tim is the Founder and Principal of Walbrook Partners rail safety consulting firm and a Special Advisor for HoustonKemp Economists. An experienced Non-Executive Director, he holds positions at the Rail Industry Safety and Standards Board Australia and Metro Trains Melbourne. He is also a graduate of the Australian Institute of Company Directors (AICD) and the Chairperson of the TROG Finance, Audit, and Risk Management Committee.

Mr Denis Byron

Independent Director

Mr Denis Byron is a Fellow of CPA (Certified Practicing Accountants) Australia and a retired CEO with extensive experience in the aged care, primary health, and not-for-profit sectors. He is also a member of the Australian Institute of Company Directors (AICD). Denis brings a wealth of experience to the TROG Board as an Independent Director with a keen interest in governance, and is a current member of the TROG Finance, Audit, and Risk Management Committee.

Mr Rob Ferguson

Independent Consumer Representative

Mr Rob Ferguson is a Consumer Representative for cancer patients at St Vincent's Hospital Kinghorne Cancer Centre and a Telephone Support Group Counsellor at Cancer Council NSW. Rob has previously held senior leadership roles including Chair of Muscular Dystrophy Foundation Australia, President of Muscular Dystrophy NSW, and a Director of Colliers International. Rob is passionate about consumer advocacy and is a current member of the TROG Finance, Audit, and Risk Management Committee.

Dr Melissa James

Full Member Director, NZ

Dr Melissa James is a Radiation Oncologist at Canterbury District Health Board in Christchurch, New Zealand. Melissa has sub-specialty interests in brain, breast, and skin cancers and has been involved in the TROG Genitourinary Working Party and Breast Working Party. Engaging with TROG since her days as a registrar, Melissa is passionate about expanding TROG's activities in New Zealand to provide better patient outcomes in the future.

Mrs Sue Naeyaert

Independent Director

Mrs Sue Naeyaert is an experienced international executive in the pharmaceutical industry and joined the TROG Cancer Research Board as an Independent Director in 2021. She has worked in research as a health economist and in outcomes research in various cancers, and currently consults to the pharmaceutical industry. Sue has previously held board positions internationally and is passionate about quality care for cancer patients.

Research is in Icon's DNA

Icon Group is Australia's largest dedicated cancer care provider and conducts the nation's leading private cancer clinical trials portfolio. Icon operates in Australia, New Zealand, Singapore, Mainland China and Hong Kong and is committed to delivering the best care possible, to as many people as possible, as close to home as possible.

RESEARCH AND CLINICAL TRIALS:

- 35 years' experience in delivering clinical trials across medical oncology, haematology and radiation oncology
- 90 principal investigators actively involved in over 300 trials across 14 Icon centres
- Works with over 200 industry collaborators
- A growing national Investigator Initiated Trials portfolio:
  - Established national IIT framework
  - Leading new and emerging radiation medicine and technical research
  - International partnerships collaborating on global registries

View list of Icon Australia's current clinical trials

icongroup.global

OUR PEOPLE

TROG 2021

COLLABORATIVE GROUP SERVICES

TROG Cancer Research Collaborative Group Services provide oversight for the sponsorship of clinical trials and clinical research projects. This may be in conjunction with or independent of TROG specialist Central Trial Coordination and Radiation Therapy Quality Assurance Services.

Collaborative Group Services enables TROG to provide specialist support to members through grant administration, collaborative trial insurance and indemnity, comprehensive legal contracting, financial remuneration, regulatory compliance and reporting.

Additionally, Collaborative Group Services provides central activities that support the conduct of clinical research, including the facilitation of an Independent Data and Safety Monitoring Committee (IDSMC) which supports all the clinical trials in the TROG portfolio.

RESEARCH DEVELOPMENT

TROG Cancer Research fosters and promotes the design of high-quality investigator-initiated cancer collaborative clinical trials involving radiation. The Research Development team supports proposals throughout their development from a new concept or idea to a complete robust protocol, ensuring peer-review and value add as the proposal progresses along the TROG new proposal pathway by:

- **Providing expert review of trial concepts and protocols via the TROG sub-specialty working parties, subcommittees (New Techniques and Technologies Committee, Secondary Data Analysis Committee) and/or special interest groups, Cancer Australia funded national technical services (quality of life, health economics and genomics) and TROG Scientific Committee.**
- **Developing trial budgets.**
- **Supporting applications for research funding.**
- **Developing clinical trial protocols.**
- **Providing access to the suite of TROG essential trial document templates, including protocol, PICF and the site activation pack.**
- **Providing database development services and advice.**
- **Promoting collaboration between other Collaborative Cancer Trial Groups and international organisations.**
- **Conducting Radiation Medicine specific concept development workshops.**
- **Collaborating with other Collaborative Cancer Trial Groups on tumour specific concept development workshops.**

New trial proposal applications are accepted for consideration at any time throughout the year.

RESEARCH OPERATIONS

The Research Operations team oversee the management of our clinical trials from start-up to completion within the TROG Central Trial Coordinating Centre. The Operations team works closely with investigators to coordinate all aspects of the clinical trial activities during the life cycle of a trial until closeout and publication.

TROG Research Operations provides comprehensive clinical trial coordination and oversight, including:

- **Expert central trial coordination.**
- **Data management and oversight.**
- **Support for participating sites.**
- **Facilitation of patient recruitment.**
- **Risk based monitoring to ensure patient safety and data integrity.**
- **Ensuring regulatory compliance.**
- **Ensuring reporting requirements are met.**
- **Providing administrative support to Trial Chair and Trial Management Committee.**
- **Ensuring oversight by TROG Working Parties, TSC and TROG Publication committee for the trial duration.**

RADIATION THERAPY QUALITY ASSURANCE

TROG's Radiation Therapy Quality Assurance (RTQA) program provides the framework to monitor radiation therapy protocol compliance and clinical trial data quality. Our RTQA Program is integral to ensuring data accuracy so that reliable trial results can be published and adopted into clinical practice. Together with the Research Operations team, the RTQA team also ensures that safety issues for participants on trial are expediently identified and rectified.

TROG continues to actively collaborate with national and international experts as well as lead and contribute to international standards and best practice in the management and incorporation of new and complex techniques and technology in radiation medicine.

Technologically advanced software and procedures are continually being incorporated into TROG's RTQA program. In doing this, we ensure our members and collaborators have access to the best available resources for conducting research involving radiation medicine. The TROG RTQA team actively supports clinical trial activities through:

- **The development of robust risk-adapted radiation therapy quality assurance programs.**
- **The development of radiation therapy planning, delivery and quality assurance guidelines; with periodic review.**
- **Facilitation of the New Techniques and Technologies Committee and Sub-committees including the development of guidelines and recommendations.**
- **Monitoring feedback on protocol compliance and radiation therapy plan quality.**
- **Data management and oversight.**
- **Support for participating sites.**
- **Maximising collaborative efforts to ensure TROG maintains high standards and responds to changing national and international best practice.**
- **Ongoing horizon scanning and forward planning.**

BUSINESS SERVICES

TROG Cancer Research conducts a range of essential business functions, including information technology, events management, financial management, human resource management, governance, Board management, regulatory compliance, and communication and marketing services in support of our staff, members and research portfolio.

Major projects in 2021 included the development of a Trial Management Database as an internal project management tool and the development of a new TROG website, together with streamlined member application processes. We continue to review the most efficient mechanisms to fulfil these business functions with the following services outsourced during 2021:

NewtonGreen Technologies

INFORMATION TECHNOLOGY

HR ASSURED smarter workplace solutions

HUMAN RESOURCES AND WORK HEALTH AND SAFETY

encanta event management

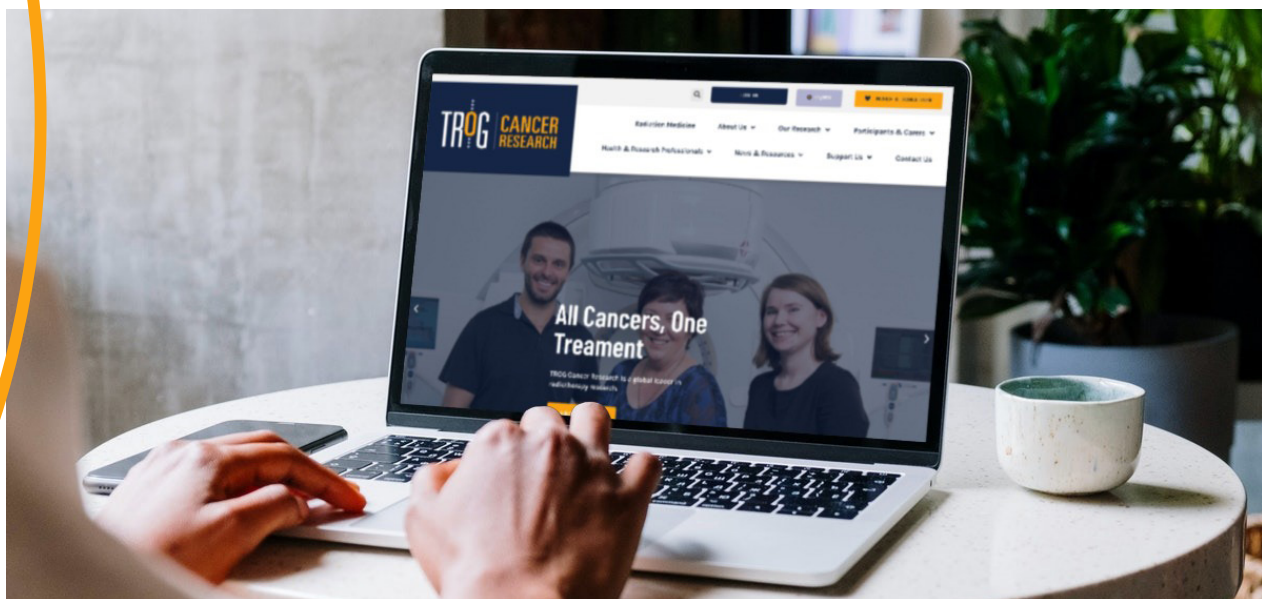
ASM EVENT MANAGEMENT

THE MARKETING GP

COMMUNICATIONS AND MARKETING

Cutcher&Neale ACCOUNTING AND FINANCIAL SERVICES

FINANCIAL AUDIT



SCIENTIFIC COMMITTEE

TROG 2021

DIRECT BOARD APPOINTED POSITIONS

POSITION	NAME
Scientific Committee Chair *(until June 2021)*	Prof Trevor Leong Peter MacCallum Cancer Centre
Scientific Committee Chair *(as of June 2021)*	A/Prof Sashendra (Sasha) Senthi The Alfred Hospital

APPOINTED POSITIONS

POSITION	NAME
Radiation Oncology	A/Prof Puma Sundaresan Westmead Hospital
Radiation Oncology *(until June 2021)*	A/Prof Sashendra (Sasha) Senthi The Alfred Hospital
Radiation Oncology	Prof Michael MacManus Peter MacCallum Cancer Centre
Radiation Oncology *(as of June 2021)*	Prof Trevor Leong Peter MacCallum Cancer Centre
Radiation Oncology *(as of September 2021)*	Dr Yoo Young (Dominique) Lee Princess Alexandra Hospital
Radiation Therapy	Ms Shivani Kumar Liverpool Hospital
Medical Oncology	Dr James Lynam Calvary Mater Newcastle
Interventional Oncology	Dr Jonathan Tibballs Sir Charles Gairdner Hospital

APPOINTED POSITIONS CONT.

POSITION	NAME
Statistics	Mr Chris Brown NHMRC Clinical Trial Centre
Physics	Prof Paul Keall The University of Sydney
Consumer Representative	Mr John Stubbs

EX OFFICIO POSITIONS

POSITION	NAME
Health and Pharmaco-economic technical service	A/Prof Richard De Abreu Lourenço Centre for Health Economics Research and Evaluation, University of Technology Sydney
QoL technical service *(until June 2021)*	Prof Madeleine King Sydney Quality of Life Office, University of Sydney
TROG Research Service Manager	Ms Narelle Williams TROG Cancer Research
TROG Radiation Therapy Manager	Ms Alisha Moore TROG Cancer Research
TSC Secretary	Ms Rebecca Montgomery TROG Cancer Research

COMMITTEES

TROG 2021

INDEPENDENT DATA SAFETY MONITORING COMMITTEE

The TROG Independent Data and Safety Monitoring Committee (IDSMC) plays a vital role in monitoring the progress of all TROG phase III and late phase II clinical trials. Feeding into the TSC, the IDSMC is responsible for making recommendations on the continuation of trials based on analysis from an ethical perspective, keeping the rights, safety and welfare of participants first and foremost.

The reviews take place twice a year at six monthly intervals, and/or at times when trials reach vital milestones. The IDSMC operates independently of the TROG Central Operations Office, TROG trials and other committees, and is made up of the following multidisciplinary group of members:

Prof Bryan Burmeister
Chairperson/Radiation Oncologist

Ms Peta Forder
Statistician

Prof Michael Michael
Medical Oncologist

Dr Guy Hingston
Surgical Oncologist

A/Prof Paul Nguyen
Radiation Oncologist

NEW TECHNOLOGIES AND TECHNIQUES COMMITTEE

The New Technologies and Techniques Committee (NTTC) comprises medical physicists, radiation therapists and radiation oncologists as well as TROG Central Office representatives. The scope of the committee is to provide guidance, develop policy and advise on quality assurance requirements for the use of new and complex technology and techniques in TROG trials.

Major new developments in radiation oncology technology and treatment methods including MRI Linacs and online adaptive treatments are continuing to evolve and require careful analysis to ensure the continuation of TROG's high quality trial conduct and data collection.

There are several sub-groups working on guidelines for specific complex areas. A technical framework document for stereotactic radiosurgery (SRS) trials has been developed and endorsed by the TROG Scientific Committee (TSC). Acknowledgements to both A/Prof Mark Pinkham and Dr John Shakeshaft as well as the subgroup members for their hard work on this document.

Other endeavours include image registration (led by Dr Nick Hardcastle), adaptive radiation therapy (led by Dr Michael Jameson), and a subgroup developing a risk assessment approach to inform the development and ongoing monitoring of radiation therapy quality assurance programs for clinical trials. Other pertinent issues have been the standardisation of naming conventions/nomenclature for treatment planning in trials to aid in reporting and comparisons of results, as well as for automation of plan quality assurance.

A manuscript on the SEAFARER audit of IMRT QA procedures has been submitted for publication. The VESPA remote auditing program has had a new lease of life with auditing of international centres for participation in TROG trials including centres in Canada, Taiwan, UK, Spain and Switzerland. We continue to liaise with several other groups including the Australian Clinical Dosimetry Service and the Global Harmonisation Group. Facility questionnaires are also currently under review. Discussions on TROG's quality assurance infrastructure including that for secondary analysis are ongoing.

The NTTC has been very active in 2021 and as a result the membership of the group has grown, including two New Zealand representatives. We look forward to another productive year in 2022.

Prof Peter Greer
Chairperson

Mr Michael Bailey

Prof Annette Haworth

Prof Tomas Kron

A/Prof Joerg Lehmann

Mr Rob McDowall

Mr Kenton Thompson

Ms Alisha Moore

Ms Olivia Cook

Ms Alana Rossi

Ms Sofee Holmes

Dr John Shakeshaft

Dr Nick Hardcastle

Dr Andrew Cousins

Dr Michael Jameson

Prof Martin Ebert

Ms Maddison Shaw

Ms Rhonda Brown

A/Prof Farshad Foroudi

Mr David Willis

Dr Ben Hindson

SECONDARY DATA ANALYSIS COMMITTEE

During 2021, the TROG Secondary Data Analysis Committee (SDAC) continued to support efforts to make use of TROG's existing data assets, as well as develop resources to ensure the improved collection and greater availability of clinical trial data in the future.

Specific activities during 2021 included:

- **The review of four new secondary analysis proposals.**
- **The curation of multiple retrospective data sets in support of the RANZCR-TROG Research Grant.**
- **Establishment of a TROG trial data set summary, which provides a description of available data (fields, formats, availability etc.) for each of TROG's trial data sets.**
- **Promotion of TROG's involvement in the ARCD Health Studies Australian National Data Asset (HeSANDA) program, with TROG now participating via the "National Cancer Cooperative Trials Groups" HeSANDA node.**
- **Welcoming Dr Sweet Ping Ng and Dr Vanessa Panettieri onto the committee.**
- **A focus on development of data-handling infrastructure, which will be essential for facilitating secondary data analysis without overburdening TROG office staff. In this respect, during 2021:**
    - **An application was submitted to the MRFF Clinician Researchers in Health Grant to develop data repository infrastructure. *Unfortunately the outcome of this grant was unsuccessful. We will continue to seek new opportunities for funding as they arise.***
    - **An application was submitted for a Perpetual IMPACT grant to employ an officer to help coordinate data infrastructure. *No outcome has been announced at the time of this report.***

The SDAC operates principally as an advisory panel with TROG office staff largely responsible for implementing the SDAC's recommendations. As such, the SDAC wishes to acknowledge the exceptional efforts of TROG office staff in ensuring that the committee's vision can be realised.

Prof Martin Ebert
Chairperson

Ms Narelle Williams

Ms Alisha Moore

Ms Sofee Holmes

Dr Sweet Ping Ng

Mr Stuart Greenham

A/Prof Richard De Abreu Lourenco

Dr Vanessa Panettieri

Mr Kenton Thompson

Prof Val Gebski

Mr Michael Bailey

A/Prof Lois Holloway

TROG PUBLICATIONS COMMITTEE

The 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. We are proud to have over 246 publications attributed to TROG.

The TROG Authorship, Publication, and Spokesperson guideline remains available to all TROG members via the TROG website and it is hoped that this provides guidance for investigators and authors regarding TROG sponsored research.

Two TPC meetings were held in 2021 and 16 publications were reviewed by the TPC. A breakdown of these reviews can be found below.

	NO. OF MANUSCRIPTS REVIEWED BY TPC IN 2021
Category A	12
Category B	1
Category C	3
TOTAL	16

Sixteen manuscripts arising from TROG sponsored research were published in 2021, with all but one of these manuscripts acknowledging TROG appropriately! We thank all of these authors for continuing to ensure TROG receives the appropriate acknowledgement.

For details of these published manuscripts, please refer to page 54 of this report.

We are looking forward to a busy 2022 with several TROG trials nearing data maturity time-points.

Dr Shivani Kumar
Chairperson

A/Prof Sashendra (Sasha) Senthi
Radiation Oncologist & Scientific Committee Chair

Dr Chris Brown
Discipline Representative – Statistics

Mr Patrick Wheeler
Secretary (until April 2021)

Dr Ryan Davey
Secretary (as of April 2021)

CONSUMER ENGAGEMENT

TROG 2021

TROG Cancer Research continued to engage consumers in a variety of ways in our clinical trials and research activities despite the challenges of COVID 19 preventing us from meeting face to face in 2021.

Together with our TROG members, our TROG consumers embraced the virtual world joining our committee meetings via zoom and attending our virtual TROG 2021 Annual Scientific Meeting.

Mr John Stubbs continues to provide important insights from a consumer perspective as a member of our TROG Scientific Committee. John was diagnosed with Chronic Myeloid Leukaemia over 20 years ago and he volunteered to take part in a clinical trial testing a new drug treatment. So like many other consumers John wanted to advocate for cancer clinical trials, and he joined TROG as a consumer advisor in 2015. John is motivated to help and support others who are facing a cancer diagnosis and advocate for increased opportunities to participate in clinical trials.

Another long standing consumer advisor for TROG Cancer Research is Ms Sue McCullough. Sue is a Lung Cancer Survivor who joined TROG as a consumer in 2014. She is a passionate advocate for supporting others with lung cancer and she helped to form a Lung Cancer Support Group in 2014. Through this group Sue has met a lot of people who have lived and died with lung cancer, having a first-hand insight into the needs of these patients through listening to their stories.

Sue is driven to help all people in Australia and beyond to be able to live with lung cancer and thrive. Having been a member of the TROG Lung Group Working Party for a number of years, she has brought a very valuable patient perspective to our trials. As a member of the program committee for our annual Clinical Research Education Workshop Sue has ensured that patient perspectives in trial conduct are a theme of the workshop.

TROG Cancer Research has a robust process of developing new clinical trial proposals and protocols which is supported via funding from Cancer Australia.

We see patients and consumer advocates as integral in the design and conduct of clinical trials. Consumers make a unique contribution of their expertise and knowledge from the perspective of a person who has experience of a cancer diagnosis or supported someone during their cancer journey.

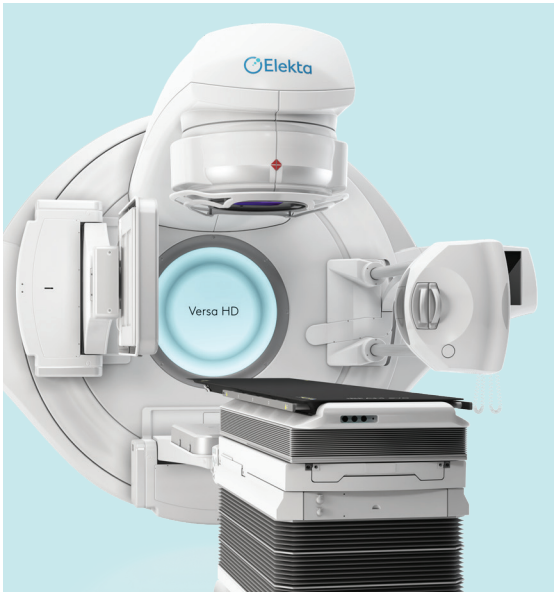
Through our established new proposal pathway, TROG actively engages with consumers in the development of each new clinical trial with consumer input. Through continuous review of the participant information and consent forms and input into trial design and grant applications, our consumers help enormously to ensure that our research is patient centred.

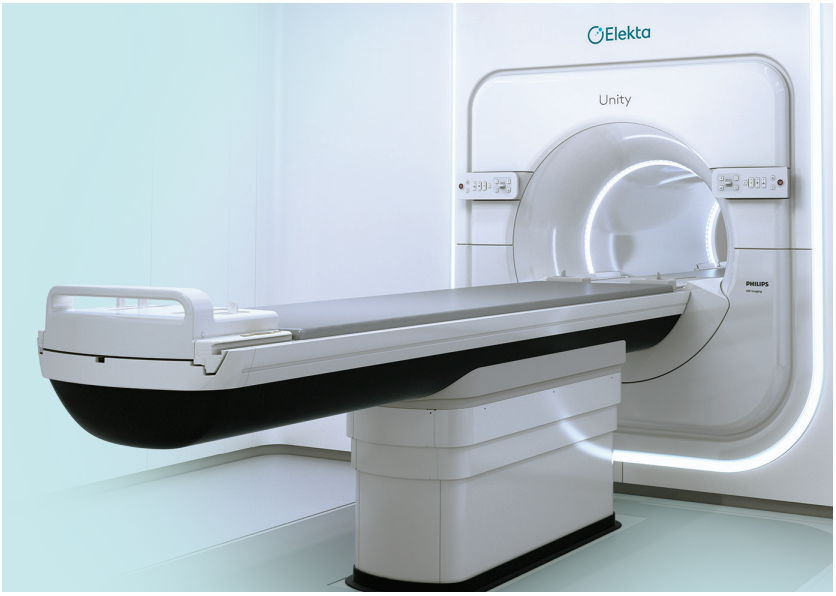
As part of the Trial Management Committee, consumers also are involved in the continual monitoring and supervising of the progress of the trial until its completion and dissemination of results.

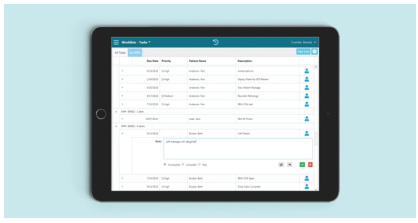
TROG would like to thank the many consumers involved with our 100+ trials over the last 30 years for their time and efforts, ensuring the relevance of TROG clinical research.

During the last quarter of 2021, with a view to expand consumer engagement, TROG reached out to several consumer organisations including Cancer Voices NSW and Canteen and are pleased that these consumer views are now adding to the value of all TROG activities.

TROG Cancer Research are privileged to have a wonderful group of health consumers and advocates, who are committed to promoting and encouraging access to cancer trials, making a significant contribution to the TROG's mission of conducting world class research in radiation medicine that leads the global effort to better control and cure cancer.







AWARD WINNING
Elekta Care
SERVICE

LADXX200216

Elekta Harmony Pro is not available in all markets

Hope for everyone dealing with cancer.

At Elekta, we don't just build technology, we build hope for everyone dealing with cancer by accelerating cancer care innovations and improving global patient access to the best cancer care.

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Elekta

RESEARCH ACHIEVEMENTS

YEAR IN REVIEW

In December 2021, we hosted our first online Concept Development Workshop, for which 13 proposals were submitted. We are looking forward to running more workshops to support new proposal development in 2022.

TROG are pleased to report that four new TROG trial proposals were endorsed for further development throughout 2021. We look forward to working closely with the investigators to secure funding.

NEW TRIALS ACTIVATED IN 2021

TROG 19.06 DECREASE

DarolutamidE + Consolidation Radiation Therapy in Advanced proStatE Cancer Detected by PSMA, was opened at five centres and enrolled 10 participants in 2021 (TROG Trial Chairs: A/Prof Shankar Siva and A/Prof Arun Azad, Peter MacCallum Cancer Centre, VIC).

TROG 20.01 CHEST RT

A trial of Chemotherapy and Immunotherapy in Extensive-Stage Small-Cell Lung Cancer with Thoracic Radiation Therapy. The trial was activated at three sites in 2021 (TROG Trial Chairs: Dr Eric Hau, Westmead Hospital, NSW and A/Prof Paul Mitchell, Austin Hospital, VIC).

ACTIVE TRIALS IN 2021 - ACHIEVEMENTS

CCTG SC.24/TROG 17.06

A randomised phase II/III study comparing stereotactic body radiation therapy versus conventional palliative radiation therapy for patients with spinal metastases (TROG Trial Chair: A/Prof Shankar Siva, Peter MacCallum Cancer Centre, VIC) was published.

See page 54 Publications.

TROG 13.01/ALTG 13.001 SAFRON II

Stereotactic Ablative Fractionated Radiation Therapy versus Radiosurgery for Oligometastatic Neoplasia to the Lung. Randomised trial has been published (TROG Trial Chair: A/Prof Shankar Siva, Peter MacCallum Cancer Centre, VIC).

See page 54 Publications.

TROG 17.02 OUTRUN

Phase II randomised trial of Osimertinib with or without Stereotactic Radiosurgery for EGFR Mutated NSCLC with Brain Metastases, TROG Trial Chairs: Dr Fiona Hegi-Johnson (Peter MacCallum Cancer Centre, VIC) and A/Prof Chee Lee (St George Hospital, NSW) has continued to enrol participants despite COVID and other challenges, with 28 participants by the end of 2021.

TROG 18.01 NINJA

Novel Integration of New prostate radiation therapy schedules with adjuvant Androgen deprivation – has seamlessly transitioned from phase II to phase III trial, accruing over 150 participants. (TROG Trial Chairs: Prof Jarad Martin, Calvary Mater Hospital, NSW and Dr Mark Sidhom, Liverpool Hospital, NSW).

ICR-CTSU/2015/10052/TROG 16.03 CORE

A randomised trial of Conventional care versus Radioablation (stereotactic body radiation therapy) for Extracranial oligometastases – completed two years out of five planned follow up years (TROG Trial Chairs: Prof Farshad Foroudi, Austin Health/ Olivia Newton John Cancer Wellness and Research Centre, VIC and A/Prof David Pryor, Princess Alexandra Hospital, QLD).

USYD/TROG 17.03 LARK

Liver Ablative Radioation Therapy utilising Kilovoltage intrafraction monitoring (KIM) – achieved accrual of 15 participants from three sites. This trial is led by TROG Trial Chairs: Dr Tim Wang, Westmead Hospital NSW and Dr Yoo Young (Dominique) Lee, Princess Alexandra Hospital, QLD.

TROG 16.02 Local HER-O

A Phase II study of local therapy only (stereotactic radiosurgery and/or surgery) for treatment of up to five brain metastases from HER2 positive Breast Cancer – achieved completion of follow up for all participants (TROG Trial Chair: Dr Claire Phillips, Peter MacCallum Cancer Centre, VIC).

TROG 18.06 FIG - FET-PET In Glioblastoma

TROG 18.06 FIG trial is led by TROG Trial Chairs A/Prof Eng-Siew Koh (Liverpool Hospital, NSW) and Prof Andrew Scott (Austin Hospital, VIC). The FIG trial is investigating how the addition of FET-PET imaging to standard MRI imaging affects radiation target volume delineation and treatment planning for Glioblastoma. 24 participants were enrolled from eight recruiting sites in 2021.

EORTC 1308/TROG 15.02 ROAM

Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial (TROG Trial Chairs: Dr Gail Ryan and Dr Neda Naghighi, Peter MacCallum Cancer Centre, VIC) reached target accrual internationally.

TROG 12.01 HPV OROPHARYNX

A Randomised Trial of Weekly Cetuximab and Radiation versus Weekly Cisplatin and Radiation in Good Prognosis Locoregionally Advanced HPV-Associated Oropharyngeal Squamous Cell Carcinoma (TROG Trial Chairs: Prof Danny Rischin, Peter MacCallum Cancer Centre, VIC and Prof June Corry, Department Radiation Oncology Genesis Care, St Vincent's Hospital, VIC) – practice changing results were published.

See page 54 Publications.

PMCC 17/013/TROG 17.05 AZTEC

A randomised phase II trial comparing the efficacy of single fraction or multi-fraction SABR (Stereotactic ablative body radiation therapy) with AteZolizumab in patients with advanced Triple Negative Breast Cancer (Trial Chair: Prof Sherene Loi, Peter MacCallum Cancer Centre, VIC) – completed final patient accrual.

RADIATION THERAPY QUALITY ASSURANCE

TROG Radiation Therapy Quality Assurance (RTQA) activities have continued to evolve and grow in 2021. We have recently refined our risk-based assessment tools which will allow us to more consistently assess the risks of each trial and generate robust, risk appropriate RTQA programs that can be efficiently monitored and adapted over time as needed. We have recently developed an adaptive risk-based model to aid the implementation of efficient radiation therapy quality assurance in our clinical trials.

TROG is currently collaborating with the Thoracic Oncology Group of Australia (TOGA), Australasian Gastro-Intestinal Trials Group (AGITG), Breast Cancer Trials Group (BCT), Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP), Melanoma and Skin Cancer (MASC) Trials Group and several other groups, to conduct clinical trial radiation therapy quality assurance activities.

TRIAL IN FOCUS!

TROG 19.06 DECREASE

Over 18,000 men were diagnosed with prostate cancer in Australia in 2021 and the disease was the second most common cause of cancer death amongst males.

Although those with castrate-resistant prostate cancer (CRPC) may have progression of metastatic disease, a subset of men with CRPC will have no detectable metastatic disease on computed tomography (CT) and whole body bone scans (or conventional imaging). Recently, promising data has been published on the utility of PSMA-PET/CT in localisation of early castrate-resistant metastatic disease.

Investigators, A/Prof Shankar Siva and A/Prof Arun Azad of Peter MacCallum Cancer Centre in Victoria (pictured) have led the development of TROG 19.06 DECREASE trial (DarolutamidE + Consolidation Radiation Therapy in Advanced protate Cancer Detected by PSMA). In men with CRPC who are treated with Darolutamide - the hypothesis is that the addition of consolidation radiation therapy to PSMA detected sites of disease will improve clinical outcomes, when compared to receiving Darolutamide alone. This phase II randomised trial will assess the efficacy of Darolutamide, with or without local consolidation radiation therapy after twelve weeks of therapy, in men with castrate-resistant prostate cancer (CRPC) with no evidence of metastases on conventional imaging but detectable disease on PSMA-PET/CT scan.

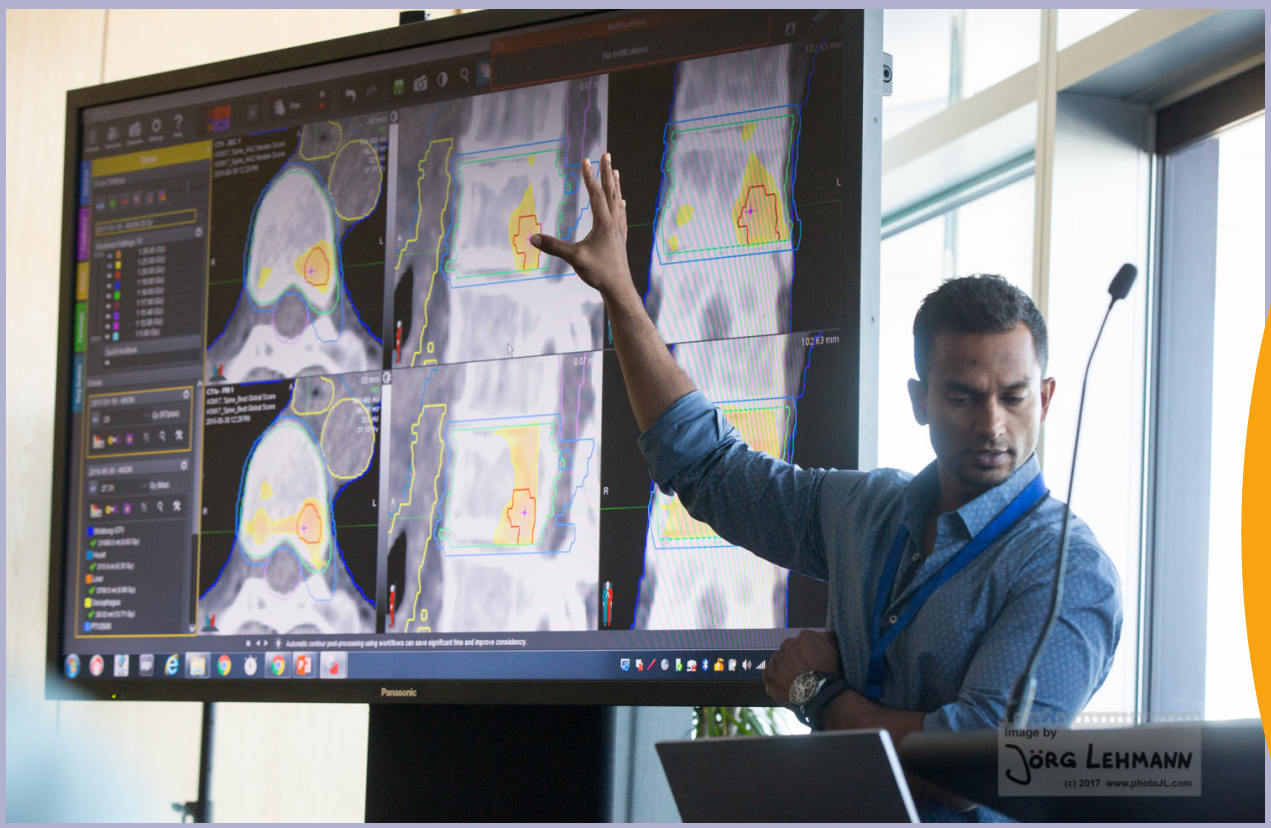
Progression at known sites of macroscopic disease is the predominant cause of failure of systemic therapies, therefore local consolidation therapy with stereotactic ablative body radiation therapy (SABR) or hypofractionated radiation therapy may improve progression free survival (PFS) and overall survival (OS). A key objective of this study proposal is to better understand the pattern of disease distribution at first diagnosis of CRPC in the new era of PSMA PET/CT.

"Radiation therapy is a well-tolerated and effective treatment for localised disease, and we are increasingly recognising its potential to improve outcomes in men with advanced prostate cancer," A/Prof Shankar Siva said.

"I'm thrilled that we can combine state-of-the-art molecular imaging with targeted radiation therapy in the DECREASE trial, and as we gear up to activate more sites in 2022, we hope to offer more men access to the potential benefits of these therapies.

I am really excited about the DECREASE trial. Apart from being the first study I am part of with the terrific TROG team, this is an important trial that will test the hypothesis that targeting residual sites of tumour activity in the setting of highly active systemic therapy will improve outcomes in men with advanced prostate cancer," A/Prof Arun Azad added.

The DECREASE trial aims to recruit 87 patients from 15 Australian centres over 30 months and opened in June 2021. This trial is financially supported by Bayer.



RESEARCH PORTFOLIO

TROG 2021 OVERVIEW

TROG Cancer Research continues to maintain a large and diverse portfolio of clinical trials across varied tumour groups. In 2021, there were 13 trials in development, two in start-up and 29 open. A further 72 trials were either closed or completed.

BREAKDOWN OF TROG STUDY PORTFOLIO AS OF 31 DEC 2021

	TRIAL CATEGORY				
TRIAL STATUS	**A**	**B**	**C**	**D**	**TOTAL**
In Development	7	2	3	1	**13**
Start up	0	0	2	0	**2**
Open	13	6	10	0	**29**
Closed	18	5	4	0	**27**
Completed	37	7	1	0	**45**
Data Requested	-	-	-	19	**19**
					135

CATEGORY KEY

A: TROG initiated and sponsored trial
B: International trial with TROG as Australian Sponsor
C: Not led by TROG but TROG collaborates with the Sponsor
D: Consists of registries and special projects

WORKING PARTIES

YEAR IN REVIEW

BREAST WORKING PARTY

CHAIR | PROF BOON CHUA
DEPUTY CHAIR | PROF TOMAS KRON

The Breast Working Party continues to meet quarterly to oversee the TROG breast portfolio. Several trials were completed in 2021 and are planned for analysis and publication in 2022.

The TROG 16.04 EXPERT (ANZ 1601/BIG 16-02, Trial Chair: Prof Boon Chua) study continues accrual with 505 patients randomised to the trial at the end of 2021 from up to 35 Australian and New Zealand active centres. This collaboration with Breast International Group (BIG), Breast Cancer Trials (BCT), TROG and other international collaborative groups will include participation from about 50 recruiting centres worldwide. This trial aims to improve personalised use of radiation therapy in patients with molecularly characterised luminal A early breast cancer according to individual risks of local recurrence.

The APBI (TROG 06.02, Trial Chair: Prof Boon Chua) study is a multicentre feasibility study of accelerated partial breast irradiation (APBI) using three-dimensional conformal radiation therapy (3D CRT) for early breast cancer. This trial was completed in 2021 and results have been drafted with plans for publication to commence shortly.

The Local HER-O (TROG 16.02, Trial Chair: Dr Claire Phillips) phase II study has now completed follow up and the results will be available in 2022. Local HER-O is a study of local therapy for the treatment of brain metastases from HER2 positive breast cancer and this study has enrolled 25 patients.

The BIG 3-07 / TROG 07.01 DCIS trial (Trial Chair: Prof Boon Chua) practice-changing trial results are planned for publication in 2022. The ongoing follow up of DCIS trial participants will continue until 2024 and several other publications are in draft.

Results of the TROG 14.04 HART trial (Trial Chair: Prof Tomas Kron) have been submitted for publication.

The Breast Working Party has been exploring new trial concepts and research directions and looks forward to expanding its membership and portfolio in 2022. The Working Party aims to continue the exploration of artificial intelligence in trials and hopes to attract more members into active roles within the Working Party.

LUNG WORKING PARTY

CHAIR | DR FIONA HEGI-JOHNSON
DEPUTY CHAIR | DR YU YANG SOON

CURRENT PORTFOLIO

Congratulations to Dr Eric Hau and Dr Paul Mitchell, with the TROG 20.01 CHEST RT trial opening in November 2021. This trial will examine the role of immunotherapy and consolidative thoracic radiation therapy in Small Cell Lung Cancer. It is set to recruit 45 participants.

TROG 17.02 OUTRUN (RCT of Osimertinib with or without stereotactic radiosurgery for EGFR mutated Non-Small Cell Lung Cancer with brain metastases) opened in Singapore early in 2021 and aims to finalise accrual by the end of 2022.

HIGHLIGHTS

Several new proposals have been brought to the working party for review, which is promising for a productive and successful 2022 for the Lung Working Party.

Prof Paul Keall is leading the recently endorsed TD 21.08 VITaL proposal and the team are currently seeking funding for this proposed phase III randomised trial of 'Ventilation Imaging for Thoracic Lung radiation therapy' (VITaL). The trial is set to determine if an Australian-invented imaging modality can improve lung cancer patient treatment outcomes after radiation therapy for those with locally advanced disease.

GENITOURINARY WORKING PARTY

CHAIR | A/PROF SHANKAR SIVA
DEPUTY CHAIR | DR STEPHEN CHIN

The Genitourinary (GU) Working Party held a strategic planning day in February to identify gaps and opportunities for genitourinary cancer research through TROG. We welcomed new working party members: Biostatistician, Kristy Robledo, Medical Oncologist, Megan Crumbaker and Radiation Oncology Registrar, Anzela Anzela and thank them and our other members for their ongoing contribution.

Congratulations to Prof Jarad Martin and team for completing recruitment of the phase II component of the TROG 18.01 NINJA trial (RCT of two different SABR fractionations for prostate cancer). The phase III expansion has commenced.

The TROG 19.06 DECREASE trial (SABR for castrate resistant oligoprogressive prostate cancer) led by A/Prof Shankar Siva and A/Prof Arun Azad opened in 2021. The TD 20.02 CHyPPR (RCT of Conventional versus Hypofractionated Post Prostatectomy Radiation Therapy) led by Dr Stephen Chin was further developed including presentation at the ANZUP prostate concept development workshop, and the search for funding continued.

Publications from TROG genitourinary trials include knowledge-based planning from the TROG 15.03 FASTRACK II trial of kidney SABR (Hardcastle et al.) and a secondary analysis of tumour grade from the TROG 0.3.04 RADAR trial (Delahunt et al.).

CENTRAL NERVOUS SYSTEM WORKING PARTY

CHAIR | A/PROF MARK PINKHAM

The Central Nervous System (CNS) Working Party was formed in June 2021 and comprises 15 individuals from a range of craft groups and institutions across Australia, including consumer representation.

Subsequently, we have met quarterly to cultivate future trial opportunities and to note the progress of current TROG studies that have now been adopted within the CNS portfolio (TROG 18.06 FIG, 17.01 SC.24, 15.02 ROAM and 06.01 Low Grade Glioma). It has been determined that studies pertaining to people with brain metastases from a single histology will remain under the WP of their primary disease, with input from the CNS WP as required.

Treatment gaps and CNS trial priorities have been identified through horizon scanning, and I am particularly grateful to Dr Kylie Jung and Prof Michael McKay for their hard work in this regard. Collaboration with other national and international cooperative groups has been agreed as a strategic priority. The group have commenced development of a new trial proposal assessing bevacizumab for radiation necrosis led by Dr Kylie Jung.

TROG 18.06 FIG assesses the utility of FET-PET in the management of patients with glioblastoma (Trial Chairs: A/Prof Eng-Siew Koh and Prof Andrew Scott). There are 8 of 10 sites now activated and 20 participants have been recruited. Abstracts have been accepted and presented at the 2021 TROG, EANM, and SNO annual scientific meetings.

Congratulations to A/Prof Shankar Siva (TROG Trial Chair) and team for publication of TROG 17.01 SC.24 results “Stereotactic body radiation therapy versus conventional external beam radiation therapy in patients with painful spinal metastases: an open-label, multicentre, randomised, controlled, phase 2/3 trial” in Lancet Oncology.

TROG 15.02 (EORTC-1308) ROAM is an international, multicentre randomised controlled trial assessing the role of adjuvant radiation versus observation following surgical resection of atypical meningioma (TROG Trial Chairs: Dr Gail Ryan and Dr Neda Haghighi). A total of 15 patients were recruited from Australia and New Zealand and the study closed to accrual in 2021. Participants will remain in follow up until September 2025.

TROG 06.01 (EORTC 22033) is an international, multicentre randomised controlled trial comparing temozolomide versus radiation therapy in high-risk low-grade gliomas (TROG Trial Chairs: Dr Gail Ryan and Dr Claire Phillips). A total of 68 patients were recruited at TROG sites and the study closed to accrual in 2010. Participants remain in long term follow-up.

Finally, I would like to acknowledge Dr Gail Ryan’s significant contributions to neuro-oncology radiation research, and in particular as TROG Trial Chair for both TROG 15.02 and TROG 06.01 up until 2021.

HEAD & NECK / SKIN WORKING PARTY

CHAIR | A/PROF CHARLES LIN
DEPUTY CHAIR | DR LACHLAN MCDOWELL

TROG Head & Neck and Skin Working Party (HNS WP) members have made some great achievements in 2021.

We would like to congratulate Prof Danny Rischin, Prof June Corry and team for the publication of the TROG 12.01 HPV OROPHARNX main results *(see page 5)*. There are a number of ongoing secondary analyses from TROG 12.01 HPV OROPHARNX data underway, including a number of health-related quality of life studies and a radiation therapy quality assurance study. We look forward to seeing the results of these in 2022. The study continues to collect outcome data on participants in follow-up.

TROG 09.03 MP3 "A phase II efficacy study of chemo-radiation therapy in PET stage II and III Merkel cell carcinoma of the skin" (Category A) led by Prof Michael Poulsen and Dr Andrew Pullar has completed follow up, with the final participant completing five years of follow up on 01 June 2021.

MASC 01.09 TROG 08.09 RTN2 "A randomised trial of post-operative radiation therapy following wide excision of neurotropic melanoma of the head and neck" (Category C) led by A/Prof Matthew Foote has completed follow up of 50 participants.

TROG has also supported the MASC 03.18/TROG 21.01 I-MAT "Immunotherapy Merkel Adjuvant Trial" (Category C) led by Dr Wen Xu which is actively recruiting nationally.

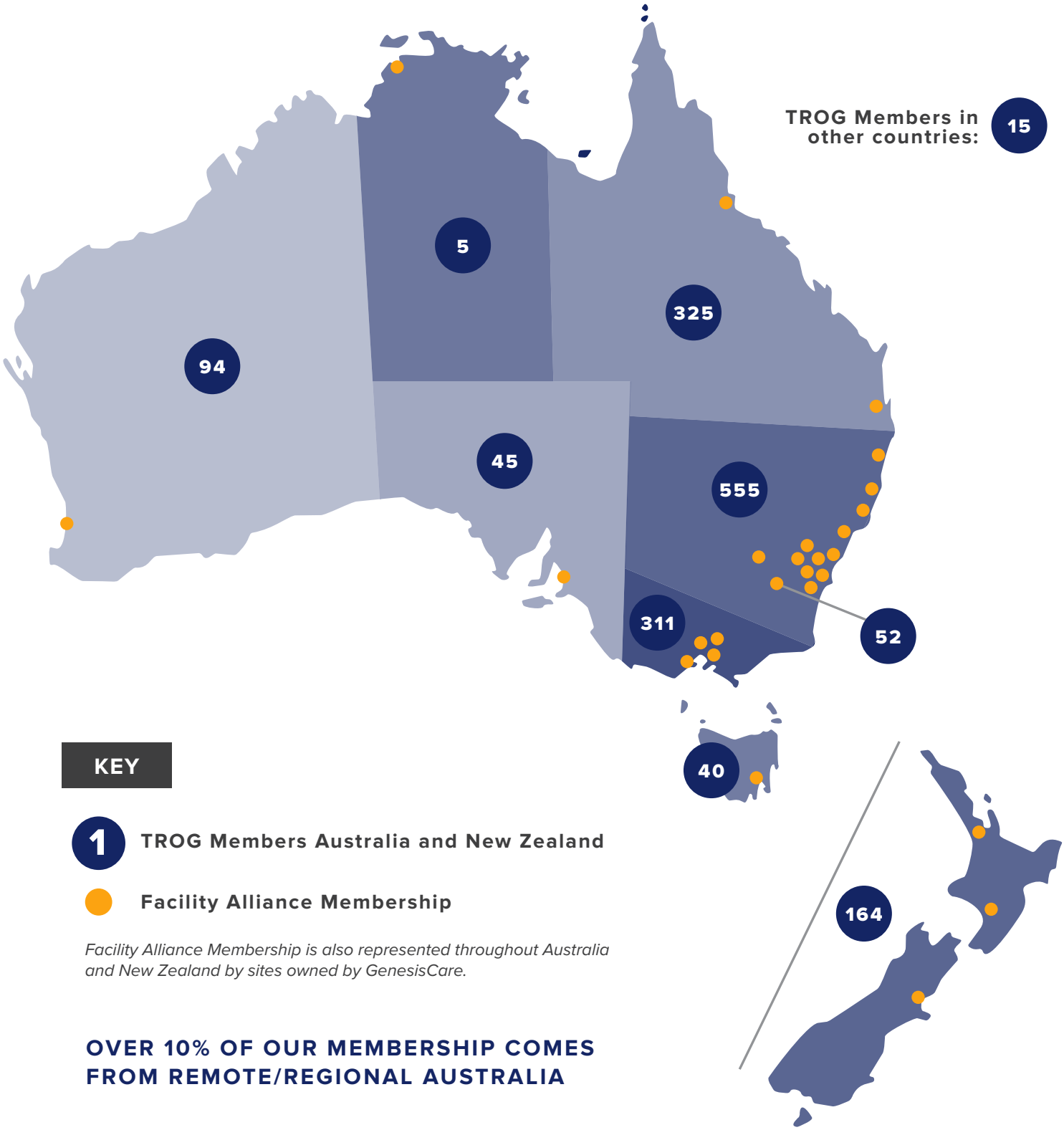
We are fortunate that TROG is a member organisation and is represented by Prof Sandro Porceddu and Prof Danny Rischin on the board of the Head and Neck Cancer International Group. Dr Lachlan McDowell, Deputy Chair is also the co-chair of the young investigators committee.

The HNS WP have been considering opportunities for future research and collaborate widely at a national and international level. I would like to say a big thanks to all the hardworking party members who contribute to TROG Cancer Research and meet regularly.

TROG MEMBERSHIP

TROG 2021

TROG Members in other countries: 15



KEY

1 TROG Members Australia and New Zealand

Facility Alliance Membership

Facility Alliance Membership is also represented throughout Australia and New Zealand by sites owned by GenesisCare.

OVER 10% OF OUR MEMBERSHIP COMES FROM REMOTE/REGIONAL AUSTRALIA

TOTAL TROG MEMBERS

DISCIPLINE	2021	FULL / LIFE MEMBER	AFFLILIATE
Radiation Oncologists	326	159	167
Radiation Therapists	530	6	524
Radiation Oncology Registrars	154	3	151
Trial Coordinators/Data Managers	195	3	192
Medical Physicists	88	7	81
Medical Oncologists	8	3	5
Interventional Oncologists	8	1	7
Statisticians	6	0	6
Consumers / Other	272	10	262
TOTAL MEMBERSHIP	**1,587**	**192**	**1,395**

FACILITY ALLIANCE MEMBERSHIP

The TROG Facility Alliance Membership (FAM) was introduced in 2012 to allow TROG Central Operations Office to continue to provide support to the membership and sites for the conduct of clinical trials and radiation therapy quality assurance. With the support of treatment centres involved in TROG trials, the FAM provide us to continue our business as a not for profit (NFP) organisation conducting investigator initiated scientifically robust clinical trials; provide faster access to new technologies and treatments; translate research outcomes into policy and practice, and implement new treatments to benefit patients and improve patient outcomes.

Benefits of the FAM to members includes the utilisation of specialised infrastructure and IT support, access to expertise from sub specialty groups, and facilitation by way of partnership and collaboration with Cancer Cooperative Trial Groups as well as support and expertise from our RTQA team.

Once again we are pleased to thank our dedicated FAM sites for their continued support and engagement, as we look forward to reaching a ten year milestone next year.

PUBLICATIONS

YEAR IN REVIEW

PROARCT (TROG 9.01) *1/02/2021*

Ng SP, Chu J, Chander S, Bressel M, McKendrick J, Wong R, Steel M, Murray WK, Leong T, Heriot A, Michael M, Ngan SY. Results of phase II trial of intensified neoadjuvant treatment with interdigitating radiation therapy and chemotherapy with oxaliplatin, 5- fluorouracil and folinic acid in patients with locally advanced rectal cancer (PROARCT trial). Radiother Oncol. 2021 Feb; 155:27-32.

PORTEC-3 (TROG 8.04) *1/03/2021*

Post CCB, de Boer SM, Powell ME, Mileshkin L, Katsaros D, Bessette P, Haie-Meder C, Ottevanger N(P)B, Ledermann JA, Khaw P, D'Amico R, Fyles A, Baron MH, Kitchener HC, Nijman HW, Lutgens LCHW, Brooks S, Jürgenliemk-Schulz IM, Feeney A, Goss G, Fossati R, Ghatage P, Leary A, Do V, Lissoni AA, McCormack M, Nout RA, Verhoeven-Adema KW, Smit VTHBM, Putter H, Creutzberg CL. Long- term toxicity and health-related quality of life after adjuvant chemo-radiation therapy or radiation therapy alone for high-risk endometrial cancer in the randomised PORTEC-3 trial. Int J Radiat Oncol Biol Phys. 2021 Mar; 109(4):975-86.

LARK (TROG 17.03) *1/04/2021*

Lee, Y.Y.D., Nguyen, D.T., Moodie, T. et al. Study protocol of the LARK (TROG 17.03) clinical trial: a phase II trial investigating the dosimetric impact of Liver Ablative Radiation therapy using Kilovoltage intrafraction monitoring. BMC Cancer 21, 494 (2021).

MGMZL (TROG 5.02) *1/05/2021*

MacManus MP, Roos D, O'Brien P, Capp A, Wirth A, Tsang R, Bressel M, Lade S, Seymour JF. Prospective Phase II trial of radiation therapy in localised non-gastric marginal zone lymphoma with prospective evaluation of autoimmunity and Helicobacter pylori status: TROG 05.02/ALLG NHL15. Eur J Cancer. 2021 Jun 4;152:129-138.

GLOBAL HARMONISATION GROUP (GHG) *6/06/2021*

Kry SF, Lye J, Clark CH, Andratschke N, Dimitriadis A, Followill D, Howell R, Hussein M, Ishikawa M, Kito S, Kron T, Lee J, Michalski J, Filippo Monti A, Reynaert N, Taylor P, Venables K, Xiao Y, Lehmann J. Report dose-to-medium in clinical trials where available; a consensus from the Global Harmonisation Group to maximize consistency. Radiother Oncol. 2021 Jun;159:106-111. doi: 10.1016/j.radonc.2021.03.006. Epub 2021 Mar 17. PMID: 33741471.

SC24 (TROG 17.06) *11/06/2021*

Sahgal A, Myrehaug SD, Siva S, Masucci GL, Maralani PJ, Brundage M, Butler J, Chow E, Fehlings MG, Foote M, Gabos Z, Greenspoon J, Kerba M, Lee Y, Liu M, Liu SK, Thibault I, Wong RK, Hum M, Ding K, Parulekar WR; trial investigators. Stereotactic body radiation therapy versus conventional external beam radiation therapy in patients with painful spinal metastases: an open-label, multicentre, randomised, controlled, phase 2/3 trial. Lancet Oncol. 2021 Jul;22(7):1023- 1033. doi: 10.1016/S1470-2045(21)00196-0. Epub 2021 Jun 11. PMID: 34126044.

P_LUNG GP (TROG 11.03) *11/07/2021*

Lehman M, Bernard A, See A, King M, Michael M. A Randomized Phase 3 Trial of Palliative Radiation Therapy Versus Concurrent Chemotherapy and Palliative Radiation Therapy in Patients With Good Performance Status, Locally Advanced, or Metastatic Non- Small Cell Lung Cancer With Symptoms due to Intrathoracic Disease Who are Not Suitable for Radical Chemo-radiation Therapy: Results of the Trans-Tasman Radiation Oncology Group 11.03 Trial. Pract Radiat Oncol. 2021 Jul-Aug;11(4):252-263. doi: 10.1016/j.prro.2020.11.009. Epub 2020 Nov 30. PMID: 33271352.

FASTRACK II (TROG 15.03) *1/08/2021*

Hardcastle N, Cook O, Ray X, Moore A, Moore KL, Pryor D, Rossi A, Foroudi F, Kron T, Siva S. Personalising treatment plan quality review with knowledge-based planning in the TROG 15.03 trial for stereotactic ablative body radiation therapy in primary kidney cancer. Radiat Oncol. 2021 Aug 3;16(1):142. doi: 10.1186/s13014-021-01820-7. PMID: 34344402; PMCID: PMC8330099.

PROM (TROG 07.01/11.03) *1/08/2021*

Calvert M, King M, Mercieca-Bebber R, Aiyegbusi O, Kyte D, Slade A, Chan AW, Basch E, Bell J, Bennett A, Bhatnagar V, Blazeby J, Bottomley A, Brown J, Brundage M, Campbell L, Cappelleri JC, Draper H, Dueck AC, Ells C, Frank L, Golub RM, Griebsch I, Haywood K, Hunn A, King-Kallimanis B, Martin L, Mitchell S, Morel T, Nelson L, Norquist J, O'Connor D, Palmer M, Patrick D, Price G, Regnault A, Retzer A, Revicki D, Scott J, Stephens R, Turner G, Valakas A, Velikova G, von Hildebrand M, Walker A, Wenzel L. SPIRIT-PRO Extension explanation and elaboration: guidelines for inclusion of patient-reported outcomes in protocols of clinical trials. BMJ Open. 2021 Jun 30;11(6):e045105. doi: 10.1136/bmjopen-2020-045105. PMID: 34193486; PMCID: PMC8246371.

MASTERPLAN (TROG 18.04) *19/08/2021*

Oar, Andrew et al. AGITG MASTERPLAN: a randomised phase II study of modified FOLFIRINOX alone or in combination with stereotactic body radiation therapy for patients with high-risk and locally advanced pancreatic cancer. BMC cancer vol. 21,1 936. 19 Aug. 2021, doi:10.1186/s12885-021-08666-y.

SAFRON II (TROG 13.01) *29/08/2021*

Siva S, Kron T, Bressel M, Haas M, Mai T, Vinod S, Sasso G, Wong W, Le H, Eade T, Hardcastle N, Chesson B, Pham D, Høyer M, Montgomery R, Ball D. Cost-effectiveness of Single-Fraction vs Multifraction Stereotactic Ablative Body Radiation Therapy for Pulmonary Oligometastases (SAFRON II). The Trans Tasman Radiation Oncology Group 13.01 Phase 2 Randomized Clinical Trial. JAMA Oncol. Published online August 29, 2021. doi:10.1001/jamaoncol.2021.2939.

SAFRON II (TROG 13.01) *1/10/2021*

Siva S, Bressel M, Mai T, Le H, Vinod S, de Silva H, Macdonald S, Skala M, Hardcastle N, Rezo A, Pryor D, Gill S, Higgs B, Wagenfuehr K, Montgomery R, Awad R, Chesson B, Eade T, Wong W, Sasso G, De Abreu Lourenco R, Kron T, Ball D, Neeson P; Stereotactic Ablative Fractionated Radiation Therapy Versus Radiosurgery for Oligometastatic Neoplasia to the Lung (SAFRON) II Study Investigators. Single-Fraction vs Multifraction Stereotactic Ablative Body Radiation Therapy for Pulmonary Oligometastases (SAFRON II): The Trans Tasman Radiation Oncology Group 13.01 Phase 2 Randomized Clinical Trial. JAMA Oncol. 2021 Oct 1;7(10):1476-1485. doi: 10.1001/jamaoncol.2021.2939. PMID: 34455431; PMCID: PMC8404145.

HPV OROPHARYNX (TROG 12.01) *15/11/2021*

Rischin D, King M, Kenny L, Porceddu S, Wratten C, Macann A, Jackson JE, Bressel M, Herschtal A, Fisher R, Fua T, Lin C, Liu C, Hughes BGM, McGrath M, McDowell L, Corry J. Randomized Trial of Radiation Therapy With Weekly Cisplatin or Cetuximab in Low-Risk HPV-Associated Oropharyngeal Cancer (TROG 12.01) - A Trans-Tasman Radiation Oncology Group Study. Int J Radiat Oncol Biol Phys. 2021 Nov 15;111(4):876-886. doi: 10.1016/j.ijrobp.2021.04.015. Epub 2021. Jun 4. PMID: 34098030.

VIRTUAL ANNUAL SCIENTIFIC MEETING (ASM)

TROG EVENTS 2021

Given the COVID-19 situation, a decision was made to proceed once again with the virtual ASM format in 2021.

Several international and nationally renowned keynote speakers were presenters at the online event, alongside key TROG Cancer Researchers and Clinicians. More than 200 delegates attended our meeting, including Australian and New Zealand Radiation Oncologists, Radiation Therapists, Interventional Oncologists, Medical Physicists and Clinical Trials Personnel.

Just a few of the highlights of the 2021 ASM were updates given on the Genitourinary Cancer Research Portfolio, Breast Cancer Research Portfolio, Oligometastatic Disease, Technology driven clinical trials and TROG Radiation Quality Assurance (RTQA) updates as well as a session on Expanding the TROG Portfolio and Emerging Technologies.

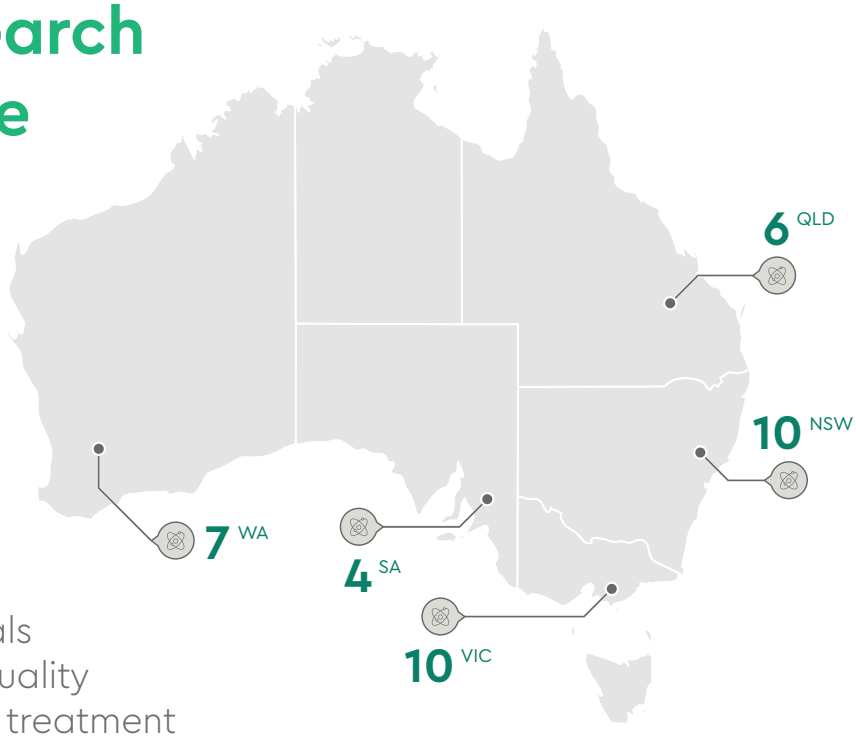
Another hugely successful Technical Research Workshop (TRW) with over 80 attendees was run parallel to the scientific sessions. The workshop covered TROG radiation therapy quality assurance and technology driven clinical trials.

We would like to sincerely thank ASM Co-Convenors, Dr John Shakeshaft and Dr Renee Finnigan for their commitment to bringing this meeting to fruition. A special thanks also to the Program and Organising Committees for all their hard work in ensuring that this ASM showcased ground breaking cancer research and facilitated discussion of new clinical trials, future research directions, and other developments in radiation oncology.

Thank you to everyone who attended and to TROG members, non-members, and special guests for your participation, and we also extend our thanks to our ASM Sponsors and Exhibitors. Our team is unable to host such events without your dedicated support.

Oncology research at GenesisCare in 2021

At GenesisCare, we challenge ourselves every day to find new and better ways to treat illness and disease and deliver better outcomes for our patients. Our participation in clinical trials allows us to collect high-quality clinical evidence to inform treatment protocols, product development and new therapies.



37 Australia Site Research Organisation locations

GenesisCare 2021 research in numbers

	Oncology Australia	Oncology Globally
Active clinical trials	85	148
Total ongoing patients in trials	1699	2467
Top tumour streams	Prostate Breast Lung	Prostate Lung Breast
External trial sponsors	49	77
Number of sites and investigators actively conducting trials		
Sites	37	86
Principal investigators	53	74
Dedicated research staff	37	63
Observational research projects	38	52
Publications	52	155

For information, please contact:
oncology.research@genesiscare.com

genesiscare.com

GenesisCare

STUDY PORTFOLIO
FULL TROG TRIAL LIST 2021

CATEGORY KEY

A: TROG initiated and sponsored trial

B: International trial with TROG as Australian Sponsor

C: Not led by TROG, but TROG collaborates with the Sponsor

D: Consists of registries and special projects (excludes secondary analysis)

BREAST

	CATEGORY	STATUS
EUROPA (TD 21.05) ExclUsive endocRine Therapy Or Partial Breast Irradiation for Women Aged ≥70 Years With Luminal A-like Early Stage Breast Cancer (EUROPA): a Randomized Phase 3 Controlled Trial.	B	Development
DCIS (TROG 07.01/BIG 3-07) A randomised phase III study of radiation doses and fractionation schedules in non-low risk ductal carcinoma in-situ (DCIS) of the breast.	A	Open
STARS (TROG 08.06) A randomised comparison of anastrozole commenced before and continuing during adjuvant radiation therapy for breast cancer versus anastrozole and subsequent anti-oestrogen therapy delayed until after radiation therapy.	A	Open
PET LABRADOR (TROG 12.02) PET scans for locally advanced breast cancer and diagnostic MRI to determine the extent of operation and radiation therapy.	A	Open
Local HER-O (TROG 16.02) 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.	A	Open
SUPREMO (MRC/BIG 2-04/TROG 11.01) A phase III randomised trial to assess the role of adjuvant chest wall irradiation in 'intermediate risk' operable breast cancer following mastectomy. SUPREMO (Selective Use of Postoperative Radiation Therapy after MastectOmy)	B	Open
EXPERT (ANZ 1601/BIG 16-02/TROG 16.04) A randomised phase III trial of adjuvant radiation therapy versus observation following breast conserving surgery and endocrine therapy in patients with molecularly characterised low-risk luminal A early breast cancer. (EXPERT)	C	Open
AZTEC (PMC 17/013/TROG 17.05) A randomised phase II trial comparing the efficacy of single fraction or multi-fraction SABR (Stereotactic ablative body radiation therapy) with AteZolizumab in patients with advanced Triple nEgative breast Cancer.	C	Open
AVATAR (TROG 20.03) A randomised phase II trial comparing the efficacy of single fraction or multi-fraction SABR (Stereotactic ablative body radiation therapy) with AteZolizumab in patients with advanced Triple Negative Breast Cancer.	C	Open
APBI (TROG 06.02) A multicentre feasibility study of accelerated partial breast irradiation using three-dimensional conformal Radiation Therapy for early Breast Cancer.	A	Closed
HART (TROG 14.04) A phase III study of Regional Radiation Therapy in early Breast Cancer.	A	Closed

	CATEGORY	STATUS
MA.20 (MA.20/NCIC CTG/TROG 03.05) A phase III study of regional Radiation Therapy in early Breast Cancer.	B	Closed
RAPID (OCOG/TROG 10.02) Randomized trial of accelerated partial breast irradiation.	B	Closed
Cavilon Breast (TROG 04.01) A paired Double Blind randomised comparison of Cavilon Durable Barrier Cream (CDBC) to 10% Glycerine ("Sorbolene") cream in the prophylactic management of Post-Mastectomy Irradiation Skin Care.	A	Completed
TROG 89.02 Simultaneous adjuvant radiation and CMF chemotherapy following surgery for Breast Cancer.	A	Completed

BRAIN & CENTRAL NERVOUS SYSTEM

	CATEGORY	STATUS
FIG (TROG 18.06) Prospective, multi-centre trial evaluating FET-PET in Glioblastoma.	A	Open
Low-Grade Glioma (EORTC 22033-26033/TROG 06.01) Primary chemotherapy with temozolomide vs. radiation therapy in patients with low grade gliomas after stratification for genetic 1p loss: a phase III study.	B	Open
ROAM (EORTC 1308/TROG 15.02) Radiation versus observation following surgical resection of Atypical Meningioma: a randomised controlled trial (The ROAM trial).	B	Open
TROG 98.05 A randomised trial of immediate versus delayed whole Brain Irradiation following surgery and/or Radiosurgery for patients with one or two brain metastases.	A	Completed
Glioblastoma/Temozolomide (26981/22981) (EORTC/TROG 01.03) Concomitant and adjuvant Temozolomide and Radiation Therapy for newly diagnosed Glioblastoma Multiforme. A randomised phase III study.	B	Completed
QUARTZ (MRC LU24/TROG 07.02) 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 radiation therapy in the treatment of patients with inoperable brain metastases from non-small cell lung cancer.	B	Completed
GBM in Elderly Patients (NCIC CTG CE.6/TROG 08.02) A Randomised Phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients.	B	Completed

GASTROINTESTINAL

	CATEGORY	STATUS
MRL SABR (TD 21.06) MRI-Guided Stereotactic ablative radiation therapy for Abdominal Malignancies.	A	Development
SOCRATES HCC (TD 21.07) A randomised controlled trial of Standard Of Care versus RadioAblaTion in Early Stage HCC.	A	Development
NEEDS (AGITG/TD 21.03) Neoadjuvant chemo-radiation therapy for Esophageal squamous cell carcinoma versus Definitive chemo-radiation therapy with salvage Surgery as needed.	C	Development
RESOLUTE (AGITG/TROG 21.03) Randomised phase II trial to evaluate the strategy of integrating local ablative therapy with first - line systemic treatment for unresectable Oligometastatic Colorectal Cancer.	C	Start Up
TOPGEAR (AGITG AG0407GR/TROG 08.08) A randomised phase II/III trial of preoperative chemo-radiation therapy versus preoperative chemo therapy for resectable gastric cancer.	C	Open
MASTERPLAN (CTC 0245/AGITG AG0118PS/TROG 18.04) Randomised phase II study from the AGITG Mfolfirinox And STEreotactic Radiation Therapy for Pancreatic cancer with Locally AdvaNced disease.	C	Open
TROG 03.01 A randomised phase III study in advanced oesophageal carcinoma to compare dysphagia in patients treated with radiation therapy versus chemo-radiation therapy.	A	Closed
PROARCT (TROG 09.01) A phase II trial of integrated preoperative radiation therapy and chemotherapy with oxaliplatin 5 - FU and folinic acid in patients with locally advanced rectal cancer.	A	Closed
TROG 01.04 A randomised trial of Preoperative Radiation Therapy for stage T3 Adenocarcinoma of the rectum.	A	Completed
TROG 03.02 A feasibility study to evaluate adjuvant chemo - radiation therapy for Gastric Cancer.	A	Completed
TROG 89.03 Upper aero - digestive track (Accelerated RT)	A	Completed
TROG 89.04 Synchronous radiation therapy and chemotherapy in Oesophageal Cancer.	A	Completed
TROG 94.01/AGITG IG9401 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.	A	Completed
TROG 95.01 A randomised trial comparing adjuvant protracted venous infusion and Bolus 5FU/Leucovorin with either early or late radiation therapy in Rectal Cancer.	A	Completed
TROG 96.02 Standard radio - chemotherapy for Oesophageal Cancer patients.	A	Completed
TROG 96.03 Concomitant accelerated radiation therapy boost for good prognosis Oesophageal patients.	A	Completed
TROG 98.06 A phase II trial of preoperative radiation therapy with protracted infusion 5 - Fluorouracil for resectable Adenocarcinoma of rectum.	A	Completed

	CATEGORY	STATUS
TROG 98.06 Concurrent radiation therapy and chemotherapy for Oesophageal Cancer patients.	A	Completed
TROG 99.02 A prospective single arm non randomised study of concurrent radiation and chemotherapy for the organ conserving treatment of early Anal Canal Cancer.	A	Completed
DECO (AG0307OS/TROG08.07) The DECO Study: A randomised phase II trial of weekly Docetaxel (Taxotere) Chemo-radiation therapy +/ - Cetuximab (Erbitux) in the treatment of localised resectable cancer of the oesophagus.	B	Completed

GENITOURINARY

	CATEGORY	STATUS
CHyPPR (TD 20.02) Conventional vs HYpofractionated Post Prostatectomy Radiation Therapy (CHyPPR) - a pilot randomised controlled trial.	A	Development
ASCENDE - SABR (TD 21.11) Androgen suppression combined with elective nodal and dose escalation with stereotactic body radiation therapy or brachytherapy.	B	Development
RAVES (TROG 08.03) A phase III multi - centre randomised trial comparing adjuvant radiation therapy (RT) with early salvage RT in patients with positive margins or extra prostatic disease following radical prostatectomy.	A	Open
FASTRACK II (TROG 15.03/ANZUP 16.001) Focal ablative stereotactic radiosurgery for cancers of the kidney - a phase II clinical trial.	A	Open
NINJA (TROG 18.01) Novel Integration of new prostate radiation schedules with adjuvant Androgen deprivation.	A	Open
DECREASE (TROG 19.06) DarolutamidE + Consolidation Radiation Therapy in Advanced proStatE cancer detected by PSMA.	A	Open
RAIDER (ICR - CTSU/2014/10 049/TROG 14.02) A randomised phase II trial of adaptive image guided standard or dose escalated radiation therapy in the treatment of transitional cell carcinoma of the bladder.	B	Open
ENZARAD (ANZUP 1303/TROG 14.01) Randomised phase III trial of radiation plus androgen deprivation therapy with or without enzalutamide for high risk, clinically localised, prostate cancer.	C	Closed
DASL - ICAP (ANZUP 1801 / TROG 21.02) Darolutamide Augments standard therapy for localised very high - risk cancer of the prostate (ANZUP1801). A randomised phase III 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.	A	Closed
RADAR (TROG 03.04) 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.	A	Closed

	CATEGORY	STATUS
BOLART (TROG 10.01) A multicentre feasibility study of online adaptive image guided radiation therapy for muscle invasive bladder cancer.	A	Closed
PROFIT (OCOG/TROG 08.01) A randomised trial of shorter radiation fractionation schedule for the treatment of localised prostate cancer. (Prostate Fractionated Irradiation Trial)	B	Closed
TROG 95.03 Phase III Double Blind Study of Pentosan Polysulphate Sodium (PPS) in the treatment of late (Chronic) Radiation Proctitis.	A	Completed
TROG 96.01 A randomised trial investigating the effectiveness of different durations of maximal Androgen deprivation prior to and during definitive radiation therapy for locally advanced Carcinoma of the Prostate.	A	Completed
TROG 97.01 A phase II study of Trans - Urethral Resection followed by Synchronous Chemo - radiation in the definitive management of localised invasive TCC of the urinary bladder.	A	Completed
TROG 98.03 Randomised trial to compare the rates of disease - free survival in margin - positive patients after radical Prostatectomy with or without Adjuvant Post - Operative Radiation Therapy.	A	Completed
TROG 99.06 Phase I/II study of Trans - Urethral Resection followed by modified Synchronous Chemo - Radiation in the definitive management of localised invasive TCC of the Urinary Bladder.	A	Completed
TOAD (TROG 03.06/VCOG PR 01 - 03) A collaborative randomised phase III trial: The timing of intervention with androgen deprivation in prostate cancer patients with a rising PSA.	C	Completed

GYNAECOLOGICAL

	CATEGORY	STATUS
ADELE (ANZGOG 1910/2020 TD21.04) ADjuvant tislelizumab plus chemotherapy after post-operative pelvic chemoradiation in high risk EndometriaL cancer (ADELE): a randomised phase 2 trial.	C	Start Up
PORTEC-3 (CKTO 2006-04/TROG 08.04) Randomised phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma.	C	Open
Cervical (FIGO Stage and Tumour Volume) (TROG 04.02) Prospective Study to Determine the Relationships Between Survival and FIGO Stage, Tumour Volume and Corpus Invasion in Cervical Cancer.	A	Completed

HEAD & NECK / SKIN

	CATEGORY	STATUS
TD 18.03 Phase II exploratory trial of reduced dose radiation and atezolizumab in low risk HPV oropharyngeal squamous cell carcinoma (OPSCC) defined by >5% PDL1 positive intraepithelial immune cells.	A	Development
UTILITY (TD 19.07) Unilateral Treatment In all Well-Lateralized Tonsillar Primary Tumours.	C	Development
HPV OROPHARYNX (TROG 12.01) 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.	A	Open
EORTC-1219 (EORTC-1219 ROG-HNCG/TROG 14.03) A blind randomized multicentre study of accelerated fractionated chemo-radiation therapy 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.	B	Open
CPOST (R2810-ONC-1788/TROG 17.11) 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.	C	Open
I-MAT (MASC 03.18 / TROG 21.01) Immunotherapy Merkel Adjuvant Trial.	C	Open
POST (TROG 05.01) Post-operative concurrent chemo-radiation therapy versus post-operative radiation therapy in high-risk cutaneous squamous cell carcinoma of the head and neck.	A	Closed
RadioHUM (TROG 07.03) Radiation therapy with humidification in head and neck cancer. A randomized phase III trial of the Trans Tasman Radiation Oncology Group.	A	Closed
TROG 07.04 A phase I/II trial of Cetuximab, Carboplatin and Radiation Therapy for patients with locally advanced head and neck Squamous Cell Carcinoma.	A	Closed
MP3 (TROG 09.03) A phase II efficacy study of chemo-radiation therapy in PET stage II and III Merkel cell carcinoma of the skin.	C	Closed
WBRT (MASC 01.07/TROG 08.05) Whole Brain Radiation Therapy following local treatment of intracranial metastases of melanoma-A randomised phase III trial.	C	Closed
RTN2 (MASC 01.09 / TROG 08.09) A randomised trial of post-operative radiation therapy following wide excision of neurotropic melanoma of the head and neck.	C	Closed
ANZMTG 1-02/TROG 02.01 A randomised clinical trial of surgery versus surgery plus Adjuvant Radiation Therapy for regional control in patients with completely resected Nodal Metastatic Melanoma.	A	Completed
HEADSTART (CPRR04-EFC4690/TROG 02.02) Phase III randomized trial of Concomitant Radiation, Cisplatin, and Tirapazamine (SR259075) versus Concomitant Radiation and Cisplatin in patients with advanced head and neck cancer.	A	Completed

	CATEGORY	STATUS
TROG 91.01 A phase III prospective randomised clinical trial of Accelerated Radiation Therapy (ART) for stage III and IV Squamous Carcinoma of the upper aerodigestive tract.	A	Completed
TROG 96.06 A phase II study of radiation therapy following Nodal surgery in malignant melanoma.	A	Completed
TROG 96.07 A phase II study of Synchronous Carboplatin/Etoposide and radiation In Merkel Cell Carcinoma of the skin.	A	Completed
TROG 98.02 / EFC3344 Randomised phase II study of two different strategies for chemo-radiation therapy in advanced Squamous Cell Carcinoma of the head and neck.	A	Completed
EORTC 22996-24002 / TROG 01.01 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.	B	Completed

LUNG

VITaL (TD 21.08) The Ventilation Imaging for Thoracic Lung cancer radiation therapy trial.	A	Development
PRIME LUNG (TOGA 20/005 / TD 21.10) A randomised phase 2 trial of up-front stereotactic radiation therapy before standard-of-care systemic therapy in advanced lung cancer.	C	Development
OUTRUN (TROG 17.02) Randomised phase II trial of Osimertinib with or without stereotactic radiosurgery for EGFR mutated NSCLC with brain metastases.	A	Open
CHEST RT (TROG 20.01) A phase II study of carboplatin and etoposide chemotherapy, durvalumab with or without thoracic radiation therapy in the first line treatment of patients with extensive-stage small-cell lung cancer.	A	Open
CHISEL (TROG 09.02) A randomised phase III trial of highly conformal hypofractionated image-guided ("Stereotactic") radiation therapy (HypoRT) versus conventionally fractionated radiation therapy (ConRT) for inoperable early stage I non-small-cell lung cancer.	A	Closed
PLUNG GP (TROG 11.03/ALTG) A randomised phase III trial of high dose palliative radiation therapy (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-radiation therapy.	A	Closed
SAFRON II (TROG 13.01/ALTG 13.001) Stereotactic ablative fractionated radiation therapy versus radiosurgery for oligometastatic neoplasia to the lung: A randomised phase II trial.	A	Closed
NIVORAD (ALTG 14/002/CTC0135/TROG 16.01) Randomised phase II trial of nivolumab and radiation therapy versus nivolumab alone in advanced non-small-cell lung cancer progressing after first line chemotherapy.	C	Closed

TROG 03.07 A randomised phase II study of two regimens of Palliative Chemoradiation Therapy in the Management of Locally Advanced Non-Small Cell Lung Cancer.	A	Completed
TROG 99.05 Tumour Volume as an independent prognosis factor in patients with Non-Small Cell Lung Cancer: A protocol for a progressive database.	A	Completed

LYMPHOMA

	CATEGORY	STATUS
Follicular Lymphoma (TROG 99.03) A randomised multicentre trial of involved Field Radiation Therapy versus involved Field Radiation Therapy plus chemotherapy in combination with Rituximab (Mabthera®) for stage I – II low-grade Follicular Lymphoma.	A	Closed
MALT Lymphoma (TROG 05.02) A prospective single-arm trial of involved field radiation therapy alone for stage I-II low grade non-gastric marginal zone lymphoma.	A	Closed
ALLG HDNLHL04/TROG 03.03 An ALLG/TROG Prospective Multicentre Study of Involved-Field Radiation Therapy with Transplantation for Patients with Hodgkin's Disease and non-Hodgkin's Lymphoma.	C	Closed
PCNSL (TROG 01.02) A phase II study of Idarubicin-Based combined Modality Therapy in Primary Central Nervous System Lymphoma.	A	Closed
Osteolymphoma (OL) (TROG 99.04/ALLG LY02) A Prospective, Non-Randomised study of Chemotherapy and Radiation Therapy for Osteolymphoma.	A	Completed
Hodgkins Disease IFRT (HD3) (ANZLG HD3/TROG 99.01) A prospective study of Limited Chemotherapy and Involved Field Radiation Therapy for patients with Clinical Stage I-II Hodgkin's Disease.	B	Completed
PCNSL (TROG 92.01) A phase II study of Intravenous Methotrexate and Cranial Irradiation in the Treatment of Primary Central Nervous System Lymphoma (PCNSL).	A	Completed

MULTIPLE

	CATEGORY	STATUS
TD 21.09 A phase II study of consolidation radiation for induced oligo-persistent disease following initial immunotherapy.	A	Development
APTCQR (TD 21.12) Australian Proton Therapy Clinical Quality Registry.	A	Development
ACCELERATE (TD 18.07) TROG ACCELERATE Project: accelerating cancer therapy research via a national collated data asset.	D	Development
LARK (USYD/TROG 17.03) Liver ablative radiation therapy utilising Kilovoltage Intrafraction Monitoring (KIM)Audit.	A	Open
CORE (ICR-CTSU/2015/10052/TROG 16.03) A randomised trial of conventional care versus radioablation (stereotactic body radiation therapy) for extracranial oligometastases.	B	Open
ANROTAT (TROG 11.A) The assessment of new radiation Oncology technologies and treatment.	A	Completed
ARORP (TROG 11.B) ANROTAT Radiation Oncology Register Pilot.	A	Completed

SYMPTOM MANAGEMENT

	CATEGORY	STATUS
SCORAD III (UCL/TROG 11.02) A randomised phase III study of single fraction radiation therapy compared to multifraction radiation therapy in patients with metastatic spinal cord compression.	B	Closed
SC.24 (CCTG SC.24/TROG 17.06) A phase III randomized feasibility study comparing Stereotactic Body Radiation Therapy (SBRT) versus Conventional Palliative Radiation Therapy (CRT) for patients with Spinal Metastases.	B	Closed
TROG 01.05 A pilot randomised controlled trial of Dexamethasone 96mg versus 16mg per day for Malignant Spinal Cord Compression treated by radiation therapy - TROG SuperDex Pilot.	A	Completed
TROG 95.02 A phase III Double-Blind randomised trial of Rectal Sucralfate Suspension in the treatment of Radiation Proctitis.	A	Completed
TROG 96.04 Phase III comparison of radiation therapy with glucocorticoid steroid support for the palliation of liver metastases.	A	Completed
TROG 96.05 A prospective randomised trial of single fraction verses fractionated radiation therapy of Neuropathic pain due to bone metastases.	A	Completed
BONEMETS (NCIC CTG SC.20/TROG 03.08) A phase III international randomized trial of single versus multiple fractions for re-irradiation of painful bone metastases.	B	Completed

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